IN THE HIGH COURT OF SOUTH AFRICA

GAUTENG PROVINCIAL DIVISION, PRETORIA

Case Number: 3623/21

In the application of:

HEALTH JUSTICE INITIATIVE	Applicant for admission as an *amicus curiae*

In the matter between:

SOLIDARITY	First Applicant
AFRIFORUM NPC	Second Applicant
and	
MINISTER OF HEALTH	First Respondent
PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	Second Respondent
MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	Third Respondent
THE CHAIRPERSON OF THE COVID-19 SCIENTIFIC MINISTERIAL ADVISORY COMMITTEE	Fourth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, WESTERN CAPE	Fifth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, GAUTENG	Sixth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, FREE STATE	Seventh Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, EASTERN CAPE	Eighth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, NORTHERN CAPE	Ninth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, LIMPOPO	Tenth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, MPUMALANGA	Eleventh Respondent

MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, NORTH WEST	Twelfth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, KWAZULU-NATAL	Thirteenth Respondent
PHARMACEUTICAL SOCIETY OF SA	Fourteenth Respondent
COUNCIL FOR MEDICAL SCHEMES	Fifteenth Respondent
SOUTH AFRICAN MEDICAL ASSOCIATION	Sixteenth Respondent
PHARMACEUTICAL INDUSTRY ASSOCIATION OF SA	Seventeenth Respondent

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EXPERT AFFIDAVIT: PROFESSOR LESLIE LONDON

I, the undersigned,

PROFESSOR LESLIE LONDON

do hereby make oath and say that –

1 I am a Professor at the School of Public Health and Family Medicine at the University of Cape Town (UCT). I attach a copy of my curriculum vitae marked **"LL1"**.

2 The facts contained in this affidavit fall within my own personal knowledge, except where I indicate otherwise. To the extent that I rely on information supplied by others, I believe that such information is true and correct.

3 I have been asked to provide an expert opinion in respect of this matter, which concerns a challenge to the strategy and policy adopted by national government for the procuremenmt and distribution of COVID-19 Vaccines.

4 As a public health medicine specialist, I have extensive knowledge and experience of public health, including infectious diseases, outbreak control, health and human rights, and delivery of health services in the Western Cape and South Africa. I have been involved in health systems research for the past 25 years and have published extensively in this field, particularly on questions of the balance between public health measures and justified limitation on human rights. I was President of the College of Public Health Medicine of South Africa from 2014 to 2020 and am currently assisting both the Provincial and National Departments of Health in their COVID-19 response. I have worked as jointly appointed Public Health Medicine specialist for the Western Cape Health Department, provide support to its Health Impact Asessement Directorate and am serving currently on the Provincial Vaccine Expert Advisory Committee, amongst other roles in supporting the provincial COVID-19 response. I am a B2 rated researcher under the National Research Foundation system, which equates to recognition of considerable international standing for my research.

5 I have read the notice of motion and the founding affidavit of Mr. Hermann in the main application. I provide my expert opinion in response hereunder.

6 I start by summarising Mr. Hermann's contentions as follows. Mr. Hermann contends that:

6.1 The COVID-19 epidemic is a major public health emergency and is an urgent health crisis (referred to as a life-threatening second wave in paragraph 57) that requires urgent measures to address the epidemic.

6.2 The discovery of vaccines that are effective against SARS CoV-2 provides the opportunity to address this health crisis and there is, therefore, an urgent need to vaccinate as much of the population as speedily as possible, "in order to achieve herd immunity as soon as possible". (I refer interchangeably to "herd immunity" and "population immunity" as the same concept in my affidavit, being a level of immunity to the virus SARS CoV-2 in the population sufficient to interrupt transmission of COVID-19 at a population level and thereby bring the epidemic under control.)

6.3 There is a restriction on the ability of private health care entities to procure vaccines in some places, Mr. Hermann refers both to a restriction on procurement of vaccines and on the distribution of vaccines being adversely affected.

6.4 This restriction on the ability of private health care entities to procure vaccines will (a) delay or protract the vaccine from reaching those who need it and (b) prevent South Africa from attaining herd immunity in as quick a fashion as possible.

6.5 Allowing the private sector to procure vaccines will enable the vaccine to (a) reach those who need it and (b) allow South Africa to

attain herd immunity more rapidly than if the vaccination rollout were based on solely government procurement.

6.6 The restriction on the ability of private sector entities to procure vaccines is an unreasonable limitation on the human rights of the members of Solidarity, on members of various medical schemes, and on practitioners in private practice and provincial health departments.

6.7 I examine each of these arguments in turn below.

COVID-19 AS AN EXTRAORDINARY EMERGENCY

7 First, it is common knowledge that the COVID-19 epidemic is a major public health emergency and requires extraordinary efforts to address it. To the extent that Mr. Hermann recognises the COVID-19 epidemic as requiring urgent responses, I am in agreement. However:

7.1 As an emergency, the crisis cannot be dealt with through measures we would normally expect to be present in the South African health care system. The world has recognised this necessity in the World Health Organisation (WHO) declaring a global Public Health Emergency of International Concern (PHEIC) on 30 January 2020. A copy of the statement by WHO is attached marked **"LL2"**.

7.2 To the extent that existing health systems are stretched and disrupted by the epidemic, the WHO has provided guidance to countries in how best to cope with these extraordinary circumstances. In this regard, the WHO has provided extensive

guidance on, amongst other matters related to COVID-19, the prevention and treatment of COVID-19, the protection of health systems, and most recently on how best to roll out vaccines for COVID-19 in the form of the '*WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*' ('WHO Values Framework') and the 'WHO Roadmap for Prioritizing Uses of COVID-19 Vaccines in the context of limited supply' ('WHO Roadmap') A copy of the WHO Values Framework and the Roadmap are attached and marked **"LL3"and "LL4"** respectively.

7.3 The idea that what pertains under normal circumstances should necessarily pertain under emergency circumstances is therefore not plausible in the present epidemic.

7.4 Extraordinary measures have previously been adopted by nation states in relation to other global health crises such as Ebola, H1N1, and SARS.

7.5 The measures proposed by the South African government with regard to vaccine procurement and allocation are not in my expert view incompatible with the global recognition of the need for extraordinary measures. As I explain below, they are:

7.5.1 rationally based on understanding the need for equity in access to a life-saving health technology for COVID-19;

7.5.2 rationally based on the past experience of uncontrolled private sector procurement of scarce health technologies;

7.5.3 consistent with all the major global vaccine allocation guidance documents rooted in public health and epidemiological considerations that are currently available.

7.6 The measures proposed by Mr. Hermann essentially involve returning the control of the COVID-19 epidemic to the pre-COVID-19 scenario of the private sector paying for those who can afford medical supplies, while the public sector should 'focus on the vaccination of the most vulnerable members of society'. It is therefore a departure from what numerous jurisdictions around the world have recognised – that stewardship of the entire health system is needed to ensure a coordinated response to COVID-19. In this regard, I attach a copy of the *'WHO COVID-19 Strategy Update of 17 April 2020'* (**"LL5"**).

7.7 Returning to the pre-COVID-19 scenario would only be justifiable if it could be shown that such an arrangement would expedite the goals of controlling this epidemic and minimise loss of life. As I explain below, there is no evidence that such an approach would benefit COVID-19 public health control measures. On the contrary, there is much evidence that such an approach would harm our capacity to survive the epidemic with the minimum loss of life and would exacerbate inequality in our country.

VACCINES CAN HELP US REACH POPULATION (HERD) IMMUNITY FASTER

8 We face a global crisis that requires scientific consensus and cooperation, using the best evidence and data available, given that severe acute respiratory syndrome coronavirus 2 ('SARS-CoV-2') presents many complex

and scientific uncertainties, while we deal with imperfect scientific knowledge. This is why the integrity of any vaccine programme is critical to ensuring, over time, widespread access to vaccines that are safe and effective, and convincingly so for the public.

9 It is correct that several new vaccines for COVID-19 have been reported to be effective to varying degrees in providing protection against COVID-19 infection, severe disease, and death associated with COVID-19. However, there are a number of scientific uncertainties regarding the vaccines:

9.1 None of the vaccines available globally have been formally registered as yet in South Africa other than through a Section 21 authorisation by the regulatory body in South Africa, SAPHA, for Covishield and the authorisaton for the Johnson and Johnson vaccine to be 'rolled out' to health care workers through a research study (the Sisonke study).

9.2 Although much is said about many vaccines in the public domain and used in other countries, the producers of some of these vaccines have generally not approached the SAPHRA with their information dossiers, which slows down the registration process and which complicates assessments of efficacy, risk, and guidance for use. I attach a copy of the SAPHRA authorisation for Covishield, as well as a copy of a news article related to the rollout of the Johnson & Johnson (the Jansenn) vaccine (annexures "**LL6**" and "**LL7**" respectively).

9.3 In several cases, global vaccine manufacturers have pre-committed hundreds of millions of doses for certain governments first (including but not limited to the US, countries in the EU, UK, Canada, Israel, Australia, China, Russia, UAE), with limited immediate supplies for the COVAX facility and other regional blocs such as the African Union (AU). A recent academic article in the Lancet, published on 12 February 2021, illustrates the current status globally of inter alia vaccine approvals, COVAX participation, and forecasted supplies. A copy of the article, entitled '*Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment*', is attached marked '**LL8**'.

9.4 As yet, there is no consensus on how long immunity is conferred through vaccination;

9.5 The effectiveness of these vaccines varies, and it is unclear if effectiveness for the strain most prevalent in South Africa will turn out to be the same as that found to date in vaccine trials elsewhere in the world;

9.6 There is no current certainty regarding the effects of receiving multiple different vaccines;

9.7 Delivering a vaccine requires adherence to vaccination schedules, maintaining a cold chain, and ensuring quality control in the stocks and the administration of the vaccine.

9.8 Thus, while promoting the uptake of vaccines will, in general, be a positive development towards population levels of immunity that will interrupt transmission (also known as 'herd' immunity), an uncoordinated and poorly applied vaccination programme may hinder our country from attaining population or herd immunity. For example, if vaccinees do not receive a second dose of a two dose regimen, or receive it late, or receive a different vaccine the second time, or receive a vaccine that has expired or been damaged by the failure of the cold chain, then they will have been vaccinated, but ineffectively.

10 Furthermore, it is incorrect to assume that population or herd immunity can be achieved simply by vaccinating the highest number of people as quickly as possible.

10.1 It is an incontrovertible reality that there is an absolute shortage of vaccine supplies globally, at least at this early stage of the epidemic.

10.2 For this reason, it is widely recognised that rationing based on public health evidence, data and need, and the input of public health and scientific experts, will be necessary, at least at the early stages of the epidemic.

10.3 The 'WHO Roadmap for Prioritizing Uses of COVID-19 Vaccines in the context of limited supply' notes that "*sufficient vaccine supply will not be immediately available to immunise all who could benefit from vaccination.*" The guidance goes on to model three scenarios of constrained vaccine supply (different levels of availability). In all

three models, it proposes strategies for vaccination of priority groups. In this regard, I refer to **"LL4"**.

10.4 Mr. Hermann's proposal that anyone who wants vaccination should be able to access vaccination is unscientific and contrary to global public health guidelines which also emphasise equity in access alongside an effective rollout.

10.5 As stated by the UN Committee on Economic, Social and Cultural Rights (UNCESR) in its Statement on Vaccines for COVID-19: *'It is impossible to guarantee that everyone will have immediate access to a vaccine for COVID-19, even if several vaccines are approved soon. The mass production and distribution of vaccines implies not only enormous financial costs but also complex administrative and health procedures. The prioritisation of access to vaccines by specific groups is unavoidable, at least in the initial stages, not only nationally but also at the international level. In accordance with the general prohibition of discrimination, such prioritization must be based on medical needs and public health grounds.* A copy of the statement by the UNCESR is attached to the affidavit by Dr. Tlaleng Mofokeng.

10.6 It is generally accepted public health practice to focus on those at high risk who can benefit maximally from vaccination. This meets both utility and justice principles. If one vaccinates *ab initio* fit and healthy adults or young people, who are low risk, even if one does reach high numbers, then one is doing so at the expense of individuals who have immediate health risk-based needs and who

should be vaccinated first, on public health grounds. Thus, if a vaccination programme rolls out as proposed by the applicants there will be many persons at high risk who will be exposed to infection before they are vaccinated. This will result in preventable and unnecessary illness and death in the country because of failure to follow a common national strategy.

10.7 The pathway to population or herd immunity cannot be reached by disregarding the priority needs of those most at risk. This principle is enunciated in several international guidance documents on vaccine access. For that reason, vaccination of fit and healthy young adults is generally left for the last phase of vaccine rollout plans, as is reflected in the South African government's national plans. I attach a full copy of the *'WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supply'* (""LL4" above)

10.8 Mr Hermann's affidavit appears to pay no attention to the fact that attaining population or herd immunity as rapidly as possible cannot be achieved at the expense of the health and survival of persons at risk of severe COVID-19 disease.

10.9 The 'rapid and effective' distribution of vaccines (as articulated in paragraphs 28, 36, and 59 of Mr Hermann's affidavit) will only contribute to the effective management of the COVID-19 epidemic if done in line with scientific principles. There is no evidence in his argument that he has taken account of any scientific principles, the most widely accepted of which is the *WHO SAGE Roadmap for*

Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supply, attached above as "**LL4**".

10.10 I also draw attention to the *WHO Values Framework* for guiding the allocation and prioritisation of COVID-19 vaccination attached above as "LL3". The framework articulates the aim of any vaccination programme as recognising that "COVID-19 vaccines must be a global public good. The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world". The document goes on to elaborate on six principles that should guide vaccine allocation, these being Human Well-Being, Equal Respect, Global Equity, National Equity, Reciprocity, and Legitimacy.

10.10.1 By promoting a vaccine programme that vaccinates on the basis of first-come, first-served, the applicants' proposed programme will fail to "protect and promote human well-being including health, social and economic security, human rights..."

10.10.2 If healthy adults secure vaccination earlier because they able to pay, then the applicants' proposed programme will fail the principle of recognising and treating "...all human beings as having equal moral status..."

10.10.3 The requirement to ensure "equity in vaccine access and benefit within countries for groups experiencing greater burdens from the COVID-19 pandemic" will be undermined

by diverting vaccines to those who have lesser or no burden, which will be a consequence of the applicants' proposed programme.

10.10.4 There is no recognition of reciprocity in the applicants' proposals for private sector procurement.

10.11 Professor Keymanthri Moodley, head of Bioethics at the University of Stellenbosch, has noted that, with regard to COVID-19 vaccines, "Rationing processes should be fair and based on transparent, consistent criteria that can be subjected to objective scrutiny with the goal of ensuring accountability, equity, and fairness". A copy of Professor Moodley's article is attached marked "**LL9**". The relief sought by the applicants will create inconsistency in who will receive the vaccine, inequity in distribution and unfairness in a situation of already extreme pre-existing inequalities.

10.12 The claim that South Africa is 'lagging' behind other countries in acquiring vaccines shows a lack of understanding of the problems facing countries classified as middle income – which are increasingly shouldered out of the market by richer and more powerful countries. Paragraphs 71 to 76 of Mr. Hermann's affidavit appear to attribute the entire responsibility to the South African government when many observers and commentators, including the Director-General of the WHO and the UN Secretary-General, have lamented the behaviour of richer nations and vaccine manufacturers in creating the conditions where less developed countries are disadvantaged in the global

marketplace. A copy of an article highlighting the UN Secretary General's warning is attached marked "**LL10**".

10.13 For example, in Paragraph 78, the applicant appears to think South Africa's inability to secure speedy supplies of safe and effective vaccines in a pandemic lies in the fact that it 'did not commit sufficient funds into COVAX'. However, it would seem that the applicants do not appreciate that given the design of COVAX, South Africa would not necessarily obtain any preferential supplies or better price by purchasing through COVAX and may even be substantially disadvantaged to do so. This is a serious design fault of the COVAX mechanism, amongst a number, which the applicants do not seem to appreciate.

10.14 COVAX depends on funding from donors and high-income countries but is still hugely underfunded. It also depends on voluntary participation by manufacturers and imposes tiered cost-recovery with Upper Middle-Income countries having to self-finance and pay higher prices. Only Low-Income countries will be supplied at a subsidised cost, and only some vaccine producers have put their products into COVAX. As a result, COVAX does not provide supplies of all efficacious vaccine candidates, is not yet transparent in the pricing of its vaccines, and procurement through COVAX involves forfeiture fees and penalties associated with transacting in a commercial arrangement. Further, COVAX is not accountable to any domestic institution in South Africa, including Parliament, as a result of which

millions of Rands of public funds have to be spent with little or no oversight and accountability in the event that prices are excessive or supplies do not arrive on time, or at all.

10.15 In any event, South Africa has now seemingly secured supplies from other mechanisms, including bi-lateral negotiations for large quantities and through the African Union (AU) Vaccine Access Task Team.

10.16 Given the above scenario, the claim that South Africa's late payment was somehow responsible for delays in procurement appears to be irrelevant.

10.17 What is clear is that the procurement landscape is extremely complex. It is simplistic to contend that a free market would enable efficient private sector procurement and rational allocation of vaccines.

10.18 Moreover, it is now evident that some vaccine manufacturers are requiring governments to purchase vaccines on the basis that those governments indemnify the manufacturers against claims should vaccinees develop adverse reactions. Mr. Hermann gives no indication that private sector actors in South Africa would be willing to accept such liability. It is extremely unlikely that a private entity would do so.

10.19 It is therefore implausible that, in the current situation, a vaccine manufacturer will directly sell its vaccines to a South African trade

union, a health insurance entity, a local pharmacy chain, or even a provincial government. I have not seen any evidence that a vaccine producer will do so.

RESTRICTING THE PRIVATE SECTOR FROM DIRECTLY PROCURING VACCINES IN A PANDEMIC

11 It is correct that the South African policy on vaccines is that the State shall be the sole procurer of vaccines with a negotiating team that includes representatives from business associations, the largest medical scheme in the country (Discovery Medical Scheme) and the National Treasury. I do not comment on the legal question of whether the policy imposes or proposes a legal prohibition on procurement by other entities. The policy is however in accordance with international practice. The affidavit deposed to by Ms Hassan of the Health Justice Initiative deals with the approach of foreign jurisdictions including India, the United States and the European Union. For the sake of brevity, I will not repeat those examples in this affidavit.

12 There are important reasons why this is the case.

12.1 This is a pandemic with global impact and consequences.

12.2 Vaccines for COVID-19 are not just any ordinary commodity that can be purchased by someone with the resources to do so. They are, as UN Secretary-General António Guterres articulated, "a global public good, affordable and available to all."

12.3 A global public good that should be affordable and available to all cannot be distributed through a private market or just by some

provinces or nations. Mr. Hermann has said 'that a state monopoly should not exist' for the procurement of COVID-19 vaccines (paragraph 56). As a public health expert, I do not understand what this means as it is the obligation of the state to negotiate, select and procure vaccines for everyone in our country to meet the requirements of our Constitution. The private market in South Africa, which serves less than 20% of our people, cannot distribute a public good for reasons outlined below, nor should just one or two provinces.

12.4 Global experience, including our own experience in South Africa, has shown that private acquisition and allocation cannot be relied on to achieve equitable availability of health resources.

12.4.1 The huge divide between public and private health care sectors, which characterises South Africa's current divided health system, results in significant resources being inefficiently sequestered in the private sector.

12.4.2 Inequity arises because the private sector will service those who pay, be they members of a medical scheme or wealthier individuals but will not reach people in need who cannot afford private health care – the majority of people living in South Africa. Lack of access to private medical aid schemes is discussed in Dr. Mofokeng's affidavit.

12.4.3 As a result, South Africa has severe inequalities in health status by race, rurality, class, and gender. This inequality is

associated with poor health outcomes for the amount of money we spend on health. It reflects inequalities in the distribution of both the determinants of health and in access to health care.

12.4.4 It is within this context that the COVID-19 epidemic hit South Africa in 2020. The epidemic has exacerbated inequalities, both in social conditions and livelihoods and in health outcomes.

12.4.5 An analysis of data from the National Income Dynamics Study (NIDS) in 2017 and the first wave of the NIDS-Coronavirus Rapid Mobile Survey (NIDS-CRAM) suggested that income-related health inequality in the COVID-19 era increased six-fold compared with what was obtained in 2017. For example, cumulative mortality due to COVID-19 was noted in January 2021 as approximately twice as high in poorer township areas of Cape Town compared with the rest of the city. This is partly explained by differences in access to care between the public and private sectors. A copy of the relevant portions of the data by the NIDS and article of the cumulative mortality in poorer areas are attached marked "**LL11**" and "**LL12**" respectively.

12.5 We also saw the impact of public-private inequality first-hand in South Africa in the last year. During the COVID-19 epidemic, disparate or unequal access to testing technologies (test kits) for diagnosis of

COVID-19 was well documented. A copy of an article describing this is attached marked **"LL13".** As a result, many public sector patients could not be tested, or their tests were wasted as a result of long delays. The consequence in terms of missed infections, failure to prevent transmission, and any associated deaths have not been quantified. However, it was clear that the private sector laboratories did not always share scarce resources to ensure that there was equitable testing capacity across the health system, but deployed testing for those who were paying customers. Those who could not afford private care and who could, therefore, not access testing, were likely to have worse outcomes.

12.6 Even with the best of intentions, charities and major pharmacy chains that stepped in could only provide limited tests and, in some cases, carried out limited stop-start programmes with limited reach and an urban bias. These voluntary efforts are not sustainable unless coordinated through a national programme that prioritises equity in access.

12.7 Centralised procurement of a scarce resource thus ensures that there is the possibility of ensuring equity in its distribution. It does not guarantee equitable distribution, but it does make equitable distribution possible if it is an explicit policy objective of a vaccine programme, which is the case in South Africa and in almost all major democracies right now.

12.8 The converse of centralised procurement, in the form of uncoordinated and 'independent' procurement, makes equity in allocation impossible to achieve, as confirmed in a US National Academics of Science guideline referred to in the affidavit of Ms. Hassan from the Health Justice Initiative.. I note that this does not preclude all stakeholders, including those in the private, business or NGO sectors, assisting with the administration of a vaccination programme. The scale of the epidemic surely requires everyone's cooperation.

12.9 However, as Mr. Hermann implies in paragraph 84, it is unclear if all private sector providers will be able to administer vaccines or will want to administer vaccines to the maximum degree possible if vaccination is to be offered through private purchase or through a medical scheme. There is a very real possibility that stock purchased in the private sector could remain unused, sequestered within private contractual arrangements and unavailable to those who need it most.

12.10 Where there are multiple entities independently procuring a scarce resource, it is inevitable that there will be difficulties in ensuring adequacy of supplies and equity in distribution. This has been demonstrated at an international level in the uneven access to vaccines between countries, where according to the WHO, those with more economic and political power have purchased more vaccines than their population needs, at the expense of poorer countries.

12.11 Lastly, while Mr. Hermann asserts that centralised procurement of vaccines and 'stifling of the private sector ... can only result in unwarranted protraction in the distribution and administration of vaccines to the population,' he presents no evidence that this will be the case – only that the private sector has the capacity to deliver vaccination. Since the private sector, medical schemes and businesses will be involved in the distribution and delivery of vaccines and has been included in almost all relevant task teams including on the National Vaccine Acquisition Task Team, it is unclear on what basis Mr. Hermann makes this claim of central procurement delaying administration of vaccines to the whole population.

12.12 If one accepts that there is an absolute shortage of vaccines at this early stage of the epidemic, then it is clear that affording the private sector or some provinces the capacity to also procure vaccines and then decide whom to vaccinate and when to do so (i.e. outside of a national strategy of prioritisation and without central allocation) will mean that persons at low risk, with financial means, will be free to be vaccinated – assuming the regulatory authority, SAHPRA, approves a vaccine for use. At the same time, some of those at risk to severe COVID-19 disease will have to wait longer in other sectors / provinces, therefore risking their health and their survival and the country's ability to achieve population immunity safely.

12.13 The approach that the most rapid path to population immunity is through vaccinating the highest number of people as quickly as

possible, irrespective of who is vaccinated, is therefore not justifiable on public health grounds, nor on medical and epidemiological practice and needs.

13 Mr. Hermann appears to conflate selection, regulatory approval, procurement, allocation and distribution when describing what is prevented by national policy, and as to what would be implemented, should the applicants be granted the orders which they seek.

13.1 I point out that there is nothing in the national strategy documents released thus far that precludes private practitioners from *participating* in the vaccine roll-out. To the contrary, Mr. Hermann himself cites evidence of government's commitment to *involve* the private sector in administering and delivering vaccines (paragraphs 43, 47).

13.2 The fact that the mining industry has health services capable of providing health care services to the members of Solidarity (Para 29) is irrelevant to the question of private procurement. On the contrary, it is entirely consistent with the state procuring vaccines and allocating vaccines to the mines to administer to its employees in line with a national policy focusing on priority groups based on risk, age, or co-morbidity status.

13.3 Further, Mr. Hermann provides no evidence that even if the private sector were to procure vaccines, the providers in the private sector would speedily vaccinate as many people as possible. Current evidence shows that private providers' behaviours are largely

determined by financial incentives, and that they are unlikely to adopt behaviours that will specifically focus on maximising the numbers of persons vaccinated unless incentivised to do so. I attach, in this respect, the Competition Commission Health Market's Inquiry Report: An overview and key imperatives, marked **"LL14"**.

13.4 Even then, financial incentivisation of private sector providers to achieve population health goals has a weak evidence base internationally and in South Africa. I attach an extract from a discussion paper entitled 'Private sector involvement in funding and providing health services in South Africa: Implications for equity and access to health care' written by Professor Diane McIntrye. Pages 13 to 23 of the paper are attached, marked **"LL15"**.

13.5 It is therefore unclear how Mr. Hermann can deduce that private procurement and allocation will advance national vaccine coverage and support earlier attainment of population or herd immunity.

COULD PRIVATE SECTOR PROCUREMENT BE COMPATIBLE WITH PROMOTING ACCESS AND ACHIEVING POPULATION IMMUNITY?

14 Implicit in Mr. Hermann's argument is that allowing the private sector to procure vaccines will (a) enable vaccines to reach those need it and (b) allow South Africa to attain population or herd immunity more rapidly than if the vaccination rollout were based on solely government acquisition and

allocation. On both counts, it is in fact more likely that it will detract from these policy objectives.

15 Firstly, it is evident that those recipients who will benefit first from private procurement / acquisition of vaccines will not necessarily be those who are at greatest risk.

15.1 As described in Mr. Hermann's affidavit, the categories of beneficiaries he cites include employed workers (about 10 000 members of the trade union, Solidarity) and its medical scheme members.

15.2 Both categories are likely to include many people who are low risk – younger adults and people with no co-morbidities.

15.3 StatsSA reported in December 2020 that almost 60% of all deaths due to COVID-19 in hospitals occurred in adults over the age of 60 and less than 12% occurred in adults under the age of 45. A copy of the relevant portions of the StatsSA report is attached marked "**LL16**". It has been demonstrated that there is a higher risk of death from COVID-19 in older adults. This is consistent with evidence from around the world.

15.4 In November 2020, the StatsSA Quarterly Labour Market Survey indicated that less than 10% of workers employed in South Africa were over the age of 55% and 63% were less than 45 years old.

15.5 Also, by definition, ordinary workers are generally healthier than the general population. The Healthy Worker Effect is well recognised in

public health epidemiology, reflecting the fact that if you are ill, you are less likely to get a job and more likely to leave the workforce. Those who enter and remain in the workforce are generally healthier than those outside the workforce and will have fewer co-morbidities than the general population. The relevant page of a journal article showing this is attached marked **"LL17."**

15.6 I have not been able to source any data on the age distribution within Solidarity members, and the applicant's affidavit does not provide such data. It is unlikely to differ substantially from that of the wider labour force. This suggests that the vast majority of its members would fall in the low-risk category for COVID-19 since it is likely that the majority are young, fit healthy adults.

15.7 Secondly, medical scheme membership comprised 8.95 million people (principal members and beneficiaries) in 2019. Of people who have access to medical insurance through medical schemes, only about 8.6% were pensioners, and the average age of beneficiaries was 33 years. The age distribution of medical scheme membership is therefore heavily biased away from those at high risk though age, and it is skewed towards some provinces.

15.8 Medical scheme members are also more likely to be wealthier than non-insured persons and more likely to be employed, and therefore include many people at lowered risk from COVID-19.

15.9 It is therefore clear that if private procurement leads to 'independent' access to vaccines – whether as Trade Union members or as

members of a medical scheme – many persons who are at low risk will likely be vaccinated before persons whose vulnerability places them at higher risk. It is the latter group who should be vaccinated first in any efforts to reach population immunity.

15.10 This inequality is the reason why the South African health system is in need of reform, and why the South African government is pursuing National Health Insurance. It cannot be acceptable that 27 years after democratic change in South Africa, we can still accept a health system that treats people differently on the basis of their ability to pay, which overlaps substantially with their racial group - and particularly so during an emergency and in a pandemic.

15.11 Mr. Hermann's affidavit presumes that if the private sector is able to procure vaccines, then the State can "focus on the vaccination of the most vulnerable members of society." This is as unacceptable formula as it removes any responsibility from the applicants' organisations to think beyond their own membership and own self-interest, in the face of overwhelming public health evidence which shows that 'no-one is safe until everyone is safe'. This is a policy that is the antithesis of what is globally and recommended by health experts.

15.12 The Vaccine Alliance, GAVI, notes that "only once COVID-19 vaccines are available to priority populations in all countries around the world will we bring the pandemic under control". A copy of GAVI's

article 'Why is no one safe until everyone is safe during a pandemic' is attached marked "**LL18**".

15.13 For that reason, it is unclear how the application can properly be said to represent a matter of 'broader public interest over and above the interests of the applicants and their members', given that the broader public, and particularly those who are at high risk to COVID-19, will be gravely disadvantaged should the applicants be successful.

15.14 Even the Medical Schemes industry has broadly committed itself to support national vaccination plans, working with government and its experts with regard to acquisition, selection, prioritisation, and access. I attach excerpts from a Government Employees Medical Scheme ("GEMS") Newsletter, marked "**LL19**".

15.15 There is in fact no broad lobby from the private health and insurance sector calling for the ability to procure vaccines independently. For example, Discovery Medical Scheme communicated with its members, and did not indicate any such intention. A statement by the Chief Executive of Discovery Medical Scheme on 15 February 2020 is attached and marked **"LL20".**

16 A further reason why parallel acquisition and administration efforts are likely to deliver inequitable access to COVID-19 vaccines is that private providers generally do not follow national clinical guidelines as I have encountered in my academic work and described below.

17 Even if private procurement were intended to secure vaccines first for high-risk individuals (as proposed under national clinical guidance), it is highly unlikely that private providers would comply with these rationing measures even in a time of scarcity in a pandemic, since over-servicing of patients is common in the private sector.

17.1 For example, a recent study showed that Caesarean Section rates in the private sector in 2015 were approximately three times higher than in the public sector and that decisions to resort to surgery in the private sector did not follow international norms. Relevant portions of the study published on the South African Medical Journal is attached marked "**LL21**".

17.2 Moreover, adherence to guidelines has been noted as sub-optimal in various private health care settings in South Africa, including management of STDs, antibiotic prescription in an Intensive Care Unit in a private hospital in KZN, and the management of tuberculosis. This picture is consistent with international experience. I attach copies of the relevant portions of journal articles speaking to these issues marked "**LL22**", "**LL23**", and "**LL24**".

17.3 Thus, even if private providers were asked to follow national protocols to, at first, restrict vaccination to high-risk groups, under conditions of 'independence', it would be extremely unlikely to see private providers withholding vaccination from all private sector users or Trade Union members, irrespective of their health risk status (i.e. even if their health risk was low). Mr. Hermann's affidavit, by quoting

trade union demands for access to vaccines 'freely' and 'independently', makes clear his intent that there should be no prioritisation or rationing of who receives vaccination in a pandemic where vaccine supplies are scarce.

17.4 Such a scenario stands in direct contradiction to the WHO SAGE recommendations which state that "countries should ensure that individuals are not able to use their social, financial or political privilege to bypass country-level prioritization".

18 Operationally, even if private procurement were to secure sufficient doses of vaccines for members of medical schemes in South Africa, there are numerous challenges to a coherent and scientifically-based roll-out of vaccines.

18.1 Private providers would have to commit to sharing information on patient vaccinations with the state so as to ensure monitoring coverage towards population or herd immunity. This is extremely unlikely under conditions of 'independence' proposed by Mr. Hermann, as illustrated by past experience of the extremely poor compliance by private practitioners with any statutory notification mandated by legislation for infectious and other diseases. I attach marked "**LL25**" excerpts of a dissertation addressing this, entitled '*Evaluation of the notifiable disease surveillance system in Gauteng Province, South Africa*'.

18.2 If patients are able to buy vaccination simply on the basis of their purchasing power, there would be little to stop them being vaccinated

twice or more with the same or another vaccine, with the result that a scarce resource will be consumed in a manner that is inefficient and iniquitous. There may also be double-dipping with some patients being vaccinated both through the state and by private purchase.

18.3 Further, in the absence of oversight of delivery, vaccinees may not receive a second dose where they are eligible for a two dose regimen, or receive it late, or receive a different vaccine the second time.

18.4 If a purchased vaccine is found in new scientific developments to be inappropriate, ineffective or less effective for a population or for a particular group (as may be the case with the Astra-Zeneca vaccine), then the stewardship of how to use that vaccine, if at all, or pausing the programme, will be unclear. Private providers may then be entitled to choose whether to follow state recommendations or not.

18.5 In the event that scientific experts in the field adjust recommendations for use of specific vaccines in our context (for example, given new variants discovered against which some vaccines have limited efficacy), it is unclear how a parallel system of private procurement and independent distribution will be able to adapt. Stewardship of the epidemic through scientific guidelines on vaccine use is the responsibility of the state or intergovernmental organisations and the private sector is not geared to take on such a role. Having a parallel system in the private sector will represent an added burden on the state while it manages the national roll-out and

any change in strategy required by new scientific information and data.

18.6 Additionally, any purchase of large amounts of vaccines by the private sector will have knock-on effects on other role-players in the market, including both the South African government and the governments of other African countries seeking to access vaccines. Under the current global governance of vaccine distribution, vaccine producers can decide to whom they sell, at what price, and when they supply the vaccines. If there are multiple procurers, this will increase competition between them for the limited supplies which are available. If the private sector is willing to pay a higher price, this will likely result in an increase in the prices which are charged, with obvious perverse results for the public sector, which serves the majority of the population who are most in need. A large private sector purchase may push up the price and reduce the availability of vaccines to others, as well as displace orders that might otherwise have reached vulnerable populations, both within South Africa and in other countries. The market would then determine access to priority supplies. This cannot be acceptable.

18.7 Thus, even if one somehow disregards ethical and human rights concerns, there are numerous operational challenges which will arise with free and independent availability of vaccines through private procurement, which may undermine the need to move as soon as possible towards population immunity.

19 I note that that the applicants have included the notion of provincial procurement of vaccines in this application. It is not clear to me what standing they have to demand that provinces be given the freedom to act independently of national policy.

20 I understand that the National Health Act 61 of 2003 provides that the National Department and Minister of Health should provide policy guidance to the provinces with regard to matters including the control of epidemic disease (section 21 of the National Health Act), while the provincial head of health "must ensure the implementation of national health policy, norms, and standards in his or her province".

21 There is good reason for this:

21.1 Our health system was established to replace the divisive, fragmented, and discriminatory health system inherited from apartheid, with the purpose of promoting health within a comprehensive, coordinated and unified health system based on a range of principles, one which is the recognition of the importance of equity for health (Preamble to the National Health Act).

21.2 If provincial entities were allowed to subscribe to different policies, we would rapidly see the collapse of a unified health system and likely see even greater disparities and dysfunction across the health system. The South African health system is already characterised by sizeable inequalities and the redress of such inequalities is a major priority of the Health Department and highlighted in the National Development Plan.

21.3 It should be evident that on a matter of such importance as to how to respond to a global pandemic, national scientific consensus and expert input will be essential to identifying the most effective and equitable policies and strategies. It would undermine our national response if the court was to sanction provincial independence from a coordinated and coherent national programme.

21.4 If provinces were able to procure vaccines directly, there is no reason to anticipate that this would turn out any differently to the vaccine nationalism we have seen at a global level, where rich and powerful countries secured vaccine supplies for their citizens at the expense of less powerful or wealthy countries, a situation described by the WHO DG as vaccine nationalism and 'morally indefensible'. 'The affidavit deposed to by Ms Fatima Hassan includes an annexure speaking to this.

21.5 Translated to a sub-national level, one would reasonably expect competition between provinces for the acquisition of vaccines (likely resulting in an increase in cost), and large disparities in access to vaccination between provinces, and especially if criteria for vaccination follow what is asked for in the applicants' papers – i.e. no consideration of risk-based or health criteria.

21.6 This may also result in substantial cross-border movement, if people seek vaccination in another province, an over-run of the health services in the receiving province, stock-outs of vaccines, and, almost certainly, a failure to prioritise vulnerable groups. This, in turn,

could prompt temporary bans on cross-province travel with resultant economic disruption.

21.7 Additionally, such chaotic movement may itself magnify the risks of COVID-19 transmission if vaccination sites are overrun by people with low risk for COVID-19 demanding vaccination that they would not receive in their own province, until their turn.

21.8 A provincially independent procurement process as proposed by the applicants is not only ethically problematic but extremely disruptive to the health system and likely to be counterproductive for health managers trying to run vaccination programmes. I am not aware of any jurisdictions where such double standards for an essential public health good can be run efficiently or equitably.

21. I note that the applicants appear to make claims on behalf of non-governmental organisations (going so far as to name a particular organisation, Gift of the Givers) as potentially able to help the vaccine response and benefit if procurement were opened beyond the state. This statement is entirely unsupported by any evidence that NGOs wish to procure or would procure at the scale needed. The standing of the applicants to make claims on behalf of third parties is again unclear.

22. Ultimately, the very notion of private procurement as envisaged in the applicants' papers is entirely speculative. Vaccine manufacturers at this time are dealing directly with national governments, given that regulatory approval, selection and acquisition are taking place simultaneously in this unprecedented global crisis, where research was accelerated, and

efficacious vaccines are still in the process of being researched and being approved globally. The scale and rapidity of the roll out is one of the reasons for manufacturers seeking indemnity from those who purchase vaccines from them in the procurement process.

23. It is therefore simply unrealistic to believe that a right to procure vaccines independently would be compatible with the very complex and rapidly changing vaccine availability environment.

24. Difficult decisions will have to be made about the best combination of vaccines that should be used in South Africa to achieve population immunity and protect the lives of all who live in South Africa, particularly those at high risk of severe disease. These decisions have to take place in the context of limited vaccine choices available to South Africa. It is only the South African government, which is constitutionally obligated to make decisions about protecting the population and which is accountable for these decisions, that can play this role, drawing on expert scientific evidence and consensus. This is not a choice to be made by private sector organisations, provincial governments, medical schemes or private providers, acting independently. That approach would be inconsistent with sound public health principles.

JUSTIFIED LIMITATIONS OF RIGHTS FOR THE PUBLIC GOOD

25. Mr Hermann asserts that the limitation of the rights of private health sector users and private sector providers is 'unjustified'. I have been asked to

comment on this, on the assumption that Mr Hermann is correct in his contention that this is a limitation of rights in the Bill of Rights.

26. There are currently many situations in South Africa where limitations on individuals' rights are in place for health reasons which are justifiable in terms of section 36 of the Constitution to give effect to section 27 of the Constitution.

27. For example, the very fact that the State is allowed to prescribe minimum benefits for medical scheme members could, in Mr Hermann's terms, be regarded as a limitation of rights, since it precludes Medical Scheme administrators from unilaterally deciding what benefits they will and will not provide. Yet, vaccines are now Prescribed Minimum Benefits (PMB.).

28. This is primarily because medical schemes are now premised on social solidarity, unlike in apartheid days, and because they are now set up as not-for-profit schemes that can no longer risk rate along ordinary insurance principles.

29. Mr. Hermann appears to accept that the limitation of rights produced by the imposition of PMBs is justifiable, because he uses the prescription of the COVID-19 vaccine as a PMB to argue that vaccines are something that 'members and beneficiaries of medical schemes are entitled by law".

30. His concern is that the limitation which prevents the private sector from procuring and allocating vaccines is unjustified.

31. I point out that limitations of rights in the interest of public health are common and widely applied, and may be fully justified when they meet human rights standards. There is an extensive literature on this, to which I have been a

contributor.[1] I attach a copy of a research article which I wrote entitled 'Issues of equity are also issues of rights': Lessons from experiences in Southern Africa', attached marked "**LL26**".

32. I understand whether a limitation is permissible depends on whether it is reasonable and justifiable in an open and democratic society based on human dignity, equality, and freedom, in accordance with the considerations set out in section 36 of the Constitution. In relation to not permitting parallel procurement / acquisition and allocation of COVID-19 vaccines outside of a national strategy:

32.1 Equality is promoted in that any private sector user or trade union member who qualifies based on health risk for priority vaccination and who wants a safe and effective vaccine will not be denied vaccination – they will be treated the same as any other person in the country with an equivalent risk profile or occupational risk. Should they be a health worker, they will be included in Phase I. If they are an essential worker other than a health worker, they will be included in Phase II. Other workers are included in Phase III. If the latter group

[1] London L. What is a human-rights based approach to health and does it matter? Health and Human Rights 2008; 10(1): 65-80. Accessible at URL: http://www.hhrjournal.org/2013/09/13/what-is-a-human-rights-based-approach-to-health-and-does-it-matter/; London L. Confinement for extreme drug-resistant TB (XDR-TB): Balancing protection of health systems, individual rights and the public's health. International Journal of Tubercle and Lung Disease 2009; 13(10): 1200-9; Bertscher A, London L, Rohrs S. A Human Rights analysis of South Africa's Control of Marketing of Alcoholic Beverages Bill. Homa Publica - Revista Internacional de Derechos Humanos y Empresas, (International Journal of Human Rights and Business) 2020; 4(1): e:065. https://periodicos.ufjf.br/index.php/HOMA/article/view/30678; Loewenson R, Accoe K, Bajpai N, Buse K, Deivanayagam TA, London L, Méndez CA, Mirzoev T, Nelson E, Parray AA, Probandari A, Sarriot E, Tetui M, van Rensburg AJ. Reclaiming comprehensive public health. BMJ Glob Health. 2020; 5(9): e003886. doi: 10.1136/bmjgh-2020-003886.

includes workers with co-morbidities that increase their risk, they will be included in Phase II.

32.2 Achieving equitable vaccine coverage is of the greatest importance, and consistent with the equality provisions of our Constitution. Allowing people with money or employment or financial means who are able to jump the queue simply because they do not want to wait in turn will defeat the purpose of our vaccination programme – to prevent unnecessary illness, debility and death;

32.3 The relationship between any prohibition of private procurement and the objective of achieving an equitable roll out of the vaccines is clear, as detailed above;

32.4 There is no less restrictive means to achieve the purpose of the vaccination roll out;

32.5 The state will, to the best of my knowledge, involve the provinces, private sector, business and others, to the maximum, in assisting in rolling out vaccines to those who qualify based on health criteria, not wealth criteria;

32.6 In my opinion, all of the above would justify a proscription on private and parallel provincial acquisition, selection, and administration of vaccines as fully consistent with Section 36 of the Constitution. (I repeat that I do not express an opinion on the legal question of whether the national government's policy constitutes a proscription.)

33. As a public health physician with more than 30 years of experience and with a detailed understanding of how the Western Cape province, in particular, administers health services, it is clear to me that the intent of the Declaration of the State of Disaster in March 2020 was to implement extraordinary measures to curb and contain the spread of the virus. The national plan to vaccinate according to globally accepted public health and epidemiological principles which govern acquisition, allocation, and selection is consistent with my understanding of best public health practice and what is needed to address a health emergency.

34. Under the International Covenant on Economic, Social and Cultural Rights (ICESCR), which South Africa ratified in 2015, our State has an obligation to "ensure the prevention, treatment and control of epidemic ... diseases" so as to enable people in the country to realise their right "to the enjoyment of the highest attainable standard of physical and mental health.' The measures it must take to respect, protect and fulfil this right may involve limitations of the rights of some individuals as long as these limitations meet recognised human rights principles, both international and national.

35. In particular, to protect rights of people vulnerable to COVID-19, the state must take action to prevent third parties from acting in ways that threaten people's human rights of access to health care and their equality under the Constitution. The state ought to proceed in a way that fulfils its obligation to protect the rights of vulnerable groups against individuals who are not at high risk from COVID-19.

CONCLUSION

36. In summary: If provinces and some trade unions and private groups select, procure, and administer vaccines independently and outside of national processes and guidelines, there will be a lack of coordination, poor accountability and an inability to ensure equity in access, which will be at the cost of the health and survival of high-risk and vulnerable groups in our country. Such an approach has no support in any of the large body of technical, scientific, and ethical guidance presently available in the public domain.

PROFESSOR LESLIE LONDON

I hereby certify that the deponent stated that he knows and understands the contents of this affidavit and that it is to the best of his knowledge both true and correct. This affidavit was signed and sworn to before me at CAPE TOWN on this the 18 day of February 2021. The Regulations contained in Government Notice R.1258 of 21 July 1972, as amended, have been complied with.

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1. QUALIFICATIONS:

Degree		University	Year
MB. ChB.	Bachelor of Medicine	Cape Town	1983
B.Sc (Hons)	Honours in Epidemiology	Stellenbosch	1987
DOH	Diploma in Occupational Health	Wits	1989
MD	Doctorate in Community Health	Cape Town	1995
MMed	Masters in Community Health	Cape Town	1996

PREVIOUS POSITIONS:

Groote Schuur Hospital, Cape Town	Internship	1984
South African Defence Force	Medical Officer and religious objector	1985-1986
Food Workers Medical Benefit Fund	Medical Officer: Occupational Health, Primary Care services	1987-1991
Department of Public Health and Primary Health Care (formerly Community Health), University of Cape Town	Guy Elliot Research Fellow	1991-1992
	Registrar	1993-1995
	Specialist/lecturer	1996-1998
	Senior Specialist& Associate Professor	1998-2000
School of Public Health and Family Medicine, University of Cape Town	Senior Specialist & Associate Professor	2000-2004
	Senior Specialist & Professor	2004-2007
	Director of School	2007-2012
	Senior Specialist & Professor	2011-2013
	Acting Head: Division of Public Health Medicine	
	Chair of Public Health Medicine Head of Division of Public Health Medicine	2013 -

Current registered with the HPCSA as specialist in public health and occupational medicine.

2. PUBLICATIONS

(For PubMed listing of articles, see
http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/47971846/?sort=date&direction=descending)

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2.1.1 Articles in international peer-reviewed journals

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2.2.3 Letters and reports in local non-peer-reviewed journals

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2. London L. A checklist for the correct use of key terminology in public health. S Afr J Epilnf1996 ; 11 : 92.
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2.4 Other Contributions

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2.4.2 Book and chapter reviews

1. London L: "A legacy from which to learn." Review of: Human rights and health: the legacy of apartheid. Chapman A, Rubenstein L, editors. American Association for the Advancement of Science. Washington, 1998. Torture, 1999.
2. Review: Climate Change and Human Health. Risks and Responses. AJ McMichael, DH Campbell-Lendrum, CF Corvolan, KL Ebi, A Githeko, JD Scheranga and A Woodward. World Health Organisation, Geneva, 2003. SAMJ 2004; 94(7): 527.
3. Review: Perspectives on health and human rights. Gruskin S, Grodin MA, Annas GJ, Marks SP. JAMA 2006; 295: 219.
4. Review: Backman G. Health and Human Rights: Theory and practice. Royal Society for Public Health. Public Health 2012; 127: 297.
5. Review: Hilgert J. Hazards or hardship. Crafting global norms on the right to refuse unsafe work. New Solutions 2014; 24(3): 449-451.

2.4.3 Manuals, training publications and DVDs

1. Training trainers in Health and Human Rights. Baldwin-Ragaven L, London L. University of Cape Town: 2005.
   Available at http://www.hhr.uct.ac.za/train/train.php
2. Zama, M., Rendall-Mkosi, K., London, L., Morojele, N. Prevention of Fetal Alcohol Syndrome: A Motivational Interviewing Training Manual for Service Providers. Pretoria, South Africa: University of Pretoria, Medical Research Council, University of Cape Town,2010.
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4. Fick N, London L, Coomans F. Toolkit on the Right to Health. University of Cape Town, Learning Network on Health and Human Rights. Cape Town: 2011.
   Available at http://www.hhr.uct.ac.za/docs/Toolkit_final%20version.pdf
5. Better health together: A training DVD on community participation and health committees for health professionals. Director Mareike Kramper, 2015. URL: http://salearningnetwork.weebly.com/dvds.html. UCT informants: L London and P Mayer.

2.4.4 Other popular and community publications

1. London L. Perspectives on Human Rights: Furthering the Debate. PAMBAZUKA NewsVolume 81; 28 Sep 2002.
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2. London L, Pointer R. Using human rights to promote health equity. EQUINET, Harare: 2004.
3. London L. What can Human Rights do for Health & Health Equity in South Africa. Critical Health Perspectives 2005: 1. (People's Health Movement, South Africa).
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5. London L. Human rights and public health: More than just about civil liberties. Editorial. EQUINET Newsletter October 2006
6. EQUINET, TARSC and UCT in cooperation with SEAPACOH. (2008). Parliament roles in protecting rights to health in East and Southern Africa. Parliament Briefing 3. July 2008. EQUINET, Harare
7. EQUINET, TARSC and UCT in cooperation with SEAPACOH. (2008). Using health rights to promote equity oriented health budgets Parliament Briefing 4. July 2008. EQUINET, Harare.
8. Work and Health in Southern Africa. Policy Briefs: 1) Pesticide Laboratory Capacity in the SADC Region – A Vital Link in Pesticide Risk Reduction; 2) Reducing the impact of pesticides through Community Pesticide Monitoring; 3) Acute pesticide poisoning and the need for national surveillance systems – the case example of Tanzania; 4) Reducing pesticide risks through Building capacity of African Regulators. Contribution as co-author to briefs. Durban, August 2008.
9. University of Pretoria, Medical Research Council and University of Cape Town. Policy Brief: Fetal Alcohol Spectrum Disorders in Cape Town, South Africa: A huge challenge requiring multi-faceted prevention strategies. University of Pretoria, Pretoria, November 2008.
10. Bowers Y, London L, Holtman Z, Messina S, Arendse B, Lindoor E, Rhodes G. Obstacles to the rights of access to health care for farm worker women in the Western Cape. Critical Health Perspectives; 2009 Number 1.
11. London L, Reynolds L. Beware think-tanks! Corporate think-tanks, free market ideology and the attack on the Right to Health. Critical Health Perspectives. Critical Health Perspectives October 2010 Volume 2. Issue 2. People's Health Movement. Accessed on URL: http://www.phmovement.org/sites/www.phmovement.org/files/CHPOctober2010Vol2Issue2.pdf.
12. Naledi T, London L, Dudley L, Valabhjee K. Collaboration to provide Public Health expertise to a provincial health department: The Western Cape story. PHASA Newsletter August 2013. URL: http://www.phasa.org.za/wp-content/uploads/2013/08/Naledi_Collaboration-to-provide.pdf
13. London L. Can the NHI achieve Health for All? PHASA Newsletter September 2018.
14. London L. Children's Rights provide a powerful lever to challenge chronic disease risks. (Editorial). EQUINET Newsletter #223 March 2020.
15. London L. Where there's Smoke, there's Fire! Conflicts of Interest of Covid-19 Research Funders. PHASA Health Promotion Special Interest Group. The Pulse Newsletter. July 2020. Edition 8. Public health Association of South Africa. At http://phasa.samrc.ac.za/news/SmokeFire.pdf.

3. Personal scientific / scholarly presentations at congresses

3.1 International Congresses / meetings

3.1.1 Invited Presentations – International Conferences

1. Occupational Epidemiology in Agriculture: A Case study in the Southern African context. Keynote speech for the 6th International Symposium on Epidemiology in Occupational Health, September 1997.
2. Invited presentation "Medical accountability and Human Rights: South Africa's doctors under apartheid. Presentation to the symposium "Doctors under scrutiny", Institute of Medical History, University of Vienna, October 1999.
3. Guest speaker: "Pesticides, social justice and women agricultural workers in South Africa: A developing country perspective" on the Ecosystems Approach to Health Lecture tour in Canada (Montreal, Halifax, Toronto and Edmonton), February 2001, hosted by the University of Quebec at Montreal, and sponsored by the International Development Research Commission.
4. Invited presentation "Chemical Hazard Comprehensibility – a Global Challenge" to WHO-HQ/AFRO Conference on Chemical Safety in Africa: Preparing the Health Sector for the Challenges of the 21st Century, Cape Town, July 2001.
5. Keynote address to SOUTH-SOUTH Workshop on Scientific Information Exchange and Research Collaboration for the Prevention of Adverse Health Effects of Pesticides in the Tropics: Suicide and Exposure to Organophosphate Insecticides: Cause or Effect? Heredia, Costa Rica, February 2002
6. Invited presentation to Public Health Discussion Series at Harvard School of Public Health, March 2002. Panel: "The future of Public Health: Ethical Issues in Health Research in Vulnerable Populations." Topic: "What role can rules and Institutional Review Boards play?"
7. Guest speaker for the Annual Meeting of the South Atlantic States Association for African and Asian Studies, University of North Carolina, Wilmington, March 2002. "Cognitive Dissonance and New Struggles: AIDS policy, human rights and transformation in South Africa."
8. Invited presentation to the 8th Annual Meeting of the Association of Medical Councils of Southern Africa, Maseru, August 2003: "Dual Loyalties and Human Rights: Challenges for the Practice of Health Professionals."
9. Keynote address to Amnesty International health professional network meeting: "Health and Human Rights: An evolving view from South Africa." London, October 2003.
10. Invited speaker on Panel at the Society of Toxicology Annual Meeting in 2005, New Orleans. "Organophosphate Pesticides and Suicide: Cause or effect?" Hosted by Freya Kamel, National Institutes for Environmental Health Sciences.
11. Invited speaker in the workshop section of the Emory University/CDC/CARE conference *Lessons Learned from Rights Based Approaches to Health:* "Human Rights, Dual Loyalty and Public Health Policy," Atlanta, April 2005.
12. Invited speaker – "Dual Loyalties in Occupational Health'" Conference on Dual Loyalties, Ben Gurion University, Beer Sheva, Israel, Physicians for Human Rights Israel, November 2005.
13. Invited speaker – "Dual Loyalties." Seminar: Health, Rights & Ethics. Zimbabwe Association of Doctors for Human Rights (ZADHR) in collaboration with Paediatric Association of Zimbabwe (PAZ). Harare, March 2005
14. London L. Community Agency: The key to making Human Rights work for public health. Commissioned paper for the African Religious Health Assets Programme (ARHAP) Annual International Colloquium, University of Cape Town, 2007, Cape Town.
15. London L. Use of confinement in the management of drug-resistant TB: Balancing individual rights and the public good. Presentation to the 38th Union World Conference on Lung Health, Cape Town, November 2007.
16. London L. Neurobehavioural methods, effects and prevention: Why the field matters for developing countries. Hainninen Lecture: Joint conference:

Epidemiology in Occupational Health (20th International Conference) and Neurobehavioral Methods and Effects in Environmental and Occupational Health (10th International Symposium), Costa Rica, June 2008.

17. London L. What is a human rights approach in health and why does it matter? Invited presentation to Global Health Issues and Human Rights Seminar, Institute of Health, Warwick University, June 2008
18. London L. Human rights and health: Opportunities to advance rural occupational health. Invited keynote presentation to 17th Symposium on Agricultural Medicine & Rural Health, Cartagena, Colombia, October 2009.
19. London L. Taking Toxins Home: Exposure pathways for hazardous materials. Keynote address to ICOH conference on Occupational Health and Safety in Small and Medium Enterprises, Accra, October 2011.
20. London L. Justiciability and enforceability of the right to health: a South African view. Presentation to a consultation of the UN Special Rapporteur on the Right to Health. Delhi, July 12th and 13th 2014.
21. London L. Human rights and public health policy: Synergies rather than contradictions. Keynote address to the 10th International Dental Ethics and Law Congress, Cape Town, September 3-5, 2014.
22. London L. Health equity in Southern Africa: the role of health committees. Keynote presentation to International Seminar of the Citizen Engagement Programme (CEP). Jointly organized by Citizen Engagement Programme and Institute for Development Studies. Maputo, December 2017.
23. London L. Integrating Human Rights in Public Health Curricula. Keynote presentation to the Annual Conference of the Association of Schools in Public Health in Africa (ASPHA), 14-16 October 2019.
24. London L, Bertscher A, Roehrs S, Child right protection and industry advertisement, promotion and sponsoring (APS) in the NCD crisis: The case of Alcohol. Invited presentation to a *Roundtable on* Child rights protection and industry advertisement, promotion and sponsoring (APS) in the NCD crisis. Geneva 25th June 2019.

3.1.2 Other Presentations – International

1. London L, Dowdall T. Torture and the Medical Profession - A view from South Africa. Presented to the Fourth International Conference on Torture and the Medical Profession. Budapest, October 1991.
2. London L, Myers JE, Nell VN, Thomson ML, Mbuli S. Neurotoxic effects of long-term agrichemical exposures amongst farm workers in South Africa. Paper presented to the Fifth International Symposium of Neurobehavioural Methods and Effects in Occupational and Environmental Health, Cairo, 1994.
3. L London, G McCarthy, J van Heerden, S Wadee, N Walaza, T Winslow. Preparing Future Doctors to meet Ethical Challenges: An historic training course for medical students at the University of Cape Town. Presentation to the VIIth International Symposium: Caring for survivors of torture - challenges to the health professions. International Rehabilitation Council for Torture Survivors, Trauma Centre for Victims of Violence and Torture, Cape Town, November 1995.
4. London L. Use of a Job-exposure Matrix to assess long-term exposure in studies of the adverse chronic effects of pesticides. Presentation of Paper at the Second Conference of the Pan-African Environmental Mutagen Society, Cape Town, January 1996.
5. London L, Thomson ML, Nell V, Taylor T, Myers JE. The performance of neurobehavioural test methods in low-education working populations in South Africa. Presentation to the 25th International Congress on Occupational Health, Stockholm, September 1995.
6. London L, Myers JE. The Use of a Job-exposure matrix for agriculture. Pre-conference workshop for the 6th International Symposium on Epidemiology in

Occupational Health, Harare, September 1997.

7. London L, Thomson ML, Myers JE. Measurement of alcohol consumption amongst South African Farm Workers. 6th International Symposium on Epidemiology in Occupational Health, Harare, September 1997.
8. London L. Consumption of Alcohol amongst farm workers in the Western Cape. Paper presented to the International Birth Defects Clearinghouse Meeting Workshop on Foetal Alcohol Syndrome, Cape Town, November 1997.
9. London L. Alcohol abuse amongst farm workers in South Africa. Presentation to the conference on "The Epidemiology and Prevention of ATOD (Alcohol, Tobacco and Other Drugs) abuse and violence in South Africa and the US." Howard Univeristy South Africa Programme, Washington, January 1998.
10. London L, Bailie R. Challenges for improving surveillance for pesticide poisoning: Policy implications for developing countries. Paper presented to the International Conference on Pesticide Use in Developing Countries: Impact on Health and the Environment, Costa Rica, February 1998.
11. London L. Education in health and human rights for health professionals: A South African perspective. Presentation to the International Conference on Health and Human Rights, Cape Town, December 1998: Conflict, Health and Reconstruction. International Society for Health and Human Rights.
12. London L, Rayners A, Mahomed C, Dausab M, Cornelius L, du Toit R, Taylor N, Sanders D, te Water Naude J, Visser S. Alcohol Abuse and the legacy of the DOP system in South Africa: Challenging the social control of farm workers. Presentation to the International Conference on Health and Human Rights, Cape Town, December 1998: Conflict, Health and Reconstruction. International Society for Health and Human Rights.
13. London L, Thompson ML, Capper WL, Myers JE. Utility of vibration sense testing for use in developing countries. Presentation to the Seventh International Symposium of Neurobehavioural Methods and Effects in Occupational and Environmental Health, Stockholm, June 1999.
14. London L, Baldwin-Ragaven L, de Gruchy J. Human Rights training for medical professionals – Core business or add-on? A South African perspective. Paper presented to the Ottowa Conference on Medical Education: Ottowa in Africa, March 2000.
15. London L, Alperstein M. Diversity in the learning environment: New skills needed for curriculum reform in developing countries. Presentation to pre-conference workshop on "Curriculum Change in Developing Countries" for the Ottawa conference on Medical Education: Ottawa in Africa, March 2000, Cape Town.
16. London L. Human Rights and Public Health: Dichotomies or Synergies in Developing Countries? Examining the case of HIV in Africa. Presentation to "Health, Law and Human Rights: Exploring the Connections. An International Cross-Disciplinary Conference honoring Jonathan M. Mann." American Society of Law, Medicine & Ethics, Philadelphia, September – October 2001.
17. London L, Rother HA. Presentation to SOUTH-SOUTH Workshop on Scientific Information Exchange and Research Collaboration for the Prevention of Adverse Health Effects of Pesticides in the Tropics: Hazard Communication, a Global Challenge. Heredia, Costa Rica, February 2002.
18. Rother HA, Prinsloo T, London L. Pesticides Health Policy and Practice: A Review of the Role of Environmental Health Officers in South Africa. Presentation to International Conference on Pesticides Exposure and Health. Natcher Centre, Bethesda, Maryland, USA, July 2002
19. London L, Flisher A, Wesseling I. Suicide and Exposure to Organophosphate Insecticides: Cause or Effect? Implications for pesticide policy in developing countries. Presentation to International Conference on Pesticides Exposure and Health. Natcher Centre, Bethesda, Maryland, USA, July 2002

20. Rother HA, London L, Maruping M, Miller S. Hazard Communication for Pesticide Safety in Developing Countries: When Is the Message Adequate? Presentation to International Conference on Pesticides Exposure and Health. Natcher Centre, Bethesda, Maryland, USA, July 2002
21. London L, de Grosbois S, Wesseling C, Kisting S, Rother HA, Mergler D.Pesticide usage and health consequences for Women in Developing Countries: Out of sight, out of mind? Presentation to International Conference on Pesticides Exposure and Health. Natcher Centre, Bethesda, Maryland, USA, July 2002.
22. London L. Health rights as a tool for health equity. Third Southern African conference on equity in health. "Reclaiming the State: Advancing Peoples Health, challenging Injustice," hosted by the Network for Equity in Health in Southern Africa (EQUINET), Durban, South Africa, June 8-9 2004
23. London L. How can human rights serve as a tool for health equity? Third International Conference of the International Society for Equity in Health (ISEqH), Durban, South Africa, June 10-12, 2004.
24. London L. Flisher A, Major V, Kromhout H, Mergler D. Organophosphate exposure, depression and suicide: matching epidemiological data to models based on animal studies and case series Society of Toxicology Annual Meeting, New Orleans, March 2005.
25. London L. How can human rights serve as a tool for health equity? Emory University/CDC/CARE conference *Lessons Learned from Rights Based Approaches to Health:* "Human Rights, Dual Loyalty and Public Health Policy," Atlanta, April 2005.
26. London L. Health and Human Rights: What can 10 years of democracy in South Africa tell us ? Emory University/CDC/CARE conference *Lessons Learned from Rights Based Approaches to Health:* "Human Rights, Dual Loyalty and Public Health Policy," Atlanta, April 2005.
27. London L, Ngowi AVN, Perry M, Rother HA, Cairncross E, Solomon A, Du Toit A, Hall R, Ajayi O. Health and Economic Consequences of Pesticide Use: The experience of the Health, Environment and Economic Development (HEED). Presentation to 17th International Society for Environmental Epidemiology Conference, Sandton, South Africa,September 2005.
28. London L, Ngowi AVN, Perry M, Rother HA, Cairncross E, Muangirwa C. Action on Pesticides - Health and Economic Consequences of Pesticide Use: The experience of research collaboration on pesticides in Southern Africa. Presentation to 17th International Society for Environmental Epidemiology Conference, Sandton, South Africa,September 2005.
29. London L. Human rights and social justice for South African farm workers. Presentation to 17th International Society for Environmental Epidemiology Conference, Sandton, South Africa,September 2005.
30. London L, Rother HA, Dalvie MA, Maruping M, Tolosana S. Chemical Hazard Communication Comprehensibility in South Africa: Implications for the adoption of the Globally Harmonised System for Chemical Hazard Classification (GHS). Presentation to Collegium Ramazzini's International Ccientific Conference "Framing the Future in Light of the Past: Living in a Chemical World," Bologna, Italy, September 2005.
31. London L, Miller M, Adams S, Rother HA. Occupational health hazards in child labour: Information for policy. Presentation to 8th World Conference on Injury Prevention and Safety Promotion, Durban, April 2006.
32. London L, Thompson ML, Myers J. Measurement of alcohol consumption amongst South African farm workers. Presentation to 134th Annual Meeting of the American Public Health Association, Boston, November 2006.
33. Kirstie Rendall-Mkosi, Neo Morojele, Milo Zama, Leslie London, John Matjila, Kuku Jacobs. Comprehensive FAS Prevention Programme Model Development in South Africa. Presentation to the 2nd International

Conference on Fetal Alcohol Spectrum Disorder. Research, Policy and Practice around the World. Victoria, Canada, March 2007.

34. London L, Rubenstein L, Baldwin-Ragaven L Dual Loyalty: Human Rights and Ethical Challenges for the Health Professions. Presentation to 134th Annual Meeting of the American Public Health Association, Boston, November 2006.
35. Leslie London. Funding for Behavioral Neurotoxicology Research in Southern Africa: Opportunities and obstacles. Joint conference: Epidemiology in Occupational Health (20th International Conference) and Neurobehavioral Methods and Effects in Environmental and Occupational Health (10th International Symposium), June 2008
36. London L, Major V, Kromhout H, Flisher A. The association of hostility, impulsivity and psychiatric symptoms with pesticide exposure amongst South African farm workers. Joint conference: Epidemiology in Occupational Health (20th International Conference) and Neurobehavioral Methods and Effects in Environmental and Occupational Health (10th International Symposium), June 2008.
37. London L. Human rights and health: A neglected perspective in the Occupational Health setting. 29th International Congress on Occupational Health, Cape Town, March 2009.
38. London L, Coggon D,Colosio C, Moretto A, WesterholmW, Wilks MAn ICOH workgroup to investigate the ethical and scientific issues in the use of data from studies involving deliberate exposure of human volunteers in the Regulation of Pesticide Usage. 29th International Congress on Occupational Health, Cape Town, March 2009.
39. London L, Coggon D,Colosio C, Moretto A, WesterholmW, Wilks MUse of data from studies involving deliberate exposure of human volunteers in the Regulation of Pesticide Usage: Ethical and Scientific Issues. 29th International Congress on Occupational Health, Cape Town, March 2009.
40. London L, Manjra S. Employability and HIV infection: Can the military claim to be an exception? 29th International Congress on Occupational Health, Cape Town, March 2009.
41. London L, Kootbodien T, Besseler C,Flisher A, Kromhout H, Little F, Major V, Stallones L. The association of hostility, impulsivity and psychiatric symptoms with pesticide exposure amongst South African farm workers. 29th International Congress on Occupational Health, Cape Town, March 2009.
42. Major VJ, Kromhout H, Flischer A, London L.The role of exposure to organophosphate pesticides in the aetiology of depression and suicidality amongst farm workers on grape farms in the Western Cape, South Africa. 29th International Congress on Occupational Health, Cape Town, March 2009.
43. Weselling I, London L. SALTRA and WAHSA in Central America and Southern Africa: promising but truncated models. 29th International Congress on Occupational Health, Cape Town, March 2009.
44. Garcia DE, Baldwin-RagavenL, London L. Training Trainers in Health and Human Rights: Implementing curricula reform in South African health sciences institutions. Presentation to 3rd conference of the South African Association of Health Educationalists (SAAHE), University of Cape Town, 2-4 July 2009.
45. London L, Schneider H. Globalisation and health inequalities: Can a human rights paradigm offer a solution? Presentation to Third EQUINET Regional Conference on Equity in Health in East and Southern Africa, Speke Conference Center, Munyonyo, Kampala, Uganda, September 23-25, 2009.
46. London L, Dalvie MA, Rother HA. Chemical Hazard Comprehensibility: Supporting the development of the GHS. Presentation ICOH conference on Occupational Health and Safety in Small and Medium Enterprises, Accra, October 2011, Accra, Ghana.

47. London L. Promoting farm workers' occupational health in South Africa: challenging social exclusion through human rights. Workshop session on "An Ecohealth Approach for Environmental and Social Justice." Ecohealth 2010, London, August 2010.
48. London L, Kootbodien T, Little F, Kromhout H, Major V, Flisher A. The association of suicidality, depression and organosphosphate exposure amongst farm workers in South Africa. Presented at the joint conference of the 13th meeting of the International Neurotoxicology Association (INA) and the 11th International Symposium on Neurobehavioral Methods and Effects in Environmental and Occupational Health (NEUREOH) June 2011, Xian, China.
49. London L, Rother HA, Dalvie MA. Chemical Hazard Communication Comprehensibility in South Africa: Safety Implications for the adoption of the GHS. Presentation to the 30th International Congress on Occupational Health, Cancun, March 2012.
50. London L. Revisiting the ICOH ethical code: Perspectives of the Africa working group. Presentation to the 30th International Congress on Occupational Health, Cancun, March 2012.
51. London L, Major V, Kromhout H. Gender Differences in Exposure to Pesticides amongst South African Farm Workers. Presentation to the 30th International Congress on Occupational Health, Cancun, March 2012.
52. London L. Occupational health challenges and services in agriculture in South Africa. Presentation to the 30th International Congress on Occupational Health, Cancun, March 2012.
53. London L. Universal health care and the right to health - no gains without community agency. American Public Health Association Conference, Boston, 2013.
54. Haynes L, Legge D, London L, McCoy D, Sanders D, Schuftan C and the People's Health Movement (PHM). Will the struggle for health equity and social justice be best served by a Framework Convention on Global Health? American Public Health Association Conference, Boston, 2013
55. London L, Ahmed AK..Science for sale or science for the people? Civil society and scientific engagement in United States and Africa. Presentation to Workshop on Public Health at University of Modena, October 24th 2014.
56. London L, Donald K, Adnams C, Tsze D, Rother HA. Neurodevelopmental deficits in children surviving acute organophosphate intoxication. Presentation to 31st International Congress on Occupational Health, Seoul, May 2015.
57. Lekei EE, Ngowi AV and London L. Surveillance of Acute pesticide poisoning in Tanzania: Experience from Hospital review and other sources. Presentation to 31st International Congress on Occupational Health, Seoul, May 2015.
58. London L, Mall S. MPH Core Competencies: A survey of 7 African Schools of Public Health compared to international experiences. Presentation to 4th Annual Meeting of the Association of Schools of Public Health in Africa (ASPHA) and the Joint Annual Scientific Health Conference, Kampala, September 2015.
59. London L, Mulumba M, Haricharan H, Fritz D, Mayers P, Nantaba J. Promoting community participation in health system governance: Health Committees in rural Uganda and urban Cape Town. Presentation to Southern African Nordic Centre (SANORD) Conference, Uppsalla, September 2016.
60. London L, Ahmed K. Science for sale or science for the people? Civil society and scientific engagement in the US and Africa. 3rd International Symposium on Ethics of Environmental Health, Budweiss, Czech Republic, Sept 2016.
61. London L, Ruff K, Castleman B, Watterson A. Scientific integrity in journal publication practice for Occupational and Environmental Health. Collegium Ramazzini annual conference, October 2017.
62. London L. A rights-based approach to access to Occupational Health Services – what might that offer working populations in the developing world?

Presentation to the 32nd International Congress on Occupational Health, Dublin, 29 April to 4 May 2018.

63. Kootbodien T, Ramesar R, Holtman Z, Asmal L, Chiliza B, Joska J, Smith P, Stallones L, London L. Organophosphate pesticide exposure as a risk factor for suicide attempts. Presentation to the 32nd International Congress on Occupational Health, Dublin, 29 April to 4 May 2018.
64. London L, Olivier J, Ryan L, Kibido F, Mdayi M, Benjamin S, Kelly K, Mort R. Health system governance from below? Exploring progress towards Health for All through the implementation of health committees: The Community Systems Strengthening Project. Presentation to International Conference on the Social Determinants of Health. Medicus Mundi, Maputo, Mozambique, 4-7th December 2018.
65. London L. The right to enjoy the benefits of scientific progress for small farmers facing pesticides hazards. Presentation to Agroecology for the 21st Century Conference, Cape Town 28-30 January 2019.

Posters

1. London L, Eastman R, Sayed R, Bourne D, Kuhn G. An outbreak of Guillan-Barre syndrome in a rural farming district in South Africa: A possible relationship to environmental organophosphate exposure. Poster presentation to the 25th International Congress on Occupational Health, Stockholm, September 1995.
2. London L, de Kock A. Alcohol abuse amongst South African farm workers: New paradigms for old problems. 9thInternational Conference on the Treatment of Addictive Behaviours, Somerset West, Cape Town, September 2000.
3. Naidoo S,, London L, Clapp R, Janulewicz P, Mnyaiza S, Vieira V, White R Potential occupational and non-occupational exposures to pesticides amongst pregnant women in northern Kwazulu Natal province of South Africa.Joint ISEE/ISEA International Conference on Environmental Epidemiology and Exposure, Paris, September 2006
4. Maruping M, London L, Flisher A. Suicide and organophosphate pesticide exposure amongst South African farm workers.Joint ISEE/ISEA International Conference on Environmental Epidemiology and Exposure, Paris, September 2006
5. London L, Rother HA, Dalvie MA, Maruping M, Tolosana S. Chemical Hazard Communication Comprehensibility in South Africa: Implications for the adoption of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).Joint ISEE/ISEA International Conference on Environmental Epidemiology and Exposure, Paris, September 2006.
6. London L, Mazok, C, Adam H, Parry C. If the alcohol doesn't get you, then the toxins will: The health impacts of bulk wine provision in the Western Cape province of South Africa. 134th Annual Meeting of the American Public Health Association, Boston, November 2006.
7. London L, Manjra S. Employability and HIV infection: Can the military claim to be an exception? Presentation to Annual Scientific Conference of the Collegium Ramazzini, Carpi, Oct 24 to 27, 2008.
8. London L, Loewenson R, Thomas J, Mulumba M, Mbombo N. Can parliamentary action advance the right to health? Experiences from East and Southern Africa. Poster presentation to the 3rd Global Health Systems Research Symposium, Cape Town, October 2014.
9. Fick N, Stuttaford M, Abrahams L, Rajap A, Cornelius A, London L. Picturing Health: Using photo-voice as a participatory method to explore community perceptions of health. Poster presentation to the 3rd Global Health Systems Research Symposium, Cape Town, October 2014.
10. Haricharan HJ, London L, Stutafford M. Improving primary health care through

community participation in health. Poster presentation to the 3rd Global Health Systems Research Symposium, Cape Town, October 2014.

11. Meier BM, Flores W, Mulumba M, Colvin C, London L. Social Participation to Realise the Right to Health: A Comparative Case Study of Rights-Based Participation in Health Systems. Poster presentation to the 3rd Global Health Systems Research Symposium, Cape Town, October 2014.
12. London L, Haricharan H, Boulle T, Stuttaford M, Kiewitz D, Marshall A, Mayers P, Kibido F. Enhancing Health System responsiveness through Community Participation: Health Committees as vehicles for meaningful participation. Presentation to the Fourth Global Symposium on Health Systems Research, Vancouver, November 2016
13. London L, Kramper M. Better health together. Audiovisual presentation (DVD) at the 4th Global Health Systems Research Conference, Vancouver, Nov 2016.
14. London L. Scientific Integrity, Conflict of Interest and Journal Publication Practice in Occupational and Environmental Health. Poster presentation to the 32nd International Congress on Occupational Health, Dublin, 29 April to 4 May 2018.
15. Gouse H., Marcotte TD, Masson CJ, Henry M, London L, Kew G, Robbins RN. HIV provider and vocational driver knowledge of HAND and needs for health management. Poster presented at the 10th IAS Conference on HIV Science. Mexico City, Mexico, 21-24 July 2019

In addition, co-author on 20 papers and 18 poster presentations at international congresses since 1997 in which I was either a co-investigator or supervisor or mentor for a junior researcher or post-doc. (not presented personally).

3.2 Local Congresses / meetings

3.2.1 Invited Presentations – Local Conferences

1. Invited presentation "Human Rights in the Health Sector: Opportunities, obstacles and challenges." National workshop by the Centre for the Study of Violence and Reconciliation "The implementation of the TRC's recommendations: Where are we in relation to reparations; and institutional transformation in the health sector?" Johannesburg, 16th February 2000.
2. Invited presentation "Ethics in Occupational Health: Challenges for South Africa." 3rd Annual Conference of the Mine Medical Officers Association of South Africa, Rustenberg, May 2000.
3. Invited presentation "Poverty and the Constitution: The right to health." Seminar on "Poverty and the Constitution", Legal Resources Centre, Braamfontein, August 2000.
4. Invited presentation "Guidelines on Ethical and Professional Conduct" Presentation to the SASOM congress: "New approaches to old problems in COID issues." Cape Town, March 2001.
5. Invited presentation "Taking Toxins Home." Presentation to the SASOHN congress, Gordons Bay, August 2004.
6. Invited presentation "Human rights and Ethical Challenges" to South African Nutrition Congress, Worcester, August 2004.
7. Invited presentation "Human Rights, Ethics, Professional Practice and Sickness Absenteeism in the workplace." SASOM Annual Conference, CSIR, Pretoria, 2ndAugust 2005.
8. Invited speaker – "Risks from Exposure to Hazardous Chemical Substances: Beyond regulatory compliance to protecting health and the environment." Presentation to the South African Institute of Occupational Hygiene (SAIOH), September 2006.

9. Invited speaker – "Patient confidentiality in occupational health: balancing public health and individual rights." Presentation to the South African Society for Occupational Medicine Conference, 'Get hands on with Occupational Diseases and new Compensation instructions', Cape Town, March 2007.
10. Invited guest lecturer to Wits University "Ethics Alive" programme, March 2010: Three talks on 'Withdrawal of services as a form of advocacy', Is it Professional for Healthcare Practitioners to Engage in Strike Action?' and 'Global Human Rights in Medical Practice.'
11. Keynote presentation to the joint South African Society for Occupational Medicine / African Regional Association of Occupational Health (SASOM/ARAOH) conference August 1st 2014: "Ethics in occupational health: An African perspective." Johannesburg.
12. Plenary panel on the Future of Public Health Education at the Public Health Association of South Africa Conference, East London, September 2016.
13. London L. The right to enjoy the benefits of scientific progress: A tool to improve health and safety related to pesticides. Keynote address to the Joint SASOM-MEDICHEM Congress in Johannesburg, SA, 31 July - 3 August 2019
14. London L. Why is Conflict of Interest a problem for public health policy? Invited presentation to the Paediatric Priorities Conference, North-West University, 28-29th November 2019.

3.2.2 Other Presentations – Local Conferences

1. L London. Organising for Women's Health in the Canning Industry. Paper presented to the 4th NAMDA Conference, Johannesburg, July 1989.
2. L London. Occupational Dermatoses in the Canning Industry. Paper presented to the Dermatology Congress of South Africa, Durban, May 1992.
3. London L, Myers JE. Critical Issues in Agrichemical Safety. Paper presented to Association of Societies for Occupational Safety and Health, Johannesburg, May 1993.
4. London L. The Ray Alexander Workers Clinic - A Model for worker-based health services for South Africa? Paper presented to 13th Epidemiological Society of Southern Africa (ESSA) Conference, Durban, September 1993
5. London L, Myers JE. Critical Issues in Agrichemical Safety. Paper presented to 13th Epidemiological Society of Southern Africa (ESSA) Conference, Durban, September 1993
6. L London. The role of occupational health services in AIDS prevention. Paper presented to a Planned Parenthood Association (PPA) conference on AIDS in the workplace. University of Western Cape, Cape Town, June 1994.
7. London L, Bachmann OM, Barron P. The importance of service integration for improving the quality of care and efficiency of service utilisation for children under 6 at a large primary care facility in Khayelitsha. Paper presented to 14th Epidemiological Society of Southern Africa (ESSA) Conference, Bloemfontein, September 1994
8. London L, Myers JE, Thomson ML, Nell VN, Taylor T. An investigation into neurotoxic effects of long-term agrichemical exposures amongst farm workers in South Africa. Paper presented to 14th Epidemiological Society of Southern Africa (ESSA) Conference, Bloemfontein, September 1994
9. London L.A public health approach to potential water pollution by pesticides. Presentation to the annual MPAQASA symposium, Agricultural Research Council, Roodeplaats, May 1997.
10. te Water Naude J, London L, Pitt B, Mohamed C. A hidden epidemic? Ongoing application of the DOP system on farms in a Western Cape farming district. Paper presented to 15th Epidemiological Society of Southern Africa (ESSA) Conference, Cape Town, September 1997.

11. London L, Baillie R. An elusive target: Enhanced suveillance for pesticide poisoning in the Western Cape. Paper presented to 15th Epidemiological Society of Southern Africa (ESSA) Conference, Cape Town, September 1997.
12. London L, Cooper D, Shongwe B. Community Participation in Primary Care service development: A case study from the informal settlement of Matthew Goniwe, Khayelitsha, Cape Town. Health Systems Trust. Report back of Work-in-Progress. Durban, October 1997.
13. London L. Prevention – A South African approach. Wellington Foetal Alcohol Syndrome Prevention Programme. Foundation for Alcohol Related Research, Wellington, November 1997.
14. Baldwin-Ragavan L, London L, deGruchy J. Learning from our apartheid past: Human rights challenges for health professionals in contemporary South Africa. Conference: Mental Health beyond the TRC. October 1998, Medical Research Council, Cape Town.
15. London L. Alcohol consumption amongst South African farm workers: A challenge to post apartheid health sector transformation. Presentation to the 16th National Conference of the Epidemiological Society of Southern Africa. Johannesburg, October 1998.
16. London L, Dalvie MA, Nowicki A. Impact of Aerial Application of Organophosphate Insecticides on Cholinesterase Levels in a rural farming community in the Northern Cape Province. Paper presented to the 17th National Conference of the Epidemiological Society of Southern Africa. East London, February, 2000.
17. L London. Human Rights and Health: Challenges for the Training of Nurses in South Africa. Presentation to the SA Nursing Council National Conference, Benoni, September 2001
18. L London. Research in Vulnerable Populations: Do Human Rights have any bearing on arbitrating ethical standards in HIV Vaccine trials? Presentation to Cape Technikon HIV/AIDS programme. 15th April 2004.
19. L London, HA Rother, MA Dalvie, M Maruping, S Tolosana. Chemical Hazard Communication Comprehensibility in South Africa: Implications for the adoption of the Globally Harmonised System for Chemical Hazard Classification (GHS). Presentation to SASOM Annual Conference, Tygerberg, November 2005.
20. London L, Thomas J, Holtman Z, Gilson L, Erasmus E. Health professionals as gatekeepers or facilitators of community agency: Can a social movement realize the Right to Health? Presentation to the Municipal Services Project conference on 'Services for all: Theory, practice, struggle," Cape Town, March 2007.
21. London L, Holtman Z, Gilson L, Erasmus E, Khumalo G, Oyele S, Ngomoa B. Operationalising health as a human right: The implementation of the Patients' Rights Charter. Presentation at the Health Systems Trust Research Conference, October 2007, Durban
22. London L, Adnams C, Sinanovic E, Van der Spuy E, Rendall-Mkosi K.Costing the burden from FAS in South Africa. Presentation to the Symposium on the Prevention of Fetal Alcohol Syndrome, 9th& 10th September 2008, Medical Research Council Conference Centre, Tygerberg, Bellville.
23. London L, Mazok C, McLoughlin J, Adam H, Parry C. If the alcohol doesn't get you, then the toxins will: Contamination of papsak wine in the Western Cape and implications for FAS incidence. Presentation to the Symposium on the Prevention of Fetal Alcohol Syndrome, 9th& 10th September 2008, Medical Research Council Conference Centre, Tygerberg, Bellville.
24. Katwan E, Adnams C, London L. Childhood behavioral and developmental disorders: association with maternal alcohol consumption and use of health services in Cape Town, South Africa. Presentation to Public Health Association of South Africa Conference, East London, November 2010.

25. Gardner K, Holtman Z, Dalvie MA, London L. Validity and reliability of a Field Kit for Cholinesterase Estimation amongst workers exposed to Organophosphate Insecticides. Presentation to Public Health Association of South Africa Conference, East London, November 2010.
26. Crede S, Sinanovic E, Adnams C, London L. The Utilization of Health Care Services by Children with Foetal Alcohol Syndrome in the Western Cape, South Africa. Presentation to Public Health Association of South Africa Conference, East London, November 2010.
27. Heap M, Haricharan H, Cassidy A, London L. Sign (SASL) language interpreting services working to advance the right of access to health care. Presentation to Public Health Association of South Africa Conference, Bloemfontein, October 2013
28. London L, Tangwa G, Matchaba-Hove R, Mkhize N, Nwabueze R, Nyika A, Westerholm P. Ethics in occupational health: An African perspective. Joint conference of the African Regional Association of Occupational Health (ARAOH) and the South African Society for Occupational Medicine (SASOM), Johannesburg, August 2014.
29. Haricharan HJ, London L, Stutafford M. Public voice in public health care: Improving Primary Health Care through Community Participation. Paper presented to the Municipal Services Project Conference, Cape Town, April 2014.
30. London L. Health Committees: Vehicles for realising the Right to Health through Community Participation? South African perspective. Presentation to Regional Consultation on Health Committees, University of Cape Town, Cape Town Sept 2014.
31. L London, H Haricharan, D Fritz, T Boulle, F Kibido, I Kamaar, Z Sofayiya, N Fick, P Mayers, C Colvin, M Stuttaford. Making health committees work for health system responsiveness and sustainability Public Health Association of South Africa Conference (PHASA), Durban, Oct 2015.
32. London L, Holtman Z, Joska J, Asmal L, Chiliza B, Smith P, Ramesar R, Stallones L. Organophosphate exposure as a risk factor for suicide attempts. Public Health Association of South Africa Conference (PHASA), East London, 2016.
33. London L, Ruff K, Watterson A. Protecting scientific integrity in journal publication practice: challenges for a Global Charter for Public Health. _Public Health Association of South Africa Conference (PHASA), Johannesburg, 2017

Posters:

34. London L.PAP Smear coverage amongst rural workers. Presented at the 11th Epidemiological Conference of Southern Africa, Johannesburg, August 1992.
35. London L, Dalvie MA, Nowicki A, Cairncross E. Do we have Regulatory Standards in South Africa to control the presence of pesticides in water? International Comparisons. Poster presented to the 17th National Conference of the Epidemiological Society of Southern Africa. East London, February, 2000.

In addition, co-author on 16 papers and 14 poster presentations at national congresses since 1997 in which I was either a co-investigator or mentor for a junior researcher. (not presented personally).

3.3 Refresher / educational courses

3.3.1 Seminars and Continuing Education presentations

1. L London. Occupational safety at the workplace and the role of NOSA - the experiences of a union-linked health service. Paper presented to a seminar on Occupational Health and Safety, NOSA, Cape Town, June 1990.

2. L London. Ethical Issues for General Practitioners in relation to the treatment of civil unrest injuries. Paper presented to a meeting of the Academy of Family Practice, Cape Town, Feb 1990.
3. L London. FAWU takes up the campaign against AIDS. Paper presented to Institute of Personnel Management seminar on "Developing an AIDS policy at the workplace", September 1991.
4. L London. AIDS Education at the workplace - Scope for Union-management cooperation?. Presented to Institute of Personnel Management AIDS group, Cape Town, November 1991.
5. L London. Observation of Constitutional Rights in the Health Care Setting. Presentation to Seminar on Medical Law and Ethics, Valkenberg Education Centre, PAWC Health Department, August 2001
6. Invited to present two papers at the Department of Health cluster meeting: Occupational Health, Environmental Health and Health Promotion, White River, Mpumalanga, July 2001. Papers: "Pesticides – challenges for Department of Health Staff" and "Ethical Issues in Occupational Health."
7. L London. Dual Loyalties and Human Rights – Challenges to the Health Professions. Presentation to Psychiatry Department, Valkenberg Education Centre, PAWC Health Department, January 2004.
8. London L. Health and Human Rights: What can 10 year of democracy in South Africa tell us? or... Memory and Forgetting: What does South Africa's past mean for building a better future? Presentation to Impilo Student Society, Sept 2006, University of Cape Town, Cape Town.
9. Xaba B, London L. Registrar training at the University of Cape Town: Experiences and challenges. Presentation to Faculty Education Research Day, University of Cape Town Health Sciences Faculty, March 2007.
10. London L. Nutrition and HIV/AIDS: Human rights implications for the health system. Presentation to Nutrition And HIV/AIDS Symposium, Medical Research Council of South Africa, September 2008.
11. London L. Use of confinement in the management of drug-resistant TB: Balancing individual rights and the public good. Presentation to Drug Resistant TB Doctors Training, City of Cape Town and MSF, Cape Town, Nov 2008.
12. London L. HIV and Work: Ethical and Human Rights Issues. Presentation to HIV/AIDS & TB Symposium, Boland-Overberg Health Department, November 2008.
13. London L. Decision making in a time of scarcity. Presentation to a Seminar "Influenza – Unity in Complexity. STIAS, Stellenbosch, June 2009.
14. London L. Public Health Perspective, in response to Is Race a Valid Research Variable? IRENSA Research Ethics Seminar 6-7 September 2010, Rondebosch, Cape Town.
15. London L. Ethical Aspects concerning Drug Resistant TB. Workshop on Drug-Resistant TB: Current Practice, Controversies, and Clinical Challenges. UCT, September 2010.
16. London L, Cox H. Discussion: XDR TB treatment should only be initiated in a designated TB facility. Workshop on Drug-Resistant TB: Current Practice, Controversies, and Clinical Challenges. UCT, September 2010.
17. London L. How should a TLV be set? Ethical issues in the use of human volunteer data involving experimental exposure to pesticides. Presentation to SASOM AGM, November 2011, Cape Town.
18. London L. Ethical and human rights issues: What role do they play in the prevention and management of DR TB amongst health workers. UCT colloquium, Department of Medicine, October 2012.
19. London L. Ethical Aspects concerning Drug Resistant TB. Workshop on Drug-Resistant TB: Current Practice, Controversies, and Clinical Challenges. UCT,

October 2012; Also talk to TB clinicians Feb 2015 as part of the DTTC forum for TB clinicians.

20. London L, Ahmed KA. Science for sale or science for the people? Civil society and scientific engagement in United States and Africa. Presentation to Science and Society in Africa workshop. Stellenbosch University, September 2014.
21. London L, Coomans F, Cox H. The Right to Enjoy the Benefits of Scientific Progress. Invited presentation to Colloquium for NRF Research Chairs in Public Health, June 2015.
22. London L. A human rights and public health perspective on the White Paper on National Health Insurance. Presentation to a workshop jointly organised by the Foundation for Human Rights, Steve Biko Centre for Bioethics and the Department of Justice and Constitutional Development.
    a. Johannesburg: Sunnyside Hotel, 14th October 2016.
    b. Durban: UKZN, February 2017
23. London L. Balancing individual rights and the public good in the management of drug-resistant TB: Health workers caught in the middle? Presentation to Regional Meeting: Evidence to Action on Current Status and Strategies for LTBI among Health Care Workers and DR TB Treatment Failure Cases. Cape Town, March 15 2017.
24. London L. Balancing individual rights and the public good in the management of drug-resistant TB. Continuing education talks to NHLS staff at Somerset (Nov 22nd 2017) and Groote Schuur Hospitals (February 28th 2018)
25. London L. Individual Freedoms, Human Rights and Tobacco Control. Presentation to pre-conference workshop at the World Conference on Tobacco end Health. Cape Town, 6th March 2018.
26. London L. The Right to Health. Presentation to Community Dialogue on Social and Economic Rights. ICESCR Ratification Campaign and Shadow Report, Dullah Omar Institute, 13 June 2018.

3.3.2 Facilitation of Conference Workshops

1. Facilitator at a Workshop on Union-based Health Care Initiatives and the scope for integration in a future National Health Service at the Joint Conference on People's Health at the University of the Western Cape, July 1991.
2. Facilitator at a Workshop on "Occupational health - role of health professionals": Federation of African Medical Students Associations (FAMSA), Cape Town, 1993.
3. Co-facilitator of pre-conference workshops on training in human rights and the prevention of torture at the VIIth International Symposium on Torture - Caring for survivors of torture: Challenges for the health professions, Cape Town, November 1995.
4. Group facilitator at "The New World Order: A challenge to health for all by the year 2000." Hosted by the International People's Health Council (IPHC), the National Progressive Primary Health Care Network (NPPHCN) and the South African Health and Social Services Organisation (SAHSSO), Cape Town, January 1997.
5. Workshop Facilitator on Training in Health and Human Rights at the International Conference on Health and Human Rights, Cape Town, December 1998: Conflict, Health and Reconstruction. International Society for Health and Human Rights.
6. Workshop co-facilitator for the EQUINET Conference: Building Alliances for Equity in Health. Broederstroom, South Africa, September 2000.
7. Workshop facilitator at SOUTH-SOUTH Workshop on Scientific Information Exchange and Research Collaboration for the Prevention of Adverse Health

Effects of Pesticides in the Tropics: Hazard Communication, a Global Challenge. Heredia, Costa Rica, February 2002.

8. Facilitation of workshop for the Network for Equity in Health in Southern Africa (EQUINET): Health Equity and Human Rights: What role for Health Rights in Equinet work? Benoni, November 2003.
9. Facilitation of workshop on health equity and human rights - Third Southern African conference on equity in health, "Reclaiming the State: Advancing Peoples Health, challenging Injustice," hosted by the Network for Equity in Health in Southern Africa (EQUINET), Durban, South Africa, June 8-9 2004.
10. Co-chair of session on Safe Farms and 15th International Safe Communities Conference, University of Cape Town, April 2006.
11. Chair of conference panel: Crisis? What crisis? Health sector responses to HIV. Public Health Association Conference (PHASA), Midrand, May 2006.
12. Facilitator of pre-conference Pesticide Registrars Workshop, Arusha 13-14th October 2006, linked to the joint SETAC-ANCAP International Conference on Pesticide Use in Developing Countries: Environmental fate, Effects and Public Health Implications, 16th – 20th October 2006, Arusha, Tanzania.
13. Facilitator of a short course session on Dermal Exposure Assessement at the International Conference on Pesticide Use in Developing Countries: Environmental fate, Effects and Public Health Implications, 20th October 2006, Arusha, Tanzania.
14. Facilitator of a pre-conference workshop "Your life or your liberty: When is it legitimate to limit human rights for the public good." 16th Congress of the South African Association for Child and Adolescent Psychiatry and Allied Professions (SACAPAP). University of Cape Town, 11th September 2007
15. Facilitator of a pre-conference workshop "Your life or your liberty: When is it legitimate to limit human rights for the public good."Public Health Association of South Africa (PHASA) conference, June 2008, Cape Town.
16. Co-chair of session on "Health sector reform" at the Conference "A Long Road to Redress: Revisiting the TRC Recommendations" co-hosted by the Desmond Tutu Peace Centre, the Foundation for Human Rights and the Institute for Justice and Reconciliation. Cape Town, October 2008.
17. Chair of scientific session T57: Occupational Health, Human Rights and Economic Development. 29th International Congress on Occupational Health, Cape Town, March 2009
18. Chair of conference workshop S21: Ethical & scientific issues related to studies in human volunteers forregulation of pesticide usage. 29th International Congress on Occupational Health, Cape Town, March 2009.
19. Convener of short course: Detection of neurotoxicity in occupational and environmental health: A short course for Researchers in Southern Africa. Precourse workshop for the International Congress on Occupational Health, Cape Town, March 18 to 21 2009.
20. Workshop co-facilitation with M Torres: Social Mobilization for Occupational Health as a Human Right. 17th Symposium on Agricultural Medicine & Rural Health, Cartagena, Colombia, October 2009.
21. Co-Facilitator with Dr Rendall-Mkosi of a pre-conference workshop: "Foetal Alcohol Syndrome in South Africa." Public Health Association of South Africa (PHASA) conference, November 2010, East London.
22. Co-Facilitator with Prof David Sanders, and Dr Louis Reynolds of a pre-conference workshop: "System Reform in South Africa: How can the Right to Health be strengthened?" Public Health Association of South Africa (PHASA) conference, November 2010, East London.
23. Co-facilitator with Sam Adu-Kumi on The Globally Harmonized System of Classification and Labeling of Chemicals (GHS).ICOH conference on Occupational Health and Safety in Small and Medium Enterprises, Accra, October 2011.

24. Co-Facilitator with Prof David Sanders of a pre-conference workshop: "Can the NHI deliver? PHM's vision of an equitable, quality health system, and the role of the Global Peoples Health Assembly as a platform for promoting this." Public Health Association of South Africa (PHASA) conference, November 2011, Johannesburg.
25. Chair of Special Scientific Sessions at the 31st International Congress on Occupational Health, Seoul, May/June 2015: SS119 SS120: Risks and prevention in developed and developing countries; SS119: Surveillance for acute pesticide poisoning; Joint chair of semi-plenary presentation by Professor Emile Tompa.
26. Co-facilitator with David Sanders, Penny Morrell and Thomas Cousins. Building a Broad-Based Movement for Health for All: Challenges and Opportunities in Health Activism for a People-Centred NHI. Public Health Association of South Africa (PHASA) Conference, October 2015, Durban.
27. Co-facilitator with Fundiswa Kibido. Health Committees – vehicles for democratic governance in the South Africa health system. Public Health Association of South Africa (PHASA) Conference, October 2015, Durban.
28. Co-facilitator with David Sander and Shehnaz Munshi, Is there a better pill in the house? Civil Society action to address the health crisis in South Africa. Public Health Association of South Africa (PHASA) Conference, September 2016, East London.
29. Facilitator: Research integrity and dissemination of science: Implications for Public Health Policy and for a Global Charter for Public Health. Public Health Association of South Africa (PHASA) Conference, September 2017, Johannesburg.
30. Chair of a round-table on 'Deconstructing States' Obligations to realise the Right to Health' at the Dullah Omar Institute, 11 April 2018.
31. Invited respondent: Global Health Law Conference, University of Cape Town, 8 April 2019.
32. Co-facilitator with Hanne Haricharan: Community Participation and the Right to Health - Health Committees' role in Primary Health Care. Public Health Association of South Africa (PHASA) Conference, September 2019, Cape Town

3.4 Other presentations

3.4.1 Other scientific / scholarly participation

1. Invited participant to a Rockerfeller Foundation sponsored meeting in Bellagio, Italy on the topic of a Global Health Watch, November 1998.
2. Facilitation of two workshops (on child labour and on pesticides) at a meeting hosted by the South African Medical Research Council and funded by the National Institute Of Environmental Health Research (USA) – "Building Research Capacity for Children, Environment & Health in South Africa", May 2001.
3. Invited presentation to the Health Professionals Council of South Africa, Pretoria, September 2003: "Human Rights and Health: Challenges for the Health Professions in South Africa."
4. Organiser and co-facilitator of grantwriting capacity building workshop in Arusha, Tanzania as part of the Work and Health in Southern Africa programme, May 2006.
5. Workshop facilitation for the International Federation of Health and Human Rights Organisations (IFHHRO) on training in human rights for health professionals, Nairobi, May 2006.
6. Invited participant to regional consultation on Participatory Research into the right to health co-hosted by Lisa Forman (University of Toronto) and Gorik Ooms (University of Antwerp), May 2012, Johannesburg.

7. Invited participant to Interdisciplinary Symposium on Leading Causes of Life, Stellenbosch, February 2013. Organised by the LCL Initiative Core Team and IHRAP.
8. Invited participant in a meeting at Bellagio, Italy, to plan a research programme developing a Health Impact Assessment tool for Transnational Corporations, May 2015. (Convener: Prof Fran Baum, Flinders University).
9. International Academic Programmes Office (IAPO) visit to Lusaka Apex Medical University and University of Lusaka, June 2015.
10. Invited participant for an International Seminar on Accountability for Health Equity, Mozambique, October 2016. Hosted by IDS, N'weti, CEBRAP and CEP.
11. Loewenson R, Flores W, Amaya A, London L, Kun KK. Skills building on methods and tools for learning from action in participatory action research: Building action learning within affected actors and communities for resilient and responsive health systems. Preconference workshop at the 4th Global Health Systems Research Conference, Vancouver, Nov 2016.
12. Invited participant to a meeting on "Towards a global research agenda on governance, ethics and conflicts of interest from corporate interactions in public health research, practice and policy," Feb 8-9th 2018. From this meeting, I a member of the Governance, Ethics and Conflicts of Interest in Public health: GECI-PH Network.

3.4.2 Congress Scientific Committees

1. Member of the Scientific Committee for the VIIth International Symposium on Torture - Caring for survivors of torture: Challenges for the health professions, Cape Town, November 1995.
2. Member of the Scientific Committee for the Conference: Mental Health beyond the TRC. October 1998, Medical Research Council, Cape Town.
3. Member of the Scientific Committee for the VIIth International Symposium of Neurobehavioural Methods and Effects in Occupational and Environmental Health, Stockholm, 1999.
4. Member of the Programme Committee for the Workshop "Building Research Capacity for Children, Environment & Health in South Africa" hosted by the South African Medical Research Council and funded by the National Institute of Environmental Health Research (USA), May 2001.
5. Member of the Scientific Committee for the VIIIth International Symposium of Neurobehavioural Methods and Effects in Occupational and Environmental Health, Brescia, 2002.
6. Member of the Coordinating Committee for the International Conference of Pesticide Exposure and Health. Natcher Centre, Bethesda, Maryland, USA, July 2002.
7. Member of the Scientific Committee for the International Society for Environmental Epidemiology meeting, Pretoria, for 2005
8. Member of the Scientific Committee for the Xth International Symposium of Neurobehavioural Methods and Effects in Occupational and Environmental Health, Costa Rica, 2008.
9. Member of the Scientific Committee for the 29th International Congress on Occupational Health, Cape Town, 2009.
10. Member of the Scientific Review panel for Track 4: Social and Economic Sciences, Human Rights and Ethics for the 4th SA AIDS Conference 2009.
11. Co-chair of XIIth International Symposium of Neurobehavioural Methods and Effects in Occupational and Environmental Health, Cape Town, 2013.
12. Member of Scientific Committee for the Third Global Symposium on Health Systems Research, Cape Town, September 2014.

4. Awards/Recognition from Peers

4.1 Honours, awards, prizes

4.1.1 Awards linked to Academic qualifications

- M.B. Ch.B. (cum laude) at the University of Cape Town.
  - ⇒ Recipient of the Zwarenstein prize for best performance in the first year course.
  - ⇒ Recipient of the MR Drennan prize for highest mark in Anatomy course in second year.
- B.Sc. (honours) in Epidemiology at University of Stellenbosch, Department of Community Health. Obtained degree cum laude.
- Diploma in Occupational Health at the University of Witwatersrand. Obtained diploma with distiction.
  - ⇒ Recipient of the Joan and Ian Webster medal in Occupational Health for 1989.
- Winner of the Bronte Stewart Research Prize, Faculty of Medicine, UCT, for the most meritorious doctoral thesis in 1996

4.1.2 Other recognition from Peers: Academic appointments

- Honorary Professor in the School of Geography and Geosciences at the University of St Andrews, Scotland, 2005-2008.

4.1.3 Other recognition from Peers

- Shortlisted for the Nelson Mandela Health and Human Rights Award, one of 5 finalists, March 1998
- Co-author (2nd) on paper given the 2004 Merit in Authorship Award from the American College of Occupational and Environmental Medicine. (Lee et al, 2003).
- Co-author (senior) on book ("An Ambulance of the Wrong Colour: Health professionals, human rights and ethics in South Africa") which won a Meritorious Publication Award from the University of Cape Town, 2001.
- Invited to serve as Faculty Member in the Environmental health Section of the Public Health and Epidemiology Faculty of F1000 Medicine (an online literature evaluation tool to filter out and evaluate the best papers from the mass of medical literature) 2004 to 2007.
- Certificate of Merit for Teaching, University of Cape Town, 2006.
- Nominated as Leading Causes of Life Initiative (LCL-I) Fellow in 2014. The LCL-I is a project to think through new approaches to valuing and measuring health in a social context lead by an inter-disciplinary international group developing these concepts.
- Awarded the SAMA-Bonitas Housecall Doctor's Awards for Equity and Justice, September 2015.
- PHILA Lifetime achievement award in Public Health from the Public Health Association of South Africa (PHASA) Sept 2017

4.2 Research collaborations and profile

4.2.1 Research Awards / Recognition

- Recipient of the Guy Elliot post-graduate research fellowship at UCT from September 1991 to August 1992.
- Winner of the 3rd Alan Pifer Award from the UCT Foundation, 1996.
- Takemi Fellowship in the Department of Population and International Health, Harvard School of Public Health, Harvard, Mar- Aug 2002.
- Fulbright Research Scholarship to support sabbatical at the Harvard School of Public Health for 2002.

- Award by the Society for Occupational and Environmental Health for Pesticide Research, Bethesda, July 2002.
- Elected to the Collegium Ramazzini, 2004
- NRF Rating: C1 in 2002, 2007; upgraded to B3 in 2012.
- Fulbright Research Scholarship to support sabbatical at the Boston University School of Public Health for 2013.
- Fellow for the Leading Causes of Life Initiative, housed in the International Health Religious Assets Programme, UCT and Wake Forest Medical School since 2014.

4.2.2 National Research Collaborations/Steering Committees

- Member: Steering Committee "Agricultural Pollution of Soil and Water in the Lourens River (Western Cape)", ENVIROMAP, Universities of Cape Town and Stellenbosch 2000-1.
- Member: Steering Committee "A survey of pesticide wates in the RSA and a preliminary study of their biodegradation." WRC K5/1128. Water Research Commission, 2001.
- Member Social Research Review Panel for the Working for Water Programme of the Department of Water Affairs and Forestry 2002-5.
- Member: South African Bureau of Standards Committee set up to revise SABS 0248 on the management of health care waste (now SANS 10248) since 2002.
- Member: Review panel for the National Research Foundation – Focus Areas of Conservation and Management of Ecosystems and Biodiversity and Sustainable Livelihoods: Eradication of Poverty, October 2004.
- Member: reference panel for National Nuclear Regulator to review theoretical acceptability of borehole disposal of low-level nuclear waste, September 2004.
- Member: Advisory Board for the Centre for Public Mental Health, since 2012.
- Member of Project Technical Committee for a Health Risk Assessment, Western Cape, 2014-2016: Nova and CSIR for the DEAD, W Cape Government.
- Member of an Expert Working Group for South African Values and Ethics for Universal Health Coverage (SAVE-UHC); PI: Prof Karen Hofman, PRICELESS, Wits University, 2018+
- Member of the Reference Group for a Stakeholder Information and Implementation Campaign on National Health Insurance (NHI) run by the Institute for Social and Economic Research at Rhodes University (Prof R van Niekerk) 2017-2018.
- Member of the Advisory group for the Research Programme on Childhood Street Pesticide Poisoning run by Division of Environmental Health, SOPHFM, UCT (Prof HA Rother), 2017-2018.
- Member of the consensus panel on Challenges of Good Governance and Management in the South African Health System, Academy of Science of South Africa (ASSAf), Oct 2019.

4.2.3 International Research Collaborations

- Member of the Advisory Group for the Epidemiology of Pesticide Poisoning Project, International Programme for Chemical Safety (IPCS), WHO, 1998-2000.
- Member of the Scientific Committee for Rural health: agriculture, pesticides and organic dusts of the International Congress on Occupational Health (ICOH) since 1998.

- Member of the Scientific Committee for Neurotoxicology and Psychophysiology of the International Congress on Occupational Health (ICOH) since 1998.
- Member of the Advisory Committee for a Wellcome Trust-funded cluster randomised controlled trial to determine whether safe storage containers can reduce the incidence of intentional and unintentional pesticide poisoning in rural Sri Lanka, 2010-2018. (K Hawton, M Eddlestone, F Konradsen).
- Member of the International Advisory Committee for "Vozes Desiguais": Accountability for Health Equity in Brazil and Mozambique. Joint IDS/N'weti project funded by DFID/ESRC. 2016-2018.
- Project Manager for Action on Pesticides within the SIDA/SADC Programme on Work and Health in Southern Africa (WAHSA) 2008-2013.
- Theme Coordinator for Health Rights for the Network on Equity in Health in Southern Africa (EQUINET) and member of EQUINET Steering Committee since 2003.
- Convenor of the ICOH Taskgroup on the Ethics of Human Testing of Pesticides, 2007-2008.
- Convener of the ICOH Africa Taskgroup on the ICOH Ethical Code, 2010-2013
- Member of AGRICOH: A Consortium of Agricultural Cohorts, since 2010 (see http://www.mdpi.com/1660-4601/8/5/1341/htm)
- Member of an Expert Working Group to prepare an ISO Technical Report on Biomechanical Overload in Agriculture (PI Daniella Colombini, EMP member (MILAN - Italy). Invited in June 2018 by Professors Claudio Colosio and Daniela Colombini.
- Coordinating Committee for the Governance, Equity and Conflict of Interest in Public Health Network (GECI-PH) from 2018 convened by the American University of Beirut.

4.2.4 International visitors – research collaborations

- Hosting of international academic visitors: Fons Coomans (U Maastricht), 2008-2019), Ben Meier (UNC, 2014); Maria Stutafford (Cardiff) 2011-2015); Walter Flores (CGI, Guatemala, 2014, 2015, 2017); Karim Ahmed (NCSE, Fulbright Scholar, 2015); Colin Soskolne (U Edmonton) 2015; Audrey Chapman (U Conn, 2015), Mary Miller (U Washington) 2017-8 as Fulbright scholar; Erik de Jonge (Erasmus University) research fellow 2017, Moses Mulumba (CEHURD) 2017, Susan Braunhut (U Mass Lowell) on Fulbright 2017; Lisa Forman (U Toronto) visiting professor 2018; Ademola Adjuwon (U Ibadan) 2019.

4.4 Other Scholarly Activities

4.4.1 Reviewing activities

- Journals - Reviewer for the following journals:
  General: South African Medical Journal, PLOS Medicine, Lancet, AIDS Care, American Journal of Public Health, Bulletin of the World Health Organisation, African Safety Promotion, Theoria,Journal of Education, African Journal of AIDS Research; Cuture, Health and Sexuality; South African Journal of Science.
  OEH: American Journal of Industrial Medicine, Occupational and Environmental Medicine, Environmental Health Insights, BMC Environmental Health, International Journal of Occupational and

Environmental Health, Environmental Health Perspectives; Environmental Research; Ecohealth, Chemosphere, Natural Resources Forum, Journal of Environmental and Public Health, Neurotoxicology.
Human Rights/Social Science: Social Science and Medicine, Health Policy and Planning, Health Policy, Law Democracy & Development, Health and Human Rights, BMC Ethics, Journal of Medical Ethics, Bioethics, Developing World Bioethics, Ethnicity and Health, South African Journal of Juridical Sciences, Journal of Human Development and Capabilities, Journal of Human Rights Practice.
Reviewer of rating, research proposal and fellowship support applications: South African Medical Research Council, National Research Foundation, Wellcome Trust, Netherlands Organisation for Scientific Research (NWO); New Zealand Medical Research Council.

- Referee for academic promotion for staff at Harvard, Brown and Johns Hopkins Universities; Mount Sinai Medical School; University of South California; American University of Lebanon, University of Ghana, Medical College of Malawi, University of Zimbabwe, University of Montreal.
- Book reviews for the following journals: Public Health (Elsevier), South African Medical Journal, Torture, JAMA.
- Peer review of manual for the AIDS Law Project, Medical Research Council text on A Rights-based Approach to Community Nutrition in South Africa, Khoza S, Maunder I. In: (ed) N Steyn. Community nutrition textbook for South Africa: A rights-based Approach. Medical Research Council, Cape Town: 2008.
- Scientific and Ethical Review of proposals for the Faculty Research Committee and Faculty Research Ethics Committee at UCT.
- Scientific Review of proposals for the Provincial Administration of the Western Cape Health Department.
- Comment to the World Health Organisation on its policy document "Mainstreaming health and human rights within the WHO."
- Consultant Editor to "Torture", journal of the Rehabilitation Centre for Torture Victims (Copenhagen), 1993 - 2002
- Human Subjects Review for Physicians for Human Rights in 2008 for their mission "Assessing the Collapse of Public Health Systems in Zimbabwe."
- Member of the editorial boards of: New Solutions; The International Journal of Occupational and Environmental Health (resigned along with all other board members in November 2017); Environmental Health (BMC Central); The Journal of Scientific Practice and Integrity and the European Journal of Oncology, Occupational and Environmental Health.

4.4.2 Guest Editorship

Guest editor for special edition on human rights and ethics in Occupational Health Southern Africa, Dec 2005.
Co-guest editor for special edition of Neurotoxicology for papers at the 13th International Symposium on Neurobehavioural Methods and Effects in Occupational and Environmental Health, 2014.
Co-guest Editor for a Special Edition of New Solutions on the Extractive Industries, 2014/5.
Co-guest Editor for a Special Edition of Environmental Health Insights on Pesticide Poisoning in developing countries 2017.

4.4.3 Other Capacity Building Roles/Activities

- South African Liaison Committee for the University of Michigan Fogarty International Programmes Award Project to support occupational and environmental health in South Africa 2000-2001.
- Project Manager for Action on Pesticides within the SIDA/SADC Programme on Work and Health in Southern Africa (WAHSA).
- Convener of workgroup on Core Competencies in Public Health for the Association of Schools of Public Health in Africa (ASPHA) 2011-2012 and since 2016.
- Host for Dr Hetta Gouse, Research Development Career award from the NIH (K award), 2016 – 2019.

5. Education and Scholarship

5.1 Undergraduate teaching

5.1.1 MB ChB 4th years PPH402W

Convener of MB ChB 4th year programme in Public Health (PPH4013W)from1995 to 2008.As well as convening, I have taught epidemiology, research methods, research ethics and human rights to medical students on the programme, though since 2008, I have restricted my teaching to seminars on research ethics and human rights (approximately 16 contact hours in the year).The course is structured as an 8-week block which hosts 32 to 36 students per block. Public Health (PPH4013W) is taught in an integrated fashion with Primary Health Care (PPH401W).

Course objectives: To provide students with a basic understanding of core public health knowledge and concepts relating to Epidemiology, Research Methods and Biostatistics, Health Economics and Occupational Health; equip student to apply epidemiological principles to critically appraise published research, conduct epidemiological research projects, understand public health approaches to addressing the health needs of vulnerable groups, appreciate the importance of human rights for health professionals, and understand and be able to apply the population approach to health and disease.

5.1.2 MB ChB Semesters 3 to 5 (DOM200W – DOM302F)

From 2003 to 2005, I was responsible for overseeing Public Health input to the Integrated Health Systems course (DOM200W+) in Semester 3 to 5 of new curriculum as part of a cluster involving Public Health, Family Medicine and Culture and Psychiatry, as well as giving one or two of the lectures in the course.

Course objectives: The course is an integrated problem-based learning course. The Public Health learning objectives identified by the School as core knowledge for students are summarised as understanding the principles, philosophy and approach of PHC; understand and apply epidemiology, biostatistics and demography and apply the principles of disease prevention to the control of common communicable and non-communicable diseases; to understand health surveillance, the principles of environmental and occupational health; to understand and apply the principles of evidence based medicine; to understand human rights and ethics as applied to population health care and research; and to have a basic understanding of costing in public health.

5.1.3 MB ChB Special Study Modules

Convenor Special Study Modules on Health and Human Rights for undergraduate medical students, 2003 (9 students) and 2004 (2 students) and 2008 (2 students).

Course objectives: To equip students with a basic understanding of human rights, and health as a human right; to enable students to apply an understanding of human rights to problem solving in relation to a public health dilemma.

5.1.4 Other curriculum development:

- Development of, and Co-ordinator of undergraduate Epidemiology and Research Method teaching to students in the professions allied to medicine 1997 – 1999. This course was subsequently taken over by other teaching staff.
- Development of joint teaching in Primary Health Care for fourth year medical students in 1996. This teaching evolved into an independent block housed in the Primary Health Care Directorate with a separate course code to that of Public Health. (PPH 4014W).
- Regular participant in School cluster meetings for the new MB ChB curriculum from 2004 to 2006. This is a meeting that deals with all Semesters of the new curriculum, from Phase I through to Phase III.

5.1.5 Other undergraduate teaching:

- Lectures to University of Stellenbosch undergraduates on ethics since 2010.

5.2 Postgraduate teaching

5.2.1 Course convener: PPH 7053S
Development of, and coordination of a Module in Health and Human Rights (PPH7053S) on the Masters programme in Public Health following return from sabbatical leave in 2002. The module has now run for 10 years and gets consistently positive feedback from students and from external examiners.

Module objectives: To provide students with an understanding of what human rights are, and how they apply internationally and in South Africa; to enable candidates to understand the role of human rights in public health practice; an appreciation of the inter-relationship between human rights and health; to apply rights approaches to planning and evaluating public health policies and programmes.

5.2.2 Course convener: (PPH 7089F/S)
In 2012, I co-developed a module for the MPH which is a practicum experience. It was introduced for credit in 2013, and runs with 4 or 6 students per annum.

Module objectives: To provide students with practical experience in the practice of public health in a service or NGO context. The outcomes reflect the student's ability to apply public health skills in a service context, to meet a service need and to process and communicate the practical experience.

5.2.3 Programme Convener for Public Health Medicine registrar programme:(MM001PPH11)
Since 1997, I have supervised public health registrars in their training programme. Registrars for whom I have had direct mentorship responsibilities include U Onwucheckwa, B Jacobs, P Bock, S Kariem, S Mametja, D Pienaar, V Zweigenthal, R English. I currently mentor two registrars (M Dombo; S Mabunda). In 2011, I took over convenership of the programme. I have been responsible for expanding the platform for registrar training beyond the limited number of provincial posts available, with two registrars on the programme currently who rotate through the programme but in non-provincial posts.

Objectives: The programme is the professional degree for specialisation in Public Health Medicine. Registrars receive their formal teaching through other programmes in the School but receive their practical training in public health service in placements with the provincial health department. The allocation and oversight of the learning activities in the programme according to the curriculum of the College of Public Health Medicine is the convener's responsibility.

5.2.4 Course convener: (Environmental Health Policy – number to be determined)

Developed module for the Environmental Health stream in the MPH on Environmental Health Policy and run annually since 2017. The course objectives are to provide students with an understanding of how to shape health and other public policies to promote environmental health and environmental justice. It is a core course for the Environmental Health stream in the MPH.

5.2.5 Other miscellaneous postgraduate teaching

Regular teaching:

- Post graduate teaching in epidemiology on the M.Phil (Epid.) and subsequently MPH at UCT SOPH since 1992 – approx 2 lectures (4 hours contact time) on average per year.
- Post graduate teaching in Diploma courses in occupational health at UCT, Stellenbosch, Wits and Durban – approx1-2 lectures per year at UCT and once or twice in a two year cycle for other institutions.
- Post graduate teaching on Human Rights in the Diploma in Health Management, Economics and Financing at UCT, 1995-6; and then annually since 2008, approximately 4 hours per annum).
- Post graduate teaching in environmental health at UCT (Interdisciplinary Masters Programme run by Environmental Sciences Dept) 1996 – 2001; between one and two lectures annually.
- Postgraduate teaching to students on the Diploma in Pesticide Management since 2012

Occasional teaching:

- Postgraduate teaching to community health nurses at PENTECH – occasional lectures
- Teaching Farm and Rural Health module for UWC MPH Programme – Farm and Rural Health, 1994.
- Lecture on M Phil Emergency Medicine, 2003
- Teach on LLM degree on Human Rights specializing in reproductive and sexual health rights, University of the Free State: Seminars every two years 2004-2008 (4 hours contact time).
- Lecture to Human Genetics Honours students, UCT, 2005.
- Taught on the Bioethics Module of the Masters in HIV Management at the University of Kwazulu Natal, October 2005.
- Taught on the International Human Rights Academy in the Health and Human Rights stream on Dual Loyalty organised by the International Federation of Health and Human Rights Organisations (IFHHRO), Cape Town, October 2005.

1.3 Other course development

- Member: Steering Committee to investigate the development of a course linking nutrition, health and human rights in South Africa (Community Law Centre (UWC) and others, 2004.

5.4 Professional training

- From 2014 to 2020, I served as President of the College of Public Health Medicine for the Colleges of Medicine of South Africa which oversee examination of Public Health Medicine specialists. The College ran regular training programmes in curriculum design, assessment and core competencies for Public Health Medicine graduates. Further developed in 2018 to lay basis for total revision of the CPHM curriculum.

5.5 External examining: Under- and Postgraduate

- External examiner for University of Natal, Diploma in Occupational Health, 2002.
- External examiner for Medical University of South Africa, Masters in Public Health - Module PTOX 701, 2004
- External examiner for the University of Western Cape, Masters in Public Health – Module Primary Health Care and Transformation of the Health Services, 2006.
- External examiner for the University of Witwatersrand, Masters in Law; Public Health & Health Systems Law(LAWS7052/LAWS7051), 2008.
- External moderator for the University of Stellenbosch, Postgraduate Diploma in Research Ethics, Project report, 2012.
- External examiner for the University of Stellenbosch, Postgraduate Diploma in Medical Ethics and Law, 2013-2014.
- College of Public Health Medicine exams:
  Sub-convenor of college exams for Public Health Medicine in 2003; Convener for college exams for Occupational Medicine in March 2010; examiner for College of Public Health Medicine in August 2011 (core), March 2012(additional) and March 2014 (additional). Convener May 2016.

5.6 External examining dissertations and theses

- Ms Kimberley Ann Porteus: MSc(Med), Wits, 1999. Cost and quality of care: a comparative study of public and privately contracted chronic psychiatric institutions.
- Ms Juanita John: MSc Community Health, Pretoria University, 2003: Lead exposure of children attending pre-school facilities in certain geographical areas of Pretoria.
- Hassan Ali Adam: M Tech (chemical engineering), PENTECH, 2003. A solid phase microextraction /gas chromatography method for estimating the concentrations of chlorpyrifos, endosulphan-alpha, enddosulphan-beta and endosulphan sulphate in water.
- Dr Brenda de Klerk: Masters in Health Professions Education, University of the Free State, 2004. Factors associated with students' assessments of teaching quality in a module in the MB ChB programme.
- Mr Richard Mamba: Mini-thesis for MPH (Occupational Hygiene), WITS, 2005: An assessment of occupational health and safety in the informal mechanical industrial sector in Mbabane with special focus on car maintenance, welding and spray painting.
- Dr Flavia Senkunbuge: M Med Thesis, University of Pretoria, 2009: Psychosocial factors associated with tobacco use among a population of medical students in Pretoria
- Dr MarianelaCorriols: PhD thesis, Karolinska Institute, 2010: Acute Pesticide Poisonings in Nicaragua: Underreporting, Incidence and Determinants.
- Mr YA Vawda: PhD thesis, University of Kwazulu-Natal, 2011: Thesis submitted in fulfilment of the degree of Doctor of Laws: "Access to life-saving medication in South Africa: The case for legislative reform."
- Mr David Balikowa, University of the Western Cape: The human rights-based approach to public health: An inquiry into the challenges of its adoption in

Uganda. Minor dissertation for the degree of Masters in Public Health, December 2011.

- Ms Sabina Luputa, University of Stellenbosch: Extrapolating principles of corporate governance to research ethics committees: perspectives from Zambia. Postgraduate Diploma in Bioethics, 2012
- Ms Rebecca Mlelwa, Muhimbili University of Health and Allied Sciences. "Musculoskeletal disorders amongst truck operators at a gold mine in N Tanzania." MSc Environmental Health, July 2015.
- Mr Israel Paul Nyarubeli, Muhimbili University of Health and Allied Sciences. "Respirable dust exposure and respiratory symptoms amongst Open Cast Conventional Gold Miner in Tanzania." MSc Environmental Health, July 2015.
- Mr Hope Rutatina, Muhimbili University of Health and Allied Sciences. "KAP on the effect of noise on hearing amongst workers at the north Mara gold mine." MSc Environmental Health, July 2015.
- Mr Philemon Msangi, Muhimbili University of Health and Allied Sciences. "Dust exposure and respiratory disorders among small scale gold miners in Nyamongo." MSc Environmental Health, July 2015.
- Ms Naanjela Msangi, Muhimbili University of Health and Allied Sciences. "Occupational Injuries and fatalities amongst gold miners in N Tanzania." MSc Environmental Health, July 2015.
- Ms Melissa Pearson, University of New South Wales. "A political analysis of policy to reduce the burden of suicide in Sri Lanka." January 2015.
- Dr Erik Jors, University of Southern Denmark, Odense. "Acute pesticide poisoning among Bolivian small-holder farmers - frequency, risk factors and prevention", February 2016.
- Mr Disang Nelson Osele, Muhimbili University of Health and Allied Sciences. "Occupational Injuries and Associated Factors Among Small-Scale Metal Industry Workers in Dar es Salaam." MSc Environmental Health, Aug 2016.
- Mr Elias Birago, Muhimbili University of Health and Allied Sciences. "The effect of poultry dust exposure on lung function of poultry farm workers in Pwani region, Tanzania." MSc Environmental Health, September 2017.
- Mr Eugene Benjamin Meshi, Muhimbili University of Health and Allied Sciences. "Thermal exposure and related heat illness symptoms among workers in Mara gold mines." MSc Environmental Health, September 2017.
- Ms Matilda Rusibamayila, Muhimbili University of Health and Allied Sciences. "Respiratory impairment and personal respirable dust exposure among underground and open cast gold miners in north-Mara, Tanzania." MSc Environmental Health, September 2017.
- Ms Witness John, Muhimbili University of Health and Allied Sciences. "Noise exposure and reported noise-induced hearing loss among gas fired electric plants workers in Dar es Salaam, Tanzania." MSc Environmental Health, September 2017.
- Mr Suten Geofrey Mwabulambo, Muhimbili University of Health and Allied Sciences. "Health symptoms associated with pesticides exposure among agricultural pesticide applicators in Arusha region, Tanzania." MSc Environmental Health, September 2017.
- Mr Kyangwe Wambura, Muhimbili University of Health and Allied Sciences. "Assessment of noise-induced hearing loss and related factors among tobacco processing industry workers, Morogoro, Tanzania." MSc Environmental Health, September 2017.
- Mr Venance Buliga, Muhimbili University of Health and Allied Sciences. "Assessment of dust exposure and associated respiratory health symptoms among small-scale sunflower oil industry workers in Singida, Tanzania." MSc Environmental Health, September 2017.

- Mr Godfrey George Meena, Muhimbili University of Health and Allied Sciences. "Assessment of occupational exposure to metal fumes and associated respiratory health symptoms among small-scale welders in Dar es Salaam." MSc Environmental Health, September 2017.
- Ms Eunice Matongo, University of the Witwatersrand. "Determining the potential for enhanced ventilation using wind-driven roof turbines in reducing risk probability for Tuberculosis transmission in households in Diepsloot, South Africa, 2019. MPH (Occupational Hygiene), December 2020.

5.7 Dissertation Committees at UCT

- Committee of Assessors for PhD – Dr M Blecher, 2006-7.
- Committee of Assessors for PhD – Dr V Sewram, 2007
- Departmental review for PhD students: 2011-2012 – Kate Sherry
- Departmental review for MSc students: 2011-2012 – Nicole Fick
- Departmental review for PhD students: 2014 – Cliff Zinyembe, Hussein Mwanga
- Departmental review for PhD students: 2015 – Idriss Kallon
- Departmental review for PhD students: 2016 – Thulani Masilela, Paulino Chambo, Tryphine Zulu
- Departmental review for PhD students: 2017 – Dimakatso Lebina, Monika Kamkuemah
- Departmental review for PhD students: 2018 - Ivan Zahinos

5.8 Other Dissertation Comittees

- External reviewer for Mr D Goldstone – upgrade from Masters to PhD at University of Stellenbosch: 2017

5.8 Personal supervision of theses

[S = Primary Supervisor; Co-S = Co-supervisor]

Past Students– Masters

Name	Super-visor	Degree	Race/ gender	Institu-tion	Dept	Date first reg	Year grad.	Comment
D Joubert	S	MSc	W/M	UCT	SOPHFM	1998	2001	P/T; from DbnTechnicon
U Onwu-checkwa	S	M Med	B/M	UCT	SOPHFM	1997	2003	Registrar in Public Health; Non-SA citizen
S Kisting	Co-S	M Fam Med	B/F	Wits	Family Medicine	1999	2003	P/T; Staff member at UCT IHRG
H Adams	Co-S	M Tech	B/M	PEN-TECH	ChemEn g	2000	2004	Full-time at PENTECH
L Cloete	Co-S	M OT	B/F	UCT	SOHR	2003	2005	Staff member in SOHR at UCT
D Monyeki	S	MPH	B/M	UCT	SOPH	2003	2006	P/T, from MRC
A Appavou	Co-S	M Comm	B/F	UCT	Commer ce	2004	2006	Non-SA citizen
F Kaminga kmmfro001	S	MPH	W/F	UCT	SOPHFM	2004	2007	Non-SA citizen
Sumaya Mall	S	MPH	B/F	UCT	SOPHFM	2005	2007	
J McCloughlin MCLJOA001	S	MPH	W/F	UCT	SOPHFM	2004	2007	
P Bock	S	MPH	W/M	UCT	SOPHFM	2003	2008	Switched from MMed to MPH UCT
Jacky Thomas	Co-S	M Phil Ad Ed.	B/F	UCT	CHED	2007	2009	UCT staff member; P/T student
Judith Mwansa MWNJUD002	S	MPH	B/F	UCT	SOPHFM	2006	2009	Non-SA citizen
Selaelo Mametja	S	M Med	B/F	UCT	SOPHFM	2005	2009	
Debbie Kroon	S	MPH	W/F	UCT	SOPHFM	2007	2009	
Elizabeth Katwan	S	MPH	W/F	UCT	SOPHFM	2008	2010	Non-SA citizen
V Major	S	MSc	B/F	UCT	SOPHFM	2001	2010	PT student, tutor at CPUT
Gabriella Glattstein-Young	S	MPH	W/F	UCT	SOPHFM	2008	2010	Staff researcher Non-SA citizen; won class medal best MPH student

Sarah Crede (Maughn-Brown)	S	MPH	W/F	UCT	SOPHFM	2008	2010	
Morgan Strecker	S	MPH	W/F	UCT	SOPHFM	2009	2011	Non-SA citizen
Tahira Kootbodien	S	MPH	B/F	UCT	SOPHFM	2009	2011	Won class medal for thesis
Tate Lowry	S	MPH	W/F	UCT	SOPHFM	2011	2012	Non-SA citizen
Nazia Peer	S	M Med	B/F	UCT	SOPHFM	2011	2012	
Makobelsa Khali	S	MPH	B/M	UCT	SOPHFM	2010	2013	
E Weimann	Co-S	MPH	W/F	UCT	SOPHFM	2012	2013	
L Muheiwa	Co-S	MPH	B/F	UCT	SOPHFM	2013	2014	
Mieke Willems	Co-S	MPH	W/F	UCT	SOPHFM	2014	2015	Won class medal for thesis
S Mabunda	S	M Med	B/M	UCT	SOPHFM	2013	2015	
T Abrahams	Co-S	MPH	B/M	UCT	SOPHFM	2012	2015	
C Aboo	Co-S	M Phil	B/F	UCT	Psych		2017	Non-SA citizen
A Bertscher	Co-S	MPH	W/M	UCT	SOPHFM	2014	2017	
E Burress (Makin)	S	MPH	W/F	UCT	SOPHFM	2011	2017	
Vimbai Mandizviza	S	MPH	B/F non SA	UCT	SOPHFM	2016	2017	Non-SA citizen
Grace Labadarios	S	M Med	WF	UCT	SOPHFM	2012	2018	Part-time

Past Students - Doctoral

Name	Super-visior	Degree	Race/ gender	Institu-tion	Dept	Date first reg	Year grad.	Comment
S Strasser	S	PhD	W/F	UCT	SOPHFM	1999	2006	P/T; based at HST
D Michaels	S	PhD	B/F	UCT	SOPHFM	2004	2008	UCT Researcher
Amina Saban	S	PhD	C/F	UCT	Psych	2009	2011	Took over supervision when main supervisor died
C Serote SRTABR001	Co-S	PhD	B/M	UCT	Sociology	2005	2011	Co-supervisor with Dave Cooper, Sociology
L Cloete	Co-S	PhD	C/F	UCT	OT	2008	2012	Took over as primary supervisor in last 6 months
EE Lekei	S	PhD	B/M	UCT	SOPHFM	2004	2012	Upgraded from Masters in 2008
Nadine Harker-Burnhams	S	PhD	C/F	UCT	SOPHFM	2009	2013	

Z Holtman	S	PhD	B/F	UCT	SOPHFM	2005	2014	Staff member
Virginia Zweigenthal	S	PhD	W/F	UCT	SOPHFM	2012	2015	Staff member
Hanne Haricharan	S	PhD	W/F	UCT	SOPHFM	2015	2019	Staff member and Non-SA citizen perm res
Liz Gwyther	S	PhD	W/F	UCT	SOPHFM	2009	2019	Staff member
Remmy Shawa	S	PhD	B/M	UCT	SOPHFM	2015	2020	Non-SA citizen perm res
Mayara Fontes	S	PhD	W/F	UCT	SOPHFM	2015	2020	Non-SA citizen perm res

Current Students- Masters

Name	Super-visor	Degree	Race/ gender	Institu-tion	Dept	Date first reg	Comment
Bibi-Aisha Wadvallah	S	MPH	C/F	UCT	SOPHFM	In process	
Linda Mureithi	S	M Med	BF	UCT	SOPHFM		
Tafadzwah Muatse	Co-S	MPH	BF non-SA	UCT	SOPHFM	2019	In process registrering
Christine Peta	S	MPH	BF non-SA	UCT	SOPHFM	2020	Starting
Naomi Chitsa	S	MPH	BF SA	UCT			

Current PhD students

Name	Super-visor	Degree	Race/ gender	Institu-tion	Dept	Date first reg	Comment
Wendy Nefdt	S	PhD	B/F	UCT	SOPHFM	2009	PT student
Ardil Jabaar	CoS	PhD	B/M	UCT	SOPHFM	2015	
Tahira Koolbodien	Co-S	PhD	C/F	UCT	Human Genetics	2017	
Moses Mulumba	Co-S	PhD	B/M	UP	Law	2015	Non-SA citizen
Thiloshini Govender	CoS	PhD	B/F	UKZN	Public Health	2017	
Tracey Naledi	Co-S	PhD	B/F	UCT	Medicine	2018	
Abraham Opare	Co-S	PhD	B/M	UCT	SOPHFM	2019	Non-SA citizen

Post Doctoral Fellows:

Name	Race/ gender	Years
M Heap	W/F	2004-2007
C Colvin	W/M	2007-2009
Alex Muller	W/F (non-SA)	2012-2014

Amina Saban	C/F	2014-2017
Hetta Gouse (K award from NIH)	W/F	2016-2020
Hanne Haricharan	W/F (non-SA)	2019-2021

Student awards:

- D Michaels -UCT Research Associateship award in 2005.
- Z Holtman UCT Research Associateship award in 2006
- Z Holtman won a fellowship from the South Africa Netherlands Research Capacity-development Initiative (RCI) in 2004.
- W Nefdt won a fellowship from the South Africa Netherlands Research Capacity-development Initiative (RCI) in 2009.
- Gabriela Glattstein-Young won the David Bourne prize for the best marks achieved by a student graduating in the MPH programme in 2010.
- Tahira Kootbodien won the prize for the best poster by a first time presenter at the Public Health Association conference in East London in 2010
- Tahira Kootbodien won the EthneJacka prize for the student with the best marks for her MPH thesis in 2011.
- Mieke Willems won the EthneJacka prize for the student with the best marks for her MPH thesis in 2015.
- Virginia Zweigenthal won the Harry Crossley Fellowship in the Faculty of Health Sciences in 2015.
- Hanne Haricharan won a Wellcome Trust fellowship for her PhD studies in 2015.

5.9 Adult or Community Education

5.9.1 Short Course Co-ordination

- Coordinator of a course on Farm and Rural Health for the MPhil in Public Health as part of the School of Public Health winter and summer schools in the Western Cape 1994-7. Taught on short course on Community-based alcohol programmes, 2000.
- Convenor of an annual course for Teachers of Health Professionals in Training in Health and Human Rights (Train-the-Trainer), 1998-2013. To date, has trained over 250 participants from Universities, technicons, colleges and services around South Africa, and participants from a range of African countries.
- Co-facilitator of course on Pesticides and Health, Arusha, March 2003. Co-hosted with the Tropical Pesticides Research Institute, as part of the University of Michigan Southern African Program to develop capacity in Occupational and Environmental Health, funded by the Fogarty International Centre, National Institutes of Health, USA.
- Coordinator of a short course on Agricultural Health and Safety for Department of Labour Health and Safety Inspectors, September 2005.
- Co-facilitator of a grantwriting workshop as part of the WAHSA Action on Pesticides, for researchers from Southern Africa, May 2006.
- Coordinator of a short course on the detection of neurotoxicity in occupational and environmental health prior to the International Congress on Occupational Health in Cape Town, March 2009.

5.9.2 Other Community Education

- Co-organiser of a course on a National Health Service, run by NAMDA, as part of the Extra-Mural Studies programme at the University of Cape Town in 1989.
- Teaching in Occupational Health to the Academy of Family Practice in the Western Cape since 1990.
- Facilitator at a Workshop on "AIDS/HIV - Strategies for Control". In UCT Extra-mural studies course on "Topical Issues in Community Health", August 1992.
- Coordination of training seminar to Environmental Health Officers on pesticides and occupational health in the Northern Cape Health Department, 1997.
- Participation in teaching on joint Earthlife Africa – NAMREC capacity building workshop on nuclear awareness, Springbok, August 2003.
- Training for primary care health professionals and community groups in the Western Cape since 1997. Total of 11 seminar sessions given in this period. Recipients include: Primary care nurses (Worcester, part of a DFID funded capacity building programme organised by the Industrial Health Research Group); Boland-Overberg environmental health forum, farm health workers; TB doctors as part of outreach by the DTTC, 2015.
- Training for the Provincial Administration Metro Region Human Resource Directorate since 2000 (Human Rights, Pesticides, Ethical issues in DR TB management).
- Talk to Christian Barnard Memorial Hospital Academic Programme on "Health care without harm – the problem of dioxin emissions from hospitals." July 30th 2009.
- Plenary presentation on Health Rights at the Western Cape Provincial Health Summit. 'Moving from Right of Access to Healthcareto Rights to Health...'. Metropolitan Health Care Forum and others. 17th April 2009.
- Presentations on Health Rights to the Belhar Health Committee AGM August 11th 2009 and to the Klipfontein Sub-District Health Summit Nov 7th 2009
- Workshops on the Right to Health and National Health Insurance for community groups, 2009-2016, for People's Health Movement, Learning Network.
- Workshop series at the People's Health Assembly held by the People's Health Movement in Cape Town in July 2012, on community participation in health as a vehicle for realising the right to health.
- Facilitation of Community Consultations for the District Health Council in May 2014, Feb and June 2015 on community participation.

5.10 Academic development and transformation

- School of Public Health and Family Medicine

I served on the School Postgraduate Programme Committee and the School Exco from 2002 to 2007 when I took over Directorship. Through this I have successfully argued for the School's Units to adopt a policy of consciously planning career pathing for Unit staff, especially for junior staff. This is now in place for the School as a whole – each Unit Head is expected to map a career path for their junior staff in terms of academic development. Of the 16 junior researchers who have been appointed on contracts on various research projects under my supervision over the past 10 years, 12 have been female, 13 black, including 3 African. At least three have gone on to establish independent academic careers, and 3 are public servants in career tracks. Two of the staff in the Centre for Occupational and Environmental Health Research are academics whom I have actively nurtured over the past decade. One (Aqiel Dalvie) was promoted Ad-hominem to Associate Professor in 2011 and has been a recipient of a number of awards including an MRC Career

Development Award. The other (Andrea Rother) is head of the Risk Communication programme in the Centre and is a recipient of the Social Responsiveness Award from UCT, for which I nominated her.

In 2000, I facilitated a diversity training programme in the School in 2002 run by CHED (Ms Salma Ismail) to provide skills to department staff in managing groups that are diverse in race, gender and social identity. This course was prompted by an incident of criminal violence involving our students in the community, and which exposed racially-based attitudes and prejudices amongst students and the fact that staff were poorly equipped to deal with this kind of problem. The course was run as a once-off and has resulted in a training manual produced by CHED for use in other departments and settings. It as also provided basic experience for wider diversity work planned in the Faculty.

I have actively sought to encourage students to see an academic future in public health, particularly black and female students. One student who worked for us on a Ford Foundation programme was a co-author on a paper published in the SAMJ (London et al, 1994) and went on to obtain a PhD in his field (Biology) and teach at UCT. Over the past 10 years, five students have obtained funding for vacation and career-building research attachments on my projects. Of our 7 Public Health registrars in the past 4 years, four have been former graduates of UCT, all black (2 male), who have chosen to specialise in public health at UCT. Of the current group of 9 registrars, three are former UCT alumni, all black, two women, and all have held leadership roles as students or as junior doctors.

I have also acted as mentor for the Rural Support Network, having been invited to speak at their meetings and at other student groups. The RSN is a powerful tool to build capacity of future leadership amongst predominantly black students and an important potential source of trainees and staff for future appointments.

In 2003, I initiated the idea of a Research Day for undergraduates to acknowledge the importance of community-based research. This proposal was accepted by the Faculty Research Committee as a Faculty-wide initiative and is now a regular event on the undergraduate academic calendar.

- Health Science Faculty programmes:

I have been active in Faculty structures intended to foster community-based learning (viz. PHC Stewards; Faculty Community-based Education Committee) and been part of the ongoingsupport for site facilitators employed to provide community-based teaching to our students, initially in line management role, and more recently in an advisory role over the past 15 years.

Through the Portfolio for Transformation and Equity, I was involved in the development of a mentorship programme to support junior staff, and in programmes to address diversity in the learning environment. This work has contributed to University policies on diversity support, mentorship and transformation.

From 1998, I have co-facilitated a Train-the-Trainer course in Health and Human Rights aimed at assisting teaching staff from institutions throughout South Africa incorporate human rights in their curricula for health professionals. The course runs over a week in mid-year. Over the years, UCT staff have been afforded the opportunity to attend this course and have used the teaching in their inputs to the new MB ChB curriculum and on other courses. For example, Semester 1 MB ChB students in the new curriculum engage in developing posters around human rights, as a result of a staff member's insights into the value of human rights for

professional practice. This course continues to be offered on a yearly basis to teaching staff in South, Southern and other Anglophone African countries.

5.11Visting Interns

Hosted interns from Mt Sinai School of Medicine since 2007 on a FIC programme for minority students (PI Dr Luz Claudio); Harvard University, University of North Carolina (PI Dr Ben Meier); Stanford (Convener Dr Tim Stanton).Vrije University (2012); Fulbright student from Brown University 2013; Maastricht University (2014).

6. Research

6.1 Research Projects currently in progress

Learning Network for Health and Human rights: Health Committees	R 250 000 over two years	FHR	Two sites – Phillipi and Franschoek	
Learning Network for Health and Human rights: Community Systems Strengthening	Approx R 14 million over three years	EU Mission to South Africa	Partners with WFP, TFT, range of community groups	
Learning Network for Health and Human rights: HCC strengthening	Approx R 650 000 over two years	CWGH	Regional project	
Attitudes of SPHs to accepting industry funding for NCD research	$ 12 000 over two years	AUB		

6.2 Research Productivity

6.2.1 Research projects and output over past 25 years (since 1994).

Since joining UCT, I have raised a total of over R40 million in over 80 research projects. These have includes 28 grants from international funders on a competitive basis, including an R21 grant from the Fogarty International Centre of the US NIH as a South African PI (the US partner was my Co-investigator and the NIEHS noted this was the first time they had a South African as a PI on these grants). Most recently, I have been successful in raising two grants from the European Union for 2 year projects with budgets in excess of Euro 1 mill. I have been Principle Investigator on 12 and Co-investigator on 4 international collaborative projects, including the following partners: Physicians for Human Rights (USA); Institute for Risk Assessment Sciences, University of Utrecht; Harvard Occupational Health Programme; Boston University School of Public Health, Physicians for Human Rights (USA), Tropical Pesticides Research Institute (Tanzania), University of Michigan School of Public Health, Muhimbili University of Health and Allied Health Sciences, Centre for Human

Rights at the University of Maastricht, Institute of Health in the University of Warwick, the Network on Equity in Health in Southern Africa (EQUINET), the Community Working Group on Health and the American University of Beirut. International funders include the International Labour Office, the World Health Organisation, the United Nations Institute for Training and Research, Danish Cooperation for the Environment, Swedish NGO Foundation for Human Rights, the South Africa – Netherlands Programme for Alternative Development (SANPAD), the National Institutes for Health (Fogarty International Centre), the International Development Research Council (IDRC Canada), the European Union and the Wellcome Trust (Ethics small grant and PhD fellowship for a PhD student).

Publications since 1991 include a total of 180 peer-reviewed publications in peer-reviewed journals, the majority (67%) being papers in international journals, and 136 as first or senior author, as well as 26 book chapters or books. The journals in which I have published have included many highly regarded in the public health field. Additionally, I have been approached to review by many high quality journals, and have done so extensively (approximately 50 journal articles reviewed) in past 10 years.

6.2.2 Conference presentations and attendance (see section 3)

I have been invited to present keynote addresses at over 30 conferences, 22 of which were international meetings and one of which was an honorary memorial lecture for an ICOH meeting in Costa Rica in 2008. Other than keynote presentations, I have presented papers at over 110 international and national conferences and facilitated more than 20 workshops linked to scientific conferences nationally and internationally. I have served on scientific committees for 12 international academic meetings and co-chaired the 14th international meeting on Neurobehavioural Effects in Occupational and Environmental Health in Cape Town in March 2013.

6.2.3 Research Funding

I have been principle investigator on 56 research projects since 1994, which have raised research funding totalling over ZAR 34 million over this period.

6.2.4 Travel and other awards

Since 2000, I have received travel awards for myself, junior staff and visiting academics to the value of R 650 000, from sources including the MRC, the Fulbright Foundation, the Ernest Oppenheimer Trust Fund, the Third World Academy of Sciences, the Wellcome Trust and the NRF.

6.2.5 Reviews for journals and agencies

Journal reviewer for journals in the fields of occupational/environmental health, health policy and health systems, ethics and human rights, health sciences education, behavioural and social sciences, and HIV. These include Social Sciences and Medicine, Health and Human Rights, Occupational and Environmental Medicine, PLoS Medicine and Lancet. Twelve book or book chapter reviewers since 1994.

Journal	Number of reviews since 1991
African Disability Rights Yearbook	1
African Journal of AIDS Research	1
African Journal of Safety Promotion	1
African Safety Promotion	1

AIDS Care	1
American Journal of Industrial Medicine	2
American Journal of Public Health	1
Archives of Occupational and Environmental Medicine	1
Bioethics	1
BioéthiqueOnline	1
Biomed Central Environmental Health	1
Biomed Central Medical Education	2
Biomed Central Public Health	1
BMC Environmental Health	1
BMC Ethics	1
BMC Health and Human Rights	1
Chemosphere	1
Developing World Bioethics	1
Ecohealth	1
Environmental Health	1
Environmental Health Insights	1
Environmental Health Perspectives	4
Environmental Research	3
Ethnicity and Health	1
European Journal of Oncology (Collegium Rammazzini)	1
Health and Human Rights	7
Health Policy	1
Health Policy and Planning	3
Human and Experimental Toxicology	1
Human Resources for Health	1
International J Occup Env Health	2
International J Occup Env Med	3
International Journal of Population Research	1
Journal of Agromedicine	1
Journal of Education	1
Journal of Environmental and Public Health	2
Journal of Human Development and Capabilities	1
Journal of Human Rights Practice	4
Journal of Juridicial Sciences	1
Journal of Medical Ethics	1
Journal of Public Health Policy	1
Lancet	1
Law Democracy and Development	3
Natural Resources Forum	1
Neurotoxicology	1
New Solutions	2
Occupational and Environmental Medicine	4
Occupational Health Southern Africa	1
PLoS Medicine	1
PLoS One	1
Public Health Reviews	1
SA J Bioethics and Law	1
Social Science and Medicine	9
South African Journal of Bioethics and Law	1
South African Journal of Science	1
South African Medical Journal	6
South African Sociological Review	1
Theoria	1

Water SA	1
Grand Total	100

Book or Chapter reviews since 2004

Year	Book/Chapter	Author/s	Source
2004	Health Rights, Law and Policy	Mark Haywood	AIDS Law Project
2005	Internally Displaces Persons: Human Rights, In: Learning to dance: Advancing women's reproductive health and well-being from the perspectives of public health and human rights, Ed. AE Yamin.	Charles Ngwena	UFS
2005	Perspectives on health and human rights	Gruskin S, Grodin MA, Annas GJ, Marks SP	American Medical Association
2006	Health and Human Rights. Basic International Documents	Stephen Marks	FXB Centre, Harvard University
2007	Building and maintaining the capacity, representativeness, legitimacy, diversity and voice of civil society in order to allow for authentic, bottom up, effective and informed engagement: The case study of a community based organization (CBO) at a Black informal settlement area, South Africa –	Nomafrench Mbombo	Knowledge Network on Health Systems for the Commission on Social Determinants of Health (CSDH)
2007	Chapter 1.A right to based approach to community nutrition in South Africa	Sibonile Khoza and Eleni Maunder	Community nutrition textbook for South Africa: A rights-based Approach, MRC, 2008
2009	Challenges in Pesticide Risk Communication	Andrea Rother	Encyclopedia of environmental health
2010	The Pesticide Story	MunaLakai	Institute for Zero Waste Management in Africa
2010	Constitutional Provisions relating to the Right to Health in Southern and East Africa	Moses Mulumba	EQUINET
2011	Dual Loyalties and Military Medical Ethics	Editor: Michael Gross	Military Medical Ethics which is a volume in Ashgate's Military and Defence Ethics Series
2012	International Occupational Health	Jo Ladou	Textbook on Occupational Health
2012	Human Rights and Health Systems	GunillaBackman	Studentliteratuur (Poland)
2014	Hazards or hardship. Crafting global norms on the right to refuse unsafe work	Jeffrey Hilgert	Cornell Press

Proposal reviews for national and international agencies, including the NRF (6), MRC (5), the Wellcome Trust (3) and NWO (Netherlands Research Organisation) (1), Physicians for Human Rights (1), World Health Organisation (2), the New Zealand Medical Research Council (1).

6.2.6 Academic Reviews

- Served on Review Panel for the Medical Research Council for its Health Promotion Programme, 2001.
- Served on Review Panel for the University of Cape Town for its Division of Communication Science Disorders 2005.
- External reviewer for the Bioethics and Human Rights curriculum (Health Management and Ethics 511), University of Stellenbosch, February 2006

- Served on Review Panel for the University of Western Cape School of Public Health in 2010.
- Served on Review Panel for the University of the Witwatersrand MPH programme in the Wits School of Public Health in April 2015.

6.2.7 Other independent review and comment

- NIH R21 grant application for Health and Environmental costs of pesticides (HEED project) was my first NIH grant application as PI and was successful first time. Of the the only non-US PI amongst 11 HEED grantees, I was. Chris Schonwalder, Programme Manager from the National Institute for Environmental Health Sciences requested permission to use this grant for a grantwriting training workshop in 2003.
- Served on Reference Panel for the Working for Water Programme, reviewing research proposals and reports for the Programme from 2002 to 2005.
- Provided review of the policy on mainstreaming of human rights in the WHO in 2007.
- Provided peer review to the Physicians for Human Rights investigation into health rights abuses in Zimbabwe, 2009.
- Review for chapter on international occupational health by Joe Ladou in forthcoming textbook on occupational health in 2012; review of a book on the right to health by Audrey Chapman in 2013.

6.2.8 Postgraduate student throughput

My student supervision record includes supervision to completion of 34 Masters and 13 PhDs to date. Of the 34 Masters students, I have been primary supervisor for 20, and for the 13 PhD students, primary supervisor for 10. From a transformation perspective, of the 47 students, 25 (53%) have been black South Africans, and 35 (74%) women. Four of my students have won awards for their theses, 2 being awarded UCT Research Associateships.

6.3 Research dissemination

a) St. Charles J. Pesticide Use among Tanzanian Farmers in Africa. Global Environmental Health Newsletter October 2014. URL: http://www.niehs.nih.gov/research/programs/geh/geh_newsletter/2014/10/spotlight/index.cfm#a734017
[commentary on Lekei EE, Ngowi AV, London L. . 2014. Farmers' knowledge, practices and injuries associated with pesticide exposure in rural farming villages in Tanzania. BMC Public Health 14:389.]

b) London L. South Africa fails to tackle its high foetal alcohol syndrome rate. Published in the Conversation 9 September 2015 at https://theconversation.com/south-africa-fails-to-tackle-its-high-foetal-alcohol-syndrome-rate-46791

c) Anaf J, Baum F, Fisher M, London L. Assessing the health impacts of transnational corporations. Published in Croakey on May 16th 2019 at https://croakey.org/assessing-the-health-impacts-of-transnational-corporations/

d) Heap M, Haricharan H, London L. Sign (SASL) Language Interpreting Services. Working to advance the right of access to healthcare. Provincial Research Newsletter Issue No.3 June 2013: 3.

e) London L, Morojele N, Amanuel H. How easy access to alcohol, and adverts, affect women in South Africa. Published in the Conversation 29 January 2019 at https://theconversation.com/how-easy-access-to-alcohol-and-adverts-affect-women-in-south-africa-109585.

f) Cited in "*New Findings from University of Cape Town Update Understanding of Drug Resistance (Multidrug-Resistant TB: Implementing the Right to Health through*

the Right to Enjoy the Benefits of Scientific Progress)." Obesity, Fitness & Wellness Week, 6 Aug. 2016, p. 1304. Gale Academic OneFile, https://link-gale-com.ezproxy.uct.ac.za/apps/doc/A459581754/AONE?u=unict&sid=AONE&xid=5594e137. Accessed 19 Feb. 2020.

g) London L, Fontes M, Ryan L. Strengthening Community Action to address Social Determinants of Health: Health Committees as key agents of Change. Provincial Research Newsletter Issue No.13 Jan 2020: 4-6.

7. Community and Clinical Services

7.1 Public Health Service

- Public health specialist providing technical support to the Western Cape Health Department [Directorate of Policy and Planning 1998-2001; Chief Directorate Health Programmes 2002-2009; Health Impact Assessment Directorate 2010-current]; Since 2010 focus on technical support to the Health Research sub-directorate; and to the Provincial Health Research Committee;
- COVID-19: Technical support on inter-departmental task team; Vaccine advisory committee to the Western Cape Health Department 2021+
- Service on Provincial XDR TB Reference Panel, 2009-current; technical support to the City of Cape Town / MSF XDR TB decentralisation pilot in Khayelitsha; member of the Provincial TB advisory group, 2011.
- Processing of health input to Environmental Impact Assessments for the Provincial Health Department since 2010.
- Nationally:
  - Served on the Interim National Health Research Ethics Council from 2000 to 2001 and the National Health Research Ethics Council from 2006 to 2010.
  - Served on the Advisory Committee on Human Rights, Ethics and Professional Practice for the Health Professions Council of South Africa from 2007 to 2010.

7.2 Direction of Community Services

- Trustee for the Health Care Trust 1986-1999 and chairperson 1991-1995. The Health Care Trust is a resource organisation providing health education and primary health care programmes for communities in Cape Town and Cala, Transkei. It merged in 1997 with other health worker projects to form Zanempilo Trust, an EU-funded initiative for primary health care in Metropolitan Cape Town. Zanempilo has provided undergraduate students with sites for their community-based learning.
- Facilitation of Organisational Review for Zibonele Community Health Worker Project, 1994.
- Founder since 1995 and Chairperson of the DOPSTOP project from 1998 to 2007. The DOPSTOP is a community-based not-for-profit NGO that aims to address alcohol abuse amongst farm workers and the legacy of the DOP system on farms in the Western Cape. It has undertaken research, advocacy, training and awareness raising activities around substance abuse on farms in the Western Cape within a Health Promotion framework. The project has also facilitated skills training for nurses in rural areas to deal with alcohol abuse.
- In my personal role for DOPSTOP, I have
  - facilitated the training of a DOPSTOP community worker in alcohol rehabilitation and motivational interviewing through a collaboration with the Cambridge Substance Abuse services, Addingbrook NHS Trust, UK, 2004.
  - secured funding for, and supervised an intern placed at DOPSTOP in 2000/2001.
  - DOPSTOP research has generated a number of publications and research

grants for UCT, as well as enabling student SSMs and UCT to meet an important aspect of its social responsibility.

- Committee member of the Emergency Services Group (ESG), a network of counsellors and doctors providing medical and counselling services for ex-detainees, released political prisoners and victims of political violence (1987-1993). Subsequently, this structure provided medical and social services to exiles returning to South Africa between 1990 and 1993.
- Board Member of the Trauma Centre for Victims of Violence and Torture from its establishment in 1993 to 2006. Served as Chairperson 1995 – 1997 and again from 2003 to 2006. The Trauma Centre is a human rights NGO addressing mental health needs related to violence and trauma. Human rights research through the centre has been an important component of my involvement with the Centre; Patron of the Trauma Centre since 2007.
- Advisor to Wellington Community Action Group on FAS, 2002-2004.

7.3 Participation in Community/Outreach Services

- Provided medical and counselling services for ex-detainees, released political prisoners, victims of political violence and returned exiles from 1987 to 1996 as part of the ESG and Trauma Centre. This work has also been part of research and publication under UCT's affiliation.
- Ran a primary health care service for workers and their dependents in the food industry in the rural Western Cape from 1987 to 1991, including health promotion activities, health education, AIDS awareness, child health screenings and related services. Facilitated social work student placements to improve access to social services and grants amongst rural workers and their families in Paarl. This work has also been part of research and publication under UCT's affiliation.
- Assisted SHAWCO clinics with medical supervision in Khayelitsha, 1992 to 1996. This is direct service provision by UCT students.
- Participant as Interested and Affected Party in the Environmental Impact Assessment for the Pebble Bed Nuclear Reactor, managed by the Department of Environmental Affairs and Tourism.

7.4 Participation in Extension Services

- Participant in the Committee that assisted the Truth and Reconciliation Commission organise the Health Sector Hearings, 1997.
- Consult to members of the public and health services on pesticide issues, on HIV and ethics – average 3 to 5 enquiries per year.
- Expert witness to the AIDS Law Project in cases involving discrimination against people with HIV: Cases involving SAA and SANDF; expert witness for the TAC Case against Matthias Rath and the Department of Health.
- Advisory service to the Legal Resources Centre on Environmental Health and Professional Services in the health sector
- Provision of Health Educational talks on Bush Radio and information for Community Newspapers on occupational and environmental health matters.
- Input to the Limmud (Jewish Cultural) Festival on Human Rights and Public Health, August 2007, Strand, Cape Town.
- Currently on the Steering Committee for the People's Health Movement, an advocacy grouping lobbying for health as a right and the realisation of PHC in South Africa, as part of an international network.

7.5 Community Supervision of Students

- Supervision of 4th year medical student epidemiology projects since 1989 and of students in the professions allied to medicine since 1997. Students

undertake community-based and community-identified projects as part of their training.
- Assisting supervision of final year social work students from the University of the Western Cape during their practical placement at the Ray Alexander Clinic, 1990-1991.
- Supervision of 6th year medical students undertaking health screenings of workers' children as part of their family medicine allocations at the University of Cape Town, 1987-1989.
- Special study module students in 2003 and 2004 undertook research projects for community stakeholders (Prison Health Care personnel, Patients Rights, AIDS Law Project, etc).

7.6 Social Responsiveness Activities
Research within the Health and Human Rights programme has established a Learning Network with civil society organisations in the Western Cape (including Women on Farms Project, Ikamva Labantu, The Women's Circle, Epilepsy South Africa and the Cape Metropolitan Health Forum) to identify best practice for health and human rights. This project, along with the HHRP's Training of Trainers course in Health and Human Rights, and Dr Heap's work on the role of South African Sign Language interpretation in providing access to health care for deaf persons in the Western Cape, was featured in UCT second Social Responsiveness Report as an example of a Portfolio of Practice. The research with farm workers occupational health was recognised through the Alan Pifer award in 1996.

Besides research and teaching, I have been an active contributor through letters to the newspaper and interviews on the media relating to alcohol policy, human rights and health.

- Member of the Advisory Council to Physicians for Human Rights, USA 2003-2008.
- UCT representative on the Association of Schools of Public Health in Africa (ASPHA) since 2014.

7.7 Public Media Engagement

Public Engagement in Popular Media:
- Te Water Naude J, London L. South Africa refuses to support initiative to restrict deadly asbestos trade. Groundup Opinion. 14 March 2017. http://www.groundup.org.za/article/south-africa-not-supporting-initiative-restrict-deadly-asbestos-trade/
- London L. Stampede for securitisation of UCT clouds logical argument. Groundup Right to Reply. 8 November 2016. http://www.groundup.org.za/article/stampede-securitisation-uct-clouds-logical-argument/
- Oni T, London L. UCT doctors join campaign for Tafelberg housing. Groundup Opinion. Open letter to Premier Helen Zille. 8 June 2016. http://www.groundup.org.za/article/tafelberg-site-ucts-school-public-health-supports-call-affordable-housing/
- London L. Scientific journal threatened by vested interests. Groundup Opinion 3rd May 2017. http://www.groundup.org.za/article/scientific-journal-threatened-vested-interests/
- London L, Vellios N, Kalideen S, Nyatsanza S. Philip Morris's reinvention as crusader for public health is disingenuous. Business Day letter 5 February 2020;

https://www.businesslive.co.za/bd/opinion/letters/2020-02-05-letter-philip-morriss-reinvention-as-crusader-for-public-health-is-disingenuous/.

- Parry C, Matzopoulos R, London L, Goldstein S. Targeted limits on alcohol consumption is urgently required. Business Day 11th December 2020. https://www.businesslive.co.za/bd/opinion/2020-12-11-targeted-limits-on-alcohol-consumption-is-urgently-required/

Cited in:

- Furlong A. SA health system is "broken." Groundup News. 27 June. http://www.groundup.org.za/article/broken-health-system-says-civil-society/
- De Greef K. Dagga spraying: police 'expert' accused of bad science. Groundup Feature. 8 May 2016. http://www.groundup.org.za/article/dagga-spraying-police-expert-accused-bad-science/
- De Greef K. Battle to stop dagga spraying. Groundup Feature. 20 April 2016. http://www.groundup.org.za/article/battle-stop-dagga-spraying/
- Kelly S, Mian N. High level of foetal alcohol syndrome found in Saldanha Bay. Groundup News 4 April. http://www.groundup.org.za/article/high-level-foetal-alcohol-syndrome-found-saldhana-bay/
- Washinyira T. Man loses use of hand at work, but can't get compensated. Groundup News 30 January 2013. http://www.groundup.org.za/article/man-loses-use-hand-work-cant-get-compensated_726/
- Gontshana M. Cheap wine trending in townships. Groundup News 24 October 2012. http://www.groundup.org.za/article/cheap-wine-trending-townships_547/

8. Leadership and Administration

8.1 University leadership

8.1.1 Current University leadership:

- Member of University Senate since 2003.
- Member of Senate Academic Freedom Committee 2010 - 2014
- Member Senate Committee on Ethics in Research since 2014

8.1.2Past University leadership:

- Member of Environment Task Team and the Partnership for a Sustainable Environment (PASE), University of Cape Town, 1999-2000.
- Member of Senate extended taskgroup on disciplinarity in 2009

8.1.3Current faculty leadership:

- Head of the Division of Public Health Medicine.
- Associate Director for Environmental Health of the Centre for Occupational and Environmental Health Research since 1996.
- Member of Faculty Board, UCT Health Sciences Faculty since 1998
- Member Professional Masters Committee, UCT Health Sciences Faculty since 2012.
- Member of the Dean's Transformation Advisory group, 2015+

8.1.4Past faculty leadership:

- Director of the School of Public Health and Family Medicine 2007 – 2012
- Chair of the Oliver Tambo Fellowship Advisory Board 2007 – 2012
- Member of the Faculty Ad-hom Committee 1999, and 2003-2012
- Portfolio Manager: Transformation and Equity, University of Cape Town, Health Sciences Faculty from 1999 to 2007.

- Member of the Senior Management Team, Health Sciences Faculty, 1999 – 2007; member of Faculty Exco 2007-2012.
- Ad hoc policy work on behalf of the Deanery since 2007.For example, in 2003, I coordinated Faculty comments on the National Health Bill and in 2011, coordinated comments on the National Health Insurance Policy Paper. In 2004, I coordinated a task team examining ways of remediating differential conditions of service for contract staff compared to academic staff whose work is ongoing, and have been part of a task team addressing the health hazards from EMF emissions from a cell phone tower on the Anatomy Building over 2011-2012.
- Member of the Exco of the School of Public Health and Family Medicine, 2002 to 2007; regularly acted as HoD when the HoD and Deputy HoD were unavailable
- Member, Health Science Faculty Human Bioethics Committee, 2000.
- UCT Health Sciences Faculty Primary Health Care Executive, 1996 –1998
- Primary Health Care Steward for the Department of Community Health, 1997-1998.
- Acting representative for the School of Public Health and Family Medicine on the Medical Faculty Research Committee (MERC), 1997-1998.
- Since 1999, I have served on numerous Search and Selection Committees in the Faculty, including as Chair on 6 occasions.

- Member of the Advisory Council to Physicians for Human Rights, USA 2003-2008.
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8.2 Health Services

- Member of the Interim National Health Research Ethics Committee for the Department of Health in 2000-2001, and then as member of the National Health Research Ethics Council from 2006 to 2010.
- Participant in expert consultation for the Department of Health on the National Health Insurance, December 2011, Midrand.
- Convenor of a Taskgroup investigating an outbreak of Guillain-Barre syndrome for the Northern Cape health department, 1995.
- Consultant to the Policy and Planning Directorate in the Health Department of the Provincial Administration Western Cape (PAWC) 1998-2001. Member of the District Bed Plan working group, 1998, and the Hospital Reconstruction and Rehabilitation Programme Working Group, 1999.
- Consultant to Pesticides Research Group at the National Centre for Occupational and Environmental Health, Department of Health
- Acting Chair: Provincial Health Research Committee, Western Cape, 2014-5.

8.3 Professional Organisations

- Executive member of the National Medical and Dental Association (NAMDA) local branch and National Council delegate 1987-1992.
- Publicity Secretary of the South African Health and Social Services Organisation (SAHSSO) Western Cape, 1992 - 3.
- Member of the South African Medical Association
- Member of the Public Health Association of South Africa (PHASA) and member of Special Interests Groups (SIGs) on (a) Health Promotion; and (b) Climate, Energy and Health.
- Associate of the College of Public Health Medicine of South Africa
- Vice-chairperson of the Committee on Human Rights, Ethics and Professional Practice of the Medical and Dental Professional Board of the Health Professions Council of South Africa 2000-2001.

- Member of the Committee on Human Rights, Ethics and Professional Practice of the Health Professions Council of South Africa, 2005.
- President College of Public Health Medicine, 2014+
- Member of the CMSA FGPC Committee

8.4 Policy inputs

- Comments on draft legislation/policy papers: Pesticide Management Policy (2010); National Health Insurance (2011); National Road Traffic Amendment Bill, 2012; Provincial Health Facilities Boards Act (2012); National Public Health Institute of South Africa (2016); White Paper on the National Health Insurance (2016); Western Cape Health Facilities Boards and Committees Bill (2016); National Draft Liquor Amendment Bill (2016); Western Cape Green Paper on Alcohol Harm Reduction (2016).
- Part of global workgroup providing technical support to the UN Special Rapporteur on the Right to Health for the report on Occupational Health as a Human Right (http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session20/A-HRC-20-15_en.pdf), 2011-2012.
- Convener of an African workgroup to input to the revisions of the ICOH Ethical Code, 2010-2012.
- Submissions to UN bodies:
  - du Toit M, London L, de Keukelaere A, Reagon G, Paramoer L, Rizvi Z, Lake L, Heap M. HEALTH RIGHTS, ISSUES AND RECOMMENDATIONS. Joint Submission of Health Stakeholders in South Africa to the United Nations Committee on Economic, Social and Cultural Rights, 64th Session, 24 September – 12 October 2018.
  - Shawa R, Cox H, London L. Written contribution in response to the invitation to comment on the draft general comment *on the right to enjoy the benefits of scientific progress and its applications* Article 15 of the ICESCR. February 2020.

8.5 Other Extension Services

- Served as member of the African National Congress Health Department policy group on Occupational Health - involved in formulating ANC policy on Occupational Health and future health service provision.
- Served on the Voluntary Advisory Forum on Responsible Care for the Chemical and Allied Industries Association (CAIA) 1999-2001
- Board Member for the Health Systems Trust 1998 - 2001. The Health Systems Trust is a funder of health systems research focused on equity and district development.
- Patron of the Trauma Centre for Survivors of Violence and Torture, Cape Town since 2007

8.5 Private work

Consultancies

- EIA for Rainbow Chickens: Siting of informal settlement, Durbanville, 1995.
- Specialist Health Study: SANACHEM review of its Berlin pesticide production plant, September 1997
- Specialist Health Study: Coastal Park Waste Disposal site, Cape Town, 1999.
- Specialist Health Study: Bellville South Waste Disposal site – permitting extension, Cape Town, 2001.
- Specialist Health Study: Cape Metro new Waste Disposal site, Cape Town, 2004.
- Scoping study: Health impacts from pollutants released from Denel Swartklip plant, 2005-2006.

- Development of regulations to address children's work-related hazards. Programme Towards the Elimination of Child Labour (TECL), Department of Labour, 2005-6.
- Health study for Chameleons Montessori School at Nitida Vineyards on pesticide drift, 2010-2011
- Expert report on the application by Shell to undertake hydraulic fracturing gas exploration ('fracking'): Environmental Management Report South Western Karoo Basin gas exploration application, 2011.
- Drafting team for a chapter on health for the Strategic Impact Assessment of Fracking in South Africa for the CSIR joint team, 2016
- Commissioned to develop a commentary on the National Health Insurance for the Foundation for Human Rights, 2016

9. Societies

9.1 Membership

- The South African Society for Occupational Medicine.
- The South African Medical Association
- Member of the Epidemiological Society of Southern Africa, now the Public Health Association of South Africa
- Member of the International Congress on Occupational Health.
- Member of the International Society for Environmental Epidemiology
- Health Systems Global (HSG): Social science approaches for research and engagement in health policy & systems (SHaPeS) thematic working group of Health Systems Global

9.2 Offices held

- Co-ordinator of the SASOM Scientific Committee on Ethics and Legal Issues.
- Member of the ICOH Scientific Committee on Pesticides and Rural Health.
- Member of the ICOH Scientific Committee on Neurotoxicology and Neurophysiology.
- Member of the Ethics Sub-committee of the Collegium Ramazzini
- Vice-chairperson of the Voluntary Advisory Forum on Responsible Care for the Chemical and Allied Industries Association (CAIA) 1999-2001.

10. Comments

My community involvement and extension work has always sought to ensure a mutually beneficial interaction such that learning and research both benefits from, and helps to support community action for health. To me this is the particular form of scholarship that most befits excellence from a Public Health Professional. I see the role of Public Health Medicine as feeding into the building of a responsive health system promoting universal access.

Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV)

30 January 2020
Statement

Geneva, Switzerland

Reading time: 6 min (1737 words)

العربية
中文
Français
Русский
Español

The second meeting of the Emergency Committee convened by the WHO Director-General under the International Health Regulations (IHR) (2005) regarding the outbreak of novel coronavirus 2019 in the People's Republic of China, with exportations to other countries, took place on Thursday, 30 January 2020, from 13:30 to 18:35 Geneva time (CEST). The Committee's role is to give advice to the Director-General, who makes the final decision on the determination of a Public Health Emergency of International Concern (PHEIC). The Committee also provides public health advice or suggests formal Temporary Recommendations as appropriate.

Proceedings of the meeting

Members and advisors of the Emergency Committee were convened by teleconference

The Director-General welcomed the Committee and thanked them for their support. He turned the meeting over to the Chair, Professor Didier Houssin.

Professor Houssin also welcomed the Committee and gave the floor to the Secretariat.

A representative of the department of compliance, risk management, and ethics briefed the Committee members on their roles and responsibilities.

Committee members were reminded of their duty of confidentiality and their responsibility to disclose personal, financial, or professional connections that might be seen to constitute a conflict of interest. Each member who was present was surveyed and no conflicts of interest were judged to be relevant to the meeting. There were no changes since the previous meeting.

The Chair then reviewed the agenda for the meeting and introduced the presenters.

Representatives of the Ministry of Health of the People's Republic of China reported on the current situation and the public health measures being taken. There are now 7711 confirmed and 12167 suspected cases throughout the country. Of the confirmed cases, 1370 are severe and 170 people have died. 124 people have recovered and been discharged from hospital.

The WHO Secretariat provided an overview of the situation in other countries. There are now 83 cases in 18 countries. Of these, only 7 had no history of travel in China. There has been human-to-human transmission in 3 countries outside China. One of these cases is severe and there have been no deaths.

At its first meeting, the Committee expressed divergent views on whether this event constitutes a PHEIC or not. At that time, the advice was that the event did not constitute a PHEIC, but the Committee members agreed on the urgency of the situation and suggested that the Committee should continue its meeting on the next day, when it reached the same conclusion.

This second meeting takes place in view of significant increases in numbers of cases and additional countries reporting confirmed cases.

Conclusions and advice

The Committee welcomed the leadership and political commitment of the very highest levels of Chinese government, their commitment to transparency, and the efforts made to investigate and contain the current outbreak. China quickly identified the virus and shared its sequence, so that other countries could diagnose it quickly and protect themselves, which has resulted in the rapid development of diagnostic tools.

The very strong measures the country has taken include daily contact with WHO and comprehensive multisectoral approaches to prevent further spread. It has also taken public health measures in other cities and provinces; is conducting studies on the severity and transmissibility of the virus, and sharing data and biological

material. The country has also agreed to work with other countries who need their support. The measures China has taken are good not only for that country but also for the rest of the world.

The Committee acknowledged the leading role of WHO and its partners.

The Committee also acknowledged that there are still many unknowns, cases have now been reported in five WHO regions in one month, and human-to-human transmission has occurred outside Wuhan and outside China.

The Committee believes that it is still possible to interrupt virus spread, provided that countries put in place strong measures to detect disease early, isolate and treat cases, trace contacts, and promote social distancing measures commensurate with the risk. It is important to note that as the situation continues to evolve, so will the strategic goals and measures to prevent and reduce spread of the infection. The Committee agreed that the outbreak now meets the criteria for a Public Health Emergency of International Concern and proposed the following advice to be issued as Temporary Recommendations.

The Committee emphasized that the declaration of a PHEIC should be seen in the spirit of support and appreciation for China, its people, and the actions China has taken on the front lines of this outbreak, with transparency, and, it is to be hoped, with success. In line with the need for global solidarity, the Committee felt that a global coordinated effort is needed to enhance preparedness in other regions of the world that may need additional support for that.

Advice to WHO

The Committee welcomed a forthcoming WHO multidisciplinary technical mission to China, including national and local experts. The mission should review and support efforts to investigate the animal source of the outbreak, the clinical spectrum of the disease and its severity, the extent of human-to-human transmission in the community and in healthcare facilities, and efforts to control the outbreak. This mission will provide information to the international community to aid in understanding the situation and its impact and enable sharing of experience and successful measures.

The Committee wished to re-emphasize the importance of studying the possible source, to rule out hidden transmission and to inform risk management measures

The Committee also emphasized the need for enhanced surveillance in regions outside Hubei, including pathogen genomic sequencing, to understand whether local cycles of transmission are occurring.

WHO should continue to use its networks of technical experts to assess how best this outbreak can be contained globally.

WHO should provide intensified support for preparation and response, especially in vulnerable countries and regions.

Measures to ensure rapid development and access to potential vaccines, diagnostics, antiviral medicines and other therapeutics for low- and middle-income countries should be developed.

WHO should continue to provide all necessary technical and operational support to respond to this outbreak, including with its extensive networks of partners and collaborating institutions, to implement a comprehensive risk communication strategy, and to allow for the advancement of research and scientific developments in relation to this novel coronavirus.

WHO should continue to explore the advisability of creating an intermediate level of alert between the binary possibilities of PHEIC or no PHEIC, in a way that does not require reopening negotiations on the text of the IHR (2005).

WHO should timely review the situation with transparency and update its evidence-based recommendations.

The Committee does not recommend any travel or trade restriction based on the current information available.

The Director-General declared that the outbreak of 2019-nCoV constitutes a PHEIC and accepted the Committee's advice and issued this advice as Temporary Recommendations under the IHR.

To the People's Republic of China

Continue to:

• Implement a comprehensive risk communication strategy to regularly inform the population on the evolution of the outbreak, the prevention and protection measures for the population, and the response measures taken for its containment.

• Enhance public health measures for containment of the current outbreak.

• Ensure the resilience of the health system and protect the health workforce.

• Enhance surveillance and active case finding across China.

• Collaborate with WHO and partners to conduct investigations to understand the epidemiology and the evolution of this outbreak and measures to contain it.

• Share relevant data on human cases.

• Continue to identify the zoonotic source of the outbreak, and particularly the potential for circulation with WHO as soon as it becomes available.

• Conduct exit screening at international airports and ports, with the aim of early detection of symptomatic travellers for further evaluation and treatment, while minimizing interference with international traffic.

To all countries

It is expected that further international exportation of cases may appear in any country. Thus, all countries should be prepared for containment, including active surveillance, early detection, isolation and case management, contact tracing and prevention of onward spread of 2019-nCoVinfection, and to share full data with WHO. Technical advice is available on the WHO website.

Countries are reminded that they are legally required to share information with WHO under the IHR.

Any detection of 2019-nCoV in an animal (including information about the species, diagnostic tests, and relevant epidemiological information) should be reported to the World Organization for Animal Health (OIE) as an emerging disease.

Countries should place particular emphasis on reducing human infection, prevention of secondary transmission and international spread, and contributing to the international response though multisectoral communication and collaboration and

active participation in increasing knowledge on the virus and the disease, as well as advancing research.

The Committee does not recommend any travel or trade restriction based on the current information available.

Countries must inform WHO about travel measures taken, as required by the IHR. Countries are cautioned against actions that promote stigma or discrimination, in line with the principles of Article 3 of the IHR.

The Committee asked the Director-General to provide further advice on these matters and, if necessary, to make new case-by-case recommendations, in view of this rapidly evolving situation.

To the global community

As this is a new coronavirus, and it has been previously shown that similar coronaviruses required substantial efforts to enable regular information sharing and research, the global community should continue to demonstrate solidarity and cooperation, in compliance with Article 44 of the IHR (2005), in supporting each other on the identification of the source of this new virus, its full potential for human-to-human transmission, preparedness for potential importation of cases, and research for developing necessary treatment.

Provide support to low- and middle-income countries to enable their response to this event, as well as to facilitate access to diagnostics, potential vaccines and therapeutics.

Under Article 43 of the IHR, States Parties implementing additional health measures that significantly interfere with international traffic (refusal of entry or departure of international travellers, baggage, cargo, containers, conveyances, goods, and the like, or their delay, for more than 24 hours) are obliged to send to WHO the public health rationale and justification within 48 hours of their implementation. WHO will review the justification and may request countries to reconsider their measures. WHO is required to share with other States Parties the information about measures and the justification received.

The Emergency Committee will be reconvened within three months or earlier, at the discretion of the Director-General.

The Director-General thanked the Committee for its work.

WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination

14 September 2020

World Health Organization

Executive Summary

This Values Framework offers guidance globally on the allocation of COVID-19 vaccines between countries, and to offer guidance nationally on the prioritization of groups for vaccination within countries while supply is limited. The Framework is intended to be helpful to policy makers and expert advisors at the global, regional and national level as they make allocation and prioritization decisions about COVID-19 vaccines. This document has been endorsed by the Strategic Advisory Group of Experts on Immunization (SAGE).

The Framework articulates the overall goal of COVID-19 vaccine deployment, provides six core principles that should guide distribution and twelve objectives that further specify the six principles (Table 1). To provide recommendations for allocating vaccines between countries and prioritizing groups for vaccination within each country, the Values Framework needs to be complemented with information about specific characteristics of available vaccine or vaccines, the benefit-risk assessment for different population groups, the amount and pace of vaccine supply, and the current state of the epidemiology, clinical management, and economic and social impact of the pandemic. Hence, the final vaccination strategy will be defined by the characteristics of vaccine products as they become available.

SAGE is currently engaged in the process of applying the Values Framework to emerging evidence on specific vaccines, and the evolving epidemiology and economic impact of the pandemic. The first stage of this process was the identification of populations and sub-populations which would be appropriate target groups for prioritization under the various values-based objectives in the Framework (Table 2), before data on Phase 3 vaccine performance are not yet available. Specific priority group recommendations for specific vaccines will be made as vaccine products become authorized for use; initial vaccine specific policy recommendations are expected in the final quarter of 2020 or early 2021, depending on timing of and findings from phase 3 vaccine trials.

The Framework also complements the principles on equitable access and fair allocation of COVID-19 health products developed for the ACT Accelerator COVAX facility.

Framework Goals and Principles at a Glance

Overarching Goal

COVID-19 vaccines must be a global public good. The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world.

Principles

Human Well-Being
Protect and promote human well-being including health, social and economic security, human rights and civil liberties, and child development.

Equal Respect
Recognize and treat all human beings as having equal moral status and their interests as deserving of equal moral consideration.

Global Equity
Ensure equity in vaccine access and benefit globally among people living in all countries, particularly those living in low-and middle-income countries.

National Equity
Ensure equity in vaccine access and benefit within countries for groups experiencing greater burdens from the COVID-19 pandemic.

Reciprocity
Honor obligations of reciprocity to those individuals and groups within countries who bear significant additional risks and burdens of COVID-19 response for the benefit of society.

Legitimacy
Make global decisions about vaccine allocation and national decisions about vaccine prioritization through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties.

Introduction

While there has been unprecedented progress in developing a vaccine against COVID-19, supplies of the first vaccine (or vaccines) to be authorized will be limited in the short to medium term. This Values Framework is intended to offer guidance globally on the allocation of COVID-19 vaccines between countries, and to offer guidance nationally on the prioritization of groups for vaccination within countries; particularly while supply is limited. It also complements the principles on equitable access and fair allocation of COVID-19 health products developed for the ACT Accelerator COVAX facility.

The Framework has been developed to provide a values foundation for SAGE recommendations on priority target groups for specific COVID-19 vaccines at different stages of supply availability. The intention is for the Framework to be a helpful tool to policy makers and expert advisors at the global, regional and national level as they make allocation and prioritization decisions about COVID-19 vaccines. In addition, the Framework is intended to be useful to all stakeholders, including community and advocacy groups, the general public, health professionals and other civil society organizations as they contribute to decisions about how limited supplies of COVID-19 vaccines should be deployed for optimal impact. The Framework is designed to address only ethical issues relating to the allocation and prioritization of COVID-19 vaccines. Other ethical issues related to COVID-19 vaccines, for example, vaccine trial design and the regulatory process, are outside of its scope.

The Framework articulates the overall goal of COVID-19 vaccine deployment, provides six core principles that should guide distribution and twelve objectives that further specify the six principles (Table 1). To provide recommendations for allocating vaccines between countries and prioritizing various groups within each country, the Values Framework needs to be complemented with information about specific characteristics of available vaccine or vaccines, the benefit-risk assessment for different population sub-groups, the amount and pace of vaccine supply, and the current state of the epidemiology, clinical management, public health response, and economic and social impact of the pandemic.

This document has been prepared by the SAGE Working Group on COVID-19 vaccination, and reviewed and endorsed by SAGE at an extra-ordinary plenary meeting of 26 August 2020.

SAGE is currently engaged in the process of applying the Values Framework to emerging evidence on specific vaccines, and the evolving epidemiology and economic impact of the pandemic. These assessments will be continuously updated as data become available. The first stage of the process in utilizing the Framework, now completed, was the identification of candidate priority groups for vaccination that, in an abstract scenario for a vaccine and based on current knowledge, are appropriate candidates for prioritization under the different values-based objectives in the Framework, shown in the "Values to Priority Groups" section below (Table 2). One benefit of this step is that it allows policy makers to identify the evidence and modeling questions that need to be answered while data are being collected about specific vaccine candidates. Another is that the values- based justification for different candidate priority groups is now explicitly displayed to guide decision-making.

SAGE will make specific priority group recommendations for specific vaccines as they become authorized for use; initial recommendations are expected in the final quarter of 2020 or early 2021.

Table 1. Values Framework

Goal Statement	COVID-19 vaccines must be a global public good. The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world.
Principles	**Objectives**
Human Well-Being	Reduce deaths and disease burden from the COVID-19 pandemic;
	Reduce societal and economic disruption by containing transmission, reducing severe disease and death, or a combination of these strategies;
	Protect the continuing functioning of essential services, including health services.
Equal Respect	Treat the interests of all individuals and groups with equal consideration as allocation and priority-setting decisions are being taken and implemented;
	Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify under prioritization criteria.
Global Equity	Ensure that vaccine allocation takes into account the special epidemic risks and needs of all countries; particularly low-and middle-income countries;
	Ensure that all countries commit to meeting the needs of people living in countries that cannot secure vaccine for their populations on their own, particularly low- and middle-income countries.
National Equity	Ensure that vaccine prioritization within countries takes into account the vulnerabilities, risks and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic;
	Develop the immunization delivery systems and infrastructure required to ensure COVID-19 vaccines access to priority populations and take proactive action to ensure equal access to everyone who qualifies under a priority group, particularly socially disadvantaged populations.
Reciprocity	Protect those who bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others, including health and other essential workers.
Legitimacy	Engage all countries in a transparent consultation process for determining what scientific, public health, and values criteria should be used to make decisions about vaccine allocation between countries;
	Employ best available scientific evidence, expertise, and significant engagement with relevant stakeholders for vaccine prioritization between various groups within each country, using transparent, accountable, unbiased processes, to engender deserved trust in prioritization decisions.

Why a Values Framework?

Decisions about how to allocate and prioritize limited supplies of COVID-19 vaccines must be guided by the best available science about the epidemiology of the pandemic and the measures available to control it, the clinical course of COVID-19, the transmissibility of the virus, the efficacy and safety of available vaccines, and their delivery characteristics. However, decisions about how to deploy limited COVID-19 vaccines should not be based on only public health considerations. Nor should they be driven by economics considerations alone, even though the impact of this pandemic on the economies of nations and the financial security of families has for many been devastating.

There are two reasons why allocation and prioritization decisions cannot be made on the basis of public health science or economics alone. The first is that the two are inextricably linked; economies cannot recover so long as the public health crisis continues. The second, and perhaps more foundational, reason is that the COVID-19 pandemic is having a devastating impact on many important aspects of social and individual life, and not just public health and the economy. Determining how best to deploy vaccines requires taking into account the various ways in which vaccines can make a difference, and the many different groups whose lives could be improved as a consequence.[1]

Starting with a Values Framework allows decision makers to think through these competing demands with an explicit recognition of the values and principles that are at stake. Employing a Values Framework also decreases the likelihood that decision-makers will overlook morally important uses or claims to vaccination. In addition, basing allocation and prioritization decisions on the *integration of explicit values with evolving scientific and economic evidence* will help keep decision-makers accountable, in at least three ways. First, it will assist decision makers to be as clear as possible about the reasons for the decisions they take, reasons that they can then share in ways that can be readily understood, if not always readily accepted, by the people affected by these decisions. Second, being clear and explicit about the full range of reasons behind allocation and prioritizing decisions will permit groups who think they qualify under the reasoning to press their case for inclusion. And third, being explicit about the values as well as the data that were used to make decisions will allow for more precise and therefore potentially more useful feedback and criticism.

Orientation to the Framework

The Framework proposes six values principles to guide COVID-19 vaccination programs, the promotion of: human well-being, equal respect, global equity, national equity, reciprocity and legitimacy (Table 1). Human well-being, equal respect, global equity, national equity and legitimacy are all of comparable importance and significance. While COVID-19 vaccination programs would be remiss if they did not take reciprocity into account, reciprocity is a principle of narrower scope and more limited importance than the other five.

The Framework identifies twelve objectives that further specify these six principles (Table 1).
As with the principles, these twelve objectives are not presented in order of importance. Ideally, a COVID-19 vaccination program would secure all of these objectives simultaneously without needing to balance competing objectives. In the real world, however, constraints on timely supply and the specific characteristics of the vaccines that become available will narrow the options for vaccine allocation between countries and prioritization of groups for specific vaccines within countries.

In some cases or phases of vaccine supply, multiple objectives will provide justification for prioritizing some countries or groups. For example, prioritizing health care workers directly engaged in the COVID-19 response is supported by objectives linked to both the well-being and reciprocity principles. In other cases, hard choices may need to be made. For example, a decision may need to be taken about which objective to prioritize when several come into conflict, or about which groups to prioritize when there is insufficient supply to offer vaccine to all who would otherwise qualify under a particular objective. Sometimes these choices will be dictated by the characteristics of the initial vaccine products that become available for use. For example, early vaccines may show more promise in reducing deaths and disease than in containing transmission, or they may not work well in older adults. In some cases, candidate priority groups may encompass multiple values objectives. For example, some groups who are at increased risk for social reasons may also be disproportionately represented in some workforces that are important to the functioning of essential services.

Thus, priority groups cannot be simply read off from the list of objectives, not only because the objectives are not themselves rank ordered, but also because which objectives are most salient and most able to be met will depend on multiple contextual features, including the epidemiology of COVID-19, the characteristics of specific vaccine products, and the level of societal and economic disruption at the time vaccine is available. Nevertheless, identifying the groups that correspond to the values objectives is essential for planning.

Explication of the Principles

The Values Framework

The Framework articulates the overall goal of COVID-19 vaccine deployment, puts forward six core principles that should guide distribution, and twelve objectives that further define the six principles*.[1,2,3,4,5,6,7,8,9,10,11,12]

Overarching Goal

COVID-19 vaccines must be a global public good.† The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world.[13,14]

Traditional approaches to the allocation of limited public health resources, including vaccines, have implicitly or explicitly appealed to a utilitarian value in which the aim is to maximize the amount of societal good or benefit that can be secured from the resource available. Typically, the good to be maximized is health benefit, although occasionally broader social or economic benefits are also considered. Maximizing benefit is critical, especially when resources are limited and stakes are high. However, it is not the sole or necessarily most important value that should guide the deployment of limited public health resources. Equity is equally important, where the aim is to ensure that the interests and rights of all groups and individuals are treated fairly.

The Goal for Covid-19 vaccination incorporates *both* the value of producing benefit, broadly construed, through the promotion of human well-being, *and* the value of ensuring equitable access to these benefits, both globally and within countries.

Principles

Human Well-Being

Protect and promote human well-being including health, social and economic security, human rights and civil liberties, and child development.

As of 1 September 2020, globally, over eight hundred thousand people have died from COVID-19 disease, many more have suffered from significant clinical disease and over 25 million cases of SARS CoV-2 infection have been reported.[15] The pandemic's negative impact on health has not been limited to COVID-19 mortality and morbidity. Essential public health services have been disrupted in many countries, including routine immunization services (increasing the risk of vaccine-preventable disease like measles); prevention and treatment services for non-communicable diseases and their complications (including hypertension, diabetes, cancer, cardiovascular and chronic respiratory diseases); maternal and child health services; and mental health and rehabilitation services (a key to healthy recovery following severe illness from COVID-19).[16,17,18,19,20,21,22,23]

Health is not, however, the only dimension of well-being that has been severely affected by the pandemic. The closures of businesses, interruptions to trade, transport, and value chains, reduced consumer and business demand, and concomitant slowdown in economic activity have caused severe economic harms, undoing many recent gains made in global poverty reduction, and destroying or threatening the livelihoods and access to food of millions.[24,25,26,27,28] School closures have not only resulted in significant setbacks in learning for over 1.5 billion young people, worldwide, they have also undermined their socioemotional development, and in many cases their physical health and safety.[29] Lockdowns and travel restrictions have separated loved ones for long periods of time, isolating many. This pandemic thus continues to negatively impact numerous human rights, including the right to health, freedom of movement, food, an adequate standard of living and education.

The human well-being principle requires that those making vaccine allocation and prioritization decisions determine what vaccine deployment strategies will best promote and protect all the implicated dimensions of well-being,[30] including strategies for containing transmission, reducing severe disease (including long term sequelae) and death, or a combination.

Equal Respect

Recognize and treat all human beings as having equal moral status and their interests as deserving of equal moral consideration

The principle that all people are and should be treated as moral equals, entitled to equal respect and equal consideration of their interests, is enshrined in the Universal Declaration of Human Rights[31] and in the constitutional documents of many countries. Equal respect is also generally understood to be a foundational principle of ethics, and of justice or equity in particular.

* Other ethics frameworks for COVID-19 vaccines have been proposed, for both the national[2,3] and the global[4,5] context. See also WHO and Nuffield Council ethics briefs for COVID-19 treatments and vaccine,[6,7] other ethics frameworks for the allocation of COVID-19 interventions,[8,9] a general ethics framework for vaccines,[10] and a WHO ethics framework for allocation of health resources.[11] Note that the World Health Organization's Strategic Advisory Group of Experts (SAGE) on Immunization has also previously released guidance on ethical considerations necessary for vaccination programs in acute humanitarian emergencies.[12]

† We use the term "public good" as it is used in global health to mean a good that should be available universally because of its critical importance to health, and not as the term is used in economics to mean a good that is both non-excludable and non-rivalrous.

Global Equity

Ensure equity in vaccine access globally among all countries, particularly for low-and middle-income countries

Because the havoc wrought by the COVID-19 pandemic on human well-being and rights has been global, people living everywhere in the world are entitled to equal consideration for COVID-19 vaccine access and in allocation decisions. Countries and territories have primary responsibility for protecting and promoting the well-being and human rights of those living within their borders. It is thus reasonable and appropriate for countries to be concerned with securing sufficient COVID-19 vaccines to meet the needs of their own populations. However, this national concern does not absolve nation-states of obligations to people in other countries.[32] Although there is little consensus about the meaning and reach of global justice[33,34,35], at a minimum, nation-states have an obligation in global equity not to undermine the ability of other countries to meet their obligations to their own populations to secure vaccines.**Error! Bookmark not defined.** The global community also has an obligation to address the human rights claims to vaccines of people living in countries who cannot, without assistance, meet their needs by, for example, reducing obstacles to obtaining vaccines that confront countries with fewer resources and geopolitical power.

The reasons why all nations should be concerned to ensure that people everywhere have access to COVID-19 vaccine are not limited to obligations of global equity.[36,37] Infectious threats to health know no borders; as long as there is active SARS-CoV-2 transmission anywhere there will be a risk of transmission everywhere. Moreover, protecting the public health of one's residents is not the only national interest countries have in containing the pandemic globally. The recovery of national economies also depends on securing stable global supply chains and global markets and regularizing international travel, which will not be possible until the pandemic is contained globally. Hence the equitable allocation of vaccines globally is in all countries' enlightened self-interest.

National Equity

Ensure equity in vaccine access and benefit within countries for groups experiencing greater burdens from the COVID-19 pandemic

There are many ways to think about what equity or justice requires within a country when COVID-19 vaccine is in short supply.[38] It is clearly important to be efficient in the use of constrained resources, especially when the resource is as high-value as vaccines in a devastating pandemic. From the perspective of some utilitarian positions, maximizing the net good that can be secured is considered the most just way to deploy limited resources. However, relying solely on maximizing utility to make decisions about limited vaccine supply can perpetuate and even exacerbate existing injustices affecting human well-being. In public health, the moral importance of looking beyond efficiency to address other pertinent justice concerns is often expressed as the obligation to pursue health equity. Health equity requires that public policies, including how to prioritize vaccines when supply is limited, reduce unjust disparities in health and other aspects of well-being.**Error! Bookmark not defined.**[39]

Although everyone is affected by the COVID-19 pandemic, it is not the case that the burdens of the pandemic are being experienced equally by all people. Some groups are experiencing serious illness and death at higher rates. In some cases, these higher rates are specifically associated with biological factors. For example, those who are older or have comorbidities like chronic kidney disease and diabetes have claims for prioritization because of their greater risk of severe disease and death.[40,41,42] Other groups, however, are experiencing disproportionately greater health and other burdens in this pandemic because of societal factors that are arguably unjust. Sometimes, but not always, the elevated risk in these groups is mediated by high rates of co-morbidities that are themselves causally connected to societal conditions, serving to compound further their disproportionate burden.

Although the evidence is not yet available globally, there are emerging reports that people living in poverty, especially extreme poverty, are suffering disproportionately during this pandemic, as they have done in past pandemics and in emergencies and disasters generally. It can be extremely difficult for people living in poverty to practice physical distancing in their living arrangements or at work;[43,44,45,46] they are more likely to experience food and housing insecurity, both before and because of the pandemic, and to be in poorer health. They also have barriers to accessing quality health care. Systemic disadvantage associated with racism and other forms of denigrated group membership, sometimes but not always intersecting with poverty,[47,48] is also associated with disproportionate pandemic burden. Promoting equity requires addressing higher rates of COVID-19 related severe illness and mortality among systematically disadvantaged or marginalized groups.

Reciprocity

Honor obligations of reciprocity to those individuals and groups within countries who bear substantial additional risks and burdens of COVID-19 response for the benefit of society

Obligations and norms of reciprocity can take many forms. In the context of the COVID-19 pandemic, when some show exceptional courage or face

exceptional risks that give the rest of society an opportunity to experience better health, physical security, and quality of life, those who benefit have an obligation to reciprocate accordingly.

Reciprocity, thus understood, is similar to but broader than the moral emotion of gratitude. [49] Expressions of gratitude, while welcome and appropriate, are not sufficient to discharge obligations of reciprocity. Offering vaccine to those who take or bear exceptional risks during a pandemic, often because of their occupations, is one way to honor obligations of reciprocity and also express gratitude.

Reciprocity and gratitude are not the only reasons to offer vaccine to occupational groups to whom duties of reciprocity are owed, however. Their being in good health is often critical to securing the well-being of others, which is why the designation "essential workers" is often used. That said, occupation groups judged to be essential differ in the degree of risk their jobs entail and therefore obligations of reciprocity do not apply evenly to all of them. Another reason for offering vaccine to front-line health and social care workers is that they often come into close contact with people who are biologically most likely to experience serious COVID-19 if infected and who might be afforded some level of protection if these workers were vaccinated.

The principle of reciprocity should be interpreted with caution to preempt inappropriate claims by people and entities with disproportionate power and resources to reciprocity-based entitlement to COVID-19 vaccine.

Legitimacy

Make global decisions about vaccine allocation and national decisions about vaccine prioritization through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties

Legitimacy in the context of COVID-19 vaccines and this pandemic refers to the appropriate authority to make recommendations and governing decisions about who gets vaccine and when. Because different stakeholders, including different countries at the global level and different interest groups at the national level, are likely to have different views about vaccine allocation and prioritization, it is important that all concerned are aware that the recommendations and decisions are emanating from a legitimate body through a legitimate process. [1]**Error! Bookmark not defined.**[50]

What is required for decision-making bodies to be legitimate in the context of COVID-19 vaccine decision-making includes, but is not limited to: transparency in decision processes, outcomes, and reasoning; reliance on best available evidence; articulation and incorporation of shared social values in the decision process and outcome; and appropriate representation, influence and input by affected parties, with no tolerance for personal, financial or political conflict of interest or corruption. In all cases, decision-makers must be able to defend their decisions by appealing to reasons that even those who disagree can view as reasonable, and not arbitrary or self-dealing.

From Values to Priority Groups

The "Values to Priority Groups" section of this document represents the first step in prioritizing groups for COVID-19 vaccination that is grounded in values principles and objectives (Table 2). Some groups appear more than once in this table because they are important to securing two or more values objectives. For example, health care workers at high to very high risk appear three times in the values to priority groups document in relation to three different values objectives: 1) reduce deaths and disease burden; 2) protect the continuing function of essential services (where they are included under health care workers); and 3) protect those who bear significant additional risks and burdens for the welfare of others. Final prioritization and specific vaccine recommendations will await more evidence, including a range of epidemiological, economic and clinical factors, specific characteristics of the vaccines, benefit-risk assessment data for particular priority groups (e.g. age specific vaccine efficacy and safety), as well as storage and supply chain requirements for a given product.

The Values to Priority Groups table can be a useful resource for countries as they decide on priority groups for COVID-19 vaccination. The document explicitly connects priority groups with specific value principles and objectives. Given country-specific nuances in epidemiology, demographics, and vaccine delivery systems, these priority groups will need to be further interpreted at a national level. This process should be led by national health experts/National Immunization Technical Advisory Groups (NITAGs) in wide consultation with stakeholders. Country-level decision making will require data collected, or at least collated, at the country-level. The Values to Priority Groups section can help countries identify where more local data are needed and where investment now might be required to ensure vaccine delivery platforms that can effectively reach prioritized groups. Moreover, this section may assist important regional discussions about the priorities, for example by Regional Immunization Technical Advisory Groups (RITAGs). Of note, two principles that do not directly implicate particular priority groups have important implications for national prioritization processes. The equal respect principle requires that careful attention be given to the question of who should be eligible for inclusion in national immunization programs, so that no one is left out of consideration for unjustifiable reasons. The equal respect principle also requires that everyone who

satisfies the criteria and reasoning supporting the prioritization of a certain group be included within that group. The legitimacy principle provides guidance on how the process of prioritization should proceed, with safeguards to ensure trust, and to help protect against corruption and self-dealing.

Also of note, the groups identified under the national equity principle may need to be further refined at the global level. Countries must ensure that vaccine access is equitable based on gender, race, socio-economic status, ability to pay, location and other factors that often contribute to inequities within population

The global equity principle applies to allocation at the global level. The considerations identified in Table 2 under this principle further characterize how countries can operationalize global equity obligations.

Table 2. Translation of values to (unranked) priority groups for COVID-19 vaccination. This table also includes equal respect, global equity, legitimacy considerations that apply to all groups

Principle	Objective	Groups & Other Considerations
Human Well-Being	Reduce deaths and disease burden from the COVID-19 pandemic	Populations with significantly elevated risk of severe disease or death: • Older adults defined by age-based risk - may vary by country/region, specific cutoff to be decided at the country level by national health experts/NITAGs based on differential mortality by age • Older adults in high risk living situations (examples: long term care facility, those unable to physically distance) • Groups with comorbidities or health states (e.g. pregnancy/lactation) determined to be at significantly higher risk of severe disease or death (list to be developed later) • Sociodemographic groups at disproportionately higher risk of severe disease or death Populations with significantly elevated risk of being infected: • Health workers at high or very high risk, as defined by interim guidance forthcoming from WHO and ILO • Employment categories unable to physically distance • Social groups unable to physically distance (examples: geographically remote clustered populations, detention facilities, dormitories, military personnel living in tight quarters, refugee camps) • Groups living in dense urban neighborhoods • Groups living in multigenerational households
	Reduce societal and economic disruption (other than through reducing deaths and disease burden)	• Age groups at high risk of transmitting SARS-CoV-2 • Non age-based population groups with significantly elevated risk of infection and transmission • School-aged children to minimize disruption of education and socioemotional development • Groups targeted as part of an emergency outbreak response using emergency vaccine reserves • Workers in non-essential but economically critical sectors, particularly in occupations that do not permit remote work or physical distancing while working
	Protect the continuing functioning of essential services, including health services	• Health workers • Essential workers outside health sector (examples: police officers and frontline emergency responders, municipal services, teachers, childcare providers, agriculture and food workers, transportation workers) • Government leaders and administrative and technical personnel critically needed for indispensable functions of the state (this group should be narrowly interpreted to include a very small number of individuals) • Personnel needed for vaccines, therapeutics, diagnostics production

Equal Respect	Treat the interests of all individuals and groups with equal consideration as allocation and priority-setting decisions are being taken and implemented	The equal respect principle requires that careful attention be given to the question of who should be eligible for inclusion in national immunization programs, so that no one is left out of consideration for unjustifiable reasons. The equal respect principle also requires that everyone who satisfies the criteria and reasoning supporting the prioritization of a certain group be included within that group.
	Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify under prioritization criteria	
Global Equity	Ensure that vaccine allocation takes into account the special epidemic risks and needs of all countries; particularly low-and middle-income countries	Priority groups that are identified through this values framework process inform allocation decisions at the global level, with special attention to the needs of low- and middle-income countries.
	Ensure that all countries commit to meeting the needs of people living in countries that cannot secure vaccine for their populations on their own, particularly low- and middle-income countries	Countries with sufficient financial resources should refrain from undermining vaccine access to low and middle-income counties by contributing to market conditions that substantially disadvantage countries with less economic power. Financially able countries should participate and support approaches to ensure access to COVID-19 vaccine for resource constrained populations, including multi-lateral (e.g. COVAX Facility), bilateral procurement mechanisms, and/or other means of support.
National Equity	Ensure that vaccine prioritization within countries takes into account the vulnerabilities, risks and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic	• People living in poverty, especially extreme poverty • Homeless people and those living in informal settlements or urban slums • Disadvantaged or persecuted ethnic, racial, gender, and religious groups, and sexual minorities and people living with disabilities • Low-income migrant workers, refugees, internally displaced persons, asylum seekers, populations in conflict setting or those affected by humanitarian emergencies, vulnerable migrants in irregular situations, nomadic populations • Hard to reach population groups
	Develop the immunization delivery systems and infrastructure required to ensure COVID-19 vaccines access to priority populations and take proactive action to ensure equal access to everyone who qualifies under a priority group, particularly socially disadvantaged populations	
Reciprocity	Protect those who bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others, including health and other essential workers	• Health workers at high or very high risk, as defined by interim guidance forthcoming from WHO and ILO • Health workers at low or moderate risk, as defined by interim guidance forthcoming from WHO and ILO • Essential workers outside the health sector (see above) who are at high or very high risk of infection • Essential workers outside the health sector (see above) who are at low or moderate elevated risk of infection

Legitimacy	Engage all countries in a transparent consultation process for determining what scientific, public health, and values criteria should be used to make decisions about vaccine allocation between countries	The legitimacy principle provides guidance on how the process of prioritization should proceed, with safeguards to ensure trust, and to help protect against corruption and self-dealing.
	Employ best available scientific evidence, expertise, and significant engagement with relevant stakeholders for vaccine prioritization between various groups within each country, using transparent, accountable, unbiased processes, to engender deserved trust in prioritization decisions	

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WHO SAGE ROADMAP FOR PRIORITIZING USES OF COVID-19 VACCINES IN THE CONTEXT OF LIMITED SUPPLY

An approach to inform planning and subsequent recommendations based upon epidemiologic setting and vaccine supply scenarios

Version 1.1
13 November 2020

World Health Organization

Contents

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The *WHO SAGE Roadmap for prioritizing the use of COVID-19 vaccines in the context of limited supply* was prepared by the SAGE Working Group on COVID-19 vaccines. The drafting of the Roadmap was led by Saad B. Omer, Ruth Faden, Sonali Kochhar, David Kaslow and Sarah Pallas with input from the members of the Public Health Objectives Subgroup (Folake Olayinka, Muhammed Afolabi, Celia Alpuche-Aranda, Hyam Bashour, David Durrheim, Sonali Kochhar, Peter G. Smith, Yin Zundong, Peter Figueroa and Helen Rees) and Annelies Wilder-Smith and Joachim Hombach from the WHO Secretariat, with support of Matthew A. Crane from the Johns Hopkins University School of Medicine. Hanna Nohynek leads the SAGE Working Group on COVID-19 vaccines.

Abbreviations

Allocation Framework	fair allocation mechanism for COVID-19 vaccines through the COVAX Facility
COVAX	COVID-19 Vaccines Global Access
COVID-19	coronavirus disease 2019
NITAG	National Immunization Technical Advisory Group
Prioritization Roadmap	WHO SAGE roadmap for prioritizing uses of covid-19 vaccines in the context of limited supply
SAGE	Strategic Advisory Group of Experts on Immunization
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
RITAG	Regional Immunization Technical Advisory Group
Values Framework	WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination
YLL	years of life lost
WHO	World Health Organization

Introduction

As countries prepare to implement their respective coronavirus disease 2019 (COVID-19) vaccination programmes, the Strategic Advisory Group of Experts (SAGE) on Immunization of the World Health Organization (WHO) is undertaking a three-step process to provide guidance for overall programme strategy as well as vaccine-specific recommendations.

Step 1: A Values Framework. The *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination (1)*, issued on 14 September 2020, outlines the general principles, objectives and related (unranked) target groups for prioritization of COVID-19 vaccines.

Step 2: Roadmap for prioritizing uses of Covid-19 vaccines (Prioritization Roadmap) (this document). To support countries in planning, the Roadmap suggests public health strategies and target priority groups for different levels of vaccine availability and epidemiologic settings. The Roadmap will be updated, as necessary, to accommodate the dynamic nature of the pandemic and evolving evidence about vaccine impact.

Step 3: Vaccine-specific recommendations. As market-authorized vaccines become available, specific recommendations for the use of these vaccines will be issued. These recommendations may be updated as additional evidence of effectiveness and safety of market-authorized vaccines (as well as other interventions) becomes available, and as epidemiologic and other contextual conditions evolve.

Rationale

Given the urgency and wide-ranging effects of the COVID-19 pandemic, SAGE has developed an approach to help inform deliberation around the range of recommendations that may be appropriate under different epidemiologic and vaccine supply conditions. The SAGE consensus is that currently available evidence is too limited to allow any recommendations for use of any specific vaccine against COVID-19 at this time (7 October 2020). This document should be regarded as a Roadmap for planning purposes only.

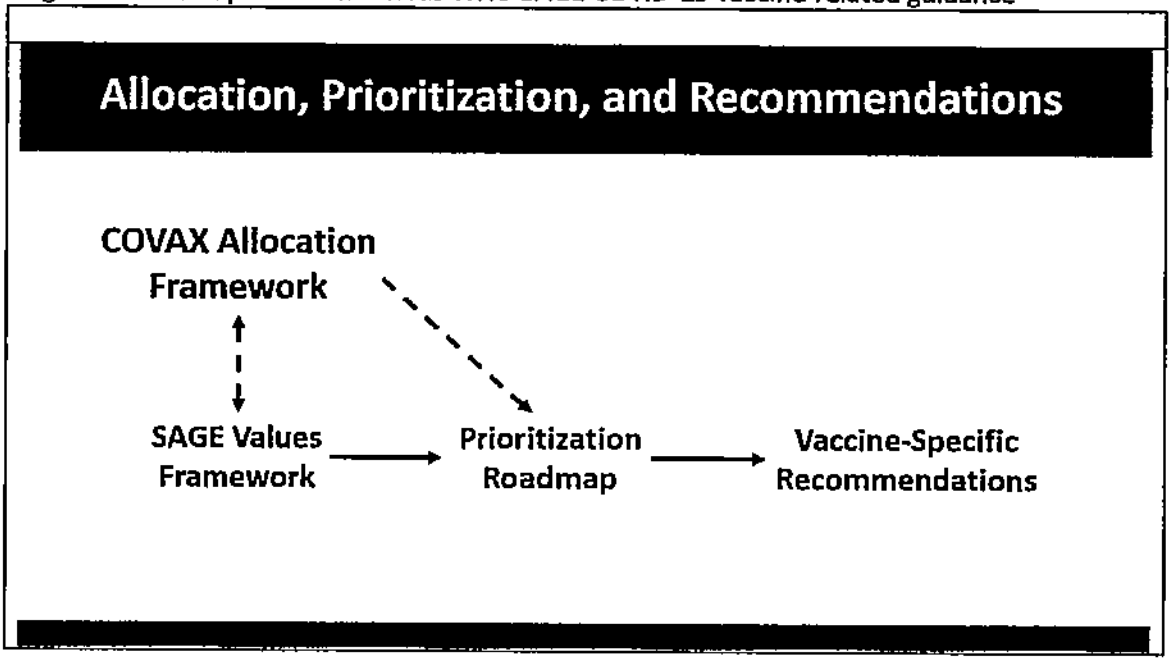
This Roadmap builds on the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*. The Values Framework listed over 20 population subgroups that, if vaccine use needed to be prioritized because of limited supply, would advance one or more of its principles and objectives. The Values Framework did not rank the subgroups in any order. Specific priority group recommendations for each vaccine product as it becomes authorized for use will require the integration of these ethical principles detailed in the Values Framework with evidence and information about: i) the status of the pandemic in the proposed implementation area (that is, the epidemiologic setting in terms of the degree of ongoing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission and COVID-19 burden); ii) the amount and timing of vaccine supply and availability, respectively; iii) specific product characteristics of the available vaccine(s); and iv) the benefit–risk assessment for the different population subgroups at the time vaccination is being considered for deployment; as well as other standard criteria used in developing SAGE recommendations (for example, feasibility, acceptability and resource use). These factors, together with the Values Framework, should guide the appropriate public health strategy for vaccine deployment of specific vaccines.

To assist in developing recommendations for use of vaccines against COVID-19, SAGE proposes a Prioritization Roadmap of COVID-19 vaccines that considers priority groups for vaccination

based on epidemiologic setting and vaccine supply scenarios. These use cases are also set in the context of the overall public health strategy for each epidemiologic setting (Table 1).

This Roadmap is intended to serve as guidance on preparing for vaccine prioritization decisions within countries. Although the Values Framework does include the principle of global equity, this Roadmap does not directly address global allocation decisions. A COVAX Facility allocation mechanism for countries participating in the COVAX Facility has been proposed *(2)*. Fig. 1 shows how it aligns with this Roadmap and the Values Framework.

Fig. 1. Relationship between various WHO SAGE COVID-19 vaccine-related guidance



Process of Roadmap development

The Roadmap builds on the population subgroups identified in the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination* as significant for advancing the Framework's principles and objectives. After prioritization exercises by a subgroup of the SAGE Working Group on COVID-19 Vaccines, a draft of the prioritization table was developed and then critiqued by the full Working Group that includes the chairpersons of all six Regional Immunization Technical Advisory Groups (RITAGS) as well several SAGE members. The draft table was then revised and reviewed multiple times. A similar process was used to develop the narrative sections of the Roadmap. Prioritization took account of emerging modelling information exploring the effectiveness and optimal impact of different vaccination strategies and best available epidemiologic information from academic literature as well as various surveillance organizations. A penultimate round of review by multiple SAGE members resulted in further substantive changes to the Framework, followed by a final review by the full SAGE committee.

Guiding considerations

The following considerations guided the development of this Roadmap.

- This Roadmap must remain fully aligned with the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination* that preceded it.

- To be useful in driving discussions at regional and national levels, the Roadmap needs to be kept as straightforward and concise as possible.
- The Roadmap may be revisited through i) rolling review as new information becomes available; and ii) ongoing dialogue with RITAGs and National Immunization Technical Advisory Groups (NITAGs).

Key assumptions

- The Roadmap assumes any vaccine deployed is fully licensed and has met all the minimal or critical criteria in *WHO Target Product Profiles (TPP) for COVID-19 vaccines (3)*. Less conclusive evidence on benefit–risk, as expected for an emergency-authorized product, might lead to more restricted recommendations.
- The current degree of uncertainty regarding age-independent vaccine efficacy of any specific vaccine was considered (for example, a scenario in which the vaccine is assumed to have the same efficacy at all ages, and another scenario in which the vaccine is assumed to have much lower efficacy in older adults). However, the Roadmap relies on the underpinning assumption, supported by current modelling results, that, given the many-fold higher mortality rate among older individuals *(4, 5)*, even a vaccine with relatively low efficacy in older adults would not significantly change the recommendations for priority use cases in older populations *(6–8)*. If however it were determined that vaccine efficacy in older adults relative to other age groups were so low that individual protection and public health impact became significantly suboptimal, the individuals in older age groups in each scenario would likely be moved to a lower priority use case.
- Similarly, it was assumed that there would not be substantive differences in vaccine efficacy in subgroups (for example, people with comorbidities that increase the risk of severe COVID-19 such as HIV-positive status).
- The Roadmap assumes that non-pharmaceutical interventions are in place to varying degrees as vaccines are introduced and coverage expands. The Roadmap further assumes that vaccine efficacy will not deteriorate if use of non-pharmaceutical interventions is relaxed.
- Although a vaccine's effect on reducing transmission is an important consideration in the recommendations for use, direct evidence of impact on transmission will likely not be available when the first vaccines are authorized for use. The Roadmap assumes that at some point demonstrated evidence of vaccine effectiveness in reducing transmission will be available, sufficient to justify prioritizing vaccination of some groups on the basis of their role in transmission.
- The Roadmap does not account for variation in population seropositivity rates or existing degree of protection within countries or communities which may have already experienced a high degree of community transmission.
- Prioritization exercises undertaken for development of this Roadmap did not directly take account of severe disease, as the risk of this will be closely correlated with the risk of death. Similarly, long-term sequalae from SARS-CoV-2 infection have not been taken into account as evidence on chronic morbidity is still emerging.

Epidemiologic setting scenarios

The epidemiologic setting scenarios used here take into consideration the relative benefits and potential risks of vaccination. Moreover, the public health strategy for use of vaccines

depends upon the burden of disease and on the local epidemiology, particularly the incidence rate of infection in a setting at the time vaccination is being contemplated for deployment. The three proposed broad epidemiologic settings are: (i) Community Transmission, (ii) Sporadic Cases or Clusters of Cases, and (iii) No Cases (Table 1) *(9)*.

Vaccine supply scenarios

As sufficient vaccine supply will not be immediately available to immunize all who could benefit from vaccination, three scenarios of constrained vaccine supply were considered: a Stage I scenario of very limited vaccine availability (ranging from 1–10% of each country's total population) for initial distribution; a Stage II scenario as vaccine supply increases but availability remains limited, (ranging from 11–20% of each country's total population); and a Stage III scenario as vaccine supply reaches moderate availability (ranging from 21–50% of each country's total population). How each of these three vaccine supply scenarios could be considered in recommendations for use in priority groups is illustrated in Table 1.

The Roadmap recognizes that many countries' prioritization decisions will be tied, in part or in whole, to vaccine distribution through the COVAX Facility. Stages I and II in the Roadmap correspond to the Phase 1 supply of up to 20% of each country's population detailed in the latest draft of the WHO *Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility*. The Roadmap's Stage III scenario aligns with the Allocation Framework's Phase 2 supply of more than 20% population coverage (Annex 1).

Overall public health strategies by epidemiologic setting and vaccine supply stage

SAGE recommends overall public health strategies, grounded in the Values Framework, for each of the three epidemiologic scenarios (Table 1). The strategies accommodate the dynamic nature of vaccine supply and epidemiologic conditions in each country.

Community Transmission setting: When vaccine supplies are severely constrained, what is feasible to achieve with limited vaccine availability justifies an initial focus on direct reduction of morbidity and mortality (Annex 2) and maintenance of most critical essential services, while considering reciprocity towards groups that have been placed at disproportionate risks to mitigate consequences of this pandemic (for example, front-line health workers). As vaccine supplies increase, depending on the vaccine characteristics, the strategy expands to reduction in transmission to further reduce disruption of social and economic functions. Special attention is paid to functions that disproportionately impact children (see below) and to the reduction of morbidity and mortality in disadvantaged groups, in keeping with the principles of the SAGE Values Framework.

Sporadic Cases or Clusters of Cases setting: When vaccine supplies are severely constrained, the initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services, and reciprocity, remains. However, in contrast with the Community Transmission epidemiologic setting, this initial focus is concentrated in locations with high transmission or anticipated high transmission. In addition, some vaccine is allocated for emergency reserve use for outbreak response or mitigation (for example, for localized outbreaks). Special attention to reduction of morbidity and mortality of disadvantaged groups in areas of high or anticipated high transmission is maintained. As vaccine supplies increase,

the strategy expands to substantially control transmission and further reduce disruption of social and economic functions.

No Cases setting: This epidemiologic setting applies to countries that have managed to stop transmission through non-pharmaceutical interventions and border controls. When vaccine supplies are severely constrained, the initial focus is on prevention of community transmission from importation of cases, and reciprocity to critical workers, particularly front-line health workers. As vaccine supply increases, older adults, the highest risk group for severe disease and death, are included to minimize harm should epidemic conditions change suddenly. Also, as vaccine supply increases, the strategy expands to preserve control of transmission and, if possible, to reduce reliance on burdensome non-pharmaceutical interventions.

Priority uses of COVID-19 vaccines

The rationale for the inclusion of each prioritized vaccine use case based upon population subgroup is anchored in the Values Framework principles and objectives. For each priority group, the Values Framework objective(s) that would be supported by prioritizing this population for vaccination are indicated by parenthetical abbreviations after the population description (for example, A1); the legend that links these abbreviations to the objectives is provided below Table 1.

While a detailed explanation of the rationale for each of the priority groups is beyond the scope of this document, three examples of rationales are provided in Box 1.

Box 1. Three examples of rationales for priority uses of COVID-19 vaccines

Example 1. Health workers at high to very high risk of becoming infected and transmitting SARS-CoV-2 in the Community Transmission epidemiologic setting

For the Community Transmission epidemiologic setting, health workers at high to very high risk of becoming infected and transmitting SARS-CoV-2 are included in Stage Ia. There are three reasons, linked to the Values Framework, supporting this prioritization. First, protecting these workers protects the availability of a critical essential service in the COVID-19 pandemic response. Also, the indirect health effects of the pandemic beyond COVID-19 are likely to be much worse if such services are compromised or overwhelmed. Second, evidence suggests that health workers are at high risk of acquiring infection and possibly of morbidity and mortality *(10, 11)*. There is also a risk of onward transmission to people who are also at high risk of serious COVID-19 outcomes. Third, prioritization of these workers is also supported by the principle of reciprocity; they play critical roles in the COVID-19 response, working under intense and challenging conditions, putting not only themselves but also potentially their households at higher risk for the sake of others.

There are also pragmatic reasons for prioritizing health workers at high to very high risk of infection. Health workers already interact directly with health systems, which should facilitate effective deployment of a vaccine programme, particularly including if two or more doses need to be administered. Launching a vaccine programme with a relatively accessible target population will allow more time for the development of delivery mechanisms to other priority groups.

In a second step (Stage Ib), older adults defined by age-based risk specific to country or region are included.

Example 2. Sociodemographic groups at significantly higher risk of severe disease or death

For the Community Transmission epidemiologic setting, sociodemographic groups at significantly higher risk of severe disease or death are included in Stage II. The reasons for this prioritization are grounded in the principles of equal respect and equity.

In keeping with the overall public health strategy that places an initial focus on direct reduction of mortality and morbidity, groups with comorbidities or health states that put them at significantly higher risk of severe disease or death are prioritized to Stage II. However, there are other groups in the population who may be at just as high a risk of these severe outcomes but who are not captured in a prioritization solely by comorbidities. These groups disproportionately include those who are systematically disadvantaged with respect to social standing and economic and political power. In many contexts, disadvantaged groups are more likely to experience a higher burden of infection and consequent COVID-19 because of crowded work or living conditions over which they have no effective control *(12–15)*, as well as a higher prevalence of background states of poor health that increase their risk of severe COVID-19 *(16)*. They may also have less access to appropriate health care necessary for the diagnosis of high-risk conditions such as heart failure or chronic kidney disease *(17)*. Some individuals in these groups would likely qualify for prioritization if their comorbidities were known or ascertainable, but because of inequitable access to health care their conditions often will be undiagnosed and untreated.

Which disadvantaged sociodemographic groups are at significantly higher risk of severe disease or death will vary from country to country. In many contexts, the evidence of elevated risk for COVID-19 severe disease and death will be lacking or less clear than for the risk factors like age or comorbidities. Policy-makers may have to decide which disadvantaged groups are likely to be sufficiently burdened by COVID-19 to include in Stage II. While broader efforts must be made to reach out and identify risks among disadvantaged groups, these decisions may have to be based on reasonable assumptions about differential impact inferred from other relevant contexts, including past public health emergencies *(18)*. Table 1 provides examples of groups that, depending on the country context, may fall under this prioritization category.

Example 3. Social/employment groups at elevated risk of acquiring and transmitting infection because they are unable to effectively physically distance

For the Community Transmission epidemiologic setting, social/employment groups at elevated risk of acquiring and transmitting infection because they are unable to effectively physically distance are included in Stage III. There is considerable overlap in the groups that should be considered in this category and the Stage II sociodemographic groups category just discussed. The relevant difference is that for some disadvantaged groups there may not be good reasons to conclude that they are at significantly elevated risk of severe disease and death (and thus that they do not qualify under Stage II). However, these groups may nevertheless still be at increased risk (if not significantly increased risk) of severe COVID-19 due to the reasons related to inequity discussed above. Groups that have no choice but to work without physical distancing or access to personal protective equipment, or no choice but to live in high-density homes in high-density neighbourhoods fall into this category *(19, 20)*. They are disadvantaged relative to other groups in the population who benefit more easily and more significantly from non-pharmaceutical interventions, both in terms of their own risk and in terms of onward transmission to loved ones and co-workers. Incarcerated people also fall into this category, although the rationale is somewhat different. Even if the restriction of their liberty is justified, that does not justify leaving unaddressed the elevated risk associated with being incarcerated.

In an ideal world, policy-makers could clearly distinguish, based on evidence regarding level of risk, which disadvantaged groups fall under Stage II criteria and which under Stage III criteria. In the real world, these decisions may have to be made with only limited relevant data. Adherence to the principles of equal respect and equity will require a careful assessment to ensure that all relevant sociodemographic groups are given equal consideration for both Stages.

How staging of priority groups relates to group size

The staging of priority groups is sequential. If there is insufficient vaccine supply to cover the priority groups in Stage I, the intention is that all these groups are offered vaccine before groups enumerated in Stage II.

With the exception of Stage Ia and Stage Ib, the priority groups within a vaccine supply stage are not ordered for prioritization. The assignment of priority groups was based on assumptions about the size of different priority groups in high-, middle- and low-income country settings. For some priority groups, even estimates of the sizes of different groups were not available. Considerable national variation is expected. In some countries, the amount of vaccine

projected for a vaccine supply stage may be insufficient to cover all the priority groups assigned to that stage and countries will have to prioritize groups within stages.

As an example, consider Stage II in the Community Transmission epidemiologic setting. Receiving vaccine supply up to an additional 10% of population coverage in this stage may be insufficient to address all the groups assigned to that stage, even if Stage I supply is sufficient to cover the groups assigned to Stage I. In deciding which groups in Stage II to prioritize, countries may wish to consult the Values Framework for guidance. For example, determining which ethical principles are most important to the country at a given time may help identify which groups to privilege, if vaccine supply is insufficient to cover all the groups assigned to Stage II.

Gender considerations

While there is evidence that the risk of severe disease and death is higher in males than in females, particularly in older age groups, this difference in risk is diminished when comorbidities and other factors are taken into account *(4, 21)*. In many contexts, women are disproportionately represented in high-risk occupation groups and they often have direct responsibility for caring for elders. Also, in some contexts, women are disadvantaged in terms of access to health care, political and social status, and decision-making authority due to social structural features in some communities. Prioritizing men or women for vaccination could exacerbate underlying gender-based inequities. For these reasons, the Roadmap does not use gender to identify prioritized vaccine use cases. The equal respect principle of the Values Framework underscores the importance of ensuring that immunization delivery systems place equal focus on reaching both men and women in every priority group.

Addressing pregnant women

Pregnant women warrant particular consideration, as this group has been disadvantaged with respect to the development and deployment of vaccines in previous pandemics. Also, specific to COVID-19, evidence is emerging that pregnant women are at elevated risk of serious disease, further increased if they have pre-existing comorbidities, and may be at elevated risk of adverse pregnancy and birth outcomes as well *(22–25)*. However, it seems likely there will be relatively little data about the safety and efficacy of COVID-19 vaccines in these groups when Stage I and perhaps even Stage II vaccine supplies become available, making the prioritization of pregnant women in these early stages problematic. It is imperative that data specific to pregnancy be generated now from, for example, pregnancy-specific safety and bridging studies and from participants who inadvertently become pregnant during Phase III trials. Vaccine developers and funders should prioritize an assessment of vaccine safety and immunogenicity among pregnant women in their clinical development and of safety and effectiveness in post-marketing surveillance plans *(26)*.

Of particular concern is that several groups prioritized in the Roadmap, including health workers and teachers, are in age groups likely to include significant numbers of women who are pregnant (including some who might not be aware of their pregnancy). Guidance on pregnant women in groups prioritized for vaccination before these urgently needed safety data are available will need to await information about the specific characteristics of the vaccines authorized for use, as well as the latest evidence on risks of COVID-19 for pregnant women and their children.

The Roadmap currently prioritizes pregnant women as specific groups in Stage III of two epidemiologic scenarios. By that time, there should be sufficient evidence to assess whether the net benefit of COVID-19 vaccination for pregnant women (with at least some vaccine candidates) outweighs the risks of community-acquired infection and subsequent severe COVID-19. It is possible that as evidence accumulates the risks to pregnant women and to their children will be judged to be great enough to warrant offering vaccine even in the absence of pregnancy-specific evidence about vaccine risk, in which case pregnant women may be added as a priority group to Stage II. Similarly, if the pregnancy-specific risks of vaccines (which may vary with vaccine product) are determined to be higher than the risks from infection and disease, these groups will need to be prioritized for non-vaccine preventive interventions.

Addressing lactating women

Historically, lactating women have also been overlooked in pandemic vaccine development and response. There is, as yet, no evidence that lactating women or their infants are at elevated risk of severe COVID-19. Therefore, they have not been prioritized in the Roadmap. Currently there are no data on any risks to the infant from immunization of their lactating mothers. As data become available, recommendations on lactating women may be provided for vaccine-specific recommendations. At least one manufacturer is enrolling lactating women. As with pregnant women, it is imperative that evidence on the safety of vaccination in lactating women be quickly gathered.

Addressing children

Children also warrant specific consideration for at least two reasons. Children are dependent on adults and the wider society for their well-being, and setbacks in well-being during childhood can have severe negative and sometimes permanent effects that can last a lifetime. Although children are less subject to direct morbidity and mortality impacts of infection from SARS-CoV-2 when compared to other age groups, they have suffered significantly in other ways during the COVID-19 pandemic *(27, 28)*. Physical distancing measures designed to decrease or prevent community transmission of SARS-CoV-2 have included withdrawing children from in-person learning at schools or closing schools altogether. The extent of learning loss and its impact on life prospects is expected to be far greater for children living in poverty or in otherwise disadvantaged groups. Beyond poor learning and constraints of life prospects from disruption in school provision, students have lost social and developmental benefits afforded by in-person learning. Schools often also provide a number of additional functions important for child health and well-being such as social interactions, meal provision and health services including immunizations and shelter from unstable or unsafe home living environments. These additional functions are especially important for children living in disadvantaged circumstances. Taken together, while all children are being harmed by educational disruptions, these effects are hitting the most disadvantaged children hardest, who also have less access to distance learning options, widening further existing inequities in child well-being *(29)*. The health of all children, and especially low-income children, is also being threatened by COVID-19-related disruptions to routine immunization and other child health programmes *(30–32)*.

Although the pandemic has greatly impacted child well-being, children themselves are not directly prioritized as a population group in Table 1 for two reasons. First, trials of COVID-19 vaccine candidates in children have not yet been initiated and thus data on safety and efficacy in this age group are not expected for some time. Second, as already noted, the low risk of severe COVID-19 and death in children does not make them a high priority for direct immunization. However, child well-being is addressed within this Roadmap through the

prioritization of other groups that directly contribute to child well-being. Within the Community Transmission epidemiologic scenario, health workers engaged in immunization delivery are prioritized to ensure that routine childhood immunization delivery will be safely maintained. Teachers and other adult staff employed in school settings are prioritized within this epidemiologic scenario as well to facilitate the full reopening of in-school education.

Considering comorbidities in vaccine prioritization

The evidence on specific comorbidities and the increased risk of severe COVID-19 is increasing. What is already clear is that i) several comorbidities increase this risk; ii) the increase in risk varies between specific comorbidities, and thus equity concerns would arise if all comorbidities were to be given similar weight; iii) in many countries, if everyone with a comorbidity were to be prioritized in early vaccine supply scenarios, those eligible for vaccination would well-exceed supply; and iv) the list of relevant comorbidities will be location dependent *(4, 21, 33)*.

Based on these considerations, countries should use relevant local and regional data to identify the comorbidities associated with different levels of risk from COVID-19 (for example, significant versus moderate risk). One approach is to identify the additional risk associated with each comorbidity. Another approach is to prioritize individuals who have two or more relevant comorbidities *(34)*. As evidence develops, further guidance from SAGE on comorbidities and risk associated with severe COVID-19 will be communicated. Moreover, the SAGE Working Group on COVID-19 Vaccines is currently developing further guidance on comorbidities that put individuals at significantly higher risk.

Community engagement, effective communication and legitimacy

Community engagement and effective communication are essential to the success of COVID-19 vaccine programmes. These elements are grounded in the legitimacy principle of the Values Framework. This principle requires that prioritization decisions be made through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties. Adhering to the legitimacy principle is a way to promote public trust and acceptance of a COVID-19 vaccine.

When applied in practice, countries may embrace the legitimacy principle through practical strategies which improve the public's perception and understanding of vaccine development and prioritization processes. Examples of such strategies include i) culturally and linguistically accessible communications made freely available regarding COVID-19 vaccination; ii) recruitment of community opinion leaders to improve awareness and understanding of such communications; and iii) inclusion of diverse and affected stakeholder opinions in decision-making. Efforts towards community engagement and effective communication are additionally important in subpopulations which may be unfamiliar with or distrustful of health-care systems.

As outlined in the Values Framework, there must be no tolerance for personal, financial or political conflict of interest or corruption in the prioritization of groups to have access to COVID-19 vaccines. In all cases, decision-makers must be able to publicly defend their decisions and actions by appealing to reasons that even those who disagree can view as reasonable, and not arbitrary or self-serving. Countries should ensure that individuals are

not able to use their social, financial or political privilege to bypass country-level prioritization.

Guidance development and decision-making under conditions of considerable uncertainty

The Roadmap was developed with only limited information, under conditions of considerable uncertainty. The novelty of the SARS-CoV-2 pathogen and evolving epidemic, economic and social circumstances present challenges in making decisions about priority groups for vaccine use at this time. Aside from unknown factors of clinical and epidemiologic importance, this document makes a number of plausible assumptions regarding vaccine characteristics. If a candidate vaccine does not meet these assumptions, the selection of priority groups may warrant reconsideration to best fulfil the principles and objectives adopted within the *WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*. Moreover, nuanced models of various prioritization scenarios are only now starting to emerge, and modelling-based evidence is rapidly evolving. For all these reasons, the Roadmap may be amended in light of evolving evidence.

Another limitation of the Roadmap is that it is unable to address all possible contingencies. Table 2 considers the implications of some changes in circumstances that could affect use of the Roadmap.

Ongoing activities and next steps

To assess both the usefulness and robustness of the Roadmap in a variety of settings worldwide, RITAGs and NITAGs will be engaged in reviewing and critically assessing the Roadmap. It is anticipated that refinements of the Roadmap will be needed after the engagements of and feedback from national and regional stakeholders, including potentially further prioritization within priority groups.

Table 1. Epidemiologic setting and vaccine supply scenarios, and recommendations for priority use cases for vaccines against Covid-19 in the context of limited supply[a,b]

(a) Epidemiologic setting scenario: Community Transmission – defined in Legend 2

Vaccine supply scenario	Priority groups
Overall public health strategy for this epidemiologic setting: Initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to reduction in transmission to further reduce disruption of social and economic functions. (A1) (A2) (A3) (B1) (B2) (C1) (C2) (D1) – labels explained in Legend 1	
Stage I (very limited vaccine availability, for 1–10% nat. pop.)	Stage Ia (initial launch): • Health workers at *high to very high risk* of acquiring and transmitting infection as defined in Annex 3. **(A1) (A3) (D1)** Stage Ib: • Older adults defined by age-based risk specific to country/region; specific age cut-off to be decided at the country level. **(A1) (C1)**
Stage II (limited vaccine availability, for 11–20% nat. pop.)	• Older adults not covered in Stage I. **(A1) (C1)** • Groups with comorbidities or health states determined to be at *significantly higher risk* of severe disease or death. Efforts should be made to ensure that disadvantaged groups where there is underdiagnosis of comorbidities are equitably included in this category. **(A1) (C1) (C2)** • Sociodemographic groups at *significantly higher risk* of severe disease or death (depending on country context, examples may include: disadvantaged or persecuted ethnic, racial, gender, and religious groups and sexual minorities; people living with disabilities; people living in extreme poverty, homeless and those living in informal settlements or urban slums; low-income migrant workers; refugees, internally displaced persons, asylum seekers, populations in conflict settings or those affected by humanitarian emergencies, vulnerable migrants in irregular situations; nomadic populations; and hard-to-reach population groups such as those in rural and remote areas). **(A1) (B1) (B2) (C1) (C2)** • Health workers engaged in immunization delivery (routine programme-specific and COVID-19). **(A1) (A2) (B2) (C1) (C2) (D1)** • High-priority teachers and school staff (depending on country context, examples may include: preschool and primary school teachers because of the critical developmental stage of the children they teach, teachers of children where distance learning is very difficult or impossible). **(A2) (A3) (B1) (C1) (C2)**

Stage III (moderate vaccine availability, for 21–50% nat. pop.)	• Remaining teachers and school staff. **(A2) (A3) (B1) (C1) (C2)** • Other essential workers outside health and education sectors (examples: police officers, municipal services, child-care providers, agriculture and food workers, transportation workers, government workers essential to critical functioning of the state not covered by other categories). **(A2) (A3) (D1)** • Pregnant women (see text under *Addressing pregnant women*). **(A1) (B1) (B2) (C1)** • Health workers at *low to moderate risk* of acquiring and transmitting infection as defined in Annex 3. **(A1) (A3) (D1)** • Personnel needed for vaccine production and other high-risk laboratory staff. **(A1) (A2) (A3) (D1)** • Social/employment groups at *elevated risk* of acquiring and transmitting infection because they are unable to effectively physically distance (depending on country context, examples may include: people living or working in detention facilities, incarcerated people, dormitories, informal settlements or urban slums; low-income people in dense urban neighbourhoods; homeless people; military personnel living in tight quarters; and people working in certain occupations such as mining and meat processing). **(A1) (B1) (B2) (C1) (C2)**

(b) Epidemiologic setting scenario: Sporadic Cases or Clusters of Cases – defined in Legend 2

Overall public health strategy for this epidemiologic setting: Initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to substantially control transmission and minimize disruption of social and economic functions.
(A1) (A2) (A3) (B1) (B2) (C1) (C2) (D1) – labels explained in Legend 1

Vaccine supply scenario	Priority groups
Stage I (very limited vaccine availability, for 1–10% nat. pop.)	• Health workers at *high to very high risk* of acquiring and transmitting infection as defined in Annex 3, *in areas with high transmission or anticipated high transmission.* **(A1) (A3) (D1)** • Older adults defined by age-based risk specific to country/region – specific age cut-off to be decided at the country level – *in areas with high transmission or anticipated high transmission.* **(A1) (C1)** • Emergency reserve of vaccines for utilization for outbreak response or mitigation (for example, severe localized outbreak). **(A1) (A2)**
Stage II (limited vaccine availability, for 11–20% nat. pop.)	• Health workers at *high to very high risk* of acquiring and transmitting infection as defined in Annex 3, *in the rest of the country.* **(A1) (A3) (D1)** • Older adults defined by age-based risk specific to country/region – specific age cut-off to be decided at the country level – *in the rest of the country* **(A1) (C1)** • Groups with comorbidities or health states determined to be at *significantly higher risk* of severe disease or death *in areas with high transmission or anticipated high transmission*. Efforts should be made to ensure that disadvantaged groups where there is underdiagnosis of comorbidities are equitably included in this category. **(A1) (C1) (C2)** • Sociodemographic groups at *significantly higher risk* of severe disease or death *in areas with high transmission or anticipated high transmission* (depending on country context, examples may include: disadvantaged or persecuted ethnic, racial, gender, and religious groups and sexual minorities; people living with disabilities; people living in extreme poverty, homeless and those living in informal settlements or urban slums; low-income migrant workers; refugees, internally displaced persons, asylum seekers, populations in conflict settings or those affected by humanitarian emergencies, vulnerable migrants in irregular situations; nomadic populations; and hard-to-reach population groups such as those in rural and remote areas). **(A1) (B1) (B2) (C1) (C2)**
Stage III (moderate vaccine availability,	• Primary and secondary teachers and school staff *in areas with high transmission or anticipated high transmission.* **(A2) (A3) (B1) (C1) (C2)** • Other essential workers outside health and education sectors (examples: police officers, municipal services, childcare providers, agriculture and food workers, transportation workers, government workers essential to critical functioning of the state not covered by other categories) *in areas with high transmission or*

for 21–50% nat. pop.)	*anticipated high transmission.* **(A2) (A3) (D1)** • Social/employment groups at *elevated risk* of acquiring and transmitting infection because they are unable to effectively physically distance *in areas with high transmission or anticipated high transmission* (depending on country context, examples may include: people living or working in detention facilities, incarcerated people, dormitories, informal settlements or urban slums, low income people in dense urban neighbourhoods, homeless people, military personnel living in tight quarters, and people working in certain occupations for example, mining, meat processing). **(A1) (B1) (B2) (C1) (C2)** • Health workers at *low to moderate risk* of acquiring and transmitting infection as defined in Annex 3 *throughout the country.* **(A1) (A3) (D1)** • Age groups at high risk of transmitting infection by age-based risk specific to country/region; specific age cut-off to be decided at the country level. **(A1) (A2)** • Personnel needed for vaccine production and other high-risk laboratory staff. **(A1) (A2) (A3) (D1)** • Pregnant women (see text under *Addressing pregnant women*). **(A1) (B1) (B2) (C1)**

(c) Epidemiologic setting scenario: No Cases – defined in Legend 2

Overall public health strategy for this epidemiologic setting: Initial focus on prevention of community transmission; also, reciprocity. Expand to preserve control of transmission and reduce reliance on most burdensome non-pharmaceutical interventions, as well as to protect highest risk individuals in the event of importation-associated outbreaks.
(A1) (A2) (A3) (B1) (C1) (C2) (D1) – labels explained in Legend 1

Vaccine supply scenario	Priority groups
Stage I (very limited vaccine availability, for 1–10% nat. pop.)	• Health workers at *high to very high risk* of acquiring and transmitting infection as defined in Annex 3. **(A1) (A3) (D1)** • Essential travellers at risk for acquiring infection outside the home country and reintroducing infection upon return to home country (for example, students, business travellers, migrant workers, aid workers). Countries should define essential travellers in a way that constrains the ability of economically and politically powerful individuals to exploit this priority group to their advantage. **(A1) (A2) (A3)** • Border protection staff screening for imported cases and workers for outbreak management (for example, isolation and quarantine managers, immunization deployment staff). **(A1) (A2) (D1)** • Emergency reserve utilization for focused outbreak response (for example, importation outbreaks). **(A1) (A2)**
Stage II (limited vaccine availability, for 11–20% nat. pop.)	• Health workers at *low to moderate risk* of acquiring and transmitting infection as defined in Annex 3. **(A1) (A3) (D1)** • All travellers at risk for acquiring infection outside the home country and reintroducing infection upon return to home country. **(A1) (A2)** • Emergency reserve of vaccines utilization for outbreak mitigation (for example, importation outbreaks). **(A1) (A2)**
Stage III (moderate vaccine availability, for 21–50% nat. pop.)	• Older adults defined by age-based risk specific to country/region; specific age cut-off to be decided at the country level. **(A1) (C1)** • Age groups at high risk of transmitting infection by age-based risk specific to country/region, specific age cut-off to be decided at the country level. **(A1) (A2)** • Primary and secondary school teachers and staff. **(A2) (A3) (B1) (C1) (C2)** • Other essential workers outside health and education sectors (examples: police officers, municipal services, child-care providers, agriculture and food workers,

	transportation workers, government workers essential to critical functioning of the state not covered by other categories). **(A2) (A3) (D1)**

National equity considerations: Ensure that vaccine prioritization within countries takes into account the disproportionate burdens of the COVID-19 pandemic on social groups that are systematically disadvantaged. **(C1) (C2)**

[a] For individuals in more than one priority group, the highest applicable priority group determines the order in which they should receive COVID-19 vaccine.

[b] Current modelling suggests that (given the many-fold higher mortality rate among older individuals) age-dependent vaccine efficacy would not significantly change the recommendations for priority use cases in older populations for a strategy based on mortality reduction *(6–8, 35)*. If vaccine efficacy in older adults relative to other age groups were so low that individual protection and public health impact became significantly suboptimal, the individuals in older age groups in each scenario would likely be moved to a lower rank.

Legend 1. Value objectives applied to priority groups

A. Well-being	**(A1)** Reduce deaths and disease burden from the COVID-19 pandemic.
	(A2) Reduce societal and economic disruption (other than through reducing deaths and disease burden).
	(A3) Protect the continuing functioning of essential services, including health services.
B. Equal respect	**(B1)** Treat the interests of all individuals and groups with equal consideration as allocation and priority-setting decisions are being made and implemented.
	(B2) Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify under prioritization criteria.
C. Equity	**(C1)** Ensure that vaccine prioritization within countries takes into account the vulnerabilities, risks and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic.
	(C2) Develop the immunization delivery systems and infrastructure required to ensure priority populations have access to COVID-19 vaccines, and which ensures equal access to everyone who qualifies under a priority group, particularly socially disadvantaged populations.
D. Reciprocity	**(D1)** Protect those who bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others, including health and other essential workers.

Legend 2. WHO transmission categories corresponding to epidemiologic setting scenarios

Transmission category[a]	Definition

No Cases	Countries/territories/areas with no confirmed cases.
Sporadic Cases	Countries/territories/areas with one or more cases, imported or locally detected.
Clusters of Cases	Countries/territories/areas experiencing cases, clustered in time, geographic location and/or by common exposures
Community Transmission	Countries/area/territories experiencing larger outbreaks of local transmission defined through an assessment of factors including, but not limited to: • large numbers of cases not linkable to transmission chains; • large numbers of cases from sentinel laboratory surveillance or increasing positive tests through sentinel samples (routine systematic testing of respiratory samples from established laboratories); • multiple unrelated clusters in several areas of the country/territory/area.
Scenario transitions: From lower to higher transmission scenario: change to be reported at any time (in the next weekly update). From higher to lower transmission scenario: observe during a 28-day period before confirming downgrading of transmission.	

[a] Definitions correspond to those used elsewhere in WHO epidemiologic reports, using definitions published in the WHO Interim guidance on public health surveillance for COVID-19 published on 7 August 2020, available here.

Table 2. Summary table of the application of the Roadmap under various contingencies

Contingency	Change in the application of the Roadmap
Number and timing of vaccine doses	
Fewer vaccine courses available than expected	The Roadmap is unchanged. Some individuals receive vaccination later than they would otherwise.
Vaccine requires two doses rather than one	The Roadmap is unchanged, but some individuals receive vaccination later.
Vaccine efficacy	
Low vaccine efficacy among older adults or other population subgroup	Current modelling suggests that (given the many-fold higher mortality rate among older individuals) age-dependent vaccine efficacy would not significantly change the recommendations for priority use cases in older populations *(6–8, 35)*. If vaccine efficacy in older adults relative to other age groups were so low that the prioritization of older adults was expected to lead to substantially worse overall outcomes in number of lives saved, individuals in the older age groups in each scenario would likely be moved to a lower rank. Similar considerations apply for individuals with comorbidities.
Low vaccine efficacy in preventing transmission	The importance of high coverage of the most vulnerable groups is increased.
Vaccine safety	
Unanticipated vaccine adverse events	Only prioritize individuals or groups for whom vaccine benefits continue to outweigh the risks.
Vaccine uptake	
Vaccine acceptance and uptake is lower than expected	The Roadmap is unchanged. Community engagement and risk communication are enhanced.
Number of vaccine types	
More than one vaccine type available	The Roadmap is unchanged, but which vaccines are allocated to which population groups must take into account the benefits and risks of the vaccine for each population subgroup. As authorized vaccines become available, SAGE will make vaccine-specific recommendations.
Epidemic conditions and immune status	

Epidemic spread is continuing when the vaccine becomes available	The Roadmap is unchanged. Public health messages must continue to stress the need for personal protective measures (for example, masks, social distancing, hand washing, ventilation).
Risk profile of a previously identified high-risk group changes (for example, due to higher infection rate in earlier infection waves than in later waves)	The general structure of the Roadmap is unchanged. The relevant consideration is risk level; if a group is no longer high-risk it should be lowered in priority. However, due to equity concerns, as many of these groups are likely to be disadvantaged there must be a substantial level of evidence supporting the change, which the immunization programme/government should present to justify the change.
Social, Economic and Legal Contexts	
Some countries do not provide free vaccine access to non-citizens or people without documentation of legal status	The Roadmap is unchanged. This practice violates the principle of equity and the goals of public health. However, in such cases, other sources of financial support (for example, philanthropy, civil society organizations, pharmaceutical companies) should be sought to provide vaccination for those individuals.
Source: Adapted from National Academies of Sciences, Engineering, and Medicine's Framework for Equitable Allocation of COVID-19 Vaccine *(34)*, with permission.	

References

In the interests of specificity during the COVID-19 pandemic – during which new data become available by the day – the references below that deal with COVID-19 or SARS-CoV-2 exceptionally include both the day and month of publication (where available). This is meant to assist the reader in quickly determining the exact date of publication.

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Annex 1. Alignment of the COVAX Facility allocation mechanism and Prioritization Roadmap

COVAX Facility allocation mechanism[a]		Prioritization Roadmap	
Phase	*% country population to be covered by vaccine supply*	*Stoge*	*% country population to be covered by vaccine supply*
Phase 1: Proportional allocation, to cover Tier 1 target groups	Indicative initial tranche: 3% Subsequent tranches to reach 20%	Stage I	1–10%
		Stage II	11–20%
Phase 2: Weighted allocation based on risk assessment	> 20%	Stage III	21–50%
[a] Note: the COVAX Facility allocation mechanism is still in draft form; further details from the current draft approach are available (here).			

Annex 2. Reduction of deaths versus reduction of years of life lost

Years of life lost (YLL) is a measure that is thought by many to integrate a commitment to maximizing health benefit with a commitment to promoting equity, where equity is understood to include an obligation to ensure that younger people have a fair chance to reach later stages of life. There are good ethics arguments for using YLL in many allocation contexts, including in this particular pandemic *(1,2)*. However, the particular epidemiology of the current pandemic supports using reducing deaths as a preferred strategy for within-country prioritization. The risk of COVID-19-related mortality is extremely high in older age groups compared to that in younger age groups. For example, in the United States, the mortality risk has been estimated to be 90 times higher among 65–74-year-olds compared to 18–29-year-olds *(3)*. A similar pattern of significantly higher mortality in older age groups has been observed in multiple other countries. The evidence identified to date from modelling analyses suggests that using YLL instead of deaths would not substantially alter the priority ranking of older people relative to younger people when age is the only dimension considered *(4, 5)*. Supplementary unpublished sensitivity analyses prepared for the WHO SAGE Working Group on COVID-19 Vaccines support this finding. As priority rankings would not change, expressing the policy objective in terms of reduction in the number of deaths rather than YLL has programmatic advantages, even if YLL reaches the same conclusions about relative prioritization. Reduction of number of deaths is more easily understood by and communicated to the general public and is likely to be widely endorsed as an important objective at a time when securing public support for and confidence in vaccine programmes is critically important. A prioritization approach relying on YLL could be viewed as disrespectful to older people by failing to address their disproportionately higher risk of death *(6)*.

YLL also does not address the primary equity challenges in prioritization of COVID-19 vaccines within countries and thus the commitment of the Values Framework to equity does not in this pandemic require use of YLL. In a pandemic with a mortality pattern similar to seasonal influenza where the very young as well as older adults have disproportionately high mortality, or that of the 1918 influenza pandemic where young adults were a high-mortality risk group, equity considerations could well require a focus on YLL. Also, in the current COVID-19 pandemic the equity issues in allocation of vaccine between countries are markedly different from those in within-country prioritization. Standard expected years of life lost, a measure of disease burden often used for cross-national comparative purposes, can help illustrate the commitment of the Values Framework to global equity, as long as global inequities in access to testing and other surveillance technologies do not unfairly skew assessments of this metric.

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Annex 3. Definition of health workers[1]

Health workers are all people engaged in work actions whose primary intent is to improve health. This includes health service providers, such as doctors, nurses, midwives, public health professionals, lab-, health- and medical and non-medical technicians, personal care workers, community health workers, healers and practitioners of traditional medicine. It also includes health management and support workers, such as cleaners, drivers, hospital administrators, district health managers and social workers, and other occupational groups in health-related activities. Health workers include not only those who work in acute care facilities but also those employed in long-term care, public health, community based care, social care and home care and other occupations in the health and social work sectors as defined by the International Standard Industrial Classification of All Economic Activities (ISIC), revision 4, section Q: Human health and social work activities.

The following levels may be useful in assessing the risk of occupational exposure to SARS-CoV-2 for jobs or tasks of health workers, prior to introducing mitigation measures:

a) Low risk (caution) - Jobs or work without frequent, close contact with the public or others that do not require contact with people known to be or suspected of being actively infected with the virus responsible for COVID-19. Workers in this group have minimal occupational contact with the public and other co-workers, for example performing administrative duties in non-public areas of healthcare facilities, away from other staff members, telehealth services in individual offices

b) Medium risk - Jobs or tasks with close, frequent contact with the general public or others but that do not require contact with people known to be or suspected of being actively infected with the virus responsible for COVID-19. In areas where COVID-19 cases continue to be reported, this risk level may apply to workers who have frequent and close contact with the people in busy staff work areas within a healthcare facility and work activities where safe physical distance may be difficult to maintain, or tasks that require close and frequent contact between co-workers. In areas without community transmission of COVID-19, this scenario may include frequent contact with people returning from areas with known higher levels of community transmission. Examples include, providing care to the general public who are not known or suspected of having COVID-19, or working at busy staff work areas within a healthcare facility

c) High risk - Jobs or tasks with high potential for close contact with people who are known or suspected of having COVID-19, as well as contact with objects and surfaces possibly contaminated with the virus, e.g. the direct patient care, domestic services or home care for people for people with COVID-19. Jobs and tasks that may fall under this category may include: entering a known or suspected COVID-19 patient's room, providing care for a known or suspected COVID-19 patient not involving aerosol-generating procedures; transportation of people known or

[1] Classifying health workers: Mapping occupations to the international standard classification, based on the International Standard Classification of Occupations (ISCO, 2008) revision)https://www.who.int/hrh/statistics/Health_workers_classification.pdf?ua=1#:~:text=The%20classification%20of%20health%20workers,service%20providers%20not%20elsewhere%20classified, accessed Nov 2020.

suspected to have COVID-19 without separation between the driver and the passenger.

d) Very high risk - jobs and tasks with risk of exposure to aerosols with SARS-CoV-2, the settings where performing aerosol-generating procedures are performed on patients with COVID-19, such as tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation, sputum induction, bronchoscopy, spirometry, and autopsy procedures and working with COVID19 patients in crowded, enclosed places without adequate ventilation.

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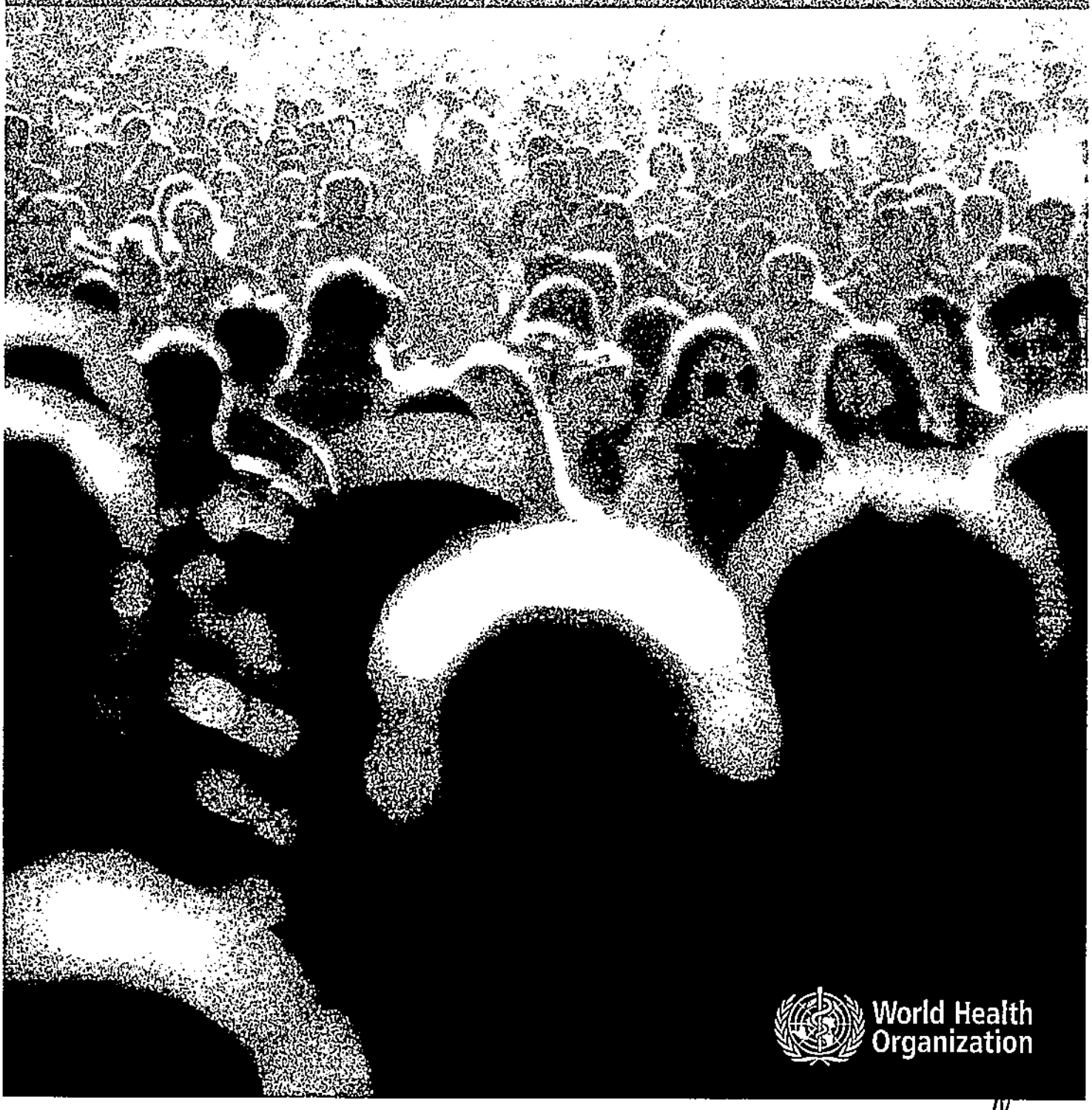
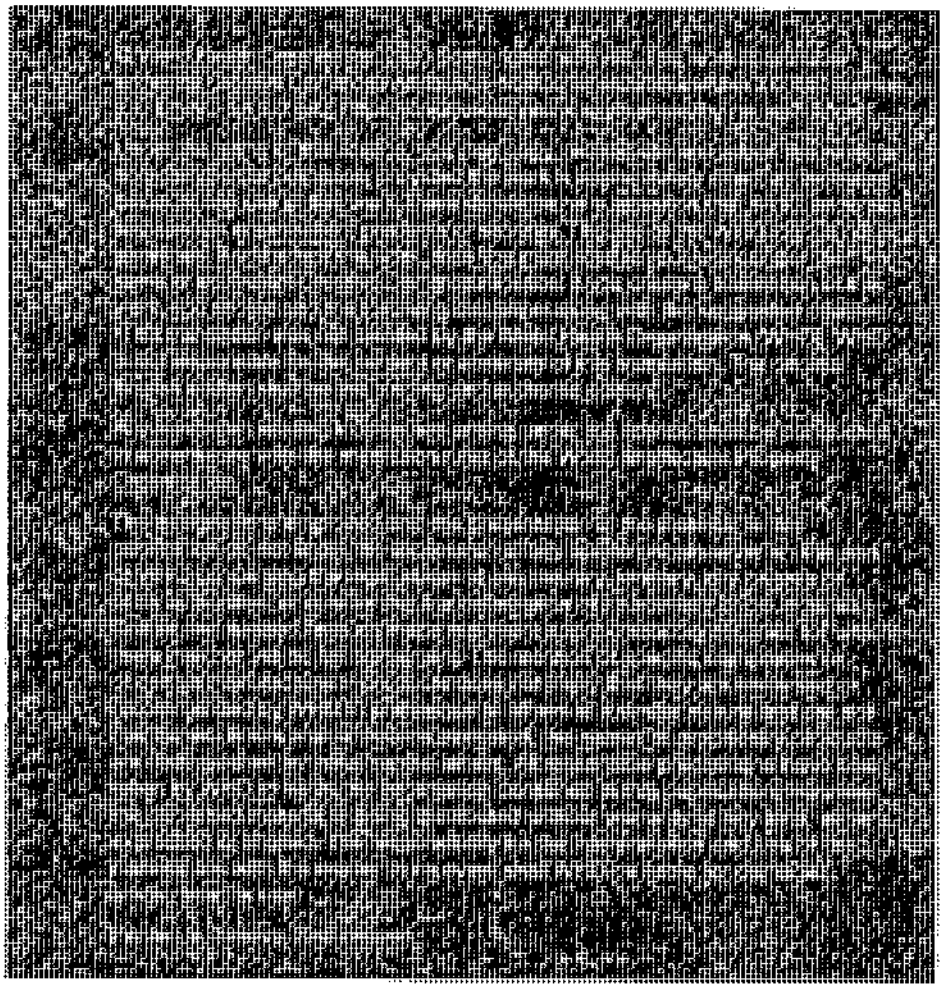
14 April 2020

COVID-19 STRATEGY UPDATE



World Health Organization



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FOREWORD

Overcoming COVID-19

It has now been more than 100 days since WHO was notified of the first cases of what we now call COVID-19, and much has changed since we launched the first Strategic Preparedness and Response Plan two months ago.

As of 13 April, more than 1.7 million people have been infected, and almost 85 000 people have lost their lives. WHO grieves with all families who have lost a loved one, and salutes health workers all over the world who have put themselves in harm's way every day to save lives.

The global spread of the virus has overwhelmed health systems, and caused widespread social and economic disruption.

By putting societies and economies on hold, we have curtailed the ability of the virus to spread through our communities. These defensive measures have helped to limit some of the short-term impacts of the virus, and bought us time to translate what we have learned about the virus into solutions so that we can get back to a more normal way of living: a new normal.

We have learned so much about this virus, and we're still learning. This strategy update is based on the evidence the world has accumulated in the past three months about how COVID-19 spreads, the severity of disease it causes, how to treat it, and how to stop it.

One of the main things we've learned is that the faster all cases are found, tested and isolated, the harder we make it for this virus to spread. This principle will save lives and mitigate the economic impact of the pandemic.

This document guides the public health response to COVID-19 at national and subnational levels, including practical guidance for strategic action, tailored to the local context.

This pandemic is much more than a health crisis. It requires a whole-of-government and whole-of-society response. The resolve and sacrifice of frontline health workers must be matched by every individual and every political leader to put in place the measures to end the pandemic.

We're all in this together, and we will only succeed together. There is no time to waste. WHO's singular focus is on working to serve all people to save lives and stop the pandemic.

Dr Tedros Adhanom Ghebreyesus
WHO Director-General

ABOUT THIS DOCUMENT

The coronavirus disease 2019 (COVID-19) pandemic is exacting a huge toll on individuals, families, communities, and societies across the world. Daily lives have been profoundly changed, economies have fallen into recession, and many of the traditional social, economic, and public health safety nets that many people rely on in times of hardship have been put under unprecedented strain.

In just a short time, a localised outbreak of COVID-19 evolved into a global pandemic with three defining characteristics:

- **Speed and scale:** the disease has spread quickly to all corners of the world, and its capacity for explosive spread has overwhelmed even the most resilient health systems (figure 1).
- **Severity:** overall 20% of cases are severe or critical, with a crude clinical case fatality rate currently of over 3%, increasing in older age groups and in those with certain underlying conditions.
- **Societal and economic disruption:** shocks to health and social care systems and measures taken to control transmission have had broad and deep socio-economic consequences.

This document is intended to help guide the public health response to COVID-19 at national and subnational levels, and to update the global strategy to respond to the COVID-19 pandemic. This document complements, and provides links to, the technical guidance published by WHO on preparing for and responding to COVID-19 since the beginning of the response. It translates knowledge accumulated since the publication of the Strategic Preparedness and Response Plan (SPRP)[1] on 3 February 2020, into additional practical guidance for whole-of-government and whole-of-society strategic action that can be adapted according to specific national and subnational situations and capacities.

This strategy update provides guidance for countries preparing for a phased transition from widespread transmission to a steady state of low-level or no transmission. This update also highlights the coordinated support that is required from the international community to meet the challenge of COVID-19: it complements plans (including the Global Humanitarian Response Plan)[2] that specifically address the issues of COVID-19 response in humanitarian and fragile settings, and plans currently under development that will address the broader social and economic impacts of COVID-19.

1 For the Strategic Preparedness and Response Plan see: https://www.who.int/docs/default-source/coronaviruse/srp-04022020.pdf

2 For the Global Humanitarian Response Plan see: https://www.unocha.org/sites/unocha/files/Global-Humanitarian-Response-Plan-COVID-19.pdf

CURRENT SITUATION AND KEY INSIGHTS

COVID-19 is a new disease, distinct from other diseases caused by coronaviruses, such as Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). The virus spreads rapidly, and outbreaks can grow at an exponential rate. At present, there are no therapeutics or vaccines proven to treat or prevent COVID-19, although national governments, WHO and partners are working urgently to coordinate the rapid development of medical countermeasures.[3] According to data from countries affected early in the pandemic, about 40% of cases will experience mild disease, 40% will experience moderate disease including pneumonia, 15% of cases will experience severe disease, and 5% of cases will have critical disease.

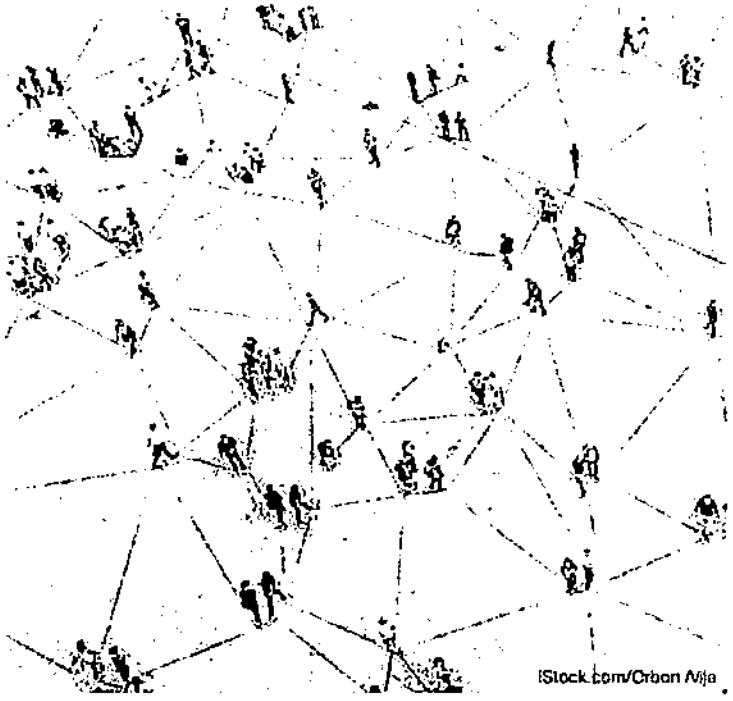
The crude mortality rate varies substantially by country depending on the populations affected, the point a country is at in the trajectory of its outbreak, and the availability and application of testing (countries that only test hospitalized cases will have a higher reported crude mortality rate than countries with more widespread testing). The crude clinical case fatality is currently over 3%, increasing with age and rising to approximately 15% or higher in patients over 80 years of age. Morbidity associated with COVID-19 is also very high. Underlying health conditions that affect the cardiovascular, respiratory, and immune systems confer an increased risk of severe illness and death.

Countries are at different stages of national and subnational outbreaks. Where there has been early action and implementation of comprehensive public health measures – such as rapid case identification, rapid testing and isolation of cases, comprehensive contact tracing and quarantine of contacts – countries and subnational regions have suppressed the spread of COVID-19 below the threshold at which health systems become unable to prevent excess mortality. Countries that have been able to reduce transmission and bring outbreaks under control have maintained the ability to deliver quality clinical care, and minimize secondary mortality due to other causes through the continued safe delivery of essential health services.

In many countries where community transmission has led to outbreaks with near exponential growth, countries have introduced widespread population-level physical distancing measures and movement restrictions in order to slow spread and set in place other control measures. Physical distancing measures and movement restrictions, often referred to as "shut downs" and "lock downs," can slow COVID-19 transmission by limiting contact between people. However, these measures can have a profound negative impact on individuals, communities, and societies by bringing social and economic life to a near stop. Such measures disproportionately affect disadvantaged groups, including people in poverty, migrants, internally displaced people and refugees, who most often live in overcrowded and under resourced settings, and depend on daily labour for subsistence.

For countries that have introduced widespread physical distancing measures and population-level movement restrictions, there is an urgent need to plan for a phased transition away from such restrictions in a manner that will enable the sustainable suppression of transmission at a low-level whilst enabling the resumption of some parts of economic and social life, prioritized by carefully balancing socio-economic benefit and epidemiological risk. Without careful planning, and in the absence of scaled up public health and clinical care capacities, the premature lifting of physical distancing measures is likely to lead to an uncontrolled resurgence in COVID-19 transmission and an amplified second wave of cases.

For countries that currently have few reported cases, there is no time to lose in learning and applying the lessons of others to specific national contexts and capacities.



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3 For the Global Research and Development Roadmap see: https://www.who.int/blueprint/priority-diseases/key-action/Roadmap-version-FINAL-for-WEB.pdf?ua=1

A renewed focus on public health

Perhaps the most important insight from the global COVID-19 response to date has been that to successfully slow transmission and protect health systems, it is essential to accurately diagnose and effectively isolate and care for all cases of COVID-19 including cases with mild or moderate disease (in health setting or home setting, depending on the context and degree of illness).

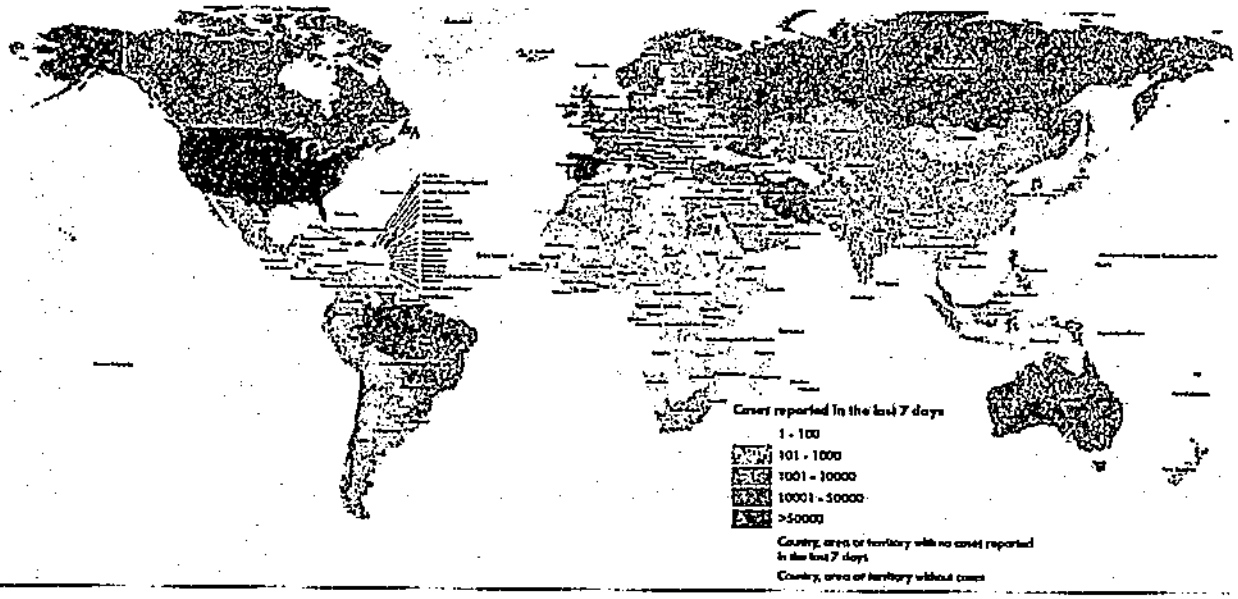
As COVID-19 transmission has advanced globally, the primary focus of most countries has been the rapid identification, testing and treatment of patients with serious and severe COVID-19, and the sheltering of individuals at the highest risk of poor outcomes. Fewer have put in place measures for those with mild disease, or contacts of cases.

Countries must do everything they can to stop cases from becoming clusters and clusters from becoming explosive outbreaks. They must put in place the capacities for testing and diagnosis, isolation, contact tracing and quarantine; they must engage everyone in the response.

A renewed focus on large-scale public health capacities must be implemented with urgency. The world stands at a pivotal juncture in the course of this pandemic. Collaborative research and knowledge sharing have helped to answer crucial questions about the benefits and costs of different response strategies in different contexts, the transmissibility of the virus, the clinical spectrum of the disease, and its capacity to rapidly overwhelm even the most resilient health systems. We know now what we are up against, and we are learning how to beat it. COVID-19 threatens human life, threatens livelihoods, and threatens the way of life of every individual in every society.

Speed, scale, and equity must be our guiding principles. Speed, because the explosive nature of the virus means every day lost in implementing effective response capacities and behaviors costs lives; scale, because everyone in society has a part to play in building the capacities required to control this pandemic; and equity, because everyone is at risk until the virus is controlled everywhere in the world: collective resources must be directed to where there is greatest risk. COVID-19 is a truly global crisis: the only way to overcome it is together, in global solidarity.

Figure 1 Countries, areas or territories with COVID-19 cases reported in the last 7 days, as of 31 March 2020, 10:00 (CET)



(1) All references to Kosovo in this document should be understood to be in the context of the United Nations Security Council resolution 1244 (1999).

Number of cases of Serbia and Kosovo (UNSCR 1244,1999) have been aggregated for visualization purposes.

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Data Source: WHO and ministries of health

GLOBAL STRATEGY TO RESPOND TO COVID-19

The overarching goal is for all countries to control the pandemic by slowing down the transmission and reducing mortality associated with COVID-19.

The global strategic objectives are as follows:

- **Mobilize** all sectors and communities to ensure that every sector of government and society takes ownership of and participates in the response and in preventing cases through hand hygiene, respiratory etiquette and individual-level physical distancing.
- **Control** sporadic cases and clusters and prevent community transmission by rapidly finding and isolating all cases, providing them with appropriate care, and tracing, quarantining, and supporting all contacts.
- **Suppress** community transmission through context-appropriate infection prevention and control measures, population level physical distancing measures, and appropriate and proportionate restrictions on non-essential domestic and international travel.
- **Reduce** mortality by providing appropriate clinical care for those affected by COVID-19, ensuring the continuity of essential health and social services, and protecting frontline workers and vulnerable populations.
- **Develop** safe and effective vaccines and therapeutics that can be delivered at scale and that are accessible based on need.

Every country should be implementing a comprehensive set of measures, calibrated to their capacity and context, to slow down transmission and reduce mortality associated with COVID-19, ultimately with the aim of reaching and/or maintaining a steady state of low-level or no transmission. Appropriate strategies at the national level and subnational level must balance measures that address the direct mortality attributable to COVID-19, the indirect mortality caused by the overwhelming of health systems and the interruption of other essential health and social services, and the acute and long-term detrimental effects on health and wellbeing of the socioeconomic consequences of certain response measures.

Maintaining a steady state of low-level or no transmission is important because, as the pandemic has spread, its public health and socioeconomic impacts have been profound, and have disproportionately affected the vulnerable. Many populations have already experienced a lack of access to routine, essential health services. Migrants, refugees, displaced populations, and residents of high-density and informal settlements, are at a particularly high risk from the interruption of already limited health and social services. The closure of schools increases the risk of some students being neglected, abused or exploited, and risks the interruption of basic services such as school meals. Every action taken now to slow the transmission of COVID-19 is an action that brings forward the day that these services can return.

The risk of re-introduction and resurgence of the disease will continue and will need to be sustainably controlled through the rigorous application of public health interventions as the virus circulates between and within countries. Ultimately, the development and delivery of a safe and effective vaccine or vaccines and therapeutics may enable a transition away from some of the measures necessary to maintain this state of low-level or no transmission.

To prevail against COVID-19, we need an approach that unites in common cause every individual and community, every business and non-profit, every department of every government, every non-governmental organization, every international organization, and every regional and global governance body, to harness their collective capacity into collective action. Everyone has a crucial role to play in stopping COVID-19:

- Individuals must protect themselves and others by adopting behaviours such as washing hands, avoiding touching their face, practicing good respiratory etiquette, individual level distancing, isolating in a community facility or at home if they are sick, identifying themselves as a contact of a confirmed case when appropriate, and cooperating with physical distancing measures and movement restrictions when called on to do so.
- Communities must be empowered to ensure that services and aid are planned and adapted based on their feedback and local contexts. Critical functions, such as community education, protecting vulnerable groups, supporting health workers, case finding, contact tracing, and cooperation with physical distancing measures can only happen with the support of every part of affected communities.
- Governments must lead and coordinate the response across party lines to enable and empower all individuals and communities to own the response through communication, education, engagement, capacity building and support. Governments must also re-purpose and engage all available public, community and private sector capacity to rapidly scale up the public health system to find and test, isolate, and care for confirmed cases (whether at home or in a medical facility), and identify, trace, quarantine and support contacts. At the same time, governments must give the health system the support it needs to treat patients with COVID-19 effectively and maintain other essential health and social services for all. Governments may have to implement blanket physical distancing measures and movement restrictions proportionate to the health risks faced by the community, if they need more time to put in place the above measures.
- Private companies must ensure the continuity of essential services such as the food chain, public utilities, and the manufacture of medical supplies. Private companies can provide expertise and innovation to scale and sustain the response, most notably through the production and equitable distribution of laboratory diagnostics, personal protective equipment, ventilators, medical oxygen and other essential medical equipment at fair prices, and the research and development of diagnostic tests, treatments and vaccines.

NATIONAL STRATEGIES TO RESPOND TO COVID-19

Each country must continue to implement National Action Plans based on a whole-of-society approach and a realistic appraisal of what is feasible to achieve first in terms of slowing down transmission and reducing mortality, and subsequently in terms of sustaining low level transmission while society and economic activity resumes. Plans must be flexible enough to react to rapidly changing epidemiological situations in different parts of the country, and take into account the local contexts and capacities to respond.[4] The core pillars of an effective national response were set out in detail in the SPRP.

Every national strategy has a crucial part to play in meeting the global objectives, and must, at a minimum, set out the basis for a) coordination of the national and subnational response; b) engagement and mobilization of affected and at-risk communities; c) implementation of context-appropriate public health measures to slow transmission and control sporadic cases; d) preparation of the health system to reduce COVID-19-associated mortality, maintain essential health services, and protect health workers, and e) contingency planning to ensure continuity of essential public functions and services.

Coordination and planning

Successful implementation of adaptive COVID-19 preparedness and response strategies will depend on all of society being engaged in the plan, and strong national and subnational coordination.[5] To provide coordinated management of COVID-19 preparedness and response, national public health emergency management mechanisms, including a multidisciplinary national coordination cell or incident management structure, should be activated, with the engagement of relevant ministries such as health, foreign affairs, finance, education, transport, travel and tourism, public works, water and sanitation, environment, social protection and agriculture. In certain contexts, this may be through the support of National Disaster Management or other crisis management authorities.

If they have not done so already, national authorities should, as a matter of urgency, develop operational plans to address COVID-19. Plans should include capacity assessments and risk analyses to identify high-risk and vulnerable populations. Plans should include civil society and national NGOs to extend the reach of public health and socioeconomic interventions. National plans should also be developed for the prevention and mitigation of the social impacts of the crisis, including areas of the response that disproportionately affect women and girls.

For example, many countries that have implemented restrictions on movement outside of households have reported sharp increases in gender-based violence, primarily impacting women. Additionally, women are often most likely to be in insecure work and least likely to be covered by income-protection schemes, which are primarily designed for workers in formal employment.

Engage and mobilize communities to limit exposure

Slowing the transmission of COVID-19 and protecting communities will require the participation of every member of at-risk and affected communities[6] to prevent infection and transmission. This requires everyone adopting individual protection measures such as washing hands, avoiding touching their face, practicing good respiratory etiquette, individual level distancing and cooperating with physical distancing measures and movement restrictions when called on to do so.

It is therefore essential that international, national, and local authorities engage through participatory two-way communication efforts proactively, regularly, transparently and unambiguously with all affected and at-risk populations.

Understanding knowledge, behaviours, perceptions, and identifying the right channels and community-based networks and influencers to promote scientific and public health messages will be a key determinant of the effectiveness of the response. Building the capacity of national, regional, and local stakeholders is essential to establish authority and trust. The role women play in communities needs to be harnessed in community mobilization efforts.

Participatory community engagement interventions should include accurate information on risks, what is still unknown, what is being done to find answers, what actions are being taken by health authorities, and what actions people can take to protect themselves.

4 For all current WHO guidance related to Critical preparedness, readiness and response actions for COVID-19 see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/critical-preparedness-readiness-and-response-actions-for-COVID-19

5 For all current WHO guidance related to national coordination and planning see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/country-readiness

6 For all current WHO guidance related to risk communication and community engagement see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/risk-communication-and-community-engagement

Ensuring that global recommendations and communications are tested and adapted to local contexts is an essential part of helping countries to empower communities to own the response and control the COVID-19 pandemic. Informed and empowered populations can protect themselves by taking measures at the individual and community level that will reduce the risk of transmission.

By contrast, misleading, ambiguous, and false information can have serious negative public health consequences, including by undermining adherence to physical distancing measures and movement restrictions, promoting the hoarding and inappropriate use of essential supplies and equipment, and encouraging the inappropriate use of potentially dangerous or fatal curative and prophylactic measures without any evidence of benefit.

In all the above, countries must ensure that communities, including the most hard-to-reach and vulnerable groups, have a voice and are part of the response.

Find, test, isolate and care for cases and quarantine contacts to control transmission

Stopping the spread of COVID-19 requires finding and testing all suspected cases so that confirmed cases are promptly and effectively isolated and receive appropriate care, and the close contacts of all confirmed cases are rapidly identified so that they can be quarantined and medically monitored for the 14-day incubation period[7] of the virus.

To achieve this, countries and communities must fundamentally increase their capacity to identify suspected cases of COVID-19 in the general population quickly based on the onset of signs or symptoms. This will require a shift from reliance on existing surveillance networks to system of rapid, population-level active surveillance. In addition to active case finding in communities, health facilities, and at points of entry, it will be necessary to enable the general population to practice self-surveillance, in which individuals are asked to self-report as a suspected case as soon as they have symptoms or signs and/or if they are a contact of a confirmed case. To achieve this shift, countries will need to rapidly scale up their workforce to find cases, including by looking outside the traditional public health system to train non-public-health workers, and by using innovative technology such as online applications to enable individuals to self-report.

Once suspected cases are identified they should be tested immediately to confirm or rule out infection with COVID-19. In contexts where testing is not possible, confirmation of COVID-19 may instead be based on reported symptoms or signs.

Confirmed cases – whether confirmed through testing or on the basis of symptoms or signs – should be safely, effectively, and rapidly isolated to prevent onward transmission in the community. Ideally, confirmed cases should be isolated in dedicated facilities to minimize the potential for onward transmission and maximize the provision of any support necessary. If this is not possible, and cases are instead required to self-isolate in households, there should be appropriate follow-up and support to ensure that individuals are able to self isolate effectively with no social contact.

It is also essential to identify and trace the close contacts of every confirmed or probable case, and quarantine and monitor them for 14 days. This ensures that even pre-symptomatic cases (and potentially asymptomatic cases) that arise as a result of contact with a confirmed case do not mix with the general population. Quarantine can be a stressful experience and a significant imposition and disruption to the life of the quarantined individual and their family. Every effort must be made to support individuals required to undergo quarantine, including through the provision of basic necessities, income support, psychosocial support, and health care as needed.

Provide clinical care and maintain essential health services to reduce mortality

One of the defining features of COVID-19 is the huge stress placed on health systems and health workers by the large proportion of COVID-19 patients who can require quality clinical care.[8] Many patients need help to breathe, with outbreaks placing acute burdens on staffing levels, availability of equipment, and crucial supplies such as medical oxygen, ventilators and personal protective equipment (PPE). Frontline health workers have had to put themselves in harm's way to save lives, and some have lost their own lives as a result. In many countries, women account for up to 70% of the health workforce, and have therefore been disproportionality affected. Even very robust health systems can be rapidly overwhelmed and compromised by an explosive COVID-19 outbreak. Contingency planning should include extreme scenarios, such as the need to rapidly and completely reconfigure and largely repurpose the entire health sector.

7 For all current WHO guidance related to COVID-19 surveillance see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/surveillance-and-case-definitions

For all current WHO guidance related to national laboratories see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance

8 For all current WHO guidance related to maintenance of essential health services see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/maintaining-essential-health-services-and-systems

For all current WHO guidance for health workers see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/health-workers

For all current WHO guidance on infection prevention and control see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/infection-prevention-and-control

In addition to the direct mortality caused by COVID-19, response at the national and subnational level must also address the risks of indirect mortality posed by the possible interruption of essential health and social services. The acute burden that COVID-19 places on health systems, combined with the disruptive effects of shielding strategies, physical distancing and movement restrictions, must be mitigated in order to minimize the negative health impacts of COVID-19 on individuals who depend on essential, non-COVID-19-related services.

Maintaining population trust in the capacity of the health system to safely meet essential needs and to control infection risk in health facilities is key to ensuring appropriate care-seeking behavior and adherence to public health advice. Continuation of primary health care services is essential. Where possible, the use of technological solutions such as telemedicine to monitor patients and remote consultations should be considered, to minimize risk to patients.

Countries will need to make difficult decisions to balance the demands of responding directly to COVID-19, while simultaneously engaging in strategic planning and coordinated action to maintain essential health service delivery, mitigating the risk of system collapse. Many routine and elective services might have to be postponed or suspended. In addition, when routine practice comes under pressure due to competing demands, simplified purpose-designed governance mechanisms and protocols can mitigate outright system failure. Establishing effective patient flow (through screening, triage, and targeted referral of COVID-19 and non-COVID-19 cases) is essential at all levels.

Adapt strategies based on risk, capacity, and vulnerability

The ability of countries to engage and mobilize communities; find, test, and isolate cases; provide effective clinical care; and maintain essential health services will differ according to their capacity and context as well as the intensity and prevalence of COVID-19 transmission. The combination of public health measures that should be implemented at any one time will depend to a large extent on whether there is community transmission, clusters of cases, sporadic cases, or no cases and the capacity of the public health system.

Every country must put in place comprehensive public health measures to maintain a sustainable steady state of low-level or no transmission and have the surge capacity to rapidly control sporadic cases and clusters of cases to prevent community transmission from occurring. If community transmission occurs, exceptional measures will need to be taken to suppress transmission as quickly as possible and transition back to a steady state of low-level or no transmission. This approach needs to be applied at the lowest administrative level possible in each country to ensure a tailored and appropriate response depending on the situation and capacities to respond.

Suppressing community transmission

Even with the proactive implementation of comprehensive public health measures, transmission of COVID-19 can rapidly become established in countries and subnational regions, with explosive outbreaks that grow at an exponential rate.

In countries and/or subnational regions in which community transmission has become established, or that are at risk of entering this phase of an epidemic, authorities must immediately adopt and adapt population-level distancing measures and movement restrictions in addition to other public health and health system measures to reduce exposure and suppress transmission, including the following:

- Personal measures that reduce the risk of person-to-person transmission, such as hand washing, physical distancing, and respiratory etiquette;
- Community-level measures to reduce contact between individuals, such as the suspension of mass gatherings, the closure of non-essential places of work and educational establishments, and reduced public transport;
- Measures to reduce the risk of importation or reintroduction of the virus from high-transmission areas, such as limits on national and international travel, enhanced screening and quarantine;
- Measures to ensure the protection of health workers and vulnerable groups, such as through the provision of correct personal protective equipment.

Targeted and time-limited implementation of these measures will potentially reduce mortality by flattening the trajectory of the epidemic and relieving some pressure on clinical care services. However, these measures are blunt tools with considerable social and economic costs, and should be implemented with the understanding, consent, and participation of communities, and based on the principle of doing no harm. The risks of implementing these measures must be effectively communicated to the affected populations and communities engaged to own and participate in them.

Support systems must be in place to ensure communities are able to comply with these measures. Individuals, especially the most vulnerable, must also be supported (and be provided with refuge or safe spaces where necessary) through coordinated economic and social measures that provide incentives to participate, and which mitigate negative social and economic consequences. Food security, mental health, and gender safeguarding issues, including the need to protect women from an increased risk of domestic abuse, are high-priority areas for attention.

The precise nature and feasibility of implementing these measures will be heavily dependent on the context of affected communities. In low-income and crisis settings, physical distancing and movement restrictions are structurally more difficult to implement, and should only be implemented where justified by an analysis of the trade-offs between public health measures against COVID-19 and the necessity for people to meet their basic food and protection needs.

During periods of sustained community transmission, diagnostic capacity may be insufficient, and it may be necessary to prioritize testing of vulnerable populations who are at risk of developing severe disease; symptomatic health workers and essential staff; and the first symptomatic individuals in a closed setting (e.g. schools, long term living facilities, prisons, hospitals) to quickly identify outbreaks and implement effective isolation of all confirmed and suspected cases.

Innovative solutions to increase clinical care capacity will be required, such as substantially reconfiguring existing health facilities and repurposing existing public and private facilities to provide safe areas for emergency case management, quarantine and isolation – this should be feasible even in remote and low resource areas. Rapid expansion of clinical capacity for life-saving measures should be focused on care for the majority of patients through simple treatments such as providing oxygen. Other essential health and social services and systems must be maintained wherever possible with a focus on primary health care.

The necessary duration of physical distancing measures and movement restrictions will be difficult to calculate accurately before their implementation: it is prudent to plan for the application of such measures for two to three months based on the experiences of the countries first affected by COVID-19.

Transitioning to and maintaining a steady state of low-level or no transmission

For many countries and subnational authorities and communities, managing a controlled and deliberate transition from a scenario of community transmission to a sustainable, steady state of low-level or no transmission is, at present, the best-case outcome in the short and medium term in the absence of a safe and effective vaccine. For countries yet to report community transmission, preventing the escalation of transmission and maintaining a steady state of low-level or no transmission may be feasible.

Achieving either of these aims will hinge on the ability of national and/or subnational authorities to ensure that six key criteria are satisfied:

1 **COVID-19 transmission is controlled** to a level of sporadic cases and clusters of cases, all from known contacts or importations and the incidence of new cases should be maintained at a level that the health system can manage with substantial clinical care capacity in reserve.

2 **Sufficient health system and public health capacities are in place** to enable the major shift from detecting and treating mainly serious cases to detecting and isolating all cases, irrespective of severity and origin:
- Detection: suspect cases should be detected quickly after symptom onset through active case finding, self-reporting, entry screening, and other approaches;
- Testing: all suspected cases should have test results within 24 hours of identification and sampling, and there would be sufficient capacity to verify the virus-free status of patients who have recovered;[9]
- Isolation: all confirmed cases could be effectively isolated (in hospitals and/or designated housing for mild and moderate cases, or at home with sufficient support if designated housing is not available) immediately and until they are no longer infectious;[10]
- Quarantine: all close contacts could be traced, quarantined and monitored for 14 days, whether in specialized accommodation or self-quarantine. Monitoring and support can be done through a combination of visits by community volunteers, phone calls, or messaging.[11]

3 **Outbreak risks in high-vulnerability settings are minimized**, which requires all major drivers and/or amplifiers of COVID-19 transmission to have been identified, with appropriate measures in place to minimize the risk of new outbreaks and of nosocomial transmission (e.g. appropriate infection prevention and control, including triage, and provision of personal protective equipment in health care facilities and residential care settings).[12]

4 **Workplace preventive measures are established** to reduce risk, including the appropriate directives and capacities to promote and enable standard COVID-19 prevention measures in terms of physical distancing, hand washing, respiratory etiquette and, potentially, temperature monitoring.[13]

5 **Risk of imported cases managed** through an analysis of the likely origin and routes of importations, and measures would be in place to rapidly detect and manage suspected cases among travelers (including the capacity to quarantine individuals arriving from areas with community transmission).

6 **Communities are fully engaged** and understand that the transition entails a major shift, from detecting and treating only serious cases to detecting and isolating all cases, that behavioural prevention measures must be maintained, and that all individuals have key roles in enabling and in some cases implementing new control measures.

9 For guidance on the strategic use of diagnostic testing in different COVID-19 transmission scenarios see: https://apps.who.int/iris/bitstream/handle/10665/331509/WHO-COVID-19-lab_testing-2020.1-eng.pdf

10 For advice on home care of individuals with suspected COVID-19 see: https://www.who.int/publications-detail/home-care-for-patients-with-suspected-novel-coronavirus-(ncov)-infection-presenting-with-mild-symptoms-and-management-of-contacts

11 For guidance on quarantine of individuals see: https://www.who.int/publications-detail/considerations-for-quarantine-of-individuals-in-the-context-of-containment-for-coronavirus-disease-(covid-19)

12 For IPC guidance for long-term care facilities see: https://apps.who.int/iris/bitstream/handle/10665/331508/WHO-2019-nCoV-IPC_long_term_care-2020.1-eng.pdf

13 For all guidance related to schools, workplaces and institutions see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/guidance-for-schools-workplaces-institutions

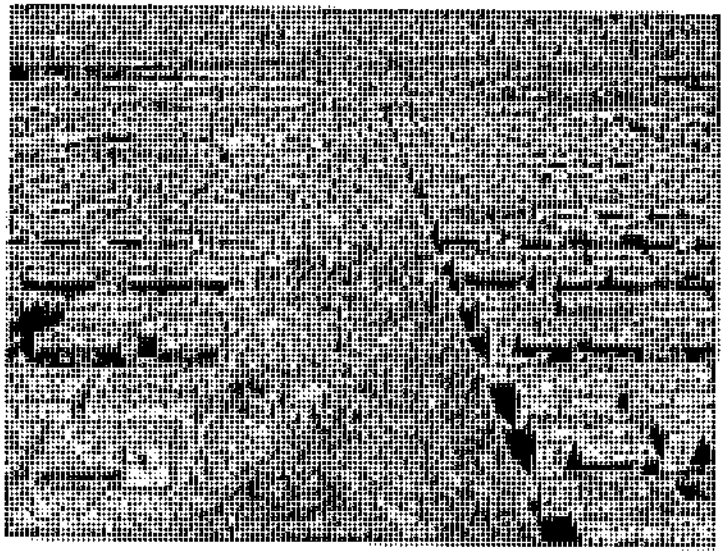
Decisions about when and where to transition must be evidence based, data driven and implemented incrementally. It is essential to have real-time, accurate data on the testing of suspected cases, the nature and isolation status of all confirmed cases, the number of contacts per case and completeness of tracing, and the dynamic capacity of health systems to deal with COVID-19 cases.

To reduce the risk of new outbreaks, measures should be lifted in a phased, step-wise manner based on an assessment of the epidemiological risks and socioeconomic benefits of lifting restrictions on different workplaces, educational institutions, and social activities (such as concerts, religious events, sporting events). Risk assessments may eventually benefit from serological testing, when reliable assays are available, to inform understanding of population susceptibility to COVID-19.

Ideally there would be a minimum of 2 weeks (corresponding to the incubation period of COVID-19) between each phase of the transition, to allow sufficient time to understand the risk of new outbreaks and to respond appropriately.

Low-capacity and humanitarian settings

Many low-capacity countries with comparatively weak health systems and limited capacity to offset the economic and social costs of population-level physical distancing, including some countries with health system fragility and extremely vulnerable populations, are now reporting sporadic cases, clusters of cases, and community transmission.[14] The window for containment at the subnational and national level may be closing in many of these countries.



The trajectory of national outbreaks in these settings will depend not only on how effectively the health system capacity can be increased and public health measures implemented, but also on the complex interplay of demographics, the prevalence of underlying conditions associated with poor COVID-19 outcomes, the prevalence of infections that could complicate the diagnosis of COVID-19 (such as malaria, bacterial pneumonias, and tuberculosis), and the relative importance of social, religious, and cultural gatherings that have been shown to be important drivers of COVID-19 transmission in other contexts.

Within the broader categories of low-capacity settings, it is also essential to consider the need for measures tailored specifically to humanitarian settings and high-risk groups. People affected by humanitarian crises, particularly those displaced and/or living in camps and camp-like settings, are often faced with specific challenges and vulnerabilities that must be taken into consideration when planning for COVID-19 readiness and response operations. Under the umbrella of the Inter-Agency Standing Committee, WHO has worked with the IFRC, IOM, and UNHCR to produce interim guidance[15] to scale up readiness and response capacities for people in humanitarian settings, which may include internally displaced persons (IDPs), host communities, asylum seekers, refugees and returnees, and migrants.

People living in collective sites are vulnerable to COVID-19 in part because of the health risks associated with movement or displacement, overcrowding, increased climatic exposure due to sub-standard shelter, and poor nutritional and health status among affected populations. Although some adaptations of site plans may not be feasible, maximizing site planning for better distancing among residents and crowd management, adherence to infection prevention and control standards, strong risk communication and community engagement and a good surveillance system to detect initial cases early can greatly reduce the propensity for COVID-19 to spread within such settings. Appropriate case management can reduce mortality among those infected with the virus. The Interim Guidance outlines the necessary steps to ensure all of these capacities are in place.

As national governments act rapidly to protect their most vulnerable populations, it is essential that the international community come together in solidarity to protect the most vulnerable global populations. To address the needs of countries where urgent humanitarian activities must be supported to continue in addition to urgent new health and non-health requirements due to COVID-19, WHO is part of the IASC COVID-19 Global Humanitarian Response Plan (GHRP; issued on 25 March 2020) coordinated by the UN Office for Coordination of Humanitarian Affairs (OCHA). The GHRP sets out the most urgent health and humanitarian actions required to prepare and respond to COVID-19 in these contexts.

14 For all current WHO guidance on preparing for and responding to COVID-19 in humanitarian operations, camps and other fragile settings see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/humanitarian-operations-camps-and-other-fragile-settings

15 For the IASC interim guidance see: https://interagencystandingcommittee.org/other/interim-guidance-scaling-covid-19-outbreak-readiness-and-response-operations-camps-and-camp

INTERNATIONAL COMMUNITY'S RESPONSE TO COVID-19

The scale of the COVID-19 crisis requires a significant shift in the international system to support countries to plan, finance and implement their response. Countries need authoritative real-time information on the evolving epidemiology and risks; timely access to essential supplies, medicines and equipment; the latest technical guidance and best practices; rapidly accessible and deployable technical expertise, access to an emergency health workforce and medical teams; and equitable access to newly developed vaccines, therapeutics, diagnostics and other innovations, as well as complementary socio-economic measures, including material and protection assistance.

Particular attention and support will be required in countries with low-capacity and humanitarian settings ill-equipped to cope with COVID-19 due to weak health systems and workforces that are heavily reliant on the support of donors, UN and NGO partners.

Coordination and monitoring of country preparedness and response

This document builds on the Strategic Preparedness and Response Plan (SPRP), which was published on 3 February 2020 and outlined the public health measures that the international community stands ready to provide to support all countries to prepare for and respond to COVID-19. Overall UN coordination is provided through the UN Crisis Management Team, which was established on 4 February 2020. This is the highest possible level of crisis alert in the UN system, and this is the first time this mechanism has been activated for a public health crisis. On 12 February 2020, the Operational Planning Guidelines to support the development National Action Plans were issued and the COVID-19 Partners Platform was launched to enable national authorities, UN Country Team and partners to plan resource needs, allocate resources and identify funding gaps, and monitor progress against the National Action Plans at the national and subnational level.

On 25 March 2020, OCHA issued the COVID-19 Global Humanitarian Response Plan and activated the IASC scale-up protocol to mobilize the whole humanitarian system to support its implementation. Simultaneously, the UN Development Coordination Office (UNDCO) has led the development of a UN framework for the immediate socio-economic response to COVID-19, which outlines an integrated support package offered by the UN Development System to protect the needs and rights of people living under the duress of the pandemic, with a focus on the most vulnerable countries, groups, and people who risk being left behind.

WHO coordinates actively with Member States. They have been actively engaged in the response and the WHO Director-General has provided the highest possible level of representation, advice, and support to all requests coming from various Member State groupings such as the African Union, ASEAN, the EU, the G7, the G20, the G12 donors, as well as other regional multilateral organizations to support and finance the response. WHO provides Member States the best available advice based on all available evidence and science as it becomes available.

The World Bank Group, International Monetary Fund and other multi-lateral development banks and financial institution's including GAVI, the Global Fund and UNITAID, have provided emergency support for developing countries to fast-track financial and operational facilities for COVID-19 response. Collaborative arrangements established under Global Action Plan for Healthy Lives and Well-being for All are being utilized for the COVID-19 response.

Organizations representing aviation, maritime, trade, and tourism sectors have worked with WHO to develop joint guidance, joint statements of support, to monitor the measures taken by governments and private entities that impact international travel and trade, and to assess and mitigate the health and economic impact of such measures, in line with the provisions of the International Health Regulations (2005). WHO has also developed risk-based approaches and guidance for the organization of mass gathering events,[16] and is continuing to work with key partners from many sectors, including sports and entertainment sectors, as well as faith-based organizations.

The unique scale of the COVID-19 crisis requires the international community to reach out beyond its own capacity. The private sector has been actively engaged in the response, with high-level regular participation into the weekly consultations on the pandemic organized by industry bodies such as the World Economic Forum and the International Chamber of Commerce.

16 For WHO guidance on point of entry and mass gatherings see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/points-of-entry-and-mass-gatherings

Epidemiological analysis and risk assessment

Ongoing, comprehensive and verified global surveillance data about COVID-19 is crucial for response at the global, national, and local levels. Epidemiological surveillance information is collected from all countries, territories, and areas and is made accessible through multiple channels, including a dynamic dashboard, a daily situation report, as well as downloadable data extracts.[17]

There are challenges to conducting global surveillance includes the lack of a global data architecture that facilitates the rapid and efficient sharing of data and information from countries, states, or territories. While the IHR stipulates the legal responsibilities to inform WHO about the occurrence of certain public health events, there is currently no harmonized public health reporting mechanism that enables information exchange from public health institutes and agencies directly to WHO. The lack of such a mechanism is a barrier for access to disaggregated data, which is needed to understand age- and sex-specific epidemiologic features, risk characteristics of certain sub-groups, and distributions of cases over time and geographic areas.

The global response to the COVID-19 pandemic requires the capacity to conduct ongoing risk assessment at the global, regional, national, and subnational levels. To fully leverage the investments and capacities for data collection and analysis for risk assessment, a new global public health data architecture will be required.

The foundations of such an architecture have already been laid through the creation of the Epidemic Intelligence from Open Sources (EIOS) data platform, which enables multiple communities of users to collaboratively assess and share information about outbreak events in real time. The future vision of the new data architecture has been articulated by the EPI-BRAIN initiative, which harnesses cutting-edge tools for big data, crowd sourcing and artificial intelligence to mitigate the impact of epidemics by allowing stakeholders to merge public health data with data on the myriad, complex factors that drive epidemics, including human and animal population movement, animal diseases, environmental and meteorological factors, using advances in language processing and machine learning to provide a more comprehensive analysis that helps to predict outbreaks and track their spread.

Risk communication and community engagement

Accurate information of COVID-19 has been communicated through multiple media channels to provide the right information, at the right time, to the right audience, so that it triggers the right action. Unfortunately, the global public health response to the COVID-19 pandemic has been accompanied by an infodemic, which is an over-abundance of information – some accurate and some not – that makes it hard for people to find trustworthy sources and reliable guidance when they need it. This misinformation hampers public health responses to epidemics and prevents people from taking adequate measures to effectively prevent disease transmission. Some misinformation may also lead to dangerous behaviours, such as self-medication with harmful substances.

To manage the infodemic, the communication around COVID-19 has been monitored to detect as early as possible misinformation or gaps in information. Using the WHO Information Network for Epidemics (EPI-WIN)[18] – a close partnership with various sectors and their respective members such as faith-based organizations, sporting event organizers, travel and trade sectors, international employers' organizations, trade unions organizations, health care delivery sector and others – existing trusted sources of information have been amplified and tailored for particular audiences. This has allowed for the timely corrective action such as displacing misinformation through a high output of public health messages that inform individuals and populations how to protect themselves and support outbreak control activities.

The COVID-19 pandemic continues to evolve rapidly. This heightens the need for accurate, trusted information adapted to changing scenarios. Trusted channels of communication and information through EPI-WIN play a critical role in meeting information needs.

Through the Global Outbreak and Alert Network (GOARN),[19] IFRC, UNICEF, and WHO are coordinating technical and operational updates on risk communication and humanitarian partners, with a special focus on highly vulnerable populations, and the integration of humanitarian partners to support physical distancing solutions in migrant and camp settings.

Social science and community insights, including perception surveys and feedback from communities affected by physical distancing and movement restrictions, are being rapidly synthesized to ensure that future response measures are informed by and calibrated according to the ongoing experiences of affected communities by GOARN research partners are supporting this effort through the creation of a repository of risk communication and community engagement data collection tools (surveys, questionnaires, rapid assessment methods) to aid researchers and public health organizations to roll out quick assessments in their communities of interest.

17 For all WHO COVID-19 situation reports see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports/

18 For EPI-WIN see: https://www.who.int/teams/risk-communication

19 For more information about GOARN see: https://www.who.int/ihr/alert_and_response/outbreak-network/en/

Coordinated global supply chain management

Essential health commodities (including vaccines, therapeutics and diagnostics) are a global good. The COVID-19 pandemic has led to an acute shortage of essential supplies, including personal protective equipment, diagnostics, and medical products. The UN has rapidly convened a Supply Chain Task Force. This task force will, as an urgent priority, establish a new emergency global supply chain system (EGSCS) to provide countries with essential supplies related to COVID-19 response.

The task force will ensure that supply chains are driven by strategic and tactical health and medical priorities, and that the most critical gaps in supplies are identified and met in a timely fashion. This will include a dynamic view of global, regional, and national demand for infection prevention and control supplies, personal protective equipment, diagnostic tests, and clinical support equipment, supplies, therapeutics and vaccines (when available). A bottom-up assessment of needs through the COVID-19 partners portal is being combined with top-down modelling to provide a robust forecast of overall needs, and flag areas with urgent unmet needs, vulnerabilities, and gaps in independent procurement capacity.

A hub-and-spoke distribution chain will form the basis of a global logistics distribution chain. The system will include four strategic international consolidation hubs, including a sourcing hub in Shanghai and additional international consolidation hubs in Dubai, Atlanta, and Liege, as well as six regional staging areas located along primary corridors serving all countries.

Airlifts will move cargo between international and regional hubs and onward to countries – these services are a crucial contribution of the task force given current disruptions to commercial operators and competing demand. A similar hub-and-spoke model will be established for passenger air services where commercial airlines are disrupted, to ensure that frontline health and humanitarian responders are operational in priority countries.

Technical expertise and health emergency workforce

Operational, technical and research networks have all been activated in the fight against this pandemic. Experts from around the world and frontline responders are reviewing all available evidence to develop and update technical guidance for countries to prepare and respond to COVID-19. Much has been learnt about COVID-19 in the four months since this outbreak began, but there remain significant knowledge gaps that must be filled by ongoing surveillance and research activities. Research protocols to address these gaps have been rapidly and transparently developed.

The first comprehensive set of technical guidance[20] was published on 10 January 2020, and is being constantly reviewed and revised based on available evidence. Technical guidance is being adapted for different settings and contexts based on the intensity of transmission, the capacity of countries to implement public health measures, and available resources, and translate key actions required for countries through the EPI-WIN platform and other information products. 1.2 million people have enrolled in the OpenWHO training platform which has COVID-19-specific courses available in 43 languages.

Direct technical assistance to Member States is also facilitated through GOARN which has made 209 offers of technical support. Experts have been deployed from 27 partner institutions and technical networks to provide support to countries directly and by remote assistance. GOARN colleagues from UNICEF, IFRC, US CDC, and OCHA are embedded in the global COVID-19 incident management team and are supporting all pillars of response.

Access to emergency health workforce capacity is coordinated through the over 100 Emergency Medical Teams (EMTs)[21] and focal points worldwide, who are working closely with the EMT secretariat to continuously monitor, guide, and facilitate national and international COVID-19 response operations.

The EMT secretariat is involved in intensive discussions to strengthen capacity and support to countries in Africa. In addition, EMTs worldwide are identifying technical experts and coordinators who can support integrated public health and clinical teams.

In addition, the Global Health Cluster (GHC)[22] continues to support Health Clusters in 29 countries to implement the COVID-19 GHRP to respond and preserve existing humanitarian health action and commitments in line with the GHRP 2020.

20 For an overview of all technical guidance available for COVID-19 see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance
For OpenWHO see: https://openwho.org/

21 For more on the EMT initiative see: http://extranet.who.int/hac/techguidance/preparedness/emergency_medical_teams/en/

22 For more on the GHC see: https://www.who.int/health-cluster/about/structure/global-cluster-unit/en/

Accelerating research, innovation, and knowledge sharing

On 11 and 12 February 2020, the Global Research Forum, hosted by WHO in Geneva, developed an initial COVID-19 Global Research Roadmap to guide a united COVID-19 agenda for research and development.[23] The forum was unanimous that there is an urgent need to research and develop medical countermeasures, including vaccines, therapeutics, and diagnostics.

Important investments are already funding many efforts and activities to address the challenge of COVID-19. A report on the landscape of global research efforts on vaccines is issued weekly and provides updates on the progress of research and innovation efforts including the stages of advancement of candidate vaccines, two of which are currently in clinical evaluation phase. There are already areas of targeted coordination and funding such as CEPI for vaccines and the WHO Solidarity Trial for therapeutics, which is a trial testing potential old and new therapies to fight COVID-19. Many other efforts are also being independently organized and financed. For maximum impact, the global community will require a truly unified and international effort. Acting now requires the public and private sectors to come together in support of a transparent and coordinated global process to pursue research and innovation priorities for collective action around this common global threat.

A global COVID-19 accelerated vaccine venture has been established to coordinate an unprecedented partnership of stakeholders with WHO that is needed to align the ecosystem around a dedicated vaccine master plan and uncover every opportunity to maximize speed of innovation and scale of delivery. Within the context of the broader Research and Innovation Action Plan, this special initiative drives the unique targeting and intense global focus to achieve mass immunization from COVID-19 at breakneck speed.

Building and expanding on the Global Research Roadmap, WHO is working with partners to develop a framework for coordinated research and innovation and an overview of the scale of investments required for financing. Enabling the greatest global good will require solidarity and collaboration, establishing sufficiently funded, collaborative, cross-agency and public-private partnerships, and facilitating open data access and information sharing. Support and investment will be necessary across public, private and philanthropic sectors along with prioritization and proper stewardship of those resources.

Coordination and the combination of efforts will be critical to collective success. Individual and isolated action, however dedicated and determined, will not be sufficient to meet the current challenge of COVID-19. In order to be successful we will need to pool, build, and pass innovation from strength to strength. This will require proactive and intentioned coordination rather than more passive monitoring and reporting of activities.

A concerted and ongoing effort will be required to ensure coordination across stakeholders. Convening, coordination and benefit sharing will be critical to ensure that all stakeholders are appropriately engaged. Data, virus and technology sharing arrangements can facilitate expedited discovery and early development efforts while also creating a foundation for longer-term research and development beyond the current outbreak. Tactically, aligning on common protocols and standards, priority setting, and the development of target product profiles will be important to ensure that innovation flows seamlessly from one stage to the next, while simultaneously ensuring key milestones for decision making are understood and downstream development and delivery vehicles are proactively prepared. To facilitate this, resource mobilization and investment prioritization as well as monitoring and oversight will be required and are underway.

Given the differences in research platforms, development processes, timelines, key players, and coordination considerations for vaccines, therapeutics and diagnostics, a set of detailed action plans for each countermeasure is under rapid development.

Strengthening pandemic preparedness for the future

With the world facing an unprecedented threat, there is an opportunity to emerge with stronger health systems, and improved global collaboration to face the next health threat. As we focus on the immediate response to the COVID-19 crisis, it is important to keep in mind the breadth and depth of consequences already being felt across the globe. We must learn the lessons of this pandemic now and, in so doing, ensure that our response, wherever possible, leaves a lasting positive legacy, and makes the world of the future a safer place.

23 For more on research and development see: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov


World Health
Organization

SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
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Kirkness Road
Arcadia
0083

185
"LL6"

SAHPRA AUTHORISES COVISHIELD - AN ADENOVIRUS-VECTORED VACCINE FOR THE PREVENTION OF COVID-19

In an effort to enable and support the country's response in fighting the COVID-19 pandemic, SAHPRA has on 22 January 2021 granted a Section 21 authorisation to the Department of Health for COVISHIED (a covid-19 vaccine manufactured by Serum Institute of India) for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

The regulatory process involved a thorough and rigorous review of the data submitted to ensure that the vaccinees will receive safe, efficacious and quality-assured vaccines.

SAHPRA is currently reviewing applications for registration of the Janssen and Pfizer covid-19 vaccines. SAHPRA had pre-submission discussions with a few other manufacturers where they are able to share the readiness of data for submission.

SAHPRA has and will continue to prioritise all COVID-19 applications and will apply an expedited approach to all COVID-19 related health products, including vaccines. SAHPRA will keep the public updated on any new developments.

SA ROLLOUT OF THE J&J COVID VACCINE WILL BE EXPEDITED - PROF BEKKER

"LL7"

South Africa has secured 9 million doses of the J&J vaccine with the first consignment of 80,000 vials expected to arrive in the country next week.

Kevin Brandt | 5 days ago

CAPE TOWN – The rollout of pharmaceutical company Johnson & Johnson's COVID-19 vaccine for health workers will be expedited.

In the run-up to the country's mass vaccination drive, the Sisonke open-label COVID-19 vaccine programme was established to help speed up the plan, while an application for commercial use of the shot is being finalised.

South Africa has secured 9 million doses of the J&J vaccine, with the first consignment of 80,000 vials expected to arrive in the country next week.

Professor Linda-Gail Bekker has been part of the study that was rolled out in South Africa last year.

She explains there's usually a waiting period from the time results of a vaccine's clinical trial was known until it's licensed for commercial use.

To bridge this delay, Bekker explained they had drawn up a plan to rollout the vaccine while waiting for the authorisation process to be finalised.

"Can we together bring this expedited plan forward so that we can make sure we, as quickly as possible, rollout phase one recipients – mainly healthcare workers – into a kind of emergency programme."

She said 32 sites across the country will be utilised.

"This is not clinical research in the clinical trial concept; it really is programme evaluation, and many eyes are on it at the moment to make sure that we have covered all aspects – ethical, safety and scientific. We will not move without those approvals."

Trial data shows the single-dose jab has an 85% efficacy against severe COVID-19 and offers 57% protection against the virus' second variant.

"LL8"

Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment

Olivier J Wouters, Kenneth C Shadlen, Maximilian Salcher-Konrad, Andrew J Pollard, Heidi J Larson, Yot Teerawattananon, Mark Jit

The COVID-19 pandemic is unlikely to end until there is global roll-out of vaccines that protect against severe disease and preferably drive herd immunity. Regulators in numerous countries have authorised or approved COVID-19 vaccines for human use, with more expected to be licensed in 2021. Yet having licensed vaccines is not enough to achieve global control of COVID-19: they also need to be produced at scale, priced affordably, allocated globally so that they are available where needed, and widely deployed in local communities. In this Health Policy paper, we review potential challenges to success in each of these dimensions and discuss policy implications. To guide our review, we developed a dashboard to highlight key characteristics of 26 leading vaccine candidates, including efficacy levels, dosing regimens, storage requirements, prices, production capacities in 2021, and stocks reserved for low-income and middle-income countries. We use a traffic-light system to signal the potential contributions of each candidate to achieving global vaccine immunity, highlighting important trade-offs that policy makers need to consider when developing and implementing vaccination programmes. Although specific datapoints are subject to change as the pandemic response progresses, the dashboard will continue to provide a useful lens through which to analyse the key issues affecting the use of COVID-19 vaccines. We also present original data from a 32-country survey (n=26 758) on potential acceptance of COVID-19 vaccines, conducted from October to December, 2020. Vaccine acceptance was highest in Vietnam (98%), India (91%), China (91%), Denmark (87%), and South Korea (87%), and lowest in Serbia (38%), Croatia (41%), France (44%), Lebanon (44%), and Paraguay (51%).

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For more on COVID-19 mortality see https://coronavirus.jhu.edu/map.html

See Online for appendix 1

Introduction

The COVID-19 pandemic has caused substantial excess mortality and plunged national economies into deep recessions.[1] Although the spread of the virus can be mitigated through physical distancing, face coverings, and testing and tracing—and potentially with therapeutics—the risk of outbreaks and disruption to economic and social life will probably remain until effective vaccines are administered to large portions of the global population to prevent hospitalisation and severe disease, and preferably achieve herd immunity to halt transmission of the virus.

Several COVID-19 vaccines have now been authorised or approved for human use, with many more in the late stages of clinical development. Yet having licensed vaccines is not enough to achieve global control of COVID-19: they also need to be produced at scale, priced affordably, allocated globally so that they are available where needed, and widely deployed in local communities (figure 1). These four dimensions of the global vaccination challenge are closely related, and the development and production steps have important implications for pricing, allocation, and public confidence.

In this Health Policy paper, we review potential challenges to success in each of these dimensions and discuss policy implications. To guide our review, we developed a dashboard (figure 2) to highlight the key characteristics of 26 leading vaccine candidates, based on the target product profiles for COVID-19 vaccines set by WHO.[2] We focused on characteristics that distinguish individual vaccine candidates from one another. We used a traffic-light system to signal the potential contributions of each candidate to achieving global vaccine immunity, with the colour red indicating high risks to achieving widespread immunity, amber indicating medium risk, and green indicating little or no risk. Appendix 1 outlines the methodology for

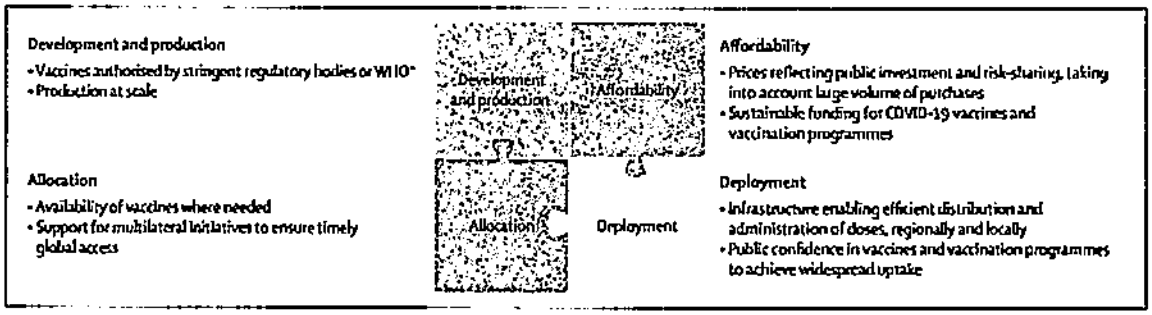

Figure 1: Four dimensions of an effective global immunisation strategy against COVID-19
*Stringent regulatory bodies can approve vaccines or authorise their use in emergencies (eg, emergency use authorisation during public health crises, such as pandemics); WHO can grant emergency use listing (comparable to emergency use authorisation by a stringent body) or prequalification (comparable to approval by a stringent body). WHO publishes a list of stringent regulatory authorities.[3]

	Development and production			Affordability	Allocation		Deployment	
	Authorised by a stringent regulatory body or WHO*	Efficacy in phase 3 trials†	Estimated production capacity for 2021	Lowest price offered (US$ per course)‡	Percentage of doses pre-purchased by HICs for 2021 (based on known deals)	Supply agreement with COVAX§	Number of doses	Storage requirement during transport
AnGes with Osaka University	–	–	–	–	–	No	2	−70°C
Anhui Zhifei with CAMS	–	–	300 m	–	–	No	2 or 3	2–8°C
AstraZeneca with Oxford University	Yes	62%¶	3 bn	$5	27%	Yes	2	2–8°C
Bharat Biotech	No	–	700 m	$6	0%	No	2	2–8°C
Biological E	–	–	–	–	–	No	2	2–8°C
BioNTech with Pfizer	Yes	95%	2 bn	$14	77%	Yes	2	−70°C
CAMS with IMB	–	–	–	–	–	No	2	2–8°C
CanSino	–	–	320 m	–	0%	No	2	2–8°C
Clover Pharmaceuticals with Dynavax	–	–	1 bn	–	–	No	2	2–8°C
Covaxx with Nebraska University	–	–	1 bn	–	0%	No	2	2–8°C
CureVac	–	–	300 m	$24	100%	No	2	5°C
Gamaleya	Yes	92%	1 bn	$6	0%	No	2	−18°C
Inovio	–	–	100 m	–	–	No	2	2–8°C
Johnson & Johnson	–	66%††	1 bn‡‡	$9	38%	Yes	1††	2–8°C
Medicago	–	–	80 m	–	100%	No	2	2–8°C
Moderna	Yes	94%	1 bn	$31	97%	No	2	−20°C
Novavax	–	89%‖§§	2 bn	$6	31%	Yes	2	2–8°C
RIBSP	No	–	60 m	–	–	No	2	2–8°C
Sanofi with GlaxoSmithKline	–	–	–	$19	73%	Yes	2	2–8°C
SII with Max Planck Institute	–	–	–	–	–	No	–	−50°C to −15°C
Sinopharm with Beijing Institute	Yes	79%¶¶	1 bn	$62	8%	No	2	2–8°C
Sinopharm with Wuhan Institute	No	–	600 m	$62	8%	No	2	2–8°C
Sinovac	No	50–91%††¶	1 bn	$21	18%	No	2	Room temperature
SK Biosciences	–	–	–	–	–	No	–	2–8°C
University of Hong Kong	–	–	–	–	–	No	–	−50°C to −15°C
Vector Institute	No	–	11 m	–	–	No	2	2–8°C

Figure 2: **Key characteristics of leading vaccine candidates with traffic-light system signalling potential for achieving global vaccine immunity**
The sources and methodology are documented in appendix 1, including the criteria for assigning a green, amber, or red light for each characteristic. Candidates shown in this figure have been approved or authorised on an emergency basis for human use in one or more countries, are in phase 3 clinical testing, or are under contract with CEPI or the COVAX Facility, as of Feb 3, 2021. Where there are no entries, either the data are unavailable or it is too early to know (eg, for vaccines in the early stages of development). Both Institut Pasteur (in collaboration with Merck) and the University of Queensland were developing COVID-19 vaccine candidates with funding from CEPI, but these clinical trials have been discontinued. CAMS=Chinese Academy of Medical Sciences. CEPI=Coalition for Epidemic Preparedness Innovations. HIC=high-income country. IMB=Institute of Medical Biology (China). RIBSP=Research Institute for Biological Safety Problems (Kazakhstan). SII=Serum Institute of India. *Only for vaccines that have been approved or granted emergency authorisation by at least one regulatory body; WHO publishes a list of stringent regulatory authorities,[3] and can itself grant emergency use listing or prequalification for vaccines. †Clinical trial designs, including efficacy endpoints, differed for the various vaccine candidates; the efficacy figures might therefore not be perfectly comparable. Some of these results are interim analyses from phase 3 studies. Due to the emergence of new variants of the virus, the conditions under which trials take place vary, and not all vaccines are tested against the same variants. ‡These prices are the lowest the developers offered to any country or purchasing bloc; median prices for a range of countries are presented in figure 3. §The COVAX Facility has first right of refusal for a potential combined total of more than 1 billion doses in 2021 of vaccine candidates being developed by CEPI-funded companies: Biological E, Clover Pharmaceuticals, CureVac, Inovio, Moderna, Novavax, Oxford University/AstraZeneca, SK Biosciences, and the University of Hong Kong.[3] ¶This was the result in the main efficacy analysis for participants receiving two standard doses, as specified in the protocol. The result in the out-of-protocol arm (a half dose followed by a standard dose) was 90%. This first-generation vaccine might offer less protection against a strain of SARS-CoV-2 first identified in South Africa. ‖For the assignment of risk levels, we treated a single dose of a one-dose vaccine as equivalent to two doses of a two-dose vaccine. **One | IIC (Hungary) has purchased 2 million doses, corresponding to 0·4% of all purchased doses; due to rounding, the figure presented in the dashboard is 0%. ††These interim phase 3 results have not been published in peer-reviewed journals; the figures were sourced from press releases by companies or researchers running the clinical trials. ‡‡The developer is also testing a two-dose version. §§This was the efficacy reported from a phase 3 trial in the UK; Novavax reported a lower efficacy level in a smaller phase 2b clinical trial in South Africa (49%). These results have not yet been published in peer-reviewed journals. ¶¶Sinovac and its research partners have reported a range of efficacy levels on the basis of phase 3 trials in Brazil (50%), Indonesia (65%), Turkey (91%), and the United Arab Emirates (86%), but none of these results have been published in peer-reviewed journals.

constructing the dashboard, including the criteria for assigning a green, amber, or red light for each characteristic. Although specific datapoints and their corresponding traffic-light categorisations are subject to change as the pandemic response progresses, the dashboard will continue to provide a useful lens through which to analyse the key issues affecting the use of COVID-19 vaccines.

Development and production

Several manufacturers have successfully developed COVID-19 vaccines in less than 12 months—an

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extraordinary achievement, given it typically takes a decade or longer to develop new vaccines.[3,4] The world now needs more doses of COVID-19 vaccines than it has done for any other vaccine in history to inoculate enough people for global vaccine immunity.

Vaccines often suffer from underinvestment,[5] but that has not been the case in this pandemic. As of Feb 3, 2021, there were 289 experimental COVID-19 vaccines in development, 66 of which were in different phases of clinical testing, including 20 in phase 3. Only five of these 66 vaccines—those developed by AstraZeneca in partnership with Oxford University, BioNTech in partnership with Pfizer, Gamaleya, Moderna, and Sinopharm in partnership with the Beijing Institute—have been authorised by stringent regulatory authorities (as per WHO criteria of such authorities[2]) or WHO (figure 2). Another five—from China, India, Kazakhstan, and Russia—have received approval or been authorised for emergency use by other regulatory agencies; some of the organisations developing these vaccines have submitted documentation to WHO for emergency use listing or prequalification, but these submissions are still under review.[6] Additional vaccines from Novavax and Johnson & Johnson are expected to be authorised on the basis of positive interim phase 3 results. Several vaccines have shown high levels of efficacy (ie, more than 70%) in clinical trials, although not all developers have published their results; most of the authorised vaccines have been shown to provide strong protection against hospitalisations and deaths due to COVID-19.

Whereas public support for basic research and early-stage drug development is widespread,[7] the urgent need to develop COVID-19 vaccines and scale up supply has inspired new ways of aiding research, development, and production activities and enlisting broad participation among private companies.[8] Governments and non-profit organisations have financed clinical trials, invested in the building and expansion of production facilities, and established contract manufacturing and distribution networks to enable the rapid roll-out of successful vaccines.[9]

The table summarises publicly available data on investments by governments and non-profit organisations into the research, development, and production of advanced COVID-19 vaccine candidates (appendix 2). In total, developers have received approximately $10 billion in public and non-profit funding for their vaccine candidates, although this number is probably an underestimate, given the scarcity of data on some of these projects. The top five companies have each received between $957 million and $2·1 billion in funding commitments, mostly from the US Government and the Coalition for Epidemic Preparedness Innovations (CEPI). The Chinese and Russian Governments have invested in several vaccine candidates being developed by private companies or state-owned enterprises. Because many funding arrangements are confidential, details regarding the specific breakdown of spending are unclear.

Attention has now turned to expanding production capacity to promote the widespread roll-out of successful vaccines, as well as efficiently distributing them to administration facilities. Companies with leading candidates have reported widely different supply capabilities up to the end of 2021 (figure 2). Nine developers have said they will be able to produce at most 700 million doses each this year, while ten other manufacturers have set production targets of 1 billion doses each or more. No single company will be able to supply all countries in this period, even if they meet these estimated production figures.

For more on COVID-19 vaccines in development see https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/

Scaling up production to meet global demand is a monumental challenge.[10,11] Before this pandemic, there were no existing networks of contract manufacturers for several of the leading vaccine candidates that feature novel technologies, including those relying on mRNA delivery platforms. Additionally, the volume of vaccines that is needed places pressure on global supply chains for inputs, such as glass vials, syringes, and stabilising agents.

The production of COVID-19 vaccines is limited by the highly concentrated state of global vaccine manufacturing capacity,[12] and the relationships established between lead developers and contract manufacturers. A successful solution to the production bottleneck would probably require widespread technology transfer to enable the expansion of manufacturing capacity. Currently, few countries have the domestic capacity to rapidly produce COVID-19 vaccines on their own and instead will need companies to actively share knowledge, technology, and data with domestic manufacturers.[13] Some of the lead developers of COVID-19 vaccines have collaboration agreements with manufacturers in middle-income countries—AstraZeneca has such agreements with the Serum Institute of India, Fiocruz in Brazil, mAbxience Buenos Aires in Argentina, and Siam Bioscience in Thailand; Johnson & Johnson has an agreement with Aspen Pharmacare in South Africa; and Novavax with the Serum Institute of India—although the terms of these partnerships, including the extent to which the licensed manufacturers can negotiate their own supply arrangements with countries, are unclear.

Affordability

See Online for appendix 2

Mechanisms are needed to ensure the affordability and sustainable financing of COVID-19 vaccines in low-income and middle-income countries, which are home to about 85% of the global population and which might lack the resources to buy adequate quantities of vaccines.[14,15] Even in high-income countries, it is important to ensure access to COVID-19 vaccines for poor and marginalised populations.

Pricing

Companies have gradually been disclosing the prices they are offering to countries of different income levels, with marked variation in the lowest price per course

	Technology	Known public and non-profit funding, US$	Funders
Sanofi with GlaxoSmithKline	Protein subunit	$2·1 billion	US Government
Novavax	Protein subunit	$2·1 billion	Bill & Melinda Gates Foundation, CEPI, US Government
AstraZeneca with Oxford University	Non-replicating viral vector	$1·7 billion	CEPI, UK Government, US Government
Johnson & Johnson	Non-replicating viral vector	$1·5 billion	US Government
Moderna	mRNA	$957 million	CEPI, Dolly Parton COVID-19 Research Fund, US Government
BioNTech with Pfizer	mRNA	$445 million	German Government
Clover Pharmaceuticals with Dynavax	Protein subunit	$430 million	Bill & Melinda Gates Foundation, CEPI
CureVac	mRNA	$348 million	CEPI, German Government
Sinopharm with Wuhan Institute	Inactivated virus	$142 million	Chinese Government
Medicago	Virus-like particle	$137 million	Canadian Government
Inovio	DNA	$107 million	Bill & Melinda Gates Foundation, CEPI, US Government
Covaxx with Nebraska University	Protein subunit	$15 million	Taiwanese Government
SK Biosciences	Protein subunit	$14 million	Bill & Melinda Gates Foundation, CEPI
Biological E	Protein subunit	$9 million	Bill & Melinda Gates Foundation, CEPI, Indian Government
University of Hong Kong	Replicating viral vector	$4 million	CEPI, Hong Kong Government
CAMS with IMB	Inactivated virus	$3 million	Chinese Government, Jack Ma Foundation
AnGes with Osaka University	DNA	Unknown	Japanese Government
Anhui Zhifei with CAMS	Protein subunit	Unknown	Chinese Government
Bharat Biotech	Inactivated virus	Unknown	Indian Government
CanSino	Non-replicating viral vector	Unknown	Unknown
Gamaleya	Non-replicating viral vector	Unknown	Russian Government
RIBSP	Inactivated virus	Unknown	Kazakh Government
SII with Max Planck Institute	Live attenuated virus	Unknown	Unknown
Sinopharm with Beijing Institute	Inactivated virus	Unknown	Chinese Government
Sinovac	Inactivated virus	Unknown	Unknown
Vector Institute	Protein subunit	Unknown	Russian Government

Data are as of Feb 3, 2021. The sources and methodology are outlined in appendix 2, which also includes more information about the funding arrangements. In brief, for developers with COVID-19 vaccines that have been approved or authorised for human use in one or more countries, are in phase 3 clinical testing, or are under contract with CEPI or the COVAX Facility, we searched press releases from developers and funders, as well as financial reports filed by developers with regulators in various countries, for information on public and non-profit funding. We did not count funds provided to licensees that produce and distribute vaccines on behalf of lead developers or to contract development and manufacturing organisations, nor did we count loans (ie, debt financing) from international financial institutions (eg, European Investment Bank) or national governments. We included pre-purchase agreements between governments and companies where it appeared as though a substantial portion of the funding went towards late-stage development (ie, phase 1–3 trials) or scaling up production at risk before the completion of clinical testing. CAMS=Chinese Academy of Medical Sciences. CEPI=Coalition for Epidemic Preparedness Innovation. IMB=Institute of Medical Biology (China). RIBSP=Research Institute for Biological Safety Problems (Kazakhstan). SII=Serum Institute of India.

Table: Public and non-profit funding for the research, development, and production of leading vaccine candidates

(figure 2). Some companies such as AstraZeneca and Johnson & Johnson, which are benefiting heavily from public-sector investments, have pledged to sell their vaccines globally at low prices. Both companies have committed to maintaining these prices during the pandemic,[20,21] although more clarity is needed on how it will be determined that the pandemic is over, as well as on post-pandemic pricing models. These factors have implications for the durability of vaccination campaigns, especially if yearly injections become necessary. Other companies are charging considerably more, with some companies setting prices that are among the highest of any in existence for vaccines (figure 3). Some manufacturers are also planning to sell COVID-19 vaccines at a premium in private markets in countries such as Bangladesh, Brazil, and India.[22–24] There are concerns that wealthier patients in these countries might gain quicker access to vaccines through these markets than poorer patients will.

Multiple factors could be driving the observed variation in prices. These include, for example, differences in technological platforms and the associated development and manufacturing costs; the amount of public funding that developers received; companies' approaches towards licensing and the establishment of production networks; the extent to which COVID-19 vaccines fit into pharmaceutical companies' overall profit-making strategies; the presence of intellectual property rights; funders' demands (eg, CEPI's access conditions); and political pressure on companies to keep prices low.

To illustrate how the prices of COVID-19 vaccines compare with those of other vaccines, figure 3 shows the median price per dose of existing vaccines by procurement

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or income group, as of the end of 2018. Generally, countries covered by Gavi, the Vaccine Alliance (a major buyer of vaccines for low-income countries), paid the lowest prices per dose (median across all vaccines $0·57 [IQR 0·16–1·90]), followed by countries covered by UNICEF (median $0·80 [IQR 0·16–2·80]) and the Pan American Health Organization (median $3·50 [IQR 0·87–13·0]), self-procuring middle-income countries (median $5·30 [IQR 0·79–18·30]), and self-procuring high-income countries (median $16·3 [IQR 6·5–22·0]).[22] Many self-procuring middle-income countries, which receive little external assistance, have historically been charged vaccine prices that are largely unrelated to income levels.[23]

Vaccine prices are especially important for COVID-19, on account of the volumes demanded. Countries are aiming to administer COVID-19 vaccines to nearly their entire populations, making these vaccines potentially unaffordable for many governments, even at low prices per dose. Depending on the duration of protection offered by these vaccines, as well as the potential need for modified vaccines that protect against new variants, these purchases could become recurring expenses.

Sustainable funding

To fund COVID-19 vaccines and vaccination programmes, including the costs of distribution, administration, record-keeping, and surveillance, governments will need substantial national revenue generation or external aid. Experiences with mass drug administration in previous health crises, such as during the HIV/AIDS epidemic, have shown that, even when pharmaceutical products are inexpensive or free, countries need financial support to both purchase and deploy them.[23,24]

These financial pressures are coming at a time when many economies are in crisis due to the pandemic. If governments in resource-constrained settings divert resources from other vaccination programmes or essential health-care services to pay for COVID-19 vaccines and vaccination programmes, health budgets could be distorted with long-term adverse consequences for health and economic development.

Major donors and lenders, such as the World Bank and other multilateral development banks, have earmarked billions of dollars in funds for COVID-19 vaccination programmes in low-income and middle-income countries.[11,25] These funds can be used to buy vaccines that have been authorised by stringent regulatory bodies or WHO. The G20 group of high-income countries' Debt Service Suspension Initiative might provide additional fiscal space too, by allowing the world's poorest countries to spread repayment of debt owed to other countries over extended periods. Although this initiative does not address debt owed to private creditors, the hope is that the temporary suspension of some repayments could release resources for more countries to better meet the costs of obtaining and administering vaccines.[11]

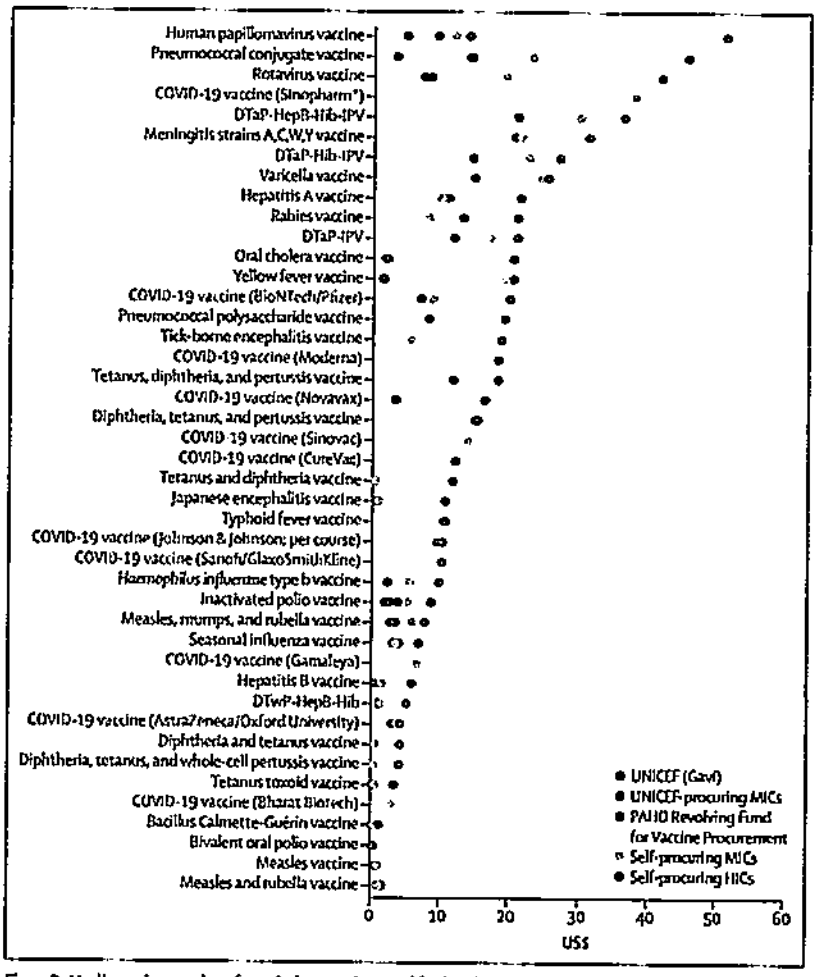

Figure 3: Median price per dose for existing vaccines and for leading COVID-19 vaccine candidates by procurement or country income group

Data obtained from the WHO Global Vaccine Market Report.[22] Data for non-COVID-19 vaccines are as of 2018; data for COVID-19 vaccines are as of Feb 3, 2021. Prices were not available for all procurement or income groups for all vaccines. Appendix 1 outlines the sources for all COVID-19 vaccine prices, which were obtained from press releases, investor documents, and media reports. The prices reported for COVID-19 vaccines are median prices for each country group; these prices might therefore not match those reported in figure 2, which show the lowest price offered. DTap-HepB-Hib-IPV=diphtheria, tetanus, acellular pertussis-hepatitis B-*Haemophilus influenzae* type b-inactivated polio vaccine. DTap-Hib-IPV=diphtheria, tetanus, acellular pertussis-*H influenzae* type b-inactivated polio vaccine. DTap-IPV=diptheria, tetanus, acellular pertussis-inactivated polio vaccine. DTwP-HepB-Hib=diphtheria, tetanus, whole-cell pertussis-hepatitis B-*H influenzae* type b vaccine. HIC=high-income country. MIC=middle-income country. PAHO=Pan American Health Organization. *Sinopharm is charging the same price for both of its vaccine candidates.

Global allocation

In addition to the development and affordability of vaccines, an essential pillar of the vaccination challenge is ensuring that enough doses are available globally. Current decisions regarding allocation are being made in the context of constrained supply, with demand exceeding current and projected levels of output.[26,27] Scarcity in supply coupled with the large volumes of pre-orders made by richer countries creates challenges to achieving timely, universal access. Billions of individuals around the world might not have access to COVID-19 vaccines in 2021, which could prolong the pandemic and raise the

risk of further mutations of the virus emerging, possibly undermining the efficacy of existing vaccines.

COVAX approach to global allocation

Uneven access to vaccines would not be unprecedented. During the 2009 H1N1 influenza pandemic, rich countries bought up most of the global supply of pandemic influenza vaccines, leaving inadequate amounts for resource-poor countries, many of which were among the world's worst affected.[13,14] Some countries went as far as to block locally manufactured vaccine doses from being exported elsewhere,[15] something that EU member states are considering in the present pandemic too.

To avoid a repeat of the H1N1 scenario, in April, 2020, WHO announced the creation of a global allocation mechanism, the COVID-19 Vaccine Global Access (COVAX) Facility, coordinated jointly with CEPI and Gavi. COVAX is a pooled procurement initiative that, in addition to seeking to secure low prices, aims to provide all countries with access to a diversified portfolio of vaccines during the acute phase of the pandemic in 2021. High-income, self-financing countries can purchase vaccines from COVAX at an estimated average price of $11 per dose, whereas 92 low-income and middle-income countries can receive them at considerably lower prices ($1·6–2·0 per dose), subsidised through official development assistance.[16]

At the core of the COVAX approach to global allocation is that vaccination should proceed in stages, with priority given to protecting older adults, health-care workers, and other high-risk individuals, before proceeding to vaccinate wider sections of the population.[17] According to the COVAX model, all participating countries would initially receive enough stock for 20% of their populations, after which distribution would adhere to the WHO framework for allocating COVID-19 vaccines internationally on the basis of need.[17] The overarching logic of COVAX is that no country should vaccinate more than 20% of its population until all countries have vaccinated 20% of their populations, in accordance with principles of global equality. Others have suggested alternative allocation frameworks, although all share their roots in principles of fairness and ethical distribution.[18–21]

Threats to equitable allocation

For COVAX to succeed, it needs substantial funding to purchase vaccines. As of February, 2021, governments and other partners have committed around $4 billion in funding for COVAX,[22] but Gavi and WHO estimate that a further $6·8 billion will be needed for COVAX to procure and deliver at least 2 billion doses by the end of 2021.[3,16]

A greater threat to equitable allocation comes from national procurement strategies that might leave COVAX with inadequate supply.[15–21] Many high-income countries have opted not to purchase their vaccines via COVAX and instead have sought to gain priority access to abundant quantities of COVID-19 vaccines by striking advance purchase agreements with developers. The goal of such agreements is to secure access to enough vaccines to inoculate most, if not all, of countries' adult populations in 2021. Securing large quantities of vaccines in this way amounts to countries placing widespread inoculation of their own populations ahead of the vaccination of health-care workers and high-risk populations in poorer countries. On the basis of public records, governments in high-income countries, representing 16% of the global population, have struck pre-orders covering at least 4·2 billion doses of COVID-19 vaccines. These countries have secured at least 70% of doses available in 2021 of five leading vaccine candidates, on the basis of known deals (figure 2).

Although the pattern of purchasing vaccines directly from developers and not via COVAX began with high-income countries (including the EU as a unified buyer), numerous other countries have followed suit. This dynamic is self-reinforcing: as more countries procure doses directly, concerns about the reliability of COVAX's supply heighten, thus creating greater incentives for countries to procure doses on their own. The incentives to procure vaccines this way increases further after positive trial results are announced, which reduces the risk of purchasing in advance for the successful vaccines. As of Feb 3, 2021, at least 62 countries or blocs of countries had signed purchase agreements with manufacturers.[22]

But not all countries can procure enough COVID-19 vaccines on their own. Instead, most countries are counting on COVAX, which has reached agreements with five companies for about 2 billion doses (figure 2).[3] This amount could allow COVAX to achieve the goal of vaccinating 20% of the populations of participating countries. However, because it is unclear which vaccines will be distributed to which countries at what time, it is challenging for governments reliant on COVAX to plan vaccination programmes. Similarly, uncertainty about COVAX supply complicates governments' decisions about how to acquire the best vaccine portfolios for their populations, including doses beyond those covered by COVAX.

Apart from the cross-country equity concerns raised by a scenario of low-income countries vaccinating 20% of their population after much wider (if not universal) vaccination in high-income countries, there is uncertainty about the supply earmarked for COVAX. Many of the doses secured by COVAX are of vaccines that, as of February, 2021, are just completing clinical trials and might not be available for months to come.[3] COVAX might also gain access to vaccines being developed by CEPI-funded companies that are not as far along in trials, and it might negotiate further agreements with other suppliers. Yet overall, COVAX's supply is precarious and depends on what happens to the vaccines in clinical trials, how much of the successful candidates can be produced quickly, and how much of the output is left for COVAX after sales to national governments.

Although COVAX was created to achieve equality in the initial stages of vaccination, as all countries inoculate

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the first 20% of their populations, it is unlikely to achieve that goal. Instead, what COVAX can hopefully achieve is to help countries procure doses at lower prices and thus launch their vaccination campaigns earlier than they would without external assistance. With additional funding, COVAX could probably compete better in the global scramble for vaccines and secure a place further towards the front of the queue.

Given the scarce supply of some of the vaccines developed in Europe and the USA, governments in Latin America, Africa, the Middle East, and Asia have turned increasingly towards vaccines developed by Chinese, Indian, and Russian manufacturers.[51,52] These vaccines, which are far along in the development process, might relax the global supply constraint. To the extent that high-income countries continue to refrain from purchasing these products, their emergence might allow low-income and middle-income countries to also procure abundant doses to achieve national vaccination goals. Although few of these vaccines have been authorised by WHO or WHO-classified stringent regulatory authorities, as they do so, these vaccines could also contribute to the COVAX portfolio.

Deployment

Beyond issues related to determining which countries will get vaccine doses when and at what prices, it is essential to ensure the smooth deployment of COVID-19 vaccines. The rapid pace of production and development has shortened the time available for national, regional, and local health officials to plan training and preparedness for COVID-19 vaccination programmes.

Logistical and administrative challenges

Robust data infrastructure will be needed for local authorities to identify eligible individuals by priority group, send invitations, arrange transport for older patients and patients with disabilities, and recall individuals to receive the second doses of some vaccines. Several of the leading vaccine candidates require ultra-cold chains and have short shelf-lives once they are removed from storage. The mRNA vaccine by BioNTech and Pfizer, for instance, must be administered within 5 days of leaving ultra-low temperature conditions (–70°C);[53] similar, if less extreme, requirements apply to Moderna's mRNA vaccine. Strong coordination will be needed between workers at central depots and local vaccinators to ensure the timely and efficient distribution of mRNA vaccine batches to areas without freezers.

Many low-income and middle-income countries will face barriers in delivering vaccination programmes to their entire adult populations, ensuring completion of two-dose vaccination schedules, and maintaining cold or ultra-cold supply chains. As of 2018, 74 of 194 WHO member states had no adult vaccination programme for any disease; fewer than 11% of countries in Africa and South Asia reported having any such programme.[54] These countries might lack immunisation registries for adults and the storage, delivery, and waste management systems needed to administer vaccines at this scale.[54] It is worth noting that Gavi and its partners established ultra-cold supply chains in several sub-Saharan African countries after the 2013–14 Ebola epidemic to deploy an Ebola vaccine developed by Merck that had to be kept at –60 to –80°C.[17,55] However, this infrastructure was set up on a much smaller scale than what is currently needed and would be prohibitively expensive for the global administration of vaccines during this pandemic.

Several vaccines that only require refrigeration during transport have been authorised for human use, while a few single-dose products are in clinical development (figure 2); one in particular—that developed by Johnson & Johnson—has shown promising interim phase 3 results. The availability of one-dose vaccines that can be kept refrigerated or at room temperature would greatly simplify the logistical and administrative challenges associated with COVID-19 vaccination programmes. Moreover, as scientific understanding of the properties of new vaccines improves, such as the thermal stability of mRNA vaccines, or new ways of formulating these vaccines are developed, logistical barriers might be lowered. Such a development would make it easier to deploy these vaccines in resource-poor countries. Indeed, CureVac has an experimental mRNA vaccine in late-stage clinical development that can be kept refrigerated. The product profiles of COVID-19 vaccines can help governments decide which vaccines to procure; these profiles, alongside any constraints reported by governments, can also help inform COVAX's allocation decisions and might become increasingly important as additional, differentiated vaccines are authorised.

Beyond technical issues related to data and storage infrastructure, vaccination schedules, and other logistical matters, there are steps that governments can take to promote accountability, which might make COVID-19 vaccination campaigns more effective. These steps include transparency and clear communication on the part of government officials about timelines, prioritisation of different groups, choice of vaccine products, and design of administration schedules. Country-level monitoring and evaluation systems might be required to track vaccine roll-out, which can help support the efficient running of campaigns, as well as continued population adherence to non-pharmaceutical interventions, such as physical distancing and face coverings, as vaccination programmes are established and scaled up.

Vaccine hesitancy

Deployment can also be hampered by vaccine hesitancy,[56–63] potentially leading to refusal or delayed acceptance of COVID-19 vaccines. Hesitancy is prevalent in low-income and high-income countries alike, with sceptics found in all socioeconomic, religious, and ethnic groups.

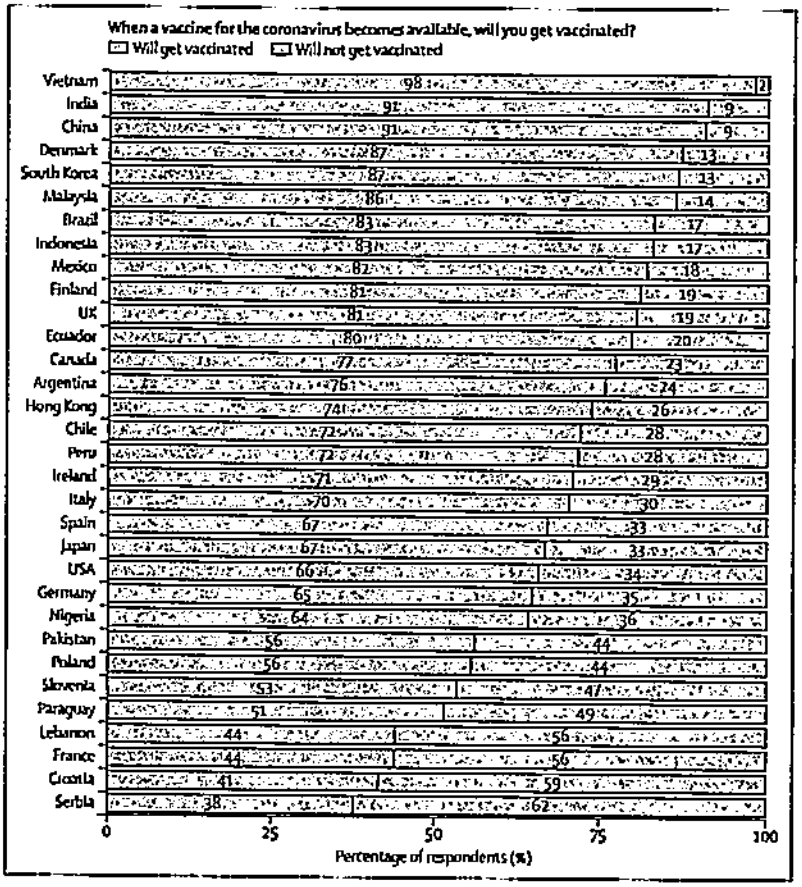

Figure 4: Survey of potential acceptance of COVID-19 vaccines
Data were jointly collected by the polling company ORB International and the Vaccine Confidence Project (London School of Hygiene & Tropical Medicine) between Oct 21 and Dec 16, 2020. Samples were random and nationally representative of the adult population in 30 of the 32 countries. Each respondent was asked, in the local language: "When a vaccine for the coronavirus becomes available, will you get vaccinated?" The possible responses were "definitely will", "unsure but probably will", "unsure but probably will not", or "definitely will not". In this figure, the category "will not get vaccinated" included respondents who said they "definitely will not" or "probably will not" get vaccinated, and the category "will get vaccinated" included respondents who said they "definitely will" or "probably will" get vaccinated. Appendix 3 describes the survey methodology.

See Online for appendix 3

Figure 4 presents original data from a 32-country survey (n=26758) of potential acceptance of COVID-19 vaccines conducted between Oct 21 and Dec 16, 2020 (appendix 3). The share of respondents who said they would definitely or probably get vaccinated when a COVID-19 vaccine becomes available was highest in Vietnam (98%), followed by India and China (both at 91%), and Denmark and South Korea (both at 87%). The country that reported the lowest number of people who would definitely or probably get vaccinated was Serbia (38%), followed by Croatia (41%), France and Lebanon (both at 44%), and Paraguay (51%).

Numerous other surveys of COVID-19 vaccine acceptance were done between March and October, 2020.[70–75] Although it is not possible to directly compare the results of all existing surveys because of differences in the countries included, and in questionnaires and methodologies used, these surveys overall seem to suggest that willingness to vaccinate against COVID-19 has declined globally between the early months of the pandemic and December, 2020, although rates tend to fluctuate.

At least three issues are contributing to COVID-19 vaccine hesitancy. First, the speed at which vaccines have been developed, which reflects the unprecedented amount of funding from governments and non-profit groups, has raised concerns that the trials were rushed and regulatory standards relaxed,[76] concerns that were similarly reported during the H1N1 influenza pandemic.[77] Second, there are no previously approved mRNA vaccines, which has also sparked hesitancy given the novelty of the approach. Third, conspiracy theories about COVID-19 vaccines are being widely circulated on unregulated social media platforms,[78–80] sometimes by highly organised anti-vaccination groups.[81–83]

The evidence for measures to mitigate vaccine hesitancy and refusal is mixed, in part due to the wide range of strategies that have been used across settings for different vaccines and target groups.[84] Common elements across successful strategies include: (1) initiatives to increase vaccination knowledge and awareness; (2) community engagement, including involvement of religious and other influential leaders, to understand concerns, build trust, and manage rumours and misinformation; and (3) making vaccines available in convenient and accessible locations.[45,85–87] Having robust pharmacovigilance systems alongside compensation schemes for severe adverse events might help build confidence in vaccine safety in post-approval periods, especially in resource-poor countries with imperfect consumer protection systems.[88,89] Moreover, disadvantaged groups, many of which have suffered historical neglect and abuse,[90] often report lower levels of trust in the medical community[91,92] and lower uptake of health-care interventions, including vaccines, than the general population.[93–95] Additional efforts are needed to build trust among these groups.

Vaccine confidence might also be strengthened as more manufacturers obtain authorisation from stringent regulatory authorities or WHO and by these bodies clearly communicating to the public the rationale behind their decisions. The approval of experimental COVID-19 vaccines by Chinese, Indian, and Russian regulators before the conduct of phase 3 trials has generated widespread consternation among regulators and scientists in other countries because of the scarcity of safety and efficacy data and concerns that it could weaken confidence in vaccines.[96–101] The European Medicines Agency has also been subject to lobbying from several EU governments, who have urged the regulator to grant authorisation for the vaccine by AstraZeneca and Oxford University as soon as possible to expedite vaccination programmes.[102] Authorisations that are perceived to be premature might undermine trust in regulators, vaccines, and vaccination programmes.

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Discussion

Many commentators have called for a cooperative approach to vaccine allocation and deployment.[6,18] In doing so, appeals to values of fairness and solidarity are common. By contrast, the widespread disregard for a global approach to vaccine allocation shown by national governments misses an opportunity to maximise the common good by reducing the global death toll,[20] supporting widespread economic recovery,[20] and mitigating supply chain disruptions.[18] More equitable distribution of COVID-19 vaccines would help contain the pandemic sooner, and thus minimise the risk of new variants of the virus arising, against which existing vaccines might be less effective.

In this Health Policy paper, we have stressed the interactions among the four dimensions involved in the global COVID-19 vaccination challenge. It is not enough to have new vaccines developed; they must be affordable, accessible, trusted, and, to maximise impact, used efficiently.

Governments and other vaccine purchasers must now decide which vaccines to procure, as well as how to secure funding for COVID-19 vaccines and vaccination programmes. To reach these decisions, government officials and partners in international organisations will need to assess the suitability of various vaccines for their respective health systems and populations—for example, in terms of availability, affordability, efficacy, and dosing and storage requirements.

The dashboard highlights the trade-offs associated with leading COVID-19 vaccines in relation to these dimensions (figure 2). Multiple vaccines, for instance, are highly efficacious—exceeding WHO targets of a minimum of 50% and preferably 70% efficacy—but require ultra-cold storage during transport or have little reserved capacity for low-income and middle-income countries. Although all currently authorised or approved vaccines require two doses, single-dose vaccines that can be stored at refrigerated temperatures are in the late stages of clinical development, with one by Johnson & Johnson likely to be authorised; these vaccines would be easier to deploy in resource-constrained settings, which might lack infrastructure for delivering and administering two-dose vaccines reliably.

Differences in product characteristics might become particularly salient in 2021, while vaccines remain in short supply. If additional vaccines are successful in clinical testing and developers meet their production targets, then COVAX could allocate vaccines, in part, on the basis of their suitability for local conditions. For instance, should single-dose vaccines that can be stored in refrigerators become available, which seems increasingly likely given the promising interim results by Johnson & Johnson, then these could be prioritised for distribution in low-income and middle-income countries that lack ultra-cold supply chains or national vaccine registries for two-dose regimens.

The dynamics of production and development have important implications for each of the other dimensions. Governments and non-profit groups have committed unprecedented sums towards the development of COVID-19 vaccines and the infrastructure to produce them at scale, which has helped companies develop new vaccines in record time. But affordability remains a concern, given the volume of doses that countries will need to purchase and the additional expenditures that distributing and delivering vaccines entails. The extensive involvement of public funders in the development and production of COVID-19 vaccines provides them with opportunities to make these vaccines globally affordable. External funders that have invested in companies developing the vaccines and who share the financial risks could try to influence the pricing of these products, as CEPI has aimed to do with uncertain levels of success.[106,107] Funders could also negotiate clear timelines for the recovery of research, development, and production costs by companies; for example, initial doses might be sold at higher prices in the first year in high-income countries and then sold closer to their marginal cost in subsequent years.[108] Determining these prices will require governments to audit the financial records of vaccine makers.

These allocation challenges also relate to production: conflicts over priority access to scarce vaccine doses could be made less acute with greater output (ie, with reduced scarcity of vaccine doses). To that end, WHO has called for member states, manufacturers, and other organisations to commit to sharing knowledge, intellectual property, and data related to COVID-19 health technologies, through the COVID-19 Technology Access Pool (C-TAP). Similarly, several countries have proposed to suspend World Trade Organization rules on intellectual property rights during the pandemic, suggesting that doing so could facilitate scale-up. Yet, as of February, 2021, no manufacturers of leading vaccine candidates have engaged with C-TAP, and the World Trade Organisation reform proposal has not gained traction.

In this domain too, the extensive public role in funding vaccine development potentially provides opportunities. Funders could encourage vaccine developers receiving public support to share their technologies and know-how systematically and widely to expand global production. Funders could also work with developers to alleviate supply chain constraints and accelerate the scaling up of production. To the extent that international control of COVID-19 is regarded as a priority for individual countries, governments might have an incentive to exercise these levers.

Public confidence and trust in COVID-19 vaccines and those who deliver them to ensure uptake are as important as the vaccines' safety, efficacy, and affordability. Policy makers should urgently engage with communities to improve confidence in vaccines and combat misinformation and rumours around COVID-19. Post-marketing surveillance is important to build confidence

during vaccine roll-out. Developing successful, locally tailored strategies requires an understanding of contextual and historical influences of vaccine hesitancy and refusal.[7]

Equally, vaccine manufacturers should aim for maximum transparency and scrutiny of their clinical trial data to build public trust. Regulatory bodies safeguard public health by assessing whether the benefits of pharmaceuticals outweigh their risks. Regulatory decisions and their rationale should be clearly communicated to the public to provide reassurance that authorised products are safe and efficacious. It is in the interest of vaccine developers to seek approval or emergency use authorisation from a stringent regulatory body or WHO: only vaccines that have gone through one of these regulatory pathways will be eligible for purchase through COVAX or through funds made available by major development banks.

Conclusion

The societal value of safe and effective COVID-19 vaccines is enormous. Yet new vaccines will mean little to individuals around the world if they are unable to get vaccinated in a timely manner. This objective requires vaccines to be affordable and available to countries around the world, and governments to have the administrative and political capacities to deliver them locally. In this Health Policy paper, we have discussed the development and production, affordability, allocation, and deployment of COVID-19 vaccines, as well as the interactions between these dimensions of the global vaccination challenge. The distinct characteristics of leading COVID-19 vaccines across each of these dimensions generate trade-offs, which mean that both globally and nationally, the availability of diversified sets of vaccine options is likely to be needed to bring the global pandemic under control.

Declaration of interests

MS-K reports receiving grants from Health Action International, outside the submitted work. AJP is Chair of the UK Department of Health & Social Care's Joint Committee on Vaccination & Immunisation (JCVI) but does not participate in policy advice on coronavirus vaccines. He is also a member of the WHO Strategic Advisory Group of Experts (SAGE) and Chief Investigator of the clinical trials for vaccine candidate AZD1222 against COVID-19, sponsored by the University of Oxford. The University of Oxford has entered into a partnership with AstraZeneca on vaccine development for candidate AZD1222. The trials are funded by UK Research and Innovation (MC_PC_19055), Engineering and Physical Sciences Research Council (EP/R013756/1), the Coalition for Epidemic Preparedness Innovations (CEPI), the National Institute for Health Research (NIHR), the NIHR Oxford Biomedical Research Centre, and the German Center for Infection Research (DZIF). HJL reports receiving grants from Merck and GlaxoSmithKline, and honoraria from Merck (for serving on a vaccine confidence advisory board) and GlaxoSmithKline (for speaking at staff training sessions). MJ reports receiving grants from the Bill & Melinda Gates Foundation (INV-016832), European Commission's Horizon 2020 programme (101003688), and National Institute for Health Research (NIHR200929, NIHR200908), outside the submitted work. All other authors declare no competing interests.

Author contributions

OJW, KCS, and MJ conceived of and designed the manuscript. OJW and MS-K collected and analysed the data. OJW drafted the manuscript. All authors had full access to all the data in the study, contributed to revisions to the article, and had final responsibility for the decision to submit for publication.

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What could fair allocation of an efficacious COVID-19 vaccine look like in South Africa?

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An efficacious COVID-19 vaccine would undoubtedly be a global public good that, in the context of a pandemic, is urgently and synchronously required by the global community. These unique features make allocation of an approved COVID-19 vaccine challenging both globally and nationally.

There is nothing new about prioritisation of scarce resources in low-income and middle-income countries. In South Africa, there has always been a need to ration scarce resources, ranging from access to basic health care at public clinics to specialised care, such as renal dialysis, organ transplantation, and critical care at tertiary hospitals. With suboptimal vaccine manufacturing capacity in Africa, fair distribution of extremely limited supplies of an efficacious COVID-19 vaccine, once approved for marketing, is likely to pose a procurement challenge. Consequently, not all people will be first in line to receive it.

South Africa has a history of reasonable childhood immunisation coverage, reaching around 82% of children under 5 years before the pandemic.[1] However, a recent Ipsos survey commissioned by the World Economic Forum showed that only 64% of South Africans would accept a COVID-19 vaccine.[2] Although the validity of generalising these findings is unclear, vaccine hesitancy is growing in prominence in Africa. Concerns relating to the safety and efficacy of experimental vaccines are understandable given the widespread publicity of adverse events leading to pauses in COVID-19 vaccines under development.[3,4]

Conceptual attempts at global distribution have been proposed, most notably, the so-called Fair Priority Model, which describes three fundamental values—benefit and minimising harm, prioritising the disadvantaged, and equal moral concern[5]—and the WHO approach, which recommends that countries receive doses proportional to their population size, ranging from 3–20%.[5,6] However, proportionality might also be considered in relation to burden of disease, raising the ethical challenge of allocating more vaccine to countries who have managed the pandemic poorly compared with those that have implemented strong public health containment measures.

Two major vaccine allocation frameworks that include national allocation criteria are worth mentioning: the WHO Strategic Advisory Group of Experts framework[6] and the National Academies of Science Engineering and Medicine (NASEM)[7] approach. Although considerable thought has been invested in both approaches, the NASEM framework holds greater potential for implementation via a phased approach. The framework underscores the moral legitimacy of priority setting in the context of this pandemic by including principles related to procedural justice (transparency, fairness, and evidence-based justification), which are indispensable in a context of vaccine hesitancy and mistrust in science. Important substantive aspects based on the risk of acquiring and transmitting infection and prevention of morbidity, mortality, and negative societal impacts are central to the framework. In this framework, a stakeholder engagement process is followed and uncertainty regarding efficacy of COVID-19 vaccines in children, pregnant women, older adults, and those who have had natural infection with COVID-19 is flagged. Solidarity and social responsibility are embraced, and countries with vaccine manufacturing capability are expected to provide for their own citizens first, but also allocate a proportion of the supply to other countries.[7]

How would this framework apply to South Africa? As a point of departure, if supplies are extremely scarce, such as in the scenario where only 3% of the population has access to a COVID-19 vaccine, those who have already acquired natural infection and those with humoral antibodies would not be first in line for vaccination. Studies in antenatal and HIV clinics in South Africa show that around 40% of those tested have antibodies.[8] In a scenario of extreme scarcity, those who decline immunisation would self-exclude.

Preferably, all frontline workers ought to be prioritised for vaccination but, if rationing within this subgroup is required, health-care workers at the highest risk and other vulnerable, high-risk frontline workers in essential services would be prioritised. All other citizens with comorbidities placing them at increased risk of severe disease or death would be next in line, followed by those with other co-morbidities, especially those who

live in crowded circumstances in low-income informal settlements and institutional settings. In South Africa, the immunological impact of the vaccine on HIV and tuberculosis would need to be explored further.[9] Although people older than 65 years constitute a high-risk group, in South Africa they account for around 5% of the population. Multigenerational households are culturally embedded in South African society and account for a third of all households,[10] which would require consideration in allocation frameworks.

We recommend that allocation frameworks for determining eligibility for efficacious COVID-19 vaccines in the first instance should focus on risk, with the caveat that this might change as vaccine supplies change globally. Given the paucity of evidence on immunological responses to COVID-19 in the South African setting, guidelines could warrant revision and adjustment in subsequent weeks. Rationing processes should be fair and based on transparent, consistent criteria that can be subjected to objective scrutiny with the goal of ensuring accountability, equity, and fairness.

We declare no competing interests.

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UN chief warns against 'vaccine nationalism'

Some countries bought more vaccines than their population, while poor countries fall behind, says Antonio Guterres

Ayhan Simsek |17.12.2020

BERLIN

UN Secretary General Antonio Guterres on Thursday urged world's rich nations to make stronger contributions to make coronavirus vaccine available to everyone on the planet.

"It is not with vaccine nationalism that we are going to defeat the COVID, it is with international cooperation," he said at a news conference in Berlin, following his meeting with German Foreign Minister Heiko Maas.

Guterres said some rich countries were purchasing vaccines in huge amounts, even several times more than their population, while UN-led programs like COVAX lacked sufficient resources to support the poor countries.

"We have a gap of $5 billion until the end of January, and a global gap of more than 20 billion that needs to be addressed in the context of the program," he said.

According to the estimates of the humanitarian groups, nine out of 10 people in poor countries are set to miss out on COVID-19 vaccine next year, unless urgent action is taken by the governments.

"We need to be able to make vaccine available to everybody, everywhere, and affordable for everybody, everywhere," he said.

"[Governments] cannot protect their peoples if other peoples are not protected. And the nature always strikes back, as we unfortunately have been witnessing in relation to the COVAX, in relation to the COVID, and in relation the climate change," he added.

Developed countries, representing 14% of the world's population, have already purchased more than 50% of the most promising vaccines, according to the People's Vaccine Alliance, a global coalition including Oxfam and Amnesty International among others.

RESEARCH Open Access

Income-related health inequalities associated with the coronavirus pandemic in South Africa: A decomposition analysis

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Abstract

Background: The coronavirus disease 2019 (COVID-19) has resulted in an enormous dislocation of society especially in South Africa. The South African government has imposed a number of measures aimed at controlling the pandemic, chief being a nationwide lockdown. This has resulted in income loss for individuals and firms, with vulnerable populations (low earners, those in informal and precarious employment, etc.) more likely to be adversely affected through job losses and the resulting income loss. Income loss will likely result in reduced ability to access healthcare and a nutritious diet, thus adversely affecting health outcomes. Given the foregoing, we hypothesize that the economic dislocation caused by the coronavirus will disproportionately affect the health of the poor.

Methods: Using the fifth wave of the National Income Dynamics Study (NIDS) dataset conducted in 2017 and the first wave of the NIDS-Coronavirus Rapid Mobile Survey (NIDS-CRAM) dataset conducted in May/June 2020, this paper estimated income-related health inequalities in South Africa before and during the COVID-19 pandemic. Health was a dichotomized self-assessed health measure, with fair and poor health categorized as "poor" health, while excellent, very good and good health were categorized as "better" health. Household per capita income was used as the ranking variable. Concentration curves and indices were used to depict the income-related health inequalities. Furthermore, we decomposed the COVID-19 era income-related health inequality in order to ascertain the significant predictors of such inequality.

Results: The results indicate that poor health was pro-poor in the pre-COVID-19 and COVID-19 periods, with the latter six times the value of the former. Being African (relative to white), per capita household income and household experience of hunger significantly predicted income-related health inequalities in the COVID-19 era (contributing 130%, 46% and 9% respectively to the inequalities), while being in paid employment had a nontrivial but statistically insignificant contribution (13%) to health inequality.

Conclusions: Given the significance and magnitude of race, hunger, income and employment in determining socioeconomic inequalities in poor health, addressing racial disparities and hunger, income inequality and unemployment will likely mitigate income-related health inequalities in South Africa during the COVID-19 pandemic.

Keywords: COVID-19, Income-related health inequality, Health, South Africa, Concentration index, Concentration curve, National Income Dynamics Study-Coronavirus Rapid Mobile Survey

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historical racial inequalities and overall living standards) will disproportionately disadvantage the poor, income-related health inequalities would become more pro-poor in the COVID-19 era than in the pre-COVID-19 era. As indicated above, this is the case, with the magnitude of income-related health inequality in the COVID-19 era six times what obtained in 2017.

Moreover, we found that income-related health inequality was higher among women than among men in the COVID-19 period. We suspect that this may not be unconnected with the fact that women have been more adversely affected by COVID-19-related lockdowns and economic disruption. For instance, women were more likely to lose their jobs, be burdened with additional childcare responsibilities and suffer from gender-based wage disparities due to the pandemic in South Africa [33]. This has the potential to further exacerbate the socioeconomic disparities between majority of women and the relatively few women who are economically secure.

The decomposition results highlight race, income and hunger as the significant contributors to income-related health inequalities in the COVID-19 era. Moreover, while not being statistically significant, income-earning employment also had a nontrivial contribution to increased health inequality.

The finding that race mediates the impact of COVID-19 on welfare corroborates prior evidence for South Africa. It has been noted that blacks/Africans are among the worst affected by the COVID-19 pandemic in South Africa [34]. One of the avenues through which such steeper African racial gradient occurs is higher exposure to hazardous jobs (by working as cleaners, nurses and in fumigation of contaminated areas). Indeed, the relative disadvantage of historically disadvantaged racial groups to pandemics is well known especially in the present situation. For instance, African Americans have disproportionately high infection and mortality rates due to COVID-19 in the United States [35]. Moreover, the pro-poor African concentration index is not surprising given that Africans are over-represented among the poor in South Africa. For instance, the real annual mean household expenditure for households headed by whites was seven times that of households headed by Africans in 2015 (131 198 Rands i.e. US$7 718, and 18 291 Rands i.e. US$1 076 for whites and Africans respectively) [36]. In fact, using median household expenditure, racial inequality appears worse as the white median expenditure was eleven times that of Africans according to the same report.

Another way through which race (being African) predicts poor health in South Africa is through access to quality health care. The deep inequalities/inequities in the South African health system are well documented [37, 38]. The South African health system is highly segmented, with a private sector similar to developed world health systems while the severely under-resourced public sector is overburdened by serving majority of the population [37]. The well-resourced private sector is mainly financed via membership of medical aid schemes which are unaffordable to majority of the population (mostly Africans). Available data indicate that in 2018, only about 16% of South Africans were members of medical aid schemes, with only 10% of Africans belonging to such schemes compared to 73% of whites [12]. However, as reported by the World Health Organization[5], private health expenditure accounted for about 44% of current health expenditure in 2017 (when only 17% of the population belonged to medical aid schemes). Given that Africans are less likely to belong to private medical aid schemes than other racial groups (especially whites) – thus, more likely to use the overburdened public health sector, it is not surprising that a positive relationship exists between poor health and race.

Hunger, which is an extreme form of food and nutrition insecurity, predisposes one to poor health outcomes. Therefore, it is not surprising that hunger was significantly associated with worsening income-related health inequality. Copious studies corroborate our findings of a positive relationship between hunger and poor health, as well as the fact that hunger is disproportionately borne by the poor [39, 40]. In particular, the fact that hunger is significantly pro-poor ($p < 0.01$) is worrying and indicates that the rights-based approach adopted by the South African constitution towards food and nutrition security, where the right to food is inextricably linked to the right to life and dignity (see Section 27 (1) (b) of the Constitution of the Republic of South Africa) is being undermined in the COVID-19 era [41]. This indicates that at the very least, various policies aimed at addressing food and nutrition insecurity in South Africa like the National Food and Nutrition Security Plan, the Agricultural Policy Action Plan, and the National Policy on Food and Nutrition Security are not sufficient for shielding the poor and vulnerable from hunger in the face of a pandemic of this magnitude.

Moreover, COVID-19 has exacerbated the threat of hunger especially among the poor. For instance, the lockdown necessitated the closure of schools, resulting in the cessation of the school feeding programme implemented under the National School Nutrition Programme. This programme serves as a major source of food for over nine million pupils and students mostly attending low income, no-fee paying (otherwise known as Quintile 1 – Quintile 3) schools [42]. This, and the massive loss of income generating opportunities due to job losses, is worrying and

[5] https://apps.who.int/gho/data/node.main.GHEDPVTDCHESHA2011?lang=en.

Death rates double in poor areas

17 January 2021 - 00:00BY SIPOKAZI FOKAZI, ORRIN SINGH, ZIMASA MATIWANE AND GRAEME HOSKEN

The funeral of a Covid-19 victim at the Motherwell Cemetery in Port Elizabeth. Experts say people living in poorer areas are at heightened risk of dying from Covid-19 due to several factors, including their relatively high burden of disease.Picture: Theo Jeptha

Covid-19 is killing twice as many people in poor communities than elsewhere.

Statistics from Cape Town showing mortality rates of more than 5% in the poorest areas are likely to be replicated nationwide, public health experts said this week.

They said poorer people are at heightened risk of dying from Covid-19 due to their relatively high burden of disease, socioeconomic status and limited access to critical care.

Their comments came after the Christmas and New Year weeks produced successive all-time records for deaths in SA as the second wave - driven by a highly contagious new Covid variant - surges through the country. Deaths officially attributed to the virus have continued to accelerate rapidly since the new records were set.

Health minister Zweli Mkhize told the Sunday Times this week that when Covid-19 arrived, a "huge concern" was how it would affect communities with a high burden of disease and poor access to health services.

"Where you have poor nutrition, unemployment, congestion, the conditions for spread of the virus are much faster and the resistance of individuals due to poor immunity is much worse. Therefore that combination becomes a toxic concoction," he said.

University of Cape Town public health specialist professor Leslie London said higher mortality in poorer areas could be linked to testing constraints that delayed diagnosis and treatment.

"There is also less access to critical care and ICU beds in the public sector as these are extremely scarce resources," he said.

Epidemiologist professor Taryn Young, head of global health at Stellenbosch University, said comorbidities were to blame for high mortality linked to disadvantaged communities.

However, wider access to Covid-19 testing in the private sector could give a flawed impression that mortality in richer communities was low. "Better access to private testing in more affluent areas will result in more cases being detected in those areas and this will also drive down the mortality rate in those areas," she said.

Detailed daily statistical updates from the Western Cape government mean it is easy to assess differences in mortality and infection rates in Cape Town's eight health sub-districts.

Klipfontein, which includes densely populated townships such as Gugulethu, Nyanga and Delft, has a mortality rate of 5.55%, and Khayelitsha's rate is 5.05%.

By contrast, the northern sub-district, which includes Durbanville, Brackenfell and Kraaifontein, has a mortality rate of 2.37%. The national mortality rate is 2.78%.

Western Cape health spokesperson Mark van der Heever said the high burden of disease in poorer areas contributed to the severity of illness. "Areas which have a higher number of people with comorbidities will in turn have higher numbers of deaths should these vulnerable persons become infected," he said.

London said that in poorer areas, "even if the prevalence of diabetes is similar to richer areas, it is more likely that people have had long-standing and poorly controlled diabetes, placing them at increased risk of poor Covid-19 outcomes. HIV and tuberculosis also increase the risk of Covid-19 death, although modestly, and these are more prevalent in poorer areas."

Poorer areas' lower infection rates but higher mortality could be because people in wealthier suburbs had relatively easy access to Covid-19 testing in the private sector, he added.

Young said Covid-19 has exposed disparities in society, particularly in people's ability to protect themselves from the spread of the disease. Authorities should use the pandemic to address the social determinants of health by adjusting guidelines and policies.

Damaris Kiewiets, chair of the Cape Metropolitan Health Forum, said the diversion of resources to fight Covid-19 has left other health services in limbo. "The suspension of routine checkups and screening means that many who are at high risk of Covid-19 complications can't have their health condition in check," she said.

"As a result, many patients have uncontrolled chronic illnesses, including diabetes, hypertension and cardiovascular diseases.

"All the department of health has been doing is to simply refill their chronic meds. There are no doctors to do screening and routine checkups. My own mother, who is a heart patient and is 90 years old, hasn't had an ECG screening that she gets every six months for almost a year now."

"When such patients get Covid-19 they often don't know their health status and if their disease is uncontrolled they are likely to die as their prognosis will be poor and won't be prioritised to get an ICU bed."

Kiewiets said the pressure on hospitals and clinics meant some patients were told to go home and take flu medication. "I've had frantic calls from people who said they had Covid-19 symptoms and were simply brushed off at clinics, only to test positive later. By that time they have infected everyone in their families."

Western Cape head of health Dr Keith Cloete said screening surveys on pregnant women and HIV patients had shown that people in different parts of the metro had different rates of exposure. This was evident in Khayelitsha, where the peak of the second wave was almost half of the first wave, and in Klipfontein, where the peak has just surpassed that of the first wave.

"In the second wave we are seeing a flatter peak in those two areas. We are making a hypothesis that there was some inherent herd immunity in those two areas because of high levels of infection from the first wave.

"Our scientists will look at this. We'll look at the data and then confirm that hypothesis if this is the case."

Dr Shakira Choonara, an independent public health practitioner in Johannesburg, said while comorbidities, age and the strain on health services were likely to be important in determining mortality rates, "researchers/scientists are still attempting to understand why some areas have higher infections and mortality compared to others".

She said so far there is "no clear-cut answer", although there is increasing debate around whether some areas are developing herd immunity, and other factors could include lower testing or poor recording of deaths.

Choonara said official mortality statistics were subject to numerous limitations, and the South African Medical Research Council's (SAMRC's) weekly reports on "excess deaths" during the pandemic had made clear that a significant proportion were likely to be attributable to Covid-19.

By January 5 - the latest date for which SAMRC data is available - there had been 83,918 excess deaths since May 6, when the phenomenon was first observed. By Friday, the official Covid-19 death toll was 36,467.

Choonara said: "Mortality is a highly complex phenomenon and Covid-19 trends will be impacted by factors such as age, comorbidities and access to health services."

Professor Mosa Moshabela, dean of the school of nursing and public health at the University of KwaZulu-Natal, said the crux of the issue was the global phenomenon of "inverse care law".

"This law means that the people who need health care the most are unlikely to access it, and the ones who need it less are likely to access it more," he said.

"So you may find that someone with milder symptoms in an affluent community is far more likely to get easier access to services than someone who is extremely sick in a poorer area.

"We need to make sure that when we do the evaluation of the impact of Covid-19 we are able to access it from a socioeconomic status. Socioeconomic status is more important for me than race because you can do something about socioeconomic status in the short term."

Covid-19 ministerial advisory committee co-chair professor Salim Abdool Karim said Covid-19 mortality rates are influenced by age more than race. There are fewer known cases in the poorer communities because infected individuals are asymptomatic more often due to the younger profile of the population.

Howard Phillips, an emeritus professor of history at UCT and an author of books about previous pandemics, said the poor are always more vulnerable to epidemics due to their socioeconomic circumstances and poor immune systems.

"On the face of it, pre-existing disparities in health, living conditions and access to health care would seem to lie at the root of the difference in mortality, which this pandemic, like others before it, has exacerbated and highlighted," he said.

"Germs driving epidemics search out weaknesses in the societies which they strike and exploit them to the full in their quest to reproduce themselves as quickly as possible.

"They thus affect the most susceptible in communities hardest, those whose constitutions have been compromised by poor health and nutrition, unsanitary and overcrowded living, and those lacking easy access to good medical care at home.

"In doing so they usually worsen these deficiencies, putting those whom they attack at increased risk of death. For these reasons the chief victims of epidemics are the poor."

Covid-19: Stark differences between public and private sector testing

By Amy Green for Spotlight• 24 June 2020

According to the National Institute for Communicable Diseases' most recent weekly Covid-19 testing report, mean test turnaround times in the public sector went from 2.1 days in early May 2020 to 12.4 days in the week ending 13 June 2020. (Photo: freepressjournal.in / Wikipedia) Less

While Covid-19 tests in the private sector are often processed within a day or two – even if the test is not urgent – many patients in public sector hospitals have to wait a week or more. Amy Green investigates the stark differences between public and private sector testing in South Africa.

In South Africa's private healthcare sector, Covid-19 tests are typically processed within a day or two. Tests are also relatively easy to get, provided you or your medical scheme are willing to pay the roughly R900 that it costs. Even if you don't want a Covid-19 test, many private hospitals require you to have one should you plan to be admitted for even a relatively minor elective procedure unrelated to Covid-19.

In stark contrast, healthcare workers and patients in the public sector often have to wait a week, or even weeks, for test results. This has serious implications, including samples being in the queue for so long that they become unusable before they are tested.

Testing crisis

"About a month-and-a-half ago is really when we started to experience a crisis," says a medical doctor, emergency medicine specialist and manager at a public sector hospital in Gauteng. The doctor asked not to be named for fear of potential consequences for her job.

The "crisis" started soon after the testing eligibility criteria were expanded on the recommendation of the National Institute for Communicable Diseases (NICD), and tests started being referred through government's ambitious testing and screening campaign.

"Then, the turnaround time for test results went from 48 hours to anything up to two weeks or more," she says. "Some samples we were waiting for two weeks and at the end of the period, the samples were too old to process and then new samples would have to be acquired from patients. In one case, this happened to a patient three times."

That test turnaround times have shot up in the public sector is confirmed by the NICD. According to their most recent weekly Covid-19 testing report, mean test turnaround times in the public sector went from 2.1 days in early May 2020 to 12.4 days in the week ending 13 June 2020.

The consequences of these delays in hospitals are severe. As the Gauteng doctor explains, not only is this a waste of time and resources, but, for isolation and infection-control purposes, patients suspected of having Covid-19 have to be kept in a separate ward – away from confirmed Covid-19 patients and away from the wards set aside for patients who tested negative. The test result delays caused many patients to remain in overcrowded wards for longer than is needed, potentially infecting negative patients stationed with them. As a result, the doctor says, isolation wards in their hospital are always full.

"Receiving a result within 48 hours is a workable solution, anything beyond that becomes impossible, endangers patients and makes everything harder," she says.

While a week's wait in a district or academic hospital is problematic, things are even worse in some rural areas. Russell Rensburg, Director of the Rural Health Advocacy Project, says in the vast majority of rural areas "test turnaround time is between 14 and 20 days – arguably rendering this tool useless". For example, patients could wait weeks to be told they are positive and need to self-isolate, but by then, they may have exposed and infected untold numbers of individuals in their community.

A different picture in the private sector

While public sector patients, who make up the vast majority of the population, sometimes wait weeks, private sector patients typically get results in a day or two. The Gauteng doctor *Spotlight* spoke to has opted to test privately due to the public sector backlog and, in one case, she says, her results came back to her on the same day.

According to Dr Mzukisi Grootboom, former head of the South African Medical Association and now working as a physician consulting in the private sector and who also consults at a Life Healthcare hospital in Durban, results of tests he performs on his patients return in under 48 hours and the longest wait would be 72 hours.

More recently, be says the turnaround time averages at 24 hours or less. Grootboom suggests that competition and quick turnaround time from smaller labs have pushed the big private laboratories to shorten their times for fear of losing business.

Grootboom also says the private sector has taken healthcare worker testing seriously and has prioritised samples from these individuals with a 24-hour turnaround time having been the norm for this group for some time.

Wasteful testing?

Various sources *Spotlight* spoke to, shared the concern that, while the public sector suffers with capacity, the private sector is testing too liberally. On the face of it, there appears to he something to this argument given that roughly half of the country's almost 1.4 million Covid-19 tests have been done in the private sector (which serves less than 20% of the population), and half in the public sector (which serves over 80% of the population). The actual numbers might be a bit more balanced, given that some people without medical scheme coverage may have paid the R900 out of pocket to get a test in the private sector.

In the private sector, criticism has been levelled at a particular practice, which results in health workers who test positive for Covid-19 (at most hospitals), having to provide two negative results, 48 hours apart, in order to return to work – a practice regarded hy some as both wasteful and unnecessary.

There have been further concerns related to private sector testing practices, especially since the downgrade to Level 3 and elective surgeries once again permitted.

Grootboom says all elective patients have to provide a negative Covid-19 test before they can be admitted, regardless of how healthy or symptom-free they are. In contrast, the public sector rations testing to individuals with symptoms.

"The private sector has a policy that absolutely all admissions must be tested – regardless of risk or symptoms. Since the first week of May 2020, every single admission who comes through the doors of a private hospital needs a Covid-19 test – even if they are coming in for a fractured toe," said a well-placed source. This source also mentioned a case of a private specialist in Cape Town requiring Covid-19 tests for consulting with outpatients.

The public sector has, however, had its own controversies around low-yield testing in the form of the mass screening and testing campaign. It seems likely that the extra testing from this campaign, in part, drove the large public sector testing backlogs (at times over 80,000) reported in recent weeks. Some experts have called for tests to be discarded if it was in the public sector testing queue for too long, but Health Minister Dr Zweli Mkhize has rejected these calls.

According to the NICD, the proportion of people testing positive in the week up to 13 June 2020 was higher in the public sector versus the private sector (14.9% and 14.3% respectively). This difference may or may not indicate that there is more unnecessary testing in the private sector at the moment than in the public sector, hut the difference could also he due to several other factors. Taken over the entire epidemic until 13 June, the proportion testing positive is higher in the private sector than in the public sector (7.6% and 6.4% respectively).

Supply challenges

While the testing hacklog has reportedly been cleared in the Western Cape, the backlog in Gauteng reportedly now stands at 35,000.

"I am greatly concerned hy this huge backlog of tests which is 12,000 higher than the 23,000 backlog reported last week," says DA MPL Jack Bloom in a statement. "The long delays undermine the test, trace and isolate strategy in hotspot areas that is so critical in Gauteng as infections climb exponentially."

Bloom also said that the National Health Laboratory Services (NHLS) "has failed to expand capacity despite claiming earlier that they could do 36,000 tests a day". "I hope that testing is speeded up in future, including greater use of private and university laboratories," says Bloom.

There appear to be two broadly related factors contributing to South Africa's public sector testing backlogs: Testing criteria, and supplies of test kits and reagents. Some emphasise the prior and some the latter.

Speaking to *Spotlight*, NHLS spokesperson Mzimansi Gcukumana places the blame solely on a scarcity of supplies needed to perform the tests. "The unprocessed specimen backlogs are due to sporadic supply of some of the key products from international suppliers," he says. Mkhize has also blamed shortages of test kits and reagents for public sector hacklogs.

Grootboom, however, points out that the private sector experienced the same international supply shortages of key products needed to perform the tests, yet the turnaround times have recovered and are down to 24 hours in many cases.

The public sector testing strategy has come in for criticism from several leading health experts, arguing that there is a mismatch between the testing strategy and the public sector's capacity to do tests. In one recent opinion piece published in *Daily Maverick*, the case was made to "stop random testing" and for the "elimination of unnecessary and wasteful testing countrywide".

While Gcukumana blames the backlogs on supply issues and does not admit errors in the testing strategy, he says that prioritisation of tests is part of the solution. He says the "challenge" of the long turnaround times had been addressed through several interventions, including priority testing and working with the private sector. (There's a list of NHLS interventions at the end of this article.)

He also says that "in many cases, the turnaround time has gone down to two days or lower" and that the NHLS "is making steady progress in clearing unprocessed specimen backlogs".

In some instances, the government is paying for tests from the public sector, but we understand that this is not done at scale.

"The most important thing as far as I'm concerned is that the outbreak is a public health problem and we as a country need to move away from this thinking of public versus private, especially in the time of Covid-19," says Grootboom. "We should start sitting around a table to see how we can collaborate because we are all working towards the same goals."

When to test healthcare workers

One area in which testing criteria and guidelines are particularly controversial relates to healthcare workers. The Gauteng doctor says she is "very, very concerned" by a guideline issued by the Gauteng Department of Health requiring that health workers who test positive for Covid-19 must, after the mandatory 14-day quarantine period, produce a negative result to return to work.

"A big problem with these long turnaround times using the NHLS is that many health workers are sitting at home much longer than they should or need to because they are awaiting a negative result," she says.

This has potentially serious ramifications for a further shrinkage of the public sector's already overstretched workforce.

However, because Covid-19 is such a new disease, there is some confusion when it comes to healthcare worker management.

According to the Gauteng doctor, while the provincial department has issued this rule, guidance from the national Department of Health does not recommend the production of a negative test, provided the health worker is well enough.

The national Department of Health declined to comment on this and other issues put to it by *Spotlight*, and instead referred requests for comment to the NHLS.

"We don't know for sure, but the evidence suggests people are probably not infectious after seven days after they first show symptoms," says the Gauteng doctor.

There is some international guidance suggesting drastically shortened quarantine periods for asymptomatic individuals. The US' Centers for Disease Control has recommended that, as long as one has had no symptoms for three days, one can return to work.

"Another problem is that an individual can remain positive for Covid-19 for up to two months after showing symptoms, with the majority of this time spent asymptomatic and un-infectious," she says. However, Grootboom says that testing positive for Covid-19 for extended periods is usually limited to individuals who become severely ill. "Those with mild symptoms clear the virus rapidly from the body," he says.

NHLS interventions implemented to address the public sector Covid-19 testing backlogs, as communicated to *Spotlight,* include:

1. Prioritising all in-hospital tests, patients under investigation, contacts and critical care workers.
2. Monitoring the rate of test positivity in the provinces and districts to ensure that the NHLS is prioritising resources to these high positivity hotspots.
3. Improving sample workflow and testing process with innovative methods of extraction, including heat and lysis to manage the demand of extraction and testing kit shortages. The supply of extraction kits has improved slightly.
4. Engage private and academic research laboratories to assist where they have spare capacity and test kits available.
5. Reaching out to smaller private laboratories with molecular testing platforms to help manage the increased testing demand. **DM/MC**

** Note: An unnamed source is quoted in this article. While we generally avoid quoting unnamed sources, we sometimes do so when the following three conditions are met: (1) We have good reason to believe the information to be true, (2) publication of the information is clearly in the public interest, and (3) the source might suffer harm if identified.*

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ISSUES IN PUBLIC HEALTH

The Competition Commission Health Market Inquiry Report: An overview and key imperatives

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The Competition Commission's Health Market Inquiry (HMI) is the most systematic and comprehensive investigation carried out into the South African private health sector. The recommendations as set out in the HMI Final Report merit extensive discussion and debate, as they could – if implemented – have far-reaching consequences for the future of the healthcare system. The objective of this article is to contribute to this discussion by providing an overview of the key findings and recommendations of the HMI and highlighting the resultant key imperatives at this critical juncture of policy development.

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The South African (SA) private healthcare system is relatively well resourced, with substantially higher per capita spending than the public sector. Private healthcare inflation has been consistently higher than the consumer price index, making cover increasingly unaffordable.[1] In the light of these increases, which only a minority of South Africans can afford, the Competition Commission (CC) initiated the Health Market Inquiry (HMI) in 2013 to investigate and provide explanations for these increases in price and expenditure.[2]

Spanning 7 years, the HMI is the most systematic and comprehensive investigation that there has yet been into the SA private healthcare sector. The HMI Final Report,[3] published in September 2019, documents its findings and recommendations in over 250 pages. The recommendations merit extensive discussion and debate, as they could – if implemented – have far-reaching consequences for the future of the healthcare system.

This article is written in the context of significant proposed reform to the SA health system as outlined in the National Health Insurance (NHI) Bill,[4] which will have important implications for the design and regulation of the private healthcare sector. To improve the feasibility and sustainability of NHI, it is imperative that action is taken to address the many issues identified by the HMI in parallel with the incremental NHI implementation process. Well-regulated, efficient, responsive and affordable private voluntary health insurance will be key to achieving universal health coverage (UHC), aligned with the vision of NHI. The collapse of private insurance in SA, a very real risk if the HMI recommendations are not implemented, will only serve to delay UHC, and impede progressive realisation of the right to health for another generation. The objective of this article is to contribute to discussion by providing an overview of the key findings and recommendations of the HMI and highlight the resultant imperatives at this critical juncture of policy development.

Purpose and process

The HMI was initiated in response to concerns regarding affordability of private healthcare cover in SA. The Terms of Reference published in the *Government Gazette* on 29 November 2013 stated that the CC wanted the HMI 'to establish whether there are any factors that prevent, distort or restrict competition in the private healthcare sector' and to collect information to 'provide a factual basis upon which the Commission can make evidence-based recommendations that serve to promote competition in the interest of a more affordable, accessible, innovative and good quality private healthcare'.

While Judge Sandile, Chairperson of the HMI panel, acknowledged 'that the crucial issue of equitable and fair access to good quality healthcare services does not rest entirely on competition',[2] the HMI carried out its investigation primarily through a competitive lens to answer 'whether there are features in the private healthcare markets for services and goods which harm competition or have the potential to harm competition'. Judge Sandile further noted that 'A comprehensive commission of inquiry into the state of healthcare in both the public and private sectors may be more appropriate to evaluate the general state of healthcare services in South Africa in order to give effect to the constitutional right of access to healthcare services and goods guaranteed in section 27 of the Constitution'.[2]

The CC appointed a panel of six experts to conduct the HMI. The establishment phase involved setting up the platform for the inquiry process, and initial engagement with stakeholders. The evidence-gathering phase entailed: (*i*) background research; (*ii*) more than 15 000 pages of written submissions from stakeholders, mainly technical data and information on various healthcare markets; (*iii*) data from 175 stakeholders (including financial data and detailed claims data for 2010 - 2014 from 80 medical schemes); and (*iv*) public hearings and seminars on selected topics. The third phase

entailed analysis of the data and information collected, to determine expenditure and cost trends, profitability and market power. The fourth phase included the publication of the Provisional Report on 5 July 2018[5] and an invitation to stakeholders to submit comments. Following review of the comments received, the Final Report was published on 30 September 2019.

Key findings and recommendations

The focus of the inquiry was the 8.8 million lives (total SA population 53.7 million) covered by private health insurance. The key role players in the healthcare market identified by the HMI were the public health sector, regulatory bodies, medical product suppliers, private healthcare providers (practitioners, facilities, emergency services and pharmacies), private healthcare funders and industry bodies. The HMI focused largely on the interplay between private financers and providers, and the role of regulation and regulatory bodies governing that interaction.

Chapter 3 of the Report sets out the Competitive Assessments Framework, where the HMI assessed the competitive issues related to the private healthcare market. The framework comprised six 'harms to competition' (any effect adverse to the realisation of more competitive outcomes for consumers). These included distortions in relation to: (*i*) financing; (*ii*) facilities; (*iii*) practitioners; (*iv*) barriers to entry, expansion, intervention and innovation; (*v*) imperfect information; and (*vi*) the regulatory framework.

In effect, the HMI relied on a broad microeconomic assessment framework. For the purposes of this article, we summarise the findings and recommendations within a more generic classic microeconomic framework as set out by Parkin *et al.*[6] and summarised in Table 1. The framework identifies four key conditions to be met for a market to be competitive: (*i*) no or limited market concentration, with a large number of buyers and sellers; (*ii*) free entry into and/or exit from the market, with no or lower barriers to entry and exit; (*iii*) 'transparency' with regard to the product being bought/sold in the market – producers should be competing on the price and quality of a fairly homogeneous product; and (*iv*) perfect consumer information – consumers should be sufficiently informed to make an informed choice when purchasing the product. Although the HMI examined competitive issues at a more granular level, we use this framework to summarise the findings and recommendations broadly for (*i*) providers of healthcare services (providers), and (*ii*) funders of healthcare services (funders).

The overall conclusion of the HMI is that the private SA healthcare market suffers from multiple market failures from both provider and funder perspectives, with structural, behavioural and regulatory problems that harm competition and undermine access to healthcare. The HMI ascribes this situation to regulatory failure due to deregulation in the 1980s, followed by partial and incomplete re-regulation and failure to monitor and ensure regulatory compliance.

The provider-side problems and recommendations to address the problems are summarised in Table 1.

The HMI found that the combination of healthcare practitioners acting as agents for ill-informed individuals requiring healthcare and the perverse incentives associated with the largely fee-for-service remuneration environment facilitated supplier-induced demand; this was the key driver for increases in healthcare utilisation and costs.

The HMI found the healthcare facilities market to be highly concentrated, with three groups (Netcare, Mediclinic and Life) dominating and little evidence of competition between them; this led to the conclusion that the absence of any meaningful recent entry into the facilities market was suggestive of significant entry/exit barriers. The HMI found a lack of transparency in the services provided by facilities and providers, including a lack of price transparency and reporting on quality and outcomes, with non-compliance with protocols and guidelines. It also reported a lack of information and/or communication from healthcare suppliers and facilities that would allow consumers to make informed choices.

The HMI recognised the need to improve the regulatory environment governing suppliers and recommended the establishment of a dedicated supply-side regulator of health (SSRH)

Table 1. Provider problems and recommendations

Condition	Problem	Recommendations

Market concentration	• Three dominant hospital groups
	• Little evidence of competition between practitioners across specialties
		• Improve regulatory environment by establishing an SSRH responsible for:
		  • Facility planning, including licensing
		  • Conducting economic value assessments of health technology and interventions
		  • Monitoring of health services
		  • Pricing of health services
		• Implement interventions to promote competitive and value-based contracting, moving away from fee-for-service contracts
		• Establish an OMRO
		• Separate academic and business functions of practitioner associations
		• Change HPCSA ethics rules to promote innovation in models of care
		• Institute guidelines for associations to ensure that they are not anti-competitive
		• Effect curriculum changes in training of healthcare practitioners to ensure greater awareness of cost implications of treatment decisions

Free entry/exit	• No meaningful entry in past decade	
Transparent product	• No price transparency • Lack of reporting on quality, outcomes • Non-compliance with protocols and guidelines • Fee for service – perverse incentives	
Perfect consumer information	• Practitioners act as agents	

SSRH = supply-side regulator of health; OMRO = outcome monitoring and reporting organisations; HPCSA = Health Professions Council of South Africa.

with four main functions: (*i*) facility planning (including licensing); (*ii*) economic value assessments; (*iii*) monitoring of services; and (*iv*) pricing. A primary concern is the high level of national and local concentration in the hospital market and the need to implement and update the provisions on the Certificate of Need in the National Health No. 61 of 2003.[2]

The funder-side problems and recommendations to address them are summarised in Table 2.

Overall, the HMI concluded that 'funders compete in an environment which is characterized by an incomplete regulatory framework, so distorting the parameters of competition'. The HMI found the funder market to be highly concentrated, with 70% of insured lives in two medical schemes (Discovery Health and GEMS (Government Employees Medical Scheme)) and 76% of insured lives administered by two companies (Discovery Health and Medscheme). The HMI concluded that there was little competition and that funders, together with administrators and managed care companies, had failed to manage supplier-induced demand or moral hazard. Competition between schemes to improve affordability and value-for-money cover was limited: instead schemes competed based on risk factors, such as attracting healthier members.

The complexity of the offerings by medical schemes (270 products) made it difficult for consumers to compare and make informed choices. Consumer information was incomplete, and the role of brokers and other agents in directing consumer choice was questionable. The HMI further concluded that scheme and member interests were misaligned, with limited incentives to ensure that scheme employees and trustees act in the best interests of members and hold administrators to account.

The HMI funder recommendations 'are designed to complete the regulatory framework, and to create a market environment conducive to effective competition on pro-consumer metrics'. While funders were better regulated than suppliers, regulation was incomplete and needed to be improved. Interestingly, while the HMI recognises that mandatory cover would address the problem of anti-selection, it recommends that the 'industry needs to show clear indications of close alignment to consumer interests and better cost containment' before mandatory cover is introduced. To 'remove the current incentive for schemes to compete on low level competitive factors such as attracting a younger population', the HMI recommends the implementation of a risk-adjustment mechanism (RAM) and income cross-subsidisation to mitigate the impacts on scheme costs.

To address the issue of product transparency and homogeneity and consumer information, the HMI recommends the implementation of a standardised package of benefits, explicitly defined and offered by all schemes, with supplementary packages provided in a transparent manner. It further recommends that the standard package be based on revised Prescribed Minimum Benefits (PMB), covering catastrophic expenditure and some level of out-of-hospital and primary care, with a view to encouraging reduced use of higher levels of care. The package should be based on assessments conducted by an SSRH economic value assessment unit using health technology assessment (HTA) and clinical treatment protocols to encourage effectiveness and efficiency. The HMI concludes that establishing an appropriate regulatory framework is necessary to facilitate innovative and alternative models of care that permit interprofessional and interdisciplinary group practice; this would have a positive effect on the provision of care and prevent revenue-maximising behaviour.

A number of recommendations were aimed at enhancing governance, including more stringent reporting requirements, review of reimbursement requirements to better align scheme and member interests, minimum education and training standards for trustees and principal officers, and steps to encourage member participation in trustee elections.

Key imperatives

The findings and recommendations of the HMI are broad and wide ranging, though neither profound nor unexpected, especially from a process that cost at least ZAR196 million and took 7 years to complete. At a broader level, the HMI process and outcomes highlight the need for a review of policy development and co-ordination processes. If government is committed to healthcare for all, would a more comprehensive inquiry into the state of healthcare in both the public and private sectors – as recommended by the chairman of the HMI panel – not have been more appropriate? Alternatively, if government is committed to NHI as the solution to the problems of healthcare, the usefulness of a major enquiry into private healthcare at this time must be questioned.

In any event, the HMI recommendations need to be contextualised within the broader political context of healthcare policy and planning initiatives, especially the government's intention to address the inequities and failings of the two-tiered SA healthcare system through the proposed NHI. Within this context, it makes sense to prioritise the HMI recommendations that not only assist in

Table 2. Funder problems and recommendations

Condition	Problems	Recommendations
Market concentration	• High level of concentration in schemes and administrators • Lack of competition among funders and administrators • Scheme and member interests not aligned • Failure to manage supplier-induced demand, moral hazard	• Introduce single, comprehensive, standardised base benefit option • Introduce a risk-adjustment mechanism • Review contracts to ensure move to value-based contracting • Review training requirements and incentives for boards of trustees and principal officers • Introduce an active opt-in system for brokers • Continue with existing CMS functions • Review PMB • Review governance • Improve anti-selection measures
Free entry/exit	• No meaningful entry in past decade	
Transparent product	• Multiple product offerings • Lack of transparency and comparability	
Perfect consumer information	• Incomplete information • Distortions due to brokers and other intermediaries	

CMS = Council for Medical Schemes; PMB = Prescribed Minimum Benefit.

improving the current healthcare environment but are also necessary for the successful implementation of NHI.

Taking into account the above, the HMI provider-side recommendations, and in particular the recommendation to establish the SSRH, should be a major implementation priority to address some of the major problems in the current healthcare environment. This is also necessary for the NHI environment; while NHI would have power as a funding body, it would have no regulatory powers and would have to rely on a suitably empowered regulatory body to deal with supplier regulatory issues. There is also a need for a major review of the regulatory environment of the statutory councils that govern health professionals.

The introduction of an economic value assessment unit within the SSRH or as an independent entity is a particularly low-hanging fruit. Through such an entity, the benefit package can be explicitly defined[9] through the inclusion of cost-effective interventions enabled by HTA. The establishment of an economic value assessment unit would ease pressure on the Council for Medical Schemes by alleviating the need to make coverage decisions on a case-by-case basis and contribute to the determination of a revised standardised benefits package, a highly urgent task as the last substantial revision to the PMB was almost 20 years ago. Crucially, this unit could inform and later merge with the HTA and benefits package design process envisioned under NHI. There would be highly useful synergies in a common institution providing economic assessment in both the public and private healthcare sectors, noting critical differences between the decision frameworks underpinning a regulated standard benefits package under a voluntary health insurance mechanism (constrained by criteria such as average premium relative to national household income and scheme viability) and the comprehensive package of benefits under a tax-based UHC mechanism under NHI (constrained by total government health expenditure). Should voluntary health insurance be restricted to supplementary care, following full implementation of NHI (in 2026 at the earliest) the differentiation between a regulated private insurance package and the publicly funded package may become more stark, but both sectors would still require economic assessments to determine efficiency, effectiveness and equity.

A critical concern in the recommendations relating to an economic value assessment unit is the institutional capacity, human resources and research funding required to support economic value assessment of all services within the base benefit package. The HMI correctly determined that the current absence of regulations on HTA is a significant regulatory failure, yet no interim recommendations are made as to how the institutional capacities should be developed. International experience indicates that comprehensive HTA functionality requires dedicated, stepwise strategies related to institutional development and skills and knowledge capacity strengthening.[9] These strategies cannot be limited to NHI processes only and should be funded, developed and implemented urgently.

The case for the HMI funder recommendations is less clear cut. There is currently a need for regulatory coherence between the Council for Medical Schemes and the Health Professions Council of South Africa. The publication of the Medical Schemes Amendment Bill[10] prior to completion of the HMI underlines the question of co-ordination between statutory bodies. While some of the HMI recommendations have been incorporated into the Medical Schemes Amendment Bill, the establishment of the RAM, a key recommendation, was not, and it remains unclear whether it will be adopted.

Conclusions

The efficiency of the process used for the HMI can be questioned, and the findings are neither profound nor unexpected. However, the recommendations are important and should be acted upon, as they will not only assist in improving the current healthcare environment but are critical for successful implementation of NHI.

Declaration. None.

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Conflicts of interest. GCS is employed on a contractual basis by NMG Consultants and Actuaries, an independent consulting firm providing consulting and actuarial services to SA private health insurance funds. NMG did not have any role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript. As such, there were no conflicts of interest in the conduct of the study.

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Private sector involvement in funding and providing health services in South Africa: Implications for equity and access to health care

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3.4.3 Pharmaceutical manufacturer groups

The two largest South African owned pharmaceutical manufacturers are Aspen-Pharmacare and Adcock Ingram. Aspen (Aspen Holdings, 2009) is Africa's largest pharmaceutical manufacturer and the largest generics manufacturer in the southern hemisphere. It has eleven manufacturing sites (four in South Africa, two in East Africa, two in India and three in Latin America) and business interests in South Africa, Australia, India, Brazil, Mexico, Venezuela, Kenya, Tanzania, Uganda, Mauritius and the United Kingdom. In 2008, it recorded revenue of R4.9 billion and an operating profit of R1.4 billion. The major shareholders of Aspen (i.e. those with more than 5% of shares) are: the Chemical, Energy, Paper, Printing, Wood and Allied Workers Union (CEPPWAWU) (5%); the Public Investment Corporation (6%); Allan Gray Asset Management (9%); and Pharmacare Ltd (10%). Aspen directors, particularly Stephen Saad (Chief Executive) and Gus Attridge (Deputy-Chief Executive), also own substantial shares.

Adcock Ingram (2009) has a large over-the-counter (OTC) medicine component, but also produces prescription medicines and hospital products. Adcock Ingram had a turnover of R3.3 billion in 2008 — R1.1 billion was related to OTC medicines, R1 billion to prescription medicines, and R1.2 billion to hospital products. Key shareholders are: mutual funds (22%); banks (17%); pension funds (14%); investment companies (mainly the Public Investment Corporation) (13%); insurance companies (8%); and public companies (7%).

3.4.4 Key issues

There is evidence of sizeable concentration in the private health care industry in South Africa, in terms of three large private hospital groups, a handful of pharmaceutical manufacturers, and a number of different medical scheme administrators owned by one company. The full extent of vertical integration could not be untangled due to limited disaggregated shareholder information, but it is likely that certain banks and investment companies have large shareholdings across medical scheme administrator, private hospital and pharmaceutical manufacturer groups. For example:

- two of the largest private hospital groups (Netcare and Medi-Clinic) each own the two largest private emergency response groups (Netcare 911 and ER24 respectively) (see www.netcare.co.za and www.mediclinic.co.za);
- private health care providers (doctor groupings and private hospitals) and organisations with interests in pharmaceutical and medical equipment manufacturers are investing in medical scheme administrators (particularly via Lethimvula) (see www.medscheme.co.za and www.lethimvula.co.za); and
- one of the largest private hospital groups (Medi-Clinic) runs the largest private health professional employment agency (see www.mediclinic.co.za).

Many South African owned private health care companies also have considerable business interests outside of South Africa. In some cases this is restricted to other African countries or low- and middle-income countries in Asia or Latin America, but in others, it also includes high-income countries such as Australia, the United Kingdom and Switzerland. There has been a growing diversification of business interests in recent years to the extent that in some cases (e.g. Netcare) the major share of turnover is now from external business interests.

4. Critical evaluation of private health sector

This section evaluates the key challenges facing the private health sector, focussing on changes in the private health sector over the past decade or more and the drivers of these trends. We then consider how the private health sector impacts on the overall health system in South Africa, which provides a basis for considering recommendations for major health system change, in the form of introducing a National Health Insurance (NHI) in section *5*.

4.1 Extent of expenditure increases in medical schemes

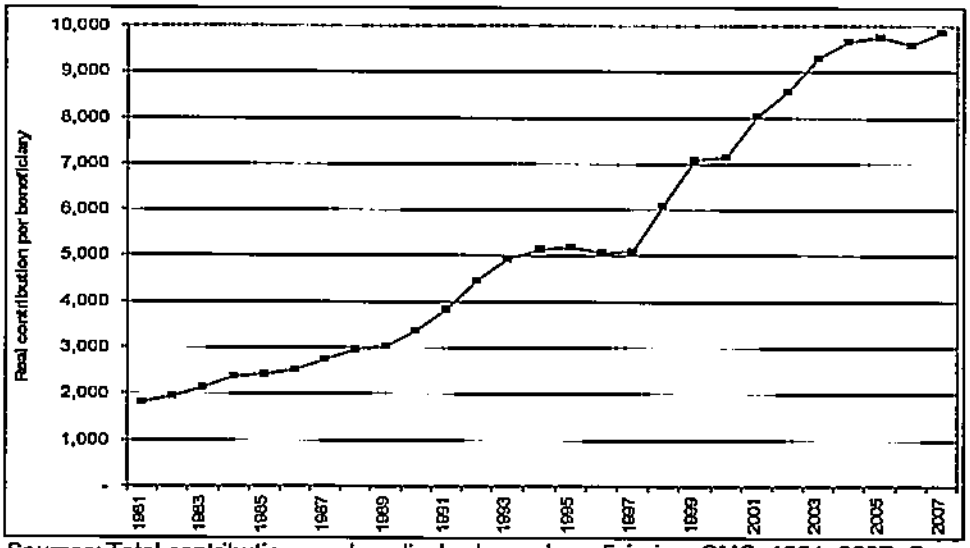
Possibly the greatest challenge facing the private health sector is the rapid increase in spending, particularly by medical schemes. Medical schemes operate on a 'pay as you go' basis, i.e. contribution revenue roughly approximates spending on health services, administration and related activities in any year. As spending increases, so do contributions.

However, contributions to medical schemes have far exceeded inflation rates in the past two and a half decades — except in 1996 and 2006, when contribution increases did not exceed the consumer price index (CPI). *Figure 12* shows increases in medical scheme contributions over and above CPI, i.e. increases in real terms. Scheme contribution increases exceeded CPI by an average of 7.9% annually between 1981 and 1990, by 8% per year between 1991 and 2000, and by an average of 3.5% annually between 2001 and 2007. In some years, contribution increases were very large, such as exceeding inflation by 19.6% in 1998 and 16.6% in 1999.

In nominal terms (i.e. actual increases — some of which may result from general inflation), annual medical scheme contributions per beneficiary increases:

- exceeded 30% in 1991 (31%) and 1992 (32%);
- equalled or exceeded 25% in 1984 (25%), 1987 (26%), 1990 (27%) and 1998 (28%); and
- exceeded 20% in 1982 (22%), 1983 (24%), 1986 (24%), 1988 (21%), 1993 (21%) and 1999 (23%).

Figure 12: Real average medical scheme contribution per beneficiary per year, 1981–2007 (2008 base CPI)



Sources: Total contributions and medical scheme beneficiaries: CMS, 1981–2007; Consumer Price Index: Statistics South Africa, 1981–2007

In effect, medical scheme members have been faced with substantial increases — far greater than general inflation — in their contribution rates on an annual basis for an extended period. Although there was a period of respite from increases in the mid-1990s, this was followed by huge increases in 1998 and 1999. There is no guarantee that this trend will not be repeated in the next few years, to follow on from the constrained contribution rate changes since 2004. The average real contribution per medical scheme beneficiary per year has increased from about R1,800 in 1981 to nearly R9,900 in 2007 (both expressed in 2008 Rand values). Expressed differently, after taking into account the effect of general inflation, medical scheme contributions have increased five-fold in the past two and a half decades. The most rapid real increases were experienced between 1997 and 2004, with an increase in the real per beneficiary contribution rate of nearly 100% in seven years.

The profound implication of annual increases in medical scheme contribution rates above CPI is possibly best seen in relation to average wages. To explore the relationship of medical scheme contributions to average wages, and how this has changed over time, total scheme contributions for the principal member plus their dependents can be compared with average wages of formal sector workers. Unfortunately, no trend data on the average wages and salaries of medical scheme members over time exists, so average wages of all formal sector workers (whether or not they are scheme members) has to be used. The average number of dependents per principal member decreased from 1.65 dependents per principal member in the early 1980s, to 1.36 dependents per principal member in 2007.

A household with only one member working in the formal sector would have had to devote just over 7% of average wages to medical scheme contributions in 1981 (to cover ±2.65 beneficiaries[2]). This increased to 14% of average wages by 1991, 20% by 2001 and almost 30% by 2007. Not only have annual increases far exceeded CPI, they have also outstripped the rate of increase in average formal sector wages. Medical scheme contributions thus impose a sizeable burden on the average working household in South Africa.

This does not reflect the actual percentage of medical scheme members' wages devoted to medical scheme contributions as the calculation is based on the average wages of all formal sector workers and not only those who are medical scheme members. Most formal sector workers who belong to medical schemes fall into the higher income bracket. The IES indicates that contributions are about of 9% of household income (which includes wages and other income such as interest from investments) for medical scheme members, but vary significantly from less than 6% for the highest income medical scheme members to 14% for the lowest income members (see *Figure* 2).

Nevertheless, the fact that medical scheme contributions are currently 30% of average formal sector workers' wages is significant, as it explains why medical schemes have found it impossible to extend coverage to lower income workers over the past decade or more. More importantly, it shows why a Social Health Insurance (SHI) option is unlikely to be feasible in South Africa at this point in time. (In the early 1990s, a SHI to cover all formal sector workers and their dependents (via medical schemes) was seen as a possible way to address challenges in the health sector. The lowest income workers who are currently not medical scheme members would be drawn into a SHI.) If a SHI were introduced using the current medical scheme model, SHI contributions would be about 30% of average wages — this is likely to be a realistic estimate of the burden of SHI contributions: even though contribution rates of the newly insured would approximate those of the lowest cost schemes currently available, SHI would still amount to an average 30% of wages, because SHI would be required to cover all dependents, while current medical schemes do not.

Unfortunately there are no reliable trend data on OOP payments. This prevents a similar analysis of these payments as provided above for medical schemes. However, it is known that these payments have also been increasing quite rapidly as medical schemes have introduced more co-payments and as benefit packages, particularly for 'day-to-day' expenses, have become more restricted.

4.2 Factors contributing to expenditure increases

As indicated earlier, contribution increases occur because spending by medical schemes has increased; schemes have to ensure that contribution revenue approximates spending levels each year. But, what aspects of medical schemes expenditure has been rising and why?

[2] The principal member plus average of 1.65 dependents per principal member = 2.65 beneficiaries

4.2.1 Increased spending on medicine

In the 1980s through to the early 1990s, the largest increases in spending by medical schemes related to medicines, followed by private hospitals and then specialists. Increased spending can arise from both increases in unit costs (i.e. the fees charged by providers) and increases in utilisation. Previous research highlighted that a key reason for increased spending on medicines in the 1980s to early 1990s was the growth in dispensing by medical practitioners (i.e. instead of writing a prescription for a patient to take to a pharmacy, doctors began dispensing and selling medicines directly to patients). In 1988, 4,400 doctors were registered to dispense medicines and this nearly doubled by 1992 when over 8,300 were registered as dispensing doctors (McIntyre et al, 1995a). More and more medicines, and more expensive medicines, began to be dispensed by doctors. The cost of medicines dispensed by general practitioners per medical scheme beneficiary increased from R85 in 1985 to R233 in 1990 (ibid).

Part of the explanation for doctors increasingly taking on a dispensing role, was that the fee being paid to general practitioners by medical schemes was tightly controlled in the 1980s and early 1990s. At the same time, the number of doctors practicing in the private sector was rapidly increasing. In the early 1980s, about 40% of doctors worked in the private sector (Naylor, 1988). By 1990, 62% of general doctors and 66% of specialists were in private practice (Rispel and Behr, 1992). However, the population being served by private doctors was not increasing much (either in terms of people covered by medical schemes or in terms of those not covered by schemes but able to occasionally visit a GP and pay on an OOP basis). Dispensing and selling medicines by medical practitioners was a way to ensure an acceptable income for private doctors.

Private hospitals also contributed to the rapid increase in spending on medicines, as they were able to secure substantial discounts from pharmaceutical manufacturers, but sold these medicines to patients at full retail price. As became clear during court cases in 2004, which challenged newly introduced medicine pricing regulations, a large share of private hospitals' profit was generated from the sale of medicines. This provided an incentive to sell as many medicines as possible, as well as to focus on more expensive medicines.

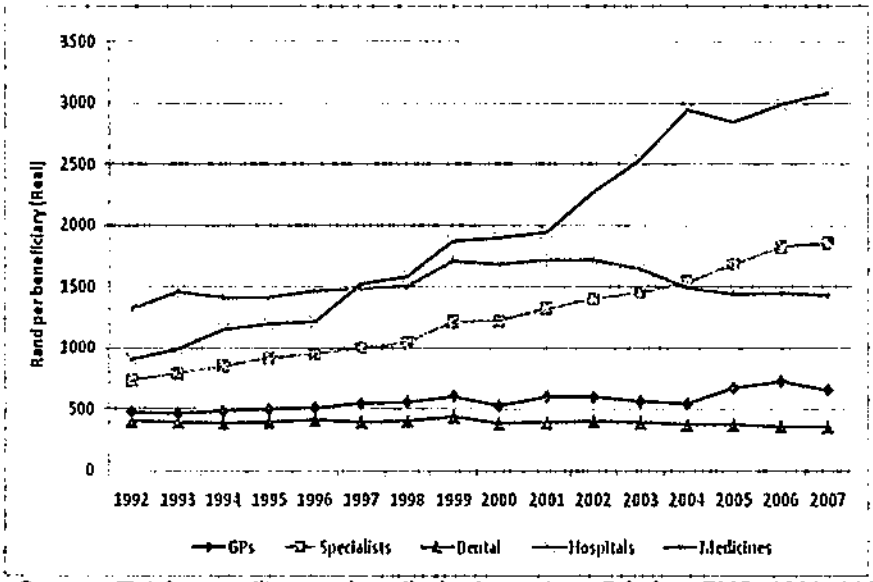
Increased spending on private hospital services (over and above their sale of medicines) was related to a rapid growth in the number of private for-profit hospitals. The number of beds in such hospitals increased from 9,825 in 1988 to 18,432 in 1993 (McIntyre et al, 1995a). Doctors, who ultimately decide on hospital admissions, have a stake in the financial performance of some hospitals through share ownership or other forms of financial relationships, such as rent-free or subsidised consulting rooms within hospitals. This may encourage higher levels of hospitalisation, longer periods of admission and greater use of expensive diagnostic technology provided in these hospitals.

Figure 13 illustrates the trend in spending on different health services by medical schemes over the past decade and a half. These figures are expressed in terms of real spending per medical scheme beneficiary, so reflect spending increases over and above general inflation and that are not associated with any change in medical scheme membership numbers. It is very clear from this figure that spending increases over this period have been largely driven by private for-profit hospitals and specialists. By 1997, private hospitals had overtaken spending on medicines as the largest component of medical scheme spending.

Spending on medicines levelled off for most of the 1990s and then decreased in real per beneficiary terms. Several factors contributed to this including efforts by medical schemes to actively manage chronic medicines for members; those with a chronic illness had to register a request for approval of their medication with the scheme and the scheme would generally approve the least cost alternative. Legislation was also introduced requiring pharmacists to offer a generic substitute of prescribed medication to patients. There has been a dramatic increase in use of generic products over the past decade. Regulations, in early 2004,

introduced price control on medicines and outlawed discounting, so manufacturers were required to sell at a 'Single Exit Price' (i.e. the same price to all purchasers).

Figure 13: Trends in real spending on different health services by medical schemes, 1992–2007 (2008 base CPI)



Sources: Total expenditure and medical scheme beneficiaries: CMS, 1992–2007; Statistics South Africa, 1992–2007

Previously, purchasers such as private hospitals and dispensing doctors were granted enormous discounts (up to 80% of the stated price) to ensure that their product was included on the hospital formulary or dispensed by doctors. Small retail pharmacies, particularly in rural areas, paid the highest price for medicines. These discounts were not necessarily passed on to consumers. The introduction of a Single Exit Price, set at the level of the previous list price less the value of previous discounts, translated into an average price decrease of about 22% (McIntyre et al, 2007).

4.2.2 High cost services and fee increases in private hospitals

The growth of private-for-profit hospitals has continued unabated, with the number of private hospital beds increasing from 18,432 in 1993 to 28,361 beds in 2007, with similar effects to those seen in the late 1980s and early 1990s. There are also more private hospital beds relative to the population served (almost wholly medical scheme members – see *Figure 11*) than many OECD countries (CMS, 2008b). Annual CMS reports recently highlighted that private hospitals were performing more high cost services, e.g. Caesarean sections, magnetic resonance imaging (MRI) and computed tomography (CT) scans and angiograms. When private hospitals buy expensive high-technology equipment (mainly to attract the best specialists to their hospital) substantial pressure is applied on clinicians to use the equipment to earn hospital revenue. The South African private sector has more MRI and CT scanners per million population than countries like Canada, France, Germany, the Netherlands, Sweden and UK) (CMS, 2008b). Effectively, the private hospital market is heavily over-capitalised.

Prices of various private hospital services (e.g. ward fees, theatre costs, etc.) have also greatly increased in the past few years. Private hospital beds owned by three large hospital groups now exceeds three-quarters of all private hospital beds. As shown in a submission to the Competition Commission (van den Heever, 2007), there are clear indications that these groups are using oligopoly power to charge excessively high prices, and not to engage in price competition with each other.

Recent fee increases at private hospitals are driven by the mismatch in power between the three large hospital groups dominating the private hospital market and the 120 individual medical schemes. Initially, the Representative Association of Medical Schemes (RAMS) — now called the Board of Healthcare Funders (BHF) — annually published a list of recommended fees that medical schemes used as the basis for reimbursing providers. At the same time, various professional associations (e.g. representing doctors or dentists) published recommended fees for their members to charge — usually much higher than the RAMS/BHF fees. Nevertheless, at first, many providers charged RAMS/BHF fees so that medical schemes would fully reimburse their bill and providers did not have to rely on patients to pay and claim back from their medical scheme, so a provider could avoid 'bad debts' or unpaid bills (McIntyre et al, 1995a). Over time, however, providers judged it more profitable to run the risk of incurring some bad debts but being able to charge any fee they wished (McIntyre et al, 2007).

In the early 2000s, the Competition Commission ruled that it was anti-competitive for a body like BHF or a professional association (like SAMA) with no statutory to publish a fee schedule (Competition Commission, 2009). Although the *National Health Act 61 of 2003* makes provision for a National Health Reference Price List (NHRPL), which recommends fees for different health services provided by private practitioners or hospitals, these are not mandatory, so the over 120 individual schemes have to negotiate with the oligopoly of three large private hospital groups.

Increases in spending on specialists are also related to utilisation and fee increases. The Health Professions Council particularly contributed to fee increases by generalist and specialist doctors, when it stated in 2004 that it would regard a fee of up to three times the NHRPL fee to be ethical, when considering patient complaints about excessive charges. Doctors have interpreted this as a signal, and most (particularly specialists) started charging 300% of the NHRPL fee since the council decision (van den Heever, 2007).

4.2.3 The ageing population

Over the years, medical schemes and private providers have regularly attributed health care spending and contribution increases to ageing of the population (Fourie and Marx, 1993). This can be partly assessed by considering the proportion of medical scheme members who fall into the category of pensioners. There was a quite dramatic change in this indicator in the late 1980s; in 1986, 5.3% of scheme beneficiaries were pensioners, which had increased to 7.2% by 1992 (McIntyre et al, 1995b). However, in 2007, only 6.2% of scheme members were pensioners. The average age of medical scheme members in 2007 was 31.4 years (down from 31.6 in 2006) (CMS, 2008a). A recent analysis of medical schemes expenditure found that ageing of the population is only a minor contributor to increased spending (CMS, 2008b).

4.2.4 Third party payments

All things considered, the heart of the problem of expenditure increases in the medical schemes sector is reimbursement of private for-profit health care providers by a 'third-party payer' (medical schemes) on a fee-for-service basis. The notion of a third-party payer relates to the fact that a health care provider (e.g. a doctor or a hospital) provides services to patients, but a 'third-party' pays the provider for this service on behalf of the patient. Since these payments take the form of fee-for-service, provider earnings are directly related to the volume of services provided, so there is a clear economic incentive to providers to increase the number and type of services provided (so-called supplier-induced demand). As payments are made by a 'third-party', providers are less concerned about the impact of such practices on their patients, who are not paying them directly. At the same time, patients are less likely to question the diagnosis and treatment advice of a provider and may use health care providers more frequently and intensively than they would if they were paying the provider directly. This web of perverse incentives arising from fee-for-service payments by a third-

party is exacerbated by the growing power imbalances between schemes and providers, which allows providers to unilaterally increase their fees.

4.2.5 Non-health care costs

It is also important to recognise that contribution increases are not only attributable to increased spending on health services but also to increases in non-health care costs. At present, administration costs account for just under 10% of total medical scheme spending. However, a further 9% is attributable to managed care activities and brokers' fees (CMS, 2008b). Although there is no legislated maximum administration charge, for decades there has been an unwritten understanding that administration costs should not exceed 10% of total spending by medical schemes. This unofficial maximum has been respected, but as annual contributions and spending on health services have increased at rates far exceeding inflation, administration costs have also increased rapidly in real terms.

Managed care mainly relates to chronic medicine management and pre-hospital authorisation. Managed care activities are usually undertaken by organisations owned by a 'parent' company that also owns medical scheme administration companies. For example, Metropolitan Holdings Limited owns both Qualsa (a managed care organisation) and Metropolitan Health Group (the third largest medical scheme administrator). So Metropolitan Holdings Ltd (and other large medical scheme administrators) can extract administration fees **and** managed care fees from medical schemes.

Brokers are a relatively new phenomenon in South Africa. They persuade individuals interested in medical scheme cover to join certain schemes. Brokers' commissions are paid by the scheme in line with the number of new members secured. As the overall number of medical scheme members has been fairly static over the past decade, much of brokers' work has involved switching members from one scheme to another. Until 2004 when regulation was introduced to cap broker fees, schemes and their administrators incentivised brokers to favour their scheme by offering high commissions.

In sum, medical schemes in South Africa are faced with uncontrolled expenditure increases. Even though there has been some respite in the last few years, historical experience shows that this tends to be short lived (see *Figure 12*). Efforts to regulate medical schemes and private health care providers seem to have been ineffective.

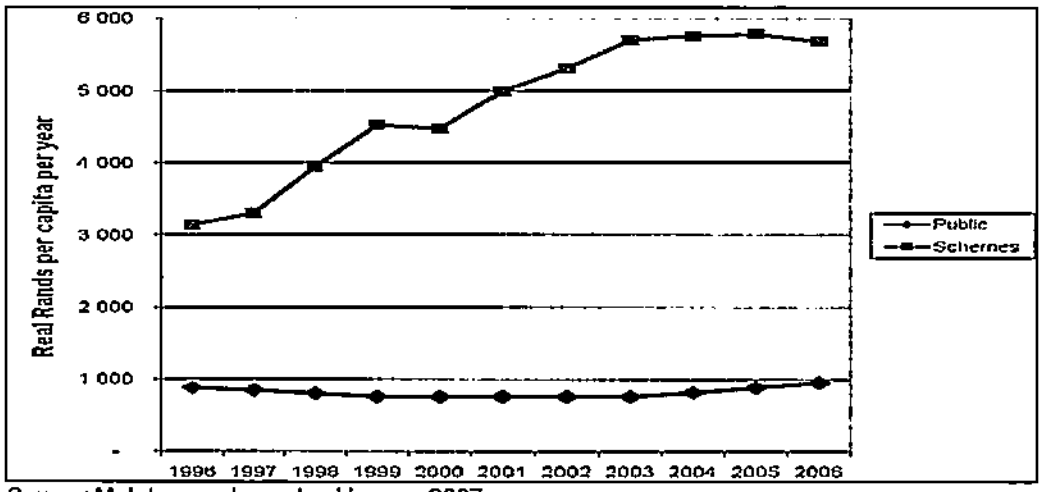
4.3 The private sector and the overall health system

What happens in the private health sector in a particular country inevitably impacts on that country's public health sector (Tuohy et al, 2004), as the South African context clearly illustrates. For example, in the 1990s when medical schemes were deregulated and open schemes were allowed to exclude high-risk individuals from membership and engage in risk-rating, there was extensive 'cream-skimming' resulting in the public health sector bearing the burden of caring for South Africans with the greatest risk of ill health. Similarly, the design of medical scheme benefit packages impacts considerably on the public health system; when medical scheme members' benefits are 'used up' in a particular year, members then often turn to the public health sector for specialist and hospital-based care.

One of the greatest challenges facing the South African health system is the relative sizes of the public and private sectors, in terms of the amount of resources (financial and human) and the population size served. *Figure 14* shows the difference in per capita spending between the public and private sectors, and the growth in this difference in recent years. While real per capita government spending on health care declined in the late 1990s and only returned to its 1996 levels by 2005, there was a concurrent rapid increase in real medical scheme spending (see also *Figure 12*). In 1996, per capita spending by medical schemes was three times more than government spending; by 2006 it was almost six times more.

As indicated in *Figure 7*, most health professionals (except enrolled nurses) work in the private sector. The relative distribution of health professionals between the public and private health sectors continues to move in favour of the private sector (e.g. from 40% of doctors in the private sector in the early 1980s, over 60% by 1990, and about 70% currently). Although there has been no systematic research to date on the reasons for this movement, there are both push and pull factors. In terms of push factors, a growing perception of poor conditions of service in the public health sector has been critical, not only in relation to salaries but also workload, the lack of available equipment and supplies seen as important for the provision of quality health care, and whether or not policy makers and managers are seen to provide a supportive working environment (Gilson et al, 2005). A vicious cycle is created: as more health professionals leave the public sector, and vacant posts are not filled due to funding constraints (see *Figure 14*), so the relative workload per health worker increases which then 'pushes' more and more professionals into the private sector.

Figure 14: Trends in real per capita spending in the public sector and medical schemes, 1996–2006 (2000 base year)

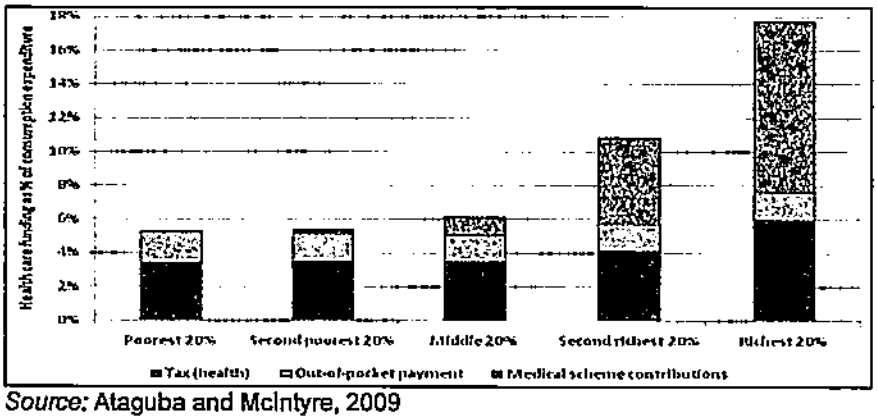


Source: McIntyre and van den Heever, 2007

However, 'pull' factors are also critical. In particular, the far better resourced medical schemes (with 44% of all funds for health care in South Africa in 2007 serving only 15% of the population), combined with the third-party funder and fee-for-service mechanisms, provides a more conducive work environment than the public sector (McIntyre et al, 2007). Further, when providers are paid on a fee-for-service basis (creating an incentive to provide more and higher levels of service), have relative freedom in setting their fee levels and where history shows that there is limited ability to control supplier-induced demand, the 'pull' to this sector is strong.

The impact of this public-private mix can be clearly seen when one considers the financing and benefit incidence patterns in the overall health system. Financing incidence indicates which socio-economic groups bear what part of the burden of funding health care. Health care financing is usually judged according to the principle of contributing according to one's ability-to-pay (or income level). Thus 'progressivity' (i.e. higher income groups contribute a larger percentage of their income than lower income groups) is seen as good. *Figure 15* shows that health care financing in South Africa can be described as very progressive. However, and inevitably, the element of health care financing that most contributes to this 'progressivity' is that of medical schemes, whose funds only benefit scheme members. The more fundamental principle, however, is not honoured: while the highest income groups certainly bear the heaviest financing burden, their medical scheme contributions do not result in income cross-subsidisation in the whole health system.

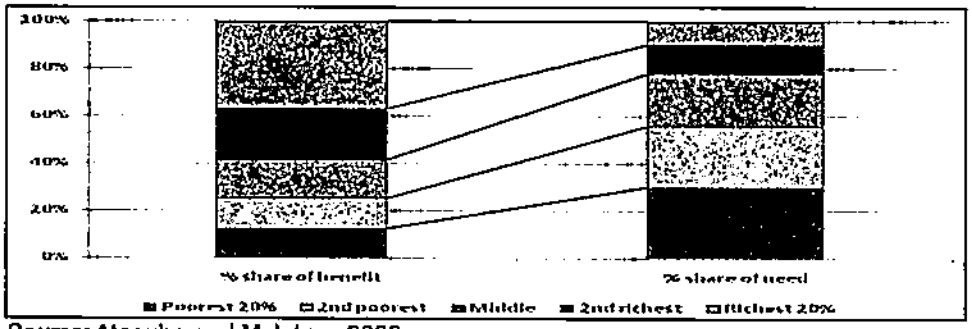
Figure 15: Incidence of types of health care funding in South Africa, 2005/6



Source: Ataguba and McIntyre, 2009

Benefit incidence indicates what benefit different socio-economic groups get from using health services, and is normally assessed in terms of individuals benefiting from health care according to their need for care (not their ability-to-pay). While a definition of need is not universally agreed, the measure used most often internationally is self-assessed health status collected through household surveys; *Figure 16* compares the relative share of health care benefits for different socio-economic groups with this measure of need. It shows that poorer groups bear the heaviest burden of ill-health, but the distribution of benefits of using health services in South Africa is not in line with the distribution of the need for health care.

Figure 16: The incidence of health care benefits in South Africa



Source: Ataguba and McIntyre, 2009

These financing and benefit incidence patterns suggest there are problems in relation to income and risk cross-subsidies in the overall South African health system. Although South Africa has a 'progressive' health system, because the high spenders in the medical schemes are in essence spending on their own health, the more fundamental principle of cross subsidy from rich to poor is not honoured. Interestingly within medical schemes as *Figure 2* shows there are 'reverse' income cross-subsidies since the lower-income members of schemes contribute a higher proportion of their incomes than richer members. There are also 'reverse' risk cross-subsidies in the overall health system in that those in greatest need of health care receive the lowest share of benefits from using health services.

4.4 Recent efforts to regulate the private health sector

The preceding sections have highlighted that the private health sector faces serious challenges, and that the way the private and public health sectors have developed (or in the case of the public sector, been underdeveloped) has created equally serious challenges in the overall health system. This section considers the extent to which regulations have been put in place to address these challenges.

A range of regulations govern the private health sector in South Africa, but these are quite fragmented (contained in a myriad of different pieces of legislation and with different bodies responsible for regulation development and implementation) and sometimes contradictory. A relatively comprehensive overview of private sector regulation is provided elsewhere (McIntyre et al, 2007), so this section only highlights some of the key gaps and challenges.

The key focus of private health sector regulation has been on protecting the public in relation to quality of health services and products. In addition, the most extensive regulations relate to the production and sale of pharmaceutical products, and to some extent of health professionals' issues, with relatively little regulation of health facilities and equipment.

Very few regulations and legislation directly influence the quantity and distribution of health care providers in South Africa. In terms of the National Health Act, which came into effect in mid-2004, the Director-General (DG) of the national DoH is responsible for issuing licenses or a 'Certificate of Need' for all private hospitals, private practices and 'prescribed health technology' or 'high-tech' equipment, both for existing services and for proposed future services. All facilities and practices that existed when the Act was promulgated had to apply for the certificate within 24 months. Before issuing or renewing a certificate, the DG must consider the quality of services provided and the

> *need to promote an equitable distribution and rationalisation of health services and health care resources,... the need to ensure that ownership of facilities does not create perverse incentives for health service providers and health workers.*

The Certificate of Need is a potentially powerful mechanism to influence the quantity, distribution and quality of health services, and a way to address potentially perverse incentives (e.g. shareholding in private hospitals by doctors) that could contribute to excessive expenditure. The Certificate of Need legislation is highly controversial, with health professional associations and private hospital groups vociferously opposing it, so it has not yet been implemented.

Regulation of the prices of health services is very limited, with only price regulation of medicines in place (which controls pharmaceutical product prices, the fees charged by wholesalers and distributors and dispensing fees). Other aspects of the legislation that can impact on medicine prices and expenditure include generic substitution by pharmacists, compulsory licensing and parallel importation.

The National Health Act makes provision for a NHRPL, which recommends the fees to be charged for different health services provided by private practitioners or private hospitals. However, the Act states that the NHRPL

> *may be used – (i) by a medical scheme as a reference to determine its own benefits; and (ii) by health establishments, health care providers or health workers in the private health sector as a reference to determine their own fees, but which are not mandatory.*

In terms of medical schemes, they were initially regulated to have community-rated contributions and were based on social solidarity principles, but were deregulated in the late 1980s and allowed to risk-rate contributions from 1993 to 1999. A comprehensive regulatory framework was introduced with the promulgation of the *Medical Schemes Act of 1998* and associated regulations, which came into effect on 1 January 2000. The Act aimed to ensure that each scheme, and individual benefit options in that scheme, is financially sound and sustainable. It also aimed to protect medical schemes from adverse selection (where those at higher risk are more likely to take out insurance) and to put some mechanisms in place to protect the public from 'cream-skimming' by schemes (whereby the scheme tries to exclude high risk individuals and attract the young and healthy). The Act also prescribes that contributions must be community-rated. Regulations ensure that every scheme has to provide cover for a 'prescribed minimum benefit package', which includes health services that could impose catastrophic costs on members. While a more comprehensive regulatory

framework governing medical schemes' operations and a strong regulatory authority (the CMS) is now in place, *Figure 12* raises serious questions about whether these regulatory interventions address the key challenges facing medical schemes.

5. National Health Insurance policy developments and debates

There is currently considerable debate about the proposed introduction of national health insurance (NHI) in South Africa, which could have considerable implications for the private health sector. This has followed from the decision at the 2007 policy conference of the ruling African National Congress (ANC) to introduce a NHI. However, this is not a new debate; since the late 1980s a number of proposals have been made to introduce mandatory health insurance. This section provides a brief historical overview of these debates and then critically considers the current proposals on mandatory health insurance.

5.1 Overview of historical debates on mandatory health insurance in South Africa

This section provides a brief overview of the specific proposals for developing a mandatory health insurance system, put forward as part of official policy processes since 1994. These are summarised in chronological order in *Table 4*, and include proposals made by:

- the 1994 Health Care Finance Committee (DoH, 1994);
- the 1995 Committee of Inquiry into a National Health Insurance System (SA, 1995);
- the 1997 SHI Working Group set up by the national Department of Health (DoH, 1997);
- the Taylor Committee of Inquiry into a Comprehensive System of Social Security for South Africa (which included proposals on the health sector and other social security mechanisms) (Department of Social Development, 2002); and
- the Ministerial Task Team which considered which, if any, of the Taylor Committee proposals to take forward (Ministerial Task Team, 2004).

The overview is summarised using a Kutzin (2001) framework, focusing on the key functions of a health care financing system, namely:

- **revenue collection:** the sources of funds, their structure, and how they are collected;
- **pooling of funds:** the size and composition (in terms of which socio-economic groups) of the population covered by a particular pool;
- **purchasing:** the transfer of pooled resources to health service providers so that appropriate and efficient services are available to the population (i.e. the benefit package and the provider reimbursement mechanisms); and
- **provision** of health services.

"LL16"

COVID-19 PANDEMIC IN SOUTH AFRICA
DEMOGRAPHY VOLUME

2020

Embargoed until:
14 December, 2020
10:30

Statistics South Africa

Risenga Maluleke
Statistician-General

Report No. 00-80-05 (2020)

2.3.4 Distribution of COVID-19 reported deaths

Table 2.3 and Table 2.4 below highlight information of cumulative COVID-19 deaths as reported in a report titled *"Covid-19 Sentinel Hospital Surveillance Update, Week 47 of 2020* by the National Institute of Communicable Diseases. The results indicate that the highest proportion of reported deaths due to COVID-19 were in Gauteng (25,0%), followed by Eastern Cape (22,4%). Limpopo (1,8%) and Northern Cape (1,7%) reported the lowest proportion of reported deaths due to COVID-19. By age group, deaths were high amongst persons aged 60–69.

Table 2.3: Observed COVID-19 death statistics by province

	Reported deaths	Per cent
Gauteng	4 398	25,0
KwaZulu-Natal	2 523	14,4
Western Cape	3 782	21,5
Eastern Cape	3 940	22,4
Free State	1 398	8,0
North West	529	3,0
Mpumalanga	385	2,2
Limpopo	324	1,8
Northern Cape	298	1,7
Total	17 577	100,0

Source: Covid-19 Sentinel Hospital Surveillance Update, Week 47 2020 (NICO)

Table 0.4: Observed COVID-19 deaths statistics by age

Age group	Female	Male	Total	Sex ratio at death
0-4	0,2	0,2	0,2	
5-9	0,1	0,0	0,1	
10-14	0,1	0,1	0,1	
15-19	0,3	0,2	0,3	
20-24	0,4	0,5	0,5	
25-29	0,7	1,3	1,0	
30-34	1,6	2,4	2,0	
35-39	3,1	3,4	3,2	
40-44	4,7	4,3	4,5	
45-49	6,7	6,3	6,5	
50-54	9,2	8,6	8,9	
55-59	13,0	12,2	12,6	
60-64	15,1	13,1	14,1	
65-69	13,2	13,0	13,1	
70-74	10,8	10,4	10,6	
75-79	8,7	8,7	8,7	
80+	10,7	14,1	12,4	
Unknown	1,4	1,3	1,3	

Source: Covid-19 Sentinel Hospital Surveillance Update, Week 47 2020 (NICO)

Occup. Med. Vol. 49, No. 4, pp. 225–229, 1999

0962-7480/99

"LL17"

A review of the healthy worker effect in occupational epidemiology

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This review article aims to anatomize sources of the healthy worker effect (HWE) and to summarize advantages and limitations of several approaches frequently proposed to eliminate the HWE. Although the HWE is frequently addressed in the context of selection bias, our review suggests that the selection of occupational cohorts with advantageous health status would preferably be addressed as a source of confounding biases. The authors also conclude that the exclusion of unhealthy workers at employment and the study of active workers are the two main sources of HWE, and that the use of the general population as a comparison group in occupational epidemiology should be avoided if possible. The authors encourage investigators to make distinctions between the underlying factors related to the use of the general population as the comparison group in occupational epidemiology.

Key words: Confounding; healthy worker effect; occupational epidemiology; selection bias; validity.

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INTRODUCTION

The healthy worker effect (HWE) is a term applied to the deficit of both morbidity and mortality ascribed to various employment-associated factors when workers and the general population are compared. First used by McMichael *et al.*,[1] the HWE reflects that an individual must be relatively healthy in order to be employable in a workforce, and both morbidity and mortality rates within the workforce are usually lower than in the general population. As a result, real excesses in both morbidity and mortality due to harmful exposures at work might be wholly or partially masked.[1] Although well-recognized, the HWE has been considered to be a poorly defined phenomenon and a popular but vague concept.[2–4] To a certain extent, the above-stated criticisms are justifiable as neither rigorous definition of the HWE nor a consensus upon how to deal with the HWE have been available. Additionally, although years of effort by occupational epidemiologists have been devoted to reducing or even eliminating the HWE, it remains one of the most annoying methodological difficulties in the study of occupational hazards and human health. This paper is a review of the publications dealing with the HWE in occupational studies, and systematically presents the sources, components, magnitude, effect modifiers and strategies for reducing the HWE.

SOURCES AND COMPONENTS OF THE HEALTHY WORKER EFFECT

The HWE has long been considered as a source of selection bias.[5–8] It is true that there is a selection process of excluding unhealthy individuals from the workforce, and this selection process leads to a difference in health status between workers and the general population. From this perspective, in an industry free of significant life-shortening hazards, both morbidity and mortality rates within the workforce of interest are likely to be lower than that in the general population. In addition to bias due to the selection process at employment, occupational studies of both morbidity and mortality, which compare workers and the general population, appear to be influenced by additional sources of biases. For example, healthier workers are more likely to stay in the workforce than those who are sick, which may also give rise to a healthier occupational cohort. From this perspective, the HWE can be viewed as a consequence of selecting an occupational cohort with a process based on health and/

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226 Occup. Med. Vol. 49, 1999

or survival effects. This review classifies the HWE and the other biases related to the comparison of workers and general population into election bias, information bias, and confounding bias as addressed below.

Selection bias

Many investigators have suggested that incomplete follow-up of the section of workers who leave employment could be a source of the HWE.[8–11] Such incomplete follow-up can be attributable to (1) good health required of workers for continued employment and (2) the tendency for those who develop diseases to leave their employment. Thus, if comparisons are made between workers who remain in employment during the time period of observation (*i.e.*, active workers) and the general population, the HWE may arise.

In addition to incomplete follow-up, lower morbidity and mortality rates of workers could be simply a consequence of an improper local *vs.* national comparison. If the worker population belongs to a region with better health conditions than large geographic areas or a nation as a whole, then regional differences in the occurrence of a particular disease may contribute to observed deficits of morbidity and mortality among workers.[12] Such regional differences may result from dissimilar qualities of health and clinical care and/or local peculiarities in diagnostic criteria, and have little to do with the good health of workers.[12]

Information bias

The comparison of both morbidity and mortality between workers and the general population might leave room for information bias. For example, the differences in both morbidity and mortality between an occupational cohort and the general population may arise from different criteria in the diagnosis of diseases, or from differences in the methods and quality of recording health outcomes between the two populations being compared.[13,14] The difference in the mortality ascertainment may entail different degrees of misclassification of diseases between populations. If the number of deaths among workers is under-ascertained, a study may report deficits in both morbidity and mortality among workers, and such deficits are unrelated to the selection process of an individual into the workforce.

Confounding bias

As mentioned earlier, many researchers consider the HWE to be a source of selection bias because it is a result of the selection process of relatively healthy individuals into industries. Such selection processes may have the following consequences. First, because people who are diagnosed with illnesses with a symptomatic pre-diagnostic phase are less likely to obtain employment, the selected workers may have a better-than-average health status. Second, employment regulations set by industries may restrict certain risk factors for diseases and causes of death. For example, some health-related behaviours, such as smoking, are not allowed during the work hours, and some personal traits, such as obesity, may be thought unfit for particular labour forces by industry.[15] A study exemplified such phenomena by demonstrating a significant deficit in lung cancer mortality among petrochemical workers in which the authors hypothesized that since smoking was prohibited in the workplace, the proportion of smokers in that group of workers was smaller than in the general population.[16] In addition to such selection processes, the differences in both morbidity and mortality between specific groups of workers and the general population may be attributed to non-comparability of socio-economic status. It has been suggested that once hired, workers in large industries may have greater access to medical services that protect them from diseases.[15] Thus, the HWE may reflect the selection of workforces for study rather than selection of individuals into workforce.

BEHAVIOUR OF THE HEALTHY WORKER EFFECT

In addition to the sources and components of the HWE, determining size and effect-modifiers of the HWE has been another challenge to researchers. Specifically, the HWE can be very serious in some studies, but may be moderate in others. We summarized, in the following section, factors affecting the HWE.

Causes of death

Many investigators have argued that the HWE is of little or no consequence in interpreting data on cancer mortality.[5,14,17,18] The reason for this is that it is unlikely that factors predicting eventual cancer deaths would be presented at 20 years of age, when many people become employed, which may not be true for factors that predict other causes of death. In other words, most cancers are not associated with a prolonged period of ill-health that would affect employability for a long time before death occurred. Although the verification of this argument is almost unfeasible empirically, it is quite reasonable to conceptually be convinced that the influence of the HWE should be relatively moderate for mortality studies of diseases with an absence of a prolonged disabling illness preceding death such as cancer.

Demographic factors

Fox and Collier analysed data collected in a cohort study of all men ever exposed to vinyl chloride monomer in manufacturing processes in Great Britain. The results showed that the standardized mortality ratio (SMR) for all causes was lower for younger workers than that for older workers, even after adjustment for length of employment.[5] This finding is contradictory to the common belief that older individuals seeking employment are healthier than individuals of the same age in the general population while it is not so obvious for younger people looking for employment. Thus, if age at start of employment modified the size of the HWE, it would favour the

older workers more than the younger workers. However, it is again not possible to empirically verify the above-stated argument. Even if the SMRs are found to be equal across the different age ranges, it provides no convincing evidence of equal operation of the HWE at different ages, and may only reflect the mix of possible different HWEs and different age-specific effects from occupational hazards. Additionally, Hernberg[19] argued that the HWE would have greater influence on male workers than on female workers, since women are less likely to be rejected from the workforce for poor health status than men are.

Types of occupational cohort

Different workforces usually have different hiring policies with respect to physical fitness and/or certain health-related behaviours, such as smoking. As a result, the HWE is likely to be different across industries. The HWE in the study of active employees can be even more serious since workers who remain in the workforce are generally healthier than those who are retired or disassociated from the workplace.[20] Thus, the HWE would tend to be more observable for physically demanding occupations than for those with little need of physical labour.

The time elapse

Some studies have noted that SMRs were approaching one with increased time before follow-up and concluded that the advantage of a health selection process at the initial stage disappeared gradually. Thus, for older age groups, the proportion of healthy persons in the general population and that in the occupational cohort would become more and more alike.[5,21] The decline of the HWE with time since first employment may be because the effect of selective exclusion from entry into work only operates during the period when an illness impairs employability. For example, a man who dies from chronic obstructive lung disease may have been too ill to obtain a job for 10 years before his death, but it is less likely to have restricted him from employment 40 years before his death. Breslow[23] demonstrated this in a cohort of smelter workers by examining the joint effects of time of hire, birth place, years since employment and levels of arsenic exposure on the SMRs for respiratory cancer mortality. He noted that the change of SMR with time was largely determined by time of hiring. Additionally, one could also speculate that the advantageous health status of workers at the start of employment would decline with the passage of time because the advantages resulting from the selection process would gradually disappear as a result of physical and psychological work pressure.

With the exception of the above-stated argument for the increase of SMR with time, researchers have different viewpoints on the change of SMR. Firstly, it has been suggested that the comparison of two age-adjusted SMRs should not be allowed unless there is homogeneity across strata of ratios of mortality rates in cohort 1 and cohort 2 and in the general population.[22] As time goes on, the age-specific mortality rate might change and the condition for comparing SMRs derived at two different points in time could be violated. Thus, the customary observation of the increase of SMR over time may not necessarily be due to the disappearance of HWE (or the increase in mortality risk), but is instead an artefact of SMR methodology.[9] Secondly, researchers have argued that the increase of SMR for certain diseases with time may simply be a consequence of accumulated hazardous exposures rather than the disappearance of the advantages of the selection process at employment.[9]

STRATEGIES FOR REDUCTION OF HEALTHY WORKER EFFECT

Among a variety of biases arising from the comparison between workers and the general population, the selection bias can be effectively minimized if studies include not only active workers but also pensioners and those who left work before retirement. Additionally, the information bias would be much less serious than the selection bias if an appropriate general population with comparably accurate information on both morbidity and mortality was identified. However, once the general population is used as a comparison population and the industry's recruitment of workers is based on health status or/and certain health-related behaviours, the confounding bias would invariably occur. The only way of adjusting for confounding bias is to conceive the baseline health status and risk factor distributions of the occupational cohort and of the general population, which is, unfortunately, unrealistic.

A number of strategies for minimizing the HWE have been frequently proposed. Nearly every strategy has its strengths and limitations and these are comprehensively summarized in the literature.[13] Among the strategies, 'use external work comparison groups' and 'use internal comparison groups', in our view, are the most methodologically plausible. Ideally, we should identify a theoretically correct external comparison population, or a representative sample from it, which comprises other employed persons who have entered and remained in the workforce through an equivalent selection process. Moreover, the correct external population should consist of workers from certain occupations who are comparable with the index occupation in terms of extraneous effects on the outcomes of interest.

In addition to 'use external work comparison groups', researchers may consider another strategy that examines variation in the health outcome rate across a gradient of increasing exposure within the workforce, *i.e.*, 'use internal comparison groups'. This strategy is justifiable in that employees from the same industry tend to experience a similar selection process, and they are likely to share a similar potential confounding effect. As a result, the presence of the HWE can be effectively controlled by comparing rates of the health outcomes of interest

"LL18"

Why is no safe until everyone is safe during a pandemic?

No one is safe until everyone is safe. This phrase has become a slogan for global health figures but what does it mean in the worldwide COVID-19 response?

17 August 2020 – updated on 14 September 2020

Prior to COVID-19 our world was more interconnected than ever. Our economies and societies were heavily reliant on international trade and travel. Not only for the import and export of food and other products, as well as business and recreational trips, but also for the shipment of vital medical supplies and equipment. In 2000, nearly 1.7 billion people were traveling on planes; by 2018 this figure nearly tripled to about 4.2 billion. But now we have seen the widespread disruption infectious diseases can cause in this global order.

Several months into the pandemic, many countries have relaxed lockdown measures to restart economic and social activity - a direct result of the drastic reduction in cases made possible by adherence to earlier public health restrictions. As anticipated, however, we are subsequently seeing a rise in cases globally. Following this increase in rates of infection, many countries are reinstating lockdown measures and issuing mandatory quarantines and other travel restrictions.

This has been driven by a desire to prevent the reintroduction of cases from a country or region with ongoing community transmission. But with an impending economic crisis worse than the 1930s depression, the cost of this pandemic is becoming even more profound. Never before have so many lives, livelihoods, and economies depended on a single health intervention: vaccines. If we fully return to the way people used to travel in a pre-pandemic world without a vaccine being widely administered, we will possibly see an unrelenting progression of COVID-19.

ONE WORLD PROTECTED

Only once COVID-19 vaccines are available to priority populations in all countries around the world will we bring the pandemic under control. Several COVID-19 vaccine candidates are showing promising early results in clinical trials, but the international community must remember that our goal is two-

fold: to produce a widely available, safe and effective vaccine and to bring the pandemic to an end. That can happen only after billions of doses are produced affordably and made available to everyone, particularly those in low-income countries. Every government has a responsibility to put its citizens first – and during a pandemic, this means thinking and acting globally. If manufacturing agreements or export restrictions obstruct the deployment of vaccines and the virus survives anywhere, no one can be safe from the impact of the pandemic.

Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance speaks about equitable access to COVID-19 vaccines on CNN's Quest Means Business.

Taking a global, coordinated approach is essential – global health actors, manufacturers and research groups have to work together towards a common goal: that when the first safe and effective vaccines emerge, the capacity exists to manufacture them, and the framework is already in place to make sure they are accessible to the most vulnerable all over the world. Through COVAX, Gavi, CEPI and WHO are working to make the ideal of equitable global access a practical reality.

IS GLOBAL HEALTH SECURITY A REAL POSSIBILITY?

More than 150 countries have been involved in discussions on the COVAX Facility, which is looking to secure commitments from self-financing participants by the beginning of September to share their risk by participating in a scheme that gives them access to the world's largest actively managed portfolio of COVID-19 vaccine candidates in return for a guaranteed number of doses to protect the most at-risk sections of their population.

These early commitments are critical to making sure COVAX is able to continue investments in R&D and manufacturing at risk across a diverse portfolio of promising COVID-19 vaccine candidates. Within the COVAX Facility, the COVAX Advance Market Commitment (AMC) has been established to support 92 lower-income economies' participation – so that ability to pay is not a barrier to access to vaccines. The pharmaceutical ndustry has also been a close collaborator: The COVAX Facility has already seen a 300 million dose commitment from AstraZeneca and, most recently, Gavi, the Serum Institute of India, and the Bill & Melinda Gates Foundation launched a collaboration to accelerate manufacturing and delivery of up to 100 million doses of future COVID-19 vaccines for low- and middle-income countries in 2021 through the COVAX AMC.

However, much more needs to be done to make sure everyone is safe from the devastating impacts of the COVID-19 pandemic – and we can come together as one world, protected.

"LL19"

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Government Employees Medical Scheme

DISCOVER the BRILLIANCE of GEMS

2021 GEMS Member Newsletter

PO's Note

Dear Valued member,

Welcome to the first member newsletter of 2021

Compliments of the New Year! May this new year be filled with great accomplishments and a renewed spirit to conquer for you and your loved ones.

As we have just closed off the eventful year that was 2020, there are many lessons to be learnt from it about the resilience of the human spirit. At GEMS, we pride ourselves on being a medical aid scheme that was there every step of the way as our members navigated what is now widely known as the "new normal."

A new year is also a great opportunity for all of us to reflect on our health and wellness, as well as to consider how we can further enhance our health and wellbeing by adapting to healthier lifestyles.

In this newsletter, we share important updates and notices, which include the opening of new GEMS offices in the Northern Cape and Western Cape; how to avoid Medicine Price List (MPL) co-payments, an update on Trustee elections, what you need to know about orthodontic treatment, the importance of whistleblowing, COVID-19 safety guidelines and most importantly, ways to get answers quickly.

At GEMS, we continue to closely monitor the healthcare needs of our members and expand access to quality healthcare to all our members and beneficiaries. For the year 2021, the Scheme has accordingly enhanced benefits which includes a significant increase in the medicine benefit on the Tanzanite One and Beryl options. All options will have access to SAHPRA approved COVID-19 vaccines which will be administered in accordance with the national COVID-19 vaccination implementation roll-out plan, once available. We hereby announce a 4.25% contribution increase on the Tanzanite One and EVO options. The increase is to enable the Scheme to make the necessary benefit enhancements to the 2021 benefits based on our members' needs. The option selection period is open from 15 December 2020 till 14 January 2021 should you wish to join a different option offered by the Scheme.

Despite the ups and downs we've faced in 2020, GEMS remains committed to providing clinically appropriate care amid the COVID-19 pandemic, ensuring each member gets the best healthcare for their needs in 2021 and beyond. We hope you enjoy this first edition of the GEMS member newsletter for 2021 and look forward to being of great service to you and your family.

Yours in Health
Dr Stan Moloabi
Principal Officer

Adrian Gore, Discovery Chief Executive, shares Discovery's position on South Africa's COVID-19 vaccination programme

- COVID-19
- 15 February 2021

There is considerable anxiety about South Africa's COVID-19 vaccination programme. I am reaching out to you to explain Discovery's position on it, and our deep commitment to helping to make it successful for all South Africans. Right now, nothing is more important.

This is a crucial, complex process with many unknowns, and we fully understand our members' anxiety. The environment is fluid - for example, the rapidly changing information about the efficacy of vaccines such as Oxford-AstraZeneca's vaccine against the 501Y.V2 variant currently prevalent in SA. People are also unsure about which vaccines will be available in South Africa, when they will be available, and who will have access to them.

Simply put, we need to support our country in executing an effective vaccination campaign while ensuring that every one of our adult Discovery Health Medical Scheme (DHMS) members can be vaccinated quickly and efficiently.

Upfront, I need to stress the importance of helping to make the national rollout a success, given the scale of the pandemic and its tragic impact. There have been over 2.3 million deaths globally, and approximately 120,000 excess natural deaths in South Africa during the period of the pandemic - most of which are almost certainly attributable to COVID-19.

We have also experienced the tragic COVID-related deaths of almost 5,000 Discovery Health administered scheme members, and of 12 of our own staff. We are acutely aware of our responsibility in this pandemic and the crucial role we need to play in ending it. I assure you that we have not and will not shirk our responsibility.

In this context, we are often asked why we don't just procure the vaccines ourselves for our DHMS members, and rapidly vaccinate them. There are two important constraints that make this narrow approach problematic.

First, there is a global shortage of vaccines, and the pharmaceutical companies manufacturing the vaccines will currently sell only to national governments, and not to any other entities. Second, there are specific risk factors that make some people more susceptible than others to severe illness and death should they contract COVID-19. This means that to be both fair and effective, the vaccination programme must be planned and implemented at a country level, according to a schedule that prioritises high-risk individuals first, and matches appropriate vaccines to at-risk groups according to clinical and scientific guidelines.

Not following this process would mean low-risk people get vaccinated before the clinically vulnerable, resulting in unnecessary illness and death. This cannot and should not happen.

Ensuring appropriate clinical prioritisation across the nation is therefore critical. We need social solidarity; but in return, we need to make sure that this coordinated approach is implemented as quickly and as effectively as possible.

In this regard, I want to assure you of Discovery's deep involvement in these processes. We have been working closely with the National Department of Health (NDoH), Business for South Africa, Business Leadership SA, and other stakeholders, on many aspects of the national vaccination programme. Our team has been involved in supporting the population analytics, research-supported procurement processes, distribution planning and system development that has been taking place.

There will no doubt be learnings as we implement the vaccination programme to frontline healthcare workers - a containable and well-defined group - potentially as early as this week, and these lessons will be applied as the programme is scaled up.

Of course uncertainty still exists with regard to whether a centralised model of distribution will be pursued - whereby our government leads on procurement and coordinates distribution - or whether there will be more active involvement of the private sector in some, or all, of these elements of the programme.

Either way, we have made sure our DHMS members will be covered and protected. We have been engaging directly with several of the key vaccine manufacturers since Q3 2020 and remain in active contact with them. Should their position of selling only to governments change in the near future, we will rapidly engage with the NDoH to agree on a role for Discovery and other private sector players to become directly involved in procurement and distribution.

DHMS has budgeted for sufficient funding to fully cover vaccines (whichever vaccines are procured) for all of its members. We stand ready to fund their vaccination and are also confident that the private healthcare sector's robust medicine supply chain is ideally positioned for a rapid and efficient rollout of vaccines to members of all Discovery Health client schemes.

In addition, while there has been talk that DHMS has already agreed to finance vaccines for non-members through a cross-subsidisation agreement - this is simply not true. Schemes are awaiting clarity from government on exactly how vaccines will be funded, and what the legislated Single Exit Price will be. Any arrangement will be subject to the supporting legislation, to oversight by the Council for Medical Schemes and to consideration and approval by each Scheme's Board of Trustees.

While the detail of the rollout is yet to be confirmed, we are optimistic that the priority groups identified for early vaccination will receive their vaccines during the first half of 2021.

We are actively supporting this project with our resources and expertise and are working tirelessly to contribute towards the best outcome for the country, while ensuring that you and your family always have access to the best possible care.

I recognise that this note does not answer all of the questions that you may currently have in mind. We undertake to write to you regularly, to keep you fully updated as the details of our country's COVID-19 vaccination project become clearer.

Sincerely,
Adrian Gore
Discovery Chief Executive

"LL21"

ISSUES IN PUBLIC HEALTH

Caesarean section rates in South Africa: A case study of the health systems challenges for the proposed National Health Insurance

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Broader policy research and debate on the issues related to the planning of National Health Insurance (NHI) in South Africa (SA) need to be complemented by case studies to examine and understand the issues that will have to be dealt with at micro and macro levels. The objective of this article is to use caesarean section (CS) as a case study to examine the health systems challenges that NHI would need to address in order to ensure sustainability. The specific objectives are to: (*i*) provide an overview of the key clinical considerations related to CS; (*ii*) assess the CS rates in the SA public and private sectors; and (*iii*) use a health systems framework to examine the drivers of the differences between the public and private sectors and to identify the challenges that the proposed NHI would need to address on the road to implementation.

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As proposed in the National Health Insurance Bill,[1] National Health Insurance (NHI) will be a strategic purchaser of healthcare services for the entire South African (SA) population. There is a need for broader policy research and debate on the planning and implementation of NHI to be complemented by case studies to examine and understand the issues that will need to be dealt at a more micro level.

Objectives

To use caesarean section (CS) as a case study to examine the health systems challenges that NHI would need to address in order to ensure sustainability. This case study has been chosen because: (*i*) maternal and child health is a major public health concern in SA, with 1.2 million recorded births in 2018;[2] (*ii*) there is growing local and global concern about the appropriateness and safety of increasing CS rates;[3] and (*iii*) there is a substantial difference between reported CS rates in the SA private and public sectors.[4] This difference provides an ideal opportunity to assess and understand the underlying health systems drivers and how these would need to be addressed in an NHI environment. The specific objectives of the paper are to: (*i*) provide an overview of the key clinical considerations related to CS; (*ii*) assess the CS rate in the SA public and private sectors; and (*iii*) examine the drivers of differences between the public and private sectors and use a health systems framework to identify the challenges that the proposed NHI would need to address on the road to implementation.

CS: The clinical considerations

When indicated for health reasons, CS is an important surgical intervention to save lives of women and children. However, unnecessary CS (without medical/obstetric indication) should be avoided, as maternal mortality is three times higher for CS than for normal vaginal delivery (NVD),[5] which is associated with fewer complications and is more sustainable for healthcare systems.[6] Most healthy women prefer to give birth via NVD.[7,8] A woman who has had a CS is more likely to require one for subsequent births, thus increasing the CS rate.

The 2015 World Health Organization (WHO) statement,[9] based on country data, demonstrates that CS rates >10 - 15% conferred no further benefit in reducing maternal and perinatal mortality. In many countries, CS rates are consistently higher than is considered medically justifiable,[3] and are rising, leading to debates about appropriate rates and concern about the costs associated with inappropriately high rates.[9,10] For many low-income countries, CS rates are too low to save lives. The WHO statement therefore recommends that 'Every effort should be made to provide CS to women in need, rather than striving to achieve a specific rate', and further recommends against CS on maternal request based on the finding of increased maternal mortality for CS compared with vaginal delivery.[9] Further reviews of the relationship between CS rates and the reduction of maternal and newborn mortality suggest that CS rates >20% do not confer benefit in reducing mortality. However, if reduction of maternal and newborn morbidity (e.g. severe perineal tears, newborn hypoxic brain injury) is taken into account, rates >20% may be acceptable.[11]

There is global (and in-country) inequity in provision of safe CS, with the case fatality rate (CFR) varying from 21.9 per 100 000 CSs in The Netherlands[12] to an average of 760 for low- to middle-income countries (LMICs).[13] Deaths of women who have CS may be

unrelated to the procedure (e.g. due to pre-eclampsia), but for many the CS may be contributory (e.g. due to a bleeding or anaesthetic complication at CS). Increasing CS rates in LMICs need to be accompanied by measures to ensure that the operations are done safely. Complications of CS include bleeding, anaesthetic adverse events, sepsis, visceral injury and thromboembolism. In many LMICs there are serious skills shortages in surgery and anaesthesia, especially in rural hospitals that are far from urban centres and have limited back-up to manage complications.

CS rates in SA

The provincial public sector CS rates for 2006 and 2015, and the private sector CS rates for 2015, are summarised in Table 1.

The public sector CS rates in Table 1 are based on data from the 2015/16 District Health Barometer.[11] Public sector CS rates increased from 15.1% in 2006 to 24.1% in 2015. The largest increases were in North West, Eastern Cape and Gauteng. There were marked differences in the CS rates between provinces (reflecting inequitable access), with the lowest rates in the predominantly rural provinces. More recent data from 2017 indicate that the CS rate had increased further to 27.4% overall.[15] Of note, CS is not done on maternal request in the public sector.

The private sector CS rates are based on data used for a recent study that analysed 6 542 births in 2015 among members of 10 medical schemes.[4] The overall CS rate for this group was 73.2% in 2015. This is one of the highest rates in the world, and almost three times higher than that reported for the SA public sector. This trend was evident across all provinces, with the largest private-public differences in North West, Northern Cape and Free State. The high CS rate reported by the study is in line with findings of previous studies on the SA private sector. Naidoo and Moodley[14] reported a CS rate of 65% in 2009 based on an audit of private practice. A chapter on maternal deaths in the private sector in the 2011 - 2013 *Saving Mothers* report gave a CS rate of 67% for the private sector.[12] A press article reported a CS rate of 74% for members of Discovery Health, the largest medical scheme in SA.[18] In its 2017/18 annual report[19] the Council for Medical Schemes reported CS rates of 60 - 70% for the private sector over the period 2007 - 2017, and in its 2018/19 annual report,[20] the CS rate is reported to have increased to >75% in 2018.

While there is no available information on the safety of CS in the private sector, the issues related to safety of CS in the SA public sector are well documented. In line with patterns seen in other countries, the CFR for CS in SA is three times higher than for vaginal delivery.[21] The by-province CFRs for CS overall and for CS associated with bleeding as reported by the Saving Mothers Report for 2017[15] are summarised in Table 2.

The CS-related CFR varies across provinces, ranging from a high of 235.5 per 100 000 CSs for the Free State to a low of 87.5 for the Western Cape. Death from bleeding associated with CS has been noted as a major issue in several African countries by the African Surgical Outcomes Study[22] and by the WHO global meta-analysis of LMICs.[13] SA appears to have a similar issue, with 19.1% of the CS-related CFR associated with bleeding. The variations between provinces in CS-related CFR and the proportion of the fatalities associated with bleeding point to differences between provinces in the safety of CS procedures. One of the key factors identified as contributing to the variation in safety of CS between provinces is the lack of appropriately skilled staff.[15]

CS rate drivers and challenges for the proposed NHI

The evidence on public sector CS rates and safety and underlying provincial inequities highlights urgent issues in the public sector, notably: (*i*) the importance of more equitable access to safe CS across the country; and (*ii*) the need to limit further increases in the CS rate, which is thought to be at a ceiling above which no further benefits would be achieved. There is also an imperative to improve safety of CS in the public sector. Doing this requires improving the skills of doctors performing surgery and anaesthesia for CS in all facilities and ensuring an appropriate enabling environment in terms of equipment, infrastructure and supplies to manage complications.

Table 2. CFR for CS by province in SA, 2017

Province	CFR/100 000 CSs: All CS (A)	CS with bleeding (B)	% of CS with bleeding (B/A)
North West	128.1	45.2	35.3
Limpopo	208.3	69.4	33.3
Mpumalanga	190.6	41.7	21.9
Northern Cape	111.8	22.4	20.0
Free State	235.5	45.6	19.4
Eastern Cape	144.5	24.1	16.7
Gauteng	127.3	19.1	15.0
KwaZulu-Natal	141.7	17.9	12.7
Western Cape	87.5	10.5	12.0
SA	145.7	27.8	19.1

CFR = case fatality rate; CS = caesarean section; SA = South Africa.

Table 1. CS rates (%) in the SA public and private sectors

Province	Public sector: 2006	Public sector: 2015	Private sector, 2015	Public sector movement, 2015 v. 2006	Private v. public difference, 2015
North West	12.6	27.6	86.5	15.0	59.0
Northern Cape	11.0	16.3	74.7	5.3	58.4
Free State	11.6	16.0	72.9	4.4	56.9
Limpopo	15.1	22.3	73.4	7.2	51.1
Gauteng	13.7	25.6	75.0	11.9	49.5
Mpumalanga	13.1	19.3	68.2	6.2	48.8
KwaZulu-Natal	21.1	28.8	76.8	7.6	48.0
Eastern Cape	9.5	22.7	66.1	13.2	43.4
Western Cape	19.9	28.1	68.2	8.2	40.1
SA	15.1	24.1	73.6	9.0	49.5

CS = caesarean section; SA = South Africa.

"LL22"

STD CARE IN THE SOUTH AFRICAN PRIVATE HEALTH SECTOR

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Objectives. To establish the accessibility and quality of sexually transmitted disease (STD) care provided by private general practitioners (GPs) and workplace health services in South Africa.

Design. Structured telephone interviews were conducted with a random national sample of 120 GPs and 244 occupational health nurses (OHNs) between May and July 1997. The interview schedules covered indicators of access (including utilisation) and processes (drug treatment, partner management, counselling and condom promotion) of STD care.

Results. An estimated 5 million STD-related visits were made to private general practices in 1997. Reported treatment of STDs was assessed for effectiveness using well-established syndromic case management guidelines. Only 28% of GPs reported effective treatment for urethral discharge. This dropped to 14% for genital ulcer and 4% for pelvic inflammatory disease. Fifty-five per cent of the OHNs interviewed indicated that their workplace clinics provided STD care. Nurses provided this care, with or without the support of doctors, in 87% of clinics. Reported urethral discharge and genital ulcer treatment regimens were assessed as effective in 34% and 14% of responses, respectively.

Conclusions. The private sector is a major provider of STD care and is key to national efforts to achieve better STD control, thereby preventing the spread of HIV. However, the results of the research suggest that the poor quality of STD care may be undermining attempts to control these epidemics in our society. Although a complex task, strategies need to be found to improve the quality of care provided within the private sector.

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In 1995, the private health sector accounted for 55% of total health expenditure and 58% of medical practitioners in South Africa.[1] Although only 18% of the country's population has full access to the private sector through a medical scheme,[2] the non-insured population makes frequent use of private providers, particularly for ambulatory care. It has been estimated that 5% of total health expenditure in South Africa involves out-of-pocket, cash payments to private general practitioners (GPs),[3] of whom there were 8 620 in 1997 (Decision Surveys International — personal communication). These GPs are widely spread across the country; even in rural areas doctors in private practice outnumber those in the public sector.[2]

Sexually transmitted diseases (STDs) appear to be one set of conditions for which treatment is regularly sought in the private sector. STDs often cause acute symptoms that can be dealt with in a once-off consultation. Because of the associated stigma and embarrassment of STDs, patients tend to prefer the privacy and anonymity of GP consulting rooms. In the Hlabisa district of KwaZulu-Natal, for example, 50% of all STD cases are seen in the private sector[4] and in urban Alexandra (Gauteng) 63% of health service visits for STDs in 1994 occurred in private general practice.[5] While patients may experience GP care as more humane than public sector care, the evidence from small-scale studies is that the technical quality of STD care provided by GPs is often less than ideal.[6,7]

Work-based health services are a small but significant additional source of private primary care in South Africa. A total of 1 233 workplace clinics were registered with the Department of Health in 1996, and an estimated 400 medical practitioners (mostly part-time) and 1 000 nurses work in the occupational health setting.[8] Studies in three provinces (Gauteng, the Western Cape and KwaZulu-Natal) have found that between 51% and 58% of workplace clinics provide STD care.[9,10] Two of these studies[9,10] assessed the quality of STD care, and in both, less than 10% of clinics providing STD care reported effective treatment for urethral discharge.

The Department of Health (DOH) has adopted and promoted the World Health Organisation (WHO)-recommended, syndromic approach to STD care.[10] Syndromic STD case management has as its central principle the effective treatment of all major diseases associated with particular STD syndromes, such as urethral or vaginal discharge, rather than trying to diagnose and treat specific diseases. It is based on the understanding that laboratory tests are expensive and not available in many settings and that the aetiological diagnosis of an STD (e.g. gonococcal urethritis, chancroid) on clinical grounds alone, even in the most experienced hands, is very often inaccurate.[11] In a recent study in Lesotho,[12] only 62% of patients with genital ulcer disease were correctly diagnosed clinically by STD specialists, whereas the use of a syndromic protocol ensured that more than 90% of patients were adequately treated. The ability of STD organisms such as

Neisseria gonorrhoeae and *Haemophilus ducreyi* to develop resistance to commonly used antibiotics, has also led to significant changes in recommended STD treatment regimens over the last few years.

Since 1994, a concerted effort has been made in the public sector to implement an updated and effective approach to STD management that reflects the current understanding of best practice. This appears to have been at least partially effective. In a 1998 national survey[13] of 294 public sector clinics, 82% and 72% of nurses interviewed knew the correct drug management for urethral discharge and genital ulcer, respectively. Eighty-six per cent of clinics had ciprofloxacin in stock.

Increasing recognition of the role of the private sector in STD control prompted the DOH to commission a national evaluation of STD care in the private sector. This formed part of a broader national HIV/AIDS and STD review conducted during the course of 1997.[14] The aim of the evaluation was to establish the accessibility and quality of STD care provided by private GPs and workplace health services.

Methods

For the purposes of this study, two cross-sectional descriptive surveys were conducted, one of private GPs and one of workplace clinics. A private research company, Decision Surveys International (DSI), was contracted to draw a national, random sample of 120 GPs, representing 1.4% of the total GP population. DSI does regular surveys of prescribing patterns of private practitioners and is regarded as having one of the most accurate listings of GPs in the country. The list of nurses who are members (paid and unpaid) of the South African Society for Occupational Health Nurses (SASOHN) was used as the sampling frame for workplace clinics. In mid-1997, there were 704 members of SASOHN, constituting nearly three-quarters of the estimated population of nurses in workplace clinics. A simple random sample of 248 members was drawn from the list.

Structured telephone interview schedules were designed and tested for the two groups of providers. The interview schedules combined open and closed-ended questions, covering indicators of access (including utilisation) and processes (drug treatment, partner management, counselling and condom promotion) of STD care. The GP and occupational health nurse (OHN) interview schedules were administered by trained interviewers. GPs were paid a nominal fee of R50 for the time taken by the interviews. The data were collected during the months of May, June and July 1997.

Data were entered and analysed using the Statistical Package for the Social Sciences (SPSS). Treatment practices were coded and analysed for each STD syndrome at two levels: (*i*) the proportion of respondents that reported recognised, effective treatment of the STD syndrome; and (*ii*) the proportion of respondents that reported treatment regimens containing more than one antibiotic and therefore implicitly accepted the need for management of syndromes rather than single aetiologies.

The influence of various factors on whether or not the GPs and occupational clinics prescribed effective treatment was evaluated using multiple logistical regression for each of the STD syndromes.

Ethical approval for the studies was obtained from the Committee for Research on Human Subjects of the University of the Witwatersrand. Participation was voluntary and this was made clear to respondents before each interview.

Results

STD care by GPs

All the GPs contacted agreed to be interviewed. Of the 120, 67% were based in a city or metropolitan area, and more than one-third came from Gauteng (Table I). Approximately three-quarters (76%) dispensed medication from their practices. On average, 63% of their patients were covered by health insurance (range 0% - 100%).

Table I. Distribution of GPs interviewed

Province	N	%	Area	N	%
Gauteng	44	37	Greater Johannesburg	33	28
Western Cape	23	19	Durban	14	12
KwaZulu-Natal	23	19	Cape Town	12	11
Eastern Cape	13	11	Pretoria	8	7
Free State	7	6	Port Elizabeth	4	3
Mpumalanga	4	3	Bloemfontein	4	3
Northern Province	4	3	East London	4	3
North West	2	2	Small town and rural	40	33
Northern Cape	0	0.0			
Total	120		Total	120	

Practices were open between 5 and 7 days a week, and the mean daily load per GP was 28 patients (median 30, range 10 - 80). All 120 GPs treated STDs, and the reported number of STD-related visits ranged from less than 0 to 25 per day (median 1). Assuming that the mean reported utilisation (2.5 visits per day, standard deviation (SD) 3.2) corresponds to reality for at least five days of the week for 48 weeks of the year, and extrapolating this to the entire GP population, it can be estimated that a total of 5.2 million STD-related visits were made to GPs in 1997. This estimate makes no distinction between new and follow-up visits. The latter are likely to be high in the presence of inadequate treatment, and the estimate should not be regarded as an STD incidence rate.

In a series of open-ended questions, respondents were asked to describe their usual management of four STD syndromes: urethral discharge, genital ulcers, vaginal discharge and pelvic inflammatory disease (PID). The findings on three of these syndromes are given in Table II.

Less than one-third (28%) of the GPs reported a drug regimen that was effective against the syndrome of urethral discharge. This dropped to 16% for genital ulcers and 4% for PID. Fifty-seven per cent of respondents indicated that they would administer a long- or short-acting injectable penicillin for urethral discharge. Overall, 60% of urethral discharge regimens contained a quinolone or other antibiotic effective against gonococcal infection, sometimes in combination with penicillin. Depending on the syndrome, between one-third and two-thirds of GPs prescribed only one systemic antibiotic for the syndrome.

Reported treatment regimens for vaginal discharge were analysed differently. There were two distinct types of responses — those who approached vaginal discharge as a vaginal wall infection, and treated it as such, and those who approached it as a cervical infection or combination of cervical and vaginal infection (Table III). Of the 71 GPs in the latter category, 10 (14%) provided effective treatment for both chlamydial and gonococcal infection (the two main causes of cervical infection).

Table III. GP management of vaginal discharge

	Number		Effective cervical infection treatment	
Approach	N	%	N	%
Vaginal infection	45	39	—	—
Cervical infection	12	10	2	17
Both	59	51	8	14
Total	116			

Several GP responses suggested different management of STDs for 'medical aid' and 'cash' patients, and related to this, for black and white patients. One GP responded to the question 'How would you treat a man presenting to you with urethral discharge?', by saying that 'It depends on his socio-economic situation and what he can afford. For blacks, probably a procaine penicillin injection and Flagyl. I may also use Bicillin or Ciprobay depending on severity and affordability.'

In response to the question: 'How would you treat a woman who comes to you with a vaginal discharge?', another GP replied: 'I have got to give patients the treatment they can afford to pay. If Mrs Jones comes in for treatment and she has medical aid and her maid comes in and she doesn't, obviously treatment is going to differ from patient to patient.'

When asked, all GPs stated that they tried to notify partners through the index case, and 18% reported that they provided a card or a letter to inform partners of the need for treatment.

Table II. Reported treatment of STD syndromes by GPs and workplace clinics

	Urethral discharge (N = 120)		Genital ulcer (N = 110)		PID (N = 114)	
	N	% (95% CI)	N	% (95% CI)	N	% (95% CI)
GPs						
Effective treatment prescribed	34	28 (20.7 - 37.4)	17	16 (9.5 - 23.9)	5	4 (1.6 - 10.4)
More than one antibiotic prescribed	71	59 (49.8 - 67.9)	36	33 (24.3 - 42.4)	77	68 (58.0 - 75.8)
Workplace clinics						
Effective treatment prescribed	41	34 (25.9 - 43.5)	13	14 (8.2 - 23.8)		
More than one antibiotic prescribed	80	67 (57.4 - 74.8)	42	47 (36.2 - 57.4)		

PID = pelvic inflammatory disease.

When asked, in an open-ended question, what tests (if any) they would do on pregnant women, 52% of GPs mentioned syphilis serology, while 33% indicated that they would test for HIV. Fifty-one GPs (43%) had seen the DOH's 1997 protocols for management of STDs.

Of the variables selected for the multiple regression analysis, there were no significant predictors of effective treatment for urethral discharge or PID. However, urban GPs (odds ratio (OR) 8.69, 95% confidence interval (CI) 1.52 - 49.58) and GPs from KwaZulu-Natal (OR 6.81, 95% CI 1.64 - 28.33) were more likely to prescribe appropriate treatment regimens for genital ulcer disease (Table IV).

STD care in workplace clinics

Of the 248 OHNs contacted, 4 declined to be interviewed, giving a response rate of 98% and a sample size of 244. Respondents were based in a range of sectors and spread across six provinces (Table V). Their workplaces varied in size from 38 to 15 000 employees. Fifty-two per cent of workplaces employed less than 500 people and the overall male-to-female ratio of employees was 3:1, with only 15% of workplaces reporting a greater number of women than men.

The workplace clinics were most commonly staffed by full-time nurses (median 40 hours/week), who were supported by part-time medical practitioners (median 2 hours/week).

Of the 244 OHNs interviewed, 135 (55%, 95% CI 49 - 62%) indicated that STD care formed part of the services at their clinic. When employee numbers were taken into account, 78% of workers served by the OHNs had access to STD care at work. This reflects the fact that workplaces with 500 or more

Table IV. Results of multiple logistical regression analysis to identify factors influencing the provision of effective STD treatment by GPs and workplace clinics

	Urethral discharge		Genital ulcer		PID	
	OR*	95% CI	OR*	95% CI	OR*	95% CI
GPs						
Urban practice	0.91	0.39 - 2.16	8.69	1.52 - 49.58	3.00	0.29 - 31.20
From KwaZulu-Natal	2.08	0.75 - 5.78	6.81	1.64 - 28.33	5.15	0.52 - 50.42
Dispense medication	2.18	0.71 - 6.71	0.43	0.10 - 1.90	0.75	0.06 - 9.71
Predominantly medical aid patients (> 80%)	1.33	0.48 - 3.70	0.67	0.12 - 3.82	4.68	0.49 - 44.67
See STDs frequently (> 2 patients/day)	1.07	0.42 - 2.78	2.81	0.74 - 10.67	1.95	0.20 - 19.53
Have seen DOH guidelines	1.19	0.51 - 2.79	0.43	0.12 - 1.53	1.40	0.20 - 9.75
Workplace clinics						
From KwaZulu-Natal	1.04	0.29 - 3.78	8.40	1.75 - 40.26		
Large factory (> 500 workers)	2.58	0.76 - 8.67	1.27	0.22 - 7.17		
See STDs frequently (> 2 patients/day)	0.59	0.14 - 2.43	0.63	0.96 - 4.08		
Claim to use syndromic management	19.68	6.45 - 60.00	5.74	1.02 - 32.34		

PID = pelvic inflammatory disease; OR = odds ratio; CI = confidence interval; DOH = Department of Health.

Table V. Distribution of OHNs interviewed

Province	N	%	Industry	N	%
Gauteng	129	53	Manufacturing	151	62
KwaZulu-Natal	41	17	Mining and minerals	33	14
Eastern Cape	38	16	Service industry	27	11
North West	19	8	Construction and engineering	9	4
Western Cape	16	7	Agriculture	9	4
Mpumalanga	1	0.4	Retail	8	3
Northern Province	0		Other	7	3
Free State	0				
Northern Cape	0				
Total	244		Total	244	

employees were more likely to provide STD care, probably as part of a package of primary care services, than those with less than 500 employees (univariate, OR 2.4, $P = 0.001$). The OHNs reported daily clinic attendances of between 3 and 320 patients (median 25/day), and in the 135 clinics that provided STD care there was a median of 0.6 STD-related visits per day (range 0 - 34). Extrapolating the mean utilisation (1.8 STD visits/day, SD 3.9) to 55% of all workplace clinics, and using similar types of assumptions as for GPs (availability of a nursing service for a mean of 4.86 days a week, 48 weeks per year), about 285 000 STD-related visits were made to workplace clinics in 1997. As with GPs, this utilisation rate cannot be regarded as an STD incidence rate.

STD care was provided by nurses, with or without support from doctors, in 87% of the 135 clinics. In the remaining 13%, care was provided by doctors only. Of the total sample of 244 OHNs, 42% had heard of the syndromic approach to STD management, and 17% indicated that they had used this approach. One-quarter (27%) of clinics providing STD care also treated the partners of STD cases, and 36% routinely handed out a letter, slip or card to notify partners of the need for treatment.

Respondents were asked to describe the usual treatment of two STD syndromes in men, namely urethral discharge and genital ulcers. Of the 135 OHNs whose clinics provided STD care, 120 and 90 were able to describe the management of urethral discharge and genital ulcers, respectively. Thirty-four per cent of the urethral discharge regimens were judged to be effective (Table II). Penicillin was mentioned in 30% of responses. As with GPs, a low proportion of clinics (14%) reported effective drug regimens for genital ulcer disease.

Occupational clinics that indicated they used syndromic management were more likely to prescribe appropriate treatment for both urethral discharge (OR 19.68, 95% CI 6.45 - 60.00) and genital ulcers (OR 5.74, 95% CI 1.02 - 32.34). In addition, workplace clinics in KwaZulu-Natal were more likely to provide effective treatment for genital ulcers (OR 8.40, 95% CI 1.75 - 40.26) (Table IV).

Condoms were distributed in nearly all workplaces (98%), almost always for free, although in one-third (33%) of these workplaces, condoms were only supplied on request. A nurse trained in counselling was present in 63% of workplaces; more than half (52%) of these nurses had been trained by the government-sponsored AIDS training, information and counselling centres (ATICCs).

Discussion

The results of this study emphasise the enormous opportunity for addressing the burden of STDs through the private sector. Currently, however, this opportunity is largely being missed. GPs see an estimated 5 million STD cases per annum, yet a distressing number of these appear to be inadequately managed. In particular, women who present to their GPs with PID have very little chance of being adequately treated. Only half the pregnant women presenting are likely to be screened for syphilis.

There are several possible reasons for this situation. Firstly, reported management may not correspond with actual management, although the tendency would be to report better rather than worse practice. More probable is a lack of knowledge and acceptance of the syndromic approach to STDs in the private sector. GPs may rely on outdated knowledge gained at medical school, and despite evidence to the contrary, many may believe that an aetiological STD diagnosis and single therapy are appropriate. For example, more than two-thirds of GPs prescribed only one antibiotic for genital ulcer disease. Lack of consensus in the scientific community, particularly concerning the management of vaginal discharge, may have also delayed acceptance of the principle of syndromic management on the part of certain doctors.

Alternatively, single therapies may be prescribed in the expectation that patients will return for follow-up care if co-infection is present or if the infection does not respond to treatment. However, the probability of poor clients returning (and paying) for a follow-up consultation is low. Moreover, modelling work has shown that the dynamics of STD epidemics are highly sensitive to the duration of an infective episode,[15] and one of the key goals of syndromic management is to treat STDs as early as possible. In our experience many GPs are simply not aware of current trends in STD management, and at the time of the research were not accessing reliable information on the topic. This may change with recently introduced compulsory re-certification.

Cost is often cited as a reason for poor quality of private STD care. The biggest cost factor in STD care is the need to prescribe newer antibiotics effective against particular STD organisms that have a high ability to develop antibiotic resistance. However, it is interesting to note that 60% of regimens for urethral discharge contained a quinolone, suggesting awareness of antibiotic resistance. By the same token, levels of resistance may be deemed sufficiently low to continue prescribing ineffective regimens for cash-paying patients, where drugs are provided as part of the package of care and the overriding incentive is to minimise costs.

Workplace health services also represent a missed opportunity. Of those workplaces that do employ an OHN, just over half actually provided treatment for STDs. In those that did provide treatment, the quality was poor. Partner management was suboptimal and although condoms were widely available, very often they were provided on request only. In key informant interviews conducted as part of the evaluation process[16] the non-issuing of permits for nurse prescribing, and problems of trust and perceived lack of

confidentiality, were raised as key barriers to expanding STD care in this sector. The last problem has been noted by others[8] and may be a significant reason for low utilisation of these services by workers.

This evaluation had a number of limitations. Firstly, while the focus of the evaluation was on the more easily measurable aspects of drug management, it is important to emphasise the other equally important components of good-quality STD care. These include establishing a relationship of trust with the client, partner management, provision of appropriate and sensitive advice and condom distribution. Secondly, the sample of GPs was relatively small and both surveys relied on reported practices. Utilisation data, in particular, are likely to be rather crude estimates, and the inability to distinguish between new and follow-up visits means that the estimates should not be regarded as incidence rates. Finally, it was beyond the scope of this study to address STD care by other private practitioners such as pharmacists and traditional healers. We do not believe that these limitations, while real, change the overall conclusions of the study.

Conclusions

The private sector is crucial to the success of STD control in South Africa. In the context of a devastating and growing HIV epidemic, providing early and effective STD care is one of the most feasible and immediate measures that could be invoked, and is far easier to achieve than change in sexual practices. STD care is but one example of the broader public health impact of private health care, and points to the need for a stronger interaction between public and private sectors around problems of national priority. However, the international evidence suggests that improving the quality of privately provided services is a complex task that requires careful thought as to the economic, professional and patient factors influencing the nature of this care.[17] Recent changes in the professional, regulatory and organisational environment in the private sector may provide opportunities for reaching this sector and need to be investigated.

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An evaluation of antibiotic prescribing patterns in adult intensive care units in a private hospital in KwaZulu-Natal

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The emergence of resistant microorganisms and its association with antimicrobial use is widely recognised as a global concern. Therefore, rational and regulated antimicrobial use is essential in both the public and private healthcare sectors in South Africa. A retrospective chart review was conducted of patients who were prescribed antibiotics over a two-month period. Prescriptions were assessed for adherence to the guidelines, either local or international, and/or to drug registration information, as a measure of rational prescribing practice. Accuracy of dose, and the frequency and duration of administration were evaluated, as were microbiologically informed treatment and de-escalation. 28.8% of patients (n = 226) received antibiotics during their intensive care unit (ICU) admission. A clear indication for antibiotic therapy was noted in 58.5% (n = 131) of the patients, of whom 70.2% were prescribed treatment consistent with the guidelines or drug registration information. Doses were deemed to be correct for 91.1% of the sample, microbiological investigations were evident for 61.2% of patients and de-escalation was noted in only 13.1% of the 70.8% of cases where de-escalation was indicated. Antibiotic prescription rates were relatively lower than those described in the international literature on antibiotic use in the ICU. Antibiotic prescription in the absence of indication in 41.1% of patients, the lack of microbiological verification in 38.8% of patients, inaccurate drug choice in 29.8% of the subset for whom antibiotics were indicated and incorrect dosing in 8.9% of the subset necessitates microbiologically informed therapy and compliance with the treatment guidelines.

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Introduction

The growing burden of antibiotic resistance and its association with antibiotic use highlights the need for the control and regulation of all aspects of antibiotic usage, including prescribing, dispensing and administration.[1] A number of factors have been implicated in the development of antimicrobial resistance, with inappropriate prescribing being one of the most important.[1]

Deuster, Roten and Muehlebach (2010) demonstrated that implementation of the treatment guidelines for the most commonly occurring infections in a tertiary care hospital in Switzerland resulted in an increase in the appropriate use of antibiotics.[2] When devising the treatment guidelines for urinary tract infections and hospital-acquired pneumonia, the published guidelines, local sensitivity patterns and hospital antibiotic formulary were taken into consideration, and were therefore current and appropriate to the setting.[2]

In the South African context, as part of the National Drug Policy, the government has made a commitment to ensuring the "availability and accessibility of medicines for all people".[3] The Essential Medicines List and the Standard Treatment Guidelines form part of the strategy to achieve the specific objectives of the National Drug Policy in the public health sector.[3] The Essential Medicines List and Standard Treatment Guidelines are available for the primary care and hospital level management of patients.[3] The hospital level guideline is available for adults and children. It outlines the management of conditions, including infectious diseases, under various categories, such as dermatological, nephrological and urological disorders.[3] Specific chapters dedicated to ensuring rational antibiotic usage include systemic and nosocomial infections, as well as surgical antibiotic prophylaxis.[3]

While the private sector is encouraged to adopt the guidelines, if applicable,[3] anecdotal evidence shows that they are seldom, if ever, referred to in private hospital settings. The private sector remains largely unregulated in this regard, with formularies developed at some facilities at the discretion of hospital management.[4] There is a paucity of information on the implementation of and adherence to these formularies.

It is imperative in a healthcare system in which both public and private sectors co-exist, that adequate steps are taken to ensure that both sectors contribute to rational antibiotic use in order to curb the growing threat

of antibiotic resistance which affects both the local and international context. While the public sector is guided by the Essential Medicines List and Standard Treatment Guidelines, guideline use appears to be suboptimal in the private sector. The factors which govern the selection of antimicrobial agents for infectious diseases in the private sector, where physicians and prescribers are largely independent, have yet to be defined and explored. Hence, there is a need for baseline surveillance of antibiotic prescriptions in the private sector in South Africa. Primarily, this would establish whether or not, and to what extent, the Essential Medicines List and Standard Treatment Guidelines or other guidelines are followed when managing patients who present with infection. This would ensure optimal outcomes, while limiting the emergence of resistant microorganisms in these facilities.[1]

Since antimicrobial agents are frequently prescribed to patients who are admitted to intensive care units (ICUs),[5] the latter are an ideal setting with respect to the investigation of prescribing practices.

Method

Ethical considerations

Ethics approval was obtained from the Humanities and Social Sciences Research Ethics Committee of the University of KwaZulu-Natal, as well as the National Research Committee of the hospital group. Approval was also obtained from the hospital general manager of the private hospital in which the study was conducted. The collected information was anonymised, thus maintaining patient confidentiality.

Study design

A retrospective analysis of antibiotic prescriptions generated in three adult ICUs in a private hospital in KwaZulu-Natal was conducted over a two-month period, where the electronic profiles of patients were reviewed post discharge. These open ICUs included a surgical, medical and neurosurgical or post-cardiac surgery unit comprising 25, 26 and 8 beds, respectively. Patients who were prescribed antibiotics were included in the study and data were recorded as per the data collection tool shown in Table I.

Antibiotic prescriptions were evaluated against the clinical records to ascertain whether or not antibiotic therapy was indicated, and whether or not the choice, dosage and duration of the antibiotics were consistent with one or more of the guidelines stipulated within the Standard Treatment Guidelines and the Essential Medicines List for South Africa (2012 hospital level for adults),[5] Infectious Diseases Society of America[6-8] and the indications contained in the *South African Medicines Formulary*.[9] Antiviral, antituberculosis, antifungal, prophylactic prescriptions and antibiotics used for off-label, non-antimicrobial indications, such as prokinetic use, were excluded, as were cases with missing or incomplete patient records. Patients presenting with *Helicobacter pylori* infection were also excluded from the analysis. In addition, patients presenting with evidence of established infection and antibiotic prescription prior to hospitalisation were excluded to provide an accurate picture of antibiotic use within the ICU setting alone.

Prescription analysis

Prescriptions were categorised as either treatment or prophylaxis, based on information, including theatre events, contained in the patient file, and prophylactic treatment was excluded from the study. Antibiotic treatment was then stratified according to the speciality, such as Orthopaedics, Nephrology and General Surgery, on the basis of the primary diagnosis undertaken by the primary physician or intensivist, and augmented by information contained in the patient records. In cases where an infection unrelated to or different from the primary diagnosis was present or suspected, this was categorised as a mixed infection, as was the case with patients making use of more than one specialty, as reflected in the primary diagnosis. Each prescription was assessed firstly in terms of whether or not antibiotic therapy was indicated on the basis of vital signs, inflammatory markers, laboratory tests[10] and/or symptoms, and thereafter, one or several guidelines were applied, and therapy assessed in the context of choice, dosage and frequency.[3,6-9] Duration was also measured for all prescriptions. If a microbiological evaluation was undertaken, the analysis included whether or not the choice of drug was consistent with the culture sensitivity result, and whether empiric therapy was de-escalated based on the culture result, if applicable. The preliminary categorisation and analysis conducted by a pharmacist were referred to a specialist microbiologist for confirmation. Consensus was achieved by a joint review of the patient records, where necessary.

Statistical analysis

SPSS® version 21 was used to analyse the data. A p-value < 0.05 was considered to be statistically significant at the 95% level of significance. Descriptive statistics, in the form of frequency (count) and percentage, were computed. Pearson's chi-square was used for inferential statistics to determine whether or not the association between the variables was significant. The binomial test was used to determine whether or not a difference in the proportion of patients within a variable was significantly different.

Results

Eight hundred and twelve patients were admitted to the ICU over the two-month data collection period. Thirteen patients were still in progress at the time of discontinuation of the data collection and were thus excluded, as were 5 paediatric patients, resulting in a final total of 784 eligible patients. Of these, antibiotics were prescribed to 478 (61.0%) during their hospital stay. Patients on prophylactic antibiotics ($n = 164$) were excluded, and only those prescribed an antibiotic in the ICU for treatment purposes were included for further analysis. Following the application of additional exclusion criteria, the total number of patients to whom therapeutic antibiotics were prescribed in the ICU was 226 (28.8%). Two were excluded as the files were unavailable. Thus, the final sample for inclusion in the study was 224.

Table II provides a synopsis of the results, stratified according to specialty, in terms of whether or not antibiotic therapy was indicated, whether or not the correct dose of the antibiotic was administered at the correct frequency. Thus, Table II reflects an independent evaluation of the three separate parameters of antibiotic prescribing by the primary

Table 1: Data collection tool

Patient number		Site of infection	
Gender		Patient allergies	
Number of days in the ICU		Specimen source	
Transfer ward		Wounds	
Length of stay		Invasive procedures	
Medical speciality		Discharged on antibiotics	

Drug therapy								Microbiology cultures		Vitals						Guidelines
Date commenced	Date stopped	Antibiotic prescribed	Dose	Frequency	Route	Number of doses administered	Time administered	Time of therapy (T/P)	Cultures taken (Yes/No)	De-escalation (Yes/No)	Temp	WBC	PCT	CRP	Other	

CRP: C-reactive protein, ICU: intensive care unit, Temp: temperature, T/P: treatment/prophylaxis, PCT: procalcitonin, WBC: white blood cells
Adapted with permission from the Ampath clinical sepsis monitoring spreadsheet

physician or intensivist. A clear indication for antibiotic therapy was noted in 58.5% (n = 131) of patients, as shown in Table II, based on vital signs, inflammatory markers, laboratory tests and/or symptoms.[10] 41.1% (n = 92) did not demonstrate any definitive signs of infection, and were thus deemed to have had no indication, while 0.4% (n = 1) remained unclear.

While the dose and frequency of administration was accurate in 91.1% of patients, it was concerning that antibiotics were indicated in 58.5% of patients, and that treatment was informed by microbiology in only 61.2% of them, clearly suggesting overuse in terms of the former, and misuse in terms of the latter. Upon stratification, overuse was most evident in Cardiology patients. While the correct dosage regimens were prescribed to the majority of patients, the number of patients with a clear indication for antibiotic therapy was low.

Table II: Summary of results per specialty

Speciality	Total	Indication		Microbiology		Correct dose and frequency	
	n	n	%	n	%	n	%
Cardiology	42	9	4.0	22	9.8	40	17.9
Endocrinology	9	3	1.3	4	1.8	9	4.0
Gastroenterology	4	2	0.9	0	0.0	3	1.3
General surgery	26	18	8.0	15	6.7	25	11.2
Mixed infection	72	58	25.9	55	24.6	62	27.7
Nephrology	10	5	2.2	8	3.6	10	4.5
Orthopaedics	2	0	0.0	1	0.4	2	0.9
Pulmonology	38	30	13.4	23	10.3	33	14.7
Trauma	19	6	2.7	9	4.0	18	8.0
Neurology	2	0	0.0	0	0.0	2	0.9
Total	224	131	58.5	137	61.2	204	91.1

Microbiology, and dose and duration were positively and statistically significantly associated with indication using Pearson's chi-square test ($p < 0.05$), attesting to the importance of microbiologically informed antibiotic therapy in terms of drug choice and a duration of 7-14 days or ≥ 14 days in terms of duration of therapy. Of all the patients in the sample (n = 224), microbiological tests were performed for 61.2% to guide antibiotic therapy. De-escalation was evident in only 13.1% of cases, while 8.0% of patients received the appropriate prescribed treatment according to the test results, and therefore could not be de-escalated any further.

The subset of patients with a clear indication for antibiotic therapy (n = 131) was further analysed in terms of choice, dose and frequency of therapy prescribed.

Of the total antibiotic prescriptions that were warranted, a statistically significant 70.2% were compliant with the guidelines when using the binomial test, as shown in Table III.

When stratified, the binomial test indicated a significantly higher proportion of compliance at the 95% significance level (p-value < 0.05) in the Cardiology, General Surgery and Pulmonology patients, while the proportion of compliance with regard to mixed infections was significant at the 90% significance level. There was also a significant association with indication at the 95% significance level (p-value < 0.05), with mixed infection patients showing the highest proportion of indication, followed by Pulmonology patients and those in General Surgery. A significant association was not found between drug choice, dose, microbiology and de-escalation.

Discussion

The percentage of patients for whom antibiotic therapy was prescribed during their ICU stay was 28.8%. This prescription rate is lower than that reported in previous studies, where rates as high as 73.4% were recorded,[11,12] albeit inclusive of both prophylaxis and treatment. This may

Table III: Compliance with the guideline and drug registration information, per specialty

	Total	Guideline or drug registration compliance		Comment
	n	n	%	
Cardiology	9	8	89	The binomial test indicates a significantly higher proportion of compliance at the 95% significance level for this group (p-value 0.039)
Endocrinology	3	1	33	No statistical significance
Gastroenterology	2	1	50	No statistical significance
General surgery	18	17	94	The binomial test indicates a significantly higher proportion of compliance at the 95% significance level for this group (p-value 0.000)
Mixed infection	58	36	62	The binomial test indicates a significantly higher proportion of compliance at the 90% significance level for this group (p-value 0.087)
Nephrology	5	4	80	No statistical significance
Pulmonology	30	21	70	The binomial test indicates a significantly higher proportion of compliance at the 95% significance level for this group (p-value 0.043)
Trauma	6	4	67	No statistical significance
	131	92		

be attributed to the well-established antibiotic stewardship programme currently in place at the facility where the stewardship committee meets regularly to provide updates on the hospital's antibiotic consumption data, thus ensuring that a level of awareness is consistently maintained. While engagement with prescribers in the private sector has traditionally been a challenge, pharmacists in the hospital are an integral part of the healthcare team. In addition to multidisciplinary ward rounds, pharmacist ward rounds ensure continued focus and a bedside review of individual patient prescriptions. However, antibiotic overuse and misuse is still evident, and more concerted effort is required by the antibiotic stewardship team.

Pharmacokinetic and pharmacodynamic parameters must be taken into consideration when prescribing and administering antibiotics to ensure that the concentration of drug achieved at the source of infection is sufficient[5] to treat or eradicate infection. Understanding and applying these parameters contributes to the efficacious use of these agents.[13] Dosing regimens should be designed based on the fundamental characteristics of individual antibiotics, particularly time-dependent versus concentration-dependent killing activity.[14] Incorrect dosing and the excess use of antibiotics have also been identified as a driver for the development of resistance.[13] Thus, the dose and frequency of administration are critical in ensuring optimal drug concentrations which ultimately contribute to effective therapy and the prevention or containment of resistance.[5]

The percentage of patients prescribed correct doses was 91.1%, albeit not always indicated. Doses were deemed to be correct if the prescribed antibiotics were consistent with the drug registration information or currently accepted dosing regimens, while also taking into consideration patient risk factors, such as renal impairment.[9,15] Non-compliance included incorrect dosing intervals, particularly for clarithromycin, cloxacillin, amoxicillin and clavulanic acid, co-trimoxazole, erythromycin, metronidazole and vancomycin. Incorrect doses were also noted for telithromycin, ciprofloxacin and vancomycin, and there were cases in which loading doses were not prescribed for teicoplanin, necessitating the implementation and awareness of the treatment guidelines.

Of the 58.5% of patients with a clear indication for antibiotic therapy, compliance with a guideline (national or international)[1,6-9] or drug registration information,[10] was noted in 70.2% of patients. Drug choice was assessed for appropriateness and rational therapy. The combination drugs used were deemed to be appropriate if the combination was rational and pharmacologically justifiable. The choice of empiric therapy and combination therapy was a specific area of concern in this regard. Inappropriate combinations were evident in 69.2% of the 29.8% patients for whom there was a clear indication for antibiotic therapy, and included amoxicillin/clavulanic acid plus piperacillin/tazobactam, and meropenem plus imipenem.

Empiric antibiotic selection is based on a number of factors, including the site of suspected infection, likely causative organisms and local resistance patterns.[14] Microbiology investigations, namely microscopy and culture, are essential in refining empiric therapy to the most appropriate and cost-effective, narrow-spectrum agent.[13,14] In addition, de-escalation on the basis of microbiology results may limit the

development of antimicro [redacted]
the collection of the samp [redacted]
microbiological means as th [redacted]
empiric treatment has been [redacted]

In terms of microbiologi [redacted]
microbiological investigati [redacted]
de-escalation was practi [redacted]
appropriate therapy was pr [redacted]
de-escalated, despite being [redacted]
attributed to the reluctance [redacted]
ill patients' treatment regim [redacted]
that appears to be effective [redacted]
and represents a definite [redacted]
prescribing practice.

The results also indicate [redacted]
an indication for antibiotic [redacted]
compared to those with no [redacted]
patients seemed to be pre- [redacted]
by covering for possible infe [redacted]

Prolonged duration of the [redacted]
contributor to the inappropri [redacted]
hospitals.[17] According to Hav [redacted]
in the treatment duration re [redacted]
and selection pressure.[17] Ot [redacted]
may be effective in preventin [redacted]
selective pressure on bact [redacted]
should be individually deter [redacted]
duration.[5] However, there are [redacted]
regard to optimal duration sh [redacted]
laboratory data.[13]

The duration of antibiotic th [redacted]
descriptive, and included the [redacted]
stay. Antibiotics were admini [redacted]
days, regardless of whether [redacted]

Conclusion

While antibiotic prescription [redacted]
described in the internation [redacted]
antibiotic prescription in the [redacted]
and the lack of microbiologica [redacted]
with inaccurate drug choice in [redacted]
were indicated and incorrect [redacted]
microbiologically informed the [redacted]
guidelines. Inappropriate pres [redacted]
practice guidelines aimed at i [redacted]

Antibiotic stewardship is a key [redacted]
in individual patients, while [redacted]
Significant emphasis has bee [redacted]
hospital group which served as [redacted]
in some areas, such as appr [redacted]
exists for further improvement [redacted]

be attributed to the well-established antibiotic stewardship programme currently in place at the facility where the stewardship committee meets regularly to provide updates on the hospital's antibiotic consumption data, thus ensuring that a level of awareness is consistently maintained. While engagement with prescribers in the private sector has traditionally been a challenge, pharmacists in the hospital are an integral part of the healthcare team. In addition to multidisciplinary ward rounds, pharmacist ward rounds ensure continued focus and a bedside review of individual patient prescriptions. However, antibiotic overuse and misuse is still evident, and more concerted effort is required by the antibiotic stewardship team.

Pharmacokinetic and pharmacodynamic parameters must be taken into consideration when prescribing and administering antibiotics to ensure that the concentration of drug achieved at the source of infection is sufficient[5] to treat or eradicate infection. Understanding and applying these parameters contributes to the efficacious use of these agents.[13] Dosing regimens should be designed based on the fundamental characteristics of individual antibiotics, particularly time-dependent versus concentration-dependent killing activity.[14] Incorrect dosing and the excess use of antibiotics have also been identified as a driver for the development of resistance.[13] Thus, the dose and frequency of administration are critical in ensuring optimal drug concentrations which ultimately contribute to effective therapy and the prevention or containment of resistance.[5]

The percentage of patients prescribed correct doses was 91.1%, albeit not always indicated. Doses were deemed to be correct if the prescribed antibiotics were consistent with the drug registration information or currently accepted dosing regimens, while also taking into consideration patient risk factors, such as renal impairment.[5,15] Non-compliance included incorrect dosing intervals, particularly for clarithromycin, cloxacillin, amoxicillin and clavulanic acid, co-trimoxazole, erythromycin, metronidazole and vancomycin. Incorrect doses were also noted for telithromycin, ciprofloxacin and vancomycin, and there were cases in which loading doses were not prescribed for teicoplanin, necessitating the implementation and awareness of the treatment guidelines.

Of the 58.5% of patients with a clear indication for antibiotic therapy, compliance with a guideline (national or international)[3, 6-8] or drug registration information,[10] was noted in 70.2% of patients. Drug choice was assessed for appropriateness and rational therapy. The combination drugs used were deemed to be appropriate if the combination was rational and pharmacologically justifiable. The choice of empiric therapy and combination therapy was a specific area of concern in this regard. Inappropriate combinations were evident in 69.2% of the 29.8% patients for whom there was a clear indication for antibiotic therapy, and included amoxicillin/clavulanic acid plus piperacillin/tazobactam, and meropenem plus imipenem.

Empiric antibiotic selection is based on a number of factors, including the site of suspected infection, likely causative organisms and local resistance patterns.[14] Microbiology investigations, namely microscopy and culture, are essential in refining empiric therapy to the most appropriate and cost-effective, narrow-spectrum agent.[13,14] In addition, de-escalation on the basis of microbiology results may limit the development of antimicrobial resistance.[14,16] Timing with regard to the collection of the samples is also crucial in detecting infection by microbiological means as the causative organism may not be detected if empiric treatment has been commenced.[13,14]

In terms of microbiological tests, 61.2% of patients underwent microbiological investigations to guide therapy. Of these patients, de-escalation was practised in only 13.1% of patients, while appropriate therapy was prescribed to 8.0%. 70.8% of therapy was not de-escalated, despite being warranted. The lack of de-escalation may be attributed to the reluctance of prescribers to make changes to critically ill patients' treatment regimens or the tendency to continue with therapy that appears to be effective.[16] Nevertheless, this rate was concerning and represents a definite focus area for intervention with regard to prescribing practice.

The results also indicate that a greater percentage of patients with an indication for antibiotic therapy underwent microbiological tests compared to those with no definite indication. Therapy in the latter patients seemed to be pre-emptive, with prescribers exercising caution by covering for possible infection.

Prolonged duration of therapy has been identified as the largest contributor to the inappropriate use of antibiotics in wards and ICUs in hospitals.[17] According to Havey, Fowler and Daneman (2011), a reduction in the treatment duration reduces usage and also limits adverse effects and selection pressure.[17] Others have also noted that a shorter duration may be effective in preventing the development of resistance by reducing selective pressure on bacteria.[18] While optimal duration of therapy should be individually determined, evidence exists to support a shorter duration.[5] However, there are exceptions to this,[5] and the decision with regard to optimal duration should be guided by clinical assessment and laboratory data.[13]

The duration of antibiotic therapy measured in this study was purely descriptive, and included the complete duration of the patient's hospital stay. Antibiotics were administered to the majority of patients for 7-14 days, regardless of whether or not there was an indication.

Conclusion

While antibiotic prescription rates were relatively lower than those described in the international literature on antibiotic use in the ICU, antibiotic prescription in the absence of indication in 41.1% of patients, and the lack of microbiological verification in 38.8% of patients, together with inaccurate drug choice in 29.8% of the subset for whom antibiotics were indicated and incorrect dosing in 8.9% of patients, necessitate microbiologically informed therapy and compliance with the treatment guidelines. Inappropriate prescribing has frequently been addressed by practice guidelines aimed at improving antimicrobial utilisation.[19]

Antibiotic stewardship is a key strategy in optimising treatment outcomes in individual patients, while limiting the emergence of resistance.[5] Significant emphasis has been placed on these initiatives within the hospital group which served as the study site. While the impact was seen in some areas, such as appropriate dosing regimens, the opportunity exists for further improvement. Antibiotic stewardship should not only be

extended to include additional strategies, such as guideline development and implementation, but should also serve as the framework for best practice to ensure optimal patient care.

Declaration

Dipika Chunnilall is currently employed by the hospital group, and has received funding towards completion of a postgraduate qualification. The hospital group did not contribute to the study design, data collection methods, analysis and interpretation of the results, and writing of the manuscript.

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"LL24"

To the Editor: Poor-quality tuberculosis (TB) care is now a larger barrier to reducing mortality than poor access.[1,2] South Africa (SA) has one of the highest TB burdens globally. Despite ongoing efforts to improve access to testing and treatment in primary care settings,[3] only half of South Africans with drug-susceptible TB and 22% with rifampicin-resistant TB successfully navigate TB care pathways to the public sector.[4] Furthermore, a recent study showed that 29% of South Africans with TB symptoms first report to the private sector.[5] Delays in TB diagnosis have been reported in the public and private sectors.[6,7] Efforts to evaluate and improve quality of TB care must therefore involve both sectors.

The standardised patient (SP) methodology, which involves the training of individuals to act as 'mystery patients', has helped to identify early bottlenecks in the TB care cascade. SP studies in India, China, Kenya and SA[8-12] have shown that, with regard to TB testing, higher-level clinics generally do better than lower-level clinics, formal practitioners outperform informal practitioners, and public providers perform better than private health carers (Fig. 1).[13] In a recent study, providers at public clinics in urban SA performed comparatively well – sputum for GeneXpert (Cepheid, USA) testing was collected in 84% of SP encounters, HIV testing was done in 47%, and unnecessary prescriptions were provided for only 26%.[8,13] SA's leading role in prioritising TB in policy and practice possibly contributes to its strong public sector performance.[14-16] However, it is unclear to what degree recent advancements in TB screening and care recommendations have permeated the private sector.

In other high-burden countries, such as Kenya and India, when SPs presented with classic TB symptoms, nearly all private practitioners were found to dispense and collect fees for medications, including antibiotics and steroids.[10] Such clinical practices could delay diagnosis and/or harm patients with undiagnosed TB.[10] In SA, however, general practitioners (GPs) cannot profit from medication dispensing and many include the cost of common medications in their consultation fee, thus removing financial incentives for dispensing, as has been suggested in other settings.[12,17] In India, private practitioners are commonly involved in TB treatment,[18] and referral to the public sector for free TB testing and treatment is as low as 4%.[11] Conversely, SA physicians do not traditionally treat TB in the private sector[19] and there are few existing public-private TB programmes. Hence, private GPs may be more likely to refer patients with TB to the public system. A systematic study evaluating quality of care, including drug dispensing and referral practices, would identify current practices in the private sector, as well as strategies for more effective GP engagement.

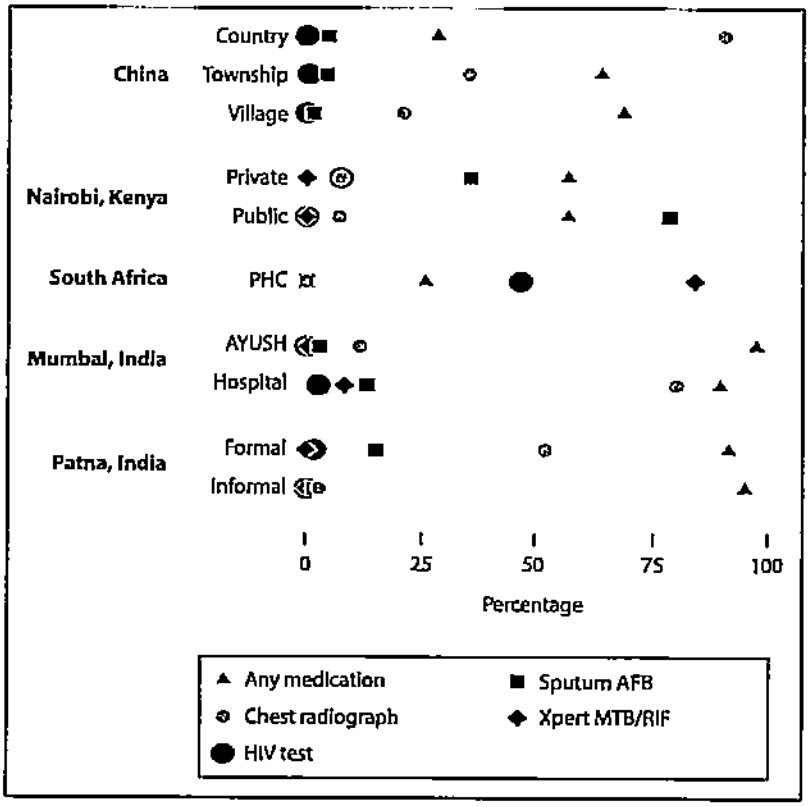

Fig. 1. Key findings of standardised patient studies on how suspected tuberculosis was managed.[13] (PHC = primary health centre; AYUSH = practitioners trained in Ayurveda, Yoga and naturopathy, Unani, Siddha, and Homeopathy; AFB = acid-fast bacillus; MTB/RIF = Mycobacterium tuberculosis/rifampicin.)

TB remains a daunting health problem in SA. Efforts to improve access to TB care must be coupled with commensurate efforts to improve healthcare quality. SP studies have been used in high-burden settings to describe the quality of TB care. As nearly one-third of symptomatic TB patients first present to the private sector in SA, the SP methodology would be a useful approach to understand and describe current practices among private healthcare providers.

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EVALUATION OF THE NOTIFIABLE DISEASE SURVEILLANCE SYSTEM IN GAUTENG PROVINCE, SOUTH AFRICA

by

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Submitted in (partial) fulfilment of the requirements for the degree Master of Medicine in Community Health in the Health Sciences Faculty
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(January 2007)

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capturer in some years. At the end of 2005 an assistant was appointed to the unit for 6 months but this only alleviated the situation temporarily.

4.2: Survey of private sector primary health care providers in Gauteng Province examining notifiable disease awareness and reporting practices

Characteristics of the sample

The survey was conducted over a period of six weeks and 69 private practitioners were interviewed. The response rate was 18.4% (69 out of 375). The majority of the non-responses (299) were due to unavailability of the practitioner at the times that calls were made. Three attempts were made to contact each practitioner before classifying them as a non-response. Three practitioners explicitly refused participation on the grounds that they were too busy. Another three were excluded on grounds of relevance to the study as two of them were exclusively doing anaesthetics and the third had moved out of clinical medicine into lifestyle counselling. The characteristics of the sample are reflected in Table 4.4.

Table 4.4 Characteristics of General Practitioners who responded

Characteristic	Number (n)	Percent (%)	95% Confidence Limits	
District where practice is situated				
Ekurhuleni Metro	10	15	7.2%	25%
Johannesburg Metro	30	44	31.6%	56%
Sedibeng	2	3	0.4%	10.1%
Tshwane Metro	19	28	17.5%	39.6%
West Rand	8	12	5.1%	21.6%
Years since medical graduation				
0 to 10 years	14	20	11.6%	31.7%
11 to 20 years	16	23	13.9%	34.9%
21 to 30 years	18	26	16.3%	38.1%
More than 30 years	21	30	19.9%	42.7%
Number of patients seen per day				
1 to 10	14	21	11.7%	32.1%
11 to 20	26	38	26.7%	50.8%
21 to 30	22	32	21.5%	44.8%
31 to 40	5	7	2.4%	16.3%
>40	1	1	0%	7.9%
Access to communication media				
Land line telephone	68	99	92.2%	100%
Cellular Phone	57	83	71.6%	90.7%
Internet access at practice	46	67	54.3%	77.%
Fax machine at practice	64	93	83.9%	97.6%

The median length of time since qualification as a medical practitioner was 23 years (i.e. qualified in 1983) and the range was between 3 and 52 years. The

median number of general practitioners working at the respondents' practices was two (range 1 to 13), with a mode of one.

Thirty seven percent (n=26) of respondents stated that they always reported cases of notifiable conditions seen at their practices to the department of health. Twenty eight percent (19/69) of respondents reported having a notification book present in their practice. The commonest reasons cited for not consistently reporting cases were the assumption that facilities to which patients with such conditions were referred would notify them (10/69) and that the notification process was too cumbersome (9/69).

There appeared to be a negative association between compliance with disease notifications and number of years since qualification (Chi-squared test of variability, p=0.07) as shown in Table 4.5.

Table 4.5 Cross-tabulation of cohorts of years since qualification by self-reported compliance

	Self-reported Compliance with Notifications		
Years since qualifying	**Not compliant**	**Compliant**	**TOTAL**
1 to 10 years	5	9	14
Row %	35.7	64.3	100
Col %	11.6	34.6	20.3
11 to 20 years	9	7	16
Row %	56.3	43.8	100
Col %	20.9	26.9	23.2
21 to 30 years	14	4	18
Row %	77.8	22.2	100
Col %	32.6	15.4	26.1
> 30 years	15	6	21
Row %	71.4	28.6	100
Col %	34.9	23.1	30.4
TOTAL	43	26	69
Row %	62.3	37.7	100
Col %	100	100	100

Single Table Analysis

Chi-squared	df	Probability
7.0448	3	0.0705

Respondents were questioned on their awareness regarding whether or not specific medical conditions are notifiable. Of the twelve conditions listed in the survey questionnaire, nine were notifiable. Figure 4.2 demonstrates the responses to whether or not these diseases are notifiable.

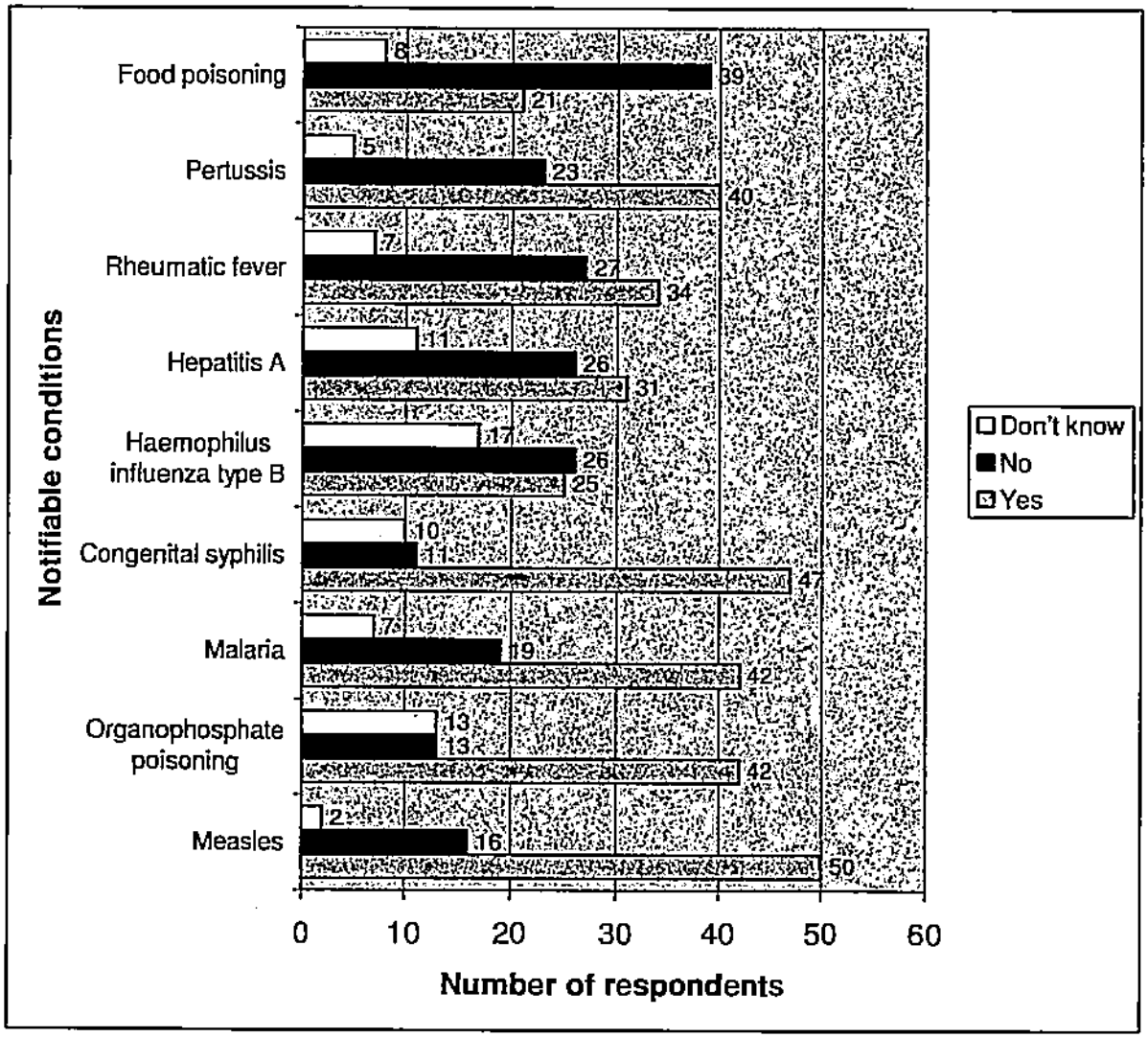

Figure 4.2 Participant responses on knowledge about notifiable diseases

A percentage score of correct answers i.e. number of correct answers as a percentage of total number of questions was calculated for each respondent. The

percentage results were approximately normally distributed around a mean of 59.5% (confidence limits 55.4% and 63.6% at α=0.05).

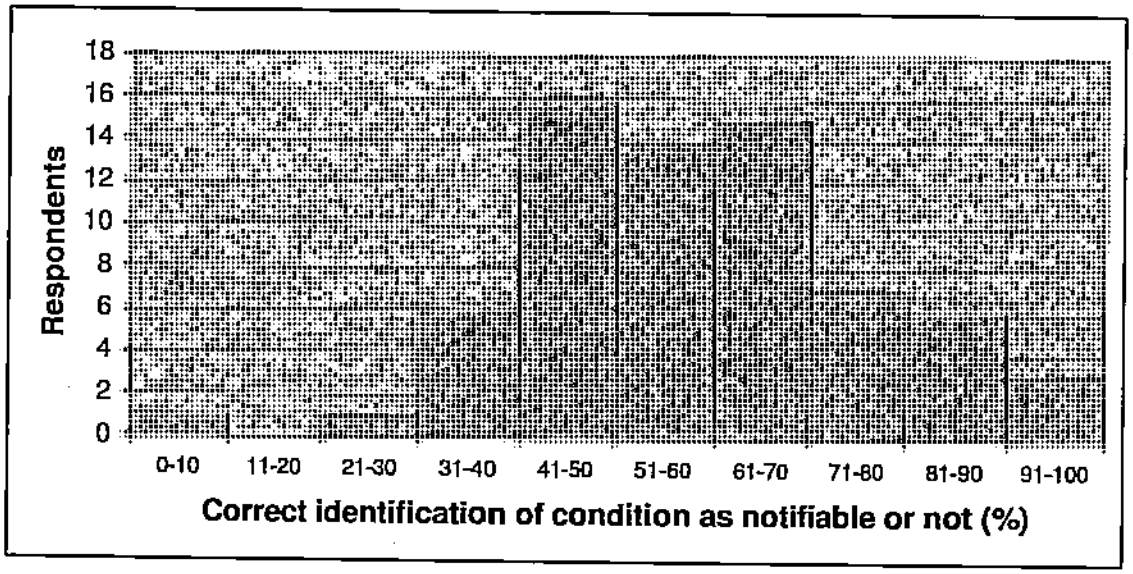

Figure 4.3 Frequency distribution of response scores on knowledge of notifiable diseases

The interval since medical graduation was inversely proportional to the result as demonstrated in figure 4.4. The linear regression model demonstrates a negative relationship is not statistically significant for α=0.05 (p=0.21).

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'Issues of equity are also issues of rights': Lessons from experiences in Southern Africa

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Abstract

Background: Human rights approaches to health have been criticized as antithetical to equity, principally because they are seen to prioritise rights of individuals at the expense of the interests of groups, a core tenet of public health. The objective of this study was to identify how human rights approaches can promote health equity.

Methods: The Network on Equity in Health in Southern Africa undertook an exploration of three regional case studies—antiretroviral access, patient rights charters and civic organization for health. A combination of archival reviews and stakeholder interviews were complemented with a literature review to provide a theoretical framework for the empirical evidence.

Results: Critical success factors for equity are the importance of rights approaches addressing the full spectrum from civil and political, through to socio-economic rights, as well as the need to locate rights in a group context. Human rights approaches succeed in achieving health equity when coupled with community engagement in ways that reinforce community capacity, particularly when strengthening the collective agency of its most vulnerable groups. Additionally, human rights approaches provide opportunities for mobilising resources outside the health sector, and must aim to address the public-private divide at local, national and international levels.

Conclusion: Where it is clear that rights approaches are predicated upon understanding the need to prioritize vulnerable groups and where the way rights are operationalised recognizes the role of agency on the part of those most affected in realising their socio-economic rights, human rights approaches appear to offer powerful tools to support social justice and health equity.

Background

Despite growing advances in medical technologies, global health status inequalities continue to persist [1-6]. Developing countries are faced with declining expenditures on health and social services, increasing burdens posed by both communicable and non-communicable diseases and economic systems that are not oriented to fostering sustainable development for the poorest and most marginalized [7,8]. In recognition of the social causation of these health trends, the World Health Organisation (WHO) established a Commission on the Social Determinants of Health, reflecting a global concern for the persistence of, and, in some cases, growth in global health inequities [9].

Under these circumstances, does the discourse of human rights offer opportunities for public health practitioners to better negotiate conflicting needs in restructuring health care in countries in transition? Human rights approaches are increasingly cited as important for translating global treaty commitments into health programmes [10,11], in community mobilization to end oppressive conditions harmful to health [12], and in developing appropriate HIV/AIDS intervention programmes [13]. Indeed, some have argued that the attainment of the Millennium Development Goals is not feasible without a commitment to human rights [14].

However, when it comes to the practice of public health, there appears to be a deep-seated ambivalence around whether human rights are really compatible with effective, efficient and equitable health policies [15,16]. This is particularly evident in debates around expanding access to anti-retroviral (ARV) treatment and the potential adverse impact on health equity [17,18] and, more recently, in proposed moves to introduce "routine" testing for HIV in an effort to increase the numbers on ARV treatment [19,20].

Human rights, when framed as entitlements, could be seen to impact negatively on resource allocation by favouring individuals over the welfare of the community, to the detriment of equity [21-23] or contribute to health system inefficiency. For example, South Africa's Minister of Finance, responding to calls for a Treatment Plan for HIV in South Africa, was quoted as arguing that money should rather be spent on poverty relief and building schools than on anti-retroviral drugs, which, in his opinion, were a "waste of very limited resources." [24]

For this reason, rather than automatically assuming that public statements on the links between human rights and health are evidence of consonance, careful analysis should be able to demonstrate why and how this is the case [25]. Otherwise, lofty intent to realize human rights in health will inevitably trip up on the reality of utilitarian public health culture. Despite more than a decade of work on the links between human rights and health [26], only recently have the conceptual links between health equity and human rights begun to receive detailed elaboration to facilitate operationalisation in public health practice [27,28].

This paper reports on the findings of research conducted by the Network for Equity in Health in Southern Africa (EQUINET) to explore the potential synergies between health equity and human rights-based approaches to health [29]; in particular, to identify the specific mechanisms by which human rights can serve to promote health equity.

Methods

A case-based approach selected three examples to illustrate health rights approaches (Table 1) based upon: a) spread of cases across the region; b) applicability across the region; c) illustrative of different ways in which social mobilization links to human rights approaches; d) accessibility through EQUINET networks of the organizations that were central to each case study.

Data collection took place through a mix of archival research, review of published and unpublished articles and documents (web based and hard copy) and two rounds of interviews with selected key informants. In the first round, members of the organizations involved in each case study were interviewed; in the follow-up, 4 fur-

Table 1: Case Studies selected for inclusion

Case	Motivation
1. Treatment Access for HIV: Struggles in Southern Africa (TAC and the Pan African Movement)	The case study illustrates numerous aspects relevant to equity and human rights, as well as providing an example of a successful civil society mobilisation. It raises issues of both legal and advocacy approaches to rights; it touches directly on equity in resource-poor environments; it raises health system concerns; the material is easily available; its lessons may be relatively easy to generalise even if the struggle's successes are not; the relationship between civil society mobilisation and the state/its policy choices will be obvious.
2. Patients' Rights Charters (South Africa, Malawi and Zimbabwe)	Patients' Rights Charters are a commonly used model for promoting the right to health care; it is a consumerist approach to improving quality of health services; it directly addresses health as a socio-economic right; it may or may not be linked to mobilising strategies; it commonly presumes success when it may not have high impact, which itself is a lesson worth exploring – i.e. the limitations of Charters may be as important as any successes; in the implementation a Charter, the role of public participation would be critical.
3. Community Working Group on Health (Zimbabwe)	Example of broad mobilising approach to health; although much of its work does not explicitly speak a language of human rights, it would be useful to tease out whether its approach is actually a rights approach; the role of the CWGH in influencing State Policy, particularly pro-poor choices; leverage over resources outside the health sector, etc. Perhaps comparisons to be made to other developing country examples (e.g. in Brazil)

ther key informants outside the organizations were interviewed. The following areas were probed in interviews: links between civil and political rights, and socio-economic rights; the organization's engagement with the state and how its work builds community engagement; what kinds of rights strategies have been used to promote health equity; global links in their work; and, intersectoral interventions made possible through the adoption of rights approaches. From the responses, key themes were drawn out so as to develop a clearer conceptual understanding of the relationship between health equity and human rights.

Participants in the informant interviews were given the summaries of discussions for their feedback and invited to join a health rights reference group and participate in a review workshop with civil society participants. Participants gave informed consent prior to interview. Ethics approval for the study was obtained from the Faculty of Health Sciences Research Ethics Committee, University of Cape Town.

Because lack of clear definitions frequently result in confusing use of public health concepts [30] and this imprecision may underlie [25] inappropriate critiques of human rights paradigms [16], the study adopted a priori definitions of key concepts as outlined in Table 2.

Results

The Treatment Access Campaign (TAC) started in 1998 as an advocacy group for people with HIV/AIDS to "campaign for greater access to treatment for all South Africans, by raising public awareness and understanding about issues surrounding the availability, affordability and use of HIV treatments." [33] Initially inspired by similar rights-oriented HIV organizations in the developed world, TAC rapidly developed into a broad-based social movement that has significantly advanced treatment access both in South Africa and in the region, facilitating the establishment of the Pan-African HIV/AIDS Treatment Access Movement. TAC's work has been at the centre of a robust civil society debate in South Africa around the provision of antiretrovirals, in which considerations of effectiveness, equity and efficiency have been prominent [23,24,34-36]. The TAC has also been instrumental in supporting civil society groups in a campaign for a basic social security grant (known as a Basic Income Grant) as a poverty alleviation strategy, and forming alliances to campaign for health system reform.

The Malawian Patients' Rights Charter (PRC) emerged following an advocacy training programme hosted by a foreign NGO in 2000, attended by a range of civil society participants who subsequently established the Malawi Health Equity Network (MHEN). While initial interest was directed at tackling conditions of service for health workers, the network shifted focus to patient advocacy, because of the seeming insurmountability of labour relations difficulties in the health sector. By doing so, it drew in a broader constituency, including professional associations and statutory councils, as well as HIV and consumer advocacy NGOs. The MHEN programme on patient rights focused on the minimum rights available to patients when attending a health service and through iterative interactions with parliamentarians, produced a Charter, which was submitted to government in early 2003. However, because the MHEN relied on leadership coming from the Ministry of Health in bringing the Charter to

Table 2: Key Concepts for the interface between Human Rights and Health Equity

A **"Public Health Approach"** is that which addresses the health of whole populations, rather than individuals, using population level analyses to identify and implement strategies for improving well-being of communities, groups or whole populations.

"Equity" (vertical equity) refers to policies and programmes that aim to address the prevention of health inequalities – differences in health outcomes that are unnecessary, avoidable and unfair, for example, by allocating greater resources to those in greater need. Vertical equity therefore applies to the process of reaching equal outcomes, of allocating greater resources to ensure reductions in health outcome differentials and, by necessity, implies addressing the power imbalances that underlie inequalities in outcomes and processes[27].

Human rights take the form of claims that individuals can legitimately exercise on society to various material or social entitlements deemed essential for dignity and well-being. These claims are based on international governmental consensus incorporated in international law. Unlike principles of medical ethics, once a treaty is ratified by a state, it can be held accountable for its conduct. Human rights are indivisible, including both civil and political, and socio-economic, as well as developmental (environmental/ecological) rights.

Civil and political rights include traditional freedoms (e.g. of speech, to vote, of movement, etc). **Socio-economic rights** (e.g. housing, health care, education, etc) are entitlements to services or goods that are social in nature. Supposed distinctions between socio-economic, on the one hand, and civil and political rights are increasingly being recognized as a historically-specific political choice driven by the the Cold War. Currently, global policy formation is therefore increasingly acknowledging the indivisibility of all human rights.

A **"Human Rights Approach"** embraces four elements[31,35]:

1. The use of human rights standards and norms to develop policy and programmes
2. The use of human rights standards and norms to analyse and critique government performance, sometimes combined with a monitoring function
3. The use of human rights standards and norms to facilitate redress for those who suffer violations of their rights.
4. The use of human rights standards and norms to support advocacy and civil society mobilization.

Health as a human right is articulated both as access to health care and as the right to health creating-conditions (such as housing, education, a safe environment, etc) in national and international statutes. Government's core obligations to realising the right of access to health care is elaborated in General Comment 14 issued by the United Nations Committee for Economic, Social and Cultural Rights[36].

finality, progress in implementation has all but ceased since the Charter's submission. [29] Organizational difficulties due to ministerial restructuring meant that key meetings could not be held and inclusion of very senior public servants (such as, amongst others, the Permanent Secretary for Health) exacerbated difficulties in coordinating such a high level Task Team.

The Community Working Group on Health (CWGH), a network of membership-based civic and worker organizations in Zimbabwe, was formed in early 1998 in response on to an ongoing decline in the quality of health services, increasing poverty, and industrial action by health workers protesting worsening conditions of service [37,38]. These developments followed the introduction of Economic Structural Adjustment Programmes that eroded post-independence health status gains achieved through heavy investments in pro-poor policies [39]. The CWGH was therefore formed to strengthen civil society capacity to engage with government over health policies through advocacy and networking. It has substantial rural presence (health committees in 21 out of 58 districts in Zimbabwe) and provides a channel for interaction between health care providers and civic organizations, enabling community input to policy processes through advocacy that seeks to reverse or at least halt government's relinquishing of its commitments to equity in health. It has set up opportunities for rural health committees to provide input to Parliamentary structures and participates in oversight of a national AIDS levy established in Zimbabwe to finance various HIV/AIDS activities. The levy was introduced in 1999 and is based on a 3% levy of all taxable income that is routed into a National AIDS Trust Fund, managed by a National AIDS Council.

The case studies illustrate that civil society campaigns for health work most effectively when emphasising the invidivisibility of civil and political, and socio-economic rights (Table 3). For example, the TAC's lobbying for treatment access has also enabled redress of discrimination against people with HIV, through links with legal advocacy groups. Similarly, the CWGH has addressed socio-economic rights under the rubric of service delivery, whilst simultaneously referring members to legal groups involved in defense of civil and political rights. An informant, commenting on the role of the PRC in Malawi, observed:

"... when you talk about ... patients' rights, it is something that emerges from several factors ... Like literacy levels, and also geographical ...and material accessibility, and availability of information in rural areas – it's not there. And of course the socio-economic status of the patient determines exposure to different information. So there is a strong linkage between patient rights, socio-economic status, and general human rights."

Evans et al [2] make the link more directly to health equity by pointing out that undemocratic societies characterized by corruption, violence and discrimination are more likely to demonstrate higher inequities in health than those where "respect for human rights, transparency and opportunities for civic engagement" flourish. Health equity therefore requires a conception of rights that operationalises the indivisibility of the full spectrum of human rights.

Theme 1: Rights alone are not enough, but need to be coupled with community engagement

All three case studies illustrate, either by example or by implication, the importance of broadening rights approaches to embrace active community engagement. One informant described the TAC as "an interesting combination of a rights based movement that also relies on grassroots mobilization. The pressure is through the courts, through the media, as well as in the communities, and on the streets. It is a kind of multipronged approach."

The TAC has used the South African constitution's commitment to socio-economic rights to force the state to provide antiretrovirals (ARVs) for the Prevention of Mother-to-Child Transmission of HIV [23,34,35]. However, while legal strategies have been one pillar of the TAC's successes, TAC bas consistently matched legal strategies with grassroots mobilisation in ways that are mutually reinforcing, arguing that "human rights arguments and legal acrion alone are of limited use. It is crucial to combine them with mass mobilization, including human rights awareness campaigns." [34] TAC has explicitly invested organizational effort in workshops to train members in under-

Table 3: Key themes from the case studies: Human rights, health equity and community engagement

- Rights alone are not enough, but need to be coupled with community engagement
- Rights, appropriately applied, can strengthen community engagement
- Rights, conceived in terms of agency, are the strongest guarantors of effective equity-promoting impacts
- Rights should strengthen che collective agency of the most vulnerable groups
- Rights approaches should aim to address the public-private and global divides in relation to Human Rights
- Information and Transparency are key to human rights approaches that build equity
- Human rights approaches provide additional opportunities for mobilising resources outside the health sector

standing health rights and treatment access as a right, as consistently evident in TAC campaign media.

By comparison, a seminal case highlighting the justiciability of socio-economic rights in South Africa, the Grootboom case, which involved the halting of evictions of a community living in an informal settlement outside Cape Town in 2000, was hailed for its important legal precedent [40]. However, the court decision produced no grassroots impacts because there was no community action to complement the legal challenge. Thus, despite the court decision, no major shifts in housing policy eventuated, nor have communities and groups in most need been able to make use of the decision to improve their situation [41]. Illustrative of TAC's arguments, therefore, legal strategies alone are of limited impact without popular mobilisation.

Theme 2: Rights, appropriately applied, can strengthen community engagement

The idea that a charter of patients' rights could assist in realizing better quality health care underlies much health planning [42,43]. However, it is less obvious how such a charter would operationalise users' rights. What emerged from the case studies was that the charter's most valuable role would be to provide community members with a standard for negotiating quality of care with providers at their facilities in the context of meaningful community participation.

"I think it will be even more important, within this new sector wide approach, to have such a charter. So that community members know what is their right, and how they can negotiate that with the health workers, or the district head office, or the district health management teams."

However, in the way the PRC was developed in Malawi, as a technical process without community input, it did not build organization around health. Indeed, evidence suggests that, once submitted to government, the PRC was allowed to fade from a development agenda.

"... in terms of the process, somehow, there was a loose link between the community members, and the people who were facilitating it. Plus, also, there wasn't the follow up, or linkage, between the facilitators, and the Minister of Health officials, who, according to my knowledge, took it up and said, okay, we need to institutionalize it, and then from there, the momentum started decreasing slowly, and now there is silence about it..."

Opportunities to challenge this demobilisation through community participation structures in Malawi were reported as severely restricted by the legacy of the previous Banda government, when civic structures were used to exercise political patronage rather than play active roles on behalf of civil society. Health Committees were therefore distrusted as vehicles for community voice. In contrast, the CWGH's work illustrates effective mobilisation around entitlements to health services using community health committees to enhance civil society capacity to input to local facility management and national policy. For example, the CGWH has brought community preferences into decisions regarding the distribution of the national HIV levy and facilitated community inputs to the Parliamentary Portfolio Committee on Health [63]. Even under difficult political conditions prevalent in Zimbabwe over the past decade, engagement with health rights, albeit in the discourse of service delivery, opened spaces for civil society to advance the needs of the most vulnerable communities, while at the same time, building community organization. Similarly, the use of rights approaches has both advanced the TAC's treatment access objectives whilst simultaneously helping to recruit members, strengthen the organization and build alliances outside of the health sector.

Thus, in pursuing health equity, human rights, appropriately applied, can strengthen community engagement to achieve health equity.

Theme 3: Rights, conceived in terms of agency, are the strongest guarantors of effective equity-promoting impacts

Diderichsen et al, identify four levels at which powerlessness lies at the root of health inequalities: social stratification; differential exposure based on social stratification; differential vulnerability given an exposure; and differential consequences [44]. Attempts to redress inequities therefore have to engage with questions of power [28,30] and it is not surprising that the public health community is increasingly returning to approaches that revive the notion of community agency in public health practice. Rather than framing the poor as candidates for protection or redistributive policies by a benevolent state, commentators have called for a "new" public health that takes seriously its commitment to community empowerment [45-49]. This agency is illustrated in all three case studies, where mechanisms were present to facilitate active community interaction with policy makers. Interactions were either collaborative (e.g. committees to develop a charter or a resource distribution decision on a national levy) or combative (e.g. a courtroom challenge for treatment access for HIV) but were all essential to achieving equitable outcomes. For example, one informant described the impact of the work of TAC as follows:

"TAC does draw a link between people's health and to the degree to which they network and mobilize, and the degree in which they are involved in other community processes. Just by nature of the fact that they are increasing

awareness and activity around people's health, and in this instance, specifically around HIV/AIDS, it is drawing a link between a kind of evident ability to impact on your world and a sense of self advocacy."

Working towards health equity, therefore, requires rights-based approaches that provide opportunities to all people (not just the most vocal) to input to policy and its implementation so as to reverse the social exclusion that is the key pathway between social inequality and health inequities [50]. More recently, attention has focused on the role of active citizenship as the key element for translating hard-won rights to ARV access into reality [36]. Of course, the strength of rights-based approach is that is can simultaneously foster community agency whilst still holding government to account for its human rights obligations, thereby avoiding the abrogation of state responsibility for the welfare of all its citizens, so typical of neoliberal constructions of the modern state.

Theme 4: Rights should strengthen the collective agency of the most vulnerable groups

In describing the work of the TAC, informants emphasized the importance of collective actions. For example:

"These are highly politicized activists whose strength is in the organization, in the fact that individuals are organized as a group, and as a movement."

The fact that agency is strengthened not for individuals but as part of a vulnerable group is critical to challenging the powerlessness [50] underlying health inequalities. For example, the advocacy work of the TAC and CWGH in bringing community preferences to bear on national health policy, has reversed the "thinness of reserves" [44] characteristic of groups suffering health inequities. Analogous to role of human rights in enabling individuals to realize their capabilities [51], is the role of community mobilization using rights strategies to provide citizens with collective avenues to ensure access to the resources needed for health. In the words of one informant:

"This is not just self, but a collective community type advocacy and health. So there is this incredible communication around what we can achieve if we are mobilized and we can network, stay focused and work together, and, in particular, the direct benefits of a certain campaign around health. There are all these kinds of side benefits that also come with it. People do realize the impact that can be made when we work together ..."

Moreover, rights approaches that prioritize the most vulnerable and provide people with opportunities for agency, intrinsically address an equity promoting agenda by privileging the experiences of poor and marginalized groups [52]. Such views, however, are not uniform. For example, Muller argued that "The fact that TAC has the financial clout to take the government to court does not mean that its case is more important than that of people living in rural poverty." [22] Implicit in this view is the notion that the TAC is a kind of aristocracy amongst marginalized people. However, this view represents an ahistorical interpretation of rights [53] that ignores the fact that rights have emerged not just from legal strategies but from a combination of political pressure, grassroots mobilisation and activism [54]. As Valente [55] (1998) argues, "... the history of human rights ... has been tortuously and painfully built from conflict to conflict, at the cost of the suffering, pain, struggle and lives of the great majority of anonymous human beings ..." (p180). A human right approach must engage the dimension of power [56], since social justice and anti-discrimination are key dimensions of its framework. Out of this challenge to power, emerges a synchrony with health equity frameworks that seek to redress health differences that are unnecessary, avoidable and unfair [57].

Theme 5: Rights should aim to address public-private and global divides in relation to Human Rights

In the context of the undermining of national sovereignty by globalisation, rights approaches have afforded opportunities for global solidarity and action to strengthen pro-poor policies at national and international levels [23,35]. For example, the TAC's support of the South African government in defending its pharmaceutical legislation from legal attack by industry drew on unprecedented global solidarity mobilized through the TAC's international networks and played an important role in defeating the industry's opposition to the legislation, forcing industry to reduce drug prices for antiretrovirals [58]. South Africa's experience in rights campaigns for treatment access has also played a key role in building a regional treatment access movement in Southern Africa, where needs are as desperate but resources far more limited than in South Africa [59].

Similarly, at international level [58], collaboration during trade negotiations between NGO's aligned to treatment access initiatives and southern states was able to ensure that access to essential medicines was addressed at the Doha round of WTO talks. In this way, community mobilisation has been able to reinforce, and be consolidated by, action at the level of state power, successfully harnessing potential synergies between formal and constituent power, even in an environment of market-driven disempowerment of nation states [35]. Rights approaches have therefore increased opportunities for mobilising support through the global human right movement, which has, in turn, strengthened state capacity to regulate in favour of pro-poor policies.

Besides private sector industry, rights approaches also place the spotlight on the behaviour of donor agencies [60,61] and non-state actors [60]. For example, one respondent drew attention to the influence of donors on policy development:

"Yes ... there are a lot of linkages ... at national level, how different factors, political, social, might influence the work to go ahead or not, and also globally, there are also several factors, it's an issue of power. Maybe the donors, they have a certain preference, they might not take it as an important issue."

A construction of rights as being simply about what entitlements citizens can expect from government is therefore neither helpful for equity, nor grounded in the political realities of globalization. Indeed, multinational companies are increasingly being expected to uphold rights, such as the right to participation hy employees and communities affected by their operations [61,62]. In its work on pharmaceutical access, the TAC has shown how it is possible to expand the purview of rights to address public-private inequalities that drive health inequities. Moreover, the inclusion of private providers' obligation to provide emergency care in the Malawian PRC reflects how rights approaches, even in less high-profile settings, can begin to tackle public-private inequalities using community agency and advocacy language. However, such strategies to extend the envelope of what rights approaches can do, will only succeed in the context of strong civil society action.

Theme 6: Information and Transparency are key elements for health equity

As both a right in itself and an enabling mechanism to realize other rights, access to information plays a key role. On the individual level, information is key to countering powerlessness:

"... when you talk about the Patients' Charter, patients' rights, it is something that emerges from several factors. Because sometimes, why patients might feel powerless, is because of lack of information."

But it is also at a collective level, that information empowers civil society to drive the shifts in political will required for policy change [55]. Systems that maximize transparency and accountability offer the most likely opportunities for community engagement and meaningful input. For example, the TAC have mobilised their own 'experts' to develop positions on key HIV-related debates, so that information is available to grassroots membership through its media and workshops, and disseminated through campaigns to the public. The CWGH have enlisted researchers to access information on health conditions and services to support campaigs for health equity in Zimbabwe. Use of research has occurred dialectically, strengthening civil society's ability to engage with the state and the private sector in the pursuit of health equity goals.

Conversely, absence of information and transparency undermines community agency, and drives conflict and distrust that undermines redress of inequity. For example, the closure of channels of access to information regarding Poverty Reduction Strategy Papers in Malawi has been interpreted as reversing gains made through interaction with policy-makers over the PRC [29].

Rights to information are therefore key to operationalising the right to health.

Theme 7: Human rights approaches provide additional opportunities for mobilising resources outside the health sector

Human rights approaches also facilitate mobilization across sectors. A legal victory in South Africa's courts relating to the right to housing was key to bolstering the TAC's rights-based arguments for ARV access, and the CWGH has been able to integrate housing and sanitation issues easily in its health advocacy. The TAC's central role in contributing to a broad-based coalition advocating a Basic Income Grant as a social security measure illustrates not only a grasp of the multisectoral origins of health but also a strategic capacity to develop alliances across a range of sectors, including the Trade Union movement, churches and other elements of civil society. The breadth of these alliances (i.e. with the 'non-vulnerable' in organized labour, academia, research, parliamentarians and health care providers) has been extremely effective through both intellectual (research data) and advocacy (media, protest mobilization), countering the social stratification implicit in the vulnerability underlying health inequities [44]. As argued by one informant:

"... government ... has been concerned with attracting international capital, it has been concerned with the so-called first economy, but not the 'second economy', the informal sector, the hopeless, the jobless, the people who work on the side of the road, waiting for job opportunities. So there is economic injustice ... I think the TAC forms part of a broader agenda to address that."

Conclusion

Where it is clear that rights approaches are predicated upon understanding the need to prioritize vulnerable groups, where the way rights are operationalised recognizes the role of agency by those most affected, and where rights are conceived as the complete spectrum of civil and political, through to socio-economic rights, human rights approaches appear to offer powerful tools to support

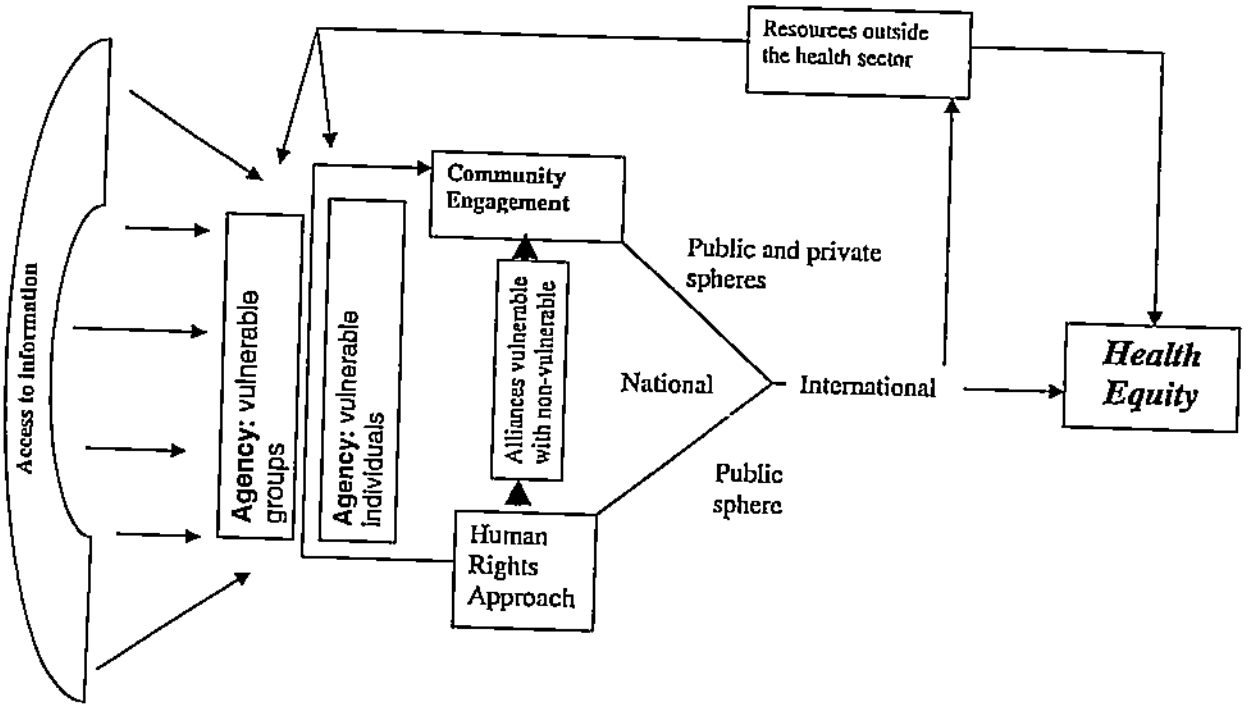

Figure 1
Human Rights approaches, Agency and Health Equity: A Model.

social justice and health equity (figure 1). Public health concerns for equity then become entirely consonant with human rights-based strategies and tactics. The synergy between public health and human rights in relation to equity lie less in the pursuit of individual rights but rather in the way social processes and consciousness are given the opportunity to the interface with the state in ways that that secure collective rights.

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

The author conceived the research idea, oversaw data collection and undertook analysis and write up of the material, including revisions recommended by reviewers.

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