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Preface

There is increasing awareness that health is a global issue in its real sense. Health workers are trained and migrate across countries; diseases travel across borders through humans, animals, air and water; medicines and equipment are developed by multilateral pharmaceutical industries; and factors such as climate change affecting health are global. This implies many of the solutions are also global, either in terms of involving a number of countries, or in terms of requiring a global level of agreements or interventions, such as through WHO.

The Sustainable Development Goals (SDGs) have a global focus, as they cover all countries including our own. SDG3, “to ensure healthy lives and promote well-being for all at all ages”, addresses health in a wide and challenging way, as well as through the life cycle. A number of the 17 SDGs with their 169 targets also have major relevance to health. Health improvements may often require interventions in other sectors or across sectors, such as education, environment or energy.

Despite its relative size, Norway plays an important role in global health. Our contributions to maternal and child health, and combating communicable diseases, especially HIV/AIDS, TB and Malaria, are well known. We are also an important partner to WHO and other agencies within global health.

Continued Norwegian engagement in global health requires a strong technical and academic base of people and institutions,

covering a wide set of health issues through independent research and debate. This is why Norad and the Centre for Global Health at the University of Oslo decided to collaborate in order to facilitate publication of a series of papers.

We are particularly grateful for the important contributions by The Journal of the Norwegian Medical Association, which enabled this endeavour. We also thank all the authors for their papers. Although we have not been able to include all contributions in the series “Global Health in the Era of Agenda 2030” in this special issue, they are all available, as they have been published in The Journal of the Norwegian Medical Association throughout the year. Our hope is that this will stimulate further engagement and debate not only in Norway, but also globally.



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Global health and its changing landscape

As the landscape of global health is changing markedly, we launch our new article series; «Global Health in the Era of Agenda 2030».

The Journal of The Norwegian Medical Association (Tidsskriftet) issued its first special edition on global health in 2011 (1). Now is the time to broaden the scope. To foster insight and better understanding of the recent developments in global health among health professionals, the Centre for Global Health, University of Oslo, and the Norwegian Agency for Development Cooperation (Norad), in collaboration with Tidsskriftet, have invited contributions to an article series entitled «Global Health in the Era of Agenda 2030». The first two articles are published alongside this issue (2, 3).

Norway has been engaged in international and global health for decades. The Millennium Development Goals (4) provided a set of common goals and priorities, and Norway was among the countries which committed strongly to them. Although the health-related goals were not reached in totality, remarkable progress was made on maternal and child mortality, as well as communicable diseases. The increasing number of global health initiatives with their potential to attract additional funds contributed to this.

United Nations member states unanimously adopted the Sustainable Development Goals (5) in October 2015. In addition to the third goal, «to ensure healthy lives and promote well-being for all at all ages», many of the 16 others have great relevance for health. Examples are elimination of extreme poverty, improved nutrition, quality education, gender equality, climate action, clean water and sanitation, urban development and affordable clean energy. The move from the Millennium Development Goals (4), with a narrow focus, to the more complex Sustainable Development Goals (5) is a major shift. It expands to areas like neglected tropical diseases, non-communicable diseases and mental health. At the same time the achievements of the Millennium Development Goals have to be sustained and improved. These challenges must be tackled while development assistance for health is unlikely to increase.

Achieving the Sustainable Development Goals will cost an estimated USD 5–7 trillion and it is assumed that their pursuit will shape the next 15 years of financing for development (6). Financial resources, including domestic public and private funds, need to be mobilised and spent in accordance with national priorities, while ensuring all people obtain the health services they need without suffering financial hardship when paying for them. This concept is often referred to as Universal Health Coverage, which requires

a concerted effort with regard to domestic and external financing of national health systems, as well as support for global public goods for health (7).

There are also a number of new challenges. The West African Ebola virus epidemic was a warning about global health threats; antimicrobial resistance requires global solutions and cooperation; conflicts and civil unrest are contributing to the largest migration crisis since the Second World War; weak health systems are unprepared for the omnipresent global health threats and are unable to guarantee provision of even very basic healthcare services. These challenges need to be tackled by the global community. At the same time as it comes of age, «that obscure object of global health» (8) is attracting a growing body of critical studies. Criticism should be encouraged and inspire us to give clear and concrete answers to current and future problems. It would not, for instance, be advisable to rely on metrics to the degree that global health does, without engaging in critical enquiries about it (9). Similarly, there is an increasing interest in understanding the long threads that connect the field with previous international health policies (10).

Global health is also gaining momentum among countries that have formerly been reluctant. Former recipients of aid are now becoming providers, including South Korea, China, Brazil and others. The research field has come onto the agenda of many academic institutions which have advocated for the concept of a multi- and cross-disciplinary approach to health. It is our hope that our new series will reflect, and reflect upon, all these different aspects of global health relevant for all individuals on the planet.

We are very grateful to the coordinating as well as administrative contribution and support of Ingeborg Haavardsson, coordinator of the Centre for Global Health, University of Oslo.

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Global health financing: Priority to poor people or poor countries?

Global health initiatives have long focused on the health of poor people in poor countries. Changes in demographic, economic, and health patterns challenge our understanding about where to direct our attention. Most of the world's poor now live in middle-income countries. How should this affect the distribution of development assistance for health? Should we give priority to poor people or poor countries?

The Sustainable Development Goals were adopted by the United Nations in September 2015. These goals have broadened the global development agenda in general, and the global health agenda more specifically (1). Goal 3 – *Ensure healthy lives and promote well-being for all at all ages* – is devoted to health.

An objective under this goal is to *achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all*. Moving towards universal health coverage will require an increase in health financing – both domestic and external – from current levels (2). External financing is commonly referred to as ‘health aid’ or ‘development assistance for health’ (3). Though health spending in low- and middle-income countries is mainly financed by government budgets and private financing where patients pay directly to healthcare providers (also known as out-of-pocket payments), development assistance also plays a role. The absolute amount reached USD 36.4 billion in 2015 (4).

The first years of the millennium (2000–2009) have been described as the ‘golden era’ of global health, where development assistance for health increased by 11.3% per year through increased contributions from high-income countries as well as philanthropic donors (4). Since 2010 the increase has faltered, with an annual growth of 1.2% between 2010 and 2015 (4). The implications for poor people in countries with low domestic spending on health care deserve further scrutiny. When resources are limited, it is crucial to discuss where and how to best invest resources for health.

The primary objective of development assistance for health could be seen as to improve the health of the world's poorest, and that funding should aim to reach populations with the greatest need. This is particularly important with respect to universal

health coverage. The poorest populations are often those who suffer the most from lack of access to health care, both due to poorer health and a greater risk of catastrophic out-of-pocket expenses. The latter refers to medical expenses that push households below, or further below, the poverty line (5).

In this article, we draw upon recent literature examining the altered classification of countries by income level, and the corresponding changes in the geographic distribution of the world's poorest. We then discuss implications for how development assistance for health should be distributed to finance universal health coverage.

The majority of the world's poorest do not live in the poorest countries

Recent developments at country level challenge traditional assumptions about the geographic location of the world's poorest populations. The landscape has drastically changed since 1990. Almost 75% of the world's poorest now live in middle-income countries (Figure 1 and Table 1) (6, 7). The altered distribution can partially be explained by economic development at country level.

Between 1990 and 2010 many countries, including populous countries such as China, Nigeria, India, Indonesia, and Pakistan, transitioned from low-income to middle-income country status. In spite of economic development and improvements in average income per capita, the absolute number of poor people fell less than expected in most of these countries (8).

Now, 90% of the world's poorest are concentrated in approximately 20 countries, and almost half of these are middle-income countries previously classified as low-income countries (8). When countries have transitioned to middle-income status, they also transition away from support from global health initiatives such as GAVI (formerly known as the Global Alliance for Vaccines

and Immunization) and the Global Fund (6, 9).

Distributing global health financing fairly

From one perspective, what should matter to development assistance is ‘poor people’, irrespective of their geographic location (10). Accordingly, middle-income countries should be eligible for development assistance for health (10–12). Further, the classification itself has been criticised as the threshold is somewhat arbitrary (12–14); countries above or below the same threshold differ widely with respect to health needs and the capacity to address them (9, 10).

On the other hand, obtaining middle-income status reflects a country's increasing internal capacity to respond to its health needs, in some cases entirely without external support. The financing gaps are thus likely to be greater for low-income countries (13). Recent estimates from the World Health Organization support a view that the poorest countries are in most need of external health financing (15). The study estimated the additional investments needed to achieve the health-related sustainable development targets in low- and middle-income countries, and identified large financing gaps.

Many countries will depend on continued external financial support to strengthen their health systems. Particularly, fragile and

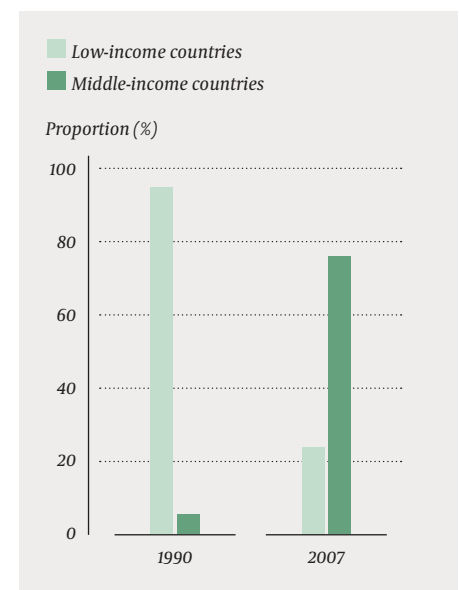


Figure 1 Proportion of the world's poorest living below USD 1.25 a day in low- and middle-income countries (6).

Table 1 Health and poverty in low-, middle- and high-income countries in 2013 (7).

	Life expectancy at birth (years)	Infant mortality rate (infant deaths/1000 live births)	% of population in poverty (USD1.90 a day, 2011 PPP)
High-income countries	80.4	4.9	0.3
Middle-income countries	70.7	32.6	9.8
Low-income countries	61.1	56.4	46.2

conflict-ridden states with weak health and welfare institutions will continue to need development assistance for health (15). Further, the study argued that middle-income countries are 'well equipped to self-finance the investment', and that the largest financing gaps are in low-income countries (15), indicating that development assistance for health should primarily be directed to these countries.

Despite gaps in healthcare financing, most countries have the capacity to increase investments in health systems (15). Spending on health care is predicted to progress faster in upper-middle-income countries, while health spending in low-income countries is estimated to remain low (16).

This is an additional argument for giving more priority to low-income countries. Even if they experience economic growth, many are far from spending the recommended 5 % of gross domestic product on health care (17). However, middle-income countries may have difficulties in the short term in mobilizing resources to replace recent bilateral, multilateral and philanthropic support. It is therefore crucial to consider potential harms induced by shifting resources away from middle-income countries.

Views diverge about whether middle-income countries, due to their share of the world's poorest populations, should continue to be eligible for development assistance for health. Scholars have proposed that middle-income countries should not be automatically excluded from development assistance for health per se, but that each country must be considered on a case-by-case basis, given their heterogeneity (10, 11, 13).

More recently, efforts have been made to systematically assess criteria guiding the allocation of development assistance for health. Two overarching criteria for distribution have been suggested (13, 18): 'need' and 'effectiveness'. The 'need' criterion prescribes that development assistance for health

(or aid more generally) should be allocated to countries with the greatest need. This could be measured using a range of indicators, including gross national income per capita, under-five mortality rate, the burden of disease, or income inequality.

«Despite gaps in healthcare financing, most countries have the capacity to increase investments in health systems»

The 'effectiveness' criterion prescribes that aid should be allocated to countries where the development gains, such as improvements in health, are likely to be the greatest. A simulation of the implications of eleven criteria identified that low-income countries would receive most development assistance for health given a needs-based approach linked to domestic capacity to address health needs (9). Upper-middle-income countries would receive a greater share of development assistance for health if an income-inequality criterion was given greater weight (9).

Depending on countries' ability to pay, as measured by gross national income per capita, should we ask whether middle-income countries ought also to contribute to financing global health (13). Some of these countries, such as China, India, and South Africa, have for some time provided aid to other countries (19). These and other countries can play a significant role in the efforts to strengthen financing of health challenges, particularly those that require global collective action.

Global public goods

Since the Ebola outbreak in 2014–15, academia and policymakers have paid increasing

attention to the need for global financing arrangements to strengthen production of *global public goods* (20, 21).

According to the classic definition, global public goods are considered to be goods that are both non-excludable and non-rivalrous (22). When a good is non-excludable, no person (or country) can be prevented from enjoying the benefits of the good once it becomes available. When a good is non-rivalrous, one person's consumption does not diminish the quantity available to others. For example, the reduced risk of infectious diseases is considered a classic global public good – the benefits are both non-rivalrous and non-excludable to the global population.

Initiatives to improve national and global preparedness to protect against future epidemics and pandemics are also referred to as efforts to strengthen global health security (23). The recent establishment of the Coalition for Epidemic Preparedness (CEPI) is an example of a shared global arrangement to finance the achievement of this global public good (20).

Collective financing to produce global public goods and strengthen global health security complicates our discussion of the allocation of global health financing. So far we have primarily discussed how financing and development assistance for health should be targeted to meet the healthcare needs of populations in low- and middle-income countries.

The World Health Organization's estimates to achieve Sustainable Development Goal 3 offer some guidance for financing of global public goods, as in-country epidemic and pandemic preparedness relates to global financing of other health needs (15). The study suggests that three-quarters of the investments to achieve the health targets should be in health workforce and infrastructure, including services that strengthen preparedness against epidemics and pandemics (15). Thus, promotion of global public goods and global health security must not entail diversion of resources away from broader efforts to strengthen general health services, but rather underpin these efforts. However, achieving this synergy will also require careful thinking about how to manage potential tensions (24).

A shared responsibility

As countries progress to achieve the health-related development goals, low-income

countries will, in spite of increased domestic financing, still face large financing gaps which require external financing (15, 17).

The majority of the world's poorest now live in middle-income countries, which should have higher domestic capacity and the ability to fund universal health coverage themselves. Yet, large within-country inequalities in income, health and other indicators of well-being represent huge challenges to these countries, which suggests that their transition from external

support should be gradual. The increasing capacities of middle-income countries present opportunities to strengthen cooperation and mechanisms to finance shared health challenges.

The main impetus for promoting universal health coverage and addressing other global health challenges should not be self-interest. Rather, our efforts should stem from the fact that it is unfair and unacceptable in a globalised and interconnected world that income levels and poverty still

determine people's opportunities to lead long and healthy lives.

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Implementing a birth registry in a developing country – experiences from Georgia

BACKGROUND

Georgia is the first developing country in the world to have established a national digital, medical birth registry. The Georgia Birth Registry was officially inaugurated on 1 January, 2016. The purpose of this article is to assess the quality of selected variables and present preliminary results from the year 2016.

MATERIAL AND METHODS

The Registry resembles the Nordic birth registries in structure. There are 285 medical facilities involved, each entering 267 variables from week 12 of pregnancy to hospital discharge. In 2016, 52 399 women and 53 236 newborns were recorded as valid entries in the Georgian Birth Registry.

RESULTS

The completeness of the Registry in 2016 was 93.9 %. The difference between the reported number of newborns in the Registry and in official statistics was 3441. The mean gestational age was 271.3 days and the Caesarean section rate 43.5 %. The mean birth weight was 3262 g. Newborns delivered by Caesarean section had a lower gestational age and lower birth weight compared to those delivered vaginally.

INTERPRETATION

There are more newborns registered annually as Georgian citizens than the number of infants born in the country. This leads to inaccurate official reporting on perinatal mortality rates.

MAIN POINTS

Previously reported perinatal mortality rates from Georgia are likely to have been underestimated.

The Caesarean section rate in Georgia in 2016 was 43.5 %, which is considerably higher than recommended as a measure to reduce mortality and morbidity.

Both birth weight and gestational age were lower in the Caesarean section group.

Population-based systematic registration of health events is vital for the development of tools to improve health care systems and health care services, and to provide a basis for research. A birth registry records data on pregnant women such as demographics, disease history, antenatal visits and treatment during pregnancy as well as data on the delivery and the newborn infant up to seven days after delivery (1). Several of the Nordic countries established birth registries for the purpose of epidemiological monitoring about 50 years ago in order to facilitate earlier detection of tragedies like the Thalidomide disaster (2).

National birth registries are vital parts of the health care system in many developed countries. Since establishing a birth registry requires a certain infrastructure and financial resources, they are rarely prioritised in less developed nations. Georgia is defined as an upper middle-income developing country, ranked 70 on the Human Development Index in 2016. The republic is located in the Caucasus region with a population estimated at 3 171 000 in 2016 (3). According to a 2014 census, 86.4 % of the population are defined as ethnic Georgians (4). Life expectancy at birth is 75 years and 56.3 % of the population lives in urban areas (5). The fertility rate in Georgia in 2015 was 2.3 (4). The current health care system was introduced in 2013 and includes a universal antenatal health care package. Additional health care services are made available through private health insurance and against out-of-pocket payment.

In Georgia, gynaecologists working either in hospitals or in antenatal out-patient clinics provide all pregnancy care. Basic

antenatal care is covered by the state, thus coverage is high (88.3 %) (3) and follows the WHO recommendation with at least four check-ups per pregnancy. Currently, the new recommendations of eight check-ups is being implemented (6). 99.5 % of pregnant women give birth with qualified personnel present in one of the country's 102 maternity wards (3). The officially reported perinatal mortality (PM) rate (13.8/1000) and the maternal mortality rate (36/100 000) (3) are higher than expected in a country ranked as high as Georgia on the Human Development Index, and where most women have adequate access to health care during pregnancy and delivery. Consequently, the Georgian health authorities, together with Georgia's National Centre for Disease Control & Public Health, UNICEF and the University of Tromsø - The Arctic University of Norway initiated work to establish the national birth registry in 2014, with the ultimate goal of improving maternal and perinatal health. The Georgian Birth Registry was inaugurated on 1 January 2016, and is the first national birth registry ever to be established in a developing country. UNICEF provided initial funding while the University of Tromsø - The Arctic University of Norway, and Georgia's National Centre for Disease Control & Public Health, provided technical assistance.

The aim of this article is to assess the quality of selected variables of the Registry and present preliminary results from the first year of registrations (2016).

Material and method

The Georgia Birth Registry

The Georgia Birth Registry uses a unique 11-digit personal identification number allocated to every citizen to link with data from the Service Development Agency at the Ministry of Justice (SDA), which is Georgia's Civil Registry. A local Georgian IT-company (CITi), created the entire registry system in 12 months, starting in September 2014. Training and piloting took place in the autumn of 2015 in the capital Tbilisi and several other cities. All clinics that provide antenatal, birthing or post-natal care have access to Internet, and Registry information is submitted online. Information is updated (or added) after every consultation related to spontaneous abortions, pregnancy terminations, antenatal check-ups or deliveries.

Doctors or midwives at the respective health facilities are responsible for entering information on all 267 variables. The variables include information on maternal medical and pregnancy history, maternal and paternal characteristics, the current pregnancy, the delivery and on the newborn. Some variables ($n = 40$) are mandatory, e.g. women's birth date and estimated blood loss, while the remaining are optional e.g. occupation, or reason for induced abortion.

Health care providers receive reimbursement from the government for each woman who follows the antenatal care programme guidelines, but only if complete information is entered into the Registry (introduced as a mandatory requirement on 1 May, 2016). The registry office, currently staffed by five full-time employees, is responsible for quality control. The Georgia Birth Registry automatically generates birth certificates and accommodates storage of all medical files on an integrated e-health platform.

Data handling and ethical considerations

The Georgia Birth Registry data are owned by Georgia. The University of Tromsø - the Arctic University of Norway has permission to use data for scientific purposes, but assumes no ownership. All personal identifiers (names and identification numbers) in the current dataset have been removed, and randomly generated numbers replace each personal identification number. The identification key has been deleted. The Regional Committee for Medical and Health Research Ethics of Northern Norway has approved the use of the data (2017/404/REK Nord).

Study sample and variables

The final sample comprised 53 236 newborns and 52 399 women. Exclusions are presented in figure 1.

Information on maternal age, number of deliveries, proportions of singleton and multiple births, mode of delivery, gestational age (GA), birth weight and sex of the newborn was extracted from the Georgia Birth Registry. Parity was not included due to substantial amounts of missing data.

The completeness of the birth registry was estimated by comparing the number of newborns in the Georgia Birth Registry with the number of newborns recorded in the Civil Registry. Missing information was calculated, with the expectance of 100 % representative-

ness for all variables, for each woman and each newborn infant.

Gestational age is primarily reported by last menstrual period (if certain) and secondarily by ultrasound estimate. Perinatal mortality rate was calculated by the number of stillborn infants + the number of live born infants who died before seven completed days / the total number of newborns. The number of perinatal deaths was extracted from the Ministry of Health and the medical department at the National Centre for Disease Control & Public Health because deaths occurring after hospital discharge were not registered in the Georgia Birth Registry at the time.

Statistical analysis

Descriptive statistics of continuous variables are presented as mean values with standard deviations (SDs). Frequencies and percentages are presented for categorical variables. Maternal and newborn characteristics are presented by reported or missing gestational age and by mode of delivery. We used the statistical software R (R Foundation for Statistical Computing, Vienna, Austria), version 3.4.0 for the statistical analyses.

Results

The total number of newborns reported to Georgia's Civil Registry in 2016 was 56 695 while the total number registered in the Georgia Birth Registry was 53 254 (fig 1), thus the Georgia Birth Registry's coverage of newborns was 93.9 %. For the selected variables presented in table 1 the following percentages of data were missing: maternal age (0 %); sex (0.4 %); gestational age days (28 %) and birth weight (0.4 %). There was a substantial proportion of missing data on gestational week (27%) and for that reason we displayed maternal and infant characteristics (by both reported and missing gestational age) in table 1, to make sure that the two groups were comparable.

Newborns with missing information on gestational age were more likely to be delivered vaginally and were slightly heavier than newborns with reported gestational age (tab 1). Since there were no indications of lower birth weight among newborns with missing gestational age, we applied the same exclusion criteria to all newborn infants (fig 1).

The mean maternal age was 27.2 (standard deviation 5.8) years. A total of 51 568 singletons and 1668 multiples were born. The

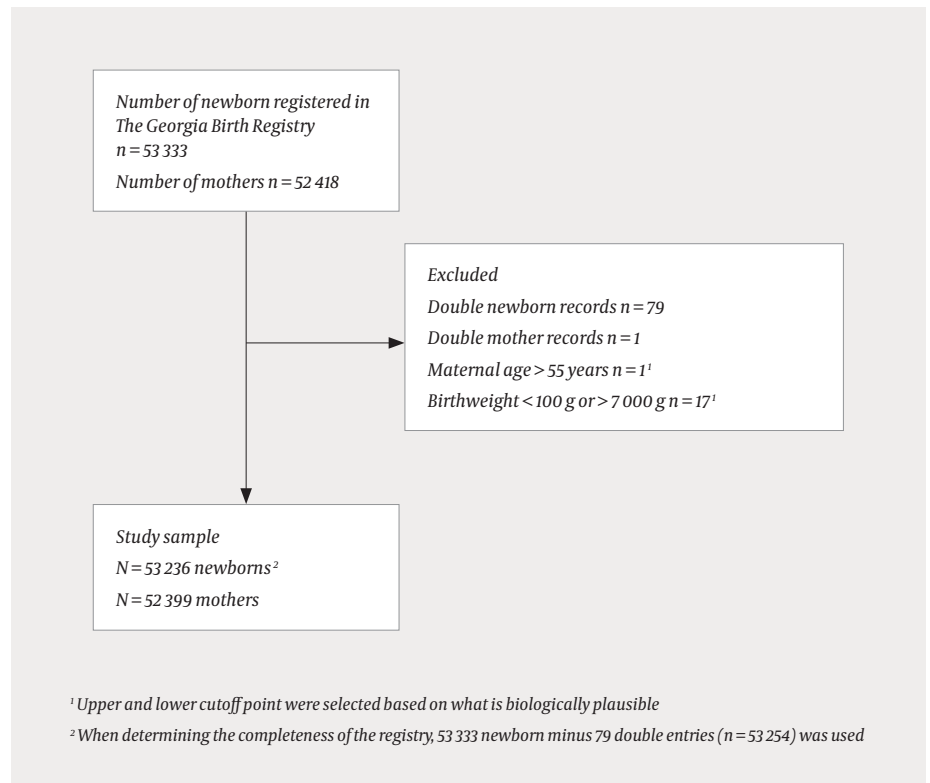


Figure 1 Flowchart of exclusion criteria for the analytical part of the paper

Caesarean section rate was 43.5 % of the total number of newborns. Of the 53 236 newborn infants, 51.4 % were males and 49.6 % females. There were 742 perinatal deaths registered in 2016, thus the total perinatal mortality was 14.8/1000 newborns, of which stillbirths contributed 10.5/1000. The mean gestational age (standard deviation) was 271.3 (14.2) days. Newborn males had a higher birth weight (standard deviation) than females, 3322 g (617) vs. 3202 g (583) respectively. Newborns delivered by Caesarean section had a lower gestational age, 269.1 (13.0) vs. 273.2 (14.9) days, and lower birth weight, 3233 g (625 g) vs. 3284 g (588 g), than those delivered vaginally (tab 2).

Discussion

Our results indicate that the Georgia Birth Registry has a rate of completeness of 93.9 % in its first year compared with the numbers officially reported to Georgia's Civil Registry. The first results from the Georgia Birth Registry show that the perinatal mortality rate in Georgia in 2016 was 14.8/1000, which is slightly higher than the officially reported rate of 13.8/1000 (3). The probable explanation for the

discrepancy in numbers is that the Georgia Birth Registry records the number of infants born in Georgia annually, except home deliveries (-0.5 %), while Georgia's Civil Registry records the number of newborn citizens.

This situation may occur in countries that do not have a well-functioning birth registry. Infants may be legally registered as citizens even if they are not born in Georgia, as long as one of the parents is a Georgian citizen (7). Parents may choose to do so because there are advantages to being Georgian, for example that Georgians may visit the Schengen area without a visa, a convenience not shared by any of the surrounding countries. Consequently, the true perinatal mortality rate is probably somewhere between 13.8/1000 and 14.8/1000, but closer to the latter.

The Caesarean section rate in Georgia is 43.5 %, which is 2 to 3 times higher than in the Nordic countries, where Caesarean section rates vary between 15 and 21 % (8). Although WHO no longer recommends a specific Caesarean section rate, proportions above 10 % are not associated with a reduction in maternal and perinatal mortality (9). The high Caesa-

Table 1 Description of maternal and newborn characteristics by reported and missing data on gestational age from the Georgia Birth Registry in 2016.

Maternal characteristics	Gestational age reported	Gestational age missing
Total number of birthing women, n	38 270	14 153
Multiple births, %		
No	98.5	98.1
Yes	1.5	1.9
Mode of delivery, %		
Vaginal	55.7	60.1
Caesarean section	44.3	39.9
Maternal age (years) ¹ , mean (standard deviation)	27.1 (5.8)	27.4 (5.8)
Maternal age ¹ (years), %		
< 13–19	0.2	8.0
20–24	28.3	26.5
25–29	31.2	31.1
30–34	20.5	21.6
35–39	9.6	10.2
40–44	2.3	2.3
> 45	0.2	0.2
Newborn characteristics		
Total number of newborn infants, n	38 839	14 397
Multiple birth, %		
No	97.0	96.5
Yes	3.0	3.6
Mode of delivery, %		
Vaginal	55.3	59.8
Caesarean section	44.7	40.2
Sex, %		
Male	51.1	51.0
Female	48.8	48.9
Undetermined	0.1	0.1
Birth weight ² (g), mean (standard deviation)		
Total	3 255 (610)	3 281 (592)
Male	3 319 (622)	3 329 (602)
Female	3 190 (587)	3 233 (574)
Birth weight ² (g), %		
< 1000	0.8	0.7
1 000–1 499	0.8	0.6
1 500–2 499	5.6	4.9
2 500–4 499	91.4	92.5
4 500–7 000	1.3	1.3

¹ Number of missing observations: 159 with reported gestational age and 37 with missing gestational age.

² Number of missing observations: 99 with reported gestational age and 127 with missing gestational age.

rean section rate is a governmental challenge because a caesarean delivery is more expensive than a vaginal birth, but it is also a burden for the women, since having one Caesarean section predisposes for Caesarean section in later deliveries (8).

The mean gestational age in Georgia is 271 days, 4 days shorter than in for example Norway (10). Newborns are much more likely to be delivered by Caesarean section in Georgia (where the mean gestational age in the Caesarean section group was only 269 days) than in Norway where the Caesarean section rate was 16.1 % in 2016 (11). If everything else was equal between the two countries, these differences could indicate that there is an association between high Caesarean section rates and lower gestational age. Unfortunately, our cross sectional design and the fact that we did not have access to reliable data on the clinical indication for performing Caesarean section in Georgia, restrict our possibility to do so. However, our results highlight that the causes and consequences of the high Caesarean section rate in Georgia need future attention.

The quality of the Georgia Birth Registry data is acceptable and in agreement with well-established international findings: i) the proportion of male newborns is slightly higher than the proportion of females (12); ii) higher birth weight among male compared to female newborns (13) and iii) 7 % of newborns had a birth weight < 2 500 g (14). The employees at the registry office perform continuous quality control of data in the Georgia Birth Registry. Additionally, there are several hundred built-in quality assurance measures e.g. ranges of acceptable values.

The Georgia Birth Registry has only been operational for one year, and system weaknesses are expected. Hospitals have reported some lack of motivation among staff to enter information into the Georgia Birth Registry as this is considered additional work without benefits to themselves or their patients. Therefore, there are substantial amounts of missing values for some optional variables, such as parity and number of fetuses. The birth weight variable also displayed inconsistencies with a disproportionate number of birth weights rounded off to the nearest hundred grams. Ideally the Wilcox and Russel method (or an adapted version) (15) should have been applied in order to double-check probable birth weight outliers routinely. Several major upgrades were implemented in the Georgia Birth Registry during May and June 2017. The same will apply to the Wilcox and Russel

Table 2 Maternal and newborn characteristics by mode of delivery as recorded in the Georgia Birth Registry 2016.

Maternal characteristics	Vaginal delivery	Missing	Caesarean section	Missing	Total	Missing
Total number of birthing women	29 820		22 579		52 399	
Multiple birth, %						
No	99.1		97.5		98.4	
Yes	0.9		2.5		1.6	
Maternal age (years), mean (standard deviation)	26.4 (5.5)		28.3 (6.0)		27.2 (5.8)	
Maternal age (years), %						
< 19	9.6		5.9		8.0	
20–24	30.9		23.7		27.8	
25–29	31.9		30.2		31.2	
30–34	19.0		23.1		20.8	
35–39	7.3		13.1		9.8	
40–44	1.3		3.6		2.3	
> 45	0.0		0.3		0.2	
Newborn characteristics						
Number of newborn infants	30 084		23 152		53 236	
Multiple birth, %						
No	98.2		95.1		96.9	
Yes	1.8		4.9		3.1	
Sex, %		126		70		196
Male	50.3		52.2		51.4	
Female	49.7		47.8		49.6	
Undetermined	0.0		0.0		0.0	
Gestational age (days), mean (standard deviation)	273.2 (14.9)	8 883	269.1 (13.0)	6 004	271.3 (14.2)	14 887
Gestational age (weeks), %		8 603		5 794		14 397
22–31	1.9		1.6		1.7	
32–36	4.6		8.6		6.4	
37–41	93.2		89.5		91.5	
42–45	0.4		0.4		0.4	
Birth weight (g), mean (standard deviation)		135		91		116
Total	3 284 (588)		3 233 (625)		3 262 (605)	
Male	3 345 (600)		3 293 (635)		3 322 (617)	
Female	3 226 (565)		3 169 (605)		3 202 (583)	
Birth weight (g), %		135		91		116
100–999	1.0		0.5		0.8	
1 000–1 499	0.6		0.9		0.7	
1 500–2 499	4.0		7.3		5.4	
2 500–4 499	93.5		89.4		91.8	
4 500–7 000	0.9		1.9		1.3	

method as soon as sufficient data material is available.

During the development period, we discovered the importance of establishing national ownership of the final product. In addition, the Georgia Birth Registry has been dependent on a national and institutional initiative that has created enthusiasm and dedication among local and national health authorities that use the registry for statistics and quality improvement purposes. These are all prerequisites for the sustainability of a system such as the Georgia Birth Registry, a finding which finds strong support in The Lancet series «Civil registration and vital statistics» from 2015 (16).

Conclusion

The Georgia Birth Registry achieved 93.9 % coverage of newborns in its first year of operation. Selected core variables display reasonable agreement with established knowledge, however; important indicators, such as parity and gestational age, still need further improvement. The higher than previously reported perinatal mortality rate and the large proportion of Caesarean section need further attention.

UNICEF funded the creation of the birth registry system and the Georgian health authorities fund the on-going operation of the The Georgia Birth Registry. There are no conflicts of interest.

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Ethics capacity building in low-income countries: Ethiopia as a case study

Ethical dilemmas are part of everyday clinical practice, and doctors worldwide must make value-based decisions. In low-income countries with very limited resources, healthcare personnel and policymakers face ethical challenges. Ethiopian policies aim to improve the ethical decision-making competence of healthcare personnel. But what are the dilemmas experienced by Ethiopian doctors and how can training and professional development equip them to deal with the ethical challenges they face?

In this text, we illustrate ethical challenges that doctors experience in a resource-constrained health and welfare system. Our discussion is based upon our own empirical data from Ethiopia, our experience as healthcare workers in low-income countries, as well as relevant literature. We will describe the challenges and opportunities that lie in education, guidance and facilitation of ethical decision-making in a low-income country like Ethiopia.

Ethiopia

Of a population of one hundred million people in Ethiopia, one-third live below the poverty line (1). The majority of the population lives in rural areas, and maternal and child mortality rates remain high. There is only one doctor per 32 000 inhabitants, compared with one per 230 inhabitants in Norway (2).

The Ethiopian government has made significant efforts in recent years to increase the number of healthcare workers. Together with the Ethiopian Medical Association and the 28 universities that offer medical training, they have formulated plans for medical ethics education for students and professional development, a programme known as 'A Compassionate-Respectful-Caring Health Workforce (CRC)' (3). Teaching in medical ethics has been part of the curriculum at all 28 medical faculties. However, there is a shortage of teachers, and students have so far received little or no ethics education.

Raising ethical competence in Ethiopia – a collaborative project

In 2009, the Global Health Priorities research group at the University of Bergen began a research collaboration in ethics and priority setting with Addis Ababa University (AAU), which later developed into a training and

development project. The initiative was based on a desire for collaboration with respect to (a) obtaining better empirical data from Ethiopia regarding ethical dilemmas, priority setting and the consequences of high-level decision-making; (b) normative discussion of these dilemmas together with Ethiopian colleagues; and (c) developing and implementing education and ethical support systems.

Because dilemmas following resource scarcity are prominent in the Ethiopian context, we have focused in particular on issues related to priority setting and distri-

bution, both in clinical practice and at the level of healthcare policies. Box 1 provides further details of the topics addressed by the collaboration (Box 1).

Clinical ethical dilemmas in Ethiopia

In order to prepare a useful educational programme, we required information and case studies relevant to the everyday clinical work of doctors and healthcare personnel in Ethiopia. In 2013, we conducted a study of one-third of all registered doctors in Ethiopia (587 participants, 91 % response rate), in which we asked about the ethical dilemmas they experience, how they deal with those challenges, and about their previous ethics education (5).

Most doctors reported dilemmas related to shortage and distribution of resources, the inability of patients to pay, and the financial implications of treatment decision for families. The doctors described difficult situations in which they had to decide, for example, whether a child with heart failure or another with a severe asthma attack should have access to the single functioning

Box 1: Overview of collaboration between the University of Bergen (UiB), Bergen Hospital Trust and Addis Ababa University (AAU) on priority setting and increasing ethical competence.

Center for Medical Ethics and Priority Setting

Collaborative project between the University of Bergen, Bergen Hospital Trust and AAU. Ethiopia's first centre for medical ethics and priority setting, opened March 2017 (4).

Research and capacity building

Various research projects on clinical ethics, priority setting and health economics. Six Ethiopian PhD candidates (two have graduated), three Norwegian PhD candidates, six Ethiopian Masters students.

Teaching:

- Development of curriculum, study materials, lectures and context-relevant examples.
- Training of Trainers in Medical Ethics (ToT ME): courses in medical ethics and priority setting tailored to the local area, primarily aimed at those who will have responsibility for the ethics education of medical students in Ethiopia.

Textbook in medical ethics and priority setting

Written in collaboration with Ethiopian co-authors from AAU and EMA, as well as international experts.

Guidelines for limiting treatment of the seriously ill and dying

Being developed together with members of the clinical ethics committee at the Black Lion Hospital.

Collaboration with the Ethiopian Medical Association

Teaching materials and legal clarifications of doctors' responsibilities, duties and patient rights.

Collaboration with the Ministry of Health regarding professional development for healthcare personnel and healthcare managers

The work has received support from Norad and the Gates Foundation for research fellows, from SPIRE (University of Bergen) for collaboration in teaching, and from Bergen Hospital Trust for the development of the clinical ethics committee and professional development courses.

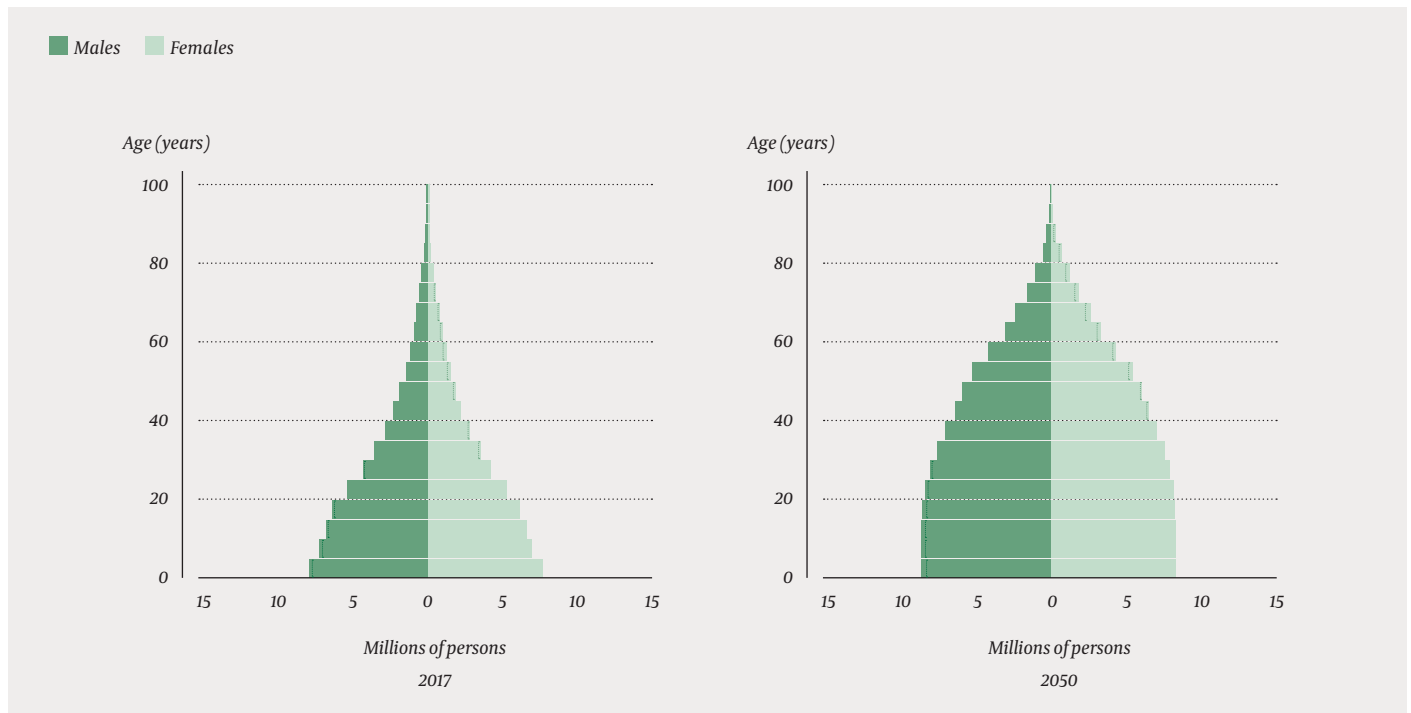


Figure 1 Demographic aging in Ethiopia illustrated by the current population pyramid (2017) and the projected population pyramid for 2050. The graphs were prepared using data from the UN (7) with permission.

respirator. They knew that their decision would result in the death of one of the children.

Others described the burdensome responsibility they felt when poor families took on debt to be able to pay for the medical treatment or diagnostics they recommended, or how they themselves intervened – and paid for treatment – when parents wanted to leave the hospital because they could not afford to pay for their child's drugs. Dilemmas related to reproductive health, disagreements with the family, and their duty to inform patients were also experienced by many doctors on a daily or weekly basis (Unpublished data: Miljeteig I, Defaye FB, Berhane Y et al. Clinical ethics dilemmas in a low income setting - A national survey among physicians in Ethiopia. 2017). Several reported witnessing unethical behaviour by colleagues (such as referring patients to their own private clinic or shouting at them).

Very few doctors reported dilemmas associated with limiting treatment of the seriously ill and dying, or issues regarding euthanasia. This differs from findings in American and European studies, in which

overtreatment and treatment limitation are the most common dilemmas encountered by doctors in everyday clinical practice (6).

Priority setting at the crossroads between clinical practice and healthcare policy

In Ethiopia, the population composition, disease panorama and health service are all changing. The number and proportion of adults is expected to increase substantially over the next 30 years (see Figure 1). More children are being vaccinated and are attending school, essential healthcare is being made accessible, and maternal and child mortality rates are expected to fall.

These are positive developments, but they will also pose challenges for the healthcare system. The Ethiopian Ministry of Health aims to reduce the burden of infectious disease and to improve child and maternal health, but non-communicable diseases are also getting on the agenda. Policy makers face difficult choices between prioritising areas covered in the previous Millennium Development Goals (such as vaccination, qualified maternity workers, treatment of infectious diseases and diarrhoea) versus

increasing access to other areas (such as treatment of myocardial infarction, stroke, diabetes, cancer and psychiatric disorders). Coverage for all of these health services is currently low in Ethiopia.

As part of efforts to achieve the UN's Sustainable Development Goals, essential healthcare packages are planned, in which the most basic and cost-effective healthcare interventions will be made available to all. Interventions such as the treatment of stroke with thrombolysis, myocardial infarction with PCI, or bipolar disorder with lithium/valproate are not cost-effective compared to vaccines or blood banks in maternity wards (8). Should these treatments not be offered to the millions of patients in need?

Two of the authors (Ole Frithjof Norheim and Kjell Arne Johansson) have been involved in the Ethiopian Ministry of Health's efforts to decide which interventions or areas should be prioritised in these packages. They have examined how key ethical criteria such as severity, poverty prevention, and equity may be given extra weight in policy decisions and health planning at population level.

Efficiency and cost-effectiveness are not

the only concerns that matter. One study showed that pneumonia treatment could be very expensive for Ethiopian families, who have to pay USD 6–8 for outpatient treatment and USD 70–80 for hospital admission (9). Patients are required to pay for transport, medicines and equipment such as gloves and bedsheets themselves. Given that the average monthly income for a family in Ethiopia is USD 60, it is clear that protecting families against such financial risk is important and that this consideration should be taken into account when healthcare priorities are set.

When context-relevant guidelines are missing

In parallel with the effort to promote cost-effective interventions, advanced treatment methods are also being introduced in Ethiopia to prolong the lives of severely ill patients.

Systematic and well-planned implementation of new techniques and interventions in tertiary care are challenged by international collaboration or aid. The latter may include donation of hospital equipment, where use and maintenance will require thorough training for healthcare workers.

«They knew that their decision would result in the death of one of the children»

One example is dialysis treatment for patients with renal failure, which is now being offered on a very limited scale in countries like Ethiopia. Few low-income countries have conducted high-level and transparent priority setting processes, or developed locally appropriate and context-relevant guidelines for treatment of chronic renal failure (10). Studies show that dialysis treatment causes a catastrophic health expenditures for many families in low-income countries, even when the treatment takes place in public hospitals (10). Many acquire debt that they never manage to repay, sell land or seeds, or use savings they had set aside for their children's education. In South Africa, dialysis treatment was shown to be distributed unfairly when the allocation of this limited resource was left to clinicians without access to guidelines

or regulations. Older, white men had a far greater chance of receiving dialysis than others with a similar medical indication (11). The study led to development of explicit priority-setting criteria for dialysis treatment in South Africa.

In our study, we found that very few doctors in Ethiopia had access to guidelines to help them prioritise whom they should treat, who should undergo surgery first, and who should receive the last bed in the intensive care unit or be admitted to an overcrowded ward. The vast majority adopted a strategy in which resources were distributed based on a first come first served strategy (5).

During a collaborative project to educate intensive care providers in Ethiopia, it emerged that lack of guidelines was making it particularly difficult to make decisions regarding restricting life-sustaining treatment. A few hospitals in larger Ethiopian cities have, in a very short period of time, acquired equipment that can help keep seriously ill or injured patients alive due to use of respirators, chemotherapy or advanced surgery.

At present no legislation or clinical ethics committees exist to assist clinicians in making such decisions. Many physicians are afraid of being accused of performing euthanasia. The newly established clinical ethics committee at Black Lion Hospital has, along with two of the authors (Ole Fritjof Norheim and Ingrid Miljeteig), prepared a draft guideline for restriction of life-sustaining treatment that take account of the economic, cultural, religious and legal context in which the guidelines will be used. The proposal is now out for local hearing in the hospital (see Box 1).

In aiming to do good, technical equipment and new opportunities are often presented as positive contributions to improve health in resource-constrained settings. Our experience, as external collaborators (in academia and healthcare institutions), suggests that stimulating and contributing to ethical debate is an important responsibility. When resources are limited, there will always be dilemmas regarding who should have priority, and when it may be unethical to provide health services. This type of capacity building must be recognised as being of equal value to donation of equipment or training in the use of these.

How can we facilitate this type of compe-

tence without contributing to what has been described as moral imperialism or colonialism (12)? In academic discussions criticism is often directed at ethics projects originating from the USA and Europe. Too often, these do not relate to the local values and the sociocultural context in which the teaching of healthcare workers takes place.

«In Ethiopia, the population composition, disease panorama and health service are all changing»

Ethical awareness, skills and knowledge in medical ethics

We consider ethical competence to be a skill, just as communication abilities are skills required by healthcare personnel. Similarly, education in ethics is about practicing, raising awareness as well as learning about new theories. Our teaching programme is concerned with encouraging participants to share their own experiences and reflections.

We have also discussed the application and relevance of our methods and of 'Western' ethical theories in an Ethiopian context. How, for example, is the ethical principle of 'respect for patient autonomy' understood by Ethiopian doctors and what role does it play compared to considerations of the patient's family and community? Based on our experiences, sustainable strategies for capacity building must be developed locally, in close collaboration with experienced ethicists, and by using specific dilemmas that are perceived as relevant and context-appropriate (13).

Despite great enthusiasm and support from the Ethiopian Ministry of Health and from the leaders of universities and hospitals, there is a long way to go before ethics education, professional development and ethical support systems (such as clinical ethics committees) are in place. The huge increase in the number of medical students and other healthcare professions leads to challenges in obtaining qualified teachers, organising training programmes, and securing sufficient time and resources to promote ethical competence in the clinic.

We hope that our collaboration, and the Center for Medical Ethics and Priority Setting, can increase the position of medical ethics in healthcare programmes, and assist Ethiopian colleagues in discussing and conducting research on ethical challenges.

With an open and curious attitude to how others experience and deal with ethical dilemmas, we can learn much about our own and others' values, and at the same time lay the foundations for learning and development among our colleagues elsewhere in the world.

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The vanishing Aral Sea: health consequences of an environmental disaster

Access to safe water and food is linked to global, regional and local climate changes. In some areas swift changes have entailed serious health-related consequences. An alarming example is found in the Aral Sea area of Central Asia.

The Aral Sea area, located on the border between Kazakhstan and Uzbekistan, was once the fourth largest inland sea in the world. Since the 1960s, water volume has been reduced by a factor of fourteen (1). Tributary water to the Aral Sea derives from the rivers Amu Darya originating in Tajikistan, and Syr Darya originating in Kyrgyzstan. Early in the 20 century demand for river water to supply local agriculture, primarily the cotton industry, led to construction of irrigation systems (2). A highly inefficient system for water allocation combined with excessive resource exploration was the result. Subsequent failure to maintain infrastructure, in tandem with large emissions of pollutants have had serious consequences for people inhabiting the areas around the Aral Sea.

After the Soviet Union created collective farms in 1929, water usage increased and the Aral Sea started shrinking. By 1987, the lake had split into two separate parts (3). Water distribution was complicated by the collapse of the Soviet Union in 1991, creating several new countries with separate water policies (4). Uzbekistan is today one of the world's largest cotton producers and needs large amounts of water to sustain production (5). A simultaneous population increase complicates the severe water shortage in the area (6) and contributes to the environmental disaster, evident by the disappearance of the Aral Sea. Its role as an important food source is impaired due to increased salinity. In 1983 more than 20 different fish species were declared extinct (7). River deltas have been replaced by desert, mediating a replacement of the original flora with hardier plants (3). Local climate change has occurred simultaneously with the disappearance of water. Formerly hot, humid regions are acquiring a cold, dry desert climate (8).

Pollution

No rivers flow out of the Aral Sea; water disappears through evaporation. Before construction of the excessive irrigation systems, water level was kept stable by inflow from

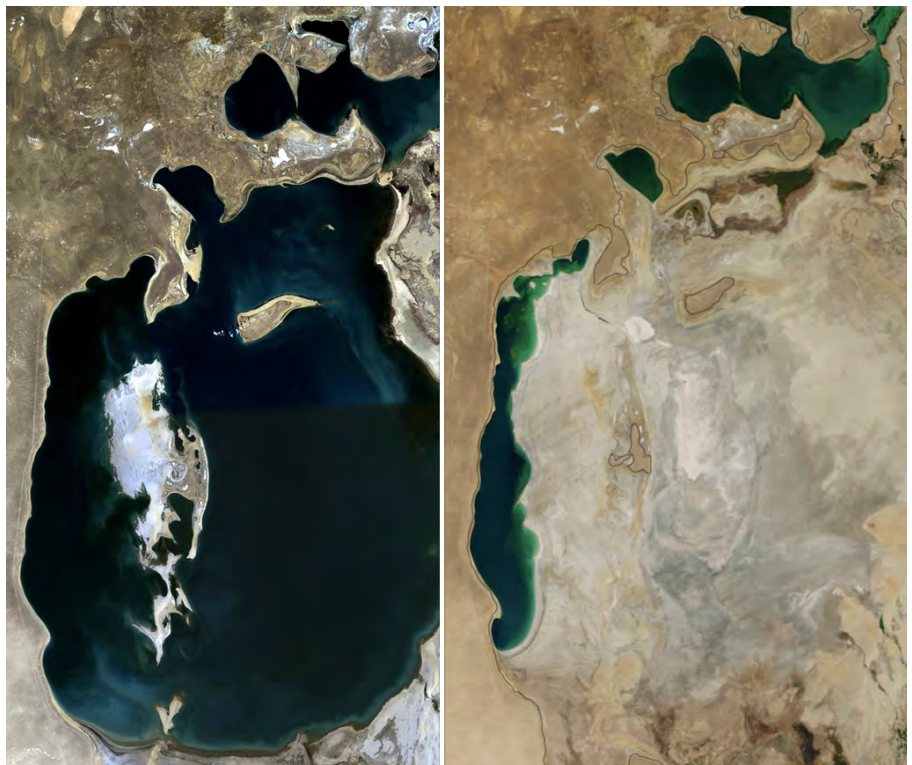
Amu Darya and Syr Darya. As human use of river water has increased, the composition of lake water has changed. Salt concentration has increased tenfold (9) and local groundwater has a salt concentration reaching 6 g/L. This is six times higher than the concentration considered safe by WHO. Naturally, local inhabitants are exposed to saline water (7) and in 2000 only 32% had access to safe drinking water (10). An increased frequency of storms carries 43 million tons of dust and sand from the dried-out sea floor through the air yearly (11, 12). Accordingly, the rate of dust deposition is among the highest in the world (12) and contains large amounts of salts and pesticides, probably related to the water quality in the tributary rivers. Fertilizers, chlorinated organic pesticides and other chemicals are used in large quantities for agricultural purposes and pollutant-rich

water returns to the rivers that supply the Aral Sea (13). Pollution also originates from the extensive mining industry in the area. Drain water contains heavy metals which flow into the rivers (14). In Amu Darya, concentrations of copper, nickel and lead all exceed WHO recommendations (14).

Aral Sea concentrations of the pesticides dichlorodiphenyldichloroethylene (DDE) and dichlorodiphenyltrichloroethane (DDT) do not exceed WHO recommendations (15). It is, however, apparent that both water (14) and soil (12) in the region are affected by toxic pollutants from industry and agriculture. The concentration of dioxin and dioxin-like compounds (polychlorinated biphenyl (PCB), polychlorinated dibenzodioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs)) has been found in fish, sheep, milk, eggs and several other foods. Carrots and onions, important in the local diet, have been shown to contain high amounts of chlorinated organic pesticides. High levels of hexachlorocyclohexane (HCH) have been found in most samples (16).

Human samples reflect the high amount of pollutants in water and food.

DDE blood levels, for example, are higher than in Russian Arctic settlements (17).



A comparison of the Aral Sea in 1989 (left) and 2014 (right). Photo: NASA

A lifelong exposure is evident. Blood samples from pregnant women and umbilical cords show high amounts of DDE, also found in breast milk (18). DDT levels in breast milk from Aralsk have been proven to be higher than in the rest of Kazakhstan (19). Although plasma concentrations of perfluoroalkyl substances (PFASs), which are used in products for their fat and water-resistant abilities, have been shown to be lower than in Arctic Russia (20), school-aged children in Aralsk have high blood levels of DDE and DDT compared to other parts of Kazakhstan and two European countries (21, 22).

Health-related consequences

Living in the Aral Sea area has detrimental consequences for fertility, both in people growing up in the area and for adult immigrants (23, 24). Furthermore, in the late 1990s infant mortality was between 60–110/1000, a figure far higher than in Uzbekistan (48/1000) and Russia (24/1000) (25). At the same time, body mass index (BMI) was inversely correlated with blood concentration of PCBs, DDTs and DDEs in children between 7 and 17 years, advocated as an effect of malabsorption. Values of insulin-like growth factor type 1 (IGF-1) tended to correlate with a reduction in body mass index (26). It is known that low IGF-1 values may be associated with high concentrations of DDT or DDT metabolites in the body (27).

In the late 1990s, Kazakh children believed to be harmed by Aral Sea pollution were sent to a rehabilitation centre in Almaty. Clinical findings included skin lesions, heart and kidney disease. Growth retardation and late sexual maturation were common (28). Further, anaemia was related to settlement near the lake (29) and local children had impaired renal tubular function. Chronic heavy-metal exposure has been shown to cause such damage, and polluted water could be causative (30). Hypercalciuria in children (31) could possibly be related to intake of saline-rich water, food and dust,

or renal tubular dysfunction, associated with toxic damage after exposure to substances such as lead and cadmium (29).

Studies conducted in 2000 examined the respiratory function of local children. In an area within 200 kilometres of the Aral Sea, schoolchildren had low vital capacity and a high cough rate (32). Surprisingly, dust exposure appeared unrelated to the prevalence of asthma (33). Therefore, it is still uncertain whether the environmental disaster has had a direct impact on the frequency of respiratory disease (29).

Compared with far eastern Kazakhstan, the Aral Sea population seems more prone to develop cancer (34, 35). During the 1980s, the occurrence of liver cancer doubled (36), while the incidence of oesophageal, lung and stomach cancer appear highest (37). Inhabitants of the Uzbek part of the Aral Sea area subjectively experience their own health as poor, correlating with concerns about the environmental disaster. A large percentage of residents wish to emigrate (25, 38).

Water access

With the disappearance of rivers flowing into the Aral Sea area, drinking water is a highly valuable resource. Water shortage and contamination of stored drinking water are important causes of faecal-oral transmission of disease in Aral Sea area households (39). Accordingly, hepatitis A (11) and diarrhoeal disease are frequently reported. At the turn of the century, the infant death rate due to diarrhoea was twice that of bordering areas (10). Parasitic infections and tuberculosis are also a challenge (28). Some claim that the high incidence of disease, including tuberculosis, is related to increased poverty, resulting in poorer personal hygiene and malnutrition (40). Indeed, multi-drug resistant tuberculosis presents a significant challenge in this region (29, 41).

Inadequate sanitation and water access represent a considerable risk for diarrhoeal disease, one of the main global contributors

to child mortality, causing one in ten child deaths (42). In total more than 600 million people lack improved drinking water (43). Although access to safe water is increasing, environmental disasters such as those affecting the Aral Sea, and unexpected effects of climate change might impede this development. In May 2007, a massive bloom of the toxin-producing cyanobacteria *Microcystis* occurred in China's third largest freshwater lake, Taihu. This crisis, attributed to an unusually warm spring, left approximately two million people without drinking water for a week (44). More predictable effects of climate change will also affect freshwater access. Models predicting global warming show that it will occur more rapidly at high altitudes (45), thus affecting communities relying on mountain glaciers for their water supply. Big cities such as Quito and La Paz in South America partly depend on water from glaciers, some of which are rapidly retreating (45). The Aral Sea area is also at risk. Both Amu Darya and Syr Darya are provided with glacial water from the Pamir and Tian Shan Mountains, respectively. The melting glaciers and Arctic ice-cap (46) entail equally disturbing challenges for small island nations, such as Kiribati, that risk being flooded (47).

An alarming signal

As we have seen, global, regional and local climate change can have negative consequences for human health. The Aral Sea disaster shows the result of short-sighted human exploitation of nature and is an alarming signal, indicating that all human activities with potential climate effects must be carefully thought through.

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The Zika outbreak in Brazil: An unequal burden

The Zika outbreak in Brazil in 2015–16 had detrimental medical, financial and social consequences for many children and their families. This article seeks to explore the current challenges that they are facing, and how these can be met. A ‘One Health’ perspective can help to address these complex issues.

The burden of the Zika outbreak in the tropical Americas from 2015–16 crucially encompasses challenges related to gender inequality, poverty, social stigma, as well as women’s actual and legal access to reproductive and maternal care, including safe abortions. Currently in Brazil, many of the affected women and their families are experiencing additional challenges in their everyday lives due to poverty, as well as systemic and structural issues related to healthcare delivery and social security. It is necessary to explore and understand these issues in order to provide proper care and support to victims of the Zika epidemic, and to ensure preparedness

for dealing with both present and future consequences.

In this article, we provide a brief overview of the recent history of the Zika outbreak in Brazil with a particular focus on women and their children born with microcephaly and other neurological complications. We seek to highlight some of the social, economic and systemic consequences the outbreak has had for the affected families, based on empirical data and interviews from a qualitative study conducted in the most affected region of Brazil during the summer of 2017 (these data constitute part of the qualitative data collected during fieldwork as part of Skråning’s research for her Master’s thesis.

The thesis will be finalised in Spring 2018 and is hence unpublished material.)

The Zika virus is vector-borne; therefore, we suggest that a ‘One Health’ perspective is appropriate when discussing the epidemic, as it provides a promising step towards a holistic alignment of causal interactions between the health of humans, animals and the environment. As described by the WHO, ‘One Health’ is “an approach to designing and implementing programmes, policies, legislation and research in which multiple sectors communicate and work together to achieve better public health outcomes” (1).

In a world of climate change and increased mobility of people and objects, there is an ever-present potential for global circulation of zoonotic and vector-borne diseases. Therefore, the governance of outbreaks and epidemics requires approaches that do not deal with human health in isolation (2), but rather see humans, animals, pathogens and their local environments as always mutually enmeshed. Such an approach allows for, as highlighted by the Zika outbreak, an under-



Aedes aegypti mosquitoes. Photo: AP/Felipe Dana/NTB scanpix

standing of not only the causal pathways between human-animal ecologies, but importantly also brings to light socio-political issues of poverty, inequity and inequality.

The beginning of an epidemic

The mosquito-borne Zika virus (ZIKV) was first discovered in rhesus monkeys in Kampala, Uganda, in 1947 (3). The Zika virus is carried by mosquitoes in the *Aedes* family, predominantly the *Aedes aegypti*. In addition to mosquito transmission, the virus can be transmitted through vaginal, anal and oral sex (4). In most cases, ZIKV infections do not cause any symptoms (5). However, the infection may lead to Zika fever, which results in mild, flu-like symptoms, and sometimes a red rash. Hence, the symptoms can be mistaken for those of Chikungunya and Dengue fever, which are both transmitted through the same vector (3).

A Zika diagnosis is obtained through laboratory testing of blood, urine or other bodily fluids. The WHO recommends two testing strategies for confirming Zika virus infection: nucleic acid testing for Zika RNA and serological testing for IgM antibodies against Zika (6). Currently, there is no treatment available for the virus, besides symptomatic treatment. Although it is believed that the Zika virus entered Brazil in 2014, the first dozen cases were identified in the Northeast region by May 2015, which later became the epicentre of the 2015–16 Zika epidemic in South America (7).

The discovery

It would become evident that the Zika virus caused far more serious conditions than Zika fever, particularly for women who were infected during pregnancy (8). During fieldwork for her Master's thesis in the Northeast region of Brazil, from June–August 2017, Skråning visited a newly-opened treatment and research centre for Zika victims run by Dr Adriana Melo and her team in the city of Campina Grande, Paraíba: Instituto De Pesquisa Professor Joaquim Amorim Neto (IPESQ). Dr Melo, a physician specialising in high-risk pregnancies, was the first to discover the link between the Zika virus and congenital anomalies.

While performing an ultrasound on one of her patients she found that the foetus had microcephaly; that is, atypical development of the brain which results in a smaller

head. However, Dr Melo was surprised to find both genetic and infectious causes in the foetus; she had never seen both at the same time throughout her 20 years of experience with ultrasounds and congenital malformations.

«The Northeast of Brazil, which was hardest hit by the outbreak, is also the poorest region in the country»

Two weeks after the first ultrasound, Dr Melo performed a second: the head of the foetus had not grown. During the same period, Dr Melo had seen another woman whose sonogram showed similar, but more severe symptoms; she sent both samples of amniotic fluid to a research institution in Rio de Janeiro. A few days later the results came back; traces of the Zika virus were found in both samples, which established an association between Zika infection during pregnancy and severe, congenital anomalies.

The response

Dr Melo explained that it would take nearly two months from this discovery for the information to be made available to the public. In November 2015, the virus was officially linked to an increase in cases of microcephaly and other central nervous system malformations, henceforth referred to as Congenital Zika Syndrome (CZS) (9). In addition, the virus was associated with an increase in cases of Guillain-Barré syndrome. In response, the Brazilian government declared a national health emergency and set up a system for notification of all suspected cases of CZS and Guillain-Barré (8). In addition, the government created an action plan to prevent the spreading of Zika through the *Aedes aegypti* mosquito, which focused on three main areas of intervention; mobilisation of the population to fight the mosquito, providing assistance to the population, and education, technological development and research.

These severe outcomes of the Zika epidemic eventually led to the declaration of a Public Health Emergency of International Concern by the WHO on the 1 of February, 2016 (8). According to the latest situational report by the WHO from February 2017, 2366

cases of congenital Zika syndrome in Brazil are associated with Zika infection during pregnancy (10). However, most of the registered cases of congenital Zika syndrome in Brazil occurred in late 2015, with a steady decrease until mid-2016 (11). There was a slight increase in Zika-associated congenital anomalies in the latter half of 2016, however in 2017 there have been very few registered cases, and only a slight increase in Zika infections (11). Due to this decline, the Public Health Emergency of International Concern over Zika ended in November 2016 (8). The Brazilian national health emergency came to an end on the 11 of May, 2017.

Where are we now?

Financial constraints and access to specialised healthcare

Although the number of new cases of congenital Zika syndrome has gone down, the 2015–16 Zika epidemic has had, and continues to have, a major impact on the affected children, their families and communities. The Brazilian health system is divided into a public and private sector; around 70 % of the population rely solely, or mainly on the Sistema Único de Saúde (SUS), which is publicly funded (12, p. 6). All of the 51 mothers Skråning interviewed during her fieldwork relied on the public system; at the treatment centre run by Dr Melo in Campina Grande, only two out of 120 mothers had private health insurance.

The national health system in Brazil is highly decentralised; access to specialised care and diagnostic services is restricted for those who rely on the public system, due to financial constraints of the SUS and weak referral systems for facilities that fall outside of the municipal health services (12, p. 6). Skråning met the majority of the mothers who were affected by the Zika outbreaks through Caravana do Coração, which is part of a local NGO based in Pernambuco and Paraíba that offers much-needed primary and specialised paediatric care in poor, rural areas over a two-week period annually. However, children with microcephaly require daily access to personalised medical care, as well as physiotherapy. According to Dr Melo, most of the families affected by the Zika epidemic rely on the public system, and some of the children may have to wait up to one year for referrals.

The Northeast of Brazil, which was hardest hit by the outbreak, is also the poorest region in the country (8). Indeed, the vast

majority of mothers to children with congenital Zika syndrome whom Skråning interviewed during her fieldwork were facing financial constraints, and many were living in over-crowded slum areas, referred to as *periferias*. The main vector of the virus, the *Aedes aegypti* mosquito, breeds in clear, stagnant water; thus, poor areas that lack sufficient sanitation systems, piped water lines and infrastructure for waste management form ideal breeding grounds for the mosquitoes (3).

According to a recent report by Human Rights Watch, “more than one-third of Brazil’s 208 million people do not have access to a continuous water supply [...]” (8, p. 23). Each house therefore stores water in a tank on the roof, or in buckets; if these are not covered, they form perfect habitats for breeding mosquitoes. In this sense, human activity has an influence on disease burden and incidence. The complexity of the situation in Brazil thus illustrates the need for a multidisciplinary approach that links the health of people to the well-being of the environment and animals. A One Health perspective provides a promising conceptual framework and point of departure for addressing these linkages.

Access to treatment in a decentralised system

Little is known about how the various impairments associated with congenital Zika syndrome will affect the future development of the children. Yet, what is clear is that children with life-long Zika-associated conditions rely on continuous access to rehabilitation treatment, such as physical, occupational and speech therapy (13). Following the Zika epidemic, the Brazilian government has invested in 63 new specialised public rehabilitation centres for people with disabilities (8).

However, many of the mothers that Skråning met in the field came from smaller municipalities that did not offer such services, resulting in long journeys of 4–6 hours to urban centres for treatment sessions. A 17-year-old mother, whose son with microcephaly was one year and three months, explained that she had to leave her town at in the middle of the night to make it to the morning appointments in a larger city. She made this journey four times a week; twice to the governmental hospital in the city, and twice to the clinic run by Dr Melo. Due to the long travel distances, some

mothers ended up spending the night at the clinic with their children. A mother of two children with autism and microcephaly explained:

My life has changed a lot. I am very tired. [...] This is my life now. Therapy for one, then the other. It is just this.

Due to the considerable amount of time that the weekly treatment sessions require, none of the mothers were able to work; this resulted in further financial constraints on the families.

«Children with life-long Zika-associated conditions rely on continuous access to rehabilitation treatment, such as physical, occupational and speech therapy»

Social security

Bolsa Família is a conditional cash transfer programme for poor families that earn less than R\$ 140.00 (NOK 370) per person, per month (12, p. 14). Many of the mothers that Skråning met during her fieldwork received, or had previously received this support. In 2016, all children with Zika-associated conditions became entitled to a federal financial benefit for people with disabilities of R\$ 937 (NOK 2530) monthly (8). Some were struggling to access this benefit, particularly if their husbands were working. The families who started receiving this benefit subsequently lost their support from Bolsa Família, as they could not receive two benefits at once. The federal financial benefit for children with congenital Zika syndrome is only provided for three years; in three instances, mothers told Skråning that they had asked social workers at the hospital why they did not receive support for longer. All three received the same answer; according to studies, their children would not survive beyond the age of three.

The majority of mothers who received the disability benefit said that the amount was too low, and that it barely covered monthly medical expenses. What became evident from the conversations with mothers affected by the Zika epidemic was that having a child with severe disabilities caused addi-

onal economic constraints for the already disenfranchised families, with the state support barely meeting their social and medical needs.

An interdisciplinary and multilevel approach

The Zika outbreak underscores the importance of seeing the environment and animal behaviour as inseparable from human activity. The spread of the Zika virus relied on a range of unfortunate circumstances, of which poor physical living conditions coupled with lack of access to clean, running water and sanitation was crucial.

As has become apparent in the aftermath of the Zika outbreak in Brazil, people already living in poverty were clearly affected the most, highlighting the escalating vulnerability and precariousness poor people face in societies with severe socio-economic inequalities. Hence, poor sanitary conditions, lack of a national vector control programme and drought that had spanned over several years all contributed to excellent conditions for mosquitoes and the diseases they carry, including Zika. A comprehensive framework such as a One Health perspective that embraces multilevel, systemic, as well as contextual approaches is essential to understand and tackle the consequences of the Zika epidemic.

In order to meet global health challenges like the Zika outbreak, interdisciplinary collaborations are vital to the development of knowledge and to establish scholarly synergies from which concrete strategies, policies and interventions can emerge. As the anthropologist Wolf has noted: “...it is important for both - the natural and the social sciences - to recognize that the global embeddedness of infectious disease ecologies is a product of biological and social relations” (2, p. 6). Thus, to fully grasp, and to act on, the consequences of events like the 2015–16 Zika outbreak, we need to acknowledge the social, political and economic determinants in the One Health triad of humans, animals and the environment.

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Leaving them behind: healthcare services in situations of armed conflict

In the 2030 Agenda for Sustainable Development in 2016, the international community agreed to 'leave no one behind'. However, the community is doing precisely that by failing to act as millions living in conflict-affected areas are deprived of access to healthcare services. The few healthcare services operating in these situations are attacked with impunity. We need to seek new ways to protect healthcare workers operating in armed conflicts.

In times of conflict, the number of persons in need of emergency medical care increases substantially. People are wounded in attacks, while deterioration in living conditions increases the number of sick. A lack of access to food, clean water, adequate sanitation, shelter and other basic necessities increases the affected population's exposure to infection and disease. A review of nine armed conflicts in sub-Saharan Africa concluded that deaths in battle accounted on average for 6–8% of deaths, while the vast majority of deaths were caused by disease and malnutrition (1). Additionally, the capacity of the healthcare system is weakened by disruptions in the supply chains, the lack of a continuous electricity or water supply, and fewer available healthcare workers.

It is a sad irony that help is most difficult to provide precisely where it is most sorely needed. Healthcare delivery is also the subject of attacks, further widening the gap between needs and capacity. Humanitarian agencies attempt to fill this gap with rapid life-saving activities but are often faced with issues related to access, security and funding. Development actors, with their more sustainable, long-term approach, are seldom present in the midst of conflict. In order to close this yawning gap, the global health community needs to strengthen the respect for and protection of impartial healthcare services. Additionally, development actors need to engage responsibly in the midst of conflict, to ensure the continued functioning of the healthcare system.

Impact of conflict on healthcare systems

Collapsing healthcare systems in times of conflict result in massive human and financial costs both during and after the conflict. These include excess mortality among patients with chronic diseases, permanent disabilities for people with traumatic injuries, higher rates of maternal and infant

mortality, outbreaks of vaccine-preventable diseases and psychological trauma (2). It is therefore unsurprising that countries that have made progress towards reaching national health goals will most likely see it reversed if armed conflict occurs (3).

Additionally, the above-mentioned consequences are not confined to a particular territory. Syria's ongoing conflict and healthcare crisis has substantially increased the risk of infectious diseases becoming an epidemic beyond the geopolitical borders of the conflict itself (4). Nor are these consequences time-bound to ongoing hostilities. During a typical five-year conflict, infant mortality rates not only increase by 13% during the conflict; they remain at an 11% higher rate than the baseline for the first five years thereafter (5).

Beyond mortality, an estimated eight million disability-adjusted life years (DALYs) were lost in the year 1999 from civil wars that occurred during the period 1991–97 (6). The public health consequences of conflict can in fact persist for up to ten years after hostilities cease (7).

One might be encouraged by the mantras of the Sustainable Development Goals (SDGs) to 'leave no one behind' and 'to reach those furthest behind first', as they suggest an emphasis on hard-to-reach areas including those ravaged by conflict. In reality, however, resources dedicated to developing healthcare systems are more likely to be invested in times of peace, when issues related to security or access are less likely. Consequently, non-conflict-affected regions receive almost 60% more funding for reproductive health than conflict-affected regions (8). Given that the poor and their health are disproportionately affected by conflict and that the share of the world's poor living in fragile and conflict-affected situations is projected to reach 46% by 2030 (9), conflict-affected regions must receive more support if we

are to 'ensure healthy lives and promote well-being for all at all ages' (SDG 3).

The consequences of this lack of engagement are compounded by the fact that the existing healthcare services are increasingly attacked during situations of armed conflict. Between 2012 and 2013, the International Committee of the Red Cross (ICRC) recorded 1 809 violent incidents from 23 countries (10), and 2 398 incidents from 11 countries between 2012 and 2014 (11). The reports reveal patterns of insecurity covering a wide range of acts that hinder the delivery of healthcare – from direct attacks against patients and health facilities, to arrests and kidnapping of health personnel, major delays at checkpoints and the looting of facilities. Furthermore, while such attacks cause immediate harm, they also have longer-lasting effects as thousands of future patients may be deprived of treatment as a result.

Protecting access to and delivery of healthcare services

In response to the increasing number of attacks against healthcare services, the Red Cross and Red Crescent Movement launched an initiative known as 'Health Care in Danger' (HCiD). In 2011, it called on the ICRC to initiate expert consultations to formulate practical recommendations for making the delivery of health care safer in armed conflict or other emergencies. Thus, there is a considerable amount of guidance available for how states, healthcare facilities, ambulance services, militaries, armed groups and others can contribute to safer access to and delivery of healthcare services (12).

Nevertheless, the fundamental and non-derogable human right to access immediate and necessary health care, as stated in article 12 of the UN Covenant on Economic, Social and Cultural Rights (13), is constantly violated. Practical solutions may indeed have been developed, but the political will to implement them is often limited to conference halls in Geneva or New York and the political cost of attacks on healthcare services is disappointingly low. States must be held accountable for their implementation of the resolutions that they have voted for, such as the United Nations Security Council (UNSC) Resolution 2286, which demanded an end to impunity for those responsible for attacks against healthcare services and respect for international law on the part of all warring parties (14). Norway has already shown strong initiative, including by pre-

senting a resolution for the protection of health workers at the United Nations General Assembly (UNGA) in 2014 (15), but could also envisage following this up in its bilateral dialogue with other states. For example, bilateral aid agreements could include commitments to strengthen and implement domestic legislation that reflects the state's international obligations with regard to safeguarding the access to and delivery of health care.

Norwegian bilateral or multilateral funding for healthcare systems should ideally always include elements related to the protection of these systems against attacks. The establishment of mechanisms to record threats, obstructions and attacks against healthcare providers and patients would constitute a good starting point. Such data can in turn inform the selection of the measures taken by the state to safeguard access to and delivery of healthcare services. They will also be useful in monitoring the barriers to progress towards reaching SDG 3. Unfortunately, while the implementation of national data collection mechanisms has already been called for by the World Health Assembly in 2012 (16), in the UNGA resolution put forward by Norway in 2014, and the UNSC resolution 2286 passed in 2016 (14), there are very few examples of such initiatives being undertaken.

Other approaches to generating accountability exist that do not rely on the state. Another powerful avenue could be to pair hospitals operating in conflict situations with hospitals in countries that can influence the parties to the conflict. An attack on a partner hospital can result in an effective domestic outcry from the partner hospital within the country of influence, thus raising the political cost of allowing allies to target healthcare services.

Maintaining healthcare services in situations of armed conflict

Beyond strengthening the protection of healthcare services, the healthcare system should also be supported so that it can function at the required capacity. For such an endeavour to succeed, a stronger investment is needed during the conflict itself and not just in the post-conflict reconstruction phase. Allowing massive setbacks in healthcare development in times of conflict, including through neglect, prevents SDG 3 from ever being 'sustainable'.

Presently, states and development institutions are not actually compelled to 'help those furthest behind first' in accordance with the SDGs' pledge. Existing global health initiatives do, however, have the potential to promote greater accountability in the future. One such example is the proposal for a Framework Convention on Global Health (FCGH). Based on the right to health with a national and international funding framework and a special concern for marginalised populations, the FCGH would be a treaty aimed at eliminating global health inequities, providing standards to ensure health care and underlying determinants of health for all (17). This could help to promote investment in healthcare service delivery for those marginalised by conflict or violence. In addition, states could use such a convention to leverage a fairer distribution of global health resources to conflict-affected regions through the agencies where they are well represented. Norway, for instance, would be in a position to promote fairer funding prioritisation in the World Health Organization, the Global Alliance for Vaccines and Immunizations (GAVI) or the Global Fund to fight AIDS, Tuberculosis and Malaria.

An intended fairer distribution of resources does not, however, automatically result in universal coverage, meaning access to health services of sufficient quality to be effective without exposure to financial hardship (18). Security and access would still remain major challenges to reaching communities in need of healthcare in situations of armed conflict.

Engagement with armed groups

The overwhelming majority of today's armed conflicts are not between states, but within states between armed forces and armed groups, or between various armed groups. Traditionally, the presence of armed groups is seen as a barrier to the safe implementation of humanitarian and development activities.

However, while armed groups can be perpetrators of attacks or obstruction, they are also beneficiaries of services, facilitators of access to services and at times service providers. To name a few examples of the latter, some Al Qaeda among the Maghreb's (AQIM) members have nursing skills, Hezbollah has its own ambulance service and the Revolutionary Armed Forces of Colombia (FARC) have developed a sophisticated health service (19).

In addition, whilst there is a contended lack of knowledge and ownership of the formal rules of International Humanitarian Law by armed groups, many of them do in fact have regulations, codes of conduct and behavioural patterns that reflect adherence to humanitarian norms, such as the respect for health care. In other words, engagement with armed groups can help overcome barriers to strengthening healthcare provision in hard-to-reach areas.

Outdated stereotypes of armed groups result in lost opportunities to reduce suffering and the loss of lives. In some contexts, the state criminalises any form of support (including medical) to the areas under the armed group's control. This criminalisation clearly prioritises matters of national security over universal health coverage. Ironically though, preventing medical resources from flowing into areas under the control of armed groups can also adversely affect national security as it increases the risk of infectious disease outbreaks not being contained and spreading beyond conflict zones.

Armed groups do not cease to exist as a consequence of their marginalisation by governments, and any meaningful attempt at universal health coverage in conflict-affected regions will need to include them in one way or another. How to approach and involve these actors of influence is highly contextual and dependent on the characteristics of the groups themselves. One thing is certain: with regard to reducing attacks against healthcare services and closing the gap between healthcare needs and capacity in situations of armed conflict, armed groups are part of the problem and need to be part of any significant solution that is sustainable in the long term.

Salvaging yesterday's developments for tomorrow's sustainability

The current global health and development architecture is not equipped to deliver on the promises to 'leave no one behind' and 'to reach those furthest behind first'. Additionally, the few services able to operate in the midst of conflict are directly and indirectly attacked, further reducing the sorely needed health capacity. Political incentives to safeguard the healthcare system at the national level must be strengthened, as must incentives for development actors to support existing healthcare capacity during the conflict.

In conflict settings, tomorrow's develop-

ment starts with what we are able to salvage today. It requires all actors of influence to seek new ways of both maintaining and protecting healthcare systems in situations of armed conflict.

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Towards universal health coverage for undocumented migrants?

Norway has committed to the UN's Sustainable Development Goals. Securing universal health coverage for all is one of the key objectives. This commitment challenges Norwegian practice and legislation relating to undocumented migrants' access to healthcare services in Norway.

In 2015, the Millennium Development Goals were replaced by the UN's Sustainable Development Goals, which introduced new perspectives on global health (1). Whereas the Millennium Development Goals had highlighted poverty; the Sustainable Development Goals are broader in scope and aim to address poverty, inequality and climate change. While the Millennium Goals focused on low and middle-income countries, the Sustainable Development Goals apply for all countries – the goals are universal.

Universal health coverage is one of the main health-related objectives. The aim is to ensure that everyone has access to affordable essential healthcare. Universal health coverage means that high-quality services are accessible to all at a price that does not cause financial hardship. As countries gear towards the goal of universal health coverage, the World Health Organisation (WHO) recommends that decision-makers focus on extending coverage along three different dimensions: to previously non-covered groups (population - who is covered?), to services that were previously not provided (which services are covered?), and by reducing direct payments (proportion of the costs covered) (2).

While the sustainable development goals are global, it is the responsibility of member states to ensure that the goals are reached. In a world where 244 million people do not live in their country of citizenship – 8% of whom are refugees (3, 4) – challenges arise. Whose task is it to ensure that the goal of universal health coverage is reached for those who have no identity papers? As Norwegian doctors and healthcare professionals meet undocumented migrants in their everyday practice, they are forced to grapple with health coverage issues of global concern.

Who should have access to healthcare services?

The right to the highest sustainable standard of health is recognised in the European Convention on Human Rights, the UN Inter-

national Covenant on Economic, Social and Cultural Rights, and in other international treaties and conventions. By ratifying these documents, countries such as Norway have committed to protect the human rights of anyone who resides within its borders (5). Furthermore, the Norwegian Constitution and the Human Rights Act stipulate that Norwegian authorities are responsible for ensuring that human rights are protected by the nation's legal system. Norway has been criticised by the UN, among others, for failing to ensure that undocumented migrants receive healthcare beyond emergency assistance (6).

«Undocumented migrants in Norway do not have access to universal health coverage»

There are considerable differences between the health services available to members of the Norwegian National Insurance scheme and those available to undocumented migrants. In most countries, the latter group is not covered by the public health service in the same way as permanent residents. There are however considerable differences between countries when it comes to healthcare provision for undocumented migrants. In countries like Spain and Sweden, people without identity papers are entitled to receive certain medical services beyond emergency care, while in Belgium and the Netherlands they have access to the same health services as the rest of the population (7). A middle-income country such as Thailand stands out in that it offers universal health coverage for everyone residing in the country, including refugees and undocumented migrants (8). In this context, Norwegian policies are restrictive; the current strategy is similar to that of Poland and Bulgaria (7). This has created particularly striking differences between the healthcare services available to undocumen-

ted migrants and those available to members of the Norwegian welfare state.

Which health services should be covered?

Undocumented migrants in Norway have limited access to health services and, with a few exceptions, their entitlement is restricted to emergency healthcare. According to Norwegian regulations ("Forskrift om tjenester til personer uten fast opphold"), migrants with no legal right to remain are only entitled to receive 'immediate medical assistance if intervention cannot wait without risk of imminent death, permanent severe disability, serious injury or acute pain' (9). Some groups, such as children and pregnant women, have access to services beyond this minimum.

A Norwegian study shows that in everyday practice, it can be difficult for healthcare professionals to define what constitutes 'immediate medical assistance that cannot wait' (10), particularly if the healthcare workers have neither talked to nor examined the patient. For instance, should patients with progressing diabetes have to wait until they develop ketoacidosis before medical care is offered? How psychotic does a patient have to be before healthcare is provided? Healthcare workers interpret the Norwegian legislation in different ways – some are disinclined to offer healthcare, while others provide services beyond emergency assistance (10, 11).

Undocumented migrants also encounter practical barriers. They often lack information about health services and their own entitlements, and may be living in fear of deportation. This may affect the degree to which undocumented migrants seek medical assistance when they are in need of healthcare. In response to the limited health services available to undocumented migrants, volunteer healthcare centres for undocumented migrants have been established in Oslo and Bergen. These centres report that patients present with illnesses ranging from upper respiratory tract symptoms to chronic pain, diabetes and acute psychosis. The healthcare centre in Bergen, which is open one evening a week, reported a total of 236 consultations in 2016. The majority of patients were young adults from countries in the Middle East, and mental health was the most frequent cause of consultation (12). It is unclear whether undocumented

migrants who make use of these services would have received medical assistance from the Norwegian health care system, and whether they meet the formal criteria for accessing its services. These patients may well be using the volunteer-led healthcare centres because they are of limited means, feel ill at ease with using public health services, or are unaware of their own rights.

To what extent should undocumented migrants pay for health services?

Undocumented migrants in Norway are charged for making use of health services, as reimbursements and subsidised medical care are only available to members of the National Insurance scheme. If they cannot pay, patients will find it difficult to access the health services that they are formally entitled to. General practitioners who treat undocumented migrants do not get their costs reimbursed. The same applies in the specialist health service.

Because the health trusts are not reimbursed by the National Insurance scheme for healthcare services provided to undocumented migrants, they demand, to varying degrees, out-of-pocket payment for care provided, such as emergency caesarean sections (13). Undocumented migrants in Norway have been found to put off seeking healthcare due to a lack of funds (14). Studies from low and middle-income countries show that high out-of-pocket charges for health services may cause real financial hardship for patients (15).

Towards universal health coverage in Norway?

Undocumented migrants in Norway do not have access to universal health coverage. The Norwegian public health service provides emergency medical care, but this can be costly. There are relatively few private providers of medical services, and the out-of-pocket payments can be very high. The home countries of undocumented migrants rarely provide health services. Undocumented migrants thus find themselves in a situation where their access to healthcare services is restricted by law, and where

financial and other practical barriers further restrict their access to medical care.

Access to healthcare services for undocumented migrants is often linked to immigration policy. Restricting access to the welfare system may be seen to form a part of this strategy; migrants should never be seen to benefit from gaining illegal access to the country (10). Liberal access to healthcare services for undocumented migrants may be considered to encourage 'health tourism' in that people in ill health may choose to migrate to Norway for the purpose of accessing expensive treatments such as cancer

«In humanitarian and professional healthcare circles there is broad consensus that medical treatment must be offered based on need rather than legal status»

drugs or treatment against auto-immune diseases. However, very few undocumented migrants quote access to health services as a reason for migrating to an EU country (16). In humanitarian and professional healthcare circles there is broad consensus that medical treatment must be offered based on need rather than legal status. This view is founded on weighty ethical arguments (17). The Norwegian Medical Association, Norwegian Nurses Organisation and eleven other organisations launched an appeal to improve access to health services for undocumented migrants in Norway (18). Earlier this year, the Norwegian parliament rejected a proposal to increase access to primary health services for undocumented migrants and to work up funding arrangements for these services (19). One of the main arguments against the proposal was the fear of health tourism. In these discussions, Minister of Health Bent Høie stated that he did not see a need to consider extending the healthcare rights of migrants without an indefinite leave to remain (20).

Countries move towards the UN's Sustainable Development Goals on different paths. As other countries take steps towards universal health coverage, Norway should also consider its current strategies. According to the World Health Organisation's recommendations, universal health coverage is best achieved by gradually increasing access to health services. It is recommended that essential services should be prioritised. When services are provided free of charge, or at a low cost, they will be accessible even to vulnerable groups (21). It is difficult, in theory as well as in practice, to come up with a definition of essential healthcare services. Many may agree that experimental cancer treatments or rehabilitation programmes cannot be considered essential healthcare services, but that treatment for diseases such as diabetes, or the provision of maternity care, is. In discussions about universal health coverage in Norway, it is necessary to clarify which healthcare services should be offered to undocumented migrants. In order to safeguard their fundamental right to the highest attainable standard of health, it is crucial that they are given affordable access to essential health services. Services such as caesarean sections and treatment for pneumonia should therefore, in most cases, be provided free of charge.

The UN's Sustainable Development Goals and our obligation to protect human rights challenge the practical, legal and financial organisation of healthcare services made available to undocumented migrants in Norway. For Norway to be able to claim that universal health coverage is provided, it is necessary to ensure access to further essential healthcare services for undocumented migrants, and the level of out-of-pocket charges must be reduced.

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Social inequality – a forgotten factor in pandemic influenza preparedness

Reducing social inequality in health is at the core of international health work, but does not form part of the discussion on international preparedness plans for pandemic influenza. This is surprising given that influenza pandemic mortality rates are highest among those with the lowest socioeconomic status. This is not conducive to achieving the international goals of reducing social inequality in health and ensuring good health for all by 2030.

The World Bank's latest «Global Crisis Response Platform» report claims that the most serious threats to human life and economic security are climate change, conflicts and pandemics (1). In recent years, several infectious diseases, such as Middle East respiratory syndrome coronavirus (MERS-CoV), Zika and Ebola, have been characterized as pandemic threats.

The Ebola epidemic in West Africa killed more than 11 000 people in the period 2014–15, and exposed failings in the global epidemic preparedness. In response, the Coalition for Epidemic Preparedness Innovations (CEPI) was formed recently (2). The aim is to produce vaccines, initially against the three aforementioned viruses, and then to conquer new local epidemic outbreaks. During the launch of CEPI at the World Economic Forum in January 2017, the head of CEPI, Bill Gates, argued that the pandemic threat with the greatest potential to harm society and the economy was a new influenza pandemic (3).

The World Bank suggests that the annual cost of a new, less serious pandemic is USD 570 billion, which represents 0.7% of the global gross domestic product (GDP). A serious pandemic like the Spanish influenza of 1918–19 can cost as much as 5% of the global GDP, or almost USD 4 trillion (1). The Spanish influenza killed 50–100 million people (4); 5–10 times more than the number who perished during World War I.

Influenza pandemics past and present

Influenza pandemics have occurred 3–4 times every century since the 16th century, and have not been linked to fluctuations in the economy or conflicts (5). In the last century, in addition to the Spanish influenza, we also had the Asian influenza in the period 1957–58 and the Hong Kong influenza from 1968 to 1970. The last pandemic, in 2009–10, killed 200 000 people globally (6).

The number of pandemic-related deaths per 1 000 inhabitants has fallen over time: 1918–19 (27–54), 1957–1958 (0.7), 1968–1970 (0.3) and 2009–10 (0.03) (4–6).

Who will be most at risk in a new influenza pandemic? A natural answer is young children, the elderly and people who are already sick, as is the case during the annual influenza epidemics. During pandemics, people who are already ill are vulnerable, but it is young adults who are affected the most (6–8). What about the socioeconomically disadvantaged? During the Spanish influenza pandemic, mortality rates differed considerably between high and low-income countries (9) and between the rich and the poor in towns with a large degree of social inequality. In Oslo, the highest mortality rate was among the working classes, those living in small flats and people on the east side of the city (10). In Chicago, it was the illiterate, the unemployed and those with the most cramped living conditions who suffered the highest mortality rates (11). During the 2009 pandemic, the mortality rate was 20 times higher in some South American countries than in Europe (6), and three times higher in the poorer parts of England compared to the affluent parts (12).

There is not much we can do to reduce the likelihood of a new pandemic. However, we can draw on historical experience to prevent social inequality in mortality rates during future pandemics.

Social inequality and global pandemic response plans

The European Union (EU), Norway, the World Health Organization (WHO) and the USA aim to reduce social inequality in health in a generation (13–17). The World Bank, the EU and the Centers for Disease Control and Prevention in the USA have adopted a «One Health» strategy with a view to improving the preparedness for pandemic threats, with a particular focus on lo-

wincome countries (18–20). The strategy is a transdisciplinary approach for the early identification, prevention and reduction of health threats to humans, animals and the environment. In addition to the aforementioned CEPI, the World Bank also launched a pioneering funding scheme – the Pandemic Emergency Financing Facility (PEF) in 2016 – aimed at the rapid prevention of the spread of pandemic threats in low-income countries (21). These measures can play an important role in the UN's goal to eradicate poverty and ensure good health for all by 2030 (22).

In view of the international objectives of reducing social inequality in health and implementing measures to conquer pandemic threats that arise in low-income countries, it is striking that international documents do not address the question of how social disparities in mortality rates are to be reduced during the next influenza pandemic. This applies to the preparedness plans by WHO, the USA, Canada, Australia, the EU and its 28 member countries, Iceland, Norway, Switzerland, Turkey, Macedonia, policy documents by the World Bank, general sociodemographic projections, and plans to reduce the impact of pandemics on indigenous populations (23–30). The complete absence of discussion on social inequality in the pandemic response plan for England (12) has already been pointed out, but the failing in international pandemic plans is something that is only now coming to light.

Internationally, the biomedical target groups for pandemic vaccines are health workers, high-risk age groups, pregnant women and people with underlying diseases, while target groups defined on the basis of socioeconomic status are not mentioned (23, 27, 29–31). However, indigenous populations are covered in pandemic plans for the USA, Canada and Australia in the same way as the biomedical target groups (29–31).

It is unclear why those who devise plans do not discuss how to avoid social inequality in mortality rates in the event of a new pandemic. Have the rich countries – who have prepared such plans – been most concerned about reducing social inequality in diseases that take the most lives in rich parts of the world, such as cardiovascular disease and cancer? Has this been at the expense of the interest in social inequality in infectious diseases that are rare or have little prestige, or which have been eradicated or have a low

mortality rate in our part of the world? Could it be that those who devise pandemic plans consider influenza to be a disease which, beyond the biomedically defined risk groups, is random, and therefore socially blind? Is that the reason why there is little emphasis on research showing that social conditions have a bearing on who dies during a pandemic?

Need for transdisciplinary pandemic research and pandemic preparedness plans

Although several studies have shown social inequalities in pandemic mortality rates both 100 years ago and in 2009 (6, 9–12), more studies are needed on the biological and social mechanisms that drive the inequality. These may relate to poor nutritional status, concurrent illnesses, cramped living conditions and a lack of understanding of or access to health advice/vaccination recommendations due to poor reading and writing skills. There is also a lack of studies that can reveal whether the mortality rate for the socially disadvantaged was higher due to a greater incidence of influenza or a higher mortality rate – or a combination of these.

The influenza models used in the pandemic plans often study the effects of earlier immunity, use of antiviral drugs, vaccination strategies and non-pharmaceutical measures such as the closure of schools and the isolation of infected persons. The pandemic outcome measures are usually incidence of infection, hospitalization, intensive care and death (27). However, international and national preparedness plans should be expanded such that these models also illustrate how nonpharmaceutical and pharmaceutical interventions can prevent social inequality in morbidity and mortality in new pandemics, thus saving lives and limiting social and economic losses. In this way, international health institutions and national public health institutes will also work to put social inequality in infectious diseases such as influenza on the agenda along with non-infectious diseases.

As part of the initiative, influenza researchers and pandemic groups at the international health institutions and national public health institutes – which normally consist of doctors or professionals with backgrounds in other health disciplines and science disciplines – should collaborate with or recruit pandemic historians and social scientists who research influenza pandemics. If medi-

cal and natural scientists, social scientists and historians work together to develop common issues, theories, frameworks and languages – including joint analyses and publications – this will generate more robust and tenable empirical and theoretical results than when they work individually (32). In order to conduct high-quality epidemiological research on the Spanish influenza, for example, it is not enough just to have a good understanding of the influenza virus, immunity and virulence; researchers also need to be aware of the historical context in which data was collected and produced, and take into account that the events of the time, such as World War I, may have affected the pandemic outcomes (33, 34). For example, the refugee camps in Europe, the Middle East and North Africa that sprang up during the recent migration and refugee crisis are at a high risk of becoming a breeding ground for the spread of disease if a new influenza pandemic were to break out today. A holistic research approach to historical influenza pandemics and transdisciplinary collaboration in the development of pandemic plans will mean more robust research and will have a long-term influence on the formulation of influenza pandemic preparedness policy.

Social conditions as an indicator for pandemic vaccines?

Based on the research showing that there are clear social disparities in the pandemic mortality rate (6, 9–12), it is natural to recommend changes in the vaccination policy on the basis of social conditions in addition to biomedical priorities for pandemic vaccination. This requires the development of good social indicators. For Norway's part, the following groups are assumed to be at risk: those on long-term sick leave, disability benefit claimants and those with a reduced ability to work, i.e. people with complex social and/or health challenges. Other examples are people with a low level of education and low income (16). The health authorities in most countries currently translate the international biomedical recommendations for influenza vaccination into their own national context. The social conditions for recommending vaccination therefore need to be investigated and determined nationally. Globally, there is no doubt that prioritizing poor countries in relation to the distribution of scarce pandemic vaccines will have the greatest impact on reducing social and economic consequences.

Towards a paradigm shift in vaccination strategies against influenza?

In order to aid the international goals of reducing social inequality in health and ensuring good health for all by 2030, preparedness plans should be revised to reflect the need to avoid the socially unjust burden of disease in future influenza pandemics.

A broader indication of influenza vaccination, based on both social and biomedical conditions, will have greater potential to reduce the risk of death than if only the biomedical indications are used. Such a change, where social conditions have implications for vaccination recommendations, would be a paradigm shift in the policy to combat influenza.

A transdisciplinary approach to the study of influenza pandemics and the preparation of preparedness plans, in which social and biomedical conditions are taken into account simultaneously, can also inspire research and formulation of policy that can help reduce social inequality in pandemic threats that are not related to influenza, thereby lessening the social and economic consequences.

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Developing a vaccine for leishmaniasis: how biology shapes policy

One aim of the Sustainable Development Goals is to end the epidemics of neglected tropical diseases by 2030. A multifaceted approach is needed to tackle leishmaniasis, keeping in mind the parasite, as well as its vector, host and reservoir. Attention should be focused on sustainable and achievable solutions rather than fairytale goals, and biology should play a more prominent role.

Leishmania is a highly adaptable parasite. At least 20 different species can cause the disease. Clinical manifestations include cutaneous (CL), mucocutaneous (MCL), visceral (VL, also known as kala-azar in Africa and Asia), and post-kala-azar dermal leishmaniasis (PKDL). Cutaneous leishmaniasis causes skin lesions that usually self-heal but may metastasise, causing scarring and stigmatisation. Mucocutaneous leishmaniasis may cause facial disfigurement. Visceral leishmaniasis affects organs such as the spleen, the liver and lymph nodes and, if left untreated, is fatal in 80–95 % of patients (1). After treatment, post-kala-azar dermal leishmaniasis may develop with few or no symptoms, but patients are potentially harbouring parasites in the skin (2, 3). In addition, there are vast numbers of asymptomatic individuals who serve as reservoirs for the *Leishmania* parasite (3, 4).

Leishmaniasis is prevalent in 98 countries and endemic in some of the poorest regions of the world. Around 350 million people are at risk of infection (5). Annually, 200–400 000 people are infected with visceral leishmaniasis, and 700 000–1 200 000 with cutaneous leishmaniasis (5). Visceral leishmaniasis ranks second only behind malaria in terms of mortality caused by a parasitic disease. Risk factors for leishmaniasis include poverty, malnutrition, human migration and inadequate housing. In Europe, leishmaniasis is endemic in the Mediterranean region.

Almost 50 different sand fly species are known to transmit *Leishmania* (6, 7), and they exist in diverse environments, from the humid rainforests of Brazil to the dry climate in Afghanistan. Strategies to tackle the sand flies have so far not proven to be effective, and resistance to insecticides has been reported (1, 3).

Dogs and rodents are an important reservoir of *Leishmania* in several endemic areas. Dogs may be targeted using insecti-

cide-impregnated dog collars, topically applied insecticide, drug therapy or vaccines, or more drastically, culling. However, all these measures have limited effect on human transmission and are impractical (1, 3). Drugs have limited usability in dogs, due to relapses and development of parasite resistance (3, 8). Questions have also been raised about the efficacy of the vaccines available for dogs in Europe and Brazil, especially on the effect of transmission from dog reservoir to humans (1, 8, 9).

«Leishmaniasis is prevalent in 98 countries and endemic in some of the poorest regions of the world»

Furthermore, when the transmission involves wild animals, such as rodents, control of the animal reservoir is almost impossible. Crucially, the feasibility of vector and animal reservoir control programmes in poor resource settings is also questionable due to high costs and complexity of implementation (10).

Fighting leishmaniasis

Leishmaniasis, given its complex interplay between host, vector and reservoir, probably requires a multifaceted approach. Approaches to the vector and the animal reservoir have been discussed above. For humans, potential control strategies could include early detection, drugs and vaccine. Although dogs and rodents are important reservoirs in most endemic areas, there are areas such as India, where the transmission is thought to be anthroponotic, occurring only between humans. In these areas especially, early detection and treatment are essential to control leishmaniasis (11).

For humans, several of the available drugs have toxic side-effects, and parasite resis-

tance has developed. In addition, long-term hospitalisation might be challenging in a low endemic setting. Therefore, in our opinion a vaccine is probably the best way forward, especially since infected people are known to acquire long-lasting immunity against infection from parasites of related strains (1, 3, 10, 12).

A vaccine could work

There are several unanswered questions concerning the development of vaccines for leishmaniasis. First, for which *form* of leishmaniasis is it most urgent to develop a vaccine? Ideally, a vaccine for leishmaniasis should be broadly protective against all the species of the parasite causing the different variants of clinical disease, but this has so far proven difficult. However, in theory, it should be possible. When selecting antigens for a recombinant, vector or nucleic acid vaccine, antigens that are highly conserved among different species of the pathogen are typically selected. Even if two species are relatively distant in evolutionary terms, a vaccine based on conserved antigens could give protection against several species. Intuitively, it may be most pressing to develop a vaccine for the potentially fatal visceral form, commonly caused by only two species – *L. donovani* or *L. infantum*.

Second, *Leishmania* has a complex digenic life cycle between the mammalian host and the vector sand fly. The host-vector-reservoir relationship is only partly understood – making vaccine development more difficult. For example, when developing new vaccines, antigens that might enhance the susceptibility of the host to the infection have to be avoided (13). Likewise, a vaccine has to be tested for adverse effects among already infected individuals, such as what has been reported for the Q-fever vaccine (14, 15). Another example is the role of the sand fly and how it may affect the immune response in humans. This is only partly understood and may affect the efficacy of a vaccine (11). Furthermore, antibodies against *Leishmania* may facilitate infection rather than limit it (13, 16), also potentially complicating vaccine development.

Third, there is a debate about how the vaccine *should* work. Traditionally vaccines work prophylactically. But a vaccine could also work therapeutically, alone or in combination with drug therapy (3, 17). For leishmaniasis, it is unclear which approach is most viable and most important to prioritise.

Table 1 Potential vaccine strategies for leishmaniasis and their pros and cons

Vaccine approach	Inducing antibody production	Inducing cellular immunity	Allows diagnostic testing ¹	Safe for immuno-suppressed individuals
Inactivated pathogen	Yes	No	No	Yes
Live attenuated pathogen	Yes	Yes	No	No
Recombinant antigens	Yes	No	Yes	Yes
Vector- based vaccines ²	Yes	Yes	No	No
Nucleic acid vaccine ³	Weak	Yes	Yes	Yes

¹ To discriminate infected from vaccinated

² Includes both bacterial and viral vectors

³ DNA, mRNA, RNA replicons

Fourth, which type of vaccine is most likely to be effective against leishmaniasis? (See Table 1 for a brief overview of potential vaccine strategies and their pros and cons.) First generation vaccines include killed or live attenuated pathogens. Such vaccines have the potential to closely mimic natural infection. In the Middle East, so-called leishmanisation has been practised, whereby pus from cutaneous lesions and parasites from culture were used to induce a local infection (10). Leishmanisation was discontinued because of problems with reproducibility and safety issues. Furthermore, a leishmanisation strategy involving a viscerotropic strain, such as *L. donovani*, is highly unlikely.

Moreover, ill-defined mutants may lack important epitopes necessary for protective immune responses, while at the same time carrying wild-type alleles that could potentially cause disease. The live attenuated approach is especially unattractive because endemic areas for leishmaniasis are also endemic for HIV and those infected with the latter are thereby also immunosuppressed. Another path would be to inactivate the parasite. However, there have been issues with standardisation of the culture from which the vaccine would be produced, and initial tests show that these vaccines give limited protection in humans (10).

Second generation vaccines are purified or recombinant proteins expressed in bacteria or eukaryotic cells. Such vaccines usually require an adjuvant to induce a good T-cell response (18). The Infectious Disease Research Institute in Seattle has developed a vaccine where several proteins conserved across several species of *Leishmania* are expressed in a single vaccine using a toll-like-receptor agonist as an adjuvant to

induce a strong T-cell response (18, 19). This vaccine has shown promising results (19).

Third generation vaccines are nucleic acid vaccines where expression vectors encoding for a protein antigen are introduced. Here not the antigen itself, but the information required to produce it, is introduced. The recipient's cells produce and present the antigens to immune cells (20). This vaccine strategy has obvious attractions, such as the

«There are several unanswered questions concerning the development of vaccines for leishmaniasis»

fact that the vaccine can be rapidly and cheaply produced. The DNA-vaccine approach has been tested with several antigens against *Leishmania*-infected mice, but its effect remains unconvincing. Also, to the best of our knowledge, there are currently no pre-clinical or clinical trials using RNA-based vaccine technology for *Leishmania*. Vectors such as Adenovirus, expressing recombinant antigens, can also be used as vaccines. A novel vaccine uses this approach by expressing a gene encoding for two *Leishmania* proteins, and initial results are promising (17). But this is only in the phase I clinical trial stage, and there are significant challenges ahead.

It takes great effort to develop vaccines. So far, vaccine development has been carried out with limited information on the pathophysiological and immunological complexity of *Leishmania* infection.

Over the years, several vaccine targets

and vaccination routes have been proposed and tested (21). Some of them have shown great potential in protecting animals against leishmaniasis (2). Remarkably few have been able to proceed to a clinical trial. This lack of progress is partly due to lack of a small-animal model that reflects human disease, and to the fact that many vaccines are tested with cutaneous strains where the testing has been undertaken by injections instead of sand fly bites (18).

Policy and biology

Leishmaniasis is one of the numerous examples of communicable diseases where the transition from laboratory testing to field trials has proved difficult. Researchers may put considerable efforts into optimizing vaccine administration. By doing so, they risk removing themselves further from reality.

Many people with a risk of leishmaniasis infection live in areas that lack electricity supply and necessary infrastructure. How useful then is a vaccine that requires a cold-chain? And how beneficial is a vaccine that requires multiple boosts at specific time intervals, when there is a significant challenge in getting patients to the clinic? This is how a two-way approach between biology and policy comes into practice. In addition to a proper understanding of pathophysiology and immunology, an in-depth understanding of the day-to-day situation in several endemic areas is essential.

Currently, the World Health Organization classifies 20 communicable diseases and conditions as neglected tropical diseases (NTDs) (22). These neglected tropical diseases affect more than one billion people and cause high levels of morbidity and mortality (9, 22). Most neglected tropical diseases are treatable, and they are first and foremost diseases of the poor (22). The Global Burden of Disease study – a critical tool for monitoring global health and prioritising between health programmes – systematically undervalues the neglected tropical diseases (23).

According to Sustainable Development Goal 3, we should: 'end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases' (24) by 2030. Much has been said about the hurdles in securing adequate funding for fighting neglected tropical diseases (9, 12). The market is not lucrative enough to recover the cost of developing

vaccines (25). Therefore, there is a requirement for a need-based rather than a market-based approach.

In recent years, the neglected tropical diseases have received increased attention worldwide. Advances include the 2012 London Declaration (26), the Global Network for neglected tropical diseases (27) and several World Health Assembly resolutions (28). The development of drugs and vaccines for neglected tropical diseases is progressing, albeit slowly (29). This improvement includes the Drugs for Neglected Diseases Initiative (30), and other partnerships between industry, government and academic institutions such as BIO Ventures for Global Health (31) and the Tres Cantos Open Lab Foundation (32).

Priority to biology

Neglected tropical diseases are ignored in several ways: They are underreported, underestimated, underfunded and under-

prioritised (9). Although we applaud the initiatives to put neglected tropical diseases higher on the global agenda, through for example the Sustainable Development Goals, much remains to be done. There is a need for coordinated leadership if Sustainable Development Goal 3 is to be reached by 2030. Attention should be focused on *sustainable* and *achievable* solutions rather than fairytale goals. In policy initiatives for fighting neglected tropical diseases, biology should have a more prominent role. One reason for this is the complexity in targeting the diseases and conditions that often require an in-depth knowledge of the intricacies of the biology of the pathogen and the host.

In this article we have given some insight into how a potentially effective preventive strategy has proven difficult for leishmaniasis and why that might be so. Partnership and cooperation between the public and private sectors must be strengthened, as

Sustainable Development Goal 17 highlights. Significant advances could be ensured by improved collaboration between various actors and stakeholders to allow real translation from basic scientific research to the development of a commercially available protective vaccine for leishmaniasis.

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The paradox of access – abortion law, policy and misoprostol

The relationship between the law and access to safe abortion services is complex. Country case studies from sub-Saharan Africa show how the political, economic and social contexts in which the laws are embedded often generate unexpected outcomes.

Legal frameworks are recognised as vital for securing the right to health. The articulation between law, health policy and actual access to health services is not a straightforward matter. Unsafe abortion is perhaps one of the most neglected sexual and reproductive health problems in the world today. With almost 22 million cases annually, unsafe abortions contribute substantially to maternal mortality and morbidity rates globally (1). Abortion-related maternal deaths occur predominantly in low-income countries. In sub-Saharan Africa, deaths due to unsafe abortions have increased steadily since the 1990s

(2). Abortions currently account for approximately 14 % of the maternal mortality rate (1). Young women are disproportionately affected.

The high rate of unsafe abortions has been referred to as a 'silent pandemic' (3). Unsafe abortions are surrounded by stigma and neglect (4). In global health policy, abortion has been treated with caution, due to its controversial nature. The International Conference on Population and Development Programme of Action in 1995 adopted a human rights-based approach to reproductive health. However, it did not gain sufficient support from member states to

include safe abortion as a 'reproductive right'. Rather, it concluded with the weak statement that safe abortion services should be provided 'where legal' and that 'any measures of change related to abortion within the health system can only be determined at the national and local level according to the national legislative process' (5).

In an increasingly conservative policy environment, the Millennium Development Goals in 2001 (6) and more recently the Sustainable Development Goals in 2015 (7), similarly omitted safe abortion from the agenda of reducing maternal mortality. The highly politicised nature of the abortion issue was perhaps most compellingly illustrated by the reinstatement of the 'Mexico City Policy' or the 'global gag rule' by President Trump this year, blocking US funds to organisations involved in abortion service and care (8). It is within this moral-political climate that sub-Saharan countries cur-



A Family Health Options clinic. Photo: Reuters/Baz Ratner/NTB scanpix

rently struggle to reduce the high rates of abortion-related death and illness.

In this chronicle we share our experiences from Ethiopia, Zambia and Tanzania through the Research Council of Norway funded (Norway-Global Partner programme) project 'Safe abortion and fertility control in Ethiopia, Zambia and Tanzania' (SAFEZT).

Law and policy

It has previously been established that highly restrictive abortion laws are not associated with lower abortion rates (5). Conversely, a liberal abortion law is not a sufficient condition for access to safe abortion services (4). Law and policy on abortion vary greatly between Ethiopia, Zambia and Tanzania, making them interesting comparative cases.

In Zambia, abortion is judicially legal and the law classified as liberal; in Ethiopia, abortion is categorised as illegal, but the stated exceptions make the law appear as semi-liberal; in Tanzania, abortion is illegal and highly restrictive. Considering the status of the abortion law, one would expect that women in Zambia would have easiest access to safe abortion services, followed by women in Ethiopia and finally Tanzania, but a complex web of factors mitigate this association.

«In global health policy, abortion has been treated with caution, due to its controversial nature»

Of the three countries, Ethiopia has the most progressive policy on safe abortion services. While still classified as illegal in the country's revised criminal code (9), the law permits abortion not only to save the mother's life, but also in the case of rape, incest or minority (<18 years). The abortion-seeker is not required to provide evidence on the circumstances, other than giving a testimony. Technical and Procedural Guidelines for Safe Abortion Services in Ethiopia were issued in 2006 (10). Notably, health workers down to the primary care level have been trained in safe abortion procedures, safe abortion rooms are available in urban and semi-urban areas down to the health

centre level, and rates of unsafe abortions have decreased from 73 % in 2010 (11) to 47 % in 2014 (12).

In contrast, in Zambia abortion may legally be carried out on broad health and socioeconomic grounds – under the 1972 Termination of Pregnancy Act (13). However, the law does not translate into safe abortion practices. Access has been made very difficult, particularly for young, poor, rural girls. A written consent from three medical doctors, including a specialist only found in referral hospitals in urban centres is required. New guidelines for safe abortion services were developed in 2009. However, they have not been effectively disseminated and remain largely unfamiliar to doctors. Currently, the prevalence of unsafe abortion in Zambia is reported at 85 % (14). This indicates that an apparent liberal abortion law is far from a sufficient condition to secure access to legal abortion.

Lastly, in Tanzania, the penal code allows abortion only when the life of the mother is in danger (15). In contrast to the complicated consent procedures in Zambia, one health worker's consent is sufficient to obtain an abortion in Tanzania. This leaves room for considerable health worker discretion. No guidelines for safe abortion services exist, and no incidence data on unsafe abortion are available. However, in response to the highly restrictive law, particularly adolescent women have been shown to resort to illegal abortions provided under unsafe conditions (16).

The paradox of access

Although high rates of unsafe abortion are – broadly speaking – linked to restrictive abortion laws, the country cases demonstrate that there is an unclear and at times paradoxical association between the status of the law and actual access to safe abortion procedures. The complexity of the relationship between abortion laws, policy and access cannot, however, be fully grasped without recognising how abortion is fundamentally embedded in social, religious and health-system contexts.

Globally, three different discourses dominate the debate on abortion: a human rights discourse, a public health discourse and a religious/moral discourse. In Ethiopia, Zambia and Tanzania the discourse on safe abortion as a 'human right' is largely absent

while the discourses on safe abortion as a 'public health' issue and as a 'moral transgression' are competing for prominence. Below we take a look at how these normative discourses are played out and their importance for actual outcomes in the three country contexts.

«Unsafe abortion is one of the most easily preventable causes of maternal mortality, but moral and religious reasoning hinders political commitment to address the problem»

The official governmental discourse on abortion in Ethiopia is based in public health. Rooted in mortality and morbidity figures related to unsafe abortion, the public health discourse on safe abortion gains legitimacy through the aim of reducing abortion-related death rates, and protecting girls and women from the adverse health consequences of unsafe abortions (1). The changes in the earlier, more restrictive abortion law were fought through in an alliance between civil society actors and the Federal Ministry of Health, promoting safe abortion as a public health measure to reduce maternal mortality.

Different religious groups, particularly the Ethiopian Orthodox Christian Church to which the majority of the population belong, challenge the public health argument and retain the position that abortion is a religious offence and morally wrong. The increasing availability of safe abortion services thus to some extent remains silenced, the law is not widely known and high numbers of young women continue to resort to unsafe procedures (12).

The case of Zambia, possibly more than the other two countries, highlights the importance of the religious-moral dimensions of abortion. Zambia has declared itself a Christian nation, the Catholic Church is powerful and the independent churches – including the Pentecostal church – are increasingly visible in the discourse on abortion, promoting a pro-life agenda that constructs abortion as a sin and a religious

offence. A new bill of rights has recently proposed an amendment to the constitution with vast implications for abortion-seeking women stating that: 'The right to life begins at conception' (17).

The ontology of human life and personhood lies at the core of this, as well as of other major abortion controversies. Within the Christian discourse, politicisation and diverse interpretations of the point at which human life begins is particularly pertinent (18). In Zambia, this discourse has opened up for a renewed political dispute over abortion that may curb recent public health efforts to simplify access to safe abortion services in the country.

In Tanzania, where Islam and Christianity are practised by approximately equal proportions of the population, the discourse on abortion as a sin and as a moral transgression predominates at official level. Although the media regularly raises the problem of unsafe abortion-related complications and deaths among young girls, the public health argument is not officially endorsed. Despite the public condemnation there seems to be room for considerable pragmatism, particularly when it comes to the increasing availability and accessibility of misoprostol (19).

The game changer

WHO has recently promoted medical abortion globally, and more recently misoprostol as a 'harm reduction strategy' that can replace risky abortion procedures world-

wide (20). Studies from South America have documented that self-use of misoprostol obtained from pharmacies reduces abortion-related morbidity and mortality (21). Misoprostol is registered as a drug for postpartum haemorrhage in all three countries, but is not legally marketed for medical abortion purposes. Yet, in Tanzania, emerging evidence suggests that pharmacies and medicine shops across the city of Dar es Salaam offer misoprostol off-label over the counter for abortion purposes (19).

A study in Zambia similarly found that misoprostol was widely available in pharmacies and sometimes prescribed by medical doctors for abortion purposes (19). No study has yet documented access to Misoprostol off-label through pharmacies and medicine shops in Ethiopia.

The rapidly emerging picture globally is that access to misoprostol increases women's power to decide over the timing of their pregnancies. For the individual woman seeking to terminate a pregnancy, abortion may be experienced as morally problematic and contrary to one's faith, but still a better option than bearing the shame and burden of an untimely birth.

The marketing of misoprostol through pharmacies and medicine shops makes it possible to circumvent both the law and gatekeepers in the health system and to access the drug secretly. While this unregulated marketing and unauthorised self-administration of misoprostol involves

medical risks, it does also facilitate access to a self-induced abortion procedure that is safer, more private and less invasive than other methods (21).

The relevance of the law

With misoprostol, yet another factor is added to the complex and paradoxical articulation between law and access to safer abortion procedures that we have sought to illustrate through our country cases. It seems that the abortion law in many countries is lagging behind scientific developments (20) as well as the market. Highly restrictive abortion laws may become increasingly irrelevant in determining access to medical abortion procedures in the future.

According to the WHO, unsafe abortion is one of the most easily preventable causes of maternal mortality, but moral and religious reasoning hinders political commitment to address the problem. In order to pay justice to women's reproductive health and rights, access to medical abortion under legal, safe conditions should be prioritised on the global health agenda in the years ahead.

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Protecting the vulnerable is protecting ourselves: Norway and the Coalition for Epidemic Preparedness Innovation

Norway has played a critical role in the recent launch of the new Coalition for Epidemic Preparedness Innovation, revealing Norway's powerful position in global health. But how will Norway help put the coalition's governance principles – political legitimacy, representation and accountability – into practice? And how will a more security-based approach impact Norwegian global health policy and research?

On January 19, 2017, a new Coalition for Epidemic Preparedness Innovation entered the global health architecture. Launched at the World Economic Forum by Norwegian Prime Minister Erna Solberg and Bill Gates, the coalition aims to finance the development of vaccines against emerging infectious diseases. In the coalition's own words, its objective is nothing short of «outsmarting epidemics» and giving the world «an insurance against epidemics» (1).

The coalition is designed as a public-private partnership with representation from governments, philanthropies, non-governmental organisations, pharmaceutical companies, research institutes, regulatory bodies and multilateral organisations (box 1). Although branded as a global initiative, it is very much «made in Norway,» with its creation highlighting Norway's financial and agenda-setting power as a major global health actor.

A Norwegian diplomatic success

The idea to establish a new coalition to develop vaccines against emerging diseases can be traced back to the Ebola crisis of 2013–2015. The Norwegian Institute of Public Health then cooperated with the World Health Organization (WHO) on a collaborative vaccination trial in Guinea, which found the vaccine to be 100% effective (2). Following the Ebola crisis, many reports and panels called for global action to prevent similar epidemics, including setting up mechanisms to ensure the development of vaccines against emerging diseases (3–5). Based on their experience during the Ebola crisis, the Norwegian Ministry of Foreign Affairs and the Norwegian Institute of Public Health took the initiative to convene a working group in Oslo in April 2016 to address this issue (6). Shortly afterwards, the Coalition for

Epidemic Preparedness Innovation was created as an international non-profit association under Norwegian law.

The coalition's organisation reflects Norway's decisive influence (box 2). It is a diplomatic success for the Norwegian government, which, since the mid-2000s, has continued to make global health one of its foreign policy priorities (7). At the same time, the coalition is indicative of a shift in emphasis during the past fifteen years away from Norway's historically strong commitment to addressing health through the multilateral UN system in favor of new-public-private partnerships for health (8). Much of the increase in Norwegian funding to global health during this period has been support to public-private partnerships, including Gavi, the Vaccine Alliance, and the Global Fund to fight AIDS, TB and malaria, often in partnership with new philanthropic foundations, notably the Bill and Melinda Gates Foundation. Tore Godal, a leading Norwegian health diplomat, has even been described as the «founding father» (9) of Gavi, whose innovative institutional and financing models certainly influenced the creation of the Coalition for Epidemic Preparedness Innovation. The coalition is thus an expression of not only Norway's financial power, but also its recognised expertise and moral authority, deriving from its long involvement in the field.

Power dynamics and governance principles

From the outset, the coalition has been explicit about defining its core governance principles (10), espousing commitment to «political legitimacy» and «public interest representation», «accountability», «independence and neutrality», and «transparency». As the coalition is operationalised

Box 1 Who supports the CEPI (10)?

- The founding partners: Norway, India, the Wellcome Trust, the Bill and Melinda Gates Foundation, the World Economic Forum
- The investors: Norway, Japan, Germany, the European Commission, India, the Bill and Melinda Gates Foundation, and the Wellcome Trust
- The interim board members (with voting rights): United Kingdom, Australia, the United States, Norway, the European Union, India, South Africa, Liberia, Ethiopia, the Wellcome Trust, the Bill and Melinda Gates Foundation, Merck, GSK, the Serum Institute, Pax Vax, Médecins sans Frontières, and three «independents» connected to the World Economic Forum, the US National Academy of Medicine, and the London School of Hygiene and Tropical Medicine.
- CEPI's coalition partners, advising the board: donors (including Norway), research institutes, pharmaceutical companies, regulatory and normative bodies (among others, the World Health Organization and the US Academy of Medicine), procurement and distribution partners (for instance, Gavi, the Vaccine Alliance) and non-governmental organisations (including those that are part of the No More Epidemic Campaign, such as Save the Children and International Medical Corps).

Box 2 Norwegian influence in the CEPI (10)

- Interim CEO (until April 2017): John Arne Røttingen, current Director of the Research Council and former Director of the Division for Infectious Disease Control at the Institute of Public Health
- Interim Secretariat: hosted at the Norwegian Institute of Public Health, Oslo
- Board: Norway holds one of the five seats allocated to high income countries
- Financial contribution: NOK 1 billion, second largest after Japan

and develops, it will be important to clarify and monitor what these principles mean, and how Norway will make use of its power to put them into practice. Already, some important questions are evident.

Political legitimacy and public interest representation

The coalition claims to strive for «political legitimacy», but what does this mean, and from where does its claims to legitimacy derive? Are its founders appealing to normative democratic criteria such as representati-

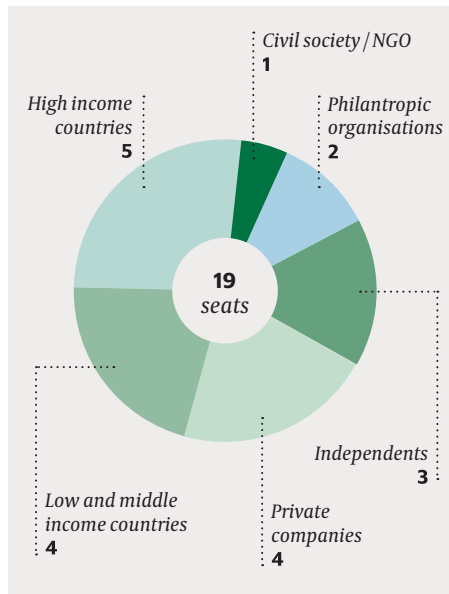


Figure 1 Composition of CEPI's interim board

veness, in the sense of «democratic legitimacy» (11)? Or do they assume a less normative definition of legitimacy that assesses audiences' views about which values they believe give an institution legitimacy? The initiative's formation has been justified with reference to a global consensus following the Ebola crisis on the need for new mechanisms to develop vaccines against emerging diseases. But who shaped this consensus in the first place? Does this global interest reflect only the interests of donor countries or those of the low-income countries who were affected by the Ebola epidemic as well? It is striking that two of the most influential commissions drawing lessons from Ebola were funded by high-income countries and rich foundations and hosted by European and American institutions, such as the London School of Hygiene and Tropical Medicine, the Harvard Global Health Institute and the US National Academy of Medicine (4, 5). Experts from donor countries clearly played a major role in drafting these commissions' recommendations (12), but the role of their low-income country counterparts is less clear.

The participation of a wide range of actors on the coalition's board could be another source of legitimacy. However, among the board's 19 seats, five are reserved for high income countries, four for low- and middle-income countries, two for philanthropic organisations, four for private companies, three for «independents» (individuals invi-

ted to sit on the board because of their personal merits, not their institutional attachments) and only one seat for civil society (fig 1). This low level of representation for low- and middle-income country governments and civil society raises doubt about public interest representation. In theory, multilateral organisations such as the World Health Organization could represent the public interest, but the World Health Organization has only observer status on the board and thus has no formal power within the new coalition.

Accountability

In its governance principles, the coalition espouses the value of accountability, though without defining what this means. To whom is it accountable? *To its donors* – high-income countries, India and philanthropic organisations? The donors do hold a substantial share of the votes on the board, and they even have a clear majority with the independents, representing the London School of Hygiene and Tropical Medicine, the US National Academy of Medicine and the World Economic Forum – three institutions located in high income countries likely to hold policy views on global health security similar to those of the donors. Or is the coalition accountable to *its intended beneficiaries*, the vulnerable populations located in low-income countries? The beneficiaries have a very limited number of seats on the board, although their interest is seen as specifically important in the coalition's preliminary business plan with the intended development of a policy for questions related to vaccines' affordability and availability (10). Or is it accountable to *its partners*, the pharmaceutical companies receiving support to develop vaccines? These companies are guaranteed coverage of all the direct and indirect costs involved in the vaccine development process and have secured almost a quarter of the seats on the board. The partners may also benefit from the support of their home countries, many of which are represented on the board (the United States, the United Kingdom and India). The industry is thus, as is often the case in public-private partnerships (13), in a position of power with a win-win outcome for its involvement: its costs are covered (companies might even profit financially from the cooperation), and in case of success, businesses can use their involvement for public relations purposes.

«Independence and neutrality»

Behind the concepts of independence and neutrality can be read a normative understanding of global health policies, strongly advocated by the Gates Foundation and increasingly adopted by Norway (8, 14). The coalition's claims of independence and neutrality are indeed symptomatic of a technical, vertical approach to global health issues. Within this approach, vaccines – delivered through top-down programs designed to be applicable everywhere – have been cast as the ultimate cost-effective global health panacea. At the same time, the weak health systems and surveillance mechanisms that would help diagnose, treat and isolate patients before the epidemic gets too large have been relatively neglected (4, 12). The aim seems to be having a technological tool ready for the next crisis, no matter how bad the situation becomes before an epidemic strike.

«Public trust», «transparency» and «no conflicts of interest»

The coalition plans to elaborate policies to promote transparency and prevent conflicts of interest. Such policies are indispensable to ensure public trust, and we encourage the coalition to be very strict when developing and applying them. A future assessment of these policies will give insight into the Norwegian interim administration's capacity to promote these norms within the organisation.

The Securitisation of the Norwegian Global Health Policy

The Norwegian contribution to the Coalition for Epidemic Preparedness Innovation has been framed by Prime Minister Erna Solberg as a contribution to the Sustainable Development Goals, the United Nations's 2030 development agenda (1).

Traditionally, Norway has approached development from a humanitarian perspective – its aim being to help others. However, these goals paved the way for a new conception of development, more centered on win-win projects, as every country (including the wealthiest ones) is due to report its policies to meet the goals and targets. The coalition is clearly framed as one of these win-win projects. Solberg has justified it by declaring that «*protecting the vulnerable is protecting ourselves*» (1).

The coalition, meanwhile, frames its contribution as providing *the world* an insurance against emerging infectious disease

outbreaks. Norwegian support for the initiative is thus motivated by multiple concerns: showing solidarity with the most vulnerable, ensuring national security and securing diplomatic gains.

Norway has used global health as a foreign policy tool for a long time, as a way to gain status and diplomatic recognition and to secure a seat at the table (15). It is, however, a relatively new development to include national security considerations in global health – a tendency that extends to other fields of development, as demonstrated, for instance, by the aid provided to Afghanistan. An assessment of the ongoing development of the coalition's governance principles and underlying promise to promote affordable and available vaccines for everyone will indicate if a balance has been found between these different, and potentially competing, objectives.

Finally, the blurring between security and solidarity in initiatives such as the Coalition for Epidemic Preparedness Innovation raises ethical questions about their financing: will they be financed solely with the aid budget? If so, this would signify a securitisation in Norway's humanitarian policy, meaning that security concerns would be integrated in projects framed as altruistic and humanitarian, potentially trumping the ambition to help the most vulnerable.

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Nutrition – A global challenge for health

Malnutrition represents a serious global burden with around 800 million people being undernourished and over 2 billion people being overweight or obese. The associated medical, developmental, social and economic consequences are serious, lasting and extremely costly for the affected families, communities as well as countries. While nutrition is increasingly being paid attention, rarely is it discussed in an all-encompassing way.

It is worth noting that we are currently witnessing a decade of political actions aimed at ending hunger and all forms of malnutrition that exist worldwide. Important commitments have been made (box 1). In addition, the Sustainable Development Goals that were released in 2015 are a particularly useful concept since they highlight the interdisciplinary and intersectoral nature of nutrition. Goal 2 has been specifically allocated to nutrition (“Zero hunger: End hunger, achieve food security and improved nutrition and promote sustainable agriculture”), but many other goals make reference to food and hunger. Goal 3 on health as well as Goal 12 on responsible consumption and production are cases in point, since they highlight the relationship between nutrition, food and health as well as production and consumption patterns that relate to our eating behaviours and thus ultimately the health of our planet and its ability to sustain us.

Malnutrition and its consequences for health

Amongst the global nutrition targets adopted by the World Health Assembly in 2012 are

Box 1 Political Actions on Nutrition (1, 2)

2012: the World Health Assembly adopts the 2025 Global Targets for Maternal, Infant and Young Child Nutrition
2013: the World Health Assembly agrees upon the targets for non-communicable diseases
2013: the first Nutrition for Growth summit takes place – donors commit US\$ 23 billion to actions to improve nutrition
2014: the Second International Conference on Nutrition takes place in Rome with a commitment to eradicate hunger and prevent all forms of malnutrition worldwide
2016: UN calls for a Decade of Action on Nutrition from 2016–2026

1) 40 % reduction in childhood stunting (low height-for-age), 2) 0 % increase in childhood overweight and 3) a reduction in childhood wasting (low weight-for-height) to less than 5 % (3). The necessity to achieve these targets is very clear. In particular, when considering that in 2016 an estimated 155 million, 22.9 % of all children under five worldwide, were

«The costs of the triple burden of malnutrition for the global economy are considerable»

stunted, 52 million (7.7 %) were wasted and 41 million (6 %) were overweight (4), and that malnutrition is associated with both illness and premature death (4).

While a detailed discussion of the complex mechanisms underlying the relationship between malnutrition, metabolism and immunity go beyond the scope of this paper, it can be said that much of the relationship between malnutrition, in terms of macro- and micro-deficiency, and disease is explained by a greater susceptibility to infectious agents as a result of immunodeficiency (5). Chronic undernutrition in children leads to an appearance of immature T cells, which results in reduced antibody responses to infectious agents challenging the person’s body or to commonly used vaccines.

Moreover, an immune system stimulated by an infection requires an increased demand for energy in order to work effectively – thus the better the nutritional status, the better the outcome of the infection (5).

Double burden of disease and its economic consequences

According to the nutrition transition theory (6) changes in food habits over time, due to changes in food production and lifestyle, would be reflected in a parallel transition

in prevailing epidemiology, from under- to overnutrition and from infectious diseases to non-communicable diseases. However, what we see in some low- and middle-income countries is a rise in obesity and non-communicable disease prevalence as well as persisting incidence rates of infectious diseases, since changes in nutrition and improvements in health care do not take place simultaneously or equally across populations. This co-existence of disease types is called “the double burden of disease” (7).

What is more is that food consumption and production patterns keep converging towards the “western diet” of highly processed/energy-dense foods. The result is a deficiency in micronutrients (7). Since both chronic macro- and micronutrient deficiency leads to growth restriction (stunting) in children, stunting has long been taken as proxy for chronic undernutrition.

However, it has now been realised that micronutrient deficiency could be a common cause for stunting in both undernourished and obese children (7). This triple burden theory implies a co-existence of both micro- and macronutrient deficiencies as well as an anomalous intake of surplus energy, all of which can coincide within communities, families and even individuals and lead to a plethora of health implications. The compounding and long term sequelae of stunting in undernourished children is emphasised by the link to obesity as stunted children who are then exposed to energy-dense, nutrient-poor food, tend to have a higher likelihood of obesity later in life (8).

The costs of the triple burden of malnutrition for the global economy are considerable. According to the Food and Agriculture Organization of the United Nations, the loss of productivity and direct health care costs could be as high as 5 % of global Gross Domestic Product, which is equivalent to US\$ 3.5 trillion per year (9). On top of that come the individual and social costs, including increased risk of compromised development, health and ultimately thriving, learning and productivity (10).

Nutrition – not just a matter of weight

According to Margaret Chan, former Director General of the World Health Organization, “We can reduce (...), low birth weight and child stunting and bring down the risk of NCDs within a generation. We can achieve

this by giving nutrition the attention it deserves” (11). While the World Health Organization’s commitments to and targets for nutrition in terms of overweight and underweight are unquestionably important, there are concerns that the nutrition and food security strategies employed do not fully address malnutrition and nutritional threats.

The Global Nutrition Report 2016, for example, states, “food security strategies do not comprehensively address malnutrition in all its forms, including the vicious circle of malnutrition and foodborne and other infectious diseases” (12). Aspects of food safety and food insecurity in terms of agriculture, ecosystem services, and climate change are also not sufficiently addressed.

Food Safety

According to World Health Organization estimates, 600 million people per year fall ill and 420 000 die after eating contaminated food. This adds up to the loss of 33 million Disability Adjusted Life Years (a Disability-Adjusted Life Year can be considered as one year lost of “healthy life”, measuring the gap between current health status and an ideal health situation). Contamination here refers to unsafe food containing harmful bacteria, viruses, parasites or chemical substances, which are said to cause more than 200 diseases – ranging from diarrhoea to cancers (13).

Neglected tropical diseases, now called poverty-related diseases, are good examples of the interactions between malnutrition and foodborne- and infectious diseases. These diseases can lead to diarrhoea, anaemia, and nutrient deprivation and are common in poor communities lacking clean water, sanitary facilities, and access to medical treatment. When chronically infected, many of these diseases can cause stunting as well as cognitive impairment (14). A classic example that bridges the field of food safety and infectious diseases is the pork tapeworm, *Taenia solium*. Infection takes place as a result of consumption of parasitic cysts in undercooked pork meat. The worm was declared the number one food-borne parasite in 2014 (15).

Moreover, given that agri-business is a global chain of activities, from production, processing, transportation to consumption, bacterial contaminations and naturally

occurring toxins e.g. mycotoxins, as well as the use of certain pesticides or chemicals, can affect consumers globally. The recent scandal in Europe concerning eggs contaminated with fipronil demonstrates this nicely. The insecticide fipronil, not authorised for use in animals farmed for human consumption purposes, was combined with a plant-based disinfectant and bottled up by a company in Belgium. Poultry farmers in the Netherlands and in Germany then used this mixture in their henhouses. Eggs contaminated with fipronil have since reached cafés, supermarkets and the like in twelve European countries (16).

To alleviate the risks from contamination with microorganisms and toxins, simple hygienic measures or coarse sorting are most efficient. However, in particular at the level of small-scale farmers this would require for more appropriate information to be disseminated about what constitutes good hygienic and storage measures. Likewise, careful controls and regulations for marketed foods as well as coordination between governments and producers are required to ensure global food safety.

Food Security and Global Warming

For food and nutrition security strategies to be complete, we believe they also have to make some reference to sustainability of food and agricultural systems as well as the impact climate change has on the quality and quantity of bred, farmed and fished food. Agriculture itself is already responsible for up to 30 % of global greenhouse gas emissions and 70 % of total freshwater withdrawals, as well as it has expanded like no other human land use at the expense of carbon sequestering forests (17, 18).

Moreover, greenhouse gas emissions generated by all of human activities are almost unanimously considered to alter the earth’s climate, with average temperatures rising, seasonal patterns changing and weather conditions becoming more severe and frequent. For the Middle East and North Africa (MENA) region, maximum temperatures on the hottest days are projected to increase from 43 °C to 46 °C by the middle and even 50 °C by the end of this century (19).

This affects human health in many ways, one of which is nutrition, via challenges to agri- and aquacultural production and output. For example, it is currently projec-

ted that there will be a reduction in global crop production by 10 % by 2050 (20). The pressure to produce more food will consequently increase, which in turn, will put more pressure on land and water systems. Food security is thus increasingly threatened, and possible consequences include migration, displacement and even conflict (21), all of which can add additional strain on food production and availability and are themselves associated with forms of malnutrition.

A discussion on global challenges to nutrition must thus include global food consumption, distribution, and production patterns as they directly determine our future food security. We believe this interconnectedness of physical and planetary health is not sufficiently being paid attention to in the form of discussion and concrete policy action.

A systematic approach is needed

We are witnessing a rise in diseases that are associated with our current nutritional habits as well as we are facing threats to our food security that are of increasing complexity. Governments across the globe are facing high costs, if they are to ensure sustainable health and livelihoods for the global population. Importantly, because nutrition and food production have become so multifactorial and global, the associated concerns cannot be tackled in isolation as well as access to sufficient, nutrient-rich and safe nutrition goes beyond governmental responsibility. Instead, the global community needs to increasingly work together to address all aspects of nutrition.

The Sustainable Development Goals may act as a useful guide, highlighting the interconnectedness of health, nutrition, food production, food consumption and the climate. The targets and indicators of the individual goals should be used to direct researchers of different backgrounds to research areas that require transdisciplinary collaboration.

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Multistakeholder partnerships in global nutrition governance: Protecting public interest?

Multistakeholder partnerships, involving public and private actors, have become key instruments in global food and nutrition governance. Such partnerships have the potential for conflicts between profit and public health goals, which may harm the integrity of nutrition policy. How can conflicts of interest be adequately addressed, and by whom?

Multistakeholder partnerships involving governments, international organisations, civil society and private sector actors have become key instruments for implementing the 2030 Agenda and the Sustainable Development Goals. In food and nutrition governance, such partnerships have proliferated as mechanisms to address the multiple burdens of malnutrition, from hunger and undernutrition to obesity and diet-related non-communicable diseases. While promoted as effective responses to complex development challenges that require expertise and resources from multiple sectors, partnerships between public and private actors can create tensions between profit motives and public health goals. Businesses whose profit depends on marketing and sales of unhealthy food and beverages may for example contribute to reframe malnutrition problems in their own interests (e.g. as the result of individual behaviour only), influence public health agendas and priorities, and interfere with legislative processes to derail industry regulation. Such undue influence may, however, be overcome through effective prevention and management of conflicts of interest. The question is how, and who should be responsible for developing 'the rules of the game'?

In order to explore these questions, we discuss the respective roles of the World Health Organization (WHO) and the Scaling Up Nutrition Movement (SUN Movement) in providing normative guidance for governments on how to protect nutrition policy from undue influence. The SUN Movement was established in 2010 as a global multistakeholder partnership for nutrition, involving governments, international organisations, business, civil society organisations and private donors, committed to supporting 59 developing countries in their efforts to reduce undernutrition. While WHO has been mandated by its Member States to develop guidance on conflicts of interest in nutrition, the SUN Movement has developed its own guidance for its member countries.

Rather than protecting the integrity of public sector agencies, the guidance of the SUN Movement seems primarily to aim at protecting the inclusiveness of the multistakeholder process. This not only risks undermining public health priorities, but also the authority and legitimacy of WHO's role as a norm-setting agency.

What are conflicts of interest?

Thompson defines conflicts of interest as 'a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)' (1, p. 573).

Conflicts of interest can occur at different levels; for instance, at institutional level, when an organisation has financial ties that conflict with its vision and mission; or at the individual level, when a financial interest may impair an individual's (e.g. health professional's, civil servant's) ability to make a judgement in the public interest. Both institutional and individual conflicts of interest can damage public trust in and the credibility of public sector officials or agencies, and undermine the quality of policies and services they deliver.

Conflicts of interest in global food and nutrition governance

As private sector actors have gained increased influence in nutrition policy through participation in partnerships with governments, many have raised concerns about the need to safeguard nutrition policy-making from undue influence (2, 3). While partnerships may provide effective solutions to policy problems by drawing on skills and resources from different stakeholders, there should be a limit to the level of involvement of actors whose interests conflict, or may seem to conflict, with public agencies' agendas. Actors that arguably should be kept at arm's length when food and nutrition policy is developed are for example businesses that profit from marketing and

sales of products harmful to health. Negative health impacts are widely recognised in the case of heavy marketing and widespread use (beyond what is medically recommended) of breastmilk substitutes, and extensive marketing of food products rich in salt, sugar and fat to children (4, 5).

WHO's efforts to prevent and manage conflicts of interest in nutrition

Through the endorsement of the *Comprehensive implementation plan on maternal, infant and young child nutrition* by Member States in 2012, WHO was mandated to 'form alliances and partnerships to expand nutrition actions with the establishment of adequate mechanisms to safeguard against potential conflicts of interest' (6). Member States also mandated WHO to 'develop risk assessment, disclosure and management tools to safeguard against possible conflict of interest in policy development and implementation of nutrition programmes consistent with WHO's overall policy and practice' (6).

Since then, WHO has adopted a policy to guide its engagement with non-state actors (7) and is currently working to develop guidelines for countries on prevention and management of conflicts of interest in the nutrition policy process. The guidelines will be presented at the World Health Assembly in 2018. When adopted, they should serve as authoritative advice to governments on how to engage with non-state actors without compromising the integrity of health authorities or nutrition goals. However, in a number of countries burdened by high levels of malnutrition, WHO's guidelines are at risk of being undermined even before dissemination, by alternative guidelines developed by the SUN Movement.

The SUN Movement's approach to conflicts of interest

What is the role of the SUN Movement? In contrast to WHO, the SUN Movement is not a specialised UN agency whose role is to perform normative and analytical functions mandated by Member States. Rather, the SUN Movement has the self-appointed role of coordinating nutrition actors at the global level, advocating for and mobilising funding for nutrition, and supporting country-level action in the area of malnutrition. One of its key aims is to establish multistakeholder partnerships for nutrition within its member countries (8).

The close involvement of food corporations in these partnerships raises concerns about whose interests are promoted through the SUN Movement. Initially focused on reducing stunting (low height for a child's age), the SUN Movement has recently broadened its scope to reduce all forms of malnutrition, including overweight and obesity (8). This aim seems to conflict with the interests of many of the food corporations involved. Through its Business Network, 268 companies have committed to supporting countries' efforts to scale up nutrition action (9). Among these, a large number of corporations selling products harmful to health, such as Coca-Cola, PepsiCo and Mars, are members and represented on the Movement's governance boards (10).

In 2013 and in parallel to WHO's ongoing work on conflicts of interest in nutrition, the SUN Movement started to develop guidelines for its member countries on how to address such conflicts. The guidance, *A Reference Note and a Toolkit for Preventing and Managing Conflicts of Interest*, was financed by the private Bill and Melinda Gates Foundation, and developed by a private consultancy firm (11). This guidance has been widely disseminated within the SUN Movement's 59 member countries and is currently being used by its members, including the Business Network, to guide governments' efforts to address conflicts of interest when developing their nutrition policies and programmes.

While this might seem like a welcome development and proactive response by the SUN Movement to prevent conflicts of interest from arising within the partnerships it promotes, a closer look at the guidance raises concerns regarding its intentions and the appropriateness of its interference with WHO's norm-setting role.

Concerns regarding the SUN Movement's conflicts of interest guidance

There are several reasons why the SUN Movement's guidance on conflicts of interest is problematic. Firstly, the purpose of the guidance does not seem to be to protect the integrity, independence and public trust in individuals and institutions serving public interests, but rather to ensure effective functioning of the partnership itself and to strengthen inclusion of new partners (12, p. 14). The definition applied is unclear and states that a conflict of interest arises when a secondary interest conflicts with the aims

of the partnership, which in the case of the SUN Movement is to promote multistakeholder collaboration. It also states that it is important to manage conflicts of interest 'because it can promote inclusiveness in recruiting and working with stakeholders. (...) and contributes to the effectiveness of the collective effort' (12, p. 18).

Secondly, the SUN Movement's guidance confuses conflicts of interest with concepts such as 'diverging interests' between different actors, and by suggesting that any type of collaboration can lead to conflicts of interest, downplaying the concern about conflicts arising between primary and secondary interests (for example public health versus profits) within an institution or an individual. The guidance also underplays the significance of conflicts of interest by distinguishing between actual and perceived conflicts of interest. The concept of 'perceived' conflicts of interest suggests that a conflict of interest only arises if actual bias or harm to public health occurs. This is misguided and opens up for treatment of perceived conflicts of interest as less serious (13). Indeed, the SUN Movement's guidance states that perceptions of conflicts of interest only sometimes merit an intervention (12, p. 14).

Thirdly, many of the principles of engagement upon which the guidelines are based conflict with an effective conflict of interest policy. Of particular concern are the principles 'to be inclusive' and 'to be willing to negotiate' (12, p. 11). In order to avoid undue influence on public policy-making, exclusion of actors with perceived or actual conflicts of interest is sometimes necessary, and there is not always room for negotiating ways around it. However, the guidance of the SUN Movement encourages to 'limit the scope and duration of any exclusionary decision' (12, p. 21) on the grounds that it contradicts the principles of the partnership. If multistakeholder partnerships mean that the principle of inclusion must be followed above all else, this model is not reconcilable with effective prevention or management of conflicts of interest. The principle of inclusiveness is also problematic, as it does not recommend any limitation to the involvement of non-state actors at any point in the policy process. Having committed to being members of the SUN Movement, governments' abilities to withstand pressure and attempts at industry interference may be undermined, as well as their

The Scaling Up Nutrition (SUN) Movement (14)
Established in 2010.
A global multistakeholder partnership for maternal and child malnutrition.
Members include UN system organisations, civil society organisations, businesses, private foundations, bilateral donors and 59 developing countries.
Stakeholders are organised into four networks: donors, business, civil society and the UN.
Led by a global multistakeholder Lead Group and an Executive Committee.
Promotes multi-sector and multistakeholder partnerships for nutrition in SUN countries.
Aims to scale up evidence-based nutrition-specific and sector-wide approaches to nutrition in member countries.

political power to decide on the extent to which private actors should be allowed into policy-making processes, and at which stage.

The SUN Movement's principle number 5, 'to be predictable and mutually accountable' is also problematic as it suggests that governmental and non-governmental actors alike have equal responsibilities. While every partner has a role in a partnership, the roles and responsibilities of the various actors are not at the same level. Most importantly, governments are primarily accountable to citizens, not to other members of such partnerships.

Finally, the SUN Movement's guidance is weak in the measures it proposes to prevent and manage conflicts of interest. It recommends protection of confidentiality and privacy in the disclosure process (12, p. 18), which contradicts the principle of transparency. Rather than ensuring an independent process, the guidance recommends that 'Mechanisms for managing conflicts of interest should include all stakeholders - including those with a perceived or potential conflict of interest' (12, p. 20). This will seriously limit the effectiveness of a conflicts of interest policy.

These issues indicate that the SUN Movement's Reference Note and Toolkit do not provide an appropriate or sufficient response to the very real question of how to protect food and nutrition policy-making from undue commercial influence. Rather than providing clear advice to

governments on how to address conflicts of interest while engaging in partnerships, the SUN Movement's guidance seems to encourage inclusiveness above all else, without any risk assessment. This contributes to governments' existing confusion about when and how to enter into partnerships, and may even legitimise engagements that clearly create conflicts of interest. Additionally, the overlap with WHO's work on country guidance on conflicts of interest may lead to slower and weaker measures to protect nutrition, and an additional burden on already over-stretched government staff.

Protect democratic processes

While multistakeholder partnerships have the potential to draw on resources and skills from different actors in order to improve effectiveness of nutrition interventions, they create real risks and challenges to food and

nutrition policy-making that need to be acknowledged and appropriately addressed.

The analysis of the SUN Movement's guidelines on how to prevent conflicts of interest suggests that organisations with a self-interest in promoting multistakeholder partnerships should not provide normative guidance to governments on how to protect public health from undue influence. The SUN Movement conveys a misguided understanding of what 'conflicts of interest' means and contributes to undermine the authority of member-state mandated organisations such as WHO, and of governments themselves.

The fact that the SUN Movement promoted a parallel process to that of WHO on conflicts of interest can be seen as an attempt to establish norms of engagement in line with its own agenda that downplays the risks of stakeholder engagement. Rather than protecting the institutional integrity

and independence of public sector agencies, the SUN Movement is legitimising its own mission through its guidelines. Over time, this can lead to reduced public trust in public health agencies, and be an impediment to the fulfilment of existing international nutrition goals, including those in the Sustainable Development Goals. Rather than uncritically promoting multistakeholder partnerships for food and nutrition, more efforts should be made to protect democratic processes and prevent corporate influence on public policy.

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