



Global health: responsibility, ethics and policy

22 June 2011

Report of anniversary symposium

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Foreword

This symposium was part of the 20th anniversary celebrations of the Nuffield Council on Bioethics. Established by the Trustees of the Nuffield Foundation in 1991, the Council's founding reflected a growing concern among those in science and medicine that important developments in biomedical research were taking place without a corresponding understanding of their social and ethical implications. Hence, the Council's remit then (as it is now) involved identifying and defining the ethical questions raised by advances in biomedical research in order to respond to, and anticipate, public concern. Two years later, funding from the Nuffield Foundation was supplemented by grants from the Wellcome Trust and the Medical Research Council.

The Council decided that the best way in which to celebrate our 20th anniversary was to reflect upon our future responsibilities. The most important of these was to consider and plan for future work on the most important ethical challenge that confronts the global community today, namely how to ensure that public health and medical interventions might be brought to bear on improving the wellbeing of the least well-off.

The Council has a history of examining issues of global and international concern. Our 2002 report, *The ethics of research related to healthcare in developing countries*, marked the Council's first report devoted fully to questions of medical ethics in the developing world. That report began by noting that the disparities in levels of health across the world correlated highly with the degree of social and economic development of societies. In this context, injustice can arise – indeed may principally arise – from inequalities of power and therefore in that context, setting standards for the conduct of clinical trials is crucial. In the follow-up document of 2005, based on a workshop held in South Africa, a number of key issues were identified, including ways of encouraging community participation, the development of indigenous expertise, sustainability, partnerships and intellectual property rights.

Similar themes emerged in the Council's two reports on genetically modified crops (one in 1999, the other in 2004) in which the potential was noted for such crops, properly used, to make a contribution towards greater food security for poor farmers as well as promoting improved nutrition, through developments such as that of golden rice. Both reports recognised that there were legitimate concerns about human health effects and environmental damage. However, they noted that these concerns needed to be dealt with on a case-by-case basis, and they could not be used as an excuse not to use the technology if it proved advantageous.

Our report, *Biofuels: ethical issues*, published shortly before the symposium, developed an ethical framework for the analysis of biofuels policy, stressing the essential rights of the poor, the principle of just reward and equitable distribution of costs and benefits – all considerations relevant to global justice and health.

During this symposium, discussion – as shown in this admirable report prepared by the Council's staff – highlighted the need to consider health in development issues as well as in the development of public health measures. The 'double burden' of infectious and non-communicable disease was also an issue. All the discussions in one way or another underlined the extent to which scientific understanding – whether from the natural, medical or social sciences – needed to be joined with robust and clear-headed ethical understanding.

On the day of the symposium we were fortunate in being joined by colleagues from around the world with experience of the issues that we discussed and the reader will find in this report their thoughts and contributions. At the end of the report, I suspect that the reader will share my view as to the urgency of

advancing policies so that in twenty years' time the need for another symposium on this topic will no longer exist.

A handwritten signature in black ink that reads "Albert Weale". The letters are cursive and slightly slanted to the right.

Professor Albert Weale

Chair of the Nuffield Council on Bioethics

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Preface

Global health has been an enduring concern for many national governments. Additionally, intergovernmental organisations provide leadership where joint action is required, and this is supported by a myriad of research funding bodies, pharmaceutical companies, campaigners, and local community groups. But despite this activity, gross global health inequalities exist, with the burden of disease affecting the poorest countries resting at unacceptable levels.

This symposium, arranged as part of the Nuffield Council on Bioethics' 20th anniversary celebrations, brought together academics and practitioners from around the world to consider the most urgent bioethical question of our time: how should the responsibility for tackling global health inequalities be met?

The day-long symposium was comprised of a series of sessions which focussed on a selection of the ethical and policy issues raised by the challenge of addressing global health: the programme can be found in Annex 1. In addition, three specific aspects of global health were discussed in detail, including: the social determinants of health; chronic and non-communicable diseases; and the role of 'emerging biotechnologies' in addressing global health. The symposium concluded with consideration of how the Council could engage further in the debate.

This report summarises the main issues and themes that arose from the speakers' presentations and subsequent discussions. Going forward, it will help to inform the Council as it considers how it could contribute to this most important of bioethical problems.

In addition, delegates and speakers of the symposium were asked to describe briefly what they thought ought to be the focus of a future Nuffield Council on Bioethics inquiry regarding global health inequalities. These suggestions can be found in Annex 2.

NB: The opinions expressed in this report do not necessarily represent the views of the Nuffield Council on Bioethics.

Part I: Ethics and responsibility in global health

Responsibility in global health

Professor Florencia Luna, Coordinator, Bioethics Program of Latin American University of Social Sciences (FLASCO), Argentina

Summary

- 1 In considering how to address global health inequalities, it was important to consider: why health should be addressed; how could responsibility for addressing global health be justified; and which actors should bear responsibilities. A 'consensus' among different ethical theories was useful in justifying the responsibility to address global health. Responsible agents included the individual and collectives, such as states or intergovernmental organisations. In a non-traditional view of human rights, it was possible to consider collectives such as non-governmental organisations (NGOs), transnational and multinational corporations also as responsible for addressing global health.

Why health matters

- 2 There were strong ethical arguments supporting the need to care about health. For example, health was a strong determinant of happiness; and whilst a happy life was neither guaranteed by good health nor ruled out by illness, there was a clear enough correlation for a utilitarian argument for pro-health policies. Health also helped to foster equality of opportunity, thus satisfying a requirement of liberal egalitarians. Access to health could additionally be thought of as a human right, and in many national constitutions it was recognised as such. If there was resistance to the notion of calling access to health a human right, then health could at the very least be thought of as a precondition for the enjoyment of human rights. The justification for considering health could also be supported from an economic perspective: no society was able to prosper without a healthy workforce.

Responsibility for global health

- 3 While it was important to acknowledge arguments for why health should be addressed, a second issue remained: was there any *responsibility* to address global health? There were a number of ethical theories which could be invoked to justify responsibility for addressing global health.

Egalitarian utilitarianism

- 4 In 1972, Peter Singer challenged the way that established ethics justified helping the poor: this was then based on the moral value of beneficence. Singer refused the notion that any help should be based on charity: charity was an imperfect duty, dependent on the individual's or collective's good will and feelings, and as such was unreliable. Singer considered whether there might be an obligation to help those who might suffer a preventable and premature death. For Singer, sentience was the key characteristic relevant to moral status, and he therefore provided the principle:

"If it is within our power to prevent something very bad from happening, without thereby sacrificing anything of comparable moral significance, we ought, morally to do it."

Thus under this principle, helping was not charity: rather, helping was something one had an *obligation* to do. Thus Singer moved from beneficence to argue for an obligation to help. He linked this to a bystander who saw a child drowning in a shallow pond and had an obligation to rescue the child.

Cosmopolitan egalitarianism

- 5 A stronger argument for helping the poor was later provided by Thomas Pogge using a cosmopolitan perspective. This argument was based on the need to compensate those who had been wronged: a need which engendered a compensatory health-related moral obligation. In this argument, the rich were not innocent bystanders as Singer's example had suggested; rather, the rich had benefitted from wrongs committed in the past, such as slavery and the current world economic order.
- 6 Pogge further argued that these moral obligations extended beyond borders. He reasoned that poor conditions for health were caused either directly or indirectly by the actions of powerful global actors. Pogge argued that there was a responsibility for these harms; therefore, there was a clear duty to correct unjustified distributive impacts and to assist people living under unfavourable conditions, even if these occurred beyond one's borders.
- 7 There was criticism of Pogge's argument. For example, some asserted that it was impossible to quantify the previous harm done by the world economic order or slavery; and yet this quantification was needed if responsibility were to be attributed. Pogge's argument also had limitations: for instance when health needs arose as a result of 'natural' forces, such as a tsunami, was there then any responsibility for addressing global health? Despite these problems, Pogge undoubtedly presented a forceful argument for a commitment to the global poor.

Humanitarian model and overlapping consensus

- 8 The humanitarian model, presented by Christopher Lowry and Udo Shucklenk, followed Singer's path. The humanitarian model was based on the premise that all human beings were fundamentally the same in terms of moral status. Therefore, it was desirable to reduce suffering and disease in the world, and Lowry and Shucklenk argued that affluent global citizens had a moral obligation to assist less fortunate ones in this way. They proposed to supplement Pogge's proposal with their 'humanitarian reasoning'.
- 9 In the same vein, Allen Buchanan and Matthew Decamp argued that responsibilities for ameliorating the most serious health problems of the world's worst-off people could be seen as the focus of an 'overlapping consensus', derived from disparate views of justice that ranged from strict egalitarianism to extreme prioritarianism.¹ Buchanan and Decamp pointed out that using an overlapping consensus allowed progress to be made in meeting responsibilities, without first having to determine which of the competing conceptions of justice was correct.
- 10 There were problems with the overlapping consensus theories. For example, in the debate about global health responsibility, there were some libertarian positions, following Robert Nozick's path, which held that the state should provide minimal services, thus avoiding healthcare provision and affording even less global health assistance. Such views could not enter the overlapping consensus suggested by Buchanan and Decamp. Nonetheless, it could be argued that on the whole there was agreement that there was a basic ethical argument to ameliorate the most serious health problems of the world's worst-off people.

Responsible agents

- 11 It was important to consider where responsibility should lie; for example: individuals or collectives; state or non-state actors; or others?

The individual

- 12 Philosophers such as Singer focussed on individual responsibility where the individual had a moral obligation to fulfil. In today's world, it was relatively easy to fulfil these obligations: for example, it was possible for two distant countries to be connected through the internet and air travel. If there was

¹ This is the view that the goodness of an outcome is determined by the total wellbeing of all individuals, with extra weighting being given to those worst-off.

greater exercise of values such as solidarity in the fulfilment of one's moral obligations, many more individuals would be committed; and there would then be more possibilities of help to those who needed it.

Collectives

- 13 Even with the help of individuals, general and harmonised policies performed by collectives were required for sustainable and global changes in health. Thus, could collectives have responsibility for global health? As a moral concept, responsibility was usually attributed to individuals; however, it was also true that in practice *groups* were held to account. Therefore it could be argued that in a subsidiary sense to the strict definition of responsibility, there was the notion of collective responsibility, which was very useful.
- 14 Philosophical positions, such as the one put forward by Pogge, could be applied to collectives. Pogge believed that not only individual citizens from rich countries but also, elites from resource-scarce countries and global institutions – collectives – were morally responsible for the extreme condition of the global poor. This proposal also appealed to human rights arguments. There were numerous human rights legal instruments which cited the right to the enjoyment of the highest attainable standard of physical and mental health; however, there was the question of who should be responsible for providing this right. Under traditional interpretations of human rights, each state was responsible for its citizens' access to healthcare – overlapping with Pogge's argument. However, in a non-traditional interpretation of human rights, Onora O'Neill argued for a plurality of agents of justice. In this, there were primary agents, generally the nation states, who could construct other agents or agencies with specific competencies: primary agents typically had some means of coercion. There were then secondary agents who contributed to justice mainly by meeting the demands of primary agents, for example by conforming to any legal requirements they establish. In this interpretation, it was possible to hold private collectives to account in satisfying this right to health.

Types of collective

- 15 The question then followed: what were these agents of justice for global health?

The state

- 16 Global health obligations were typically carried out by nation states as these were best suited to fulfil them. There were differences in what different states achieved, however: for example, weak states as primary agents of justice could fail. At least two interpretations could be made regarding this situation. The first and more benevolent interpretation was that such states were resource-poor, lacked the necessary organisation and international power to assist the health of their citizens. A less charitable interpretation acknowledged that many of these states spent money on corruption, wars or simply unwisely. Whilst it was possible to condemn those states which misspent money, it was important to distinguish as separate the fate of the citizens suffering due to their inefficient or corrupt governments.

Other states

- 17 What then was the responsibility of *other* states to address global health obligations? This responsibility should vary by the ability of those states to provide aid without suffering unreasonably high costs to their own quality of life and wellbeing. Hence, rich countries could provide international help, but in reality this did not occur. Investigating the responsibilities of all governments to the world's poor, Lawrence Gostin and colleagues found that high-income countries had not come close to fulfilling pledges made in 1970 to spend 0.7 percent of gross national product per annum for aid: four decades later, the average contribution stood at 0.3 percent only.
- 18 From a human rights perspective, it was possible to invoke the United Nations (UN) Charter. This was designed to foster international cooperation for the solution of economic, social, cultural or humanitarian international problems. Articles 55 and 56 explicitly established – among other duties –

international cooperation of all states for health as an obligation. Therefore, it was possible to hold responsible international or intergovernmental agencies/programmes such as the World Health Organization (WHO), which were created for the purpose of delivering the UN Charter.

NGOs, transnational and multinational corporations

- 19 It was therefore possible to hold responsible all states for the health of their people; rich states for international assistance; as well as intergovernmental organisations. Onora O'Neill had developed an approach to hold responsible international NGOs and, specifically, transnational or multinational companies or corporations. O'Neill reasoned that the typical mission of international NGOs was to contribute to specific transformations of states, governments and policies, often with regards to a single issue or objective. Therefore, although international NGOs could not themselves become primary agents of justice, they could contribute to justice in certain ways.
- 20 O'Neill also scrutinised the role of transnational and multinational corporations. On the challenge of why these might be concerned with justice, over and above justice required by conformity to law, she said:

"Many transnational companies are evidently capable of throwing their considerable weight in the direction either of greater justice, or of the status quo, or of greater injustice... Corporate power can be used to support or strengthen reasonably just states. Equally, they can accept the status quo, fall in with local elites and with patterns of injustice, and keep powers to keep things as they are – or indeed to make them more unjust."

Therefore, within this framework even transnational corporations could help in the improvement of health: for example, developing better health habits within their employees, supporting local hospitals, or local efforts for providing a better access to health etc.

Global health: putting it into practice

- 21 In terms of global health responsibility, there were many other questions still to consider. For example, how should the different agents of justice interact? Should there be a harmonised global approach? How could this be achieved without being too intrusive to countries?

A Chinese perspective

Professor Renzong Qiu, Chinese Academy of Social Sciences; Vice-President, Ethics Committee, Ministry of Health, China

Summary

- 1 It was important to determine when a health inequality became a health inequity. There was also the question of whether a nation state had a responsibility for ameliorating health disparities globally. Each nation state should have prime responsibility for health disparities in its own nation; but there were a number of arguments for justifying the responsibility of a state for *global* health too: for example, reciprocity; restorative justice; human rights; solidarity and intergenerational justice. Although these arguments had limitations, they were important because developing countries would likely require some assistance to address their own health inequalities.

When health inequality became an inequity

- 2 Global health disparities were evident in today's world; but some inequalities did not reflect health inequity. For example, in life expectancy, women typically lived longer than men if all other conditions were equal. As argued by Norman Daniels, such health inequalities were not unfair because they arose from biological factors and were inevitable.

- 3 When then did a health disparity become an *inequity*? Some commentators argued that a health disparity became an inequity when the disparity was “extremely great”. But this was unsatisfactory as it prompted the further question: how great did the disparity have to be to achieve this status? Further, it was unclear as to why the greatness of the inequality made it an inequity. An alternative line of argument was that a health inequality became an inequity when it was either avoidable or a consequence of poor policy or social institutions. This was the case where basic survival or healthcare needs – such as sanitation, nutrition, water security, disease control and tobacco control – were either unavailable or inaccessible.

Responsibility for global health inequalities

- 4 There was the question as to whether richer countries had a responsibility for the world’s least developed countries. Each country should take prime responsibility for its own health disparities; therefore, it was the responsibility for the rich citizens in less developed countries to ameliorate health inequalities at home. Many richer countries, such as China, already had a great number of priorities, and so in the context of limited resources, *global* health could not feature as a priority. Often global health debates contrasted the global South with the global North; but within the global South there were often significant inequalities in the same country.
- 5 With increasing globalisation however, the citizens of a country could become part of the global community. Therefore, it was possible to argue that in some instances, a country should assist the global community – for example during a pandemic – in order to help its citizens abroad. It was also likely that developing countries would require assistance from richer countries in addressing their own health inequalities; and there were various arguments that could be invoked for justifying a state’s responsibility for *global* health.

Justifying a state’s responsibility for global health

Reciprocity

- 6 It was possible to appeal to the principle of reciprocity, or mutuality, as justification for states taking responsibility for global health. Using this it could be argued that, given no state could act alone to protect itself from health threats, there was a reciprocal responsibility for all states to maintain global health. The reciprocity-based argument was easily challenged, however, if other countries did not adhere to it. Therefore, such justification was inadequate.

Restorative justice

- 7 As shown by Thomas Pogge, restorative justice could also be invoked. It could be argued that richer countries were responsible for the policies that had benefitted them but at the detriment of the poorer countries: for example; free trade, intellectual property protection and international financial arrangements. As a consequence, these wealthy states owed a duty to those who had been harmed by such measures. Similarly, if institutions and policies of a richer country, practised in developing countries, perpetuated harms (for example, paying bribes to officials in developing countries), a responsibility was raised for that richer country to address global health.
- 8 Lawrence Gostin had outlined the counter-arguments to this argument of restorative justice. He argued that whilst it was true that policies of richer countries had been self-beneficial, it was difficult to distinguish the impact of these factors on global health from that of other factors, such as climate change. There were further complications in that these international policies often entailed a mixture of harms *and* benefits for less developed countries. There was also the issue of whether developing countries themselves contributed to the global health inequalities due to incompetence, corruption, or excessive militarisation. There were questions too as to whether restorative justice was adequate justification.

Human rights

- 9 The human rights-based argument was applicable in that people had a right to health, as recognised in the Universal Declaration of Human Rights and the UN treaty, the International Covenant on Economic, Social and Cultural Rights. However, Gostin argued that this argument was insufficient because human rights discourse was a rhetorical device, with no explanatory power as to how to put it into practice. Gostin further noted that the internationally recognised 'right to health' principally focussed on the state's obligation to satisfy the right, rather than the individual's obligation. In addition, the human rights discourse could provide the opportunity for powerful countries to undermine a state's national sovereignty. There was a tension here as, given that all countries could be affected by the act of one nation, national sovereignty did to some extent have to align with international order.

Solidarity and intergenerational justice

- 10 It was said in Confucianism that "the sage sees the world as one family, one country as one person, this is not his illusion." From this perspective, the principles of solidarity and intergenerational justice were applicable when justifying responsibility for global health.

Part II: Policy and global health

UK policy for global health

Professor Anthony Kessel, Director of Public Health Strategy and Medical Director, Health Protection Agency, UK; Coordinator, International Programme for Ethics, Public Health and Human Rights, London School of Hygiene and Tropical Medicine, UK

Summary

- 1 The UK Health Protection Agency (HPA) is an independent non-departmental public body with responsibility for health protection in the UK. The HPA receives its international policy mandate from the World Health Organization International Health Regulations 2005 and the UK Government's publication, *Health is global*. The HPA's approach is principally 'bottom-up'; involving working in collaboration with developing countries, and it is engaged in activities ranging from capacity building to providing support. The HPA's engagement typically arose through opportunism and pragmatism but is also very much shaped by government priorities as well as public health need. In difficult economic times, it was possible to justify responsibility for global health still by invoking John Rawl's theory of justice, where to treat all people equally, attention should be given to those with fewer assets.

HPA's mandate

- 2 The HPA was established by the UK Health Protection Agency Act 2004 as an independent government agency with responsibility for health protection in the UK. With regards to international work, the HPA was required by the World Health Organization (WHO) International Health Regulations (IHR) 2005:² to assess events that may be public health emergencies of international concern and to notify the WHO; and to contribute to broad IHR 2005 implementation on behalf of the UK Government, for example strengthening public health surveillance. Although the IHR 2005 contained only *domestic* public health obligations, it effectively allowed governments to engage in humanitarian work in developing countries under the remit of improving domestic public health. This was a useful duality between prudential and humanitarian issues. The UK Government's 2008 publication *Health is global*³ also provided further guidance on the HPA's mandate for international work. This report asserted that the HPA should have a leading role in global health security, addressing challenges outside the UK's borders. The recently updated version of the publication identified other priorities, including trade for better health and international development.

HPA's global health activities

- 3 The UK Government currently had health priorities in certain locations including: Commonwealth countries; overseas territories and crown dependencies where British citizens lived; and the BRICS countries.⁴ But these activities represented only a part of the UK's work: the UK also did a great deal of work as directed by pragmatism and the opportunities to help.
- 4 The HPA's approach to global health work was principally 'bottom-up', which involved working in collaboration with developing countries. It focussed on capacity building and providing expert support.

² This was an international legal instrument that was binding in 194 countries, and was adopted into UK law in 2010.

³ UK Government (2008) *Health is global: a UK Government strategy 2008–13*, available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_088753.pdf.

⁴ BRICS refers to Brazil, Russia, India, China and South Africa.

The principles developed by Norman Daniels regarding healthcare priority setting were relevant to the HPA's work, i.e. transparency, evidence of what works and reversibility.

- 5 Some of the HPA's current global health activities ranged from working on flu surveillance in South America to working with the WHO on chemical risk assessment/capacity building. In recent years, the HPA had also engaged in international secondments, and hosted eight WHO collaborating centres, covering a range of activities, such as reference and research on hospital infections. Examples illustrating the HPA's involvement in global health were provided (Box 1).

Box 1: Examples of the range of HPA's global activities

Cambodia: infection prevention and control

In 2009, the HPA participated in a WHO mission to Cambodia for infection prevention and control (IPC). At that time, there was no framework for IPC in Cambodia. The HPA team was involved in the development of an IPC policy, which was eventually adopted by the Cambodian Ministry of Health.

Hungary: chemical waste spill

The HPA was involved in a WHO mission to Hungary in 2010, following the declaration of a state of emergency after a chemical waste spill. The field mission was charged with assessing health, environmental and long-term impacts. Recommendations were made to minimise effects.

WHO: policy on disasters

In 2011, the HPA engaged in work with the WHO on the *Global platform for disaster risk reduction*. The HPA was tasked with creating factsheets for responses to natural or man-made disasters.

Justifying global health in hard economic times

- 6 It was undeniable that the HPA's work still represented 'a drop in the ocean' in terms of need. There was a further concern that in times of economic austerity, global health and international development could fall down the political agenda. The Nuffield Council could examine the justification for committing to global health and international development in such austere economic times.
- 7 Justification for resisting the de-prioritisation of global health could be found in John Rawls' *A theory of justice*. In his book, Rawls made procedural justice the basis of his theory, i.e. he held that the 'social contract' would lead to the fairest distribution of risks. Rawls asserted that a 'council of people' existed which determined the social contract, and that in this council, members were shielded by a 'veil of ignorance': no member recognised their place in society, and therefore their fortune in the distribution of natural assets, abilities, intelligence and strength. Rawls argued that with the council of people thus situated, the different parties could agree to two principles. The second of these was called the 'difference principle'. This held that undeserved inequalities (resulting from where an individual was born) called for redress. To treat all people equally, attention should be given to those with fewer assets. This argument could be invoked to justify global health work, even as the economy worsened.

Policy approaches: strengthening health systems

Dr Amar Jesani, *Indian Journal of Medical Ethics*, Centre for Studies in Ethics and Rights, Mumbai, India

Summary

- 1 Within global health debates, there was increasing talk of strengthening national health systems, and this was often advocated through the use of technology. As the demonstration project for the human papillomavirus vaccine in India showed, there were significant limitations to this type of approach in the context of existing iniquitous health systems. Rather than strengthen existing iniquitous systems,

it was important to change these by introducing universal healthcare access, which would require political will.

Strengthening health systems and the role of technology

- 2 Some global health discussions mentioned “strengthening health systems”; but it was crucial to ask *which* systems. Global policies that helped to reproduce or strengthen existing iniquitous systems were of no use to developing countries. India had a history of technology-based health interventions which illustrated the limitations of these types of policies in the context of iniquitous systems.

Case study: India and the HPV vaccine

Healthcare and vaccines in India

- 3 In India, there was no universal access to healthcare and the high cost of healthcare was a major contributor to poverty. Healthcare regulations for private for-profit companies were grossly inadequate: existing hospitals were not registered and/or did not operate by adequate standards; and existing weak regulation had been barely implemented due to corruption, bureaucracy and a lack of will. As a consequence, there were regular reports of unethical medical practices and clinical trials. Little was done in response to this crisis in healthcare; there was a prevailing attitude of *laissez-faire*. Vaccines had a dominant role in public health in India; this could perhaps be explained by the influence of the pharmaceutical industry. Due to underfunding and increased privatisation, the public healthcare system was also weak and demoralised.

HPV vaccine demonstration

- 4 When the human papillomavirus (HPV) vaccine became available in India in 2008, the market price of the vaccine was 9000 Indian Rupees (INR), then equivalent to 180 USD. To vaccinate all girls between the ages of 10 and 14 years (approximately 62.5 million) and the additional 12.5 million new girls entering the relevant age group, would have been prohibitively expensive for the Indian Government, by some calculations totalling more than four times India’s total healthcare budget. On account of the cost, there had been great resistance to the uptake of the HPV vaccine. Critics argued that there should be greater emphasis on screening for cervical cancer and other methods of prevention.
- 5 Despite this criticism, an international NGO – with charity funding and bypassing the federal vaccine policy-making body – enlisted two provincial state governments to participate in a HPV vaccine demonstration project. However, there were reports that the parents of the girls involved were not consulted; these families were amongst some of the most deprived in India, with low levels of education. Furthermore, there was poor documentation and investigation of serious adverse events that occurred. Deaths were recorded, but as the documentation was so poor, it was difficult to link these conclusively to the vaccine.

Implications

- 6 The problems associated with the demonstration project temporarily stalled the introduction of the HPV vaccine in India. Whilst this may have been the right outcome, it was unfortunate that it had taken certain ethical violations to achieve this. In contrast, Thailand had been more effective than India. Following a technology assessment, Thailand decided that it would be more cost-effective to focus on a cervical screening programme than using the HPV vaccine.
- 7 Despite the case against it, India still wanted to use the HPV vaccine; and meanwhile it had been reported that there would be the possibility of cheap vaccine production in the future. However, there would still be a question of cost. The temporary provision of a cheap vaccine was insufficient: it was necessary to have a long-term guarantee for low prices in order to make vaccines public goods. In the case of Thailand, the screening programme was not only cost-effective, but also had more potential for future system building. From this it was possible to observe that developing countries

would benefit more from policies that were cost-effective and strengthened appropriate systems, rather than campaign/technology-based programmes.

Future directions

- 8 To achieve real change in global health, it was crucial to make global health policy for universal access to healthcare. History showed that this had only been delivered through public policy. Without universal healthcare, any other programme and new technological interventions would not be as effective as it could be. It was likely, however, that each country would have its own model of universal access; it might not be public but private like in the US.
- 9 To achieve universal access to healthcare, global health policies had to align with those forces in the developing world which were already demanding universal access. South-South collaborations could also be useful. It would be a challenge; but a real change would then be achieved for the impoverished and deprived people of the developing world.

Policy approaches: 'turning the world upside down' and co-development

Lord Nigel Crisp

Summary

- 1 Aspects of today's global context would impact significantly on future global health. Therefore, when considering future global health policy, it was important to consider these elements, which included: interdependence; the 'unfair health trade'; unbalanced – though shifting – global power; the right to health; and co-development. The notion of 'turning the world upside down' was very useful in addressing global health: this was where the developed world learned from healthcare innovation occurring in the developing world, for example in relation to product development, healthcare access and healthcare practices. This concept would be of growing importance to the UK and other developed countries where increasingly, due to socio-economic changes, existing healthcare systems were no longer fit for purpose. Co-development in global health also offered benefits for both developing and developed countries. There were questions to be asked too, about the role that scientific research should take in the context of global health.

Key features of global health

- 2 In thinking about future global health, it was important to take into account some critical aspects of today's global context. Firstly, there were a number of ways in which different national health systems were interdependent. The foremost of these was through the ability of disease to spread rapidly from country to country. Interdependence also arose through a common global market for medical professionals, a common knowledge and pharmaceutical base, and global challenges (e.g climate change) which required concerted global action.
- 3 Secondly, an 'unfair health trade' existed. This involved the 'import' of medical professionals from poorer countries by rich countries, and the export of ideas and ideologies from rich countries to poorer countries, regardless of whether these worked.
- 4 Thirdly, there was an imbalance in distribution of global power to consider, where developed countries were more powerful politically and economically. This was starting to change, however, as developing countries began to assert themselves and to develop economically. For example, a few years ago the Indonesian Government refused to release tissue from those who had died from one of the epidemic influenzas to the rest of the world. The Indonesian Government believed that vaccines would be developed using this tissue, to which Indonesia would have no access.

- 5 As a fourth element, the right to health, enshrined in 1966, was likely to feature in future debates about global health. Finally, the notion of co-development would become increasingly important. Previously, international development had adopted a 'top-down' approach; however, in the future it would be preferable to adopt co-development.
- 6 Thus, in devising an ethical framework for determining future global health policy, it was important to consider these elements. For example, what did the right to health entail? Was it the right to healthcare access? Did it extend, for example, to being able to choose your own gynaecologist?

Healthcare in the developed world: the need for change

- 7 Healthcare systems in the developed world had enjoyed a number of advances during the 20th century, including: greater professionalism; scientific discovery; commercial development; and increased funding. As a result, there had been new drugs and surgical procedures, and greater access to healthcare. Large-scale, state-organised socio-economic changes had also led to improvements in health, for example: the introduction of the minimum wage; increased employment; better education; the notion of welfare; and political will to redress inequalities. Increases in life expectancy reflected these successes.
- 8 In the 21st century, significant socio-economic changes impacted on the suitability of these healthcare systems. For example, people now suffered from diseases (e.g. chronic, age-related) that were better suited to community-based healthcare, rather than hospitals. As resources stretched and 'lifestyle' diseases became more common, patient behaviour was increasingly seen as part of the solution. Science and technology were also advancing, and health was becoming increasingly global in terms of its determinants. In view of this, it was clear that the UK National Health Service (NHS) model was no longer fit for purpose. The UK and other developed countries could learn, not only from pioneers within its own borders – such as other industries, young people, disability rights groups – but also from low and middle-income countries (LMIC). This was the notion of 'turning the world upside down'.

Turning the world upside down: lessons from LMIC

- 9 In LMIC, there were challenges to health that were far worse than those facing even the poorest parts of the UK. These related to poverty and socio-economic issues, such as gender inequality and a substantial shortage of health resources and workers,⁵ due to medical migration and a lack of training. Increasingly developing countries were also contending with non-communicable and communicable diseases, leading to a double burden of disease.

Innovation in product development and healthcare access

- 10 In response to these challenges, LMIC were innovating in product development and healthcare access. For example, telemedicine was developing in many countries, enabling access to healthcare in remote areas. Some of these initiatives developed in LMIC had even been trialled later by developed countries. For instance, a similar scheme to Mexico's Conditional Cash Transfer Program⁶ was trialled in New York City, US, in 2007. Research suggested that innovation in healthcare delivery was taking place around the world, and predominantly in India and countries in South America and Africa.

New healthcare practices

⁵ For example, although Sub-Saharan Africa accounted for 25 percent of the global disease burden, it accounted for only 3 percent of global healthcare resources and 1 percent of global health workers.

⁶ This was a programme for addressing poverty. It required beneficiaries to fulfil certain conditions in order to receive financial benefits; for example, all family members must obtain specified healthcare.

- 11 New healthcare practices were emerging in LMIC also and developed countries could learn from these. In LMIC, healthcare was increasingly making use of the community, the family unit and women as agents; also the health, education and work sectors were being linked together in recognition that health was not an isolated issue. For example, there was the non-governmental organisation, BRAC, in Bangladesh which helped mothers with sick children, as well as supporting their education and providing microfinance so that they were able to start their own businesses. There were more social enterprises, and also a greater linking of public health with clinical medicine. This more socially-placed, holistic and preventative approach to healthcare was especially relevant to the UK which was dealing with long-term conditions associated with an ageing population.
- 12 Training people for the job, rather than the profession, was also a new practice in LMIC. For example, in Mozambique nurses were trained to perform Caesarean sections. Research showed that these procedures were half the usual cost of the procedure carried out by surgeons, yet comparable results were achieved. Whilst it might not be appropriate to replicate such initiatives in the UK, the thinking behind them was applicable: i.e. finding different approaches to address new challenges.

New aim of independence

- 13 A new aim of healthcare was also being articulated in developing countries, that of independence. People in LMIC saw health in terms of helping people to be more independent, rather than just the provision of services. Indeed, this idea was also increasingly relevant to people in the UK.
- 14 These changes in thinking about healthcare development were apparent around the world; however, there was a need to accelerate these changes. This could be achieved through: making it visible and coherent; experience and exchange; and addressing the issue of health worker education and training.

Learning lessons from LMIC

- 15 There was a role for public engagement and the media in challenging healthcare norms in developed countries. People's perspectives of healthcare were already changing there; for example, with the advent of chronic diseases, there was the increasing notion of community-based rather than hospital-based healthcare. There was also a role for local government to assist in changing the norms and expectations of healthcare.

Other observations for global health

Benefits of co-development

- 16 There was a role for co-development in global health. 'Rich' and 'poor' countries no longer existed; rather, there was a continuum along which co-development could occur with benefits for both poorer and richer countries. Co-development benefitted poorer countries in that it could be country-led and owned, culturally sensitive and could draw on existing traditions. Co-development could also help avoid the faults of rich countries' systems being replicated in poorer countries.
- 17 For rich countries, co-development offered the opportunity for: refreshment and personal development of medical staff; developing greater cultural awareness for use in home-based practice; learning specific skills and practices; and challenging existing norms. There was also the benefit for both rich and poorer countries in being able to shape the future together, drawing on respective strengths and innovations.

What role for scientific research?

- 18 This new context for global health raised ethical questions regarding scientific research. For example, to what extent should research be focussed on 'early health' (promoting health and preventing disease) and 'late disease' (treatment for disease)? Given the interdependence of countries, should science be working towards that which was available to all countries, or just a few?

Session 1: Chronic and non-communicable diseases

Chaired by: Professor Jonathan Wolff; Professor of Philosophy, University College London and Member of the Nuffield Council on Bioethics

Political responses and ethical issues

Vanessa Baugh, Health Adviser, Social Transformation Programmes Division, Health Section, Commonwealth Secretariat

Summary

- 1 Non-communicable diseases (NCDs) were a priority policy area on account of: their high mortality rate; the increasing prevalence of NCD risk factors (e.g. tobacco use); the increasing occurrence in developing countries where many health systems were already overstretched; and the socio-economic cost of NCDs (e.g. ability to work). In light of their pressing status, the Commonwealth and the UN had responded to NCDs by, for example setting policy objectives and organising a UN High-level Meeting respectively. The ethical issues relating to NCDs concerned: the impact of the private sector (e.g. in terms of research funding and direct harms); the difficulties of strengthening already weak health systems in developing countries; and protecting children from the impact of NCDs.

Non-communicable diseases: a priority area

- 2 The major non-communicable diseases (NCDs) were cancers, cardiovascular diseases, chronic respiratory diseases, and diabetes. NCDs were a priority policy area in the Commonwealth and globally for several reasons. Firstly, there was the high mortality rate of NCDs: within the Commonwealth, 47 percent of deaths in 2008 were due to NCDs. In addition to this, the risk factors for NCDs were increasingly prevalent in all countries, including tobacco use, alcohol abuse, unhealthy diets and physical inactivity.
- 3 NCDs were also a priority area because the social distribution of NCDs was changing. NCDs were no longer the diseases of only the rich and elderly in developed countries: they were increasingly diseases of the poor. This was illustrated in the UK where there was a strong correlation between deprivation, and tobacco use and obesity. Further, in 2008, 80 percent of the 35 million NCDs deaths worldwide were in low and middle-income countries. Many of the health systems in these low and middle-income countries were struggling to respond to the impact of NCDs, as these systems were already over-stretched and lacking in funding. Furthermore, they were faced with communicable diseases – a double burden of disease – poor access to essential medicines, healthcare worker migration and weak surveillance systems.
- 4 Finally, NCDs had a socio-economic cost, including at the micro level – i.e. the cost at the level of the household due to out-of-pocket expenditure on treatment and care. For instance, 25 percent of Indian families where a member had suffered a cardiovascular disease experienced substantial expenditure, and a further 10 percent were driven into poverty. Illness also meant that family members – mainly women and some children – took the role of carer. This impacted on the family members' ability to work and therefore earn an income, and the children's opportunity to have an education. There was also the macro-level of socio-economic cost to consider: in 2009, the World Economic Forum stated that NCDs posed a threat to global well-being.

- 5 In light of these issues, there had had been calls for action from national and regional governments and NGOs, particularly those representing Caribbean communities, such as the Caribbean Community (CARICOM) Secretariat. There had been a large civil society movement: for example, the NCD Alliance, an umbrella organisation of more than 400 NGOs, addressed NCDs in countries across the world.

Political responses

- 6 In 2009, the Commonwealth Heads of Government Meeting resulted in a Communique, which, in its *Statement on Commonwealth Action to Combat Non-Communicable Disease*, called for a UN High-level Meeting on NCDs. In 2010 the Commonwealth Health Ministers Meeting resulted in the *Commonwealth Road Map on NCDs*, which was being implemented by the Commonwealth Secretariat. It contained action areas such as advocacy; helping to improve surveillance systems; working with the media to help improve the awareness and reporting of NCDs in countries; and sharing good practice – this included dialogue with other countries and a new online publication.
- 7 The UN High-level Meeting on non-communicable diseases in September 2011 was a significant move by the UN. Previously, there had only been two High-level meetings, and only one on a health-related issue. This was on HIV/AIDS in 2001 and it was widely recognised as being a policy turning point in addressing HIV/AIDS. There were similar hopes for the September meeting on NCDs.

Ethical issues

- 8 There were several ethical issues related to NCDs. The first regarded funding NCD research, since most of the funding came from the private sector, including the fast food industries. As such, there were questions as to whether and – if yes, *how* – there should be engagement with the private sector for funding NCD research. In addition, significant non-medical areas, such as the food industry, impacted on health, raising questions as to whether there should be regulation of these.
 - 9 In the context of NCDs, there were calls for strengthening those health systems faced with double burdens of disease, such as those in low and middle-income countries. However, there were prevailing issues of healthcare worker migration and difficulty in accessing essential medicines and anti-cancer vaccines, which needed to be addressed. The prevalence of ‘top-down’ NCD programmes and their effectiveness also raised concerns.
 - 10 The Commonwealth Secretariat had, in particular, focussed on reducing the impact of NCDs on young people. The Commonwealth Secretariat took the view that there should be intervention during the early years to prevent certain risk factors from being developed and entrenched later on. However, this raised ethical issues in areas such as: education; restriction of advertising; and developing an appropriate environment for physical activity and healthy lifestyle choices. There were also ethical issues relating to the protection of child carers (if a family member was ill with an NCD).
 - 11 There was also the concern that a drive to address NCDs could limit resources for communicable diseases. However, it was important to recognise that there should be no competition: in addressing NCDs, the focus should be on strengthening health systems which would benefit NCDs *and* communicable disease.
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Culture and ethics of care for mental illness

Professor Nouzha Guessous, Researcher and Consultant in Bioethics and Human Rights, Professor Emeritus of Hassan II, University of Casablanca, Morocco; Former Chair of the UNESCO International Bioethics Committee

Summary

- 1 Mental illness was a significant non-communicable disease (NCD) globally, where the surrounding culture and ethics of care impacted deeply on the illness itself. The example of Morocco, a largely Muslim culture, illustrated the prevalence of 'traditional' practices to treat mental illness, and also some of the associated ethical concerns. However, different cultures and practices could, and indeed *should*, be harnessed to treat mental illness, whilst also respecting universal principles of bioethics and human rights.

Mental health: the situation

- 2 According to the WHO, in 2010 there were more than 450 million people globally suffering from mental disorders. In low-income countries, there was a growing burden of mental and behavioural problems. Most research studies showed an association between the risk of mental disorders and poverty indicators, including income, occupation and education. According to the WHO, those in lower socio-economic groups were two-and-a-half times more at risk of mental illness than those in higher socio-economic groups.

Role of culture

- 3 Cultural context was a major factor in the course of psychiatric disorders, since family and community understanding of psychiatric disorders was crucial. There were different beliefs as to the causes of mental illness between cultures. For example, in the case of schizophrenia, the so-called 'traditional' societies (i.e. low-income, non-modern societies where the nuclear family was prevalent) often believed in supernatural or magic origins: meanwhile, western cultures proposed 'psychogenic families' theory. There were also different attitudes towards social care, with traditional societies being more tolerant of family members in need of support. In these societies, the whole family was usually expected to be involved in the care for a relative with a psychiatric disorder, be it through a traditional healer or a mental health professional.
- 4 When access to institutional public assistance in low-income countries was possible, the social support largely depended on family involvement and their sense of solidarity and interdependence. The capacity of the household to maintain the mentally ill individual, and the size of the family, were also important factors. For example, care was easier in extended, richer families. As such, in developing countries, up to 90 percent of households were able to maintain the mentally ill. However, this figure was changing due to societal changes: for example, families were becoming less extended. This might mean that familial solidarity could not be expressed in the same way as previously.

Traditional practices in Morocco and ethical issues

- 5 In Muslim culture, health and illness were seen as 'God's will' or Mektoub – i.e. destiny. Within this, suffering could be viewed as a reward or punishment; or illness could be perceived positively as an ordeal of purification leading to reward in the 'Hereafter'. Such thinking could help Muslims to cope better with suffering; however, it could also delay medical consultation and/or lead to a mechanical acceptance of what was proposed as a therapy. There was the belief that the individual had to wait for God's will.
- 6 Mental illness was a problem in Morocco. A survey conducted by the Moroccan Ministry of Health and the WHO between 2003 and 2006 found that 41 percent of the Moroccan population had faced a

mental disorder within the two previous years. Amongst them, 5.6 percent had been psychotic. The healthcare system in Morocco was struggling to cope with this burden. There were too few beds and doctors to care for the mentally ill. Today, for 35 million inhabitants, there were only 2,100 hospital psychiatric beds and five mental health centres for children and adolescents. Further, there were only 200 psychiatrists in the whole of Morocco.

- 7 This shortage of mental healthcare in Morocco partially explained the great number and range of alternative healing rituals and practices in Morocco. Dances and trances involving religious songs and prayers were very common. The example of Sidi Fredj Maristane, a hospital built in the 13th Century in Fès City, illustrated the use of music therapy for mentally ill and handicapped travellers and pilgrims under the supervision of a medical and nursing team. Closed in 1943, this Maristane was now under restoration, and an art therapy unit for psychotic patients was established in Casablanca's main hospital in 2011. Some of these practices and systems raised ethical concerns about regulation. For example, there was a shrine in the south of Morocco, built around the tomb of the Saint Bouya Omar, which involved forced residence of mentally ill individuals using chains. This practice raised issues concerning dignity, protection against harm, consent and access to adequate care. This required attention as many Muslim cultures, the Moroccan government and medical practitioners were trying to combine traditional non-harmful practices with conventional modern medicine.

Universal principles of bioethics and human rights: using traditional practices

- 8 Making use of traditional, non-harmful ritual healing practices could be beneficial. It could, for example, provide a culturally compatible holistic approach, and help the medical profession to forge closer connections with the family and the community who felt more confident in the system. Use of traditional practices could also avoid the stigma associated with mental illness: the medical labelling of a mental illness could often induce or enhance stigmatisation. Furthermore, there was evidence which suggested that there were better prognosis rates when treatment of a psychiatric disorder included ongoing social rituals. In fact, in absence of sufficient access to healthcare facilities, it was possible that some traditional non-harmful practices could be useful. The WHO had recognised the strength of integrating traditional healing into systems of care for psychiatric disorders.
 - 9 As with conventional medicine, the government and health professionals were accountable for traditional practices and their impact on the welfare of the patient. It was clear that there was still some work to be done in this respect. Article 7 of the UNESCO Universal Declaration on Bioethics and Human Rights 2005 held that there should be special requirements to take care of patients who lacked the capacity to decide; this could involve the family and social hierarchy 'taking over' an individual's consent, i.e. the notion of relational autonomy. If necessary, there should be laws to secure such protection. However, in 62 percent of low-income countries, either no legislation was in place to protect mentally ill people; such legislation was in place but had only been so for no longer than 10 years; or the existing legislation could even violate the rights of the mentally ill individual.
 - 10 Thus, using effective traditional non-harmful practices could be useful, but only if these respected universal principles of bioethics and human rights. In addition, there was a need for specific research and cooperation regarding how to use both conventional medicine and 'alternative' care practices, and identifying and combating harmful practices, for example, those with no supporting evidence for therapeutic benefit, and those which violated the patient's dignity.
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Cardiovascular disease

Professor Sir Magdi Yacoub FRS; Professor of Cardiothoracic Surgery, Imperial College London

Summary

- 1 Heart disease was a significant problem around the world, and major inequalities existed in its treatment. Devastating 'neglected' cardiovascular diseases also existed, which received little attention or funding. Charitable groups had responded to this situation by developing research partnerships with affected countries.

Heart disease and inequalities in treatment

- 2 According to the WHO, cardiovascular disease (CVD) was the major cause of mortality worldwide with 29 percent of deaths, ahead of infectious and parasitic diseases at 26 percent and cancer at 12 percent. CVD affected all sectors of the community, regardless of age, sex and social strata, and both developing and developed countries. CVDs were a major cause of reductions in quality-of-life and resulted in loss of earnings to individuals and nations.
- 3 There were large global inequalities in terms of life expectancy, resource allocation, health delivery and research in CVD. For example, the number of congenital heart surgeries in Africa stood at 1 per 38,000,000 people compared to 1 per 3,000,000 people for the US and Europe. The possible causes of this were explained by poverty, culture, climate, healthcare delivery and resources. To address NCDs, it was necessary to:
 - raise public awareness;
 - enhance economic, legal and environmental policies;
 - modify risk factors;
 - engage businesses and the community;
 - mitigate health impacts of poverty and urbanisation; and
 - re-orientate health systems.

Neglected cardiovascular diseases and responses

- 4 A 'neglected disease' referred to those tropical diseases which were endemic in the poorest populations of developing countries. Despite their prevalence and impact, they had typically received little attention on global health agendas compared to HIV/AIDS, TB and malaria. The neglected disease, Chagas, endemic in South Africa, affected many organs but its most devastating impact was on the heart. Another neglected CVD was endomyocardial fibrosis: this affected many countries in Sub-Saharan Africa and South America, as well as India. This was a devastating disease; yet it was under-researched.
- 5 In light of this situation, a group from Imperial College London, the Chain of Hope charity, had formed a partnership with medical practitioners in Inharrime, Mozambique. An epidemiological study was carried out as a result, providing for the first time the chance to study endomyocardial fibrosis with the aim of therapeutic intervention. Elsewhere, the Chain of Hope charity had established local projects in Ethiopia, in collaboration with the Children's Heart Fund of Ethiopia. It brought together stakeholders to build the first Ethiopian Heart Centre. A basic science research facility was also being planned.
- 6 Local charities were also responding. In Egypt there was a large project in Aswan, the Aswan Heart Center for Science and Practice. This centre had been established in recognition of the lack of CVD healthcare in the region, and it was built with the help of local charities and local government. The centre was now operational with cardiology, screening, research and surgery amongst its activities. It also disseminated knowledge for global medicine. It was hoped that a knowledge network would be created.

Session 2: Emerging biotechnologies in a global context

Chaired by: Professor Ray Hill, President, British Pharmacological Society and Member of the Nuffield Council on Bioethics

Making progress in biotechnology

Professor Andrew Tylecote, Professor of Economics and Management of Technological Change, University of Sheffield Management School; Member of the Nuffield Council on Bioethics Working Party on Emerging Biotechnologies

Summary

- 1 The example of artemisinin illustrated that compatibility with the business model of 'big pharma' had traditionally been necessary for a drug to progress (i.e. such that it was further developed and became widely used). To determine what might be necessary in the future, it was useful to consider emerging biotechnologies. By considering synthetic biology and the use of genomic medicine to identify individuals at risk of adverse drug reactions, it was apparent that biotechnological progress could follow a different trajectory in the future.

A historical understanding

- 2 Artemisinin was illustrative of what had been required to make progress in biotechnology. Artemisinin, an antimalarial agent of herbal origin, was reintroduced to Chinese medical practice in the 1970s, having been known about since around 340 AD. However it was initially neglected outside China, largely because (having been publicised first) it could not be protected by patent and was thus unattractive to 'big pharma'. Subsequently Chinese scientists worked with the big pharma firm Novartis to develop, test and manufacture a 'combination therapy' based on artemisinin which was protected by patent. This became the dominant antimalarial drug, thanks to vigorous promotion by Novartis.
- 3 From this, it was possible to conclude that if a biotechnology was compatible with the business model of 'big pharma', it would be further developed and used widely. Indeed, this was also suggested by the counter example of phages (viral infectors of bacteria) which were potential means of tackling MRSA, the so-called 'superbug'. Phages had not been suitable for big pharma, and therefore they had displayed little progress since their initial development.

Looking to the future

- 4 To determine what might be necessary in the future for biotechnological progress, it was useful to consider emerging biotechnologies.

Genomic screening for ADR risk

- 5 There was the possibility that genomics could be used to identify the relatively small number of individuals who were at risk of adverse drug reactions (ADRs) from 'blockbuster drugs'. Compared to current and other proposed applications of genomic medicine,⁷ this would be a less demanding use and one that was applicable to many rather than a few. Indeed, in 2008, the European Commission estimated that ADRs killed 19,700 European Union citizens annually.

⁷ Genomic medicine used understanding of the genome to identify pathways of disease in a specific genetic type, and sought to design an appropriate drug to block that pathway. It was highly demanding and usually applicable to small minorities of the population.

- 6 It was apparent, however, that there would be institutional obstacles to this type of development. First, the patent protection available would be relatively weak. Second, the ‘rescued’ drugs would have to be sold in combination with diagnostic tests, a big step away from big pharma’s traditional business model. Whilst it was true that spin-offs and dedicated biotechnology firms (DBFs) would more likely be the context for future biotechnology development,⁸ there would be difficulties here also since DBFs were threatened by capital shortages and sometimes a limited understanding of the financial market. DBFs could work with big pharma but such relationships were difficult. Thus, for pharma biotechnology to progress, it was clear that the obstacles facing big pharma’s involvement would have to be overcome, or a new business model envisaged involving DBFs.

Synthetic biology

- 7 Synthetic biology used principles derived from biology, chemistry and engineering for the construction of novel biological networks or organisms (or the re-construction of pre-existing organisms) with bespoke properties, using standardised biological parts that were well-characterised and had known functions. The British theoretical physicist and mathematician, Freeman Dyson, had suggested that synthetic biology would eventually be ‘domesticated’, i.e. it would become cheap enough for small-scale use. An historical example of biotechnology domestication was the ‘unofficial’ cross-breeding of Monsanto’s GM Bt cotton with an Indian landrace⁹ after the former’s introduction in 2002: the resulting crop was one suitable to conditions in India. What might be the implications of domestication of synthetic biology for making progress in biotechnology?
- 8 Currently the global South featured little in synthetic biology; but through domestication this was likely to change. The global South might adopt an ‘anarcho-capitalist’ use of the products of synthetic biology, and then of the techniques themselves. It would be interesting to see how effective intellectual property rights exclusion would be in the South and whether this anarcho-capitalist movement could lead to the development of biotechnologies through pathways that did not require big pharma. The open-source approach to synthetic biology, which sought to encourage and enable public access to the fundamental resources of synthetic biology, could also distinctly change the trajectory of biotechnology development.

Emerging biotechnologies: ethical issues

Contributions from: Dr Aceme Nyika, Ethics Coordinator, African Malaria Network Trust (AMANET) and Dr Manuel H Ruiz de Chavez, National Bioethics Commission, Mexico

Summary

- 1 Emerging biotechnologies (EBTs) offered significant potential benefits relating to health, environmental and socio-economic issues. However, there were also direct health and environmental risks, as well as concerns relating to distributive justice; intellectual property rights; and culture and religion.
- 2 It was important that potential benefits were brought forward and developed, and that risks were highlighted, investigated, and minimised. In addressing potential benefits and risks, it was critical to engage diverse stakeholders in ethical discourse at various levels of EBT development. Research

⁸ Biotechnology therapies appeared to be most easily discovered by academic researchers, presumably due to the close connections between basic academic research and translation research.

⁹ In this context, a local variety of a plant species that has been improved through traditional agricultural methods.

was crucial in order to have an accurate understanding of risks and benefits, and any governance arising should be reviewed regularly as more knowledge was gathered. It was imperative that international cooperation structures for ethics in EBTs be developed, given that developing countries may lack the legal ability to regulate in this area.

Emerging biotechnologies: an overview

- 3 There was a wide range of EBTs which included: bioinformatics; nanotechnology; biotechnology; information technology; cognitive technology; robotics; e-health; and genetics. Researchers and other stakeholders had categorised different EBTs into various branches: for instance, there was 'NBIC', which included nanotechnology, biotechnology, IT and cognitive technology. Since there was significant overlap in the application of EBTs, they had also been referred to as 'converging' biotechnologies.
- 4 EBTs could be categorised on the basis of the field in which they were applied:
 - 'red' biotechnologies – applied in the medical field (e.g. pharmacogenomics);
 - 'green' biotechnologies – applied in the agricultural field (e.g. genetically modified organisms, GMOs);
 - 'white' biotechnologies – applied in the industrial field (e.g. production of laundry detergents);
 - 'blue' biotechnologies – applied in the marine and aquatic field (e.g. biosensors to detect water contamination); and
 - 'animal' biotechnologies – this involved the use of biotechnology to introduce certain beneficial phenotypic features in animals or to produce certain products using animals or aquatic species.

Potential benefits

- 5 EBTs had many potential benefits, which were broadly related to the improvement of health, environmental, socio-economic, short-term and long-term issues. For example, there was 'personalised' medicine which aimed to develop tailor-made diagnostics and pharmaceuticals matching the needs of particular patients. Another example was ongoing efforts to use GMOs to contribute to improving food security. Of particular relevance to developing countries were the potential benefits of e-health, which could improve the accessibility of healthcare to people in remote areas.

Risks

- 6 However, there were potential risks associated with the development and use of EBTs. The potential risks or concerns related to the health of mankind, information or the environment. For instance, GMOs had raised concerns about possible direct or indirect harmful effects on the health of humans. Bioinformatics and e-health raised concerns about privacy/confidentiality of data. There were also fears that EBTs could have unintended negative impacts on the environment. For example, accidental release of GMOs into the environment or inadequate mechanisms of controlling some self-propagating products of EBTs could be detrimental to other forms of life and humanity. There were also issues relating to distributive justice, intellectual property rights (IPRs) and culture or religion.

Distributive justice issues

- 7 There were some concerns relating to the distribution of costs and benefits of EBTs. For EBTs, the benefits could be less accessible to developing countries compared to the developed world, due to barriers effectively being imposed by the capital costs, R&D, infrastructure and human resources required for the development of EBTs. At the same time, populations of the developing world were most likely to be involved as research participants for EBT development, and therefore were exposed to potential risks associated with EBTs. There was also a concern that focusing on EBTs may increasingly divert funding away from tackling diseases that affected developing countries.

- 8 It was likely that there would be interest from many countries in adopting EBTs. As such, it was important that the policy makers in those countries were involved as stakeholders in the development of the EBTs. In addition, healthcare providers (HCPs) would be involved in the use of EBTs on the 'frontline'; therefore, it was necessary that HCPs should be appropriately trained in order to enable maximum utilisation of the products of EBTs. In order to reap the benefits of EBTs, developing countries should improve their investment in R&D and identify their own research agenda that addressed their major challenges and needs. Public-private partnerships could help to improve accessibility of products of EBTs to the poor developing countries.

Intellectual property rights issues

- 9 The issue of Intellectual Property Rights (IPRs) posed a dilemma; on one hand IPRs could be viewed as an incentive for invention and innovation, while on the other hand they could be viewed as a barrier to universal accessibility of products emanating from research, thus making science a means for corporate profitability rather than a public good. There were critical questions to be considered. Would investment in R&D continue even without IPRs? Do IPRs in EBTs increase the risk of inventors/companies 'owning' or 'controlling' critical aspects of people's lives? For instance, there were ethical concerns over patenting life forms, as well as geopolitical tensions given that IPRs were held mainly by those in the developed North.
- 10 Open source had been proposed as one potential solution to some IPRs issues. It was an approach for design, development, production and distribution that sought to encourage and enable public access to the fundamental resources upon which a product was based or constructed. Open source was commonly applied to software engineering where the source code would be published freely; but the term was now applied to many fields including, for example, synthetic biology.

Cultural and religious issues

- 11 Issues that were cultural and religious in nature were also relevant to EBTs. For example, what would be the perception by people of different backgrounds of 'unnatural' man-made products, derived from EBTs? This could include organs for transplantation that were derived from animals but intended for people; and the use of synthetic prosthetics in human bodies. It could also encompass the use of GMOs for food.
- 12 Some scientists had proposed using EBTs to help overcome physical, physiological, psychological and intellectual limitations of human beings. The main aim of such efforts would be to create 'super-humans' who would potentially live for centuries or forever. It was such ideas and efforts that led to criticisms that some scientists want to 'play God'. Widely unacceptable applications of EBTs to humans had the potential to create social disharmony

Governance: dealing with potential benefits and risks

- 13 It was important that potential benefits of EBTs were brought forward and developed. Whilst risks ranged from being very likely to being very remote, it was necessary that all were highlighted, investigated, and minimised. In addressing potential benefits and risks, it was critical to engage diverse stakeholders in ethical discourse at various levels of EBT development. Research was crucial in order to have an accurate understanding of risks and benefits, and any governance arising should be reviewed regularly as more knowledge was gathered. Developing countries may lack the legal ability to regulate in the area of EBTs as this was a field still in its infancy. Thus, it was imperative to promote the development of an international cooperation structure for ethics in EBTs.

Existing ethical frameworks

- 14 The US Presidential Commission for the Study of Bioethical Issues had identified five ethical principles relevant to considering the social implications of EBTs. These included:
- public beneficence;

- responsible stewardship;
- intellectual freedom and responsibility;
- democratic deliberation; and
- justice and fairness.

15 Each principle related to different aspects. The principle of public beneficence stipulated that public benefits should be maximised while public harm was minimised. Responsible stewardship was to do with a shared obligation among members of the domestic and global communities to act in ways that demonstrated concern for both those who were not in a position to represent themselves, and for the environment in which future generations would either flourish or suffer. Democracies depended on intellectual freedom coupled with the responsibility of individuals and institutions to use their creative potential in morally accountable ways. The principle of democratic deliberation emphasised the need for collaborative decision making that embraced respectful debate of opposing views and active participation by citizens. The principle of justice and fairness related to the distribution of benefits and burdens across society.

Session 3: Social determinants of health

Chaired by: Professor Nikolas Rose, Martin White Professor of Sociology, London School of Economics and Political Science and member of the Nuffield Council on Bioethics

Moving beyond evidence: the need for political and popular support

Professor Francis Baum, Commissioner, WHO Commission on Social Determinants of Health; Australia Research Council Federation Fellow and Director, Southgate Institute of Health, Society and Equity, Flinders University, Australia

Summary

- 1 In 2008, the World Health Organization's Commission on the Social Determinants of Health (CSDH) called for universal healthcare and lifelong social protection; 'health in all policies'; and research and training to address global health inequalities. Since the CSDH's report, there had been additional epidemiological evidence, highlighting the impact of societal factors on health. However, to achieve global health equity, it was clear that evidence *and* political support were necessary. To this end, pressure from civil society organisations and academics was needed.

Commission on Social Determinants of Health: recommendations

- 2 The Commission on Social Determinants of Health (CSDH) was established by the World Health Organization (WHO) in 2005 to provide advice on how to reduce persisting and widening inequities. In August 2008, the CSDH published *Closing the gap in a generation*.¹⁰ In this report, three main target areas were identified to achieve health equity: i) daily living conditions; ii) power, money and resources; and iii) knowledge, monitoring and skills. The first was about creating environments which made it easier to make healthy choices if desired. Within this, the CSDH called for universal healthcare and social protection across the course of an individual's life. The second area concerned the underpinning factors that created health inequities, with recommendations including 'health in all policies', i.e. developing policies that support health, for example water and sanitation, education and market responsibility. The third target area related to research and training and the need to build a global health movement.
- 3 The CSDH report further asserted that comprehensive – rather than vertical – approaches were needed, that dealt with the underlying causes of ill health. The field of global health was currently dominated by a number of parallel vertical approaches by private foundations (e.g. targeting HIV/AIDS, malaria and tuberculosis), and such approaches could weaken global health systems. A whole-society approach was also necessary involving action by all levels of government, health services, NGOs, private sector and community groups. Effective local delivery required participatory decision making at the local level, and required empowering local communities and individuals.

Epidemiology of global health

- 4 Since the publication of the CSDH report, there had been additional epidemiological evidence adding weight to the argument that there were social determinants of health. Academics were crucial in researching and affording social commentary about global health and the state. Unfortunately, this

¹⁰ Commission on Social Determinants of Health (2008) *Closing the gap in a generation: health equity through action on the social determinants of health*, available at: http://www.who.int/social_determinants/thecommission/finalreport/en/index.html.

role was under threat as short-term academic contracts were now common, which engendered less ability and confidence for academics to speak out.

- 5 In *The spirit level*, Richard Wilkinson and Kate Pickett argued that more equal societies were actually healthier societies. This might be because greater equity led to more just social policies, and also because more equal societies had greater cohesion and less crime. Additionally, in 2008, Michael Chandler and Christopher Lalonde investigated cultural continuity factors to understand why some groups of Canadian indigenous people had higher suicide rates than others. These factors included, for example, whether these groups had control over their land and education system, and whether there was use of the traditional language. Chandler and Lalonde found that there was a strong negative correlation between the cultural continuity factors and the prevalence of suicide: the more control a community had, the lower the rate of suicide.

Role of civil society

- 6 Social power relations were very significant to health, and as such, evidence was not enough to instigate action; political and social support was also necessary. Indeed, state-led social reforms throughout history had typically been prompted by civil movements. Thus, to achieve global health, pressure from civil society was required, as well as concerted effort from governments, international agencies and other organisations.
- 7 An example of a civil society organisation was the People's Health Movement (PHM), a global network which developed in 2000. The PHM included a series of country-based groups advocating: for health as a human right; attention to social determinants; community-controlled health services; and against privatisation of services essential to health. The PHM also passed critical commentary on the WHO. The vision of the PHM was based on equity and recognising – and *using* – all voices. This vision was encoded in the People's Health Charter, which was endorsed in December 2000.

Pathways for addressing social determinants of health

Dr Thelma Narayan, Co-ordinator, Centre for Public Health and Equity, and joint convenor of the People's Health Movement India

Summary

- 1 The current economic order impacted on health, for example through loss of livelihoods and income; and food insecurity. Furthermore, the economic order worsened existing social determinants of health, such as gender-related issues. Although India was heralded by many as an example of economic growth, there was still significant poverty and consequently 'biological poverty'. Over the past decade, the community, civil society, government and academics had responded to this. Their responses highlighted what partnerships and pathways might be necessary to address health inequalities. It was likely that each nation would take its own path, using different actors to different extents.

Role of the current economic order

- 2 In order to address global health inequalities, it was crucial to target the social determinants of health. This approach was receiving increasing prominence on the global agenda. For example, the WHO Commission on Social Determinants of Health (CSDH) in 2008 concluded that there was an urgent need to address the root causes of health inequalities. In 2005, the United Nations Development Programme (UNDP) called for underlying determinants of health and development at the global, national and local levels, to be a priority area.

- 3 Corporate-led globalisation, neo-liberal economic reforms and negative macro-policies had each played their part in harming health by delivering adverse social impacts at the national and global level. These harms manifested through loss of livelihood and income; food insecurity; increased conflict, war and violence; water insecurity; reduced access to healthcare; and environmental degradation. Globalisation and macro-policies also worsened existing social determinants of health: for example, gender; race; ethnicity or caste; language; belief system; disability and mental illness.

Health in the emerging economy, India

- 4 India was often portrayed as an example of economic growth despite the recession. However, studies showed that there was such a thing as 'jobless growth': for example, in the 1990s, overall employment was almost two-thirds of that in 1980. There had been a worsening of working conditions of labourers in the informal sector and agriculture in the past decade. Furthermore, so-called 'open unemployment' (when unemployment was easy to recognise) was a serious problem in India.
- 5 The biological consequences of poverty were often termed 'biological poverty'. According to figures from the Indian Government, between 2005 and 2006 the proportion of women suffering from anaemia was 53 percent; men, 24 percent; and children (aged 6–59 months), 70 percent. It was considered a public health emergency when the prevalence of anaemia was above 10 percent; however, in comparison with health issues such HIV/AIDS, there had been little global action in response to this. Large inequalities existed also between states in India, and sometimes between communities within states. Indeed, this was worsening.

Addressing health in India

- 6 A people-centric and decentralised approach was crucial to meeting the health challenges of the new millennium. People needed to be brought back into the heart of primary healthcare, and the public back into the heart of public health and health systems. Further, the community voice and power had to be brought back into health policy discourse and decision making. It was important to note, however, that there should be some limit to decentralisation: decentralisation had dangers, and there was already a world order that made use of certain centralised systems. Thus, a combination of the two should exist.

Role of civil society

- 7 The People's Health Movement (PHM) was a global network of activists and organisations, which called for a revitalisation of the principles of the Alma-Ata Declaration 1978 that had promised health for all by the year 2000. The PHM also called for the revision of international and domestic policies that had been shown to impact negatively on health status and systems. The First People's Health Assembly was held in December 2000 in Savar, Bangladesh. Almost 1500 health activists from 75 different countries met to discuss the challenge of attaining the goal of the campaign 'Health for all, now!' The campaign on the right to healthcare was ongoing. For example, since 2000, there had been state and district-level action, as well participation in the World Social Forum – the annual meeting for NGOs and civil society organisations that were opposed to neo-liberalism and the dominance of capitalism in today's world. There had also been an increasingly analytical approach to disease; this was partly due to many of the health activists previously having been public health practitioners.

Role of the public and the state

- 8 Members of the public had also been increasingly engaged in health. For example, in 2003 the Asian Social Forum was held in Hyderabad where there were public workshops on: the right to healthcare; environment and health; tobacco and health; and the People's Health Movement. Subsequently, the World Social Forum was held in Mumbai in 2004, including workshops on health rights and health determinants organised by the PHM.
- 9 There had also been governmental campaigns on gender issues. For example, since 2000, there had been a campaign tackling violence against women as a public health challenge. A campaign against

sex-selective abortion or female foeticide had been launched in 2001, and there had also been campaigns focussing on gender and power issues in medical education. Such state-led interventions were useful and sometimes fundamental for change; however, there were sometimes limitations to what the state could achieve. The relationship between the public and state was, in some countries, undermined by corruption or the state's vested interests. In view of this, the state had to be held accountable.

Progress in India

- 10 There had been some progress in achieving social justice in healthcare in India. For example, the PHM had become involved with initiatives that encouraged democratic involvement, such as the National Rural Health Mission. In this, villagers were engaged in decision making related, for instance, to health and sanitation. There was also the People's Rural Health Watch – an organisation which scrutinised the activities of the Indian Government in the countryside – and the Asha initiative which empowered women in villages. More recently, India has established a National Mental Health Policy Group to respond to the needs of people with mental illness.

A Jamaican perspective

Dr Anthony Mullings, Senior Lecturer, Obstetrics and Gynaecology; Chairman, National Bioethics Committee of Jamaica

Summary

- 1 Jamaica was undergoing a major demographic transition, with a growing elderly population group and a shrinking young population group. Further, Jamaica faced significant challenges in addressing its social determinants of health: urbanisation; poverty; unemployment; crime and violence; and 'health literacy'. Although Jamaica had made progress with regards to meeting some of the Millennium Development Goals (MDGs), this was threatened. With regards to some of the other MDGs, Jamaica had to make significant progress; but these MDG targets were probably inappropriate given Jamaica's existing relatively 'high' standard. On account of the social determinants of health, significant international assistance was required to meet the MDGs; but, Jamaica was actually restricted in its access to some paths of aid due to its classification as a middle-income country. The experience of Jamaica raised ethical questions about what impact country classification should have on health aid, and what should be the relationship between global health and national health agendas.

Context: demography and social determinants of health

- 2 According to data from the WHO, in 2008 the estimated life expectancy at birth was 70.1 years for males and 75.3 years for females in Jamaica. In 2005 the total fertility rate (i.e. the average number of children born to a woman over the lifetime) was 2.5. Due to low fertility rates and increasing life expectancy, the Jamaican population distribution was moving towards the typical 'ageing population': that is, a growing elderly population group, with a shrinking young population group. Jamaica was expected to complete this demographic transition by 2020. As this transition occurred, the prevalent diseases in Jamaica also altered, tending towards non-communicable diseases (NCDs). Indeed, between 2000 and 2008 the prevalence of diabetes, hypertension and obesity – all diseases associated with ageing – increased in Jamaica. The social demands of healthcare also changed, with there being an increased need for elderly care. Within this context, Jamaica faced a challenge in addressing its social determinants of health: urbanisation; poverty; unemployment; and crime and violence. There was also the possible impact of low levels of 'health literacy': the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions.

Millennium Development Goals: Jamaica's progress

- 3 The Millennium Development Goals (MDGs) were established in 2000 and concerned eight international development targets to address extreme poverty and multiple deprivations by 2015. Some of these focussed on the social determinants of health whilst others focussed on health outcomes, for example child mortality. Jamaica had achieved some success in achieving the MDGs. For example, in terms of MDG 1A: Reduction in absolute poverty, Jamaica had already achieved this. This achievement was fragile though with many now employed in the informal sector, relatively low inflation and increases in remittances¹¹ by emigrants. Furthermore, all of these aspects were threatened by the global economic recession.
- 4 With regards to MDG 4: Reduction of child mortality and MDG 5A: Reduction of maternal mortality, Jamaica had much progress to make in meeting these targets. However, the targets required an improvement on an already low child mortality rate and a maternal mortality rate related to an increase in chronic diseases. As such it was comparatively more difficult to achieve the proportionate reductions as required by the MDGs, compared to a country with far higher mortality rates.
- 5 Because of the social determinants of health facing Jamaica, achievement of the MDGs was unlikely without significant international intervention. However, Jamaica's country classification effectively restricted its access to significant international funding such as the Global Fund – the aid initiative to fight HIV/AIDS, tuberculosis and malaria. The absence of aid for these purposes created additional strains for the Jamaican economy and health sector.

Ethical considerations relating to Jamaica

- 6 There were several ethical issues within the context of global health, which had been highlighted by the Jamaican experience. What role should the global health agenda take in relation to national health agendas? As highlighted with the MDGs for child and maternal mortality, there could sometimes be tensions between the global and national level. Should a generic health standard be imposed on all countries? Was there a moral imperative to provide resources to meet MDGs if they were not available in the country?
- 7 Further, what was the impact of country classifications – for example in terms of low, middle and high-income countries – on health inequities in nations? Should health statistics be involved in evaluating a country's classification (i.e. health and economic measure)?

¹¹ The action of the emigrant sending money back to their country of origin.

Part III: What contribution could the Nuffield Council on Bioethics make?

Sharing responsibilities and sharing benefits

Dr Aissatou Touré, UNESCO Bureau of the International Bioethics Committee; Head, Unit of Immunology, Pasteur Institute, Dakar, Senegal

Summary

- 1 In order to determine what contribution the Council could make, it was useful to consider the concerns that were regularly encountered by bioethics professionals and individuals, and how these issues were affected by the context of the developing world. From the example of biobanks and epidemics, the cross-cutting themes of sharing responsibilities and sharing benefits were apparent. The Council could investigate how these concepts could be put into practice: a complex, but timely contribution to global health.

Approaching the question

- 2 In answering the question of what contribution could the Nuffield Council make, it was wise to 'retrace one's steps': i.e. to consider concerns that were regularly encountered in practice as a bioethics professional and in one's daily life as a member of the human community. This would enable focus on issues that regularly arose and were timely. This could include those issues which were felt to have been insufficiently addressed by existing texts, or those raising difficulties when put into practice. It was then instructive to consider these issues in the context of developing countries.

Biobanks

- 3 There was much interest in the development of biobanks due to the progress – and *need* for progress – of science and technology. The plethora of ethical and legal issues associated with biobanks (for example, privacy, confidentiality, autonomy and ownership) had been addressed by many texts. However, biobanks in the context of a developing country created additional and unaddressed concerns. These were due to the countries being resource-limited and included: capacity and resources for controlling circulation and use of samples and data; access to knowledge and the benefits generated; and the exploitation of poor populations. These concerns also related to the risk of increasing global health inequalities.

Epidemics and pandemics

- 4 There were already several reports addressing the ethical and legal issues of epidemics and pandemics. Ethical issues included: research in the scenario of epidemics; management of the epidemics; distribution and availability of resources, drugs and vaccines; acceleration of the drugs validation and marketing pathway (with the tension between addressing urgent needs and maintaining safety); and the right to information versus the need not to overestimate (for example, with regards to the media). There were also legal issues concerning intellectual property rights (IPRs).
- 5 Once again, there were additional concerns for resource-limited developing countries, such as: delayed access to treatments and preventive measures; obligation to choose between priorities in allocating limited resources; and endorsing and taking responsibility for decisions taken elsewhere. These concerns also raised the risk of deepening global health inequalities.

Cross-cutting concepts

- 6 From the examples of biobanks, and epidemics and pandemics, cross-cutting concepts could be identified. Most of the issues raised related to the principles or concepts of: sharing responsibilities; sharing benefits; and fair international cooperation. These concepts were widely discussed as principles in most of the texts addressing bioethics and in particular in the UNESCO Declaration on Bioethics and Human Rights 2005. This could be an area of reflection for the Council: i.e. *How to share responsibilities and benefits in order to diminish global health inequalities?*

Sharing responsibility and sharing benefits

- 7 Neither the concept of shared responsibility nor that of shared benefits was easy to put into practice. For example, respecting the concept of shared responsibility could involve responsibility for what happened, or could happen, not only domestically but also elsewhere in terms of the activity of one's nationals, companies and groups. This would require navigation of complex international and national law, and dealing with the issue of respect of sovereignty. Where companies were owned by more than one nation, it would also be problematic to define the sole country responsible.
- 8 Addressing the concept of shared benefits also raised problems. For example, how could this principle actually be put into practice? Should there be international engagement for this? How to deal with economic interests and respect of IPRs? How to help and strengthen resource-constrained countries in negotiating benefit-sharing? Finally, how to preserve the interests of communities?
- 9 Tackling how to make both sharing responsibilities and sharing benefits a reality would represent an exciting challenge for the Council. An inquiry by the Council would be helpful to all vulnerable people (at the level of the individual as well as of the country) and the policy makers that needed to go beyond the adoption of general principles.

The role of bioethics committees

Ms Valerie Bonham, Executive Director, Presidential Commission for the Study of Bioethical Issues, US

Summary

- 1 In considering the question about the Council's contribution to addressing global health inequalities, it was helpful to reflect on the opportunities available to national bioethics commissions. Bioethics committees played an important role in contributing to and advancing public debate about bioethics. For example, the work of the US Presidential Commission for the Study of Bioethical Issues on synthetic biology and the Council's global health symposium were illustrations of both this and the benefits that public debate could afford. Bioethics committees were also useful in terms of developing 'products', such as policy recommendations, which were of use to policy makers and other stakeholders.

Public debate

- 2 To address the question about the Council's possible contribution to addressing global health inequalities, it was helpful to make a few observations about the opportunities facing national bioethics commissions. Chief amongst these was the establishment of an impartial public forum for real discourse. Dr Amy Gutmann, Chair of the US Presidential Commission for the Study of Bioethical Issues (the Presidential Commission) observed in 2010 that "by creating a public forum for careful deliberation, we maximise the possibility of improving the quality of both public debate and public policy."¹² These were twin, but distinct, ends that demanded attention if the creation of sound public

¹² Dr Gutmann speaking in the Plenary Session at the 8th Global Summit of the National Bioethics Advisory Bodies in Singapore, in 2010.

policy and solutions to seemingly intractable problems like global health inequalities were to be secured.

Presidential Commission's work on synthetic biology

- 3 The Presidential Commission's work in the emerging field of synthetic biology in 2010 had been illustrative of the importance of national bioethics committees establishing fora for public debate. Through several public meetings held across the US, the Presidential Commission created a forum for open dialogue to hear and assess competing – and sometimes conflicting – views on the science, ethics and public policy relating to synthetic biology.
- 4 In formulating its recommendations, the Presidential Commission emphasised the need for 'democratic deliberation' as a means to embrace respectful debate of opposing views and active participation by all citizens. Within this, the Presidential Commission called for individuals and their representatives to work towards agreement whenever possible, and to maintain mutual respect when it was not. Democratic deliberation was important for the perceived legitimacy of outcomes – even if those outcomes were unlikely to satisfy all interested parties. Further, it encouraged participants to adopt a societal perspective over individual interests.
- 5 While it was too soon to draw conclusions about the direct effect of the Presidential Commission's work on US policy, there was no doubt that its public process yielded important benefits. Much of the work of the early US bioethics bodies, including the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which produced the Belmont Report in the late 1970s, undertook a similar process and transformatively influenced public policy in the US – and perhaps around the world – regarding the protection of human subjects. Whilst it was possible and even desirable to think of ways to improve on that work, there was no doubt that the independent, neutral, and well-reasoned discourse underlying that work had contributed to its acceptance, effectiveness and perceived legitimacy.

Nuffield Council's global health symposium

- 6 There was similarly no doubt that the problems faced today, such as continuing health disparities around the globe, demanded the same level of impartial, open and public discourse. The Council's symposium was an excellent example of how bioethics committees could contribute to and advance both public debate and public policy. Firstly, the Council had raised the profile of the issue by embracing substantive debate on the topic. Secondly, the Council had pulled together speakers with different strengths, experiences and perspectives from many different countries. Thirdly, the Council was acting creatively to open public debate through its embrace of social media and plans to make today's meeting accessible through video and other outlets around the globe.

Products

- 7 The 'products' developed by national bioethics commissions also represented an important contribution. Specific advice based on well-reasoned analysis could lay the groundwork for wise policy developments. Many types of products were available, from recommendations for government policy makers; to best practice or model document guidance for practitioners; to educational tools for patients. Even when bioethics committee members disagreed on individual policy choices, products offering a range of options often yielded useful guideposts for future action.

Global health and responsibility: Presidential Commission's status

- 8 With regards to the issue of global health and responsibilities, the Presidential Commission had not yet embraced this due to issues of time and limited resources. However, the Presidential Commission's strategic framework, as well as its work on synthetic biology and protection for human participants in research, recognised and illustrated the importance of *global* dialogue. As Presidential Commission member Colonel Nelson Michael observed: "...We are embedded in a global community; and the issues that we have been debating...transcend borders." In its recommendations on synthetic

biology, the Presidential Commission emphasised that “international coordination is essential for safety and security”.

- 9 Dr Gutmann’s words in Singapore 2010 were salient also to addressing global health. She had asked: “What can we gain – or regain – from rejecting tidy ‘soundbites’ and embracing substantive debate about issues of global importance?” It was clear that public trust, scientific integrity, and the effectiveness of proposed solutions to tackle global health inequalities demanded that style of approach.

Healthcare-related research in developing countries: new ethical issues

Dr Jimmy Whitworth, Head of International Activities, The Wellcome Trust, UK

Summary

- 1 Healthcare-related research in developing countries raised some now well-known perennial ethical issues, regarding: exploitation of populations; seeking informed consent; treatment for comparison groups; what should happen once the research was over; and single-country ethical review. Indeed, the Wellcome Trust had developed measures in response to some of these concerns. Going forward, the Council could examine some of the *new* ethical issues associated with healthcare-related research, with respect to: conveying understanding of genetics and genomics; how to develop and fund ‘generic’ proposals for emergencies and pandemics; how to provide ethical oversight for studies in disasters and humanitarian emergencies; the role of national sovereignty; and data sharing.

Perennial ethical issues

- 2 Low and middle-income countries (LMICs) faced many perennial ethical issues in the context of healthcare-related research that had been the focus of much work. These issues centred on, for example: exploitation of populations; seeking informed consent; treatment for comparison groups; what should happen once the research was over; and single-country ethical review. The Wellcome Trust was interested in how it could both foster research regarding these ethical issues and develop mechanisms which addressed these issues. It had already generated some mechanisms to this end.

Exploitation of populations

- 3 It was almost inevitable that global health research typically worked with populations that were poorer, less powerful and therefore more vulnerable to the risk of exploitation. It was important to note that such populations existed not only in LMICs, but also as sub-populations of high-income countries. Indeed, there was mounting evidence that the proportion of poor people living in middle-income countries was increasing.
- 4 Other factors compounded the risk of exploitation. For example, in almost 25 percent of trials conducted in developing countries, there was no mechanism for local official ethical review. In anticipation of this, when The Wellcome Trust reviewed a clinical trial, it now looked to see: whether there was sufficient focus on those issues that were relevant to the host country; whether the treatment would be affordable by the local population; whether the treatment would be available after the study; whether the existing health systems could use and distribute the production; had there been avoidance of undue inducement; and whether there was appropriate compensation.

Informed consent

- 5 Regarding the seeking of informed consent, there were issues owing to the literacy of the population. Further, research could occur in populations where there were no such terms like ‘research’ or ‘trial’ in the vernacular: this made explanation of the trial – as required for informed consent – problematic.

There were also issues regarding individuals having to seek permission from the community or group to enter a study; and understanding the use of placebo.

- 6 In the experience of The Wellcome Trust, seeking individual consent – though challenging – was not as problematic as perhaps first thought; for example, there were many ways of explaining a study. For instance, research trials were needed because there was uncertainty regarding what was the best thing to do; in explanation the concept of a trial could be made analogous to the event of farmers trying different varieties of seeds in different conditions. The concept of randomisation could be explained through the example of lotteries and the role of chance involved there. In some cases, people knew of the difference between blank and live bullets; this could be a useful analogy for explaining the concept of the placebo. There was an informative video explaining clinical trials to participants in South Africa, available on the internet.¹³
- 7 There were also ways of explaining a study to children: this had been illustrated by a study that had asked 11-year old Norwegian children to design an experiment to find out if red sweets helped children think quicker. For example, the children had recognised the need for blinding through hiding the colour of the sweets from the participants; and the need for ‘double blinding’ through hiding the colour of sweets from the observers to reduce biases.

Treatment for comparison groups

- 8 The issues concerning treatment for comparison groups included what treatment should be used: should it be the best available in the world; the best available in the country or locality; or the best attainable in the country or locality? This might be nothing. The significance of this dilemma was highlighted by trials into prevention of HIV transmission from mother to baby, in countries where there was no treatment available.

What happens once the research is over?

- 9 The issue of what should happen once the research study was complete was highly controversial. Who should take responsibility for this: the investigators; sponsors; funders; or the domestic national government? Who should decide what was the best treatment, and for how long should it continue? Also, who should benefit: the control group as well as the test group?

Single-country ethical review

- 10 There were also concerns over single-country ethical review. However, The Wellcome Trust was comfortable with ethical review being conducted by the LMIC, if this was where all the work was being conducted with professionals there, and there was sufficient evidence of ethical oversight.
- 11 In terms of ethical review, it was also important to be aware that most developing countries were developing their own systems in order to ensure that their voices were heard. For example, many LMICs now required that, in order for research to be carried out there, it had to incorporate researchers from that country. Indeed, these domestic reviews were often taking place with no attention to the reviews in developed countries. Where there were no regulatory mechanisms to fulfil this role, decisions were often considered by the Ministers of Health, although this mechanism was open to abuse and therefore caused concern.

New ethical issues

- 12 These ethical issues were perennial and there had already been significant work to address these. New issues were emerging, however, which had received little scrutiny. These were areas that could be examined by the Council, and included:

¹³ <http://www.youtube.com/watch?v=uckmgymTWcE>.

- conveying understanding of genetics and genomics;
- how to develop and fund 'generic' proposals (i.e. those which would be available for 'off-the-peg' use) for emergencies and pandemics;
- how to provide ethical oversight for studies in disasters and humanitarian emergencies;
- role of national sovereignty; and
- data sharing.

Part IV: Concluding remarks

Themes at play

Professor Albert Weale, ESRC Professorial Fellow and Professor of Political Theory and Public Policy, University College London; Chair of the Nuffield Council on Bioethics

Summary

- 1 It had been clear from the symposium that there was widespread awareness of global health disparities; and that these were ethically troubling. Disagreement arose regarding the way and extent to which these were ethically troubling. Several major themes had emerged from the symposium, which would be instructive to the Council as it considered whether or how to go forward with work on global health inequalities. These themes included: the concept of 'health for all'; medical training and migration; interdependence; responsibility; and 'health for all' policies. Co-development and more nuanced application of intellectual property rights were themes that had received little scrutiny, which could also be fruitful for the Council to pursue.

Major themes

- 2 Over the course of the symposium, major themes had emerged. Interestingly, these themes were based on the assumptions that there was widespread awareness of global health disparities; and that these disparities were ethically troubling, though there was disagreement about the ways and extent to which these were troubling. These major themes would be instructive to the Council as it considered its future global health work. They included: 'health for all'; medical training and migration; interdependence; responsibility; and 'health for all' policies.

Health for all

- 3 A number of issues had been described which related to the concept of 'health for all'. For instance, in the example of cervical screening versus the administration of the human papillomavirus (HPV) vaccine in India, the link had been drawn between health policy assessment and health for all. Screening was cheaper and could provide all women and girls in India a preventive step to developing cervical cancer: in contrast, the HPV vaccine was so expensive that it could only be administered to a small proportion of women. The experience in Thailand, where there had been the decision to conduct cervical screening rather than administer the HPV vaccine, had been instructive and it also highlighted the false dichotomy between medicine and public health in achieving health for all. It had also emerged that in many healthcare systems, insurance coverage was low, leading to the prospect of significant out-of-pocket expenses for many which often deterred access to healthcare. This highlighted how designing a system of universal coverage was a challenge.
- 4 The ethical issue concerning the concept of health for all seemed to be one of opportunity costs: i.e. in a world of limited resources, resources devoted to A were then not available to B. Thus, what were the ethics of opportunity costs in low and middle-income countries? It appeared that this was to place more emphasis on cost-effectiveness of use of resources and setting of priorities, and more emphasis on sharing available benefits.

Medical training and migration

- 5 The migration of medical professionals was clearly a longstanding significant problem; and a new context was emerging, partly in response to measures implemented to address global health inequalities. For example, 'training people for the job not the profession', which related to the training of midwives to carry out Caesarean sections, could afford a means of dealing with medical migration: people's skills became specific to their locality, meaning the skills were less transportable. To what

extent was this true? Further, what effect did this have on those surgeons, in terms of migration, who had traditionally carried out such surgery?

- 6 In addition, there were calls for international research partnerships to help address global health inequalities: what was the consequence of these on medical migration? Would researchers in the host country become more internationally transportable? With this emerging context in mind, would it be possible to think of a code of practice on recruitment that could be agreed by different states? Problems arising from international recruitment were already evident.

Interdependence

- 7 It had been stressed that there was interdependence between humanitarian and prudential concerns. Whilst it was possible to see when there might be some high-level examples of interdependence, how true was this notion? The rhetoric of interdependence was highly useful to those working within global health as a driving force for action; but it was important to determine whether this was indeed the case. If not, should there be policy which fostered interdependence?

Responsibility

- 8 The idea of responsibility in global health was very interesting. There seemed to be consensus that there was responsibility beyond those who suffered the burden of disease. However, the problem arose in how to map the numerous responsibilities onto the equally numerous stakeholders. Here a Confucian perspective could be invoked, which focused on the virtue of agents rather than the needs of recipients. This could be a concept that crossed different cultures in a useful way.
- 9 It was clear that although non-state actors such as health activists could be useful, these – like state actors – should be subject to governance or guiding principles. How could such guidance be designed? Were there existing models of good practice that could be drawn on? Florence Nightingale's idea that the first principle of a hospital was to do no harm was very important; other principles might then include: do not worsen health inequalities; pay attention to local conditions; think about the consequences of your actions when brought together; and let local communities set their own priorities.

'Health for all' policies

- 10 By considering the social determinants of health, it was clear that non-health policies bore heavily on health: for example, policies in housing; employment; finance and transport. This related not only to public policies, but also to private policies; for example, whether a company provided a gym for workers. It seemed as if there would be a need for a health audit of all policies; however, this would be difficult to do, especially considered from a global point of view within the context of multi-level governance. However, it might be possible to select a number of illustrative case studies.

Missing themes

- 11 There had been little discussion of some themes, which might be fruitful for the Council to examine. There was the notion of co-development: this was in recognition that there was a continuum along which poorer and richer countries existed, and therefore along which co-development could take place with benefits for both. The lack of discussion in this area could reflect a common perception that in addressing global health inequalities, there was a need for *translation* of existing technologies rather than wholly new innovation.
- 12 Intellectual property issues had been discussed, for example relating to the tension between just reward for inventors and wider distributive justice. In encountering this area, the Council tended to say that it was important not to draw the patent limits too broadly. The Council could investigate how intellectual property rights could be employed in a 'smarter' way which helped deal, for example, with the access/just reward issue.

Annex 1: Symposium programme

Chair: Sarah Boseley, *The Guardian*

Williams Lounge

10.00 Registration and coffee

10.30 **Introduction**

Professor Albert Weale FBA

Chair, Nuffield Council on Bioethics

Henry Wellcome
Auditorium

10.45 **Keynote presentation**

Lord Nigel Crisp

Henry Wellcome
Auditorium

11.15 Coffee break

Williams Lounge

11.45 **Ethics and responsibility in global health**

Professor Florencia Luna

Coordinator, Bioethics Program of Latin American University of Social Sciences, Argentina

Henry Wellcome
Auditorium

Professor Renzong Qiu

Professor of Bioethics, Chinese Academy of Social Sciences & Vice-President, Ethics Committee, Ministry of Health China

12.30 **Policy and global health: how can things change?**

Professor Anthony Kessel

Director of Public Health Strategy, Health Protection Agency & Honorary Chair, London School of Hygiene and Tropical Medicine, UK

Henry Wellcome
Auditorium

Dr Amar Jesani

13.15 Lunch

Williams Lounge

14.15 **Parallel breakout sessions: Ethics, responsibility and policy in the context of three global health issues**

Session 1: Chronic and non-communicable diseases

Dale Room

Chair: Professor Jonathan Wolff

Professor of Philosophy at University College London and member of the Nuffield Council on Bioethics

Vanessa Baugh

Adviser, Health Section, Commonwealth Secretariat

Professor Nouzha Guessous

Researcher and Consultant in Bioethics and Human Rights, Professor Emeritus of Hassan II University of Casablanca (Morocco), Former Chair of the UNESCO International Bioethics Committee

Professor Sir Magdi Yacoub

Professor of Cardiothoracic Surgery, Imperial College London, UK; Founder and Director of Research, Magdi Yacoub Institute; and Founder and President, Chain of Hope

Session 2: Emerging biotechnologies in a global context

Burroughs Room

Chair: Professor Ray Hill

President, British Pharmacological Society and member of the Nuffield Council on Bioethics

Professor Andrew Tylecote

Professor of the Economics and Management of Technological Change, University of Sheffield, and Member of the Nuffield Council on Bioethics Working Party on Emerging Biotechnologies, UK

Dr Aceme Nyika

Ethics Coordinator, African Malaria Network Trust, Dar es Salaam, Tanzania

Dr Manuel H Ruiz de Chavez

Presidente del Consejo, Comision Nacional de Bioetica, Mexico

Session 3: Social determinants of health

Franks & Steel Room

Chair: Professor Nikolas Rose

Martin White Professor of Sociology, London School of Economics and Political Science and member of the Nuffield Council on Bioethics

Professor Frances Baum

Commissioner, WHO Commission on Social Determinants of Health; Australia Research Council Federation Fellow and Director, Southgate Institute of Health, Society and Equity, Flinders University, Australia

Dr Thelma Narayan

Co-ordinator, Centre for Public Health and Equity, and joint convenor of the People's Health Movement India

Dr Anthony Mullings

Senior Lecturer, Dept Obstetrics Gynaecology and Child Health, University of The West Indies and Chairman, National Bioethics Committee of Jamaica

15.45 Coffee break Williams Lounge

16.15 **Feedback from breakout sessions** Henry Wellcome Auditorium

16.45 **What contribution can the Nuffield Council on Bioethics make?**

Dr Aissatou Touré [video message]

Henry Wellcome Auditorium

Vice-Chairperson, UNESCO Bureau of the International Bioethics Committee; Head, Unit of Immunology, Pasteur Institute, Dakar, Senegal

Valerie Bonham

Executive Director, Presidential Commission for the Study of Bioethical Issues, US

Dr Jimmy Whitworth

Head of International Activities, The Wellcome Trust, UK

17.45 **Concluding remarks**

Professor Albert Weale FBA

Chair of the Nuffield Council on Bioethics

Henry Wellcome
Auditorium

18.00 **End of symposium**

18.30 **Evening reception**

Medicine Now Gallery

Annex 2: Delegates' suggestions

What should be the focus of the future Nuffield Council on Bioethics inquiry regarding global health inequalities?

Summary

- 1 Delegates and speakers of the symposium were asked to complete feedback cards, describing briefly what they thought ought to be the focus of a future Nuffield Council on Bioethics inquiry regarding global health inequalities. Twenty-four submitted a response. The suggestions have been grouped into themes, with areas of overlap highlighted. The views represented here do not necessarily represent those of the Nuffield Council on Bioethics.

Global health: responsibility and governance

- 2 Overall there was most interest in the Council pursuing a project related to global health responsibility and governance. This could include deliberation of the following:
 - Who should have responsibility for addressing global health? How should responsibility be determined? For example, should responsibility be based on the actor's capability to help or geographical closeness to the locale?
 - How should responsibility and power be balanced between different actors, both nationally and internationally? What kind of institutional arrangements might be necessary to achieve this sharing of, and adherence to responsibility?
 - How should work to address global health (i.e. in contrast to responsibility) be divided between different actors?
 - What is there a responsibility to address? For example, should there be prioritisation for curing disease and ill health, or preventing it?
 - Should actors in global health be held accountable or evaluated for their activities? Which actors should be included, for example, the UK or other developed countries, NGOs, private foundations, industry? How should this happen?
 - What justification is there for addressing global health, and what drives global health interventions in reality (for example, institutional and national interests, opportunism). What *should* drive the address of global health?
 - By whom, for whom and in what ways should R&D be targeted? Who influences research priorities currently? How could the determination of research priorities be more inclusive?

Re: specific actors

- What role should private foundations take in addressing global health?

- What should be the role of the private sector (e.g. trans-national food corporations) in addressing health; either in shaping lifestyle-based interventions (for example, industry-sponsored public initiatives or industry-led voluntary initiatives) or in mitigating their impact on public health?
- What role could – and should – the public take through the use of new social media in global health governance and ethical oversight?

Social determinants of health

- 3 There was some interest in the Council establishing an inquiry related to the social determinants of health. Questions that could be considered include:
- What is the impact of both privatisation of healthcare and major determinants of health (for example, water, sanitation, housing, education)?
 - What are the ethical issues raised by public health in the context of global health (this could be analogous to the Council's 2007 report *Public health: ethical issues*)? For example, are paternalistic interventions justified to combat poor public health, in order to address global health inequalities?
 - Is there some overlap between the social determinants of health and the role of the private sector, such as food, drink and tobacco industries, in global health responsibility and governance?

Political issues

- 4 There were suggestions for inquiries that required more political – rather than ethical – deliberation. For example:
- How could a universal access healthcare system be achieved? What could be the role of international bodies to achieve universal access healthcare systems in local settings? Could such a healthcare system be publicly provided?
 - How could existing health and R&D systems be strengthened so that local needs could be addressed?
 - How could South-South partnerships be established and/or supported?
 - What outcomes should be used to evaluate global public health?

Other topics

- 5 Finally, there were other suggestions made regarding topics that were deemed to contribute to – and indeed were often be caused by – global health inequalities. These included:
- medical immigration;
 - trade in bodily commodities (e.g. gametes, organs, bioinformation);
 - medical tourism (e.g. stem cell tourism and reproductive tourism); and
 - drugs trade, weapons trade and human trafficking.