• The 197th Council Meeting
• Market Structure in the South African Health Care System
Delegates from more than 30 national medical associations were welcomed by the Deputy Governor of Tokyo, Tatsumi Ando. He delivered a brief speech on behalf of the Governor who was not able to attend, saying that Japan was experiencing an unprecedented ageing society. From the year 2020 the population of Japan would start to decline and in 2025 one in every four residents in Tokyo would be older than 65. With this ageing population, the demand and the need for health care services would grow. As a result Japan had been developing a society where everyone could have peace of mind in terms of receiving health care services. Moving forward they would like to develop services where everyone would secure quality care at home.

Dr. Mukesh Haikerwal, Chair of Council, thanked Mr. Ando and then opened the formal Council proceedings. Dr. Otmar Kloiber, Secretary General, gave apologies and introduced two new members of Council, Dr. Walter Vorhauer from France and Dr. Kenji Matsubara from Japan.

Dr. Margaret Mungherera, President of the WMA, presented an interim report on her Presidency, giving details of the many meetings she had attended and thanking those NMAs that had hosted her visits. She spoke about progress on her Africa medical initiative to support the role of African national medical associations by strengthening the health systems in their country. She reminded delegates that only 21 out of the 54 African NMAs were members of the WMA.

Dr. Kloiber presented his detailed written report of the secretariat’s activities over the year (see box) and highlighted several issues.

He referred to the comments that Dr. Mungherera had made in Uganda at the time when the Ugandan Government was introducing legislation stigmatising homosexuals and proposing punishment. He said it had taken a lot of courage for her to speak out on television in Uganda against this legislation.

He said he had attended a recent conference of the International Association of Patients Organisations and had spoken on the issue of universal access to health care. The concept was still very cloudy and not ambitious enough. What the WMA was asking for was more than universal health care by looking at the social determinations of health and it was time to take this further step.
He also spoke about continuing medical education and continual professional development and the growing dissatisfaction with the current ways of dealing with these issues in rigid frameworks of recertification. The bureaucracy involved was not welcomed by physicians who wanted something more tangible that led to better outcomes in patient treatment if they had to undergo such a bureaucracy.

He then alerted the meeting to a problem that was approaching on the international non-proprietary names of medicine, what were called the generic names of medicine. This was a consequence of the new classes of medicines that were far more complicated than conventional medicines. The structure of how the names were given, their classification and how they were being reimbursed were all issues that were likely to become an important topic in the near future.

Dr. Haikerwal gave his interim report as Chair and spoke about the WMA’s work to increase the level of awareness of health as a core component of a successful and fair society. Health was a wise investment and brought with it human, political and economic dividends. Physicians were actually part of the solution in health and health care research and planning implementation. But too often international organisations chose not to work with physicians. The WMA’s aim was to emphasise the role of physicians as a solution.

Medical Ethics Committee

The Medical Ethics Committee met under the chairmanship of Dr. Heike Pälve (Finland).

Person Centered Medicine

Dr. André Bernard (Canada), Chair of the Workgroup on Person Centered Medicine, reported on progress in developing a new policy document. He said there was still a lack of consensus on this subject and the question was whether the definition of person centered medicine needed to be broadened. He suggested that further discussion and debate were needed before proceeding.

After a brief debate it was decided to recommend to Council to authorise the Workgroup to develop a discussion paper as an explanatory note with the aim of facilitating consensus among members.

Databases

Dr. Kloiber highlighted the importance of revising WMA policy on health databases and biobanks. The part of the revised Declaration of Helsinki that related to the secondary use of material information from clinical research led to the question of how to deal with data information and material in health databases or in biobanks. This had the potential to be one of the key WMA policies.

Dr. Jon Snaedal (Iceland), Chair of the Workgroup on Health Databases and Biobanks, reported on progress in drafting a Declaration on Ethical Considerations regarding Health Databases. A successful meeting had been held in Reykjavik and another meeting was planned for August. He also spoke about the possibility of a wider discussion.

During a brief debate it was recommended that the title of the document should be extended to include biobanks. It was also suggested that there was a need for urgency in developing policy because of legislation passed by the European Commission and Parliament which included a new concept of broad consent instead of individual consent. The WMA needed a speedy answer to this in a new policy document.

The committee recommended to Council that the proposed Declaration be circulated to NMAs for comment along with a list of key questions relating to the topic. It was also suggested that NMAs might want to consult outside groups.

Classification of Policies

The committee recommended rescinding and archiving WMA Statements on Human Organ Donation and Transplantation and on Human Tissue for Transplantation as these were now covered by new Statements.
Human Rights

Clarisse Delorme, the WMA’s Advocacy Advisor, reported on the work undertaken to support the Turkish Medical Association in its opposition to a new law criminalising medical professionals helping in emergencies and in the legal action taken against the Association regarding the health services provided by it during the Gezi Park protests.

The WMA had also been involved in advocacy activities in support of the WHO resolution ‘Strengthening of palliative care as a component of integrated treatment within the continuum of care’. This has been adopted by the WHO Executive Board in January this year with a broad consensus and Ms Delorme said she was confident that this resolution would be adopted by the World Health Assembly in May.

Financial Statement

Mr. Hällmayr provided a detailed explanation of the pre-audited Financial Statement for 2013 and the committee recommended that it be sent to Council for approval.

New Dues Structure

The Treasurer, Prof. Dr. Frank Montgomery, gave an oral report on the new dues structure and said the financial situation of the WMA was well balanced.

Strategic Plan

Dr. Kloiber reported on progress in implementing the strategic plan and its four major sections – ethics, advocacy and representation; partnership and collaboration; communication and outreach; and operational excellence.

Business Development

Prof. Vivienne Nathanson, Chair of the Business Development Group, summarised progress on the round table initiative. The first meeting had taken place last September and the second meeting was imminent. She said that future meetings should take place in North America or Europe, possibly parallel to the World Health Assembly.

Future WMA Meetings

The committee considered planning for future Assemblies and recommended that Assemblies should be held in Taipei, Taiwan in 2016, in Chicago, USA in 2017 and in Reykjavik, Iceland in 2018.

Declaration of Helsinki

It was decided that this year’s 50th anniversary of the Declaration of Helsinki should be celebrated with a special ceremony in Helsinki on November 11 2014. It was agreed that this should be recommended to the Council. A celebratory book had been published, marking the 50th anniversary, and it was agreed that this should be used by the WMA as a gift.

Membership

The committee considered an application for membership from the Ordre National des Medicins de Guinée and recommended to Council that it be forwarded to the Assembly for approval.

Associates report

Reports were received from the Associate Members, the Juniors Doctors Network (add) and the Past Presidents and Chairs of Council. The total number of Associate Members whose annual subscriptions have been paid was 818.
Reports were received from the editor of the World Medical Journal and from the Public Relations Consultant.

Presidential Elections

Following the decision at the General Assembly in Brazil to lift the suspension of the inauguration as President of Dr. Ketan Desai (India), a debate took place on the timing of his Presidency. The suspension was imposed in October 2010 when Dr. Desai was unable to attend for his inauguration following charges filed against him in India. Dr. Haikerwal said the Indian Medical Association had requested that Dr. Desai be reinstalled as President following the withdrawal of charges.

After a debate it was decided that the committee should recommend to Council that:
• nominations for President in 2015 be called for at the 2014 Assembly;
• there be no election at the 2015 Assembly for President in 2016;
• Dr. Desai be inaugurated as President in October 2016 as long as he remains in good standing pursuant to WMA byelaws.

Socio-Medical Affairs Committee

Sir Michael Marmot (British Medical Association) took the chair.

Health and the Environment

Dr. Shin (Korean Medical Association) reported on the environment caucus that had taken place that day, when the outcome of the 2013 Global Climate and Health Summit had been discussed as well as the report of the Intergovernmental Panel on Climate Change. Dr. Shin said they had discussed the importance of ministers of health in every country being involved in these issues, as well as the WHO’s role. It was agreed that the WMA should continue working on the impact of climate change on health.

Health Care in Danger

Prof. Nathanson, Chair of the Workgroup, reported on the activities of the group, including the development of a toolkit for health professionals addressing potential difficulties faced by health professionals working in situations of conflict. The toolkit aimed to provide a framework of practical responses to the ethical conflicts physicians might come across.

Chemical Weapons

It was reported that the Workgroup had not yet met, but Prof. Nathanson offered to draft a document on behalf of the group to present to the meeting in Durban.

Violence Against Women

The committee heard that a WMA side event on this issue would take place during the World Health Assembly in Geneva on May 20. Several delegates reported on work their NMAs were undertaking in this area, particularly relating to the linked issue of child abuse.

Recruitment of Physicians

The committee considered a proposed revision of the 2003 Statement on Ethical Guidelines for Recruitment of Physicians and a shorter amended version by the American Medical Association. Some delegates wanted to see the AMA draft recirculated among NMAs for comment. But Dr. Haikerwal said this was an issue of concern in every country he had visited and was a matter of some urgency. After a brief debate it was decided to postpone further discussion until the meeting of Council.

Non-Commercialisation of Human Reproductive Material

The committee considered a revised version of the Resolution on Non-Commercialisation of Human Reproductive Material written by the Israel Medical Association. The draft had received many comments. The chairman proposed that in the absence of
any delegates from Israel, the paper should be reconsidered by the Israel Medical Association in the light of the comments made for further debate at the meeting in Durban. This was agreed.

**Reality TV**

Dr. Haikerwal reported that the Israel Medical Association had agreed to withdraw a draft document it had submitted on the role of physicians in reality TV.

**Trafficking**

A proposed Resolution from the Spanish Medical Association on the Role of Physicians in Preventing the Trafficking with Minors and Illegal Adoptions was considered.

The meeting heard a report about the activities being undertaken at the University of Granada in Spain on this problem, helping countries to develop DNA databases about missing children and their relatives. This had led to more than 800 children being identified and returned to their families.

During the debate that followed, delegates agreed that this was an important matter, although it was tied up with the wider issue of trafficking. It was decided that the WMA was not in a position to involve itself in this sort of work. However it was agreed to recommend to Council that a Workgroup be set up to undertake further consideration of this matter and to submit a revised text for consideration at the next meeting in Durban.

**Aesthetic Treatment**

The Swedish Medical Association updated the committee on its proposed Statement on Aesthetic Treatments which had arisen from two documents, one on aesthetic treatment for minors drafted by the Israel Medical Association and a broader document from the Sweden. A combined document had been circulated to NMAs for comment. Delegates were reminded that the reasoning behind these documents was the absence of regulations governing aesthetic treatment, partly because of the question about whether it was really health care. There were circumstances in which aesthetic treatment was more cosmetic than medical. It was in an effort to protect people that the draft Statement had been produced. The document as written was addressed primarily to physicians although it was hoped it would encourage other practitioners performing aesthetic treatment to adopt these principles.

During the debate that followed there was discussion about whether the document should be directed to physicians only and whether the title should be changed to Statement on ‘Aesthetic Medical Treatments’. On a vote it was decided not to change the title. The discussion about whether the document should refer to ‘practitioners’ or to ‘physicians’ illustrated sharp differences of opinion. As a result it was decided to recommend to Council that the document, as retitled, be recirculated to NMAs for comment after being revised by the Swedish Medical Association.

**Physicians Wellbeing**

The committee considered the proposed Statement on Physician Wellbeing drawn up by the Junior Doctors Network. Delegates congratulated the JDN on its work, and several NMAs said this was an area on which they had also been working. The general view was that doctors were not good at looking after their own health, with some refusing to seek help because of privacy and confidentiality. It was suggested that more attention should be paid to the issue of the mental health of physicians and substance-abusing physicians. After several speakers referred to the need for the document to be expanded and strengthened, it was decided to set up a Workgroup to submit a more comprehensive policy for consideration at the next meeting. It was agreed to recommend to the Council that membership of the Workgroup should be representative of the various regions of the world.
Social Determinants

Plans were discussed for holding a conference on the role of physicians and NMAs in addressing the social determinants of health and health equity. The proposal was for a two-day conference to be held in London in March 2015, jointly organised by the British and Canadian Medical Associations and the Institute for Health Equity. The aims of the meeting would be to look at what NMAs could do in their own countries with their governments, to look at clinical-level practice and to create an international network of physicians and medical associations working on this issue.

The committee agreed to recommend to Council that arrangements should go ahead for the conference in London.

It was also reported that the subject of the social determinants of health was on the agenda for an African conference under WMA auspices also due to be held next March. It was hoped that the 54 countries of the African continent would come together at this conference.

Air Pollution

A proposed Statement on the Prevention of Air Pollution and Vehicle Emissions was introduced by the Austrian Medical Chamber. It was argued that the WMA should have a policy on what was a global problem. The Statement referred to the negative health effects of air pollution and called for a reduction in vehicle particulate matter emissions through the implementation of Euro emission standards, and recommended the installation of soot filters for all new vehicles and the retrofitting of existing ones. It also called on NMAs to raise awareness of these negative health effects, and to advocate via their national governments for the introduction of compulsory emission standards as a measure to promote clean air and a healthier environment. The draft Statement said that air pollution reduced life quality for hundreds of millions of people worldwide, causing a large burden of disease, as well as economic loss and costs in the health systems.

This prompted a debate in which the Japan Medical Association reported on the measures taken in their country against air pollution. Japan used to have a major pollution problem, but now had the world’s leading measures against air pollution. They had learned a lot in the process. They had experienced lots of long term litigation which had been settled and had introduced various standards from the US and Europe. As a result the country now had the most stringent standards for air pollution.

Speakers said that this was a crucial issue which needed further consideration and after further debate the committee recommended to Council that the proposed Statement be circulated among NMAs for comment.

Solitary Confinement

A proposed Statement on Solitary Confinement was presented by the Finnish Medical Association. The paper sets out guidelines about the physician’s role in solitary confinement, which, it says, should only be used as a last resort, and never as a prolonged punishment. A brief debate took place on the inhumane treatment experienced by prisoners who suffer solitary confinement, particular those suffering from mental illness. The problems of how to deal with particularly violent prisoners or prisoners who needed protection from themselves were also raised.

It was agreed to recommend to Council that the document be circulated to NMAs for comment.

Protection of Health Care Workers

The German Medical Association proposed that the WMA should draw up a stronger policy on the issue of protecting health care workers, particularly in the light of recent events in Syria, Turkey and Ukraine, where medical personnel and facilities had been deliberately targeted by the police and security forces. Physicians had been exposed to intimidation and prevented from carrying out their ethical duties. A proposed Declaration on the Protection of Health Care Workers in Situations of Violence was put forward, focusing on the obligations of
physicians rather than governments. It was agreed to recommend that the document be circulated for comment.

Street Children

The Conseil National de l'Ordre des Médecins introduced a proposed Statement on Protecting Health Support to Street Children. The committee was told that the document’s aim was to raise awareness of the scale of the problem. These children were the victims of urbanisation and economic deprivation. They were excluded from society, from education, health care and family care. The first link should be the doctor-child relationship.

During a brief debate it was suggested that the WMA should seek to find out why street children existed and to protest about their existence. It was argued that there should be a way of finding homes for all people and particular children. It was also suggested that the issue of protecting these children from unethical research should be considered. The committee agreed to recommend this.

Advocacy

The committee received an oral report from the new Chair of the Advocacy Advisory Group, Dr. André Bernard. He spoke about plans for the publication of the book commemorating the 50th anniversary of the Declaration of Helsinki and how various stakeholders might use it. He referred to the advocacy training session being planned for the scientific session at the General Assembly in Durban in October around the question ‘Can physicians be activists for change with respect to universal access to health care?’ and it was agreed to broaden this question to include social determinants of health. Dr. Bernard stressed the importance of advocacy and communications being integrated into the WMAs work.

Millennium Development Goals

Sir Michael Marmot referred to the enormous activity going on about MDGs post-2015. He said the problem for the WMA was finding the right forum to influence this important debate and how to broaden the goal of universal health coverage to include social determinants of health. He said the way forward should be for the WMA to make a strong statement at the Assembly in Durban.

Alliance for Clinical Research Excellence and Safety

The meeting heard a presentation by Dr. Greg Koski, President and Co-founder of the Alliance, with the request for greater collaboration between the WMA and ACRES. (see page…?

African Medical Initiative

The President, Dr. Mungherera, brought the meeting up to date with her initiative to involve African NMAs more in the activities of the WMA. She said globally there had been progress in making people healthier. But there had been hardly any progress in Africa. This was the continent with some of the lowest health indices in the world. While Africa had 11 per cent of the world’s population it had a much higher level of the disease burden. Forty-nine per cent of the women who died in the world from childbirth related problems were in Africa and 50 per cent under five-year-olds who died were in Africa. Sixty-seven per cent of HIV/AIDS cases were in Africa. She said her Presidential initiative was based on the fact that only about 20 of the 54 national medical associations in Africa were members of the WMA and only about five were actively participating in WMA discussions. Africa’s poor health indices were largely because of weak health systems and poor universal health coverage and access. She wanted to see not only more African NMAs join the WMA, but also increased participation by those NMAs that were members. It was also important that African NMAs influenced their governments’ health policies. To achieve this it was necessary to strengthen the capacity of African NMAs in medical education, continuing professional development and national health policies.
Under the chairmanship of Dr. Haikerwal, the Council met to approve reports from the three committees. The reports of the Medical Ethics Committee and the Finance and Planning Committees were agreed with little debate. Discussion took place on several items from the Socio-Medical Affairs Committee.

**Ethical Guidelines for the International Recruitment of Physicians**

Further debate took place on the document produced at the committee by the American Medical Association. This set out a series of recommendations which should govern the recruitment of physicians, including a proposal that countries wishing to recruit physicians from another country should only do so in accordance with the provisions of a Memorandum of Understanding entered into between the countries. An amendment was agreed under which countries recruiting physicians should ensure that recruiters provided full and accurate information to potential recruits on the requirements of the position to be filled, on immigration, administrative and contractual requirements, and on the legal and regulatory conditions for the practice of medicine in the recruiting country, including language skills. The Council agreed the Statement as revised and this will now be considered by the Assembly in October for adoption.

**Physician Wellbeing**

It was agreed that a Workgroup should be set up under the chairmanship of the American Medical Association.

**Alliance for Clinical Research Excellence and Safety**

Following the presentation by Dr. Koski, President of the Alliance, the Council agreed that the idea of the WMA becoming involved in the activities of ACRES should be explored by the Executive Committee.

**Immunization**

During what was World Immunization Week, Dr. Julia Seyer, WMA Medical Advisor, gave a presentation on the WMA Campaign for Physician Immunization to Prevent Influenza Outbreaks. She spoke about the facts of influenza and immunization and the role of physicians. Phase one of the campaign had started last year and phase two from 2014-2016 had just begun. The WHO had estimated that the prevalence of influenza was five to 10 per cent of adults and 20 to 30 per cent of children per year. Influenza was responsible for three to five million cases of severe illness and caused 250,000 to 500,000 deaths annually. US data showed influenza had been associated with about 230,000 hospitalisations.

The priority risk groups were the elderly, people with underlying health conditions, children between six and 24 months old, pregnant women and healthcare workers. Fifty per cent of those with chronic disease failed to get immunised, 30 per cent of the elderly and ten per cent of health professionals. Yet influenza was one of the leading causes of catastrophic disability such as strokes, chronic heart failure, pneumonia, ischemic heart disease, cancer and hip fractures. And once people became ill they were often unable to live at home or on their own. This was not only a personal burden, but a burden on society. The European rate of immunization varied a lot, between 1.7 per cent up to 64 per cent. If the immunisation rate could be increased to 75 per cent, 3.2 million cases could be avoided. The benefits of immunisation included fewer GP visits and hospital visits, as well as lives and costs saved.

The reasons people did not get vaccinated included the low perception of risk, including the risk of infecting others, the fear of possible side effects, questions about its effectiveness and the issue of cost, availability and convenience. Immunization advice from healthcare professions was the most important driver for patients’ vaccine acceptance. The aims of the WMA campaign were to increase physicians’ awareness of the importance of immunization, to encourage physicians themselves to get vaccinated and to enhance physicians’ communication skills to promote health and prevent disease.
Prime Minister

Mr. Shinzo Abe, Prime Minister of Japan, addressed the WMA Council Session. He expressed his appreciation for the participation of 40 medical associations from around the world. Mr. Shinzo Abe also thanked President Yokokura for his efforts as a representative of the host country and praised the Japan Medical Association for their hospitality.

Mr. Shinzo Abe stated that the theme for the WMA this year is 'universal access to healthcare.' Japan is now the country with the longest lifespans. He emphasized the importance of universal healthcare, stating that anyone in possession of a health insurance card can receive medical treatment at any medical institution. Universal health insurance and the freedom to choose where to receive medical treatment are precious assets that the public, including those involved in healthcare in Japan, have been safeguarding for over half a century.

Mr. Shinzo Abe also discussed the importance of home care and nursing care in the face of the declining birth rate and ageing population. He highlighted the crucial role of medical associations in fostering such doctors.

Lastly, Mr. Shinzo Abe concluded his remarks as Prime Minister, wishing for the further expansion of the activities of everyone gathered and for the further development of the WMA. He thanked the Japan Medical Association for their hospitality during the meeting.

Mr. Nigel Duncan, Public Relations Consultant, WMA

The address of the Prime Minister of Japan Mr. Shinzo Abe in the WMA Council Session

It gives me great pleasure to see the 2014 WMA Council Session being held today in Tokyo with the participation of 40 medical associations from around the world. I also would like to express my appreciation to President Yokokura for all his efforts as a representative of the host country, and to everyone else in the Japan Medical Association. All people share a common desire of building a society in which we can live long and healthy lives. Regardless of the era, the trust we place in medicine to support our health, and in the medical professionals who bear this responsibility, remains the same. Over the long, 67 year history since its founding, the WMA has worked to improve global health standards and establish medical ethics. I would like to once again express my respect for all your activities to date.

I have heard that the theme for the WMA this year is 'universal access to healthcare.' Japan is now the country with the longest lifespans. And it is precisely universal access to healthcare that is the principle behind Japan's health care policy. Anyone in possession of a health insurance card can receive medical treatment at any medical institution. Universal health insurance and the freedom to choose where you receive medical treatment are precious assets which the public, including those involved in healthcare in Japan, have been safeguarding for over half a century. We must fully hand these assets down to future generations.

In addition, in the midst of the rapid advancement of the declining birth rate and ageing population, an important issue is the creation of an environment that allows people to continue to live in the communities they are accustomed to for the rest of their lives, even if they need medical treatment or nursing care. To that end, we must enhance home care and nursing care. The doctors in charge of primary care in each region play a key role in bringing together medical treatment and nursing care. The role of medical associations in fostering such doctors is also important. Japan will present the world with a model for a society in which anyone can live to their old age with peace of mind.

Personally, I have long struggled with the incurable disease of ulcerative colitis. The worsening of my condition forced me to suddenly resign from my post as Prime Minister seven years ago. I am now serving as Prime Minister for a second time, which is quite unusual for Japan. That I am now able to carry out my job in good health is thanks to the blessing of advanced medical treatment, including new pharmaceuticals. I believe that no other Prime Minister recognizes the importance of medical treatment and pharmaceutical products as much as I do. Progress in medical technology does not just improve the quality of life for patients, it is also a driver of economic growth that generates wealth and employment. In addition to leading the world in the promotion of the practical application of advanced medical treatment such as regenerative medicine, I would like to share the results of such efforts with the people around the world struggling with difficult diseases. Furthermore, it is also important that we use the experience and knowledge that we have cultivated in Japan over the years and make an international contribution in the medical field. I would like to not only supply medical technology, pharmaceutical products, and medical devices, but also to export packages built around the establishment of whole systems, including the universal healthcare system that Japan is so proud of. In the past six months, we have already constructed cooperative relationships with the healthcare sectors of 14 countries. We will continue to promote efforts to make such an international contribution.

Lastly, I would like to conclude my remarks as Prime Minister by wishing for the further expansion of the activities of everyone gathered here today and for the further development of the WMA. Thank you for listening.
Secretary General Report to the 197th WMA Council Session

(October 2013 – March 2014)

1. Ethics

1.1 Declaration of Helsinki

The Declaration of Helsinki is one of the most important international ethical regulations of biomedical research, and also one of the core documents of the WMA. It has been revised several times since its adoption in Helsinki in 1964. As a “living document”, it is continuously adapted to new developments and challenges in biomedical research. The 7th revision was adopted by the WMA General Assembly in Fortaleza in October 2013.

In a special agreement with the Journal of the American Medical Association (JAMA), the revised Declaration of Helsinki was published online on the same day it was adopted by the WMA General Assembly, and then later in print.

The revised Declaration attracted considerable attention around the world and was apparently positively received. WMA Officers and the Secretariat have been invited to comment on the new version and the process of revision on several occasions. We are currently preparing a celebratory event, hopefully with the President of Finland, to commemorate the 50th anniversary of the Declaration.

1.2 Databases and Biobanks

In March 2014, the Icelandic Medical Association organized a seminar in Reykjavik, Iceland together with the WMA workgroup on the proposed revision of the WMA Declaration on Ethical Consideration Regarding Health Databases on the ethical problems connected with health databases and biobanks. The meeting focused on the potentials of such repositories, but also on the regulation of their use with special emphasis on the informed consent necessary for research. The results of the discussion have been incorporated by the workgroup in a revised draft, which will now be brought to the attention of the Council.

2. Human rights

2.1 Right to health

The WMA secretariat continues to monitor the activities of the UN Special Rapporteur on the Right to Health, as well as health-related matters addressed by the UN Human Rights Council. In October 2013, the Special Rapporteur, Anand Grover, presented to the UN General Assembly a report dedicated to the right to health obligations of States and non-State actors towards persons affected by and/or involved in conflict situations. The report describes a wide range of abuses occurring against health workers and highlights the need for better monitoring and accountability. The special rapporteur’s report is the first UN human rights analysis to describe the responsibilities of countries to provide and protect health workers and services in conflict. The WMA Secretariat sent a letter to Mr. Grover welcoming the report.

In early December, the Special Rapporteur and the WMA issued a joint press release warning against criminalizing independent medical care in the context of the draft health bill in Turkey.

[See also item 2.2.1 on the situation in Turkey and 2.2.2 on Healthcare in Danger]

2.2 Protecting patients and doctors

2.2.1 Actions of support (see table 1)

2.2.2 Protection of health professionals in areas of armed conflict and other situations of violence

The WHO’s role in humanitarian emergencies

In January 2014, on the occasion of the WHO Executive Board meeting, the WMA took the lead in drafting a public statement on the implementation of the resolution “WHO’s response, and role as the health cluster lead, in meeting the growing demands of health in humanitarian emergencies”. The statement recommends, within the framework of the resolution’s implementation, that Member States adopt as a matter of priority solid measures to ensure that health care personnel, facilities and transports exclusively assigned to caring for the sick and injured are fully respected and protected in all circumstances, in accordance with ethics
Table 1

<table>
<thead>
<tr>
<th>Country</th>
<th>Case</th>
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<tbody>
<tr>
<td>TURKEY 01/2014-03/2014</td>
<td>Last January, the WMA, together with Physicians for Human Rights, the British Medical Association (BMA), the German Medical Association (GMA) and the Standing Committee of European Doctors (CPME), sent a joint letter to the Turkish President, Mr. Abdullah Gül, expressing their grave concerns about the health bill passed by the Turkish parliament on 2nd January that criminalizes emergency medical care. The signatories called upon the President to refuse to sign the bill into law.</td>
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<tr>
<td>Sources:</td>
<td>TMA Amnesty International Human Rights Foundation of Turkey</td>
</tr>
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<td></td>
<td>[See also under 2.1 above the joint press release with the UN Special Rapporteur on Health]</td>
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<td></td>
<td>In March, the same organizations wrote a letter to Prime Minister Erdogan regarding the punitive actions taken by the Ministry of Health against physicians who acted ethically in providing emergency medical care to demonstrators injured during the Gezi Park protests that began in May 2013. The authors of the letter asked Mr. Erdogan to take immediate action to drop the current legal actions against members of the Turkish Medical Association. The letter was published in the British Medical Journal and a press release was issued.</td>
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<tr>
<td>IRAQ</td>
<td>Our attention was drawn to the situation of Iranian exiles in Camp Liberty in Iraq. According to various sources, serious restrictions are imposed on the residents’ access to medical services. Allegations of psychological and physical torture of the residents were made as well.</td>
</tr>
<tr>
<td>Sources:</td>
<td>Individual call for support Amnesty International UN Working Group on Arbitrary Detention C. Delorme met with two representatives of Camp Liberty in February 2014. The Secretariat is currently checking information with its partners before considering how best to take up the matter with the Iraqi authorities.</td>
</tr>
<tr>
<td>RUSSIA 11/2013</td>
<td>Last November, our attention was drawn to the case of Dr. Marat Gunashev from Russia’s North Caucasus region of Dagestan. He was arrested and charged with complicity to murder the police chief of the Dagestan capital in 2010. He has been in prison ever since and – according to sources – without evidence of the charges against him, has been exposed to ill-treatment and subject to a lack of respect for the standards of fair trial. The Secretariat contacted the Russian Medical Association, alerting them to the case and asking whether any action had already been taken by the medical association in support of Dr. Gunashev. The Secretariat also suggested writing a letter to the Russian authorities enquiring about the conditions of detention of Dr. Gunashev and asking for international fair trial standards to be fully respected. There has been no response so far.</td>
</tr>
<tr>
<td>Source:</td>
<td>Individual call for support Amnesty International</td>
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<tr>
<td>BAHRAIN 11/2013</td>
<td>On 15th November, the WMA sent a letter to the King of Bahrain expressing serious concerns about the two remaining health professionals, Dr. ‘Ali Issa Mansoor al-‘Ekri and Ebrahim ‘Abdullah Ebrahim al-Dumestani, still in detention (out of the 20 professionals placed in detention during the March-April 2011 events). In the letter, the WMA requested their immediate and unconditional release as it is believed that they have been imprisoned solely for peacefully exercising their rights to freedom of expression and assembly and are, as such, prisoners of conscience. It also recommended that the Bahraini authorities investigate the prisoners’ allegations of torture.</td>
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<tr>
<td>Source:</td>
<td>Amnesty International</td>
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<tr>
<td>EGYPT 09/2013</td>
<td>A letter was sent to the Egyptian authorities regarding the case of Canadian physician Tarek Loubani and filmmaker John Greyson who were arrested during violence in Cairo on 16th August. The letter expressed the WMA’s concerns that the Canadian detainees have been accused of a broad array of offences without apparent consideration of their individual criminal responsibility. The letter therefore urged the Egyptian authorities to release them immediately, unless they had sufficient admissible evidence to try them before a civilian court in line with international fair trial standards. They were released early October.</td>
</tr>
<tr>
<td>Sources:</td>
<td>CMA Amnesty International</td>
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</tbody>
</table>
principles and the rules of humanitarian law.

The statement was made on behalf of the WMA, the International Council of Nurses, the International Pharmaceutical Federation, the World Confederation for Physical Therapy and the World Dental Federation, as well as the International Hospital Federation, the International Confederation of Midwives, the International Federation of Medical Students Associations and the International Pharmaceutical Students’ Federation.

[See also items 2.1 and 2.2 on the situation in Turkey]

**ICRC “Health Care in Danger” (HCiD) project**

The WMA Secretariat has developed a close working relationship with the International Committee of the Red Cross (ICRC) headquarters over recent months in the context of the HCiD project.

As part of the Health Care in Danger project, the ICRC organizes expert consultations with policymakers, academics, doctors, weapon bearers and civil society in order to develop practical recommendations to improve safe access to health care. Two expert consultations took place during the reporting period with the involvement of WMA. On 3rd December, the ICRC, together with the Conflict and Catastrophes Forum of the Royal Society for the Protection of Health Workers, facilitated a workshop with the Indian Medical Association and the International Federation of Medical Students Associations. In view of the upcoming thematic revision of the United Nations Standard Minimum Rules for the Treatment of Prisoners (SMR) on 10th July 2013, he also met with the South African Medical Association and connected with the ICRC delegation in South Africa. WMA President Dr. Mungherera will speak at the workshop.

Dr. Eshaya-Chauvin attended the French-speaking Conference of Medical Orders (Conférence Francophone des Ordres Médicaux) in Douala, Cameroon last November.

In December, the ICRC delegation in Kathmandu, in collaboration with the Nepal Medical Association (NMA) and the Nepal Red Cross Society (NRCS), organized a half-day Health Care in Danger (HCiD) workshop in Kathmandu. The objective of the workshop was to sensitize medical personnel to the issue, share efforts made by the ICRC to deal with the HCiD issue at the global level, and to reflect at the situation of Nepal and receive participants’ feedback.

**Other related activities**

Last November, 19 experts from the fields of humanitarian practice, human rights, human security, academic research, government, and philanthropy, along with UN representatives and leaders from health professional associations, including the WMA, represented by Dr. Mungherera, issued a Call to Action to address the problem of attacks on health care. Read the Call to Action from the Bellagio Conference on the Protection of Health Workers, Patients and Facilities in Times of Violence (Nov. 2013).

**2.3 Doctors working in places where people are deprived of liberty**

The Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Mr. Juan E. Méndez, and the Center for Human Rights & Humanitarian Law of the American University Washington College of Law invited the WMA to participate in an expert meeting on the revision of the United Nations Standard Minimum Rules for the Treatment of Prisoners (SMR) on 10th July 2013 at the University of Oxford, United Kingdom. Prof. Vivienne Nathanson represented the WMA at the meeting.

In late September, the latest thematic report of the Special Rapporteur focusing on this topic was published. One section of the report is dedicated to medical and health services and includes recommendations related to the role of health professionals in documenting ill-treatment and acts of torture.
2.4 Prevention of torture and ill-treatment

2.4.1 Cooperation with the International Rehabilitation Council for Torture Victims (IRCT)

In Budapest in November 2012, C. Delorme was re-elected as an independent expert to the IRCT Council and the Executive Committee with a new mandate of three years. Three Executive Committee meetings took place during the reporting period and a Council meeting was held in March 2014.

C. Delorme is a member of the IRCT working group on detention and torture, putting forward the WMA’s perspective during discussions. Physicians’ views are also included in the two other working groups on migration and rehabilitation.

2.4.2 Psychiatric treatment

The annual report of Mr. Méndez, the UN Special Rapporteur on torture, which was submitted to the Human Rights Council last March, was dedicated to abuses in health care settings. In the report, Mr. Méndez explores an emerging recognition of different forms of abuses against patients and individuals under medical supervision.

In May 2013, the WMA Secretariat sent a letter to the Special Rapporteur welcoming the selection of this topic, but expressing serious concerns about some of the report’s recommendations in relation to ‘persons with psycho-social disabilities’. In particular, it is feared that the report may generate prejudice against psychiatric services, holding health professionals responsible for all abuses and ill-treatment of mental health patients.

The Secretariat drew the attention of the World Psychiatric Association, as well as the International Council of Nurses, to the report. In June, C. Delorme met with the WHO’s relevant department, as well as Christian Pross, a member of the UN Sub-Committee on the Prevention of Torture, to discuss this matter within the framework of the Mental Health Monitoring Guide, on which the Sub-Committee is currently working.

Furthermore, national medical associations were informed and invited to take action. The Norwegian Medical Association alerted the Norwegian Psychiatric Association, which wrote an open letter to the Special Rapporteur last November.

In December, the WMA was consulted about the WHO's project MINDbank, an online platform bringing together country and international resources covering mental health, substance abuse, disability, general health, human rights and development. The platform is now online: http://www.who.int/mental_health/mindbank/en/

2.5 Homosexuality

In early March, the WMA wrote to the President of Uganda expressing its deep concern about the new law in the country concerning homosexuality, and urging him to reverse the measure. On the day that President Museveni signed the bill into force, WMA President Dr. Margaret Mungherera and WMA Chair of Council Dr. Mukesh Haikerwal appeared on Ugandan television to make the WMA position clear by speaking out against this law. Previous international protests had at least led to the abolishment of a mandatory reporting clause, which was part of the original law proposal. The WMA will continue its efforts to get this legal act reversed.

2.6 Violence against women

During the 195th session of the WMA Socio-Medical Affairs Committee (Fortaleza), members discussed concrete actions concerning the implementation of the WMA Resolution on Violence Against Women (Vancouver 2010).

The initiatives proposed included the organization of a side-event during the upcoming World Health Assembly (May 2014). The WMA Secretariat is currently working on this and, in particular, is looking for a Member State which will agree to sponsor the event in accordance with the WHO’s rules. The event, co-organized with the International Federation of Medical Students Association (IFMSA), would aim to discuss concrete ways for the health sector to engage in stopping violence against women and, as an outcome, draw recommendations from the debate.

2.7 Children’s health

Since 2012, the mission of the Every Woman Every Child initiative, spearheaded by UN Secretary-General Ban Ki-moon, has been to mobilize and intensify global action to improve the health of women and children around the world. The WMA is an observer in the advocacy group of this initiative. http://www.everywomaneverychild.org

At the Council Session in Sydney, the question was raised, but not answered, as to the impact of smoking in the vicinity of children. It was discussed whether smoking in the vicinity of children should expressively be generally prohibited, including in private spaces, instead of calling only for general protection.

Following this discussion, the Secretary-General asked the WMA Cooperating Center at George Mason University for advice. The Center for the Study of International Medical Policies and Practices performed a literature review to analyze the evidence on the effect of second hand smoke on children. The conclusion of the
study clearly points to a recommendation to call for a stronger policy, including legal instruments, to ban smoking in the vicinity of children. (Individual copies can be obtained from the Secretariat upon request.)

2.8 Pain treatment

Last January, the WHO’s Executive Board adopted a strongly worded resolution entitled "Strengthening of palliative care as a component of integrated treatment within the continuum of care". The resolution recommends integrating routine training on palliative care into the curricula of healthcare professionals. The resolution was referred to the World Health Assembly next May with the recommendation that it be adopted.

Over recent years, the WMA has been involved in advocacy activities led by Human Rights Watch together with global/regional palliative care organizations in support of this resolution. The Secretariat will keep monitoring future developments.

2.9 Death penalty & organ transplantation

In late September, Amnesty International drew our attention to the practice of the death penalty in Taiwan. They informed us, in particular, of a recent letter from the Taiwan Minister of Justice for their attention, demonstrating medical involvement in executions (giving sedatives and declaring the prisoner dead). Another issue of concern was the practice of organ procurement for transplantation from executed prisoners. The Secretariat had an exchange of correspondence with the Taiwan Medical Association, which reiterates its commitment to WMA policies on these issues and provided information on the action taken towards the Taiwanese authorities in this regard.

In November, C. Delorme made contact with the International Commission against the Death Penalty in order to exchange information and explore potential joint activities.

In March, Dr. O. Kloiber and C. Delorme met with TAICOT (Taiwan Association for International Care of Organ Transplants) and DAFOH (Doctors Against Forced Organ Harvesting) to share information on ways to approach an end to forced organ harvesting.

3. Public health

3.1 Non-communicable diseases (NCDs)

3.1.1 General

Member States and the WHO have made progress in fulfilling their commitments according to the 2011 UN Political Declaration on Prevention and Control of NCDs. In the last two years, Member States have adopted a Global Monitoring Framework with a set of global NCD targets, a Global NCD Action Plan 2013–2020, and a formalized UN Interagency Task Force on NCDs, which will coordinate a UN system-wide response to NCDs.

The NCD Global Monitoring Framework comprises nine global targets and 25 indicators. Nine additional voluntary global targets are aimed at combatting global mortality from the four main NCDs, accelerating action against the leading risk factors for NCDs and strengthening national health system responses. The main target is to reduce premature mortality from non-communicable diseases by 25% by 2025. The WMA was strongly engaged in the development process and tried to shift the focus to overarching targets related to health care systems rather than single diseases.

At the UN High-level Meeting on NCDs in 2011, Member States committed to holding a comprehensive UN NCD Review and Assessment in 2014 on the progress achieved on NCDs. The 2014 NCD Review will provide a significant opportunity for stocktaking on progress in implementing the Political Declaration. The next step is now to develop the modalities resolution for this UN NCD Review. This resolution will determine the date, level, scope, participation, and outcome of the NCD Review. The co-facilitators of the Review are Jamaica and Belgium. At a WHO meeting in November, Member States did not reach agreement on the WHO’s engagement with non-state actors, in particular the private sector, and the organizational structure of the mechanism. The WMA is following this process and trying to advocate for an overarching NCD review approach.

Health professionals play an important role in reducing the global NCD burden through appropriate health promotional action, disease prevention, treatment and rehabilitation, and advocating for research and finance. Therefore the WMA, together with the members of the World Health Professions Alliance (WHPA), has developed a campaign to help prevent NCDs by targeting common risk factors and social determinants of health. More information on this campaign is included in Section 5.6 of this report.

3.1.2 Multidrug-Resistant Tuberculosis Project

The WMA has collaborated with the New Jersey Medical School Global Tuberculosis Institute and the World Health Organization, with financial support from the Eli Lilly MDR-TB partnership, to create a new application for tablet computers that will allow physicians to access a training course on the treatment of Multidrug-Resistant TB (MDR-TB).
The new application contains the eight training modules which comprise the WMA’s course on MDR-TB. It is intended as an introduction to MDR-TB management, and is consistent with the principles of the WHO Stop TB Strategy. The application, which will be accessible from the Google and iPhone app webpages, will be available on 10-inch screen tablets as well as smaller displays, including smartphones.

The New Jersey Medical School Global TB Institute, together with the University Research Company in the USA and the WMA, will update the TB refresher course for physicians, which was originally developed in 2008. A revision of the course now is both appropriate and necessary given changes in the WHO Guidelines and the upcoming release of the 3rd edition of the International Standards of Tuberculosis Care.

The goal of the project is to improve physician understanding and knowledge of TB management in order to improve patient outcomes, ensure adequate treatment and decrease community transmission of TB. The PDF version of the course will be updated first. After finalizing its content, it will be used as a basis for the revision of the interactive online course, which will subsequently undergo pilot testing with interested users. Both courses will be made widely available, so the WMA can disseminate the course materials to its member organizations and promote the courses at international meetings and conferences.

3.1.3 Tobacco
The WMA is involved in the implementation process of the WHO Framework Convention on Tobacco Control (FCTC) [http://www.who.int/tobacco/framework/en/]. The FCTC is an international treaty that condemns tobacco as an addictive substance, imposes bans on advertising and promotion of tobacco, and reaffirms the right of all people to the highest standard of health.

3.1.4 Alcohol
In May 2010, the World Health Assembly endorsed the Global Strategy to Reduce the Harmful Use of Alcohol. The Strategy provides a portfolio of policy options and interventions for implementation at national level with the goal of reducing the harmful use of alcohol worldwide. The successful implementation of the strategy requires concerted action by countries, effective global governance, and appropriate engagement of all relevant stakeholders, including health actors. In line with the WHO Statement on Reducing the Global Impact of Alcohol on Health and Society, the WMA Secretariat monitors progress in this area to ensure that medical associations at the national and global levels are engaged in the process. The Secretariat maintains regular contact with the WHO staff in charge of this topic, as well as with the Global Alcohol Policy Alliance (GAPA).

3.2 Social determinants of health
The Rio Political Declaration on Social Determinants of Health, adopted at the World Conference on Social Determinants of Health in Rio de Janeiro, Brazil in October 2011, identifies five action areas for health professionals to engage in to address the social determinants of health. One of these action areas emphasizes the role of the health sector in reducing health inequities.

Within this framework, the WMA monitors the WHO’s activities and keeps national medical associations informed of relevant developments.

On the initiative of the Canadian Medical Association, the WMA is considering organizing a meeting of interested NMAs to develop plans to address the social determinants of health and health equity through the collection/dissemination of successful clinical practice interventions and through advocacy, as well as policy development initiatives for NMAs.

3.3 Millennium Development Goals
The United Nations development agenda is prioritizing the move forward from the Millennium Development Goals (MDGs) era. The health-related MDGs have raised the profile of global health, mobilized political support and contributed to the achievement of significant improvements in health outcomes, particularly in low- and middle-income countries. To sustain the health-related gains and make the linkages between health and sustainable development even clearer, the UN saw a need to build on the momentum achieved by the MDGs and develop a more overarching development framework post-2015. The UN has linked all their other health and development related key activities to the post MDG discussion. For example, the Rio+ discussions and the climate change negotiations will feed the development process of the new post-2015 MDGs. The aim is not just to focus on poverty eradication, but also on the health of the planet.

The United Nations Secretary-General (UNSG) Ban Ki-moon appointed a High-level Panel of eminent persons chaired by the UK Prime Minister and the Presidents of Liberia and Indonesia to advise on the global development agenda beyond 2015. The Panel delivered a report entitled “A New Global Partnership: Eradicate Poverty and Transform Economies through Sustainable Development” to the UN General Assembly in September 2013.

A compilation of the global conversation on the post-2015 development agenda can be found at the ‘World We Want 2015’ website, which is jointly owned by United Nations agencies and civil society organizations. This site gives an overview of the different stakeholders involved in the
post-MDG discussions and the various thematic focus areas.

Within the health track of the post-MDG discussions, the WHO and the World Bank have developed a draft framework for the monitoring of Universal Health Coverage at country and global levels and opened it up for consultation. The World Medical Association has commented on the proposed framework. The main criticism was that governments would need to offer universal health coverage to only 40% of the poorest people in the country and only 80% of them would need to receive health care, which leads to a coverage of only one third of the population. This can hardly be called “universal health coverage”. Besides this, the framework again focuses only on single diseases. With this approach, the WMA fears that governments would concentrate only on improvements in these specific disease areas, detracting from the significant needs caused by other major health, social, and environmental threats. In order to achieve universal access we need to strengthen health systems at the point of service, with a special emphasis on increasing the number and appropriate distribution of health professionals per head of population.

The Geneva-based Global Social Observatory hosted a series of events devoted to the MDGs with the participation of Unilever, whose CEO Paul Paulman served on the High-Level Panel. Representatives of a variety of international NGOs, diplomatic missions and UN institutions were invited to participate in an inter-active dialogue and identify opportunities for innovation and partnerships to tackle future global health and development challenges. The WMA was an active participant in these events and will continue to contribute to thematic consultations and seminars organized by the WHO and other international institutions to make sure that health-related development goals remain high on the political agenda.

3.4 Immunization campaign

At the beginning of 2013, the WMA identified low vaccination rates among physicians as a significant public health threat that was receiving little attention, particularly from the medical profession. After conducting background research of the literature, the WMA national association members were invited to participate in a survey to document the magnitude of the problem and its root causes. The survey results helped the WMA plan a campaign that reflected the needs of our members. The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) provided funding for the campaign, which was officially launched during the 66th WHO World Health Assembly week for which the WMA hosted a luncheon seminar entitled: “Influenza: We Can Do Better.”

The campaign went smoothly and received positive feedback. It was featured on the WHO, CDC and Vaccine Europe websites. Several national associations approached the WMA with a request to use the WMA campaign materials for their national campaigns.

Over the course of the campaign, a variety of promotional and advocacy materials were developed that were widely circulated and posted on the WMA website. For example, a brief promotional video featuring real healthcare workers in a clinic caring for their patients and getting vaccinated by a colleague was launched at the WMA luncheon in May 2013. The luncheon itself was videotaped, which included interviews with experts encouraging physicians to get immunized against seasonal influenza. Both videos, the promotional video and the event video, are available on the WMA influenza campaign website: http://bit.ly/15wcpmt.

In addition to the videos, some printed materials were produced, including a calendar for 2014 with campaign messages, an infographic postcard, and letters for member associations to send to their governments in support of physician immunization against influenza. Other promotional activities included Dr. Julia Seyer hosting a campaign booth and giving a presentation at the Global Health Workforce Alliance/WHO Global Forum on Human Resources for Health from 10th-13th November 2013 in Brazil. Dr. Téa Collins gave an interview to Vaccine Today, which is available at: http://www.vaccinetoday.eu/vaccines/doctors-tell-doctors-get-your-flu-shot/ and published an article in Person-Centered Medicine on the campaign: ‘The Role of Physician Immunization in Preventing Influenza Outbreaks: Practicing Person-Centered Medicine’.

By the end of November 2013, Phase I of the campaign was successfully completed. In order to maintain the momentum achieved during Phase I and expand the campaign’s reach and impact in 2014, the World Medical Association requested additional funding from IFPMA to continue the project.

Phase II will build on the success of Phase I with the goal of expanding the campaign’s scope and will include vulnerable populations (people with chronic diseases, the elderly, children and pregnant women) and identify flu champions and peer vaccinators who will serve as role models to physicians and stimulate their interest in getting immunized. The campaign will also make a greater effort to ensure national member associations’ active involvement in the campaign and to streamline global and national advocacy efforts.

Hence, the overarching objective for this phase will be to expand the influenza immunization educational campaign among physicians with a greater focus on:
• Enhancing physicians’ advocacy skills to address the barriers to seasonal flu vaccinations on multiple levels (personal, organizational, national)
The WMA and the members of the World Health Professions Alliance (WHPA) have stepped up their activities on counterfeit medical issues and developed an anti-counterfeit campaign with an educational grant from Pfizer Inc. and Eli Lilly. The basis of the campaign is the ‘Be Aware’ toolkit for health professionals and patients, which is intended to increase awareness of this topic and provide practical advice for actions to take in case of a suspected counterfeit medical product. The WHPA organized several regional WHPA Counterfeit Medical Products workshops to implement this toolkit. This year’s focus of the campaign is on active women aged 30–45 in urban areas.

The WMA joined the Fight the Fakes campaign that aims to raise awareness about the dangers of fake medicines. Coordination among all actors involved in the manufacturing and distribution of medicines is vital to tackle this public health threat.

As part of this effort, Fight the Fakes is collecting and sharing the stories of those who are impacted by fake medicines and are speaking out. The website also serves as a resource for organizations and individuals who are looking to support this effort by outlining opportunities for action and sharing what others are doing to fight fake medicines.

3.6 Health and the environment

In April 2012, an Environment Caucus was set up on the initiative of the Korean and British medical associations together with Dr. Peter Orris, associate member and expert on environmental issues. The Caucus provides a forum for open discussion between medical associations interested in environmental issues and willing to exchange experiences. Since then, the Caucus has been meeting during WMA statutory meetings and is open to any medical associations interested in attending.

3.6.1 Climate change

The WMA continues to be involved in the UN climate change negotiations. Due to its UN observer status to the Convention, the WMA Secretariat can facilitate the participation of medical associations interested in the various official meetings taking place within this framework.

At the conclusion of the first Climate and Health Summit*, where the WMA was represented by Dr. Dong-Chun Shin (KMA, Korea), the health NGO organizers adopted the Durban Declaration on Climate and Health and the Health Sector Call to Action. The same partners organized a second Climate and Health Summit parallel to the 19th COP negotiations in Warsaw on 16th November with the support of the WHO. It provided an opportunity for groups to collaborate and share progress in the development and implementation of strategies and projects to build resilience to the impacts of climate change on health. Prof. Vivienne Nathanson (British Medical Association), co-chair of the WMA Environment Caucus, attended the event and chaired the opening plenary session.

This second Summit was also an opportunity to formalize the Global Climate & Health Alliance, composed of the health organizations’ partners, working together to ensure that health impacts are integrated into global, national and local responses to climate change and to encourage the health sector to mitigate and adapt for climate change. The WMA is not part of the Alliance, but is committed to work with its members towards the same goals, when appropriate.

* The Summit was co-organized by Health Care Without Harm, Climate and Health Council, World Public Health Associations, and the Nelson Mandela School of Medicine, with the support of the WMA, WHO, Public Health Association of South Africa, International Council of Nurses, the International Federation of Medical Students’ Associations, groundWork, Health and Environment Alliance, Europe, and the Climate and Health Alliance, Australia.
3.6.2 Mercury
The WMA has been a member of the UNEP Global Mercury Partnership (Mercury product) since December 2008 in order to contribute towards the partnership's goal of protecting human health and the global environment from the release of mercury and its compounds. This engagement is based on the WMA Statement on Reducing the Global Burden of Mercury (Seoul, 2008).

Representing the WMA, Dr. Peter Orris has been following the negotiating process of the UNEP (UN Environment Programme) for a legally binding instrument on mercury. The Mercury Treaty was adopted in January 2013 in Geneva. The Treaty sets a phase-out date of 2020 for most mercury containing products and calls for the phase-down of dental amalgam. This aspect of the treaty is a major victory for all who have worked for mercury-free health care. The WMA is following the ratification process of the Treaty.

3.6.3 Chemicals
In December 2009, the WMA joined the Strategic Approach to International Chemicals Management (SAICM) of the Chemicals Branch of the United Nations Environment Programme (UNEP), which aims to develop a strategy for strengthening the engagement of the health sector in the implementation of the Strategic Approach. In consultation with the WHO, Prof. Shin (Korean Medical Association) has represented the WMA at several SAICM meetings, bringing forward the WMA Statement on Environmental Degradation and Sound Management of Chemicals (October 2010, Vancouver).

3.6.4 WMA Green Page
At the request of the WMA Green Group, which was set up in 2011, the Secretariat created a Green Page in the environment section of its website. The green page focuses on the role of doctors in making health-care practice environmentally responsible.

4. Health systems
4.1 Person-centered medicine
The WMA co-sponsored and participated in the sixth Geneva Conference on Person-Centered Medicine, which took place in Geneva from 28th April to 1st May 2013. The conference was organized by the International College of Person-Centered Medicine in collaboration with Geneva University Hospital and the World Health Organization. The conference included thematic symposia on Person-Centered Health Research, interactive workshops and oral presentations by experts. Dr. Otmar Kloiber delivered a presentation on the revisions of the WMA Declaration of Helsinki and Dr. Tea Collins spoke about the importance of physicians’ immunization to prevent influenza outbreaks.

4.2 Health workforce
4.2.1 Third Global Forum on Human Resources for Health (GHWA)
The GHWA Third Global Forum on Human Resources for Health, entitled Human Resources for Health – Foundation for Universal Health Coverage and the Post-2015 Development Agenda, was held in Recife, Brazil from 10th–13th November 2013. With 1800 participants and attendance by 93 Member States, including more than 40 ministers and/or deputy ministers, the Third Global Forum on Human Resources for Health was the largest ever HRH event. The Forum had two major goals. The technical goal was to provide the best evidence available and share the lessons learned among the HRH experts. The political goal was to inspire and facilitate support and action by policy-makers.

High-level plenaries, technical sessions and satellite meetings with exhibition areas, poster presentations, photo galleries and awards for excellence provided opportunities for professional development and networking. The Conference program was organized around the following thematic areas:
1. Health workers and health goals: Progress in HRH actions over the past decade
2. Matching health workforce production to population needs and expectations
3. Social needs and the regulatory role of the State
4. Deployment, retention and management
5. Empowerment and incentives

The WMA served on the technical advisory board of the Conference and contributed to the content of the program. The WMA also organized a session on building collaborations and synergies among healthcare professions for the World Health Professions Alliance. The objectives of the session were to demonstrate the role of professional associations in policy-making, to advocate for inter-professional education and collaborative practice at the national and global levels using the example of the WHPA, and to highlight the importance of inter-professional education for inter-professional teamwork and collaborative practice. The WHPA presidents and CEOs participated in the session, which was well attended and received in Brazil.

In addition, the WMA organized a parallel session on the role of the health workforce in meeting citizens’ needs and expectations in collaboration with colleagues from the African Medical and Research Foundation and the Capacity Plus Project in the USA. WMA’s Dr. Julia Seyer served on the panel and gave a presentation on healthcare workers responsiveness as one of the goals of health systems and a main component of quality person-centered care. Dr. Seyer also hosted a WMA booth to showcase the WMA influenza immunization campaign materials.
4.2.2 The Prince Mahidol Award Conference (PMAC)
The Prince Mahidol Award Conference was hosted by the Prince Mahidol Award Foundation and the Royal Thai Government, in cooperation with the World Health Organization (WHO), the World Bank, the U.S. Agency for International Development (USAID), Japan International Cooperation Agency (JICA), the Rockefeller Foundation and the China Medical Board. The Conference, entitled “Transformative Learning For Health Equity”, took place in Thailand from 27th–31st January 2014.

The PMAC had four main objectives:
1. To identify, share and learn about the strengths and weaknesses of current health professional education, teaching and learning systems in different country contexts.
2. To identify how health professional education, teaching and learning systems can be transformed by advancing the health equity agenda and be responsive to the health of people in a dynamic socio-economic environment.
3. To support the development of strategies and interventions for transforming health professional education systems at the national level.
4. To strengthen the regional networks contributing to evidence for health professional education transformation.

Through a number of plenary and interactive parallel sessions, as well as a number of side events, the conference aimed to foster collaboration and partnerships among health professional education and training institutions, along with health service delivery organizations, with the goal of transforming health professional education systems and advancing the health equity agenda.

The PMAC was a closed, invitation only event. The WMA President, Dr. Margaret Mungherera, Chair of Council, Dr. Mukesh Haikerwal, and Secretary General, Dr. Otmar Kloiber, were invited as speakers and served on the panels of the plenary and parallel sessions of the conference.

4.2.3 Education & research
In fall 2013, Prof. David Gordon (U.K.) was elected as President of the World Federation for Medical Education (WFME). Dr. Gordon has advised the WMA on educational and workforce issues several times in the past. The WMA welcomed his presidency and is fully prepared to continue its intensive collaboration with the WFME. The Federation has now started to revise its standards for Medical Education. The WMA Secretariat will share the new draft standards with its members as soon as they are available.

The World Health Organization’s Department for Human Resources for Health has formed a Technical Working Group on Health Workforce Education Assessment Tools and invited the WMA to become a member. In view of the historical problem of, not only a global health workforce shortage, but an urgent need to ensure that such a workforce has a broader training, which more accurately reflects their everyday working practices, a WHO Resolution was passed in 2013 to develop a standard protocol and health workforce education assessment tool. The aim of the workgroup is to produce different quality measurements for trainees or practitioners since no single assessment tool can evaluate all competencies and, in addition, the same competency may be measured by more than one tool. Another important point is that the use of multiple assessment tools reduces the risk of bias towards any one tool.

4.3 Violence in the health sector
During the reporting period, the Secretariat has been working on the preparation of the fourth International Conference “Towards safety, security and wellbeing for all”, which will take place in Miami (FL), USA from 22nd–24th October 2014. The WMA is represented in the Steering Group in charge of the organization of the event and C. Delorme is part of the Scientific Committee.

The Steering Group met in early April for the final review and selection of the abstracts in order to establish the preliminary program. It is already planned that Dr. Margaret Mungherera will represent the WMA in Miami.

4.4 Caring Physicians of the World Initiative Leadership Course
The CPW Project began with the Caring Physicians of the World book, published in English in October 2005 and in Spanish in March 2007, which is now available in html and pdf. Some hard copies (English and Spanish) are still available from the WMA Secretariat upon request. Please visit the WMA website (http://www.wma.net/en/30publications/60cpwbook/index.html) to access the electronic versions and to order any hard copies. Regional conferences were held in Latin America, the Asia-Pacific region, Europe and Africa between 2005 and 2007. The CPW Project was extended to include a leadership course organized by the INSEAD Business School in Fontainebleau, France in December 2007 in which 32 medical leaders from a wide range of countries participated. The curriculum included training in decision-making, policy work, negotiating and coalition building, intercultural relations and media relations.

The fifth course was held at the INSEAD campus in Singapore from 13th–18th January 2013. The courses were made possible by educational grants provided by Bayer HealthCare and Pfizer, Inc. This work, including the preparation and evaluation of the course, is supported by the WMA cooperating center, the Center for Global
CHAPTER II
Partnership & Collaboration

During the reporting period, the WMA Secretariat held bilateral meetings with the WHO and staff of other UN agencies on the following areas: Prevention of alcohol abuse, mental health, violence against women, the environment, the migration of health professionals and the prevention of torture. In addition, the Secretariat voiced the WMAs concerns in various public settings as follows:

1. World Health Organization (WHO) (see table 2)

2. UNESCO Conference on Bioethics, Medical Ethics and Health Law

In recent years, the WMA has already supported the “UNESCO Chair in Bioethics World Conference on Bioethics, Medical Ethics and Health Law” organized by the UNESCO Bioethics Chair, Prof. Dr. Amnon Carmi. In November 2014, *More information on activities mentioned is set out under the relevant section of the report.*

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### Table 2.

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<tr>
<th>Governance</th>
<th>WHO public events</th>
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<tr>
<td>34th session of the Executive Board (January 2014):</td>
<td>Global Health Workforce Alliance 2013:</td>
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<tr>
<td>• Written statement (on behalf of the WHPA) on the WHO’s role in humanitarian emergencies;</td>
<td>The WHO invited the WMA to co-organize a session at the Third Global Forum on Human Resources for Health in November 2013 in Brazil. The WMA is working with the African Medical and Research Foundation and IntraHealth International to organize the session.</td>
</tr>
<tr>
<td>• Written statement (on behalf of the WMA, IFMSA1 and WONCA2) on the global challenge of violence, in particular against women and girls;</td>
<td></td>
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<tr>
<td>• Written statement on antimicrobial resistance (influenza)</td>
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</tbody>
</table>

67th World Health Assembly (May 2014): The Secretariat monitors issues of interest that will be addressed at the next World Health Assembly, such as non-communicable and communicable diseases, palliative care, violence against women, the global vaccine action plan, and antimicrobial resistance (influenza).

Prince Mahidol Award Conference 2014: The WHO invited the WMA to engage in the WHO side session on the social determinants of health (SDH), as well as in the WHO proposed e-book on SDH.
Table 3.

<table>
<thead>
<tr>
<th>Agency</th>
<th>Activities</th>
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</table>
| Human Rights Council                        | • Circulation of the SR’s report to the UN General Assembly on the right to health obligations of States and non-State actors towards persons affected by and/or involved in conflict situations along with a WMA letter welcoming the report (October 2013)  
  • Joint press release regarding the Turkish health bill (December 2014)  
  • Monitoring the follow-up to the annual report on torture and ill-treatment in healthcare settings  
  • Meeting with Suzanne Jabour, Vice-President/Continuing exchange of information. |
| UN Special Rapporteur (SR) on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (A. Grover) – See item 2.1 for details | Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment (J. E. Mendez)  
  Sub-Committee on the Prevention of Torture (SPT) |
| United Environment Programme (UNEP), Chemical Branch | Discussion of the Minamata Convention on Mercury and the ratification process. |

Table 4.

<table>
<thead>
<tr>
<th>WMA Cooperating Center</th>
<th>Areas of cooperation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center for the Study of International Medical Policies and Practices, George-Mason-University, Fairfax, Virginia, USA</td>
<td>Policy development, microbial resistance, public health issues (tobacco), publishing the World Medical and Health Policy Journal.</td>
</tr>
<tr>
<td>Center for Global Health and Medical Diplomacy, University of North Florida, USA</td>
<td>Leadership development, medical diplomacy</td>
</tr>
<tr>
<td>Institute of Ethics and History of Medicine, University of Tübingen, Germany</td>
<td>Revising the Declaration of Helsinki, medical ethics</td>
</tr>
<tr>
<td>Institut de droit de la santé, Université de Neuchâtel, Switzerland</td>
<td>International health law, medical ethics, deontology</td>
</tr>
<tr>
<td>Steve Biko Centre for Bioethics, University of Witwatersrand, Johannesburg, South Africa</td>
<td>Revising the Declaration of Helsinki, medical ethics, bioethics</td>
</tr>
</tbody>
</table>

Table 5.

<table>
<thead>
<tr>
<th>Organization</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amnesty International – Health Unit</td>
<td>Ongoing contacts (exchange of information and support) during the reporting period on the situations in Turkey, Iraq, Bahrain, Egypt and Russia.</td>
</tr>
<tr>
<td>Human Rights Watch</td>
<td>Regular contacts on palliative care (WHO resolution) and on matters relating to mercury and human rights.</td>
</tr>
<tr>
<td>Global Alliance on Alcohol Policy (GAPA)</td>
<td>Regular exchange of information.</td>
</tr>
<tr>
<td>International Committee of the Red Cross (ICRC)</td>
<td>Partners in the Health Care in Danger project since September 2011. Cooperation with the health and legal units.</td>
</tr>
<tr>
<td>International Federation of Health and Human Rights Organisations (IFHHRO)</td>
<td>Regular exchange of information on human rights and health matters, in particular during the reporting period: the health bill in Turkey, homosexuality, mental health.</td>
</tr>
<tr>
<td>International Federation of Medical Students Associations (IFMSA)</td>
<td>Internship program since 2013 (3 students in 2013 and 4 students in 2014)</td>
</tr>
<tr>
<td>University of Pennsylvania International Internship Program</td>
<td>Internship program on health policy, public health, human rights, project management (2 students in 2014) Planning of a joint side-event on violence against women at the next World Health Assembly (May 2014).</td>
</tr>
<tr>
<td>International Rehabilitation Council for Torture Victims (IRCT)</td>
<td>Member of the Council and Executive Committee (seat as an independent expert) Member of IRCT working group on detention. Regular input on policy development in advance of the next Council meeting in March 2014.</td>
</tr>
<tr>
<td>Global Climate &amp; Health Alliance</td>
<td>Participation in the joint Global Summit on Health and Climate Change (COP 19th November 2013, Warsaw) Exchange of information in the follow-up.</td>
</tr>
<tr>
<td>New Jersey Medical School Global TB Institute</td>
<td>The WMA is working with the New Jersey Medical School Global TB Institute and the University Research Company (URC) to update its online TB refresher course for physicians with the support of the US Agency for International Development (USAID)</td>
</tr>
<tr>
<td>Safeguarding Health in Conflict Coalition</td>
<td>Observer status in the coalition. Regular exchange of information.</td>
</tr>
</tbody>
</table>
the WMA for the first time took an active role, structuring its own sessions at the conference in Naples, Italy. WMA Past-President, Dr. Yoram Blachar, WMA Ethics Advisor, Dr. Jeff Blackmer, and WMA Legal Counsel, Ms. Annabel Seebohm, organized sessions on the Declaration of Helsinki and the ethical and legal aspects of hunger strikes. Among the speakers were WMA advisors Prof. Vivienne Nathanson, Dr. Hernan Reyes and Ms. Malke Borrow.

3. Other UN agencies (see table 3)

4. World Health Professions Alliance (WHPA)

The WMA submitted a proposal for a side session at the Global Health Workforce Alliance (GHWA) Global Forum in November 2013: ‘From Interprofessional Education to Interprofessional Collaborative Practice: The Role of Professional Associations’. The proposal was accepted by the Global Health Workforce Alliance.

The WMA made interventions on behalf of the WHPA at the 134th Executive Board of WHO on antimicrobial drug resistance, the WHO’s role as the health cluster lead in meeting the growing demands of health in humanitarian emergencies, multi-sectorial action for a life course approach to healthy ageing and the engagement of the WHO with the non-state sector.

The WHPA will hold the third World Health Professions Regulation Conference in Geneva from 17th–18th May 2014. The conference will take place immediately prior to the WHO World Health Assembly and discuss the challenges and provide insights into the issues surrounding health professions’ regulation.

As a continuation of the NCD health improvement card in paper form and the interactive version on the internet, the WHPA is now developing an application for mobile phones. It should better encourage and support people to develop a healthier lifestyle in their everyday lives. Finally, the health improvement card will be available free of charge in three different formats.

5. WMA Cooperating Centers

The WMA is now proud to enjoy the support of four academic cooperating centers. The WMA Cooperating Centers bring specific scientific expertise to our projects and/or policy work, improving our professional profile and outreach.

The latest addition to our cooperating centers is the Institute of Health Law at the University of Neuchâtel, Switzerland (Institut de droit de la santé, Université de Neuchâtel). (see table 4)

6. Other partnerships or collaborations (see table 5)

CHAPTER III

Communication & Outreach

1. WMA newsletter

In April 2012, the WMA Secretariat started a bi-monthly e-newsletter for its members. The Secretariat appreciates any comments and suggestions for developing this service and making it as useful for members as possible.

2. WMA social media (Twitter and Facebook)

In 2013, the WMA launched its official Facebook and Twitter accounts (@medwma). The Secretariat encourages members to spread the word within their associations that they can follow the WMA’s activities on twitter and via Facebook.

3. The World Medical Journal

The World Medical Journal is issued every 3 months and includes articles on WMA activities and feature articles from members and partners. It enjoys a wide circulation.

4. Roundtable Meeting

During recent years, the Business Development Group of the World Medical Association has developed the Roundtable concept under the leadership of the Secretary of the British Medical Association, Tony Bourne. The idea of the Roundtable is to provide a forum for international business leaders and the leaders of the WMA to meet up and discuss issues of common interest relating to medicine and health care, etc.

The first roundtable took place at BMA House in London on 26th September 2013. The second meeting is scheduled to take place in Tokyo on 24th April 2014.

5. WMA African Initiative

WMA President Dr. Margaret Mungherera has started an initiative to bring African medical associations closer to the WMA. A stronger inclusion of organized medicine in international cooperation should not only help to get the African voice better heard, but would also leverage their national visibility and standing.

Dr. Mungherera has been bringing together medical associations from various parts of Africa in small regional meetings to discuss issues around their current work, what obstacles they are facing and where they have had success. Invitations are open to all African medical associations, regardless of whether they are members of the WMA already or not.

Three meetings have been held up to the reporting date, with the West African medical associations in Nairobi, Kenya in November 2013, with the Southern African medical associations in Johannesburg, South Africa in February 2014, and in March 2014 with the North African medical associations in...
In April 2013, the Committee conducted an advocacy survey of the WMA membership in order to identify the needs of the constituent members regarding advocacy, as well as potential synergies that could be developed in a more global context. One clear outcome of the survey was a request from members that the WMA provide advocacy training. In this context, the Committee is considering the organization of an advocacy training session in Durban, South Africa during the 2014 WMA General Assembly in collaboration with the South African Medical Association.

2. Business Development Group

Please see Chapter IV “Roundtable meeting”

3. Secondment program

The WMA has continued a secondment program with its members. Constituent members may send staff members or volunteers to the WMA office for a limited period of time.

4. Paperless meetings

At the 188th Council meeting, the WMA Council expressed its desire to reduce its environmental impact by going paperless. Since the 189th Council meeting, documents posted on the website before the meeting have no longer been provided at the venue in print. Council members and officials are responsible for downloading documents from the members’ area of the WMA website and bringing them to the meeting via electronic media or on paper, if desired. Documents developed on site during the meeting will be available online through a Wi-Fi connection or in print.

5. gTLD (generic Top Level Domains in the Internet)

The WMA Executive Committee explored the suggestion by the British Medical Association to consider building a consortium to tender for a generic top-level domain of the Internet. Currently there is a suggestion to install a gTLD “.med”, which may be of interest to physicians, medical facilities and medical associations, but also to pharmaceutical companies, medical technology companies, insurers and many others. An exploratory group could not determine the chances of success of such a business venture and found that the financial and legal risks outweigh the potential benefits.

Meanwhile, the WHO expressed concern that the applications that had been made for a potential gTLD “.health” were too commercially orientated. The WHO requested our support in asking the Internet steering body ICANN for a moratorium and not to issue this gTLD for the time being. On behalf of the WMA, and in support of the WHO request, the Secretary General raised concerns with ICANN via the request for comments from the organization, as well as to their government relations body.

CHAPTER V
Acknowledgement

The Secretariat wishes to record its appreciation to member associations and international organizations for their interest in, and cooperation with, the World Medical Association and its Council during the past year. We thank all those who have represented the WMA at various meetings and gratefully acknowledge the collaboration and guidance received from the officers, as well as the association’s editors, its legal, public relations and financial advisors, staff of constituent members, council advisors, associate members, friends of the association, cooperating centers and its officials.
Background: Informed consent is premised on the participants' understanding the scope of the research and the associated risks and benefits. The objective was to evaluate the improvement in knowledge in a population unfamiliar with clinical trial concepts about “what it means to be part of a clinical trial” using an innovative educational tool called the 'Speaking Book'.

Methods: This was a randomized controlled trial conducted at a research site in Uganda. 201 participants were randomized to: (1) clinical trials information session control arm, or (2) clinical trials information session followed by instruction in the use of the Speaking Book with a take-home copy (intervention arm). After the session, participants of both groups completed a 22-item multiple-choice test on the rights and responsibilities of participants. Participants returned after one week to complete the same test to assess knowledge retention. The mean pre- and post-test score difference was assessed according to trial arm using an unpaired t-test of proportions.

Results: Ninety-one (90%) participants completed both the initial and follow-up tests in the control arm and 100 (100%) in the intervention arm. The average age of participants was 38 years, 53% were female and 67% were employed; 20% had previously been invited to participate in a clinical trial; of these, 19% had participated. The mean difference in proportion of correct responses from test 1 to test 2 was 2.7% (95%CI 0.3–5.0%) for the control arm and 11.6% (95%CI 9.3–13.7%) for the intervention arm (t-score=-5.3, p-value<0.0001).

Conclusion: Participants who had instruction in the use of the Speaking Book had a larger increase in knowledge than those who had no access to this tool. To better engage patients unfamiliar with clinical trial concepts, innovative educational techniques can assist to increase knowledge to make an informed decision about participation in a clinical trial.

In the twentieth century, a participant's informed consent became the backbone of ensuring ethical participation in a clinical trial. The key elements of the informed consent are: the provision of information about the research, the understanding of the information that is passed on, and the free agreement by the patients to participate in the study [1]. Research participants should be informed about the purpose of the research, the study procedures, the risks and the benefits of such procedures; the participant should also be informed regarding alternative options and the extent to which confidentiality will be maintained. Many of the precautions and considerations involved in ethical conduct rest on the basic foundation of informed consent. However, with conventional informed consent procedures, it has been observed that patients often misunderstand or forget basic practical information regarding the trials in which they participate [2, 3]. It is important to note too, that the consent procedure alone does not necessarily ensure that research participants have obtained sufficient knowledge to make an informed choice about participation [4], and that limitations specific to populations with low literacy levels have been identified [5].

A number of studies have found low levels of understanding in terms of what constitutes a clinical trial and details on participation. For example, one study found that only 28% of participants knew the study’s aim [4] while in another, 88% of women reported that they felt that trial participation was mandatory [6]. There appears to be a need for better ways of presenting information about clinical trials to enable research participants to make an informed decision. Various methods of improving patient knowledge and understanding of clinical trials used during the informed consent process could be beneficial.

Multi-media Educational Tool Increases Knowledge of Clinical Trials in Uganda

Barbara Castelnuovo Kevin Newell Yukari C Manabe Gavin Robertson
consent process have been evaluated, such as discussion groups, booklets and videotapes, “teach back” methods, educational modules to discuss research terminology, and audio/visual presentations [7–12]. The success of these approaches often depends on literacy level.

In a meta-analysis by Flory and Emanuel of 12 trials of multimedia interventions, all but one intervention failed to improve the participant’s understanding of the clinical trial [13]. The one trial which showed efficacy had a small sample size and used a computerized presentation of information for participants who were primarily mentally ill [14]. The authors concluded that multimedia and enhanced consent forms had a limited impact on participant understanding and targeted individualized education was preferable. Another recent study of a video intervention corroborated this finding [15]. Two recent publications on a targeted educational session and a video intervention to increase participant’s understanding of informed consent without the details of a particular clinical trial did show improved post-training scores in addition to retention of this information [16,17].

Research initiatives driven by both external and local investigators are rapidly increasing in countries within Sub-Saharan Africa where the familiarity with clinical trial concepts is generally low. Potential risks in conducting research in these environments are increased vulnerability to research exploitation and abuse but also low compliance to the study procedures, which can include low adherence to medication schedules. Educating people who are unfamiliar with clinical trial concepts often requires more creative methods to ensure a sufficient level of comprehension.

One such creative method to support these populations in understanding their rights and responsibilities when participating in a clinical trial is a multi-media educational tool, a “Speaking Book” entitled ‘What it means to be part of a Clinical Trial’. Clinical trials are the gold standard method for collecting safety and efficacy data for health interventions. The Speaking Book (SB) is a richly illustrated book designed to enhance knowledge and understanding of what clinical trials are, how they are conducted, and the rights and responsibilities of participants in a clinical trial. The SB consists of sixteen pages and sixteen corresponding buttons. The text on each page describes one topic around the participation in clinical trials and can be read aloud in English by a sound device within the book, which can be activated by pushing the corresponding button. Each monologue lasts less than a minute. The content of this particular book was reviewed by the World Medical Association to ensure alignment with the principles of the Declaration of Helsinki [1]; by the South African Medical Association to ensure the clinical relevance; and by the Steve Biko Centre of Bioethics to ensure that the rights of human research subjects were addressed. The book can be used by researchers to provide general education to potential clinical trial participants. In a pilot study of 52 participants working in a mass catering company conducted in South Africa [18], the SB was evaluated for efficacy in knowledge uptake and ease of use. The results of this pilot study indicate that incorporating the SB into the consent process increases the level of knowledge of clinical trials among study participants. The study also showed that the participants perceived the educational tool as easy to use.

In order to obtain information about the efficacy of the SB in a research setting in Uganda, a clinical trial was conducted in a busy public clinic located within the National Hospital where patients are recruited for clinical trials. The research team sought to provide information about the effectiveness of the SB in the type of environment for which it was designed. The team also assessed the acceptability of the SB by research participants and health professionals working on clinical trials.

The study was reviewed and approved by the Joint Clinical Research Centre (JCRC) Ethics Committee and by the Uganda National Council for Science and Technology (UNCST). Written consent was obtained from each participant and the ethics committee approved this procedure. The clinical trial is registered with the Pan African Clinical Trials Registry, trial number PACTR201307000574378.

This study was a randomized, controlled clinical trial design comprising 2 groups, each of approximately 100 adult (older than 18 years) participants, in a research site in Kampala, Uganda. Patients attending a health clinic in Kampala were invited to participate in the study by a site research assistant. Those consenting to participate and who could understand and read English (as assessed by a literacy test) were randomized sequentially according to pre-allocated group assignments in blocks of 4 to either the control group or the SB group. Both groups took part in a standard clinical trial information session and participants were assessed immediately afterward using a written 22-item knowledge assessment that was developed by the study team based on the information covered during the session. The total score was calculated as the percentage of correct answers. The assessment addressed the nature of clinical trials, and the rights and responsibilities of participants in clinical trials. After the initial information session and assessment of knowledge, the participants in the SB group were provided instructions on the use of the SB, received a copy of the SB to take home and were encouraged to listen to it as many times as they wished to as well to invite other people to listen to it. After one week, participants in both groups were re-assessed using the same tool to determine retention of knowledge. Participants in the SB group were also asked a set of additional qualitative questions about their experiences with the SB.
Participants in both groups were given approximately $3 to cover transport costs on each of the 2 days.

In a separate qualitative evaluation, ten health professionals employed in the same research clinic, but not part of the study, were given the book to listen to and were asked to respond to a brief survey about their perceptions of informed consent, and the efficacy and acceptability of using the SB as part of the consent process.

The mean pre- and post-test score difference was assessed by trial arm using an unpaired t-test of proportions. Qualitative data was summarized using tabulations. Data was analyzed using SAS version 9.2.

A total of 201 participants were randomized on this trial, including 100 participants in the SB group and 101 in the control group. Ninety-one (90%) participants in the control group and 100 (100%) in the Speaking Book group completed both the initial and follow-up tests. The average age of participants was 38 years, 53% were female and 67% were employed. Forty (20%) participants reported they had been invited to participate in a clinical trial, including thirty-nine (19%) who reported they had participated previously in a clinical trial. The demographic characteristics of study participants in the two arms were similar (Table 1), though there was a trend toward higher education level in the control group.

The mean score for the first assessment was 76.5% in the control group and 71.7% in the SB group, which was similar (Table 2). The change in proportion of correct responses from test 1 to test 2 was 2.7% (95% CI 0.3–5.0) for the control group and 11.6% (95% CI 9.3–13.7) for the SB group, which was statistically significant ($p < 0.0001$). The allocation group was the only variable associated with significance for knowledge increase, measured by proportional score difference; there was no association between knowledge change and other variables such as demographic characteristics, educational level, or previous exposure to clinical trials.

We reviewed item-level responses to the knowledge assessment to determine if there were any trends in knowledge uptake or retention by trial arm. In the intervention arm, there were improvements of greater than 10% from pre-intervention to post intervention in the proportion responding correctly for 11 of 22 (50%) the assessment items, whereas in the control arm, there were improvements of this same magnitude in only 2 (9%) questionnaire items. Among intervention participants, there were no items with a decrease in proportion responding correctly between the assessments; however, in the control group there was a decrease in proportion of correct responses for 7 of 22 (32%) assessment items.

All participants in the intervention group were asked questions about their experience with the SB. Almost all participants (99%) liked the illustrations and found the book easy to use (98%). Most participants (96%) heard the spoken voice clearly and understood the content.
98% reported understanding the content. Almost all participants (99%) indicated that members of their community would understand the content if given the speaking book to use. On average, participants showed the book to others. Seventy-two percent of participants reported showing the book to others. On average, participants showed the book to 8 other people in their homes, workplace, church, mosque, clinic or hospital. Most participants (93%) reported that after listening to the speaking book, they would, in principle, be willing to participate in a clinical trial. Table 3 summarizes the responses given by participants in the SB group.

Interviews were conducted with ten health professionals to assess their perceptions of the potential efficacy, acceptability and use of the SB. The average age of the health professionals interviewed was 31.6 years and they had been working in their current position for an average of 3.8 years. Of the ten health professionals surveyed, seven (70%) thought that their current consent process at their clinic provided participants with sufficient understanding to sign an informed consent before entering a clinical trial. Most (90%) thought that participants in clinical trials are aware of their role and responsibilities prior to signing the informed consent form. Four (40%) thought the person who explains the information sheet and consent form to the patient does not have enough time to make sure that the patient completely understands all the information. Nine (90%) thought that the consent process would be easier if patients were asked to read the SB first on their own. Seven (70%) thought that participants take study drug as prescribed and inform the study staff about any additional drugs used. Of the health professionals who thought participants do not take study drug as prescribed (30%), all thought that the SB would help in explaining the importance of this to them. Five (50%) of the health professional respondents reported that they had been asked about the term “placebo” during the consent process. Most (80%) of these thought they understood the term placebo well enough to explain it. Six (60%) of all health professionals interviewed thought the SB explained the concept sufficiently. All ten (100%) interviewed reported that they usually told patients that they can quit participation in the trial at any time, and nine (90%) thought the SB addressed this issue adequately. Three (30%) thought that the SB contained all the necessary information while seven (70%) thought the SB contained most but not all of the information necessary to make a decision about participating. Almost all (90%) thought that each participant should be given a SB to take home before agreeing to participate in a clinical trial, and all ten (100%) thought the SB would assist participants better than a brochure when screening or informing them about a clinical trial (Table 4).

In settings with patients unfamiliar with clinical trial concepts, innovative techniques can improve knowledge acquisition and retention in order for individuals to make a more informed choice about participation in clinical trials. Participants who had instruction in the use of the SB and used it for one week had a larger improvement in knowledge assessment score compared to those who had no access to this tool. Our data is in contrast to a meta-analysis by Flory and Emanuel [13].
The SB seems to be a valuable tool in improving patients’ understanding of clinical trials and their rights and responsibilities associated with participation in a trial. The qualitative assessment of the intervention group showed that participants who were instructed in the use of the SB and brought it home for a week found it useful and shared it extensively with friends, family, work colleagues and other associates, thereby increasing the value of the book as an educational tool. This allowed patients to discuss the ethical aspects of clinical trials with others whose opinions they valued.

A structured questionnaire was used with a limited pool of health professionals who viewed the SB as a useful tool for increasing the capacity of patients to make an informed decision regarding participation in a clinical trial.

One limitation of our study was that the participants included only those who spoke and understood English since the SB was not translated into local languages. Therefore, participants likely had a higher educational status than the average for the clinic. In the meta-analysis [13], research participants with higher education status were more likely to have better understanding. Nonetheless, having a group of participants capable of taking the test represented an appropriate first group in whom to test the intervention. The investigators also noted that despite the randomization the control arm had slightly higher education level, though of marginal sig-

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Table 4. Summary of Health Professionals responses to questions about the Speaking Book

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes n(%)</th>
<th>No n(%)</th>
<th>No response n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you think that the consent process at your clinic now is enough for the participants to understand the consent forms provided and the details of the trial?</td>
<td>7(70)</td>
<td>3(30)</td>
<td></td>
</tr>
<tr>
<td>In general, do you think that participants in clinical trials are aware of their medical responsibilities prior to signing the consent form?</td>
<td>9(90)</td>
<td>1(10)</td>
<td></td>
</tr>
<tr>
<td>Do your patients understand that they should inform the doctor or nurses about any other medication that they take before or during the trial, even from a pharmacy or a traditional healer?</td>
<td>7(70)</td>
<td>2(20)</td>
<td>1(10)</td>
</tr>
<tr>
<td>Do you think the participants in a clinical trial take their medication exactly as they are told to do?</td>
<td>7(70)</td>
<td>3(30)</td>
<td></td>
</tr>
<tr>
<td>If NO, do you think the book can help you explain the importance of this to them?</td>
<td>3(30)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do patients ever ask you what a placebo is during the consent process?</td>
<td>5(50)</td>
<td>4(40)</td>
<td>1(10)</td>
</tr>
<tr>
<td>If YES, do you think that you know about a placebo well enough to explain it properly?</td>
<td>4(40)</td>
<td>1(10)</td>
<td></td>
</tr>
<tr>
<td>Do you think the speaking book explains the concept of a placebo enough?</td>
<td>6(60)</td>
<td>4(40)</td>
<td></td>
</tr>
<tr>
<td>Do you usually tell the patient that they can stop the clinical trial at any time?</td>
<td>10(100)</td>
<td>0(0)</td>
<td></td>
</tr>
<tr>
<td>Does the book tell the patient clearly enough that they can stop the clinical trial at any time?</td>
<td>9(90)</td>
<td>1(10)</td>
<td></td>
</tr>
<tr>
<td>Do you think that the person who explains the information sheet and consent form to the patient has enough time to make sure that the patient completely understands all the information?</td>
<td>6(60)</td>
<td>4(40)</td>
<td></td>
</tr>
<tr>
<td>Do you think that the consent process would be easier if the patient was asked to read the book first on their own?</td>
<td>9(90)</td>
<td>1(10)</td>
<td></td>
</tr>
<tr>
<td>Do you think that the information in the book gives all the information needed to make a decision about participating?</td>
<td>3(30)</td>
<td>0(0)</td>
<td></td>
</tr>
<tr>
<td>Do you think the book should include any other information we have forgotten?</td>
<td>3(30)</td>
<td>7(70)</td>
<td></td>
</tr>
<tr>
<td>At what time do you think that the books should be given to the new person applying for the trial?</td>
<td>4(40)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At time of first visit to the research clinic</td>
<td>6(60)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you think that each participant should be given a speaking book to take home before agreeing to participate in a clinical trial?</td>
<td>9(90)</td>
<td>1(10)</td>
<td></td>
</tr>
<tr>
<td>If you were going through screening or informing a patient about a clinical trial, in addition to normal practices which do you think would help a participant more? Speaking Book</td>
<td>10(100)</td>
<td>0(0)</td>
<td></td>
</tr>
<tr>
<td>Brochure</td>
<td>0(0)</td>
<td></td>
<td></td>
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</table>
Significance (p=0.10), and therefore the use of the SB could have had an even higher impact on the absolute score change if groups had a more similar level of education. The fact that a differential improvement in knowledge was identified between the study groups suggests that the SB might demonstrate an even greater improvement in knowledge among a less literate population. Further studies with use of the tool in the local language such that participants with lower educational status could be included would be warranted.

A disadvantage of using the SB to pass information on clinical trials is that it requires a two-visit procedure with increase in study costs and potential for loss to follow up in between the visits. However in our study all participants in the SB arm (as compared to 90% in the control arm), returned for the follow up visit after the week, possibly as the result of learning the importance of participating clinical trials; in addition most of the participants showed the book to an average of 8 other people in their homes, contributing to the sensitization of the general population on clinical trials.

In summary, the use of a SB multi-media tool for one week after a standard explanation of clinical trials was able to increase comprehension scores significantly compared to participants who received only one educational session. The SB is an introductory tool that can be used to inform patients on topics common to all clinical trials and may be a valuable adjunctive instrument for use among potential research participants to improve understanding of clinical trials and make an informed decision during the consent process.

References

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Market Structure in the South African Health Care System

The South African health care system consists of both the public and private health systems and these are very similar to the types found in similar middle income countries as well as other developed markets. The private health system in South Africa is currently serving close to nine (9) million people and these are people who currently have medical aid and those who can afford and are able to pay for health care from their own pocket. It is also a well known phenomenon and has been covered extensively in literature that private health system in South Africa is costly and mostly used by the middle to high income individuals and families. Comparisons have also been made assessing levels of inequalities between the private and public health system, where it is stated that more than forty (40) million people solely use the public health systems. There have been policy developments towards the introduction of the national health insurance. This is a major health sector reform which is currently in the pilot phases, and is likely to increase public–private partnership between the two health sectors.

Notwithstanding; the inequality challenges between the private and public health sector – the health financing and health delivery components of health systems – there are other challenges facing the health care system in South Africa. These are also observed in other global markets and include increasing cost of health care. The private health care expenditure data reported by the CMS (Council for Medical Schemes) revealed that private hospitals, medical specialists and medicines accounted for more nearly eighty (80) percent of risk benefits paid by medical schemes in 2012.

Another factor of significance is; the impact of market structure on the conduct and performance of market participants. The structure of private voluntary health financing markets has impact on:

• The nature of health plan concentration (the market penetration of health plans);
• The level of health plan rivalry (market participation) [11,18]; and
• The conduct of all market participants is thus informed by patterns in market organization.

Market structure has an impact on consumer welfare policy objectives, these are observable in (but not exclusive to) the following factors:

• Benefit design (the role of product design) [9];
• Differences in demographic profiles across risk pools ([15];

Thus; cost pressures in health sector, are partially, a function of the impact market structure on market segments covering vulnerable risk groups [19]. The absence of price regulation in health insurance markets – i.e. price regulation on health service procedures – may fuel market failure outcomes [12; 6].

Economic theory suggests that absence of regulation may result in low-quality services at high-quality prices for unacquainted consumers [12; 19; 6]. This analysis seeks to provide similar evidence for the South African private health financing system.

Purpose

Healthcare providers and consumables have been stated in the aforementioned section to contribute significantly to the escalating costs of health care in the private health sector. Commentators such as Halse et al [7] studied the role of competition policy in healthcare markets and the impact thereof on price increases. Studies by Gaynor, [4], Morrisey [11], Wholey [18] also identified ways in which competition policy can be used to ensure the effective functioning of healthcare markets. Van den Heever [16] advocates for regulatory
framework which; enhances solidarity in health plan risk pools [17].

The objective of the current research note is to conduct a high level review of the consolidation in the medical schemes industry, structural features of the healthcare sector and policy themes. The covered policy themes are directly related to the interpretation of restricted and prohibited conduct, in terms of the Competition Act of 1998. Most of these prescriptive standards regarding market conduct were enacted on the promulgation of the Competition Act 89 of 1998. The timing of this enabling Act was simultaneous with that of the Medical Schemes Act 131 of 1998. At the time of instituting both these Acts; the policy agendas within the regulatory environments are discussed in the sub headings which follow.

Stakeholders & Policy Landscape

Medical schemes industry policy landscape

The Medical Schemes Act 131 of 1998 came about at a time when market failure was present in the private medical schemes industry. Vulnerable risk groups, such as the sick and healthy, were not able to secure affordable access to health insurance. That situation was as a direct result of a series of deregulation occurring in the 1990's. These deregulations resulted in a gap in the product, as a market for covering vulnerable risk groups was not provided in the private sector.

The anti-trust policy landscape

The regulatory philosophy behind the competition Act was to increase the transparency of market behaviour. The intention was to promote the efficiency of industries, and prohibit conduct deemed to be anti-competitive. This has resulted in efficiency focused interpretations of provisions of the Competition Act. Thus, the socio-economic goals of industrial policy were mostly not considered in assessing the competitive nature of transactions and market conduct.

Resulting policy gap

The enabling clauses of the two statutes resulted in a polarities; i.e. public interest relative to pure market efficiency objectives. The current inquiry into the private health sector by the Competition Commission (Comp.Com); seeks to establish whether their interventions in the private health sector have negatively impacted access to health care.

All activities related to collecting information, and sharing information pursuant to setting a guideline on prices, after the Competition Act, were now violations of section 4. Although the practice of setting the "scale of benefits" (SOB) was previously, an activity conducted among professional and statutory organizations - that said; it was now prohibited practice.

The purpose of SOB was conducted for the purposes of:
• Upholding the social solidarity principles of medical schemes; and
• Coordinating the activities between providers and funders for the purpose of producing accessible health financing.

Although section 4(1)(b)(i) expressly makes exception for instances when prohibitive conduct can shown to be the result of normal commercial activities prevailing in the market; this did not apply in considering all three of these cases. Notwithstanding that HASA (Hospital Association of South Africa) had previously able to gain exemption from section 4, that exemption was not considered in the hearing. The interpretation of the Competition commission was based on new evidence submitted in other court cases.

Most importantly, we have learned that the socio-economic policy objectives of the Competition Act come second to efficiency practices. In fact, collusive practices allowed in the provider environment (arrangements between specialists and providers) are allowed as normal commercial practice for efficiency purposes [8; 13].

In fact, the reason behind all three judgements by the Competition Tribunal, were as a result of [13]:
• Submissions made in other cases regarding the conduct of HASA, BHF (Board of Healthcare Funders of South Africa) and SAMA (South African Medical Association) – as it relates to setting price benchmarks;
• On the basis of these submissions, an investigation/inquiry into the private health sector was conducted by the Competition Commission; and
• The investigation focused on the price benchmarking activities of the SAMA, BHF and the HASA.

As a result of the inquiry into the provider sector, emerging policy issues had significant impact on the health financing regulatory framework and market outcomes.

Significant observations

• Anti-trust policy made in the interests of efficiency markets were not balanced with socio-economic policy objectives; therefore
• The public interest intentions behind the Competition Commission inquiry into the health sector are an important window of opportunity, the CMS policy agenda; and
• Table 1 reports the significant policy issues and regulatory impact of the Competition Commission's intervention into issues related to RPL (Reference Price List).
Defining Market Structure From Different Perspectives

Willig [22] explains the analytic process required to be undertaken, in order to, understand the different perspectives related to potential merger outcomes. Danzig states the steps to this process:

- An understanding the how product and geographic markets delineated; i.e. product and geographic definition of market structure;
- Once discrete market demarcations are established, all the firms belonging to each market segment are to be identified;
- The market participants within each market need to be taken into consideration when calculating and making interpretations regarding market share and concentration;
- On the quantification of market concentration and market shares, an assessment of how existing market conditions impact market rivalry and ease of access (concentration/potential for abuse of power) need to be taken into consideration; Assessing ease of entry;
- Consideration of other factors may be made; i.e. the outcome of an amalgamation (merger) on market efficiency and public interest issues/consumer welfare.

This section proceeds to paint a picture of the market structure from numerous dimensions. The intentions is to provide a situational analysis on how product and consumer demarcations of the market, could potentially impact solidarity. On the basis that solidarity is affected positively or negatively, judgements can be made. To the extent that market organization compromises or improves solidarity; a judgement could be made on the implied effect of a prospective amalgamation may have on community rating.

Solidarity: Scheme VS. Benefit option level

Figure 1 and 2 illustrates industry solidarity from two different perspectives. A picture of risk pool solidarity is provided at scheme level and at option level.

Solidarity in medical schemes – industry level
- Overall the industry lost more than a third of schemes over the review period; the declining trend is likely to continue in the next few years, thus giving a positive perspective of how consolidation has increased the solidarity of both the open and restricted scheme markets.
- The open* scheme sector saw a reduction of nearly half from a level of 49 schemes (2002) to 25 (2012);
- The restricted** schemes sector saw a reduction of nearly thirty percent by 2012 from a level of 94 schemes (2002) to 67 (2012);

Solidarity in benefit options – industry level
- Overall the industry lost more than a third of schemes over the review period; the declining trend is likely to continue in the next few years, thus giving a positive perspective of how consolidation has increased the solidarity of both the open and restricted scheme markets.
- ‘The open’ scheme sector saw a reduction of nearly half from a level of 49 schemes (2002) to 25 (2012);
- ‘The restricted’ schemes sector saw a reduction of nearly thirty percent by 2012 from a level of 94 schemes (2002) to 67 (2012);

Table 1. Emerging policy issues & regulatory impact

<table>
<thead>
<tr>
<th>1. Consequences of Intervention by the Competition Commission (Comp.Com):</th>
</tr>
</thead>
<tbody>
<tr>
<td>• As a result providers and schemes could only negotiate prices on a bilateral agreement between a single seller and single payer</td>
</tr>
<tr>
<td>• Implication – price divergence between tariffs and reimbursement rates across providers and payers</td>
</tr>
<tr>
<td>• As a result, copayments increased and balanced billing was the result.</td>
</tr>
<tr>
<td>• Subsequent attempts at instituting and independent reference list of prices by NDoH &amp; CMS from 2004/5 were unsuccessful</td>
</tr>
<tr>
<td>• As a result; medical schemes offer cost sharing benefit options, these have been effected through:</td>
</tr>
<tr>
<td>- Discriminatory structuring of supplementary benefits to the essential benefit package</td>
</tr>
<tr>
<td>- These have been effected through efficiency based options with out-of-network penalties &amp; financial limits on formularies</td>
</tr>
</tbody>
</table>

| 2. Although RPL was supposed to be non-binding effective guideline on tariff levels; it effectively determined re-imbursement rates |
| 3. Providers are not able to recoup costs based on low RPL tariff rates |
| 4. At the risk of leaving the market – doctors would have to generate revenue on high volumes and not quality care |
| 5. RPL rates set as low rates – means members are under-covered for true costs of health care |
| 6. There could not be any certainty in setting prices for scheme members, and uncertainty in benefit entitlements |
| 7. Low tariff rates would force providers to embark in double billing practices |
| 8. Financial viability of options would be prejudiced without proper cost productions by providers included in RPL |

* Health plans that accept all applicants regardless of health status
** Health plans that are Employer based
trend. That said; risk pool solidarity for open schemes show an increasing but moderate trend.

The average number of benefit options per scheme in:
- Open scheme benefit options increased from a base of 5 (2002) to 6 (2012) options per scheme; and
- Restricted scheme benefit options remained around two (2) benefit options per scheme on average.

What may lie behind the different observed patterns at scheme and benefit option may be related to the following factors:
- Product diversification or proliferation more benefit designs in open schemes, relative to, restricted schemes;
- The need to diversify against the changing demographic profile experienced in the open scheme market. This occurred after the establishment of the GEMS (Government Employees Medical Scheme).

Significant observations
- Changes in market structure from the overview at industry level shows strong consolidation; that said
- This scenario is not sustainable at the benefit option level of market structure, i.e.:
  - Market structure from a product perspective shows that scheme communities are potentially split as a result of option/product diversification
  - This type of market rivalry is much stronger in the open scheme environment
  - This may have unintended consequences for community rating
  - This observation may also be of interest to the Competition Commission’s Inquiry into the Private Health Sector, as market structure is affected by product diversification (benefit option proliferation within schemes)

Figure 1. Schemes Solidarity – Sector and industry level (2002–2012)

Source: CMS annual reports 2002–2012

Figure 2. Benefit option Solidarity – Sector and industry level (2002–2012), figures in the graph are rounded off.
Market Entrants

Describing the trends

Figure 3 reports the number of new market entrants (new scheme registrations) from 2002 to 2012. The development of new registrations was as follows:

- There were twelve new registered schemes;
- Five of the twelve, were within the open scheme environment; and
- The other seven, were within the restricted scheme environment

On the viability of new market entrants (2002–2012)

- Six of the twelve new schemes were going concerns (still in operations)
- Five of the six going concerns were schemes from the restricted scheme environment
- One (1) of the six going concern schemes are within the open scheme environment

Significant observations

- The consolidation that has occurred at the industry level has been driven through amalgamations and liquidations
- There have been far less market entrants, and their survival rate has been 50%. That said, new scheme registration like GEMS, have had a far reaching impact on the conditions of market rivalry and consolidation in the medical schemes industry

Outcomes of Market Rivalry:
Amalgamations & Liquidations

Amalgamations (Mergers) & Liquidations (2002–2012)

- There were a total of 63 schemes amalgamations and liquidation between 2002 and 2012:
  - 44% occurred in the open scheme environment; and
  - 56% occurred in the restricted scheme environment.
• The highest peaks of activity occurred in 2003 and 2008 (10 and 11 liquidations and amalgamations, respectively). The twin peaks are characterized by double the market exit activity for the relevant period; i.e. the median of both amalgamations and liquidations was five (5) for the period (Figure 4).

Liquidations (2002–2012)
• There were a total of 28 liquidations;
• These were 32% for open schemes and 68% in the restricted scheme environment; and
• Liquidations accounted 44% of market exits in the period over review.

Amalgamations (2002–2012)
• There were a total of 35 amalgamations;
• Amalgamations accounted 56% of the market exits;
• There were significantly more amalgamation in restricted schemes, 61% (n=23) than open schemes, 39% (n=15).

Policy Trajectory

Figure 5 illustrates a projection of expected number of medical schemes. The projected is based on an exponential trend model derived from actual trends from 2001 to 2012. Therefore, the expected medical schemes are based on a three year forecast. Based on the forecasted projection there will 64 medical schemes in 2016. This provides an estimate of the projected rate of consolidation in the industry, and an estimated quantification of the policy trajectory; assuming that trends continue as they did since 2012.

Market Concentration & Rivalry

The concept of market concentration was assessed using the Herfindahl–Hirschman Index (HHI). HHI is a measure of market concentration that incorporates the market share of the largest firms within an industry or sector. This measure is defined as the sum of the squares of the market shares of the fifty largest firms within an industry, where the market share is expressed as a proportion of the total market share.

The method applied in analysing – the relative extent of market participation (level of competition), and market concentration (level of market penetration) – is based on a similar used by Wholey and Morrisey [18; 11]. In this analysis, the health insurance industry is divided into 8 market segments. Market share calculations are based health plan turnover in 2011. Armstrong and Kotler [1] describe how market

Table 2. Market participation and penetration

<table>
<thead>
<tr>
<th>Market segments</th>
<th>Market Participation: (%) of competing medical scheme</th>
<th>Market Penetration: (%) share of enrollees</th>
</tr>
</thead>
<tbody>
<tr>
<td>S 1</td>
<td>5</td>
<td>0.3</td>
</tr>
<tr>
<td>S 2</td>
<td>5</td>
<td>0.2</td>
</tr>
<tr>
<td>S 3</td>
<td>15</td>
<td>1.2</td>
</tr>
<tr>
<td>S 4</td>
<td>24</td>
<td>3.4</td>
</tr>
<tr>
<td>S 5</td>
<td>24</td>
<td>7.4</td>
</tr>
<tr>
<td>S 6</td>
<td>15</td>
<td>16.3</td>
</tr>
<tr>
<td>S 7</td>
<td>5</td>
<td>11.3</td>
</tr>
<tr>
<td>S 8</td>
<td>4</td>
<td>59.9</td>
</tr>
</tbody>
</table>

Source: developed by the authors
positioning in targeted market segments impacts of certain sale and thus gaining competitive advantage.

Table 2 shows the relative degree of market rivalry (health plan participation) and market concentration (market penetration). Market participation quantifies the distribution of medical schemes across market segments. Market participation quantifies the distribution of beneficiaries covered by medical scheme across all market segments. The table below depicts that there is a disproportionate share of medical scheme enrollees across the industry.

### Product Diversification

Most medical schemes offer multiple benefit options where contributions/ premiums and access to benefits differ. Willie [20] and colleague [21], find that open schemes (individual plans) offer more benefit offerings than restricted schemes (group plans). The CMS annual report denotes that 55% of open scheme benefit options are making losses and this different to the 45% in restricted schemes. This is a worrying phenomenon in the industry in particular with regards to the principle of risk-pooling at benefit option level, the medical schemes act clearly stipulates that benefit options need to be self-sustainable.

Figure 6 reports the average number of benefit offerings offered by open and restricted schemes, there are significantly more benefit options in open schemes compared to restricted schemes (nearly as twice). The average number of benefit options in the open schemes market segments is generally higher than the industry average of three (3). Overall, more than half (55%) of benefit options in opens schemes on market segment 8 (2 market players who account for 65% of open schemes) are in loss making options. There is a high degree of product differentiation in the market segments and suggesting variation in the risk characteristics of the individuals in those benefits options making them less sustainable.

Figure 7 extends on the analysis conducted by Morrissey [11] and Wholey [18].

The figure illustrates the market positioning of medical schemes across the industry. Two scenarios are presented, they are described below.

**Scenario 1**
- Market structure and concentration effects when all eight market segments (S1 to S8) are included in the analysis;
- The trend shows the results of market positioning and market power across the industry market segments;
- There is a negative trend in terms of the proportion of scheme competing across market segments, and the proportion of enrollees covered by the medical schemes;
- The share of market power is unequal and thus, resulting in less competition as one moves across the market segments.

**Scenario 2**
- Market structure and concentration effects when all eight market segments (S1 to S4) are included in the analysis;
- The trend shows the results of market positioning and market power across the industry market segments;
- There is a positive trend in terms of the proportion of scheme competing across market segments, and the proportion of enrollees covered by the medical schemes;
- The share of market power is more equal and thus, resulting in a more competitive market environment as one moves across the market segments.

Table 3 reports two different standard guidelines for triggering concerns about market abuse power. These are: An international standard used as an anti-trust guideline

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**Figure 6.** Average number of benefit options by market sector and segment

<table>
<thead>
<tr>
<th>Market segment</th>
<th>Open schemes</th>
<th>Restricted schemes</th>
<th>Consolidated</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.4</td>
<td>1.2</td>
<td>2.2</td>
</tr>
<tr>
<td>2</td>
<td>3.0</td>
<td>3.5</td>
<td>3.3</td>
</tr>
<tr>
<td>3</td>
<td>4.8</td>
<td>2.4</td>
<td>5.5</td>
</tr>
<tr>
<td>4</td>
<td>3.3</td>
<td>3.0</td>
<td>3.5</td>
</tr>
<tr>
<td>5</td>
<td>2.2</td>
<td>2.2</td>
<td>2.2</td>
</tr>
<tr>
<td>6</td>
<td>8.8</td>
<td>5.5</td>
<td>10.0</td>
</tr>
<tr>
<td>7</td>
<td>3.5</td>
<td>1.2</td>
<td>4.7</td>
</tr>
<tr>
<td>8</td>
<td>9.0</td>
<td>3.5</td>
<td>12.5</td>
</tr>
</tbody>
</table>

*Source: developed by the authors from the CMS annual reports, 2011*
• Trigger point for a moderate level of concern:
  - HHI of 1,000 points for an individual firm;
  - Percentage transformation 32% market share for an individual firm.
• Trigger point for a High level of concern:
  - HHI of 1,800 points;
  - Percentage transformation 42% market share.

- The South Competition Act guideline
  • Trigger point for a Moderate level of concern:
    - HHI of 1,225 points for an individual firm;
    - Percentage transformation 35% market share for an individual firm.
  • Trigger point for a High level of concern:
    - HHI of 2,025 points for an individual firm;

  - Percentage transformation 45% market share for an individual firm.

The significance of what is reported in the table (table 3) is; the trigger points in international jurisdictions are, somewhat lower than what is prescribed by the South African Competition Act. Table 4 reports the relative market influence from different sectors/industries.

**Table 3. Trigger point for concern of abuse of market power**

<table>
<thead>
<tr>
<th>Description</th>
<th>Trigger Points – Abuse of market power</th>
<th>Moderate level of concern</th>
<th>High level of concern</th>
</tr>
</thead>
<tbody>
<tr>
<td>International standard¹</td>
<td></td>
<td>index (%)</td>
<td>index (%)</td>
</tr>
<tr>
<td>Prescription of South African Competition Act²</td>
<td></td>
<td>1,000</td>
<td>32¹</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1,800</td>
<td>42¹</td>
</tr>
</tbody>
</table>

¹ (Robinson, [14])
² section 7 of the South African Competition Act
³ Generated using (Gaynor, [4]) method

**Table 4. Relative market influence of different industry market participants (2011)**

<table>
<thead>
<tr>
<th>Sector/Industry</th>
<th>Market Concentration Indicators</th>
<th>Indicator</th>
<th>HHI²</th>
<th>Square root of HHI²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals Market (upstream)</td>
<td>Hospital beds¹</td>
<td></td>
<td>2,273</td>
<td>48</td>
</tr>
<tr>
<td>Administrators Market (downstream)</td>
<td>Beneficiaries</td>
<td></td>
<td>2,498</td>
<td>50</td>
</tr>
<tr>
<td>Medical Schemes Industry (non-profit)</td>
<td>Risk contribution income</td>
<td></td>
<td>1,157</td>
<td>34</td>
</tr>
<tr>
<td>Open Medical Schemes Market (non-profit)</td>
<td>Risk contribution income</td>
<td></td>
<td>778</td>
<td>28</td>
</tr>
<tr>
<td>Restricted Medical Schemes Market (non-profit)</td>
<td>Risk contribution income</td>
<td></td>
<td>379</td>
<td>19</td>
</tr>
</tbody>
</table>

¹ Data on hospital beds (van den Heever, [16])
² Method for calculating HHI – (Baker, [2])
³ Method for HHI transformation to percentage – (Gaynor, [4])
sides of the private health financing and provider sector. The figure provides a consolidated index for HHI, and then splits the index for restricted and open schemes. The reasons for the split are:

• It would methodologically incorrect to reflect a combined HHI score for product markets which not direct substitutes;
• Reflecting HHI score restricted schemes only and open schemes only, as in other reports on the same axis with providers. Suggests, administrators and hospitals only exclusively accept either open scheme contract or restricted scheme contract; that said
• The HHI for restricted and open schemes is much lower than that of both administrators and providers.

The table (table 4) shows the level of market concentration for, hospitals (upstream market participants) and medical scheme administrators (upstream market participants), are higher than that of medical schemes. This is significant since, the downstream beneficiaries [10].

necessary, particularly in instances when vulnerable risk groups are covered by individual contracts (open schemes), as opposed to, group contracts (restricted schemes). Gaynor has shown that, medical schemes with vulnerable risk groups are not able to contract low prices with managed care providers [5]. As a result, the market contestability and sustainability of such health plans have waned. Wholey and colleagues found that there are scope diseconomies in providing access to health care services [19]. This outcome is to the detriment of achieving affordable health insurance policy objectives.

References

Discussion & Policy Implications
Lately, there have been numerous policy recommendations emerging from research findings. Most of the recommendations advocate; greater market concentration in medical schemes creates more bargaining power. Greater bargaining power for medical schemes means better contracting arrangements with health care providers and thus, lower premiums for medical scheme beneficiaries [10].

What this analysis has shown is; market structure needs to be scrutinized and defined from many perspectives. This is necessary, particularly in instances when vulnerable risk groups are covered by individual contracts (open schemes), as opposed to, group contracts (restricted schemes). Gaynor has shown that, medical schemes with vulnerable risk groups are not able to contract low prices with managed care providers [5]. As a result, the market contestability and sustainability of such health plans have waned. Wholey and colleagues found that there are scope diseconomies in providing access to health care services [19]. This outcome is to the detriment of achieving affordable health insurance policy objectives.

Mr. Michael Mncedisi Willie, Senior Researcher (until 30 April 2014), Council for Medical Schemes
Mr. Phakamile Nkomo, Senior Policy Analyst, Council for Medical Schemes
The Indian Medical Association (IMA) was established in 1928 with 222 members as an offshoot of the Indian freedom struggle. The IMA was a founder member of the WMA in 1946. Any doctor of modern medicine irrespective of the field and discipline may become an IMA member voluntarily. The IMA has a three tier structure. The IMA headquarters are in New Delhi. It has 29 state and 7 territorial branches. The current IMA membership is 230,000 embracing members of 1700 branches spread all over India. The IMA has a sub-district level representation in almost all 640 districts of the country. The IMA has a democratic structure. The office bearers are elected every year at all the three levels. Bicameral legislative bodies assist in decision making at all the levels.

The IMA objectives focus on the advancement of medical sciences, improvement of public health and medical education, and upholding the honour and dignity of the medical profession. The aim is to provide affordable, accessible and quality health care for all. The IMA members have a strong presence in the Medical Council of India and various state medical councils which are statutory bodies to regulate medical education and practice. The IMA is also represented in various committees of the central and state Governments. The IMA takes its role as a nation builder seriously and voices the opinion of the people. All legislation pertaining to health are carefully scrutinized and commented upon by the IMA. The Health policy of the country has substantial inputs from the IMA which is the parent organization of numerous service and professional organizations. The IMA forms a bridge between the public and private sectors and also between various specialists and family physicians and acts as a coordinator for a national cause as well. The IMA is a major player in the public private mix for the National TB Control Programme. The IMA has sensitized 87292 and trained 15099 private doctors in tuberculosis care. 4359 DOT centres and 93 microscopy centres have been initiated by the IMA. The IMA played a major role in India’s successful polio eradication programme. The Association directly manages the entire biomedical waste of the southern state of Kerala and assists in other states. Across the country the IMA runs several blood banks and in some states handles as much as 20% of the blood demand. Pain and palliative care centres are run by many local branches. Through the initiative ‘Aao Gaon Chalen’ (Let us go to the villages) the IMA is involved in holistic health care in 1040 villages. The IMA is a strong participant in the ‘Save the Girl Child’ project in India’s struggle against female feticide. The IMA has its own ‘Care of the Elderly’ programme and has the capacity to execute PAN INDIA health surveys. The IMA has recently added a hospitals division – the IMA Hospital Board of India. The IMA serves as a family circle in towns and villages of India for its members. The IMA participates in all the National Health Programmes starting from HIV-AIDS control to blindness prevention. The IMA remains a dynamic interface between the people and the
Bosnia and Herzegovina renewed its 1000-year statehood in the process of the creation of new states as a result of the dissolution of Yugoslavia. A price of its independence was bloodshed. The Dayton Peace Agreement ensured peace but it did not make Bosnia and Herzegovina a functional country. It consists of three parts: the Federation of Bosnia and Herzegovina (BiH), the Republika Srpska and the Brčko District. Bosnia and Herzegovina is a unique model of the state organisation that does not exist anywhere in the world. The state health care system is divided accordingly.

There is an additional division within the Federation of BiH. The Federation consists of 10 cantons. It is important to mention that there is no single legal framework for health care at the level of Bosnia and Herzegovina, and it is also divided into entities – the Federation and the Republika Srpska, while the health care in the Federation is organised at the level of cantons. Thus, in Bosnia and Herzegovina there is one Ministry of Health in the Republika Srpska, one Ministry of Health in the Federation, 10 Ministries at the level of 10 cantons in the Federation and one Ministry of Health in the Brčko District. There is a total of 13 Ministries of Health at the level of Bosnia and Herzegovina with slightly less than 4,000,000 inhabitants and slightly more than 9,000 doctors of medicine. (This information is for the Guinness Book of Records, but it is a result of the Dayton Peace Agreement). If health care were organised at the level of the State of Bosnia and Herzegovina, there would be the 14th Ministry of Health in this poor country exhausted by the war.

The budget amounts for health care differ significantly from one canton to another with 5,600 doctors working in the Federation. Political divisions to entities and cantons were not beneficial for the health care system that has been trying to be effective and functional, and in the mutual interest of doctors and patients. Such differences discriminate not only patients in terms of providing health care services between the “rich” and the “poor” cantons, but also discriminate doctors who work in the 10 different health care systems in the Federation. The number of doctors ranges from 2,300 in the Sarajevo Canton (SC), 1,400 in the Tuzla Canton (TC), 700 in Mostar (HNK), 680 in the Zenica Canton (ZDC), 334 in the Bihać Canton (USC), 343 in the Travnik Canton (CBC), 96 in the Livno Canton (HBC), 72 in the Široki Brijeg Canton (WHC), 48 in the Orašje Canton (PC) and 24 in the Gorežđe Canton (BPC). Proportionally, the health care budgets vary from one canton to another, but such dynamics worsens the quality of health care and working conditions for doctors in those cantons. It is compensated not only with cooperation in the provision of health services between the “rich” and the “poor” cantons, but also with the health care systems of the neighbouring countries (Croatia and Serbia for the Republika Srpska).

The main task of the Ministry of Health of the Federation of BiH is to decide on the development of the health care system in the Federation harmonising the 10 legal
cantonal health care strategies in the 10 cantons of the Federation. The further issue is harmonising the development of the health care system in the Federation between the "poorer" and the "richer" cantons. How could it be done if the establishment of good health care system depends upon the political stability in the state which is currently non-existent.

The same issues are equally important for the Medical Chamber of the Federation, though in a different way: how to ensure equal working conditions for doctors, for their professional development and advancement, for CME in the Federation, unhindered flow of doctors from one canton to another, i.e. how to eliminate discrimination among colleagues that arises merely from the fact that doctors work in different cantons. While the WMA is dealing with equalizing standards for doctors in entire Europe and in the world, the Medical Chamber of the Federation is trying to do it in the Federation of BiH and entire Bosnia and Herzegovina.

If we want to provide good level health care services, then the medical space in Bosnia and Herzegovina must be free and open for all patients and doctors. There must be no rigid administrative or political boundaries in that unique health space. There should be a principle of solidarity among the health care institutions of the same or different level.

Answers to these questions should be sought not only in a new, better organisation of the health care system of the Federation but also in the use of all available health care benefits and medical capacities in the Federation of BiH including entire Bosnia and Herzegovina.

Prim.dr. Harun Drljević
President of the Medical Chamber of Bosnia and Herzegovina

35th World Medical and Health Games

MEDIGAMES will take place in Wels (Upper-Austria), from June 21 to 28 2014.

Many participants from more than 30 countries already confirmed their registration, so join them shortly! Massages and medical care on the afternoons, visit of the city of Wels, climbing initiation, gokart race... we prepare you lots of nice surprises!

Do not forget that you have the possibility to take part to various competitions! This is a nice opportunity to test yourself on a discipline that you usually don't practice in competition.

If you wish to take part to our Congress, please send us your abstract by email to fanny@medigames.com

For any further information, contact us by email to info@medigames.com or by phone to 0033 1 77 70 65 15.

The Organising Committee
Physicians should routinely ask their women patients about domestic abuse where they have reason to suspect violence.

Professor Sir Michael Marmot, speaking in Geneva, said that physicians should ask about domestic abuse more often so that it normalises the question. He said domestic violence was a global public health concern with one in three women throughout the world experiencing physical and/or sexual violence by a partner or sexual violence by a non-partner.

Sir Michael, Director of University College London Institute of Health Equity, and chair of the World Medical Association’s Socio-Medical Affairs Committee, was speaking at a luncheon seminar during the World Health Assembly, organised by the WMA and the International Federation of Medical Students’ Associations.

He outlined the extent of domestic violence around the world and said that in many countries married women believed a husband was justified in beating a wife if she refused to have sex. Education, however, is key, he said. The more educated women are the less likely they are to think that violence from a husband is justified.

Sir Michael said that although domestic violence was evident across all classes, economic and ethnic groups, the statistics showed that this pattern of behaviour was more prevalent among the less well educated. A study among nine countries showed that those women most likely to report having experienced violence were married at a young age, had multiple children and a family history of domestic violence between their parents.

As well as resulting in murder and injury, domestic violence also led to suicide, induced abortions, depressive disorders and alcohol problems. And women with mental health disorders were also more likely to have experienced domestic violence.

Sir Michael said that physicians and health professionals had to be more active in this field. Staff training in equality and diversity issues should be improved so that physicians and others could detect more easily cases of abuse among their patients and could ask relevant questions.

‘For instance, much domestic abuse starts during a woman’s pregnancy and physicians should be aware that asking questions during this time is particularly effective. Previously silent women may come forward because of fear of harm to their baby’. In addition, he said, women and girls should be empowered through education and social support.

Dr. Margaret Mungherera, WMA President, who also spoke, said: ‘Domestic “Gender Based Violence” is only one of the many forms of violence that women experience worldwide. In conflict situations, sexual violence is common and is often associated with physical violence and abductions. Unwanted pregnancies, HIV/AIDS, mental disorders and traumatic fistula are common complications. In addition, low use of family planning services has also been associated with GBV and hence the need to integrate such services into the reproductive health services. It is also important that GBV is included in the pre-service training and continuing education curricula of physicians and other health workers. GBV services should be integrated into mental health and primary care services and these should be made available universally.

‘The recent kidnapping of young Nigerian girls illustrates in the most horrific way this devastating scourge. It is not enough to deplore the magnitude of the phenomenon. Urgent, strong and concrete policies must be taken now with the participation of all sections of society, including the health sector, to meet this major global public health, gender equality and human rights challenge.’