World Medical Journal

Contents

World Medical Association Officers, Chairpersons and Officials

Official Journal of The World Medical Association

Opinions expressed in this journal – especially those in authored contributions – do not necessarily reflect WMA policy or positions

World Medical Journal

The General Assembly in Moscow

October 14–17, 2015

An Invitation

The World Medical Association was founded in the wake of World War II. After a two-year preparation period, 27 medical associations met in Paris in September 1947 to found a new association. Since then, medical ethics and socio-medical affairs have been at the core or our work and we are proud to have shaped major international medical guidelines and regulations over the past seven decades.

Of course, physicians have had many other interest groups both before and since, but the WMA became, and still is, an advocacy group striving to make the best health care possible for all, including through health education, prevention, rehabilitation and palliative therapy, aside from curative care and public health.

Over past years, aspects of human rights and social determinants have become more prominent and important for the work of the association. The spectrum we deal with stretches from equitable access to treatment through to issues of human rights violations in medicine right up to the challenge of preserving medical neutrality. We are now working more closely than ever on human rights issues with partners like the International Committee of the Red Cross, Amnesty International and Physicians for Human Rights, to name just a few.

We support member associations in making their case for the ethical practice of our profession, we call upon governments to allow physicians to perform properly and we advise on how to stay within the rules. We are searching deeper for the causes behind the causes of diseases, and we often find very simple mechanisms that determine our health and our chances of dealing with disease.

The WMA has become a strong voice for physicians and their patients worldwide and we need to stay that way: able to raise questions, willing to find answers, and able to speak out. We invite our members – Constituent and Associate Members – to join us in Moscow from 14–17 October for the Council Session and the 2015 General Assembly. Please register on our website now. We need every single one of you!
http://www.wma.net/en/50events/10statutorymeetings/13ga_2015/index.html

Dr. Otmar Kloiber
WMA Secretary General

World Medical
Journal

World Medical
Journal

200th WMA Council Session, Oslo, April 2015

The 200th WMA Council meeting, was held at the Hotel Bristol in Oslo, Norway. The meeting was opened by the Secretary General Dr. Otmar Kloiber, who began by reminding delegates that this was a confidential meeting and that tweeting should not take place. There were no apologies for absence. He welcomed three new members of Council, Dr. Heidi Stensmyren from Sweden, Prof. Rutger Jan Van Der Gaag from the Netherlands and Dr. Carlos Jorge Janez from Argentina. He also welcomed delegates from more than 35 national medical associations, Past Presidents, observers and guests and in particular the return of one of the WMA's founding members, the Italian Medical Association.

Council

Elections and Appointments

The Council began with an election for Chair of Council. Two nominations were received – from the sitting Chair Dr. Mukesh Haikerwal (Australian Medical Association) and from Dr. Ardis Hoven (American Medical Association). Both candidates briefly addressed the meeting. Dr. Haikerwal, a former President of the Australian Medical Association, spoke about his achievements as a leader of the medical profession throughout his career and talked about his vision for the future of the WMA to build on his work of the past four years. Dr. Hoven, Immediate Past President of the American Medical Association, spoke of the great opportunity the WMA had to influence medical practice and global health, and the complex and far reaching challenges facing the Association – shrinking resources, complicated and difficult practice environments, shifting government regulations and dangerous working conditions. The WMA's current work spoke to its impact and credibility. She said she valued consensus and the WMA's diversity and she would work to increase the Association's visibility and strengthen its voice. In the vote, Dr. Hoven was elected and immediately took the Chair, thanking the Council for its support and in particular thanking Dr. Haikerwal for his work as Chair.

Prof. Dr. Frank Ulrich Montgomery (German Medical Association) was elected unopposed as Vice-Chair to succeed Dr. Masami Ishii and Dr. Ishii (Japan Medical Association) was elected unopposed as Treasurer to succeed Dr. Montgomery.

The Council approved the membership of the Council committees and approved the names of their advisers.

President's Report

The President Dr. Xavier Deau gave an interim report on his activities since his inauguration in Durban last year. He referred to the work on the Health Care in Danger project and the H20 Health Summit in Melbourne, where it was concluded that health was a wise investment and an economic driver in society for the creation of employment. He also spoke about WMA's role on the issue of climate change, the importance of the issue of the Social Determinants of Health and the successful revision of the Declaration of Helsinki.

Secretary General's Report

Dr. Kloiber had presented a lengthy written report to Council about the secretariat's activities. In his oral report he highlighted two issues to illustrate the WMA's influence and impact.

The Association had received an invitation from the United States Defence Health Board to advise the US Defence Secretary and the US military on issues relating to health and the military. The WMA was invited to take part in a session on medical ethics. Past President Dr. Cecil Wilson represented the WMA at this meeting and the Board came out with 16 recommendations. Dr. Kloiber then quoted from a letter from the Vice Chair of the US Senate Committee on Intelligence, Senator Dianne Feinstein, to the US Defence Secretary referring to the WMA's Declaration of Malta on the issue of ending the forced feeding of detainees at Guantanamo Bay.

The second development illustrating the WMA's impact related to the issue of scheduling the drug Ketamine some weeks ago by the United Nations Commission on Narcotic Drugs. The WMA had asked its members to argue against this scheduling as many people would have suffered from the absence of the drug. Eventually it was decided to postpone the decision for a year and Dr. Kloiber thanked those NMAs who had lobbied on this issue.

Dr. Margaret Mungherera, the Immediate Past President, said that the largest threat to global health were the African health systems, but there was not enough attention being paid to this. She said the WMA needed to keep this issue on the agenda. The WMA had done a lot of work to reduce the deafening silence of NMAs in Africa on this issue, but it had a moral authority to do more and could not afford to sit back.

Chair's Report

In his report, Dr. Haikerwal reported on the WMA's increased footprint on the global health map. He referred to the first "H20+" Health Summit in Melbourne, adjacent to the G20 World Leader's Summit. He said ethical guidance and ensuring access to health and healthcare remained core and key. He and the WMA's leaders continued to remind people that health was a core component of a successful fair and just society, that health was a wise investment and that health brought human, political and economic dividends. Physicians were part of the solution in health and healthcare research planning implementation.

Emergency Resolution

A proposal was put forward by the British Medical Association that the meeting should consider an urgent Resolution about the several trade agreements being negotiated throughout the world and their impact on the provision of health. The Council accepted this as an urgent matter which should be discussed in committee. The Council then adjourned for the committee meetings.

Finance and Planning Committee

Dr. Dongchun Shin (Korean Medical Association) was elected unopposed as Chair of the Committee. The Committee received a report on membership dues payments and on the Financial Statement for 2014. The Committee approved the document as an interim financial statement. A debate took place on a new dues structure.

Alcohol Session

The Committee meeting then adjourned to hear two invited speakers talking about the alcohol policy in Norway. Mr Øystein Bakke, Senior Adviser, FORUT, Campaign for Development and Solidarity and Secretary of the Global Alcohol Policy Alliance, spoke about Norway's 40 years of experience with a ban on alcohol advertising. He said that increasing amounts of evidence showed that alcohol advertising and other marketing efforts had an impact on consumption. Marketing was a dominant feature of the global alcohol trade, and drinks companies spent massively towards "investments in the brands". Advertising and marketing had the strongest impact on young people, speeding up onset of drinking and increasing the amount consumed by those who already drank. The alcohol industry looked for new markets as the traditional markets of the West were becoming less profitable. In these emerging markets in Africa and Asia, marketing was effective in recruiting new consumers from the non-drinking population.

The alcohol industry's response to calls for marketing regulations was "self-regulation". This approach to alcohol marketing had generally been deemed ineffective by several studies, but the alcohol producers and their so called "social aspects organizations" still referred to this as the best way forward.

He said that, marketing restrictions existed in many countries around the world and not only in Norway. Almost 50 countries had a total ban on alcohol advertising on national television in 2012, while another 50 had some sort of partial restriction on TV advertising. That added up to about half the world's countries. Advertising bans were effective measures, particularly in reducing the impact on underage and young consumers.

The second speaker, Lilly Sofie Ottesen, Deputy Director General of the Unit for Alcohol and Illicit Drugs Policy at Norway's Ministry of Health and Care Services Department of Public Health, spoke about 40 years' experience of the alcohol ban in Norway. She said the ban, which was introduced in 1975, was very strict and probably the most comprehensive in Europe. It covered all the media and all expressions associated with alcoholic beverages. Phrases such as 'happy hour' and 'a cold one' were even covered, as well as the mere use of a neutral picture of a beverage and alcohol sponsorships such as beer brands on football shirts and on boards at sport venues.

The aim of the ban was twofold – to reduce directly the demand and thereby the consumption and harm of alcohol, and secondly to reinforce the effect of other alcohol policy measures and to contribute to the support for the alcohol policy as a whole.

Addressing the question of whether the ban was working, Ms Ottesen replied that it was. Alcohol consumption in Norway was low compared to the rest of Europe and there was evidence to back up the assumption that the ban reinforced other alcohol measures. Public support for the ban had grown in recent years. There had been challenges to the ban from the alcohol industry, but there was now a broad political consensus that Norway should keep the ban.

She concluded: 'We believe that it is important to maintain a strict and media neutral advertising ban. We do not see any threats to the ban as such, but as there will always be changes in society, communications and industry, and we must make sure that the ban and its exceptions adapts to these changes. This, along with an efficient control and sanction system, is important to safeguard the support for the ban also in the years to come.'

Finance and Planning Committee (resumed)

WMA Strategic Plan

The Secretary General spoke about the WMA's strategic alliances and highlighted a number of activities implemented according to its strategic plan. These included organising another Regulation Conference with the World Health Professions Alliance in May 2016. There would be a Global One Health Conference with the World Veterinarian Association on 21–22 May in Madrid with an agenda concerning issues relating to both professions. There would be a UNESCO Bioethics Conference from October 20–22 in Naples at which the WMA would be organising two sessions and the WMA was now participating in the World Federation of Medical Education as a voting member.

Business Development

A report was given on the Business Development Group's work and the issue of finding external sources of funding. The Group had worked on the first principle that the core work of the WMA had to be funded by membership subscriptions. The question was whether other activities, such as educational activities, should be funded in some way by external sources. The meeting agreed that the Group should prepare a paper on the issue and come back to the Committee.

World Medical
Journal

World Medical
Journal

Future Meetings

The Committee considered the planning and arrangements for future WMA statutory meetings. The Taiwan Medical Association suggested that at the Assembly meeting in Taipei in October 2016 the scientific session should be on 'Healthcare System Sustainability' with two sessions, the first on 'Health System Performance' and the second session on 'eHealth'. This was agreed.

The Secretary General reported that as in previous years, a WMA luncheon in Geneva would again be held during the WHO World Health Assembly period. The main theme this year would be public health issues, including health and investments. Dr. Haikerwal reported that a second H20+ Health Summit was also being planned following the success of the Melbourne meeting.

Associate Members

The Committee received an oral report from the Chair of the Associate Members, Dr. Joe Heyman. He informed the Committee of his plans to draw more commitment from individual associate members by promoting membership through introducing life membership. An international conference call was planned for May and he also spoke about holding regional, on-site meetings when statutory meetings were held and linking up with the Junior Doctors Network and the Past Presidents and Chairs of Council Network.

Junior Doctors Network

The Chair of the Junior Doctors Network, Dr. Ahmet Murt, gave an oral report on the JDN's activities. Among the current topics it was working on were physicians' wellbeing, medical work force, medical education, Ebola and social media.

Past Presidents and Chairs of Council Network

Delegates received a written report on the activities of the Past Presidents and Chairs of Council Network. Dr. Cecil Wilson had represented the WMA at the U.S. Defence Health Board Subcommittee Meeting in February, Prof. Dr. José Luiz Gomes do Amaral had given expert advice on the possible scheduling of Ketamine as a narcotic drug and Dr. Dana Hanson was presenting a paper entitled, "Global Physician Resilience: The Role of Social Context to the European Association for Physician Health" in Barcelona in April. Dr. Jon Snaedal gave an oral report and said the activities of the Network were increasing.

World Medical Journal

The WMJ Editor, Dr. Peteris Apinis, in his oral report, said the transition producing a digital edition of the Journal had been complicated. Four issues had been scheduled for this year and the first digital edition would be published within days.

Public Relations

The WMA's Public Relations Consultant, Mr. Nigel Duncan, spoke about the importance of social media and the advantages this pre-

sented for the WMA. He said there was a need for some guidelines and rules for a more efficient and productive use of social media.

IFMSA Memorandum of Understanding

Dr. Kloiber reported on a new Memorandum of Understanding with the International Federation of Medical Students Associations. Dr. Agostinho de Sousa, President of IFMSA, explained that IFMSA had been cooperating with the WMA since the 1960s, and that the official MoU would facilitate future collaboration. The Committee agreed to recommend to the Council to accept the new Memorandum of Understanding.

Internship and Secondment

The Committee received an oral report from the Secretary General on internships and secondment to the WMA. He reported that two bioethics students from the University of Pennsylvania and medical students from the IFMSA had been interning at the WMA Secretariat in Ferney Voltaire annually. He asked NMAs to consider secondment for intensive contact with the WMA for mutual benefit.

Violence Against Doctors

The meeting heard a report from the Indian Medical Association about increasing incidents of assaults on doctors by patients in India. Dr. Kloiber agreed that this was a very pressing issue that had arisen in countries around the globe. He had received reports in recent months from every continent, from Asia, Eastern Europe and from Latin America. The WMA had recently issued a press release about the case of a surgeon murdered in a Boston hospital in the USA. There had also been a recent case in Germany. He added that this was a second line of violence in addition to the violence taking place in areas of armed conflict, about which the WMA was working with the International Committee of the Red Cross. He told the meeting that the WMA would need to step up its work on violence against doctors not connected with armed conflict.

Socio-Medical Affairs Committee

Elections

The proceedings began with a contested election for Chair of the Committee, following the decision of President Elect Sir Michael Marmot to stand down. Two candidates were nominated, Prof. Miguel Roberto Jorge (Brazilian Medical Association) and Dr. André Bernard (Canadian Medical Association). After both candidates addressed the meeting, the Committee elected Prof. Jorge, Associate Professor of Psychiatry and Chair of the Research Ethics Committee, at the Federal University of São Paulo.

Oral Report

Dr. Kloiber noted the increasing number of items on the SMAC agenda, reflecting the increased involvement of the WMA in socio-

medical issues. He again highlighted the key importance of addressing violence against health care personnel and facilities that occurred not only in situations of armed conflict, but also in civil situations. There were some instances, such as in Mexico, where violence was reaching armed conflict in a war on drug gangs between the state and the people, and doctors were being taken hostage and killed. He mentioned the WMA's commitments in this area, in particular within the Health Care in Danger Project, initiated by the ICRC. He called on national medical associations to cooperate with the Secretariat in sharing information on situations in their countries and to become further engaged in addressing this issue.

Health and the Environment

Dr. Shin, Chair of the Environmental Caucus, reported on the activities of the Caucus that had met the previous day. The meeting had focused on the forthcoming United Nations Climate Change Conference in Paris in early December 2015. The expected outcome of the event was to reach a new universal agreement on climate aiming at keeping global warming under 2°C. So far the draft negotiating text included a plan to completely phase out fossil fuel emissions. The text also for the first time included language on the health benefits of climate action.

Participants in the Caucus had discussed ways of influencing the process and have doctors' voices heard at the national and international level. Dr. Deau had presented a plan for the WMA in collaboration with the Société Française de Santé Publique (French Society of Public Health) and the European Public Health Association to target the French negotiating team, which would have a major role in the negotiations as it was the host country of the event.

Health Care in Danger

Prof. Vivienne Nathanson, Chair of the Work Group on Health Care in Danger, reported on the activities of the Group, which had met the previous day. She said Dr. B. Eshaya-Chauvin (ICRC) had updated the Group on the latest developments on the ICRC project. He said the project had been extended by two years. The Group discussed ways of translating into action the recommendations emerging from the project. Two actions were identified: that NMAs make contact with Red Crescent societies at the national level and that the WMA website include a defined area featuring activities developed by NMAs in this area.

The Group had examined a proposed revision of current WMA policy on Ethical Issues Concerning Patients with Mental Illness adopted in 2006. This revision would reflect doctors' concerns about recent policy developments in this area and reaffirm medical ethics principles in relation to patients in psychiatric centres. It was proposed that the revised version be submitted to the Committee for consideration.

Finally Prof. Nathanson referred to the draft toolkit the British Medical Association had developed for doctors going into situations of armed conflict for the first time. It was proposed that the

document, which would be an online publication only, be submitted to the Committee for consideration

Violence Against Women and Girls

Sir Michael Marmot reminded the Committee of the very successful WMA luncheon held in Geneva in May 2014 alongside the World Health Assembly that was dedicated to violence against women. He said that one in three women globally would experience physical or sexual violence. This was a huge public health issue. It was now proposed that the British Medical Association would host a discussion meeting of interested NMAs in London about how the WMA could continue working on this subject.

Social Determinants of Health

A report on the successful BMA symposium that was held in March organised jointly by the British Medical Association, the Canadian Medical Association and the Institute of Health Equity was given by Sir Michael Marmot. He updated the Committee on his plans for following up the conference. The first aim would be to continue strengthening global networks and building a social movement. The next would be to increase the visibility of the WMA Statement on Social Determinants of Health and build on the best evidence to produce a report. The third aim would be to develop educational tools for physicians to learn what they could do to tackle the Social Determinants of Health through online courses and training workshops.

Role of Physicians in Preventing the Trafficking with Minors and Illegal Adoptions

It was reported that experts on the topic had been consulted over recent months. However, having not received enough material or responses, it had so far not been possible to submit a paper to the Work Group. It was hoped that the Work Group would be in a position to submit a draft policy in October 2015.

It was decided to postpone further discussion until the next committee meeting in Moscow.

Proposed Statement on Physicians' Well-Being

A new draft Statement on Physicians' Well-Being was presented to the Committee by the Work Group. There was a brief debate about the need for doctors with disabilities to be enabled to return to work by making the necessary adaptions to the workplace. It was also argued that the paper should contain a more expanded section on physicians at risk from alcohol abuse. It was agreed to recommend to Council that the paper should be recirculated to NMAs for comments.

Revision of the WFME Standards for Post-Graduate Education and Continuing Professional Development

A report was received on the activities of the Work Group on Medical Education. The Group had made comments on revising

World Medical
Journal

the World Federation of Medical Education Standards for Post-Graduate Education. The revision was considered thorough and comprehensive.

Dr. Kloiber reported that he has been consulted by the WFME in a personal capacity on the revision of standards for Continuing Professional Development. He thanked those members that had sent comments on the proposed revision and he expected there would also be an open consultation with the opportunity for NMAs to submit further comments.

Statement on Providing Health Support to Street Children
New guidelines for National Medical Associations on providing health support to street children were set out in a revised Statement on Providing Health Support to Street Children.

The reworded Statement was introduced by the Conseil de l'Ordre National des Medecins. Delegates were told that the issue effected a large number of countries in all continents. It was difficult to quantify this phenomenon but it was a reality in large cities which children sought out after leaving their villages and towns. Many children were dumped in ships and sent across the sea to find a better future. They often travelled in groups and many died on the way. So how could doctors help them? A specific response was required. It was argued that the WMA had a duty to support local organisations working with these children and a duty to sensitise governments. It was urgent to work together with people working in the field and on the streets.

The Committee agreed that the proposed Statement should go to Council to be approved and forwarded to the General Assembly for approval and adoption.

Proposed revision of WMA Statement on Child Abuse and Neglect
It was decided that this proposed document should be withdrawn.

Statement on Chemical Weapons
The Committee considered the proposed revision of the WMA Statement on Chemical Weapons which deals with the appropriate use of riot control agents. It was proposed that the title of the paper be changed to Statement on Riot Control Agents.

This was approved and it was decided to send the document to Council for forwarding to the General Assembly for approval and adoption.

Proposed Declaration on Alcohol
The Australian Medical Association introduced a draft Declaration on Alcohol which recommends priority legal and regulatory measures as well as social policy interventions to address alcohol-related harm. The document was welcomed by a succession of speakers and after a brief debate it was agreed that with two minor amendments it should be sent to Council for forwarding to the General Assembly for approval and adoption.

Mobile Health
A proposed new Statement on Mobile Health was presented to the Committee by the German Medical Association. Delegates were told that National Medical Associations had commented on the paper and many of their suggestions had been included.

Speakers welcomed the document on what they said was a very important issue. There was one suggestion that the Statement should include more about secrecy and confidentiality. This led to a debate during which many speakers argued that the guidelines should remain as broad and as general as possible. The meeting decided to reorder the wording of the document and the Committee agreed that the proposed Statement, as amended, be approved by the Council and be forwarded to the General Assembly for approval and adoption.

World Day for Eliminating Violence Against Health Professionals
The Turkish Medical Association introduced a revised Statement on a World Day for Eliminating Violence against Health Professionals. This would be in memory of all those health professionals who had died in the course of duty, including the young Turkish surgeon Dr. Ersin Arslan who was stabbed by a relative of his patient while on duty in his hospital three years ago.

Several speakers questioned whether there was a need to adopt new policy and it was suggested that this proposal should be referred to the WMA Advocacy Group. Other speakers supported the idea for a special day. It was reported that the Conseil de l'Ordre National des Medecins had set up an observatory to monitor physician safety and a form had been devised for physicians to report physical and verbal attacks. In 2014 they had noted a major increase in incidents of violence. In France it was not as usual for physicians to report such attacks and therefore the known figures should be multiplied to get a correct picture of what was going on.

Speakers also said that one of the reasons for violence was the lack of resources for hospitals and doctors when it came to working conditions, and the public sometimes reacted violently as a consequence. Doctors felt helpless when confronted with this type of problem and often resorted to defensive medicine. It was said that in Mexico over four years more than 60 physicians had died at the hands of the drug trafficking industry. The Committee agreed that the proposed Statement be forwarded to the Advocacy Group for considering possible action.

Nuclear Weapons
The Committee considered the proposed Statement on Nuclear Weapons requesting all National Medical Associations to join the WMA in urging their respective governments to work to ban and eliminate nuclear weapons.

Members of the Committee welcomed the Statement and recommended that it be sent to Council for forwarding to the General Assembly for approval and adoption.

Statement on Destruction of Smallpox Virus Stockpiles
The Junior Doctors Network re-presented a revised proposed Statement on Destruction of Smallpox Virus Stockpiles. The JDN suggested setting up a Work Group to work on bringing forward a further paper at the next Committee meeting. This prompted a debate on the complexity of the issue. Several speakers said that although they supported the Statement they would prefer to wait for a pending report on the issue from the World Health Organisation scientists. At the end of the debate the Committee decided that the Statement should be postponed to the next Council meeting, so that members could review the WHO report when it was published.

Corporal Punishment of Children
A proposal was made to endorse a statement by international health organizations in support of Prohibition and Elimination of all Corporal Punishment of Children. The Committee considered the Statement and recommended Council that the Statement should be endorsed by the General Assembly.

Guidelines on Mass Media Appearances by Physicians
The Korean Medical Association introduced a draft Statement containing guidelines for physicians appearing in the media. Delegates were told that some physicians misused appearances on the mass media for marketing purposes misleading patients' trust in physicians. Speakers generally supported the document but said there needed to be some clarification about whether it related to all media appearances or only appearances related to marketing products. The Committee recommended that the guidelines be circulated among NMAs for comment.

Statement on Transgender People
The German Medical Association brought forward a proposed Statement on Transgender People as a new item of business. This referred to the crucial role played by physicians in advising and consulting with transgender people and their families about desired treatments. It was meant to serve as a guideline for patient-physician relations and to foster better training to enable physicians to increase their knowledge and sensitivity toward transgender people and the unique health issues they faced.

Speakers welcomed the paper, although one delegate expressed some concern that WMA policy might enter into conflict with national legislation. However another speaker referred to the saying 'Ethics trumps national law'. The issue of medical ethics and intersexuality was also raised and it was agreed that this was a separate topic and that a specific paper should be drafted on this. The Committee recommended that the Statement be circulated among constituent members for comments.

Statement on Vitamin D Insufficiency
A proposed Statement on Vitamin D Insufficiency was introduced by the Czech Medical Association. Delegates were told this was an important global health issue with an estimated one third of the population having insufficient vitamin D concentrations. It was argued that Vitamin D should now be considered essential for overall health and well-being and that attention should be focused on adequate action in populations at risk, such as young children, older people and pregnant women. The Committee recommended that the Statement be circulated among NMAs for comments.

Ageing
The Brazilian Medical Association proposed that a new policy on ageing should be drafted. In the last hundred years life expectancy had increased by more than 30 years worldwide. By 2050 the proportion of those over 60 years old was likely to increase from 11.9 per cent to more than 21 per cent, a total of over two billion people of whom 83 per cent were living in developing countries. There would be a consequential increase in diseases such as NCDs, cardiovascular disease, cancer, diabetes and chronic respiratory diseases. These diseases could be controlled but doctors were not sufficiently prepared for these challenges. It was time to begin considering guidelines on this issue. Committee members heard about the experience of several countries and supported the proposal for a policy. The Committee recommended that a Work Group be set up with the mandate to produce a draft policy on ageing.

Classification of 2005 Policies
The Committee considered the potential revision of SMAC policies for which it had been 10 years since adoption or revision.

It recommended that the following policies be rescinded and archived:
• the Council Resolution on Chronic Non-Communicable Disease
• the Council Resolution on the Healthcare Skills
• the Council Resolution on the Genocide in Darfur

It recommended that the following policies undergo a major revision:
• the Council Resolution on Implementation of the WHO Framework Convention for Tobacco Control
• the Statement on Boxing
• the Statement on Body Searches of Prisoners
• the Statement on Female Genital Mutilation

It recommended that following policies be reaffirmed:
• the Declaration of Hong Kong on the Abuse of the Elderly
• the Statement on Drug Substitution
• the Statement on Medical Liability Reform

Advocacy
Dr. André Bernard, Chair of the Advocacy Advisory Committee, reported on the activities of the Committee, including the use of social media and the need to develop guidelines on how social

World Medical
Journal

media and particularly twitter might fit into WMA's proceedings. He said a task group would be set up to draft some guidelines and bring them back to the next meeting of the Advocacy Committee. He also referred to the need to follow up the advocacy training session held at the Assembly in Durban and said that the Committee would explore how to advance the various initiatives discussed.

Finally he said the Committee was considering how advocacy fitted with the Association's policy making process. There was a need to have clear messaging and to consider what levers for advocacy communication were available for each piece of work produced by the WMA.

Resolution on Trade Agreements and Public Health
The British Medical Association submitted a proposed urgent Resolution on Trade Agreements and Public Health. It was reported that there were a large number of trade agreements moving towards finality. It was very difficult for individual NMAs to have a significant impact on these agreements because of the secrecy surrounding the negotiations. But it was possible to get concerns heard if it was handled collectively. The key issue was that the WMA wanted to protect the ability of governments to make decisions about promoting health and well-being and health equity in each country. It did not want to have those policies damaged or stopped because it was felt by some companies that their trading rights had been infringed and to use the new trade agreements to either stop the policy changes or even worse to make governments pay for damage to their trade. This could be policies as simple as plain packaging of cigarettes or something more complicated such as bringing in a new form of competition within the provision of health care.

What was needed was a process within the negotiations which said that these services introduced by governments for the public would be protected.

Speakers agreed that this was a particularly hot topic in Europe and in Asia. Health care was being endangered by these negotiations. It was also said that the Trans-Atlantic Trade and Investment Partnership might lead to the commercialization of education, particularly medical education. It was argued that Government medical services should not be hindered by a trade agreement. Following agreement on an amendment to the Resolution on securing services in the public interest, the Committee agreed to recommend that the proposed Resolution, as amended, be adopted by the Council.

Medical Ethics Committee

Dr. Heikki Pälve (Finnish Medical Association) was re-elected Chair of the Committee.

The Secretary General highlighted four current international topics of discussion within the committee's remit:
- The potential of health databases and biobanks for improving treatment, while at the same time facing the risk of undue commercial exploitation
- Reproductive health (surrogacy, and social freezing)
- End of life (physician assisted suicide and euthanasia)
- Medical confidentiality and reporting of medical findings following the recent German air crash
- Conscientious objection

On the issue of medical confidentiality, Dr. Kloiber said this had become an issue following the recent German air crash when the question arose about the pilot's medical fitness. This raised the issue of the obligation on physicians for mandatory reporting of medical fitness. So far the medical associations had reacted very appropriately, pointing out the value of medical confidentiality and the potential damage that could be done by lifting medical confidentiality and secrecy. Delegates were told that in South Africa and Holland physicians were either legally obliged to or allowed to release information about a patient if it was in the public interest. However in Australia, on the issue of the mandatory reporting for physicians who were unwell, it was unclear whether this was for all physicians when they were unwell or only when they were a danger. Although this was supposed to be a national law, certain states had not adopted that policy and doctors were going to these states to get their treatment.

Person Centred Medicine
The Committee received an oral report about the activities of the Work Group on Person Centred Medicine which had begun its work in 2012. It was reported that a white paper would be developed for the next meeting in October explaining the different existing concepts and their challenges. The language had evolved over the different definitions of person centred medicine. The white paper would address the difficulty in balancing the patient focus of medicine and public health and the physicians' perspective. A WMA policy would be developed out of this white paper.

This led to a brief debate in which speakers elaborated on the definition of person centred medicine and the reason why the name patient centred medicine was an incomplete term.

Health Databases and Biobanks
The activities of the Work Group on Health Databases and Biobanks were outlined to the Committee in an oral report. It had produced a draft policy paper and an open public consultation had been started, which would run until 5 June 2015. The Work Group invited all constituent members to contact experts in their country to comment on the draft paper or to send the WMA Secretariat suggestions of who to contact for this process. A small drafting group

World Medical
Journal

would incorporate the comments received at a drafting meeting in Berlin later this year. The Work Group then proposed to hold an open meeting with additional experts at the beginning of September 2015. The Danish Medical Association had offered to host this meeting in Copenhagen and the Work Group would report back at the next Council meeting in October.

Speakers emphasised that this was an ever changing topic and even when a paper was produced it would only be a work in progress. The topic was a core issue for the profession of patient confidentiality.

Inclusion of Medical Ethics and Human Rights in the Curriculum of Medical Schools
A report was given to the Committee on a major revision of the WMA Resolution on the Inclusion of Medical Ethics and Human Rights in the Curriculum of Medical Schools World-Wide. The aim was that the teaching of medical ethics and human rights at every medical school should be obligatory. It was also recommended that medical schools should ensure they had sufficient faculty skilled at teaching ethical enquiry and human rights to make courses sustainable. The revised draft argued that there was a clear need for physicians in training to understand the social and environmental context within which they would practice. Failures of individual physicians to recognize the ethical obligations they owed their patients and communities damaged the reputation of doctors throughout a country, and could have a global impact. The Committee recommended that the proposed revision be circulated to NMAs for comment.

Declaration of Geneva
The German Medical Association put forward a proposal that it should form an informal workgroup to explore the potential revision of the Declaration of Geneva. The Declaration was due to be revised in 2016 and the German Medical Association said it would like to express its support for re-exploring this crucial document from a 21st century perspective. This would be to ensure an appropriate level of careful preparedness for when the official revision process began. The informal work group would create an initial draft to serve as a basis for the final revision next year.

Some speakers agreed with this approach and said the Declaration needed a thorough revision. This led to a lengthy debate during which many other speakers questioned whether such a working group would be set up to revise the Declaration or simply to review whether the Declaration should be revised. Several speakers were doubtful whether the Declaration needed revising at all, although there was general agreement that any work group set up should be a formal and not an informal group.

The Committee concluded by recommending to the Council that a formal WMA Work Group be set up to review the Declaration of Geneva and come back to the Committee with recommendations.

Classification of 2005 Policies
The Committee considered the status of several policies which were adopted or last revised 10 years ago. It was proposed that the Statement on Physician-Assisted Suicide, rather than being automatically reaffirmed, should undergo a major revision. The Canadian Medical Association volunteered to do this. This prompted a brief debate when it was pointed out that in responses from NMAs, the majority opinion was that this policy should not be revised. On a vote, the Committee recommended that the Statement on Physician-Assisted Suicide and three other policies be reaffirmed:
- The Declaration of Lisbon on the Rights of the Patient
- The Declaration on Euthanasia
- The Resolution on Academic Sanctions or Boycotts

It recommended that the Statement on Non-discrimination in Professional Membership and Activities of Physicians be reaffirmed with a minor revision by the Secretariat and be submitted to the Committee and Council at the next meeting.

Human Rights
Clarisse Delorme, the WMA's Advocacy Advisor, reported on the WMA's work on human rights in Turkey, Saudi Arabia and elsewhere. She highlighted that the WHO and PAHO were developing a training curriculum for health professionals about care for women subjected to intimate partner violence and sexual violence. As a first step, a survey had been prepared with the aim of identifying the needs of health professionals in providing adequate care for women subjected to violence and she asked members to respond to the survey.

Council

On the final day of the conference, the Council meeting reconvened to hear reports back from the three Committee meetings.

Medical Ethics

Health Databases and Biobanks
The Council approved the Committee's recommendation to hold an open meeting as part of the public consultation on the Health Databases and Biobanks draft document. The meeting, at the beginning of September 2015, would include outside experts.

Physician-Assisted Suicide
A lengthy debate took place on the recommendation from the Committee to reaffirm the Statement on Physician-Assisted Suicide. Some speakers spoke strongly in favour of reviewing this policy in view of changing public opinion. It was argued that very few of the 111 national medical associations consulted on the issue had argued

World Medical
Journal

World Medical
Journal

for reaffirmation and that the WMA should not attempt to hush up debate. Delegates were reminded that there was already legislation on physician-assisted suicide in several countries. Other speakers, however, said it was not the WMA's role to follow public opinion and argued that discussion on this policy should not be re-opened. After further debate the Council voted to accept the recommendation of the Committee that the Statement on Physician-Assisted Suicide be reaffirmed and invited any NMA who wished a review to produce a paper.

Classification of 2005 Policies
The Council also approved the reaffirmation of the Declaration of Lisbon on the Rights of the Patient, the Declaration on Euthanasia and the Resolution on Academic Sanctions or Boycotts. It agreed that the Statement on Non-discrimination in Professional Membership and Activities of Physicians should undergo a minor revision by the Secretariat and be submitted to the Committee and Council at the next meeting.

Declaration of Geneva
The Council approved the Committee's recommendation to set up a Work Group to review the Declaration of Geneva.

Person Centered Medicine
The proposal for a white paper on person-centred medicine to be developed for the next meeting in October was agreed by the Council.

Inclusion of Medical Ethics and Human Rights in the Curriculum of Medical Schools
The Council approved the Committee's recommendation that the WMA Resolution on the Inclusion of Medical Ethics and Human Rights in the Curriculum of Medical Schools World-Wide be circulated to NMAs for comment.

Finance and planning committee

Dues Structure
The Council agreed that a recommendation should be sent to the General Assembly for setting a budget based on a new dues structure.

Future Meetings
It was agreed to recommend to the Assembly that Zambia be the venue for the April 2017 Council meeting. Following the successful H20 meeting in Melbourne last year, the Council agreed that a further meeting, H20+ Health Summit, be held in Istanbul, Turkey.

Financial Statement
The Financial Statement for 2014 was approved.

Business Development Group
The report of the Group was approved.

IFMSA Memorandum of Understanding
The Council approved a new Memorandum of Understanding between the WMA and the International Federation of Medical Students Associations.

Socio medical affairs committee

Social Determinants of Health
Sir Michael Marmot welcomed the offer from the Zambian Medical for Zambia to become part of the global movement in support of the Social Determinants of Health. He said that to become an active partner needed the support of the NMA, a university and the government.

Proposed Declaration on Alcohol
The Council considered the proposed Declaration on Alcohol which had been brought forward by the Australian Medical Association. It was proposed that there should be an amendment to the document's wording on reducing the impact of harmful alcohol consumption in at risk populations, such as children and young people, alcohol dependents, pregnant and breast-feeding women, 'and minority groups'. It was proposed that the words 'and minority groups' be deleted because in some countries minority groups did not see themselves at risk. This led to a lengthy debate and opposition from the Australian Medical Association on the grounds that it was imperative to highlight Australia's indigenous population. Two further amendments were proposed, one to reword the statement to read 'and some minority groups' and the other to 'vulnerable groups'. Other speakers argued that the document should not list particular groups, which led to a lively debate. The meeting eventually decided to amend the document to read 'Reduce the impact of harmful alcohol consumption in at risk populations' and the Council approved the Declaration as amended for forwarding to the General Assembly for approval and adoption.

Proposed Statement on Physicians' Well-Being
The Council agreed that the proposed Statement on Physicians' Well-Being be recirculated to NMAs for comments.

Statement on Providing Health Support to Street Children
The Council agreed that the proposed Statement on Providing Health Support to Street Children should be forwarded to the General Assembly for approval and adoption.

Statement on Riot Control Agents.
The Council agreed to send the renamed Statement on Riot Control Agents to the General Assembly for approval and adoption.

Mobile Health
The Council approved the proposed Statement on Mobile Health and agreed that it be forwarded to the General Assembly for approval and adoption.

World Day for Eliminating Violence Against Health Professionals
The Council agreed that the proposed Statement on a World Day for Eliminating Violence Against Health Professionals be forwarded to the Advocacy Group for considering possible action.

Nuclear Weapons
The proposed Statement on Nuclear Weapons was accepted and the Council agreed that it should be sent to the General Assembly for approval and adoption.

Ageing
The Council agreed that a Work Group be set up with the mandate to produce a draft policy on ageing.

Reclassification of Policies
The Council agreed that several 10-year-old SMAC policies should be reclassified as recommended by the Committee.

Resolution on Trade Agreements and Public Health
The Council approved the emergency Resolution on Trade Agreements and Public Health without debate.

World Health Assembly
Delegates heard a report on likely items to be discussed at the World Health Assembly agenda in May. This included the Millennium Development Goals, air pollution, anti-microbial resistance and the Social Determinants of Health. Side events included a WHPA Leadership Forum, the WHPA luncheon celebrating collaborative practice and the WMA luncheon on the topic of investments and their effects in health and healthcare. The Junior Doctors Network would also be having a side event with the International Committee of the Red Cross on the roles of education and training for preparing students and junior doctors for their possible roles for health care in danger.

Social Determinants of Health
The Council decided to upgrade the WMA Statement on the Social Determinants of Health. It was decided that the Statement should be named the Declaration of Oslo. The Council agreed to recommend this change to the General Assembly for adoption.

World Veterinary Association

The meeting concluded with an address from Dr. René Carlson, President of the World Veterinary Association. Dr. Carlson, a general private practitioner, said she wanted to share two very important messages with the WMA. The first was the common ground on which the two organisations could collaborate. These included zoonotic diseases, such as rabies. Rabies still killed around 60,000 humans every year primarily through exposure to unvaccinated and infected dogs. It killed more people every year than Ebola had killed over several decades. Yet rabies was almost one hundred per cent preventable. If the WMA and WVA worked together to strengthen health care systems, and advocate to the appropriate government agencies to establish policies that would protect their own citizens' lives, they could have a large impact on improving human and animal health just by eliminating dog-mediated human rabies.

A second area of collaboration was animal welfare, which directly affected human well-being in many cases. Healthy and well-cared for animals produced a safer, more nutritious, more abundant, and more economically profitable and affordable food supply.

A third area was good quality education which improved the knowledge and core competencies of veterinarians around the world as it did for physicians, and which benefited the global public good. Finally was pharmaceutical stewardship. According to the World Health Organization, antimicrobial resistance was the next major global public health threat. Physicians and veterinarians must be part of the solution and must work together to move toward keeping people and animals healthy in the first place, rather than depending on medicines to treat the consequences of poor management and illness, especially with excessive use of antimicrobials.

Her second message was that the WMA and the WVA were hosting the Global Conference on One Health in Madrid shortly, along with the Spanish Medical and Veterinary Associations. This meeting could be a real turning point and was receiving a lot of attention worldwide. This was their opportunity to move past the usual rhetoric and continuing justification that One Health issues were important from both their perspectives. But they must define how they could truly bridge the gap between the two professions to strengthen collaboration as these diseases became more prominent in the future.

Dr. Carlson concluded: 'The continuing good collaboration between our two organizations is both important and beneficial in many ways. People are intricately interconnected to animals as fellow members of the animal kingdom. We know why we should work together, so now how do we work together to more effectively protect and improve the health of humans, animals, and our planet? That is the question we want to answer next month in Madrid. For that to happen, it is important that both physicians and veterinarians attend that meeting. 'If we continue to work jointly on many of these common issues, we will become a working model for national and regional collaboration between our two professions leading to a much greater impact on improving human, animal, and environmental health'.

Mr. Nigel Duncan,
Public Relations Consultant, WMA

World Medical
Journal

WMA Council Resolution on Trade Agreements and Public Health

Adopted by the 200th WMA Council Session, Oslo, April 2015

Preamble

Trade agreements are sequelae of globalization and seek to promote trade liberalization. They can have a significant impact on the social determinants of health and thus on public health and the delivery of health care.

Trade agreements are designed to produce economic benefits. Negotiations should take account of their potential broad impact especially on health and ensure that health is not damaged by the pursuit of potential economic gain.

Trade agreements may have the ability to promote the health and wellbeing of all people, including by improving economic structures, if they are well constructed and protect the ability of governments to legislate, regulate and plan for health promotion, health care delivery and health equity, without interference.

Background

There have been many trade agreements negotiated in the past. New agreements under negotiation include the Trans Pacific Partnership (TPP), [1] Trans Atlantic Trade and Investment Partnership (TTIP)[2], the Trade in Services Agreement (TiSA) and the Comprehensive Economic and Trade Agreement (CETA [3].

These negotiations seek to establish a global governance framework for trade and are unprecedented in their size, scope and secrecy. A lack of transparency and the selective sharing of information with a limited set of stakeholders are anti-democratic.

Investor-state dispute settlement (ISDS) provides a mechanism for investors to bring claims against governments and seek compensation, operating outside existing systems of accountability and transparency. ISDS in smaller scale trade agreements has been used to challenge evidence-based public health laws including tobacco plain packaging. Inclusion of a broad ISDS mechanism could threaten public health actions designed to effect tobacco control, alcohol control, regulation of obesogenic foods and beverages, access to medicines, health care services, environmental protection/climate change and occupational/environmental health improvements. This especially in nations with limited access to resources.

Access to affordable medicines is critical to controlling the global burdens of communicable and non-communicable diseases. The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) established a set of common international rules governing the protection of intellectual property including the patenting of pharmaceuticals. TRIPS safeguards and flexibilities including compulsory licensing seek to ensure that patent protection does not supersede public health. [4].

TiSA may impact on eHealth provision by changing rules in licensing and telecoms. Its impact on the delivery of eHealth could be substantial and damage the delivery of comprehensive, effective, cost-effective efficient health care.

The WMA Statement on Patenting Medical Procedures states that patenting of diagnostic, therapeutic and surgical techniques is unethical and "poses serious risks to the effective practice of medicine by potentially limiting the availability of new procedures to patients."

The WMA Statement on Medical Workforce states that the WMA has recognized the need for investment in medical education and has called on governments to "… allocate sufficient financial resources for the education, training, development, recruitment and retention of physicians to meet the medical needs of the entire population…"

The WMA Declaration of Delhi on Health and Climate Change states that global climate change has had and will continue to have serious consequences for health and demands comprehensive action.

Recommendations

Therefore the WMA calls on national governments and national member associations to: Advocate for trade agreements that protect, promote and prioritize public health over commercial interests and ensure wide exclusions to secure services in the public interest, especially those impacting on individual and public health. This should include new modalities of health care provision including eHealth, Tele-Health, mHealth and uHealth.

Ensure trade agreements do not interfere with governments' ability to regulate health and health care, or to guarantee a right to health for all. Government action to protect and promote health should not be subject to challenge through an investor-state dispute settlement (ISDS) or similar mechanism.

Oppose any trade agreement provisions which would compromise access to health care services or medicines including but not limited to:
- Patenting (or patent enforcement) of diagnostic, therapeutic and surgical techniques;
- "Evergreening", or patent protection for minor modifications of existing drugs;
- Patent linkage or other patent term adjustments that serve as a barrier to generic entry into the market;
- Data exclusivity for biologics;
- Any effort to undermine TRIPS safeguards or restrict TRIPS flexibilities including compulsory licensing;
- Limits on clinical trial data transparency.

Oppose any trade agreement provision which would reduce public support for or facilitate commercialization of medical education.

Ensure trade agreements promote environmental protection and support efforts to reduce activities that cause climate change.

Call for transparency and openness in all trade agreement negotiations including public access to negotiating texts and meaningful opportunities for stakeholder engagement.

References

1. TPP negotiations currently include twelve parties: the United States, Canada, Mexico, Peru, Chile, Australia, New Zealand, Brunei, Singapore, Malaysia, Japan and Vietnam.
2. TTIP negotiations currently include the European Union and the United States.
3. CETA negotiations currently include the European Union and Canada.
4. See World Trade Organization, Declaration on TRIPS and Public Health ("Doha Declaration") (2001).

World Health Assembly Week

Geneva, May 18–26, 2015

The Sixty-eighth session of the World Health Assembly, the supreme decision-making body of the World Health Organisation, was held in Geneva May 18–26. As usual it attracted to the city an array of world leaders, health ministers, chief medical officers, global leaders from the health professions and countless lobbyists. More than 3000 delegates from the WHO's 194 Member States, including a large proportion of the world's health ministers, attended the Assembly. This year, the WMA leaders who were present were ably assisted by a particularly active group from the Junior Doctors Network (JDN), as well as by representatives from the International Federation of Medical Students Associations (IFMSA), with whom the WMA has recently signed a Memorandum of Understanding.

During the Assembly delegates discussed a host of topics, including antimicrobial resistance, Ebola, epilepsy, the International Health Regulations, malaria, nutrition, polio, public health, innovation, intellectual property, counterfeit medical products, surgical care and anaesthesia. They also reviewed progress reports on a wide range of issues such as adolescent health, immunization, noncommunicable diseases, women and health, and the WHO's response to severe, large-scale emergencies. This year, for the first time, the WHO provided a live feed from the Assembly to allow people to follow its proceedings remotely. Although the official Assembly dominated the week, it was the many side events and unofficial meetings held simultaneously that proved just as beneficial.

During the weekend before the Assembly opened, the World Health Professions Alliance held a successful Leadership Forum, bringing together representatives from the nursing, pharmaceutical, physical therapy, dental and medical associations. The Forum held two sessions, one devoted to discussing human resources as a health component in all WHO policies and the other concerning issues around ageing populations and the ageing health workforce.

Participants discussed the fact that health workforce implications were often largely ignored when public health goals were set, as was the case when targets were set for both the Millennium Development Goals and the Sustainable Development Goals. On the issue of ageing populations, the Forum considered the challenges that would be faced as the number of citizens over 65 increased to almost 30 per cent by 2060, while those over 80 would nearly triple. During this time, health and health care services would need to adapt to a growing demand.

At the same time as the WHPA Forum was meeting, the WMA's Junior Doctors Network was gathering to prepare its activities for the week. It organized a two-day workshop at the WMA office in Ferney-Voltaire which was attended by more than twenty JDN members from four continents. The focus of the workshop was on preparing JDN delegates for the Assembly.

JDN members met with Dr. Xavier Deau, WMA President, and Dr. Otmar Kloiber, WMA Secretary General. Highlights included discussions on the International Recruitment of Healthcare Personnel, influenza preparedness with Dr. Julia Seyer from the WMA, Emergency and Disaster Risk Reduction, Air Pollution and Climate Change, advocacy at the WMA and trade and health.

World Medical
Journal

World Medical
Journal

Dr. Caline Mattar, Chair of the JDN's Pre-WHA Organizing Committee, provided attendees with an introduction to the WHA and what to expect for the week to come. In addition, JDN members joined the International Federation of Medical Students' Associations' Pre-WHA workshop at the Graduate Institute in Geneva for a successful panel discussion and collaborative issue-based small group sessions on human resources for health, climate change and antimicrobial resistance. These sessions prepared participants for the Assembly and provided the opportunity to learn more about WHA agenda items.

Representatives from both the JDN and IFMSA helped to prepare the various interventions to be made by the WMA and the WHPA to the Assembly during the week.

On the Monday morning, while thousands of delegations gathered for the opening of the Assembly, leaders of the World Health Professions Alliance were meeting a group of African journalists to brief them on the events of the coming week. Organised by the World Health Editors Network and its founder Franklin Apfel, the gathering allowed the Presidents and CEOs of the five WHPA professions to talk to the African media about their priorities at the Assembly and their respective roles. Among the priorities mentioned by the WHPA leaders were childhood obesity, antimicrobial resistance, the social determinants of health and the problem of counterfeit medicines.

This was followed by a meeting between the WHPA leaders and representatives from the World Health Students Alliance and the International Federation of Medical Students Associations. This was a useful opportunity for student bodies to explain to the leaders of the global health professions the role and workings of their organizations.

Meanwhile, at the UN Palais des Nations the World Health Assembly was getting under way with an opening address from Angela Merkel, Chancellor of the Federal Republic of Germany. She said that the WHO was the only international organization that had universal political legitimacy on global health issues, but said she would like to see a new plan to deal with "catastrophes" like the recent Ebola outbreak. The outbreak had highlighted the critical need for urgent, collaborative action in emergencies, and the importance of having efficient structures in place.

She said that under Germany's presidency, the G7 would focus on fighting antimicrobial resistance and neglected tropical diseases. She emphasized the need for all countries to have strong health systems and highlighted the key role of health in sustainable development.

In the afternoon, WHO Director-General Dr. Margaret Chan spoke about the WHO's response to the Ebola outbreak and criticism that it should have reacted earlier. She admitted that the world was ill prepared to respond to the outbreak, but promised that the WHO would learn from what happened and would not be overwhelmed again. She outlined new plans to create a single new WHO programme for health emergencies, uniting outbreak and emergency resources across the three levels of the Organization. She said she had heard what the world expected from the WHO and she promised it would deliver.

The new programme would set up a new global health emergency workforce, as well as strengthening its own core and surge capacity of trained emergency response staff. Dr. Chan reiterated Chancellor Merkel's points about the importance of building resilient health systems and defeating antimicrobial resistance, citing the "spectre of a post-antibiotic era in which common infections will once again kill," and urging

delegates to adopt the draft global action plan on antimicrobial resistance on this year's Assembly agenda.

She also noted the need to ensure that the International Health Regulations, the world's legal instruments for outbreak preparedness and response, were effective. She urged the delegates to ready themselves for the post-2015 development agenda and to ensure that health received the attention, and the resources it needed

At lunchtime on the Monday the WHPA held its annual reception at the InterContinental Hotel when it presented the first of what will become an annual award for collaborative practice. This is a new award which aims to recognise an outstanding interprofessional team which has improved patients' health and promoted a collaborative approach to healthcare.

The winner of the award was the Thai Health Professional Alliance Against Tobacco (THPAAT). The award was presented by Dr. Carmen Peña, President of the World Dental Federation. She reminded the audience that the WHPA spoke for more than 26 million healthcare professionals through more than 600 national associations of healthcare professionals.

She went on: "WHPA works to improve global health and the quality of patient care and facilitates collaboration among the health professions and major stakeholders. For several years, our motto has been "Teaming up for better health" and clearly, this is the vision that guided our activities: we believe that healthcare professionals' impact is bigger when we are working in synergy."

In 2013 the WHPA adopted its joint statement on Interprofessional Collaborative Practice, defining collaborative practice as when multiple health workers from different professional backgrounds worked together with patients, families, carers and

communities to deliver the highest quality of care across settings.

Dr. Peña said that the Thai Health Professional Alliance Against Tobacco brought together more than 21 different associations, most being healthcare professionals bodies. It had initiated many projects covering different areas such as public promotion of smoking-free environment, education, and national health policy. It was also the pioneer in starting educational centres on tobacco hazard in 12 provinces of Thailand.

The WHPA award was received by Prof. Dr. Somsri Pausawasdi, President of the THPAAT and CEO of the Medical Association of Thailand. She said that THPAAT was established in 2005 under the vision of the Medical Association of Thailand and a time when the King of Thailand, Bhumibol Adulyadej, had expressed his wish to reduce the growing problems of cigarettes addiction in Thailand. The Medical Association of Thailand had responded to the King's wish and to the WHO campaign by initiating the THPAAT with the goal of recruiting a mixture of health professionals for an antismoking campaign.

She went on: "It was clear that the best way to accomplish our goals was to create a collaborative interprofessionals team and thus the Medical Association collaborated with the Thai Health Foundation and recruited four more organizations including the Pharmacy Council, the Nurses' Association, the Dental Association, and the Public Health association to join the team. Over the years, our network has expanded and we currently comprise 21 different health professional bodies under the support of the Thai government. The goals of our team are to promote a reduction in tobacco use and enforce the smoking free society as national health policy."

She said the Alliance's activities included the aim of improving the awareness of

tobacco hazards to all levels of education, creating a national network of 321 smoking cessation clinics in the network hospitals in over 77 provinces throughout the nation and conducting research in 85 projects.

Dr. Somsri Pausawasdi continued stating: "The ultimate goal of our campaign is to create a tobacco-free environment for the nation. We now have smoking-free environment in 47 universities, all hospitals and most of the pharmacy in the nation. We have implemented a larger graphic health warning on cigarette packages from 55% to 85% of the cover and actively involved in the national policy on tobacco control.

Finally, we have joined together with other organizations and many foundations to initiate "the National Alliance for Tobacco Free Thailand-NATFT" in 2013 to push forward the act of legislation on tobacco control for our nation. Currently, the NATFT has more than 1,400 members and 729 organizations. We are working towards the United Nations policy on non-communicable diseases (NCD) to decrease the tobacco consumption rate to 15% by the year 2025.

We do hope that our experience can inspire some tobacco control initiatives in many countries, and together we create a healthier world for us and for our next generations to come."

The following day it was the turn of the WMA to host its annual luncheon seminar at the Pavillon Gallatin, Chateau de Penthes. This year the theme was "Health Support to Street Children" and the speaker was WMA President Dr. Xavier Deau. He began by saying that the United Nations had estimated there could be around 150 million street children throughout the world. This was "a worldwide and growing phenomenon". He said physicians were often the first point of contact for these

children and should use their trusted positions and skills to reintegrate these children back into society. He also said that national medical associations had an important role to play in educating their members about what they could do to help.

Dr. Deau quoted WMA policy deriving from the Declaration of Ottawa on Child Health adopted in 1998. This stated that children needed to grow up in a place where they could thrive, spiritually, emotionally, physically and intellectually. This required a safe and secure environment, the opportunity for growth and development, health services when needed and monitoring and research for evidence-based continual improvement.

He said that assisting street children required a method, such as a multi professional team including health professionals, social workers, drivers, teachers and police. There had to be a medical and psycho-social approach and co-operation with local and governmental authorities.

He said that although there was no official definition of street children, all such children faced common issues – they suffered from a lack of cultural identity, they lived in the streets, they were no longer part of any social or family environment, they were organised in small societies and they hardly survived.

Finally, Dr. Deau said that at the WMA's General Assembly in Moscow delegates would consider a new Statement for adoption, calling for all street children to be provided with care and where necessary returned to a living environment. He said that remaining indifferent towards street children was not an option.

During the Assembly, the JDN and IFMSA delivered a number of interventions they had drafted on behalf of the WMA and/or World Health Professions Alliance. These were based on the WMA policy and

World Medical
Journal

in collaboration with the WMA staff and leadership and included interventions on antimicrobial drug resistance, polio, noncommunicable diseases, climate change and Ebola.

On the Global Action Plan on Antimicrobial Drug Resistance the WMA said that antimicrobial resistance was a threat to all countries without regard for geographical boundaries. A commitment was needed from both member states and the WHO to ensure financial sustainability to implement interventions in LMICs. The WMA's intervention emphasized that the Global Action Plan could not be separated from strengthening healthcare systems, building on lessons learned from the Ebola epidemic. A focus on access to primary care, availability of diagnostic labs including rapid diagnostic methods and surveillance systems was needed to fight the spread of resistant pathogens. The Assembly went on to agree on resolutions to improve access to affordable vaccines.

On polio eradication, the WMA said, it had condemned in the strongest terms the recent killing of five health care workers in Pakistan while providing polio immunization to the citizens of Pakistan. This tragedy had underscored the urgent need to ensure the protection of health care workers in conflict areas. It urged the WHO and member states to ensure adequate security for the healthcare workers to enable effective implementation of immunization protocols, to develop systems sensitive surveillance and immediate notification to the WHO of any detected poliovirus transmission and to implement adequate immunization training for health professionals. The WMA also wanted to see an increase in effective public awareness and education to prevent and dispel myths.

The IFMSA spoke about the need to tackle, prevent and control the global burden of noncommunicable diseases (NCDs), and reduce the worldwide mor-

bidity and mortality related to cardiovascular diseases, cancers, chronic respiratory diseases and diabetes, as well as reduce the four shared risk factors. It strongly recommended that interventions aimed at reducing the burden of NCDs must include addressing risk factors during childhood and adolescence.

The IFMSA also spoke on the issue of health in the post-2015 development agenda asking the WHO to focus its attention on supporting the development of realistic targets and clear indicators, which would remain a main topic of discussions in the following months. However, it referred to the absence of several important health areas, such as recognizing primary health coverage and the importance of health literacy, patient centered care and patient empowerment.

On the issue of the International Recruitment of Health Personnel, the IFMSA raised a concern that the current Code was mainly focused on regulating the migration of health personnel. It was important that member states tackled fundamental factors that caused the migration, such as poor or unsafe practice environments, poor education and excessive workload. Medical students were facing mental and physical strain, harming their practice, decreasing patient safety and exponentially increasing the costs of healthcare systems, and sometimes even leading to suicide. Health workers and students must be protected from violence, discrimination and exploitation in the workplace, and be allowed to operate within a positive practice environment that guaranteed occupational safety and health.

The Assembly passed several landmark resolutions on air pollution, on epilepsy and the next steps in finalizing the framework of engagement with non state actors.

Among the many side events attended by WMA representatives and JDN delegates

was one which the JDN co-hosted with the International Committee of the Red Cross on the Healthcare in Danger. This focused on the role of education and training in addressing healthcare in danger and featured a panel discussion including Dr. Ahmed Berzig (Head of Health Unit, ICRC), Prof. David Gordon (President, WFME), Dr. Bruce Eshaya-Chauvin (Medical Adviser, Healthcare in Danger) and Dr. Ahmet Murt (Chair, JDN).

At the end of the Assembly, IFMSA President Agostinho Sousa said: "The voices of medical students, and of youth more generally, have been recognized several times during this World Health Assembly. Addresses by Dr. Margaret Chan, Director General of the World Health Organisation, and references made by numerous Ministers of Health or their representatives, have shown the crucial role that future health professionals play in shaping the global health agenda."

The Assembly ended with thousands of delegates returning to their countries, feeling they had spent a worthwhile 10 days in Geneva.

Among the JDN representatives who spoke at the Assembly were:
Dr. Ahmet Murt (JDN Chair) speaking at the Assembly
Dr. Thorsten Hornung (JDN)
Dr. Kostas Roditis (JDN)
Dr. Mike Kalmusz-Elias (JDN)

Mr. Nigel Duncan,
Public Relations Consultant,
WMA

Global Epidemics. Industrialised Nations Must Develop Global Strategies to Counter Epidemics

Frank Ulrich Montgomery

In March 2014, the Ebola virus was identified as the force behind a wave of illness in Guinea. According to the latest figures from the WHO, there have been nearly 27,000 cases of Ebola reported in West Africa and 11,120 deaths. The approach taken in response to previous outbreaks of the Ebola virus (i.e. quarantining patients and monitoring their immediate social circles) proved to be inadequate in this case due to the mobility of the population and the prolonged duration of the disease. As a result, major cities in West Africa had to contend with large numbers of victims for the first time.

One particular problem facing the affected countries was the lack of appropriately trained professionals needed to contain the virus. In Germany, the German Medical Association teamed up with the Federal Ministry of Health and the German Red Cross, as well as the national professional associations of physicians, to promote volunteer efforts in the affected regions. On an international level, the World Medical As-

sociation and the Standing Committee of European Physicians (CPME) called for concrete measures to contain the virus. The necessary structures must be developed on a national and international level in order to combat epidemics more efficiently in the future. Providing protection for physicians before, during and after they engage in relief efforts is a key component of this. This protection must include, for example, guaranteed repatriation for physicians in the case of infection, access to comprehensive medical and psychological care upon their return, as well as sufficient life insurance.

In hindsight, we must concede that governments, the scientific community and relief organisations underestimated the severity of the Ebola crisis in West Africa for far too long. Although the situation appears to be largely under control and the Ebola epidemic is now only a passing reference in the media, we cannot fall back into the old habit of ignoring and avoiding the problem. The Ebola outbreak continues to demand the full attention of the international community.

At the same time, it demonstrates by example that in a globalised world, epidemics not only have the potential to wipe out entire populations, but also that they do not stop at national borders, nor are they confined to certain continents. We must work to develop effective global strategies to ensure that viruses can be contained early going forward. These strategies must incorporate elements of prevention, as well as rapid response facilities.

The Ebola outbreak made it clear that vaccines, a sensible tool for combating epidemics, were initially not developed by the pharmaceutical industry because the market was not deemed profitable enough. Although

there are promising trials in progress, there is still no approved vaccine available. The World Medical Association and the CPME have demanded that adequate funding finally be made available for immunization programmes and for vaccine research and development. The Declaration of Helsinki can and must serve as the basis for these developments. But this call from the European and global medical communities should not be limited to research focused on Ebola vaccines. As a matter of principle, if there is a lack of incentives for conducting research and if the development of diagnostic tests, therapies and vaccines is not being pursued rigorously, governments are called upon to take effective measures in this regard, starting with providing access to adequate financial resources.

Above and beyond research into vaccines, the international community and, in particular, the industrialised world are called upon to provide the resources needed to develop the appropriate infrastructure to ensure the early containment of epidemics. The German government recently announced that it will earmark 200 million euros in funding to support the development of healthcare systems in the countries affected by this crisis. The administration also plans to organise a team of physicians and other medical personnel that could be deployed anywhere in the world within three to five days, and to provide additional medical supplies, like field hospitals and mobile laboratories. However, a breakthrough will only be possible if the G7 countries agree to coordinate their activities effectively on an international level and to commit sufficient financial resources. It is therefore a welcome sign that neglected diseases and diseases associated with poverty, as well as Ebola, were addressed at this year's G7 summit in Germany.

World Medical
Journal

West Africa's Ebola epidemic demonstrated the consequences of uncontrolled outbreaks of infectious disease. For this reason, this year's 118th German Medical Assembly in Frankfurt deliberated the most pressing issues relating to civil protection under the heading "Medicine in times of global epidemics". The discussion was initiated by presentations meant to shed light on the domestic and international aspects of battling global epidemics. Dr. Tankred Stöbe, chairman of the board of the German chapter of Médecins Sans Frontières (Doctors Without Borders), drew attention to the preconditions and challenges of establishing a preventive medical infrastructure in regions affected by epidemics. He reported on practical measures taken to stem the disease, which included educating the population and increasing public awareness about infectious disease and safe burials, as well as efforts to strengthen countries affected by epidemics. From the perspective of an international non-governmental organisation, it is also essential to address what is needed to protect and safeguard medical and non-medical personnel and their employment rights during their deployment abroad.

Following this talk, Prof. Dr. René Gottschalk, Director of the Public Health Office of the city of Frankfurt/Main, discussed the domestic and European aspects of the fight against global epidemics. Prof. Dr. Gottschalk addressed options for regional, national and European crisis intervention, as well as the limits of each. He also presented early warning and response systems for monitoring and controlling the spread of communicable diseases and options for improving risk and crisis communication.

The level of engagement with which the parliament of the German medical profession dealt with this issue and formulated political demands through a very lively discussion is noteworthy. In the battle against global epidemics like Ebola, the 118th German Medical Assembly called for Germany, Europe and the international community to promote the research of infectious disease and the development and implementation of diagnostic tests, therapies and vaccines. One resolution of the Medical Assembly expressed that "government funding must be made available for the development and provision of pharmaceuticals and vaccines to curb epidemics and to finance comprehensive vaccination programmes". The parliament of physicians also called upon drug manufacturers to conduct targeted research, even at low profit margins, in order to develop the pertinent drugs and vaccines.

Financial resources to combat epidemics and to rebuild healthcare systems and public life in the wake of an epidemic should be allocated to the affected countries in the form of a fund, according to the Medical Assembly. This fund should be financed by the United Nations, the World Bank, the International Monetary Fund and the European Union, among others. The Medical Assembly also demanded essential protection for medical and non-medical personnel during their deployment abroad, as well as approved leaves of absence and job security for physicians who volunteer to participate in aid missions.

The Medical Assembly also called upon the German federal government to establish a state-funded and organised medical relief organisation to provide emergency medical relief with specially trained health professionals in crisis areas. This would make it possible for doctors and other health professionals to be deployed faster by simplifying the process of obtaining approved leaves of absence from their employers and providing social protection. The Ebola epidemic in West Africa demonstrated that the systems in place for gathering the appropriate medical personnel to engage in crisis situations were inadequate. According to the Medical Assembly, a state-organised medical relief organisation must be created to work with non-governmental organisations to facilitate prompt delivery of healthcare in crisis areas.

Prof. Dr. Frank Ulrich Montgomery,
President of the German
Medical Association,
Vice-Chairperson of the WMA Council
E-mail: international@baek.de

WMA Roles for Climate Action

The 21st Conference of the Parties (COP21) to the UN Framework Convention on Climate Change (UNFCC) will be held in Paris for two weeks from November 30 to December 11, 2015. COP21 is practically the last opportunity to reach an agreement on a plan where all nations would participate to achieve substantive reduction in greenhouse gas emissions to limit global warming within 2 °C. That is why some are even calling it the "historic two weeks."

Due to the earth's feed-back mechanism, any change, once gaining enough momentum in a certain direction, becomes extremely difficult to reverse. Even if all emission of greenhouse gas is stopped now, it would still be difficult to completely prevent global warming. The goal of limiting global warming to 2 °C is the minimum measure necessary to prevent the worst case scenario.

Health needs to be given the greatest priority in efforts to minimize climate change. Climate change causes change in temperature, wind, and precipitation with profound effects on all natural systems. These, in turn, have effects on the health, safety, and livelihoods of people-especially the poor.

Dong Chun Shin

ture, wind, and precipitation with profound effects on all natural systems. These, in turn, have effects on the health, safety, and livelihoods of people-especially the poor.

We have already seen previews of the health impact that lies ahead if extreme weather events continue to increase. Heat waves like the one that hit Chicago in 1995, killing some 750 people and hospitalized thousands, and the 2003 European heat wave, killing 21,000 to 35,000 people in five countries, are becoming more common.

But even more subtle, gradual climatic change can still harm human health. Elevated carbon dioxide levels promote the growth and sporulation of some soil fungi, and diesel particles help deliver these aeroallergens deeper into our alveoli and present them to immune cells along the way.

Mosquitoes, which can carry many diseases, are very sensitive to temperature changes. Warming of their environment – even within its viable range – boosts their rates of reproduction and prolongs their breeding season, and shortens the maturation period for the microbes they disperse. Extremely wet weather may bring its own share of ills. Floods are frequently followed by disease clusters. Major coastal storms can also trigger harmful algal blooms ("red tides"), which can be toxic, help to create hypoxic "dead zones" in gulfs and bays, and harbor pathogens.

These are only a few examples of what is in store. The impact of climate change comes in many shapes and sizes from not only damage from increase in harmful substances or chemicals in the air but also the increase in prevalence of various contagious diseases, which are all major public health challenges. In particular, the detrimental effects of climate change on health are far more serious among the more vulnerable population such as children, the elderly and people in less developed countries.

WMA has continuously expressed its concern over the health impact by climate change, and has worked to raise awareness regarding the benefits of putting health in the center of the climate change agenda. As a way to tackle the issue in the WMA, the Environment Caucus was organized. It aims to exchange opinions among WMA members and related bodies regarding WMA future activities related with health and environment.

The main activity of the Environmental Caucus is sharing global trends and conference information regarding environment and identifying common topics of interest and to discuss follow-up measures. It encourages free exchange of opinions by adopting an informal setting. Major themes discussed at the Environmental Caucus with regards to the direction of future WMA activities include the role of physicians and of constituent members in greenhouse gas reduction, promoting research on the health co-benefits of countering climate change and expansion of green hospitals and clinics.

At the last meeting of the Environmental Caucus held in Oslo, Norway, during the 200th Council Session of WMA, participants all agreed on the importance of forming a coordinated voice representing the entire medical community in anticipation of COP 21 and shared ideas about what we can do.

The discussion can be summarized into the following approaches:
1. Recognition of co-benefits of dealing with health issues in climate action
2. Getting involved in liaising with each government's negotiation representatives
3. Active media coverages and journal exposes
4. Collaboration with other professional organizations and NGOs on joint initiatives on the issue
5. Promoting awareness of members on green policies for daily operation of health facilities.

As described by LANCET, climate change is "the greatest global health challenge of the 21st century." This is a battle cry for all physicians to take on a more active role in tacking climate change, and for us to feel a greater sense of responsibility starting from our everyday lives and also at a national level through each NMA, and at an international level through the WMA.

Much is at stake as COP21 approaches, and hopes are high that we will be able to deliver our voices effectively so that COP21 will find a meaningful framework to prevent and resolve health problems caused by climate change.

Dong Chun Shin, MD, PhD,
Chair, Environment Caucus, WMA
Chair, Finance and Planning
Committee, WMA
Prof., Dept. of Preventive Medicine
Yonsei Univ. College of Medicine
E-mail: dshin5@yuhs.ac; intl@kma.org

World Medical
Journal

The Art and Heart of Medicine

James Appleyard

The Art of the conversation between a physician and their'patien; is at the heart of medical practice [1]. It is a dialogue between a person seeking help and a physician who possesses the relevant medical knowledge and skills This patient/physician relationship is founded both on service and on trust within which two way communication is key. The physician's professional service to their patient must be conducted within a professional code of ethics which has become enshrined within the World Medical Associations International Code of Medical Ethics 1949 et seq.

This statement includes the requirement that "a physician shall be dedicated to providing competent medical service in full professional and moral independence with compassion and respect for human dignity'.

Trust

Trust can only be assured if the patient believes that the physician respects them as individuals, will act only in their best interests, avoid 'harms' where possible, be truthful and be treated equally with others according to their needs.

The physician also has a duty of care to their patients and should keep their medical records secret within applicable national laws. These ethical principles need to become 'internalized' as the individual physician's 'professional' conscience and act as a compass through the complex scientific, medical, psychological, social, cultural and spiritual scene. These principles relate both to the individual health care professional as a basis for the 'trust' given by the patient as a person to them and to society in general where they form part of the essential 'contract' between the health care professions and society allowing the physician to work as an independent clinician whose primary duty is to their patient. Only in this 'trusting' culture will a 'patient's inner worries and secrets be gradually shared with their physician".

A person's narrative

A patient's own story is the key to the physician finding out what may be right and what may be wrong during a professional consultation. A narrative approach encompasses an open awareness of health and disease within a storied structure from which the meaning and purpose in both an illness and the experience of recovery emerge. Diagnostic 'labels' become secondary to the life of the individual person. A story is recounted in a complicated narrative of illness told in words, silences, gestures, physical observations, overlain not only by the objective findings but also with the fears, hopes and implications associated with it [2].

The narration is a therapeutic central act because to find the words to contain the disorder and its attendant worries gives shape to and control over the uncertainties of the illness. As the physician listens to the patient, he or she follows the narrative thread of the story in all its existential, cultural, familial, biological, social, psychological and spiritual dimensions.

The act of listening, so essential to the process, enlists the physician's interior resources – memories, association, curiosities, creativity, interpretive powers and allusions to other stories by the person and others to identify meaning. Only then the physician can hear and confront the person's narrative questions wWhat is wrong with me? Why is this happening to me? And what will be the result?" [3]

Listening to stories of illness and recognizing that there are often no clear answers to patients' narrative questions demand the courage and generosity to tolerate and to bear witness to unfair losses and random tragedies [4]. Accomplishing such acts of witnessing allows the physician to proceed to his or her more recognizably clinical narrative tasks: to establish a therapeutic alliance, to generate and proceed through a differential diagnosis, to interpret physical findings and laboratory reports correctly, to experience and convey empathy for the patient's experience [5], and, as a result of all these, to engage the patient for effective care.

If the physician cannot perform these narrative tasks, the patient might not tell the whole story, might not ask the most frightening questions, and might not feel heard [6].

The resultant diagnostic workup might be unfocused and therefore more expensive than need be, the correct diagnosis might be missed, the clinical care might be marked by noncompliance and the search for another opinion, and the therapeutic relationship might be shallow and ineffective. The narrative is absorbing. It engages the listening physician and invites an interpretation. It gives him or her the experience of "living through", not simply "knowledge abou" the characters and events in the story.

The erosion of humanistic medicine

Where this professional space is taken over by an authoritarian organization not only is this patient/physician relationship seriously damaged but also the independent spirit of enquiry that drives advances in medicine is distorted [7]. As the cost of health care has escalated, additional pressures on this 'professional' space by Healthcare providers, Insurance Companies and Governments are occurring which are distorting the patient/physician discourse [8].

During the professional consultation, eliciting a 'history' from a patient is one of the least perfected and most neglected clinical skills despite a wealth of research and time spent in undergraduate training [9]. Yet for the great majority of 'patient' the narrative history is the most important and most revealing part of any personal health data base. Too often a computer generated form is completed with the minimum of narrative followed by a cursory clinical examination and a huge array of expensive investigations from which a diagnosis is expected to emerge. It is important to realize that not only is the patient presenting with symptoms of a possible illness but experiencing the effect of all of their life's events in their biological, social, mental, psychological, cultural and spiritual dimensions.

A person centered approach

Those starting out on a medical career may need a format to act as guidance. The person centered Integrated Diagnostic model is being developed and refined to meet this need. It proposes the whole person in context as the Centre and goal of clinical care and public health [10]. This encourages a more flexible and conversational style.

It is only through this open style interactive conversation and questioning the physician sorts, extracts, subtracts and adds information into a meaningful format. As rapport is established elements of the patient's temperament and personality become more apparent and the patient's reaction to each question can be noted.

Very often the physician will have a very good idea of the likely diagnosis of the patient's problem within the first two minutes through his or her experienced pattern recognition of the common disease processes. The physician will search for additional clues – information that will aid in the solution of the person's problem. There is then a tendency to move to gather more specific information to exclude other possibilities and confirm the presumptive diagnosis. The danger is that at this stage other pertinent information may not be given by the patient or sought by the physician. Some physicians may avoid eliciting multiple concerns due to the fear of extending the encounter when time is limited.

However, unexpressed patient concerns may lead to a prolonged investigation of a concern hypothesized to be the "chief complaint" but which in reality was the second most important problem. Repeated invitations to express additional concerns early in the consultation may enhance the efficiency of the interview by decreasing late-arising concerns, allowing the physician and patient to prioritize problems at the outset, to make the best use of their time and minimize implicit assumptions of what the patient wants to discuss. Patients may defer emotionally laden topics until the trustworthiness of the physician is better known or until the physician brings up the topic [11].

The tendency of even experienced family physicians not to seek the patient's complete agenda is similar to the finding of Beckman and Frankel 15 years ago. Despite concern that a patient-centered approach will take more time, the study further reinforces that exploring all of the patient's concerns does not decrease efficiency. Using a simple opening empathic enquiry, such as "What concerns do you have?," then asking "Anything else?" repeatedly until a complete agenda has been identified appears to take 6 seconds longer than interviews in which the patient's agenda is interrupted. Agenda setting is a teachable and learnable skill that deserves emphasis and reinforcement.

A few verbal affective remarks can be effective and this is not necessarily time consuming [12]: In one study it took only 38 seconds to make a difference! The affective statements that caused this reduction were related to emphasizing being there for the person – the sense of a physician's duty of care – providing reassurance of continuing medical support. These points have been defined as fundamental for effective patient-physician communication. Whilst one of the most difficult tasks for physicians is to convey bad news, physicians who are emotionally supportive can influence patients' emotional functioning with little effort and time [13].

Affective communication may have the power to elicit beneficial effects in clinical encounters as it enables patients to adjust better to the emotional and cognitive impact of medical information [14]. Indirect effects might also be present. When patients remember more about treatment procedures and their consequences, this may affect adherence to treatment or medication regimen. A few affective statements can have a large impact on patients' anxiety, uncertainty and recall. Affective communication allows physicians to temper patients' emotional responses and improve their ability to remember medical information.

Conclusion

A person-centered approach involves a renewal of our ethical commitment both to each person as a patient and to society as a whole within a wide biomedical, psychological, social, cultural and spiritual framework. It attends to both ill health and positive health and focusds on the diagnostic

World Medical Journal

communication between the patient and physician. There is shared understanding and decision making with prevention and health promotion as shared commitments and the promotion of partnerships at all levels.

References

1. Mezzich J.E. (2011) Building Peron Centered medicine through dialogue and partnerships. *International Journal of Person Centered medicine,(),* 10–13
2. Genette G. (1980) *Narrative Discourse: An Essay in Method.* Lewin J., trans. Ithaca, NY: Cornell University Pres
3. Greenhalgh T. Hurwitz. B. (1999)"Narrative based medicine: Why study narrative" *BMJ 318,*:48–50)DeSalvo L. (1999) *Writing as a Way of Healing: How Telling Our Stories Transforms Our Lives.* San Francisco, Calif: Harpe
4. Laine C., Davidoff F. (1996) Patient-centered medicine: a professional evolution. *JAMA; 27:,*152-156
5. Charon R. (2001) Narrative medicine: form, function, and ethics. *Ann Intern Med;134,*:83-87.
6. Acare G., Pulmarski B., Acare (2015). Lost in translation *WMJ 61,* 28-30
7. Lown B. (1996) *The Lost Art of Healing.* Houghton
8. Cutler P. (1998) *From data to diagnosis.* 3rd En. Lippincott Williams and Wilkins
9. Salloum I,M, Mezzich J.E. (2011) Conceptual appraisal of the person centered Integrative Diagnostic Model. *International Journal of Person Centered medicine 11,* 39-42
10. Epstein R.M., Morse D.S., Frankel R.M., Frarey L., Anderson K., Beckman H.B. (1998) Awkward moments in patient-physician communication about HIV risk. *Ann Intern Med.12:,*435-442
11. Marvel M.K, Epstein R. M., Flowers K.. Beckman H. B, (1999) Soliciting the Patient's Agenda Have We Improved? *JAMA 281*:283-287
12. van Osc, M., Sep M., van Vliet,L. M., van Dulme, S., Bensin, J. M. (2014)
13. *Reducing patients' anxiety and uncertainty, and improving recall in bad news consultations. The impact of affective communication.* In press
14. Street R. L. J., Makoul G., Neeraj K. A., Epstein R.M. (2009). How does communication heal? Pathways linking clinician-patient communication to health outcomes. *Patient education and counseling, 74,* 295-301

James Appleyard MD FRCP,
President, International College of Person centered medicine Thimble Hall, Blean Common Kent CT2 9JJ UK
E-mail: jimappleyard2510@aol.com

One Health: A Concept for the 21st Century

One Health is a new term, but an ancient concept that recognizes the inherent links between human, animal, and environmental health. Humans and animals cannot be healthy if the environment in which they live is sick. The One Health concept seeks to increase communication and collaboration between human, animal, and environmental health professionals.

The One Health concept is important for many reasons. Zoonotic disease risks from wildlife, livestock, and pets cannot be adequately addressed without meaningful collaboration and cooperation between veterinarians and physicians. Microbes do not necessarily recognize the differences between species and could infect across them if given the right conditions. Indeed, approximately 75 percent of emerging infectious diseases and approximately 60 percent of all human pathogens are zoonotic in origin [1].

Some of the greatest discoveries in the history of medicine and public health were made at the intersection between human and animal health. For example, Dr. Edward Jenner, an apprentice surgeon, learned from dairymaids that they were immune from smallpox because they had had cowpox. He applied this concept to the practice of variolation and developed the word "vaccination" from the Latin word "vacca" meaning cow [2]. Approximately two centuries later, Dr. Jenner's vaccine was used to eradicate smallpox from global human populations [3].

Drs. Louis Pasteur and Robert Koch, a French chemist who studied chicken cholera and a German physician who studied anthrax, respectively, independently developed the germ theory of disease. Dr. Pasteur discovered the theory of immunity and developed the world's first rabies vaccine, and Dr. Koch developed "Koch's Postulates" for establishing the infectious causations of disease [4, 5].

Drs. Theobald Smith and Frederick L. Kilbourne, a physician and veterinarian team, respectively, discovered that an arthropod, in this case a tick, could transmit cattle fever from animal to animal [6]. This monu-

Laura H. Kahn

mental discovery stage for the widespread recognition that other arthropods could serve as vectors for zoonotic diseases, such as mosquitoes transmitting yellow fever.

As the twentieth century progressed, scientific knowledge exploded, and medicine became increasingly specialized. Collaboration between medicine and veterinary medicine waned, but the challenges of the twenty-first century demand that these two disciplines re-establish ties and begin working collaboratively again. Increasing global populations, widespread deforestation and environmental destruction, intensive agriculture, global trade and travel, and likely climate change will adversely impact life on the planet [7]. Zoonotic diseases such as HIV/AIDS, West Nile virus, SARS, MERS, and Ebola that cross species barriers require increased communication and collaboration between the health professions. Occasionally, animals become infected before humans and should serve as important sentinels for looming epidemics in human populations.

For people who live with chronic immunosuppression such as organ transplant recipients or people taking immunosuppressive medications, the risk of zoonotic disease transmission becomes much greater than for the general population. Grant and Olsen found that assessing zoonotic disease risks in this vulnerable population often gets ignored because physicians are not familiar with the diseases while veterinarians defer to physicians for human health care [8]. Physicians rarely ask their patients about pet ownership or animal exposures, yet pet-associated infections are common and can be deadly [9].

Beyond zoonoses, comparative medicine is the study of disease processes such as asthma, diabetes, and cancer across species. Discoveries in veterinary medicine can benefit human medicine and vice versa. As with humans, an increase in canine and feline obesity has led to an increase in diabetes [10]. Studying disease similarities and differences between species could shed important new information on disease progression, treatment, and control. In another example, a canine vaccine for oral melanoma was the first therapeutic vaccine approved for the use in either animals or humans [11]. An important benefit to studying diseases in animals is that they do not experience the placebo effect, so improvements resulting from novel treatments demonstrate actual benefits that warrant further study in humans.

Animals have served as sentinels for toxic environmental contamination. In the mid-1950's, dancing cats of Minamata Bay, Japan were exhibiting mercury poisoning from industrial pollution [12]. Humans began suffering from mercury poisoning as well [13]. Pets and other small animals can develop symptoms of lead poisoning from very small doses and should serve as sentinels for potential human cases if they become sick [14, 15].

Physicians and veterinarians have much to learn and benefit from each other. Recently, the World Medical Association and the World Veterinary Association held a joint global conference on One Health. Information was shared, and collegial relationships formed. These two professions are complementary and synergistic, and ideally, if they re-forge old ties, they will make great new discoveries that will benefit the health of all species as the twenty-first century progresses.

References

1. Taylor LH, Latham SM, Woolhouse ME. "*Risk Factors for Human Disease Emergence.*" Philos Trans R Soc Lond B Biol Sci July 29, 2001. http://rstb.royalsocietypublishing.org/content/356/1411/983
2. Riedel S. "*Edward Jenner and the history of smallpox and vaccination.*" BUMC Proceedings. 2005; 18: 21–25. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1200696/
3. Deria A, Jezek Z, Markvart K, et al. "*The world's last endemic case of smallpox: surveillance and containment measures.*" Bull World Health Organization. 1980; 58: 279-283. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2395794/
4. Smith K.A. "*Louis Pasteur, the Father of Immunology?*" Frontiers in Immunology. 2012; 3: 68. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3342039/
5. Committee to Update Science, Medicine, and Animals, National Research Council. "*Science, Medicine, and Animals.*" 2004. National Academies Press. Washington DC. Page 7. http://www.ncbi.nlm.nih.gov/books/NBK24656/pdf/Bookshelf_NBK24656.pdf
6. Assadian O, Stanek G. "*Theobald Smith—the discoverer of ticks as vectors of disease.*" Wien Klin Wochenschr. 2002 114 (13-14): 479-81. http://www.ncbi.nlm.nih.gov/pubmed/12422586
7. Morse SS. "*Factors in the Emergence of Infectious Diseases.*" Emerging Infectious Diseases. 1995; 1: 7-15. http://wwwnc.cdc.gov/eid/article/1/1/95-0102_article
8. Grant S, Olsen CW. "*Preventing Zoonotic Diseases in Immunocompromised Persons: The Role of Physicians and Veterinarians.*" Emerging Infectious Diseases. 1999; 5: 159-163. http://wwwnc.cdc.gov/eid/article/5/1/99-0121_article
9. Rabinowitz PM, Gordon Z, Odofin L. "*Pet-Related Infections.*" 2007; 76: 1314-1322. http://www.aafp.org/afp/2007/1101/p1314.html
10. Hoenig M. "*Comparative Aspects of Human, Canine, and Feline Obesity and Factors Predicting Progression to Diabetes.*" Vet Sci. 2014; 1: 121-135. http://www.mdpi.com/2306-7381/1/2/121
11. Heflin M. "*Canine Melanoma Vaccine Gets Conditional OK.*" Veterinary Practice News. May 2007. http://www.veterinarypracticenews.com/April-2009/Canine-Melanoma-Vaccine-Gets-Conditional-OK/
12. Aronson S. "*The Dancing Cats of Minamata Bay.*" Medicine and Health Rhode Island. 2005; 88.7: 209. http://search.proquest.com/docview/195779436/fulltext/2FCF9AF281834074PQ/1?accountid=13314
13. Eto K, Marumoto M, Takeya M. "*The pathology of methylmercury poisoning (Minamata disease).*" Neuropathology 2010; 30: 471-479. http://onlinelibrary.wiley.com/store/10.1111/j.1440-1789.2010.01119.x/asset/j.1440-1789.2010.01119.x.pdf?v=1&t=iao5jp4n&s=bf561531ab8e6609a20ea4d31ebeb4a45513790a
14. Newman AA. "*For Small Animals, a Fleck is a Lot.*" New York Times. December 22, 2007. http://www.nytimes.com/2007/12/22/business/22petside.html
15. Morgan RV. "*Lead poisoning in small companion animals: an update (1987–1992).*" Vet Hum Toxicology 1994; 36: 18-22.

Laura H. Kahn, MD, MPH, MPP,
Research Scholar,
Program on Science and Global Security,
Woodrow Wilson School of Public and International Affairs,
Princeton University
E-mail: lkahn@princeton.edu

World Medical
Journal

Pros and Cons of the Over-the-counter Sales of Antimicrobials

Carl Llor

Ana Moragas

Most antimicrobial use is probably inappropriate. It has been estimated that up to 50% of human antibiotic use and up to 80% of veterinary antibiotic use could be eliminated without serious consequences [1]. The inappropriate use of these drugs increases the risk of selection of resistant bacteria and may contribute to antibiotic resistance [2]. Antibiotic resistance has become a global health problem and is responsible for significant morbidity and mortality and, therefore, restriction of antibiotic use and marketing regulations are among many important strategies to control this problem [3,4].

The sale of antibiotics and other antimicrobial medicines without prescription remains widespread, with many countries lacking standard treatment guidelines; thereby increasing the potential for overuse of antimicrobial medicines by the public and medical professionals [5]. In general, governments support policies on the prudent use of antimicrobials in order to control resistance and recommend control measures to support careful use by encouraging doctors and pharmacists to promote the appropriate use of antimicrobials. However, implementation has generally been weak in many countries, and the prevalence of bacterial resistance continues to increase since antimicrobial resistant bacteria are common in communities where over-the-counter policy is still available.

Prevalence

The prevalence of over-the-counter sale of antibiotics varies across countries, being common outside Northern Europe and North America [5]. The percentage of non-prescription access to antimicrobials is often underestimated, and also depends on the methodology used to estimate it. In 2013, the European Commission published a questionnaire-based study (Eurobarometer), carried out in 28 European countries, including 27,680 respondents, in which 35% admitted having taken at least one dose of antibiotic in the previous 12 months [6]. The large majority of those who had used antibiotics during the time covered by the survey had got them from a healthcare provider, but 3% of users reported to have obtained them without prescription and 2% more stated that they used the leftovers from a previous course. However, when more reliable methods are used the results are much higher. One of the most reliable ways to estimate how frequent the sale of antibiotics is includes simulated-client-method pharmacy studies in which actors simulating certain infectious diseases manage to obtain antibiotics at community pharmacies. Table 1 describes the 30 studies published so far and applying this methodology.

In 2007 in Spain, making use of a mystery shopper who presented at community pharmacies requesting an antibiotic for one of three different clinical scenarios, our group observed that these drugs were sold in 45.6% of the pharmacies without a medical prescription [7]. This percentage was slightly higher at 54.1% when the study was repeated in 2014 using the same methodology [8]. However, according to the Eurobarometer, the percentage of Spanish people who admitted having bought an antimicrobial at the pharmacy was only 4% [6].

By contrast with Northern Europe and North America, non-prescription access to antimicrobials is common in the rest of the world [5], as shown in Table 1. In a nice study carried out in a Finnish community living in Spain, Väänänen et al. found that antibiotics, which are considered as prescription-only medicines in Finland, were purchased by 41% of the immigrants who admitted having taken an antibiotic in the previous 6 months [9].

Drawbacks of the over-the-counter sale of antimicrobials

The link between the over-the-counter sale of antibiotics and antibiotic overconsumption is clearly established. Southern European countries usually rank at the top in

World Medical
Journal

Table 1. Frequency of the sale of antimicrobials based on simulated client method surveys

Author, year	Country	Type	URTI	OM	Sin.	Sore throat	LRTI or flu	Dia.	UTI	STI	Specific anti-microbials	Various[a]
EUROPE												
Contopoulos-Ioannidis DG, 2000	Greece	D			78%							
Plachouras D, 2008	Greece	D									53–100%[b]	
Marković-Peković V, 2010	Bosnia&Herzegovina	D			58%							
Simó S, 2006[c]	Spain	I	12%									
Llor C, 2007	Spain	D			35%		16%		80%			
Gastelorrutia, 2009	Spain	D							17%			
Simó S, 2012[c]	Spain	I	6%									
Guinovart M, 2014	Spain	D			48%		33%		81%			
AMERICA												
Gellert GA, 1994	Mexico	I					100%					
Bartoloni A, 1992	Bolivia	D, I[d]	24%			91%	24%	40–92%[e]	58%	67%[f]		
Volpato DE, 2002	Brazil	I			74%							
Vacca CP, 2007	Colombia	D										80%
AFRICA												
Nyazema N, 2004	Zimbabwe	D						9%		8–65%[g]		
MIDDLE EAST												
Amidi S, 1975	Iran	D				60%		40%				
Tomson G, 1985	Yemen	I						9%				
Al-Faham Z, 2009	Syria	I			97%							
Dameh H, 2005	United Arab Emirates	D										69%
Al-Ghamdi MS, 1999	Saudi Arabia	D							82%			
Bin Abdulhak AA, 2010	Saudi Arabia	I	51%	40%	90%	73%		90%	75%			
ASIA												
Wolffers I, 1983	Sri Lanka	D									100%	
Tomson G, 1985	Sri Lanka	I						41%				
Tomson G, 1985	Bangladesh	I						68%				
Hadi U, 2006	Indonesia	D									74%	
Puspitasari HP, 2010	Indonesia	D									91%	
Quagliarello AB, 1999	Vietnam	D						99%	75%			
Chalker J, 1999	Vietnam	D						98%				
Wachter DA, 1996	Nepal	D, I[h]						97%	38%			
Thajlikitkul V, 1986	Thailand	D										50–100%
Chalker J, 1999	Thailand	I						76%				
Apisarnthanarak A, 2006	Thailand	I			80%	74%	65%	76%	100%			

Type=type of simulated patient (D, direct: the patient him-/herself; I, indirect: simulating having a relative or friend with an infectious disease); URTI=upper respiratory tract infection (including rinorrhoea, sneezing, with or without fever); OM=otitis media; Sin.=sinusitis; LRTI=lower respiratory tract infection; Dia.=diarrhoea; UTI=urinary tract infection; STI=sexually transmitted infection

[a]Various infectious diseases considered; [b]Mistery shoppers requested ciprofloxacin (53% of success) and amoxicillin/clavulanate (100% of success); [c]Related to a 9-month old baby with an upper respiratory tract infection and fever; [d]The indirect simulated patients corresponded to children; [e]40% in case of a 6-month old child and 92% when an adult with this infection was simulated; [f]Case of male urethral discharge; [g]8% in the case of a male urethritis and 65% when a vaginal discharge was simulated; [h]The direct simulated patient corresponded to the case of UTI; the indirect case corresponded to his 5-year son with diarrhoea

terms of the consumption of antibiotics, as described in the last report issued by the European Surveillance of Antimicrobial Consumption Network (ESAC-Net) [10]. Indeed, over-the-counter sale of antibiotics is reportedly common in countries such as Italy, Greece, and Spain [5]. In a study on pharmaceutical surveillance in Spain, Campos et al. observed that about 30% of the outpatient antimicrobials purchased was not identified by reimbursement data, largely because over-the-counter sales were not tracked [11].

Self-medication with antimicrobials is also widespread, occurring among the population in the same countries where over-the-counter sale is available [12]. Antibiotics available at home have been found to be an important risk factor for this practice [13], and leftover medication may later be considered for self-medication, leading to inappropriate usage of these drugs. In a study carried out in 2006, the prevalence of antibiotic storage in Spanish households was 37% [14]. This in-home antibiotic storage might also increase the risk of self-prescription of antibiotics to families and friends. In a population survey conducted in 19 European countries, covering 15,548 respondents, Grigoryan et al. found that the main reason for self-medication was a previous medical prescription of the same medication [15]. Thus, the over-the-counter sale of antibiotics both encourages self-medication and the storage of leftover antimicrobials, creating a vicious circle that increases the consumption of antimicrobials (Figure 1).

Public awareness of the issue is low, with many people still believing that antibiotics are effective against viral infections. According to the last Eurobarometer available, carried out in November 2013, 84% of respondents were aware that the overuse of antibiotics makes them ineffective. When asked questions about antibiotics and how they work, 49% of Europeans replied that antibiotics kill viruses and 52% correctly replied that antibiotics are not effective against colds and influenza. A north-south gradient was also observed, with better knowledge of how antibiotics work in northern countries and, conversely, citizens living in southern countries were less knowledgeable about this subject [6]. Since 2008, the European Union, through the European Centre for Disease Prevention and Control, has encouraged public information campaigns on prudent antibiotic use in its member countries, by promoting the European Antibiotic Awareness Day on the 18 November [16]. Nevertheless, concerns have been raised that such campaigns are not having their anticipated effect [17]. In addition, the recent Eurobarometer stated that 60% of respondents had taken at least one course of antibiotics in the previous year for flu, acute bronchitis, colds, or sore throat [6].

Another factor is patients' non-adherence to antibiotic therapy. Our group observed an intentional non-adherence to antibiotic regimens of 35% for respiratory tract infections with the use of Medication Event Monitoring System or MEMS containers [18], resulting in the presence of some leftover drugs that might be used on future occasions by the members of the household. Although a relationship between intentional non-compliance and the storage of antibiotics has not been proven, the fact that approximately one third of individuals store antibiotics in their households and a similar percentage intentionally do not take them as requested makes this association very likely.

Over-the-counter sale of antimicrobials often leads to a wrong choice of these drugs. For instance, in our study carried out in 2007, fluoroquinolones, which are considered as critically important antimicrobials by the World Health Organization as also are third- and fourth-generation cephalosporins and macrolides [19], accounted for 40% of the antibiotics sold for urinary tract infections [7]. Similarly, essential antituberculosis drugs are available without prescription in many areas, with streptomycin, rifampicin and isoniazid being sold for indications other than tuberculosis as over-the-counter antimicrobials [20,21]. This easy access and inappropriate use of these drugs clearly constitute risk factors for further development of multidrug resistant tuberculosis, which is nowadays challenging due to the associated high morbidity and mortality [22]. Over-the-counter sale without a prescription may also lead to the use of insufficient dosages, with lower doses dispensed being more common when the antibiotic is sold at the pharmacies compared to other healthcare facilities [23].

Safety issues associated with non-prescription use also include adverse drug reactions and masking of underlying infectious processes (Table 2). Antimicrobials frequently cause side effects, despite most being mild; however, side effects accounted for nearly one fifth of all visits to the emergency room for adverse drug events in a US study [24]. Linked to this, low-quality and counterfeit antimicrobials have been more frequently reported among antimicrobials sold without a medical prescription, mainly in developing countries, resulting in a possible direct harm and treatment failure [25]. Another concern of the non-prescription status is the possibility of drug interactions, particularly in children, elderly patients and pregnant women. In another study carried out in Taiwan, patients with detectable antibiotic concentrations in urine were nearly twice as likely to have a missed diagnosis of a true bacterial infection compared to the patients without any antimicrobial detected [26]. Proper diagnosis of an infectious disease can also be challenging in a pharmacy. Diagnosis is even often difficult in the primary care clinic and to distinguish between bacterial and viral aetiology is even more so, mainly in respiratory tract infections.

Another inconvenience is the pressure of the population on both the pharmacist and the physician. In the first case this pressure is related to the selling of the antimicrobial and in the second, to obtaining the prescription of the drug sold by the pharmacist to thereby be partially or totally reimbursed for the cost of the antimicrobial.

Advantages of over-the-counter sale of antimicrobials

Accessibility to over-the-counter antimicrobials has also some advantages. Some of these are for the patient, others for the physician, the pharmacist, the pharmaceutical industry itself and others for the government. The individuals would have a greater choice of access to healthcare both in the way it is delivered and at a time and place convenient to them. For instance, patients with recurrent urinary tract infections, who clearly know their symptoms, can be benefitted from an over-the-counter policy. Physicians may gain from having fewer consultations for minor ailments; pharmacists would have a further opportunity to use their professional knowledge and develop their range of services to the public. In our study, however, the pharmacists who refused to sell antibiotics without a prescription gave responses related to health or resistance issues in only 30% of the cases and pharmacists only asked about possible allergies, or potential pregnancy and side effects in less than half of the subjects to whom antibiotics were sold [7]. Education is therefore particularly important in the over-the-counter sale of antimicrobials; when patients choose self-care, there is often no possibility to obtain advice from a physician, and thus the responsibility of providing appropriate information falls on pharmacists. It should not be forgotten that one of the greatest beneficiaries of the non-prescription use of antimicrobials is the pharmaceutical industry, which sees a new marketing opportunity with this policy. Furthermore, the government could be relieved of some costs of antimicrobials obtained on National Health Service prescriptions. In addition, non-prescription status of antimicrobials might be an important mechanism of access to antimicrobials in countries with low resources. Further-

Table 2. Drawbacks of the over-the-counter sale of antimicrobials

- Self-medication with antimicrobials
- Storage of antimicrobials in households
- Inappropriate use of antimicrobials
- Potential side effects
- Masking of underlying clinical syndrome
- No questioning by pharmacists regarding allergies, pregnancy and side effects
- Contraindicated antimicrobials
- Inadequate dose regimens
- Low-quality medication
- Pressure of having an antimicrobial prescribed
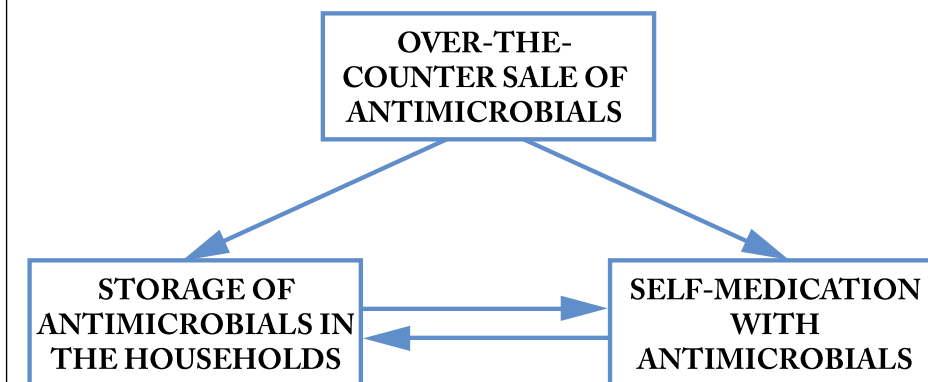
Figure 1. Relationship between over-the-counter sale of antimicrobials, storage and self-medication

more, in these low-income settings, a high demand for antibiotics without a prescription might be expected from customers who cannot afford to consult a doctor.

Conclusions

Antimicrobial resistance is a global issue [27]. According to the current UK Health Chief Officer, we are losing the battle against infectious diseases since bacteria are fighting back and are becoming resistant to modern medicine so that, in short, antibiotics will no longer work [28]. This reinforces the need to prescribe antimicrobial agents only when there is good evidence that the benefits outweigh the risks. Barring the dispensing of antibiotics without a prescription constitutes one of the most valuable strategies to accomplish this objective. The over-the-counter sale of antimicrobials has pros and cons but, in any case, this policy requires that pharmacists have a key role as healthcare agents and it must be forbidden to pharmacists who are not familiar with the management of some mild infectious diseases, mainly in non-low-income countries. Notwithstanding, critically important antimicrobials should never be purchased without a medical prescription anywhere.

References

1. Wise R., Hart T., Cars O., Streulens M.; Helmuth R., Huovinen P., et al. (1998) Antimicrobial resistance. Is a major threat to public health? *BMJ, 317,*609–10.
2. Goossens H., Ferech M., Vander Stichele R,. Elseviers M.; ESAC Project Group. (2005) Outpatient antibiotic use in Europe and association

World Medical Journal

with resistance: a cross-national database study. *Lancet,;365*, 579–87.

3. Butler C.C., Rollnick S., Pill R., Maggs-Rapport F., Stott N. (1998) Understanding the culture of prescribing: qualitative study of general practitioners' and patients' perceptions of antibiotics for sore throats. *BMJ, 317*, 637–42.

4. Carbon C., Bax R.P. (1998) Regulating the use of antibiotics in the community. *BMJ, 317*, 663–65.

5. Morgan D.J., Okeke I.N., Laxminarayan R., Perencevich E.N., Weisenberg S. (2011) Non-prescription antimicrobial use worldwide: a systematic review. *The Lancet Infectious Diseases.,11*, 692–701.

6. European Commission. Special Eurobarometer 407 'Antimicrobial resistance'. (2013) Available from: http://ec.europa.eu/public_opinion/archives/ebs/ebs_407_en.pdf

7. Llor C., Cots J.M. (2009) The sale of antibiotics without prescription in pharmacies in Catalonia, Spain. *Clinical Infectious Diseases.,48*, 1345–49.

8. Guinovart M.C., FIgueras A., Llop J.C., Llor C. Obtaining antibiotics without prescription in Spain in 2014: even easier now than 6 years ago. (2015) *Journal of Antimicrobial Chemotherapy,70*, 1270–71.

9. Väänänen M.H., Pietilä K., Airaksinen M. Self-medication with antibiotics--does it really happen in Europe? (2006) *Health Policy, 77*,166–71.

10. European Centre for Disease and Prevention Control. Summary of the latest data on antibiotic consumption in the European Union, November 2014. Available at: http://ecdc.europa.eu/en/eaad/Documents/antibiotic-consumptio-ESAC-Net-2014-EAAD.pdf

11. Campos J., Ferech M., Lázaro E., de Abajo F., Oteo J., Stephens P., Goossens H. Surveillance of outpatient antibiotic consumption in Spain according to sales data and reimbursement data. (2007) *Journal of Antimicrobial Chemotherapy, 60*, 698–701.

12. Grigoryan L., Haaijer-Ruskamp F.M., Burgerhof J.G.M., et al. Self-medication with antimicrobial drugs in Europe. (2006) *Emerging Infectious Diseases,12*, 452–59.

13. McNulty C.A., Boyle P., Nichols T., Clappison D.P., Davey P. Antimicrobial drugs in the home, United Kingdom. (2006) *Emerging Infectious Diseases12*, 1523–26.

14. González J., Orero A., Prieto J. Almacenamiento de antibióticos en los hogares españoles. (2006) *Revista Espanola de Quimioter, 19*, 275–85.

15. Grigoryan L., Burgerhof J.G., Haaijer-Ruskamp F.M., Degener J.E., Deschepper R., Monnet D.L., et al., on behalf of the SAR group. Is self-medication with antibiotics in Europe driven by prescribed use? (2007) *Journal of Antimicrobial Chemotherapy 59*,152–56.

16. Earnshaw S., Mancarella G., Mendez A., Todorova B., Magiorakos A.P., Possenti E., et al., on behalf of the European Antibiotic Awareness Day Technical Advisory Committee; on behalf of the European Antibiotic Awareness Day Collaborative Group. European Antibiotic Awareness Day: a five-year perspective of Europe-wide actions to promote prudent use of antibiotics. (2014) *Eurosurveillance,19*, 20928.

17. Stockley J.M. European Antibiotic Awareness Day 2010: why doesn't promoting antibiotic awareness always work? (2010) *Journal of Infection,61*, 361–63.

18. Llor C., Hernández S., Bayona C., Moragas A., Sierra N., Hernández M., et al. A study of adherence to antibiotic treatment in ambulatory respiratory infections. (2013) *International Journal of Infectious Diseases,17*, e168–72.

19. World Health Organization Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR). Critical important antimicrobials for human medicine. (2012) World Health Organization. Available at: http://apps.who.int/iris/20.bitstream/10665/77376/1/9789241504485_eng.pdf

20. Kobaidze K., Salakaia A., Blumberg H.M. Over-the-counter availability of antituberculosis drugs in Tbilisi, Georgia in the setting of a high prevalence of MDR-TB. (2009) *Interdisciplinary Perspective of Infectious Diseases*, 513609.

21. Lambert M.L., Delgado R., Michaux G., Volz A., Van der Stuyft P. Tuberculosis control and the private health sector in Bolivia: a survey of pharmacies. (2004) *The International Journal of Tuberculosis and Lung Diseases,8*, 1325–29.

22. Gandhi N.R., Nunn P., Dheda K., Schaaf H.S., Zignol M., van Soolingen D., et al. Multidrug-resistant and extensively drug-resistant tuberculosis: a threat to global control of tuberculosis. (2010) *The Lancet, 375*, 1830–43.

23. Mukonzo J.K., Namuwenge P.M., Okure G., Mwesige B., Namusisi O.K., Mukanga D. Over-the-counter suboptimal dispensing of antibiotics in Uganda. (2013) *Journal of Multidisciplinary Healthcare;6*, 303–10.

24. Shehab N., Patel P.R., Srinivasan A., Budnitz D.S. Emergency department visits for antibiotic-associated adverse events. (2008) *Clinical Infectious Diseases, 47*, 735–43.

25. Taylor R.B., Shakoor O., Behrens R.H. Drug quality, a contributor to drug resistance? (1995) *The Lancet, 346*, 122.

26. Liu Y.C., Huang W.K., Huang T.S., Kunin C.M. Inappropriate use of antibiotics and the risk for delayed admission and masked diagnosis of infectious diseases: a lesson from Taiwan. (2001) *Archives of Internal Medicine, 161*, 2366–70.

27. Okeke I.N., Edelman R. Dissemination of antibiotic-resistant bacteria across geographic borders. (2001) *Clinical Infectious Diseases, 33*, 364–69.

28. Davies S.C., Grant J., Catchpole M. (2013) *The Drugs Don't Work. A Global Threat*. London: Penguin Specials

Carl Llor, Primary care physician,
Primary Healthcare Centre,
Via Roma, Barcelona
Ana Moragas, Primary care physicians,
Primary Healthcare Centre,
Jaume I, Tarragona, Spain
E–mail: carles.llor@gmail.com

World Medical Journal

Medicines Shortages: Global Problems Need Global Solutions

Richard Price

Is there a health system in the world at this moment not suffering from the impacts of medicines shortages? With strong documentation of the problem in such countries as the USA [1], Australia [2], South Africa [3], Canada [4] and elsewhere, to the understanding of the pan-European dimensions of the problem was recently added the publication of the report by the European Association of Hospital Pharmacists "Medicines Shortages in European Hospitals" (November 2014) [5].

Distributed across Europe by the network of 34 EAHP national country associations [6], over 600 hospital pharmacists from 36 countries responded to a call for information about the problems being faced in practice as a result of medicines shortages. A definitive answer was returned: 86% responded in the affirmative that, yes, medicines shortages are a current problem in the hospital the responding pharmacist works in, in terms of delivering the best care to patients and/or operating the hospital pharmacy. Indeed, no country

surveyed responded with less than 60% agreement that medicines shortages are a current problem. 88% of the respondents experience medicines shortages at least monthly, with 66% expressing it as a daily or weekly problem.

But what kinds of problem are being created? The report sheds some further light on the nature of the negative impacts entailed for pharmacists, but above all, patients, when a medicine prescribed for the patient simply becomes unavailable.

For pharmacists, enormous amounts of time can suddenly be absorbed into the pressing task of finding a new source of supply for the medicine. In the European context, this might often be from other countries, with all the delay, and potential knock-on impacts for supply in the source country that can be involved [5]. EAHP's 2014 report finds that 55% of hospital pharmacists in Europe say that up to 5 hours of staff time a week is being diverted from other tasks in order to deal with shortage problems, with a further 32% indicating that more than 5 hours a week is consumed with managing the situations caused by shortages. Indeed, some respondents reported the need to employ full time equivalents dedicated solely to locating new sources for out-of-stock medicines.

However, if the medicines shortages problem was simply a question of inefficiency it would not excite the attention and momentum that the matter has been gaining at the international level [8]. The most telling and pressing impact is for patients. Here again, EAHP's 2014 report provides some additional insight.

Over 75% of the respondents to the survey either agreed or strongly agreed with the

statement "medicines shortages in my hospital are having a negative impact on patient care". Many respondents then went on to provide examples including:

• The aggravation caused to patients, mainly elderly, when explaining the required changes or delays to their treatment;
• The distress caused by delays or interruptions to chemotherapy treatments;
• The confusion experienced by prescribers and nurses when out-of-stock but familiar medicines must be replaced by available alternatives, and the potential increase in medication error risk;
• Heightened risk of hospital acquired infection as a result of antibiotic shortage;
• Deterioration in patients' condition due to shortage of the most efficacious medicines;
• Raised risk levels from the required use of unlicensed alternatives to a medicine in shortage; and,
• Additional hospital admissions as a result of some shortages (e.g. cardiology medicines).

As suggested by the title, however, simply drawing attention to the problems caused by medicines shortages is not enough. Effort, energy and awareness must be drawn to potential solutions. With the causes of shortages acknowledged to be so multi-faceted, as well as situation and region-specific, it need barely to be mentioned that it is a list of mitigating policy actions that are required, rather than any single answer.

The reflections of the International Pharmaceutical Federation (FIP) and, indeed, the regulatory action advocated for by our colleagues at the American Society of Health System Pharmacists (ASHP) have certainly informed the outlook of the European Association of Hospital Pharmacists on the matter of potential solutions to the medicines shortages problem.

In 2013 FIP brought together pharmacy professionals from across the globe in an international summit on medicines shortages

World Medical
Journal

Approximately how often does your hospital pharmacy experience shortages?

Most hospital pharmacists responded that they are affected by shortages on a weekly basis.

Hospital pharmacists are affected by shortages on a daily basis, with 21.1% (n=111) replying that they experience a shortage of a medicine every day.

The situation for the majority of those who replied was that they experience shortages at least weekly, 45.2% (n=238) selecting this response.

21.2% (n=112) replied that they are affected by shortages on a monthly basis with 12.4% (n=65) stating that they are affected occasionally.

This resulted in a combined 87.6% (n=112) of the respondents replying by saying that they are affected by medicines shortages at least monthly.
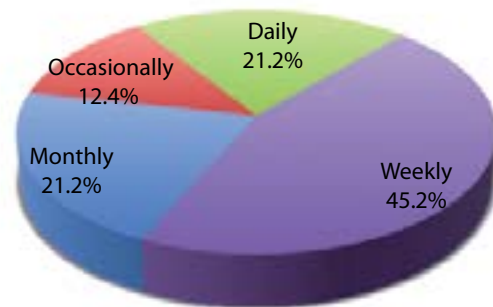

Figure 1.

Which type of medicine do you most commonly experience to be in short supply?

According to the respondents they most commonly experience originator (patented) products to be in short supply. 51.8% (n=221) reported them as the most common category of shortage.

Generic products (including branded generics) were affected to a lesser degree, with 36.5% (n=156) of hospital pharmacists starting that they are the most affected category in theri experience.

11.7% (n=50) of respondents considered that unlicensed medicines are the most common type of medicines in short supply.
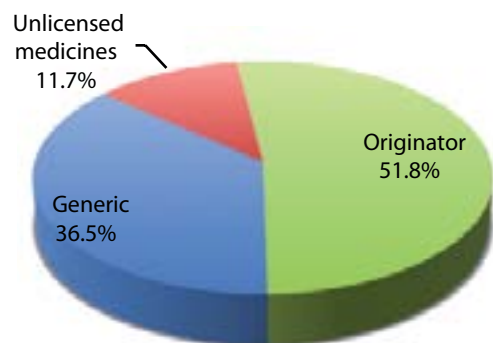
The countries with highest recordes prevalence of originator (patented) shortages are Belgium (78.3%, n=69), Spain (64.5%, n=62), Austria (73.3%, n=15) and Slovakia (78.6%, n=14). The pharmaceutical markets of Bulgaria, Ireland, Switzerland, Italy, Norway, France, and Poland also expressed that patented products were the most common category of shortages.

Figure 2. Nature of the shortages reported from all of the respnseces. N=427

held in Toronto, Canada [8]. At the end of two days of deliberations they made a series of principal recommendations for tackling the problem, including:
• Improved publicly available information on shortages;
• A globally agreed list of critical/vulnerable products;
• Improved procurement processes to assure continuity of supply; and,
• Improved regulatory cooperation between countries on the matter.

Meanwhile, in the United States, some case study examples of what can be achieved, at least as interim steps, have been provided via the FDA Innovation Act (FDASIA) of 2012 [9]. This legislation not only clarified the statutory remit of the USA's medicines agency to be involved in resolving medicine shortages problem, but also addressed problems in relation to the legal responsibilities of manufacturers to supply at an early stage in order to enable better contingency planning. Some early monitoring results from the University of Utah has suggested such action, whilst by no means eliminating the problem, it has proven effective in so far as reducing the difficulties [10].

Drawing inspiration, EAHP's 2014 report on medicines shortages in European hospitals ends with a set of policy calls to political decision makers:
• Improved collection and sharing of information about medicines shortages in Europe, by both national medicines agencies and the European Medicines Agency;
• Clarification and enforcement of legal responsibilities on manufacturers of medicines to report disruptions to supply;
• An inquiry at the European level into the primary factors causing medicines shortages;
• Criteria for a fair distribution of supply in cases of shortage, based on primary consideration of patient need.

World Medical
Journal

EAHP is now working with counterpart healthcare professional and patient organisations at the European level to promote this much needed policy agenda [11] and hope that in time a positive European example of response to the shortages problem may yet be provided to our colleagues elsewhere in the world. That work, however, remains ongoing. A new European Commission settling into its 5 year term of office could provide the opportunity required [12].

References

1. McLaughlin M., et al. Empty Shelves, Full of Frustration: Consequences of Drug Shortages and the Need for Action. (2013) *Hospital Pharmacy, 48(8)*. 617-618
2. Quilty S. Medicines shortages in Australia – the reality. (2014). *The Australasian Medical Journal, 7(6)*, 240-242
3. Bateman C. Drug stock-outs: Inept supply-chain management and corruption. (2013) *SAMJ: South African Medical Journal, 103*, 600-602.
4. Barthelemy I., Lebel D., Bussieres J-F. Drug shortages in health care institutions: perspectives in early 2013. (2013) *Canadian Journal of Hospital Pharmacy, 66(1)*, 39–40
5. European Association of Hospital Pharmacists. *Medicines shortages in European hospitals.* (2014) Available: http://www.eahp.eu/press-room/patients-suffering-medicines-shortages-all-european-countries. Accessed 17 June 2015.
6. European Association of Hospital Pharmacists. *EAHP Members*. (2015) Available at: http://www.eahp.eu/about-us/members. Accessed 17 June 2015.
7. Gray A., & Manasse H. R. (2012). Shortages of medicines: a complex global challenge. *Bulletin of the World Health Organization, 90(3)*, 158–158A.
8. Besancon L., Chaar B. Report of the international summit on medicines shortage. (2013) *International Pharmaceutical Federation (FIP)*, Toronto. Available at: http://www.fip.org/files/fip/publications/FIP_Summit_On_Medicines_Shortage.pdf. Accessed 17 June 2015.
9. *Fact Sheet: Drug Products in Shortage in the United States*. (2015) [ONLINE] Available at: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/

In which area of medicine does your hospital experience shortage most commonly?

The areas in which shortages of medicines are most commonly reported are:
• antimicrobial agents
• oncology medicines
• emergency medicines
• cardiovascular medicines
• anaesthetic agents

It is interesting to note that at least 19 (4.5%) reports were received for the lowest affected category: transplant medicines. This indicates the many categories of medicine are affected by shortage.
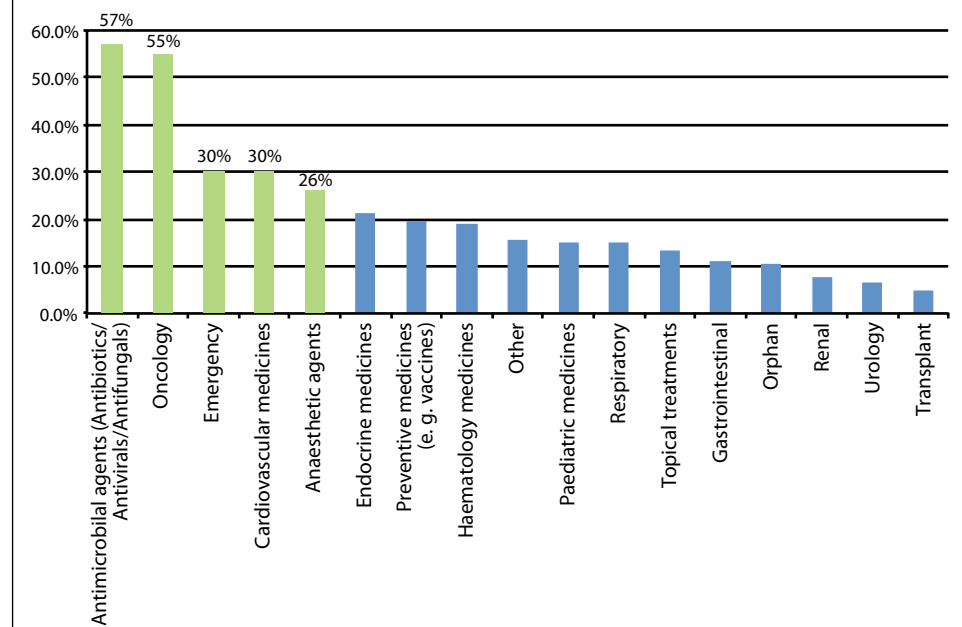
Figure 3. Category of shorages reported overall. The categories with the highest responds include antimirobials (56.7%), oncology (54.5%), emergency medicines (30.4%) and cardiovascular medicines (30.4%). n=418

FDASIA/ucm313121.htm. Accessed 17 June 2015.
10. *Are Shortages Going Down Or Not? Interpreting Data From The FDA And The University Of Utah Drug Information Service*. [ONLINE] Available at: http://healthaffairs.org/blog/2015/04/08/are-shortages-going-down-or-not-interpreting-data-from-the-fda-and-the-university-of-utah-drug-information-service/ Accessed 17 June 2015.
11. Houÿez F., et al. Common position between patients', consumers, and healthcare professionals' organisations involved in the activities of the European Medicines Agency on Supply Shortages of Medicines. (2013) [cited 21.03.2014.]; Available from: http://download.eurordis.org.
s3.amazonaws.com/documents/pdf/common-position-supply-shortages-final-10-2013.pdf.
12. European Commission (2014, Sep 10) *The Juncker Commission: A strong and experienced team standing for change*, http://europa.eu/rapid/press-release_IP-14-984_en.htm Accessed 17 June 2015.

Richard Price,
Policy and Advocacy
Officer at the European Association of
Hospital Pharmacists (EAHP)
E-mail: richard.price@eahp.eu

World Medical
Journal

World Medical
Journal

Do Ethics Need to Be Adapted to mHealth?
A Plea for Developing a Consistent Framework

The rapid advancement of technology does not stop at mobile devices: For most people, these sophisticated gadgets have become an integral part of their daily life. Smart phones and tablets as well as various wearable devices, e.g. smart watches, perform their duties in an unobtrusive way but still provide users with impressive functionalities that would have been unthinkable of only a few years ago: the sensor technology included in most of these devices can record data relating to many different aspects of the user's life and these data can easily be stored and evaluated either on the devices themselves or be sent to some remote location for further processing and storage.

At first gaining great popularity with businesspeople as well as private users who feel they can rarely do without their constant mobile companions, the devices have also become accepted in other sectors, including the medical field. Part of this stems from the fact that economists as well as politicians have come to realize that mobile devices along with the (public) health related apps running on them offer great potential for the medical field, not only by improving the quality of care for patients, but also from an economic point of view. Their uses in the medical context are manifold. For example, they are regarded as invaluable for prevention, e.g. for monitoring chronic conditions such as high blood pressure or diabetes [1, 2] and improving adherence to therapies. For patients, the main aspect is the added comfort of such mobile solutions compared to conventional methods, while from a professional point of view, better adherence to a prescribed regimen as well as meticulous monitoring may serve to prevent long-term damages that might be caused as a result of a more careless approach. Nevertheless, despite the perceived benefits mo-

bile technologies can offer in healthcare, the highly sensitive nature of this field of application raises a number of ethical questions that need to be answered [3].

People who use health related apps for recreational purposes, training or other health related tasks are usually confident that those who provide the apps (vendors as well as developers) follow the unwritten rules with respect to how personal data should be handled or not. They are not necessarily ignorant or careless, but often, they like to think that datasets recorded by the mHealth applications they use are deleted as soon as they are no longer needed or that only they themselves can gain access to their data because they do not suspect anything else. However, there are divergent interests involved that may lead some providers of mHealth apps to collect data and use them for purposes that the users are not aware of (and would never or only hesitatingly acquiesce to if they were told), e.g. marketing. The consequences of this "misinterpretation" of the other party's goals are not trivial. This is not about whether people should clap hand in the British House of Parliament or not – it is about serious issues regarding autonomy, participation, personal health, economy and public interests. Different interests and different notions about "what should be done" cause tensions and conflicts of goals and norms. Conflicts like these are well known to medicine at large, but mHealth in its ubiquity, availability and accessibility may provoke a new and enhanced debate about some ethical aspects that are already being discussed in medicine in general.

The power of mHealth apps to medicalise [4] the behaviour of individuals causes us to start a debate about ethics in mHealth. Users often make excessive use of mobile

technologies when it comes to monitoring their health because they have been told this may help to reduce their risk for disease. Also, they believe that being well informed may also serve to mitigate potential risks. At the same time apps have already proven to be effective tools for boosting adherence to therapies (for example, via text messaging reminders) or for disease management [5]. However, these developments go hand in hand with technical challenges and ethical concerns: Above all, the medicalisation of apps results in limited consumer choices. This refers as much to using the apps themselves as to targeted advertising users may receive which is specifically adapted to their "health"-related data or their health profile. Consumers may be led to think that they need certain apps or commercialized products for their well-being. Having these radical examples in mind, we believe that it is essential to transparently describe what people using mobile devices for mHealth can expect from mHealth providers. Thus, mHealth ethics is not so much about finding out which rules people want mHealth providers to follow, but about which rules mHealth providers promise to follow in the future.

Our objective in this article is to provide some starting points for the clearly needed discussion about ethics in mHealth. Therefore, after an introductory definition of what constitutes "mHealth", we outline how the fundamental principles of medical ethics as they are described in several standard codices can be transformed in order to make them applicable to mHealth. In a nutshell, we propose mHealth specific ethical principles to be developed that – while they are still based on established principles and guidelines – also take the specific requirements of mHealth under consideration.

What Constitutes mHealth?

As specified by the WHO's Global Observatory for eHealth (GOe), mHealth, also known as mobile health, can be seen as the "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices." [6]. However, considering the rapid technological evolution that of course does not stop at mobile devices, this definition (dating back to 2011) falls short of what is possible nowadays. Even sensors commonly found in mobile devices but developed with entirely different fields of application in mind are often used for medical and health related purposes. Apart from applications making use of sensor based data, there are also those that aim at providing users with health related information, while even others target biomedical research or can be used for (preventive) healthcare. Often, it is impossible (and not even desirable) to clearly distinguish between these areas, since they all make use of monitoring, recording as well as surveillance functionalities and there are many overlaps. A "definition" guideline has been provided, for example, by the FDA in their "Guidance for Industry and Food and Drug Administration Staff – Priority Review of Premarket Submissions for Devices" [7] revised on February 9, 2015. Also, the manner in which mHealth is being used means that the access to health related services is no longer restricted to time or location, i.e. getting to a doctor's office or a hospital at a specific time. Instead, by using mHealth technologies, users can gain access to an impressive number of health related services whenever they need them [5].

Evaluating Existing Biomedical Principles and Codes

Due to the vast number of imaginable areas of application for mHealth solutions, starting with their use in private settings in the patient's home and further extending to re-

mote monitoring of various data as well as large scale collection of health related data for biomedical research (the so called "big data" approaches [8, 9]), many different levels of medical ethics are affected and must be considered.

For example, as soon as data originally recorded in a care context is (additionally) evaluated in a research project, research ethics need to be included in the equation. On the other hand, if mobile devices are employed to record physiological parameters (independent of whether this patient care or research in mind), patient autonomy as well as the patient's right "not to know" must be respected. Also, sometimes, the target oriented approach commonly used in medicine, namely, research vs. treating patients, stands in the way of applying the value-rational principles of medical ethics as would be appropriate. And lastly, the use of mHealth may also influence the relationship between patients and their physicians. A striking example is the reference to the traditional issue of confidentiality: mHealth app users might use them to communicate their disease specific parameters with their physician, either actively, for example, via text messaging or passively by having their data monitored. This communication can only be frank, trustful, true and free of manipulation if confidentiality, as a crucial element of patient-physician relationships, is guaranteed. For both sides, confidentiality is of utmost importance and this also holds true for third parties because this is essential for guaranteeing mutual respect, full disclosure of symptoms to the physician and privacy, including protection from stigmatization.

Considering the different spheres of patient's life which apps can monitor and record, it becomes clear that at least in the medical field, the health related use of apps needs some ethical guidance. Referring to classical elements of medical ethics this means that, for example, the four principles of "autonomy", "nonmaleficence", "beneficence", and "justice" mentioned in the so-

called "Georgetown mantra" [10] as well as similar aspects mentioned in other documents and normative analyses have to be an essential part of all further work.

Codes of ethics that are already available and deal with issues related to the consequences of using technologies, public health [11], research [10, 12], or telemedicine [13] as well as the general use of internet based services [14] or other subject areas such as medical informatics [15] also need to be scrutinized with respect to their applicability to the mHealth sector.

However, such an analysis reveals that there are certain dimensions that might be in conflict with each other. For example, while a user may simply want to have his or her data monitored to stay healthy and continue to be able to participate in public, mHealth providers may rather have the collection of data for research or marketing purposes in mind and may also want to influence the behavior of consumer in one or the other direction. Here, specifically the above mentioned traditional concepts like autonomy, confidentiality, beneficence and maleficence are at stake. At the same time and on another level, a consumer using mHealth may have the impression that the promise of confidentiality commonly applied in medical contexts also extends toward mHealth settings in general and, thus, his or her health related data are also protected similarly. However, many mHealth providers have a more or less legitimate interest to simply make use of the data they obtain. Additionally, the interest in data does not stop with researchers. Public health officials, a "medical police", insurances or employers might also have interest in these data to increase their chances on the market by choosing the clients or employers with the best risk profile. Transparency usually has a good reputation, but from a patient perspective, mHealth transparency interpreted in this manner may go too far.

As a first approach, we would therefore suggest to follow the classical codes of medical

World Medical
Journal

ethics and codes for e-health and telemedicine in order to examine the dimensions of normative conflicts involved. From this basis, we propose to develop a specific WHO mHealth code of ethics along the following lines:

1. Above all, patient interests need to be addressed and questions of autonomy have to be integrated in such a mHealth code as well. This would involve
- respecting the right to self-determination with respect to active or passive participation where use or application of mHealth are concerned,
- voluntary participation and the right to withdraw at any time,
- providing comprehensive and target-group as well as situation specific information to allow for an informed decision,
- promotion of health awareness for (self-) confident decision making in health contexts.
2. Furthermore, the mHealth code of ethics needs to address possible settings where mHealth apps can be beneficial, their inclusive or exclusive character and their accessibility for people potentially benefitting from their use. This would for example mean that
- the primary benefits for the affected persons must be obvious or deducible,
- objectives of the mHealth app must be achieved based on valid data,
- decision processes must be transparent and need to include all stakeholders concerned (affected persons) in order to justify an intervention in a comprehensible manner.
3. Additionally,
- mHealth interventions must be available to everyone, regardless of social status, income, education, political orientation, religious faith, inclinations and ideals, gender, age, ethnic group but also when it comes to technical affinity, health competence, mental or physical impairments. Neither discrimination nor stigmatization may be caused by the intervention.

- mHealth interventions should aim at eliminating existing inequalities. For this, the fair distribution of potential benefits and potential harm within the target group is a prerequisite.
4. It is often forgotten that mHealth apps differ from other apps in the very aspect that they address the fundamental issue of health. Therefore, mHealth providers should – in line with the medical tradition – promise not to cause harm to their users. For example,
- the mHealth intervention shall not in any way have a negative impact on its user or on the receiving party. Specifically, this applies to the physical and mental wellbeing of each individual, a group of individuals or the individual's environment.
- The risks of an intervention must be commensurate with its expected benefits. This requires carefully weighing up the risks and benefits based on valid and reliable information.
- The right to privacy, which aside from confidentiality also includes protecting personal integrity, must be protected in order to prevent any harm.
5. Finally, when using mHealth tools for research purposes, one should be careful to respect the existing principles for good scientific practice, specifically
- that research using mHealth applications needs to generate valid and reliable data and that the commonly known principles of good scientific practice as well as the biomedical principles of research must be observed.

Conclusion

The presented catalogue of principles is supposed to offer a first glimpse of a possible code promising certain behaviors (on the part of mHealth providers) to users of mHealth apps. Users seek health, providers may seek data as well as novel revenue generating areas of application and, thus, they may follow public, individual or eco-

nomic interests. Maintaining the overview of all aspects that need to be respected by stakeholders involved in mHealth is not an easy task as the aforementioned considerations reveal. Although several codes regarding eHealth exist, we think that, due to its ubiquity, the requirements to be met for mHealth are even more challenging. Having a unified "code of ethics" specifically targeting mHealth would simplify the tension caused by the mismatch between users' expectations and the morals of providers and it might improve compliance with the required principles.

References

1. Eng D.S., Lee J.M. The promise and peril of mobile health applications for diabetes and endocrinology. (2013) *Pediatric Diabetes,2013,14(4,)* 231–238.
2. Fangerau H., Martin M. (2014) Blutdruck messen: Die ,Technikalisierung' der Kreislaufdiagnostik. *Technomuseum (Hrsg):* "Herzblut. Geschichte und Zukunft der Medizintechnik", Theiss/WBG, Darmstadt, S. 74-93
3. Albrecht U.V., Pramann O. (2014) Ethical and Legal Implications on Apps in Clinical Trials. (2014) *Biomed Tech 59 (s1,)* pp. 674-675 DOI 10.1515/bmt-2014-4290
4. Conrad P. (2007) *The Medicalization of Society. On the Transformation of Human Conditions into Treatable Disorders.* Baltimore
5. Boulos M.N., Brewer A.C., Karimkhani C., Buller D.B., Dellavalle R.P. Mobile medical and health apps: state of the art, concerns, regulatory control and certification. (2014) *Online Journal of Public Health Informatics.5(3),*229. doi:10.5210/ojphi.v5i3.4814.
6. World Health Organization. (2011) *mHealth – New horizons for health through mobile technologies. Global Observatory for eHealth series. V.3,* 6
7. FDA. Mobile Medical Applications. Guidance for Industry and Food and Drug Administration Staff. http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf. (Last access: 18.06.2015)
8. Sungmee Park, Jayaraman S. A transdisciplinary approach to wearables, big data and quality of life. (2014) *Conference Proceedings of the IEEE Engineering in Medicine and Biology Society.4,*155-58.
9. Hsieh J.C., Li AH, Yang C.C. Mobile, cloud, and big data computing: contributions, challenges, and new directions in telecardiology.

World Medical
Journal

(2013) *International Journal of Environmental Research and Public Health, Nov.10(11),*6131-53.
10. Beauchamp T.L., Childress J.F. (2009) *Principles of Biomedical Ethics.* Oxford University Press.
11. Public Health Leadership Society. (2002) *Principles of the Ethical Practice of Public Health.* http://phls.org/CMSuploads/Principles-of-the-Ethical-Practice-of-PH-Version-2.2-68496.pdf
12. World Medical Association. (2014) World Medical Association Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. *JAMA.* 2013; 310(20):2191-2194. doi:10.1001/jama.2013.281053
13. Iserson K.V. Telemedicine: a proposal for an ethical code. (2000) *Cambridge Quarterly of Healthcare Ethics.9,* 404–406
14. Rippen H., Risk A. e-Health Code of Ethics. (2000) *Journal of Medical Internet Research. 2(2):e9* URL: http://www.jmir.org/2000/2/e9 DOI: 10.2196/jmir.2.2.e9 PMID: 11720928 PMCID: PMC1761853
15. International Medical Informatics Association. *IMIA Code of Ethics for Health Information Professionals.* http://www.imia-medinfo.org/new2/node/39

Dr. med. Urs-Vito Albrecht, MPH,
Hannover Medical School,
Peter L. Reichertz
Institute for Medical Informatics, Germany
E-mail: albrecht.urs-vito@mh-hannover.de
Prof. Dr. med. Heiner Fangerau,
Institute of the History,
Philosophy and Ethics
of Medicine at Cologne
University of Cologne, Germany
E-mail: heiner.fangerau@uni-koeln.de

Health Apps – Sound and Trustworthy?

Urs-Vito Albrecht

A gold rush mood is prevailing among all stakeholders who are active in healthcare and everybody is clamoring for "their" app: Healthy users want to track their fitness and to obtain health related information and patients hope to get a comfortable means to manage their condition or to get into contact with their doctors. For manufacturers, apps and mobile technology in general stand for an additional chance for selling "health", either under a new guise, or ideally based on entirely new and exciting ideas. The market is diverse and it is hard to maintain an overview – for those interested in health related

mobile offers, the situation is often confusing. The most difficult part in determining whether an offer is acceptable or not is rating the quality of health apps. Most users – patients and healthcare professionals alike – are simply not familiar with the strategies needed for carrying out such an assessment on their own. Although various tools exist that could help them in this process (e.g. [1, 2]), many of these are still under development or users are simply not aware of their existence. What are the dangers users may be confronted with in this context? This article is meant to shed some light on the current situation and to provide some remedies.

The App Market, Health Apps and Medical Apps

The smartphone and app hype really started in 2008 when 500 apps were made available on one app store [3]. In May 2015, the number of offered apps had already grown to the formidable number of 3,730,000 [4] for four mobile platforms in five app stores. The continuing growth of the app market in general also applies to apps for health and fitness and, in fact, some analysts predict that this part of the app market will have the largest percentage change [5]. Recent estimates are that there are about 100 000 mHealth apps [6] with an estimated growth of about 1 000

apps per month [7]. An exact number for mHealth apps cannot be determined since the app stores only offer very basic rules for assigning apps to one category or another. Rather, this is left to the manufacturers, who will often choose a category that promises better sales. To clarify the classification and to give users a better understanding, we recommend the following to clearly differentiate between health apps and medical apps [8]. While, following the WHO's definition of health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" [9] – the term "health apps" encompasses a wide range of health related apps, "medical apps" are primarily intended for diagnosing, treating or preventing illnesses or injuries.

Risks and Limitations

The relevance of this categorization becomes apparent when one considers the potential risks and ramifications that may arise in the intended field of application. For medical apps, the inherent risks of causing harm are considerably greater, since their focus is primarily on diagnosing or treating patients – supported by the app and the mobile devices they run on – whose health is already compromised in some way. However, the desired success may either fail to materialize or, in a worst-case scenario, it may come to an exacerbation or additional health problems. Of course, this outcome is highly undesirable,

World Medical
Journal

not only for the patients themselves but often also for the medical staff, their employers, as well as the manufacturers. There exist many possible sources of risks and the following paragraphs will mention the most obvious ones – the list is by no means exhaustive. Roughly speaking, two areas where problems can arise can be discerned:

1. "The app does not do what is supposed to do!" This sentence and other similar utterances, often voiced by discontented users, for example in user comments that they leave on the stores, is often caused not only by shortfalls in performance that may for example be caused by technical limitations of the devices used to run the app, but also by programming errors, deficiencies of the content or simply bad usability.

2. "The app does more than it should!" This is often caused by non-obvious "features" of an app, for example when data protection and data security or the user's right to self-determination are compromised. This may be caused either with or without intent, e.g. by failing to observe due security measures when dealing with this highly sensitive type of data, lack of providing users with adequate information regarding data handling or even worse, secret and illicit data transmission and evaluation.

The App as a Medical Device

Although many aspects of the app business give the impression of a "wild west" scenario, at least some apps, namely, those where the manufacturers have specified that they are a "medical device", have to conform to the official regulatory requirements that apply to such products. However, whether these requirements apply also depends on whether the manufacturer has assigned a medical purpose to his product, in this case the app. Going through the processes is often time-consuming and costly. Thus, although some apps can be medical products and would therefore have to comply with regulations for such

products, manufacturers often avoid or ignore this due to the considerable hurdles raised by the necessary regulatory processes. Currently, compared to the number of available apps, only a relatively small number of apps have so far gained approval by a federal authority (e.g. by the Food and Drug Administration in the USA) or passed an assessment following the federal laws of other states (e.g. conformity assessment for European countries). The impossibility of closer scrutiny of all apps by the authorities, which would be appropriate, can also easily be explained by the sheer number of apps and additionally contributes to the uncertainties in this area, although the intent of regulation is to protect patients as well as users of these products. An exhaustive overview of the subject of "apps and regulations" can be found in [10].

Private Certification

For many apps, regulations simply do not apply, while for others, manufacturers ignore the regulatory processes either due to a lack of knowledge about the requirements or intentionally. Unfortunately, this means that in order to obtain some sort of quality seal for their product, the manufacturers have to resort to using the services offered by a number of private contractors. These seals can also be used for advertising purposes. Of course, this comes with a price and such services are offered both nationally as well as on an international level. Still, the reliability of these offers is highly variable, as was recently underlined by the deficiencies found in the recently halted certification processes offered by Happtique [11].

Appraising the Trustworthiness of Apps

Ultimately, the decision on whether to use an app or to refrain from using it remains with the users. They carry the prime responsibility and can also be held accountable – at least in a professional context – when using apps

[12]. Users of health apps are in a difficult situation: they have to decide for themselves whether they place their trust in an app. This is a difficult and error prone decision making process. The probability for errors can be reduced if users can base their decision on readily available and valid information, but such information is often hard to come by.

Available Information Is not Always Reliable and Reliable Information Is Only Rarely Available

Users often rely on comments made by other users on the distribution platforms. Such comments can be easily created and publicized. The more "stars" and positive comments an app has received, the greater its attractiveness for users as well as for the search algorithms of the stores. However, these comments and ratings are not subject to any review and do not follow any standards. They can be freely assigned and given pseudonymously. Their quality is often questionable, but still they are generally the main source of information for those interested. Other information can usually only be found via time-consuming searches: blogs, evaluations done by (private) initiatives or databases containing specific information provided by the manufacturers that are often not widely known. If available, peer reviews of apps or corresponding scientific studies provide more reliable information, but finding this information often requires considerable effort on the users' part.

Which Information Is Important for Making a Decision?

For users, the situation is quite chaotic due to the vast number of available apps. Identifying apps that match the desired use and are trustworthy is like a mixture between finding a needle in the haystack and playing Wheel of Fortune. The emphasis of available information is often on marketing aspects and information that can support the claimed credibil-

---

ity and trustworthiness can rarely be found. Alternative sources of information need to be identified and are often only available some time after an app has been published. Certifications are also rare and they often suffer from questionable credibility. There are even fewer apps conforming to regulatory standards. What can be done to make things work?

Sensitizing Users as well as Manufacturers Combined with Standardized Information

Users need reliable applications, especially where either their own health or that of the patients they treat is concerned. This is not only an ethical imperative, but also a strict requirement from a legal point of view (buzzword: "medical device"). Imprudent use of apps can cause serious harm. There is no alternative to requiring manufacturers to actively provide reliable and trustworthy apps and corresponding information. Exerting pressure will work best if sales are affected. In order to enable users to use their power in this context, they need tools that can support them in their decision whether to purchase an app or not. Information to be used towards this end may be gained from a number of different sources. For example, it may be based on standardized reporting mechanisms, such as an app synopsis [4, 10] which covers all important aspects and provides the crucial information in a single location. Information covered by the synopsis contains not only the background of the manufacturer or distributor of an app and his associates as well as the experts involved in the development, but also the rationale behind the app, i.e. its intended purpose(s) and target audience. It also makes provisions for aspects such as functionality and reliability of the app as well as data acquisition, data transmission and storage and, of course, also calls for information on how data protection and privacy are handled. A more exhaustive description of the app synopsis can be found in [8, 13, 14].

Transparency as an Added Value

The situation in the market can be improved as soon as manufacturers acknowledge that providing transparent information about their product can significantly contribute towards an app's perceived quality. Users will appreciate the added value they receive via this transparent reporting. For manufacturers, it is an easy task to compile the information point by point and to publish it, for example on the app stores, since they already possess the necessary knowledge. Thus, users have a fair chance to inform themselves about an app even before they download it. For users, this is only fair since they are also affected by the potential consequences of using the app. This can serve both as an important confidence building measure as well as towards improving sales. Still, just providing this information does not suffice as in addition users must be made aware of the inherent risks of apps that are to be used in a health context and they must also learn to ask the right questions. Educating users towards this goal is imperative.

Conclusion

One objective of the article was to present aspects relevant for assessing the trustworthiness of a health related app, while also sensitizing readers to what needs to be included even during the development phase of a trustworthy app. Only based on trustworthy apps will it be possible to fully realize the potential apps offer for healthcare without risking to lose the trust users place in them – only an app that can be used without any problems will be a success.

References

1. Bonacina S., Marceglia S., Pinciroli F. A pictorial schema for a comprehensive user-oriented identification of medical Apps. (2014) *Methods of Information in Medicine;53*, 208–24. doi:10.3414/ME13-01-0093.
2. Lewis T.L. A systematic self-certification model for mobile medical apps. (2013) *Journal of Medical Internet Research;15;e89*. doi:10.2196/jmir.2446.
3. Engadget. Jobs: App Store launching with 500 iPhone applications, 25% free. (2008) http://www.engadget.com/2008/07/10/jobs-app-store-launching-with-500-iphone-applications-25-free/(accessed June 17, 2015).
4. Statista. Number of apps available in leading app stores as of May 2015. (2015) http://www.statista.com/statistics/276623/number-of-apps-available-in-leading-app-stores/(accessed June 17, 2015).
5. Research2Guidance. *Mobile Health Market Report 2013-2017*. Available from http://www.research2guidance.com/shop/index.php/mhealth-report-2 (accessed June 17, 2015).
6. Research2Guidance. *mHealth App Developer Economics 2014*. Available from http://mhealtheconomics.com/mhealth-developer-economics-report/(accessed June 17, 2015).
7. Becker S., Miron-Shatz T., Schumacher N., Krocza J., Diamantidis C., Albrecht UV. mHealth 2.0: Experiences, Possibilities, and Perspectives. (2014) *Journal of Medical Internet Research, 2*:e24.
8. Albrecht U.V., Pramann O., von Jan U. Synopsis for Health Apps – Transparency for Trust and Decision Making. (2014) In: Househ M, Borycki E, Kushniruk A (Hrsg): Social Media and Mobile Technologies for Healthcare. (pp. 94-108) *Medical Information Science Reference* (an imprint of IGI Global), Hershey PA, USA.
9. WHO. Preamble to the constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 states (official records of the World Health Organization, No. 2, p. 100) and entered into force on 7 April 1948
10. Pramann O., Albrecht UV.: Medical Apps – Alles was recht ist: Ein rechtlicher Überblick über den Einsatz von Apps und Mobilgeräten im Kinikbetrieb. (2013) *E-HEALTH-COM, 1*, 22-27.
11. Dolan P.L. Health app certification program halted. (2013) *Irving, TX: MultiView, Inc,*. URL: http://exclusive.multibriefs.com/content/health-app-certification-program-halted [accessed 2014-02-15]
12. Pramann O., Albrecht UV.: Medical-Apps im Krankenhaus – Sicherheit, Verantwortung, Haftung. (2013) *Krankenhausjustitiar 04*, 16-17.
13. Albrecht UV.: Transparency of Health-Apps for Trust and Decision Making (2013) *Journal of Medical Internet Research 15(12)*: e277.
14. Albrecht UV., Pramann O., U von J. Medical Apps – The Road To Trust. (2015) *European Journal for Biomedical Informatics,11*:en7–12.

Dr. med. Urs-Vito Albrecht,
MPH, Deputy Director,
Peter L. Reichertz Institute for Medical
Informatics, Hannover Medical School,
Germany
E-mail: albrecht.urs-vito@mh-hannover.de
http://www.plrimedapplab.de

World Medical
Journal

World Medical
Journal

Interview with Vytenis Andriukaitis, EU Commissioner for Health and Food Safety

By Dr. Peteris Apinis. June, 2015

Vytenis Andriukaitis

Q. The half-year of the Latvian Presidency of the Council of the European Union has come to an end. As to healthcare, we have organised a number of European-level conferences on the topics of healthy lifestyles and nutrition for children, tuberculosis, eHealth, popular sports, healthcare financing as well as addressed a number of other important issues. How do you evaluate Latvia's performance in its half a year of presidency?
I would like to congratulate Latvia for succeeding in delivering results on a set of priority issues during its Presidency of the Council of the EU. Latvia took up the Presidency at a very important moment and contributed to the discussions on the future directions for health policy at EU level. In addition, the European conferences organised under Latvian leadership helped make progress in reducing the risks associated with poor nutrition and lack of exercise. The Latvian Presidency has put the spotlight on tuberculosis – and led discussions towards the adoption of the Riga Declaration which

will be guiding action to address this important – and often neglected – disease in the European Union. The Presidency has further explored how eHealth could benefit both citizens and health systems, and contributed to the discussions on how to create efficient, equitable health systems.

Q. Currently there is a tendency all across Europe that patients obtain information about diseases and health from the Internet or magazines. Over 80% of Internet portals and social sites which are dedicated to health topics are financed by businesses: drugs, dietary supplements or a special method. More often than not, it is difficult for patients to discriminate between the truth about health and surreptitious advertising. As to Latvia, there is even a publication, the magazine *Ko Ārsti Tev Nestāsta* (What Doctors Don't Tell You), advertising dietary supplements, Ayurveda, unjustified diets, and at the same time discouraging patients from seeing an oncologist or gynaecologist. How to deliver correct information to the patient? Is the European Commission going to set up a health information site for Europe containing evidence-based information, similar to MedlinePlus in the USA? What is your opinion on pan-European level information campaigns on healthcare topics?
The European Commission has a dedicated website on health and healthcare topics [1] and several specialised EU agencies offer health-specific information to the citizens [2]. The Commission has also supported a number of recent and ongoing health campaigns, carried out by the EU in collaboration with Member States and neighbouring countries, for example, awareness raising campaigns about tobacco, the initiative European Action Against Cancer, healthy

workplaces campaigns and European Antibiotic Awareness Day, to name a few. With Member States facing common challenges such as a rise in chronic diseases, and increasing antimicrobial resistance, I find these types of pan-EU initiatives extremely valuable.
One of my priorities is to increase the availability of scientifically sound, comparable and high quality health information to identify the key challenges in health. Policy makers need this type of reliable health information, based on good indicators, sound data and regular analysis. The overall aim of EU health information policy is to support evidence-based development, implementation and evaluation of actions for health at EU-level and in Member States.

Q. Right now, there is quite an opposition to vaccination in Latvia. The situation is pretty similar in other European countries. There are excellent lecturers, nice-looking books and You Tube files discouraging people from vaccination and explaining about the dangers of vaccination. What could the European Commission do in order to present information on the need of immunization in an equally attractive manner from the visual and informative aspect? Maybe it is the time to have a common immunization calendar in Europe? This issue is more and more topical due to the increasing labour mobility in Europe. Children are moving along with their parents. Each single country in Europe has its own vaccination calendar, which is the reason why many children do not get adequate vaccination and immunization. Shouldn't such vaccinations as against diphtheria, poliomyelitis, tetanus and some more be declared as mandatory, to be administered according to strictly defined time schedule, whereas the rest (rotavirus, German measles, pneumococci) could be left on the national level? Isn't it high time that we have a mandatory requirement to vaccinate all immigrants from third countries because their earlier vaccination is unreliable?

Vaccination is one of the most effective means of preventing diseases. I am keen to support Member States in securing efficient vaccination programmes, and to foster co-operation at European level in this area, while bearing in mind that in the EU vaccination is a responsibility of the individual Member States. As such, the way national immunisation programmes are organised differs considerably between countries. National immunisation strategies range from voluntary vaccinations to almost complete mandatory vaccination programmes.
The Commission provides support to Member States on vaccination, e.g. in the field of seasonal influenza and childhood vaccination. The Commission is working with Member States within the Health Security Committee to be better prepared to address vaccine shortages as well as scepticism about vaccines; to prevent cases like the recent tragic death of an unvaccinated child in Spain. Last year's Council conclusions on vaccination provide an opportunity to co-operate further in this area, and encourage Member States to share best practices on their vaccination policies.
When it comes to vaccination of immigrants from third countries, this is also the responsibility of individual Member States. The Commission, together with ECDC, is developing screening guidance that includes the issue of vaccination of migrants to support EU countries. We have also financed the project "Promote Vaccinations among Migrant Populations in Europe" under our health programme, which has resulted in recommendations for policy-makers on the immunisation of migrants and educational material for health professionals and migrants.

Q. In Europe, the manufacturing and distribution of dietary supplements is becoming increasingly widespread. Contrary to drugs, the supervision of manufacturing, distribution and advertising of dietary supplements is much more lenient. As a rule, dietary supplements

contain chemically active substances: vitamins, ferments and minerals, and their abuse may cause health problems. Is the Commission for Health going to introduce somewhat more stringent restrictions to the distribution and advertising of dietary supplements?
EU rules are in place to ensure that food supplements placed on the EU market are safe. The list of vitamins and minerals that may be used in food supplements is harmonised at EU level; however, maximum levels of such substances are not harmonised and may be set by Member States in accordance with the rules of the Treaty. Botanicals are covered by the general framework on food safety together with applicable national rules. The Commission does not envisage at this stage any measures to restrict the marketing of such foods.

Q. Today, health of and polypragmasia in senior citizens is becoming an ever increasing problem all across Europe. On average, each senior citizen in Europe consumes 6.4 various drugs daily. Doesn't the pharmaceutical business have a too heavy influence on the healthcare system?
Demographic and epidemiologic trends, together with a range of other factors as pharmaceutical markets' own dynamics, changes in medical practice and pharmaceutical policies influence pharmaceutical spending, which is an important component of healthcare expenditure in Member States. In addition, changes in the therapeutic mix of medicines used that occur with new treatments can also influence the share of the overall pharmaceutical bill accounted for by hospitals. The use of multiple medications in elderly increases the possibility of adverse reactions to drugs, increases the risk of hospitalisation, of medical errors caused by these medicines and may question the quality of healthcare in general. This is an area of Member States competence; however, the Commission supports Member States to exchange experience and in particular on developing of tools and methodologies to assess the quality of care.

Q. More often than not, the pharmaceutical business in Europe would not supply all countries with drugs on equal terms, and the prices vary significantly across the countries. If there were a common pharmaceutical policy for Europe, what would the effect be like?
At EU level, prices of medicines are under the responsibility of Member States. The only field of EU regulatory intervention is the so-called "transparency directive" (Directive 89/105/EEC) which lays down procedural rules for regulating prices of medicines and their inclusion in the scope of health insurance systems. I am keen to foster discussions and support co-operation between Member States in this area so as to make medicines more affordable and accessible to patients. I am encouraged by recent developments including the Council conclusions whereby Member States have agreed to exchange information about the prices of innovative medicines; about on-going discussions on this issue, as well as emerging pilot project amongst some Member States.
Other challenges of pharmaceutical policy in Member States that also gained attention lately at EU level relate to the optimal use of current regulatory framework, the early dialogue with all relevant stakeholders and the bilateral agreements between member states. Such issues also relate to the efficiency of pharmaceutical spending, i.e. the capacity to get the most value from today's expenditure while keeping appropriate incentives for future innovation, associated with challenges for affordability in some countries. It is agreed in the Council that further cooperation between Member States is needed in such areas and the Commission is ready to further cooperate based on an integrated approach and a long term agenda.

Q. Today the biggest issue concerning children all over Europe is sedentary lifestyle and obesity. Every fifth child in Europe is overweight. Unfortunately, in Latvia the national Ministry for Educa-

World Medical
Journal

World Medical
Journal

---

tion resists to introduce the third sports class per week. Could the European Commission be more active in making the national governments to introduce daily sports classes for children?

I regret to report that the figures are even worse. One out of three children in Europe in 2010 was overweight or obese. This is a major increase compared to 2008 when one out of four children was overweight or obese.

Member States play the key role in providing education for school children in relation to nutrition, physical activity, overweight and obesity – and this is something most are addressing.

I am ready to use all the tools at my disposal to support them in their efforts to promote healthy lifestyles. The Commission is working with Member States in this regard within the High Level Group on Nutrition and Physical Activity. In 2014 this group adopted an Action Plan on Childhood Obesity with the aim to prevent the increase in obesity in children by 2020. A Joint Action on Nutrition and Physical Activity will start after the summer period to further support Member States in the implementation of this Action Plan.

Q. In Latvia, the attitude of the Ministry of Education to children's health is quite an issue. Since 2002, health education is no longer in the school curricula. The situation (i.e., no health education for children) is similar in many countries in Eastern Europe. Could the Commissioner make some pressure on national governments with regard to educating children in the basics of health?

Again, the competence in the field of education lies with the 28 EU Member States. However, under the EU Strategy on Nutrition, Overweight, and Obesity-related Health Issues for example, the Commission closely cooperates with the national governments to promote healthy lifestyles in children. The High Level Group on Nutrition and Physical Activity brings together governmental experts that promote

and exchange best practices in this area. The promotion of healthier environments, especially at schools and pre-schools, is one of the key areas of the 2014 Action Plan on Childhood Obesity.

Q. In the past two years, the Latvian Medical Association managed to introduce two important regulations in legal acts. The first is that smoking in the presence of minors should be treated as child abuse. This means that in Latvia an adult must not smoke in the presence of a child, be it at home, in the street or at a bus stop. The other amendment to the law stipulates that a person has the statutory right to clean smoke-free air, and this right has a priority over other persons' right to smoke. Thereby, smoking in the presence of another person is impermissible, unless the latter has given permission. Apart from that, in Latvia it is absolutely prohibited to smoke at sports and cultural facilities, in the premises of central and local government institutions, in cafes, restaurants, work places, on loggias, balconies, common staircases and elsewhere where it can harm other people's health. How would you evaluate our achievement and how could we attain this in entire Europe?

I am very pleased to hear about Latvia's efforts towards achieving a smoke-free environment and, in particular, to protect children. Furthermore, strengthening the right of the individual person wishing to be protected against tobacco smoke is an important step in that direction. While the legislative competence in this area lies primarily with the Member States, the European Commission is indeed committed to continue working with Member States in their implementation and enforcement of the Council recommendation on smoke-free environments (2009/C 296/02). We regularly discuss the state-of-play and progress in this area with representatives of the Member States' competent authorities. We know from past experience that good examples from one country often motivate others to follow.

Q. In terms of percentage of GDP, Latvia has the lowest healthcare financing in Europe, it is less than 3%. Could the European Union make a pressure on national governments that the accessibility to healthcare services for population is a priority and thus healthcare financing throughout Europe should be at least 4.5% of GDP?

The Commission acknowledges that healthcare systems need to be reformed to provide accessible and quality healthcare through efficient structures. Sustainability challenges of healthcare systems in the EU are addressed and monitored within the process of the European Semester.

Under the 2014 European Semester Latvia received for the first time a country-specific recommendation (CSR) calling for the reform of its health system with concrete, targeted areas including the quality and accessibility. Since then, the Latvian government increased the health budget by € 31.2 million in 2015 compared with 2014 and approved a € 30.6 million increase each year until 2017. But even with this additional funding, still below 3% of GDP, the financial burden on patients in Latvia remains very high and accessibility is still a problem. Therefore, in 2015 the Commission once again proposed the same health CSR to Latvia, and we will closely monitor its implementation.

The Commission provides help and support, which is what countries that are facing difficulties need. For example, Member States can make use of the European Strategic and Investment Funds (ESIF) for health investments. I welcome the commitment made by the Latvian authorities to use ESIF for better access to healthcare, especially for those socially and territorially excluded. For the years 2014–2020 the health infrastructure allocation for Latvia exceeds €152 million and further allocations have been programmed for measures such as health promotion and prevention, enhancing qualifications of the medical staff and health.

Q. Shouldn't public health issues override the national level? For example, isn't it the time for the European Union to declare that it has a common policy as to pesticides and other substances which inhibit the development of hormonal system? Isn't it the time to have a common European strategy in place for reducing the consumption of alcoholic beverages and tobacco products, and for prohibiting trans fatty acids?

The overriding principle of EU health policy is that human health is well protected and accounted for in the development of all EU policies and activities. All EU policies are required by the EU treaty to follow this "*Health in all Policies*" (HIAP) approach.

Taking some of your specific examples: Endocrine disruptors are already regulated in some sectors. Currently, the European Commission is carrying out an impact assessment to analyse different options for defining the criteria for the identification of endocrine disruptors in the context of the plant protection products and biocidal products regulations. The decision at EU level concerning the criteria will be made once the impact assessment is concluded.

On alcohol, whereas the main responsibility for public health interventions lies with Member States, the Commission will continue to support them in reducing alcohol related harm. This will be done based on the objectives of the 2006 Strategy and by making use of existing structures like the Committee on National Alcohol Policy and Action. In line with the Commission's "health in all policies" approach, we will further consider how to enshrine alcohol harm into a holistic approach to reduce the burden of chronic diseases.

Q. Would you agree that the vast difference as to the availability of medical services is actually a shame for Europe? Maybe it is the time we start considering a common European health strategy, unified health tax, unified standards for emergency medical care and first aid?

At present there is no unified health systems policy in the EU: it is for Member States to decide which services to provide to their citizens and how this should be funded. However, the EU does have a role in supporting Member States and we are actively working on ways to try to help

them increase availability of services. The cross-border healthcare Directive makes it easier for patients to access services in other Member States. We are in the process of setting up European Reference Networks which will bring together centres of expertise for conditions or treatments where expertise is rare: these will act as a resource for all Member States. We are working together to deliver the considerable potential benefits of Health Technology Assessments and eHealth. And we are increasingly looking at the question of how collaboration in border areas can improve the delivery of health services.

References

1. See link: http://ec.europa.eu/health/index_en.htm
2. e.g. the European Centre for Disease Prevention and Control (ECDC) (http://ecdc.europa.eu/en/Pages/home.aspx), the European Medicines Agency (http://www.ema.europa.eu/ema/), the European Agency for Health and Safety at Work (https://osha.europa.eu/), and the European Monitoring Centre for Drugs and Drug Addiction (http://www.emcdda.europa.eu/).

Position of Israeli Medical Association in Forced Feeding Issue

Hunger strikes have been used as a means of non-violent resistance by political prisoners throughout history in an effort to achieve specific objectives.

Famous examples include Mahatma Gandhi, British and American suffragettes, and the Irish Republican hunger strike of 1981. In Israel, Palestinian detainees and prisoners have used the hunger strike as a tool for soliciting acquiescence to their demands. Over one thousand hunger strikes have occurred in Israel to this point. In general, these hunger strikes began in the facilities of the Israeli Prison Services (IPS),

and, when the prisoners' medical condition deteriorated, this stage was followed by hospitalization in public hospitals. The hunger strikes lasted everywhere from several days to weeks and months, during which most, though not all, prisoners drank and agreed periodically to undergo tests, and take vitamins and carbohydrates intravenously. Each time, the duration and extent of cooperation with IPS and/or hospital physicians varied. No detainee or prisoner in Israel has ever died during a hunger strike.

In the early months of 2014, the Israeli Medical Association (IMA) became aware

of legislation being prepared in Israel that would allow the forced feeding of prisoners. The IMA immediately requested a meeting with the Ministry of Health and the Ministry of Justice, in which we expressed, in no uncertain terms, our complete opposition to such a bill and the fact that we would instruct our physicians not to comply with it. We followed this with a letter to then Justice Minister, Tzippi Livni, explaining our strong ethical positon.

Our objections notwithstanding, the Ministry of Justice continued work on the bill and brought it before our Parliament (the Knesset). We sent a letter to the Knesset members before the bill was considered in the Ministerial Committee for Legislation, but unfortunately it passed this committee. Although we urged those Ministers

---

Leonid Eidelman

Malke Borow

who opposed the bill in the Committee to appeal the decision, the bill continued to a first review in the Knesset plenum, where it passed.

Seeing that the bill was progressing, and against the backdrop of a mass hunger strike in the Israeli prisons in June 2014, the IMA and its Ethics Bureau convened an emergency consensus conference, under the title "Treatment of prisoners/detainees on hunger strikes – the medical challenge." Participating in the conference were representatives of the IMA scientific associations, members of the IMA ethics bureau, representatives of the Ministry of Health, the National Council for Bioethics, IPS physicians, representatives of the International Committee of the Red Cross and others.

At this conference, IMA officials made it clear that the law does not change a doctor's ethical obligations not to coerce feeding on a competent individual. At the end of the conference, all parties agreed on a list of principles which can be viewed on the IMA website [1].

Recently, Gilad Erdan, the new Israeli Minister for Interior Security, announced plans to renew the proposed legislation regarding forced feeding of hunger strikers. The proposal will be put for discussion in the Knesset Committee for Internal Affairs and then for final voting.

The proposal enables obtaining legal permission for the provision of medical care and/or nutrients (including force-feeding through a tube) despite the active opposition of the prisoner.

In our view, the proposed law is both unethical and unrealistic and does not help solve the problem. It creates an illusion that forced feeding will prevent medical harm to the patient, whereas the opposite may in fact be true. We cannot approve a law that puts physicians at the forefront of a policy – both as a group and as individuals – which is against their professional and ethical obligations.

The fundamental change underlying this proposal is in contradiction with and contrary to the accepted medical ethics in Israel and throughout the world, including the IMA's ethical Code and the WMA's Declaration of Tokyo and Declaration of Malta, which recognize it as a form of inhuman and degrading treatment.

The IMA is strongly opposed to the intended force feeding law. Our opposition was expressed to the government offices and representatives of the attorney general at every possible opportunity. We are prepared to continue to protect the doctors at all levels, including in the public sphere and parliamentary level, in order to thwart the legislative process.

We know our hospital doctors will be presented with ethical dilemmas and be placed in an impossible position professionally. Therefore, we have established a hotline for these physicians to call with any questions they may have, as well as professional and ethical guidelines that we released in a handbook following last year's mass hunger strikes.

Our concern is that the proposed law will move quickly through the legislative process and we are taking measures to ensure that it does not materialize. The IMA took out paid announcements in major Israeli newspapers (in addition to regular press coverage on the matter) explaining our opposition to the proposed law.

The World Medical Association (WMA) has also been a steadfast partner in our struggle against this unethical bill. On June 22, Drs. Deau and Hoven sent a letter to Prime Minister Benjamin Netanyahu explaining the WMA's position and its support of the IMA, and the inevitable international condemnation that would follow the passage of such a law.

In its letter, the WMA stated the following:

"Over the past four decades there have been clear directives developed on what physicians can do, and from what they must refrain. Clearly torture, inhuman and degrading treatments are nothing with which a doctor should be involved in any way. Force-feeding is violent, very painful and absolutely in opposition to the principle of individual autonomy. It is a degrading, inhumane treatment, amounting to torture. But worse: It can be dangerous and is the most unsuitable approach to save lives.

The evidence from many cases around the world that our colleagues have been working on over the past four decades shows that the best results are obtained when the patient/physician relationship is maintained, even under the difficult circumstance of a hunger strike. This includes patient confidentiality, proper medical care and advice by the physician, but also respecting the free will of the patient. Force-feeding is completely incompatible with this and destroys any patient/physician trust."

We are determined to prevent force feeding in Israel and we will continue to support our physicians and remind them of their ethical obligations.

References
1. http://www.ima.org.il/ENG/ViewCategory.aspx?CategoryId=4497
2. http://www.ima.org.il/Ima/FormStorage/Type8/IMAHungerEN.pdf

Dr. Leonid Eidelman, President, IMA
Malke Borow, Director, Division
of Law and Policy, IMA
E-mail: malkeb@ima.org.il