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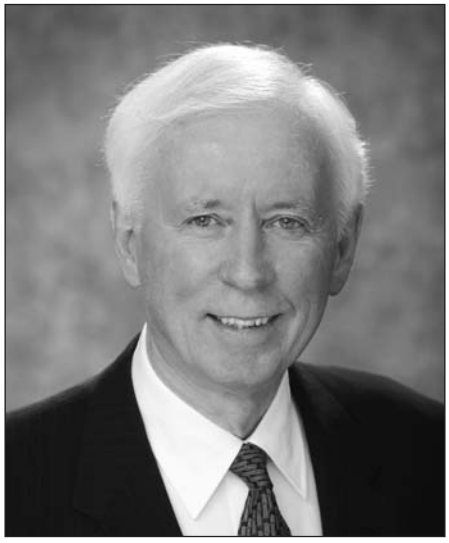
President's Report

World Medical Association Cecil B. Wilson, MD, MACP April 4, 2013 Bali, Indonesia

It has been a great privilege for me over the past five months to represent the World Medical Association as your president.
I have found the responsibility sobering, the experience fascinating and the opportunity personally rewarding.
In my inaugural address at the General Assembly last October in Bangkok I shared with you the message that I would carry in my travels around the world on behalf of the WMA.

That message consisted of three parts:
1. The moral imperative of ethics in medicine
2. The challenge of noncommunicable diseases and their Siamese twins, the social determinants of health
3. The threat of climate change



Cecil B. Wilson

That message has gone with me as I have traveled to four continents,
To twelve countries and
Fifteen cities within those countries for a total of
Sixteen meetings and conferences in the past five months.
The countries visited include the US, Canada, Taiwan, South Africa, Israel, Egypt, Singapore, China, Japan, Nepal, England and Latvia.
I would be remiss if I did not express my appreciation to the medical associations and others in each of those countries, many of which are here in this room today, for their warm hospitality to me and their expressions of support for the World Medical Association.
Thank you all.

Posted on the web last week is a list of all the events in which I have participated with a brief description of each.
In addition, following the meeting in Bangkok I started a president's blog titled "Around the World with WMA President Cecil Wilson, MD". The blog site is accessible from the WMA home page at www.wma.net. These blogs total 38 to date, almost two a week.
In them I have chronicled each of the events in which I have participated.

They have also dealt with other issues of importance to the WMA.
Each event in which I have participated has warranted at least one blog and there are some for which I wrote two – "two blog meetings" – if you will.
I will not describe each visit today in detail, but I would like to highlight some of the themes that were a part of the meetings and were only some among the many issues that caught my attention.

I will conclude with some observations about the WMA based on my experience in this office to date.
The themes include:
- NCDs and the social determinants of health,
- Violence in the health sector,
- Revision of the Declaration of Helsinki,
- Medical students and junior doctors
- Leadership training for physicians.

First, the social determinants of health.

Two weeks ago at a conference in London organized by our Chair of the Socio-Medical Committee, Sir Michael Marmot, a new report was presented, "Working for Health Equity: The Role of Health Professionals in the Social Determinants of Health.
This report from the University College of London, Institute of Health Equity addresses what medical professionals can do to address this problem.
Twenty-one national professional organizations participated in the report.
Proof that when Sir Michael calls, people say yes.
I provided an international perspective based on WMA policy.
And Dr. Anna Reid, President of the Canadian Medical Association reported on a simultaneously released Canadian study based on a survey of Canadian physicians titled "Physicians and Health Equity Opportunities in Practice".
At the Taiwan Health Forum held in Taipei in November Dr. Wen-Ta Chiu, Minister of Health emphasized the importance of the social determinants of health.
Dr. Chiu is credited with leadership in passing a bike helmet law in Taiwan a number of years ago.

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During the time since passage of the law the number of people in Taiwan has increased, the number of motor bikes has increased exponentially and likewise the number of accidents.
However the number of deaths has decreased or at least remained relatively stable.
Since head injuries are the primary cause of deaths from bike accidents, this social determinant of health has been addressed in large part by the helmet law.
Estimates are this law saves approximately 4000 lives a year in Taiwan.
At the annual scientific conference in Beijing in January Dr. Chen Zhu, President of the Chinese Medical Association and Minister of Health for China reported on the status of health system reform in China and the influence of social determinants of health.
Dr. Zhu commented positively on my remarks to the conference about the importance of governments recognizing that all policy has health effects – that we should think not just about one minister of health but all ministers should be considered health ministers.
At the All Nepal Medical Conference in Kathmandu in March, Dr. Ram Baran Yadav, President of Nepal and a physician, described the threat of earthquakes in Nepal where buildings lack structural integrity.
He highlighted the increasing burden of communicable disease with its strains on the health care infrastructure.
He reported on the high incidence of accidents in a developing country with roads in a poor state of repair, the absence of street lights and only a few traffic lights in Kathmandu a city of roughly three million people where vehicles, bikes and pedestrians all share the same roadways.
All social determinants of health.
Next is the issue of violence in the health sector:
Last October Chair of Council Dr. Mukesh Haikerwal, Dr. Dana Hanson, former WMA president and I attended the third international conference on violence in the health sector in Vancouver, Canada.
Dr. Haikerwal gave the opening keynote speech.
The evidence that this is a major problem of epidemic proportions was illustrated by the attendance of 482 health care workers from 43 countries who presented 189 papers documenting violence against health professionals in their countries.
An additional aspect of this problem is the increase in violence against health care professionals and facilities in areas of armed combat.
The WMA is working with the ICRC/Red Crescent Society on the Health Care in Danger Initiative seeking to develop ways to decrease the danger of violence in these circumstances.
Vivienne Nathanson of the British Medical Association and I were in Cairo, Egypt in December participating in one of the regional conferences to seek advice from those actually working in the field.
The meeting included 70 physicians from areas of armed conflict in Egypt, Libya, Syria, Yemen, Kenya, Pakistan and Afghanistan.
These true heroes of medicine described in dispassionate professional detail the work they are doing and measures that can help decrease danger based on their experience.
In February I spoke to the Syrian American Medical Society (SAMS) Conference in Clearwater, Florida in the US and described the WMA's work with the ICRC and our publically calling on President Assad of Syria to protect health care workers and facilities.
SAMS is involved in a major effort to provide medical relief to wounded Syrian citizens in Turkey, in border refugee camps and inside Syria.
Of their 10 chapters nationwide, over 100 volunteer physicians to date have traveled across the Turkish border to reach field hospitals.
Once there, these doctors treat hundreds of casualties while under the constant threat of attacks by Syrian military artillery and airstrikes.
SAMS has established eleven hospitals in Syria, supported twenty-five already existing medical facilities, and has appropriated over $2 million to specific relief projects since April 2012.
In the area of ethics, it was my privilege to attend and present opening remarks at the two expert conferences our workgroup on the Declaration of Helsinki has held since we met in Bangkok.
I was impressed by the quality of the conferences and the input received.
I believe the work group was similarly impressed and appreciative.
I was also impressed by the hospitality and arrangements of our host countries – the South African Medical Association hosting the conference in Cape Town, South Africa in December and the Japanese Medical Association (JMA) serving as host for the conference in Tokyo in February.
Thank you both.

Some of you may know, others not, that at the conference in Tokyo I gave my opening remarks in Japanese.
Dr. Yoshitake Yokokura, JMA President, and Dr. Massami Ishii, vice chair of the WMA Council were kind in complimenting me on my efforts.
In fact when I asked Dr. Yokokura how I had done he said "perfect!"
Yokokura san, Ishii san, thank you very much for your most generous assessment of my performance.
Doomo Arrigato Gozaimasu.

Now to medical students.
The WMA is a strong supporter of medical students through the International Federation of Medical Student Associations (IFMSA).

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In March I gave the opening speech to their annual meeting held in Baltimore, Maryland in the United States.
I focused on optimism about the future of the profession tempered by an understanding of the major challenges we face.
During the conference I led a president's session on conflicts of interest physicians face particularly in their interaction with commercial interests.
I also spoke to the alumni section and Junior Doctors group on worldwide health care systems and the future of medicine.
The group meeting in Baltimore, the medical student association, is most favorably impressed with the support of the WMA and eager to continue a positive relationship.

Next is leadership training:
The INSEAD/WMA sponsored weeklong leadership-training course was held this year in January in Singapore.
Our Secretary General Otmar Kloiber, Dr. Yank Coble, former WMA President, Leah Wapner, Secretary General Israeli Medical Association and I participated in the course along with the faculty of INSEAD.
32 medical association leaders from 20 countries were enrolled in this course, which began initially in 2006.
A superb faculty and an enthusiastic, engaged group of physician leaders highlighted the week.
This effort to provide leadership training for physicians is truly a star in the WMA crown.
Over the years I have had the opportunity to attend similar courses in premier institutions in my country – Kellogg Business School in Chicago, Harvard Kennedy School of Government in Massachusetts and Stanford University School of Business in California.
I can say based on my experiences, and in comparison, that the WMA course in Singapore is the gold standard.
I would recommend WMA member associations take advantage of this outstanding opportunity for their rising leaders to receive training.

Let me conclude with some thoughts based on my initial experiences as your president.
The WMA has a powerful positive message to share with the world.
It is a message based being a voice for ethics, good health policy and seeking to support physicians to achieve the best of health care for patients around the world.
We are speaking out on matters of importance.
We are pointing out violations of health related human rights – violations against health care workers and patients.
We are fortunate to have a professional, creative, energetic staff led by our Secretary General Otmar Kloiber.
My thanks to them for what they do and for their support of my efforts over the past months, especially facilitating work on the president's blog.
Nigel Duncan, our communications director, is working diligently and creatively moving into social media to expand communication of our message to the world.
Those around the world who know of the WMA's work and interact with us appear to hold the WMA in high regard.
For those around the world who do not know the WMA, just our name the World Medical Association suggests to them an organization of importance.
After all, we are not just another medical association.

We are The World Medical Association.

That being said, organizations thrive and endure if they continue to grow.

Our resources are limited and as everyone in this room knows, come primarily from dues income.

Therefore it is important in preserving those resources that our member organizations, which provide the dues income, are aware of the importance of the WMA.

And it is incumbent on us as leaders to keep our associations aware so that they continue to support the WMA.

The achievements of the WMA, which are considerable, are accomplished with extremely limited resources for an organization so important to world medicine.

It is a credit to our staff that they are able to achieve so much given the limited resources.

Going forward I believe the existing dues income structure is inadequate to support the significant role the WMA should play in representing the medical profession on the world stage.

I understand that we have struggled for a number of years with how to increase income while remaining true to the ethical principles that are the foundation of this association.

However, I believe it is important for us to continue to look for ways to expand the power of our voice by increasing our interaction with other international organizations – and by finding more resources (translation – more money).

Thank you for the opportunity to share this report with you.

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Opening Speech by H. E. Dr. Nafsiah Mboi, Md, Pediatrician, MPH Minister of Health of the Republic of Indonesia at the 194th World Medical Association Council Session

Honorable Governor of Bali,
Chairman of the World Medical Association,
Chairman of the Indonesian Medical Association,
Head of the Agency for Development of Human Resources for Health
Ministry of Health, Indonesia
Head of the Provincial Health Services of Bali,
Members of the World Medical Association Council,
Distinguished Guests,
Ladies and Gentlemen.

Nafsiah Mboi

It is a great pleasure for me be here with you at the opening of this important ***194th World Medical Association Council Session***. Let me extend my warm welcome to all participants who have travelled here from the four corners of the world to join this meeting today. I am impressed that your organization includes representation from north and south, from east and west and, happily, reflecting the make up of the modern medical profession, I see both men and women.

I would like to thank the World Medical Association for organizing this council session in Bali. Although some of you may have visited here before, I am sure you will agree this is always a good place to revive the body and renew the soul. I have never heard anyone complain when they had reason to come back to this beautiful island. Let me also extend thanks to the Organizing Committee and the partners who have worked so hard to make this event a success.

The values and practices which were identified as important in 1947 when your organization was founded are just as crucial today as they were then. Innovation in medicine enables doctors to extend life and cure more patients than ever before. If, however, this is done without reference to the highest professional and ethical standards we are all placed at risk – patients, practitioners, the health systems within which we practice. Doctors looses touch with their limitations, patients become merely "objects of concern", and health services loose the human touch.

As we gather here today, what are some of the most significant changes in our field?

Diseases like leprosy used to need lifelong treatment, while today they can be cured in a year. Many cancers are also curable, while a decade ago the number of people with even a five year survival rate was limited. Now we find "cancer survivors" leading full, independent, normal lives. Advances in diagnostic technology, likewise, contribute to improved health outcomes and make outreach of diagnosis to new patients possible. Disease can be identified and treated far earlier than was possible formerly and telemedicine can make diagnosis and consultation possible for patients who without such technology would have been altogether unreached and unserved.

These rapid advances of technology in medical care combined with revolutions in communications and information present us with both opportunity and challenge. Health outcomes **can** without doubt be improved but almost without exception these innovations are costly and beyond the reach of many, perhaps most, of our people. To meet this challenge some governments have developed national health financing schemes which increase accessibility of service while distributing health costs more equitably. Such health insurance systems have generally proved extremely effective.

While changes have been taking place relative to medical technology there have also been epidemiological changes across the globe. Many communicable diseases have become curable resulting in steadily increasing life expectancy. At the same time there has also been an increase in prevalence of non communicable diseases many of which are particularly dependent on advanced technology for diagnosis and treatment. This, in turn, has contributed to increasing health care costs, leading many countries to

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more careful evaluation of the effectiveness, structure, and equitability of their health expenditures.

In fact, in most situations technological advances account for the bulk of health care costs, now. Responsible management of health care systems requires good cost benefit analysis to assure that benefits to health outcomes justify the costs. Calculations are complicated, nonetheless, it is clear that correct and equitable use of new technologies has contributed to reductions in mortality, increases in longevity, improvements in quality of life, and reductions in productivity losses resulting from ill health.

The objectives of the World Medical Association are attuned to assisting physicians in learning to be sensitive, skilled, and consistent in making such decisions. This commitment is reflected in your programs to "achieve the highest international standards related to Medical Education, Medical Science, Medical Art, Medical Ethics, and Health Care for all people in the world."

I take this opportunity to call upon the WMA to encourage physicians around the globe, including those in Indonesia, to remain faithful to the highest professional standards of service to their patients as they evaluate and utilize technology. At the same time I would underscore that no cost benefit analysis of treatment is complete without due attention to the issue of equity in the provision of health services.

I would like to comment on the issue of Human Resources for Health or HRH. In Indonesia, one of the main challenges to improving our health services has been related to the inadequate supply and uneven distribution of trained health care personnel to meet the needs of our widely scattered people. The Government of Indonesia has used various approaches to increase the number of health workers, improved the range and quality of their skills, and to achieve their more equitable distribution across the country.

In the early 2000s management of health services was decentralization in Indonesia. While in some parts of the country the importance of Human Resources for Health was well recognized by local government, in other areas it was not regarded as a priority issue. Local budget allocations were uneven in this field, and in some cases were extremely low.

In 2008, to increase the availability of specialist care in more remote areas, the Ministry of Health established a scholarship program to support education of medical specialists. Upon graduation, scholarship awardees have a service obligation (twice as long as their residential education) in areas lacking appropriate specialists. At the end of 2012, a total of 4,311 doctors had been granted the scholarships. 320 had already graduated. Although this program has gotten off to a good start, there is concern that this approach may only meet the needs temporarily, because at the end of their term of service, if they wish, these specialists will be free to move to other posts.

Before closing, let me comment briefly on the importance of the work of WMA. I believe that collaboration among WMA members is important, especially working together and information sharing to tackle common health problems of developing countries, such as malnutrition, and infant and maternal mortality. Additionally, many of us experience a "*brain drain*" with various faces – the movement of doctors from short assignments in rural areas to settle in the city, from the public service to the private sector, and from their low paying home country to higher paying service abroad. Finally, as provision of health care is increasingly driven by market forces and international boundaries become more opened, physicians in some countries find themselves at a disadvantage competing with externally funded health care providers and facilities which are part of the evolving global health care market.

This is a comparatively new issue and one I believe is of considerable long term importance. I urge the World Medical Association to engage itself and its members in exploring this important issue. The global market is here to stay and will undoubtedly expand but it is important that as medical practitioners and health care providers we not jump into the world market and sell our souls to the highest bidder.

I would argue that we are a service-based profession and should fight hard to remain so. We should not loose our identity in the search for a bigger profit. Likewise, the countries that are most likely to be targets of new international medical enterprise need advice and support in considering how to respond to this new challenge. This is a challenge calling for national and international reflection and cooperation if we are to protect our profession and the rights and the well being of our patients. I believe that only with collaboration between developed and developing countries, between "sending" and "receiving" countries, between technical and ethical specialists will we be able to influence the global health market and better serve the global family.

We need doctors whose of obsession is the best interest of the patient, still inspired by the principle "*primum non nocere*" that is to say "*first, do no harm*". As it is mentioned the Hippocratic Oath: "I will use treatment to help the sick according to my ability and judgment, but will never use it to injure or wrong them."

Now, with rising education the world around and information technology available to all, patients are no longer passive. Doctors

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have to be prepared to answer difficult questions from the patients, often to work more with them, not just issue instructions!. Improvement in the quality of doctors – their technical knowledge and skills as well as professionalism, commitment to service, and perhaps strengthening of human skills – should begin in medical education. Teachers in medical school are role models for doctors and, in their knowledge and manner they train their students. I thank you WMA, therefore, for your attention to the important field of medical education.

In closing, let me repeat my thanks to the WMA for organizing this meeting and for bringing it to Indonesia. We are pleased to host your gathering and have high hopes for your discussions. May you have fruitful deliberations and a pleasant stay in this island paradise called Bali.

Finally, asking the Grace of God The Almighty, on our deliberations, I declare the ***194th World Medical Association Council Session*** officially open.

194th WMA Council Session. General Report

Bali, Indonesia (April 4–6, 2013)

The 194th Council Session, held at the Laguna Resort and Spa, Nusa Dua, Bali, Indonesia (April 4–6) was opened wiseth a speech of welcome from Indonesia's Minister of Health Madame Nafsiah Mboi, a paediatrician.

Council

Following the speech, which was warmly received, the Council went into formal session and Dr. Mukesh Haikerwal (Australia) was re-elected Chair, Dr. Masai Ishii (Japan) was re-elected Vice-Chair and Prof. Frank-Ulrich Montgomery (Germany) was re-elected Treasurer. All three were re-elected unopposed.

Dr. Wilson then gave his Presidential report on his activities since his inauguration in Bangkok in October 2013. He said he had travelled to four continents with his threefold message on ethics in medicine, the challenge of non-communicable diseases and the social determinants of health, and on climate change. He had attended 16 meetings in 12 countries and 15 cities. He spoke about his twice-weekly President's blog on the WMA website which had detailed these trips. He said the WMA had a powerful positive message to share with the world. It was a message based on a voice for ethics, good health policy and seeking to support physicians to achieve the best of health care for patients around the world. The WMA was speaking out on matters of importance, pointing out violations of health-related human rights, violations against health care workers and patients. But the organisation's achievements were accomplished with extremely limited resources and he thought it was very important for the WMA to increase its inter-action with other organisations and to find more resources.

Dr. Otmar Kloiber, Secretary General, in his oral report elaborated on the secretariat's activities as set out in his written report (*see page 54).* He detailed the actions taken in support of the 2012–15 strategic plan and the 20 strategic initiatives set out in the plan. He spoke about partnerships and collaboration with other organisation, as well as the activities of the Junior Doctors Network, the Business Development Group and the potential for the growth of the organisation.

Dr. Haikerwal reported on his many visits around the globe during his chairmanship and praised the work of the WMA secretariat.

The Council then heard arguments why two emergency Resolutions should be discussed at the meeting as matters of urgency.

The first was a Resolution proposed by the American Medical Association on the Criminalisation of Medical Practice. It was argued that three developments had made this a matter of urgency – the case of Professor Cyril Karabus, who had faced manslaughter charges in the United Arab Emirates, reports that more than 400 physicians were under arrest in Syria for giving care to wounded combatants and state legislatures in the USA that were proposing to force doctors to do procedures without medical indications.

The second Resolution, proposed by the South African Medical Association, related specifically to the case of Professor Karabus who had been acquitted of all charges against him concerning the death of a child under his care, but faced an appeal against the acquittal by the prosecuting authorities. The South Africans wanted the WMA to send a strong message to the government in the UAE that this was not acceptable.

The Council decided that both Resolutions were urgent and should be debated, as well as a third motion on Patient Safety and Standardisation in Medical Practice presented jointly by the Conseil National de l'Ordre des Médecins France, the Consejo General de Colegios Médicos de España and the German Medical Association.

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Socio Medical Affairs Committee

Sir Michael Marmot (British Medical Association) was re-elected unopposed as Chair of the Socio-Medical Affairs Committee.

Professor Karabus

The emergency Resolution on the case of Professor Karabus was formally proposed to thecCommittee by the South African Medical Association. The Resolution expressed concern that Professor Karabus remained on bail in the United Arab Emirates despite being absolved of all charges against him. It stated that he was being treated in a manner which failed to meet international fair trial standards and that he should be allowed to return home immediately. But the South African delegates argued for stronger measures than those outlined in the Resolutio, such as sanctions against the UAE. When the committee voted for the Resolution to be sent to the Council, the South Africans declined to support it.

Later in the meeting the South African Medical Association returned with an amended Resolution, adding that the Council should publish an advisory notice in the World Medical Journal and on the WMA website to note the working conditions in the United Arab Emirates and encourage NMAs to publish similar advisories in their publications.

This was agreed on and thecCommittee recommended the Resolution to the Council.

Chair's Report

In his opening words, Sir Michael Marmot reported on the development of the post-

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2015 Millennium Development Goals agenda. He said the British Prime Minister was co-chairing the global planning activities. Sir Michael said he had made the case that the health-related MDGs should include health equity that covered not only averages for countries, but the unequal distribution of health and disease within countries. The United Nations Development Programme was the lead UN agency. Sir Michael said he had made the case to the UNDP that their policies and activities related to the development were, in fact, social determinants of health. A similar approach had been made to UNICEF. He also welcomed the recent four-year plan of activities adopted by the Canadian Medical Association, which included actions on social determinants of health and health equity, as a good example of concrete action that medical associations could do in the area of social determinants.

Violence Against Women and Girls

The British Medical Association reported that it would submit written proposals to the committee on implementing the WMA Resolution on Violence against Women. Sir Michael said it was important for the WMA to take a strong stand on this issue following a number of high profile cases of violence against women and girls. The BMA said its proposals could include online learning courses for doctors on the topi, and developing co-operation with relevant partner, such as the International Federation of Gynaecology and Obstetrics.

Health Databases

Dr. Jon Snaedal (Iceland), Chair of the Workgroup on Health Databases, presented a proposed Declaration to the committee on The Ethical Considerations Regarding Health Databases. He said this was not a final document but only information and he invited thecCommittee members to send their comments to the group. The aim was to present the final text to the committee at the General Assembly meeting in Brazil in October. It was agreed to refer the paper to the Medical Ethics Committee for consideration.

Right to Reparation of Victims of Torture

The committee considered a proposed Statement from the Danish Medical Association on The Right to Reparation of Victims of Torture. The paper noted with grave concern the continued use of torture throughout the world and said doctors had a critical role to play in the reparation process of victims of torture. During a brief debate it was argued that the definition of reparation needed further consideration.

The committee decided to recommend to the Council that the document be circulated to NMAs for comment.

Standardisation in Medical Practice and Patient Safety

A proposed Resolution on Standardisation in Medical Practice and Patient Safety was put forward jointly by the Conseil National de l'Ordre des Médecins France, the Consejo General de Colegios Médicos de España and the German Medical Association. It was explained that the Resolution was tabled to enable the WMA to react to plans currently under way in the European Union to allow the European Community of Standardisation to set standards in medical practice in the fields of aesthetic surgery services. This would cover procedures as well as post-graduate education and would open the door to similar efforts in other medical fields. The concern was that this move might be followed in other parts of the world. The three NMAs proposing the Resolution wanted to send a clear message that allowing industrial standardisation bodies that did not have the required professional, medical, ethical or technical competenc, to set standards in medical practice could have negative implications for patient safety.

Following a debate, it was decided to defer further consideration and amend the Resolution to make it shorter and punchier.

When the shortened amended Resolution was later presented, the committee agreed it should be sent to the Council for approval and then forwarded to the Assembly for adoption.

Human Papillomavirus Vaccination

The American Medical Association reported that it had set up an internal working group with a view to developing a policy on HPV which would be submitted at the next Council meeting in October.

Fungal Disease Diagnosis and Management

The Brazilian Medical Association produced a proposed Statement on Fungal Disease Diagnosis and Management giving guidance to NMAs and physicians on how they should be involved in providing diagnostic tests and prescribing antifungal therapy most effectively.

After a brief debate it was agreed to recommend that work should continue on the document and afterwards to be circulated to NMAs for comment.

Criminalisation of Medical Practice

An emergency Resolution on the Criminalisation of Medical Practice was presented by the American Medical Association. This urged that NMAs should oppose criminalizing medical judgment. But the following concern by some delegates that the Resolution might give the impression doctors should be above the law, an amended paragraph was proposed making it clear that doctors who committed criminal acts unrelated to patient care must remain as liable to sanctions as all other members of society. This provoked a lengthy debate about criminal intent and how incompetent doctors who committed errors should be dealt with.

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The committee eventually recommended that the amended Resolution should be sent to the Council for approval and then forwarded to the Assembly for adoption as policy.

Classification of 2003 Policies

Under the rules stating that policies that are 10 years old should come up for revision, it was decided that the Statement on the Ethical Guidelines for Recruitment of Physicians and the Resolution on the Non-Commercialization of Human Reproductive Material should undergo major revision.

The committee agreed that the Resolution on SARS (Severe Acute Respiratory Syndrome) be rescindet and NMAs be invited to come forward with a new policy on chronic respiratory diseases.

Health and the Environment

Dr. D.C.Shin (Korea) reported on a meeting of the Association's environment caucus that had taken place earlier in the da, where participants had discussed the global mercury treaty recently signe, as well as the outcome of the Doha United Nations summit on climate change. The caucus had also discussed the results of a WMA survey of the NMA activity in the field of environment. It was agreed to recommend that the work of the caucus should continue.

WMA Advocacy

Paul-Emile Cloutier (Canada), Chair of the Advocacy Advisory Group, reported on the activities of the group and said that it was proposing to develop an advocacy plan in relation to the Declaration of Helsinki. This would emphasise the WMA's ownership of the document.

He said that as part of developing tools for the benefit of NMAs, the group was willing to organise an advocacy training session at a future Assembly meeting.

Collaboration between the Stakeholders and the Pharmaceutical Industry

The Secretary General informed thecCommittee about a collaborative project between the stakeholders and the pharmaceutical industry on the ways of dealing with common issues relating to sponsorship of research, support and gifts. This was a draft Joint Framework on Collaboration between the pharmaceutical industry, healthcare professionals, medical institutions and patient organizations. The plan was for the document to be published later in the year on a common website, although a common policy was not the intention. Dr. Kloiber emphasised that this did not constitute a new policy since the Framework documentdcontained common existing policies of all participants. This could then be used as a toolkit for others wanting to develop the policy.

After a brief debate the committee agreed that the item be referred to the Council for further consideration.

Council

Professor Karabus

The Council reconvened to consider the amended Resolution on Professor Karabus and it was agreed on (*see page 59*).

Medical Ethics Committee

Dr. Heikki Palve (Finnish Medical Association) was elected unopposed as Chair of the Medical Ethics Committee, succeeding Dr. Torunn Janbu (Norway) who stepped down after three years.

Declaration of Helsinki

Dr. Ramin Parsa-Parsi (Germany), Chair of the Workgroup revising the Declaration of Helsinki, reported that considerable progress had been made, with essential input on the part of the expert conferences held in South Africa and Japan. The Cape Town conference was attended by 76 delegates from 22 countries, while in Tokyo 135 delegates from 23 countries participated.

Professor Urban Wiesing, adviser to the Workgroup, reported on the key issues discussed at these meetings – the structure of the Declaration, vulnerable groups, post-study arrangements, research ethics committees, compensation, bio-banks and the frequency of revisions. He said that a general consensus had been reached, except on the final two points.

Dr. Parsa-Parsi presented a preliminary draft revision which he hoped the committee would recommend to be posted on the WMA website for a two-month consultation with NMAs and the public. This would last from mid-April to mid-June. At the end of this period, in August, a meeting would be held in Washingtontto assess all the comments and a further revised version of the Declaration would be presented to the committee at its meeting in Brazil in October. If approved, the document would be forwarded to the Council with a view to submitting to the General Assembly in Brazil for adoption.

Dr. Jeff Blackmer (Canada) presented the revised document, explaining paragraph by paragraph the proposed changed.

After further debate and unsuccessful moves to amend the draft document, the committee agreed to recommend to the Council that the document should be posted on the WMA website for public consultation and comments from NMAs.

Person Centered Medicine

ThecCommittee considered a proposed revision of the WMA Statement on Person Centered Medicine. Dr. Jon Snaedal (Iceland) said the paper was intended for

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physicians to have some kind of definition of the core issue and to support the WMA in the initiative it had been working on for the last five years. The committee recommended that a Workgroup be set up to complete this work.

Euthanasia

The committee considered a minor revision to update the WMA Resolution on Euthanasia. This prompted Dr. Van der Gaag (Royal Dutch Medical Association) to say that he coult support neither the revision nor the Resolution. He said that since 2002 the Netherlands had been one of the few countries where euthanasia and physician-assisted suicide had been regulated by law under strict conditions. Therefore his Association could not and would not support the Resolution in its present form. It would not tell the doctors in his country that it considered euthanasia to be unethica, nor would it condemn doctors who performed euthanasia. He called on the Council to reconsider the revision of the Resolution and work on rephrasing it respecting the different views on this subject.

The committee Chair said that should they wish the Royal Dutch Medical Association could submit a new policy proposal. However, the committee agreed to approve the minor revision.

Use of the Death Penalty

The committee considered a proposal for the WMA to support the United Nations General Assembly Resolution calling for a moratorium on the use of the death penalty. This led to an extensive debate about whether the WMA should take a position on the death penalty, with delegates expressing opposing views. It was argued that this should be a matter for individual physicians and that by supporting a moratorium it might be demonstrated that the WMA was siding with those physicians and NMAs who were opposed to the death penalty. However, at the conclusion of the debate the committee voted overwhelmingly to recommend to the Council that the WMA should support a moratorium.

Women's Right to Health Care

The South African Medical Association presented a proposed revision to the WMA Resolution on Women's Rights to Healthcare and how that related to Mothed-to-ChildnTransmission of HIn. It was agreed to recommend to the Council that this should be circulated to NMAs for comment.

Human Rights

Clarisse Delorme, WMA advocacy adviser, highlighted some of the Association's activities on human rights in recent months, including its work on palliative care with Human Rights Watch and the Healthcare in Danger initiative of the International Committee of the Red Cross.

She said that in March representatives of ten Medical Associations from Arabic countries had met in Amman to discuss the provision of health care in detention places. The regional conference had been organized by the ICR, in collaboration with the WMA. The meeting focused on the specific health needs of prisoner, as well as the role of NMAs and the WMA in co-operating to improve the situation in prisons.

The Secretary General, who attended the conference, reported in more detail on the discussionk that had taken place during the event. He emphasized the positive outcome, notably the strong interest expressed by Arabic medical associations about the WMA and their possible willingness to join the Association.

European Union Clinical Trials Directive

Professor André Herchuelz (Association Belge des Syndicats Médicaux) reported on current developments in the EU with regard to the revision of the Clinical Trials Directive and its implications for the Declaration of Helsinki. Dr. Kloiber responded by referring to the WMA's activities on this issue. He said he was in contact with the competent EU Committee Rapporteur.

Financeand Planning Committee

Dr. Leonid Eidelman (Israel) was re-elected unopposed as Chair of the Finance and Planning Committee.

Membership Dues Payments

The committee received a report on Membership Dues Payments for 2013 and an oral report from Mr Adi Hällmayr, Financial Advisor, on Dues Arrears.

Financial Statement

Mr. Hällmayr provided a detailed explanation of the pre-audited interim Financial Statement for 2012. ThecCommittee was pleased with the favourable financial situation and recommended that the Statement be approved.

Business Development

An oral report was given by Mr. Tony Bourne (British Medical Association), Chair of Business Development Group, about the work of the group. He spoke about the WMA roundtable initiative and plans for the year ahead. Twelve organisations had expressed an interest in being involved in the roundtable. These organisations would now be approached and it was hoped to hold the first introductory meeting later in the year.

He also spoke of potential new initiatives being considere, which would be self-financing and enable the WMA capacity building.

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WMA Meetings

There was a discussion about the dates for the Council meeting in Tokyo in the Spring of 2014, about holding the 2015 Spring meeting in St. Petersburg and about the meetings in 2016 being held in Buenos Aires in April 2016 and in Taipei, Taiwan in October 2016.

The committee recommended that further consideration be given to these venues.

The South African Medical Association proposed the theme of the scientific session at the General Assembly in Durban, South Africa, 8–11 October 2014 be the subject of 'Universal Access to Healthcare after MDGs'.

50th Anniversary of the Declaration of Helsinki

The Committee received an oral report from the Workgroup on the 50th Anniversary of the Declaration of Helsinki in 2014. Dr. Eidelman reported that the main event would be held in Helsinki in November 2014, possibly at the place where the origi-

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nal Declaration was adopted 50 years ago. The Workgroup was encouraging NMAs to organise events on regional and national level. Moreover, a book was being written about the Declaration for publication in 2014.

Disaster Preparedness and Medical Response

The Committee received an oral report of the Workgroup on Disaster Preparedness and Medical Response. On behalf of Dr. Miguel Jorge, the Chair of the Workgroup, Dr. Nivio Moreira (Brazil) summarised the result of a survey of NMAs about their disaster preparedness and medical responses. Of those that replied, most had experienced disasters in recent years and almost all had plans to cope with them. Most of the NMAs had been involved in assisting people affected by disasters. Few offered general training courses for physicians on disaster issues and few also offered some basic medical guidance to the general public on how to behave when facing a disaster. But most had systems for mobilizing physicians and other health care personnel in the event of a disaster.

The Workgroup recommended that the survey should be updated in two or three years and the findings should be posted on the WMA website and be shared among NMAs.

The committee recommended that the Council approve the Workgroup's recommendations.

Associate Membership

It was reported that the total number of Associate Members whose annual subscriptions had been paid was 832. In addition members of the International Federation of Medical Student Associations would be granted Associate Membership on graduation as physicians for a period of five years and no membership fee would be charged.

Past Presidents Network

Dr. Dana Hanson (Canada), Past President of the WMA, reported on the proposal and terms of reference foraPast Presidents and Chairs of Council Network. He said this largely virtual network would be very useful for the WMA to tap into the expertise of the past officers in any projects that would be of assistance.

The committee recommended that the Council approve the establishment and the terms of reference for the Network.

Junior Doctors Network

An oral report on the activities of the Junior Doctors Network was given by the Chair of the Network, Thorsten Hornung (Germany). He reminded the meeting that the Network was a forum for experience-sharing and discussion among younger members of the Association. The Network had been liaising with other junior doctor groups around the world. Its projects included a white paper on physicians' wellbeing to be presented in Brazil, a policy paper on the ethical aspects of global health education and an environmental scan of post-graduate medical education examining conditions for junior doctors in training in countries around the world. A questionnaire was being prepared.

He said that the Network was currently discussing the definition of a junior doctor and at the moment was considering basing this on a number of years after graduation, such as eight to 10 years.

Cooperative Relations

Dr. Kloiber reminded the committee that the Council had approved three academic organisations to be the WMA Cooperating Centers from 2013–2015 – the Center for the Study of International Medical Policies and Practices, George-Mason-University, Fairfax, Virginia, on microbial resistance and the development of public health policy; the Center for Global Health and Medical Diplomacy, University of North Florida, on MedicallLeadership and Medical Diplomacy; and the Institute of Ethics and History of Medicin,: University of Tübingen. He proposed a further Center, the Institut de droit de la santé, Université de Neuchâtel, Switzerland. The committee recommended this to the Council.

Death of Dr. Perelman

Dr. Leonid Mikhailov (Russia) informed the committee of the recent death of Dr. Perelman, former President of the Russian Medical Society and a prominent thoracic surgeon.

Council

The Council then reconvened.

Dr. Ketan Desai

Dr. Ajay Kumar (India) said the Indian Medical Association had submitted an application to the Council for Dr. Ketan Desai to be installed as President of the WMA. He reminded the meeting that in 2009 Dr. Ketan Desai was elected President Elect of the WMA. But in 2010 he was arrested in India on charges that he had used his office as President of the Medical Council of India for personal gain. As a result the WMA Assembly decided to suspend his Presidency indefinitely. Dr. Desai said that the charges facing Dr. Ketan Desai had now been dropped and he should be allowed to be reinstalled as the WMA President.

Dr. Haikerwal replied that the relevant papers would be studied and the application would be considered.

The Council later requested the executive committee and Chair to ensure that due diligence takes place before proceeding.

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The Council then considered reports from three Committees, approving the following

From the Medical Ethics Committed:
- a public consultation process on the revised draft of the Declaration of Helsinki and a further meeting in Washington to review the comments received;
- a new Workgroup on person centred medicine to complete work on a revised Statement;
- a minor revision to the Resolution on Euthanasia;
- a circulation to NMAs of the proposed revision of the Resolution on Women's Right to Healthcare and how that relates to Mother and Child HIV Infection;
- a Statement supporting the UN moratorium on the use of the death penalty which should be forwarded to the General Assembly for adoption.

From the Finance and Planning Committed:
- the interim 2012 Financial Statement;
- referring future meeting venues and dates to the executivec Committee for further consideration;
- an on-going survey relating to NMA disaster preparedness and medical response;
- the establishment of Past Presidents and Chairs of the Council Network;
- the renewals and appointments of the WMA Cooperating Centers.

From the Socio-Medical Affairs Committed:
- the referral to the Medical Ethics Committee of the proposed Declaration on Ethical Considerations Regarding Health Databases;
- the circulation to NMAs of the proposed Statement on the Right to Reparation of Victims of Torture;
- the Resolution on Standardisation in Medical Practice and Patient Safety (*see page 59*);
- the circulation to NMAs of a revised paper on fungal disease diagnosis and management.

The Council heard oral reports on outreach activities.

The Editor-in-Chief of the World Medical Journal, Dr. Pēteris Apinis, said he was planning to produce six issues in 2013. He said the content of the Journal must be created by physicians from all over the world and articles were mainly related to four issues: news of the WMA and national medical associations, medical ethics, self- governance and public health. The aim was to include at least one contribution from each continent in every Journal. The concept of the WMJ was based on the assumption that, although all people were different, they all had a lot in common. The problems and situations they had to deal with were the same, especially in the domain of medical ethics and public health.

During further debate, the Council raised no objection to continuing the collaborative project between the stakeholders and the pharmaceutical industry, as reported earlier by the Secretary General.

World Health Assembly

Clarisse Delorme reported on issues due to be discussed at this year's World Health Assembly. One related the targets and monitoring framework concerning non-communicable diseases. She said that one positive move had been the inclusion of a mental health action plan in the discussions. Other issues were health workforce, Millennium Development Goals and social determinants of health.

Criminalisation of Medical Practice

A further debate took place in the Council on the Resolution on Criminalisation of Medical Practice, when amendments were proposed to deal with the issue of criminal intent and negligence. The Council eventually agreed to approve the Resolution for forwarding it to the General Assembly for consideration (*see page 58*). In the vote Canada, Finland and France abstained.

The meeting ended with thanks to the Indonesian Medical Association for hosting the event.

Mr. Nigel Duncan,
Public Relations Consultant, WMA

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Secretary General's Report

Policy & Advocacy

Non-Communicable Diseases

NCDs have emerged as one of the most important topics on the public health agenda. The WHO is developing a 2013–2020 Global Action Plan for the Prevention and Control of NCDs. The WMA's main criticism of the new plan and the monitoring framework is that it focuses only on adults and adolescents. Yet it is during childhood when many lifelong habits are developed and which are difficult to change later in life. Many countries emphasized at the last WHO Executive Board meeting the importance of health care system strengthening, universal access and the link to social determinants of health as the right approach in the fight of NCDS. A revised draft of the 2013–2020 Action Plan was opened for comment in February and was discussed in March with NGOs. The WMA will advocate for a holistic health care approach, avoiding a silo-style disease-specific approach and considering the social determinants of health.

Otmar Kloiber

Together with our partners at the WHPA, the WMA participated in the development of the NCD toolkit to assess the risk level in lifestyle behaviours and bio measures in the form of NCD indicators. We are also setting up an independent project together with Sir Michael Marmot (British Medical Association) and his team to develop a common set of Social Determinants of Health and NCD indicators.

Multi Drug Resistant Tuberculosis Project

In March, the WMA launched the revised MDR-TB online course. We now have a complete set of TB and MDR-TB courses as online versions, printed formats and CDs. The printed courses have been translated into Azeri, Chinese, French, Georgian, Russian Spanish and other languages may follow. All courses can be accessed free of charge via the WMA webpage. The printed TB refresher course and the new MDR-TB course were nominated by the United States Center for Disease Control (CDC) as an educational highlight and received an award. The WMA is collaborating with the WHO to develop the MDR-TB course as an application for tablet computers, especially for low-cost 10-inch devices running on Android, which are increasingly used in low-income countries. The app will be accessible from the Google and iPhone app webpage and, once downloaded, will be self-contained and able to run offline without an internet connection.

Tobacco Project

The WMA is involved in the implementation process of the WHO Framework Convention on Tobacco Control that condemns tobacco as an addictive substance, imposes bans on advertising and promotion of tobacco, and reaffirms the right of all people to the highest standard of health. The WMA will cooperate with the public private partnership "QuitNowTXT program" to develop an evidence-based diffusion of health information for tobacco cessation via mobile phones to reach people at risk from preventable NCDs.

Alcohol

In May 2010, the World Health Assembly endorsed the Global Strategy to Reduce the Harmful Use of Alcohol. The Strategy provides a portfolio of policy options and interventions for implementation at a national level with the goal of reducing the harmful use of alcohol worldwide. The successful implementation of the strategy requires concerted action by countries, effective global governance, and appropriate engagement of all relevant stakeholders, including health actors. In line with the WMA Statement on Reducing the Global Impact of Alcohol on Health and Society, the WMA Secretariat monitors progress to ensure that medical associations at the national and global levels continue to be engaged in implementation.

Counterfeit Medical Products

The WMA and the members of the World Health Professions Alliance WHPA stepped up their activities on counterfeit medical issues and developed an Anti-Counterfeit campaign with an educational grant from Pfizer Inc. and Eli Lilly. The basis of the campaign is the 'Be Aware' toolkit for health professionals and patients to increase awareness of this topic and provide practical advice for actions to take in case of a suspected counterfeit medical product. The WHPA organised several regional WHPA Counterfeit Medical Products workshops to implement the toolkit.

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Climate change

The WMA continues to be involved in the UN Climate Change negotiations. Due to its UN observer status to the Convention, the WMA Secretariat can facilitate the participation of medical associations interested in the various official meetings taking place in this framework. The WMA takes part in an informal consultation group set up by the WHO, which brings together civil society actors working on health and environmental issues. The goal of the group is to facilitate the exchange of information with regard to the UN meetings and coordinate potential joint approaches. In this context, the WMA signed the Doha Declaration on Climate, Health and Wellbeing that was adopted by health and medical associations from around the world on the occasion of the Climate Change Summit in Doha (COP 18 – December 2012). The Declaration calls for the protection and promotion of health to be made the one of the central priorities of global and national policy responses to climate change.

Mercury

The WMA has been a member of the UNEP Global Mercury Partnership (Mercury product) since December 2008 in order to contribute to the partnership goal of protecting human health and the global environment from the release of mercury and its compounds. This engagement is based on the WMA Statement on Reducing the Global Burden of Mercury (Seoul, 2008). Since June 2010, Dr. Peter Orris has been attending the successive negotiating sessions of the UNEP (UN Environment Programme) for a legally binding instrument on mercury, and brought forward the WMA's recommendations from its 2008 Resolution on Mercury. The Mercury Treaty was finally adopted in January 2013 in Geneva. The Treaty sets a phase-out date of 2020 for most mercury containing products – including thermometers and blood pressure devices, and calls for the phase-down of dental amalgam. This aspect of the treaty is a major victory for all who have worked for mercury-free health care.

Chemicals

In December 2009, the WMA joined the Strategic Approach to International Chemicals Management (SAICM) of the Chemicals Branch of the United Nations Environment Programme (UNEP), which aims to develop a strategy for strengthening the engagement of the health sector in the implementation of the Strategic Approach. In consultation with the WHO, Prof. Shin (Korean Medical Association) has represented the WMA at several SAICM meetings, bringing forward the WMA Statement on Environmental Degradation and Sound Management of Chemicals (adopted in October 2010 in Vancouver). In September 2012, the WMA, together with the World Federation of Public Health Associations, the Government of Slovenia and the WHO, organised a side event on the topic in the context of the third session of the International Conference on Chemicals Management, held in Nairobi in September 2012.

Social Determinants of Health

The Rio Political Declaration on Social Determinants of Health produced at the World Conference on Social Determinants of Health in Rio, Brazil, in October 2011, identifies five action areas for health to engage in to address the social determinants of health. One of these action areas emphasizes the role of the health sector in reducing health inequities. Within this framework, the WMA and the International Federation of Medical Students Associations (IFMSA) organised in May 2012 a side-event during the World Health Assembly in Geneva, with the support of the UK delegation. Participants discussed concrete ways for the health sector to implement the Rio Declaration and engage in reducing health inequities. The issue of medical education and training of health professionals regarding SDH was raised several times and there was a general agreement that efforts should focus on this matter.

Millennium Development Goals

As the 2015 target date for the MDGs approaches, there is lively debate on the contents and form of the post-2015 agenda. This debate raises important questions about how progress in improving human health should be reflected in any future set of goals, targets and indicators. At the start of the 2013 UN General Assembly there will be a high level summit to review progress and map out a forward-looking agenda. In preparation, the UN Development Group (chaired by the United Nations Development Programme – UNDP) is leading a series of national and global thematic discussion on key issues: inequalities, population, health, education, economic growth and employment, conflict and fragility, governance, environmental sustainability, and food security and nutrition. The aim is to involve a broad range of stakeholders to discuss the options for a post-2015 framework. The WMA submitted a proposal and will continue to advocate that health and health care systems are important drivers for the economies and for securing social stability and development.

Health Systems

General

Immunization rates against influenza among our profession remain worryingly low. Therefore we developed an advocacy and awareness campaign with support from IFPMA on immunisation for influenza. The campaign started with a survey of the

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activity level of our nation members on influenza immunisation and, in a second step, we will develop material for our members and individual physicians emphasizing the emotional benefits of receiving immunisation. As part of this campaign, this year's WMA luncheon during the World Health Assembly will be on 'Immunisation with a focus on influenza'. This event will give us the possibility to highlight our new WMA policy on Immunisation as well.

Person Centered Medicine

Together with the World Psychiatric Association (WPA), the World Organization of Family Doctors, the World Health Organization, the International Association of Patient Organizations and many other partners, the WMA will hold for the fifth time the Conference on Person Centered Medicine in Geneva in May 2013. The concept of person centered cedicine embodies the principles of patient-centered medicine, but goes far beyond this and better reflects the entire spectrum of medicine where we as physicians not only deal with the "patient-hood" of person, but respect the individual with his or her entire personality and in the context of his or her personal life.

Health Workforce

Third Global Forum on Human Resources for Health (GHWA). Human resources for health (HRH) challenges are in many countries the single largest impediment to scaling up access to health services and to achieving the health-related Millennium Development Goals (MDGs) and universal health coverage. Along with the revised strategy of GHWA the theme for the forum will be "Human Resources for Health: Foundation for Universal Health Coverage and the Post-2015 Development Agenda" and will be held in November in Brazil. Participation is only possible by invitation. WMA advocates that the voice of physicians will be reflected in the program and as a result Dr. Julia Tainijoki-Seyer was invited to take part in the forum working group to define the program. The WHO has developed the Guidelines on Retention Strategies for Health Professionals in Rural Areas, with the WMA taking part in the drafting process. The guidelines are based on three pillars: educational and regulatory incentives, monetary incentives and management, and environment and social support.

Workplace Violence in the Health Sector

The 3rd Conference on Workplace Violence in the Health Sector took place in October 2012 in Vancouver. The WMA was a member of the planning committee. Dr. Mukesh Haikerwal, Chair of Council, opened the conference with a keynote speech. It was a good opportunity to present the WMA policy on Violence in the Health Sector that was adopted in Bangkok last October, and to bring forward more strongly the physicians' perspective in the debate. The next Conference is scheduled for October 2014 in the US.

Education & Research

The World Federation for Medical Education (WFME) has started a discussion process on the future role of the physician. Beginning with an expert panel in March that included representatives from academia, the WHO, the WMA and international and regional organizations for medical education, the WFME rolled out a debate. The WMA participated as a member of steering groups in two projects commissioned by the European Union on the Mobility and Migration of Health Professionals. One project was led by the European Health Care Management Association, and the other by the Research Institute of the German Hartmann Bund, a private physicians' organization. The general objective of the research projects is to assess the current trends of mobility and migration of health professionals to, from, and within the European Union, including their reasons for moving.

Patient Safety

The WHO stepped up its commitment to patient safety and defined it as a major global priority in health care. To deliver safe health care, clinicians require training in the discipline of patient safety, which includes an understanding of the nature of medical error, how clinicians themselves can work in ways that reduce the risk of harm to patients, techniques for learning from errors and how clinicians can harness quality improvement methods to improve patient safety in their own organizations. The WHO revised the existing Patient Safety Curriculum Guide for medical schools and transformed it into a Multi-professional Patient Safety Curriculum Guide. The WMA was a member of the reviewing committee for the multi-professional guidelines.

Caring Physicians of the World Leadership Course

The CPW Project began with the Caring Physicians of the World book, published in English in October 2005 and in Spanish in March 2007, which is now available in html and pdf. Some hardcopies (English and Spanish) are still available at the WMA office upon request. Please visit the WMA website (*http://www.wma.net/en/30publications/60cpwbook/index.html*) to access to the electronic versions and to order the hardcopies. The CPW Project was extended to include a leadership course organized by the INSEAD Business School in Fontainebleau, France in December 2007. The fifth course was held at the INSEAD campus in Singapore in January 2013. The courses were made possible by an unrestricted educational grant provided by Bayer HealthCare and

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Pfizer, Inc. This work, including the preparation and evaluation of the course, is supported by the WMA cooperating center, the Center for Global Health and Medical Diplomacy at the University of North Florida.

Health Politics

The WMA has intervened three times on health politics matters at the request of member associations:

In Slovakia, the government declared a state of emergency in hospitals in order to stop protests and industrial action by physicians fighting for better working conditions and against the privatisation of public hospitals. In consultation with the Slovak Medical Association, the WMA wrote to the Prime Minister and the President of the Republic to call for proper working conditions and fair payment.

In Poland, physicians were made liable for managing the reimbursement entitlements of the insured. Everyone in Poland is insured under a state insurance scheme which gives various entitlements for reimbursement. These different entitlements were at least in part non-transparent to the physicians, who should not be held liable for wrongly assigning reimbursement statuses for drugs on prescription. Together with the Polish Chamber of Physicians and Dentist, the WMA protested against this measure, which was later revoked.

At the end of 2011, the Turkish Government removed key functions, such as the supervision of physicians and the regulation of post-graduate education, from the Turkish Medical Association and other self-governing institutions. Together with the Turkish Medical Association, the WMA staged public events in Ankara and Istanbul in April 2012 to fight for retaining these critical rights of physician self-governance.

Human Rights

Zimbabwe

In November 2012, the International Rehabilitation Council for Torture Victims drew our attention to the case of its member centre – the Counselling Services Unit, Zimbabwe – which faces ongoing legal harassment of its staff, with three staff arrested and in detention. The WMA wrote a letter to the authorities of Zimbabwe, expressing its concerns regarding the procedures falling short of international standards for fair trial, as well as the violation of the confidentiality principle towards patients by the security forces during the raid. The staff was finally granted bail.

Turkey

On 12 September 2012, around 60 prisoners began a hunger strike in seven prisons across Turkey as a protest against the authorities' longstanding refusal to allow Kurdistan Workers' Party (PKK) leader Abdullah Öcalan to meet with his lawyers and to demand the provision of education in the Kurdish language.

According to Amnesty, prison doctors were routinely refusing to conduct medical examinations of the hunger strikers. In November, the Turkish Medical Association drew the attention of the WMA to the gravity of the situation. The WMA wrote a letter to the Turkish authorities to support TMA's call to form boards composed of independent and experienced physicians to visit hunger strikers and check their health status. The WMA also asked for an assurance that no punitive measures were taken against prisoners on hunger strike and that the absolute prohibition of torture and other forms of ill treatment was upheld. Under increasing national and international pressure, the Turkish authorities took measures to improve the situation of the prisoners.

United Arab Emirates

WMA secretariat has sent letters to the United Arab Emirates' authorities expressing its concerns about the arrest of Professor Cyril Karabus. He was arrested whilst transiting through Dubai from UK to South Africa and was held responsible for the death of a child (member of the royal family) in 2002 when he worked there of WMA on the precarious health situation of Prof. Karabus. A range of questions – regarding the legal proceeding and guarantees for a fair trial – were also asked to the Minister of Justice.

Protection of health professionals in areas of armed-conflicts

Last January, the WMA joined a group of 18 NGOs, initiated by the Safeguarding Health in Conflict coalition to co-sign a letter to WHO Director General Margaret Chan expressing alarm at the recent spate of attacks on health workers in Pakistan.

ICRC Campaign "Health Care in Danger"

The framework of the International Committee of the Red Cross 4-year campaign "Healthcare in Danger", in which the WMA is a partner, was launched during the summer 2011. A series of workshops took place on specific themes, each designed to come up with practical measures to enhance the protection of health-care providers and beneficiaries in armed conflicts and other emergencies. The WMA participated in the workshop entitled "The security and delivery of effective and impartial health care in armed

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conflict and other situations of violence" that took place in London in April 2012. It was organised by the ICRC, the British Red Cross Society, the British Medical Association and the WMA.

Cooperation with International Rehabilitation Council for Torture Victims

As an elected member of the Executive Committee of the IRCT, Clarisse Delorme attended the Executive Committee and Council meetings that took place last November in Budapest. A new round of elections took place. Ms Delorme was re-elected as an independent expert for a new mandate of three years in the Council and the Executive Committee.

Ethics

Declaration of Helsinki

In October 2011, the Council of the World Medical Association decided to embark on a new process of revising the Declaration of Helsinki. A workgroup was subsequently formed with the mandate to present a revised wording of the Declaration to the Ethics Committee. The revision process was accompanied by a series of expert conferences. The WMA and the University of Tübingen organised a satellite meeting during the 11th World Congress of Bioethics in Rotterdam in June 2012 during which international speakers from a wide range of scientific disciplines were invited to present their views on the future of the Declaration. In addition, a call for comments was sent out to all WMA members, and selected international organisations were invited to submit their suggestions for topics requiring revision. In December 2012 the WMA together with the South African Medical Association staged the first open expert conference on the revision of the Declaration of Helsinki in Cape Town South Africa. A second conference was held in Tokyo in February. A public consultation on the revision process is envisioned for spring 2013.

World Health Professions Alliance

Health Improvement Card

Together with other members of the WHPA, the WMA launched the WHPA NCD campaign in May 2011. At the core of the campaign is the WHPA Health Improvement Card, a simple, universal educational tool that will allow everyone to assess and record his or her lifestyle/behavioural and biometric risk factors. The objective of the project is to develop a tool that can be used in all health care settings throughout the world that 1) increases awareness of the individual responsibility of each person for their health, and 2) serves as an advocacy tool for improved health care systems. The NCD health Improvement Card is translated into French, Spanish and Portuguese. An online version of the toolkit is now available on the WHPA webpage. 2012 saw the second phase start with a pilot study in South Africa.

Counterfeit Medical Products

For the past four years, the WMA together with the other health professionals of WHPA have engaged in an anti-counterfeit medical products campaign to protect public health. This year the WHPA's activity is to involve national members and national student organisation through an offer of small grants of $2500–6000. Each grant application required at least two national associations of different health professions in the same country. In the first round of applications the following were selected as recipients: Ethiopia, Lesotho, Rwanda and the Philippines. The second round of selection is still taking place.

Dr. Otmar Kloiber,
Secretary General

WMA Council Resolution on Criminalisation of Medical Practice

Adopted by the 194th WMA Council Session, Bali, April 2013

Preamble

Doctors who commit criminal acts which are not part of patient care must remain as liable to sanctions as all other members of society. Serious abuses of medical practice must be subject to sanctions, usually through professional regulatory processes.

Numerous attempts are made by governments to control physicians' practice of medicine at local, regional and national levels worldwide. Physicians have seen attempts to:

- Prevent medically indicated procedures;
- Mandate medical procedures that are not indicated; and
- Mandate certain drug prescribing practices.

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Criminal penalties have been imposed on physicians for various aspects of medical practice, including medical errors, despite the availability of adequate non-criminal redress. Criminalizing medical decision making is a disservice to patients. In times of war and civil strife, there have also been attempts to criminalize compassionate medical care to those injured as a result of these conflicts.

Recommendations

Therefore, the WMA recommends that its members:

- Oppose government intrusions into the practice of medicine and in healthcare decision making, including the government's ability to define appropriate medical practice through imposition of criminal penalties.
- Oppose criminalizing medical judgment.
- Oppose criminalizing healthcare decisions, including physician variance from guidelines and standards.
- Oppose criminalizing medical care provided to patients injured in civil conflicts.
- Implement action plans to alert opinion leaders, elected officials and the media about the detrimental effects on healthcare that result from criminalizing healthcare decision making.
- Support the principles set forth in the WMA's Declaration of Madrid on Professional Autonomy and Self-Regulation.
- Support the guidance set forth in the WMA's Regulations in Times of Armed Conflict and Other Situations of Violence.

WMA Council Resolution on Standardisation in Medical Practice and Patient Safety

Adopted by the 194th WMA Council Session, Bali, April 2013

Ensuring patient safety and quality of care is at the core of medical practice. For patients, a high level of performance can be a matter of life or death. Therefore, guidance and standardisation in healthcare must be based on solid medical evidence and has to take ethical considerations into account. Currently, trends in the European Union can be observed to introduce standards in clinical, medical care developed by non-medical standardisation bodies, which neither have the necessary professional ethical and technical competencies nor a public mandate.

The WMA has major concerns about such tendencies which are likely to reduce the quality of care offered, and calls upon governments and other institutions not to leave standardisation of medical care up to non-medical self-selected bodies.

WMA Council Resolution on Professor Karabus

Adopted by the 194th WMA Council Session, Bali, April 2013

The World Medical Association is extremely concerned that Professor Cyril Karabus, a retired paediatric oncologist remains remanded on bail in the UAE despite a long and slow judicial process, which has absolved him of all the charges against him. The WMA notes that the expert medical panel, appointed by the court to advise it whether there was any evidence against Professor Karabus, has advised the judge that Professor Karabus has no case to answer. Consequently the judge dismissed all charges and a ruling of not guilty was given. It also notes with concern that the prosecutors have indicated they will appeal the courts ruling meaning that Professor Karabus needs to remain in the UAE indefinitely.

Given the findings of the medical panel, the WMA believes that Professor Karabus is being treated in a manner, which fails to meet international fair trial standards and should be allowed to return home immediately.

In light of the above experience, the WMA will publish an advisory notice in the WMJ and on the WMA website to advise doctors thinking of working in the UAE to note the working conditions and the legal risks of employment there. The WMA will encourage member NMAs to publish similar advisory notices in their national publications.

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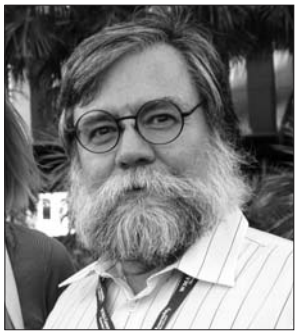
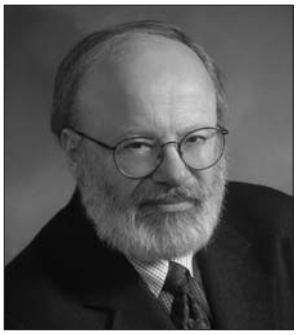
Physicians and Hunger Strikes in Prison: Confrontation, Manipulation, Medicalization and Medical Ethics (part 2) (part 1 vol. 59 N 1)



Hernán Reyes

Scott Allen



George J. Annas

Past Practices and Controversies

This second section examines specific hunger strikes from the recent past, to discuss the pitfalls and stumbling points encountered by both custodial and medical authorities. As will been seen, a conflictual situation develops mainly because the non-medical, custodial authorities decide to stop the protest by ordering the physician intervene. In some cases this may be out of genuine concern that the fasting prisoner(s) may come to harm. In our experience, however, it more often is simply to ensure taking all precautions so that no prisoner "kills him/herself." As a determined hunger striker is hardly likely to simply accept an "order" from the physician to resume eating, the doctor is then instructed to feed the fasting prisoner against his/her will, i.e. force-feed.

The examples chosen are from different countries, different contexts. What is important is the phenomenon that each example illustrates. This is neither intended to be an analysis in any way of the underlying political situation, nor to justify either side in positions taken regarding the reason for the hunger strikes. The aim is to show how these hunger strikes have been handled, or (mostly) mishandled, and to review briefly the decisions taken and why they were taken. Hence it is not important to identify the specific case and country, with the obvious exceptions of the well-publicized cases of Guantánamo Bay and Northern Ireland (N.I.). All examples are based on personal field experience or that of close colleagues.

Ethical Background: the Evolution of "WMA Malta"

The Northern Ireland hunger strikes in 1980 and 1981 took place in the context of "the Troubles" in Ulster, at a time when there were mass arrests of I.R.A. militants and accusations of brutality and worsened by the public order forces. Some years before, to avoid any medical involvement in interrogations and other such activities the British Medical Association had approached the WMA, so a clear position be taken regarding medical participation in such non-medical activities. (At one point, the British authorities had suggested that physicians sit in on interrogations to see there was "fair play"…). The WMA issued its declaration of Tokyo in 1975 against the participation of doctors in any form of torture. In this Declaration, one of the Articles (originally "5", now in the revised 2006 version, "6") mentioned hunger strikers, stipulating:

"Where a prisoner refuses nourishment and is considered by the physician as capable of forming an unimpaired and rational judgment concerning the consequences of such a voluntary refusal of nourishment, he or she shall not be fed artificially. The decision as to the capacity of the prisoner to form such a judgment should be confirmed by at least one other independent physician. The consequences of the refusal of nourishment shall be explained by the physician to the prisoner."

Few doctors know why this clause is included in what is essentially a declaration on non-physician participation in torture. The reason[1] relates to situations that may occur where torture is taking place. If a prisoner being tortured decides to protest against his plight by refusing to eat, the physician should not be obliged to administer nourishment against the prisoner's will, and thereby effectively revive him for more torture. This was the reason for the inclusion of this article in the Tokyo declaration. The wording "artificially fed", instead of "forcibly fed" was an imprecise choice of wording, as "artificially" clearly does not convey that it was feeding against the prisoner's will that was prescribed. It also implied not to resuscitate an unconscious prisoner, victim of torture, even without force being used, so as to send him back for more.

During the hunger strikes in N.I. in 1980 and 1981, force-feeding was not performed. The UK doctors never envisaged the possibility "that there be any circumstances where the *due process of law* would require a physician to force-feed anybody against

1 Reyes H., Luebeck; *op. cit.*

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their will."[1] A clear position for the upholding of patient autonomy was taken by the U.K. during the hunger strikes in Northern Ireland. Respecting autonomy came with a price. Ten deaths resulted before the prisoners broke off their strike, and the authorities quietly gave in to some of the prisoners' demands.

After these dramatic events in Ulster, it was awhile before there were any such determined protests leading to loss of life. Many hunger strikes took place during the next 15 years, in the Middle East, in Latin America and elsewhere, but never led to any showdowns as in Northern Ireland. Protest fasting in most of these contexts, without wanting to minimize neither the prisoners' sincerity nor their grievances, never went "down to the wire". In South Africa, however, in the 1980s, there were "more serious" hunger strikes. This led the South African doctors to seek further guidance from the WMA, about hunger strikes *per se*, and as a result, a new declaration, exclusively on hunger strikes in custody, was drafted and passed by the World Medical Assembly in Malta in 1991 (hereafter "Malta 1991"). This new document defined the different forms of fasting, the role of the doctor in monitoring the patient, and mentioned the effects of "terminal" hunger strikes.

While "Malta 1991" mentioned artificial feeding, still it did not explicitly forbid *force-feeding*. At the time, forcible treatment was not an issue, and hence was not considered as a problem. After the deadly mistake, occurring during a hunger strike in the Middle East in the early 1980s, which resulted in the death of two prisoners who were forcibly fed – liquid nutrients being erroneously introduced into the windpipe rather than the oesophagus – force-feeding, already rare, had practically disappeared. The hunger strikes in Turkey in the late 90s led to an unprecedented number of deaths. At least 60–70 prisoners, and also many family members fasting outside the prison, died. The deaths from fasting occurred after periods of time well beyond the "72 days", which implied they had not been "totally fasting", and so died from prolonged, not acute, malnutrition. This was a completely different situation from that of the 1981 Irish Hunger Strikes. The Turkish hunger strikes and the way they were ultimately "managed" by the authorities and by the prisoners are a complex issue, well beyond any detailed discussion here. The point to be stressed is that there was no question of any forcible feeding, the confrontation being of a very different complexity. It was the Turkish strikes that triggered the revision of "Malta 1991"[2] at the WMA. Initially, the new draft was intended to refer essentially to the confrontation in Turkey. However, as the revision was taking place and being debated within the WMA, the equally serious situation at Guantánamo Bay was taken into consideration. The use of systematic force-feeding at Guantánamo Bay led to a review of the ethical issues involved, and to reaffirming patient autonomy over just beneficence at any cost. This was the main reason for the WMA considerably strengthening the condemnation of force-feeding, distinguishing it this time clearly from voluntary artificial feeding[3]. The new "Malta 2006" was revised and passed by the World Medical Assembly in South Africa in 2006.

The Controversy Around Force-feeding

The situation at Guantánamo Bay (Gtmo) has been widely documented in the press since 2001, and there is now a large amount of information accessible to the public. Force-feeding at Gtmo is now well documented in many articles in prestigious journals, and on countless websites[4]. Force-feeding was implemented there by physicians, and may still be at the time of this publication. This constitutes a violation of the principles set down by "Malta 2006", and constitutes an example of medical complicity in what the WMA has defined as inhuman and degrading treatment. The WMA's firm position against force-feeding is explained in detail in the Background paper[5] accompanying the revised 2006 version of "Malta". Article 13 of "Malta 2006" states:

"Forcible feeding is never ethically acceptable. Even if intended to benefit, feeding accompanied by threats, coercion, force or use of physical restraints is a form of inhuman and degrading treatment. …"

Physicians now should unequivocally know that it is their ethical duty not to participate in, nor condone, any such coercive procedures. Guantánamo Bay is a typical example of "medicalization" being implemented as the "solution" to a problem the custodial authorities – in this case the military -- cannot accept. The term used, "asymmetric warfare"[6] brings to light a fundamental contradiction in the response to hunger strikes in the Guantánamo context. On the one hand, medical intervention by force-feeding is "justified" as necessary to provide humane *medical* treatment to prisoners, to save their lives. On the other hand, hunger strikes being described as a new type of "warfare" cannot have a "medical" solution. It is either suppression, by any and all means possible, of an act of warfare, or it is providing

1 Written statement to the author by a former senior medical officer who was involved at the time in the Irish hunger strikes.

2 Reyes, H. *Force-Feeding and Coercion: No Physician Complicity*. In: Virtual Mentor, American Medical Association Journal of Ethics, October 2007, Vol. 9, No 10, pp 703-708.

3 WMJ; *op. cit.*; Glossary

4 *http://www.nytimes.com/2006/02/22/international/middleeast/22gitmo.html?scp=1&sq=Force-Feeding%20at%20Guant%E1namo%20Is%20Now%20Acknowledged&st=cse*

5 WMJ; *op. cit.*

6 Annas G.J., *op. cit.*

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humane treatment – one cannot have it both ways!

Two arguments for feeding hunger strikers even against their will have been given by the military authorities responsible for Gtmo. The first argument is that force-feeding has had to be implemented to "save lives". This statement is fallacious, as the feeding was being administered very early on, after a maximum of 10-15 days of total fasting. As has been shown, at this stage there is no risk of dying from fasting. When pressed with this reasoning, the custodial authorities have switched their argument to being "not to save lives, but to save their health". This is again a fallacious argument, vaguely disguising the real intent, which is to break the protest, indeed to suppress the "asymetrical warfare".

There have been rare cases of hunger strikers dying very early on in their protest fasting. One of the ten 1981 N.I. hunger strikers, Martin Hurson, died after 46 days, from a complication that apparently did not allow him to ingest water. A recent 2012 case of a California prisoner on hunger strike, dying after one week"[1] is still being medically investigated, but the death was most certainly not due to the fasting alone.

The second argument issued by the military authorities for intervention has been that the vast majority of internees at Gtmo "accept" in fact being thus fed, meaning they do not struggle and fight against insertion of the naso-gastric tube, "because they do not want to die". If this were to be the case, i.e. voluntary acceptance of the feeding, it would *not* constitute ***force***-feeding, but artificial feeding. The latter, as has been stated, is not a transgression of ethics as by definition it implies voluntary acceptance of medical intervention from the hunger striker.

This argumentation nonetheless warrants further scrutiny. One of the higher authorities in the military command has stated that at Gtmo they have been "strapping some of the detainees (*sic*) into *restraint chairs* to force-feed them and isolate them from one another after finding that some were deliberately vomiting or siphoning out the liquid they had been fed"[2]. This is also the reason naso-gastric tubes have not been left in place, as they can indeed be used to empty the nutrients introduced into the stomach by a hunger striker not wanting to receive food. The point is obvious: the fact that restraint is "necessary" proves that the administration of nutrients is *not* accepted voluntarily, and hence constitutes force-feeding.

This being said, one must look beyond this first stage, as force-feeding has been the systematic policy at Gtmo[3] for many years now, and not merely an exceptional intervention. The military authority quoted earlier admitted that "…commanders (had) decided to try to make life less comfortable for the hunger strikers, and that the measures were seen as successful. … Pretty soon it wasn't convenient, and they [the hunger strikers] decided it wasn't worth it," … "A lot of the detainees said: 'I don't want to put up with this. [resisting force and the restraint chair] This is too much of a hassle."

It is thus deliberately misleading to ascertain that the feeding implemented at Gtmo is not coercive because a hunger striker gives up protesting and struggling. Knowing that he cannot prevail against the physicians charged with feeding him, a hunger striker may even renounce resisting at all. Seeing fellow hunger strikers being forced to submit to the naso-gastric feeding and the restraint chair may be enough to discourage any resistance.

In this respect, "Malta 2006" specifically states, in the same Article 13:
"Equally unacceptable is the forced feeding of some detainees in order to intimidate or coerce other hunger strikers to stop fasting."

The whole discussion around the policy of force-feeding hunger striking internees at Gtmo thus centers on this flouting of the clear prohibition for physicians to participate in inhuman and degrading treatment.

Much has been debated regarding the issue of whether force-feeding qualifies as a form of torture. The WMA does not use the term *torture*, but declare force-feeding as "inhuman and degrading treatment", making it a violation of Common Article 3 of the Geneva Conventions of 1949, which condemn "cruel, humiliating and degrading treatments". *Repeated* force-feedings can only make the situation more degrading and inhuman. However, legally speaking, as there is no clear *intent* "to inflict pain", the juridical definition or torture according to the UN 1984 Convention against Torture would arguably not be met. The distinction here between "inhuman and degrading treatment" and "torture" is not the point – *force*-feeding is a violation of medical ethics under any circumstances.

Indeed, in many non-military settings, the force-feeding is not only legally permissible, it is actually ordered by the courts. Court orders do not invalidate the professional obligation of the physician to act within the bounds of medical ethics. While such conflicts are notoriously challenging for individual physicians, violations of professional ethics greatly undermine the integrity and autonomy of the medical profession and may have profound consequences on the future efficacy of the profession. As a practical matter, they have the immediate impact of damaging the ability of professional colleagues and future physicians to establish

1 *http://rt.com/usa/news/california-hunger-strike-gomez-187/*

2 *http://www.nytimes.com/2006/02/22/international/middleeast/22gitmo.html?scp=1&sq=Force-Feeding%20at%20Guant%E1namo%20Is%20Now%20Acknowledged&st=cse op. cit.*

3 Annas G.J; *op. cit.* and others

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trust with fellow prisoner patients; and as we have said, without trust, medicine cannot be practiced.

In Guantánamo Bay, restraint chairs accompanied by threats and muscular interventions,were used, and any recalcitrant to the feeding thus made to comply. This situation of coercion, the force-feeding, was maintained for weeks, months and more on fasting detainees. The WMA Declaration of Malta qualifies "force-feeding" unequivocally as "a form of cruel, inhuman treatment" – but this refers to a "one-shot" force-feeding. The WMA never envisaged a situation whereby repeated force-feedings would be applied to the same individuals over such long periods of time. There is no historical precedent for hunger strikes lasting over five years and "managed" with inhumane and unethical practices in this coercive way[1]. There may be one exception to this, Irom Chanu Sharmila of India who has been on a hunger strike for more than a decade. It could arguably be necessary to now submit to the WMA the question of how long-term and repeated force-feedings should be qualified.

Lessons from Guantánamo

At Gtmo force-feeding was accordingly made mandatory. It was the Secretary of Defence who specifically decided that the decision was a **military one**, to be made by the non-medical camp commander, but that would be implemented by physicians[2] [3].

"The use of physicians to aggressively break a prison hunger strike raises complex medical ethical and legal issues that have been the subject of international debate for decades."[4] It is a perverse medicalization of the issue, imposing a medical act on an unwilling patient, thus taking the physician away from the role of medical intermediary. The issue became so politicized that the most senior physician in the Pentagon at the time contradicted his base commander on the issue of the hunger strikers being suicidal[5] and suggesting that the case of hunger strikers at Guantánamo was like the Terri Schiavo case[6]. "There is a moral question. Do you allow a person to commit suicide? Or do you take steps to protect their health and preserve their life?[7]" The order was then given specifically requiring military physicians to perform an act in direct violation of medical ethics.

Another recent case in Switzerland illustrates this point. The heated arguments between the judiciary, adamant to "break" a well-known hunger striker by having the doctors force-feed him, and the physicians, refusing to comply citing the support of their Medical Association, even though the decision to force-feed was (surprisingly) sustained by the Swiss Federal Tribunal (the equivalent in the US to the Supreme Court) led to a stand-off. In the end, the physicians stood their ground and firmly refused to give in to any judicial authority that flouted medical ethics, be it the highest Tribunal in the land.[8] They were right in doing so, and the judiciary was wrong to try to get physicians to violate medical ethics, including the clear directives on hunger strikes of the World Medical Association[9].

It is this abuse of the medical role of prison authorities and even the judiciary that has led to serious confrontations. Unfortunately, the spotlight has been turned more and more onto the extreme violation of medical ethics in the case of hunger strikes – force-feeding – neglecting almost totally the real role of physicians. This real role of doctors has been discussed earlier and it will be further addressed later on.

The US military authorities do not dispute that force-feeding violates medical ethics, but insist that physicians follow orders because force-feeding is necessary for national security reasons. National security, not the prevention of "self-harm", is the real issue. Physicians at Gtmo, mainly Navy reservists, have complied with orders, although it is possible that any physician not willing to do so may have been directed elsewhere. In Switzerland, eighty prominent physicians signed a petition resisting such "orders" from the highest court in the land, the Federal Tribunal[10], and the order was revoked.

The Conflict that Needn't Be

Guantánamo Bay has been merely the most visible example of "medicalization" of the controversy around hunger strikes, in the media spotlight because of the characteristics of the place and its inmates. Such "medicalization" occurs, however, to a lesser degree, in prisons everywhere. The custodial authorities' first and utmost priority is maintaining security and "peace and quiet". A prisoner who protests by fasting, by definition will do it "noisily", to attract as much attention as s/he can, and

1 Polgreen, L. *In India, 11-Year Hunger Strike over Military Violence is Waged in Shadows*. In: New York Times, September 11, 2011, 5. Annas G.J. personal communication.

2 Annas, G.J. *Military Medical Ethics – Physician first, last, always*. In: N Engl J Med 2008; 359; 1087-90

3 Rubenstein, L.S., Annas, G,J, *Medical Ethics at Guantánamo Bay Detention Centre and in the US Military: a time for Reform* In: *Lancet 2009*, 374; 353-55

4 Annas G.J. *op. cit.* Footnote 10

5 Wei M., Brendel J.W., *op. cit*.

6 Media Roundtable with Department of Defense Assistant Secretary for Health Affairs William Winkenwerder, News Transcript, June 7, 2006 available at: *http://www.defenselink.mil/transcripts/transcript.aspx?transcriptID=33*

7 Annas G.J., *op. cit.*

8 Editorial by Dr. Jacques *de Haller*, President of the Swiss Medical Association (FMH); *Bulletin des Médecins Suisses*, September 2010, N° 39.

9 "Malta 2006", *op. cit*.

10 de Haller J., *op. cit.*

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get as much support as possible from all sides. A hunger striker is seen therefore as a trouble-maker, a "hostage taker" as has been mentioned. The tendency to "have the doctor" solve the problem is not limited to Gtmo.

Hunger strikes elsewhere have had similar, though mostly attenuated, complications. A case in point was a collective hunger strike in a Latin American country, where an ICRC physician played a key role in finding a solution. By speaking to the prisoners both collectively and individually, it became clear that none of them wanted to die, but all wanted their protest to continue and make as much "noise" as possible. The doctor could thus persuade the hunger strikers to accept intravenous lines and the administration of vitamins and nutrients. The prisoners continued proclaiming they were still "on hunger strike". The physician played his role of intermediary discreetly, refusing to comment publicly on whether the hunger strike was "really genuine". Had he made any public statements, this would have been seen by the hunger strikers as a betrayal of trust, possibly leading to a breakdown in the process of reconciliation. It was finally a representative of the Church who brought about a peaceful resolution.

Other recent examples in the Middle East have proven again that if the physician plays his or her role of discreet, trusted medical intermediary, there will be no need for any force to be considered. The hunger striker not wanting to die may be persuaded to accept medical help in exchange for some face-saving "concession" for example. Or he may accept transferral to hospital so as to be able to "blame the prison doctor" for having to refrain from pursuing the protest fast. The prison doctor must be ready to shoulder this blame, having the interest of the patient as a priority. Furthermore, it will allow for smoothing the conflictual situation between the custodial authorities and the protestors.

Thus, there need be no conflict once all parties agree that a solution has to be found so as not to endanger anyone's life.

Allowing the Prisoner One Last Chance

The debate on respecting autonomy, and not imposing treatment on hunger strikers is most often a moot point. The hunger strikers at Guantánamo Bay were force-fed early, and it will never be known how many of them could have been coaxed out of their collective strike had the doctors been able to have an independent role of medical intermediary. Some well meaning voices have intransigently supported respect at all times of, for example, any written instructions, calling the (exceptional) hunger striker who goes "all the way", to be respected.

This is certainly the policy that was applied to the Northern Ireland hunger strikers. However, a recent personal example will illustrate exactly the contrary, and still be in accordance with the guidance in "Malta 2006".

In a hunger strike in Transcaucasia, the prison doctor took it upon himself to resuscitate a vociferous political hunger striker who had reached the confusional phase late in total fasting. This was, in fact, contrary to the hunger striker's ***written*** instructions. On the face of it, this case would seem to be a violation of medical ethics by the prison doctor.

Some time later, this same prisoner protested about the prison doctor's actions to one of the authors of this paper. When questioned as to why he had gone against the hunger striker's *written* decision not to be resuscitated, the local doctor explained that he came from the same region as the hunger striker. "In his heart", he said, he knew the patient would not want to die, so he intervened once the prisoner was no longer alert and aware of what was happening. This prison doctor did well in doing so. As the hunger striker confessed to the author, he was actually delighted to find himself alive and well – but he did not want either the authorities or the prison doctor to know this! This example may be uncommon, but it is not atypical of the ambivalence there is in many cases.

Prisoners begin a hunger strike often not really knowing what they get into. As shall be discussed further on, some will "paint themselves into a corner" at some point, and may not know how to back off. It is here the doctor can play an important role. Force-feeding will not be an issue, since this type of hunger striker does not want to harm himself. In the privacy of the medical consultation, away from any outside peer pressure, the physician often easily convinces the hesitating protester to accept artificial feeding. As to the ethical guidelines, it is important to understand that "Malta 2006" *specifically* allows such leeway to the treating physician who knows the patient, and should thus have the final word in deciding what is best[1]. Article 10 reads:
"If no discussion with the individual is possible and no advance instructions exist, physicians have to act in what they judge to be the person's best interests. This means considering the hunger strikers' previously expressed wishes, their personal and cultural values as well as their physical health. In the absence of any evidence of hunger strikers' former wishes, physicians should decide whether or not to provide feeding, without interference from third parties."

The prison doctor who thus ignored the Transcaucasian hunger strikers' *written* instructions thus took the risk of erring by going against the expressed will of the prisoner – but in fact he ended up taking the right decision. The physician retained the proper authority to exercise judgment, in

1 WMJ; *op cit.* 10. Artificial feeding, force-feeding and resuscitation; p. 40

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good faith, in assessing the patients' will in a difficult clinical situation.

"Malta 2006" allows for error. If the Transcaucasian prisoner had torn away his intravenous lines and naso-gastric tube upon revival, then the prison doctor would have been justified in not interfering a second time. This will be discussed in the final point before reaching a conclusion.

Volunteer or Volunteered ?

The common denominator to all problematic hunger strikes is the clash between medical and non-medical authorities. However, this should not distract the physician from other possible conflicts which will directly influence the ethical management of the hunger strikers.

A prisoner who decides to protest by fasting must do so voluntarily. As it has been mentioned, some voices object to *anything* being truly voluntary in a custodial setting, referring to the overall control exerted by the custodial authorities. Different pressure on the hunger striker has also been exerted, which in some contexts can be potent enough to force the hunger striker to pursue the protest that the individual would have broken off. It is here that the physician has a duty to identify such a case.

By making sure every hunger striker is seen and interviewed in the privacy of the medical consultation, the physician has a good chance of establishing sufficient trust to be able to know what the situation is. All too often, when many prisoners are all on strike together, they are kept in an open ward together. In such conditions it is easy for a "leader", identifiable or not, to exert pressure on the others to pursue a hunger strike all may not be in agreement with. To avoid this type of peer coercion, the physician must insist on seeing each hunger striker individually. If the hunger strikers initially refuse (possibly again because of peer pressure), the excuse of doing a "medical examination in private" usually gets them to consent.

Concerns about how to examine "hundreds of prisoners" individually should not be a major issue, as "mass hunger strikes" usually fade out after a few weeks, reducing the number down to the real and problematic cases. As will be developed in the recommendations and in contexts where this is feasible, hunger strikers should be kept in separate rooms – but not in isolation. To absolutely separate them and leave them incommunicado will be in most cases seen as a repressive measure, required by the physician to boot, and will not encourage the prisoners to trust the doctor.

Experience from many contexts has shown that many hunger strikers will, in the privacy of the consultation, even plead with the physician to help in getting away from peer coercion, or from a threatening leadership. If the physician can convey the message that s/he is there not to stop the strike, but to help the individual hunger striker, more than half the battle is won. It is then a question of finding a solution. This may entail transfer to the medical ward, for "further exams", or for "treatment of a medical condition". A form of "reverse medicalization" can be evoked here, the physician taking upon him/herself to give the individual a way out. This may be so as to merely "not lose face", important in many contexts. Or it may be to extract from reprisals a hunger striker who has "volunteered" to protest way beyond the length of time he may have envisaged initially. The result – medical care being provided – is the same as for the food refuser, but in the refuser's case it is clear from the start that the fasting is limited and to be under full medical control. It cannot be stressed sufficiently here the need for the physician to be able to convey to the hunger strikers that s/he is "on their side", meaning to provide care and empathy and whatever assistance is needed, and *not* as an agent of the custodial authorities.

Manipulators and Manipulated

The imposition on medical staff by judges, tribunals or other custodial authorities of orders to perform the task of force-feeding "recalcitrant" hunger strikers, knowing full well or ignoring that this is contrary to the doctors' ethical principles, is a form of manipulation. Physicians should never let themselves be manipulated this way, whatever the authority evokes, be it judicial or military. Even in situations of "dual loyalties", whereby physicians owe loyalty to, for example, the Prison Service, or the Armed Forces, the bottom line must always be respect for their ethical principles[1]. Physicians are first and foremost responsible to their patients[2] [3], and they have the full support of the World Medical Association behind them in this.

There is a different form of manipulation that physicians also should avoid. Individual or groups of hunger strikers may also seek to "use" the doctor. Recent cases of what one may call "problematic hunger strikes", i.e. going beyond a mere couple of weeks, in politically charged contexts, have given rise to such behaviour. A hunger striker may tell the physician in confidence that for sure he *neither* does want to die *nor* endanger his health. While accepting assistance in the form of an intravenous line or possibly even nutritional intake in the discretion of the medical consultation, the hunger striker tries to manipulate the doctor, for example, insisting he makes a public statement to the press, or blatantly lies to his superiors in the prison. This is unacceptable when it is obviously a form of manipulation of the physician, trying to get him to collaborate with the protest. The physician has to remain on neutral ground, and thus retain credibility

1 Reyes, H. *Medical ethics subject to national law: Should doctors always comply*? In: Medische Neutraliteit; Jaargang 51, 8 November 1996 MC NR 45; pp. 1456/1459

2 Annas G.J. *op. cit.*

3 Allen S., Reyes H.; *op. cit*.

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on all sides. While there is not need to be specific, towards the press for example, on "what type of treatment" is being given, the physician should not lie about it. To his immediate superiors he should explain his situation of intermediary, and not let them manipulate the situation either.

In another highly publicized hunger strike in Europe, a determined prisoner, who totally fasting lost more than 20 kilos but who knew *exactly* what he was doing, managed to manipulate into believing he was steadfast in his resolve not only the custodial authorities, but also the medical staff. The custodial authorities, in this case both prison and judicial, ordered the prisoner to be force-fed. The physicians refused, evoking the ethical principles in "Malta 2006". The nurses, however, took pity on the "poor old man"[1] and persuaded him (sic) to accept a naso-gastric tube. The hunger striker ascertained that if he were attached, he would yank it out. However, he then proceeded to help the nurses attach him.

This case was widely commented on and even went visually into the media. It is now clear that the prisoner had no intention of starving himself to death, but manipulated the authorities into ordering him force-fed; manipulated the medical staff into attaching him down, while accepting in fact the naso-gastric feeding; and even manipulated an outside higher authority into believing he *had* been *force*-fed. Once he obtained what he wanted, he quickly stopped fasting and walked out of custody a free man.

It is most important for physicians to maintain the high moral ground here, and refuse manipulation from *any side*. In the abovementioned case most of them refused to have anything to do with the prisoner, but some – and the nursing staff – were tricked into playing his game. It is essential the physician *not* let him/herself be manipulated by *any* side. Only this way a constructive medical role will be possible and hopefully calm down the situation and avoid coming to an impasse.

Painting Hunger Strikers Out of Their Corner

It was mentioned in the introduction to this paper that the hunger striker was sometimes "forgotten" in the heated controversies between the custodial authorities and the medical profession. Such confrontations, and their often very public "ventilation" in the media, put the hunger striker "on the spot", or more to the point, "in the spotlight". A lone hunger striker may all of a sudden find he has become a "star", talked about, held up as a "victim" or "martyr" as the case may be. From a hostage taker holding himself hostage, he effectively becomes a real one of the situation. Any "support" from outside or from the same media, may have the contra-productive effect of "painting the hunger striker into a corner". Finding oneself with the "star" or "martyr" status makes it very difficult to back out of a more and more difficult situation. Abandoning the hunger strike becomes impossible, even in exchange for lesser concessions that gladly might have been accepted initially. The hunger striker may fear the taunts from the prison guards if he now backs down; or the shaming of his family; or the reproaches of his fellow inmates who will fell "let down"… The hunger striker may thus feel obliged to fast beyond whatever limit he initially may have had in mind.

When the individual hunger striker, or group of resolute hunger strikers, gets into such a "showdown" position with the authorities, pushed by their new notoriety into radical positions they may have not initially intended to take, it may seem too late to find a useful alternative to impasse. However, even in the most politicised situations, letting the situation deteriorate and become confrontational is ***not*** inevitable.

The physician still can play a crucial role in finding a way out. It is important for the physician not to medicalize just any form of fasting during the first 72 hours, otherwise the precious time will be wasted on futile cases. The custodial authorities may certainly consult the doctor about a specific prisoner – to know whether there is a medical condition that would put him in danger very early on. As mentioned above, it is to be avoided to have the physician rush to each hunger striker's bedside before 72 hours. After this period of time, the physician can plan how to manage each situation, and first and foremost reaffirm a relationship of trust as soon as s/he can. The physician should proceed without fanfare, and most of all without pressure from any side, either from the custodial authorities or from the prisoner(s).

The Ultimate Goal: Preserving Human Dignity

A final point need be made here. It should be sufficiently clear that hunger strikers very rarely go to a final fatal conclusion. Those that do often fall into the "painted into the corner" category, i.e. a situation of impasse, created by those who have left the situation get out of hand. The Northern Ireland strikes were an exception, and no one can accuse the physicians of not having done all they possibly could to defuse a highly politicized situation. That hunger strike, like those embarked on by Mahatma Ghandi, had there been no concessions in his case, ended in fatalities. Such rare terminations of the ultimate way for prisoners to protest are rare, and it has been shown that they can be avoided in the majority of cases. However, force-feeding is not a solution, as it imposes refused medical treatment on the individual, from a non-medical authority, making the physician an accomplice of wrong-doing, if inhuman and degrading treatment. As already said, "Malta 2006" clearly states that force-feeding is never justified. A competent hunger striker can-

1 An authentic quote to the author from the interviewed medical staff…

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not be coerced, even were it to save his or her life.

Article 11 of "Malta 2006" states:
"If, after resuscitation and having regained their mental faculties, hunger strikers continue to reiterate their intention to fast, that decision should be respected. It is ethical to allow a determined hunger striker to die in dignity rather than submit that person to repeated interventions against his or her will."

This clause applies to cases where a prisoner may have been forced to sign such instructions under duress, in a repressive or dictatorial prison system for example. However, in a more normal situation, it also applies to those cases, such as the above mentioned Caucasian one, where the prison doctor has given a terminal hunger striker "one last chance". As has been said, this is admissible if the doctor who has been following the patient, and knows him, has the firm conviction there is good reason to believe the hunger striker really does not want to die. If the physician has in good faith misjudged the situation, he cannot be accused of unethical behaviour. What would *not* be admissible, it would be the physician's complicity with the coercive custodial authorities to play the game of allowing deliberate deterioration of the hunger striker's mental state through total fasting. In such a case, once the hunger striker was in a confused state and no longer able to make an informed decision, s/he would be in fact "force-fed, evoking the lack of resistance to such feeding. To thus justify "*artificial*" feeding (sic!), and then start over all again once the prisoner was resuscitated, is totally unacceptable. This type of situation actually occurred in the 1970s, in a North African country, several hunger striking prisoners submitted to what was assimilated to a "yo-yo" situation, which ended up lasting for some two years. "Malta" specifically says that a truly determined hunger striker should be allowed, if all ethical attempts to reverse his or her decision have failed, "to die in dignity."

Way Forward: How to Extricate Physicians (and their ethics) from the Imbroglio and Possibly Contribute to a Solution

How can the confrontational situations mentioned above be avoided? The authors of this paper are convinced the "Way Forward" that has been mentioned, specifically involving physicians, will work for the great majority of hunger strikers. It may not in the most extreme situations, but such cases are truly exceptional.

All physicians want to preserve life. They should do so respecting the dignity and rights of their patients, and respect for medical ethics will automatically follow.

Our analysis leads us to conclude there are many ways that physicians can act, consistent with medical ethics, to develop a true doctor-patient relationship with hunger-strikers. It is also critical that the custodial authorities do not act to undermine the fragile trust between the doctor and the patient for in doing so, they deprive themselves of the easiest solutions to the conflict. Positive and trusting therapeutic relationships will ultimately result in a reasonable outcome for all involved in the vast majority of cases. It must be recalled that hunger strikes, if they are to work, can only do so over a span of time. The key to finding a way out of the imbroglio is for the custodial authorities to realize that a hunger strike is *not* an emergency, let alone a medical emergency. If the physicians have done their job of excluding any potential cases with concurrent medical problems, there is no need for panic. There is at least a full month before reaching the stage when medical symptoms may begin to cloud the issue. These full four weeks are unfortunately seldom used to look for a solution. Instead, the custodial authorities tend to crack down from a viewpoint of mere "principle" ("Nobody kills himself in ***my*** prison!") that is when the spotlights turn on and confrontations begin.

Rigid standard operating procedures (SOP's) which decree that hunger strikers shall be force-fed already during the second or third week of fasting supposedly "to save their lives" are unethical nonsense and precisely what is to be avoided. A healthy young adult with no concurrent medical problems can usually go for a month taking only sufficient amounts of water, and have no serious health issue. The timeframe presented in this paper clearly shows that no serious medical complications of fasting will occur during this first month, leaving ample time for the physician to play a more useful role than merely monitoring blood tests, weights and blood pressures.

Paramount during this period is the meaningful discussion between the physician and the hunger striker. This whole concept of a constructive way forward is based on the physician-patient relationship. The proposed solutions and suggestions that follow have all to be seen from this perspective.

To be continued...

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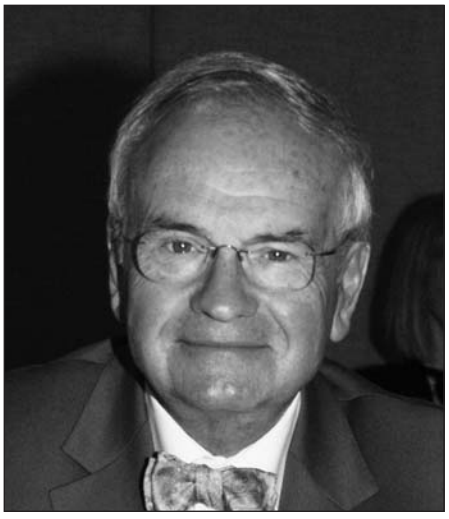
Protective Provisions for Research Participants[1]



Elmar Doppelfeld

Council of Europe

The Council of Europe, which, as an independent institution, may not be confused with the European Union, was established in 1949 for the promotion of human rights and democracy on the basis of its Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 [1]. This Intergovernmental Body, composed of 47 Member States and 5 Observer States (Canada, the Holy See, Japan, Mexico and the USA) and representing about 800 million of citizens aims at harmonizing the European legislation by using Conventions and Additional Protocols to these Conventions. Conventions and Protocols are treaties, and it is up to the decision of the Member States to incorportae them into their national law by signature and ratification. The development of modern biomedicine, in particular the in-vitro-fertilisation of man, gave a reason to the Council to pay more attention to the application of biology and medicine on man. To achieve the aim a Standing Committee, the Steering Committee on Bioethics (CDBI), was established which is the author of all provisions in that field. It was clear from the beginning that the common good of protection of human dignity, autonomy, beneficence and justice should be in the focus.

Classification of Provisions and Reasons for Legal Instruments

Provisions for the protection of research participants are commonly classified as legal instruments and other provisions, often addressed as "soft law". There are few legal instruments. Meanwhile there are recognised treaties like the Oviedo Convention (Council of Europe, 1997) and its additional Protocol concerning biomedical research, as well as Directive 2001/20/EC (2001) [2] of the European Union. The Directive is applicable only to drug research. Most States regulate biomedical research, at least drug research, by national law. It seems that there is a big number of "other provisions". The most important texts, at least in the view of the author, are the Declaration of Helsinki [3], the International Guidelines of CIOMS [4] and the UNESCO Universal Declaration on Bioethics on Human Rights [5]. The national codes of deontology, e.g. for physicians, and other professional codes are to be mentioned as parts of "soft law". Soft law may be incorporated into national binding law by the decision of the State. At least in the past, soft law played an important role in the protection of research participants. Therefore a question may arise about the need of its replacing by legally binding instruments. In this context the relation between ethics and law may be reflected upon. In modern states ethical principles are more and more adopted by legislation with the purpose to find regulations acceptable to all citizens. Free and informed consent can be considered important, e.g.,based on the doctrine of autonomy, in Germany predominantly linked to Immanuel Kant, the German law system requires this consent since 1887 for medical interventions and since 1900 for participation in research.

In the past decades, particularly since the end of the Second World War, protection of human rights and fundamental freedoms is mainly a responsibility of the States and it has been accepted and laid down in several International Conventions. In line with these internationally based provisions the States are asked to regulate the respective fields concerning these rights by the instruments under their supervision and responsibility. Soft law has no sufficient protective force in these fields. Law is a necessary instrument for the harmonization of interests, even contradictory ones, of different groups of society. No group should be entitled to impose its specific positions, even with the best intention, on other groups. Legal instruments, usually a result of compromise, are binding for all groups concerned. They give the frame for the application of soft law, a frame which might be used, but never broken.

System of Protective Provisions of the Council of Europe

The system of protective provisions of the Council of Europe in the field of biomedical research is composed by legally binding instruments and other provisions (see Box)

1 Presented at the Expert Conference on the Revision of the Declaration of Helsinki, 28 February – 1 March 2013, Tokyo

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Legally binding instruments

- Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo Convention)
- Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research

Other provisions

- Recommendation Rec(2006) 4 of the Committee of Ministers to member states on research on biological materials of human origin
- Guide for Members of Research Ethics Committees

These protective provisions address researchers of all disciplines and are not restricted to one group, e.g. physicians. The Oviedo Convention [6] contains the basic principles for the application of biology and medicine on human beings covering the whole field of health. A specific chapter on biomedical research entails the basic principles which apply, in the context with other provisions of the Convention, for the protection of research participants. These principles became legally binding in the 29 Member States of the Council which ratified this treaty. The Convention gives the framework for the elaboration of a specific protocol concerning biomedical research [7], in fact, a treaty that enters into legal force by ratification.

Moreover, the Committee of Ministers adopted a recommendation for research using biological material of human origin [8].This recommendation, even not a legal instrument, influences the practice of scientific use of those materials, as well as are the first steps to regulate this field. The recommendation, currently under revision, outlines important provisions for biobanks. The provisions need to be implemented in actual protection of research participants. Due to the important role of Research Ethics Committees (RECs) the Steering Committee adopted guidelines for Committee members [9] that may help with capacity building.

Fundamental Principles of Protection

Research involving human beings is carried out for the potential benefit of the person concerned or for the benefit of others or to enhance knowledge. The relation between the rights of the individual and the interests of society must be clarified. The Oviedo Convention (Article 2) states that the interests and the welfare of the human being "shall prevail over the *sole* interest of society or science". This provision underlines the primacy of the human being without making it an absolute priority. The word "sole" indicates that individual rights and interests of society may be balanced to develop synergy.

Freedom of research is a basic provision also for scientific projects in the field of biology and medicine. The Convention supports this freedom (Article 15), but emphasizes clearly that this freedom is subject to the protective prescriptions of the Convention and of other legal provisions ensuring the protection of the human being. This article clearly stipulates that research must not be carried out without limitations.

It is generally accepted that the quality of a scientific project is one of the main provisions to justify ethically the exposure of human beings to research related risks. Article 8 of the Research Protocol provides for scientific justification, general criteria of scientific quality and relevant professional standards. Moreover, supervision of an appropriately qualified researcher is required. The Article is a rare example of legal definition of the quality of research.

Risk and Benefit

The legal wording of this principle is as follows: "No risks and burdens to the participant disproportionate to its potential benefits" – the well known postulate of a proportion between risk and benefit. This proportion is adapted to specific kinds of research. In research without a potential direct benefit for the participant, e.g. research on healthy volunteers, no more than acceptable risk and acceptable burden is allowed. It is the obligation of the competent ethic committee to assess the acceptance. In research with a potential direct benefit for the participant, e.g. patients suffering from a specific disease for which a drug treatment is tested, risk and burden may not be disproportionate to the expected benefit

The risk/benefit relation plays a specific role in research on persons not able to consent, e.g. minors, victims of traffic accidents or patients suffering from dementia.

If research is carried out with the expectation of a potential direct benefit for the participants, the above mentioned proportion of risk, burden and benefit may take place. If such a potential direct benefit is not expected, research on persons not able to consent may be carried out in compliance with other provisions only if the project does not entail more than minimal risk *and* minimal burden. Introduced in 1997 by the Oviedo Convention these limitations of "minimal risk and minimal burden" (both must be met) have been later incorporated in national or soft law. (Main sources: Articles 16,17, Oviedo Convention; Article 6, Research Protocol)

Free and Informed Consent

Free and informed consent is the absolute precondition for participation in a research project. A valid consent can be given only

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on the basis of full information on the project given to the invited participant in a wording understandable for him or her. Consent may be given freely without any undue influence or coercion. Consent may be refused or withdrawn in the course of the research project. No discrimination, in particular no withdrawal of healthcare, may occur as a consequence of such a refusal or withdrawal. It is one of the main responsibilities of ethics committees to supervise the conditions for free and informed consent.

Protection of Persons Undergoing Research

A precondition for involving persons in medical research is the lack of alternatives of comparable effectiveness to research on humans. The risk/benefit proportion has been assessed as acceptable. The approval by a competent body has been given after an independent examination of the scientific merit, including assessment of the importance of the aim of the research, and after multidisciplinary review of the ethical acceptability. The ethical review has to precede any approval of a competent body as provided by national law. In addition to the information on the research project participants shall be informed on their rights and the safeguards prescribed by law for their protection

Free and informed consent or, in case of research on persons not able to consent, authorization by the legal representative must be given expressly and specifically; and it must be documented. Consent and authorization may be refused or withdrawn at any time. It is clear that "specific consent" only applies to specific research projects. This provision is applied to research using human materials to "open consent" (Recommendation [8]). Article 16 of the Oviedo Convention contains the protective provisions that recur in other relevant provisions.

Research on Persons Unable to Consent

Research on persons unable to consent is a world wide ethical and legal problem, specifically in research without a potential direct benefit for the person. The provisions of the Council introduce a proposal for a solution, accepted in many States. Scientific quality must be ensured, research on the envisaged group of persons has to be justified. Research which could be performed on persons able to consent is excluded. If there is an expected benefit for participants, the risk may be assessed in view of this benefit. Research without such a potential direct benefit may only be performed if protective provisions prescribed by law are applicable. Only minimal risk and minimal burden are acceptable[1].

The authorization by the legal representative according to national law is needed to include into research persons unable to consent. The representative receives full information on the research projects. The represented person participates in the authorization procedure proportionally to his/her maturity and understanding. Any objection has to be respected. The best interest of the represented person is the decision line. Refusal or withdrawal of the authorisation is possible at any time without any form of discrimination against the represented person. The legal representative should not have any financial or other interest. (Sources: Article 17, Oviedo Convention; Chapter V, Research Protocol).

1 Minimal risk and minimal burden are rather new terms. Thereis a legal definiton in Article 17 of the Research Protocol.:"Article 17 – Research with minimal risk and minimal burden
- For the purposes of this Protocol it is deemed that the research bears a minimal risk if, having regard to the nature and scale of the intervention, it is to be expected that it will result, at the most, in a very slight and temporary negative impact on the health of the person concerned.
- It is deemed that it bears a minimal burden if it is to be expected that the discomfort will be, at the most, temporary and very slight for the person concerned. In assessing the burden for an individual, a person enjoying the special confidence of the person concerned shall assess the burden where appropriate."

Research in Specific Situations

The provisions of the Council of Europe are extended to research fields that are not covered by other texts, at least not in detail.

a) Research during pregnancy or breast-feeding

Research without a potential direct benefit for the pregnant woman, or for her embryo, foetus or child after birth, are only admitted if there is expected a contribution to the benefit of that group and if comparable research cannot be carried out on women who are not pregnant. Minimal risk and minimal burden are the absolute limitations.

b) Research on persons deprived of liberty

For safeguarding human rights in research on this group protective provisions by law are required. Research without a potential direct benefit may be only carried out if comparable research on persons not deprived of liberty is not possible and if a contribution to the benefit of that group is expected. Again minimal risk and minimal burden are the limiting conditions.

For research with a potential direct benefit on pregnant women and on persons deprived of liberty the relevant provisions of the legal instruments apply.

c) Research in clinical emergency situations

Again for safeguarding human rights in this very specific field of research, which is until now rarely regulated, the permission and the determination of protective additional conditions by law are required. These provisions should define research in emergency as a situation when a person is not in a state

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to give consent, and when because of the urgency of the situation, it is impossible to obtain in a sufficiently timely manner the authorisation from the legal representative or an authority or a person or a body to be called upon to give authorization and when research of comparable effectiveness cannot be carried out on persons in non-emergency situations.

Moreover, specific provisions are compulsory. The project has been approved as "research in emergency situations" by the competent body. This approval may be given in line with the relevant articles of the research protocol, e.g. only after assessment of the scientific quality and after ethical review. Expressed objections, if known, shall be respected. For research with a potential direct benefit the risk/benefit assessment takes place. A research project without a potential direct benefit for the participant is limited by minimal risk and minimal burden. Information to the person involved or to the legal representative is given as soon as it is possible to ask for consent or authorization for continued participation. This procedure is considered as postponed consent/authorization and not as a waiver of consent/authorization. (Source: Chapter VI, Research Protocol).

Responsibility of Ethics Committees

The world wide accepted principle of independent examination of research projects by Research Ethics Committees (REC) is codified. Every research project should be submitted for independent examination of its ethical acceptability to a REC. In transnational projects this examination is required in each State in which the project or parts of it are performed. Depending on national law the scope of the examination may be restricted to ethical acceptability or extended including the scientific quality and conformity with law. The protection of dignity, rights, safety and well-being of research participants are listed as purpose of the examination. The composition of RECs is mostly regulated by national law. However, the appropriate range of expertise and experience adequately reflecting professional and lay views are the basic principles. The independence of the REC must be guaranteed. The harmonization of information for RECs plays a major role in enabling these committees to decide on a similar basis. The items for this information are listed in the Appendix to the Research Protocol. And as already stated above: any approval of a research project by an authority, if required by national law, is appropriate only after the examination by a REC! (Sources: Article 16, Oviedo Convention; Chapter III, Research Protocol).

Safety, Supervision and Duty of Care

In research risk and burden should be minimised in proportion to the scientific aims. Minimisation may not be confused with minimal risk and minimal burden mentioned above, which are absolute limitations. A qualified clinical professional shall be in supervision. The assessment of health status prior to inclusion in research with particular considerations on participants in the reproductive stage of life may be done on the basis of patients' files or by a specific assessment. Necessary preventive, diagnostic or therapeutic procedures may not be delayed or abandoned in favour of the research project. Control groups shall be assured of proven methods of prevention, diagnosis or treatment. The use of placebo is accepted when no methods of proven effectiveness are known or if withdrawal or withholding of such methods does not present an unacceptable risk or burden. A re-examination of a project is justified in the light of scientific developments or events arising in the course of the research. A decision to discontinue or to change the research project may be the result of this re-examination. In line with this procedure it may be necessary to inform the research participants or their representatives of the developments or events. An additional consent or authorisation for participation can be proven as appropriate. The information of the competent body of the reasons for any premature termination of a research project serves as a help to prevent similar projects if appropriate. (Source: Chapter VII, Research Protocol).

If results of the research can be of relevance to the current or future health or quality of life of research participants, this information must be offered to them. "That shall be done within a framework of health care or counselling. In communication of such information, due care must be taken in order to protect confidentiality and to respect any wish of a participant not to receive such information". (Article 27, Research Protocol).

Confidentiality and Right to Information

Data collected during biomedical research should be protected as confidential data. Legal provisions to prohibit inappropriate disclosure of information submitted to an Ethics Committee should be introduced to prevent any misuse of this information.

The right to information for research participants is often questioned by researchers and physicians in view of "the best for the person concerned". However, the provisions of the Council of Europe underline the right to know any information on health collected in the research project and the right not to know (Article 10, Oviedo Convention). This states clearly that researchers, including physicians, are obliged to inform the person concerned and to respect any wish not to be informed. The right not to know may only be suspended by law. Personal information outside the health field may be given in conformity with the national law on data protection.

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To improve transparency of research a report or a summary should be submitted to the Ethics Committee or to the competent body after termination of the project. Conclusions of the research should be available to the participants within a reasonable time on request. Unfortunately it was not possible to introduce a stringent provision concerning publication of the results. As a compromise appropriate measures of the researcher to make public the results of the research in a reasonable time has been accepted (Source: Chapter VIII, Research Protocol).

The protective provisions of the Council of Europe seem to be very detailed. However, it was aimed at addressing all the ethical and legal problems known at the moment of their adoption. The provisions enter more and more into legal force binding all researchers, including physicians. They are the legal framework to follow soft law which, as such, does not permit to neglect any of these provisions.

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Frequency of Hypertension in a Primary Care Setting in Buza, Tanzania

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Background: The worldwide prevalence of hypertension in established market economy countries was estimated to be 37.4% for males and 37.2% for females. The prevalence of hypertension in Tanzania ranged between 30 and 57% (<20% aware of their hypertension, <10% compliant). The purpose of our study is to identify the frequency of hypertension in our sample population, looking at gender differences, rate of previous diagnosis, compliance to medication in relation to socio-economic status, and diet.

Methods: A cross-sectional population based survey to calculate the frequency of hypertension in a primary care clinic.

Results: Satisfactory data was available on 198 patients (98.0%), 160 (85.0%) were females. The mean age of the population was 37.8years. Frequency of patients suffering from hypertension was 44.9% (89 patients), confidence intervals 95% (CI 95%) 38.0–51.9%. 19 patients (9.6%, CI 95% 3.8–15.4%) were diagnosed with malignant hypertension. 62 patients (69.7%, CI 95% 60.1–74.2%) were incidence cases while 27 patients (30.3%, CI 95% 20.8–39.9%) were prevalence. Only 6 persons (22.2%) were compliant to the previously prescribed medication and only 2 of

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these (7.4%) had their blood pressure controlled (blood pressure <140/90 mmHg).

Conclusion: Prevalence of hypertension (44.9%) in the population was significantly higher than that calculated for the market economy countries (37.3%). However, it fell within the range of previous reported studies (30–57%). No significant differences were found between males and females, though a statistical link was found to lowest and highest socio-economic states and diet.

Awareness and management of hypertension is a much needed public health service in Tanzania and one that is cheap, easy and would result in greatly improved quality of life.

Background

Hypertension (HT) is defined by the World Health Organisation as a persistent raised arterial blood pressure (BP) of over 140/90 mm Hg. HT is the main risk factor for congestive heart failure and is of great social and economic importance because of its high prevalence, mortality and impact on young, economically active individuals [1].

A systematic review calculated the prevalence of HT in established market economy countries to be 37.4% in males and 37.2% in females. The prevalence of HT varied greatly around the world, with the lowest prevalence being in rural India (3.4% in men and 6.8% in women) and the highest prevalence in Poland (68.9% in men and 72.5% in women). Control of HT (BP <140/90 mmHg while on antihypertensive medication) varied from 5.4% in Korea to 58% in Barbados [2].

A study that focused on the prevalence of HT in the United States, Canada and 6 European countries found it to be 28% in the North American countries and 44% in the European countries[3]. In a self reported study carried out in the US, overall two-thirds of the population were aware of their diagnosis (69%) and a majority of these (53% to 79%) were taking prescribed medication [4]. Another study analysing compliance rates in three Central European countries reported 53.5% as compliant and 46.5% as non-compliant [5].

The causes of heart failure in Africans remain largely non-ischemic. Hypertensive heart disease complications occur more frequently in Africans than in Europeans and North Americans, and the majority of affected patients are younger. [6] It is a growing problem in African communities of low socio-economic demographics. [7] Tanzania is an East African country with a population of 38,329,000, and an estimated growth rate of 2%. Population distribution is extremely uneven, varying from 1 person per sq km to 134 per sq km, with over 80% of the population being rural. GDP per capita stands at $1,416. [8] Whilst infectious disease continues to pose a relentless threat to life throughout impoverished regions on the continent, numerous studies carried out in Africa have brought to light the emerging problem of non-communicable disease, in particular cardiovascular disease. [9]

Another study carried out in Tanzania reported the prevalence of HT as 30% in men and 26.8% in women in Ilala (urban area), and 32% in men and 31.5% in women in Shari (rural area). In both areas, just under 20% of hypertensive subjects were aware of their diagnosis, approximately 10% reported receiving treatment, and less than 1% had a controlled BP. [10] A different study focused on gender-related differences in cardiovascular disease risk factors and their correlates in an urban area in Tanzania. They reported a higher prevalence of HT (57%) and severe HT (30%) in the population. Women had more than three-fold greater odds of having metabolic syndrome compared to male counterparts. In contrast, female participants had 50% lower odds of having hypertension, compared to men. [11]

A similar trend was noticed in other East African countries. A study in Addis Ababa, Ethiopia found the prevalence to be 31.5% among males and 28.9% among females. [12] A study in Nakuru, Kenya found the overall prevalence of HT to be 50.1%. [13] In Mozambique, the prevalence of HT was found to be 35.7% among men and 31.2% among women. Of those receiving antihypertensive treatment, only 42.9% of the women and 28.7% of the men were well controlled. [14]

Other studies carried out on the African continent showed a varying prevalence of HT. Studies carried out in Algeria (North Africa) showed that the prevalence of HT ranged between 32.7% and 44%. Of those treated, only 25% were well controlled. [15] In South Africa, a study concluded that HT was independently related to age, obesity and urbanization. Only 16% of those on treatment were controlled. [16] In central Ghana (West Africa), the overall prevalence of HT was found to be 28.7% in men andwomen, and was higher in semi-urban villages (32.9%) than in rural villages (24%). [17]

The location for our study was Buza, a slum in the outskirts of Dar es Salaam. This area is among those of the lowest socioeconomic status' (SES) in the region. The aim of this study was to identify the frequency of hypertension in our sample population, looking specifically at gender differences, the rate of previous diagnosis, compliance to medication in relation to socio-economic status, and diet. To date we believe it is the first study of this kind to be done in the area.

Methods

Study design:

The study design was a cross-sectional population based survey to calculate the frequency of hypertension in a primary care medical clinic.

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The **setting** was an urban suburb of an overall low socio-economic area, named Buza, Dar Es Salam, Tanzania.

The **Inclusion criteria** included any adult (n=202) of ages 18 and older, any gender or social class who attended this clinic for any medical reason or even for a basic medical check–up between the 19th July and 6th august 2010. Thus the cohort of people included in our study ranged from being very unwell and requiring referralor admission to hospital, to those who had simply just heard of this new clinic were passing by and asked for a medical review. This reduced any possible selection and observation bias.

Exclusion criteria:

All patients under the age of 18 years were excluded from our study for statistical purposes. This is not to say that those with a higher risk of suffering from hypertension who were under 18 years of age did not have their blood pressure checked.

Analysis:

Every person attending the clinic had their blood pressure assessed by one of the staff working at reception. If the patient was found to be hypertensive this would be recorded in the patient's case notes (repeated twice or more), and then reviewed, treated and followed up by the doctors working in the clinic.

Every patient attending the clinic had a full history taken by a doctor. Those previously diagnosed with hypertension, were asked whether they were prescribed and taking any anti-hypertensives or dietary precautions. Their blood pressure was monitored on subsequent follow-ups and recorded.

Data Protection:

All patients reviewed at this clinic gave informed consent for their blood pressure to be checked. Any person who refused to have this parameter assessed was not negatively or positively affected by the treatment received here. All data collected was anonymous and confidential.

Statistics:

All data collected were input into Microsoft Excel and analysed using SPSS. P values were calculated using Fisher's Exact test. Confidence intervals were calculated using standard formulae for rates. Gender and age specific direct standardisation of data was carried out.

Results:

The cohort consisted of 202 people. Satisfactory data was available on 198 patients (98.0%), 160 (85.0%) of whom were females and 38 (15%) were males. The mean age for the population studied was 37.8years. The ages ranged from 18 to 88 years.

Prevalence:

The frequency of patients in our population suffering from hypertension (blood pressure = or >140/or 90 mmHg) was 44.9% (89 patients), confidence intervals 95% (CI 95%) 38.0–51.9%. Of these 20 (52.6% of the male cohort) CI 95% 36.8–68.5% were males and 69 (43.1%, CI 95% 35.5–50.8) persons of our cohort were females. There was no statistical significance between the two gender groups (P=0.365).

19 (9.6%, CI 95% 3.8–15.4%) patients were diagnosed with malignant hypertension, 25 (12.6%, CI 95% 6.1–19.1%) patients suffered from stage 2 hypertension (BP >160/>100mm) and 31 (15.7%, CI 95% 8.6–22.8%) of these patients were diagnosed with stage 1 HT (BP >140–159/90–99). For more details, see table: 1

62 patients (69.7%, CI 95% 60.1–74.2%) were incidence cases as they received the diagnosis of hypertension for the first time in their lives.

27 patients (30.3%, CI 95% 20.8–39.9%) from the cohort had previously received a diagnosis for hypertension. Of these patients, only 6 (22.2%) were compliant to the prescribed medication and, following a blood pressure examination in this clinic, it was noticed that only two persons (7.4%) had their blood pressure controlled. (meaning blood pressure <140/90 mmHg).

Outcome of patients receiving treatment in the Buza clinic:

Of the 89 patients diagnosed with hypertension, 83 (93.3%) patients received some form of treatment. 20 (22.1%) patients received advice on how to live a healthy lifestyle. This included diet and exercise.

63 (87.9%) patients who attended the clinic were treated for hypertension with medication. Of these, 22 (34.9%) patients did not

Table 1. *Sample population of varying grades of severity of hypertension*

	n=	Percentage %
Blood pressure within normal range	68	34.3 (Cl 95% 25.1–43.7)
Pre-hypertensive 120–139/80–89	43	21.7 (Cl 95% 16.6–29.3)
Stage 1 hypertension 140–159 of >90–99	31	15.7 (Cl 95% 8.6–22.8)
Stage 1 hypertension >160 or >100	25	12.6 (Cl 95% 6.1–19.1)
Malignant hypertension >180/110	19	9.6 (Cl 95% 3.8–15.4)
Blood pressure >130/80 and suffering from DM, Kidney disease or CVS disease	6	3.0 (Cl 95% 0.6–6.3)
Isolated hypertension >140 but <90	6	3.0 (Cl 95% 0.6–6.3)
Total	198	100

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turn up for their follow up appointment so were never reviewed at the clinic again.

Of those who did turn up for their follow up reviews, 26 (41.3%) were found to have controlled blood pressure. Another 10 (15.9%) patients who attended the clinic attained partial control of their hypertension, whilst 3 (4.8%) other patients who had some improvement in their blood pressure recorded and were still referred on to a specialist, for further advice. Only 2 (3.2%) patients had no improvement in blood pressure recorded by the end of the study period and these too were referred for specialist advice.

Age:

When looking at the changes in frequency of hypertension with age, statistical significance P<0.001 is found in females. From the results one notices a stark increase in frequency of hypertension from the 35–44 year age group (33.3%) to the 45–54 year age group (65.5%) and keeps increasing gradually after that.

This sudden change in not observed within the male cohort of the study (P0.149), instead a constant but gradual increase with age is noticed. In this cohort the males over 75 years (n=2) were all hypertensive. Then again one must take into account the small sample size for men.

Socio-economic status:

This study looked further into whether there was a significant link between socio economic status and hypertension. Though the P value for a difference in socio-economic status and hypertension was not statistically significant (P=0.156), the difference in frequency for those placed in social class one [hypertensive: 6 (35.3%), non-hypertensive: 11 (64.7%)] and five [(Hypertensive: 5 (33.3%) non-hypertensive: 10 (66.7%)] was remarkable. The difference seen in the other social classes is not as remarkable, further details may be found in table 3.

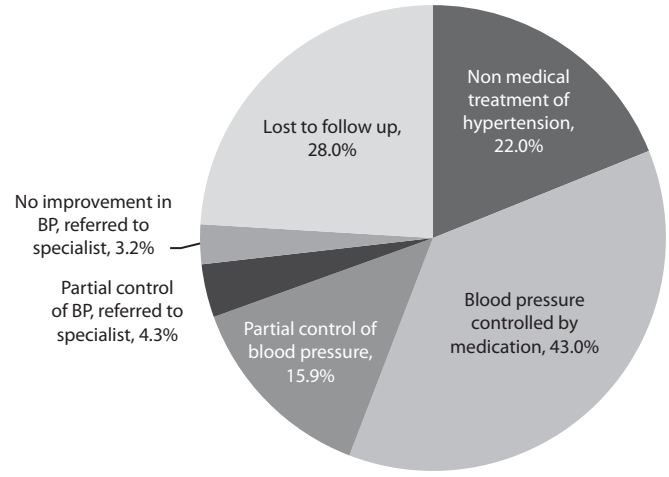

Figure 1. *Outcome of patients who received treatment in clinic*

Table 2. *BP = N (BP within normal range), HT (hypertensive) Hypertension by gender and age*

		Age							Total
		<25	25–34	35–44	45–54	55–64	64–74	75+	
Males	BP = N	3	6	1	3	3	2	0	18
		60.0%	85.7%	50.0%	60.0%	37.5%	22.2%	0%	47.4%
	HT	2	1	1	2	5	7	2	20
		40.0%	14.3%	50.0%	40.0%	62.5%	77.8%	100.0%	52.6%
	Total	5	7	2	5	8	9	2	38
		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
Females	BP = N	12	34	24	10	5	4	2	91
		85.7%	75.6%	66.7%	34.5%	31.3%	30.8%	28.6%	56.9%
	HT	2	11	12	19	11	9	5	69
		14.3%	24.4%	33.3%	65.5%	68.8%	69.2%	71.4%	43.1%
	Total	14	45	36	29	16	13	7	160
		100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Table 3. *BP = N (BP within normal range), HT (Hypertensive) Hypertension according to socio-economic status*

	Socio economic status					Total
	1 (very poor)	2 (poor)	3 (avarage)	4 (above avarage)	5 (rich)	
BP = N	6	68	22	8	5	109
	35.3%	58.6%	61.1%	57.1%	33.3%	55.1%
HT	11	48	14	6	10	89
	64.7%	41.4%	38.9%	42.9%	66.7%	44.9%

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Discussion

The prevalence of HT (44.9%) in the population from Buza included in this study was significantly higher than that calculated for the market economy countries (37.3%) [2]. However, the prevalence of HT in our target population was found to be within the range of previous reported studies (30–57%) carried out in Tanzania, [10], [11]. Once again similar results are reported in other East African countries (28% to 50%) [8], [11], [13] and to other African countries (28.7% to 44%) [6], [7], [9]. One reason for such differences could be explained by some studies reporting examined results whereas others use patient reported BP results.

There is no real statistical significance between males and females. Statistical significance was found when using age standardization for females (P<0.001). It was also observed that between the 35–44 and 45–54 year age group the prevalence in women doubled from 33% to 66%. One can hypothesise that most probably almost 100% of the women in menopause were suffering from HT. This is further substantiated by the increase in frequency of HT with age. In males this was not statistically significant (P=0.149) though this could be due to the small male sample. As found in other studies carried out around the world, therate of HT in males increases proportionally with age. [18]

The results in our study highlight another risk factor associated with HT – low socioeconomic status (SES). [19] However, results from our study have taken this association a step further and reported another peak in HT with the high SES group. In Buza being of higher SES means having a staple diet of things such as fried chicken and chips, thus bringing to light the probable association of HT to diet. This was also found in other studies. [20]

Less than a third of our patients were aware that they were suffering from high blood pressure, as found in a parallel study (20%) carried out in other cities in Tanzania. [10] This is markedly lower than awareness reported by studies carried out in the US (69%) and Europe (53%) [4], [5]. This highlights another important fact that awareness and availability of clinics to manage HT may help increase compliance. Another important finding in our study highlights the fact that over 9% of the target population had malignant hypertension, a life threatening condition which people were living with undiagnosed and, thus, untreated.

Figure 2. *International prevalence of hypertension*

The compliance rate in our study was found to be slightly higher (22.2%) to that carried out in another study in Africa (10%) [10]. We believe that this may simply be due to smaller sample size (n=198) than the other study (n=1600).

Another important finding consistent with previous studies is that less than 8% of the cohort in Buza had their HT treated adequately (BP <140/90) [14], [15], [16]. The results of this study show that a clinic open for only 3 weeks was able to get the BP of 41.4% within normal range and improve the BP for 16% of patients, meaning that such a life threatening disease can be easily and cheaply managed by increasing the availability of such clinics.

Strengths and limitations of the study

The results from our study report only examined BP as opposed to self-reported, thus reducing a recall bias. The population sample in this study did not only include patients who were ill but also those who attended the clinic for a check up, thus reducing a selection bias. All patients had their BP checked at least twice, and most were reviewed for follow up more than once.

Limitations of this study include a relatively small sample size, thus representativeness of the target population is questioned and patients were only followed up for a short while, so a longer longitudinal study is recommended.

Conclusion

The prevalence of HT is expected to rise substantially in sub-Saharan Africa, so the authors call for population-based studies and registries of the epidemiology of HT

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in the African population. The provision of awareness campaigns and more clinics available for assessment and management of HT in the health services in Tanzania is strongly recommended. As reported in this study this cheap provision of service yield quick positive results, thus improving the overall quality of life of the people living in Tanzania.

Other studies carried out worldwide found that more than half of respondents took action following the receipt of advice. [17] Thus the authors believe that this simple measure will have a highly positive effect on the people living in this country.

Conflict of Interest:

The authors declare they have no conflict of interest and this data has not been submitted for publication anywhere else.

Authors contribution:

All authors have contributed equally to the work in this study and agree with the publication of this document.

Dr. Daphne Gatt: contributed to the literature search, writing up of the background and managed the overall work of the manuscript.

Dr. Steve ME: contributed to the literature search, writing up of discussion and references.

Dr. Nigel Camilleri: Came up with the research question, was involved in the writing up of the methodology and results and supervised the work.

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Revealed: Coal's Unpaid Health Bill

European coal-fired power plants are causing 18,200 premature deaths and serious illnesses that cost the population up to €43 billion each year, say health experts in a new report entitled *The Unpaid Health Bill—How coal power plants make us sick*.

The Health and Environment Alliance (HEAL) also expresses concerns that dirty emissions from coal are contributing to climate change, which itself will create more costly public health problems-especially amongst the most vulnerable groups-the young and elderly. Despite this double threat, the use of coal as an energy source is now on the rise in Europe.

Coal use is projected to rise worldwide throughout 2013 which is, ironically, the EU's designated Year of Air. Health experts at HEAL are now urging governments to put a stop to building new coal plants in Europe and abandon coal altogether by 2040. If the share of coal in power generation is not brought down over the next decades, Europe will put in jeopardy its climate target for 2050.

In October 2011, over 500 health and security experts, including medical associations, leading medical research institutes and public health organisations, called on governments to ban the building of new coal-fired power plants without Carbon Capture and Storage (CCS) technology, and to phase out the operation of existing coal-fired plants, starting with lignite plants due to their most harmful effects on health.

Last year at the UN climate talks, medical organisations petitioned negotiators at the international climate talks in Doha, Qatar (*http://dohadeclaration.weebly.com/index.html*) to recognise that worldwide millions of deaths each year have been linked to air pollution that occurs as a result of burning coal. The World Medical Association was among the top medical group signatories to the so-called Doha Declaration on Climate, Health and Wellbeing. Dr. Cecil Wilson, President of the WMA, said he was extremely worried about the slow progress in international negotiations and called on the world's leaders to recognise the impact on health from climate change.

As the "first ever economic assessment of the health costs associated with air pollution from coal power plants in Europe", this report highlights evidence on how exposure to air pollutants affects the lungs, heart and nervous system. Effects include chronic respiratory diseases, such as chronic bronchitis, emphysema and lung cancer; and cardiovascular diseases, such as myocardial infarctions, congestive heart failure, ischemic heart disease and heart arrhythmias. Acute effects include respiratory symptoms, such as chest tightness and coughing, as well as exacerbated asthma attacks.

Children, older people and patients with an underlying condition are more susceptible to these effects. Children are particularly susceptible to air pollutants, in part because they breathe more air in relation to their body weight and spend more time outside, but also due to the immaturity of their immune and enzyme systems and their still-developing airways. In addition, coal power plants are the largest source for mercury emissions in Europe, a heavy metal that is well known to affect brain development in children. A recent study put the price tag of this mercury exposure at about €9 billion per year.

The report draws on the work of medical and health groups in the US, Australia and elsewhere around the world. The intention is that the report will stimulate further engagement of doctors and other health groups around the issue of coal and health, especially in countries where coal burning is a major contributor to poor air quality. In coming months, the Standing Committee of European Doctors (CPME), which has 27 members representing medical doctors in EU countries, will be raising awareness of the risks of coal burning as part of its work underlining the importance of cleaner air.

Medical professionals are powerful advocates for better policy to protect health. Medical doctor and German Member of the European Parliament, Peter Liese has already indicated his support for the report. He says he recognises coal as both an immediate and a long-term threat to public health because of its contribution to climate change.

HEAL will be running a Health and Coal educational and advocacy campaign throughout Europe, with national launches planned in Germany and Poland in close collaboration with medical experts, asthma groups and local experts. Expertise and testimonies from doctors and others in the health community are key to our success, and we invite you to join the collective efforts to prevent chronic disease and suffering from coal power pollution.

This article is adapted from one which appeared on the blog of the Collaborative on Health and Environment (CHE) *http://ourhealthandenvironment.wordpress.com/2013/03/07/778/*

HEAL's vision is a healthy planet for healthier people in Europe and beyond. We show how environmental action can bring down rates of asthma, obesity, diabetes, cancer and infertility working closely with our members in more than 26 countries.

Génon Jensen
Executive Director, Health and Environment Alliance (HEAL) ,
Coordinator of CHE's Climate Change and Health Working Group.

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Mass Catastrophe: dealing with crises and disasters now and in the future

The Human Factors in Crisis and Disasters Thematic Conference to be held in Melbourne, Australia from 30 September to 2 October 2013 will focus on issues of great relevance to us all.

Disasters and crises impact globally and locally, affecting diverse human populations, and the resources that sustain them. Disasters by their very nature may overwhelm communities and their capacity to respond, with mass death and damage, as we have seen across the world with tsunamis, earthquakes, hurricanes and cyclones, floods and famine, fire and pollution as after the volcanic eruption. The mass natural disasters of recent times have also lead to population displacement, huge economic loss and burden. Disasters of disease, such as pandemics of influenza and virulent infections are also a challenge and threat, requiring global collaborations. Disasters that are human caused, particularly those of violence, lead to profound human damage – not only by death, fear and threat, but also in the ongoing vulnerabilities and further violence that may be generated.

This conference will present global themes and the human factors and resources that are challenges worldwide. Dr. Judy Kuriansky will present on these themes from the global perspective looking at the United Nations and the multiple global agencies that work together to mitigate disasters and their impact; for instance the collaboration following the Japanese earthquake, tsunami and nuclear incident; and the Haiti hurricane.

Vulnerable groups require specific focus and particularly children, as she will discuss, as will others, including Professor Brett McDermott and also those dealing with children who are war affected refugees, displaced and dislocated from family and home. Threats and disasters, including nuclear accidents such as Chernobyl, hazards of Fukushima, collective trauma and the diverse crisis they bring; as do disaster traumas and mental health consequences; are all considered. Institutional aid and collaborations, through to the needs of the elderly, disabled and vulnerable, all come into these challenging fields. There is the need for recognition of practical needs such as clean water, food, shelter and support for human engagement, families and communities that help the healing processes.

Dealing with the threat and consequence of mass violence is a challenge in all societies, whether they are 'home-grown' or associated with potential external attack, such as terrorism. Professor Lars Weisaeth, from Norway will lead this component of the conference, building on his diverse experience in Europe and beyond. He will discuss the bombing and subsequent shooting of young people in Norway and its mental health and social implications then and into the future. Others will present on the short and long term consequences of terrorism, especially how this relates to mental health and social well-being. War and conflict also have both short and long term consequences particularly for those displaced from home and community, from families and place. Refugees, veterans and others face ongoing threat, uncertainties and loss, with little support. As well as their resilience and survival strength they continue to have profound vulnerabilities.

Even in the face of human induced death, the 'good' in people remains a powerful factor that supports people and gives them the courage and hope that helps people to go forward into the future.

Many forms of care and support are needed in crises and disaster. Medical experts from around the world will make a major contribution at this meting, led by Dr. Mukesh Haikerwal, Chair of the Council of the World Medical Association and his colleagues from USA, Japan and elsewhere, including Australia. How we all work together to address the effect of disasters and crisis, our health and mental health, requires a recognition and linkage across disciplines and expertise. Systems of response facilitating such linkages are critical and require global policy and adaptation to national requirements. Professor Chris Bagley, who leads Australian disaster health response will present on Australian systems in the All Hazard Framework of National Collaboration. His colleagues will also contribute, addressing the defence component of response, and health and mental health programs to mitigate impact.

IT systems and resources contribute in major and rapidly developing ways, from prevention through to longer term recovery, from warning to psychological first aid and resilience. Glenn Wightwick will lead this component with colleagues addressing the multiple chances and opportunities that can assist in such crises and their consequences.

From climate change to conflict, from tsunami to terrorism, from global epidemics to nuclear hazard, crises and disasters are relevant to us all. They can bring death and destruction, love and loss, courage and fear. Like so many aspects of life, we do best when we invest in the future, as well as look after the present, and accept the past, as it has been what we know and will use for the future preparation and planning, but learning while we do so. The human factors that flow throughout this important meeting recognize the suffering that may occur, but focuses on the courage, strength, resilience, compassion, connectedness and care. The healing and hope that will help us go forward, to the future.

Professor Beverley Raphael
Professor of Psychiatry and Addiction Medicine, Australian National University and Professor of Population Mental Health and Disasters, University of Western Sydney

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In Memoriam Dr. Peter Foley

The New Zealand Medical Association is saddened to learn of the death of Dr. Peter Foley, Chair of the NZMA for an historic two terms from 2007 until 2011.

Following in his father's footsteps, Dr. Foley practised as a GP in Napier for over 25 years, after graduating from Otago University in 1981. He became president of the NZMA's Hawke's Bay division in 1999, was an inaugural member of the NZMA's General Practice Council (GPC) in 1998, and then served two terms as Chair of the GPC before moving to chair the wider organisation. He was also the initial Chair of the General Practice Leaders Forum (GPLF).

Dr. Foley's particular contribution was in General Practice. He was at the forefront of the General Practice effort to seek meaningful engagement with the Government and its agencies during the debate over General Practice fees. The efforts of the initial GPLF team, led by Dr. Foley, resulted in effect involvement for General Practice in the contracting process, and in a successful outcome – an achievement that was recognised when he was awarded the NZMA's highest honour, the Chairman's Award, in 2006 and an NZMA Fellowship in 2011. Further recognition followed – last year Dr. Foley received the Member NZ Order of Merit for his services to health, which was presented in a special ceremony last month by Governor-General Sir Jerry Mateparae.

After ending his term with the NZMA, Dr. Foley continued his active role in the health sector with roles as Chief Medical Officer for primary care in the Hawkes Bay and Deputy Chair for the Health Quality and Safety Commission. He also headed the independent panel that reviewed health services in Queenstown and the surrounding area.

"Pete recognised that our health system requires the profession's strong guidance and in striving to do this he researched the issues, engaged in consultation and worked towards achieving consensus," says

Dr. Ockelford. "In his time as GPC Chair and NZMA Chair, he cultivated strong relationships within the medical profession, the Government and wider health sector. He was always a loyal NZMA member, and held a strong belief in the NZMA's ability to make a difference, and have significant influence. He consistently promoted the hallmarks of the NZMA – its pan-professionalism, its ability to represent all sectors of the profession and its willingness to engage with all sectors within health.

It has been a joy to have known, worked and relaxed with Pete over at least ten years.

Pete was well known, highly respected around and warmly welcomed around the World in the World Medical Association family and in CMAAO (Confederation of Medical Associations of Asia & Oceania).

Over the years we met across the World and in Australia and in his beloved New Zealand of which he would wax lyrical about without drawing breath! He taught us as Chair of the GP Council and later of the NZ Medical Association the skills energy and tenacity not to mention charm needed to work with and influence governments and lead the profession whilst achieving results and not compromising his patients, profession or himself.

Pete was a passionate advocate for General Practice and quality health care and for the rights of all to that health care he personally provided to the people of Napier. Internationally he was equally forthright for the rights of physicians and the key role they play in the health of individuals and nations and the need to maintain high moral, ethical and professional standards set by the profession.

Tireless, diligent and dedicated to his profession though he was, he would always remember the support and love and devotion for those at home who supported him in his endeavours on the road or "up in the air" of whom he spoke with great passion and pride.

The world has benefited from having Peter Foley as a champion for its health, I and numerous of his friends and colleagues are the richer for having had him in our lives. Farewell my dear friend! Keep smiling at us from where you rest – in peace.

Dr. Mukesh Haikerwal AO
Chair of Council, WMA
Australian Medical Association

World Medical Journal

Global Conference on the Right to Rehabilitation for Torture Victims

The IRCT and Restart Center are holding a global conference on the right to rehabilitation for torture victims. The conference takes place on **27–28 June 2013** in Beirut, Lebanon. We hope that you will be able to participate in this exciting global event which will provide a platform for discussion between key stakeholders in the torture rehabilitation movement on the right to rehabilitation for torture victims.

The conference will explore in detail the way rehabilitation is provided to torture victims and it will consider how States can be encouraged to strengthen their implementation efforts in providing holistic and victim-centred rehabilitation services and the necessary funding to torture victims. The four interlinked themes of the conference will provide a platform to share good practice examples in models for the delivery and funding of rehabilitation and explore ways in which rehabilitation services and other key stakeholders can assess and evaluate the services provided in their national context. Linked to this is a need to focus on the immediate situation in the MENA region which faces particular challenges with regard to the provision of rehabilitation services to torture victims. The conference will draw on the experience from rehabilitation centres worldwide as well as representatives from academia, governments, inter-governmental organisations and civil society.

Registration is free but required – please fill in the online registration form at *www.irct.org/conference2013*. Please note places are limited.

The conference programme and information on the venue and nearby accommodation are available on the website.

For more details, please contact Rachel Towers (rto@irct.org) or Dalal Khawaja (dalal@restartcenter.com).

1st International Congress of the International College of Person-centered Medicine

Whole Person in Health Education and Training. November 7–10, 2013 Westin Hotel, Zagreb Croatia

Congress Topics: Person-centered medical education, Person-centered interdisciplinary training in medicine and healthcare, Patients and family education, Stakeholders in health education, Students-centered health education, Art in health education.
Clinical topics: Primary care, Pediatrics, Geriatric medicine, Mental health, Internal medicine, Cardiovascular Cancer, Circulatory disorders, Respiratory disorders, Obesity, Diabetes, Pain management and palliative medicine.
Public health topics: Prevention, Health promotion, Services, Policies.

Congress Participants: physicians, nurses psychologists, social workers, pharmacists, dentists, policy makers and other health professionals (including students), educators and other interested scholars, representatives of patients and their families, advocates, industry, person-centered public health.

Presentation Formats: lectures, symposia, workshops, brief oral presentations and poster presentations.

Deadlines: For abstracts: July 1st, 2013; For early registration: September 1st, 2013.

Congress Committee: Juan E. Mezzich (president), Jon Snaedal, Chris van Weel, Michel Botbol, Ihsan Salloum, Tesfamicael Ghebrehiwet, Veljko Đorđević, Marijana Braš, Lovorka Brajković.

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Zagreb – the capital of Croatia, is deeply rooted in rich Central European culture. In it lives the legacy of Prof. Andrija Štampar, the president of the first WHO World Health Assembly and a pioneer of person-centered public health. Zagreb is waiting for you with its thousand fascinating faces, ready to make you feel at home.

For more information, as well as for registration and abstract forms, please visit the Congress website:
www.ICPCMzagreb2013.com

Public Consultation Opens on WMA Helsinki Declaration

A two-month public consultation on the World Medical Association's Declaration of Helsinki on medical research involving human subjects began today (Monday) with the posting of a revised version of the Declaration on the WMA website.

The public and the WMA's 102 national medical association members are being invited to comment on the proposed changes which have been drawn up following an 18-month process of deliberation. A WMA workgroup has held comprehensive discussions and three expert conferences to help it draft the changes.

In an explanatory note on the WMA website, the workgroup states that the proposed changes provide for more protection for vulnerable groups and all participants by including the issue of compensation, more precise and specific requirements for post-study arrangements and a more systematic approach to the use of placebos. In addition the workgroup states that the revised text maintains the unique character and length of the Declaration. It also provides better readability by reorganising and restructuring the document with sub headings.

For details of the major changes, people should refer to the WMA website.

All experts and stakeholders have been invited to submit comments to the WMA secretariat no later than 15 June 2013.

The workgroup will then produce a final revised draft to be considered by the WMA's ethics committee and Council at their meetings in Fortaleza, Brazil in October 2013 when a decision will be taken whether to forward the document to the WMA Assembly at the same meeting for adoption.

The document for public consultation may be downloaded here *http://ndcommunications.hosted.phplist.com/lists/lt.php?id=N0RSBgZPAAQMGVUGBg%3D%3D*

www wma.net

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