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New Trade Agreements and what They May Mean for Public Health and Health Care

In a concise article [1] in this journal, Elizabeth Wiley and her co-authors analyse the current discussions and negotiations surrounding upcoming trade agreements, which, if they come into effect, will be huge and unprecedented in terms of their in-depth regulation and the combined economic power behind them. The trade agreements discussed, TTP (Trans-Pacific Partnership), TTIP (Transatlantic Trade & Investment Partnership), CETa (Comprehensive Economic and Trade Agreement) and TISA (Trade in Services Agreement), essentially include most industrialized nations.

The authors outline the possible effects on health and health care, from public health legislation to the structure of health systems, and explain why the upcoming agreements could have negative effects for public health and health care systems within the countries concerned, but also in so-called third countries, which at first glance have nothing to do with these agreements.

The World Medical Association has never had a position on trade agreements in general, but Wiley et al. demonstrate the relation of these agreements to our policies, such as the WMA Statement on Patient Advocacy and Confidentiality [2], the WMA Statement on Social Determinants of Health [3] and the WMA Statement on Parenting Medical Procedures [4]. They argue that it is time to bring health into the arena.

The Good…

First of all, our world is undeniably networked and our economies are globally connected. This has enabled economic growth to take place globally and given some regions stability, peace and consideration for public health legislation to the structure of health systems, and explain why the upcoming agreements could have negative effects for public health and health care systems within the countries concerned, but also in so-called third countries, which at first glance have nothing to do with these agreements.

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The Bad,…

The upcoming trade agreements have been feted as generators of jobs and enhancers of business. But the euphoria of recent years has passed. The last (2010-2014) European Union (EU) Commission for Trade, Karel de Gucht, speculated about an increase in EU GDP of 0.5 percent [5] and 400,000 new jobs. However, the tone has recently become more cautious. The suggested potentially positive effects of TTIP now sound more like “maybe” and the glorious numbers have also disappeared from the EU website [6].

The creation of TTIP is one of the best kept secrets of our time. Very few officials at the EU Commission in Brussels deal with the US delegation. The documents are not publicly available, and only under immense public pressure has the EU Commission begun to reveal its strategy in a piecemeal approach. A few MEPs have “on-screen access only” to the documents. However, the majority of MEPs and national governments are not properly informed. Why the secrecy? This leads us to question who this protective shield is being built to defend against? Why are industry leaders involved in negotiations but not the Members of the European Parliament? Not even the members of the committees concerned are able to access printed copies, let alone the national governments of Member States. Are these shields meant to defend against the nations who are not sitting around the table? Groups like Health Action International, Oxfam and Médecins Sans Frontières (MSF) warn against TTIP [7] and TTP [8], seeing in them a danger to poorer nations’ access to medicines.

Or has this veil of secrecy been created to defend against the electorate? Do we the people not have a right to know? Is it us members of civil society who some politicians believe could endanger this huge step forward, as the rhetoric of our leaders constantly suggests?

In its title, “Beyond Chlor Hühner and Nürnberger Bratwurst”, the article by Wiley et al. already distances itself from the panicked reporting of the European and especially the German press, which for more than a year seized on issues such as US food industry practices beneficial for migrants or those carrying out business across borders, it will also help those within countries who may likewise be inhibited by it.
of disinfecting chicken with a chlorine solution and the fear that traditional food could be pushed from the market by low quality imitations. However, the authors distance themselves from this populist type of criticism of the trade agreements only to tell us that it could actually be far worse!

Indeed, as the real implications of the trade agreements slowly become apparent, the populist fears of chlorinated chicken and fake wurst look pale and rather unimportant in comparison. It is public health at large and the values on which health care systems are based, solidarity, equality and justice, which are under attack. From what has so far leaked through the veil of secrecy, it seems that the only common denominator in these negotiations is a spirit of mammon.

National politicians don’t get tired of reassuring us that health care systems and their social fabric will not be touched. Most impressively, Japan’s premier Shinzo Abe told us at the WMA Council Meeting in Tokyo last April that the universal health care system of Japan will be maintained and even suggested building it up as an ideal to be exported. Likewise, European politicians repeatedly state that our social systems will not be touched [9].

Really? Even if no elements of the trade agreements would directly affect the structure of our health care systems, the indirect effects would still be very real. The loss of jobs, the tearing down of protective regulation, the commoditization of health care, and the takeover of public institutions by for-profit companies – all of this could threaten the health care sector. However, as far as we know, health care is not even excluded. And why should it be [10]? In most of our economies, health care systems are one of, if not the biggest, identifiable sectors of the economy.

And the Ugly

While the potential effects on public health, social structures and health care systems are bad, there are effects that may even be far worse: The trade agreements foresee dispute settlement systems that allow companies not only to litigate other companies, but also states which are parties to the agreements, in secret private courts. They will, in fact, constitute a private system without any controls that could ultimately not only undermine systems of justice, but may lead governments and lawmakers to pre-emptively stall all public health measures that would run the risk of being sued by such a private court, regardless of how important and relevant such acts may be. The development of public health would be seriously inhibited. This might be beneficial for industries producing or marketing unhealthy products, however these agreements would place public health in invisible shackles.

Of course, since the negotiations are conducted in secret and we don’t know what is in the agreements, it can be claimed that all these fears merely represent worst case scenarios. This is correct. However, the burden of proof lies with those who are maintaining this secrecy. Only they have the means to produce evidence that the outcomes will prevail and that harmful effects are definitively ruled out.

Regardless of the outcome of the trade agreements, if they continue in this way they will not be beacons of justice and democracy.

References
7. C. Wilson. U.S. military health care professionals serve in a variety of settings, more diverse than is typically found in the civilian environment. In all settings, military and civilian, health care professionals face innumerable conflicts in the practice of their vocation. At times, health care professionals who practice in these settings may face ethical challenges in honoring the ethical standards of their profession and obeying military orders or policies. Tensions can arise if the demands of the mission or line command are at odds or in tension with the duties to attend to the health of those needing care.

In particular, military personnel serving in combat zones might be confronted with numerous ethical and moral challenges. Most of these can be resolved with effective communication, training, leadership, clear rules of engagement, and unit cohesion and support. However, the very act of experiencing, witnessing, or participating in troubling events can undermine a Service member’s humanity. An act of serious transgression that leads to serious inner conflict because the experience is at odds with core ethical and moral beliefs is called moral injury, which can be long lasting and painful.

In January 29, 2013 the Acting Under Secretary of Defense for Personnel and Readiness requested the Defense Health Board (DHB) review the unique challenges faced by military medical professionals in their dual-hatted positions as a military officer and a medical provider. Two questions were asked:
1. How can military medical professionals most appropriately balance their obligations to their patients against their obligations to the commands that they serve?
2. How can military medical professionals maintain military readiness?

The DHB tasked its Medical Ethics Subcommittee to conduct its review of military medical professional practices and policies. The Subcommittee reviewed current civilian and military health care professional medical practice policies and guidelines. The Subcommittee reviewed current civilian and military health care professional medical practice policies and guidelines as well as military ethics, education and training in the Department of Defense (DoD) and in civilian institutions. The Subcommittee members also held panel discussions with the subject matter experts and DoD personnel, including Active Duty, National Guard, Reserve, and retired military health care medical professionals and line officers as well as healthcare professionals in civilian institutions. Included among the civilian organizations were the World Medical Association, American Medical Association, American Nurses Association, American Psychiatric Association and the American Psychological Association.

On February 11, 2015 the DHB unanimously approved the report “Ethical Guidelines and Practices for U.S. Military Medical Professionals”. It is an effort that is notable for being well done. It is characterized by thoroughness and a sensitivity to the issues described.

The Subcommittee developed its own principles to guide its review and deliberations

Context: Military health care professionals face unique challenges resulting from their dual role as medical providers and military personnel. Throughout their careers, these professionals may be required to plan and participate in health care support for military operations, humanitarian assistance, disaster response and other activities, which may be conducted in austere environments with limited resources. As health care providers, military medical professionals have ethical responsibilities to their patients, which arise from a variety of legal, moral, and professional codes as well as personal moral and religious beliefs of both the caregiver and the patient. However, military health care professionals must weigh and prioritize these ethical responsibilities with their role as military officers.

Overarching Principle: DoD has a duty to provide military health care professionals with the resources, tools, and knowledge to determine the best course of action when confronted with ethical dilemmas and a practice environment in which they feel safe in raising ethical concerns and confident they will receive support in seeking a fair and just resolution to those concerns. In addition, DoD also has an obligation to assist professionals in developing the resiliency to cope with and recover from the moral injury resulting from confronting intractable ethical dilemmas.

The Guiding Principles provided herein guided the DHB and the Medical Ethics Editorial

Medical Ethics

To enhance ethics
DoD should pro

The Defense Health Board (DHB) is a
Federal Advisory Committee
- DoD should further develop and ex-
pand the infrastructure needed to promote DoD-wide medical ethics knowledge and an ethical culture among military health care professionals, to include: a code of ethics; education and training programs; cons-
sultative and online services; ethics experts; and an office dedicated to ethics leadership, policy, and oversight. To achieve these goals, DoD should form a tri-Services working group with appropriate representation to formulate policy recommendations on medical ethics. This should include development of a DoD Instruction to guide development of the infrastructure needed to support the ethical conduct of health care professionals. In addition, this working group should con-
sider the best ways to implement the rec-
ommendations in this report.

Recommenda

1. Department of De-
fer

Recommendation 1: Department of De-

Recommendation 5: To provide formal ethics training, direction, and support to the MHS and its components, DoD and the Military Departments should:

a) Publish directives/instructions re-
garding the organization, composi-
tion, training and operation of medi-
cal ethics committees and medical ethics consultation services within the MHS. DoD should review best prac-
tices at leading civilian institutions in formulating this guidance.

b) Ensure military treatment facili-
ties have access to consistent, high-

Medical Ethics,

Ethical Guidelines and Practices for U.S. Military Medical Professionals

February 11, 2015

Recommenda

1. DoD leadership, par-

Recommenda

3. DoD leadership, par-

Recommenda

2. DoD leadership, par-

Recommenda

4. DoD should formul-

Recommenda

5. To provide formal ethics training, direction, and support to the MHS and its components, DoD and the Military Departments should:

a) Publish directives/instructions re-
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cal ethics committees and medical ethics consultation services within the MHS. DoD should review best prac-
tices at leading civilian institutions in formulating this guidance.

b) Ensure military treatment facili-
ties have access to consistent, high-

III. Acknowledge the moral injury that may occur as a result of encountering an ethi-

1. To enhance ethics training for military health care profession-
als and the line command, DoD should:
   a) Ensure pre-deployment and periodic field training includes challenging medical ethics scenarios and remind-
ers of available resources and contact information to prepare both health care professionals and line personnel.
   b) Provide a mechanism to ensure sce-
narios and training curricula are continually updated to reflect spe-
cific challenges and lessons learned through debriefing from real-world deployments and garrison opera-
tions.
   c) Ensure key personnel returning from deployment who have faced signifi-
cant challenges provide feedback to assist personnel preparing for deploy-
ment.

16. To enhance health care practices in the military operating environment, DoD should:
   a) Update the Joint Knowledge Online Medical Ethics and Detainee Health Care Operations courses to improve the efficiency with which the information is communicated and maintain currency of the material.
   b) Create a medical ethics course to cover key principles, ethical codes, and case studies applicable to both garrison and deployed environments, in addition to providing resources and appropriate steps to take when assistance is needed in resolving complex ethical issues. This course should be required for all health care professionals.
Self-care – the CPME Statement: Quality and Safety, and Transparency!

Introduction

Self-care is gaining more and more attention in the European healthcare field these days and has become a central element in the strategy of many national health authorities, EU bodies, as well as for the European Council and WHO/Europe.

CPME ("Comité permanent des médecins européens"), the umbrella organization of European Doctors, has also recently issued "Statement on Self-Care", with a view to the future of self-care policy in the European Union, and is actively participating in a EU tender on this topic.

But first, what is self-care in the meaning of all these political discussions?

Self-care is considered as the ability of patients to take measures to manage, establish and maintain their own health, or, as the UK Department of Health put it in 2005 [1], self-care is "the actions people take for themselves, their children and their families to prevent and care for minor ailments and long-term conditions and maintain health and well-being after an acute illness or discharge from hospital".

Self-care policy also refers to self-medication, but self-medication is no longer at its core – patient empowerment and health literacy are nowadays considered as the key aspects that determine self-care.

This definition points to the fact that self-care has to do with 2 quite different topics:
• on the one hand, self-care deals with the so-called "minor self-limiting ailments" which, in the meaning of self-care, should not request a medical consultation,
• and on the other hand, self-care deals with two major elements of the future of the health system in our countries, which are prevention and chronic diseases.

Behind the rising political activities about self-care, there is not only the idea of patient empowerment, but also obvious financial and economic interests: self-care should reduce costs of healthcare by reducing the need for medical intervention, in a time of scarce financial resources – an effect that remains to be proven in a significant manner, as the latest studies are mostly inconclusive in this respect. And self-care is of course also a huge business for the pharmaceutical industry, bringing direct access to the patients-consumers.

All in all, this introduction shows that self-care can affect the very core of our health-care systems – the finances and, most of all, the relationship Doctors have with the patients. In other words, transparency, ethics, quality and safety are all involved.

This is definitely a discussion – one more – where we should be active to defend our understanding of medicine!

Quality and safety

I don’t think that Doctors have a problem accepting that in many different situations patients can manage their own health themselves – either it is about minor ailments that seldom require a real medical intervention (headache, common cold, indigestion, backache or whatever) or it is about a chronic disease which the patient knows very well and is able to manage in normal circumstances.

But our professional experience also tells us how difficult it is to spot a not-so-minor pathology in the bulk of the everyday consultation: we know all too well how dangerous it may be to trivialise a symptom which this time should not be overlooked!

Patients should definitely be protected from the consequences of undue trivialisation of a symptom, and this concern must make us cautious about promotion of self-care. At the same time as patients read on the internet or talk with their Doctor about self-care possibilities, they should also learn about the limits: which is the acceptable duration of symptoms? What to expect from an available treatment? What to do if the expected results don’t show?

This is all about patient empowerment (once again). Clearly, empowerment also means responsibility, for the patiet, and the means to take on this responsibility – in our view, self-care cannot be supported without making sure that quality and safety are guaranteed in this situation just as they are for patients consulting a Doctor.

Another element which should be mentioned in the discussion about quality and safety in self-care is the influence of the pharmaceutical industry, which sees huge profit possibilities in addressing directly the patients and selling the so-called “OTC” (“Over-The-Counter”) medications. Advertisement and sponsoring of internet home-pages, or in the field of chronic disease the sponsoring of patient groups, must be completely transparent and in line, to avoid unbalanced influence on the decisions being made by patients about their treatment. This is clearly also a matter of quality and safety!

These short reflections on quality and safety, in consideration to self-care, mean in fact that although we definitely, as Doctors, are not opposed to self-care and thereby to patient empowerment, we cannot support without precaution measures that can put a patient at risk or make him/her a victim of marketing campaigns.

In other words, self-care is only to be seen as a positive development if the quality of the treatment and the safety of the patients are at the center of attention. This means efficient regulations to keep marketing in line, and the necessity for all involved healthcare professionals to commit to sufficient and adequate patient information.

The CPME Statement on Self-Care

Acknowledging the importance of the ongoing discussions on self-care for the medical profession in Europe, last January the CPME Executive Committee, adopte the “Statement on Self-care”.

The CPME document reaffirms that the health education of society should always be based on evidence, ann begins with an important preliminary declaration reminding that “It is the responsibility of doctors in every EU member state to offer an appropriate diagnosis to the patient, based on qualifications and skills which in all cases include a degree in medicine. Medicine is among the most difficult sciences because of the knowledge required as well as the complexity of its practice. CPME is against any attempts to change the role of the doctor to the detriment of patient safety. The medical profession must be involved in the development of the EU policy on self-care”.

The Statement also stresses the fact that tea EU self-care policy must include a strategy on health literacy for the patient, as well as concrete recommendations for health professionals on patient empowerment. These two supporting components of self-care must be deployed in full cooperation with member states and competent national authorities to ensure the legitimacy of the EU policy on self-care (cf. “CPME joint statement: Making Health Literacy a Priority”, April 2013 [3]).

The CPME Statement continues with the following 10 recommendations:
• Self-care is an area of health and social care and it refers to the capacity of people/patients to take care of themselves. CPME therefore believes that people/patients are at the core of self-care actions and must not be defined as consumers.
• Patient empowerment and health literacy are two areas where the EU is lagging behind in terms of data and action so they need to be a priority of self-care policy (cf. “CPME joint statement: Making Health Literacy a Priority”, April 2013 [3]).
• CPME encourages doctors to support patient empowerment and health literacy as well as enhance collaboration between health and social care. The patient-doctor relation is one way of effective promotion of self-care. Empowered patients should be able to rely on the fact that physicians provide assistance, advice and information about self-care, including self-medication [4].
• The principle that treatment requires prior diagnosis is central in medicine, and a reliable diagnosis should be the prerequisite of any treatment, also in the field of self-medication.
• Self-medication should not result in inappropriate medication since it may result in delayed diagnosis and/or severe complications. All necessary measures need to be taken to avoid such situations. Great attention must be given to avoid situations of a risky self-diagnosis which may become an issue of patient safety.
• In the frame of self-care as in any therapeutic situation, circumstances where non-medical healthcare professionals can take therapeutic decisions without consulting a doctor must be strictly defined and limited. For reasons of patient safety, these situations must be defined together with the medical profession.
• Self-medication with non-prescription drugs is primarily suited for minor ailments, diseases of short duration that are easy to recognize by patients, pharmacists and/or a non-specialist/healthcare professional. Patients should be made aware of the need to consult a physician in situations where self-care needs to be complemented by medical treatment.
• CPME believes that in order to identify the areas where self-care can and should be promoted, necessary evidence needs to be collected from member states and other scientific reliable data sources, to provide a common understanding of which minor or acute ailments or long-term conditions are manageable through self-care.
• It is required that the safety and efficiency of self-medication drugs be sufficiently documented and that the use of these medicines is evidence based. Public authorities should closely monitor the development in sale and use of non-prescription drugs also the sale of pharmaceutics outside the pharmacies. When buying non-prescription drugs, it must be ensured that the patient receives sufficient information on its efficacy and on the correct use of the medicinal product, the risks and possible side effects, and the possible misuse of the product.
• Public authorities must provide objective information on medicinal products and their use. Competent authorities, experts that are independent and transparent and the representatives of professional associ-
Self-care needs a constructive approach!

We, Doctors, can gladly share the view that self-care is a step towards patients recovering more autonomy – and autonomous, empowered patients are an essential facet of the health of the population.

This, however, cannot be without informed patients. Medicine has been developed to the point where it can immensely help the populace live a better life, whereas, complex as it is, it needs people – Doctors! – who due to sufficient knowledge due to their education, are able to use it efficiently and safely. The possibilities of medicine being what they are nowadays, self-care may not be so seen as a “cheap medicine”, and may not put patients at risk.

In this meaning, it should be our contribution to the development and implementation of self-care to be committed to the best patient information, particularly in our professional daily life.

Self-care and empowered patients is good for them, and is also good for us, Doctors, as it contributes to alleviate the shortage in health professionals. But it requires the willingness of the Doctors to inform their patients whenever they need it.

And honestly, my own old GP experience, through which treating autonomous and informed patients is so much more fun!

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Sept. 1, 2013 – Diyala Province – Camp Ashraf. An emergency room nurse and six patients killed after Iraqi security forces attacked the clinic. Dr. Abubakr hours after the incident at the scene of the crime (right). UN observer is rounding the victims and eye-witness accounts [AP].

A blatant violation of the Geneva Conventions (1949) and their additional Protocols forming the core of the international humanitarian law.

Regional implications. Iraq belongs to category 3 (most severe) of ECHO’s Crisis Index. The Iranian regime and its ally, Nouri-al-Maliki, provoked widespread anger among the Sunni community and the disturbing trend facilitated the rise and expansion of extremism, particularly through the Islamic State (ISIS).

The Washington Post of 27 December 2014 reported that since last June, “Iran has sent more than 1,000 military advisers” and “elite units to Iraq and has conducted air strikes and spent more than $1 billion on military aid”. The Post added that “Iraq’s Shi’ite-led government is increasingly reliant on the powerful militias and a massive Shi’ite volunteer force, which together may now equal the Sunni of Iran’s security forces.” Pro-Iranian regime militias have vast regions of Iraq under their control and are a “mirror-image of ISIS” – or in the words of some Iraqi Kurdish officials are worse than ISIS – and are carrying out crimes against humanity. Amnesty International report of 14 October 2014 “Absolute Impunity” and Human Rights Watch report of 29 January 2015 “Tyranny’s False Comfort” are testimony to this fact.

Current turmoil in this country has brought lawlessness, terrorism, corruption and the systematic abuse of human rights each as a daily feature of life here. The World Bank lists Iraq as having one of the worst qualities of governance in the world. Transparency International lists Iraq as one of the world’s most corrupt countries. Interpol has already suspended its activities in protest to the level of corruption in the government and specially the lack of impartiality of the Judiciary branch.

The unleashed Iranian backed fundamentalist terrorist and militia groups in Iraq both pose a major threat to the civilian population in general and to the safety and protection of Camp Liberty residents in particular.

Clinical Approach
One of the most striking aspects of former Prime Minister of Iraq, Al-Maliki’s level of dependence on Iran had been his acts in violation of IHL and IHRL in connection with the Iranian regime’s opposition in camps Ashraf and Liberty.

Of course, it was expected that the new prime minister would take serious measures to distance his administration from previous policies. However, to date PM al-Abadi has not taken any positive measures to end the unlawful siege and medical blockade on Camp Liberty and has guaranteed neither the security of the residents nor their property rights. Instead, the restrictions on the Camp Liberty residents have intensified in recent months. Meanwhile no measures have been taken to prosecute and punish the perpetrators of the past 6 incursions and rocket attacks in camps Ashraf and Liberty. To rub salt into the wound, the commanders and perpetrators of these acts retain control and management of Camp Liberty.

Respecting the rights of these refugees is a clear indicator of adherence to the rule of law and respect for international treaties.
This has been also noted many times by the United Nations Office of the High Commissioner for Human Rights. The latest one is a communication by three UN special rapporteurs, Chair-Rapporteur of the Working Group on Arbitrary Detention, Independent Expert on the promotion of a democratic and equitable international order and Special Rapporteur on extrajudicial, summary or arbitrary executions to the Government of Iraq about investigations on the killings of the residents of Ashraf and Liberty in 2009, 2011 and 2013.

This document addressing the Government of Iraq was made public and posted on the OHCHR website on February 26, 2015. It reads in part as, "Without prejudging the accuracy of the information made available to us, we reiterate our concern that investigations into the attacks of 1 September 2013 appear to fall short of basic standards and principles of independence, impartiality, and have remained inconclusive. Our serious concern extends to the lack of proper investigations and of evidence and impartiality, and have remained inconclusive. Our serious concern extends to..."
We would like to emphasize that it is categorically illegal under existing international law and conventions to jeopardize the life, safety, and well-being of Protected Persons under the Fourth Geneva Convention and "a Person of Concern to UNHCR".

d. To ensure the residents of Camp Liberty to ensure recommencement of his medical therapy.

Mr. Zakery has been a victim of extrajudicial punishment by the Government of Iraq...[11]

Ongoing battle for medical ethics and human rights standards

The current turmoil has transformed Iraq into a formidable global threat, in the same line Camp Liberty has also become the front line of our medical profession in an international thrive for recognition of standards of medical ethics for dignified treatment and care. These breaches should never be regarded as separate, isolated cases of local or, at the best, regional importance. The trend of participation by national medical associations is a certain proof of the importance in a path that others are also invited to join effort. Every national medical association can take its share by writing to the Prime Minister of Iraq by reminding him of his core commitments and by requesting for medical accountability.

a. Requesting immediate release of Mr. Safar Zakery and his return to Camp Liberty to ensure recommencement of his medical therapy.

b. Requesting medical accountability on this case or similar previous cases.

c. Reminding Iraqi authorities that under international law and conventions it is illegal to jeopardize the life, safety and well-being of Protected Persons under the Fourth Geneva Convention and "a Person of Concern to UNHCR".

d. To ensure the residents of Camp Liberty to ensure recommencement of his medical therapy.

Mr. Zakery has been a victim of extrajudicial punishment by the Government of Iraq...[11]

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The Evolution of Research Ethics in South Africa

The history of health research dates as far back as the 1800’s [1] in South Africa, when Cape Town, Grahamstown, Durban, Pietermaritzburg and Kimberley were large thriving towns in with many doctors in practice. They formed their own associations as branches of the British Medical Association. By the 1920’s, these branches had spread throughout South Africa and in 1927, they joined to form a national association, the Medical Association of South Africa (MASA). The MASA was replaced by the South African Medical Association (SAMA) on the 21st May 1998. The SAMA as we know it today is the result of the unification of the fragmented pre-democracy medical groups [2]. Although medical research had been conducted in South Africa since the 1800’s, and despite oversight mechanisms being set up at individual institutional levels, there was no national guideline or policy until 1979. Even this document was limited in scope in that it applied only to researchers affiliated with the MRC, either as recipients of funding from the MRC or as researchers within its institutes, units or groups. Despite there being no safeguards for participants in research at a national level for many decades, doctors involved in research were bound by the World Medical Associations guidelines and declarations.

Following the publication of a paper by Beecher [3] on unethical research being conducted by leading and respectable scientists in the United States, the Committee for Research on Human Subjects (Medical), the first Research Ethics Committee (RECC) in South Africa (SA), was established at the University of the Witwatersrand, Johannesburg in 1966. From the seventies, tertiary institutions at which health research was conducted established local RECs. In 1979, the Medical Research Council (MRC), SA produced the first set of guidelines at a national level [4]. The protections espoused in those guidelines applied to any research being funded by the MRC or conducted by researchers affiliated to the MRC. These guidelines have undergone several revisions. While an important milestone in the participant protections endeavours in South Africa, the MRC guidelines did not have regulatory authority for non MRC associated research. Furthermore, there was no uniformity of functioning between the local institutional RECs that had been set up. Standards of review ranged from exceptionally high at some RECs to very poor at others and some RECs even served as mere “rubber-stamping” committees. Hence, ethics “shopping” was not uncommon in the country. The promulgation of the National Health Act (No 61 of 2003) brought about far-reaching changes, with research participant protections and the functioning of RECs now being regulated by the country’s statutory laws which require the registration and audit of RECs by the National Health Research Ethics Council, a statutory body established to determine the standards for participant protections in health research.

The importance of the principles in the Declaration of Helsinki in shaping South Africa’s ethics-regulatory framework, the health research must be highlighted. The Declaration has greatly influenced our national guidelines [5] from both the National Health Research Ethics Council and the Health Professions Council as well. A breach of ethics in health research could result in sanctions by both these bodies.

References


Ames Dhai
President SAMA
At the recent World Medical Association meeting in Durban, there was much appropriate concern focused on the Ebola outbreak in West Africa. Ebola, like AIDS, malaria, tuberculosis and many other public health problems affect our patients daily and demand our attention. But, we also need to consider another, even greater, threat to public health: the danger of nuclear war. It has been nearly 70 years since a nuclear weapon was exploded over a populated area. But the devastation that will follow any future use of nuclear weapons, and the high likelihood that these weapons will be used again, require that we address this problem now in the hope of preventing this future catastrophe.

Our concern with nuclear weapons flows in part from our understanding that the medical community cannot provide significant relief even to the victims of a single nuclear bomb detonated on a city. In a 2012 statement at the United Nations, the ICRC reaffirmed its belief that the world lacks any “adequate international response capacity to assist the victims if a nuclear weapon were to be detonated”[1]. Based on this understanding the medical community must prevent what we cannot cure.

Today, it is not the detonation of a single nuclear weapon that we must fear. Although the Cold War ended some 25 years ago, there are still more than 17,000 nuclear weapons in the world, most of these weapons are many times more powerful than the bombs that destroyed Hiroshima and Nagasaki[2,3]. During the Cold War, there was widespread attention to this existential threat to human survival; today the nuclear threat is largely ignored.

How Great is the Danger?
A large-scale nuclear war would threaten the survival of our species. A conflict between the US and Russia would cause worldwide climate disruption. Even if they used only those weapons they will still possess when the New START treaty is fully implemented in 2017, the firestorms caused by the detonation of these weapons over urban targets would loft 150 million tons of soot into the atmosphere, dropping temperatures an average of 8 degreesC across the globe[4]. In the interior regions of North America and Eurasia, temperatures would drop 20 to 30 degrees Celsius, producing conditions not seen on Earth since the coldest point of the last Ice Age[5]. In many regions, agricultural production would stop, ecosystems would collapse, and the vast majority of the human race would starve to death.

Since the end of the Cold War we have been assured that we do not need to worry about nuclear war between the US and Russia. Events in Ukraine have shown, however, that conflict between the nuclear superpowers is still possible. Even if the US and Russia do not engage in a deliberate use of nuclear weapons, there remains the very real danger that an accident or computer failure could trigger an unintended use of nuclear weapons. There have been many near misses during the nuclear weapons era, including at least one well after the end of the Cold War. On many occasions we have been extraordinarily lucky. The hope that we will continue to be lucky is simply not an acceptable public health policy.

Even a very limited use of nuclear weapons would cause a worldwide catastrophe. A 2006 paper by Alan Robock and his colleagues examined the impact of a limited nuclear war between India and Pakistan. The scenario in this study assumed that each side used fifty Hiroshima-sized bombs, which is less than half of their current nuclear arsenals and less than 0.03 percent of the world’s nuclear weapons[6]. The direct effects in South Asia would be catastrophic: more than 20 million people dead in less than a week from the explosions, fires, and immediate radiation effects.

The global climate impact would not be as severe as that caused by a large scale war between the US and Russia, but it would still cause a catastrophic decline in food production. In this scenario, five million tons of soot would be lifted into the upper atmosphere. Temperatures would drop an average of 1.3 degrees Celsius across the planet, enough to shorten the growing season and decrease precipitation in many key food producing areas. In the US, corn production would decline 12 percent for a full decade[7]. In China, rice production would decline 17 percent, corn production 14 percent, and winter wheat 31 percent, all for a full decade[8].

A decrease in food production of this magnitude would have profound effects on human health. Current world grain reserves amount to only some 70 days of consumption[9]. Even at current levels of food production there are some 825 million people who suffer significant malnutrition[10], and 300 million people who receive adequate nutrition but live in countries that are highly dependent on food imports[11,12]. With the large decrease in food production that would follow a limited nuclear war, all of these people would be at risk of starvation in a global “nuclear famine” which would affect people thousands of miles from the site of the actual conflict.

In addition, the very severe shortfalls in Chinese food production would put another 1.3 billion people at risk. Worldwide, more than 2 billion people would face severe food insecurity and possible starvation[13].

What Can the Medical Community Do?
It turns out that the medical community can do a great deal.

For more than 50 years, members of the medical community have worked to educate the public and world leaders about the actual consequences of nuclear war in the belief that such knowledge would affect public policy. In 1962, the American organization Physicians for Social Responsibility (PSR) published a series of articles in a special issue of the New England Journal of Medicine explaining the expected consequences of a nuclear war[14-18]. In an accompanying editorial, Joseph Garfand wrote that “the most important function of the physician, however, relates to prevention…. The employment of every reasonable means to prevent such a catastrophe becomes the concern of everyone, and not just the physician”[19].

These articles and other advocacy work by physicians and other health professionals helped create the climate which lead the next year to the Limited Test Ban Treaty, banning above ground nuclear tests.

The ability of the medical community to affect nuclear policy was even clearer during the very dangerous escalation in Cold War tensions in the early 1980s. Starting in 1983 JAMA, published a special issue each August that reviewed the history of the Hiroshima bombing dedicated to the danger posed by nuclear weapons. PSR conducted public symposia with medical schools in major cities across the United States, describing the then-available data about the medical effects of nuclear war. PSR’s sister organization in the United Kingdom, the International Physicians for the Prevention of Nuclear War (IPPNW) conducted similar educational efforts. In recognition of the importance of this work IPPNW was awarded the 1985 Nobel Peace Prize for “spreading authoritative information and… creating an awareness of the catastrophic consequences of atomic warfare…”[20] This in turn contributes to an increase in the pressure of public opposition to the proliferation of atomic weapons[21].

These educational activities had a profound impact on public policy. PSR was able to brief President Reagan at the White House and a delegation from IPPNW met with President Gorbachev in the Kremlin. Speaking of the impact of that briefing, Gorbachev said, “The International Physicians for the Prevention of Nuclear War has come to exercise a tremendous influence on world public opinion within quite a short period of time. Their work commands great respect. For what they say and what they do is prompted by accurate knowledge and a passionate desire to warn humanity about the danger looming over it. In light of their arguments and the strictly scientific data which they possess, there seems to be no room left for philicide. And no serious politician has the right to disregard their conclusions[22].”

In response to these briefings, and to the growing public concern about nuclear weapons, the US and the Soviet Union negotiated a series of agreements which halted and reversed the arms race, significantly reducing the danger of nuclear war.

Unfortunately, with the end of the Cold War, the medical community, like the broader public, became less concerned about the ongoing danger of nuclear war, and an historic opportunity to eliminate these weapons was lost.

In recent years there has been some increased attention to the message first put forward by the medical community more than 50 years ago. Inspired in significant measure by the new data on limited nuclear war, the International Committee of the Red Cross and the Red Cross/Red Crescent Movement have passed two resolutions criticizing the overwhelming humanitarian catastrophe that would result from nuclear war, calling for the abolition of nuclear weapons, and urging all national Red Cross and Red Crescent Societies to conduct educational campaigns about the humanitarian consequences of nuclear war[23,24].

In January of 2012 more than 30 deans of US medical schools and schools of public health issued a statement calling “on our colleagues in the medical and public health communities to educate their colleagues, patients and communities about the enormous danger we face as long as these weapons exist”[24].

This renewed attention to the medical consequences of nuclear war is beginning to affect public policy. There have been two large governmental conferences on the humanitarian consequences of nuclear war and the implications for nuclear weapons policy. The first, in March of 2013 was attended by representatives of 126 governments, and 146 nations attended a follow up meeting in February of 2014, and a third meeting is scheduled for December.

Unfortunately, the medical community as a whole has been less vocal in addressing this pre- eminent threat to human survival. Medical schools, medical associations, and most medical journals have ignored this issue. In a 2010 editorial in the Lancet, David Wolfe and Richard Horton chided the medical community for this failure: “Indeed, it is over a decade ago now since the Lancet published anything remotely relevant to nuclear weapons as a threat to health. Such complacency has been a serious error. Now is the moment for physicians and scientists to build new opportunities for political progress to defuse the...
danger of a new more regionally focused nuclear arms race” [25].

This complicity is indeed a serious error. The danger of nuclear war remains the most significant threat to human survival. The literature on the global impact of limited nuclear war has been developing over the last 5 years, and many outside the medical community have taken seriously our warning and are beginning to act on it. It is time for the medical community to again provide leadership on the most important public health issue of our era. Our success in helping to stop the forward momentum of the arms race in the 1990s shows clearly the impact that we can have. We need to educate our patients again about the existential threat they face and to help them become active in the growing international movement to eliminate that threat.

At the Durban meeting, a resolution was introduced by the Junior Doctors Network updating WMA statement, on nuclear weapons and calling on national medical associations to undertake educational activity.

Leadership on the most important public health question of the day

The medical community has taken seriously our warnings over the last 5 years, and many outside the medical community have taken seriously our warnings and are beginning to act on it. It is time for the medical community to again provide leadership on the most important public health issue of our era. Our success in helping to stop the forward momentum of the arms race in the 1990s shows clearly the impact that we can have. We need to educate our patients again about the existential threat they face and to help them become active in the growing international movement to eliminate that threat.

References

Rationing and Differences in Care in Health Systems

Frank Niehaus

Introduction

The health policies of all OECD countries are shaped by a similar guiding principle: each state would like to guarantee its citizens the necessary state-of-the-art medical care, regardless of ability to pay. To achieve this goal, almost all countries have developed universal healthcare coverage financed by taxes or contributions to cover the cost of illness [1]. General features include, among other things, state regulation of prices and standard service catalogues. In a global comparison, Germany has a special position with its dual healthcare system: the “Wissenschaftliche Institut der PKV [WIF]” [Scientific Institute of Private Health Insurers] has examined the extent of rationing and differences in care in health systems. Furthermore, it is analysed whether single-payer healthcare systems can provide protection from inequalities in care within the population, and which role voluntary private health insurance plays in OECD countries.

Reasons for rationing

Due to collective tax contribution financing, the traditional mechanisms of demand, supply and pricing are eliminated in the healthcare systems of OECD countries. In order to understand why this is the case, the characteristics of a perfect market with free pricing functions are explained in Figure 1.

Figure 1. Schematic representation of a perfect market

Each function of a price in a market is to allocate and ration scarce resources. Generally, as prices increase, the supply of a commodity/service increases as represented by the green line. With a higher price, suppliers produce more of the commodity/service and more suppliers enter the market. Conversely, demand drops with increasing prices (blue line), as the consumers want to purchase less of a commodity/service or relinquish demand entirely. If there is an excess of supply, the suppliers have to drop the price in order to be able to sell their goods and services; if there is an excess of demand the commodity/service becomes scarce and suppliers can charge a higher price. The price mechanism balances supply and demand. The equilibrium price P* clears the market, i.e. the quantity of a product offered is equal to the quantity of the product in demand.

Healthcare markets do not function like a perfect economic market. Not all consumers or patients are willing or able to acquire healthcare services at the price P*. Typically, neither the public nor social policy tolerate that patients cannot financially afford healthcare services. In most developed countries, there is a social consensus according to which healthcare should be accessible to an individual regardless of his or her ability to pay: As such, the healthcare market is regulated in almost all countries. In systems financed through general taxation or by contributions, the price does not play a
The extent of explicit rationing is best able in collectively financed health systems. As a result of these regulations, the price is often significantly lower or even zero due to tax-funding or contributions. In Canada, the UK, Norway, and Denmark, the right-hand side represents the systems which are predominantly financed by contributions, such as Germany, the Netherlands or France. The colour-coding of country names in red or green symbolises whether the healthcare system has official statistics on waiting times and/or waiting lists. This figure clearly shows that all systems financed predominantly through taxation show at least one kind of official information regarding waiting times, whereas systems financed by contributions do not generally do this. Poland, Estonia and the Netherlands are exceptions to this.

**Waiting times as a steering instrument**

The UK example shows that in tax-funded healthcare systems, waiting times can also be utilised as a steering instrument. The NHS England website expressly states that patients can compare waiting times of hospitals in order to choose the hospital with the shortest waiting times for their treatment [12]. Here, waiting times function as a price. The patient must decide whether to accept the long waiting time or rather to make use of another hospital.

**Limited freedom of choice for patients**

A further rationing instrument used mainly in tax-funded health systems is to limit patients’ freedom of choice. For example, in Denmark, Finland, Spain and Portugal, neither the GP nor the specialist can be chosen by the patient. In the Spanish public system in particular, there is almost no freedom of choice for patients. Here, patients may generally only visit a GP located nearby, and patients are assigned to a particular specialist or hospital. The choice of GP is also restricted in a similar manner in the UK and the Netherlands [13]. In many European countries, it is common to limit direct access to specialist care through the GP as “gatekeeper”. This means that the patient may not choose a specialist without a referral from the GP. He or she is therefore dependent on the opinion of the GP. In these systems the GP is usually required to take cost considerations into account when referring the patient, and is thus encouraged to ration. Such systems exist, inter alia, in Spain and Italy [13].

**Limited coverage**

The most direct way of rationing is not to provide services in the public healthcare system at all. This can be done by using positive or negative lists, or whole blocks of services are not covered in the system. For example, physio- and psychotherapy are not covered in the Netherlands. [14]. Dental prosthesis is not covered in Australia, Canada, Denmark, Ireland, Italy, Luxembourg, the Netherlands and Switzerland [13].

Positive and negative lists as well as other instruments are the international rationing

Figure 4. Comparison of waiting times and source of financing of the healthcare system
(Source: Authors’ own representation; OECD Health Data, 2013)
The existence of voluntary private health insurance cannot entirely remove inequalities in care, but can reduce it markedly. This becomes clear in comparison with a situation in which only the option is self-payment: in this case, a patient might have to forgo expensive treatment because it exceeds his or her budget. However, if healthcare provision is covered by insurance, he or she might be in a position to afford the insurance cover, since the costs of insurance premiums remain well below the costs of any potential treatment. If, for example, dental prostheses are not included in the service catalogue of a country’s public health system, people who would not otherwise be able to afford expensive dental treatment, may well cover this risk by taking out supplementary insurance. In this way, the existence of private dental insurance reduces inequalities in care in relation to a situation in which a patient must pay out of pocket for the treatment. More people can afford supplementary insurance through the existence of private insurance and are not exposed to high costs if they require treatment.

**Conclusion**

In conclusion, it becomes clear that medical services are rationed in all the countries surveyed, by means of waiting times, gatekeeping, limited coverage and co-payments. The options to cope with the elimination of market mechanisms, including free pricing. As a result of tax-funding and (compulsory) contributions in healthcare systems, the price does not play the function of allocation and rationing, which it has in a perfect market.

In single-payer health systems, barriers to access are reduced because all citizens have to pay the same amount due to differences in care within the population. Here, patients have an incentive to purchase the services on the private market. Public systems fall short of the target of ensuring equal access to care. Because they involve rationing, they help contribute to the spread of private markets. As only certain parts of the population can afford private health services, this promotes the so-called “two-tier healthcare”. Voluntary private health insurance, however, can help reduce these inequalities.

**References**


**Table 1. Relationship between voluntary private health insurance and rationing in the public health system Source: Authors’ own representation**

<table>
<thead>
<tr>
<th>Type of private health insurance</th>
<th>Form of rationing, which promotes the type of private health insurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duplicate</td>
<td>Waiting times, gatekeeping and low quality in public health system</td>
</tr>
<tr>
<td>Supplementary</td>
<td>Limitation of services in public system, e.g. no assumption of costs for dental treatment, medicine, rehabilitation, alternative medi- cine, single room or treatment by the head physician at the hospital</td>
</tr>
<tr>
<td>Complementary</td>
<td>Obligatory co-payments, i.e. the public health system only takes on services on a pre-rata basis</td>
</tr>
</tbody>
</table>

**Voluntary private health insurance as a reaction to rationing**

Taking out voluntary private health insurance represents an indicator for significant rationing in basic statutory care. Depending on the type of “gap” in the public system, matching private insurances develop to fill it. As a result, there is a market for voluntary private health insurance in almost all OECD countries.

Duplication insurance ensures a claim to services which the patient already officially has in the statutory system, but cannot be enforced in practice. It is used above all to avoid waiting times and limitations of free choice in the public health system and is widespread in, for example, the UK, Ireland and Denmark. The supplementary insurance reimburses services that are not covered in the public system at all. This system has an effect in the Nether- lands, France and Belgium, since the services covered by statutory health insurance only include basic medical treatment. Services that go beyond this, such as physiotherapy or orthodontic treatment, can be covered by supplementary private health insurance. The complementary insurance completes the insurance cover of the public system by reimbursing obligatory co-payments. For example, around 94 % of French people possess such complementary insurance in order to cover the high-cost sharing in the public system [1].

**Differences in care as a consequence of rationing**

Rationing measures in healthcare lead to evolu- tionary reactions, as patients are not willing to set- tle for the rationed services offered by the public system and acquire the desired services at home or abroad. In the UK, for example, they exist a well-structured private health sector in parallel to the tax-funded public sector. This is partly established within the National Health Service (e.g. private departments in public hospitals) or also outside it (e.g. in pri- vate clinics or private medical practices). Thus, British patients can be treated in the private sector in order to avoid waiting times and cover the costs either by using private health insurance or paying for the treatment them- selves [21]. In the Netherlands, various type of service are excluded from reimbursement, such as dental treatment or physiotherapy for adults. In order to supplement the range of services according to individual needs, a large range of supplementary insurances are on offer. Around 86 % of people in the Nether- lands have supplementary insurance for dental and orthodontic care, and 71 % have supple- mentary insurance for physiotherapy [22].

The options to purchase a desired service outside the collectively financed health system are generally distributed unevenly across the population. The requirements for access depend firstly on the socio-e- conomic situation of the patient. Only those who possess the required financial resources can purchase the services. That means that they either have the possibility to finance the private health services themselves or they can afford to take out voluntary private health insurance, which reimburses these services. However, there are other people who remain relegated to the (limited) level of care of the public system because they lack financial means. As a result, patients with comparable indications are treated differently completely in societies that have a single-payer healthcare system.

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standard in the supply of medicines [13]. In Ireland, 70 % of patients fund their GP privately, because they exceed the income threshold for reimbur- sement [16].

In Germany, a statutory entitlement to healthcare services applies nationwide. This differs completely from Sweden, for example. Here, the county councils decide whether the costs for medical services will be covered [16]. Thus, the decision whether someone will receive a new hip depends on the place of residence.

Co-payments

Another rationing instrument applied in each country are co-payments. In Germany, in the case of hospital stays, a minimum of 30 euro must be paid by the patient per calendar day for a maximum of 28 days. In addition, there are rules and regulations on co-payments for inter ali a, medicines, remedies and medical aids. In the Netherlands, by contrast, the statutory health insurance includes a pa- tient deductible of 360 euro per year for all insured persons over the age of 18. Only the costs for the GP and obstetrics are exempt from this [14] [17]. There is also a patient deductible in Switzerland (the so-called franchise) for health insurance. The fran- chise amounts to around 250 euro per year, converted from francs. Besides this, a fur- ther 10 % of the remaining invoice must be covered by the insured party them- selves [18]. In the French and Japanese systems, obligatory co-payments are also relatively high [19] [20]. In Japan, a contribution of 30 % can be a financial bur- den, in particular for cost-intensive inpa- tient treatment.

Even if many OECD countries have impli- cated rules to regulate co-payments, partic- ular population groups from excessive fi- nancial demands arising from co-payments, the steering effect of co-payments still ap- plies to the remaining parts of the popula-
Looking to the Life Sciences for a Healthier EU

Richard Bergstrom

Innovation is essential to progress. This is true for the pharmaceutical industry, which relies on innovation to produce new and improved medicines for patients – and I also think it holds true for the bigger picture: This thinking was part of the impetus behind EFPIA’s Health and Growth Strategy – which presents a new European life sciences strategy, with a strong innovation ecosystem at its heart. By supporting an EU framework, while ensuring that the pharmaceutical industry – where innovation is an essential piece for progress – I have no doubt that this will be the key to our success.

The progress already made this year with the European Medicines Agency (EMA) announcing its MAPPs pilot project is an excellent example. Medicine’s Adaptive Pathways to Patients (MAPPs) is an approach building on the advances in medical science, genomics, and personalized medicine to facilitate an approval process that adapts quickly to a given patient group’s response to therapies. It will launch with a clearly defined patient population with unmet medical needs, followed by continued gathering of evidence in support of expanding the pool of recipients of the new therapy as the knowledge base of MAPPs grows. The European Medicines Agency’s adaptive pathway pilot project with real medicines in development is a step forward in improving the way innovative and needed new therapies reach patients, and signals a new exciting direction for Europe. Ultimately, MAPPs is about bringing better, needed new therapies to patients who need them. This is what drives our industry.

If we continue to support creative initiatives like this, we are doing something right. Europe remains a hub for innovation and creative thinking – and it’s important we protect that. Keeping an open conversation on healthcare going and giving voice to diverse opinions is part of this process. I do believe we are on the right track.

In this context, the pharmaceutical industry has a valuable role to play. It is one of the highest value-added sectors, with a footprint that connects some of the brightest start-up ventures in Europe, academic centers, diverse health networks, and a whole infrastructure of high-value technology and science services. These workforce advantages translated to a wider, positive impact during the recent financial crisis, with the pharmaceutical sector proving more resilient than other industries between 2008–2010, largely maintaining employment at a time when other manufacturing sectors contracted by between 10% and 15%. The pharmaceutical industry employs over 600,000 people in Europe, contributing 17% of total business enterprise R&D expenditure. Additionally, in 2013, Europe’s pharmaceutical trade surplus was estimated at 90 billion.

However, the pharmaceutical industry is not capable of carrying this vision for Health & Growth forward on its own. At the core of the Health & Growth strategy is the need for collaboration: We must all endeavour to break down barriers and silos. As new European leaders and policymakers begin their work to improve Europe’s future, European Federation of Pharmaceutical Industries and Associations (EFPIA) calls for greater political collaboration to drive our industry.

As Europe begins to emerge from the financial crisis and set out its plans for a return to growth, the time is right to fundamentally review how Europe addresses the inter-connected challenges of improving the health prospects and productivity of its citizens, within an affordable financial framework, while ensuring that the pharmaceutical and life sciences industries – jewels in Europe’s economy – continue to thrive. These challenges cannot be separated and addressed in isolation.

The Growing Importance of Health Technology Assessment

Finn Børnum Kristensen

Good governance in health policy aims at improving the health outcomes and performance within financially sustainable health systems (1). Health Technology Assessment (HTA) contributes to the formulation of sustainable health policies by providing evidence-based information to those who define policies and decide on the coverage and usage of health technologies.

The economic downturn – or at least slow-growth of growth – in countries across the globe has put higher pressure on private, public and health insurance resources for healthcare. This has increased the need to prioritise limited resources – and lead to political interest in exploring and implementing the use of HTA to inform decision-makers on effective health policies and decisions that provide real value to patients. WHO resolutions and EU legislation reflect this development (2, 3, 4, 5).

HTA is a practical tool to inform decisions in healthcare on relevant scientific evidence at different levels of national health care systems in a structured transparent way. Not any decision, but decisions that involve defining general policies or guidance on the use of HTA in informing policy- and decision processes.

The policy questions or consequences of various options which the decision-makers would like to straighten out should define the questions that the HTA should address (Figure 1).

HTA a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. It aims at informing the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. Having policy goals, HTA must always be firmly rooted in research and the scientific method (6).

HTA is applied at national, regional and institutional levels (e.g. hospitals). Many countries such as Canada, Spain, and UK have implemented systems for HTA quite thoroughly at national and regional levels while several other countries like Columbia, India, and South Korea are currently implementing HTA in their health policy. The practice of HTA, however, varies considerably across national settings. It informs
HTA in Europe

A majority of Member States in the European Union (EU) now have public sector HTA agencies that provide information to decision making and policy making at the national or regional levels. Many European countries are formally building HTA into policy, governance, reimbursement, and/or regulatory processes. The development of HTA in Europe has been a unique combination of scientific, political and practical steps taken in a region of the world that provides specific conditions for that to happen – conditions such as the process of European integration and the EU and its Health and Research programmes (8).

A European Commission call in 2005 led to the European network for Health Technology Assessment (EUnetHTA) which has been organised through the initial EU

HTA Project, the EUnetHTA Collaboration, the EUnetHTA Joint Action, and EUnetHTA Joint Action 2. EUnetHTA was established to create an effective and sustainable network for HTA across Europe – and to work together to help developing reliable, timely, transparent and transferable information to contribute to HTAs in European countries (9, 10, 11, 12). EUnetHTA supports collaboration between European HTA organisations that brings added value at the European, national and regional level through

- facilitating efficient use of resources available for HTA
- creating a sustainable system of HTA knowledge sharing
- promoting good practice in HTA methods and processes.

Currently EUnetHTA consists of 44 partner organisations designated by their respective Ministry of Health in all 28 EU Member States (5). In order to meet the objectives of this Directive EUnetHTA performs the function of the scientific and technical cooperation of the voluntary HTA Network (13).

Current activities of the EUnetHTA JA2 are supported by funding from the EU in the framework of the Health Programme with the following strategic objectives: 1) to strengthen the practical application of tools and approaches to cross-border HTA collaboration, 2) to bring collaboration to a higher level resulting in better understanding of the ways of establishing a sustainable structure for HTA in the EU, and 3) to develop an implementation proposal for a sustainable scientific and technical collaboration.

EUnetHTA has activities along the whole of the life cycle of technologies from innovation to obsolescence (Figure 2). Early scientific advice aim at facilitating relevant research by technology developers and sponsors to improve the evidence-basis for HTA when the technology is matured to be introduced to healthcare. Rapid relative effectiveness assessments (REAs) were developed to inform reimbursement decisions on new pharmaceuticals and medical devices.

Examples of outputs from EUnetHTA

The HTA Core Model® is a methodological framework for shared production and sharing of HTA information.

The HTA Core Model consists of three components:

1. An ontology containing a set of generic questions that define the contents of an HTA. The questions are distributed within nine Domains which as a whole reflect the broad scope of HTA (Figure 3).
2. A methodological guidance that assists in answering the questions.
3. A common reporting structure that enables standardised reporting of HTAs. Information is created and processed as assessment elements. Some elements are prioritised over others to support European collaboration through defining them as “core elements”.

There are five applications of the model: Diagnostic Technologies, Medical and Surgical Interventions, Pharmaceuticals, Screening Technologies, Rapid Relative Effectiveness Assessment of Pharmaceuticals (14).

The EUnetHTA Planned and Ongoing Projects (PPO) database allows HTA agencies to share information with each other on planned and ongoing projects conducted at the individual agency. The aim of the database is to reduce duplication of work and facilitate collaboration among HTA agencies (14).

The Evidence database on new technologies (EVIDENT Database) allows sharing and storage of information on reimbursement/coverage and assessment status of promising technologies and on additional studies requested by decision-makers or recommended by a HTA. The EVIDENT Database’s goal is to reduce redundancy, promote generation of further evidence when necessary and facilitate European collaboration in this field (14).

Nine methodological Guidelines for Rapid REA of Pharmaceuticals are guidelines on methodological challenges that are encountered by health technology assessors while
performing a rapid REA of pharmaceuti-
cals. The primary aim of the guidelines is to help the assessors of evidence interpret and process the data that are presented to them as part of a REA (15).

Here are some examples of pilot assess-
ments that have been done jointly by vari-
cies of EUnetHTA partners across Europe (12):
- Canagliflozin for the treatment of type 2 diabetes mellitus
- Renal denervation systems for treatment-resistant hypertension
- Zostavax for the prevention herpes zoster
- Duodenal-jejunal bypass sleeve
- Prognostic tests for breast cancer re-

The following examples were provided by representatives of organisations that par-
ticipated in the joint work on the European level supported via EUnetHTA JA1 and JA2 activities:
- Accelerated and real-time informa-
tion exchange between HTA agencies in Europe on relevant topics in areas of collaboration (18). Key areas for the purpose of marketing authorisation. The same data informs the assessment of the ef-
c펙iveness of the new medicines compared to existing therapies, as part of the HTA process to support decision making on ap-
- "Denmark Health Technology Assessment Agency (HTA) bodies;"
Lost in Translation?

The doctor-patient-relationship revisited

Between doctor and patient, duties and responsibilities are shared in a very asymmetrical manner. Unlike the doctor, whose health remains in a comfortable and safe position, the patient, may be in a situation of life and death, his physical integrity in question as well as having responsibilities for loved ones. So in everyday medical practice, a third option must often be considered: The patient wants the doctor to decide for him.

This doesn’t make things easier, however.

The doctor: trusted medic or top salesman?

Medical doctors still hold a high social status in public opinion polls and achieve remarkable income levels. Enormous technical progress has added to the reputation of the profession. Consequently, doctors are confronted with high expectations by society as a whole and by the individual patient.

But something has gone wrong. Numerous publications highlight serious deficits in medical care, pointing to an increasing mutual alienation between doctors and patients. A gap of mistrust seems to have opened. Patients have become cautious because they know or have heard of doctors motivated by pressure from their administration and lured by bonuses to prescribe more expensive drugs, more lucrative diagnostic interventions and higher-priced surgical procedures; all potentially harmful. Alternative medicine may seem less of a hazard.

Sounds good, but where does this leave us? The egalitarian model is easily applied to buyer and seller at the marketplace, where the buyer looks for a certain product or service and makes an informed decision after having checked price and quality. But is a patient’s need for aid when in distress and crisis the same thing as buying a new vacuum cleaner, a favourable mobile phone tariff or an attractive spa package?

The more fit a patient is, the more he is able to act like a competent consumer. By means of the internet he is sometimes better informed about specific details than his doctor. The greater a patient’s distress however, and the younger, older or more sick he is, the less important autonomous negotiating power.

At the same time, patients seem to be fighting back. We are seeing a surge in malpractice suits and the patient’s need for and use of independent aspects of care. Boarding on the Hippocratic oath, the familiar physician is committed to the patient’s well being, his own best possible skills, personal trustful therapeutical relationship between two individuals with equal rights and obligations, two individuals with equal rights make a contract. And finally, it is the patient who decides.

The Patient: help-seeking sufferer or critical consumer?

The traditional view is strongly paternalistic. Bound to the Hippocratic oath, the fatherly physician is committed to the patient’s well being, his own best possible skills, personal integrity and privacy; “Salus aegroti suprema lex” (the well-being of the patient is the supreme law) and “primum nihil nocere” (the well-being of the patient is the primary consideration). We are confronted with a radical erosion of human medicine in its original sense. What is lost, is the specific human element.

It seems as if the trustful and sustainable doctor-patient-relationship has become a side issue. In this way medicine is losing its soul and becoming a technical engineering craft. In addition, clinical procedures are often Tayloristically elaborated, not only in preventive medicine, but also in terms of adequate medical care and efficiency.

It makes a big difference if doctor and patient meet for the first time in an emergency room, strangers to one another, than if they had already had a couple of appointments in the assessment of renal hemorhage, if they collaborate on a regular basis in the treatment of rheumatic arthritis, or if they are even engaged in a psychotherapy meeting once a week.

The consequence of this is that frustrated patients turn away from scientific medicine, and unhappy doctors seek jobs outside medical care in research, counselling, journalism or administration.

Patients and doctors – strangers or friends?

This split is something patients definitely do not want. It’s simply of no use to a suffering patient to have on the one side the medical equivalent of a plumber or clockmaker to repair the broken engine and on the other side a friendly talking psycho-conversation partner, who doesn’t know any more about the subject matter at stake than the patient himself. After a myocardial infarction, with the diagnosis of breast cancer, or with a threatening somatoform symptom, a patient has a justified wish to be cared for by a doctor, who is both medically competent and compassionate. It is an appealingly dis- tressing experience for a patient, in a short session, to be fully informed, according to all legal standards, about the diagnosis of, for example, malignant lymphoma by the responsible oncologist and then to be sent afterwards to an appointment with a psycho-oncologist to talk over the emotional elements.

The psychosomatic approach

About ten percent of the urban population suffer from psychosomatic disorders, mostly somatoform disorders with functional somatic syndromes accounting for the majority (4). The prevalence in family doctor’s practice goes up to thirty or forty percent and reaches up to sixty percent in secondary care, e. g. specialised neurologi- cal or gynecological units (5). The clinical spectrum ranges from chronic pain syndromes such as headache and back-pain, or syndromes compromised organ function such as vertigo, tinnitus, arrhythmias, hyperventilation, irritable bowel or sexual dysfunction, to more generalised pictures such as agitation or burn-out (6). Psychoco- matic medicine considers the crucial role of emotional factors in pathogenesis here.

If speaking with a patient is considered important, then listening is indispensable. Being in tune with the patient, applying the art of careful active listening, means listening with the “third ear”. This enables the doctor to...
Environmental Health

Chronic Kidney Disease of Unknown Origin in Central America and Sri Lanka

Chronic Kidney Disease (CKD) is a growing public health issue around the globe, especially as CKD leads to end-stage renal disease (ESRD) which is both very difficult and costly to treat [1,2]. In the West, CKD has been predominantly tied to an alogic use and the increasing prevalence of diabetes and hypertension. However, less attention has been given to environmental exposures as factors in the development of CKD, which may play a larger role in the developing world [3].

Many parts of the developing world such as Sri Lanka [1], Central America [4, 5] and Egypt [6] are experiencing epidemics of CKD of unknown origin (CKDu). This article presents an overview of the epidemiological and postulated etiologies for the under-recognized epidemic of CKD in Central America and Sri Lanka, two of the major regions of activity.

Central America

For the past two decades in Central America, many young men of working age have fallen victim to a form of chronic kidney disease of unknown origin—fact a silent epidemic has taken hold [4, 7, 8, 9, 10, 11]. CKDu in this context has been given the name ‘Mesamerican Nephropathy,’ or MeN.

While exact figures are unavailable, the likely death toll is at least 20,000 [4]. El Salvador, surprisingly, has the highest overall mortality from kidney disease in the world, and CKD is the second leading cause of death among men of working age in that country [10, 12]. Nicaragua and Honduras are also in the top ten countries in the world with the highest overall mortality from kidney disease [12]. While data on incidence is lacking, studies have revealed a markedly elevated prevalence despite poor survival after diagnosis (renal replacement therapies are inaccessible and prohibitively expensive for the majority of victims), indicating that the epidemic is progressing rapidly [4].

Early unpublished studies and mortality data from this region indicated that men working along the Pacific coast were experiencing a non-proteinuric chronic renal disease to a much greater extent than workers in other parts of their respective countries [7, 8]. For example, the mortality rate for males in the coastal departments of León and Chinandega in Nicaragua are three times higher than the department at the next highest elevation and five times higher than the national average [4].

Despite the important public health implications of such an epidemic, there have been relatively few studies published on the epidemic of CKD in Central America [4]. Most of these studies have been cross-sectional prevalence studies: measuring serum creatinine to determine renal function and/or administering questionnaires to ascertain medical, occupational, and environmental exposures [13, 14, 15, 16, 17]. While cross-sectional studies have limitations, such as recall bias and the inability to determine causality or incidence, the studies that have been conducted all confirm that an epidemic of CKD is underway among residents of the Central American Pacific coastline, especially among young men working in agriculture, such as in sugar cane production [4].

Torres et al. conducted one of the largest of these cross-sectional studies [14]. They examined men and women aged 20–60 years in five villages in Northwest Nicaragua, which varied by industry and elevation. Overall, 14% of men and 3% of women exhibited decreased kidney function (estimated glomerular filtration rate [eGFR] <60ml/min per 1.73m2). In the United States, on the other hand, the prevalence of eGFR <60 in both men and women aged 20–59 years is approximately 1% [19]. Torres et al. also found villages at lower elevations (e.g. 100–300m vs. 200–675m) and where the industry was mining or agriculture (e.g. banana or sugarcane) were most impacted.

The ‘usual suspects’ for CKD-pro-existing diabetes and hypertension—are largely absent in this epidemic [4, 15, 17]. The cross-sectional studies, through medical history review, clinician interviews, biological sampling, and questionnaires, have uniformly concluded that the epidemic of MeN cannot be attributed to these factors [4, 14, 20, 21, 22, 23]. There is also little evidence to implicate nephrotic metals, such as cadmium or lead [4].

There are a myriad of environmental, occupational, and behavioral factors to which the affected population may be highly exposed and which can cause renal damage, however these are not known to be associated with CKD in particular or to such an extent [4]. These factors are: strenuous labor in hot conditions leading to chronic dehydration, medications (e.g. non-steroideal anti-inflammatory agents, analgesics, or amino-glycosides), infection (e.g. leptospirosis), arsenic, and agrochemicals (e.g. pesticides). One theory postulates that an initial injury damages the kidneys, but one or more additional factors trigger the progression to CKD [24]. Thus MeN may result from a ‘multifactorial synergistic mechanism’ [4]. Evidence that initial kidney damage may be occurring at an early age comes from a pilot study, which found a similar pattern of elevated biomarkers of tubular kidney damage among adolescents without prior work...
Since the early 1990s, many studies have documented an increasing prevalence of Chronic Kidney Disease of unknown etiology (CKDu) in Sri Lanka [2]. CKDu is defined as chronic kidney disease, usually diagnosed based on evidence of microalbuminuria, that is present without any other diagnosed cause of kidney disease, especially among young males, farmers, and agricultural workers [3, 27]. Other reports have estimated a prevalence of 5.1% based on microalbuminuria [1]. In this region, the point prevalence data has helped trace most of these cases to the agricultural fields. Many studies pointed to cadmium and, to a lesser extent arsenic, as the likely cause of CKDu due to their nephrotoxic properties and elevated readings in well water [27]. A recent case-control study analyzed urine, hair, and serum for evidence of heavy metal exposures were mixed. While initial studies focused on potential heavy metal comparisons regarding the causes of the epidemic, most heavy metal exposure comes from unregulated use of pesticides and agrochemicals, etc. Patients found to be at risk for development of CKDu may then need to be counseled on the hazards posed by their occupations and referred for further care as necessary.

Prominent researchers into the epidemic of MeN/CKDu have called for the following actions to halt its progression:

1) improve surveillance systems to determine incidence and causative factors
2) develop and implement preventative strategies for putative causes
3) increase compliance and enforcement of existing laws regulating agrochemical use
4) strengthen healthcare systems to improve delivery of primary care and renal replacement therapies
5) develop evidence-based CKD guidelines and education tailored to each country [4, 36].

What can be Done from a Clinical Standpoint?

Clinicians in these regions should be aware of the heightened prevalence of chronic kidney disease, especially among young males working in agriculture. Though proposed etiologies vary by country, physicians should still note the patient’s occupation, risk factors (level of exertion in hot conditions, hydration status, exposure to heavy metals and agrochemicals, etc.). Patients found to be at risk for development of CKD may then need to be counseled on the hazards posed by their occupations and referred for further care as necessary.

Acknowledgements: Assistance provided by Dr. Peter Orvis, Chief, Occupational and Environmental Medicine with this report was greatly appreciated.

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Environmental Health

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World Medical Journal

What can be Done from a Public Health Standpoint?

Public health responses cannot wait until the mysteries are conclusively solved. The governments of El Salvador and Sri Lanka have taken steps to address the issue. For example, the Sri Lankan government has been working with WHO and in-country partners to improve surveillance and care for the affected population [36]. The Sri Lankan government is also using a measure to reduce environmental exposure to agrochemicals. The Ministry of Health of El Salvador successfully spearheaded the effort to have MeN prioritized as a major health concern by the Pan American Health Organization and the Council of Ministers of Central America [4]. In October 2013, PAHO passed a resolution formally recognizing MeN as a serious threat to public health and called on member states to conduct research on the disease and strengthen occupational and environmental health programs.

While much of the research to date has pointed to environmental heavy metal exposure as, at the very least, a major factor in the development of CKDu, there are still many questions remaining. It is widely speculated that most heavy metal exposure comes from agrochemical use, but the exact nature of the exposure has not been definitely proven. It is also unclear what role genetics, comorbidities and other environmental factors are playing in the development and progression of CKDu. Recent studies have shown that factors as variable as mycotin exposure, the mineral content of drinking water and genetic predisposition to the development of CKDu may play a significant role in the development of CKDu, showing that there is much more to be learned about this disease process and that little has been definitively proven [2, 33, 34].

What is Being Done from a Public Health Standpoint

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the European Union and Canada. CETA negotiations concluded in 2014, and the deal is currently awaiting ratification [10].

The Trade in Services Agreement (TiSA) negotiations include twenty-three parties: Australia, Canada, Chile, Taiwan, Colombia, Costa Rica, the EU, Hong Kong, Iceland, Japan, Korea, Liechtenstein, Mexico, New Zealand, Norway, Pakistan, Panama, Paraguay, Peru, Switzerland, Turkey and the U.S. While the scope of TiSA negotiations may be somewhat different as compared to TPP, TTIP & CETA, TiSA negotiations have enormous potential to affect health care services. Leaked documents suggest that TiSA may seek to realize the “unstoppable potential” for the “globalization of healthcare services” [11]. However, very limited information is available from these documents on the scope, direction and scope of TiSA negotiations.

Transparency

Public access to negotiating drafts and negotiators has been limited. There are no publicly available draft texts and restricted stakeholder access during negotiating rounds. Civil society has been forced to rely on leaked or unofficial leaked documents and rumors. This lack of transparency hinders civil society engagement and public scrutiny.

Investor-State Dispute Settlement

Investor State Dispute Settlement (ISDS) provisions have been a point of contention. ISDS provisions could have profound, cross-cutting implications for health, health care and the social determinants of health. ISDS provides a mechanism for investors to bring claims against governments and seek compensation for damages and potential loss of profit. Thus, ISDS allows multinational corporations to challenge laws and regulations that threaten their interests outside of existing legal systems of accountability.

ISDS provisions smaller scale trade agreements over the last few decades have been used to challenge evidence-based public health laws, such as tobacco control measures in Uruguay [12]. According to United Nations Conference on Trade and Development (UNCTAD) data, there have been more than 500 ISDS cases brought against governments under existing agreements. Of these cases, approximately 57% have either been settled outside of court (at the expense of the state) or adjudicated in favor of the investor [13]. This demonstrates the power that ISDS as a mechanism has to advance corporate interests over health. In addition, there is some evidence to suggest that the availability of ISDS may deter government from enacting laws and regulations that may be challenged by investors [3]. By limiting the ability of governments to adopt and implement policies to protect and advance health, ISDS may have harmful intersectoral impacts that result in numerous public health consequences, in areas such as tobacco control, alcohol control, regulation of obesogenic food and beverages, access to medicines, health care services, the health professional workforce, environmental protection and climate change regulation and occupational and environmental health [14, 17].

Noncommunicable Diseases: Tobacco, Alcohol & Nutrition Policy

Prevention and control of noncommunicable diseases (NCDs) has been recognized as a global health priority by the World Health Organization [26], and trade agreements are an "upstream driver" of NCDs [15]. As a result of both ISDS-driven legal challenges and indirect regulatory chill, ISDS provisions may be used to undermine the development of evidence-based NCD interventions including tobacco, alcohol and obesogenic product control efforts.

The potential implications of the TPP, TTIP and CETA on tobacco regulation has been one of the most well-publicized dimensions of negotiations. ISDS mechanisms in a smaller scale trade agreement have already been used to challenge tobacco control measures in Uruguay. Possible avenues for industry to challenge tobacco control measures include enforcement of trademark protections, stakeholder provisions to expand industry influence in policy-making, cross-border services provision to protect advertising and licensing, and technical barriers to trade provisions [16-20, 46]. If tobacco is not excluded, these agreements could sabotage existing tobacco control efforts under the World Health Organization Framework Convention on Tobacco Control (FCTC) [12, 21, 62-63]. Despite evidence that 4% of the global burden of disease is attributable to alcohol [22-23], ISDS may also be targeted for challenge under ISDS provisions [24-25].

Nutrition policy may be affected by this new generation of trade deals [14, 27]. Tariff reduction, intellectual property and foreign investment liberalization provisions in the setting of ISDS may threaten existing NCD control efforts [28-29]. Experience with prior bilateral and regional trade agreements suggests that trade liberalization increases the sale of unhealthy transnational products and advertising of these products resulting in significant changes in consumption patterns [15, 30].

Health Care Services & Health Workforce

TPP, TTIP, CETA and TiSA may have the potential to affect the availability, accessibility and regulation of health care services. TiSA in particular is anticipated to challenge government efforts to ensure the portability of health insurance across national borders [84] which may affect the supply and movement of health professionals globally. Trade agreement negotiations may also implicate health including telemedicine and access to medical knowledge. However, assessing the potential implications of negotiations is challenging and speculative without access to texts.

Access to Medicines

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sought to codify common principles, standards and rules for the global protection of intellectual property. TRIPS included safeguards and flexibilities, clarified by the Ministerial Declaration on TRIPS and Public Health ("Doha Declaration") in 2001, to ensure that the protection of intellectual property under the agreement can and should not compromise public health [37-38].

Despite reassurances and efforts to protect access to medicines [53], leaked texts and details of potential intellectual property provisions paint a troubling picture for access to medicines [81]. There are several possible trade agreement provisions that could exceed those protections afforded under TRIPS and ultimately reduce the affordability and accessibility of medications including (but not limited to) [39-44, 50, 65, 81, 96]:

• Evergreening, or prolonged patent protection for minor modifications of existing drugs;
• Patent linkage or other patent term extensions that may serve to as a barrier to generic entry into the market;
• Extended data and/or market exclusivity and transition periods for products including biologicals;
• Restrictions on TRIPS safeguards and flexibilities including compulsory licensing and parallel imports;
• Limits on clinical trial data transparency through trade secret or other intellectual property protections.

Trade agreements may also challenge therapeutic reference pricing and other features of effective pharmaceutical benefits programs including Australia’s Pharmaceutical Benefits Scheme [45-46,77], New Zealand’s Pharmaceutical Management Agenci (PHARMAC) Program [44, 47], the United Kingdom’s National Health Service (48, 64), Canada’s Health Canada program [67] among others.

ISDS further complicates potential implications of trade agreement negotiations on access to medicines. Under NAFTA, Eli Lilly has brought a claim in excess of $500 million against Canada over its invalidation of the company’s patents on Strattera and Zyprexa [49]. Similar claims to enforce more stringent intellectual property protections could have devastating implications for access to medicines.

The patenting of diagnostic, therapeutic and surgical techniques may also warrant attention in trade agreement negotiations. Consistent with existing World Trade Organization (WTO) Association policy opposing the patenting of such techniques [51], it is critical that an exception, similar to that used in the UCSP (76), be incorporated into any agreement to prevent potential liability for patent infringement of medical professionals performing procedures and providing care for patients [52-53].

Environmental Protection & Climate Change

Millions of deaths globally each year are attributable to sequelae of air pollution and reliance on fossil fuels—it is estimated that one in eight deaths globally is due to air pollution [98]. Without sustained global mitigation and adaptation, climate change could result in worsening outbreaks of deadly infectious diseases, exacerbation of food insecurity, increased natural disasters and conflict—all with significant health implications [57]. In this context, trade agreement negotiations may have negative implications for environmental protection and efforts to address climate change [55-56, 64]. Thus, as momentum grows in advance of Conference of Parties 21 (COP21) negotiations in Paris, trade policy may simultaneously undermine commitments under the United Nations Framework Convention on Climate Change (UNFCCC) by empowering corporate interests to directly and/or indirectly challenge domestic policies to curb greenhouse gas emissions. In
addition, ISDS provisions may be used to expand environmentally harmful practices such as fracking under these agreements with well-documented devastating environmental consequences [90].

Regulatory harmonization and “downward” regulatory pressure could weaken sanitary and phytosanitary (SPS) measures [58-59]. These measures include critical public health protections such as food safety and plant and animal health. Across Europe, concern about food safety and regulation has sparked significant controversy and garnered substantial media attention. However, it is difficult to project overall potential health impact of such provisions [77].

Labor standards, labor rights and occupa- tional health and safety may also be on the proverbial negotiating table [85]. Under existing trade agreements, social protection for workers and collective bargaining rights have been curtailed in favor of trade liberal- ization [60-61,64]. If a similar approach to labor is incorporated into this new generation of agreements, there is a risk of exacerbating social inequality and undermining efforts to address the social determinants of health.

A Call to Action for Physicians and Organized Medicine on Trade+Health

Several World Medical Association nation- al member associations and other medical groups have responded to the potential threat posed by these trade agreement negotia- tions. In 2014, the German Medical Association General Assembly adopted a resolution on the role of medicine in global activities: the Trans-Pacific Partnership. Tob Control 2014; Online First. Available at http://tobaccocontrol.bmj.com/content/early/2014/08/28/ tobaccocontrol-2014-051900.short


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