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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 upcoming trade agreements to our WMA 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 Patenting 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 considerable prosperity.

Secondly, the medical profession has always been internationally orientated. Diseases don't recognise political borders boundaries and are not confined by customs areas. International exchange and cooperation is crucial for medicine. Both physicians and patients migrate:, and cross-boarder services are a reality.

Thirdly, whoever has experienced life as an expatriate knows that there is more red tape than this world needs. Those who want to conduct cross-border business will find that protectionism and out-dated or simply meaningless regulation can be prohibitive, if not disastrous. Getting rid of unjustified regulation is not only beneficial for migrants or those carrying out business across borders, it will also help those within countries who may likewise be inhibited by it.

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) Commissioner for Trade, Karel de Gucht, speculated about an increase in EU GDP of O.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 "maybes" 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 publically 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 Frontiers (MSF) warn against TTP [7] and TTIP [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

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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 Bratwurst 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 holding 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 aspects 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 party 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 any public health act 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 positive aspects 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.

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Otmar Kloiber and Liene Puke

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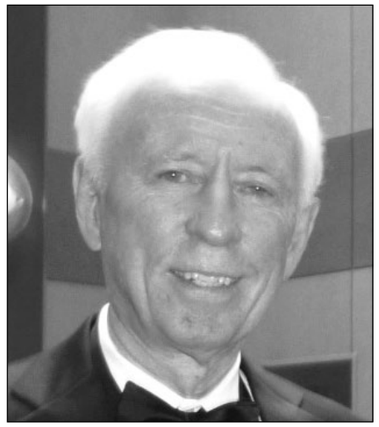
Report on "Ethical Guidelines and Practices for U.S. Military Medical Professionals"



Cecil B. 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:

- How can military medical professionals most appropriately balance their obligations to their patients against their obligations as military officers to help commanders maintain military readiness?
- How much latitude should military medical professionals be given to refuse participation in medical procedures or request excusal from military operations with which they have ethical reservations or disagreement?

The DHB tasked its Medical Ethics Subcommittee to conduct its review of military medical professional practice policies and guidelines. The Subcommittee reviewed current civilian and military health care medical professional practice policies and guidelines as well as medical 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 deliberation:

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 combat 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

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Subcommittee in its review of the dual loyalties of military health care professionals:

I. These must take into consideration:
   a. The spectrum of health care professional ethical codes, laws and licensing requirements;
   b. Military professional ethics and codes;
   c. Medical education and continuing medical education both within and outside of DoD;
   d. The spectrum of experiences of both civilian and military health care professionals;
   a. The need for military health care professionals to explore and address their own and their patient's religious beliefs, ethics, and medical preferences; and
   f. Recommendations of those within and outside of DoD.

II. Provide guidance regarding how to best educate and train military health care professionals to recognize and determine the best course of action when ethical dilemmas arise.

III. Acknowledge the moral injury that may occur as a result of encountering an ethical dilemma and incorporate practices that enhance resiliency and assist professionals in coping with and recovering from these injuries.

IV. Provide guidance to ensure a support infrastructure and environment is established and maintained to provide military health care professionals a safe avenue to raise ethical concerns and seek timely assistance in determining the best courses of action.

Defense Health Board - Federal Advisory Committee to the Secretary of Defense

The Defense Health Board (DHB) is a Federal Advisory Committee to the Secretary of Defense that provides **independent advice/recommendations** on matters relating to operational programs, health policy development, health research programs, and requirements for the treatment and prevention of disease and injury, promotion of health and the delivery of health care to Department of Defense (DoD) beneficiaries.

Mission

The mission of the DHB is to provide independent authoritative advice to maximize the health, safety, and effectiveness of the United States Armed Forces.

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

February 11, 2015

Recommendation 1: Department of Defense (DoD) should further develop and expand 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; consultative and online services; ethics experts; and an office dedicated to ethics leadership, policy, and oversight. To achieve these goals, DoD should form a tri-Service 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 consider the best ways to implement the recommendations in this report.

Recommendation 2: Throughout its policies, guidance, and instructions, DoD must ensure that the military health care professional's first ethical obligation is to the patient.

Recommendation 3: DoD leadership, particularly the line commands, should excuse health care professionals from performing medical procedures that violate their professional code of ethics, State medical board standards of conduct, or the core tenets of their religious or moral beliefs. However, to maintain morale and discipline, this excusal should not result in an individual being relieved from participating in hardship duty. Additionally, health care professionals should not be excused from militaryoperations for which they have ethical reservations when their primary role is to care for the military members participating in those operations.

Recommendation 4: DoD should formulate an overarching code of military medical ethics based on accepted codes from various health care professions to serve as a guidepost to promote ethical leadership and set a standard for the cultural ethos of the MHS. To inform this process, the ethics codes of relevant health care professional organizations should be reviewed regularly and updates should be made to the military medical ethics code as appropriate.

Recommendation 5: To provide formal ethics guidance, direction, and support to the MHS and its components, DoD and the Military Departments should:
   a) Publish directives/instructions regarding the organization, composition, training and operation of medical ethics committees and medical ethics consultation services within the MHS. DoD should review best practices at leading civilian institutions in formulating this guidance.
   b) Ensure military treatment facilities have access to consistent, high-quality, ethical consultation services, including designation of a responsible medical ethics expert for each location. For those facilities/locations without onsite medical ethics support, DoD should ensure remote consultation is available.

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   c) Provide a "reach back" mechanism for deployed health care professionals to contact an appropriately qualified individual to assist in resolving an ethical concern that has not been resolved through their chain of command.
   d) Develop a small cadre of clinicians with graduate level training in bioethics to serve as senior military medical ethics consultants.
   e) Ensure that health care professionals are knowledgeable about their rights and available procedures for obtaining ethics consultation, expressing dissent or requesting recusal from certain objectionable procedures or activities.
   f) Review compliance with ethics directives and instructions as part of recurring health service inspections.

Recommendation 6: DoD should develop clear guidance on what private health information can be communicated by health care professionals to leadership, and the justifications for exceptions to the rule for reasons of military necessity.

Recommendation 7: DoD should provide military health care professionals with privileges similar to those of Chaplains and Judge Advocates regarding their independence and obligation to protect privacy and confidentiality while meeting the requirements of line commanders.

Recommendation 8: DoD should provide specific education and training for health care professionals designated to serve as medical mentors or health care providers in foreign health care facilities or in support of humanitarian assistance or disaster relief operations. Such education and training should cover cultural differences, potential ethical issues, rules of engagement, and actions that might be taken to avert, report, and address unethical, criminal, or negligent behavior or practices.

Recommendation 9: DoD should create an online medical ethics portal. At a minimum, it should include links to relevant policies, guidance, laws, education, training, professional codes, and military consultants in medical ethics.

Recommendation 10: DoD should include in professional military education courses information on the legal and ethical limitations on health care professionals regarding patient care actions they may or may not take in supporting military operations and patient information they may and may not communicate to line leadership.

Recommendation 11: DoD should ensure that systems and processes are in place for debriefing health care professionals to help them transition home following deployment. Debriefing should occur as a team when possible. Not only could this help mitigate potential moral injury in health care professionals, but it may also provide lessons learned and case studies for inclusion in ongoing training programs.

Recommendation 12: To create an environment that promotes ethical conduct and minimizes conflicts of dual loyalty, DoD leadership should emphasize that senior military health care professionals are full members of the Commander's staff as an advisor on medical ethics as it relates to military readiness.

Recommendation 13: To minimize isolation of health care professionals, the Military Departments should make every effort to ensure personnel who are deploying to the same location train together as a team prior to deployment. Establishing relationships prior to deployment may enable better communication and trust among line command and health care professionals in the deployed setting.

Recommendation 14: DoD should issue a directive or instruction designating minimum requirements for basic and continuing education and training in military medical ethics for all health care professionals in all components and indicate the appropriate times in career progression that these should occur.

Recommendation 15: To enhance ethics training for military health care professionals and the line command, DoD should:
   a) Ensure pre-deployment and periodic field training includes challenging medical ethics scenarios and reminders of available resources and contact information to prepare both health care professionals and line personnel. Curricula should include simulations and case studies in addition to didactics.
   b) Provide a mechanism to ensure scenarios and training curricula are continually updated to reflect specific challenges and lessons learned through debriefing from real-world deployments and garrison operations.
   c) Ensure key personnel returning from deployment who have faced significant challenges provide feedback to assist personnel preparing for deployment

Recommendation 16: To enhance health care practices in the military operational 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 esolving complex ethical issues. This course should be required for all health care professionals.

Cecil B. Wilson, MD, MACP
Past President World Medical Association

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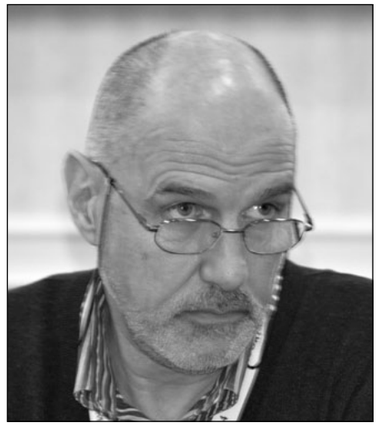
Self-care – the CPME Statement: Quality and Safety, and Transparency!



Jacques de Haller

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 a "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 healthcare 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 trivialize a symptom which this time should not be overlooked! Patients should definitely be protected from the consequences of undue trivialization 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? Wwhat to expect from an available treatment? wWhat to do if the expected results don't show?

This is all about patient empowerment (once again!). Clearly, empowerment also means responsibiliy, 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 lie, 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 reflexions on quality and safey, in consideration to self-cae, mean in fact that although we definitely, as Doctors, aren'ot 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 Committe, adopte athe "Statement o sSelf-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 patiet, 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 tea EU policy on self-care (cf. "CPME joint statement: Making Health Literacy a Priority", April 2013 [2]).

The CPME Statemenn 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-medicaion [4].
- The principle that treatment requires prior diagnosis is central in medicine, and a reliable diagnosis should be the prereq-uisite 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 drugsaalso the sale of pharmaceuticals 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-

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ations are to define the future EU policy through just and unbiased evidence.
- Self-care should not become the field of commercial advertising and product promotion. Measures must be implemented to avoid his, as well as any type of conflict of interest and the damaging consequences which can result from the proximity of commercial actors to patients.

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 population live a better life, whereas, complex as it is, it needs people – Doctors! – wnks due to sufficient knowlednks 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 o be 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 is that treating autonomous and informed patients is so much more fun!

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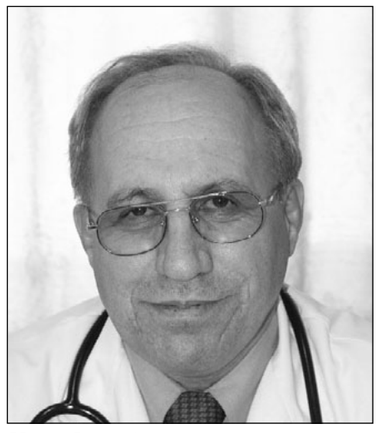
Healthcare in Camp Liberty, Baghdad, Iraq



Hassan Jazayeri

A large number of Iranian refugees, members of PMOI, an opposition to the Iranian regime, are forced to live in Camp Liberty, a desolate abandoned US military base with dilapidated infrastructure in the vicinity of Baghdad Airport. This camp falls short under the internationally accepted humanitarian and human rights standard. Prior to their eviction to Camp Liberty, these refugees were all living in "Camp Ashraf", a modern highly self-contained camp, owned and managed by them in Diyala Province.

In 2004 and following the occupation of Iraq, residents of Ashraf were recognized as "protected person" under the Fourth Geneva Convention by the U.S. government. Since then U.S. Army had the responsibility to safeguard and protect the camp. In 2009 U.S. handed over the protection and control of Camp Ashraf to the Iraqi government under then Prime Minister al-Maliki against the will and wishes of the residents. Ever since Iraqi forces under the command of PM al-Maliki committed six bloody incursions against the unarmed civilian residents of the camp at the behest of the Iranian regime as a result of which 116 have been killed and over 1,370 others were injured and maimed. An all-out siege and blockade of medical and logistical needs of the camp has cost the lives of 24 patients who died till March 2015. The aim was an Iranian dictated agenda to force the camp residents, who had left their homeland in opposition to the current theocracy to surrender to the wills of the perpetrators.

Current healthcare condition in this camp is better fully understood in a greater context of the political turmoil in the country and how it has affected the rule of law and logically our core values and commitments to healthcare and medical ethics.

Turmoil in Iraq

The current situation in Iraq is characterized by a large-scale political and security crisis with momentous local, national and regional implications. Iraq belongs to category 3 (most severe) of ECHO's Crisis Index. The Iranian regime and its ally, Nourial-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 airstrikes and spent more than $1 billion on military aid". The Post added that "Iraq's Shiite-led government is increasingly reliant on the powerful militias and a massive Shiite volunteer force, which together may now equal the size of Iraq'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.

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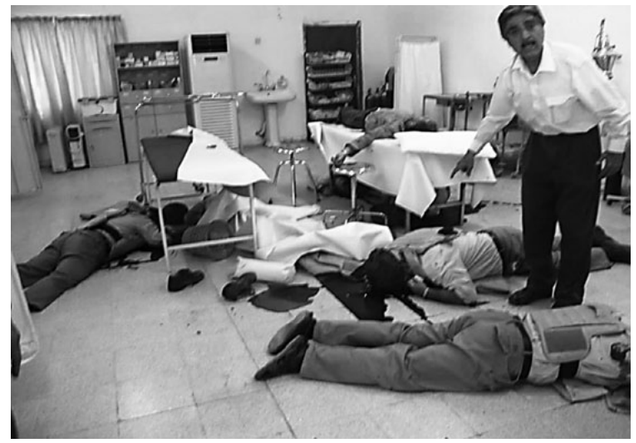

Sept. 1, 2013 – Dyalya Province – Camp Ashraf. An emergency room nurse and six patients killed after Iraqi security forces attacked the clinic. Dr. Ahmadi hours after the incident at the scene of the crime (right). UN observer is recording the evidences and eye-witness accounts (left). A blatant violation of the Geneva Conventions (1949) and their additional Protocols forming the core of the international humanitarian law.

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

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and laws. Violating those rights raises serious questions about the intentions of the new government.

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 and impartiality, and have remained inconclusive. Our serious concern extends to the five previous attacks against that community, none of which has been properly investigated, and for which no one has been brought to account. We are further concerned that the whereabouts of the seven persons abducted during the 1 September 2013 attack remain unknown.*

The past 6 attacks against that community, the lack of proper investigations and of effective measures to protect its members, heightens our concern about its vulnerability to further attacks, especially in the context of the recent upsurge in fighting in the country including in areas close to the camp.

We thus respectfully urge your Excellency's Government to step up its efforts to investigate all past attacks, to bring to justice anyone found to have been responsible for these acts, and to take effective measures to ensure the safety of the residents of Camp Hurriya and ensure that they are treated in accordance with international human rights standards. Under international law, Iraq has the legal obligation to ensure the right to life to all persons living in the country and to effectively punish those responsible for violations of this right. Severe crimes of the nature of those referred above, and the impunity that has accompanied them, entail violations of numerous international treaty provisions."

WMA's Firm Response

In a letter delivered on 10 November 2014 to the Prime Minister of Iraq, the President of the WMA Dr. Xavier Deau, strongly voiced medical profession's objection against recurrent violations of medical ethics and the right to health in Camp Liberty: *"According to testimonies and reports from human rights organisations the basic rights of the 2700 residents – such as access to physicians and medicine, the confidentiality of physician-patient relationship or the right of patients to have interpreter and accompanying nurses when needed – are frequently violated.'Furthermore, numerous reported cases relate to situations where hospitalisation of patients and purchase of medicine have been prevented. Other examples include cancellation of medical appointments, delayed transfers of patients to hospital, or denial of permission to travel outside the Camp to receive treatment. These on-going obstructions have resulted in the rapid deterioration of the health conditions of several patients of the Camp Liberty and even in the death of some."*

This resolute approach by WMA's president provoked a strong international response from other international or regional health bodies just to name a few: *International Council of Nurses ICN)*, *Standing Committee of European Doctor (CPME), European Union of Medical Specialist (UEMS), European Association of Salaried Doctor (FEMS), European Association of Senior Hospital Physicians (AEMH), Working Group of Practitioners and Specialists in Free Practic- (EANA), European Public Health Associatio (EUPHA….* Also numerous key prominent national medical associations responded to the call of the president by actively participating in this campaign including British Medical Association, American Medical Association, Canadian Medical Association, Belgian Medical Trade Unions Association, German Marburger Bund, Indian Medical Association, etc.

Year 2009: a turning point

It is noteworthy to emphasize that the public health standards of these residents were at the highest attainable quality of healthcare offered in Iraq before 2009 which was managed through integrated efforts of a 40 strong member medical team consisting of 11 doctors and specialists, all exiled refugees residing in the camp. The camp residents used to enjoy free access to medical services and facilities and they managed a privately owned hospital inside their former camp (Camp Ashraf), self-contained and fully equipped, including a newly purchased spiral CT-Scan to that date to cover primary and secondary health service, as well as medical referral services and ensured availability of life-saving emergency services.

In 2009 an all-out logistical and medical blockade of the camp was initiated by Iraqi Army forces (IAF) under the command ofAal-Maeiki who started implementing an Iranian agenda. In 2012 the residents were evicted from Camp Ashraf to Camp Liberty and the Government of Iraq blocked the transfer of the resident's medical resources (equipment and supplies) to Camp Liberty leaving the residents' doctors with no resources and capabilities to diagnose and treat or conduct surgery inside the Camp. Thus the camp healthcare system became totally dependent on what was offered by the very same government that had planned and perpetrated the attacks and incursions on their camps.

The current system is nothing but a substandard trivial primary care in a tiny Iraqi infirmary.

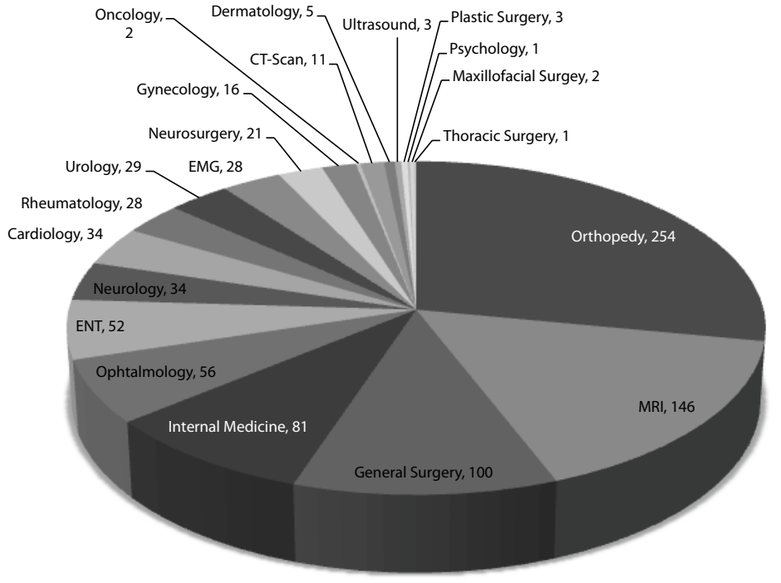
In this infirmary only a general practitioner (GP) diagnoses the patients daily. There is not enough medicine. There is no emergency medicine and facilities and the GP's job is just to refer the patients outside the camp. He only issues referral papers for incoming patients.

The outcome of this Medical Blockade, taking into account the span of almost 6 years, can be outlined into the following facts and figures:

- 24 patients died due to lack of free access to vital medical services;
- By the end of 2014 the restricted access to secondary and tertiary care services outside the camp had piled up a total number of 907 patients who had already received official referral forms from the GP at the Iraqi clinic inside the camp for an appointment with a specialist in Baghdad hospitals;
- The blockade also applies to the entrance of pesticides, bactericides and chemical disinfectants which has added to the Camp's already existing hygiene deficiencies.

Dr. Deau elucidates this situation in his letter to the Prime Minister as follows: "We *are extremely concerned by this situation that reveal flagrant violations of medical ethics principles and human rights standards. The right of everyone to the enjoyment of the highest attainable standard of physical and mental health is a fundamental element of human rights enshrined in article 14 of the International Covenant on Economic, Social and Cultural rights that Iraq has ratified in 1971."*

Camp Liberty Iraqi infirmary – The only sub-standard trivial primary care offered for the camp's population



By the end of 2014 a total of 907 patients had received referrals to make secondary and tertiary appointments outside the camp

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Current Crisis

Recurrent violations of medical ethics and the right to health in Camp Liberty are quite coincidental to the current turmoil and level of the corruption in the country, discussed above. The most recent case of a BPH (benign prostatic hyperplasia) patient, Mr. Safar Zakery, has been quite alarming and should not be regarded as an isolated incident in this new line of violations of our medical ethics.

Mr. Zakery, 61, is a hygiene worker who left the camp on 16 March 2015 for routine sewage disposal where in a scripted scenario his tanker was struck by an Iraqi Police Humvee but they arrested Mr. Zakery instead of the guilty Humvee driver! Ever since he is being kept in an arbitrary detention in Ameriah police station in Baghdad under phony charges. He was not released on bail inconsistent to routine misdemeanor court procedures. Mr. Zakery was denied access to receive proper healthcare and even to attend his BPH surgery appointment scheduled on April 5, 2015, after a long-awaited duration for admission to the hospital. This condition has already jeopardized Zakery's health with the risk of further complications and complete urinary retention.

In their letter to Iraqi Prime Minister Haider al-Abadi our colleagues at Canadian Medical Association expressed our deepest concern of medical profession regarding the unlawful detention of Mr. Safar Zakery as a clear breach of principles of medical ethics and human rights standards:

"…We find it especially alarming that Mr. Zakery has been denied access to proper healthcare, including attending his surgery appointment scheduled on April 5, 2015. This is jeopardizing Mr. Zakery's health with the risk of further complications.

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, to which Iraq is signatory.

We take this opportunity to call on you to secure the immediate release of Mr. Zakery and his immediate return to Camp Liberty to ensure recommencement of his medical therapy.

Mr. Zakery is 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 full access to adequate health care facilities and to respect their dignity, safety and protection under international law.

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The Evolution of Research Ethics in South Africa

Ames Dhai

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 later joined the WMA when it was established. 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 (REC) 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 Heath 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 ethico-regulatory framework in 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.

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Ames Dhai
President SAMA

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Nuclear War: A Greater Threat than Ebola

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 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 production16 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 today 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.

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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 Garland 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 least 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 on the anniversary 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 organizations in 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... [T]his in turn contributes to an increase in the pressure of public opposition to the proliferation of atomic weapons" [20].

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 politicking. And no serious politician has the right to disregard their conclusions [21].

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 citing 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 [22, 23].

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. 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

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danger of a new more regionally focused nuclear arms race" [25].

This complacency 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 1980s 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 activities and to urge their governments to work to "ban and eliminate" nuclear weapons. National medical associations should support this new statement at the International Council meeting in Oslo in April, and they should begin now the critically important educational and advocacy work called for in the statement.

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Rationing and Differences in Care in Health Systems

Verena Finkenstädt

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 risk 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 health system of statutory (GKV [statutory health insurance]) and private health insurance (PKV [private health insurance]). It is the only country where two parallel health insurance systems exist for major parts of the population.

However, the share of the population with health insurance coverage is an imperfect indicator of accessibility, since the range of services covered and the degree of cost-sharing applied to those services vary across countries (e.g. waiting times, exclusion of services or co-payments). In an international comparative study, the "Wissenschaftliche Institut der PKV (WIP)" [Scientific Institute of Private Health Insurance] 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 or 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.

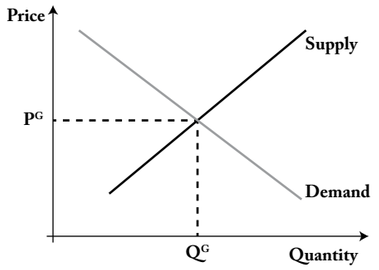

Figure 1. Schematic representation of a perfect market

One 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 increase the price. The price mechanism balances supply and demand. The equilibrium price P^G 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^G. 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

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key role in allocation of resources, but rather the community of the insured citizens or tax payers bear the costs of healthcare (either in whole or in part). Therefore, the patients are allowed to request services at a price below the market price or without charge. In addition, there usually exists a fixed price system for service providers in the healthcare system, i.e. prices cannot be freely chosen by the service provider, but rather are determined by statutes, regulations and other binding rules.

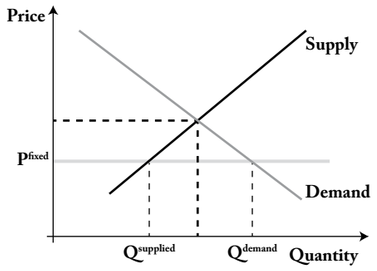

Figure 2. Schematic representation of a market in the case of price limits

As a result of these regulations, the price is below the equilibrium price for those who supply and those in demand (patients). This is represented schematically in Figure 2. For the sake of simplicity, the same price is represented for both suppliers and patients. As mentioned above, the relevant price for patients is often significantly lower or even at zero due to tax-funding or contributions. Thus, the patients are not prevented from demanding the services, and the demand exceeds the supply provided by the healthcare system. If there is no price mechanism, supply and demand must be balanced in another way. Rationing is therefore unavoidable in collectively financed health systems.

Extent of rationing across countries

The extent of explicit rationing is best shown using objectively observable indicators. These include waiting times, limited choice of doctor, restricted services and obligatory co-payments.

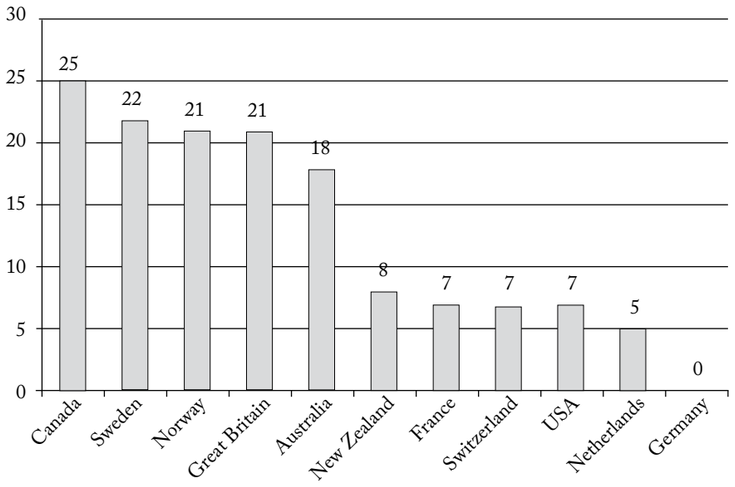

Figure 3. Proportion of patients surveyed who had to wait 4 months or longer for elective surgery in % (Source: Authors' own representation according to the Commonwealth Fund, 2010)

Waiting times

In order to counter the excess of demand for healthcare services, many countries use waiting times [2] [3] [4]. Waiting times arise if the capacity is not sufficient to satisfy the current demand. Through rationing in the form of waiting lists, access to healthcare services is made more difficult for patients, and some patients are prevented entirely from receiving treatment. Waiting times are, however, also deliberately used as an instrument to control demand on the part of patients.

From an economic point of view, waiting times represent a cost for the patients waiting. By associating this "price" to waiting times and treatment, the demand can be reduced. Instead of selling services or medical goods to those who pay the most, those who are prepared to wait the longest are the ones to receive the healthcare service.

In Germany, there are no excessive waiting times [5]. The average waiting time for an appointment with a specialist amounts to only 16 days for the statutorily insured [6]. Regarding waiting times for planned surgery or appointments with a specialist, an international survey by the Commonwealth Fund states that Germany performs best [7]. In Canada, on the other hand, a quarter of all those surveyed had to wait longer than 4 months for planned surgery. In Sweden, Norway, the UK and Australia, it is still around one fifth (see Figure 3).

A look at the official statistics of OECD countries also reveals the extent of waiting times in other health systems: in the English National Health Service (NHS), almost 4.8 million people were on waiting lists for medical treatment or diagnosis at the beginning of 2014. The average time from a GP referral up to a meeting with a specialist amounts to five weeks [8]. In Sweden, about 21,000 patients were waiting for more than 90 days in March 2014, which is the maximum guaranteed waiting time in this country [9]. Patients in neighbouring Scandinavian countries must have more patience. For example, waiting times for a new hip in Denmark vary from one to 16 weeks, or from one to 27 weeks for a meniscus operation [10]. The situation is similar in the Netherlands: in March 2014, patients in Amsterdam did not receive a prosthetic hip until after 29 weeks [11].

Connection between the source of financing and waiting times

It is conspicuous that in tax-funded healthcare systems, waiting times are particularly common and longer than in systems financed by contributions. Typically, waiting times are also statistically covered in tax-funded systems and are often used specifically as steering instruments [2].

Figure 4 makes the connection clear. Here, the countries are arranged according to the proportion of their healthcare system which is financed through taxation. The left-hand side shows the systems financed mostly through taxation such as Sweden, the UK, Australia and Denmark; the right-hand. side represents the systems which are predominantly financed by contributions, such as Germany, the Netherlands or France.

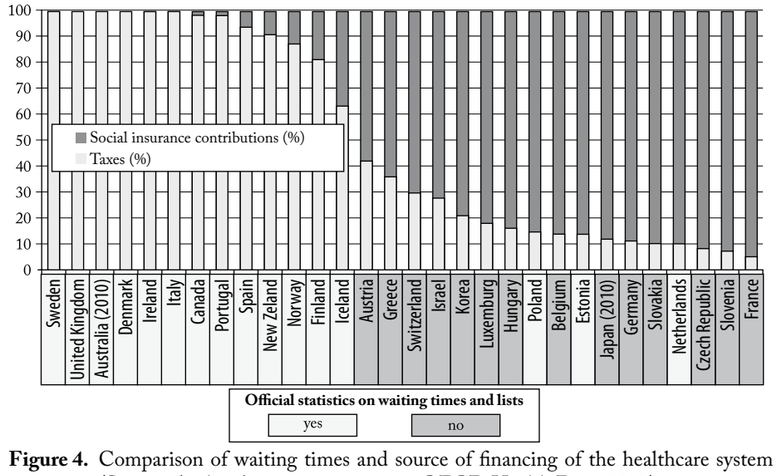

Figure 4. Comparison of waiting times and source of financing of the healthcare system (Source: Authors' own representation; OECD Health Data, 2013)

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 utilized 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 patients, 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

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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 reimbursement [15].

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, 10 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 alia, medicines, remedies and medical aids. In the Netherlands, by contrast, the statutory health insurance includes a patient 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 franchise amounts to around 250 euro per year, converted from francs. Besides this, a further 10 % of the remaining invoice amount must be covered by the insured party themselves [18]. In the French and Japanese health system, obligatory co-payments are also relatively high [19] [20]. In Japan, a contribution of 30 % can be a financial burden, in particular for cost-intensive inpatient treatment.

Even if many OECD countries have implemented rules and regulations to protect particular population groups from excessive financial demands arising from co-payments, the steering effect of co-payments still applies to the remaining parts of the population.

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

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

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.

Duplicate 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 are 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 Netherlands, for example, as 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 evasive reactions, as patients are not willing to settle for the rationed services offered by the public system and acquire the desired services at home or abroad. In the UK, for example, there exists 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 private 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 themselves [21]. In the Netherlands, various types 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 Netherlands have supplementary insurance for dental and orthodontic care, and 71 % have supplementary 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-economic 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 completely differently in societies that have a single-payer healthcare system.

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 the only 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 prosthesis is not included in the service catalogue of a country's public health system, people who would not 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 the inequalities in care in relation to a situation in which a patient must pay out of pocket for the treatment. More people can afford supplemental care 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/or co-payments. This fact is due to the elimination of market mechanisms, including free pricing. As a result of tax-funding and (compulsory) contributions in healthcare systems, the price does not take on the function of allocation and rationing, which it has in a perfect market. In single-payer health systems, barriers to access (e.g. waiting times) lead to differences in care within the population. Here, patients have an incentive to purchase the services on the private market. Public systems thus 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.

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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 environment that nurtures innovation, we can help not only the pharmaceutical industry, but also European patients – and the EU as a whole.

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.

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 690,000 people in Europe, contributing 17% of total business enterprise R&D employment. 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 agree a comprehensive strategy for life sciences, based on three separate but interdependent pillars:

1. Improvement of health outcomes and removal of inequalities to better patient benefits;
2. Support for sustainable and predictable healthcare systems to speed access to medicines;
3. The building of a thriving innovative life sciences sector to promote European competitiveness.

If we are to see this strategy succeed, we need not only collaboration but also open minds. We must be open to conversation, to new ideas and to working together with diverse stakeholders. Coming from 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 bold step 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.

Richard Bergstrom, Director General of European Federation of Pharmaceutical Industries and Associations (EFPIA)

* EFPIA (2013): The pharmaceutical Industry in Figures: Key Data (2013)

** EFPIA (2013): The pharmaceutical Industry in Figures: Key Data (2013)

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The Growing Importance of Health Technology Assessment

Finn Børlum 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 slowing 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).

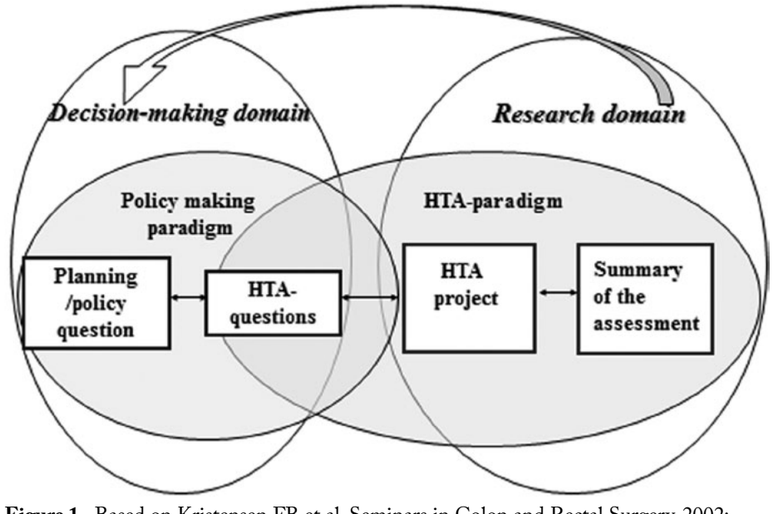

Figure 1. Based on Kristensen FB et al. Seminars in Colon and Rectal Surgery, 2002; 13: 96–103

What is HTA?

The somewhat alienating concept "technology" basically means practical application of scientific knowledge, and in healthcare this would mean diagnostics and interventions in the broadest sense (drugs, devices, medical, surgical, preventive interventions) and the organisational and support systems within which health care is provided (6).

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 – or sizable use of limited resources. HTA works best when there is a well-defined and transparent role 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

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policy- and decision-making in specific political, economic, institutional and clinical contexts. In order to be useful, HTA should fit into the relevant context where it is applied.

Scientific and professional developments that lead to the methodologies applied in HTA

Four main streams of applied research methodology have contributed to the development of HTA: (i) policy analysis; (ii) evidence-based medicine; (iii) health economic evaluation; and (iv) social and humanistic sciences (7). Policy analysis sets a general framework for HTA as an input to policy-making. Evidence-based medicine (i.e. clinical epidemiology) and health economic evaluation set the methodological frames for the analyses carried out as part of an HTA. In addition, HTA may include the application of methodologies from social sciences and humanistic (qualitative) research. This is especially true when meeting the requirements of a broad-scoped HTA which may include organisational, societal and patient/citizen aspects of technology.

What does the increasing importance of HTA mean for the medical profession?

Medical associations and academic/scientific societies should engage and encourage their members to consider getting involved in establishing and sustaining high quality HTA structures and processes in their country. They should be prepared to participate in systematic reviews of available scientific evidence and provide expert interpretation on the clinical and patient relevance of the evidence – and participate in HTA work with other professions.

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 and 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 EUnetHTA 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, Norway, Switzerland, and Turkey and a large number of regional agencies and non-for-profit organisations that produce or contribute to HTA. The network is lead by the Danish Health and Medicines Authority in Copenhagen (Table 1).

Table 1. Relationship Some of the Partner Organisations in Joint Action 2 (2012–2015), e. g.

- UK, NICE, NETSCC (+HIS)
- Germany, IQWIG, DIMDI (+GBA, Medical Valley – EMN)
- France, HAS
- Italy, AGENAS, AIFA, ASSR Emilla Romagna, Veneto Reion
- Spain, ISCIII, AETSA OSTEBA, Avalia-T, AQuAS
- Croatia, AAZ
- Poland, AHTAPOL
- Austria, LBI, HVB, GÖG
- Netherlands, CVZ
- Belgium, KCE
- Portugal, INFARMED
- Sweeden, SBU, TLV
- Norway, NOKC
- Finland, THL, FIMEA
- Denmark, DHMA (Coordinator), CFK Region Midt

An EU Directive on the application of patients' rights in cross-border healthcare was put in place in 2011 established a legal basis (Article 15) for Union support and facilitation of cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the 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 to establish 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 assessment (REA) was developed to inform reimbursement decisions on new pharmaceuticals and medical devices.

Examples of output from EUnetHTA

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

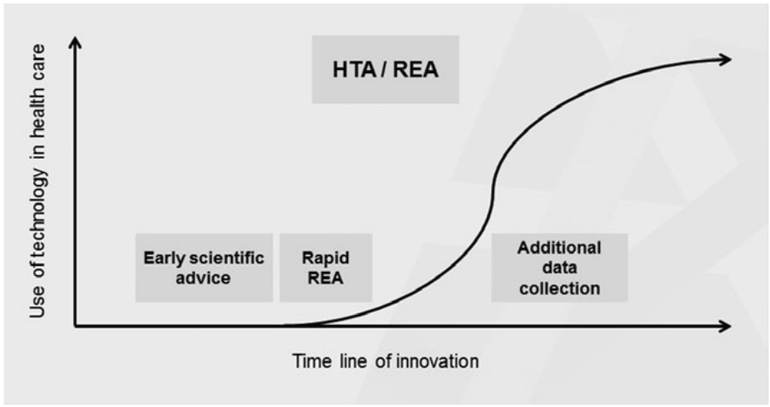

Figure 2. Health Technology Life-cycle

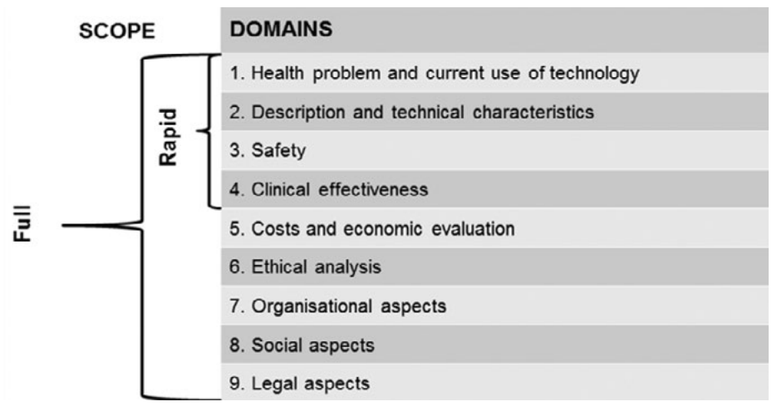

Figure 3. The Domains of the HTA Core Model

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 presented 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 (POP) 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 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 decisions-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

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performing a rapid REA of pharmaceuticals. 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 assessments that have been done jointly by various clusters 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 recurrence (uPA/PAI-1 [FEMTELLE], MammaPrint, Oncotype DX)
- Fecal Immunochemical Test (FIT) versus guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening

Examples of added value coming out of participation in the European cooperation on HTA

The following examples were provided by representatives of organisations that participated in the joint work on the European level supported via EUnetHTA JA1 and JA2 activities ():

- Accelerated and real-time information exchange between HTA agencies in Europe on relevant topics in areas of common interest such as reimbursement status updates in different countries, regulatory activities, stakeholder involvement practices "know-how"
- Particularly for new/"young" HTA agencies participation in and contribution to joint work in a EU-wide cooperation brings benefits of improving a) local competence and capacity in HTA, b) national awareness and political recognition of concrete benefits of HTA for the national/regional healthcare systems, c) methodologies and professionalism in local HTA processes, d) effective communication and cooperation with relevant national/regional policy- and decision-makers (e.g., higher standing of HTA with the national policy makers through e.g., recognition of improved efficiency via national leveraging of the HTA work done somewhere else, contribution to the quality improvement of the national work, etc).
- Development and strengthening of the EU cooperation on HTA has brought about an actual change in a) using English as the publication language for the HTA reports (while local languages are used to publish the summaries of the reports), e.g., in Norway, Austria, Finland, Italy, b) the local HTA production processes, i.e., a new project is not started without checking the POP database and identifying work already done by others or identifying potential partners for a joint work or at least information exchange on the topic, e.g., Finland (THL, FIMEA), Belgium (KCE), Austria (LBI), Croatia (AZZ) already widely practiced this approach.
- Being engaged in the joint work on an EU-level directly contributes to standardisation of the HTA methodologies and indirectly influences the HTA production routines in various HTA agencies towards more consistent/coherent approaches across borders due to the staff being constantly "exposed" to different working methods and solutions in the partner HTA organisations.
- Development of consistent and coherent stakeholder involvement practice in EUnetHTA increases attention to stakeholder involvement issues on the national and regional level and assists the development of national stakeholder involvement processes and communication with stakeholders

Principles of transparency employed in EUnetHTA JA1 and JA2 practices has a strong potential to contribute positively to developing similar national practices, however, it is a process that requires time, initiative and consistent effort on national level

- Increased international visibility of the participating organisations.

HTA and pharmaceutical regulation in Europe

Collaboration between regulators and HTA bodies on a European level has taken place since 2010 by way of the European Medicines Agency (EMA) and EUnetHTA and is part of the ongoing dialogue to support policy-maker decisions in the future. Clinical data generated by pharmaceutical companies during the development process of a medicine is the basis for the evaluation of the benefit/risk balance of a medicine for the purpose of marketing authorisation. The same data informs the assessment of the effectiveness of the new medicines compared to existing therapies, as part of the HTA process to support decision making on appropriate utilisation, price and reimbursement in EU Member States. The first joint EMA-EUnetHTA project responded to a political recommendation to consider how the assessment of the favourable and unfavourable effects of a medicine as contained in EMA's European Public Assessment Reports (EPARs) can best be used to inform the assessment of the relative effectiveness of new medicines for HTA purposes in EU Member States (17).

In 2013 the European Medicines Agency EMA and EUnetHTA have published a joint three-year work plan outlining key areas of collaboration (18). Key areas for the three years include:

- Scientific advice/early dialogue with sponsors, involving medicines regulators and health-technology assessment (HTA) bodies;
- exchange on the development of scientific and methodological guidelines to facilitate clinical-trial design that can generate data relevant for both benefit-risk and relative effectiveness assessments;

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- developing approaches for collection of post-authorisation data to support activities of both medicines regulatory authorities and HTA bodies;
- orphan medicinal products, exploring ways of sharing information for the common benefit of patients affected by rare diseases and the financial sustainability of the healthcare systems.

The EMA and EUnetHTA will review and update the work plan as necessary, and at least once annually.

EUnetHTA Stakeholder Forum

The EUnetHTA Stakeholder Forum was formed to ensure a transparent engagement with a broad range of stakeholders and is comprised of representatives from patient and healthcare consumer organisations, healthcare providers, payers (statutory health insurance) and the pharmaceutical and medical technology industry. The Stakeholder Forum's composition aims at ensuring broad and balanced representation of stakeholder interests.

The purpose of the EUnetHTA Stakeholder Forum is to provide stakeholders with the opportunity a) to participate as stakeholder representatives in the EUnetHTA Joint Actions, b) to observe and comment on the EUnetHTA Joint Action work, c) to provide advice to overarching governance questions in the Joint Actions, and d) to bring forward specific themes and concerns considered relevant by the stakeholders' constituencies and in line with the aims of the EUnetHTA Joint Actions.

The medical profession is represented in the Stakeholder Forum by the Standing Committee of European Doctors, CPME, the European Society of Cardiology and the European Society for Medical Oncology, ESMO. Patients and consumers are represented by the European Patients Forum, EPF, the European Rare Diseases Organisation, EURORDIS, European Register for Multiple Sclerosis, ESC, and the European Consumer Organisation, BEUC.

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Lost in Translation?

The doctor-patient-relationship revisited

Gunta Ancane

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Beneficial medical treatment is based on a trustful therapeutical relationship between doctor and patient. This does not just happen by itself, but must be developed with competence and maintained with care. Through the ages, the way doctors and patients meet and interact has undergone substantial changes, with every era posing specific challenges.

The Patient: help-seeking sufferer or critical consumer?

The traditional view is strongly paternalistic. Bound to the Hippocratic oath, the fatherly physician is commited 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" (first of all do not harm) are the principle professional rules. As a benevolent father-figure, it is the doctor who decides.

Enlightment and The French Revolution brought about a fundamentally egalitarian approach. Questioning authoritative rule eventually leads to the, nowadays, widely accepted concepts of "informed consent" and "shared decision making", promoting patient competence and autonomy. Negotiating disagreements becomes possible, the prevention of abuse and exploitation of the subordinate easier. Instead of command and obedience, two individuals with equal rights make a contract. And finally, it is the patient who decides.

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 tarif 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 might be for him.

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 administrations and lured by bonus payments 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.

At the same time, patients seem to be fighting back. We are seeing a surge in malpractice and negligence suits, and many colleges feel the pressure of receiving bad patient ratings in online portals.

To heal the breach of trust, doctors must account for the current state of medicine and

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decide which kind of medical care they actually prefer.

Medicine: human science or technical engineering?

Today, academic medicine is going through a dramatic structural change which is characterized by the rule of economy, bureaucracy and technology. Bernard Lown, renowned cardiologist, compellingly describes the far-reaching consequences for everyday medical practice in his book "The lost art of healing" (1). We are confronted with a radical erosion of human medicine in its original sense. What is lost, is the specifically 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 elaborate, not only in operating theaters, but wherever they are performed.

Such a development is not without consequences for the status of a profession in society. By means of historical examples, Richard Sennett describes the social decline of once highly respected professions (as was the case with the potter profession in ancient Greece), which is caused by increasing dominance of purely technical processes using mainly manual labor (2).

In this respect, it is highly alarming that personal and "talking medicine" is increasingly outsourced to non-medical professions (pedagogues, psychologists, social workers, etc.). Alongside, and to the detriment of, Cardiology, Oncology or Diabetology we see the establishing of non-medical Psycho-Cardiology, Psycho-Oncology or Psycho-Diabetology. Instead of the present traditional family doctor, we might soon see a non-medical family therapist taking over the verbal and general counselling care.

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

Patients and doctors – strangers or friends?

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 rectal hemorrhage, 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.

Whatever the setting, they face the demanding task of establishing a trustful and sustainable relationship. Coming from two very different worlds, the patient with his suffering, the medical problem and his psycho-social history and the doctor with his medical expertise and the promise to help, they have to get acquainted with one another in order to accomplish the common goal of relief, or hopefully even healing.

Numerous challenges have to be met. The average conversation time in a personal contact between patient and doctor is said to be less than ten minutes. After fifteen seconds the patient's speech is interrupted, either by the doctor's questions, or having to check the computer monitor, or other tasks such as filling in forms (3). Only half of the information conveyed by the doctor is properly understood by the patient and half of this again forgotten after half an hour. It is perfectly clear that medicine by the minute leaves no room for sufficient understanding, let alone exchange.

This is in strong contrast to the requirements of adequate medical care and efficient treatment.

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 practices goes up to some thirty or forty percent and reaches up to sixty percent in secondary care, e. g. specialised neurological or gynecological units (5). The clinical spectrum ranges from chronic pain syndromes such as headache and back-pain, or syndromes with compromised organ function such as vertigo, tinnitus, arrythmias, hyperventilation, irritable bowel or sexual dysfunction, to more generalised pictures such as agitation or burn-out (6). Psychocomatic 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

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to understand subliminal, hidden messages and to discover those problems the patient is not yet able to communicate in an open and direct manner. As Balint put it, if the patient could clearly name his problem, he would not have to present a symptom (7).

Patients with psychosomatic disorders are especially difficult to deal with. Whereas "ordinary" patients might be expectant and vulnerable, psychosomatic patients in particular are additionally prone to feeling disappointed, insulted, hurt and abandoned by their doctor. Often limited in their abilities to adequately express their fears and wishes, they make their medical counterpart offer help by proposing medical actions in the form of prescribing drugs, suggesting additional diagnostic procedures or even recommending surgical interventions.

Doctors do so especially when confronted with affect-laden signals from their patients, for example, when confronted with statements like, "Doctor, I can't stand this back pain anymore", "my head is burning like fire", or, "this tears my heart into pieces". Overstrained and overwhelmed by the patient's relational attitude it seems a way out is to at least present a medical "gift" (8). "Ut aliquid fiat" (to do something) may be one of the most frequent indications in medicine. As one collegue put it, "sending that patient to another CT-scan bought me one month of peace and quiet". This example shows that doctors, in their desperation, sometimes reject their patients by sending them to unnecessary examinations or referring them to another colleague. If in the back of the patients mind is the notion that evidence based medicine cannot understand their suffering and is even rejecting them, then alternative medicines gain appeal, which is a dangerous trend if left unchecked.

In order to offer these patients adequate care, skills and knowledge in understanding and handling patients, emotionally difficult for the doctor, are necessary. Doctors' widespread wish to offer comprehensive help, including somatic and psycho-social support, is specifically realized in Psychosomatic Medicine. Apart from specialist training, there are several opportunities. Balint-groups and courses in primary psychosomatic care are especially helpful for every physician responsible for medical care, whether it be conservative medicine or surgery.

As Edward Weiss wrote in 1943, the crucial point in psychosomatics is "not to study the soma less; it only means to study the psyche more" (9).

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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 analgesic 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], India [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-in fact a silent epidemic has taken hold [4,7, 8, 9, 10, 11]. CKDu in this context has been given the name 'Mesoamerican 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 sugarcane 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-pre-existing diabetes and hypertension-are largely absent in this epidemic [4, 15, 17]. The cross-sectional studies, through medical record 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 nephrotoxic 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-steroidal anti-inflammatories, analgesics, or aminoglycosides), 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

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history in areas with high adult CKD mortality [23].

Elucidating the cause(s) of the MeN epidemic will require investigating many potential risk factors as well as considering a "previously undescribed mechanism capable of causing CKD" [4]. As discussed below, both substantial public health and clinical efforts will be needed to tackle this problem now, even without conclusive evidence regarding the causes of the epidemic.

Sri Lanka

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 prior history of diabetes, hypertension, or other renal disease [3]. Epidemiologic data has helped trace most of these cases to a region known as the North Central Province, a relatively dry region in the interior of the country with a heavy reliance on irrigation systems for agriculture [2]. In this region, the point prevalence of CKDu has been estimated at 2-3%, a figure which is likely underreported [25]. Other reports have estimated a prevalence of 5.1% based on microalbuminuria [1]. Widely quoted figures in the lay press state the death toll as high as 20,000, more 200-450,000 currently affected [26]. Patients typically affected included young males, generally from farming communities with low-socioeconomic status. The affected population has be found to have a higher prevalence of microalbuminuria, as well as pathologic findings including tubular atrophy, mononuclear interstitial cell infiltration and tubular fibrosis [27,28]. Disease progression is greater in men than women, with disparities in prevalence widening in stage 3 and 4 CKDu [3]. Numerous factors have been proposed to account for the development of CKDu in this population, including herbal medications, snakebites, genetic predisposition, and more common causes of CKD such as diabetes mellitus and hypertension. However, the majority of the evidence in Sri Lanka points to environmental exposures as a major contributing factor to the increased prevalence of CKDu [29, 30].

Potential environmental exposures in this community are varied, and include heavy metals, pesticides, contaminated well water as well as food-borne mycotoxins and air pollution [3]. Due to the agrarian nature of the North Central Province, most studies focused on potential heavy metal and pesticide exposure from soil, well water, irrigation channels, and locally grown foods. This was supported by early studies showing that microalbuminuria in the local population was associated with drinking well water from 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 presence of heavy metals such as cadmium, lead and arsenic as well as numerous common pesticides. Statistically significant elevations in cadmium levels were found in the urine and nails of cases versus controls. In fact, urine cadmium levels corresponded with severity of CKDu on a dose-response basis. Arsenic levels were also significantly elevated in the urine and nails of cases compared to controls. Finally, various pesticides were found in cases at levels well above reference levels [3]. Results regarding the source of these exposures were mixed. While initial studies found elevated cadmium levels in well water, more recent studies have shown cadmium levels to be within normal limits [3,27]. However, elevated levels of cadmium and arsenic were found in local foods, primarily vegetables and fish, as well as the soil [3,30]. It is postulated that these heavy metals are primarily entering the food chain from unregulated use of pesticides (and possibly fertilizers).

As discussed above, evidence of CKDu in other regions such as Central America and the Balkans is leading to greater awareness of the role local environmental factors play in development of kidney disease [20, 31]. While the case in Sri Lanka is different in that heavy metals seem to be playing a more significant role in the development of CKDu, there are some commonalities. Studies have found evidence that, as in Central America, agricultural work in the hot climate of Sri Lanka leads to dehydration, which may be exacerbating the toxic effects of heavy metals and agrochemicals [14, 27]. It is possible that increasing hydration and improving access to clean drinking water may be able to prevent or slow the progression of CKDu in both Sri Lanka and Central America [3, 27].

In those already afflicted with CKDu, studies have found that the presence of comorbidities hastens disease progression, especially in men. A prospective cohort study from the North Central Province found that comorbid hypertension was significantly associated with disease progression, especially in men [32]. It is possible that treatment of hypertension and other comorbidities may slow progression, however this is yet to be shown.

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 mycotoxin exposure, the mineral content of drinking water and

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genetic predisposition to the development of CKDu may play a significant a 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?

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 [35]. The Sri Lankan government is also considering measures 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 Ministries 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.

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 preventive 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 and
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 that meet multiple criteria could then be further evaluated for the presence of albumin or protein in the urine with urine dipstick. 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.

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Beyond Chlor Hühner & Nürnberger Bratwürste: The Case for Physician & Organized Medical Advocacy to Promote Health in Trade Agreement Negotiations

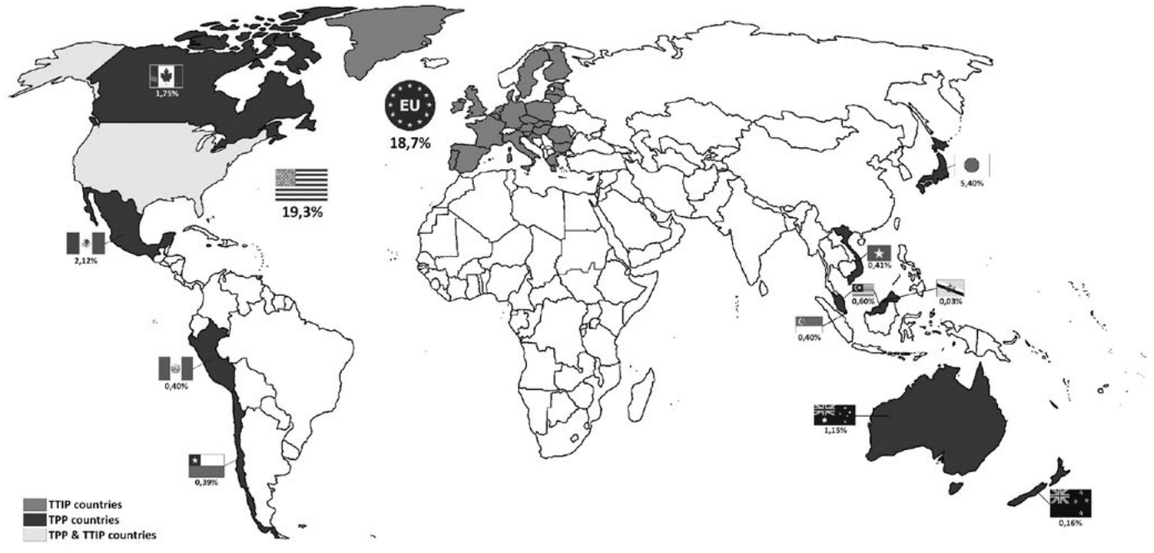
Over the last five years, a new generation of trade agreement negotiations has emerged with the purported goal of increasing economic growth [2]. The Trans Pacific Partnership (TPP), Transatlantic Trade & Investment Partnership (TTIP), Comprehensive Economic and Trade Agreement (CETA) and Trade in Services Agreement (TiSA) negotiations seek to further trade liberalization while establishing a new global governance framework for trade beyond existing World Trade Organization structures. These deals have the potential to (re) shape public health and health care globally [1] with significant implications for efforts to address health inequities and the social determinants of health [4-8], which are both emerging priorities of the World Medical Association [97].

More than fifty countries, representing more than half of the global GDP, are currently engaged in this new generation of trade negotiations. The effects of these agreements, however, are not likely to be limited to countries currently participating in negotiations. Many non-participating countries have sought or are seeking to join negotiations. Moreover, the U.S. Trade Representative has repeatedly signaled that these agreements are being negotiated as a "template" for all future trade agreements [2], suggesting that these negotiations may have truly global ramifications.

Announced in 2008 and launched in 2010, TPP negotiations currently include twelve parties: Australia, New Zealand, Singapore, Brunei, Malaysia, Japan, Peru, Chile, Mexico, the United States and Canada. The TPP mandate is broad with twenty-nine plus chapters across economic sectors.

Launched in 2013, TTIP negotiations currently include the European Union and United States. Similar to the TPP, the TTIP has a broad mandate with implications across economic sectors. Although models and estimates vary, the TTIP has been projected to result in up to a 0.5 percent increase in the European GDP with similar projections available for the US economy. In the case of the TTIP, up to 80% of these gains are projected to be attributable to reductions in non-tariff trade barriers, suggesting that the bulk of projected benefits would be a result of "regulatory harmonisation" [9].

Similar in character and scope to the TPP and TTIP, CETA negotiations included only



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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, Israel, 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 "untapped potential" for the "globalization of healthcare services" [11]. However, very limited information is available about the status, scope and direction 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 documents 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 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 [14,77].

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 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 provisions to protect advertising and licensing, and technical barriers to trade provisions [16-20,66]. If tobacco is not excluded, these agreements could sabotage existing tobacco control efforts under the World Health Organization's 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], alcohol control measures may be similarly 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 contain significant provisions which seek to redesign the health care services landscape [31]. Of particular concern are provisions which could facilitate commercialization of health systems as well as promote health tourism, "health exporting" and/or "health offshoring" [31-35]. ISDS may also have implications for health insurance and health care services markets. Under existing ISDS provisions, there have been at least two cases where legislative barriers to the expansion of private provision of services and/or coverage have been challenged. The US experience suggests that commercialization of health care coverage and services is associated with reduced coverage and access to health care services and increased costs. Thus, such commercialization could be inconsistent with current efforts to achieve universal health coverage [36]. Whether and how health care services might be "excluded" from each potential agreement has been subject to significant controversy and speculation [77].

As the World Health Organization and Global Health Workforce Alliance is seeking to develop a Global Strategy on Human Resources for Health [89], trade agreements may also unanticipated and unintended consequences on the supply and distribution of the health care workforce. In some countries, higher education including medical education may be subject to commercialization [86-88] and reduced public financing which may have negative implications for accessibility and affordability. Leaked TiSA documents suggest that the agreement may promote significant "health exporting" and expanding health insurance portability across national borders [84] which may affect the supply and movement of health professionals globally. Trade agreement negotiations may also implicate ehealth 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 [55], 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 biologics;
- 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 Agency (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 Medical Association policy opposing the patenting of such techniques [51], it is critical that an exception, similar to 35 USC 287(c), be incorporated into any agreement to prevent potential liability for patent infringement for health 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

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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 occupational 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 liberalization [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 national member associations and other medical groups have responded to the potential threat posed by these trade agreement negotiations. In 2014, the German Medical Association General Assembly adopted a resolution urging adherence to democratic principles including transparency as well as protection of patient safety and the exemption of health care services from any agreement [69]. The Standing Committee of European Doctors (CPME) has issued statements urging transparency in TTIP negotiations [70] and called for "exemption for the provision of healthcare services from the scope of application of the TTIP" [71]. The British Medical Association has expressed concern about the potential effects the TTIP may have on the privatization of the NHS and other European health care systems [73-74].

The Australian Medical Association Federal Council has approved a resolution recognizing that international trade agreements have the potential to undermine the Australian Pharmaceutical Benefits Scheme and hinder government's ability to protect public health [72]. With respect to the TPP, the AMA has also expressed concern about the secrecy of negotiations, noting that the agreement would advance commercial interests at the expense of patients, and the government's ability to improve public health [72]. The CEO of the Public Health Association of Australia highlights some key concerns around the effects of the provisions included in the TPP, stating that organisations seeking effective public health policies such as nutrition labeling will be burdened by more hurdles [79]. The New Zealand Medical Association supports the call for an independent assessment into the TPP, citing alcohol, tobacco regulation and affordable access to medicine. The NZMA Chair stated that "We need to have a clear understanding of the possible effects of the TPPA on current and future policy settings and directions – before we are committed to such a deal" [83]. The Japanese Medical Association President Yokokura has publicly expressed concern about the potential negative implications of the TPP on Japan's universal health insurance program and pharmaceutical pricing [99]. The American Medical Association maintains policy on international trade agreements [94] and has expressed support for exemption of tobacco products and alcoholic beverages in the context of ongoing TPP negotiations [95].

Last year, the International Federation of Medical Students' Associations (IFMSA) also adopted a comprehensive trade and health policy statement urging that trade agreements, "...should not prioritize multinational corporate profits over patients and consumes around the world" [80]. IFMSA and its 126 national member organizations have been active in advocacy to promote health in trade agreement negotiations [81,92-93].

While current efforts by WMA national member associations and similar groups within the organized medicine community to promote health in trade policy are encouraging, the stakes of current negotiations are high and a more coordinated advocacy response may be warranted. Although trade policy has not traditionally been an advocacy priority for global organized medicine, this new generation of trade agreement negotiations including the TPP, TTIP, CETA and TiSA pose numerous unprecedented direct and indirect challenges for health and health care – challenges that may profoundly affect our patients and the practice of medicine.

The World Medical Association (WMA) Statement on Patient Advocacy and Confidentiality stipulates that medical practitioners have a duty that includes "..advocating for patients, both as a group (such as advocating on public health issues) and as individuals" [75]. Moreover, the WMA Statement on Social Determinants of Health "[t] here is a growing movement, globally, that seeks to address gross inequalities in health and length of life through action on the social determinants of health...Doctors should be well informed participants in this debate" [76]. Given the threat of trade agreements to health and health care and the value of a health in all policies approach, the medical community – both physicians and organizations like the WMA – have a professional obligation to engage and advocate in trade agreement negotiations and policies to protect and advance health.

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