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Democracy and human rights under Public Health Emergency (PHE) threat

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SUMMARY

This issue of the ASSET paper series - Epidemics and Pandemics: The responce of Society discusses is dedicated to the discussion on “Democracy and human rights under Public Health Emergency (PHE) threat”.
Specifically Dr Solveig Wallyn from the Welzijn, Volksgezondheid en Gezin, Belgium discusses the role of Democracy and human rights in a Public Health Emergency (PHE).
Ethics in influenza pandemic planning is discussed by Eva Benelli & Alessandra Craus, from Zadig.
Finally, Open and Responsible Research and Innovation in Pandemics is presented by By Alberto d’Onofrio and Mitra Saadatian-Elahi from Lyonbiopole.

Democracy and human rights in a Public Health Emergency (PHE)

by Solveig Wallyn[1]

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Human rights are at the very core of EU democracy. With the entry into force of the Lisbon Treaty in 2009, the Charter of Fundamental Rights of the EU became legally binding and the EU acceded to the European Convention on Human Rights. The Charter contains rights and freedoms under six titles: Dignity, Freedoms, Equality, Solidarity, Citizens' Rights, and Justice.

In this contribution I would like to have a quick look at how far these principles of democracy and human rights are stressed with the current flow of migrants and people seeking protection towards the EU and how health can contribute in preserving these rights.

However very clear the EU basic principles seem, we might wonder if the European health systems can somehow coop and apply these fundamental values in the context of current migration, overburdening the health service delivery of the host countries.

Health is written as a human right since long in international texts. Examples include the 1946 World Health Organisation Constitution, the 1948 Universal Declaration of Human Rights, and the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR).

Health is indispensable in fulfilling the fundamental human rights principle that human dignity is inviolable.

The right to health covers the right to accessible, available, adequate-quality health care. It also includes a wide range of factors that can lead to a healthy life, including the protection of health, providing equality of opportunity for everyone to enjoy the highest attainable level of health; • the right to prevention, treatment and control of diseases; • access to essential medicines; • maternal, child and reproductive health.

Health as a human right therefore defines both a legal obligation and a set of values that are applied in a human rights-based approach to local, national and global health.

The individual rights to health may sometimes be balanced against the greater good for a community. Health concerns can according to the international agreements be used as potential restrictions "*No restrictions shall be placed on the exercise of these rights other than such as are in accordance with law and are necessary in a democratic society in the interests of national security or public safety, for the maintenance of order public, for the prevention of crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.*" . (Convention Protection of Human Rights).

Public health protection is a permissible ground for limiting the rights to liberty of movement, freedom of religion, of expression and of association. In various countries, quarantines

and limitations on freedom of movement often have been imposed for public health reasons.

There is a danger that such restrictions on rights may not be justified on health grounds. Under international human rights law, national decisions to limit rights may be overseen by international committees, which can require states to provide adequate justifications for rights limitations.[1] Many human rights documents acknowledge this need for extreme measures, but prioritize public health only as a method of last resort. [2]

But while the health and well-being of individuals suggests the need for adequate medical personnel, diagnostics, and treatment, public health refers to disease prevention and health promotion at the level of the collective: defined as group, community, organizational, geographical, national, or international levels.

The current situation of people trying to cross the EU borders as a consequence of social and political instability, is a humanitarian disaster and crisis which calls for emergency responses.

Since years and certainly in the aftermath of the terrorist attack of 9/11 in the US, the anthrax threat, the EU has organised itself to protect lives and assets of EU citizens as well as to provide effective assistance to non-EU countries, as an important expression of European solidarity. Enhancing Europe's resilience to crises and disasters is one of the core objectives of the Internal Security Strategy in Action (2010).

The Solidarity Clause in the EU Treaty introduces a legal obligation to assist each other in case of a terrorist attack or a natural or man-made disaster. The implementation of this clause, aims for a better organised EU and a more efficient crises management.

Different crisis coordination mechanisms have been set up to enhance the EU's crisis management capacity. The EU emergency and crisis coordination arrangements (EU-CCA) define rules for interactions between EU institutions and affected EU States, while the integrated EU arrangements with cross-border effects (EU-ICMA) facilitate practical cooperation.

At Commission level, the rapid alert system – ARGUS - brings together all relevant Commission services to coordinate efforts during an emergency.

Public health mechanisms have been strengthened to respond accurately to health threats. Decision 1082/2013/EU on serious cross-border threats to health, is coming into play for events which may constitute public health emergencies of international concern under the International Health Regulations, provided that they fall under one of the defined categories of threats in this decision.

The EU is seeking to harmonise and support national efforts to better manage returns with the Return Directive and the Asylum, Migration and Integration Fund for non-EU nationals who are staying irregularly.

We see here a package of legislation, principles, instruments to protect EU citizens and in some cases for individual non-EU citizens to benefit from an equitable treatment. However, we are confronted at our borders with a flux of people and no doubt a shortage in EU and Member States resources at a point

[1] HEALTH - A HUMAN RIGHT? Shishir Tiwari 1 and Gitanjali Ghosh - N. J. Comp. Law Vol. 1 (1) 2014, pp 13-29.

[2] PUBLIC HEALTH AND HUMAN RIGHTS IN AN ERA OF EPIDEMICS - Ryan Rollinson © 2015 by The University of Chicago.

where the concept of solidarity amongst EU Member States is becoming doubtful.

It's a very complex situation, in which without knowing the complete context, one might jump to quick conclusions.

Nevertheless, the threat is real that rights to health are less taken into account, which may lead to a violation of the individual rights, and which entails a public health risk for that community of migrants waiting for a new life in settlements and camps.

The emergency in public health is there in many ways. Continuing to protect the EU's public health, is one requirement. At the same time, protecting the individual physical and mental health of a migrant but also protecting the health of the migrant community. And organising the available resources, including respect for the aid workers.

The issue of dealing with a public health emergency and countering public health threats from outside the EU brought humanitarian aid efforts and support together. In the current context, we may wonder if the real threat is not about respecting human rights.

We should keep in mind that the role of governments, professionals, international institutions is a matter of building solidarity in order to give those seeking for protection the same opportunity as any EU citizen.

Ethics in influenza pandemic planning

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ABSTRACT

Introduction: This work evaluates the relevance and the application of ethical principles in the development of national pandemic plans.

Methodology: A semantic analysis on ethical issues was conducted of eleven national influenza pandemic plans (10 from European Union (EU) member states (MS) and one from Switzerland), including EU and WHO documents.

Results: The semantic analysis showed a lack of discussion on ethical issues in most European pandemic plans.

Discussion: This work may encourage the discussion on the necessity to update all national influenza pandemic plans in order to include ethical issues.

1. INTRODUCTION

Influenza pandemics are unpredictable but recurring events that can have severe consequences on human health and socio-economic life to global level. For this reason, the World Health Organization (WHO) has recommended all countries to prepare a pandemic influenza plan and to keep them constantly updated, following its own guidelines [1]. The WHO guidance – revised in 2009 to help policymakers to balance individual and community interests when dealing with national influenza preparedness plans – stresses the importance of ethical principles such as equity, utility/efficiency, liberty, reciprocity and solidarity. Any measure that limits the individual rights and civil liberties (such as isolation and quarantine) must be necessary, reasonable, proportional, equitable, not discriminatory, and not in violation of the national and international laws. For such purposes, WHO has developed a framework of detailed ethical considerations, in order to ensure that overall concerns (such as protecting human rights and the special needs of vulnerable and minority groups) are addressed in pandemic influenza planning and response [2].

In 2008, WHO published another document aimed at providing a more comprehensive analysis of the ethical and policy issues [3], and emphasizing that every public health interventions must be implemented within the context of internationally recognized human rights, according to the Siracusa Principles [4].

WHO has highlighted that guidelines included in these documents should be used from all countries to develop or update national influenza preparedness and response plans, in conjunction with the WHO checklist for

influenza preparedness planning published by WHO in 2005 [5].

Experts from the ASSET project conducted a study on this issue, performing a semantic analysis of national pandemic plans developed by ten European Union/European Economic Area (EU/EEA) countries (Austria, Croatia, Czech Republic, France, Hungary, Iceland, Ireland, Italy, Spain, United Kingdom) and one by Switzerland, member of European Free Trade Association (EFTA), including EU and WHO documents [6]. All documents were accessed through the ECDC official website, whenever a translation in English was available [7].



2. Methodology

The semantic analysis was based on two keyword lists: in a first, generic list, keywords represent areas of possible ethical interest; in a second, more specific list, keywords are more precisely related to ethical issues actually addressed in each one of the national plans.

Aim of the research was to assess and compare the occurrence rates of each keyword within both lists, in order to evaluate the relevance of ethical issues and the application of ethical principles in the development of national preparedness and response plans.

The results of the semantic analysis are shown through data visualizations that allow to describe a complex theme and to share it easily on the web in graphics [6].

3. Results

ASSET analysis shows that ethical issues have not been addressed in most national influenza pandemic plans. They are mentioned in some, like in the Italian and Spanish, while ethical concerns have been discussed more extensively in the French, English, Swiss and Czech pandemic plans.

However, only UK, France and Switzerland dedicated a specific section – also included in the index – to ethical questions as regards the management of an influenza pandemic.

In all national plans examined there are issues which are considered ethical. For instance, in the list of keywords generically connected to ethics, the words isolation and quarantine are mentioned in all documents examined, but mostly as measures aimed at limiting the spread of the disease. However, only some of the plans consider the ethical implications of these measures which limit personal freedom, such as the necessity of a transparent communication and the respect of personal needs and human rights.
Similarly, the word borders would also require ethical consideration, especially when a document states that an individual coming from a country at risk should be subjected to screening, facing, for example, the risk of stigma.
Although the particular human rights may be limited in exceptional circumstances, the focus on the dignity of the human being must always be a priority [6].

4. Discussion

The semantic analysis of a number of national influenza pandemic management plans in Europe showed little concern for ethical

aspects and a lack of true discussion of ethical issues in most with the exception of the UK, French, Swiss and Czech plans [6].

The relative abundance of national guidelines, international policy documents, technical reports and scientific papers that discuss fundamental rights issues and different types of ethical considerations in pandemic preparedness and response reveals the importance and the need to place those issues in the right context and the right proportions. Beyond WHO guidelines and documents, the CDC has also developed ethical guidelines in 2007, as a foundation for decision making in preparing for and responding to pandemic influenza. In these, the Ethics Subcommittee in a first section addresses general ethical considerations and in a second section deals with particular ethical issues in pandemic influenza planning such as social distancing and restrictions on personal freedom procedures [8].

The Forum on Microbial Threats of the US Institute of Medicine (IOM) in 2007 has prepared a workshop summary on Ethical and Legal Considerations in Mitigating Pandemic Disease, highlighting that many of the proposed disease mitigation strategies may have unintended – and often undesirable – consequences, such as adverse economic effects or the restriction of civil rights and civil liberties. Through this meeting, participants explored lessons learned from past pandemics, identified barriers to equitable and effective responses to future pandemics, and examined opportunities to overcome these obstacles through research, policy, legislation, communication, and community engagement [9].

On April 2015 in the framework of the EU co-funded project ASSET, experts published an Ethics, law and fundamental rights report, for contributing to the accomplishment of a major objective of the ASSET project, which is the establishment of baseline knowledge on Science-in-Society related issues about pandemics. This report identified and drew attention to the various ethical, legal and fundamental rights implications in situations of public health emergencies, such as epidemics or pandemics. Ethical considerations should not be seen as part of a problem, but rather as part of a solution with shared values for both individuals and key stakeholder groups within society. Policy and decision makers should take into account ethical considerations to inform and colour all aspects of pandemic planning for preparedness and response. More importantly, national governments and local authorities should strive to cultivate a "culture of ethics" across the entire spectrum of societal actors and stakeholders who are likely to be involved – and make or act upon decisions – at different phases of a pandemic [10].

But despite awareness of the relevance of ethical issues, they are still underestimated in national influenza pandemic plans. In fact, our study shows that some of them, like the Italian and Spanish plans, just mentioned them while other MS plans discussed them in more details.

Only 4 national plans (United Kingdom, France, Switzerland and Czech Republic) among those available in English on the ECDC website, have a dedicated section to this topic, including ethical issues among the main principles of a pandemic management plan.

This is even more relevant since the analysis revealed multiple areas of possible ethical

interest within the different plans, as data visualisations have clearly demonstrated.

This analysis has some limitations, such as the inability to examine all EU/EEA MS national pandemic plans as they were not all available in English and the fact that not all pandemic plans examined are updated in accordance with WHO guidelines revised in 2009. Also, this semantic analysis has used some keywords that are not always matching with the context in which they may occur in the documents examined.

Despite these limitations, however, this work may represent a useful tool to guide future development of influenza pandemic plans. Exceptional circumstances such as public health emergencies in case of epidemics and pandemics must not provide a reason for planners and policy makers to ignore fundamental human rights and ethical issues that can arise at different phases of a pandemic. It aims at encouraging discussion on the necessity to update all national pandemic plans in order to properly address ethical and other SiS issues, such as gender and participatory governance, which have also proved to be of great relevance in case of epidemics and pandemics [6].

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Open and Responsible Research and Innovation in Pandemics

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Abstract

In this short paper, we introduce and comment the key concept of Patient and Public Involvement (PPI), which is emerging as central in Public Health related research and development, coherently to the framework of Science in Society. In particular we report here the PPI aspects that mainly influenced the design of the Roadmap to Open and Responsible Research and Innovation in Pandemics of the EU project ASSET (Action Plan on Science in Society in Epidemics and Total Pandemics).

1. Introduction

The ASSET project (Action Plan on Science in Society in Epidemics and Total Pandemics) is a 48-month long project with the aim to address scientific and societal challenges raised by the occurrence of pandemics and epidemics.

The main objectives of ASSET are to (i) establish baseline knowledge about influenza and other epidemics and pandemics and their wider societal implications (ii) the extent of research

and innovation into epidemics and pandemics (iii) the existing operational and regulatory environments across Europe.

A fundamental task within this project has been the design of a Roadmap to Open and

Responsible Research and Innovation in Pandemics (namely it was the Task 3.2 of ASSET), with particular focus on the possibility and pre-conditions for a citizens-driven, research and innovation on vaccines and antiviral drugs. The Roadmap was central in the project, being the main complement of the strategic plan of ASSET.

A key concept is that open innovation in pandemic related research requires initial investments by traditional Public Health actors (Scientists, Policy Makers such Ministries of Health and International Organizations etc.). Indeed, this new approach demands a shift in the traditional technology-centered approach of scientific research in Public Health and its implementation.

The innovative concept of Patient and Public Involvement (PPI), which is an essential paradigm for the Science-In- Society, has been central for the development of the Roadmap. An indeed, from listing existing PPI initiatives in various fields, the roadmap has been drafted.

In this work we describe the concept and the key ideas of PPI that were most relevant to the design and writing of the Roadmap.

2. The concept of Public and Patient Involvement

PPI is defined, following the lines of the INVOLVE report of UK NHS [Hayes 2012], as a research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them. PPI represents an ideological shift within which patients and Civil Society representatives have a formal and recognized role to effectively get involved in researches that concern their health-related issues [Mitchell 2015].

The role of patients in health has already been acknowledged by the epidemiologist Richard Doll (1974) who advocated that evaluation of health care services should be based on their clinical effectiveness, economical efficiency and social acceptability. Historically, social acceptability or patient-based evidence has received less attention [Staniszewska 2014], and limited in giving consideration to the patient's suggestions and rights in clinical practice.

Recently, it emerged a more profound concept: the idea that patients have the full capacity and right to be directly involved in biomedical research: the concept of "patients as co-researchers" [van der Geest 2010], not in the more technical phases, however.

The level of patient's participation can range from tokenism to joint decision making by professionals and patients [Elberse 2011], and in particular [Caron-Flinterman 2015]:

- Consultation: Patients are consulted for their needs. A critical issue is however that there is no guarantee that their input is taken into consideration in research agendas.
- Participation: Patients are involved in the research agenda in a more formal way but again the final decision belongs to HCPs.
- Partnership with real power-sharing between HCPs and patients-partners, and where there are genuine negotiations between patients and HCPs.
- Delegated power: Patients have a dominant position in decision-making process.
- Patient control: Decision-making in biomedical research belongs to patients.

The main questions are "how" and "when" patients should be involved and "what" should be their level of involvement in different phases of R&D process i.e. 1) preparation of research topics/questions; 2) design and execution; 3) analysis; 4) communication of results/policy making decisions.

The "how" side of PPI refers to the way HCPs could come into contact with the targeted population of patients and vice versa.

The "when" part concerns the stage at which PPI could have the most beneficial impact on research agenda. PPI at the very beginning stage and throughout the process is the ideal condition [Caron-Flinterman 2015].

The "what" part is extremely important. Thus the involvement of patients and non-research HCPs needs a careful guidance by research HCPs involved in the projects.

The role of PPI is also of the utmost relevance for what concerns the part of research design concerning the interplay with patients, such as: the scheduling of visits and of blood sampling, use of invasive devices, etc.

As far as research communication is concerned, public and patients have the potentiality to add a new and extremely important dimension to scientific communication: the ability to speak to (and to be understood by) a far more large audience.

Both professionals and patients should be specifically trained in order to have good and sustainable cooperative relationship.

Different models of partnership between experts and patients have been reported in the literature [Pietroni 2003; van der Geest, 2010; de Wit 2011] (see also Table 1 of Abma 2014a).

3. How to translate PPI in the Public Health practice?

Currently, in some fields there are some cases of involvement of patients in limited phases of research (final or initial depending on the research) but what is important is their sustained involvement throughout the R&D process [Abma 2014b; Callard 2012], apart, of course, the most technical ones. For example, as far as research agendas are involved, the role of patients is limited usually in early phases [Abma 2014b] and then abolished or minor, even when patients were the initiators of research agendas. On the contrary, in translational research, the contribution of patients is marginal (and barely definable as research) in the final phases of the translational medicine pipeline [Callard et al, 2012].

ZonMw, a leading health charity in Netherlands has elaborated a list of 21 recommendations to foster PPI [van der Geest 2010]. More recently, The European League Against Rheumatism has elaborated a shorter list of recommendations [de Wit 2011] that are the following:

1. Participation of patients should be considered in the overall process of research to provide experiential knowledge that can improve the quality, relevance and validity of the research process.
2. A minimum of two patient research partners should be involved.
3. Identification of potential patient co-researchers should be supported by obvious definition of the expected contribution;
4. The selection of patients should take into account communication skills and motivation and in a team setting.

5. The principal investigator must facilitate and encourage the participation of patient partners and consider their specific needs.
6. The principal investigator must insure that partner patients receive appropriate information and training.
7. The contribution of patients should be officially recognized.

Research elaborations on PPI are not only theoretical speculations, but they have been implemented in practice in Europe and other developed countries. Public involvement in international health technology assessment activities is also growing.

4. Implementations of PPI and the case of Breast Cancer

PPI is emerging, although with some difficulties, as an important paradigm for Public Health Policies, and in a number of cases PPI really led to improve participation of the civil society, associations of consumers and patients in health-related research. Below we provide a non exhaustive list of practical implementations of PPI:

- Rare Diseases: several PPI initiatives for rare diseases are in place. The European Organization for rare Diseases (EURORIDS) is the most notable of those initiatives (www.eurordis.org). For example: Lyme Disease [Elbaum-Garfinkle 2011]; the ERA-Net project (http://www.cordis.europa.eu/coordination/era-net.htm) [Marvis 2012]; International Rare Disease Research Consortium (IRDiRC; http://www.irdirc.org/) [Marvis 2012]; RareConnect (https://www.rareconnect.org/fr); the National Organization for rare Disease (NORD; http://rarediseases.org/) ; the Life Raft Group (LRG; https://liferaftgroup.org/).
- AIDS: The European AIDS Treatment Group (EATG; www.eatg.org).
- Chron Disease: Nurses-European Crohn's & Colitis Organization (N-ECCO; https://www.ecco-ibd.eu/).
- Parkinson Disease: "devices for dignity" (http://www.devicesfordignity.org.uk/).

Moreover, one of the most important areas where PPI has been influential is Breast Cancer Research and Healthcare. Indeed, in this area a very large number of associations exists and also a general coordinating forum "Europa Donna" (www.europadonna.org), which presents itself as "the first European women's movement against breast cancer" [Mosconi 1999]. Europa Donna, which is active in more than 20 European nations, has among its main objectives the promotion and direct involvement of women in Cancer Research, and in particular in the research for the development of best treatment practices, cancer prevention and education. For example: Europa Donna has directly been involved in the definition of recent ESO-ESMO 2nd international consensus guidelines for advanced breast cancer (ABC2) [Cardoso 2014] (see also Cardoso, 2012).

Europa Donna advocates for breast cancer screening and has contributed to conceptual research for the improvement of best practice in this field [Knox 2011]. In addition, Europa Donna has developed Training Modules for Advocates who serve on Clinical Trial Committees (www.europadonna.org/research).

In particular, Europa Donna is member of the Scientific Committee of the "Breast cancer International Group" (BIG), which is one of largest non-profit organisations for academic breast cancer research groups from around the

world (www.bigagainstbreastcancer.org). In the framework of this collaboration, Europa Donna entered in the steering group of the AURORA international study, aimed the molecular investigation of metastatic breast cancer and of its responsiveness/unresponsiveness to chemotherapies (www.europadonna.org/research). Europa Donna is thus very active also in the field of translational research, and it is part of the TRANSBIG research consortium.

5. Conclusions

Despite the increased number of research programs involving patients, such as the ones we described above, we think that robust practical implementation of PPI is yet desirable. PPI could impact a research study at different levels, ranging from shaping research question to the choice of control arm, ethical issues and communication of the results. This is not only a hypothesis, but evidences exist and not only qualitative. For example, systematic reviews of published literature (1995-2009) provided evidence that at early phase of research, users' involvement had a positive effect on identifying user-relevant topics and priorities [Brett 2012; 2014].

We hope that the central role of PPI in the framework of the ASSET project, as reflected in its Roadmap, will provide an impetus to the application of PPI in the field of prevention and management of epidemics and pandemics of infectious diseases.

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