

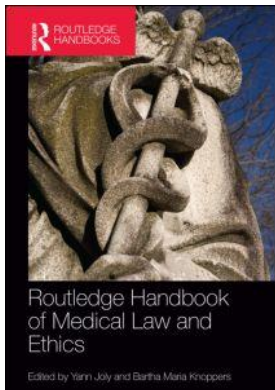
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Part V

Public health and international health trends

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Public health

Current and emergent legal and ethical issues in a nutshell

Paula Lobato de Faria and João V. Cordeiro

20.1 Public health and public health law

Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

(Charter of Fundamental Rights of the European Union 2000, *article 35*)

20.1.1 *The importance of health legislation*

Health law and legislation have gained significance in the international community for decades, particularly from the World Health Organization (WHO). During the thirtieth World Health Assembly in 1977,¹ the WHO committed itself to several important health goals, including a more efficient organization of health services; the provision of primary healthcare to needy populations; and the improvement and protection of individual and community health. In the same document, the WHO decided to strengthen its program in health law (Khoury *et al.* 2000; WHO 1977; Jennings *et al.* 2003).

This policy formed part of the WHO's program called 'Health for All by the Year 2000' (HFA2000), which sought to 'enable all of the world's citizens to enjoy by 2000 a level of health that would allow them to lead a socially active and economically productive life' (WHO 1977). According to this policy, the importance of investing in the study of health law and legislation under the HFA2000 program was based on the assumption that health legislation is a key element for the formulation and implementation of health policies, along with health education, in order to influence individuals and society to improve health behaviors and lifestyles.

Although written almost thirty years ago, this assumption is still relevant today, as health legislation continues to be the strongest social instrument which has the power, among others, to:

¹ In the same period, the Pan American Health Organization, in its recommendations for the ten-year health plan for the Americas (1971–80), encouraged updating health legislation and promoting updated health law publications and compendiums in the member countries (Horwitz 1975; WHO 1972).

create rights and responsibilities; establish principles and standards of healthy behaviors; resolve conflicts of interest between multiple groups in industrialized and globalized societies; and level equity in confrontations between the interests of populations and individual rights often witnessed in public health protection. Health legislation can also promote the required cost control measures and allow a more equitable distribution of resources.

20.1.2 Public health and public health law definitions

Public health is a constantly evolving field that is difficult to define and delimit (Hewitt and Watson 2013). Different classic and contemporary public health definitions have been proposed, from the succinct and yet broad-ranging Institute of Medicine (IOM) definition: ‘what we, as a society, do collectively to assure the conditions for people to be healthy’ (Committee for the Study of the Future of Public Health, Division of Healthcare Services, Institute of Medicine 1988); to the current definition proposed by the WHO: ‘Public health refers to all organized measures (whether public or private) to prevent disease, promote health, and prolong life among the population as a whole’ (WHO 2014b). In the first half of the twentieth century, the American public health expert, Charles-Edward Amory Winslow, provided an eclectic definition of public health. Despite all conceptual metamorphosis that ensued, Winslow’s definition remains adequate to frame a broad ethical and legal discussion. Winslow defined public health as:

The science and art of preventing disease, prolonging life, and promoting physical health and efficiency through organized community effort for the sanitation of the environment, the control of communicable infections, the education of the individual in personal hygiene, the organization of medical and nursing services for the early diagnosis and preventive treatment of disease, and the development of the social machinery to ensure everyone a standard of living adequate for the maintenance of health, so organizing these benefits as to enable every citizen to realize his birthright of health and longevity.

(Winslow 1920)

This definition is still relevant because it ‘accurately depicts the wide range of activities of people who work in the field of public health’ and has the benefit of being ‘consistent with the broad range of laws enacted in the name of public health’ (Mariner 2005, 2006). Hence, public health addresses the power of government to prevent illness and injury and to provide the infrastructure to sustain population health (Wing *et al.* 2007).

Although originally charged solely with preventing infectious disease, the field of public health currently includes matters of environmental protection, occupational health, and food and water safety, as well as epidemic preparedness. These subfields of public health are subject to a battery of legislation and regulation. However, not all enter the scope of public health law, which is distinct (at the same time narrower and more applicable) from the sum of the existing legislation that can directly or indirectly affect the public’s health.² Otherwise, an all-encompassing

² On this point see Mariner (2005), who presents several elements that characterize medicine and public health and also a typology of the laws affecting health. Mariner sustains that these ‘can be sorted into three categories familiar to most lawyers: (1) laws that target individual conduct – requiring or prohibiting specific actions; (2) laws that set health and safety standards – regulating products or companies that affect health by reducing health risks arising from products or the social or working environment; and (3) laws that affirmatively create benefit programs – offering healthcare, services, or information that individuals are free to accept or refuse’ (2005: 268). See also Mariner (2006) for an informative table with a comparison between several elements that characterize medicine and public health.

public health law would result in overlap with already developed branches of law, such as environmental law, consumer law, labor law, and administrative law, to cite a few. The study of these branches of law is often necessary given the multidisciplinary field of public health law, though the two cannot be conflated. Public health law has not yet reached the same recognition in the legal world as the aforementioned branches of law.

Tentative definitions of public health law can be found,³ but in our opinion, the scope of this branch of law is as difficult to define as public health itself. Nevertheless, the exiguous public health law community shares a consensus. That is, this legal field grants public powers to promote or implement health measures at individual or population levels, though is continuously confronted with ensuring fundamental human rights and liberties in doing so. Anti-smoking and alcohol legislation, as well as confiscation and quarantine to control transmissible diseases, illustrate this dilemma. As these disputes are commonplace in public health law, the use of public powers to promote, defend or improve the health of the population must be tempered with individual rights and liberties.

This tension is central to the ensuing discussion in this chapter. Here, we have selected what we believe are the most relevant classical and emergent ethical and legal topics of public health law, and have aimed to provide a brief but sufficiently grounded base to discuss their unique aspects. However, in such a wide-ranging arena, a legal and ethical analysis is necessarily incomplete. We have attempted to mitigate this in this chapter by informing the reader of relevant informative sources for further analysis whenever we found additional discussion necessary.

20.2 Traditional ethical and legal issues in public health

20.2.1 *Transmissible diseases*

Although preventing transmissible diseases was the main target of early public health interventions, we have witnessed the reappearance of new infectious disease outbreaks which have renewed the importance of public health legislation as a tool to respond to novel epidemic threats. These include Severe Acute Respiratory Syndrome (SARS), the influenza virus subtype H5N1, Multidrug Resistant Tuberculosis (MDR) and, more recently, Extensively Drug-Resistant Tuberculosis (XDR)⁴ (Faria 2008; Martin 2004; Martin *et al.* 2010).

The public health law response to these situations has always required a legal framework that enables health authorities to act quickly and efficiently in a ‘public health emergency’ (Martin 2006). In such circumstances, national governments and health authorities may need to take exceptional measures which go beyond the normal use of their powers. Sometimes, these measures violate fundamental rights and liberties of citizens, making indispensable the existence of legal instruments that guide and clarify the contents and limits of such interventions. Exceptional measures used in public health emergencies must be ethically and legally grounded. They must balance, on the one hand, the prevention and control of risk and damage to public health and,

³ Namely, Lawrence Gostin’s definition of public health law as ‘the study of the legal powers and duties of the state, in collaboration with its partners (e.g. health care, business, the community, the media, and academe), to assure the conditions for people to be healthy (to identify, prevent and ameliorate risks to health in the population), and of the limitations on the power of the state to constrain for the common good the autonomy, privacy, liberty, proprietary, and other legally protected interests of individuals. The prime objective of public health law is to pursue the highest possible level of physical and mental health in the population, consistent with the values of social justice’ (2008: 4).

⁴ This reality is exacerbated by inadequate or discontinuous use of anti-tuberculosis drugs and therapies.

on the other, the respect for human rights enshrined in international declarations and national constitutions.

At the peak of the pandemic influenza virus subtype H5N1 threat, there was an international resurgence of interest in public health law and in legislative reform. In the wake of public health threats, a new Portuguese law created a national system of epidemiological surveillance,⁵ the *Public Health Act* 2008 was established in the Netherlands, and the Canadian *Quarantine Act* 2005 responded to the SARS menace. Studies comparing pandemic preparedness legislation in Europe urged harmonization (Martin *et al.* 2010) given the detrimental response disparities that the lack of uniform standards could cause in a pandemic scenario. Nevertheless, no European or international legislative body has introduced further harmonization efforts on pandemic preparedness since.

There are, however, some widely recognized elements of effective public health legislation on the prevention and control of communicable diseases. These include the supremacy of protecting fundamental rights in the use of public powers, and the emphasis on standards that facilitate and boost notification to the public in emergency cases (Gostin 2008, 2006; Mariner 2006).

20.2.2 Lifestyles: tobacco and alcohol

Tobacco use and abusive alcohol drinking have been for some time the target of preventive public health measures at the international level. Both are considered by the WHO as main risk factors for a number of chronic diseases, including cancer, lung diseases, and cardiovascular diseases, alcohol use being also associated with an increased risk of acute health conditions, such as injuries, including from traffic accidents (WHO 2011, 2013). Nonetheless, as the WHO (2014) also recognizes, they are ‘common throughout the world’ and this is what makes the fight against the damage caused to individual and population health by these two substances so extremely difficult for public health professionals and authorities. In addition to the trivialization of the consumption of tobacco and alcohol, public health policies against these highly addictive and toxic substances have to deal with two industries that not only developed subtle and efficient forms of marketing, but are gaining a voice (mainly in the alcohol sector) at the negotiations table (Filho *et al.* 2010).

There are three essential international normative instruments on tobacco and alcohol. The WHO’s *Framework Convention on Tobacco Control* (FCTC) (2005) became the first treaty negotiated under the auspices of the WHO, while the World Health Assembly published its *Strategies to reduce the harmful use of alcohol* (2008) and its *Global strategy to reduce the harmful use of alcohol* (2010).⁶

The WHO FCTC (2005) established in reaction to the globalization of tobacco epidemics is an evidence-based treaty that restates ‘the right of all people to the highest standard of health.’ The main stipulations for tobacco reduction in the FCTC are enshrined in articles 6–14. They include: (1) price and tax measures to reduce the demand for tobacco; (2) non-price measures to reduce the demand for tobacco, namely the protection from exposure to tobacco smoke;

⁵ Law 81/2009 of 21 August at: <http://dre.pt/pdf1s/2009/08/16200/0549105495.pdf> (in Portuguese).

⁶ During the Sixty-third Session of the World Health Assembly, held in Geneva in May 2010, the 193 member states of WHO reached a historical consensus on a global strategy to reduce the harmful use of alcohol by adopted resolution WHA63.13. The adopted resolution and endorsed strategy gives guidance to both member states and to the WHO secretariat on ways to reduce the harmful use of alcohol. The drafting of the strategy was mandated in resolution WHA61.4 from 2008. See: http://www.who.int/substance_abuse/activities/globalstrategy/en/index.html.

(3) regulation of the contents, packaging and labeling of tobacco products; (4) education, communication, training, and public awareness; (5) prohibition of tobacco advertising, promotion and sponsorship; and (6) prevention of tobacco dependence and the promotion of its cessation through counseling and medicine (WHO 2005). In terms of the norms on reduction of supply enshrined in the FCTC, articles 15 to 17 include the control of illicit trade in tobacco products and the prohibition of tobacco sales to, and by, minors (WHO 2005).

The FCTC, which is now closed for signature, has 168 signatories, making it one of the most widely embraced treaties in United Nations history. The European Community is one of the signing Parties. In fact, it is important to mention that article 168 of the *Treaty on the Functioning of the European Union* (or Lisbon Treaty), signed by the EU member states in 2007 and adopted in late 2009, declares:

The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt ... measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol.

The document reveals the influences of WHO efforts to spread the institutional commitment to reduce the public health evidence-based harms of tobacco and alcohol.⁷

The World Health Assembly's (WHA) *Strategies to reduce the harmful use of alcohol* 'urges' member states:

- (1) to collaborate ... in developing a draft global strategy on harmful use of alcohol based on all evidence and best practices, in order to support and complement public health policies in Member States, with special emphasis on an integrated approach to protect at-risk populations, young people and those affected by harmful drinking of others;
- (2) to develop, in interaction with relevant stakeholders, national systems for monitoring alcohol consumption, its health and social consequences and the policy responses, and to report regularly to WHO's regional and global information systems;
- (3) to consider strengthening national responses, as appropriate and where necessary, to public health problems caused by harmful use of alcohol, on the basis of evidence on effectiveness and cost-effectiveness of strategies and interventions to reduce alcohol-related harm generated in different contexts.

(World Health Assembly 2008)

More recently, the WHA's *Global strategy to reduce the harmful use of alcohol* 'urges' member states:

- (1) to adopt and implement the global strategy to reduce the harmful use of alcohol as appropriate in order to complement and support public health policies in Member States to reduce the harmful use of alcohol, and to mobilize political will and financial resources for that purpose;
- (2) to continue implementation of the resolutions WHA61.4 on the strategies to reduce the harmful use of alcohol and WHA58.26 on public-health problems caused by harmful use of alcohol;

⁷ See the *Consolidated version of the Treaty on European Union*, the *Consolidated version of the Treaty on the Functioning of the European Union*, and the *Charter of Fundamental Rights of the European Union*.

- (3) to ensure that implementation of the global strategy to reduce the harmful use of alcohol strengthens the national efforts to protect at-risk populations, young people and those affected by harmful drinking of others;
- (4) to ensure that implementation of the global strategy to reduce the harmful use of alcohol is reflected in the national monitoring systems and reported regularly to WHO's information system on alcohol and health.

(*World Health Assembly 2010*)

The central ethical and legal issues associated with health behaviors such as tobacco and alcohol use are not limited to classical tensions between individual liberty and the exercise of public powers. They involve clashes between competing interests and public health policies, which may severely jeopardize the success of preventative measures. Central to enacting effective public health laws governing health behaviors is recognition of the various sociocultural features of the stakeholder group. If not, such laws risk being easily surpassed. Lobbying, marketing, and other promotional strategies used by the industry reveal strong opposing interests within public health policies, biasing and frequently impeding their efficacy.

20.3 Emergent ethical and legal issues in public health

20.3.1 Patient safety

Patient safety emerged as a major public health concern (Furrow *et al.* 2001: 29–64) in the wake of the American Institute of Medicine's report, 'To Err Is Human – Building a Safer Health System' (Kohn *et al.* 2000). The report found that medical errors (preventable adverse events in healthcare) caused an astounding 44,000 to 99,000 deaths per year, the eighth leading cause of death in the US, surpassing deaths from road traffic accidents (44,458), breast cancer (42,297), or AIDS (16,516) (Kohn *et al.* 2000). A number of different factors contributed to the growing trend, such as the influx of patients and procedures, longer life expectancy, and the current healthcare cost containment politics, the latter exacerbated already by existing scarcities in workforce and material resources, which invited an increase in adverse events and added professional stress (Faria 2010). These factors awakened the world to the need for improving quality assurance in healthcare. In response to *Resolution WHA55.18* adopted at the 55th World Health Assembly, the WHO created the 'World Alliance for Patient Safety' in 2004, urging countries to strengthen the safety of health care and monitoring systems (WHO 2004a).⁸

Patient safety is now an internationally recognized field for public health experts, lawyers, health managers, physicians, nurses, and other health professionals. In the five years following the IOM's report 'To Err Is Human', however, it was clear that quality improvement lagged in US healthcare units (Wachter 2004). As a result, progress in patient safety received a 'failing grade' in the 2009 report 'To Err Is Human – To Delay Is Deadly: Ten Years Later, a Million Lives Lost, Billions of Dollars Wasted', signed by the Consumers Union (2009), lending evidence to the difficulty of achieving patient safety goals and the fact that an efficient strategy in this area is still to be found.

In an effort to generate more creative measures to avoid medical errors (i.e. preventable adverse events), some public health authors have proposed looking to, and perhaps partnering

⁸ See also the *World Alliance for Patient Safety Forward Programme* (WHO 2004b); the WHO's *Patient Safety* (2014c); and the WHO's *Summary of the Evidence on Patient Safety* (2008).

with, the airline industry for inspiration (Pronovost *et al.* 2009; Romano 2005), although other authors argue the best approaches to preventing medical hazards come from medicine itself, citing the successes witnessed in anesthesia safety in the US (Annas 2010: 165–73).

A July 2013 report from Europe does not bring better news (European Center for Disease Prevention and Control (ECDC)). The European Center for Disease Prevention and Control conducted the first prevalence survey on healthcare-associated infections and antimicrobial use conducted in more than 1,000 hospitals in 30 European countries, and estimated that ‘on any given day, about 80,000 patients – or one in 18 patients – in European hospitals have at least one healthcare-associated infection’ (ECDC 2013). This report followed the *Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections* (Council of Europe 2009) and a 2012 report detailing its implementation (European Commission 2012d). The Report’s conclusions are far too optimistic, suggesting most member states have indeed undertaken many of the interventions proposed in the *Recommendation*.⁹ Nonetheless, the recent 2013 *Report* indicated these steps were still not enough to stop preventable injury and death in healthcare units.

Even so, there is still ‘room for improvement’ (European Commission 2012d: 13) in various areas of the EU *Recommendation* at both the member state and EU level. At the member state level, these areas include: to involve patients more actively in safety interventions, in particular to provide more information on safety measures, complaint procedures, and patients’ rights to redress; to develop a common understanding of core competencies; to encourage patients and their families to report as well as to collect information on adverse events through further developing systems infrastructures; to ensure a non-punitive context for reporting adverse events; and to evaluate reporting progress (i.e. among health professionals, other healthcare workers, and patients). At the EU level, collaboration is needed: to propose guidelines on how to construct and introduce patient safety standards beyond the *Recommendation*, as well to ‘make progress on common terminology on patient safety’ (European Commission 2012d); to pursue exchange of best practice; to promote education of health professionals on patient safety, e.g. by integrating education and training of health professionals at all levels; and to further research on patient safety, including cost-effectiveness studies on proposed strategies.

Acknowledging these needs, the European Commission suggested extending the monitoring period an additional two years for implementing the general patient safety provisions outlined in the 2009 *Recommendation*. A second progress report is scheduled for June 2014 (European Commission 2012b).

From a legal perspective, patient safety is still an emerging field where dilemmas surpass solutions. There is no consensus regarding which legal measures can actually improve patient safety in healthcare units. Nonetheless, the legal community is unanimous regarding the urgent need to prioritize patient safety in health facilities both as a public health mandate and as a patient/citizen right (Balsamo and Brown 2007: 187–205; Annas 2004: 337–61, 2010: 165–73). The latter is supported by legal frameworks which consider clinical/medication risk management and prevention in healthcare a human rights issue (i.e. fundamental rights to life and to physical integrity).

The use of incentive laws have also been put forth as legal mechanisms to improve patient safety. Given appropriate security and suitable legal mechanisms, institutions and patients

⁹ The *Report* states, ‘most Member States have embedded patient safety as a priority in public health policies and designated a competent authority responsible for patient safety. Moreover, most countries have encouraged training on patient safety in healthcare settings, though only a few have formally embedded patient safety in education and training programs for health professionals’ (European Commission 2012d: 13).

can be better informed of how experience and competence are evaluated among healthcare professionals.

However, it is our conviction that the idea of building a true ‘culture of safety’ among professionals and institutions depends less on the legal framework and more on a multidisciplinary effort to create effective practices and guidelines to avoid preventable adverse events.

20.3.2 Public health genetics

Different public health fields, such as infectious and chronic disease, occupational health and environmental health can take advantage of data-sharing progress in genomics, leading to what has been described as the ‘genetic information for all’ era (Gerard *et al.* 2002). The field of genetics is complex in scope and reach, and has expanded dramatically since the completion of the Human Genome Project in 2003 (Green *et al.* 2011). Concomitantly, public health genetics, initially defined as ‘the application of advances in genetics and molecular biotechnology to improve public health and prevent disease’ (Khoury *et al.* 2000; Jennings *et al.* 2003: 193), poses significant regulatory challenges, many of which have yet to be successfully addressed. Discrete efforts of international law to set broad principles and establish clear limits are nonetheless noteworthy, as are a number of national regulatory initiatives governing important public health genetics projects. Most importantly, the tension between private and public interest is pressing in public health genetics, as in most public health debates. That tension is materialized in specific ethical and legal issues such as privacy and confidentiality protection, the nature and depth of informed consent, individual responsibility for one’s own health, the limits of property rights, the appropriateness of quality control schemes, and the notion of genetic discrimination. Next, we discuss some of these issues in the context of genetic databanks and genetic tests.

20.3.2.1 Genetic databanks

Organized collections of biological material and/or associated information, known as biobanks, can assume multiple forms and have distinct aims (Hewitt and Watson 2013). Perhaps as an accurate reflection of the post-9/11 world, the ethical and legal discourse has focused on security biobanks to the detriment of medical research biobanks, both of which raise important public health questions (Knoppers 2003; Annas 2010). Nonetheless, medical research biobanks have also received widespread ethical and legal attention, especially following the historic case in Iceland involving deCODE Genetics and the 1998 *Act on Health Sector Database* (HSD). The *Act* created a nationwide DNA database¹⁰ for medical research purposes allowing a private company such as deCODE Genetics to carry out the licensing and development of the database. The fact that a private company managed the project without defined legal boundaries raised numerous concerns (Masood 1998), many of which have resurfaced following some of the company’s financial decisions.

Naturally, informed consent is a relevant starting point for contextualizing a discussion on genetic biobanks from a public health lens. Informed consent has deep roots in biomedical ethics, and is at the core of both doctor–patient and researcher–subject relationships (Beauchamp and Childress 2008). The focus of public health on communities rather than individuals raises the question of whether there is an ethical justification for sidelining informed consent in large-scale

¹⁰ Composed of three biobanks – one containing DNA samples covering a significant proportion of the Icelandic population, one consisting of genealogical information, and a third containing health records.

public health projects. Remarkably, Iceland's original *Act on Health Sector Database* 1998 did not include a specific requirement for obtaining informed consent from individuals; instead, an opt-out scheme was adopted (article 8). One could argue that genetic information (especially in the context of medical research) is so particular that its inclusion in large-scale DNA databases should not be regulated by traditional rules, including the classical models of informed consent (McGuire and Beskow 2010; Taylor 2008; Artizzu 2007). Alternatively, to probe the limits set by public health law and ethics, one could ask whether the potential of genetics to advance the common good (more knowledge leading to better health) is so significant that concessions to individual liberty should be considered. Major international law and ethics instruments related to research on genetic data provide, in one way or another, references to the primacy of the human being and consequently to the permanence of informed consent¹¹ (Karlsen *et al.* 2009). In turn, these principles are inscribed in several national Constitutions (including the *Constitution of Iceland*)¹² and have been transported into different national regulations.

Nonetheless, the inadequacy of current informed consent procedures for genetic databases has been widely debated and relevant arguments about a need for reform have been put forward (McGuire and Beskow 2010; Roche 2009; Lunshof *et al.* 2008; Caulfield *et al.* 2008; Glantz *et al.* 2010). These arguments cite difficulties in delimiting the research context for secondary uses of each sample, the extent to which anonymity can be granted and therefore promised, as well as the property rights retained by biobank donors (Cambon-Thomsen *et al.* 2007; Caplan 2009; Glantz *et al.* 2008; Faria 2009; Hoffman *et al.* 2009). Such obstacles are even more pronounced when we consider that many biobanks are now clustered in networks of significant scale.¹³ Accordingly, different consent models have been proposed, including open consent and gift-related models (Lunshof *et al.* 2008; Glantz *et al.* 2010).

However, the values that informed consent aims to protect (i.e. liberty, autonomy, and self-determination) remain fundamental and should be respected, including in public health. Certainly, they must be harmonized with the common good, including the access to results of scientific progress, an officially recognized human right (*Universal Declaration of Human Rights* 1948, articles 29(2) and 27; *International Covenant on Civil and Political Rights* 1966, article 15). Furthermore, according to international law, the characteristics that differentiate genetic information from other health data justify careful ethical and legal analysis and ultimately require particular protection. For example, genetic information relates not only to the individual but also to his/her family (Parker and Lucassen 2004; UNESCO 2003, article 4(a)(ii)). On this point, the issues of privacy and confidentiality in genetics databases become central to recent ethical debates in public health.¹⁴

Here again, Iceland's *Act on Health Sector Database* provides context. In a case addressing the extent of privacy rights, the Iceland Supreme Court highlighted one of the most fundamental aspects of genetics regulation – the individual nature of privacy rights is extended in the case of genetic privacy to include genetically related family members (Annas 2010: 246–9). Hence, as

11 See as examples the *Convention on Human Rights and Biomedicine* 1997 (article 2); the *Declaration of Helsinki* (WMA 2013, articles 24–29); the *Universal Declaration on the Human Genome and Human Rights* (UNESCO 1997, article 5(b) and 5(e)); and the *International Declaration on Human Genetic Data* (UNESCO 2003, articles 2(iii), 6(d), 8, and 9).

12 Accordingly, the Iceland Supreme Court declared the *Act on Health Sector Database* unconstitutional, which prompted the inclusion of an informed consent procedure (Abbott 2004).

13 See, for example, the Public Population Project in Genomics and Society (P3G 2014), and Biobanking and Biomolecular Resources Research Infrastructure (2014).

14 Policy reviews on the subject are permanently ongoing. See, for example, the *Draft NIH Genomic Data Sharing Policy Request for Public Comments* (National Institutes of Health (NIH) 2013).

individual rights blend into family rights, the lines between private and public interest blur even further. Moreover, downstream of privacy rights, confidentiality rights are also mutating. Despite the fact that most studies show that the overwhelming majority of patients choose to pass information of genetic risk to family members, in some cases confidentiality breaches collide with the carrier's will (Clarke *et al.* 2005). The fact that such heightened risk could be passed on to offspring must also be taken into account when preparing balanced public health regulations and policy, particularly when both parents are carriers and pre-implantation diagnostics could be offered. That brings us to the issue of genetic tests.

20.3.2.2 Genetic tests

The concept of a 'genetic test' is quite broad. It involves testing at different stages – pre-implantation, prenatal, newborn, during childhood or adulthood; by different providers – healthcare units or market companies; and serves different purposes – diagnostic, predictive of disease or response to drugs, forensic, or research. From a legal perspective, a uniform definition in regulatory documents is also non-existent (Sequeiros *et al.* 2012; Varga *et al.* 2012).

The difficulty in finding appropriate legal definitions is just one characteristic of an overly complex regulatory subject. The limitations of regulation in this area are particularly clear in the case of direct-to-consumer (DTC) genetic tests,¹⁵ which have important public health ramifications yet have garnered little legislative attention. DTC genetic tests result from a dramatic decrease in sequencing costs particularly from the second half of the last decade onwards¹⁶ (Mardis 2011). Under the promise of individualized healthcare, international companies – often wrapped in complex marketing, client recruitment, or results communication practices – offer to test for disease predisposition or estimate individual responses to therapies.

Such practices raise several regulatory challenges, starting with analytical validity, a measure of a test's accuracy in detecting the intended genetic marker. Efforts in the US and Europe to license laboratories that perform genetic testing are ongoing. These efforts include requiring appropriate professional training, record-keeping standards, and revision methodologies (Hogarth *et al.* 2008). Where legislation on specific genetic tests is non-existent, adapting already existent quality control mechanisms (for clinical laboratory or pregnancy tests, for example) must be considered after proper evaluation.

Clinical validity, a measure of how a positive result translates into clinical significance, also requires regulation and is charged with providing accurate scientific notions of probability, risk, or variance during legal proceedings. Finally, clinical utility must be considered as a measure of the test result's usefulness in terms of prevention, diagnosis, or treatment. The utility of a positive or negative result is difficult to estimate, particularly when no therapy or prophylactic measures can be prescribed.

Nonetheless, the limits for DTC genetic testing must be defined (Howard and Borry 2012). Areas that require attention include: the involvement of healthcare providers; premarket reviews; the stringency of advertising and marketing regulations; specific oversight of results reports; provisions from public budgets; and health insurance coverage. Due to considerable public health

¹⁵ Genetic tests that are marketed directly to consumers via the Internet, television, or other media without the involvement of a healthcare provider or practitioner.

¹⁶ For an overview on the evolution of DNA sequencing costs see *DNA Sequencing Costs: Data from the NHGRI Genome Sequencing Program (GSP)* (National Human Genome Research Institute 2014).

relevance some of these areas have been subject to US and European legislation in recent years (Hogarth *et al.* 2008; Borry *et al.* 2012).

Patients should only be tested for any genetic disease (or risk) once they have been informed and have understood what the test can reveal. Furthermore, privacy of genetic data must be protected always bearing in mind someone's 'right not to know' (Wolf *et al.* 2013). Moreover, professional counseling in DTC genetic tests should be available to help to deal with test results, as with genetic tests offered through a healthcare provider.

Balanced public health regulation that protects the population from inaccurate or invalid DTC genetic tests promotes individual empowerment in healthcare and might limit unnecessary medical tests, self-prescription, failure to take preventive action based on negative test results, elevated anxiety and stress, or unrestricted testing of the most vulnerable.

These features are relevant in an expanding and particularly contested area of genetic tests – Newborn Genetic Screening Programs (NGSP) (Bombard *et al.* 2009; Moyer *et al.* 2008). From a regulatory perspective, the role of parents and legal representatives of newborns in these programs is very important (Tarini and Goldenberg 2012). Arguments favoring the requirement of parental consent for newborn testing include the parents' position as the best proxy for children's own interest, the rarity of most diseases tested and the serious implications of false positive results. In opposition, proponents for mandatory testing argue the overall benefits far outweigh potential individual harms and the burdens of creating bureaucratic procedures are unnecessary when the vast majority of parents agree to the tests. As stated in international ethical and legal documents, parents or legal representatives should consent to individual procedures involving their children.¹⁷

Establishing the best consent model to implement in NGSP, either voluntary, opt-in, opt-out, or conditional, presents one subsequent challenge. Moreover, ways to resolve disputes should parents disagree on the best course of action should also be found. On the other hand, mandatory screening based on implied-consent models is also sometimes considered (Tarini and Goldenberg 2012; Bombard *et al.* 2009). Ultimately, the context of specific NGSP, their proportionality and whether there are realistic prospects of achieving the proposed public health aims will determine the best consent model to adopt.

In NGSP as in any genetic testing, the results must be confidential. Most national and international legal documents related to human genetics acknowledge the potential for genetic discrimination.¹⁸ Hence, directed targeting of population subsets based on genetic backgrounds for public health reasons should be minutely scrutinized. Different genetic tests pose different regulatory challenges and require dedicated attention (Howard *et al.* 2013). Nonetheless, the fact that consent, privacy, and confidentiality are valuable public health allies, the difficulty in establishing clear risk-benefit analyses and the need for functional, nuanced, and adaptable legal and ethical processes are common conclusions.

¹⁷ Additionally, the will of minors who have already the capacity to understand what is at stake should be taken into account even when parents give consent. See, for example, the *Declaration of Helsinki* (WMA 2013, article 27); the *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes* (articles 9–12); the *Convention on Human Rights and Biomedicine* (articles 5–6); and the *Universal Declaration on the Human Genome and Human Rights* (UNESCO 1997, article 5).

¹⁸ See as examples the *Universal Declaration on the Human Genome and Human Rights* (UNESCO 1997, preamble, article 6); the *Convention on Human Rights and Biomedicine* (articles 1, 11); and the *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes* (article 4). See also the *Genetic Information Nondiscrimination Act* for regulation on the matter in the US (110th Congress 2008).

Finally, other public health genetics issues, including gene therapy (Giacca 2010), genetic enhancement (Annas 2010: 251–66), gene patenting (Norrsgard 2008; Kesselheim *et al.* 2013) and the use of genetically modified organisms (Lee 2008) deserve legal attention and are the subject of discussion elsewhere (Knoppers 2003; Condit 2010).

20.3.3 Nanotechnology

In broader terms, nanotechnology refers to ‘the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications’ (National Nanotechnology Initiative, n.d.). Manipulating matter at the nanoscale can have wide applications, including in agriculture, energy storage, engineering, computer technology, and healthcare. Possible applications of nanotechnology in medicine include drug delivery, *in vivo* imaging, *in vitro* diagnostics, biomaterials, and active implants (Wagner *et al.* 2006). Accordingly, worldwide investment in nanotechnology has been steadily increasing (*Wall Street Journal* 2013; Reportlinker 2013). However, regulatory efforts have not paralleled expansion in the field. Notwithstanding this, considerable public health risks require ethical and legal attention. These include the difficulty of estimating and reducing toxicity levels of materials and particles at the nanoscale¹⁹ and the possible inhalation, dermal exposure, and/or ingestion of nanoparticles that could cross cellular membranes, reach the bloodstream, invade distant organs and lead to unpredictable consequences. Importantly, these risks are common to the public in general and also to workers who manipulate nanomaterials, such as healthcare professionals.

Overall, regulatory efforts should focus on adequate consumer information including known and unknown risks, the development of best workplace practices including rules for handling, transport and disposal, and defining limits to bioaccumulation in ecosystems based on long-term environmental impacts.

In the EU, specific nanotechnology regulation has not been straightforward. In some cases, the EU has backed specific regulation as in its recommendation for a *Code of Conduct for Responsible Nanosciences and Nanotechnology* (European Commission 2008; European Parliament 2009). In other cases, there were proposals that general regulatory rules be adapted to nanotechnology on a case-by-case basis (European Commission 2012b). An important EU document that applies to nanotechnology (although not particularly designed for it) is *Regulation (EC) No. 1907/2006* that deals with the registration, evaluation, authorization, and restriction of chemicals, known as ‘REACH’ (European Union 2006; European Commission 2013b). This and other general binding documents on chemicals, cosmetics, and food, for example, can also be applied to nanotechnology but require adaptation that is still lacking.

In the US, the *Review of Federal Strategy for Nanotechnology-Related Environmental, Health, and Safety Research* by the National Research Council in 2009, called for appropriate nanotechnology regulation. Subsequently, the Food and Drug Administration (FDA) progressed beyond the creation of a Task Force ‘charged with determining regulatory approaches that encourage the continued development of innovative, safe, and effective FDA-regulated products that use nanotechnology materials’ in 2007 and released, in 2011 and 2012, draft guidance for industry, cosmetics, and food substances involving nanotechnology. These efforts are in line with the general notion that nanotechnology regulation requires added attention, an idea that has been expressed in an important 2011 White House policy statement (Office of Management and

¹⁹ Due to intrinsic properties of these materials or their interaction with chemical and biological systems.

Budget, United States Trade Representative, and Office of Science and Technology Policy, White House 2011).

Despite recent efforts and expressed public health concerns, current nanotechnology regulation is still far from optimal. Nanotechnology combines great potential with high levels of uncertainty and a high-profile safety or health event could undermine public trust and damage the future use of this technology. Therefore precautionary action, based on proportionality and mindful of the best available science, is important.

20.3.4 eHealth

Technological progress is transforming healthcare. Medical diagnosis can now be offered at a distance. As applications of information and communication technologies in healthcare expand, the potential for self-empowerment regarding one's own health becomes considerable. The range of health issues already covered by mobile medical applications is vast and includes viewers of radiologic images, 'expert systems' to help with differential diagnoses, interfaces for medical devices (like ultrasounds and EKG machines), medical simulators,²⁰ and telemedicine devices. Hence, the right technology allows for the accumulation of considerable qualitative and quantitative health information without the need for additional intermediaries. Furthermore, this information can be uploaded onto dedicated social network platforms where symptoms, treatment, and research can be discussed by a community of patients, doctors, and scientists.

These innovations are transforming medical practice and have considerable public health law and ethics implications. First, self-diagnosis and self-prescription are a cause for concern as we have discussed before in the context of DTC genetic tests. Also, notable challenges to classic notions of consent, personal responsibility, and professional authority can be identified. Therefore legal attention should be paid to specific issues such as clarifying the rules for accrediting health professionals operating in this new system, or specifying quality control norms for software and devices that take into account informed consent or privacy and confidentiality of health data.²¹

As individual and quantified health data accumulates, the possibility that health insurance will be based on a new version of our 'quantified selves' must also be considered and contextualized from a regulatory perspective, and protection from stigmatization and discrimination must be guaranteed. Despite its progress, of which FDA regulation of mobile medical applications²² and EU efforts to promote and regulate telemedicine are good examples (Callens 2010), eHealth regulation is still lagging.

The public should have access to trustworthy advances in science and technology that can benefit their health. However, that is particularly difficult to assure in a context of scarce public resources. The role of law and ethics in minimizing the impact of economic crises on public health is the subject of the next and final section.

²⁰ For example, advanced cardiovascular life support.

²¹ Important data protection reform is ongoing in Europe (European Commission 2013a). In the US, two legal documents are of outstanding relevance: the *Health Insurance Portability and Accountability Act* 1996 and the *Health Information Technology for Economic and Clinical Health Act* 2009. For an overview see the US Department of Health and Human Services' *Health Information Privacy* section on their website (2013).

²² See the FDA's *Medical Devices* web page (2013) and the *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – eHealth Action Plan 2012–2020 – Innovative Healthcare for the 21st Century*, COM (2012) 736 (European Commission 2012a).

20.4 Economic crises and public health

It is fundamental to estimate the impact of economic crises on public health and to ascertain how best to defend and promote public health during these periods. Significant pressures on public health resulting from the socio-economic changes seen during economic downturns have been observed in the past.²³ More recently, the 2008 financial crisis, which began in the US and later spread to Europe, confirm these pressures (Stuckler and Basu 2013).

As a result of unemployment and reduction in household income and social safety nets, public health indicators such as mental health, suicide, substance abuse, and incidence of infectious disease are exacerbated, while overall access to healthcare deteriorates (Karanikolos *et al.* 2013; Stuckler *et al.* 2009; Suhrcke *et al.* 2011). The role of law, and public health law specifically, in providing protection from such effects, can be best understood through an analysis of different European responses to economic crises. During the Eurozone Crisis, austerity packages²⁴ included cuts to social welfare programs and a reduction in health budgets (Fahy 2012). These measures varied from country to country and cut the salaries of health professionals, reduced public hospital beds, increased user charges for healthcare, and decreased family support, dissolved childcare benefits and implemented other social welfare cuts. In Greece, where austerity measures were first implemented and have had the strongest impact, mental health has deteriorated significantly. Suicide rates have peaked, HIV and malaria outbreaks have been reported, and access to healthcare has been significantly constrained (Economou *et al.* 2012; Madianos *et al.* 2010; European Center for Disease Prevention and Control (ECDC) 2012). Similar effects are also emerging²⁵ in Portugal, Ireland and Spain. These effects include, a rising number of winter deaths among the elderly, increasing mental disorders, suicide rates, alcohol-related disorders, and worsening child malnutrition (Mazick *et al.* 2012; Thomas *et al.* 2012; WHO Regional Office for Europe 2012).

Therefore it is important to understand whether these detrimental public health effects are direct consequences of the economic crises, or if they also result from the drastic reduction (and in some cases the complete abrogation) of crucial social safeguards that defend the population during trying economic times. In contrast, however, Iceland was not affected by such deleterious public health effects following its own economic crisis in the last decade (Stuckler and Basu 2013: 57–75). One key reason for this was investment in social protection and reemployment programs, as opposed to strict austerity measures, proposed at the time by the International Monetary Fund (IMF). Promoting a healthy diet based mainly on local fish supplies, restricting alcohol access and fostering strong social cohesion ultimately mitigated the impacts of the crisis on population health (Stuckler and Basu 2013: 57–75). Similarly, states that furthered social welfare programs during the Great Depression in the US avoided the worst public health effects and, in some cases, actually improved health indicators (Stuckler *et al.* 2010).

One question that remains essential: can law and ethics protect public health from becoming collateral damage in the tense ongoing confrontation between financial markets and rights-based

²³ For example, the American Great Depression in the 1930s; the post-Soviet era in Eastern Europe in the late 1980s and early 1990s; or the Asian economic crisis in the late 1990s.

²⁴ Some countries, like Greece, Ireland, and Portugal, were subject to official bailouts by the so-called *troika* (composed of the International Monetary Fund (IMF), the European Central Bank (ECB), and the European Commission (EC)). Other countries, such as Spain and Italy, despite avoiding this regime, also included austerity measures in their budgets.

²⁵ Some of which are still disputed. See Ayuso-Mateos *et al.* (2013) for examples.

approaches? Three examples deserve mention. First, measures enacted by the *troika* in Greece limited spending on health to no more than 6 per cent of its GDP (Fahy 2012), effectively diminishing the role of the Greek government in defining its health budget. Second, Spanish legislation approved by a royal decree bypassing parliament led to the privatization of the previously universal Spanish health system (Rada 2012). Finally, Portugal's continued approval of unconstitutional annual budgets has impacted its health sector, where the legislative branch challenged limits that were set to protect social safeguards.²⁶

Despite the existence of specific constitutional norms for states of emergency that allow for extraordinary measures while protecting against arbitrariness and disproportionate action, none of these countries have formally declared a state of emergency as a consequence of the financial crisis. As we have discussed above, public health law is important to set rules and limits to extraordinary interventions during emergency situations. Therefore the prolongation of informal states of economic emergency, during which violations of constitutional rights and principles are justified seemingly under arbitrary discretion, can be cause for concern, particularly when severe public health effects are difficult to avoid. Therefore, in order to endure economic crises, public health must lean on its strongest allies – ethics, law, and human rights – combining that alliance with innovative action and nonconformism by members of society and the public health authorities.

20.5 Conclusion

Any text on public health legal and ethical issues is necessarily incomplete. As we have discussed throughout this chapter, public health encompasses a variety of issues that are considerably complex, all of which demand attention and appropriate regulation in order to balance the many (and sometimes conflicting) interests. The law, with its unique powers, is an exceptional tool for the implementation of public health policies. In fact, it is the only social instrument that can simultaneously impose sanctions and set rules, procedures, and requirements, as well as define competencies and establish rights and duties. As corollaries of this power, the law imposes duties on public institutions or individuals, and empowers the authorities to impose exceptional actions within some limits that protect citizens against abuses of those same powers. The law can also influence the way people think and act, allowing a change in behaviors and attitudes. Although the vocation of the law as a modulator of human behavior is a very complex issue, time has lent evidence to the ways in which the law's lifestyle model, mainly if it is accompanied by sanctions, inculcates 'good' behavior among a majority of people.

Emergent issues in public health are continuously and simultaneously posing new challenges while demonstrating great potential. Arguably, it is also in the interest of public health that the results of scientific progress and innovation reach the widest public possible. That aim, which is not only an aspiration but also a recognized human right, must be confronted with the inherent economic costs of intervention and the current asymmetries in access to basic human needs, such as food, shelter, and healthcare. Therefore public health can only benefit from clear and precise rules governing the just allocation of resources. In order to achieve this, and regulate such

²⁶ Rulings of the Portuguese Constitutional Court (PCC) were based on interpretations of fundamental public law principles, such as the principle of trust and the principle of proportionality. Relevant rulings can be found here (in Portuguese): <http://www.tribunalconstitucional.pt/tc/acordaos/20120353.html>; <http://www.tribunalconstitucional.pt/tc/acordaos/20130187.html>; <http://www.tribunalconstitucional.pt/tc/acordaos/20130602.html>; <http://www.tribunalconstitucional.pt/tc/acordaos/20140413.html>.

a broad range of issues as the ones that compose the field of public health, individual liberties and public interest must coexist as harmoniously as possible. We must be mindful that neither can completely overshadow the other as they are both fundamental in a fair and modern society.

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