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COMMENTARY
General principles and practice of the ethics of public health surveillance: comments on the situation in Italy

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Abstract
The "WHO Guidelines on ethical issues in public health surveillance" were published shortly after the Italian Presidency of the Council of Ministers published a Decree (3rd March, 2017) regarding surveillance systems and registries. The WHO document is a comprehensive framework of international import that forms a compendium of ethical principles to underlie public health surveillance. Although the Italian Decree is in line with the guidelines it contains no reference to mechanisms to ensure ethical surveillance, which instead are recommended in the WHO document. Ethics Committees would appear the most suitable candidates to fill this role.

Key words
- bioethics
- guidelines
- health surveillance
- legislation
- public health

Publication of the "WHO Guidelines on ethical issues in public health surveillance" (henceforth referred to as "WHO Guidelines" [1] by the World Health Organisation (WHO) provides the international community with a reference document that identifies a set of ethical guidelines for public health surveillance.

Coincidentally, though not intentionally, the WHO Guidelines were published shortly after the publication in Italy of the Decree 3rd March, 2017 "Identification of systems for the surveillance of registries of mortality, tumours and other pathologies" [2], a landmark reference document to provide Italy with a national health information system that is both adequate and durable.

The present Commentary will first look into the two documents separately and then compare them.

THE WHO GUIDELINES: A NEW APPROACH?

The immediate reaction to the new WHO Guidelines is: how do they compare with others already issued? This question is best addressed by dividing it into two parts: one concerning biomedical ethics in general, and the other concerning public health ethics in particular.

1. In the matter of *biomedical ethics in general*, some of the compilers of the guidelines rightly pointed out that, for the public health surveillance sector, the WHO Guidelines do not differ substantially from the numerous other ethical frameworks for biomedical ethics published since the middle of the last century [3]. The succession of frameworks for biomedical ethics and the timing of the WHO Guidelines should not, however, be taken as representing a new approach to the reference values: all the documents are based on a common set of basic values. The WHO Guidelines, naturally, identify elements that "are of particular importance for public health surveillance" and that "represent the backbone of the guidelines" (p. 21): common good, equity, respect for persons, good governance, all of which were amply acknowledged in earlier documents (e.g. "The Barcelona Declaration on Basic Ethical Principles in Bioethics and Biolaw" [4], which should "be conceived as a conceptual clarification and articulation of major ethical principles, which are central to international concerns for a universal bioethics and biolaw" [5]).

2. In the matter of *public health ethics in particular*, as noted by The Lancet, the WHO Guidelines are the "first document to address the challenge of surveillance on a global stage and the first set of international guidelines in which the ethics of public health (…) serves as a normative framework". Thanks to the efforts of various national or local institutions, as well as to experts in the field, numerous frameworks for the ethics of public health surveillance [6, 7] were in fact already available. Indeed, the WHO Guidelines "are rooted in the tradition of public health ethics" [8]; nor do they stray from a body of principles of public health ethics and, in particular, of ethics of public health surveillance, that

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are today consolidated and widely shared. The novelty is thus not in the contents but rather in the international reach of the document, in its completeness and in its organic structure, given that it addresses all the key ethical considerations applicable to public health surveillance in a single document.

THE ITALIAN DECREE ON SURVEILLANCE AND REGISTRIES

The Decree of 3rd March, 2017 follows on from article 12 of Decree law no. 179 of 18th October, 2012 [9], which was converted into Law no. 221 of 17th December, 2012 [10]. The intervening stages necessary for the Decree's enforcement were: the "Opinion on a draft Decree of the President of the Council of Ministers on surveillance systems and registries (23rd July, 2015) by the Data Protection Authority [11] and the agreement with the Permanent Conference for Relations between the State, the Regions and the Autonomous Provinces of Trento and Bolzano on 24th November, 2016 [12].

The Decree identifies 31 surveillance systems and 15 registries of nationally significant diseases, the purpose of which is to ensure prevention, diagnosis, care and rehabilitation, health planning, healthcare quality checks, and assessment of healthcare assistance and of scientific research in the medical, biomedical and epidemiological fields.

For each of the 31 surveillance systems and each registry the Decree names the reference institution: in many cases this is the Istituto Superiore di Sanità (ISS, Italian National Institute of Health), while in others it is the Ministry of Health.

The Decree divides the surveillance systems and registries into three groups:

- surveillance systems and registries of national or regional importance (attachment A);
- surveillance systems and registries of national importance formerly governed by national regulations (attachment B);
- surveillance systems and registries of purely regional importance (attachment C).

These systems and registries are essential for ensuring prevention, diagnosis, treatment and rehabilitation, healthcare planning, treatment quality checks, and assessment of healthcare assistance and of scientific research in the medical, biomedical and epidemiological fields [13].

THE WHO GUIDELINES AND THE ITALIAN DECREE: WELL ATTUNED (BUT AWAITING COMPLETION)

The Italian Decree 3rd March, 2017 is in tune with the recommendations of the WHO Guidelines from the very beginning (the heading of the WHO guideline no. 1 is "Countries have an obligation to develop appropriate, feasible, sustainable public health surveillance systems. Surveillance systems should have a clear purpose and a plan for data collection, analysis, use and dissemination based on relevant public health priorities"). The text of the first guideline goes on to state that: "The duty to protect population health is the foundation of an affirmative responsibility to conduct public health surveillance. The exercise of that responsibility may be assigned to subnational governmental bodies. Without public health surveillance systems, population health cannot be protected and inequalities cannot be adequately addressed. Inattention to pressing public health needs leads to erosion of trust (…). The importance of population health thus imposes upon States an obligation to develop systems that capture data critical to identifying and responding to (outbreaks of) infectious diseases, epidemic threats and the toll exacted by injuries and chronic disease, which demand environmental and occupational monitoring or investigation". The Italian Decree of 3rd March, 2017 names the ISS as the appropriate institution for the management of surveillance systems and registries, acknowledging that its mission is the promotion and protection of public health both in Italy and at international level, through "research, surveillance, regulation, control, prevention, communication, consultation and training" [14, 15].

Surveillance systems and registries are not an end in themselves: as the first of the WHO Guidelines recognises, "once surveillance data are available, Member States have the moral duty to use the data actively to promote better health outcomes". This task is also fully part of the mission of the ISS.

Although the WHO Guidelines and the Italian Decree are substantially in agreement, the latter does not give full effect to the former's guideline no. 2, which states that "Countries have an obligation to develop appropriate, effective mechanisms to ensure ethical surveillance (…). Countries should have appropriate, effective mechanisms for ensuring adherence to ethical standards in both emergency and non-emergency situations". We might ask what form such mechanisms should take, given that the Decree makes no mention of them. The WHO document includes examples of "mechanisms for ensuring adherence to ethical standards" that have been adopted in some institutions or nations. Ethics committees would appear to be the most appropriate institutions to pronounce on the ethical soundness of public surveillance initiatives. However, we should ask whether, at least in Europe, ethics committees are in a position to perform this task. The responsibilities already assigned to these committees for clinical trials, particularly in view of the full implementation of Regulation (EU) 536/20014 [16], place an inescapable burden of work concerning clinical trials alone, which risks detracting attention from anything else, particularly anything concerning the ethics of clinical practice or public health. It is to be hoped that in Italy this issue will be properly addressed when the organisation of ethics committees is reviewed, as envisaged in the law of 22nd December, 2017 [17], and that the institution of ethics committees for clinical practice, public health and research separate from those for clinical trials will be promoted and put to good use. There are in Italy committees with many years of experience in these fields, including the Ethics Committee of the ISS, whose experience of evaluation goes well beyond clinical trials and which from its inception has been extensively concerned with the ethics of public health

and public health surveillance. This is well illustrated in the "Codice di Etica dell'Istituto Superiore di Sanità" (Code of Ethics of the Italian Institute of Health) [18], the fourth chapter of which addresses the issues of public health research and interventions. This chapter indicates certain requisites (notably: efficacy, proportionality, necessity, information, consent, protection of personal data, transparency) that are totally in line with the WHO Guidelines.

Conflict of interest statement

None to declare.

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