

**ENGLISH VERSION**



Istituto Superiore di Sanità

Rapporto ISS COVID-19 • n. 34/2020

# **Territorial surveillance and protection of public health: some ethical and legal issues**

ISS Bioethics Working Group COVID-19

Version of May 25, 2020



# Territorial surveillance and protection of public health: some ethical and legal issues

Version of May 25, 2020

## ISS Bioethics Working Group COVID-19

Coordinator:

Carlo PETRINI

*(Head of the Bioethics Unit and President of Ethics Committee, ISS, Rome)*

Components:

Luigi BERTINATO (*Segreteria Scientifica della Presidenza, ISS, Roma*); Giovanna FLORIDIA, Sabina GAINOTTI, Luciana RIVA (*Unità di Bioetica, ISS, Roma*); Alberto GAMBINO (*Università Europea di Roma*); Ignazio GRATAGLIANO (*SIMG e Università degli Studi di Bari*); Donato GRECO (*già Direttore Laboratorio ISS, Roma e Direttore Generale della Prevenzione Ministero della Salute*); Gualberto GUSSONI (*Direttore Scientifico FADOI, Roma*); Chiara MANNELLI (*Istituto di Candiolo, FPO-IRCCS, Candiolo, TO*); Assunta MORRESI (*Università degli Studi di Perugia*); Pierantonio MUZZETTO (*Università di Parma, OMCEO Parma, Consulta Deontologia Nazionale FNOMCeO*); Federico NICOLI (*Università degli Studi dell'Insubria, Varese e Domus Salutis, Brescia*); Francesca PIERGENTILI (*Ateneo Pontificio Regina Apostolorum, Roma*); Giorgio RESTA (*Università degli Studi Roma Tre*)

### Authors of this document

Luciana RIVA, Antonietta FILIA, Giovanna FLORIDIA, Donato GRECO, Chiara MANNELLI, Assunta MORRESI, Patrizio PEZZOTTI, Giorgio RESTA, Carlo PETRINI

Translation by Julie Sawitzke

Istituto Superiore di Sanità

**Territorial surveillance and protection of public health: some ethical and legal issues. Version of May 25, 2020.**

ISS Bioethics COVID-19 Working Group

2020, iii, 15 p. Rapporto ISS COVID-19 n. 34/2020 - English version

This report examines a few ethical and legal aspects related to public health surveillance and protection activities, particularly in the context of the COVID-19 pandemic. In emergency situations, for the protection of collective health, control measures may impose restrictions on the individual, drawing a new and temporary boundary to his freedom. The measures put in place to contain the contagion may lead to a conflict between personal rights and collective interests. Ethical reflection is fundamental to assess that an adequate balance between the epidemiological effectiveness of interventions and respect for people's fundamental rights is always guaranteed, even in emergency conditions.

Thanks to Massimiliano Caldora, Carlo D'Aprile and Susanna Tamiozzo for their support in drafting this manuscript.

For information: [luciana.riva@iss.it](mailto:luciana.riva@iss.it)

The original Italian version of ISS COVID-19 Reports are available at: <https://www.iss.it/rapporti-covid-19>

The reports translated in English are available from: <https://www.iss.it/rapporti-iss-covid-19-in-english>

Cite this document as follows:

ISS Bioethics COVID-19 Working Group. *Territorial surveillance and protection of public health: some ethical and legal issues. Version of May 25, 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 34/2020 - English version)

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The responsibility for scientific and technical data lies with the authors, who declare that they do not have any conflict of interest.

Editing and graphics: ISS Scientific Communication Unit (Sandra Salinetti and Paola De Castro)

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viale Regina Elena, 299 - 00161 Roma



# Table of contents

Preface .....	iii
Introduction .....	1
Ethics in public health surveillance and health data processing .....	3
National surveillance of the COVID-19 epidemic: the role of the Istituto Superiore di Sanità .....	4
Territorial surveillance: the role of public health workers and the general practitioner .....	5
Surveillance activity related to contact tracing .....	7
Containment and data protection measures: legal aspects .....	9
Digital technologies.....	11
WHO recommendations .....	13
Conclusions .....	14



## Preface

The COVID-19 pandemic has been disruptive: it has made our fragility even more manifest and has called us to face major dilemmas both in clinical ethics (at the bedside of the patient) and ethics in public health (community level).

COVID-19 brings a heavy burden of suffering for patients and their families: doctors and other health professionals have found themselves having to deal with extremely difficult situations in an emergency and lack of resources; those with public health responsibilities have had to make decisions with a strong impact on individuals and society. From an ethical point of view, the conflicts that arise between individual rights and collective interests are particularly relevant.

If, by simplifying the complexity of the situation, we wanted to refer to the so-called classical “principles” of bioethics, the emergency forced us to mitigate the emphasis on personal autonomy to safeguard the principles of justice and beneficence.

In every activity of the Italian National Institute of Health there are, to varying degrees and ways, important ethical components. For this reason, the Bioethics Unit and the Ethics Committee are operational in the Institute, which they support in carrying out the various functions.

In the unexpected case of COVID-19, which has placed a heavy burden on the Institute, it was considered appropriate to create a Working Group entirely dedicated to Bioethics, with skills in numerous disciplines and with the participation of experts from outside the ISS. In the Working Group there are skills in various areas of clinical medicine, epidemiology, public health, law, philosophy and in other disciplines, as well as, of course, in bioethics.

The first report of the COVID-19 Bioethics Working Group addresses the issue of surveillance and protection of public health. The Institute, as a technical and scientific body of the National Health Service, is strongly oriented towards the public health perspective: surveillance, which is crucial for the management of the pandemic, is one of the components that most characterizes public health. For this reason, it was decided to address the topic at the beginning of the work group activity. The theme of surveillance, in turn, is strongly intertwined with other ethically relevant themes. Some of these issues (e.g., the ethical implications of the protection of personal data, the role of the general practitioner) are the subject of other Working Group Reports being published, or in preparation, or scheduled for the subsequent activities of the Group.

*Carlo Petrini*





# Introduction

Surveillance is a fundamental element of public health, especially in the prevention and control of infectious diseases. In fact, it allows health authorities to make epidemiological estimates and provides the knowledge base necessary to plan interventions on the population. The World Health Organization (WHO) defines it as **the ongoing, systematic collection, analysis and interpretation of health-related data essential to the planning, implementation, and evaluation of public health practice**<sup>1</sup>. In the context of infectious disease outbreaks, the International Health Regulations (IHR) explains surveillance as **the systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary**<sup>2</sup>. Surveillance activities act as a rapid alert system, documents the impact of an intervention, monitors the epidemiological status of diseases, and supports public health policies and strategies.

Three main action phases can be identified: i) system design and planning; ii) data collection, analysis and interpretation; iii) use of data by dissemination and application to specific programs.

As part of the implementation of surveillance interventions on a population, a series of ethically relevant issues arise to the decision maker. First, a conflict can arise between personal rights and collective interests when, for reasons of public health protection, it is necessary to limit the privacy or civil liberties of individual citizens. Or, for example, there may be a risk of discrimination and stigmatization towards subgroups of vulnerable individuals, if nominative reporting is required.

It is important to note that surveillance activities are rarely subjected to an evaluation by independent bodies such as Ethics Committees, unlike what happens for public health and epidemiology research, although even in the case of the latter, to date, there is not a binding regulatory framework such as that in force for clinical trials.

All public health decisions are the responsibility of the competent authorities, assisted by reference experts and are ethically relevant which, even in emergency situations, the methods of allocating resources and managing data relating to individuals are subject to scrutiny, sharing and public debate.

Evaluation of the ethical and legal aspects deserves careful consideration even today, in the context of the containment and control measures put in place to deal with the COVID-19 pandemic.

As known, in 2019, in China, an animal coronavirus has acquired the ability to infect humans: SARS-CoV-2. This new virus, unlike the usual human coronaviruses (e.g., those of the common cold) that provoke a weak immune response, has found the population totally devoid of immune memory, thus giving way to a rapid and aggressive epidemic expansion.

The virus is transmitted from an infected person to a person susceptible by the respiratory route, with a factor  $k$  (number of people infected by an infected case) greater than 2, which is why the growth of the infected, in the absence of any control measures, assumes an exponential trend.

An infected person is considered to be contagious from 48 hours before to two weeks after the onset of symptoms (or collection of the positive sample if the person is asymptomatic).

There may be cases where people continue to have a positive swab for periods even longer than 20 days, but these people are not necessarily contagious. There are also infected individuals who do not exhibit typical symptoms. Even these silent individuals, however, can infect other people.

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<sup>1</sup> WHO health topics | Public health surveillance. Geneva: World Health Organization; 2014.

<sup>2</sup> International Health Regulations. 3<sup>rd</sup> edition. Geneva: World Health Organization; 2005.

In our country there has been a rapid spread of the virus, with two distinct epidemiological patterns: an explosive expansion in some northern provinces and a much more limited spread in the remaining areas, where the epidemic has affected small areas or closed communities. From the beginning of the epidemic to 20 May 2020, 227,204 cases of COVID-19 diagnosed by the regional reference laboratories as positive for SARS-CoV-2 have been reported to the surveillance system, however it was agreed that the actual number of people infected is even higher.

The experience of other countries (China, Korea) and previous coronavirus epidemics (SARS, MERS) led to a progressive descent of the curves resulting in a situation of ceased urgency but persistent sporadic cases of infected people. The plausible scenario of a post-epidemic phase could be characterized by a still existing infectious risk that occurs in isolated cases or limited outbreaks in restricted communities. Such a scenario would require the maintenance of monitoring and surveillance measures of the circulation of SARS-CoV-2 for a long period but would allow the abolition of the generalized confinement of the population, along with a gradual recovery of productive activities and social life, modulated with specific persistent surveillance and control activities. In particular, to quickly contain any outbreaks of COVID-19 and to interrupt transmission chains, it is essential that health authorities are able to promptly identify any case of COVID-19, isolate it, treat it, identify people who may have been exposed to the case during its infectious period, and ask close contacts to quarantine themselves, monitoring them for the appearance of symptoms throughout the incubation period of the disease (14 days).

# Ethics in public health surveillance and health data processing

Healthcare institutions are the authorities responsible for protecting the health of individuals permanently or temporarily present within their borders, whether they are citizens, tourists or refugees.<sup>3</sup>

Among the duties attributed to them, the WHO includes that of developing a territorial surveillance system that respects certain standards from an ethical point of view: the measures must always be necessary, reasonable, proportionate, non-discriminatory and transparent, and be implemented in full compliance with the current national and international regulatory framework.

In emergency situations, and where strictly necessary for the protection of collective health, control measures may impose restrictions on the individual, tracing a new and temporary boundary to his freedom, sufficient to be an effective guarantee of protection for the population. During the COVID-19 pandemic, the measures necessary to contain the spread of the infection led to the issue of restrictive provisions limiting the freedom of individuals. The complexity inherent in the evaluation of these measures has been intensified by the scarce availability of pre-existing knowledge about SARS-CoV-2 infection, useful for developing recommendations quickly.

In the different phases of the emergency it was necessary to collect and use citizens' personal data, raising relevant ethical and legal issues, including the need to ensure that the use of such data remained confined to the purposes for which it was collected<sup>4</sup>.

Territorial surveillance and the massive intrusion into the personal sphere of individuals, which, in the case of certain technological proposals, can also be translated into the tracking of daily physical movements, give the institutions the great responsibility to represent a reference of reliability and competence.

In a democratic state, trust in institutions by members of the community is the fundamental premise for achieving an adequate level of adherence to the provisions issued by political decision makers, as well as to develop responsibility and an attitude of mutual reciprocity and solidarity towards each other, with particular attention to the most fragile categories.

The structural instability that characterizes the health emergency situations, governed by the urgency factor, must not lose sight of the imperative need for citizen involvement: they must be adequately informed through timely, reliable communication that is understandable to everyone.

It is of crucial ethical relevance that respect for the rights of individuals as such and of the community as a whole is also and above all guaranteed in the emergency context, where critical issues never remain limited to health aspects.

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<sup>3</sup> WHO Guidelines on Ethical Issues in Public Health Surveillance 2017, p. 25.

<sup>4</sup> WHO Guidelines on Ethical Issues in Public Health Surveillance 2017, p. 29.

# National surveillance of the COVID-19 epidemic: the role of the Istituto Superiore di Sanità

On January 22, 2020, the Italian Ministry of Health established the activation of the surveillance system for suspected cases of infection with the new SARS-CoV-2 coronavirus, indicating how cases should be reported nationwide. With the Civil Protection Ordinance, starting from February 28, 2020, the coordination of the epidemiological surveillance of SARS-CoV-2 has been entrusted to the Istituto Superiore di Sanità (ISS, the National Institute of Health in Italy), which administers a digital platform into which the Regions and the autonomous Provinces of Trento and Bolzano enter the daily data from their territorial jurisdiction.

The ISS also carries out microbiological surveillance and regularly publishes an infographic and a bulletin which presents the integrated data. The data collected as part of these activities are processed for reasons of public interest in the public health sector, pursuant to article 9, paragraph 2, of the EU Regulation 2016/679 on the processing of personal data (General Data Protection Regulation, GDPR). The ISS communicates the data concerning epidemiological and microbiological surveillance to the Minister of Health and, in aggregate form, to the Head of the Department of Civil Protection and makes them available to the Regions and Autonomous Provinces of Trento and Bolzano. All data, in anonymous form, can be shared with the specific databases of the WHO and the European Centre for Disease Prevention and Control (ECDC), in order to guarantee international scientific and epidemiological collaboration. The updated data on infected people, deaths, people healed, and regional distribution can be consulted by citizens on the website of the Ministry of Health and Civil Protection.

On April 3rd, 2020, the Ministry of Health issued a circular in which it recalls that:

“The molecular diagnosis for cases of SARS-CoV-2 infection must be performed at the regional reference laboratories and additional laboratories identified by the regions according to the methods agreed with the National Reference Laboratory of the National Institute of Health and the procedures reported in circular no. 9774 of 20 March 2020”.

It also provides that:

“Required only the sending of a representative number of clinical samples to the National Reference Laboratory in ISS, by agreement, in order to monitor the molecular epidemiology of SARS-CoV-2” and that the SARS-CoV-2 positive samples of people deceased must be kept “at the facility that carries out the collection and / or laboratory diagnosis and subsequently sent to the National Reference Laboratory in ISS at the express request of the same”.

With the Decree of April 30<sup>th</sup>, 2020 from the Minister of Health, the criteria for the monitoring of health risk related to the transition from phase 1 to phase 2A<sup>5</sup> are made explicit. It is established that:

“The Ministry of Health, through a special control room, which will involve the Regions / PP.AA. and the National Institute of Health, collects the information necessary for the risk classification and carries out a weekly classification of the risk level of an uncontrolled and unmanageable transmission of SARS-CoV-2 in the Regions / PP.AA.”

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<sup>5</sup> Decree of 30 April, 2020 from the Italian Minister of Health “Emergenza COVID-19: attività di monitoraggio del rischio sanitario connesse al passaggio dalla fase 1 alla fase 2A di cui all’allegato 10 del DPCM 26/4/2020”.

With the COVID-19 epidemic, the ISS had to provide a rapid and effective response to the request for scientific information and training from the territory on the containment measures of the new disease. As part of the training activities, the ISS has carried out the following online training courses aimed at professionals engaged in activities to combat the infection and epidemiological surveillance of COVID-19:

- Health emergency from new coronavirus SARS-CoV-2: preparation and control
- COVID-19 epidemiological emergency: elements of contact tracing

And, among the many scientific meetings and webinars:

- Contribution of the general practitioner.
- Case reporting database.
- Telemedicine and support of actions to combat the spread of COVID-19.
- Contact tracing: search and manage contacts of COVID-19 cases.
- Contact tracing, experience in comparison.
- General medicine in phase 2 of the COVID-19 epidemic: organizational and welfare news.
- Contact tracing: not just apps.

## **Territorial surveillance: the role of public health workers and the general practitioner**

Territorial surveillance is entrusted to the prevention departments of local health authorities (Aziende Sanitarie Locali: ASL or AUSL), coordinated by the Regions according to guidelines agreed at national level and expressed in the LEA (Livelli Essenziali di Assistenza: *essential levels of assistance*): surveillance is divided into defined health districts for each ASL / AUSL.

The general practitioner, a professional affiliated with the National Health Service (NHS), represents the first contact between the citizen and the NHS and he/she is, therefore, a fundamental element of surveillance in the area, especially for the timely identification of cases. Please refer to Rapporto ISS COVID-19 n. 35/2020 by the COVID-19 Bioethics Working Group to learn more about the role and meaning that this figure assumes during an emergency situation.<sup>6</sup>

In general, in the planning and organization of each data collection, public health operators must evaluate what information is necessary to acquire for the specific health protection objectives outlined by the competent authorities. The questions asked and the methods of data collection should also include the optimization of the IT flow necessary for their processing and any sharing methods with other groups, such as local and national institutions, scientific societies and professional associations. The public health operator involved in these activities acquires a profile similar to that of the “data scientist”, that is, the professional with heterogeneous skills who usually associates himself with the ability to manage Big Data and to obtain relevant information. Territorial surveillance, activated according to the modalities of continuity of care, can also make use of voluntary associations and / or, for example, of territorial committees of the Italian Red Cross; the involvement of citizens can thus become an opportunity for communication on public health issues usually reserved for professionals, promoting the dissemination of correct information and the success of the interventions that are intended to be carried out.

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<sup>6</sup> Gruppo di Lavoro Bioetica COVID-19. *Il Medico di Medicina Generale e la pandemia di COVID-19: alcuni aspetti di etica e di organizzazione. Versione del 25 maggio 2020*. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 35/2020).

In emergency conditions, the role of all public health operators present at a territorial level becomes essential so that useful data is collected and made available promptly. The staff must be specially trained and enabled to act coherently within a complex system that responds to clear and shared rules.

## Surveillance activity related to contact tracing

In all cases of epidemic risk management, in addition to quickly identifying suspected cases, testing them, isolating them, and treating confirmed cases, it is crucial to identify the subjects who have had close contact with confirmed cases, so that preventative, quarantine and interruption of the transmission chain measures can be taken. In the epidemic situation caused by COVID-19, **in the absence of a preventive vaccine, the only strategy currently available for controlling the infection is the prompt identification of infected subjects and their close isolation for at least two weeks from the start of symptoms (or from the collection of a positive sample), accompanied by the active search for contacts during the period of contagiousness (contact tracing).**

Both the person with COVID-19 and the infected but asymptomatic person can be identified with specific molecular tests conducted on nasal and pharyngeal swabs. There are also numerous types of serological tests on antibodies that identify past infections, each of which has limits and a margin of error: the centralized validation of these tests is in progress, as well as the production of guidelines for appropriate use and therefore the use of these tests is currently indicated only in serum-epidemiological studies.

The identification of the infected and their timely isolation greatly reduce the probability that they can infect other people. The **'manual' tracking of contacts** (or **contact tracing**) carried out by the staff of the health authorities is a fundamental tool of public health, for the prevention and control of the spread of communicable diseases from person to person. It is used daily by the prevention departments of local health authorities (ASL or AUSL), for the control of other infectious diseases such as tuberculosis, measles, and some sexually transmitted diseases (e.g., syphilis, HIV infections). It protects the health of the population by limiting the contact of contagious people with other people, and consequently, the possibility of transmission of the infection to the population.

In the context of COVID-19, contact tracing consists of identifying and managing people who may have been exposed to a probable or confirmed case of disease in the 48 hours preceding the onset of symptoms in the case (or prior to the collection of the positive sample if the case is asymptomatic), until the time of diagnosis and isolation of the case, to avoid that these people (contacts) who are at high risk of having acquired the infection, can in turn transmit the infection. Close contact is defined as a person who has had a high-risk exposure (e.g. a person who lives in the same house as a COVID-19 case or a person who has had a face-to-face contact with a case at a distance less than 2 meters and lasting longer than 15 minutes).

Since COVID-19 transmission can also occur during the pre-symptomatic phase of the disease, or from people who remain asymptomatic, it is important to identify close contacts very quickly and make sure that they observe quarantine for the incubation period of the disease.

Contact tracing for COVID-19 takes place through the following activities:

- 1) identify contacts through an interview with COVID-19 cases and a detailed epidemiological investigation;
- 2) speak with the contacts to inform them that they may have come into contact with a case of SARS-CoV-2 infection / disease and to confirm the information collected;
- 3) classify contacts in high or low risk contact (based on the type of exposure) and test suspicious cases;

- 4) provide contacts with information on behaviours to be followed and preventive measures to be implemented to avoid transmission of the infection, including quarantine if it is a close contact;
- 5) monitor close contacts for 14 days after exposure to quickly identify any secondary cases.

The use of digital applications can facilitate the search for contacts but they do not replace the traditional contact tracing performed by ASLs. In particular, they can help to quickly reconstruct the framework of social contacts experienced by a confirmed case in the epidemiologically relevant period. The experience of Asian countries – from China, to South Korea, to Singapore – is particularly useful from this point of view and has been the subject of numerous scientific studies.<sup>7</sup>

**In the implementation of tracking systems, however, it is always necessary that an adequate balance is always guaranteed between epidemiological effectiveness and respect for the fundamental rights of people, as well as the safety of all aspects of data management.**

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<sup>7</sup> See for example: Ferretti L, Wymant C, *et al.* Quantifying SARS-CoV-2 transmission suggests epidemic control with digital contact tracing, in *Science* 10.1126/science.abb6936 (2020); Holmes A. Singapore is using a high-tech surveillance app to track the coronavirus, keeping schools and businesses open. Here's how it works, in *Business Insider*, March 24, 2020.



## Containment and data protection measures: legal aspects

The measures adopted to contain the COVID-19 epidemic have transversely affected many sectors of domestic law, from economic law to tax, labour and administrative law. In order to make surveillance more widespread and the exchange of information between health authorities easier, it was necessary to implement a 'simplified' regulation of the protection of personal data; This is the subject of a specific "ISS COVID-19 Report" produced by the "COVID-19" Bioethics Working Group, to which you are referred<sup>8</sup>.

With the declaration of the state of emergency approved by the Italian Council of Ministers on January 31, 2020, for a period of 6 months, the Civil Protection ordinances as well as the law decrees – instruments which the Italian Constitution requires to legislate in urgent conditions – have acquired absolute operational centrality. These two sources have designed the fundamental architecture of **emergency law, which is characterized by its exceptional nature and the derogatory scope with respect to established principles and institutions of our legal system**. In the aftermath of the declaration of the state of emergency, the Department of Civil Protection has adopted various ordinances limiting the enjoyment of fundamental rights and freedoms, for the purpose of containing the epidemic and for the safety and health of citizens. In particular, the ordinance of February 3, 2020 – with the prior assent of the Guarantor for the Protection of Personal Data, n. 15 of February 2, 2020 – established in art. 5 that: "in order to ensure the most effective management of flows and the exchange of personal data", **the subjects operating within the national civil protection service and the related operational structures can implement, in compliance with the principles established by art. 5 of Regulation (EU) 679/2016 on the processing of personal data (GDPR) (proportionality, minimization, purpose, etc.), processing of personal data also belonging to the particular categories referred to in art. 9 of the GDPR (former sensitive data) and even judicial data (art. 10 GDPR) necessary for the performance of the civil protection function in the context of the emergency**. These data can be communicated to public and private subjects, if this proves indispensable, for the purpose of containing the epidemic.

Art. 14 Act March 9, 2020, No. 14<sup>9</sup> reformulated this provision by emphasizing its temporary nature and reiterating that:

- a. personal data, common and 'sensitive', can be processed and have an internal circulation to the enforcement bodies responsible for fighting the emergency;
- b. the same data may be communicated to other public entities;
- c. the principles of art. 5 GDPR apply to the treatment (lawfulness, fairness, transparency, purpose, minimization, etc.);
- d. the conferment of processing tasks pursuant to art. 2-quaterdecies of the Data Protection Code may take place in simplified ways, and also orally;
- e. as part of these activities, the health authorities and other authorized persons, if they process data collected from the interested party, may omit or simplify the information required by art. 13 GDPR.

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<sup>8</sup> *Protezione dei dati personali nell'emergenza COVID-19*, Rapporto ISS COVID-19 n. 42/2020.

<sup>9</sup> Now transfused in art. 17-bis of Law Decree 17 March 2020, No. 18, converted into law by Law 24 April 2020, No. 27.

To rebuild the surveillance system, it is appropriate to mention at least two other ordinances. The first, from the **Ministry of Health, on February 21, 2020**, concerns the active surveillance of subjects at risk of contagion: art. 3, in reiterating that personal data collected as part of surveillance activities are processed by the competent Health Authority for reasons of public interest (see article 9, par. 2, GDPR), **establishes that the term of retention of such data is 60 days from collection**. The second, from the Department of Civil Protection on February 27, 2020, widens the audience of data controllers, the type of data collected, as well as the direction (incoming and outgoing) of the communication flow. The Prime Ministerial Decree of March 4 and 8, 2020 also reformulates and extends the measures already adopted with previous measures of the Ministry of Health, establishing for the subjects who have stayed in areas at epidemiological risk, the obligation to communicate this information to the local health authority, as well as the general practitioner or paediatrician.

The provisions in question appear in line with art. 23 GDPR, which provides that EU or Member State law may limit, by legislative measures, the scope of obligations and rights (referred to in articles 12 to 22, as well as art. 5):

**“If this limitation respects the essence of fundamental rights and freedoms and is a necessary and proportionate measure in a democratic society to safeguard [...] important general public interest objectives of the Union or of a Member State, in particular a relevant interest of [...] public health and social security”.**

In summary, all the aforementioned rules integrate and partially modify the data protection system, in order to balance the respect of the protection of the same with the superordinate and irreproachable needs of protection of public health. The principles established by the GDPR in articles 6, 9 and 23, can in themselves legitimize the processing of data relating to infected people, but also the research activities of the chain of infection undertaken at various levels, from the family doctor to the hospitals or other health facilities involved.

# Digital technologies

The choices inherent to the adoption of forms of surveillance based on digital technologies are subject to a delicate balancing operation of the interests involved, represented on the one hand by the protection of personal data, the dignity of the person and the integrity of the democratic process and, by the other, from the protection of life and health.

During the COVID-19 epidemic, the debate on legitimate forms of data-driven containment was at the centre of the government and parliamentary agenda, not just in Italy<sup>10</sup>. At the European level, the *European Data Protection Board (EDPB)*<sup>11</sup> has formulated some general reference principles (such as graduality and proportionality) indicated in specific guidelines<sup>12</sup>. The European Commission, with the Recommendation of April 8, 2020<sup>13</sup> expressed indications that should be respected by Member States that resort to technological applications for the purpose of prevention, alerting and tracking of contacts.

The main operating options that have been evaluated by the competent bodies are highlighted below, emphasizing the critical issues related to their possible use:

- a. **Collection of aggregate data on communication flows.** The less invasive hypothesis consists in the acquisition by telecommunication companies and / or providers of Internet services and social networks, of anonymous data relating to the location of users in order to reconstruct mobility trends and analyze the epidemiological trend through maps. There appear to be no legal obstacles to this practice: Articles 9 and 15 of Directive 2002/58 / EC and art. 126 of the Data Protection Code allow the acquisition of data relating to the location of users, other than traffic data, if anonymous or otherwise with the consent of the interested party<sup>14</sup>.
- b. **Geolocation and selective tracking of the movements of individual users.** This hypothesis has been put forward, together with that relating to drones, mainly for repressive purposes in order to check compliance with contagion containment measures. However, it appears to be in tension with the principle of proportionality that regulates the data protection law<sup>15</sup>.
- c. **Proximity tracking through specific applications made operational through mobile telephony services.** In Italy the preference has been oriented towards an App called “Immuni” and developed by Bending Spoons. The basic idea is to make available to citizens an application that allows, through Bluetooth-Low-Energy technology, to record and maintain in encrypted form on the single device anonymous traces of close contacts (below a certain spatial distance and for a certain period of time) with other users in the epidemiologically relevant period. In the event of a positive result registered by the same user through a code, following the microbiological response, various options are configured: a) the App could automatically send an anonymous alert signal to close contacts, who would be invited to contact the healthcare personnel for the appropriate assessments; b) the health authorities, by directly accessing the data stored on a centralized platform and using a decryption

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<sup>10</sup> Cfr. art. 76 Decree Law March 17, 2020, No. 18.

<sup>11</sup> It is an EU body responsible for enforcing the General Data Protection Regulation from 25 May 2018. It is made up of the head of each data protection authority and the European Data Protection Authority or their representatives.

<sup>12</sup> Guidance 4/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak, European Data Protection Board, 21 April, 2020.

<sup>13</sup> Commission Recommendation (EU) 2020/518 of 8 April 2020

<sup>14</sup> Thus, the opinion of the European Data Protection Board, which attaches particular emphasis to anonymity; similar is the assessment of the German Federal Commissioner for Data Protection and Freedom of Information, <https://www.bfdi.bund.de/DE/Datenschutz/Datenschutz-Corona/Allgemeines/FAQ-Mobilfunkdaten-RKI/FAQ-Mobilfunkdaten-RKI-table.html>.

<sup>15</sup> As also indicated by the Commission Recommendation (EU) 2020/518 of 8 April 2020 (see paragraph 10).

key, could identify the contacts at risk and contact them quickly to take the necessary measures. The specific operational details have not yet been disclosed, but the Government has established, with art. 6 of the law decree April 30, 2020, n. 28, the minimum framework of guarantees which must be respected and which comply with the principles reaffirmed by the Commission and the European Data Protection Board. **They are summarized below:**

- **Anonymity:** the information stored on devices or platforms must be anonymous and there must be technological methods that limit the risk of re-identification to the maximum degree.
- **Exclusion of the use of any form of geolocation of the individual,** given that for the purpose of proximity tracking, the collection of data relating to the movements and geographical location of the interested party is not necessary.
- **Possibility to express a differentiated consent for different uses of the data** (e.g. symptomatology and diagnostics, proximity tracking, telemedicine, etc.).
- **Time limit:** the data must not be kept beyond the period strictly necessary for the purposes of epidemiological control and containment of the infection.

The principle established by art. 22 GDPR must be kept in place with the relative **exclusion of fully automated decisions.**

An equally important feature is:

- **voluntariness:** adherence to contact traceability programs must be voluntary, avoiding rewards or incentives to encourage participation. Citizens must be able to join because they are aware of the importance of the measures taken for their own health and for the community to which they belong.
- **accessibility:** the system must be easily understandable and accessible, to make the informed consent of each citizen effective regarding all possible options of the app. Too complex a system would risk formalizing personal consent, especially in the case of people who are unfamiliar with IT media.
- **proportionality:** the information required must be only that which is strictly necessary to achieve the infection containment goal.

## WHO recommendations

The WHO proposes 17 recommendations to promote the ethics of public health surveillance in the 2017 document entitled *Guidelines on Ethical Issues in Public Health Surveillance*:

1. 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.
2. Countries have an obligation to develop appropriate, effective mechanisms to ensure ethical surveillance.
3. Surveillance data should be collected only for a legitimate public health purpose.
4. Countries have an obligation to ensure that the data collected are of sufficient quality, including being timely, reliable and valid, to achieve public health goals.
5. Planning for public health surveillance should be guided by transparent governmental priority-setting.
6. The global community has an obligation to support countries that lack adequate resources to undertake surveillance.
7. The values and concerns of communities should be taken into account in planning, implementing and using data from surveillance.
8. Those responsible for surveillance should identify, evaluate, minimize and disclose risks for harm before surveillance is conducted. Monitoring for harm should be continuous, and, when any is identified, appropriate action should be taken to mitigate it.
9. Surveillance of individuals or groups who are particularly susceptible to disease, harm or injustice is critical and demands careful scrutiny to avoid the imposition of unnecessary additional burdens.
10. Governments and others who hold surveillance data must ensure that identifiable data are appropriately secured.
11. Under certain circumstances, the collection of names or identifiable data is justified.
12. Individuals have an obligation to contribute to surveillance when reliable, valid, complete data sets are required, and relevant protection is in place. Under these circumstances, informed consent is not ethically required.
13. Results of surveillance must be effectively communicated to relevant target audiences.
14. With appropriate safeguards and justification, those responsible for public health surveillance have an obligation to share data with other national and international public health agencies.
15. During a public health emergency, it is imperative that all parties involved in surveillance share data in a timely fashion.
16. With appropriate justification and safeguards, public health agencies may use or share surveillance data for research purposes.
17. Identifiable surveillance data should not be shared with agencies that are likely to use them to take action against individuals or for uses unrelated to public health.

# Conclusions

Territorial surveillance in public health, to which this short report is dedicated, represents a fundamental element in the prevention and epidemiological control of infectious diseases. During the COVID-19 pandemic, measures to contain the contagion led to a conflict between personal rights and collective interests, the main ethical-legal implications of which have been briefly described here. In light of the considerations that emerged, **we want to underline the importance of ethical reflection and “interdisciplinary dialogue between scientific, ethical and political actors”<sup>16</sup> even in emergency conditions, with constant reference to the following values:**

- **Solidarity.** Solidarity requires a collaborative approach between individuals, health institutions, governments and nations; requires working together and is essential in assisting people and in the deployment of human and material resources.
- **Proportionality and necessity.** The disadvantages deriving from the implementation of a particular surveillance plan (for example, the violation of the protection of personal data) must be offset by the benefits. Proportionality requires that the restrictions on individual freedom and the measures taken to protect the public from possible harm are not greater than is necessary to address the actual level of risk. The most coercive measures should only be used if the least restrictive measures have proven ineffective to achieve the public health protection goal.
- **Utility.** Decisions made regarding surveillance plans should aim to improve public health. The utility must be balanced with the other values: the health of the community is primarily achieved by protecting and promoting the health of individuals.
- **Reasonableness.** Decisions must be adequate or congruent with respect to the objective of collective health protection.
- **Damage minimization.** A fundamental principle of ethics in public health concerns the obligation to protect the public from serious damage. The concept of harm includes physical, psychological, social and economic harm. In a pandemic, restrictions on individual freedom and imposition of infection control practices may be necessary to protect citizens' health. Such restrictions should, however, always be explained and motivated by decision makers.
- **Transparency and understandability.** The purpose of the surveillance plans must be explicit. Transparency is the necessary prerequisite of the entire surveillance chain, if you want to gain and consolidate citizens' trust in the health system and in the actions taken. Transparency is not limited to the mere publication of the information available (respecting the privacy of individuals), but also means giving a reading key and an interpretative hypothesis of the same, as comprehensible as possible to the whole population.
- **Representation.** In research surveillance, all subgroups of the population should be accurately represented.
- **Equity.** Some subgroups are characterized by health problems to a greater extent than the general population: they must therefore be the subject of particular attention as the disease especially affects them.

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<sup>16</sup> Cfr. UNESCO International Bioethics Committee and World Commission on the Ethics of Scientific Knowledge and Technology, Statement on COVID-19: Ethical Considerations from a Global Perspective, 26 March 2020.

- **Participation.** The participation of specific areas of citizenship in the development of surveillance plans can be useful to ensure that the data collected is more relevant and is used better. It can also encourage the dissemination of correct information and the prevention of cases of stigma.
- **Non stigmatization.** Some indicators, if crossed with social and demographic data that identify vulnerable subgroups of the population, available for fairly small geographical units, could contribute to stigmatization processes, strengthening prejudicial dynamics.
- **Protection of personal data and consent to their use.** In some cases, it may be impossible to obtain the data subject's consent at the time of data collection. However, personal data must be processed in compliance with all legal regulations, albeit with the limits set by the regulations envisaged for the state of emergency. It is important to emphasize that **any derogation from the constitutional guarantees for data protection must always be understood as concomitant to the state of emergency and that, once the emergency ends, all the constitutional guarantees must come back into being as they were before.**

The set of values described represents a lens through which to evaluate public health programs from an ethical perspective. On the side of decision-makers and all professionals involved in health surveillance and protection activities, integrated work is essential to carry out responsible and effective actions, even in urgent conditions. Each decision-making process develops from a base of information coming from the territory and it is only through constant dialogue with public health operators present at local level, and in compliance with the ethical-legal reference values, that it is possible to plan interventions and verify its adequacy by constantly monitoring the results.

Only through synergistic work between different professionals of reference is it also possible: i) to identify the risks and benefits associated with the individual interventions proposed and to justify the risks in relation to the potential benefits; ii) verify the homogeneity of the application of the programs to the population and, if population subgroups are selected, exclude any stigmatizing profiles; iii) verify that the informed consent process is foreseen, achievable, appropriate and sufficient; iv) identify the social implications of the initiatives and the potential consequences both in the short and long term; v) communicate in a timely, transparent and understandable manner to all.



# Rapporti ISS COVID-19 in Italian

Available from <https://www.iss.it/rapporti-covid-19>

1. Gruppo di lavoro ISS Prevenzione e controllo delle Infezioni. *Indicazioni ad interim per l'effettuazione dell'isolamento e della assistenza sanitaria domiciliare nell'attuale contesto COVID-19*. Versione del 7 marzo 2020. Roma: Istituto Superiore di Sanità; 2020 (Rapporto ISS COVID-19, n. 1/2020)
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