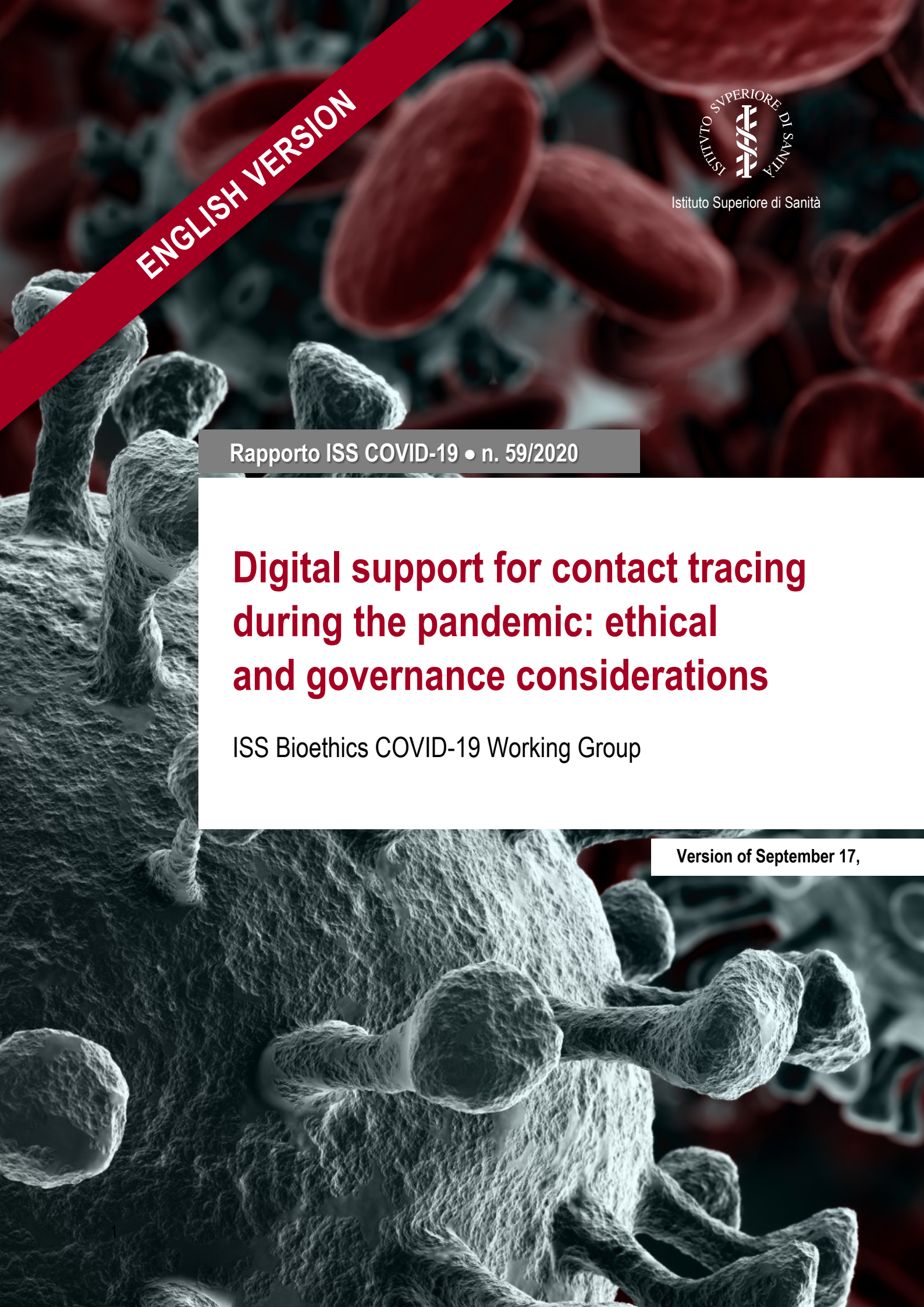

ENGLISH VERSION

Istituto Superiore di Sanità

Rapporto ISS COVID-19 • n. 59/2020

Digital support for contact tracing during the pandemic: ethical and governance considerations

ISS Bioethics COVID-19 Working Group

Version of September 17,

Digital support for contact tracing during the pandemic: ethical and governance considerations

Version 17 September 2020

ISS Bioethics COVID-19 Working Group

Coordinator:

Carlo PETRINI
(Direttore Unità di Bioetica e Presidente Comitato Etico, ISS, Roma)

Members:

Franca BENINI *(Centro regionale Veneto di Terapia del dolore e Cure palliative pediatriche, Università di Padova)*; Luigi BERTINATO *(Segreteria Scientifica della Presidenza, Istituto Superiore di Sanità, Roma)*; Ferdinando CANCELLI *(Fondazione F.A.R.O. Torino)*; Aurelio FILIPPINI *(Ordine delle Professioni infermieristiche, Varese)*; Giovanna FLORIDIA, Sabina GAINOTTI, Luciana RIVA *(Unità di Bioetica, Istituto Superiore di Sanità, Roma)*; Alberto GAMBINO *(Università Europea di Roma)*; Ignazio GRATTAGLIANO *(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)*; Valeria SALA *(Università Europea di Roma)*; Claudio SARTEA *(Università di Roma Tor Vergata)*

Authors of this document

Assunta MORRESI, Franca BENINI, Aurelio FILIPPINI, Sabina GAINOTTI, Alberto GAMBINO, Ignazio GRATTAGLIANO, Donato GRECO, Gualberto GUSSONI, Francesca PIERGENTILI, Giorgio RESTA, Claudio SARTEA, Carlo PETRINI

With the participation of

Carlo D'APRILE (1), Giuseppe D'AVENIO (2), Antonietta FILIA (3), Daniele GIANSANTI (2), Mauro GRIGIONI (2), Patrizio PEZZOTTI (3)

(1) Unità di Bioetica, ISS; (2) Centro Nazionale Tecnologie Innovative in Sanità Pubblica, ISS; (3) Dipartimento Malattie Infettive, ISS

Istituto Superiore di Sanità
Digital support for contact tracing during the pandemic: ethical and governance considerations. Version of September 17, 2020.
ISS Bioethics COVID-19 Working Group
2020, iii, 23 p. Rapporto ISS COVID-19 n. 59/2020 – English version

Contact Tracing (CT) is a fundamental public health tool for the prevention and control of the spread of communicable diseases from person to person. Digital CT makes use of telematic and digital contacts, limiting personal contacts between public health professionals and citizens and using telematic database access and proximity tracking technologies via Bluetooth or GPS. Mobile applications ("Apps") downloaded on smartphones can be a powerful technological support for the CT. CT through Apps raises multiple relevant ethical issues involving various areas: organization of health services, public health, clinical medicine, social medicine, epidemiology, technology, law and many other areas. Among the issues raised are: proportionality of the information collected, voluntariness of use, consent, information, management rules, transparency of the code and the results of its dissemination, data deletion criteria, free availability of technical and health care assistance, anonymity, and many others. The report provides the information necessary to deal with ethical issues: epidemiological, public health, technological, engineering and legal elements are included. The Working Group highlights some crucial elements from an ethical point of view, which concern in particular the evaluation of effectiveness, the separation of personal data from public health data, transparency, information, and the solidarity dimension that must characterize any public health action.

The original Italian version of ISS COVID-19 Reports are available from: **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**

We thank doctor Susanna Tamiozzo of the Bioethics Unit for her kind support.

For information: carlo.petrini@iss.it

Cite this document as follows:

ISS Bioethics COVID-19 Working Group. *Digital support for contact tracing during the pandemic: ethical and governance considerations. Version of September 17, 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 59/2020 - English version).

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)

viale Regina Elena, 299 –00161 Roma

Table of contents

Preface iii
Introduction 1
What is contact tracing? 2
Effectiveness of contact tracing 2
Traditional CT and digital CT 3
Contact-tracing Apps 4
Contact-tracing Apps in other countries 6
Ethics and contact-tracing Apps 8
Some particular users: minors, elderly 12
Apps in the current discipline 13
Contact-tracing Apps: technological aspects 16
Technological potential in the COVID-19 era 16
Proximity and location measurement features in Apps: towards choosing Bluetooth 17
Apps beyond CT 19
Highlights 20
References 22

Preface

Since the beginning of the spread of SARS-CoV-2 in Italy, the Istituo Superiore di Sanità (ISS, the National Institutes of Health in Italy) has been engaged in health surveillance activities, monitoring the epidemiological situation, development of guidelines and operational strategies in order to face the health emergency.

In this context, thematic Working Groups have been set up to provide advice and proposals. The Working Groups include internal and external experts to the ISS. The skills of the experts participating in the "COVID-19 Bioethics" Working Group cover multiple disciplinary areas beyond bioethics. In random order: clinical medicine, public health, epidemiology, jurisprudence, bio-law, nursing, philosophy, pediatrics, palliative care, and others.

Thanks to the multiplicity of skills, the "ISS Bioethics Working Group COVID-19" has produced documents on various topics, which are published in the series "ISS COVID-19 Reports", available in the thematic section of the ISS website.

This report adds to the previous ones by intervening on the issue of digital technologies to support contact tracing, which is normally carried out by the Prevention Departments for the control of diseases that can be transmitted from person to person.

As is recognized in the Extraordinary Commissioner's Ordinance for the Implementation and Coordination of Containment and Control Measures of the COVID-19 Epidemiological Emergency, contact tracing (CT) "is one of the public health actions used for the prevention and containment of the spread of infectious diseases and represents an important post-emergency and back to normal strategy" for many reasons. In particular, contact tracing aims to identify potentially infected individuals (because they are close contacts of a COVID-19 case), before symptoms emerge or even in their absence and, if carried out quickly enough, it can prevent subsequent transmission from secondary cases. It is reasonable to assume that adequate technological support for this activity, through the use of digital applications for proximity detection, can make CT much more efficient and faster, so much so that dedicated computer applications are being developed all over the world.

All this, however, raises significant ethical issues. For this reason, the "COVID-19 Bioethics" Working Group considered it appropriate to dedicate a report to the topic.

Given the complexity of the issue, additional experts from the Infectious Diseases Department and the National Center for Innovative Technologies in Public Health of the ISS participated in the drafting of this report who offered an important contribution to defining the epidemiological, technological and engineering framework.

The report is addressed both to the institutions with which the ISS collaborates (the Ministry of Health, the various components of the National Health Service, the Regions, and others), and to individual citizens, of whom the ISS serves. Institutions will also be able to find useful ideas for an adequate management of the problem. Citizens will be able to find concise information in an easily accessible form.

Carlo Petrini
Coordinator of the ISS Bioethics Working Group COVID-19
Director of the Bioethics Unit and President of the ISS Ethics Committee
Istituto Superiore di Sanità

Introduction

For the first time in history, the human community of the entire planet is experiencing a pandemic in real time awareness of the event and its dynamics. The global spread of Coronavirus disease in 2019 (COVID-19), caused by SARS-CoV-2, has already resulted in millions of sick people and hundreds of thousands of deaths, and the numbers continue to grow. Health services and scholars from all over the world are involved in the search for therapies and in the development of vaccines, relying on huge economic resources, both from national and international institutions and from private subjects, and above all on an extraordinary scientific and technological background.

Despite this, to date, there are still many gaps in knowledge about the pathogen, and a high degree of uncertainty about the contagious and pathophysiological mechanisms of the disease. There is also extensive discussion on the effectiveness of various medical treatments implemented so far; we do not know in what terms we can speak of immunity for those affected by SARS-CoV-2; we cannot say if we will have an effective vaccine, let alone when.

We must therefore be prepared to live with this virus for an indefinite time, waiting for the solutions that scientific research will be able to offer to us: economic and social recovery around the world depends on how much we will be able to contain the infection without resorting to prolonged confinement of the population.

Knowing that this virus spreads through transmission between infected and susceptible individuals, one of the most valid tools we have to interrupt the chain of contagion is the very ancient one of physical isolation, first of all of those who get sick, and then of the potentially infected, which implies measures such as quarantine, social distancing and the use of protective tools in public places. To be able to keep the pandemic under control, all our activities and behaviors must respect physical distancing from other human beings: a physical distancing never achieved so far in the history of humanity as regards the numerical dimensions of the people involved, of which we will have to monitor the effects with timely continuity in the coming months. For this purpose, the search for contacts of infected cases (contact tracing, CT), in order to identify them, becomes central in public health policies.

CT is therefore a key component of strategies to prevent and control the spread of SARS-CoV-2 infection, in combination with early case detection and in synergy with other measures such as hand hygiene and use of masks in public places.

The ISS working group has already dedicated the report “Territorial surveillance and protection of public health: some ethical-legal aspects” (1) to the issue of public health surveillance to which reference should be made for general aspects.

What is contact tracing?

Contact Tracing (CT) is a fundamental public health tool for the prevention and control of the spread of communicable diseases from person to person, which is used daily for the control of various infectious diseases such as tuberculosis, measles, and some sexually transmitted diseases (e.g. syphilis, HIV infections). The goal of CT is to quickly identify people exposed to existing cases as potential secondary cases and prevent further transmission of the infection.

The CT procedure already in place provides for the identification by the family doctor of a suspected case of infection. Therefore, it requires to:

1. confirm the diagnosis by administering specific diagnostic tests (for COVID-19, the Reverse Transcriptase-Polymerase Chain Reaction, RT-PCR);
2. interview cases to identify possible contacts occurred during the infectious period (for COVID-19 from 48 hours before the onset of symptoms or collection of the positive sample, up to 14 days after or until the case is isolated);
3. trace and interview the contacts reported;
4. quarantine close contacts for two weeks;
5. monitor contacts during quarantine;
6. repeat the procedure for contacts who test positive.

For further information on the main phases of CT activity, see the ISS COVID-19 Report n. 53/2020 “Guide to contact tracing for COVID-19” (published in Italian) (2).

If implemented systematically and effectively, these actions can interrupt the chains of transmission of the infection. In the “COVID-19 Monitoring Reports” produced weekly by the Ministry of Health and the ISS, the CT is indicated as a tool with great potential[1].

Effectiveness of contact tracing

In diseases that are transmitted from person to person, the prompt identification of contacts of infectious cases and their quarantine correspond to a clear logic of containment of the infection.

The primary indicator of the effectiveness of the CT is the number of secondary cases identified and isolated, that is, the number of persons infected by a first confirmed positive case.

In addition to the presence of an effective surveillance system and the availability of diagnostic tests, the effectiveness of CT in identifying secondary cases of COVID-19 in the population depends on numerous system variables. The main ones are listed below:

- Voluntary collaboration of the index case (i.e. the first diagnosed case, the case that gave rise to the chain of transmission)

[1] The data analysis reports published weekly by the ISS during the summer 2020 show that it is “essential to maintain high attention and continue to strengthen contact tracing activities in order to early identify all potential transmission outbreaks and continue to monitor the spread. For this reason, it is crucial to maintain a high awareness of the general population about the uncertainty of the epidemiological situation and the importance of continuing to strictly comply with all the measures necessary to reduce the risk of transmission"

- Full collaboration of contacts in following quarantine orders and monitoring their symptoms.
- Availability of laboratories capable of providing diagnostic test results rapidly.
- Ready availability of Personal Protective Equipment (PPE).
- Availability of an efficient transport network of biological samples.
- Availability of home healthcare support.

Scientific evidence on the current COVID-19 epidemic shows the importance of contact tracing, both as a method to contain the virus in the presence of a limited number of cases, and as an effective tool in the context of widespread transmission.

Traditional CT and digital CT

Traditional CT has been widely practiced so far by the Prevention Departments and consists in interviewing cases and contacts (by telephone or with home visits) and using other methods to identify all contacts, performing laboratory tests, monitoring contacts for symptoms and making sure that they are following quarantine / isolation and other preventive measures.

Digital CT makes full use of technological solutions based on digital health and, in particular, of two components, electronic health (e-health) and mobile health (m-health), drastically limiting personal contacts between public health operators and citizens and using technologies for accessing telematic databases and proximity tracing with Bluetooth[2] or GPS[3].

From the point of view of public health, there is no conceptual difference between the two forms of CT, nor do the objectives change. However, in digital CT the responsibilities of surveillance operators expand, since the latter must also monitor the functioning of the digital tools. There are also no differences in laboratory test procedures and containment and prophylaxis measures.

CT is a demanding and costly activity in terms of hours / person, so digital tools can play a role in lightening the burden of these procedures by speeding up the contact tracing process, as long as it is conducted within a built-in surveillance program into the existing public health system including health service personnel, testing services and traceability infrastructure.

However, the inclusion of digital technology in surveillance activities is not limited to a mere, neutral technological support: these tools have the potential to trigger radical changes in the behavior and attitudes of the population and of the institutions themselves, just like Internet, smartphone, and social media, etc.).

This document mainly deals with the ethical aspects related to the introduction of digital technology in support of the CT.

---

[2] Bluetooth is a technical-industrial data transmission standard for wireless personal area networks (WPAN), a technology widely used in bioengineering to be able to make measurements of relevant parameters, vital or in any case related to activity or health, by means of sensors placed in various parts of the body and to return them to a summary web page.

[3] The Global Positioning System (GPS) is a satellite positioning and navigation system. Through a dedicated network of artificial satellites in orbit, it provides a mobile terminal or GPS receiver with information on its geographical coordinates and time in all weather conditions, wherever on earth there is the possibility of unobstructed communication with at least four satellites of the system.

Contact-tracing Apps

While it is true that the pandemic is affecting the whole world, the political, value-related, geographical, religious, social and economic contexts are different in the various countries and/or geographical regions. The availability of a wide range of technological tools to support CT does not mean that these will be equally utilized and effective everywhere. Technologies, in this as in other cases, acquire different meanings and produce different effects according to the social and institutional contexts in which they must operate. For this reason, the scientific and technological knowledge in a pandemic must necessarily also make use of the human sciences in order to fully develop their potential: the pandemic is in fact a social phenomenon as well as a medical one, because it affects the human being as an individual and at the same time in his/her relationships with /her peers in the affective, work, recreational, community fields.

In other words, it is about using available technology to adapt, to the complex dynamics of our societies and local communities a seemingly simple strategy albeit the most effective at present to contain the spread of the contagion, i.e., isolation.

Taking note of the proven effectiveness of this strategy, the universal values, as described for example in the Universal Declaration of Human Rights of the United Nations of 1948, are however put to the test: just think, for example, of freedom, the personal explanation of which must be to find balance with the social one, especially in the so-called "second phase" in which, at least in Italy, the "fear" of the pandemic has subsided and the desire for freedom and normality tends to take over.

Digital tools that support and make traditional CT more effective can be the most diverse, starting with existing territorial registries, to health registries to databases for identifying the nuclei of cohabitants and those of employees and employers (this is the basic dataset of the surveillance system implemented for example by Veneto).

Internationally, various digital tools have been introduced to support traditional CT, in particular the tracking of contacts through special Apps installed on smartphones. The term "App" (abbreviated form of "mobile application") refers to computer applications that quickly perform defined, more or less simple functions on a mobile device – for example, measuring distances, counting steps, accessing the contents of a magazine or to the bank account, store scores acquired through supermarket purchases – with a graphical interface that facilitates use[4].

Installed on commonly used mobile devices, such as tablets and smartphones, or on wearable media such as watches or "bracelets", they can facilitate surveillance measures making them more rapid and effective.

Their structure can vary a great deal: in principle they should limit themselves to doing something very similar to what is already done manually and personally by health professionals when they track the chains of transmission. However, they could also become a means of tracing the personal behavior of each citizen and therefore of social control. Intermediate situations are obviously possible, with enormous consequences on the level of individual and collective freedom, public health and individuals, and therefore on crucial ethical principles and rights of constitutional importance, such as dignity of the person, freedom, equality, solidarity and democracy.

[4] Together with other telemedicine services that allow remote medical examinations to be carried out, the use, for example, of Apps for the constant monitoring of parameters in chronic pathologies can be useful in reducing waiting lists as well as in containing healthcare costs, making it possible to continue remote medical consultation activities, which are clearly useful even considering all the limits of the activity at distance.

Contact-tracing Apps were therefore motivated to speed up and improve the work of trackers: with a sufficiently wide use of telecommunication techniques available on mobile devices such as smartphones or wearable media, it is possible to reconstruct the chain of contacts by an infected person in potentially faster times and in a more complete way than by just relying on personal memory. Furthermore, in contexts of high ethnic and linguistic diversity, digital CT can solve, or mitigate, the problem of the necessary use of interpreters in communications between healthcare personnel and the index case, necessary to identify contacts at risk.

The technological implementation of manual tracking systems could offer the advantage of more effective surveillance and therefore can potentially help to identify contacts more quickly (reducing the risk of transmission) to limit the spread of the infection among the population.

However, this is a technology that is still very imprecise from a strictly technological point of view, as briefly indicated in the following chapter "Contact-tracing Apps: technological aspects", and more extensively in the ISS COVID-19 Report n. 54/2020 "Technologies supporting proximity detection: reflections for citizens, professionals and stakeholders in COVID-19 era. Version of May 31, 2020" (published in Italian) (3).

On the other hand, contact tracing is not a purely technical exercise: through the interview with the cases and with the people exposed, valuable information is obtained on the type of exposure; in addition, there may be more complex situations in which it may be necessary to extend the investigation. Another important aspect are social support measures and the activation of home care services that may be necessary for the proper conduct of quarantine and isolation.

The complementary role of the Apps in reference to the territorial surveillance policy is therefore evident: it is a technology that can support epidemic monitoring strategies, but which certainly cannot replace them.

As already reported, this technology has a potentially high rate of penetration and invasiveness precisely in the sphere of personal freedoms that its use would be meant to safeguard. Whereas in fact it is true that, with an efficient and early identification of infected people, generalized measures of confinement and physical distancing can be avoided, and therefore the suspension of many social and economic activities, it is equally true that these objectives are obtained by accepting forms of control over one's own movements and personal contacts, which risk going beyond the strict epidemiological needs and contingencies. To this are added the problems related to the security of the data collected, i.e. owing to errors in the system, unforeseen situations or malicious external interventions, personal data are made available to individuals and / organizations foreign to both the App users and the institutional authorities involved in territorial surveillance, or may be also used by the latter for unauthorized purposes. Security problems appear even more frequent when data retention is centralized; this has led to the conservation of data at local level.

Finally, it should be remembered that technologies of this type, introduced in emergency conditions, could become commonly used, especially if the pandemic were to persist over time. Paradoxically, their epidemiological success could push towards an acceptance of forms less respectful of personal freedoms, in the name of greater freedom of physical movement, and / or to increase safety. We are called to reflect precisely on this delicate ethical and social issue.

From a purely legal point of view, in light of the recent pandemic experience, the need to reconcile two main categories of interests has emerged in our, as in many other jurisdictions:

- on the one hand, the management of the crisis has convincingly shown that the right to health is, just as Article 32 of the Italian Constitution states, not only an individual right but also a "collective interest", and that in health systems like ours, inspired by a model that ranks among the most reliable and functional (4), the need to control the spread of unknown viruses activates necessary limitations of other individual rights in compliance with the principle of solidarity;

- on the other hand, the compression of fundamental freedoms and the rights that protect them cannot be without limitations, since each of those rights is able to bear only the restrictions compatible with a balanced comparative assessment of rank (with the same constitutional recognition). This is the case, as everyone knows, of traditional civil rights (freedom, religious freedom, freedom of assembly, association, manifestation of thought, and so on), political rights and more recent social rights, among which education and work have been mostly affected by the emergency.

The automation of the CT through specific Apps, beyond the individual operating methods and technological design, profoundly affects the right to the protection of personal data, guaranteed by art. 8 of the Charter of Fundamental Rights of the European Union and appropriately distinguished from the more traditional right to respect for private life (Article 7).

Italy adopted legislation on the protection of personal data in 1996, following the introduction of a specific EU directive, but the matter has now been almost entirely reformulated by Regulation (EU) 2016/679 on data protection (known as GDPR, General Data Protection Regulation) (5), which prevails over all different internal provisions and consolidates the primary rank of the subjective situation in question. For further information on this, please refer to the ISS COVID-19 n. 42/2020 “Report Data protection in COVID-19 emergency. Version of May 28, 2020” (published in Italian) (6).

Contact-tracing Apps in other countries

The production of contact-tracing Apps has developed and spread in many countries, with considerable differences at the local and sub-regional level, and a comparison remains difficult, considering both the multiplicity of political, cultural and health contexts in which each App is inserted and the lack of uniformity on the results achieved and reported in the literature. Experiences made in other countries for supporting the CT are presented below.

Singapore and several provinces in China have been able to limit the size of their initial outbreaks through widespread testing, contact tracing and quarantine, and these efforts remain critical to continued virus containment in these contexts (7-9). CT has led to the identification of many new cases, often before the onset of symptoms, and substantially reduced the time from symptom onset to isolation, thus reducing the likelihood of prolonged transmission (10, 11). CT has also been effective in helping to reduce the spread of the disease during the period of intense transmission in China and South Korea (7, 12, 13). Although the evidence suggests that CT in several Asian countries was effective in containing the virus, it is difficult to quantify the real effect as the CT was accompanied by other control measures taken at community and individual levels, such as the ban on meetings.

In terms of the efficiency of the methods, evidence from China suggests that the earlier cases are identified, and contacts are traced, the more the epidemic can be controlled (14).

Experience gained in Singapore has also highlighted the role of pre-symptomatic transmission in the overall dynamics of the epidemic, suggesting that pandemic control requires a prompt quarantine of close contacts to prevent subsequent transmission (15).

A combination of approaches, such as the use of mobile data and network searches, has been used in China to track and trace contacts. These methods have been considered effective for readily identifying individuals at risk of infection (16).

In Vietnam, where significant efforts are being made to isolate cases, and to trace and quarantine their contacts, the use of artificial intelligence is being considered to further improve contact traceability and management of potentially infected patients (17).

New Zealand has also managed to control the outbreak using traditional contact tracing supplemented by other measures (18, 19).

Experience in China also indicates that the traceability of contacts in the hospital setting, if accompanied by tests and quarantine, can provide effective nosocomial control (20).

Ethics and contact-tracing Apps

CT raises multiple ethical issues ranging from health service organization, public health, clinical medicine, social medicine, epidemiology, to technology, law, and numerous other areas. The contrast between individual rights and collective interests is particularly evident, but it is not the only aspect that causes concern. In particular, there are values which, although they all have to be respected, conflict with each other.

It is evident that, in the event of public health emergencies, the balancing of values cannot be implemented in the same way as it is done in ordinary conditions and in other contexts. For example, individual autonomy is a key criterion in clinical ethics, but it necessarily has less emphasis in public health ethics, where particular attention must be paid to the common good and justice.

This does not mean compressing the centrality of every single person, which is a cornerstone of ethics and bioethics in particular, but rather recognizing that the common good is built by protecting and promoting the value of everyone, and that sometimes this can impose individual limitations.

Although the founding values of ethics are not explicitly dealt with in the text, it is clear that the proposals of applied ethics are valid only if based on a solid framework of value references, which include among others the centrality and respect for the person, freedom and individual responsibilities, the defence and promotion of the integral good of the person, justice, and solidarity. In addressing the practical aspects, the authors made constant reference to these founding values.

In the context of public health, which deals with individual persons included in the community, the value of solidarity is particularly relevant, the notion of which runs through the history of human thought. Over time, and according to different currents of thought, it has been declined in different ways. It is an important component in public health ethics, particularly in the organization of health services and the so-called “global health”. In public health it is evoked in a descriptive sense, noting that it is an element that characterizes humanity, but sometimes also in a prescriptive sense, when it is necessary to refer to the duties of mutual help.

Every public health tool, including CT, has advantages and limitations. However, the latter must not discourage their use a priori: it is necessary to be aware of them, but also of the potential that, if effectively integrated with others, each tool offers to protect not only one’s own health, but also that of other people, to the benefit of the whole community. By using public health tools properly, therefore, every citizen protects their health, but also makes a gesture of altruism. The use of effective Apps responds to the principles of autonomy (if the choice is conscious and voluntary), of beneficence and non-maleficence (for the protection of one’s own and others’ health) and justice (to promote everyone’s health).

Although the technology used is relatively simple, we currently have limited evidence on the concrete effectiveness of technological support for CT in containing the infection, on the consequences in people’s daily social life and on those for public health and governance policies in general.

The European Commission, for example, in the Recommendation of 8 April 2020 (21), specifies that “in general the effectiveness of such applications has not been evaluated”, and that “however, according to the opinion of the experts, the applications that aim to informing and alerting users appear to be the most promising to prevent the spread of the virus “. It also adds that their effectiveness depends on many factors, such as the spread of the mobile medium on which the Apps are installed (the smartphone, above all), the number of those who will download it, trust in institutions and interoperability, that is, the ability to interface and integrate systems from different territories, the power of detection in different environments (open,

closed, large or restricted), the absence of differences between Android and iOS systems (the operating system installed on iPhones), the concomitant use of individual protection devices.

Mathematical modelling studies are available that highlight the potential effectiveness of contact-tracing Apps.

Ferretti *et al.* (22) note that the viral spread of SARS-CoV-2 may be too fast to be contained by manual contact tracing, but it could be controlled if this process were faster and more efficient, and were scalable. The study results suggest that contact-tracing Apps, which immediately notify people exposed to COVID-19 cases, can gain control of the outbreak if used by enough people.

The results of Hellewell *et al.* (23) suggest that CT and isolation may not be effective in containing outbreaks of COVID-19 unless very high levels of CT are achieved. The likelihood of controlling an outbreak decreases when there are long delays from symptom onset to isolation, when a limited number of cases are traced, and when transmission occurs before symptoms appear. The results of the study indicate that shortening the delay between the onset of symptoms and isolation (presumably achievable with an effective, technologically supported CT) is highly beneficial for containing an epidemic, for a wide range of traced contact percentages. About 80% of symptomatic contacts must be traced and isolated to control over 80% of outbreaks in the model.

A further model by Kretzschmar *et al.* (24) indicates that minimizing the time to perform diagnostic tests has the greatest impact on reducing transmission. The use of tracing Apps can potentially reduce delays and improve the effectiveness of contact tracing, with the potential to prevent up to 80% of all transmissions.

To be reliable, the evaluation of the effectiveness / risk ratio must first of all be defined in terms of merit and method.

On the merits, the use of the App is ethically justified if properly inserted in a territorial surveillance strategy that has its heart in CT, but which provides for a planning of the path that the “alerted” person must follow, that is the person advised to have been exposed to a contagion risk contact.

A further ethical requirement of the App is that it must be built in order to speed up and make the reconstruction of the contacts of an infected person more effective.

The primary purpose of the App is therefore to immediately alert people unknowingly exposed to risk of contagion, and not necessarily identify the potential infected.

For this to happen, some requirements must be verified in the method, taking into account that the evaluation itself should see two necessarily distinct phases: one prior to the introduction of the experimental App, and a subsequent monitoring of their functioning in real life of the population. At the moment this has not happened and the first ethical requirement of this instrument is missing, due to the lack of ex-ante evaluations, the great heterogeneity of the existing Apps, the different cultural contexts in which they are used (which make it difficult to compare the data collected ex-post amongst the population), the size of the current pandemic, the low number of downloads, at least in Italy, and the lack of systematic studies.

With regard to the main methodological requirements resulting from the merit considerations, the following are highlighted:

- **Proportionality of the information collected**

  No additional data should be collected other than those strictly necessary for identifying the possible contact at risk. This criterion excludes in the first instance the geolocation of the subject and directs the choice towards Bluetooth Low Energy (BLE) technologies, in which the data is limited to measures of space and time, that is, the distances below which it is believed that there is a risk of contagion, considering only those contacts whose duration is greater than an estimated time interval

necessary for the passage of viral particles in significant quantities for the transmissibility of the infection.

Comparative experience, however, makes it clear that there may be forms of geolocation that allow public health purposes without at the same time creating disproportionate interference with the privacy and personal data of the individual. In addition to the authorities' handling of the aggregate published data collected by the telecommunication companies (an issue that goes beyond the discourse on the tracking Apps and involves the general issue of digital CT), there are models tested in other systems that deserve to be investigated in order to evaluate a possible implementation adapted to the specificities of the European regulatory and institutional framework. For example, in Rhode Island an App has been developed which in a 'my location diary' section allows users to keep track of the location data that is independently collected by the smartphone through the use of other Apps (e.g. navigation and communication) in the epidemiological period of 20 days; in the event of an ascertained positive swab, the individual has the possibility, with unquestionable and discretionary choice, to share such data with the public health authorities for the purpose of reconstructing the places frequented and possible outbreaks of transmission of the infection. Regardless of the concrete transposition of this model into European systems, it is interesting because it configures an appreciable form of 'solidarity destination' of personal data for purposes of fighting the epidemic and protecting public health.

- **Voluntary use**

  At present in most countries, including Italy, there is no legal norm that obliges citizens to download the App, nor have any incentives been introduced that would indirectly "oblige" them to do so (e.g allowing or facilitating access to public transport, public spaces and buildings only to for Apps users). On the ethical level, the responsibility of the individual towards the community in which he lives must be considered, a responsibility that asks to actively collaborate in public health policies, including the CT, in the operating methods that prove to be more effective in combating contagion.

- **Information and consent**

  Each person must be able to give their consent to the use of the Apps, even after downloading them to their smartphone (or mobile support), and also differentiated with respect to the different modules that make them up. It must be ensured that consent is given in full awareness: the information to users must be clear and understandable, taking into account that an important segment of the population, especially the elderly, is not yet familiar with computer media. It would be advisable especially for these groups of users to provide explanations in the presence of the operators in the App start-up phase, or at least make videos or tutorials available. Furthermore, at the time of installation, the possibility of uninstalling must be clearly communicated, and the procedure for carrying out it must be simple and unhindered.

- **Management**

  The App must be totally managed by a public institution, excluding any direct and / or indirect profit-making purpose.

- **Transparency of the code and the results of dissemination**

  The code used by the authors of the App, as well as the results of its dissemination, its application and security measures, must be made public by the competent institutional authorities, where "public" means easily accessible and comprehensible to citizens.

- **Deleting data**

  It must take place within a reasonable timeframe with respect to the need to control the epidemic, which remains the sole purpose of their conservation, and in any case at the end of the pandemic emergency. The consent for any further use of them for research purposes must be given individually and knowingly by the user of the App, without any incentive being paid to the user, directly or indirectly (e.g. allowing or facilitating access to some services, such as public transport, or to public spaces and buildings, such as parks or administrative offices, only to those who demonstrate that they use the App).

- **Free availability of 24-hour technical and health care**

  The alerted person may need technical assistance to help interpret the report, and health care as the exposed person may have unpredictable anxious reactions when he becomes aware of the exposure.

The requirement of **anonymity** deserves a separate observation. It is clear that in the manual CT the interview is personal and generally identifies and traces the contacts at risk in order to alert them. The contact-tracing App, on the other hand, would have the ability to alert contacts at risk without identifying them, and without building a collection of names of these contacts (this is what happens for example in the design of the "Immuni" App). In the first instance, anonymity appears more guaranteed in the technologically supported CT than in the traditional one. But the concern for contact-tracing Apps has its *raison d'etre* not so much in the design of the single App, but in the pervasiveness of the technological system and in its potential for interference in private life: manual CT is in full control of the subjects involved, the boundaries are established by the patient-tracer couple for each single question-answer of the interview, conducted within a health system, in analogy to the doctor-patient fiduciary relationship and anamnestic interviews.

Supporting the CT with an App, on the other hand, means introducing an extraneous technological element into the relationships that form the basis of the healthcare system and is not easily controllable by the patient, who becomes a "user" of the App. Within the doctor-patient trust relationship, a highly penetrating technological element in their daily life present a possible risk to a healthy person.

It is a fluid objective, which can easily change over time once the tool has become part of everyday life, and above all that can change without our knowledge, for many and different reasons. There can be ill will / opacity in programmers, managers, or external agents interested in stealing data or polluting the outputs by voluntarily introducing false positives or negatives; but also, there may not always be an adequate ability to understand technologies and their development by users.

These are the obscure points of the Apps, which go beyond the known problems and the usual dilemmas on profiling and data availability by social platforms or the big giants of the web: it is a qualitative leap within public health systems, with which governments adopt tools with a high pervasive potential in the life of each of us.

On the other hand, it is reasonable to hypothesize and expect an enhancement of traditional CT due to the introduction of a dedicated digital support, with extremely positive consequences for the management of pandemics such as the one we are going through, but also in terms of general enhancement of CT for any communicable disease. Industry experts already recognize that, once digital weaving is built for surveillance strategies of the current pandemic emergency, it will be inevitable to use it and extend it in future public health policies (25). A careful and correct evaluation of this tool is therefore essential in order not to lose the valuable advantages that could derive from it and at the same time to carefully evaluate its impacts.

From this point of view, the choice of the smartphone as the basic device for the installation and operation of the App could constitute a limit to the digital implementation of the CT. The smartphone has effectively become a strictly personalized accessory, containing data, images and links intimately linked to the daily life of each of us; an instrument radically different from a first generation cell phone or a wristwatch, or even from those devices in the field of mobile health, each of which is strictly aimed at a specific use – e.g. pedometer, heart monitoring - but also different from personal symptom control means such as digital thermometer, blood pressure monitor, oximeter, etc.

A suggestion could be to provide devices dedicated exclusively to digital CT – such as tokens, for example, i.e. physical devices usually dedicated to user identification, for accessing online banking services: a choice of this type would involve the radical separation of personal data from the IT environment specifically linked to the implementation of the CT, limiting the potential pervasiveness of digital technology in the personal sphere, and helping to fuel trust in it.

Some particular users: minors, elderly

The use of proximity Apps by minors and the elderly poses particular problems, given the epidemiological characteristics of COVID-19.

As for minors, from a clinical and epidemiological perspective, the different age groups should be distinguished, while from the perspective of the Apps we know that their use is generally accessible to older children, whose age threshold varies from country to country, and in Italy for the “Immuni” App is established at 14 years.

In general, the scientific knowledge regarding minors for COVID-19 still presents a high rate of uncertainty on many aspects, and the difference in age groups. One of the few evidences that emerged clearly is that minors belong to the category least vulnerable to viral attack, at least as regards the short-term effects. But we are not certain about the actual role of minors as diffusers, and it is evident that with decreasing age the difficulties in adopting safe behaviours increase, and at the same time the need for contacts with caregivers also increase, in the family and outside.

The exclusion of groups of minors from digital CT, therefore, poses a potential bias in the general tracking of the population, and must be taken into account in the procedures of traditional CT, to avoid that minors up to 14 years remain invisible to tracking.

The elderly is the component of the population most exposed to serious COVID-19 infections, but they are also the ones less predisposed to the use of smartphones, and less familiar with digital technologies.

It might seem like a solution to support traditional CT, both for minors and the elderly, with “automated” Apps, for example those installed on non-user-configurable, wearable devices, such as “bracelets”, in which no intervention of user is necessary.

Apps in the current discipline

The ethical considerations summarized above represented one of the central themes of the debate that developed in Italy and in most European jurisdictions regarding the adoption of tracking Apps.

In many states, this debate has resulted in the introduction of a specific discipline, and therefore in the choice of a particular technological product developed directly by the public bodies involved or developed by private entities. In other systems, as in the case of Luxembourg, it was decided not to intervene, enhancing the manual tracking systems. The systems that opted for an App found themselves faced with the basic choice between the "decentralized" technological architecture, which provides for the retention of contact data in a strictly anonymous form and only on the user's local devices, and the "centralized" architecture, which provides for storage on a public platform accessible to health authorities exclusively for CT purposes. Italy, like Germany for example, has followed the first path. Unlike the German law, however, which identified the legal basis for data processing in the consent of the interested party, in our country it was considered essential to regulate the use of the App through a specific law, appointed to establish procedures and limits of the use of digital tracking. This is an essential step, which has avoided the uncertainty produced in other countries by the absence of legislation, for example regarding the central profile of the mandatory / non-mandatory use of the App in public or work contexts, and which therefore attributes greater solidity to the Italian governance model.

The provision in question, originally introduced by decree-law, is now contained in the law of 25 June 2020, n. 70 of conversion, with amendments, of the decree-law 30 April 2020, n. 28, containing "Urgent measures for the functionality of the systems of intercepting conversations and communications, further urgent measures in the field of the prison system, as well as supplementary and coordination provisions on civil, administrative and accounting justice and urgent measures for the introduction of COVID alert system". Art. 6 of the decree-law 28/2020, in the text coordinated with the Law of Conversion, provides that the purpose of this tool is to "alert people who have come into close contact with positive subjects and protect their health through the envisaged prevention measures in the context of public health linked to the COVID-19 emergency".

As already clarified in the ISS COVID-19 Report on data protection (5) in the COVID-19 emergency, the decree accepts the paradigm – clearly expressed in the guidelines of the European Data Protection Committee - of the complete voluntary use of the application. This in the sense that the download and use of the application is left to the discretion of citizens; and that, as established by paragraph 4, that failure to use "does not entail any harmful consequences". Failure to adhere to the system, therefore, does not imply any detriment to the interested party nor is it a condition for the exercise of rights. It is also envisaged that the processing carried out to alert contacts is based on the processing of proximity data of the devices, rendered anonymous or, where this is not possible, pseudonymised. In any case, the geolocation of individual users is excluded. The data relating to close contacts may be kept for the period strictly necessary for processing, the duration of which is established by the Ministry of Health, while at the expiry of these terms they will be automatically deleted. Paragraph 3 of art. 6 clarifies that the data thus collected cannot be processed for purposes other than those indicated in the article. The only exception allowed is for use "in aggregate or in any case anonymous form, solely for public health, prophylaxis, statistical or scientific research purposes" (pursuant to articles 5, paragraph 1, letter a) and 9, par. 2, lett. i) and j) of the GDPR). The use of the App and the platform, as well as the processing of the related data are, in any case, interrupted on the date of cessation of the state of emergency, and no later than 31 December 2020: "by the same date, all personal data processed must be cancelled or made permanently anonymous ".

The data controller is the Ministry of Health, which coordinates, after consulting the Minister for regional affairs and autonomies, also pursuant to article 28 of the GDPR, with the subjects operating in the national civil protection service and "Actuators" pursuant to art. 1 of the ordinance of the Head of the Civil Protection Department no. 630 of 3.2.2020, as well as with the ISS and, also through the Health Card System, with the accredited public and private structures operating within the National Health Service (SSN).

On May 28, 2020, the Ministry of Health sent the Guarantor for the Protection of Personal Data, pursuant to art. 36, § 5, of the GDPR Regulation (5) and of art. 2-quinquiesdecies of the Privacy Code[5], the impact assessment on data protection, carried out pursuant to art. 35 of the Regulation, to be authorized to start the processing of personal data relating to the "COVID-19 alert system"; the Guarantor adopted the "Provision of authorization for the processing of personal data carried out through the COVID-19 alert system - 'Immuni' App" on 1 June 2020.

Following these regulatory acts, the chosen technological solution, the "Immuni" App, was validated and made available on the main platforms throughout the country.

The circular of the Ministry of Health of 29 May 2020 clarifies the behaviour to be followed by the health authorities in the event of the emergence of a positive person who is a user of the App. It is expected that in the case of a positive user of the infection,

> "The health worker who communicated the outcome of the diagnostic test asks him if he has downloaded the App and invites him to select the option on his smartphone to transfer his anonymous keys to the Ministry of Health system. The App returns a numeric code (One-Time Pin, OTP) that the user communicates to the healthcare provider. The code is entered, by the health care worker, within a dedicated management interface, accessible via the Health Card System, and the upload is confirmed by the user. The App notifies users with whom the case has been in contact, the risk to which they have been exposed and the directions to follow, through a message whose text is unique throughout the national territory and which invites them to contact the doctor of general medicine or the paediatrician of free choice who will make an initial assessment of the subject's actual risk exposure".

Given these premises, in light of the ethical considerations presented above, it is easy to identify the advantages and disadvantages of the "Immuni" App. On the one hand, it offers the maximum guarantees in terms of personal data protection, providing for a decentralized and completely anonymous storage of contact data, limited in time and based on the idea that qualified contacts cannot have any knowledge of the identity of the index case. On the other hand, it risks being ineffective, because it excludes any prior scrutiny by the health authorities regarding the actual degree of risk of contact, leaving the matching operations exclusively to the computer system; this produces the risk of false positives, given that the BLE system is unable to give information about the context of the contact (outdoors or indoors; with or without protective devices, etc.). Since the consultation of a general practitioner is only recommended and not mandatory, the user may be prompted to ignore the alerts received; or, on the contrary, fearing the application of the isolation measures, he could pre-emptively avoid using the application.

[5] Legislative Decree no. 196 of 30 June 2003 containing the "Code on the protection of personal data" (published in Ordinary Supplement No. 123 to *the Gazzetta Ufficiale della Repubblica Italiana* 29 July 2003, n. 174) supplemented with the amendments introduced by Legislative Decree 10 August 2018, n. 101, containing "Provisions for the adaptation of national legislation to the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data, as well as the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation)" published in the *Gazzetta Ufficiale della Repubblica Italiana Serie generale* No. 205 of 4 September 2018.

Moreover, the low number of downloads recorded so far (as of 5 August 2020 there were 4,6 million downloads; it should be noted, however, that the official data does not record the number of users who, after installation, proceeded to delete the application, which often happens with any App), seems to confirm the not particular attractiveness of this type of solution.

Contact-tracing Apps: technological aspects

Technological potential in the COVID-19 era

In order to fight the COVID-19 pandemic through CT, a potentially relevant role is played by mobile technologies and in particular by the smartphone, which unlike a traditional cell phone (used for example in the previous pandemic due to the SARS-CoV-2 virus of 2003) has different potentialities (26), listed below.

- Increased memory, higher computing capacity, much more advanced data connection capacity due to the presence of dedicated operating systems.
- A great potential for the production and management of multimedia content such as taking high-resolution photos, producing video clips.
- The ability to easily install free and / or paid features and / or applications (App).
- Equipped with a high-resolution touch screen.
- The ability to use / operate a virtual keyboard to interact with the various features of the device (from the address book to the notebook), with the web, with the various applications installed and with the so-called “social networks”.
- Integration with sensors such as accelerometers, gyroscopes, magnetometers, thermometers and even, in the most advanced models: photoelectric sensors, laser depth sensors, Hall effect sensors, proximity sensors, barometers.
- The possibility of tethering (i.e. providing access to the Internet to other devices such as access points) over the wireless network, Wi-Fi or Bluetooth, to devices such as other smartphones or mobile phones, laptops or fixed computers and in general access to networks data.
- The availability of GPS sensors.

The interest in the Apps for the purpose of supporting CT lies above all in their connection capacity, enabled by different protocols.

Bluetooth, as already mentioned, is a technical-industrial standard for data transmission for wireless personal area networks (WPAN), a technology widely used by bioengineering to be able to perform and record measurements of vital parameters or in any case relating to activity or health through sensors placed in various parts of the body and return them to a summary web page.

Wi-Fi is a family of wireless local area network (WLAN) technologies that use devices based on the IEEE 802.11 standards. Its main use is the connection of devices (mobile and not) to the Internet and the transfer of information to / from remote servers.

In telecommunications, the Global Positioning System (GPS) is a US military satellite positioning and navigation system. Through a dedicated network of artificial satellites in orbit, it provides a mobile terminal or GPS receiver with information on its geographical coordinates and its time in all weather conditions, anywhere on earth or in its immediate vicinity where there is the possibility of unobstructed communication with at least four satellites in the system. The localization takes place through the transmission of a radio signal by each satellite and the processing of the signals received by the receiver.

Proximity and location measurement features in Apps: towards choosing Bluetooth

The current technological equipment of mobile devices allows different solutions for CT. As we have been experiencing for some time now, as Internet users, the possibilities of tracking individual user behavior are considerable. In particular, Apps have been developed for CT that keep track of the physical movements of the device owner, subject to the latter's consent, thus allowing a continuous localization of individuals. The obvious privacy problems that such an approach entails have directed research towards Apps that carry out the so-called proximity tracing through continuous exchange of short messages with devices in the vicinity. It is possible for a generic device to keep track of the potential contacts that a given user encounters in everyday life.

As for the location, contact-tracing Apps use GPS, Bluetooth, Wi-Fi or a combination of the above.

Instead, solutions aimed at detecting nearby devices, without recording location information, focus on the Bluetooth protocol, in particular on Bluetooth Low Energy (BLE), a version of Bluetooth introduced in 2011 in order to guarantee communications between devices using a low amount of energy. The BLE is not only able to easily put two devices in communication, but allows to deduce the distance between the coupled devices from the power measurement used: this explains the interest aroused by this technology in terms of CT. To achieve this, the so-called RSSI (Received Signal Strength Indication) is used, a quantity linked to the power of the received signal (27).

It should be emphasized that the application of BLE to the CT represents an extension certainly not foreseen by the designers of this protocol. In fact, Bluetooth was essentially created to easily connect heterogeneous devices in wireless networks, without the intention of accurately measuring the distance between devices. Therefore, it is not surprising that there are inherent difficulties with such measurements, related to the fact that the RSSI is not a linear function of the distance from the transmitter. Furthermore, the RSSI value is rather variable, even at a constant distance between transmitter and receiver (in particular, in the presence of objects between two devices). Finally, multi-propagation effects usually occur in closed environments, due to reflections, which obviously make the calculation of the mutual distance between devices less accurate than in open-field propagation.

Even the different hardware implementations of RSSI can cause differences between distance measurements, other variables being equal, depending on the particular model of mobile device used: probably in the future we will go towards an improvement of this aspect, through standardization of hardware implementations of RSSI (27).

It should also be emphasized that a proximity measurement below the threshold for contact is not always indicative of a real risk, in fact, between two neighbouring devices there may be physical barriers that are transparent to BLE signals but impenetrable by infectious agents.

At the current state of technology, the application of Bluetooth to CT is certainly subject to many improvements, given that it is an emergency application of a technology that existed before the current COVID-19 pandemic. It can therefore be assumed that proximity tracing via the App is affected by a non-negligible incidence of false positives and false negatives. Despite this, it is believed that technological support for CT is already an interesting reality, even with all its current limitations, as it allows to identify contacts otherwise unattainable with traditional methods for CT (e.g., potential infections following physical proximity among strangers, possibly asymptomatic).

Taking into account that for the measurement of the distance between individuals equipped with smartphones, the preference is falling on the Bluetooth system, different models of digital CT application are spreading throughout the world and in Europe through the use of specific Apps.

At least two digital CT application models have been proposed in Europe, one described with the acronym DP-3T (Decentralized Privacy-Preserving Proximity Tracing) and the other with the acronym PEPP-PT (Pan-European Privacy-Preserving Proximity Tracing) (https://www.pepp-pt.org/). The first model allows for the identification of the contacts on the smartphone of the single user, thus creating a decentralized model for the CT, while the second requires the transmission to a remote server of information relating to the automatic exchange of messages via BLE with other users in order to identify potential contacts, by calculation made on the server itself.

In the centralized model, therefore, the App stores all the Bluetooth codes of the other proximal devices (equipped with the same App) locally on the device (whether smartphones, smart watches or stand-alone devices such as bracelets); cryptography and pseudonymisation systems prevent the code from being associated with the identity of the owner of that device. Later,

1. the management functions of case-contact pairs are activated when a citizen is detected positive after a test for coronavirus;
2. in the event of a positive result, the health care worker generates, with a different App, a code with which the citizen can upload the data collected by his App to a server, thus providing the list of Bluetooth codes with which he has come into contact;
3. the server calculates for each of these codes the risk that there has been a contagion (proximity, contact time) and then sends a notification to the devices of people potentially at risk through the App;
4. the notification is a message by the health authorities and asks the recipient to follow a protocol (typically this can involve self-isolation and contact with local services for the execution of tests).

In the alternative scheme, the DP-3T, the mechanism is the decentralized one. The proximity data detected with BLE remain on the single device and are not transmitted to remote servers. The smartphone memory is unlocked by the same patient who was found positive, voluntarily, through the assistance of a healthcare professional. More precisely, the latter provides a code to the user with confirmed positivity, and this code enables the user to transmit their data to a central server (backend server). In turn, the server makes available to all devices on which the App is installed the necessary information to verify, by analyzing the BLE data residing on the device, any contact with the positive subject. In particular, this check concerns a period including a time window prior to the onset of symptoms, such as to intercept any infections in the asymptomatic phase. According to the DP-3T protocol, the sending of information to the central server is designed in such a way as to prevent the identification of the user, who voluntarily decides to share their personal data.

Following the automatic verification on their smartphone (mechanism that implements the decentralized CT), each potential contact receives a notification from the App, and they are invited to contact the health authorities to undergo a test for the virus. In this case, the information comes voluntarily to the organization responsible for the CT.

Italy, as is well known, has chosen the “Immuni” App of Bending Spoon and the Santagostino Medical Centre for the CT of COVID-19, selecting it from various candidate Apps for proximity tracing. The App selected by the Italian government follows the decentralized model, in accordance with the DP-3T protocol.

Apps beyond CT

It is obviously possible to extend the purpose of the Apps well beyond strengthening the CT, by developing other application modules and / or associating them with other technologies and / or databases to extend their functionality.

Each implementation transforms the App from a support element for the territorial surveillance of public health into something else, with a very wide range of possibilities that will be evaluated case by case, also an ethical level. Below, we list some examples, limiting ourselves to uses for research purposes.

The App could be implemented with a “clinical diary” of the contact to monitor their health during the period of quarantine or isolation (should it become a secondary case); this can become a tool for epidemiologists, who would have at their disposal a significant series of spatial-temporal measures related to people’s behaviour and the spread of the infection, valuable for improving existing statistical models and / or proposing others. At the same time, data form contact-tracing Apps could also provide valuable material to many scholars of the human sciences, from anthropology to sociology through psychology, as well as to all those involved in studies related to urban and extra-urban mobility, from scholars and professionals in the transport sector to those in the urban planning field.

Without entering here on the topic of so-called “big data”, each of these fields of study could be strongly enriched by a mass of data not collected so far, certainly interesting both as regards the development of the epidemic and the possibility of adopting measures to contain it, and for broader purposes. Scholars would all potentially be interested in not destroying the data collected by individual users for the CT, and perhaps implementing them by adding information related to their research.

The use of contact-tracing Apps will likely enable the collection of a large amount of data, which may be used in many areas of research: once the data has been collected, it is reasonable to expect that they will remain stored, together with the request to implement both the collection itself and to extend the technological method in areas other than that of surveillance in a pandemic context.

Highlights

Digital support for CT could be a valuable tool within public health policies, not only during the present pandemic, but also for the future surveillance of communicable diseases.

Some of the ethical issues could be effectively addressed by implementing specific actions:

- **Evaluation**

  The introduction of a technological support to surveillance, in particular contact-tracing Apps covered by this report, may require assessments similar to experimental research. The potential impact of contact-tracing Apps on tracking strategies, and therefore on public health policies; the consequences for citizens' behaviour and attitudes and for governance, not only of health care, but also of technological innovations, should not be underestimated. It is therefore important to identify efficacy assessment criteria and interdisciplinary assessment paths to offer evaluations of health and social impact regarding the entry of digital technologies in public health – such as the contact-tracing Apps – in order to be able to estimate their effectiveness / risk ratio. Bodies called to define the evaluation processes, and to evaluate digital support to the CT, should include experts in human and social sciences, cybersecurity, and public administrators, as well as scholars with a technological, legal and epidemiological background.

- **Separation of personal data from public health data**

  It would be advisable to separate the media dedicated to the CT from those containing other personal information like smartphones. In this way, the exclusive interest of the institutions for health surveillance would emerge clearly, as data collection would be aimed exclusively at the protection of public health, in full respect of personal freedoms and at the same time of the duty of mutual solidarity.

- **Transparency and information**

  The introduction of digital technologies to support public health actions requires a decision-making process and a totally transparent chain of responsibility, in institutional settings representative of citizenship. The results of the introduction of the App in support of the CT should be made public and understandable to the population to allow full democratic participation. Health institutions should accompany every health surveillance initiative with specific, comprehensive and understandable information, widely addressed to the population involved, similar to what happens for screening campaigns in health prevention. The information should encourage an informed use of health surveillance tools, in the interest not only of the individual, but also of the community. Public debate in the usual media should be supported and encouraged, but it cannot be the only source of information for citizens.

- **Solidarity**

  The value (i.e. the utility of the purpose) and validity (i.e. the effectiveness in achieving the purpose) are essential requirements for the ethics of any intervention. Among the other essential ethical requirements, however, there are also the proportionality between charges and benefits, the protection of personal data, the voluntary nature (although in emergency circumstances the use of mandatory instruments cannot be excluded), the equity in the possibilities of access and use of results. The solidarity dimension is particularly relevant. The voluntary and conscious use of effective Apps to support the CT is a gesture with not only personal value, for the protection of one's own

health, but also of solidarity, for the protection of the health of others and the community: the altruistic component in individual behaviour is central to public health ethics. Therefore, it is desirable that the limits of the technological solutions currently adopted, and relevant to both the institutional design and the integration into the traditional CT system, can be overcome in a more advanced stage of implementation by making these instruments not only more transparent, but also more effective in terms of the pursuit of solidarity objectives and the protection of public health.

References

1. Gruppo di Lavoro Bioetica COVID-19. *Sorveglianza territoriale e tutela della salute pubblica: alcuni aspetti etico-giuridici. Versione del 25 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 34/2020
2. Filia A, Urdiales AM, Rota MC. *Guida per la ricerca e gestione dei contatti (contact tracing) dei casi di COVID-19. Versione del 25 giugno 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 53/2020).
3. New Giansanti D, D'Avenio G, Rossi M, Spurio A, Bertinato L, Grigioni M. *Tecnologie a supporto del rilevamento della prossimità: riflessioni per il cittadino, i professionisti e gli stakeholder in era COVID-19. Versione del 31 maggio 2020*. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 54/2020).
4. Organisation for Economic Co-operation and Development. *Health at glance 2019. OECD indicators.* Paris: OECD Publishing,2019). https://doi.org/10.1787/4dd50c09-en
5. Europa. Regolamento (UE) 2016/679 del Parlamento europeo e del Consiglio, del 27 aprile 2016, relativo alla protezione delle persone fisiche con riguardo al trattamento dei dati personali, nonché alla libera circolazione di tali dati e che abroga la direttiva 95/46/CE (regolamento generale sulla protezione dei dati). *Gazzetta ufficiale dell'Unione europea* L119, 4.5.2016.
6. Gruppo di Lavoro ISS Bioetica COVID-19. *Protezione dei dati personali nell'emergenza COVID-19. Versione del 28 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 42/2020).
7. World Health Organization. *Report of the WHO-China Joint Mission on Coronavirus Disease 2019 (COVID-19)*. Geneva: WHO; 2020. https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf
8. World Health Organization. *Pandemic Influenza Severity Assessment (PISA): A WHO guide to assess the severity of influenza epidemics and pandemics*. Geneva: WHO; 2017. https://apps.who.int/iris/bitstream/handle/10665/259392/WHO-WHE-IHM-GIP-2017.2-eng.pdf?sequence=1
9. Pung R, Chiew CJ, Young BE, Chin S, Chen MIC, Clapham HE, *et al.* Investigation of three clusters of COVID-19 in Singapore: implications for surveillance and response measures. *The Lancet* 2020;395(10229):1039-46
10. Chen W, Wang Q, Li Y, Yu H, Xia Y, Zhang M, *et al.* Early containment strategies and core measures for prevention and control of novel coronavirus pneumonia in China. *Zhonghua yu fang yi xue za zhi* (*Chinese Journal of Preventive Medicine*. 2020;54(3):1.
11. Bi Q, Wu Y, Mei S, Ye C, Zou X, Zhang Z, *et al.* Epidemiology and Transmission of COVID-19 in Shenzhen China: Analysis of 391 cases and 1,286 of their close contacts. *medRxiv*. 2020.
12. Choe YJ. Coronavirus disease-19: Summary of 2,370 Contact Investigations of the First 30 Cases in the Republic of Korea. *medRxiv*. 2020.
13. Moradi H, Vaezi A. Lessons learned from Korea: Covid-19 Pandemic. *Infection Control & Hospital Epidemiology* 2020 Apr 3:1-2.
14. Xiong P, Xu K. How to deal with 2019 novel coronavirus (COVID-19): a public health practice from the Centers for Disease Control and Prevention in Zhanggong District, Ganzhou City, China. *Infection Control & Hospital Epidemiology*. 2020 Apr 6:1-5.
15. Wei WE. Presymptomatic Transmission of SARS-CoV-2—Singapore, January 23–March 16, 2020. *MMWR Morbidity and Mortality Weekly Report* 2020;69.
16. Ruan L, Wen M, Zeng Q, Chen C, Huang S, Yang S, *et al.* New measures for COVID-19 response: a lesson from the Wenzhou experience. *Clinical Infectious Diseases*. 3 April 2020.
17. Nguyen THD, Vu DC. Summary of the COVID-19 outbreak in Vietnam-Lessons and suggestions. *Travel Medicine and Infectious Disease* 2020:101651.
18. Baker M, Kvalsvig A, Verrall A, Telfar-Barnard L, Wilson N. New Zealand's elimination strategy for the COVID-19 pandemic and what is required to make it work. *The New Zealand Medical Journal* 2020;133(1512):10.

19. Verrall A. *Rapid audit of contact tracing for Covid-19 in New Zealand*. Wellington: Ministry of Health; 2020. https://apo.org.au/sites/default/files/resource-files/2020-04/apo-nid303350.pdf

20. Fang Y, Zhang S, Yu Z, Wang H, Deng Q. Shenzhen Experience on containing 2019 novel coronavirus-infected pneumonia transmission. *QJM: An International Journal of Medicine*. 3 April 2020. hcaa112.

21. European Commission Recommendation (EU) 2020/518 of 8 April 2020 on a common Union toolbox for the use of technology and data to combat and exit from the COVID-19 crisis, in particular concerning mobile applications and the use of anonymised mobility data. *Official Journal of the European Union* 14 April 2020; L 114: 7-15.

22. Ferretti L, Wymant C, Kendall M, *et al.* Quantifying SARS-CoV-2 transmission suggests epidemic control with digital contact tracing. Science. 2020;368(6491):eabb6936. doi:10.1126/science.abb6936

23. Hellewell J, Abbott S, Gimma A, *et al.* Feasibility of controlling COVID-19 outbreaks by isolation of cases and contacts. *Lancet Glob Health* 2020; 8: e488–96.

24. Kretzschmar ME, Rozhnova G, Bootsma MCJ, van Boven M, van de Wijgert JHHM, Bonten MJM. Impact of delays on effectiveness of contact tracing strategies for COVID-19: a modelling study. *Lancet Public Health.* 2020 Aug;5(8):e452-e459. doi: 10.1016/S2468-2667(20)30157-2.

25. Kahn JP, Johns Hopkins Project on Ethics and Governance of Digital Contact Tracing Technologies. *Digital Contact tracing for pandemic response, ethics and governance guidance.* Baltimore: Johns Hopkins University Press; 2020.

26. Giansanti D, Grigioni M (Ed.). *La salute in un palmo di mano: nuovi rischi da abuso di tecnologia*. Roma: Istituto Superiore di Sanità; 2018. (Rapporti ISTISAN 18/21).

27. Ye T, Walsh M, Haigh P, Barton J, O'Flynn, B. Experimental impulse radio IEEE 802.15.4a UWB based wireless sensor localization technology: Characterization, reliability and ranging. Paper presented at the ISSC 2011, 22nd IET Irish Signals and Systems Conference, Dublin, Ireland, 23-24 Jun 2011. https://cora.ucc.ie/handle/10468/541

Rapporti ISS COVID-19 (ISS COVID-19 Reports)

ISS COVID-19 Reports are mainly addressed to healthcare professionals to cope with different aspects of the COVID pandemic. They provide essential and urgent directions for emergency management and are subject to updates. All reports have an English abstract.

The complete list is available at **https://www.iss.it/rapporti-COVID-19**.

Some reports (highlighted below) are also translated in English and are available at **https://www.iss.it/rapporti-iss-COVID-19-in-english**

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 24 luglio 2020. Roma: Istituto Superiore di Sanità; 2020 (Rapporto ISS COVID-19, n. 1/2020 Rev.)
2. Gruppo di lavoro ISS Prevenzione e controllo delle Infezioni. *Indicazioni* ad interim *per un utilizzo razionale delle protezioni per infezione da SARS-CoV-2 nelle attività sanitarie e sociosanitarie (assistenza a soggetti affetti da COVID-19) nell'attuale scenario emergenziale SARS-CoV-2.* Versione del 10 maggio 2020. Roma: Istituto Superiore di Sanità; 2020 (Rapporto ISS COVID-19, n. 2/2020 Rev. 2)
3. Gruppo di lavoro ISS Ambiente e Gestione dei Rifiuti. *Indicazioni* ad interim *per la gestione dei rifiuti urbani in relazione alla trasmissione dell'infezione da virus SARS-CoV-2.* Versione del 31 maggio 2020. Roma: Istituto Superiore di Sanità; 2020 (Rapporto ISS COVID-19, n. 3/2020 Rev. 2)
4. Gruppo di lavoro ISS Prevenzione e controllo delle Infezioni. *Indicazioni ad interim per la prevenzione e il controllo dell'infezione da SARS-CoV-2 in strutture residenziali sociosanitarie.* Versione del 17 aprile 2020. Roma: Istituto Superiore di Sanità; 2020 (Rapporto ISS COVID-19, n. 4/2020 Rev.) Available also in English.
5. Gruppo di lavoro ISS Ambiente e Qualità dell'aria *indoor*. *Indicazioni ad per la prevenzione e gestione degli ambienti indoor in relazione alla trasmissione dell'infezione da virus SARS-CoV-2.* Versione del 25 maggio 2020. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 5/2020 Rev. 2).
6. Gruppo di lavoro ISS Cause di morte COVID-19. *Procedura per l'esecuzione di riscontri diagnostici in pazienti deceduti con infezione da SARS-CoV-2.* Versione del 23 marzo 2020. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 6/2020).
7. Gruppo di lavoro ISS Biocidi COVID-19 e Gruppo di lavoro ISS Ambiente e Rifiuti COVID-19. *Raccomandazioni per la disinfezione di ambienti esterni e superfici stradali per la prevenzione della trasmissione dell'infezione da SARS-CoV-2.* Versione del 29 marzo 2020. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 7/2020).
8. Osservatorio Nazionale Autismo ISS. *Indicazioni ad interim per un appropriato sostegno delle persone nello spettro autistico nell'attuale scenario emergenziale SARS-CoV-2.* Versione del 30 aprile 2020. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 8/2020 Rev.).
9. Gruppo di Lavoro ISS Ambiente – Rifiuti COVID-19. *Indicazioni ad interim sulla gestione dei fanghi di depurazione per la prevenzione della diffusione del virus SARS-CoV-2. Versione del 3 aprile 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 9/2020).
10. Gruppo di Lavoro ISS Ambiente-Rifiuti COVID-19. *Indicazioni ad interim su acqua e servizi igienici in relazione alla diffusione del virus SARS-CoV-2 Versione del 7 aprile 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 10/2020).
11. Gruppo di Lavoro ISS Diagnostica e sorveglianza microbiologica COVID-19: aspetti di analisi molecolare e sierologica *Raccomandazioni per il corretto prelievo, conservazione e analisi sul tampone oro/rino-faringeo per la diagnosi di COVID-19. Versione del 17 aprile 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 11/2020).

12. Gabbrielli F, Bertinato L, De Filippis G, Bonomini M, Cipolla M. *Indicazioni ad interim per servizi assistenziali di telemedicina durante l'emergenza sanitaria COVID-19. Versione del 13 aprile 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 12/2020). Available also in English.

13. Gruppo di lavoro ISS Ricerca traslazionale COVID-19. *Raccomandazioni per raccolta, trasporto e conservazione di campioni biologici COVID-19. Versione del 15 aprile 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 13/2020). Available also in English.

14. Gruppo di lavoro ISS Malattie Rare COVID-19. *Indicazioni ad interim per un appropriato sostegno delle persone con enzimopenia G6PD (favismo) nell'attuale scenario emergenziale SARS-CoV-2. Versione del 14 aprile 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 14/2020). Available also in English.

15. Gruppo di lavoro ISS Farmaci COVID-19. *Indicazioni relative ai rischi di acquisto online di farmaci per la prevenzione e terapia dell'infezione COVID-19 e alla diffusione sui social network di informazioni false sulle terapie. Versione del 16 aprile 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 15/2020). Available also in English.

16. Gruppo di lavoro ISS Sanità Pubblica Veterinaria e Sicurezza Alimentare COVID-19. *Animali da compagnia e SARS-CoV-2: cosa occorre sapere, come occorre comportarsi. Versione del 19 aprile 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 16/2020). Available also in English.

17. Gruppo di lavoro ISS Sanità Pubblica Veterinaria e Sicurezza Alimentare COVID-19. *Indicazioni ad interim sull'igiene degli alimenti durante l'epidemia da virus SARS-CoV-2. Versione del 19 aprile 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 17/2020). Available also in English.

18. Gruppo di lavoro ISS Ricerca traslazionale COVID-19. *Raccomandazioni per la raccolta e analisi dei dati disaggregati per sesso relativi a incidenza, manifestazioni, risposta alle terapie e outcome dei pazienti COVID-19. Versione del 26 aprile 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 18/2020). Available also in English.

19. Gruppo di lavoro ISS Biocidi COVID-19. *Raccomandazioni ad interim sui disinfettanti nell'attuale emergenza COVID-19: presidi medico-chirurgici e biocidi. Versione del 25 aprile 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 19/2020).

20. Gruppo di Lavoro ISS Prevenzione e Controllo delle Infezioni. *Indicazioni ad interim per la sanificazione degli ambienti interni nel contesto sanitario e assistenziale per prevenire la trasmissione di SARS-CoV 2. Versione del 14 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 20/2020 Rev.).

21. Ricci ML, Rota MC, Scaturro M, Veschetti E, Lucentini L, Bonadonna L, La Mura S. *Guida per la prevenzione della contaminazione da Legionella negli impianti idrici di strutture turistico recettive e altri edifici ad uso civile e industriale, non utilizzati durante la pandemia COVID-19. Versione del 3 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 21/2020).

22. Gruppo di lavoro ISS Salute mentale ed emergenza COVID-19 *Indicazioni ad interim per un appropriato supporto degli operatori sanitari e sociosanitari durante lo scenario emergenziale SARS-CoV-2. Versione del 28 maggio.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 22/2020 Rev.) Available also in English.

23. Gruppo di lavoro ISS Salute mentale ed emergenza COVID-19 *Indicazioni di un programma di intervento dei Dipartimenti di Salute Mentale per la gestione dell'impatto dell'epidemia COVID-19 sulla salute mentale. Versione del 6 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 23/2020).

24. Gruppo di lavoro ISS Malattie Rare COVID-19. *Indicazioni ad interim per una appropriata gestione dell'iposurrenalismo in età pediatrica nell'attuale scenario emergenziale da infezione da SARS-CoV-2. Versione del 10 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 24/2020). Available also in English.

25. Gruppo di Lavoro ISS Biocidi COVID-19. *Raccomandazioni ad interim sulla sanificazione di strutture non sanitarie nell'attuale emergenza COVID-19: superfici, ambienti interni e abbigliamento. Versione del 15 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 25/2020)

26. Gruppo di Lavoro ISS Ambiente e Rifiuti. *Indicazioni ad interim sulla gestione e smaltimento di mascherine e guanti monouso provenienti da utilizzo domestico e non domestico. Versione del 18 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 26/2020)

27. Ricci ML, Rota MC, Scaturro M, Nardone M, Veschetti E, Lucentini L, Bonadonna L, La Mura S. *Indicazioni per la prevenzione del rischio Legionella nei riuniti odontoiatrici durante la pandemia da COVID-19. Versione del 17 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 27/2020).

28. Gruppo di Lavoro ISS Test Diagnostici COVID-19 e Gruppo di Lavoro ISS Dispositivi Medici COVID-19. *Dispositivi diagnostici in vitro per COVID-19. Parte 1: normativa e tipologie. Versione del 18 maggio 2020*. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 28/2020)

29. Gruppo di lavoro ISS Malattie Rare COVID-19. *Indicazioni ad interim su malattia di Kawasaki e sindrome infiammatoria acuta multisistemica in età pediatrica e adolescenziale nell'attuale scenario emergenziale da infezione da SARS-CoV-2. Versione 21 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 29/2020). Available also in English.

30. Gruppo di lavoro Salute mentale ed emergenza COVID-19. *Indicazioni sull'intervento telefonico di primo livello per l'informazione personalizzata e l'attivazione dell'empowerment della popolazione nell'emergenza COVID-19. Versione del 14 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 30/2020)

31. Gruppo di lavoro Salute mentale ed emergenza COVID-19. *Indicazioni ad interim per il supporto psicologico telefonico di secondo livello in ambito sanitario nello scenario emergenziale COVID-19. Versione del 26 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 31/2020)

32. Gruppo di lavoro ISS Sanità Pubblica Veterinaria e Sicurezza Alimentare COVID-19. *Indicazioni ad interim sul contenimento del contagio da SARS-CoV-2 e sull'igiene degli alimenti nell'ambito della ristorazione e somministrazione di alimenti. Versione del 27 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 32/2020).

33. Gruppo di Lavoro ISS Ambiente-Rifiuti COVID-19. *Indicazioni sugli impianti di ventilazione/climatizzazione in strutture comunitarie non sanitarie e in ambienti domestici in relazione alla diffusione del virus SARS-CoV-2. Versione del 25 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 33/2020).

34. Gruppo di Lavoro Bioetica COVID-19. *Sorveglianza territoriale e tutela della salute pubblica: alcuni aspetti etico-giuridici. Versione del 25 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 34/2020). Available also in English.

35. 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)

36. Gruppo di Lavoro ISS Ambiente-Rifiuti COVID-19. *Indicazioni sulle attività di balneazione, in relazione alla diffusione del virus SARS-CoV-2. Versione del 31 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 36/2020).

37. Gruppo di Lavoro ISS Ambiente-Rifiuti COVID-19. *Indicazioni per le piscine, di cui all'Accordo 16/1/2003 tra il Ministro della salute, le Regioni e le Province Autonome di Trento e Bolzano, in relazione alla diffusione del virus SARS-CoV-2. Versione del 31 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 37/2020).

38. Silano M, Bertinato L, Boirivant M, Pocchiari M, Taruscio D, Corazza GR, Troncone R *Indicazioni ad interim per un'adeguata gestione delle persone affette da celiachia nell'attuale scenario emergenziale SARS-CoV-2. Versione del 29 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 38/2020).

39. Gruppo di lavoro ISS Malattie Rare COVID-19 *Censimento dei bisogni (23 marzo - 5 aprile 2020) delle persone con malattie rare in corso di pandemia da SARS-CoV-2. Versione del 30 maggio 2020*. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 39/2020).

40. Gruppo di Lavoro Bioetica COVID-19. *Comunicazione in emergenza nei reparti COVID-19. Aspetti di etica. Versione del 25 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 40/2020).

41. Gruppo di lavoro ISS Salute mentale ed emergenza COVID-19. Indicazioni per prendersi cura delle difficoltà e dei bisogni dei familiari di pazienti ricoverati in reparti ospedalieri COVID-19. Versione del 29 maggio 2020. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 41/2020).

42. Gruppo di Lavoro ISS Bioetica COVID-19. *Protezione dei dati personali nell'emergenza COVID-19. Versione del 28 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 42/2020).

43. Gruppo di lavoro ISS Salute mentale ed emergenza COVID-19. *Indicazioni ad interim per un appropriato sostegno della salute mentale nei minori di età durante la pandemia COVID-19. Versione del 31 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 43/2020)

44. Gruppo di lavoro ISS Salute mentale ed emergenza COVID-19. *Indicazioni di un programma di intervento per la gestione dell'ansia e della depressione perinatale nell'emergenza e post emrgenza COVID-19. Versione del 31 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 44/2020)

45. Giusti A, Zambri F, Marchetti F, Sampaolo L, Taruscio D, Salerno P, Chiantera A, Colacurci N, Davanzo R, Mosca F, Petrini F, Ramenghi L, Vicario M, Villani A, Viora E, Zanetto F, Donati S. *Indicazioni ad interim per gravidanza, parto, allattamento e cura dei piccolissimi 0-2 anni in risposta all'emergenza COVID-19. Versione 31 maggio 2020*. Roma: Istituto Suprire di Sanità; 2020 (Rapporto ISS COVID-19 n. 45/2020)

46. Gruppo di Lavoro ISS Test Diagnostici COVID-19 e Gruppo di Lavoro ISS Dispositivi Medici COVID-19. *Dispositivi diagnostici in vitro per COVID-19. Parte 2: evoluzione del mercato e informazioni per gli stakeholder. Versione del 23 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 46/2020)

47. Gruppo di Lavoro ISS Bioetica COVID-19. *Etica della ricerca durante la pandemia di COVID-19: studi osservazionali e in particolare epidemiologici. Versione del 29 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 47/2020), Available also in English.

48. Gruppo di Lavoro Immunologia COVID-19. S*trategie immunologiche ad interim per la terapia e prevenzione della COVID-19. Versione del 4 giugno 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 48/2020).

49. Gruppo di Lavoro ISS Cause di morte COVID-19, Gruppo di lavoro Sovrintendenza sanitaria centrale – INAIL, ISTAT. *COVID-19: rapporto ad interim su definizione, certificazione e classificazione delle cause di morte. Versione dell'8 giugno 2020*. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 49/2020)

50. Perilli R, Grigioni M, Porta M, Cruciani F, Bandello F, Mastropasqua L. S *Contributo dell'innovazione tecnologica alla sicurezza del paziente diabetico da sottoporre ad esame del fondo oculare in tempi di COVID-19. Versione del 31 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 50/2020).

51. Gruppo di Lavoro ISS Farmaci COVID-19. *Integratori alimentari o farmaci? Regolamentazione e raccomandazioni per un uso consapevole in tempo di COVID-19. Versione del 31 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 51/2020)

52. Gruppo di lavoro SISVet-ISS. *Protocollo di gestione dell'emergenza epidemiologica da SARS-CoV-2 nelle strutture veterinarie universitarie. Versione dell'11 giugno 2020*. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 52/2020)

53. Filia A, Urdiales AM, Rota MC. *Guida per la ricerca e gestione dei contatti (contact tracing) dei casi di COVID-19. Versione del 25 giugno 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19, n. 53/2020).

54. Giansanti D, D'Avenio G, Rossi M, Spurio A, Bertinato L, Grigioni M. *Tecnologie a supporto del rilevamento della prossimità: riflessioni per il cittadino, i professionisti e gli stakeholder in era COVID-19. Versione del 31 maggio 2020*. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 54/2020).

55. Cisbani E, Dini V, Grande S, Palma A, Rosi A, Tabocchini MA, Gasparrini F, Orlacchio A. *Stato dell'arte sull'impiego della diagnostica per immagini per COVID-19. Versione del 7 luglio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 55/2020)

56. Gruppo di lavoro ISS-INAIL. *Focus on: utilizzo professionale dell'ozono anche in riferimento al COVID-19. Versione del 21 luglio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 56/2020)

57. Gruppo di lavoro ISS Formazione COVID-19. *Formazione per la preparedness nell'emergenza COVID-19: il case report dell'Istituto Superiore di Sanità. Versione del 31 maggio 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 57/2020). Available also in English.

58. Gruppo di Lavoro ISS, Ministero della Salute, Ministero dell'Istruzione, INAIL, Fondazione Bruno Kessler, Regione Emilia-Romagna, Regione Veneto, R. *Indicazioni operative per la gestione di casi e focolai di SARS-CoV-2 nelle scuole e nei servizi educativi dell'infanzia. Versione del 28 agosto 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 58/2020 Rev.). Available also in English.

59. Gruppo di lavoro ISS Bioetica COVID-19. Supporto digitale al tracciamento dei contatti (contact tracing) in pandemia: considerazioni di etica e di *governance*. Versione del 17 settembre 2020. Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 59/2020). Available also in English.

60. Gabbrielli F, Capello F, Tozzi AE, Rabbone I, Caruso M, Garioni M, Taruscio D, Bertinato L, Scarpa M. *Indicazioni ad interim per servizi sanitari di telemedicina in pediatria durante e oltre la pandemia COVID-19. Versione del 10 ottobre 2020.* Roma: Istituto Superiore di Sanità; 2020. (Rapporto ISS COVID-19 n. 60/2020).