Original Investigations/Commentaries

The management of the Sars-Cov-2 pandemic in Italy, lessons earnt and reflections for the future

Manuel Maffeo¹, Antonio Azara², Enrico Di Rosa³, Luigi Bertinato⁴, Claudio Garbelli⁵, Silvana Castaldi^{6,7}

¹Postgraduate School in Public Health, Department Biomedical Sciences for Health, University of Milano, Milano, Italy; ²Department of Medical, surgical and experimental sciences, University of Sassari; ³Local public health office, ASL ROMA 1; ⁴Scientific secretariat to the President Head of Office, National Institute of Health; ⁵Italian hygiene and preventive medicine society; ⁶Department of Biomedical Sciences for Health University of Milan, Italy Fondazione IRCCS Ca' Granda Ospedale Maggiore di Milano, Italy; ⁷Fondazione IRCCS Ca' Granda Ospedale Maggiore di Milano, Italy

Abstract.

Background: Italy and especially Lombardy region was the first European Country hit by the covid 19 pandemic, without a proper preparedness plan. Italy's health-care service is a regionally based National Health Service (NHS) that provides universal coverage, largely free of charge at the point of service. Aim of this paper is to analyse the national and especially the regional strategies put in place to face the pandemic, focusing on the impact of the overlap of the political and health competences among national and regional authority. *Methods:* Italian hygiene and preventive medicine society (SITI) realized a questionnaire submitted to National Institute for Health and regional stakeholder to investigate the response to the epidemic analysing the strategies and actions put in place both by the national and regional governments and the regional health authorities. *Results:* The national survey highlighted several critical points in the management of the covid 19 pandemic in the different regional contexts such as lack of personnel in preventive departments and preparadness. *Conclusions:* Lessons learnt during the pandemic should shape the future of the Italian health service. (www.actabiomedica.it)

Keywords: Sars-CoV-2; Covid-19; Preparadness; Public Health

Introduction

On 20th February the first Italian case of Coronavirus Induced Disease 2019 (COVID19) due to secondary transmission outside China was identified in Codogno, Lombardia region, after the declaration of the emergency by the government on 31st January 2020 (12020, the first case of novel coronavirus disease (COVID-19). Italy was the first European Country hit by the pandemic and especially Lombardia and other regions of the north part of Italy had to cope with the first peak with no time to prepare (2). Italy's health-care service is a regionally based National Health Service (NHS) that provides universal coverage, largely free of charge at the point of service. The service is organized into three levels: national, regional and local. The national level is responsible for ensuring the general objectives and fundamental principles of the NHS. Regional governments, through their regional health departments, are responsible for ensuring the delivery of a package of benefits through a network of population-based 'local health authorities' and public and private accredited hospitals (3). NHS was created, public and universal, in 1978 with the law n°833 (4). NHS was reformed with the law n°502/1992, 517/1993 and 229/1999 (5-7). The aim of the reforms was to strengthen the power of regions in the organization of the health service, because the centralized organization established in the 1978 caused a separation between central financing responsibilities and regional and local spending powers with consequent uncontrolled rise in health-care expenditure (3reaching 79.4 years for men and 84.5 years for women in 2011. There are marked regional differences for both men and women in most health indicators, reflecting the economic and social imbalance between the north and south of the country. The main diseases affecting the population are circulatory diseases, malignant tumours and respiratory diseases. Italy's health care system is a regionally based national health service that provides universal coverage largely free of charge at the point of delivery. The main source of financing is national and regional taxes, supplemented by copayments for pharmaceuticals and outpatient care. In 2012, total health expenditure accounted for 9.2 percent of GDP (slightly below the EU average of 9.6 percent). Different regions have made different choices on how to use their increasing autonomy. For instance, Tuscany decided to keep the system heavily centralized, with most hospitals remaining under ASL (local health authority) control and only a handful becoming AOs (hospital trust) (8). Some regions, for example Tuscany and Emilia Romagna, developed health care models characterized by proactive interventions towards cohorts of elderly people with chronic health conditions (8,9). At the other extreme, Lombardy opted in 1997 for a model in which all hospital and specialist services are delivered by AOs or private providers (10). The region's main hospitals were converted to AOs, free to negotiate financing terms with ASLs - although controlled on the quality of services provided - and citizens were given full freedom of choice (3reaching 79.4 years for men and 84.5 years for women in 2011. There are marked regional differences for both men and women in most health indicators, reflecting the economic and social imbalance between the north and south of the country. The main diseases affecting the population are circulatory diseases, malignant tumours and respiratory diseases. Italy's health care system is a regionally based

national health service that provides universal coverage largely free of charge at the point of delivery. The main source of financing is national and regional taxes, supplemented by copayments for pharmaceuticals and outpatient care. In 2012, total health expenditure accounted for 9.2 percent of GDP (slightly below the EU average of 9.6 percent). The regionalisation of the NHS is an ongoing process that has both positive and negative features. Even before the pandemic there were huge and consolidated differences in the ability of the regional health services to fulfill the essential healthcare level established by the NHS (11). During the pandemic, the lack of a strong coordination by the national health authority and the differences among the regional health service caused a wide range in the response to the health emergency by the regional authorities (12,13). Furthermore the political autonomy of the Italian regions caused a wide range of actions also as for as those measures such as school closure, still widely debated, or limitation to mobility that are not strictly related to the health service but in the case of this pandemic have to be considered as important public health measures defined non pharmaceutical interventions (NPSI). Aim of this paper is to analyse the national and especially the regional strategies put in place to face the pandemic, focusing on the impact of the overlap of the political and health competences among national and regional health authority. Moreover we evaluated the consenquences of the different regional strategies.

Methods

Italian hygiene and preventive medicine society (SITI), a scientific society founded in 1878 and composed by health care workers (HCWs) specialized in preventive medicine with different backgrounds, realized a national survey to investigate the response to the epidemic analysing the strategies and actions put in place both by the national and regional governments and health authorities.

The stakeholders involved that answered to the questionnaire were:

- 1. National Institute of Health
- 2. Representatives from all 14 regional sections of

Italian hygiene and preventive medicine society: (Abruzzo-Molise, Apulo-Lucana, Calabria, Campania, Emilia-Romagna, Lazio, Liguria, Lombardia, Marche, Piemonte e Valle D'Aosta, Sardegna, Toscana, Triveneto, Umbria)

- Representative from national committee of residents in hygiene and preventive medicine. Items investigated were:
- Documents issued after the World Health Organization (WHO) alert about the disease X on February 2018 (14)
- 2. Documents and interventions adopted after the emergency declaration by the Italian Government on 31st January 2020, especially as for as:
 - Hospital and territorial networks
 - Storage of personal protective equipment (PPE), nasopharyngeal swabs, ventilators and home delivered oxygen therapy
 - Strategy for quarantine of close contacts
 - Strengthening of Intensive Care Units (ICUs)
 - Management of COVID-19 patients at home
 - Survaillance of residential homes
 - Involvement of SITI in the national scientific committee
 - Evidences of the diversity of the strategies put in place to face the epidemic by the different regions
 - 5. Analysis of the management of the competences shared between the national and local level
 - 6. Proposals for the future

Results

According to the stakeholders involved there were no national or regional plans issued after the WHO alert about the disease X. The national prevention plan (2014-2018) has a section about an emergency plan for infectious disease written after the European Commission decision (N° 1082/2013/EU) and a list of actions to take (15,16). The last update to the national emergency plan for pandemic influenza was in 2016 and contains a guide for developing regional emergency plans (17). No regions developed specific emergency plans for a new infectious disease, but all of them developed plans for pandemic influenza and references to action to take are in all regional prevention plans.

During the first peak there was an important lack in the storage of Personal Protection Equipment (PPE) (masks, gloves, and suits) both for HCWs and the population and also a lack of nasopharyngeal swab and reagents that limited the possibility to perform tests, that were dedicated to highly symptomatic patients, often admitted to hospital. Only Veneto region was able to perform a larger amount of tests by the use of a laboratory machines not linked to the provision of reagents by specific industries.

There was also a lack of ventilators and home delivered oxygen therapy, but it was less marked.

Soon after the identification of the first cases there was a rapid increase in the number of patients who needed to be hospitalised in Intensive Care Units (ICUs) and subintensive care or medical ward units. In this phase, all regions developed a plan to reorganise the activity of their regional health services and the hospital networks according to the national instructions issued with the decrees of 1st and 4th March 2020 (18,19). The main aims of this reorganisation were to:

• Suppress all non urgent medical assistance, for example cancer screening activities, vaccinations, elective surgery, ambulatory services etc.

- Organize new network of hub and spoke hospitals for urgent and time dependent pathologies such as stroke, trauma, oncologic and orthopaedic emergencies.
- Increase sars-cov-2 testing capacity,
- Increase ICUs, subintensive and medical ward units capacity,
- Organise COVID+ and COVIDpatients pathways inside the hospital which were not fully dedicated to COVID+ patients. Since the beginning of the epidemic the reorganisation of the hospital activity has not been homogenous throughout the Country, although all the regions had an almost complete shutdown of all non necessary medical activities with all the efforts focused on the management of COVID+ patients.

The pre-existing differences among regional health system had a huge impact of the adaption to new scenario. According to a research performed by Alta Scuola di Economia e Management dei Sistemi Sanitari dell'Università Cattolica del Sacro Cuore di Roma (ALTEMS) [20], 3 different strategies are were used:

- 1. Hospital based management;
- 2. Primary care based management;
- 3. Combined management.

But, after the first phase, all the regions converged to a combined management of cases (20).

It is important to underline that only 10 regions prepared a plan for reorganisation of the hospital activities at 10 June 2020 while only at 22 July all regions developed a plan for the reorganization of all the health care levels.

At the second wave of the epidemic one of the most difficult issue was to increase ICUs capacity without a total shutdown of other medical services. This need raised important organisational issues as for as lack of HCWs and infection transmission management for patients and HCWs.

Primary and territorial health care were really important in the management of the pandemic. An attempt to make the primary health care assistance homogeneous was made by the national government with the institution of the USCA (Special unit for primary care) with the decree n°14 9/03/2021, where regions were adviced to activate one USCA each 50000 inhab (21). USCA is a medical equipe in charge to deliver health care assistance to COVID19 patients at home, in order to prevent unnecessary hospitalisation. Regional Health Authorities (RHAs) actived this service in different times, even after months from their institution and so they were able to guarantee different coverage level. At 5th May the average coverage level was 31% with a range of 3% to 91% (20). It is important to underline that this disparity is not strictly correlated to the lack of primary care assistance but it is due to the fact that USCA has been integrated into the already existing primary care services which are really heterogeneous all over the nation, including general practitioners, family nurses and other forms of home delivered assistance (20).

Other important measures stimulated by the national government but applied differently by RHAs were the implementation of telemedicine and COVID residences, places where COVID+ patients could be discharged after hospitalisation in order to fully recover under medical supervision but with a low-level of assistance according to their clinical status.

Telemedicine was implemented with experimental activities in several regions, for example in Liguria for the surveillance of COVID-19 cases and closed contacts, in Lazio for the management of cases, Lombardia with the use of Wifi oximeter and clinical review of thoracic RX or in Umbria with the transmission of data regarding ECG and spirometry (20). Althought there was an increase in the use of telemedicine it was prompted by the emergency and was not integrated withing the health care assistance, because of the lack of a pre-existing strategy to use it.

One of the most critic aspect during the first peak was the management of residential homes were the virus spread among the most vulnerable people (22)]. National Institute for Health developed guidelines for the management of COVID-19 in residential homes on 14th March2020, constantly updated in the following months (23). Almost all regions activated screening programs both for patients and HCWs and restricted visits from relatives in the residential homes (23). In some regions, such as Lazio and Piemonte patients had to quarantine and have a negative test while in Liguria admissions were suspended after the first peak (23). In Lombardia positive patients were managed at residential homes whenever possible, especially during the first peak because of the lack of beds in hospital, and at least in the very initial phase, visits were still possible (23).

The management of the isolation of positive cases, contacts and contact tracing activity has been handled by prevention department of local health authority who are in charge of the surveillance, prevention and control of infectious diseases. It's important to recognize that despite the national scientific coordination by the National Institute for Health, there were differences in the management of such activities, also according to the local capacity and epidemiological framework.

To our knowledge no region developed specific plan for surveillance in specific ethnic groups, only Marche region developed a plan *ad hoc* to manage a cluster in a residential home with a large group of foreign people. Huge difficulties were encountered to surveil homeless people and to try to overcome this issue it was important to build a strong collaboration between municipalities, prevention departments, general practitioners and especially non governmental organization.

As for as the control of the environment almost all regions developed a plan for the management of urban waste, after the guidelines issued from National Institute for Health [24]. Plans for monitoring other environmental sectors were less homogenous among regions. For instance Emilia Romagna performed analysis to find sars-cov-2 in waste water and analysis to link air pollution to Covid-19 severity [24]. Veneto analysed the impacts of lockdown on air pollution and Tuscany region intensified controls on drinking and waste water, swimming pool, urban waste and put in place controls to monitor spread of the virus through air and surface in hospital, residential homes and industry (24).

The results of the national survey highlighted several critical points in the management of the covid pandemic in the different regional contexts. These factors are shown in figure 1 according to the Ishikawa cause and effect diagram.

Conclusion

We obtained answers from all regional sections of SITI that gave us the possibility to collect a wide range of regional and national documents and the possibility to highlight positive and negative aspects of the management of the pandemic and the role of public health workers. The survey highlighted some shared goals to improve the management of future waves from this or other type of infection disease tackling all the causes identified in the aforementioned Ishikawa diagram.

The survey showed that the lack of personnel in the prevention department seriously undermined its key role in the management of the positive cases and contact tracing as that, according to the European Centre for Disease Prevention and Control (ECDC) requires an average of 2 hours interview for each case (25). The lack of personnel was due to the constant definancing of the health services and in particular of the public health sector. Some regions (ie Lombardy) where more affected by this problem because the regional health service is focused more on hospital assistance rather than prevention. Thereby the HCWs hired for the management of the epidemic in the preventive and primary care department should become permanent and not dismiss after the epidemic, this is important to guarantee enough and prepared personnel for the management of future waves.

An important resource is represented by residents in public health postgraduate schools that should be more involved in the management of the epidemic, since they demonstrated to be a strategic resource dur-



Figure 1. Covid pandemic: Ishikawa cause and effect diagram

ing the first and second wave. Proof of this is that the number of residents in public health doubled at the 2020 national public examination compared to the previous year (26).

Increasing the number of people working is not enough if their work is limited by the technological capacity of preventive and primary care departments, therefore it should be implemented in order to improve the quality and effectiveness of work.

The technological improvement should not be limited to surveillance system. Special consideration has to be made for telemedicine, that has been adopted only by some regions for the management of COVID cases as well as for other pathologies during the pandemic and now has to be implemented and organized properly.

More people working, even if with the best technology, are not really useful if they are not prepared properly, therefore it's of paramount importance to train all HCWs and stakeholders, at national, regional and local level, with simulation at least once a year, in order to be ready for future waves or other pandemic.

Even with all the necessary HCWs the response to a pandemic can not be effective if the decisions to face it are not shared with all the stakeholder and are not homogeneous thoughtout the Country. An important issue highlighted by the stakeholders in our survey was the overlap of competencies between national a regional government, not only for choices strictly related to the health sector but also for all those decisions related to other sector but important for the epidemic management. For example one of the most debated decision regarded the school closure. This pandemic showed the frailty of a regionalized health system that caused an hetereogenity in the way the epidemic was faced. In order to guarantee the governance and homogeneity it is important to improve communication trough a better synergy among national, regional and local authorities and a review of the competencies should be made.

A clear and effective leadership is important not only for an effective response from the health authorities but also to guide the population that should not be confused with different messages coming from different authorities. Proof of that was that the infodemia has been a big problem during the pandemic and undermined the efficacy of several health policies (27"author":[{"dropping-particle":"","family":"INTE LLIGENCE","given":"DEPARTMENT OF EVI-DENCE AND","non-dropping-particle":"","parsenames":false,"suffix":""},{"dropping-particle":"","fami ly":"HEALTH","given":"FOR ACTION IN","nondropping-particle":"","parse-names":false,"suffix":""}] ,"id":"ITEM-1","issued":{"date-parts":[["0"]]},"title": "UNDERSTANDING THE INFODEMIC AND MISINFORMATION IN THE FIGHT AGAINST COVID-19","type":"webpage"},"uris":["http://www. mendeley.com/documents/?uuid=f76a4221-c734-4233-a43e-6e9e69ea67fe"]]],"mendeley":{"formatte dCitation":"[23]","plainTextFormattedCitation":"[2 3]"},"properties":{"noteIndex":0},"schema":"https:// github.com/citation-style-language/schema/raw/master/csl-citation.json"}).

The strength of this survey is that it provided a national overview of the regional response to the pandemic but the weak point is that the approach to the questionnaire differed from section to section, with the result of an important heterogenity in the type of data collected, some were more specific than others or more focused on the list of laws.

The pandemic is still evolving, between the hope for the vaccine campaign going on in many Countries and the fear for the new strains of the virus that are emerging, but the lessons the pandemic teached us at a very high price should not be wasted. The least we can do is to learn from our mistake and to shape the Italian health service in the next years in order to be ready for the next challenges (28).

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Correspondence:

Received: 15 June 2021 – Accepted: 26 June 2021 Silvana Castaldi Dept Biomedical Sciences for Health, University of Milan, Italy Tel 00390255038342 Fax 00390255033144

E-mail: Silvana.castaldi@unimi.it