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Transformation of Cancer Care during and after the COVID Pandemic, a point of no return. The Experience of Italy

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ARTICLE INFO

Keywords:
SSN
Cancer
Planning
Technology

ABSTRACT

Policymakers everywhere struggle to introduce therapeutic innovation while controlling costs, a particular challenge for the universal Italian National Healthcare System (SSN), which spends only 8.8% of GDP to care for one of the world's oldest populations. Oncology provides a telling example, where innovation has dramatically improved care and survival, transforming cancer into a chronic condition. However, innovation has also increased therapy duration, adverse event management, and service demand. The SSN risks collapse unless centralized cancer planning changes gear, particularly with Covid-19 causing treatment delays, worsening patient prognosis and straining capacity. In view of the 750 billion Euro "Next Generation EU", released by the European Union to relieve Member States hit by the pandemic, the SSN tapped a multidisciplinary research team to identify key strategies for equitable uptake of innovations in treatment and delivery, with emphasis on data-driven technological and managerial advancements – and lessons from Covid-19.

1. Introduction

The Covid-19 pandemic has highlighted health system inadequacies, and in Italy – hit hard and early by the pandemic – patients suffering from chronic conditions such as cancer were often left behind during the spring 2020 lockdown and now show, or risk, worse outcomes [1–3]. Negative effects from delayed/disrupted care or delayed diagnosis due to COVID-19 have also been noted elsewhere [4,5], while a survey of 343 oncologists from 28 countries, found that the pandemic has significantly influenced decision making by oncologists, both on the organizational side (protective measures, telemedicine) and in oncologists' choice of systemic therapy [6]. But the pandemic has also provided a

glimpse of new care delivery models that could positively impact oncology – and other – care, affording a preview of how changes in national cancer care planning and coordination currently under consideration (see Acknowledgements) might play out in a future, post-Covid world.

Italy's universal, National Healthcare System (SSN) provides an interesting case study to illustrate how national planning and innovations in care and delivery can both address disparities in access and improve quality of care for cancer patients as outlined in the problems and corrective actions described below, even when care is disrupted by waves of infections and lockdowns, in Italy as elsewhere.

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<https://doi.org/10.1016/j.jcipo.2021.100297>

Received 14 March 2021; Received in revised form 27 June 2021; Accepted 11 July 2021

Available online 22 July 2021

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2. Alleviating unintended consequences of clinical innovation for professionals and healthcare organizations

Clinical innovation, particularly immunotherapy and precision medicine, has improved professional satisfaction for physicians, increasingly able to achieve positive clinical results for their patients [7, 8], but with drawbacks [9]. Clinicians must keep abreast of the latest clinical evidence and service delivery changes, complicating treatment decision, planning and follow-up processes [10]. When the pandemic exploded, staff, including oncologists, was diverted to Covid-19 care, while oncology care – surgery, drug treatment, follow-up, clinical trials, screening - was delayed or cancelled to avoid infecting these vulnerable patients. The resulting difficulties in communication and care coordination highlighted the need to manage knowledge and service coordination differently, including through support from information technology (IT) and artificial intelligence (AI).

3. Stratification techniques to guide appropriate service provision

Stratification techniques using predefined algorithms based on clinical, personal and delivery system characteristics should be used to design treatment and follow-up strategies to alleviate clinicians' burden and to identify patients, aid communication and offer care services in a tailored manner, especially useful when stressors hit the system, like Covid-19. Like many countries with national health systems (e.g., United Kingdom, Canada, Spain, Sweden), Italy can access a wealth of data routinely collected through regional authorities (e.g., publicly-

financed hospital and ambulatory services, medications, home care, rehabilitation, hospice, etc.) and national agencies (including Ministry of Health (MoH) data on system capacity and expenditure data and Italian Medicines Agency (AIFA) data for monitoring adverse drug reactions and post-market prescribing appropriateness) (Fig. 1). Systematic analysis of this data can support a patient-oriented segmentation process using algorithms that differentiate based on: 1) clinical features specifically referring to the tumor; 2) patient characteristics directly related to expected clinical response; 3) contextual aspects related to care settings, location, personnel, and service consumption. Stratification strategies can embrace precision medicine (i.e., patient characterization and consequent treatment differentiation) using AI for clinical data, and guide patient management (i.e., identifying the affected population, treatment trajectories and local supply capacity) using IT with cancer registries and administrative health data.

MoH decrees on reorganization of the hospital system began in March 2020, with constant updates to manage hospital capacity to respond to the epidemic and guarantee urgent and programmed services in all areas, including cancer, often incorporating recommendations from scientific and patient associations [11]. In other nations, notably the United States, the response to Covid-19 was strongly criticized for its lack of national coordination [12]. The data-based capacity to plan and manage hospital capacity in Italy has been fundamental in avoiding system overload during the second wave, despite high infection and mortality rates, and has been listed among those worldwide government interventions found to be effective in responding to the pandemic [13]. Hospital, territorial and regional data systems allowed for patient stratification to reorganize care for oncology patients at many levels,

GOVERNANCE AND STRUCTURE

- The national government in Italy, through the Ministry of Health, sets policy and overall funding allocation for the tax-based, universal healthcare system
- Italy spends 8.8% of GDP on healthcare
- A nationally-defined health basket of essential care services (LEA, or Livelli Essenziali di Assistenza) is guaranteed through the health system to all residents
- The Italian Medicines Agency (AIFA - Agenzia Italiana del Farmaco) oversees safety and marketing approval for new drugs, sets reimbursement policy, prices, means of distribution, and conducts post-marketing surveillance.
- Italy is divided into 21 regions, each responsible for healthcare planning at the regional level and delivery at the local level
- The regions are allocated a budget based on population and health care needs. Some limited discretionary spending is allowed at the regional level to augment these budgets. Healthcare budgets represent over 70% the regions' total budgets
- Local and territorial health care delivery is organized into local health authorities (LHA)
- Physicians and nurses working in public healthcare organizations (hospitals, LHAs, territorial services) are employed by the SSN
- General practitioners are independent contractors financed through the LHAs to provide primary care to all residents

Fig. 1. The Italian Healthcare System (SSN) at a glance.

proving its feasibility and importance.

4. Need for new organizations of human and facility resources to manage uptake of innovation

Clinical innovation has improved prognosis, but also changed human resource and facilities management and delivery system organization. Growing patient demand for novel therapies, greater numbers of re-evaluation visits associated with longer lengths of time in therapy and/or unplanned presentations are just three examples [14,15]. Immunotherapy, for instance, improves treatment response but can generate different patterns of side effects, requiring reorganization of follow-up facilities and personnel, a need often poorly understood by hospital administrators and policymakers. An example of inappropriateness and unjustified costs is overcrowding of healthy subjects in hospitals for follow-up, awaiting specialists when other settings of care and professionals would be more appropriate. When infection control measures and staff reassignments forced suspensions of cancer diagnostic and care services in hospital settings [1,2], telemedicine, territorial and alternative care services struggled to quickly redirect patients - a weakness that had been clearly identified in cancer planning analyses - lengthening waitlists, delaying diagnoses and threatening to worsen outcomes.

5. New delivery scenarios to be incentivized by new reimbursement schemes

Hospitals are no longer the only place for cancer care, where increasing survivor prevalence already strains limited hospital capacity, needed to respond to stressors (like a pandemic) and better suited to augment patient access to innovative, often expensive treatments that require care in acute settings. Adaptive, alternative delivery processes had been proposed to address these problems, but Covid-19 made them urgent needs:

- In many cases patients can be treated in different, less costly settings, i.e., community and primary care (PC), based on distinct phases (nodes) in well-defined care pathways. For instance, follow-up for patients after radical surgery for colon or breast cancer, identified to be at lower risk of recurrence through stratification techniques, could be provided by PC physicians following protocols already in place, setting up preferential communication lines with specialists for consultations when necessary. Better, more appropriate use of home care and the establishment of beds in sub-acute, non-hospital settings should be thoroughly explored, especially considering that Covid-related mortality appears to have been lessened where primary and territorial services were able to monitor patients and organize timely transfers to the hospital when necessary. The MoH provides guidelines regarding Covid-19 symptoms and when to activate telemonitoring, PC or community personnel or call for an ambulance. Similar guidelines could be set up for cancer care.
- Case-managers and standardized pathways for integrated care should be instituted as a means to integrate and coordinate primary, community and hospital services to deliver a tailored pathway to individual patients. Specialist services should be delivered in hospitals only where indicated by equipment, monitoring and safety needs (e.g., innovative therapies, drug therapies, procedures, tests). Where fee-for-service payment systems tend to fragment, and often ineffectively increase, care provision, other systems (i.e., bundled payments) could provide incentives to adopt and deliver groupings of more appropriate, cost-effective services [16]. Immediate action would reduce the number of patients accessing hospitals during the pandemic, and, over time, contain hospital overcrowding due to increased prevalence of cancer patients.
- Digital health can dramatically reduce the hospital burden for follow-up, and even during the active treatment phase [17,18].

Guidance for the provision of digital health services to allow Covid-19 patients to be followed at home appeared within days of the first national spring 2020 lockdown, with extension to chronic patients soon after [19]. By July 2020, 13 regional health systems had provided norms for governing telemedicine services, from provisions for specific groups of patients to full definitions of types of services, tariffs and means of coordination. Scientific associations for oncologists and cardiologists provided guidance on how best to reorganize care and use digital health to contact and visit patients outside of the hospital as well as transfer services to home care and alternative, non-hospital settings during the lockdown and beyond [11]. Stratification techniques identifying patients undergoing oral therapies could be evaluated through telemedicine, using IT systems to upload information gathered in PC settings, permitting less frequent specialist follow-up. Patients deemed at low risk of recurrence were in fact followed up between March and June using telemedicine with few difficulties reported. When infections fell and clinics reopened during the summer, a return to old hospital setting patterns was observed, only to reactivate alternative delivery methods during the second wave. Much still remains to be done, and central guidance is imperative: healthcare services delivered through mobile technologies in Italy must be recognized and properly reimbursed, and system interoperability must be developed to realize the huge potential for cancer care beyond the pandemic, to effect long-term change.

Many of the measures to address delivery and equity issues described here and below for Italy were also included among the goals for cancer care delivery and research in light of the pandemic outlined by the American Society of Clinical Oncology [20].

6. Addressing disparities in health, access to care

Disparities in health status and access have been observed related to socio-economic status (SES), such that individuals with lower per capita income and lower rates of education experience worse health conditions, a situation further emphasized by the Covid-19 pandemic, where in Italy (as abroad), people of lower SES experienced greater mortality [21]. As observed in the well-documented north-south divide in Italy [22], southern areas exhibit lower rates of healthy life expectancy, poorer adherence to screening programs (over 90 % adherence in the North versus 47 %, 60 % and 76 % for colorectal, breast and cervical cancer screening, respectively, in the South), fewer preventive initiatives and higher prevalence of risk factors for cancer and other diseases, such as smoking and obesity. No patient is refused cancer care in Italy, however, inequalities in organization of services can translate into disparities in access to innovative therapies, especially where introduction of novel therapies is concentrated in few approved sites with no connection with smaller, peripheral centers, rather than using hub-and-spoke models. In addition, temporary suspension during first and second waves of Covid 19 risks further exacerbating health disparities because of delayed diagnosis and lower compliance with cancer treatments.

7. Strengthen cancer networks and develop a core set of indicators for cancer care

Oncology networks across national territory can help standardize clinical pathways, disseminate best practices, and homogenize adherence and performance measures across territories. Established in 2014 by the MoH, cancer networks are run at the regional level with the objective to share clinical information and facilitate communication among clinicians and hospital and territorial facilities to provide integrated, coordinated care to cancer patients, navigating local supply and directing patients to timely and appropriate treatment and follow-up according to multidisciplinary care pathways. Nationally, however,

implementation has varied greatly, and today only one bi-regional and 9 regional networks are fully functioning, mostly in the central and northern areas [23]. Where present and active, the networks facilitated reorganization of cancer care during the pandemic [23], but the MoH needs to financially sustain the development of regional networks in those territories that are still lacking, and oversee harmonization and coordination of best practices. Clear communication regarding alternative care delivery methods is also needed to increase patient familiarity and acceptance as well as counteract patients' reluctance to seek care during the pandemic for fear of infection, a phenomenon observed in greater proportion among patients of lower SES and among immigrants.

A centralized, IT-supported system should be set up to monitor disparities in access to care, service delivery methods and outcomes across patients, regions and territories. The National Healthcare Outcomes Programme (<https://pne.agenas.it/index.php?lang=EN>) currently maps 175 performance indicators; while some are in the oncological area, none directly cover care provided outside of hospitals. A core set of oncological indicators should be developed to gather data concerning quantity and quality of services accessed by patients nationwide with special attention on innovative, high-cost treatments, outpatient and home care. In this regard, data routinely collected by cancer registries, regions and AIFA must be made available to regularly populate the indicators. A national monitoring system based on outcomes could mitigate differences in regional cancer care models, while stratification techniques could identify patients with care interruptions, for Covid or otherwise, at local and aggregate levels to identify trends.

8. Conclusions

Alternative care delivery scenarios employed during the Covid-19 pandemic showed that digital health, community and primary care should at least partially replace hospital services for cancer survivor follow-up and rehabilitation, coordinated at the intra-regional, inter-regional and national levels. Leveraging health data analysis – using patient stratification techniques supported by IT and AI - and full activation and exploitation of cancer networks can provide crucial indications for integrating services and guaranteeing equal access to innovative specialty care while protecting fragile patients during the Covid-19 pandemic and, hopefully, when it is finally over. Earmarked to receive almost one-third (€191 billion) of “Next Generation EU” pandemic relief funds, Italy has been given a great opportunity to invest in areas that will most contribute to the future wealth of the nation, especially health. The measures outlined here are hopefully relevant for all nations who faced the pandemic and are intent on addressing health problems in a coordinated, global manner.

Contributions of authors

RT was assigned by the Ministry of Health the role of scientific leader of the work, has coordinated the research team and has written the manuscript. VT, GF, HB, AT and SG have contributed to developing the research and to the writing of the manuscript. EL has prepared a first version of the manuscript. All authors have contributed to the discussion of challenges and generating solutions for the future planning of cancer care in Italy.

Declaration of Competing Interest

The authors report no declarations of interest.

Acknowledgments

This work has been possible thanks to a grant “Sanità 2.0” (Health 2.0) received by SDA Bocconi School of Management from the Italian Ministry of Health – Directorate General Healthcare Services Planning. The Italian Ministry of Health (MoH) – charged with setting national

policy and allocation of funds to a decentralized, region-based health-care delivery system – is abandoning planning based on type of expenditure (e.g., infrastructure, personnel, supplies) and service categories (e.g., hospital inpatient, ambulatory, rehabilitation, palliative care) to pursue a value-based approach focused on care pathways. In 2019 and 2020, the MoH assembled a research team of oncology specialists, general managers of large, public general and oncology research hospitals, epidemiologists and health economists to provide guidance on how the future planning process should look in oncology, with the aim of identifying key strategies to implement to curb cost escalation while facilitating the entry of promising innovations in treatment and delivery to improve outcomes.

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