

ORIGINAL RESEARCH

Position paper of the Italian Association of Medical Oncology on the impact of COVID-19 on Italian oncology and the path forward: the 2021 Matera statement

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The coronavirus disease 2019 (COVID-19) pandemic has severely affected cancer care and research by disrupting the prevention and treatment paths as well as the preclinical, clinical, and translational research ecosystem. In Italy, this has been particularly significant given the severity of the pandemic's impact and the intrinsic vulnerabilities of the national health system. However, whilst detrimental, disruption can also be constructive and may stimulate innovation and progress. The Italian Association of Medical Oncology (AIOM) has recognized the impact of COVID-19 on cancer care continuum and research and proposes the '2021 Matera statement' which aims at providing pragmatic guidance for policymakers and health care institutions to mitigate the impact of the global health crisis on Italian oncology and design the recovery plan for the post-pandemic scenario. The interventions are addressed both to the pillars (prevention, diagnosis, treatment, follow-up, health care professionals) and foundations of cancer care (communication and care relationship, system organization, resources, research, networking). The priorities to be implemented can be summarized in the MATERA acronym: **M**ultidisciplinarity; **A**ccess to cancer care; **T**elemedicine and Territoriality; **E**quity, ethics, education; **R**esearch and resources; **A**lliance between stakeholders and patients.

Key words: COVID-19, cancer care, policy

INTRODUCTION

The severe acute respiratory syndrome novel coronavirus-2 (SARS-CoV-2) and related coronavirus disease 2019 (COVID-19) pandemic has impaired global health significantly, through direct and indirect consequences affecting the physical, mental, and social well-being of billions of people worldwide.¹ This unprecedented crisis has also exposed the intrinsic weakness of health care systems in many countries,

including those with robust welfare, placing health as a top priority on the global political agenda. However, whilst detrimental, disruption can also be constructive and may stimulate innovation and progress. This is a crucial time to capitalize on learnings from this pandemic, to take concrete action to address not only the harm to public health, but also the deep-rooted fragilities of health systems, as well as to implement the positive changes stimulated by this crisis. Policymakers and cancer societies have a unique responsibility in driving this challenging process of change. In this context, the Italian Association of Medical Oncology (AIOM) dedicated the ninth edition of the conference, 'Oncology Ethics Days'² held in Matera in September 2021, to the analysis of the consequences of the pandemic on cancer care continuum in Italy and to the design of the

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recovery plan for the post-pandemic scenario. AIOM and the AIOM Foundation met with Italian experts from all fields involved in the care of patients with cancer including: medical oncologists, surgeons, anaesthetists—resuscitators, general practitioners (GPs), immunologists, psycho-oncologists, nurses, epidemiologists, jurists, philosophers, theologians, journalists, as well as representatives of the Ministry of Health, industry, patients and their representatives [Federation of Voluntary Associations in Oncology (FAVO)], and other scientific societies [Italian Society of Palliative Care (SICP), Italian Society of Psycho-Oncology (SIPO), Italian Society of Anaesthesia, Analgesia, Reanimation, and Intensive Care (SIAARTI), Italian Society of Surgery (SIC)]. This was an opportunity for rich multidisciplinary discussion on several themes concerning not only the field of oncology but also the right to health in a broader sense, in light of the socioeconomic and health crisis triggered by the COVID-19 outbreak. The current position statement generated and approved by representatives of AIOM, AIOM Foundation, SICP, SIPO, SIAARTI, GPs, and FAVO is the summary of the ‘Oncology Ethics Days’—Matera 2021. Starting from the analysis of the context, it describes the priorities and needs in oncology and illustrates the strategy proposed by AIOM for enhancing the Italian oncology in the near future.

ANALYSIS OF THE CONTEXT

The impact of the COVID-19 pandemic in Italy

After China, where the pandemic started in December 2019, Italy was the second country to be hit by the outbreak and, for many weeks, the nation was most severely affected with hundreds of deaths being counted every day. The first case was reported in Codogno (Lombardy region) on 20 February 2020. Despite the prompt introduction of lockdown measures, the virus spread rapidly, particularly in the north of the country.³ More than 50% of Italian cases occurred in the region of Lombardy, where the saturation of hospitals between March and April 2020 translated into a dramatic scenario. To face the crisis in capacity, physicians were forced to use age-based cut-offs to allocate ventilators and decide who to be treated in the intensive care unit (ICU).⁴ In response to the agony of these decisions, the SIAARTI issued recommendations under the guidance of its Ethics Section, based on clinical, reasonable, and soft utilitarian approach in the face of resource scarcity.⁵ Nevertheless, physicians have been struggling with the ethical dilemmas of these forced choices for months, which have left an indelible mark and generated the need of long-term reflection on what happened and how to avoid this drama in case of future pandemics.

During the subsequent waves of the health outbreak, the entire country has been affected with 11 348 701 confirmed cases of COVID-19 and 147 734 deaths in 2 years (World Health Organization epidemiological update, 4 February 2022).⁶ Under these exceptional circumstances, the Italian National Health System (Servizio Sanitario Nazionale, SSN)

has been facing an unprecedented pressure to address the needs of patients requiring hospitalization and intensive care for SARS-CoV-2 pneumonia.⁷

The impact of COVID-19 on cancer care continuum and research

The consequences of the reallocation of resources, exhaustion of health infrastructure and workforce, and reorganization of health care provision resulted in the suspension of non-urgent medical activities and drastic change in the routine management of many diseases.^{8,9} Amongst others, the cancer care continuum has been disproportionately affected.¹⁰⁻¹² A dramatic decline in access to screening programs (–11%), delays in diagnosis, and reduction in surgical procedures (–18%) and in pharmacological treatments (–13%) have been recorded in Italy in 2020-2021 (source: Italian Ministry of Health). The containment measures to halt the spread of the COVID-19 infection, the conversion of many oncology in-patient clinics into COVID-19 units (particularly during the first wave of the pandemic and in the regions of northern Italy), the shortage of oncologists and radiotherapists diverted to COVID-19 care, and the lack of ICU beds, occupied by patients with severe acute respiratory syndrome, have contributed significantly to this scenario, albeit with substantial differences between regions.¹³⁻¹⁵ The consequences of the serious interruption of all aspects of the cancer care continuum, from screening to treatment, will potentially result in an increase in advanced-stage cancer diagnoses in the coming years and may lead to an increase in cancer-related mortality.¹⁶ Social isolation and anxiety due to delayed (or impeded) access to diagnosis, surgery, or systemic treatments have also affected mental well-being of patients with cancer, their caregivers, and cancer survivors.¹⁷ Besides, there is concern that the COVID-19 pandemic will exacerbate the existing equity gap in cancer care by penalizing the medically underserved populations.

In addition to cancer care continuum, the cancer research ecosystem has been largely affected by the pandemic. The shutdown of laboratories for several months, forced turnover of staff due to lockdown measures (during the first wave) or self-isolation (during the subsequent ones), reduction of patient samples, delays in the delivery of laboratory materials, and re-prioritization of economic resources have severely halted the discovery science and the bench-to-bedside translation.^{18,19} There was also a significant negative impact on career development opportunities, especially for women and junior investigators.²⁰ On the other side, disruptions to ongoing clinical trials facing suspension, early termination, reduced recruitment rate, and delays in new clinical trial activation resulted in a severe slowdown in therapeutic development and threaten trial outcomes.^{21,22} The concomitant financial crisis faced by academic institutions, along with cuts in research funding by prominent philanthropic organizations and charities due to the undirected consequences of the COVID-19 outbreak,

jeopardizes the future sustainability of cancer research.²³ In Italy, the Associazione Italiana Ricerca Sul Cancro (Italian Foundation for Cancer Research, AIRC) lost an estimated 20% of annual income from ordinary fundraising activities and 5 per 1000 taxpayers' donations in 2020 and 2021.²⁴

Overall, the disruption of the preclinical, translational, and clinical research will likely have a long-term impact on the prevention and treatment of cancer and will likely lead to excess in cancer-specific mortality in the years ahead.

IDENTIFICATION OF PRIORITIES AND NEEDS OF ITALIAN ONCOLOGY

The structural vulnerabilities of the SSN and the lack of financial and human resources exposed by the pandemic offer a unique chance to rethink and improve the organization of cancer care provision and strengthen the interactions between different medical disciplines, institutions, and industry in order to address the numerous patient needs. First of all, the deficit of resources must be urgently addressed with a long-term perspective. A fundamental element in this process is the understanding of the correct allocation of available resources, following criteria of clinical, economic, and ethical rationality, effectiveness, efficiency, justice, and solidarity. The decision on the allocation of resources must take into account the priorities and needs of patients.

Concerning the reorganization of cancer care continuum, many adaptations to the cancer care continuum and clinical investigation indicate a path forward for patient-focused and decentralized care which has the potential to improve the outcome and quality of life of patients in the future and reduce costs. These include, amongst others, modification to treatment regimens in favour of administration of oral drugs when possible, increased time between doses, reduced frequency of in-site blood tests and visits, simplified administrative procedures, remote consent, telemedicine, home delivery of trial medications, and collaboration with peripheral health care facilities.²⁵ The pandemic has also highlighted the tremendous value of the scientific community along with that of the technological progress, which represents an opportunity of broad evolution in health care. The use of new technologies for the investigation of drugs and messenger RNA vaccines to tackle the COVID-19 infection could one day become the basis for therapeutic development in oncology. In addition, the preventive measures widely adopted to halt the spread of COVID-19 enhanced the use of electronic information and technology to deliver health care from a distance in an unprecedented manner. In July 2021, the use of telemedicine increased by 38 times than before the pandemic.²⁶ Most Italian patients welcomed the expansion of telehealth and were inclined to continue using this approach after the pandemic.^{27,28} The rapid implementation of telemedicine during this period has opened the door to the opportunity of its permanent integration into cancer care with the potential to reduce financial and logistical burdens on patients and improve the care continuum.²⁹

THE 'RECOVERY PLAN' FOR THE ITALIAN ONCOLOGY IN THE POST-PANDEMIC SCENARIO

The ongoing health crisis represents a unique opportunity to implement positive changes in the organization of clinical and research activities that may inspire new and better care delivery models. It is necessary to reinforce both the pillars (prevention, diagnosis, treatment, follow-up, health workforce) and also the foundations of cancer care (communication and care relationship, system organization, resources, research, networking) (Figure 1). Building on what has been exposed and learned during the global health emergency, the following list indicates the objectives to be pursued in the near future, in a concrete and pragmatic way, to rebuild Italian oncology aiming for enhanced delivery of care and research. The priorities to be implemented are summarized in Table 1.

PILLARS: OBJECTIVES

- 1) Prevention
 - Implement primary and secondary prevention programs and enhance existing ones
 - Educate the population on the fundamental value of primary prevention and early diagnosis
 - Sharing good practices between regions to reduce geographical differences regarding adherence to screening programs
- 2) Active treatment
 - Management simplification, especially of day hospitals: implement oral treatments when possible; optimize accesses to blood tests and pre-treatment visits; evaluate permanent changes to the management of central venous accesses as suggested by AIOM during the COVID-19 emergency; when possible, integrate face-to-face visits with remote assessments (telemedicine)
 - Educate oncologists to actively collaborate with palliative care providers to implement the integration of simultaneous care in the early phase of metastatic disease, giving priority to the patient quality of life, avoiding the unnecessary toxicity of inappropriate therapies (i.e. active treatments at the end of life), and reducing costs
- 3) Follow-up
 - Improve the organization of follow-up paths and aim to the goal of personalized surveillance that considers the tumour stage and the patient's natural history of disease
 - Facilitate the management of long-term survivors by identifying the coordinator of the surveillance pathways (GP or oncologist)
 - Implement models of systematic use of telemedicine
- 4) Simultaneous care
 - Improve the territorial palliative care networks and their integration with hospital facilities within regions
 - Educate and train oncologists on the use of palliative sedation and on the systemic adoption of advance directives, which must be an integral part of the shared decision-making process

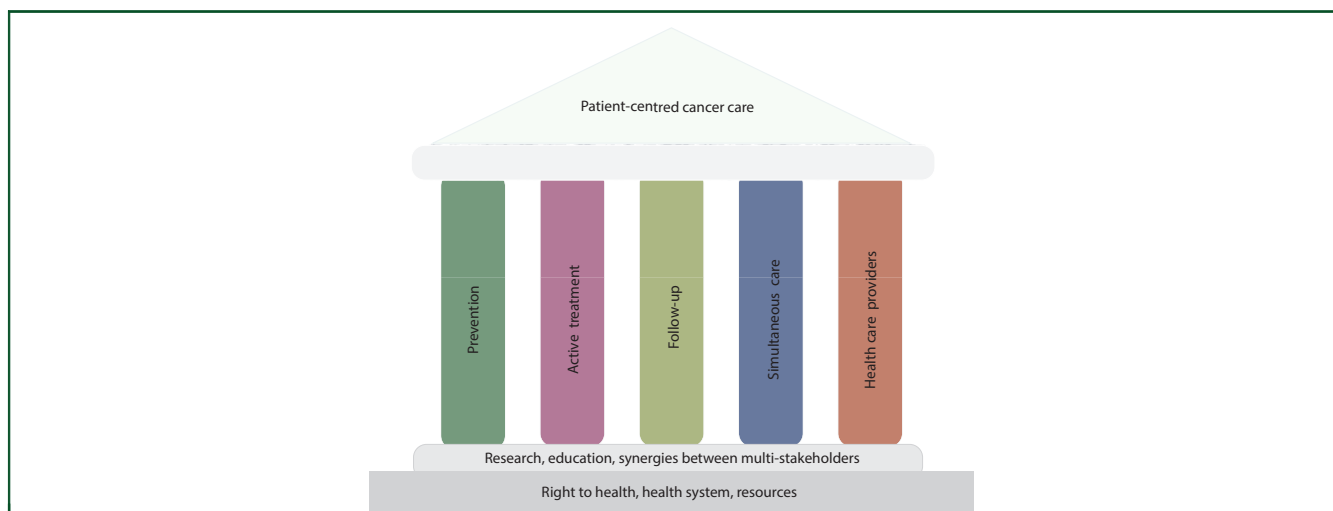


Figure 1. Foundations and pillars of cancer care to be enhanced.

- Identify an optimal model for simultaneous care and establish how to best integrate the latter within the health system, in the individual regional context, with the currently available resources
- 5) Health care providers
- Allocate economic resources to address the urgent need of health care workforce
 - Enhance support for medical oncologist in the context of a constantly changing and demanding society, in which identity crises, defensive medicine, and administrative duties are aggravated by the condition of loneliness and abandonment by the institutions witnessed during the pandemic³⁰

FUNDATIONS: OBJECTIVES

- 1) Communication and relationship of care
- Implement patient-reported outcome measures in clinical practice to guarantee the best relationship of care and the well-being of the patient
 - Educate oncologists to value the centrality of the patient, recognizing his dignity and self-determination, in all its forms, and in every phase of the disease, as an active part of the decision-making process
 - Promote training and educational activities for helping medical oncologists to develop effective and empathic communication with the patients and their caregivers

- Guarantee to all patients with cancer integrated treatment paths that avoid abandonment, especially in the advanced stage of the disease
- 2) Rights, system organization, and resources
- Place health at the centre of the political agenda and protect the public health system, established with Law 833 of 1978 which, based on the criteria of universality, equality, and equity, guarantees all citizens universal access to equitable provision of health services, as stated by the article 32 of the Italian Constitution: “The Republic protects health as a fundamental right of the individual and in the interest of the community, and guarantees free medical care to the indigent. Nobody can be obliged to a specific health treatment if not by law. The law cannot in any case violate the limits imposed by respect for the human person”
 - Address systemic health disparities experienced by patients with cancer to guarantee the equal right to health
 - Eliminate structural regional inequalities to ensure equity of access to prevention, diagnosis, and treatment throughout the country (with particular reference to the disparities in accessing services in terms of timing and complementarity of the offer)
 - Promote the creation of a unitary governance to implement shared strategies and projects concerning clinical and research contexts
 - Collaborate concretely in the development and realization of a national oncology plan
 - Increase resources, to be allocated according to targeted measures
 - Redesign the organizational models concerning hospitals as well as territorial networks
 - Strengthen the collaboration between AIOM, GPs, and other regional services to optimize the management of screening, active treatments, palliative care, and follow-up in a decentralized manner
 - Implement telemedicine: identify a framework of solutions—both organizational and technological—to

Table 1. Matera 2021 statement: summary of the priorities to be implemented	
M	Multidisciplinarity
A	Access to cancer care (from screening, to active treatment, to palliative care)
T	Telemedicine and territoriality
E	Equity, ethics, education
R	Research and resources
A	Alliance between stakeholders and patients

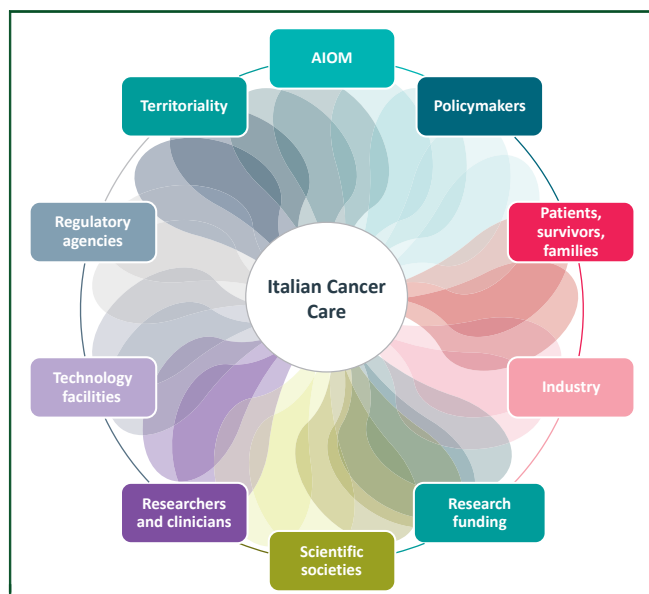


Figure 2. Alliances, networking, and new synergies. AIOM, Italian Association of Medical Oncology.

improve the integration of telemedicine in cancer care (from prevention, to treatment and follow-up)

3) Research

- Reform clinical cancer research by permanently implementing the strategies adopted during the pandemic as suggested by the American Society of Clinical Oncology (ASCO) including: electronic signatures and documentation; telehealth visits; remote monitoring of clinical sites; delivery of research-related care at local clinical sites; streamlining of administrative procedures; and acceleration of traditional regulatory timelines)³¹⁻³³
- Implement long-term holistic policies to build solid foundations for future innovation and progress³⁴
- Aim for rigorous research avoiding projects of scarce relevance or redundancy
- Promote the constitution of a national body for the evaluation of research proposals candidate for public funding
- Promote the allocation of resources by the government to support independent research
- Implement measures to simplify the evaluation of research projects by the ethics committees, on the model of what happened during COVID-19 for the protocols relating to the emergency
- Strengthen real-life studies
- Implement integration with—and between—cooperative groups to facilitate cross-fertilization
- Re-discuss privacy assessment and restrictions in light of the imminent digital revolution
- Implement research projects based on multi-omics strategies and integrate them with clinical research

4) Education

- Pursue the work of continuous education of health professionals, especially young oncologists, both in terms of clinical practice and research

- Promote education of patients and patient organizations
- Promote public education on primary prevention and cancer screening

5) Alliances, networking, and new synergies

- Strengthen the relationships and networking between oncologists, GPs, specialists from other disciplines, and territorial facilities to explore alternative, non-hospital care services
- Define shared pathways and projects (see AIOM—SIAARTI working group)
- Promote and strengthen relationships between AIOM and other stakeholders including patient organizations, pharma representatives, and institutions (at local, regional, and national level) (Figure 2)

Conclusions

In conclusion, the historical moment, of crucial importance, requires the redesign of the Italian oncology, from organizational models, to clinical assistance paths and research, and places AIOM alongside the institutions, to take up this important challenge, and as a promoter of instances of patients and health professionals. The comprehensive project we designed has the ambitious goal of achieving equitable, affordable, and sustainable cancer prevention and treatment as well as the highest quality of life for patients with cancer and survivors. The success of the plan's execution will depend on the collaboration between multi-actors and in particular on the engagement with patient organizations, whose role as stakeholders should be enhanced to ensure that the future oncology is centred around patient needs.

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DISCLOSURE

The authors have declared no conflicts of interest.

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