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Review

The experience on coronavirus disease 2019 and cancer from an oncology hub institution in Milan, Lombardy Region

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Abstract The outbreak of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)–related disease (coronavirus disease 2019 [COVID-19]) has spread rapidly to a pandemic proportion, increasing the demands on health systems for the containment and management of COVID-19. Cancer has been reported as a major risk factor for adverse outcomes of and death from COVID-19. We extracted data from the World Health Organization’s progress reports and from the Italian Council of Medicine. In addition, we retrieved clinical data on patients with cancer and with confirmed COVID-19 in our institution. As of 2nd April 2020, 110,574 COVID-19 cases and 13,157 deaths have been reported in Italy, representing a global share of 5.1% and 28.9% for incidence and mortality, respectively. In Italy, we report the analysis of the Italian Medical Council on 909 patients who died from COVID-19; of whom, 16.5% were patients with cancer. The population was enriched with subjects with multiple comorbid non-communicable diseases, with less than 1% of the population presenting no comorbid conditions. At the patient level, we identified nine patients referred to our department in the last two months who were receiving standard-of-care or experimental medications in the curative and palliative settings. The median age was 68 years (range = 42–79 years), and patients carried a median of one comorbid condition (0–2); two of nine patients presented with severe COVID-19 and were receiving inpatient care. None of the patients receiving immunotherapy experienced severe adverse outcomes, and four patients were discharged with complete reversal of the clinical syndrome and SARS-CoV-2 clearance. Learning from the experience of countries with a high burden, efforts must be made to assure the access of patients with cancer to treatments, prioritising the cancer health interventions based on their intrinsic value and limiting the exposure to an unacceptable risk of infection for both health providers and

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patients. Any significant work in the design and implementation of health system actions, including clinical care, must be framed as an initiative under the global response agenda and through a community approach, with the intention of pursuing common goals to tackle COVID-19 and cancer, as ‘One Community’ working for ‘One Health’s.

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1. Introduction

The outbreak of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has rapidly spread worldwide to a pandemic proportion. As of 2nd April 2020, the World Health Organization reported 896,450 confirmed cases, with 45,526 deaths from SARS-CoV-2–related disease (coronavirus disease 2019 [COVID-19]). Of them, 110,574 cases and 13,157 deaths have been described in Italy, representing a global share of 5.1% and 28.9% for incidence and mortality, respectively [1].

The rapid spread of the pandemic has challenged the capacity of the Italian health system, demanding the strongest resilience in the design and implementation of an emergency plan for both preparedness and response. The rapid adoption of non-pharmacological public health interventions, such as social distancing and lockdown measures, has driven the initial response to an unprecedented extent for the national health system. The national capacity of Italy’s health system has traditionally been regarded as an excellent model for a public health service, ensuring effective coverage for all, with 3.12 hospital beds per 1000 people and 3.99 physicians per 1000 inhabitants [2]; the system has been able to deliver efficient and effective healthcare, favouring the country in terms of productivity [3]. However, no health system can be truly prepared or sufficiently flexible for an impressive rise in the demand for intensive care capacity, especially if funded on vertical disease programs. An academic health model anticipated complete saturation of the number of available beds in intensive care units by 14th March 2020, prompting an intersectorial approach that could clearly estimate and communicate the risk for severe COVID-19 cases requiring intensive care [4]. Such an approach broadens the chances for all to access the appropriate treatments, while the daily rate of new COVID-19 cases requiring hospitalisation was slowing down.

Since the beginning of the COVID-19 epidemic, older subjects and patients with non-communicable diseases (NCDs), including cancer, have been shown to be at increased risk of severe complications and poor outcomes from COVID-19 [5]. Accordingly, protecting such vulnerable patient populations more than ever became a priority. In this regard, cancer care was immediately established as a health priority by the National Medical Council and the Ministry of Health.

2. At the centre of the outbreak: reorganising cancer care to respond to COVID-19 in the Lombardy Region

The Lombardy Region was the epicentre of the outbreak of COVID-19 in Italy [6]. To face the emergency, the Lombardy Region created differentiated pathways for COVID-19– and non–COVID-19–related health services. Although segregation of the patients—and to some extent of the workforce—has been proposed by multiple decision makers and framed in policies for the response to the pandemic, patients with cancer can still experience a spectrum of SARS-CoV-2–related health conditions; these include asymptomatic or *pauci*-symptomatic infections with subclinical courses, which can be managed while the patient resides at home and is referred to the telemedicine systems and the primary healthcare network.

Tackling a public health emergency while strategizing the care system has defined the priorities and modalities of the emergency response in the Lombardy Region for all patients. The rapid outbreak of COVID-19 in the Lombardy Region in Italy has prompted an urgent response to meet the needs of patient care while maintaining essential healthcare for all. As the pandemic rapidly escalated, the Italian government enforced a state of emergency on a national scale [7]. Furthermore, the regional organs of governance and the emergency regulations emphasised the need to ensure essential care for patients with cancer, a potentially frailer fringe of the population, exposed to both a higher risk of COVID-19 and fatal consequences [8,9]. The bedrock for a priority setting in oncology care is structured in value-based health system planning. Where no significant impairment of the prognosis is anticipated by temporary cessation of the service or changed eligibility conditions, a delay in the treatment can be tolerated [10].

On 8th March, a Regional Council Resolution was implemented, arranging a reorganisation of the hospital networks based on a hub/spoke design [11]. The hubs for cancer care are designated on the base of performance criteria (e.g. volumes of specialised cancer surgery), each connected to one or more spokes for selected services (e.g. administration of standard chemotherapies). The resolution aimed to assure the continuity of care for essential cancer treatments while urging a scale-up of the capacity for the serious healthcare demands of COVID-

19; the system is operationalised to also tackle the health needs for all patients without COVID-19.

The Lombardy Region defined new trajectories for the public-private relations, remodulated by temporarily abrogating the private for-profit activities, thus extending the service availability to patients with cancer. The Region provides comprehensive cancer centres, in the public and private sectors, along with several specialised departments, as eligible for building the hub-and-spoke network. The specialised hubs for oncology have been connected with spokes to design a parallel health network for the specific referral of patients with cancer, distinct from the ‘COVID pathway’, to direct the care for undeferrable services. Public and private institutions are called upon to synergise their capacities, including the workforce, liquefying the conventional boundaries under the umbrella of a synchronous leadership, a deployment of the highest national expertise for cancer control.

While strategizing the key elements of the health system to address COVID-19, a priority setting for patients without COVID resulted in an interinstitutional consensus led by the emergency response task force. Recalled to respond to the outbreak, our institutions reshaped the service delivery model in a network-based model, coordinating the referral centres under the Crisis Unit of the Lombardy Region.

3. The Italian cancer mortality for COVID-19: reporting from the National Medical Council

The Italian Medical Council updated the report ‘Characteristics of COVID-19 patients dying in Italy’ based on data available on 30th March 2020 [12]. The present report describes the characteristics of 10,026 patients with COVID-19 who died in Italy since the beginning of the disease registration (alias Feb 2020 was intended as the begin of the period of registration, occurring between Feb-30th March). The national registration system—coordinated by the COVID-19 Surveillance Group under the leadership of the Medical Council and the auspices of the Ministry of Health—includes all COVID-19 cases diagnosed locally and confirmed centrally in national reference laboratories across 19 regions and two autonomous provinces. Patients dying from COVID-19 were generally older, with a median age of 78 years (range = 26–100 years); of whom, around 70% were men ($n = 6938$; 69%). When pooled by age groups, 111 patients died before the age of 50 years, encompassing 1.1% of the population, while a half of all these patients were older than 80 years ($n = 4924$; 49.1%). Disaggregation by gender indicated that women died at an older age than men (median = 82 versus 78 years, respectively).

Data on 909 patients who died in hospital were reported in detail, with a review of the source documents and the medical records [12]. Patients experiencing a fatal outcome from COVID-19 commonly carried a median of three NCDs as comorbidities. More than 50% ($n = 470$) presented three or more comorbid conditions, including ischaemic heart disease, atrial fibrillation, heart failure, stroke, hypertension, diabetes mellitus, dementia, chronic respiratory disease, cancer, kidney diseases or liver diseases. Few patients (only 2.1%, $n = 19$) had no comorbid conditions. Fifteen of 21 patients aged younger than 40 years had pre-existing serious NCD comorbidities, and none had a history of cancer.

The diagnosis of cancer was recorded only for patients treated for a malignancy in the past 5 years, and this group of patients included both cured patients and those receiving active treatment before COVID-19-related hospitalisation. In the sample analysed, 150 patients with COVID-19 (16.5%) were patients with cancer. According to the report, the majority of patients with cancer were hospitalised for respiratory symptoms and/or pulmonary findings at imaging; overall, only 46 patients (in the entire series) were hospitalised for other medical reasons. Interestingly, of all patients with cancer, 4.7% (7/150) were initially hospitalised for cancer treatment and not for SARS-CoV-2 infection. Almost all the patients (96.5%) experienced acute respiratory distress syndrome (ARDS), 25.7% had acute kidney failure, and 11.2% were diagnosed with a secondary infection superimposed on SARS-CoV-2 infection. Of interest, cardiac injury was reported for 11.6% of patients who died, both as a consequence of blood gas and haemodynamic changes in patients with ARDS and possibly via vascular or direct myocardial effects of the virus [13].

The Medical Council is committed to updating the progress reports on a periodic basis, especially when identifying relevant data on the clinical management of patients and on policy formulations. So far, no data on treatments received by patients and the status of malignancy when COVID-19 was diagnosed have been released. Only a single report of an Italian patient with cancer has been published so far [14]; this described the case of a 65-year-old patient with metastatic non-small-cell lung cancer who had been receiving the anti-Programmed cell death protein 1 (PD-1) agent nivolumab with a sustained response of more than 6 years. After COVID-19 diagnosis and hospitalisation, the patient presented a rapid worsening of pulmonary function that caused death on the 5th day of hospitalisation. The authors suggested that the patient was still progression free at the time of death, reporting a COVID-19-related death in a long-term controlled metastatic lung cancer; this recalls the need for a deeper

discussion within the multidisciplinary teams when intensive care is a life-saving option in selected cases of patients with advanced and long-responding disease.

4. Our institution experience: interim analysis from an oncology hub for cancer care

Since the outbreak in late February, first the cancer institutions in Lombardy Region, and then those nationally have reshaped the service delivery model and set priorities in cancer care. Treatment decisions have been initially provided on a case-by-case basis, aiming to meet the safety of patients and balance against the risk of disease progression, with an impact on the outcome. To better understand the circumstances and the burden of COVID-19 and cancer, we collected the data from our institution.

We extracted the data of laboratory-diagnosed patients with COVID-19 who had been referred to our division from 1st February 2020 and retrospectively gathered clinicopathological data.

As of 2nd April 2020, the oncology team at the European Institute of Oncology in the Lombardy Region have managed nine patients diagnosed with COVID-19, both as inpatients (n = 3) and as outpatients (n = 6), all in good general condition as per performance status

(Table 1). Of these, the majority of patients were men (n = 7). The median age was 68 years (range = 42–79 years). The men were generally older than the women, with a median age of 68 and 55 years, respectively. All the patients had a smoking history, being either former smokers (n = 4) or current smokers (n = 5). No recurrent pattern of cancer type (per histology) or setting of care (neoadjuvant/adjuvant or palliative) was identified; three patients were receiving active treatment in the curative setting, and five were receiving treatment for metastatic disease; all received within 14 days at the time of COVID-19 diagnosis. Chemotherapy was the most common ongoing therapy (n = 4), followed by experimental immune checkpoint inhibitors (n = 2) and small molecules (n = 2). Possibly related to the inclusion in clinical trials, multiple NCD comorbidities were uncommon in the overall population, with a median of one comorbidity per patient (range = 0–2), represented by arterial hypertension (n = 4), diabetes mellitus type II (n = 2) and chronic kidney diseases (n = 1). Using the criteria to score SARS-CoV-2 infection proposed by the Italian Association of Anaesthesia, Analgesia, Resuscitation and Intensive Care, we scored COVID-19 severity in six stages—from stage I (non-complicated COVID-19, no pulmonary findings) to stage VI (septic shock)—and referred to stage II pneumonias as mild

Table 1
Clinical characteristics of the IEO series of COVID-19 and cancer.

Patient ID	1	2	3	4	5	6	7	8	9
Age (years)	42	68	73	79	69	68	59	73	50
Gender	Female	Male	Male	Male	Female	Male	Male	Male	Male
ECOG PS	0	0	1	1	1	1	1	0	0
Smoking	Never	Former	Former	Former	Never	Never	Never	Former	Never
Cancer type	Breast	Urothelial	Urothelial	Leukaemia	Gastric	Melanoma	Lung	NET	Head and neck
Stage	Early or locally advanced	Early or locally advanced	Early or locally advanced	Metastatic	Metastatic	Metastatic	Metastatic	Metastatic	Early or locally advanced
Active anticancer therapy	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
Setting of treatment	Adjuvant/neoadjuvant CT	Adjuvant/neoadjuvant CT	Adjuvant/neoadjuvant CT	CT	Immunotherapy	Immunotherapy	TKI	TKI	NA
Clinical trial	No	No	No	No	Yes	Yes	Yes	Yes	No
Ischaemic heart disease	0	0	0	0	0	0	0	0	0
Comorbidities (N) ^a	0	2	1	2	2	0	0	1	1
COVID-19 symptoms ^b	Mild	Mild	Severe	Mild	Mild	Mild	Severe	Mild	Mild
Hospitalised (yes/no)	Yes	No	Yes	No	No	No	Yes	No	No
COVID-19 status	Ongoing	Ongoing	Ongoing	Ongoing	Ongoing	Ongoing	Resolved	Resolved	Resolved

CT, chemotherapy; SIAARTI, Italian Association of Anaesthesia, Analgesia, Resuscitation and Intensive Care; COVID-19, coronavirus disease 2019; ECOG, Eastern Cooperative Oncology Group; PS, performance status; IEO, European Institute of Oncology; TKI, tyrosine kinase inhibitor.

^a Atrial fibrillation, ischaemic heart disease, hypertension, stroke, diabetes, dementia, chronic pulmonary diseases, chronic liver disease, chronic renal disease.

^b According to the SIAARTI system for severity scoring of COVID-19 pneumonia. See the text for details.

and stage III as severe. None of our patients accessed the intensive therapy unit; two had severe pneumonia and were hospitalised. All the other patients had a mild COVID-19 syndrome and were referred to home-based management, according to the local practice and clinical indications. For patients managed at home, a telemedicine system intended to connect doctors and nurses on a daily basis has been established, engaging with the primary health providers, and enhanced by home delivery of territorial volunteers, community workers and nurses for specific tasks: registering vital parameters twice daily along with documentation of the patients' symptoms.

Three patients, one with severe and two with mild pneumonia, were discharged, and/or the clinical syndrome resolved, testing negative on laboratory assessment of SARS-CoV-2. Although no specific pattern of increasing risk was recognised in this small series, it is interesting to report that none of our patients experiencing severe outcomes from COVID-19 or requiring hospitalisation was receiving immunotherapy, a speculated risk factor for severe COVID-19.

5. Discussion

We report the first Italian series of patients with cancer experiencing COVID-19 referred to our institution in the last two months. Making comparisons between the Italian situation and that in other countries may not be ideal as the population demography and modifying effects of NCDs on the risk and prognosis of COVID-19

can affect the epidemiology of the disease, as can a diverse response and implementation of restrictive measures at the community level.

According to the data of the Chinese case series, with special reference to the national epicentre Wuhan, an older population and multiple comorbid patients soon appeared to have the highest risk of adverse outcomes from COVID-19, especially if they had NCDs. In China, 25.3% of the population is older and potentially frail (Table 2). Almost 50% of the men in the population are tobacco smokers. NCDs account for a significant proportion of the total mortality in the country, with cancer accounting for 23% of the patients succumbing to NCDs.

The large patient series from Wuhan (n = 1099 patients) showed that subjects with COVID-19 and selected NCDs tended to present a worse disease severity, with comorbidities including diabetes mellitus, hypertension, coronary artery disease, chronic kidney disease and cancer [5,15]. In the correlation analysis of selected risk factors associated with ARDS or mortality in 201 patients [15], older age and NCDs seemed to drive the prognosis for COVID-19. Hypertension, cardiovascular diseases and diabetes were more common in patients experiencing an adverse outcome from ARDS, or dying of respiratory failure, with absolute differences ranging between 3.4% and 14%. The hazard ratios for ARDS and death were 1.82 and 1.7 for hypertension and 2.34 and 1.58 for diabetes, respectively.

Although no patient with cancer was included in the analysis and few patients with cancer have been reported

Table 2

Population, selected risk factors and mortality for non-communicable disease in China and Italy, as relevant for severe acute respiratory syndrome coronavirus 2-related disease (COVID-19).

	China	Italy	Source
Population size (2020), thousands	1,439,324	60,462	UN
Male/female, ratio	1.05	0.95	UN
Median age, years			
Total	37.4	45.5	UN
Male	36.5	44.4	
Female	38.4	46.5	
People aged >65 years, %	25.3	65.2	UN
Prevalence of tobacco smokers, %	Male: 45.7 Female: 1.4	Male: 26.9 Female: 19.6	WHO
Mortality for the principal NCDs, %			
CVD	43	36	WHO
Cancer	23	27	
COPD	9	6	
Diabetes	2	3	
Cancer incidence, age-standardised rates per 100,000	201.7	290.6	Globocan 2018
Cancer mortality, age-standardised rates per 100,000	130.1	94.1	Globocan 2018
Patients with cancer among patients with COVID-19, %	9 of 18 patients with cancer had severe events or died (0.5% of the COVID-19 cases)	150 patients with cancer/909 deaths from COVID-19 (16.5% of all COVID-19 deaths)	China: Liang et al. [8] (<i>Lancet Oncology</i> , 2020) Italy: ISS, 30th March 2020

COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; ISS, Istituto Superiore di Sanità; NCDs, non-communicable diseases; WHO, World Health Organization; UN, United Nations; COVID-19, coronavirus disease 2019.

across different Chinese studies, NCD comorbidities occur commonly in patients with cancer, both those receiving treatments and survivors, and some of them can be a direct consequence of antineoplastic treatments [16].

So far, only a single national cohort has been published on cancer and COVID-19. The investigators from Guangzhou Medical University developed a prospective registry to monitor COVID-19 cases, framing a partnership within the National Clinical Research Center for Respiratory Disease under the auspices of the National Health Commission [8]. The authors collected the cases in 31 provincial administrative regions from 575 hospitals; 1% of the patients ($n = 18$) reported a history of cancer, either survivors receiving curative or palliative treatments or those in palliative care. Eleven of 18 patients were reported as ‘in follow-up’ and ‘post-operative’, while four were receiving antineoplastic treatments for advanced disease; five of them were affected by concomitant NCD comorbidities. An excess of smokers (former and current) among the patients with cancer was reported, possibly affected by the presence of seven patients (39%) with tobacco-related tumours. In this study, cancer history represented the strongest single prognostic factor for severe events in COVID-19 (odds ratio [OR] = 5.399), more than age and the presence of other NCDs. When analysing the data only from the cohort of patients with cancer, age was the only risk factor for severe events (OR = 1.43). This finding is consistent with the previous reports on all patients with COVID-19, in which age was an independent prognostic factor for adverse outcomes or mortality [15]. For patients receiving active antitumour treatments, poor prognosis seemed to be dictated by the interval between COVID-19 diagnosis and the last treatment received (≤ 14 days), as recently reported [9].

Differences between the populations can be readily described, possibly explaining some divergences in the data. Italians are older, on average, with a larger proportion of the population, being older, deserving special care and risk protection. The number of smokers is lower among men but better balanced across genders. Cancer is causative of death in more than 25% of all NCD-related mortalities, the second cause after cardiovascular diseases (Table 2). Overall, the ageing population and the burden of NCDs could partly affect patients with COVID-19 and determine a different case fatality rate, including for multicomorbid patients with cancer.

On the other hand, our series must be regarded under the lens of the health context and referral pathways of our institution. The European Institute of Oncology currently serves the oncology network to assure cancer care as one coordinating hub. Patients are referred to the institution from other regions for disease-oriented second opinions and multidisciplinary expert discussions, to receive cancer treatments and to participate in

clinical trials, especially early-phase studies. In that regard, all the patients in our series treated with study medications were enrolled in phase I and II trials.

A possible shift to a lower comorbid cancer population, when compared with the Chinese and Italian national series, can be readily explained by the research mandate of the institutions as a significant proportion of patients were receiving experimental compounds when experiencing COVID-19. The often restrictive eligibility criteria for the enrolment in clinical trials inevitably affect the population type, determining a shift to a lower risk population for type and severity of comorbidities and perhaps resulting in less severe outcomes for COVID-19. We report a mixed cohort of patients with diverse histology types and settings of care. While the previous studies seemed to be augmented with some patients with cancer, such as smoke-related malignancies, lung cancer diagnosis could itself represent a possible risk factor for severe outcomes from the infection, as observed in single-case reports and single case series. One of the two patients with severe COVID-19 hospitalised in our study is a patient with oncogene-addicted lung cancer and no comorbidities, receiving targeted therapy. Of interest, the age range of our population falls halfway between the national median age for COVID-19 diagnosis and death. So far, we have observed no death from COVID-19 in our patients, and all the standard protocols for home-based management and regional criteria for hospitalisation have been strictly followed.

Cancer and COVID-19 still represent a less studied field, including the few cases in the Chinese series and the poor data so far derived therefrom. We report here the first Italian series. Given that cancer is an independent risk factor for adverse outcomes and mortality from COVID-19, an in-depth analysis of the cancer series is highly attractive, as advocated by national institutions, including the Italian Association of Medical Oncology and reference experts with local initiatives and regional networks. The questions of medical oncology for the correct approach in the management of COVID-19 are still multiple and unresolved, in the absence of data; questions include whether there is a need to stop certain types of treatments and whether there is a risk of impairing outcomes when continuing some medications with immune-regulating properties (both suppressing and stimulating). However, experience of colleagues facing COVID-19 successfully must be considered to understand the broader landscape around patients with cancer, persons living in societies and affected by the health environment they live in and how it is shaped by policy formulations and implementations.

The experience from Singapore has recently been reported by Ngoi *et al.* [17]. The key to success of the oncology care envisioned by the authors is embedded in a strong population and resilient health system response to the outbreak, across three principal directives: protect

and empower the health workforce, prioritise resources for cancer care for judicious allocation and ensure co-ordination mechanisms for health institutions with regional, national and global policies and workflows. The implementation of a systematised response of cancer providers, aligned to the national and regional priorities for the communities, in a population health perspective, has resulted in a reduction in the outpatient clinical workload (20% less) and inpatient admissions (30% less) of the National University Cancer Institute of Singapore. Over a period of 1 month, a model of segregation of the workforce has been established, to create parallel cohorts of providers for clinical care, education and research—with no reciprocal connections and a triage mechanism for the access of patients in the institutions. The authors reported only 34 patient admissions due to suspected SARS-CoV-2 during this period and only one confirmed case that required mechanical ventilation in the intensive care unit. These data suggest that the bedrock to protect the vulnerable population is not single-institutional decisions, recommendations and guidelines, and the role of the single providers working in isolation can be irrelevant or even harmful when not synchronised under a common agenda for preparedness and response, with a community mandate and based on a coordination mechanism for the urgent reorganisation of the healthcare delivery system, including separate referral pathways for patients with confirmed COVID-19.

As all oncologists in the world are pursuing the maintenance of the best care based on a priority-setting mechanism of health interventions, determined by their intrinsic values, the central driver to optimise clinical care should be enhanced via research implementation and less according to perspectives and opinions. This is a race where everybody must win: the application of science must be intended not only in terms of scale but also in the logic of a global security issue, intersecting the political will and global commitment to ensure healthcare for all [18].

It must be clear that the most critical element to champion in health and society in the response to COVID-19 is social responsibility: patients with cancer are frail persons and potentially more vulnerable; their protection must be ensured under a societal coordination mechanism for prevention of the infection, early recognition of symptoms, isolation protocols, and prompt initiation of treatments. It is based on the concept of OneHealth approach in health planning, meaning "take care of all the patients and consider that a single person can have multiple health conditions" and unique care and committing to formulate recommendations and perspectives under a multidisciplinary and intersectoral coordination system, shaped punctually within the agenda of the global response; any distraction must be tackled and rejected.

The key to success in COVID-19 and cancer is to ensure a continuum of healthcare, never disconnecting the cancer cause from the population health needs, understanding and implementing the scopes and goals of the global responses and enforcing community flexibility, and not merely advocating for a patient-centred approach. The resilience, capacities, skills and resources of the context must be recognized, and these must be built on to deliver protection and solutions while supporting the community's own goal. The ultimate goal now is to end COVID-19 as one global community.

Author contributions

G.C. conceived and supervised the work. D.T. and A.M. collected the data and provided data analysis. D.T. cross-referenced the data with external source references and data sets. All the authors contributed to writing and drafting the manuscript. All the authors read and approved the final proof of the manuscript.

Ethical prescription for data collection and management

Data collection has been performed under the normative regulations, indications and restrictions on the matter of retrospective clinical studies, according to the Italian *deliberazione 01 Marzo 2012, Gazzetta Ufficiale n.72 del 26 Marzo 2012* and subsequent changes. All the patients signed the institutional informed consent for using their anonymised clinical data for scientific purposes.

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Conflict of interest statement

G.C. has received honoraria from Pfizer, Novartis, Lilly and Roche; fees for expert testimony and medical education from Pfizer and has participated in advisory boards for Pfizer, Roche, Lilly, Ellipses Pharma, Novartis, Seattle Genetics and Celltrion. A.M. and D.T. have no potential conflicts of interest to disclose.

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