

REVIEW

"It ain't over ... till it's over!" Risk-mitigation strategies for patients with gastrointestinal diseases in the aftermath of the COVID-19 pandemic

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Abstract

The available COVID-19 literature has focused on specific disease manifestations, infection control, and delivery or prioritization of services for specific patient groups in the setting of the acute COVID-19 pandemic. Local health systems aim to contain the COVID-19 pandemic and hospitals and health-care providers rush to provide the capacity for a surge of COVID-19 patients. However, the short, medium-term, and long-term outcomes of patients with gastrointestinal (GI) diseases without COVID-19 will be affected by the ability to develop locally adapted strategies to meet their service needs in the COVID-19 setting. To mitigate risks for patients with GI diseases, it is useful to differentiate three phases: (i) the acute phase, (ii) the adaptation phase, and (iii) the consolidation phase. During the acute phase, service delivery for patients with GI disease will be curtailed to meet competing health-care needs of COVID-19 patients. During the adaptation phase, GI services are calibrated towards a "new normal," and the consolidation phase is characterized by rapid introduction and ongoing refinement of services. Proactive planning with engagement of relevant stakeholders including consumer representatives is required to be prepared for a variety of scenarios that are dictated by thus far undefined long-term economic and societal impacts of the pandemic. Because substantial changes to the delivery of services are likely to occur, it is important that these changes are embedded into quality and research frameworks to ensure that data are generated that support evidence-based decision-making during the adaptation and consolidation phases.

Introduction

The coronavirus disease-19 (COVID-19) pandemic presents an unprecedented challenge to health systems around the world. From a health systems perspective, a spectrum of measures that include strict isolation, avoidance of social contacts, testing coupled with contact tracing and (re-) allocation of resources, both manpower and equipment, to manage large numbers of acutely ill patients requiring inpatient or even intensive care is key to controlling this viral pandemic.^{1,2} These measures are required until effective antiviral therapies and/or vaccination are available. Despite the expectations of some that COVID-19 will be rapidly controlled, it is likely that these measures will be in place not just temporarily but for a prolonged period of time. This is driven by variable appearance and disappearance rates of the virus in different locations and the likelihood of ongoing community transmission,

albeit at a lower rate as compared with the transmission rates observed during the initial outbreaks in China, Europe, and the United States. This means that the pandemic will not disappear within weeks or even months and will, therefore, have long-lasting effects on health systems, society, and patient expectations.

Considering the wider impact of the COVID-19 crisis, our societies, governments, and central banks have rapidly initiated measures to cushion the economic downturn while resources are allocated to manage the health crisis. Considering the magnitude of these challenges, it is obvious that there will be long-lasting effects on all areas of society, including health systems, while we inoculate and prepare our societies for similar future events.

From the perspective of gastroenterology, the COVID-19 pandemic has wide-ranging implications. COVID-19 has direct effects on the gastrointestinal (GI) tract and the management of patients with GI and liver disease.³ There is a need to manage the

acute impact of the pandemic regarding staff and patient safety and to respond to potentially constrained resources related to competing health priorities. National and international guidelines or position statements (<https://www.asge.org/home/joint-gi-society-message-covid-19> or <https://www.esge.com/esge-and-esgena-position-statement-on-gastrointestinal-endoscopy-and-the-covid-19-pandemic/>) provide guidance, including recommendations on personal safety for the gastroenterologist and endoscopist through the use of specific personal protective equipment (PPE) including N95/FFP2 masks, on postponing non-urgent clinical, endoscopic, and surgical services and on maintaining contact with patients through video and telephone virtual visits. However, it needs to be noted that most of these guidelines are drafted to meet the health system needs during the acute, early phase of the pandemic, and it is evident that societies will have to cope with different phases of the COVID-19 crisis. All phases will present different challenges and require tailored responses by health systems and specialties. Thus, it is important to specifically characterize these different phases of the crisis (Fig. 1) and develop specific responses for the various phases of the crisis (Table 1).

The early response

In the early phase of the response to the pandemic, the focus is to protect patients and staff while resources are made available to support the health system's response with regard to controlling the pandemic and treating COVID-19 cases.

All non-essential services including clinical surveillance, non-emergent follow-up, and surgical and elective endoscopic procedures are curtailed, while urgent and emergency services are sustained. During this time, the gastroenterologist may be called upon to deal with GI and liver manifestations of COVID-19 and to deal with GI emergencies in a COVID-19 patient; occurrences that may carry a high risk of transmission. A substantial and ever-burgeoning literature has emerged on these topics and all who are, or could be, involved in the care of the COVID-19 infected patient are urged to continually update themselves on the latest

guidance. During a pandemic, the parameters that define the risk exposure (e.g., community transmitted cases) may be highly variable across geographic regions and may change rapidly over time. In addition, as we learn more of the global impact of this pandemic, it has become clear (though the underlying reasons may not) that local impacts are highly variable and, thus, clinical guidelines related to the provision of services such as endoscopy in the setting of the COVID-19 pandemic need to take into consideration the local situation. Such considerations should include not just the local status of the pandemic but also the local burden of non-COVID-19 diseases and availability of resources. Guidelines or position statements that fail to provide a risk-stratified approach need to be interpreted with caution because they may not provide guidance that is appropriate for the local setting. While national and international guidelines should be taken into consideration, a variety of local and patient factors must be considered, including

- risk exposure of patients (probability of adverse outcomes) if a service or procedure is delayed;
- risk exposure of staff related to uncontrolled community transmission of COVID-19 in screened patients and
- risk exposure of other health-care professionals if scarce critical resources including PPE are used and subsequently are not available for the protection of staff when treating COVID-19 patients.

Because the above factors might be highly variable across various demographic areas, decision-making should be highly individualized, balancing risks, and benefits. Besides these operational emergency responses, measures to manage stress and assist and support staff facing a potentially life-and death situation are important throughout the various phases.

The adaptation phase

After the initial urgent emergency response (initiated by governments, health authorities, hospitals, or individual clinicians) with reduction of endoscopic and consulting services, there comes

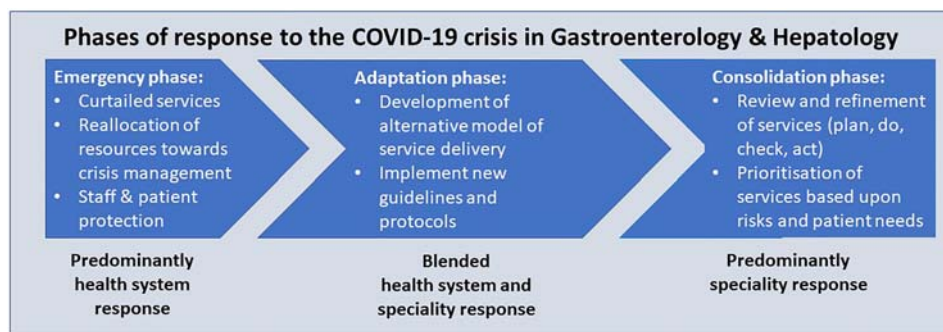


Figure 1 Phases of the response to the COVID-19 crisis. The initial emergency phase is characterized by reallocation of resources to augment capacity in the field of emergency and intensive care. As a consequence, elective services in other areas including gastroenterology are curtailed. During the adaptation phase, alternative models of care (mainly for consulting services) are developed and implemented. At the same time, national and international guidelines that guide service delivery for the emergency phase will emerge. The Consolidation phase is characterized by review and refinement of the services. Emphasis will be given to prioritization of services. It is critical that the consolidation phase is accompanied by appropriate quality assurance and research activities to generate the evidence that is required to guide decision-making in relation to service development. [Color figure can be viewed at wileyonlinelibrary.com]

Table 1 Potential adaptation of various service components to the COVID-19 crisis and staged recovery of services during the various phases of the pandemic

Service-type	Phases of the COVID-19 crisis	Adaptation phase	Consolidation phase
Gastrointestinal endoscopy	Acute phase Emergency and urgent cases	Emergency and urgent cases, risk-based provision of overdue elective services.	Normalization of services. Mitigation strategies to address overdue services.
Consultations	Discontinuation of all non-urgent consultation	Use of consultation services via phone, reintroduction of face-to-face consultations with distancing precautions, and development of telehealth services	Wider utilization of telehealth services as a standard of care
Cancer screening	No change or temporary halt	Services available	Services available
Invasive function testing (manometry, pH testing)	Services halted	Risk-based reintroduction	Gradual return to normal
Non-invasive function testing	Services reduced to low risk, high value services (e.g., <i>Helicobacter pylori</i> breath testing)	Development and testing of home-delivered breath tests	Gradual return to normal. Use of home delivered testing when advisable/possible due to local situation
Infusion services (e.g. anti-TNF)	Continues	Continues	Continues
Fibroscan/Elastography	Temporary halt	Reduced services	Gradual return of activity
Technology/enablers			
Patient reported outcome measures	Continued use of established measures	Development and gradual implementation of PROMs for new service model	Routinely use for novel services models
Secure, end-end-encrypted virtual clinics with integration of allied health and support staff with seamless patient experience	Available services used whenever possible	Transition of services to available service platforms and start to develop new additional capacity and capabilities	Increasingly routine use of novel technology platforms to deliver services
Quality assurance, research	Defining relevant quality indicators or outcome measures and drafting of research protocols or quality frameworks for new modes of service delivery	Trialing of relevant quality indicators or outcome measures	Routine use of quality measures for the refined service models. Defining quality benchmarks

All responses need to take into consideration the local situation. For all services, the local decision-making is guided by a risk–benefit analysis that takes into consideration the local situation.

COVID-19, coronavirus disease-19; PROMS, Patient-reported outcome measures.

a realization that core services are required to prevent avoidable adverse patient outcomes. These services include urgent endoscopic services to treat life-threatening conditions or manage vulnerable patient cohorts requiring immunosuppression (e.g., after organ transplant or due to inflammatory bowel disease) or require emergency treatment for GI bleedings. It is noteworthy that within a very short period of time, several publications have provided guidance on how to manage patients with IBD in the COVID-19 setting,^{4–8} while for other areas, only generic statements have been provided. These typically include recommendations in relation to the mode of service delivery (e.g., face-to-face *vs* telehealth), protection of staff and patients from the infection and focus on patients with acute health-care needs ('... to promote telemedicine in the outpatient setting, prioritize outpatient contacts, avoid nosocomial dissemination of the virus to patients and health-care providers, and at the same time, maintain standard care for patients who require immediate attention ...').⁹ It is obvious that the transition from the initial emergency response and the subsequent adaptation phase will be gradual and the boundaries between these phases might be sometimes blurred, but the adaptation phase will focus on the rapid

implementation of alternative service models. This phase is only now being tentatively initiated in some regions, and it is likely that approaches will vary considerably and provide an opportunity for medical professionals and professional bodies to provide input and shape the response. It is already clear that two goals that may not be compatible will be operative at this stage—the desire, on the one hand, to mitigate viral dissemination and to prevent its re-emergence, and on the other, to reopen economies and restore employment. While many changes are implemented rapidly to meet urgent patient needs or in order to reallocate resources to meet the demand of COVID-19 patients, it is critical that the impact of these changes are appropriately monitored. Thus, available quality frameworks need to be used (e.g., to monitor access to curtailed services or adverse outcomes) or new quality frameworks developed to ensure that novel modes of service delivery or techniques meet standards.¹⁰ Ultimately, the development of quality frameworks as early as possible will facilitate the trialing and implementation of quality frameworks. These frameworks will ensure that novel services deliver high value care,¹¹ and the quality frameworks will enable a review of current practice innovations and allow research to further validate the implemented changes.

This will be key to ensure that innovations developed during the crisis will be sustainable.

The consolidation phase

Many expect that the interruptions of service delivery due to the COVID-19 pandemic will be temporary and that the consolidation phase will be short lived with rapid return to the “pre-COVID-19 normal”. While this is a possible scenario, other developments are now more likely with long-term impact on clinical services. A key-defining factor will be how fast the pandemic can be controlled globally. Given that herd immunity needs to develop, or that effective vaccines or antiviral therapies become available, this may well require considerably more time than optimists imagine. Furthermore, it has not yet been confirmed that effective protective immunity develops among recovered patients, re-infections have been observed after recovery from the initial infection,¹² and the development of a safe and effective vaccine¹³ or antiviral therapies¹⁴ are not without challenges.¹³ It is also evident that economies around the world will continue to face financial constraints that will impact on health-care resources and may drive priorities.

Overall, it must be anticipated that the ramifications for the delivery of services in the field of gastroenterology will be felt for a prolonged period. While resources may continue to be constrained, our clinics and endoscopy units will be confronted, at this stage, by an enormous backlog of patients whose clinical needs were not met during the initial phases of the pandemic. In this context, most health systems will be required to rapidly innovate service delivery with the aim to most effectively utilize available resources. At the same time, service benefits can be

maximized by prioritizing patients who may experience the greatest benefit in outcomes. While, in some (e.g., suspected celiac disease, eosinophilic esophagitis, microscopic colitis, or mild IBS), a delay in diagnosis and initiating treatment will not result in increased mortality, others will be exposed to substantial risk through such delay. In approximately 5% of patients with a single positive fecal occult blood test, a colon cancer can be found,¹⁵ and this number can be even higher in patients with two or three positive fecal occult blood test.¹⁵ The substantial and most likely prolonged effects of the COVID-19 pandemic exposes patients to the risk of delayed diagnosis and treatment with subsequent excess morbidity and mortality.

While a “best case” scenario suggests that all will magically return to normal when emergency measures are lifted, this will not happen—recovery and return to normal will be slow, stuttered, and variable. Throughout this consolidation phase, whose duration is impossible to reliably forecast for all the aforementioned reasons, it will continue to be necessary to prioritize service delivery. While decisions regarding what constitutes an emergency may have been proven to be relatively easy in relation to the early phase, the prioritization of care in this, much likely more prolonged consolidation phase, will present much greater challenges—and ones that we must now give thought to. It is evident that the success of the system response with regard to the containment of the pandemic is critical for the overall impact of the pandemic in a given geographic area. However, the ability to contain the pandemic may still result in adverse outcomes of patients with non-COVID-19 related GI disease if gastroenterology does not provide the required specialty services in the aftermath of the COVID-19 crisis (Fig. 2).

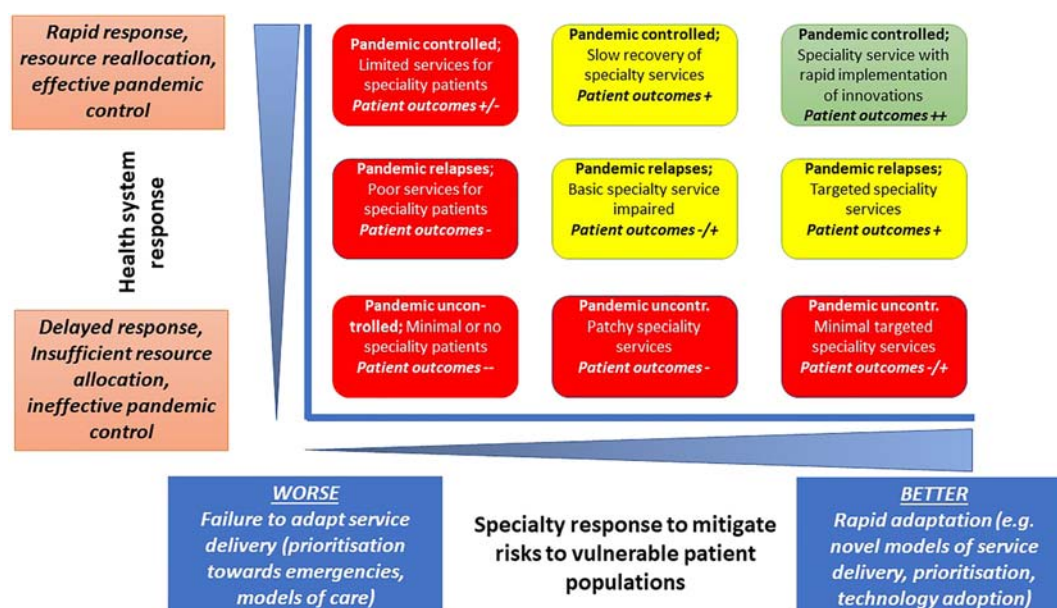


Figure 2 Interrelation of the health system response and the responses of the speciality Gastroenterology with regard to system performance in relation to patient outcomes. The health system response is aimed towards rapid containment of the pandemic (while resources are made available for the treatment of COVID-19 patients). In the changed environment of the COVID-19 crisis, specialities such as Gastroenterology are required to adapt and innovate service models and prioritize service allocation to meet patient needs and mitigate risks. If specialities fail (or are unable) to develop mitigation strategies, excess morbidity and mortality will be the consequence. [Color figure can be viewed at wileyonlinelibrary.com]

Proposed measures to mitigate risks for patients with gastrointestinal diseases in the new world of coronavirus disease-19

In order to mitigate the effects of the COVID-19 pandemic, bold and cohesive responses of health systems around the world are required. At this time, health system responses are, understandably, focused on the containment of the pandemic and clinical care of critically ill COVID-19 infected patients.

While curtailing services in the initial phase was, and continues to be, an appropriate measure to protect staff and patient safety, it is also essential that we plan now for the resumption of service delivery as soon as each local situation allows. Because COVID-19 will have long-lasting effects on health-care systems, gastroenterologists need to rapidly develop strategies to most effectively meet patient needs or—at least—minimize risks during all phases of the COVID-19 pandemic when resources continue to be constrained (Fig. 2). A variety of factors will determine the required responses. These factors include the rate of community transmission, the development of immunity, the availability of PPE, and available resources. However, a variety of measures might be considered:

- As early as possible, every Gastroenterologist, every Gastroenterology Department, and every Hospital or Health Service should start to develop strategies on how to deliver the required services after the initial acute response phase. For this planning, it is important to prepare for a variety of scenarios. The scenarios range from return to pre-COVID-19 levels of services within weeks to services that will be curtailed for months or even more than a year due to resource constraints and/or COVID-19-related restrictions.
- While services might be curtailed due to constrained resources or other services reduced due to travel restrictions and the risk to staff and patients, the available resources should be utilized as efficiently as possible to meet community needs to avoid adverse patient outcomes and a backlog of urgent cases.
- As many services as possible should be transitioned into technology-enabled encounters where the provider and patient are not physically present with each other. While some of these services may initially be delivered over the phone (even though this is just an emergency measure and not a replacement for a face-to-face consultation), available technology should be used to close potential gaps between the traditional face-to-face consultation and the technology enabled service delivery. Proliferation and rapid refinement of videoconferencing technologies will make real-time face-to-face encounters as routine service modalities possible. Conversion to alternative modes is not limited to consultations delivered via phone or videoconferencing tools^{16,17} but equally for a variety of services relevant for the care of patients with highly prevalent GI diseases. This includes internet-delivered cognitive behavior therapy for patients with functional GI disorders¹⁸ as well as similar solutions in dietetic and other areas.
- While there is the expectation that providers and their patients will rapidly recognize that these virtual visits do work and can provide substantial benefits, there is a need

to accompany these transformations with robust quality assurance measures that capture not just the volume of encounters that have been delivered but ultimately compares relevant outcome parameters for traditional face-to-face versus technology facilitated services.

- While immediately after the COVID-19 crisis capacity for endoscopic procedures and other services will be insufficient to meet the demand of acute referrals and the backlog of postponed services, criteria need to be developed on how to maximize benefits and minimize risks to patients. The key question is how the allocation of services is matched with the risk of adverse outcomes if procedures or services are delayed. While clinically established clinical prioritization criteria can be used, it might be advisable to re-examine these criteria based upon emerging evidence.^{19,20}
- While the response to COVID-19 was, and continues to be, time-critical, there is a need to be agile with regard to the indirect implications of COVID-19 for speciality services such as Gastroenterology. The needs of vulnerable patient populations need to be catered for even in the setting of the COVID-19 crisis. Thus, the development and implementation of novel modes of delivery for routine speciality services needs to be accomplished in parallel with the emergency COVID-19 responses to minimize interruptions in critical services that are required to meet patient needs and minimize excess morbidity and mortality.
- System managers and funders, including public and private health insurances, should be required to fund alternative modes of service delivery and to eliminate or refine regulatory barriers to such modes of delivery.
- While the COVID-19 crisis requires innovative and agile responses, it is important that all measures are embedded as soon as feasible into robust quality assurance or research frameworks. The delivery of services for patients with GI disorders aims to reduce morbidity and mortality. While the impact of a delayed diagnosis of cancer can be readily quantified by outcome metrics, for other conditions these need to be developed and implemented.^{21,22}
- Besides, the development of remote patient care, standardization, and optimization for regular outpatient services like infusion of biologics or monitoring of disease activity have to be considered in order to protect patients and staff from risks related to COVID-19. These may include re-organization of infusion centers, home-based calprotectin, or tough level measurement of drugs and the use of web-based apps to monitor disease activity.²³
- Numerous guidelines or recommendations have been produced to provide guidance in relation to PPE and safe delivery of services to patients during the COVID-19 pandemic.²⁴ Unfortunately, most of the recommendations are expert opinions and rarely based upon strong empiric evidence. As part of the consolidation phase, with most likely ongoing “low level” epidemic, it is important to revisit these guidelines and update them with emerging new data.
- Consumers need to be engaged and guided by appropriately tailored information to create an awareness about GI symptoms or conditions that require urgent attention by a gastroenterologist to avoid adverse outcomes.

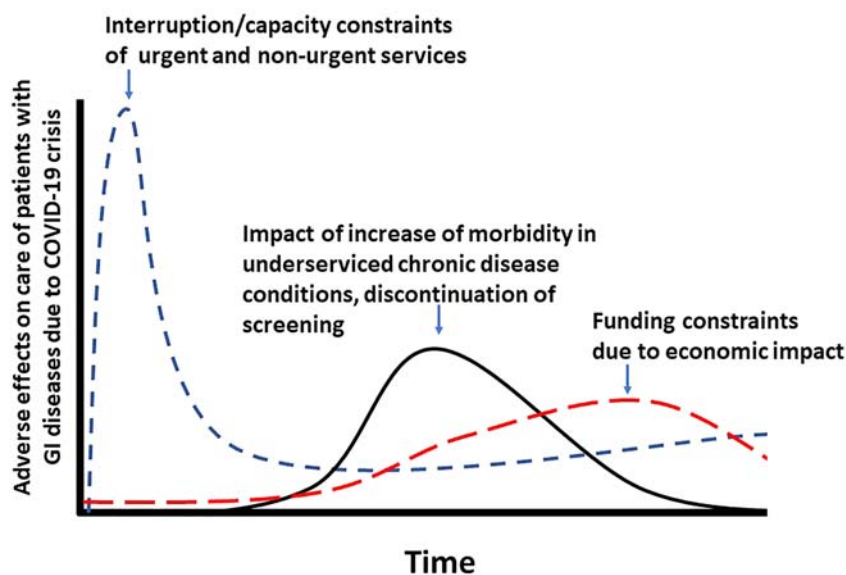


Figure 3 Sequence of adverse effects on services of patients with gastrointestinal disorders. Besides the initial impact due to reduced capacity for urgent and emergency care, it can be expected that there will be excess morbidity and mortality because of underservicing of chronic conditions and delayed diagnosis of malignancies. Subsequently, it also can be expected that the economic consequences of the COVID-19 crisis will have long lasting adverse economic effects that have the potential to impact on service delivery for patients with gastrointestinal disorders. [Color figure can be viewed at wileyonlinelibrary.com]

- Judicious use of diagnostic exams and ancillary procedures so we do not stretch further a financially challenged and manpower-challenged health-care system.
- Gastroenterologists, in cooperation with other health-care professionals, must initiate in their respective jurisdictions/countries a re-look at how we are going to be protected from present and future lawsuits in this telemedicine-based platforms of “the new normal of gastroenterology practice”.

Conclusions

The COVID-19 pandemic is major threat to human life and presents a challenge to the world community. All countries of the world are affected and health systems across the world rush to implement measures to contain the pandemic. While curtailing non-COVID-19 related services in virtually all regions of the world has been a part of the initial emergency response to the COVID-19 pandemic, it is highly likely that the post-acute COVID-19 crisis will be even more challenging. There is the risk that the death toll from COVID-19 will be exceeded by that from GI diseases whose diagnoses and treatments were delayed or postponed.

Temporarily curtailing gastroenterology services with a focus on maintaining only services for emergencies might be an appropriate response to the initial response to the COVID-19 crisis. While some may hope that COVID-19 will soon be eliminated, it is likely that the infection will coexist within our societies for a long period and this will impact on the ability to provide clinical services. Thus, gastroenterologists now need to prepare for this scenario and unless steps are taken to proactively manage the transition to the ‘new normal’ it is likely that morbidity and mortality of patients with unattended GI disease could exceed the direct death toll from COVID-19. While this can be perceived as a threat, the COVID-19 crisis presents an unprecedented opportunity to rapidly develop and implement novel models of care. In addition, it needs to be taken into consideration that curtailing services exposes

patients to risks of having, in the short- or medium-term, excess morbidity and mortality. Furthermore, the societal costs associated with the containment of the pandemic and the subsequent economic implications need to be taken into consideration (Fig. 3). A focus on high value services will be a requirement to minimize the impact on vulnerable patient cohorts.

It is critical that gastroenterologists anticipate various scenarios and act now proactively to develop responses to medium-term and long-term challenges. While the COVID-19 situation is currently fluid, it can be anticipated that there will be considerable geographic differences. Thus, part of proactive planning is the need to develop local strategies to respond to the emerging challenges. While many of the responses may require bold and innovative solutions, it is critical that these measures are embedded whenever possible in appropriate quality assurance and research frameworks. While the objective to deliver quality services in a (cost-) efficient way has not changed, COVID-19 adds further challenges that will require us to refine, if not redesign, many areas of service delivery in Gastroenterology and Hepatology. The need to redesign services is a challenge but equally offers opportunities for accelerated development and introduction of new models of care. To rapidly recognize these opportunities and proactively respond to the obvious challenges is critical to mitigate risks to patients with GI diseases in the aftermath of the COVID-19 pandemic.

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