

Impact of the COVID-19 pandemic on ongoing cardiovascular research projects: considerations and adaptations

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COVID-19, caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), was initially identified in December 2019 as a case of pneumonia in Wuhan, China.¹ The World Health Organization declared the outbreak a public health emergency of international concern on 30 January 2020, and a pandemic on 11 March 2020.² This outbreak is considered the biggest global health crisis of our times, leading to severe socioeconomic disruption, closures of educational institutions, significant mortality, shortages of medical supplies and major unprecedented challenges for healthcare systems around the world. The impact on healthcare extends beyond COVID-19 management and entails important considerations for clinical services, research and education across primary care and most medical subspecialties; the deferral of activities deemed non-essential (i.e. unrelated to COVID-19 planning and management) are commonplace during this pandemic.

Also, patients, providers and researchers in cardiovascular care are highly impacted.³ Potential challenges for cardiac patients include worrying about delayed diagnostics or treatment and the vulnerability associated with being identified at higher risk of poorer COVID-19 outcomes.³ Challenges for cardiac healthcare professionals include redeployment to critical care units, the transition to telehealth and additional COVID-19-related professional demands.³

In this editorial, we highlight unique considerations for researchers who initiated clinical cardiovascular nursing research before the outbreak of the COVID-19 pandemic and are now faced with unprecedented decision-making dilemmas. We illustrate these considerations with two specific research projects, namely APPROACH-IS II and the Tele-yoga study.

APPROACH-IS II

APPROACH-IS II (Assessment of Patterns of Patient-reported Outcomes in Adults with Congenital Heart disease – International Study II) is a global collaborative investigation of patient-reported outcomes (PROs) and experiences, frailty and cognitive functioning among adults with congenital heart disease. APPROACH-IS II is the sequel to the initial APPROACH-IS study,⁴ in which over 4000 patients were enrolled and has resulted in over a dozen published papers in journals, including the *European Journal of Cardiovascular Nursing*.^{5,6} For the next phase, APPROACH-IS II, cross-sectional data are

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obtained using self-reported questionnaires (e.g. quality of life and psychosocial functioning) and in-clinic assessments (e.g. handgrip strength). Over 80 centres in 40 countries have confirmed their participation; most centres are in the preparatory study phase (e.g. obtaining ethics approval), although one-third of centres have begun data collection.

Tele-yoga study

This is a randomised controlled trial to investigate the effects of tele-yoga on physical function, health-related quality of life, mental wellbeing, sleep and cognition in persons with heart failure. The intervention includes biweekly online yoga sessions led by a certified medi-yoga instructor plus individual daily yoga practice. Medi-yoga is a therapeutic form of Kundalini yoga with simple movements, breathing exercises and meditation. Participants use a tablet with an Internet connection for the online yoga sessions and an application to support daily individual yoga practice. The primary endpoint is a composite of physical function, health-related quality of life and symptoms of depression and anxiety; data are captured by questionnaires and a 6-minute walk test performed in the outpatient clinic. Secondary outcomes are cognition, heart rate, blood pressure, sleep and physical activity. Interviews are also conducted before and after the intervention with all patients.

Below, we summarise research considerations that arose during the COVID-19 pandemic and shared our strategies for adaptation in the following four domains: logistics of data collection, interpretation of results, competing local/institutional priorities and international collaboration.

Logistics of data collection

As care priorities in healthcare institutions have understandably shifted towards COVID-19 preparation and acute care, non-essential procedures are often being postponed and many routine outpatient clinic visits are being delayed or converted to telehealth visits. Thus, data collection for many ongoing studies has been suspended or reorganised using alternative data collection methods. This situation has far-reaching consequences for the timelines of many research projects. Given the uncertain timeline of the pandemic and the rate at which hospitals will resume usual activities, it is unknown when patient recruitment and data collection can be resumed or organised as originally intended. For APPROACH-IS II, the decision was made initially to pause data collection for three months for regions affected by the virus; this timeline will be revisited regularly and will be extended if

appropriate. As the Tele-yoga study is a randomised trial with predetermined follow-up points, it was not reasonable to suspend data collection for patients already enrolled in the trial (whether currently receiving the intervention or in the follow-up phase). Alternative data collection methods are being considered, such as performing the walk test at home, sending an activity monitor by mail, and assessing cognitive function over the telephone. The timing of the resumption of study recruitment will be consistent with guidelines from Sweden's Ministry of Health.

Interpretation of study results

Researchers may be concerned about the risk of biased responses and the confounding influence of the COVID-19 pandemic on specific study outcomes.

The main outcomes of APPROACH-IS II are PROs, including anxiety and depression symptoms, which are increasingly present during infectious outbreaks.⁷⁻⁹ Other APPROACH-IS II questions pertain to social support, parental support and advance care planning, of which responses would expect to be impacted by social restrictions and isolation accompanying the current pandemic. Thus, it would be extremely challenging to know whether responses to PRO measures reflect patients' histories of living with congenital heart disease, which was the intent of the study, or instead reflect responses to current pandemic-associated stressors. Therefore, the risk of biased data was the second reason that APPROACH-IS II researchers opted to recommend the suspension of data collection. Furthermore, there will be challenges determining the optimal time to resume data collection, given that the lifestyle and psychosocial impact of the pandemic (and therefore PROs) are likely to extend beyond the pandemic's duration for many individuals.¹⁰ For this reason, the date of survey completion will be collected and considered within statistical analyses. Yet, this will still be challenging, because PROs may fluctuate depending of the severity of the outbreak at that time.¹¹

The Tele-yoga study will face similar challenges interpreting patient-reported health-related quality of life and symptoms of depression and anxiety during these challenging times. In addition, in the Tele-yoga intervention, patient engagement may vary during the pandemic. For example, patients in the intervention group might engage more with the yoga instructor during online sessions as a means of increasing social connections. Depending on the impact on their employment and parenting, patients might have more or less time to engage in daily independent yoga practice. Another unanticipated change in the intervention

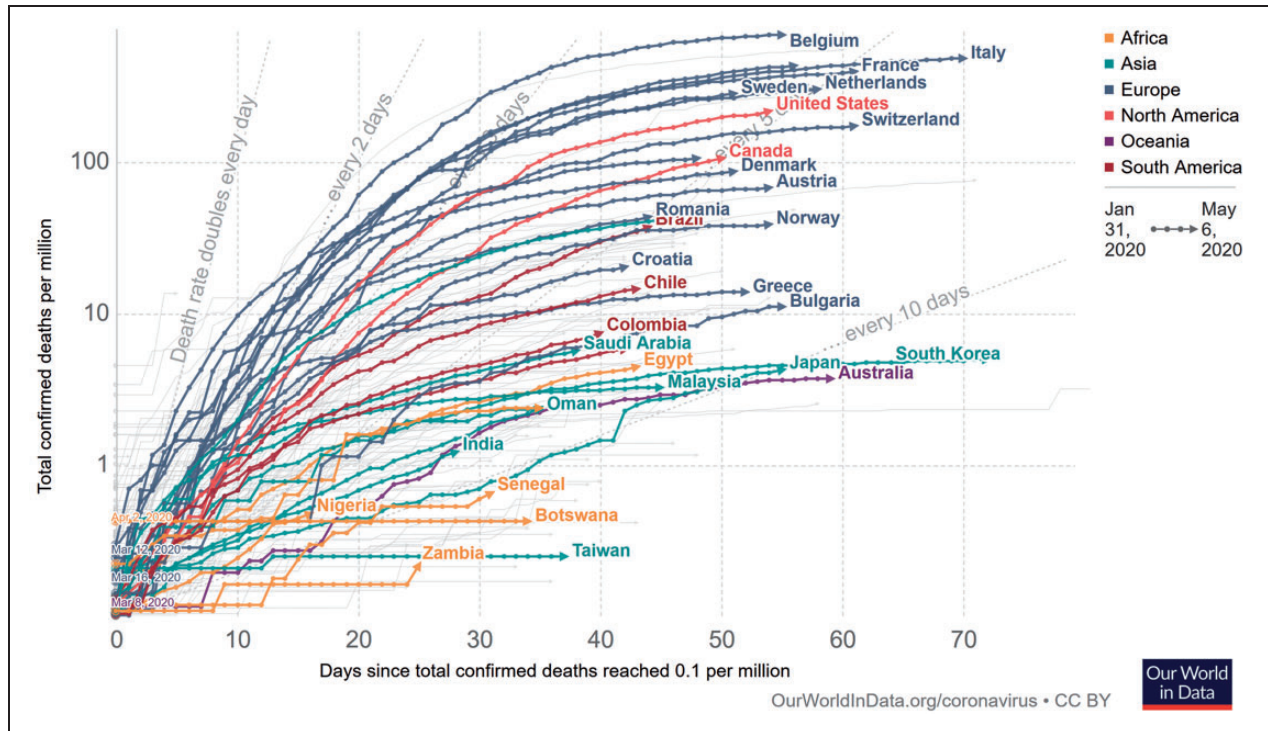


Figure 1. Total confirmed deaths of COVID-19 per million people of participating centres of APPROACH-IS II, until 6 May 2020. Limited testing and challenges in the attribution of the cause of death mean that the number of confirmed deaths may not be an accurate count of the true number of deaths from COVID-19. Source: Chart created by Our World In Data, based on data of the European Centre for Disease Prevention and Control (ECDC). Retrieved from: <https://ourworldindata.org/grapher/covid-deaths-days-since-per-million> [Online Resource].

is the reduced quality of the online live streaming service used for twice-weekly yoga sessions because the use of such platforms by the general public has increased exponentially during the pandemic. It will, therefore, be important to incorporate the timing of the intervention (before, during or after the pandemic) within statistical analyses. It will also be important for researchers to address the shift in data collection methods, namely from primarily in-clinic to at-home assessments, when interpreting study results.

Competing local and institutional priorities

Understandably, most institutions, funding agencies and ethics review boards are prioritising COVID-19-specific research. Therefore, submissions focused on protocol changes (e.g. alternative data collection methods) to ongoing studies that are affected by but not focused on the pandemic, such as APPROACH-IS II and the Tele-yoga study, may take longer than usual to undergo review. This situation may also delay the institutional ethics review of submissions of

APPROACH-IS II participating centres currently in the project start-up phase.

International collaboration

A major challenge for international multi-site research during COVID-19 is that the pandemic follows different patterns and timelines around the world. The pandemic began in China, initially spread to East Asia, next moved to Europe and North America, and then arrived in South America and Africa. The pandemic’s impact is expressed in total cases, new cases per day, total deaths and new deaths per day. A review of these data demonstrates that the impact and acuity of the pandemic differ across countries. The confirmed deaths due to COVID-19 (as of beginning of May 2020) per million citizens for countries participating in APPROACH-IS II are displayed in Figure 1. Given the variation across countries, the APPROACH-IS II investigators are working with participating centres on an individual basis to ensure that study timelines are responsive to local situations.

Conclusions

Due to the COVID-19 pandemic, data collection will be suspended or modified for many ongoing research projects due to logistical barriers and the risk of biased results. Moreover, as COVID-19-specific research is currently prioritised, projects may encounter delays or difficulties when seeking funding and/or ethics approval. International multi-site projects face unique challenges due to variations in the trajectory of the pandemic as well as regional approaches to management. The term 'unprecedented' is frequently used to describe the COVID-19 pandemic. Indeed, just as patients, providers and healthcare systems are being challenged to be creative in their management approaches, cardiovascular researchers must be adaptable and creative in their solutions to managing ongoing research projects.

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