Protocol for a patient-reported experience measures (PREMs) survey of patients discharged during the COVID-19 pandemic and their family caregivers

ABSTRACT

Introduction In the Swiss canton of Valais, the first cases of SARS-CoV-2 were detected on 28 February 2020. Discharged patients' and their family caregivers' experiences in relation to safety, quality of care, trust and communication during the COVID-19 hospitalisation period remain unexplored. The study aims to collect the patient-reported experience measures (PREMs) survey of patients discharged during the COVID-19 pandemic and their family caregivers.

Methods and analysis Patients aged ≥18 years, hospitalised between 28 February and 11 May 2020 and then discharged home, plus their family caregivers will be invited to complete a self-administered questionnaire made up of 14 closed questions and 1 open-ended question. The questionnaire will include items on the patient's hospital trajectory and assess the interpersonal trust placed in nurses and physicians based on Krajewska-Kulak et al's Trust in Nurse Scale and Anderson et al's Trust in Physician Scale. Participants' perceived stress will be assessed using Cohen et al's Perceived Stress Scale. Feelings of safety will be examined based on Dryhurst et al's questionnaire on Risk Perception During Pandemics. After ethical clearance, data will be collected using a postal paper questionnaire and via an online web link. We will analyse perceptions of the different hospital trajectories experienced by patients undergoing surgery with and without a SARS-CoV-2 infection.

Ethics and dissemination The Human Research Ethics Committee of Vaud (2020-02025) authorised this study. Gathering experiences and learning about the impact of the COVID-19 pandemic on the social determinants of health among discharged patients and families fit in well with the Triple Aim framework and the PREMs survey. The study will formulate recommendations to support interventions in the face of the second wave of COVID-19 pandemic and their effects on patients' and their family caregivers' experiences.

INTRODUCTION

The COVID-19 pandemic, caused by severe SARS-CoV-2, has brought about a sudden and substantial increase in pneumonia cases involving pneumonia and multi-organ disease. The COVID-19 pandemic continues to challenge healthcare systems, specifically public acute care hospitals, emergency departments and intensive care units (ICUs).1

Many questions about the origins of this virus remain unanswered: its mechanism of infection, risk factors, the people at risk, symptomatology and potential treatments.2,3 The medium-term and long-term physical and mental consequences on the survivors of this viral infection will require further exploration.4 Depending on the country, screening systems and study designs, SARS-CoV-2 epidemiology has shown varying incidences in different populations and differing rates of hospitalisation and mortality.5 For the canton of Valais, Switzerland’s Federal Office of Public Health (FOPH) reported an overall incidence of SARS-CoV-2 of 584 per 100 000 inhabitants.

Table 1 shows the distribution of the incidence of infection by SARS-CoV-2 per 100
Indeed, some of the processes in Switzerland could have significant family caregivers during the pandemic period. The Valais Hospital wishes to investigate the impact of its COVID-19 strategy with those patients. We believe that perceptions will be influenced by sociodemographic factors, previous experiences during hospitalisations, current health status and personal factors such as professionals’ communication or cooperation. To improve its processes, the Valais Hospital wishes to investigate the impact of its COVID-19 strategy on its inpatients’ experiences and those of their most significant family caregivers during the pandemic period. Indeed, some of the processes in Switzerland could have been likened to a war situation, with military medical and civil defence units being put to work in hospital environments. With hospital visits to patients prohibited, healthcare professionals encouraged the use of multimedia technologies to compensate for the lack of contact and communication with loved ones. Contact between the hospitalised patients and their family caregivers was then limited to exchanges through various remote communication technologies (email, video conferencing, social media and social networks). This unprecedented situation of psychosocial isolation probably induced significant stress, intense emotions and lots of uncertainty in hospitalised patients and their family caregivers. According to Towle et al, recognising family members as important partners and ensuring their involvement in preparing for discharge help ease the patient’s transition home.

Not all patients infected with SARS-CoV-2 developed life-threatening symptoms. Only a small proportion of them had very severe symptoms involving severe organ dysfunction, mainly respiratory dysfunction, requiring hospitalisation in an ICU. Patients’ experiences under respiratory assistance may have been difficult, leading to a state of emotional stress and anxiety for them and their families and friends. During this period, the usual trust which patients and their family caregivers have in the Valais Hospital’s healthcare professionals and the healthcare system, in general, came under pressure. Providing psychological support and effectively communicating the latest knowledge about SARS-CoV-2, protecting oneself from it, its prognosis and its treatment became a daily challenge for the Valais Hospital’s healthcare professionals.

For patients not infected by SARS-CoV-2 but hospitalised for an acute health event, worry, distress and uncertainty were a significant concern. The communication, psychological support and safety measures implemented by the Valais Hospital and its healthcare professionals could have had a substantial impact on the experiences of patients and their relatives. The transfer of up-to-date knowledge on SARS-CoV-2 infection mechanism, clinical symptoms, prognosis and treatment probably had a significant impact on the experiences of patients and their relatives during hospitalisation.

### Background and rationale

The COVID-19 pandemic is a factor of anxiety and stress for patients and their entourage due to the concerns caused by any new pathology, fears of dying or potential stigmatisation by the community. Concerning the disease’s clinical impact, initial studies of patients who have survived SARS-CoV-2 have shown consequences on their health status, such as fatigue, cardiac and pulmonary function disorders, moderate to severe physical decline, depression, anxiety and post-traumatic stress disorder. Patients admitted to ICUs were the most at risk of mental health consequences as a result of their frightening, life-changing experience. Psychological difficulties were also mentioned in two recent studies among patients who had had mild SARS-CoV-2 symptoms.

### Table 1 Age group distribution of incidence of infection by SARS-CoV-2 per 100 000 inhabitants in the canton of Valais—February to July 2020

<table>
<thead>
<tr>
<th>Age group (years)</th>
<th>Incidence per 100 000 inhabitants</th>
</tr>
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<tbody>
<tr>
<td>0–9</td>
<td>26.8</td>
</tr>
<tr>
<td>10–19</td>
<td>139.9</td>
</tr>
<tr>
<td>20–29</td>
<td>587.2</td>
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<tr>
<td>30–39</td>
<td>552.0</td>
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<tr>
<td>40–49</td>
<td>566.9</td>
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<td>50–59</td>
<td>821.9</td>
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<tr>
<td>60–69</td>
<td>640.9</td>
</tr>
<tr>
<td>70–79</td>
<td>708.6</td>
</tr>
<tr>
<td>≥80</td>
<td>1576.6</td>
</tr>
</tbody>
</table>

Source: FOPH (2020).
Mechanism of infection
SARS-CoV-2 incubation period is approximately 5 days. Nearly 98% of individuals who develop symptoms will do so within 12 days of infection. The median interval from symptom onset to hospital admission is about 7–8 days. Epidemiological data evoke the normal route of transmission: exposure to droplets expelled through talking, coughing or sneezing during face-to-face contact. Prolonged exposure to an infected person and brief exposure to a symptomatic individual have both been associated with a higher risk of transmission. Touching a surface with a virus on it is another possible mode of transmission. The clinical risk of SARS-CoV-2 transmission from inanimate surfaces appears to persist longer the higher the level of surface impermeability, for example, for up to 3–4 days after inoculation on stainless steel and plastic. Widespread viral contamination of hospital rooms has been documented.

Clinical presentation
The ages of hospitalised patients vary between 47 and 73 years, with an almost 60% preponderance of men. Their most common symptoms are fever (up to 90%), dry cough (60%–86%), shortness of breath (53%–80%), fatigue (38%), nausea/vomiting or diarrhoea (15%–39%) and myalgia (15%–44%). Patients can also present with non-classic symptoms, such as gastrointestinal symptoms; olfactory and gustatory dysfunctions are reported in 64%–80% of patients. About 17%–35% of hospitalised patients with SARS-CoV-2 are treated in an ICU, most commonly due to hypoxaemic respiratory failure, and 29%–91% of them require invasive mechanical ventilation. In addition to respiratory failure, hospitalised patients may develop acute kidney injury (9%), liver dysfunction (19%), bleeding and coagulation dysfunctions (10%–25%) and septic shock (6%). Acute cerebrovascular disease and encephalitis have been observed, with severe illness in up to 8% of patients and 31%–59% of these severely ill patients experiencing thromboembolic events.

Prognosis
The overall hospital mortality from SARS-CoV-2 is approximately 15%–20%, but it is up to 40% among patients requiring ICU admission. Hospital mortality ranges from less than 5% among patients aged <40 years to 35% for patients aged 70–79 years and is above 60% for patients aged 80–89 years. Depending on their intra-hospital trajectory, length of stay, and physical or mental decline, the patient’s return home may require intensive support from community healthcare professionals (general practitioner, specialist doctor, home-care nurse, physiotherapist, speech therapist, psychologist). During these transitions, passing on information and efficiently communicating on the patient’s health situation and rehabilitation recommendations have been a significant challenge for hospital healthcare professionals. At the beginning of the pandemic, initial medical results for mild cases of SARS-CoV-2 indicated 1–2 weeks of recovery time. However, many patients experienced somatic symptoms lasting 8–10 weeks or more, with fluctuating symptomatology. Given the body’s multi-organ decompensation due to SARS-CoV-2, survivors may suffer long-term organ damage, including post-SARS-CoV-2 lung pathologies similar to those documented in previous SARS studies.

Epidemiology
There is no current consensus definition of postacute SARS-CoV-2. Based on the SARS-CoV-2 Symptom Study, postacute SARS-CoV-2 is defined as the presence of symptoms extending beyond 3 weeks from the initial onset of symptoms, and chronic SARS-CoV-2 defines symptoms extending beyond 12 weeks. Postacute syndromes are well recognised among patients recovering from a serious illness, particularly illnesses that require hospitalisation and admission to an ICU.

Postacute SARS-CoV-2 syndrome has not just been observed among patients who had severe illness and were hospitalised, however. In a survey conducted by the Centers for Disease Control and Prevention among 292 adults who had a positive outpatient test result for SARS-CoV-2, 35% of 274 symptomatic respondents reported not having returned to their usual state of health 2 weeks or more after testing. This included 26% of those aged 18–34 years (n=85), 32% of those aged 35–49 years (n=96) and 47% of those aged ≥50 years (n=89). Being both older than 50 and having three or more chronic medical conditions was associated with not having returned to usual health within 14–21 days of receiving a positive test result.

Clinical signs and symptoms
The most commonly reported symptoms after acute SARS-CoV-2 are fatigue and dyspnoea; other common symptoms include joint and chest pain. In addition to these general symptoms, specific organ dysfunction has been reported, primarily involving the heart, lungs and brain. From a pathogenesis standpoint, these complications could be the consequence of direct tissue invasion by the virus, inflammation, related immune system damage, hypercoagulation or a combination of these biological factors.

Post-SARS-CoV-2 organ dysfunctions
Myocardial injury, as defined by an increased troponin level, has been described in patients with severe acute SARS-CoV-2, as has thromboembolic disease. Myocardial inflammation and myocarditis, as well as cardiac arrhythmias, have been described after SARS-CoV-2 infection. The durability and consequences of such injuries, identified using medical imaging, are not yet known, and lengthy follow-up will be needed.

Other studies have reported persistent symptoms up to 3 months after hospital discharge, with radiological abnormalities consistent with pulmonary dysfunction, such as
interstitial thickening and evidence of fibrosis, decreased diffusion capacity for carbon monoxide and diminished respiratory muscle strength.30 If this is compounded with another cardiovascular comorbidity, whether pre-existing or incident to SARS-CoV-2, a persistent decline in lung function could have major adverse cardiopulmonary consequences.

The most common long-term neurological symptoms after SARS-CoV-2 are headaches, vertigo and chemosensory dysfunction (eg, anosmia and ageusia). While stroke is a serious though uncommon consequence of acute SARS-CoV-2, encephalitis, seizures and other conditions such as major mood swings and brain fog have been reported up to 2–3 months after the initial onset of the illness.31

**Post-COVID-19 consequences of postponed ambulatory and hospital surgical interventions**

Surgery is an essential pillar of medical care, with its own daily clinical challenges. The COVID-19 pandemic’s postponement of most elective and non-urgent surgery across Switzerland, whether among patients infected with SARS-CoV-2 or uninfected patients, induced stress and insecurity. A substantial number of patients with prominent, subacute disease symptoms not specific to COVID-19 and that would normally be treated surgically were not always initially treated in this way. Delaying some elective interventions, such as cancer surgery, might have severe consequences. This could not occur without its share of emotional stress, experienced by discharged patients with SARS-CoV-2 and non-infected patients, or without psychological consequences among patients and their family caregivers. This period was extremely challenging for patients undergoing different types of surgical interventions: they could neither see nor meet their family before or after surgery, which made everything more stressful and worsened the overall situation.32–34

**Emotional health and well-being**

Although symptom persistence and clinical sequelae that may last far beyond the initial SARS-CoV-2 illness have been recognised, the extent of potential emotional and behavioural issues and general distress among those affected has yet to be determined. A diagnosis of SARS-CoV-2, and the subsequent need for physical distancing, has been associated with feelings of isolation and loneliness.34 SARS-CoV-2-related stigmas have also become pervasive and can result in a sense of hopelessness. Increasing reports of lingering malaise and exhaustion akin to chronic fatigue syndrome have described patients who may be left with physical debility and emotional disturbance. Compounded by the population-wide psychological toll of the pandemic, individuals recovering from SARS-CoV-2 may be at even greater risk of depression, anxiety, post-traumatic stress disorder and substance use disorder. Considering the sheer number of SARS-CoV-2 cases worldwide, these combined effects have the potential to result in a follow-on global health crisis.35

**Non-infected patients’ experiences of the risk of SARS-CoV-2 contamination**

An individual’s experience of the risk of contracting the virus through contamination by other patients or healthcare professionals involves a mix of different emotional, social and mental characteristics.36 Non-SARS-CoV-2 patients hospitalised during this period were also subject to permanent stress. During hospitalisation, fears and uncertainties are reinforced by a worse than normal state of health. When sensitivity to mental or neurological conditions is pre-existing, there is a risk of triggering new symptoms such as depression or a confusional state.37 38 The prescribed public health measures of social distancing were applied in hospitals and across society to ensure the protection of patients and staff. de Zwart et al described the influence of a patient’s cultural background on the risk perception of disease contamination regarding previous SARS epidemics.39 These differences are also linked to the content of the information those patients received and to how the media communicated it. The physical and psychological support provided, the communication and the level of trust in healthcare professionals and healthcare systems are probably decisive in the satisfaction, sense of safety and the lived experiences of hospitalised patients and their relatives.40 During the COVID-19 pandemic, problems that may have exacerbated patients’ feelings of insecurity included physical barriers, communication difficulties with staff due to personal protective equipment (eg, masks, plastic face protectors) and the social isolation resulting from the prohibition of visits by relatives.

**Collection of inpatients’ experiences**

At the pandemic’s peak, healthcare teams’ attention was focused on saving lives and protecting health services from being overwhelmed. Patients who survived were often discharged without follow-up rehabilitation or any collection of their experiences.41 42 Knowing patients’ experiences of the healthcare they receive is an integral part of improving patient-centred care. Indeed, it is included in the Triple Aim approach, a health policy strategy recommended by the Swiss FOPH and the Swiss Academy of Medical Sciences.42 For patients with SARS-CoV-2 recovering at home, physical, psychological and functional problems must be considered together. There are also specific aspects of the hospitalisation experience associated with psychological difficulties among patients severely affected by SARS-CoV-2. Research on the consequences of SARS indicated that psychological distress was more severe among groups that contracted these infections than other severely ill patients hospitalised at the same time.35 42 These studies documented the psychological difficulties after hospitalisation, which manifested themselves in the form of stress, fear, depression, persistent acute confusion and disorders based on continuous stress such as hallucinations, nightmares or flashbacks, sleep and memory disorders, and attention difficulties.25 It is well known that psychosocial isolation...
can affect the morbidity and mortality associated with many health problems.44–46

**Triple Aim and patient-reported experience measures to guide the study**

This study focuses on the basics of the Triple Aim approach throughout the emergency with regard to people’s medical and social needs, the impact of unmet health needs and the importance of partnerships between the healthcare system and community healthcare organisations.47 An assessment of these care pathways towards population health can reveal the population health assets available and the challenges to be overcome, breaking down population health as a whole into more manageable components for healthcare organisations to handle. The importance that interprofessional coordination has taken on in the management of the COVID-19 pandemic has enabled the Triple Aim approach to be deployed and has given a voice to patients and family members. The present research project will highlight the importance of person-centred and family-centred care—putting the patient and their family at the heart of decision-making and empowering them as partners in their own care, helping to optimise resources and improve patient outcomes.

The patient’s viewpoint on the delivery of their care is becoming a recognised and essential dimension of overall health system performance. This is often based on the principles of patient-reported experience measures (PREMs).48 49 To the best of our knowledge, no studies to date have examined patients’ experiences of hospitalisation during the COVID-19 pandemic and their subsequent discharge home.50 Our patient experience survey will provide an opportunity to report on their experiences during the COVID-19 pandemic, whether they were infected or not. Research has shown that data self-reported by patients and their relatives provide similar results to those obtained by observational studies carried out by healthcare professionals.7 49 Some health-care professionals question the significance or value of PREMs, as they may reflect factors such as the patient’s mood or reaction patterns in addition to the actual quality of care experienced. Although adjustment models have been developed to take these factors into account, associations between patient feedback and available indicators or measurements of the quality of care and safety during the COVID-19 pandemic will add credibility to the Valais Hospital’s standard measurements of patient satisfaction (COVID-19 HVS). Patients hospitalised at the Valais Hospital are systematically asked to complete a satisfaction survey after their discharge home. The proposed study would deepen the dimensions explicitly considered within the framework of COVID-19 by following the WHO recommendations on the different stages of the process, particularly by adapting the survey to the local context of the COVID-19 pandemic.51

**Study aim and objectives**

The survey’s overall aims are to collect the reported experience measures of patients and their significant relatives during their hospitalisation, with specific regard to the conditions surrounding the Valais Hospital’s COVID-19 pandemic health crisis control measures. To measure specific concepts and determinants using PREMs and to clarify the study’s aims, objectives, method and expected outcomes, we have updated our protocol with the following section:

1. We will collect feedback, suggestions, recommendations and complaints from patients’ experiences of hospitalisation during the COVID-19 pandemic period, with special regard to safety measures, the quality of the information provided, the impact of social isolation and stress, trust in professional healthcare staff, the overall healthcare experience and the conditions of their hospital discharge.

2. We will collect the experiences of hospitalised patients’ significant family caregivers, with special regard to their main concerns and worries about following their relative’s health problems from a distance.

3. We will formulate recommendations for actions to limit the harmful impact of a potential next wave of COVID-19, to optimise patient-centred care and to better support their relatives.

This study would complement the interim assessment of the Valais Hospital’s management of the COVID-19 pandemic and the key measures it has taken.

**METHODS AND ANALYSIS**

**Design and population**

This cross-sectional population-based study will use a self-administered questionnaire to collect the experiences of hospitalised patients and their close family caregivers during the COVID-19 pandemic. Although our research is based on the Triple Aim and PREMs frameworks, the study will not include each of their concepts, but will instead be selective, choosing what is relevant in this very particular pandemic situation.

**Sample**

The study population consists of all patients aged ≥18 years, hospitalised between 28 February and 11 May 2020 in a multisite public hospital. The Valais Hospital recorded over 41 000 individual hospitalisations in 2019 and is composed of two major hospital centres, each in one of the canton’s two distinct linguistic regions.20 Each hospital centre has the standard types of medical hospitalisation wards to fulfil its mission of providing general public healthcare; however, the more complex medical specialities are only present at the hospital centre in the French-speaking region. Inclusion criteria will also require patients to be domiciled in Switzerland, to have been hospitalised for >24 hours (according to LAMAL—the Swiss Federal Law on Health Insurance) and to have excellent oral and written comprehension of French.
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(online supplemental file 1A) or German. Exclusion criteria are living abroad or being under 18 years old.

**Sample extraction**

The population-based cohort sample will be extracted from the electronic patient record data in the hospital's patient register.

**The data collection instrument**

A literature review of existing relevant studies on the same topic was critically appraised to help us construct our questionnaire. Four semistructured exploratory interviews were conducted with patients who had been hospitalised during the pandemic. A thematic analysis of these interviews enabled us to identify themes important to patients or relatives and to complete the questionnaire. The questionnaire consists of 14 questions, 5 of which are addressed to a close family caregiver. The first section asks for sociodemographic data and the hospital trajectories followed by the patient. Two five-point Likert scales will be used to assess the interpersonal trust placed in nurses and physicians: the Trust in Nurse Scale developed by Krajewska-Kułak et al (Cronbach’s alpha >0.7) and the Trust in Physician Scale developed by Anderson and Dedrick (Cronbach’s alpha >0.89), respectively.52–54 Ten questions measured on a five-point Likert scale will measure perceived stress, taken from the Perceived Stress Scale (PSS-10) developed by Cohen et al.55 PSS-10 is one of the most popular scales for assessing psychological stress; it is used in multiple contexts and has a Cronbach’s alpha of >0.7.5666 One question will be used to explore participants’ feelings of safety, based on Dryhurst et al’s Risk Perception During Pandemics questionnaire.15 The questionnaire continues with three questions on the relevance and quality of the information given out by the hospital, with regard to patients’ information needs. These are based on a questionnaire developed by the Municipal Public Health Service of Rotterdam-Rijnmond.57 Finally, an opened-ended question will allow patients and their relatives to express their positive and negative opinions of their hospital stay (online supplemental file 2B).

**Conduct of the survey and data collection**

All potential participants will receive a letter in the mail, inviting them to participate in the survey. Besides the enclosed paper questionnaire, an introductory page will set out the study’s background and its data and participant protection strategy. The participant will have the choice of following a web link to the online version of the questionnaire or filling in the paper questionnaire and returning it in the prepaid envelope provided. Data collection will start in September 2020 and end in December 2020. Figure 1 presents the data collection strategy and the timeline of the survey.

**Data analyses**

Data will be extracted from the questionnaires into an Excel spreadsheet (Microsoft) and imported into IBM SPSS software V.26 (IBM). We will analyse the perceptions of the different hospital trajectories among patients with and without SARS-CoV-2 infection undergoing surgery for inpatients and outpatients. Descriptive and thematic analyses will be made according to patients’ intrahospital trajectories. The population will be described using descriptive statistics such as frequencies, distributions and leading trends. Data collected on Likert scales will be analysed using descriptive and inferential statistics. A biostatistician will review the statistical analysis plan and the application of descriptive and inferential statistical tests.

**Patient and public involvement**

Four patients were involved in constructing the research questions and in determining priorities, experience and preferences. The patients proposed to conduct the data collection online and with paper questionnaires.

**ETHICAL CONSIDERATIONS AND DISSEMINATION**

The Human Research Ethics Committee of the Canton of Vaud (CERV-VD-PROTOCOL 2020-02025) authorised, noted and stored this study in its database, although it declared that the study’s limited scope did not require it to adhere to the legal terms and conditions of a complete submission for ethical clearing (ie, the study involved no highly sensitive health data from electronic patient records). It respected the anonymity of its participants and the standards of good research practice mentioned in the Declaration of Helsinki.58 The data collected will be coded to ensure participants’ anonymity and the use of acceptable research practices, as mentioned in...
the Declaration of Helsinki. Receipt of the questionnaire from the patient will serve as his or her consent to participate.

**Expected results**
Collecting patients’ experiences and those of their close relatives during this unprecedented COVID-19 pandemic is an entirely new and unexplored avenue of research. Gathering data on these experiences and learning about COVID-19’s impact on the social determinants of health among patients and their families will enable us to identify opportunities for improving care and hospital trajectories both during and after this ongoing crisis. These goals fit well with Switzerland’s Triple Aim health policy framework and particularly with the PREMs approach.

Patients’ and their close family members’ reported experiences will provide a valuable perspective and measure of the healthcare received from professionals and the support from healthcare institutions. These measures are particularly useful for the promotion and evaluation of patient-centred care. PREMs collect patients’ views on how healthcare services are delivered, including communication with nurses and physicians, staff responsiveness, the coordination of care and of hospital discharge and their experiences while receiving that care. It is not aimed at investigating the outcomes of that care. PREMs complement patient-reported outcomes and are intended to be used together with them to provide a complete picture of the patient’s hospital stay. It is possible to have a healthcare system that works effectively and efficiently, but in which patients feel that they had a bad experience. They might also have a good experience but poor results. The use of information on patient experiences and outcomes provides a better understanding of the healthcare system’s overall performance from the patient’s perspective. This may help us to develop new care pathways, co-designed and co-produced with patients and their families and ensuring that patient care preferences are understood and honoured if possible.

Finally, this investigation will formulate overall recommendations to support patients and their relatives throughout the care interventions that may be necessary in the next wave of COVID-19. This includes ensuring that communities are able to provide support to patients discharged home so that they can remain healthy.

**Acknowledgements**
The research thanks the four patients for their contribution in designing the study protocol.

**Contributors**
NT-J, SM and HV had the original idea and provided conceptual and methodological expertise to the design of the research protocol. EB, NT-J, SM and HV were major contributors to writing the manuscript. All authors read, edited and approved the final manuscript.

**Funding**
The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

**Competing interests**
None declared.

**Patient consent for publication**
Obtained.

**Provenance and peer review**
Not commissioned; externally peer reviewed.

**Supplemental material**
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