


BMJ Open Piloting a PREMs and PROMs longitudinal survey on the integration of healthcare services for patients living with hepatitis C in Tuscany region: study protocol

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ABSTRACT

Introduction Patient-reported measures are an invaluable resource for health systems to improve the quality of healthcare services. Patients with hepatitis C virus (HCV) are an under-represented group within the stream of literature on collecting and using the experiences and outcomes reported by patients to improve healthcare performance. This protocol outlines the methodology to implement a longitudinal survey in Tuscany, Italy, to systematically gather patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) for patients with HCV, with a focus on the integration of primary and hospital care.

Methods and analysis We designed and developed a longitudinal survey to collect HCV PREMs and PROMs. The survey, which lasts 1 year, consists of three questionnaires, starting with the first visit with a specialist/treatment initiation, with follow-ups at 6 and 12 months. It was implemented in six hospitals in Tuscany, Italy, of which three are University Hospitals. The survey was offered to all patients treated for HCV at these healthcare centres, deliberately not applying a specific criterion for patient selection, through both paper based and electronic modes of completion. The data from the three structured questionnaires will be analysed quantitatively.

Ethics and dissemination The Ethics Committee for Clinical Experimentation of Area Vasta Nord Ovest approved the protocol (CEAVNO—CODE 18829). Participation in this study is voluntary. Study results will be disseminated through peer-reviewed publications and academic conferences.

INTRODUCTION

Hepatitis C virus (HCV) stands as a global health challenge, impacting millions of individuals and presenting substantial hurdles to healthcare systems across the world. Globally, as of 2023, an estimated 58 million individuals live with chronic HCV infection, including 3.2 million adolescents and children. Moreover, about 1.5 million new infections are estimated to occur yearly.¹ The introduction

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ A multicentre study facilitating benchmarking across providers.
- ⇒ This is the first patient-reported experience measures and patient-reported outcome measures observatory implemented for patients with hepatitis C virus in Italy.
- ⇒ The recruitment of patients only via health professionals might face limitations if they are not adequately engaged and motivated.
- ⇒ The findings' generalisability is constrained by the regional-based sample.

of direct-acting antivirals (DAAs) has represented a major clinical advancement in the treatment of HCV, achieving viral cure in 95% or more of patients who complete treatment.²

According to the WHO, less than 5% of individuals with chronic viral infections are aware of their condition.³ In 2016, the WHO introduced the global health sector strategy on viral hepatitis for 2016–2021, aiming to eliminate viral hepatitis as a public health threat by 2030.⁴ Despite notable advancements in several leading countries, a substantial gap persists in testing and treatment efforts.⁵ Moreover, individuals infected with HCV face vulnerabilities and are susceptible to the impact of social and structural determinants of health. These determinants, such as income, access to education, access to healthcare facilities and living in overcrowded housing, encompass various forms of discrimination and conditions of marginalisation or exclusion.^{6,7}

Embracing patient-centredness is crucial when contemplating enhancements to healthcare quality. Patients have an inherent entitlement to receive dignified, respectful

and productive healthcare.⁸ It is also evident that a focus on personalised care correlates with improved healthcare utilisation and outcomes.^{9–10} The umbrella of patient-centred measures encompasses patient-reported outcomes, assessments of patient care experience and evaluations of patient satisfaction.

Patient-reported outcomes are intended to investigate whether or not a healthcare intervention has made a difference in a patient's health condition, quality of life and/or other aspects relevant to patients. Such measures can be used for quality-of-care assessment and benchmarking of healthcare organisations by measuring the results produced along the care pathway.^{11–12}

Patient experience measures are indicative of the care process, while patient satisfaction measures effectively serve as indicators of outcomes. Additionally, it is crucial to consider the patient's outcomes of care and treatment received for specific conditions or interventions.

Nowadays there is long-standing recognition of the importance of directly involving and engaging patients to improve the quality of healthcare services.^{13–17}

Available literature reveals, to date, a notable absence of a universally accepted definition of patient experience.^{18–21} However, such consensus is desirable, given the broad relevance of patient experience across diverse domains, including public policy, performance improvement, academia and practice. At least, there is common agreement that patient experience is, by definition, different from mere satisfaction of the patient with the healthcare services. Indeed, patient satisfaction is related to their 'cognitive evaluation and emotional reaction to healthcare, as affected by underlying expectations'.²² In contrast, patient experiences encompass not only the manifestation of the patient's physiological illness experience and their lived experience of illness but also their interactions with healthcare services. This comprehensive perspective positions patient experience as a significant indicator of clinical quality.²³

Even though patient experience and satisfaction measures are now treated as indicators of process and outcome, respectively,²⁴ few examples are available in the literature regarding the collection of such measures for patients with HCV²⁵ in contrast to the more numerous examples of outcome measures reported by patients with chronic HCV infection.^{26–28}

This under-representation could be attributed, at least in part, to their status as a particularly vulnerable and challenging-to-reach population (eg, people who inject drugs, people in prison, the elderly, etc).²⁹ The Organization for Economic Co-operation and Development (OECD) has recently implemented an initiative designed to assess and quantify the aspects of care that hold genuine significance for patients. This effort aims to provide policymakers with insights into how health systems address the specific needs of individuals with long-term health challenges, offering valuable metrics to enhance understanding of the impact of healthcare policies on their well-being.³⁰

Another important aspect to be considered is the duration of the patient's care provided by the health service. Usually, the patient's experience is collected with precise reference to a specific episode, either treatment or hospitalisation, but the necessary follow-up is not considered. Furthermore, it is our understanding that, to date, the experience reported by patients with chronic HCV infection has never been collected in any Italian region, especially along with reported outcomes of treatment, and the focus has always been either on primary or hospital care, respectively. Relying on other studies that longitudinally collect patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs),^{12–31} this protocol describes the pilot implementation of a longitudinal survey in Tuscany focusing on the reported experience and outcomes of patients with HCV. Additionally, the survey described in the protocol combines both HCV PREMs and PROMs to collect evidence on the integration of healthcare services delivered at the hospital and community level in the Tuscany region.

METHODS

Study setting

The Italian National Health System is a universal health system, mainly financed through general taxation. Health services are evenly distributed throughout the country according to the 'Essential Levels of Care' core benefits package.³² Organisation, planning and budgeting powers are decentralised and attributed to the autonomous Regional Healthcare Systems in the 21 Italian regions.³³

This study focuses on the Tuscany region which is administratively organised into three Local Health Authorities covering approximately 40 local hospitals, and four University Hospitals (UHs), of which one specialises in paediatric care.³⁴ Concerning the epidemiology of HCV infection, limited research has explored the prevalence of the infection in Italy.^{35–37} Current estimates indicate that approximately 1.7% of the Italian population is living with chronic HCV infection, with a higher prevalence observed in central regions, followed by southern, island, and, finally, northern areas.^{35–38} Concerning the Tuscany region, a study carried out in 2017 by Stasi and colleagues³⁹ used a combination of administrative data and capture–recapture methods to identify individuals known to the healthcare system as well as those within the hidden population. The study estimated a total of 49517 individuals living with chronic HCV infection in the regional area, reflecting a prevalence rate of 1.3%, consistent with findings in the existing literature.³⁹

As specified in Tuscany Regional Resolution No. 647, approved on 18th May 2015, in the Tuscany region, there is a need for strong integration between community and hospital services for the diagnosis and treatment of Hepatitis C infection. Indeed, the diagnosis of the infection takes place at both publicly and private pathology laboratories on the territory. The HCV blood tests are generally prescribed by a primary healthcare doctor, such as

Box 1 Healthcare institutions of the Tuscany public regional healthcare system which voluntarily agreed to participate in the data collection.

University Hospitals and relative reference areas in brackets
 ⇒ Azienda Ospedaliero-Universitaria Careggi in Florence (Central Tuscany).
 ⇒ Azienda Ospedaliero-Universitaria Pisana in Pisa (North-Western Tuscany).
 ⇒ Azienda Ospedaliero-Universitaria Senese in Siena (South-Eastern Tuscany).
 Local hospitals, under the leadership of the Local Health Authorities
 ⇒ Presidio Ospedaliero di Grosseto, headed by the Local Health Authority of South-Eastern Tuscany.
 ⇒ Ospedale Santissima Maria Annunziata di Firenze, headed by the Local Health Authority of Central Tuscany.
 ⇒ Ospedale San Luca di Lucca, headed by the Local Health Authority of North-Western Tuscany.

the general practitioner (GP), by doctors of treatment services for people who inject drugs (PWID), through screening and prevention campaigns carried out in the territory and in penal correctional institutions. Once the diagnosis is confirmed, the patient is linked to specialised care. Treatment starts at the hospital level, as DAAs can only be prescribed by a specialist doctor and can only be supplied by public hospital pharmacies. According to national guidelines,⁴⁰ people starting treatment with DAAs against HCV undergo multiple assessments during therapy and after its completion. In particular, HCV RNA negativity must be documented both at 3 months and between 6 and 12 months after the end of treatment to declare the infection eradicated.

The data collection was conducted in three UHs and in three local hospitals that voluntarily adhered to the PREMs and PROMs surveys from April 2021 to March 2024. The data collection process is currently ongoing. **Box 1** includes the names of the hospitals participating in the observatory.

Study design

This study focuses on designing and developing a longitudinal survey to collect patient experience and outcome measures from people with chronic HCV infection. The survey follows patients throughout their care pathway, gathering evidence on primary and hospital care integration. It comprises three questionnaires administered by specialists over 1 year. The first questionnaire is given during the initial visit when medical treatment is prescribed (T0). The second questionnaire is provided at the first follow-up visit, approximately 3 months after completing the medical treatment, about 6 months after entering the care pathway (T1). The third questionnaire is administered at the second follow-up visit, typically scheduled 6 months after the first follow-up visit, around 1 year after beginning the care pathway (T2).

Sample size

According to DGRT 397/2018 guidelines,⁴¹ approximately 6000 patients should receive treatment annually. However, due to the coronavirus pandemic and based on the prevalence data in 2018 and 2019, it is anticipated that around 3000 patients per year will be treated. Based on the available data, approximately 2000 new cases of patients with chronic HCV infection were estimated in 2019. Assuming an average survey adherence rate of 20%,⁴² it is projected that a minimum of 200 patients will respond to the baseline questionnaire (T0).

Data collection tool

The data collection tool is a longitudinal survey administered three times within a 1 year time frame. The three waves, corresponding to the administration of the three questionnaires, are designated above as T0, T1 and T2. The PREMs questionnaires were not validated but were jointly developed by a multidisciplinary and multi-professional team comprising healthcare professionals from the above-mentioned healthcare institutions, professors, researchers and doctoral students from the Scuola Superiore Sant'Anna and the University of Pisa, as well as policymakers from the Tuscany region. On the other hand, PROMs are collected using a scale derived from the 'Medical Outcomes Study Short-Form 12-item survey instrument' (MOS SF-12). The MOS SF-12 Scale has already been used internationally to measure outcomes for HCV-positive patients in several countries.^{43–45} This instrument was chosen given the inclusion of measures related to several patient-relevant domains (eg, pain, physical and social functioning, vitality) and the validity that has made this instrument an international gold standard.⁴⁶ This also ensures that results can be compared with other experiences internationally, given the large-scale use of the outcome measures included in the questionnaire.

The domains of the MOS SF-12 are as follows: physical functioning (ability to perform physical activities, eg, washing, dressing); role of physical disability (problems performing work activities due to physical health); body aches and pains; general health; vitality; social functioning (problems in social life due to physical and emotional problems); role of emotional disability (problems in performing work activities due to emotional problems); mental health (nervousness and depression). **Figure 1** summarises the phases of questionnaire administration and dimensions investigated.

In terms of the content of the survey, the questionnaires were designed by the research team and validated by a group of healthcare professionals to integrate both PREMs and PROMs, along the patient's care pathway, focusing on primary and hospital care delivery. Concerning patient-reported experience, several dimensions relevant to the various phases of the patient's care pathway are investigated through the three questionnaires.

Table 1 reports the relevant dimensions of experience investigated in each of the three questionnaires,

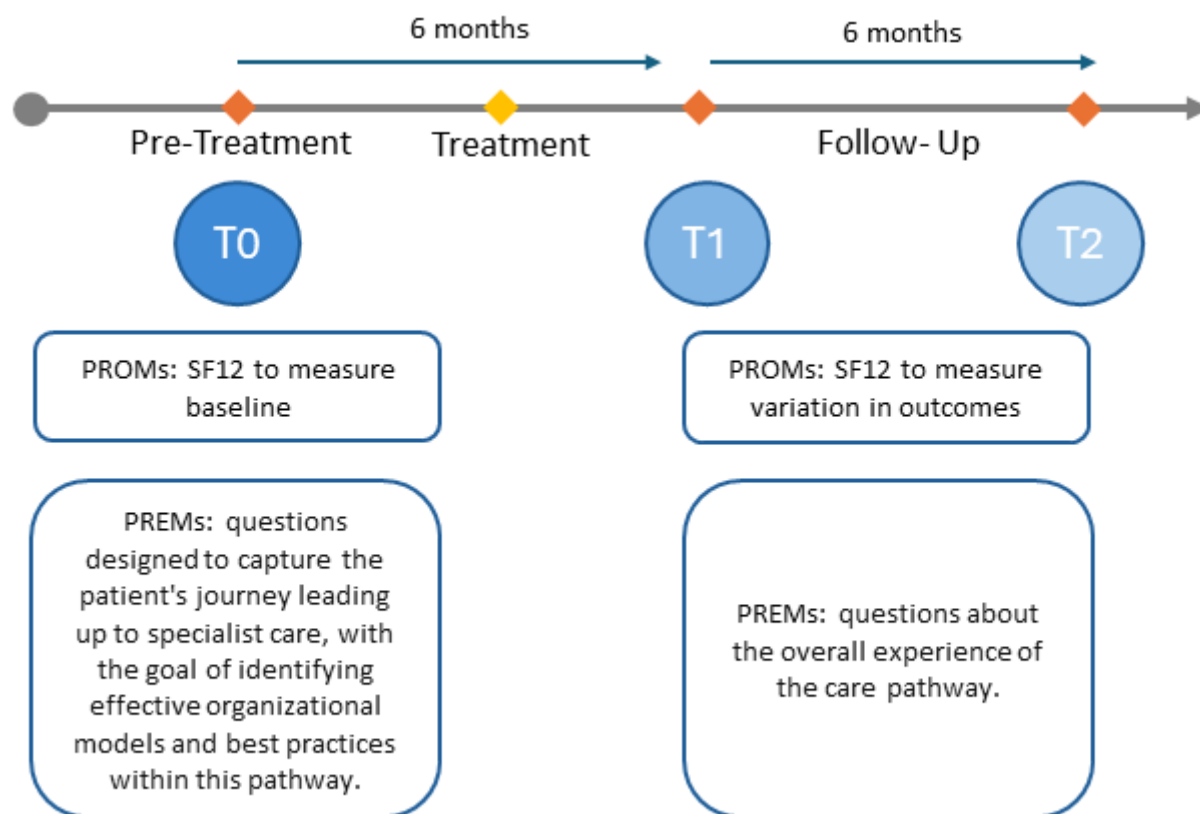


Figure 1 Flowchart of the study and dimensions investigated within each questionnaire. PREMs, patient-reported experience measures; PROMs, patient-reported outcome measures; SF-12, short-form 12-item survey.

according to the specific phase of the care pathway, along with the number of questions included:

The questionnaires are structured with single-choice questions and few multiple-choice questions. Where Likert scales are used, these present five response options. There are a few exceptions related to open-ended questions, to specify other comorbidities or the type of treatment prescribed. The different lengths of the three questionnaires provide completion times of approximately 20 min for the T0 questionnaire, 10 min for the T1 questionnaire and 15 min for the T2 questionnaire.

In some areas of the Tuscany region, large communities of individuals with migration backgrounds are present. Therefore, to make the survey as inclusive as possible, the three questionnaires were made available, both in paper and electronic format, in the following languages: English, Spanish, French, Albanian, Romanian, Arabic and Chinese. The three questionnaires are reported in the online supplemental material.

Data collection process

Each healthcare institution involved in the study temporarily recruits a dedicated non-medical professional to conduct the surveys. The specialists only inform patients about the opportunity to participate in the survey at the end of their visit. Subsequently, the trained professional assists the patients willing to participate by providing

a privacy leaflet regarding personal data processing, ensuring the complete anonymity of the questionnaire, explaining the option for voluntary participation and offering the choice to either fill out the questionnaire at home and bring it back at the follow-up visit or to fill it out in a private area within the ward. The trained professional administers the questionnaires to the patients, collects them once completed and stores them in a dedicated archive.

In terms of the administration method, the three questionnaires can be provided to the patient through either traditional or electronic tools, depending on the patient's preference.

The traditional method consists of simply administering the questionnaire to the patient in paper format after the medical consultation, leaving the patient with the choice of either filling it out in the moment or taking it home to return it later. The electronic administration method consists of the possibility for the specialist to enrol the patient using a web interface, by collecting the patient's contact data, namely the email address and mobile phone number. Once the patient's contact data are registered in the system, an invitation to participate in the survey is automatically sent to the patient at the same time as the enrolment is registered by the specialist. At that point, via the link sent to the patient by email or

Table 1 Dimensions of experience investigated among patients through the three survey waves (T0, T1 and T2) and the number of questions by dimension

Questionnaire wave	Domains investigated	Dimensions	No. of questions
T0	Sociodemographic information	Age Sex Employment Education Place of birth	6
	Patient's history of infection	Blood transfusions, blood products or transplantation before 1990 Blood donation before 1990 Use of intravenous drugs Tattoo or piercing in unsafe environments Toothbrush or razor sharing Unprotected sex Vertical transmission, both HCV and HIV Conviction status Comorbidities	12
	Information on HCV diagnosis and actions of the GP	Time elapsed since diagnosis How the infection was diagnosed Prescription of in-depth examinations by physicians Primary care accessibility Time to diagnosis Integration between primary and hospital care after diagnosis	7
	Information on the visit with the specialist	Specialist profile Time to first specialist visit Hospital care proximity Hospital care accessibility Specialist doctor visit Drug prescription	8
	Patient-provider relationship	Primary care physician: support, clear explanations, willingness to answer questions, help in dealing with fears and anxieties, involvement of the patient in the treatment choices	5
		Specialist physician: support, clear information on the infection, drug prescription, duration of therapy, side effects and expected outcomes; willingness to answer questions, help in dealing with fears and anxieties, involvement of the patient in the treatment choices	9
	Patient-reported outcomes	SF-12 Scale	12
T1	Patient-provider relationship	Primary care physician: support, clear explanations, willingness to answer questions, help in dealing with fears and anxieties, involvement of the patient in the treatment choices	5
		Specialist physician: support, clear information on the infection, drug prescription, duration of therapy, side effects and expected outcomes; willingness to answer questions, help in dealing with fears and anxieties, involvement of the patient in the treatment choices	9
	Overall experience along the care pathway	Support, point of contact with the healthcare services, willingness to recommend primary care services, willingness to recommend hospital services	5
	Patient-reported outcomes	SF-12 Scale	12

Continued



Table 1 Continued

Questionnaire wave	Domains investigated	Dimensions	No. of questions
T2	Patient-provider relationship	Primary care physician: support, clear explanations, willingness to answer questions, help in dealing with fears and anxieties, involvement of the patient in the treatment choices	5
		Specialist physician: support, clear information on the infection, drug prescription, duration of therapy, side effects and expected outcomes; willingness to answer questions, help in dealing with fears and anxieties, involvement of the patient in the treatment choices	9
	Overall experience along the care pathway	Support, point of contact with the healthcare services, willingness to recommend primary care services, willingness to recommend hospital services	5
	Patient's preferences	Preferred way to receive information about rapid antibody testing Preferred way to undertake the rapid antibody test Relevant factors following a diagnosis Most important characteristics of treatment	4
	Patient-reported outcomes	SF-12 Scale	12

GP, general practitioner; HCV, hepatitis C virus; SF-12, short-form 12-item survey.

text message, the patient has 1 month to complete the survey and can connect to the same link multiple times to complete the survey if needed. In addition, if the patient does not respond to the first invitation message to participate in the survey, the system automatically sends up to two reminders.

Adherence to data collection by the patient is voluntary, as is the choice of electronic rather than paper-based questionnaire method of administration.

Patient involvement

The study has been developed to focus on experience of patients with HCV with healthcare services, particularly from the perspective of integration between primary and hospital care. It uses tailored surveys aimed at eliciting their valuable insights. During the first phase of the project rollout, adjustments were made following the patient's sociodemographic characteristics. The questionnaire was translated into the languages of the communities with a greater presence in certain areas (Albanian, Arabic, Chinese, Romanian). In addition, a paper format was provided since many patients were either living in prison or did not have full access to electronic devices or internet connections. Finally and importantly, screening campaigns organised periodically by the Ministry of Health provide an opportunity to raise awareness among the population about HCV.

Statistical analysis

The statistical analysis aims to evaluate the quality of care for patients with chronic HCV by incorporating pathway assessment elements derived from patient-reported data on outcomes and care experiences. This objective is divided into two sub-objectives: (a) to identify factors

that may lead to varying outcomes, such as the timeliness of diagnosis, pharmacological treatment, social-health support and follow-up during the post-treatment phase and (b) to determine the level of integration between hospital care and primary care services for patients with HCV in the Tuscany region, thereby identifying best practices at the regional level. To pursue the second sub-objective, the items from the T0 questionnaire domains 'Information on HCV diagnosis and actions of the GP' and 'Information on the visit with the specialist' will be analysed.

Data from the three questionnaires will be used and linked using a unique code that identifies each patient in time. The number of enrolled patients will be compared with the number of eligible patients obtained from administrative data. For longitudinal analyses, attrition bias will be examined by analysing the rate of patient participation in subsequent questionnaires following the initial survey.

A descriptive analysis will be conducted to assess the case mix of enrolled patients based on variables such as age, risk factors, presence of comorbidities and prescribed therapy. To compare potential differences between groups at baseline, χ^2 test, Fisher's exact test and non-parametric tests (Wilcoxon's test) will be used.

To fulfil the study's primary aim, which is to identify factors contributing to diverse outcomes, regression analysis will be used to assess differences in PROM scores over time. SF-12 scores will undergo analysis using paired t-tests and Wilcoxon matched-pairs signed rank tests for parametric and non-parametric data, respectively. Furthermore, group score comparisons will be conducted to ascertain the significance of variations in PROM scores among different patient subgroups.

To address the second aim of the study, which is to measure the effect of various care models on patient-reported outcomes and experiences, statistical models will be used to examine the impact of different models derived from the domain ‘Information on HCV diagnosis and actions of the GP’ on PROM scores and PREM results.

Potential limitations and opportunities for further research

The initial pilot survey conducted in the Tuscany region marked an important milestone. While the questionnaires were developed in collaboration with healthcare professionals from participating institutions, there was no opportunity to validate them through focus groups with patients. The non-consideration of patient input at the questionnaire development stage is a possible limitation of this study that should be addressed in the event of a region-wide extension of the survey.

Moving forward, it would be interesting to systematise this initiative on a regional scale, encompassing all healthcare facilities, to conduct a census survey until HCV elimination. In such circumstances, conducting specialised focus groups and workshops with patients would be beneficial. However, it might pose significant logistical and bureaucratic challenges, particularly considering the unique nature of the patient groups involved, including the elderly, individuals using addiction services and incarcerated individuals.

A potential limitation of this study, based on its design, is recall bias due to patients having the option to fill out the questionnaire either on-site or at home. However, during the pilot study, the vast majority of patients chose to complete it on-site and in paper format, and no matter the administration mode, those who took it home rarely returned it. This result may be linked to the fact that the majority of patients were elderly, PWID and people living in prison, having limited access to electronic devices and internet connection. Therefore, when scaling up the survey in the Tuscany region, it is advisable to only offer the option of on-site paper format completion.

ETHICS AND DISSEMINATION

Ethical and privacy considerations were addressed in consultation with the Tuscan regional office responsible for supporting health research and clinical trials. This office oversees the protection of personal data in the health sector and assists ethics committees. Formal documentation, including the Participant Information Sheet, copies of questionnaires, a list of additional information collected by clinical professionals during patient enrolment, the study protocol and a data management plan, was prepared and submitted to the Ethics Committee for Clinical Experimentation of Area Vasta Nord Ovest. The study was granted approval on 17 October 2020 with CODE 18829. The research findings will be disseminated through publications in peer-reviewed journals and presentations at relevant conferences. The results will be exclusively reported in an anonymised and aggregated

format. At the conclusion of the pilot project, a final event will be organised to present the results of the study conducted. This event will also serve as a platform for engaging with patient associations, who will be invited to discuss the findings and share their perspectives. Should the survey be systematically implemented at the regional level later, it would be possible to organise recurring events and meetings to foster ongoing collaboration with patient associations, ensuring that patients’ insights and needs are regularly valued by the survey.

Regarding data management procedures, all systems aimed at ensuring data security and privacy protection have been considered. The patient’s enrolment automatically generates an anonymised code, unique to each respondent, used to initiate the investigation. This unique code is stored in the enrolment database, ensuring that the patient’s identity is not disclosed in the recorded dataset. Access to this dataset is granted to the specialist who enrolled the patients using their credentials, and to appropriately trained and authorised researchers (eg, technical staff). The unique code is used to link the questionnaires across the three waves. Each medical professional can only access information for the patients they have enrolled with their credentials. All data collection and storage systems (eg, online platforms, servers) are set up in compliance with the guidelines outlined in the new European data protection directive,⁴⁷ formally in effect since May 2018.

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Contributors MV and LT are the scientific directors and coordinators of the initiative. IC and GM were responsible for the study design and implementation. LC collaborated in the study design, including the early involvement of patients. IC and GM will be responsible for the analysis of the results. IC drafted the manuscript. GM and LC contributed to writing the manuscript. MV and LT critically reviewed the manuscript. All contributors read and approved this version submitted for publication to BMJ Open.

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