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Assessing the outcomes and experiences of care from the perspective of people living with chronic conditions, to support countries in developing people-centred policies and practices: study protocol of the International Survey of People Living with Chronic Conditions (PaRIS survey)

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ABSTRACT

Introduction In view of growing populations with chronic conditions, many countries are redesigning their health systems. However, little information is available about how health systems perform from the perspective of people living with chronic conditions. The Organisation for Economic Co-operation and Development (OECD) Member States therefore mandated the OECD to initiate the International Survey of People Living with Chronic Conditions (PaRIS survey), which aims to provide insight in outcomes and experiences of care as reported by people living with chronic conditions. The PaRIS-SUR consortium has been tasked by the OECD to support the development and implementation of the survey.

Methods and analysis As primary care services play a pivotal role in the management of chronic conditions, the PaRIS survey will be implemented in the primary care setting. Data will be collected with a survey among users of primary care services aged 45 years or older, of whom many have chronic conditions. An additional survey is conducted among their primary care providers. The nested study design will allow analysis of the patient-reported data in relation to characteristics of and care provided by primary care providers within and across countries. In 2022, the survey will be tested in a Field Trial in participating countries. Data for cross-country comparison will be collected by the Main Survey in 2023.

Ethics and dissemination Informed consent will be obtained from primary care providers and service users. National Project Managers search ethical approval of the survey in their country, if required. Reporting by the OECD will focus on questions for international comparison. A secured information technology platform will be developed for participants and stakeholders in countries to receive feedback and answer their own questions. Findings will also be disseminated through an international OECD flagship report, conferences, scientific papers and policy briefs, to inform strategies to improve care for people living with chronic conditions throughout the world.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ To maximise the relevance and usability of the International Survey of People Living with Chronic Conditions (PaRIS survey), it has been developed in a collaborative process with many stakeholders in participating countries and at international level.
⇒ Translating and revising the survey questionnaires has been a process of carefully balancing local applicability and cross-country comparability.
⇒ To ensure optimal protection of personal data and avoid registration bias, persons with chronic conditions will be identified through self-report of chronic conditions among service users aged 45 or older (assuming that many of them will have chronic conditions) who were selected from primary care practices and gave informed consent to participate in the survey.
⇒ Because we survey persons who have been in contact with a primary care provider, real care experiences are reported; this method is however less suitable to study access issues from the patient perspective.
⇒ The nested study design will allow analysis of the variation in patient-reported data in relation to the organisation of and care processes applied in primary care practices and characteristics of the health system.

INTRODUCTION

Background and rationale

Chronic conditions are a major health threat for individuals, which often also negatively impact the quality of life and functioning of these persons and their families in various life roles (eg, as a partner, caregiver, employee) as well as their social and financial position.[1–6] Besides their impact on individuals and households, chronic conditions pose a major challenge to health systems and societies. For example, the Medical Expenditure Panel Survey in the USA demonstrated that 60% of non-institutionalised adults in the USA had at least one chronic condition—42% had more than one—and that these conditions were responsible for more than 80% of healthcare spending in the USA in 2014.[7] Although the prevalence and management of chronic conditions vary across countries, a rapid growth of populations with (multiple) chronic conditions and of related healthcare expenditures have been reported from countries all over the world.[8 9] Moreover, chronic conditions affect countries' labour force and productivity substantially, irrespective of continent and income.[10]

To improve the quality of care for people living with chronic conditions as well as to improve health outcomes and control healthcare expenditures, countries are redesigning their health systems towards becoming more people-centred and integrated.[11] Primary care (PC) services play a pivotal role in these reforms, as in many countries PC providers are the first and main contact with the health system for people living with chronic conditions in the community. Ideally, PC providers offer directly accessible care of a comprehensive and continuous nature. They could serve a coordination role across disciplines and sectors, taking a holistic, person-centred approach.[12 13] Regarding chronic care management, PC providers could play a key role in all phases of the citizen/patient journey, starting from educating and supporting people to improve their lifestyle, encouraging them to engage in programmatic screening, identifying high risks by (referral to) diagnostic procedures, treating chronic conditions or referring persons for treatment in specialist settings and by providing self-management support, monitoring and follow-up care along the entire care pathway.[14–17]

While countries face rising needs because of ageing and more medically complex populations, many struggle to assess how their health systems perform with regard to the management of chronic conditions. Outcome measures available today focus on mortality, and incidence and prevalence of disease, based on health services' or health insurers' administrative data sets. Little information is available about how people-centred health services are from the perspective of users and to what extent these services provide (integrated) care that meets their needs.[18] Considering this critical information gap and the increasing recognition that patient-reported experiences and outcomes play a pivotal role in making health systems more people-centred,[19] the Health Ministers of the Organisation for Economic Co-operation and Development (OECD) Member States mandated the OECD to lead an effort to develop and implement an international survey to gain more insight in outcomes and experiences of care as reported by people living with chronic conditions.[20] This has led to the conceptualisation and development of the International Survey of People Living with Chronic Conditions (PaRIS survey).

Objectives

The PaRIS survey aims to help policymakers understand how their health system addresses the needs of people living with chronic conditions. A core element of the approach of PaRIS is the international standardisation of instruments and procedures for sampling and data collection, in order to facilitate international comparisons and cross-country learning. The ultimate goal is that the results of PaRIS will help countries to make their health systems more responsive to people's needs.

Inclusive development

A key principle of the PaRIS survey is that it is developed inclusively with stakeholders to ensure relevance, meaningfulness and the uptake of its results at all levels of countries' health systems. In view of this, the OECD established a Taskforce to advise on the development of the survey during 2017. This Taskforce consisted of representatives of patients and care providers, country representatives and experts on population and health services surveys and patient-reported indicators. The resulting proposal,[21] adopted by the OECD Health Committee in 2018, formed the basis for the current project, in which the international survey is being developed with inputs from all stakeholders and implemented in participating countries.

Governance

Figure 1 shows the governance structure of the PaRIS survey. The development of the PaRIS survey and its implementation in countries is overseen by the Health Committee, a formal body in which all OECD countries

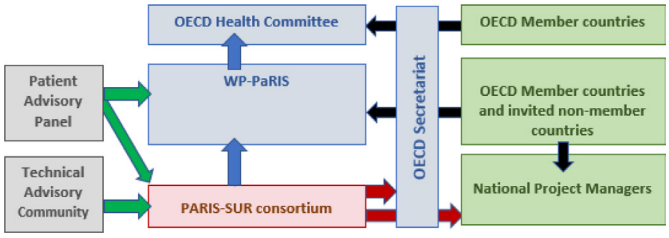

Figure 1 Governance structure of the PaRIS survey. Four types of relations among the various actors exist: (1) Formal responsibility for appointing country representatives and National Project Managers (indicated by black arrows); (2) Formal reporting responsibility (indicated by blue arrows); (3) Technical support (indicated by red arrows); (4) Advisory role (indicated by green arrows). OECD, Organisation for Economic Co-operation and Development; PaRIS, International Survey of People Living with Chronic Conditions; WP-PaRIS, Working Party for PaRIS.

are represented. The OECD Working Party for PaRIS (WP-PaRIS) resides under the Health Committee, and consists of formal representatives of all countries participating in the PaRIS initiative. These are usually officers from the Ministries of Health or governmental research institutes, who are assisted by experts in their own country or at the OECD, if needed (eg, legal or data management experts). Participation is open to all OECD members and invited non-OECD members.

To ensure that the patient perspective is fully considered, the OECD established the Patient Advisory Panel consisting of representatives of national and international patient federations.[22] This panel has been and will be consulted at all major steps of the project. Furthermore, the PaRIS-SUR consortium is seeking advice in all phases of the project from a worldwide community of independent experts, the Technical Advisory Community, covering a wide range of expertise (eg, legal, health policy, health services, survey methodology, statistics).[23]

At the national level, stakeholders and experts in the participating countries are involved in the development of the survey instruments and the national implementation plans. To this aim, each participating country appointed a National Project Manager, who works with a national team and the PaRIS-SUR consortium to coordinate the implementation of the survey in the country. The consortium provides support to the National Project Managers and ensures that the survey is being implemented consistently, allowing for cross-country comparative analyses of the survey data.

Considering their key role, the OECD provided a task profile to help countries with appointing their National Project Manager. Requested key competencies mentioned in the profile were, among others, a trusted reputation in regards to survey implementation, chronic conditions, primary care and health policy; being accustomed with national approaches towards healthcare and applied research; access to networks in the primary care or other ambulatory care community; ample experience in planning and organising large-scale surveys; familiarity with sampling, survey data collection, quality control procedures and data management. It was emphasised that the National Project Manager would need to build a multidisciplinary team to ensure that all expertise would be available to perform their tasks according to the international standards adopted by the OECD.

Main research questions

The PaRIS survey seeks to address many questions that are relevant for people living with chronic conditions and their families, PC providers, policymakers and health authorities in countries. Reporting by the OECD will predominantly focus on the main questions for international comparison in line with the overall goal of the PaRIS survey, that is, to inform countries on the patient-reported outcomes and care experiences of their citizens living with chronic conditions compared with similar populations in other countries. To strengthen policy relevance, the results of PC service users living with chronic conditions will also be compared with the results of PC service users without such conditions. As such, data analysis will be guided by the following main questions[21]:

1. What are the patient-reported outcomes of PC service users aged 45 and over with chronic conditions, compared with those without chronic conditions, in the areas of symptoms, physical, mental and social functioning, self-reported health and health-related quality of life? How do these results vary across countries?
2. What are the experiences of PC service users aged 45 and over with chronic conditions, compared with those without chronic conditions, in the areas of access, comprehensiveness, continuity, coordination, safety and people-centredness of care, self-management support, trust and overall perceived quality of care? How do these results vary across countries?
3. How do patient-reported outcomes and care experiences vary for PC service users aged 45 and over with chronic conditions by background characteristics such as age group, gender, education level, occupational status, household composition, health-risk behaviours, level of multimorbidity, disease status and confidence in managing one's own care?
4. How do key characteristics of PC practices relate to the care experiences and outcomes of PC service users aged 45 and over with chronic conditions?
5. How do characteristics of health systems and countries relate to the care experiences and outcomes of PC service users aged 45 and over with chronic conditions?

METHODS AND ANALYSIS

Study design

The PaRIS survey is designed for cross-country comparison. The main instrument is a survey among PC service users aged 45 years or older to collect patient-reported data. An additional survey among their PC providers is included to collect data on the characteristics of and care they provide, in particular related to chronic care management. The PaRIS survey has a nested design: PC service users are nested in PC practices, which are at their turn nested in (national or regional) health systems in countries (figure 2). This will allow analysis of the variation in patient-reported data in relation to characteristics

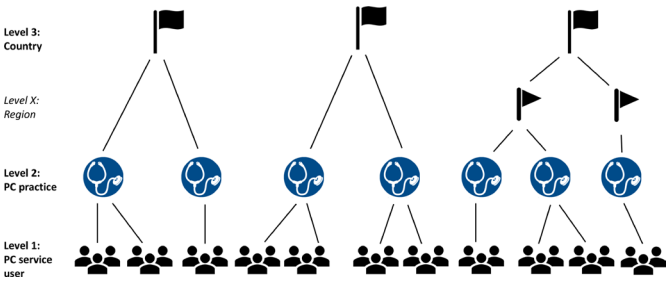

Figure 2 Multilevel design of the International Survey of People Living with Chronic Conditions (PaRIS survey). PC, primary care.

of and care provided by PC providers within and across participating countries.

The current project consists of a Field Trial (2022) to pilot the survey instruments and sampling, data collection and analysis procedures, followed by data collection for cross-country comparison with the Main Survey (February–October 2023). To monitor outcomes and experiences from the perspective of people living with chronic conditions, the PaRIS survey is expected to continue on an ongoing basis. The WP-PaRIS will decide about its frequency in 2024, based on the results of the Main Survey in this project phase. Box 1 provides an overview of the countries that committed to its implementation.

Study setting

The survey will be conducted in the primary care setting. To identify this setting in each country, we defined PC practices as *facilities or practices staffed by physicians who are licenced to serve the general population of a community and provide generalist care in an ambulatory (outpatient) setting*. Generalist care is characterised by its comprehensiveness, continuity and coordination and is not restricted to a specific category of patients. PC practices are usually accessible without referral, and staffed with medical doctors with a specialist training in general practice, such as general practitioners or family physicians. Many PC practices are also staffed with other care professionals, such as nurses or allied healthcare professionals, although single-handed general practices also exist.

Box 1 Countries that committed to implement the International Survey of People Living with Chronic Conditions (PaRIS survey)

⇒ Australia
⇒ Belgium
⇒ Canada
⇒ Czech Republic
⇒ England (UK)
⇒ France
⇒ Greece
⇒ Iceland
⇒ Israel
⇒ Italy
⇒ Luxembourg
⇒ The Netherlands
⇒ Norway
⇒ Portugal
⇒ Romania
⇒ Saudi Arabia
⇒ Slovenia
⇒ Spain
⇒ Switzerland
⇒ USA
⇒ Wales (UK)

Eligibility criteria

Since the PaRIS survey has a nested design, National Project Managers should first sample PC practices in their country and subsequently, within the selected PC practices, service users who meet the eligibility criteria. Eligible PC practices are those care practices that meet the definition mentioned above. Eligibility criteria for PC service users are: (1) aged 45 years or older at the time of sampling; (2) living in the community (in a private household, ie, not in a long-term care facility, healthcare or other residential institution); and (3) having had at least one registered contact with a PC provider—either face-to-face, by telephone or online—for any medical or administrative reason, during the 6 months preceding the selection procedure.

PC service users who cannot complete the questionnaire independently are not excluded, as there is the possibility for them to be assisted by a family member or friend, or from a helpdesk set up by the National Project Manager. Absence of medically diagnosed chronic disease(s) is neither an exclusion criterion for service users, for two main reasons. First, we want to collect data also from people who do not have a chronic condition, to compare their results with those of people living with chronic conditions. As such, the survey will provide information on whether findings relate to care delivery in general or to the management of chronic conditions in particular. Second, we want to avoid using data from patients' health records, as this may create technical or legislative barriers for participation in some countries. Recording of chronic conditions may also be different within and across countries, which would affect comparability across PC practices and countries. Therefore, people with and without chronic conditions will be identified based on their report of a number of chronic conditions as proposed by the PaRIS Taskforce (the list of chronic conditions to be included in the PaRIS survey consists of conditions proposed by the PaRIS Taskforce,[21] with minor changes made during the development process of the survey instruments: Alzheimer's disease/other cause of dementia; arthritis/ongoing problem with back or joints; breathing condition (eg, asthma, chronic obstructive pulmonary disease); cancer (diagnosis or treatment in the last 5 years); diabetes; chronic kidney disease; chronic liver disease; high blood pressure; cardiovascular/heart condition; (ongoing) mental health condition (eg, anxiety, depression, schizophrenia); neurological condition (eg, epilepsy, migraine); another chronic condition).[21] This list covers broadly defined areas of the most prevalent chronic conditions in OECD countries, and are defined in a way that is easy to understand for laymen. There is an 'other' category for conditions that are not on the list. By stating that participants should be 45 years or older, it is assumed that approximately 70% of the sampled PC service users will have at least one chronic condition. This assumption was based on available population data[7] combined with the hypothesis that restriction to individuals that visited the PC practice in the

preceding 6 months would yield a slightly higher proportion. If there is evidence or a valid reason to believe that this assumption will not hold in a particular country, the National Project Manager will adjust the sample size per PC practice for the Field Trial as outlined below.

Sample size

Sample sizes for the Field Trial are based on statistical simulations carried out on a large data set of patient-reported care experiences from 34 countries participating in the QUALIty and COsts of Primary Care in Europe (QUALICOPC) study.[24] The simulations were conducted with the data of four patient-reported experience scales (communication, access, comprehensiveness and continuity of care), each consisting of several items. The main criterion for determining the sample size was the reliability of country-level estimates for each of the four scales. Given the characteristics of the scales and the clustering within practices and countries, the value of this reliability depends largely on the number of practices per country and the number of patients per practice. The reliability of each scale was simulated for different combinations of numbers of PC practices and patients per practice. The combination of 25 practices and 50 patients per practice resulted in highly reliable scales (>0.85). Therefore, we estimate that 25 PC practices per country and 50 eligible service users per PC practice (1250 eligible PC service users per country) are required to participate in the Field Trial.

Depending on countries' expected response rates—if possible, based on previous survey studies among PC providers and service users in the participating countries—National Project Managers determine the sample sizes they need to achieve the required numbers of participants. It is evident that higher response rates are preferable above larger samples, but unrealistic expectations of response rates should be avoided to ensure we will get sufficient Field Trial data of each country to test the survey instruments and data collection procedure for the Main Survey. Response rates of 35% among PC practices and of 50% among PC service users have been set as targets for each country. Whether these targets are feasible will be concluded after the Field Trial. Based on the experiences and results of the Field Trial, sample sizes for the Main Survey will be set.

Sampling procedure

To achieve representative results, potential sampling frame(s) should be identified in each country and their quality should be assessed based on estimated coverage and risk of bias. As the unit of data collection is a PC facility (independent of size in terms of number of patients or care professionals), complete and actual national lists of these facilities are the ideal sampling frame of PC practices, or combined lists with a regional coverage. If such lists are not available or the quality is poor, registries or member lists of key professional organisations in PC, such as colleges of general practitioners or family physicians, may be used to identify (all) eligible PC practices. Sampling guidelines drafted by the consortium could help National Project Managers develop the most appropriate sampling procedure for their country, which should ensure that PC practices staffed by multiple PC professionals cannot be included in the sample more than once. The sampling procedure for PC practices should be consistent with the principle of probability sampling as much as possible. This entails that each PC practice in the sampling frame should have a non-zero and equal chance to be included in the sample.

Sampling of PC service users will be kept as simple as possible by randomly drawing a fixed number of eligible patients per PC practice. National Project Managers design the sampling procedure for PC service users together with the participating PC practices, respecting applicable legislation.

Availability of auxiliary data for survey weighting

National Project Managers are asked to provide data on key characteristics of the population of PC practices and/or of the sampled PC practices in their country, to allow calculation of weights to correct for possible response bias. Similarly, they are asked to provide basic information about the population of people aged 45 years or older who have been in contact with a PC practice in the preceding 6 months and/or the sampled PC service users. The feasibility of survey weighting will depend on the availability of such data. Accordingly, a survey weighting plan for the Main Survey will be developed based on which population/sample data National Project Managers are able to retrieve in the Field Trial.

Recruitment strategy

To support the recruitment process, National Project Managers develop a communication strategy tailored to country-specific needs and preferences, local resources and communication channels, in consultation with national stakeholders and the consortium. To invite selected PC practices, the mode of communication can be either by email, a phone call or a letter first, with follow-up contacts of any form. To invite selected PC service users, National Project Managers decide together with the participating PC providers how their patients will be approached. Regardless of the initial mode(s) of communication, all selected PC practices and service users will receive written information about the survey at some stage of the recruitment process and give informed consent.

Questionnaire development

For the development of the PC service user and practice questionnaires and for supporting the plan of analysis, a conceptual framework was developed through a systematic, replicable, iterative and inclusive process.[25] The framework identifies the following domains: patient-reported outcomes (symptoms, functioning, self-reported health status, health-related quality of life);

patient-reported experiences of care (access, comprehensiveness, continuity, coordination, safety, people-centredness, self-management support, trust, overall perceived quality of care); service users' health and care capabilities; service users' health behaviours (physical activity, diet, tobacco use, alcohol use); service users' individual and socio-demographic characteristics; PC delivery system (characteristics of the PC facility; characteristics of the main PC professional); characteristics of the health system, policy and context.

Procedures for development of the questionnaires will be described in full separately. Here we provide a brief description of the development process and content of each questionnaire.

The questionnaire for PC service users aims to assess the primary outcomes of the PaRIS survey, that is, the patient-reported outcomes and care experiences, as well as PC service users' characteristics, including demographics, chronic conditions, health and care capabilities and health behaviours. A comprehensive approach including a number of systematic reviews, engagement with international stakeholders (Patient Advisory Panel, Technical Advisory Community and National Project Managers) was conducted for the identification of eligible scales and items. Following a mapping exercise onto the conceptual framework, four instruments for each domain were shortlisted using predefined criteria. The psychometric performance of the candidate instruments was assessed using the Evaluating the Measurement of Patient-Reported Outcomes (EMPRO) method.[26] A subsequent modified Delphi procedure was implemented for selecting a core instrument for each domain and additional relevant scales/items. Further consultations took place with the relevant stakeholders to confirm the suitability of the proposed questionnaire, whose feedback resulted in a number of iterations until a final draft was agreed.[27] The draft questionnaire consists of 120 items, including the PROMIS Scale V.1.2—Global Health,[28] WHO-5 Well-being Index,[29] Person-centred Coordinated Care Experience Questionnaire[30 31] and Porter-Novelli Scale.[32]

The questionnaire for PC practices aims to collect information about the characteristics of and services provided by the PC practice. The draft questionnaire has been developed applying the same principles that guided the development of the questionnaire for PC service users, including a literature review to identify existing questionnaires, mapping of questions to the domains of the conceptual framework, ranking and selection of items. The final draft PC practice questionnaire consists of 40 items to be completed by medical staff (eg, physician, nurse) or non-medical staff (eg, practice manager). It covers the following topics: profile of the practice/facility (eg, location and type, access and services) and key elements of chronic care, including care planning, coordination, follow-up care and self-management support. In addition, the questionnaire contains some questions on the impact of COVID-19 outbreak on care delivery.

Translation and cognitive testing

The draft questionnaires have been translated in all national languages of the participating countries using a stepwise team approach based on the TRAPD model (Translation, Review, Adjudication, Pretest, Documentation).[33] For reasons of efficiency and cross-country comparability, we advised National Project Managers to establish a collaboration of their national translation team with the translation agency cApStAn, which has ample experience with this approach for international comparative surveys. However, they could also choose to apply the methodology with a completely national team, with only a final review by cApStAn. Countries that wish to have the questionnaire for PC service users available in other languages are encouraged to produce additional translations themselves or collaborate with other participating countries in this. The consortium will take responsibility for developing some translations for large minority groups, which will be offered to countries for use in the Main Survey.

The (translated) draft questionnaires are currently being tested by means of cognitive interviews with 10 PC providers and 20 PC service users in each participating country, preferably in two rounds: a first round with half the total number of participants, resulting in recommendations for either adaptation of the source questionnaires or localisations, and a second round to check and confirm the modified questionnaires. The modified questionnaires will then be piloted in the Field Trial. Based on the data collected with the Field Trial and the experiences of the National Project Managers, final adjustments may be made to the questionnaires before being used in the Main Survey.

Data collection methods

The two questionnaires have been developed for online administration; PC service users may also opt for a paper-and-pencil version. Additional administration modes (eg, by telephone or face-to-face) may be offered in countries where response to online or postal questionnaires is expected to be insufficient. National Project Managers will set up a helpline for PC service users and providers in their country, to refer to in case of questions about the questionnaire. PC service users may also contact the helpdesk for help in completing the questionnaire, if they are unable to do this alone and informal help is not available. A final question has been added to the PC service user questionnaire on whether the questionnaire was completed independently or with help from another person.

National Project Managers will receive daily overviews from the international data management team that contain unique serial numbers that correspond to online responses to the survey. Only the organisation that performs data collection within a country will be able to link these numbers to names and addresses for the purpose of sending reminders. It is recommended that non-responders are reminded at least two times within

a period of 4weeks after the invitation to complete the questionnaire.

Data management

Completed online questionnaires will be saved in the secured international database created by the consortium. For countries that cannot or do not want to use this centralised approach, National Project Managers will create national level databases to store online survey data. For those countries the consortium provides guidance to avoid deviations that could threaten cross-country comparability of the data.

Completed paper-and-pencil questionnaires will be returned by the responders to their National Project Manager (or subcontractor), who is responsible for a secured storage of these questionnaires nationally, and for data entry in a secured database. The consortium will provide instructions to ensure similar coding and equal variable and value names as in the international database. In the national databases data collected by the questionnaires will be encrypted and stored separately from any potentially identifying participant data.

Identifying participant data will be securely saved in each participating country as long as needed for data collection (eg, sending reminders) and evaluation of the representativeness of the participants. To the latter end, aggregated data on participant characteristics (eg, spread of the responding PC practices and service users across the country) will be compiled, after which identifying participant data will be destroyed. Identifying participant data will never be transferred to the international database.

Once the data collection is finished, the National Project Managers will transfer the pseudonymised microdata collected by the questionnaires as well as the aggregated data needed to assess the representativeness of the participants and to correct for response bias to the international database.

Statistical methods

The statistical analyses to answer the main research questions will be conducted by the international consortium. The plan of analysis includes a number of preparatory steps, such as the evaluation of the survey operations (eg, sampling and data collection), data cleaning, quality control and the evaluation of the psychometric performance of items and scales in the questionnaires.

To answer the research questions, a series of multilevel regression analyses[34] will be conducted based on a three-level model. Units of analysis are individual PC service users (level 1), who are nested within PC practices (level 2), which are nested in countries (level 3). Note that in some countries where regional health systems exist there will be an intermediate level.

For each of the questions, a null model will be defined to estimate the variance of the outcome variable at stake specifying random intercept coefficients only, that is, estimated variance at level 1, level 2 and level 3. Intraclass correlation coefficients will be calculated to assess the extent to which the scores of PC service users on the outcome variable are clustered in, respectively, the PC practice they had been in contact with and the country (or region) in which the PC practice is located. The country level (or regional level, if applicable) variance will be used to calculate predictions of the patient-reported indicators (posterior means or empirical Bayes estimates) corrected for case-mix variables for each country and/or region, including CIs. Case-mix variables are variables that may hamper a fair comparison of patient-reported indicators between countries or regions. Potential case-mix variables for analysis of the Field Trial data will be selected based on theoretical notions and empirical evidence.[35–40] Depending on the data analysis of the Field Trial, the case-mix adjustment in the analyses of the Main Survey data may be modified.

Research questions 1 and 2 focus on outcomes and care experiences of people living with chronic conditions compared with those without chronic conditions. This will be specified in the models by including a dummy variable: chronic condition(s) present (vs absent). This allows for examination of variance in outcomes and experiences of people living with and without chronic conditions. This dummy variable will also be used in country-level predictions to estimate the outcomes and care experiences of people living with chronic conditions compared with the outcomes and experiences of people without chronic conditions.

To answer research question 3, background characteristics of PC service users will be added to the null model; their fixed effects will be estimated separately and simultaneously, as far as the data allow. Likewise, interaction effects that are considered relevant (guided by hypotheses based on theory and empirical evidence) will be estimated, as far as feasible. To answer research questions 4 and 5, the models will be extended with independent variables at the level of PC practices and countries, and their fixed effects will be estimated. Cross-level interaction effects may also be considered. The data analysis plan for the Main Survey will be reviewed and consolidated after analysis of the Field Trial data.

Patient and public involvement

Patients' priorities, experiences and preferences form the basis of the PaRIS survey and were brought forward through the participation of the European Patients' Forum and the Picker Institute in the PaRIS Taskforce,[21] which advised the OECD Secretariat on the design and the research questions of the PaRIS survey. A patient advisory panel,[22] composed of representatives of international and national patient federations, has been established to advise the OECD Secretariat and the PaRIS-SUR consortium on all stages of survey development and implementation. National Project Managers seek advice from patient and citizen representatives in their country in developing national communication and engagement strategies. Patients and citizens from many countries also contributed to the development of the

conceptual framework and survey questionnaires through their participation in focus groups, a Delphi study, and cognitive interviews.

ETHICS AND DISSEMINATION

Research ethics approval

National Project Managers seek ethical approval of the PaRIS survey, if this is required in their country. The consortium has developed guiding materials to help them preparing the ethical review documents, including (1) information about the PaRIS survey and its rationale, (2) elements of the study protocol, (3) information about privacy protection and data security, (4) controller, processor and legal basis in different phases of data collection and analysis, (5) draft invitation letter for PC service users and (6) an overview of the PaRIS-SUR consortium and the OECD, who commissioned the PaRIS survey to the PaRIS-SUR consortium. There was no overarching or coordinating ethics committee involved.

Consent of participants

Informed consent will be obtained from PC providers and service users for participation in the survey. To this end, all invited PC providers and service users receive written information, addressing all issues that are necessary to be able to give informed consent. The consortium has prepared this information, which will be translated by the National Project Managers or their subcontractors. PC providers and service users who want to participate give informed consent by responding to a first question in the survey instrument.

Confidentiality

The PaRIS survey will meet the highest regulatory standards for the legal and safe processing of sensitive personal health data, including OECD Data Protection Rules[41] and any applicable national legislation, including the European Union General Data Protection Regulation.

Within countries, confidentiality is governed by the National Project Manager according to national legislation. Across country borders, only pseudonymised and/or de-identified data will be transferred while the key remains within country boarders. For PC service users, this key will be destroyed on completion of data collection. For practices, the key remains available to allow feedback of aggregated results.

Communication and engagement plan

To support the implementation of the PaRIS survey, National Project Managers involve local associations of citizens/patients and PC providers at an early stage in communicating about the survey with people living with chronic conditions and PC professionals. To this end, National Project Managers are developing a communication and engagement plan in consultation with national stakeholders. The consortium provides information materials that can be translated and adapted to the local context for use in countries.

Reporting of study results

The consortium develops a secured information technology platform that will allow stakeholders in participating countries to receive feedback and answer their own questions, based on the data collected by the Main Survey. Public reporting by the OECD will predominantly focus on the five main research questions, for which the consortium will provide the results of the data analysis. In addition, the consortium will publish on issues that are important from a scientific point of view, for instance methodological questions (eg, effects of administration modes on outcome variables in countries and correction methods) and questions of a more explanatory nature (underlying causal factors and processes).

Protocol amendments

Based on the evaluation of the Field Trial, the study protocol will be modified for the Main Survey. These modifications will include the calculation of the sample sizes set for the Main Survey (based on insight in response rates in countries and analysis of the Field Trial data). Other modifications may include final changes to the questionnaires or data collection procedure (eg, number or nature of reminders), if considered necessary based on the experiences of the National Project Managers or analysis of the Field Trial data. As the Field Trial is intended to pilot both the survey instruments and implementation of the survey in the participating countries, any modifications that may improve the implementation of the Main Survey or the usefulness of its results for participating countries will be considered.

DISCUSSION

The PaRIS survey is the first worldwide cross-country study implementing patient-reported indicators for the purpose of policy development and monitoring of chronic care management in PC settings. To ensure that the survey will collect information that is useful for countries in assessing the performance and quality of care from the perspective of people living with chronic conditions, it is crucial that the survey is being implemented in the daily practice of nationally representative samples of PC providers. This requires nationwide coverage of participating PC practices, including those that may be located in remote areas, have limited resources for chronic care management in terms of staff or equipment, or less advanced information technology for care delivery and practice management. This has implications for the design of the survey and its implementation. For instance, rigorous criteria for probability sampling of PC practices or service users may not always be fully met and local adaptations of the survey instruments will be needed to ensure understanding and relevance in a local context but may also affect cross-country comparability of the data. To find an optimal balance between all needs, interests and requirements, it is key that the development of the PaRIS survey is a collaborative effort of all involved.

This is crucial to achieve the ultimate goal of PaRIS, which is to assess the performance and quality of PC from the perspective of people living with chronic conditions to support countries in developing people-centred policies and practices. To date, the development process has been an experience that already provided various opportunities to exchange experiences and learning from various stakeholder perspectives within and across countries.

In 2022 Field Trial data will become available to further improve the survey instruments and countries' implementation roadmaps. Lessons learnt will be used to optimise measurements of experiences and outcomes in the Main Survey thereby providing countries with information they can use to make their health systems more responsive to peoples' needs.

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Contributors MvdB and NK designed the PaRIS survey in collaboration with other OECD staff, the Working Party for PaRIS and in consultation with the PaRIS Taskforce. WB and JMV participated in the PaRIS Taskforce. DdB, MB, WB, PG, OG, RS, LT, JMV, RW and MR drafted the initial project plan based on the Terms of Reference set by the OECD and the previous work conducted by the OECD together with the PaRIS Taskforce. MvdB, CK, KdB and NK reviewed this initial plan and contributed to the definite project plan, including the project planning, development of the PaRIS survey conceptual framework and survey instruments. DdB, MvdB, MB, JB, WB, KdB, PG, OG, CK, NK, IP, RS, LT, JMV, RW and MR prepared the implementation of the PaRIS survey together with the National Project Managers, supervised by the Working Party for PaRIS. DdB and MR wrote the draft manuscript; MvdB, MB, JB, WB, KdB, PG, OG, CK, NK, IP, RS, LT, JMV and RW critically reviewed the draft manuscript and provided additional inputs. All authors (DdB, MvdB, MB, JB, WB, KdB, PG, OG, CK, NK, IP, RS, LT, JMV, RW and MR) read and approved the final manuscript for publication.

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