

Collection and Use of EQ-5D in Swedish Health Care

– Final report of the Swedish PROMs Program

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Executive summary

There are over 100 national quality registries in Sweden. These registries follow specific patient populations defined by one or several diagnoses or by specific interventions. The collected data can be used to monitor quality and results of health care with the purpose to support continuous learning, quality improvement, management and research. The majority of the registries collect data on patient-reported outcomes and the most administrated patient-reported outcome measure (PROM) is EQ-5D.

To have a common license for the collection of EQ-5D in the registries as well as for Region Stockholm, an agreement for the license of EQ-5D was made in 2015 between the EuroQol Research Foundation and Region Stockholm, on behalf of the National Quality Registry Organization. The collection of EQ-5D data within this agreement, and the subsequent use of the data, was referred to as the “Swedish PROMs program”. QRC Stockholm was delegated the responsibility of coordinating the Swedish PROMs program by granting the appropriate collection and legal use of EQ-5D data by the registries and the health care providers within Region Stockholm, as well as by organizing the sub-licensing and distribution of EQ-5D. For this purpose, a specific service management project was initiated, which focused on strategies to facilitate the collection of EQ-5D in daily practice as well as building knowledge, competence, and IT solutions.

As part of the agreement, it was decided that the Swedish parties was to invest in a research program of mutual interest to the national quality registries, Region Stockholm, and the EuroQol Research Foundation. This program was called the “Swedish Research Program of Mutual Interest (SRPMI)” and was active from 2016 to 2020. The research program was structured into three themes: overview of EQ-5D data in the national quality registries, measurement properties of EQ-5D in specific groups, and use of PROMs data to support decision-making and quality improvement in health care. In total, the program resulted in four research studies. Furthermore, the program led to the initiation of several ongoing collaborations with the national quality registries and contributed to the funding of two additional studies conducted by other research groups.

The program has contributed to an increased understanding of the collection of EQ-5D in routine health care in Sweden and provided administrative and methodological support to the national quality registries and Region Stockholm. Nevertheless, there is still room for improvement, and it is recommended for future initiatives with the purpose to support the use of PROM data from the registries to focus on the establishment of a more permanent methodological support function directed to the collection of PROMs in general. The studies included in the program have contributed to the scientific literature regarding measurement properties and applications of EQ-5D. Areas for further study have been identified and the collection of EQ-5D data within the program constitute an interesting case for further assessment of measurement properties in the

populations covered by the registries as well as of how different uses of EQ-5D may influence decision-making and may improve patient health.

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Introduction

Health care in Sweden is decentralized and the 21 Swedish regions are the main health care providers [1]. To monitor quality and results of health care, there are more than 100 national quality registries (NQRs) following specific patient populations [2]. The populations in the registries are defined by one or several diagnoses or by specific interventions. The collected data can be used for continuous learning, quality improvement, research and/or management.

The EQ-5D is a common measure of health-related quality of life (HRQoL) in Swedish health care. Most of the national quality registries contain data on patient-reported outcomes and EQ-5D has been reported to be the most administrated patient-reported outcome measure (PROM) in the registries [3]. To have a common license for the collection of EQ-5D in the registries, an agreement for the license of EQ-5D was made in 2015 between the EuroQol Research Foundation and the Health and Medical Administration (HSF) at Region Stockholm on behalf of the National Quality Registry Organization at the Swedish Association of Local Authorities and Regions (SALAR). The license covered the collection of EQ-5D within all the Swedish national quality registries and was originally valid until July 2020 but later prolonged to December 2020. To have a valid license, each quality registry collecting EQ-5D had to sign a sub-licensing agreement to the main agreement. Further, the 21 regions had the possibility to make agreements in accordance with the main agreement. In this way, the regions would have a license for the collection of EQ-5D in all routine health care and not only within the scope of the registries. Region Stockholm was the first region to make such an agreement.

The collection of EQ-5D data within the agreements, and the subsequent use of the data, was referred to as the “Swedish PROMs program”. QRC Stockholm, which is one out of six registry centers in the National Quality Registry Organization, was delegated the responsibility of coordinating the Swedish PROMs program and all related contacts with the EuroQol Research Foundation. This meant that QRC Stockholm was to grant support for appropriate collection and legal use of EQ-5D data by the registries and the health care providers in Region Stockholm as well as to be responsible for the sub-licensing and distribution of EQ-5D to all parties in the PROMs program. In addition, it was as part of the agreements decided that the Swedish parties should invest in a research program of mutual interest to the EuroQol Research Foundation, Region Stockholm, and the national quality registries. This program was called the “Swedish Research Program of Mutual Interest (SRPMI)” and was active from year 2016 to the end of year 2020.

Due to organizational changes, the outline of the research program was rewritten during 2017. The new research program focused on large-scale application of EQ-5D data and was approved by the EuroQol Executive Committee in February 2018. A specific service management project was also initiated in 2018 to fulfill the requirements of QRC Stockholm as a coordination center for the Swedish PROMs program. This project focused on strategies for facilitating the use of EQ-5D in daily practice as well as building knowledge, competence and IT solutions to make it easy and

patient safe to use the instrument for quality improvement and decision-making on micro, meso and macro levels in the Swedish health care system. In this final report, the organization and activities of the research program and the service management project are summarized.

Organization of the Swedish PROMs program

The Swedish Research Program of Mutual Interest (SRPMI)

A research team consisting of a new constellation of researchers working within the studies in the research program was formed. A research management team was appointed to lead the research program, have the responsibility to organize the work of the research team and maintain the communication with the EuroQol Research Foundation (e.g., communicating on the progress of the program). Further, a Scientific Advisory Committee (SAC) was formed to provide advice and direction to the research program regarding the research agenda and activities. The SAC met twice per year to discuss the plans and execution of the program in support to the research team.

Research Management

Bas Janssen, PhD, Primary Investigator, EuroQol Research Foundation
Emelie Heintz, PhD, Region Stockholm and Karolinska Institutet
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Research team

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David Parkin, PhD, Honorary Visiting Professor, City, University of London. Senior Visiting Fellow, Office of Health Economics. EuroQol Research Foundation representative

The service management project

The service management project aimed to increase the quality of the data collection within the national quality registries and facilitate the use of the instrument in the Swedish context. The project was managed by a project manager and several project members from QRC Stockholm were involved. In addition, the project had a steering committee with delegates from Region Stockholm. This committee made the strategic decisions regarding the project. Reporting of

progress and discussion of strategic questions related to EQ-5D within the Swedish PROMs program was handled by the management of QRC Stockholm.

Steering committee

Susanna Lagersten (Chair and Project owner), Director, Development Department, Region Stockholm

Inger Rising, Acting director, QRC Stockholm, Development Department, Region Stockholm

Riita Bendes, Director of Unit for Statistics and Health Care Analysis, Development Department, Region Stockholm

Kerstin Ankargård, Project manager, Service management project, QRC Stockholm, Region Stockholm

Project team

Kerstin Ankargård, Senior consultant. Project manager (2018-2019)

Hans Lindqvist, Health Informatician. Project manager (2018-2019)

Thomas Emilsson, Project member (2018-2019)

Lena Söderqvist, Communicator. Project member (2018-2019)

Emelie Heintz, Research manager, SRPMI. Project member (2018-2020)

Olivia Ernstsson, Project member (2018-2019)

Gunilla Jacobsson Ekman, Registry adviser. Project manager (2019-2021)

Eva Fredriksson, Registry advisor. Project manager (2019-2020)

Results from the Swedish Research Program of Mutual Interest (SRPMI)

The research program was structured into three themes: overview of EQ-5D data in the national quality registries, measurement properties of EQ-5D in specific disease areas and patient groups, and use of PROMs data to support decision-making and quality improvement in health care. In total, the project has resulted in the finalization of four research studies, which have been included in a PhD thesis [4]. The thesis was successfully defended on June 18th, 2021. Furthermore, the program has led to the initiation of several ongoing collaborations with the national quality registries and contributed to the funding of two additional studies conducted by other research groups.

To disseminate the findings and learnings from the program, the outcome of the program and the included studies have been presented on several occasions, nationally as well as internationally. Below, the outcomes of the program are described per theme and in terms of international collaborations and dissemination. As a final closure of the program, an end-user conference with invited speakers was organized in April 2021. The outcome of this conference is described below under the theme focused on use of PROMs data.

EQ-5D data in the national quality registries

A previous study showed that approximately 90 percent of the national quality registries included at least one PROM among their outcome measures in 2015, and that EQ-5D was the most frequently administrated PROM [3]. Nevertheless, there was no overview of how the registries collected, presented and used EQ-5D data. Such information is important to better understand the value of collecting EQ-5D data, but also to identify areas for collaboration between the registries and the overall need for methodological support. Thus, a project with the aim to describe the use of EQ-5D data collected within the national quality registries was initiated in 2018. The project resulted in a paper, which was published in the Journal of Patient-Reported Outcomes (JPRO) in December 2020 [5].

The study showed that 41 registries collected EQ-5D within the agreement [5]. Most frequently, EQ-5D was used to collect PROM data in registries related to the musculoskeletal system but data were also collected within registries related to conditions of the circulatory system, the nervous system, psychiatry, cancer, endocrine organs, infection, pediatrics, obstetrics and gynecology, stomach and intestines, and lung diseases. How often and when EQ-5D was measured varied between the registries. For example, EQ-5D data were in some registries collected before and after interventions, at inclusion in the registry with several follow-up points, or only at follow-up. In other registries, EQ-5D data were collected at every health care visit, annually, at specific ages, once per patient, or whenever the patient wanted to.

The data were analysed and made available on an aggregate level in the NQR's annual reports or websites, scientific publications, and in reports to the clinics regarding their own data with or without a comparison to the results of other clinics. Data could also be used by clinics on an individual patient level to inform care givers or the individual patients. Overall, about 54 percent (22/41) of the registries reported that data were used for follow-up, decision-making or quality improvement. The analyses were sometimes conducted per dimension and/or for EQ VAS but most registries reported index values. More details regarding the use of EQ-5D for these purposes is described under the theme for the use of PROMs.

Measurement properties of EQ-5D in specific disease areas and patient groups

Two studies were conducted within this theme. Furthermore, the activities within the research program have led to the initiation of other collaborations with the registries, which continued after the end of the program.

The first study was a qualitative study about how patients think and reason when responding to EQ-5D and a non-iterative experience-based time trade-off (TTO) question, in which the respondents' valued their own health. The study was published in Health and Quality of Life Outcomes in December 2020 [6]. Qualitative interviews were conducted with 20 patients with type I diabetes. The study showed variation in the use of time perspectives, comparators, and reference points between the assessments of health with EQ-5D-5L, EQ VAS and the experience-based TTO. For example, the respondents described a focus on current or past health when responding to EQ-5D and EQ VAS, but a focus on the future when responding to the TTO question. Another interesting finding was the reported difficulty with relating to the concept of full health in the TTO question due to the chronic characteristic of diabetes. The findings raise several interesting topics for investigation in future studies and may be used in the interpretation of results from the three kinds of assessments. It should also be noted that only 2 of 20 participants were willing to trade off any life years in the TTO question and that 9 participants did not report problems in any dimension even though 13 of them reported to have at least one other health problem in addition to diabetes. Whether this discrepancy may be explained by coping mechanisms or the design of the assessments remains to be further examined.

The second study was initiated in collaboration with the Swedish Amputation and Prosthetics Registry (Swedamp) with the purpose to assess the measurement properties of EQ-5D-3L and EQ-5D-5L in patients with a major lower limb amputation [7]. The overview of EQ-5D in the registries revealed that seven registries had changed from collecting data with EQ-5D-3L to EQ-5D-5L in the years 2017-2018. Nevertheless, there were to our knowledge few studies that have compared the measurement properties of the two versions of the instrument based on data from the registries. Two studies based on the Swedish Hip Arthroplasty Register (SHAR) had compared ceiling effects, distribution of responses, and correlations between the dimensions in the

descriptive system and EQ VAS for EQ-5D-3L and EQ-5D-5L and showed reduced ceiling effects when the newer version with five response levels was administrated [8, 9]. However, we were not able to identify any analyses of the informativity, convergent validity in relation to other PROMs, or known group validity of EQ-5D based on data from the Swedish national quality registries.

Swedeamp was one of the registries in which EQ-5D-3L was replaced with EQ-5D-5L in 2017 and there was an interest from the registry representatives in understanding whether this change had led to an improvement regarding the validity and informativity of the data. As the focus of the registry was to follow-up patients with limb amputations, the registry was particularly interested in the performance of the mobility dimension in which the wording in the most severe response level had been changed from “confined to bed” to “unable to walk about.”

To meet the purpose of the study, data for patients who had a major lower limb amputation between the years 2010 and 2018 and had responded either to the EQ-5D-3L or EQ-5D-5L were extracted from the SwedeAmp registry (n=685). The measurement properties were examined by comparing the instruments in terms of feasibility, distributional characteristics, and convergent and known group validity. The findings indicated that both EQ-5D-3L and EQ-5D-5L had satisfactory measurement properties in this patient group but that EQ-5D-5L performed better in terms of improved informativity and convergent and known group validity. These results are in support of the change from EQ-5D-3L to EQ-5D-5L as it seems to have improved the informativity and validity of the measurements of HRQoL in this patient population. The manuscript was submitted to an international peer reviewed journal in early 2021 [7].

The collaborations within the Swedish PROMs program have also led to the initiation of two additional studies within this theme. These have continued after the end of the research program. One is a collaboration with the Swedish Inflammatory Bowel Disease Registry (SWIBREG), which aims to assess the construct validity of EQ-5D among patients with Inflammatory Bowel Disease (IBD). Preliminary results have been presented as a master thesis and a paper will be submitted to an international journal during the autumn 2021. The second study encompasses a comparison of measurement properties of EQ-5D-3L and -5L in patients with rheumatoid arthritis based on data from the Swedish Rheumatology Quality Register. An application for co-funding from the EuroQol Research Foundation was approved by the Executive Committee in July 2021.

Use of PROMs data to support decision-making and quality improvement in health care

Research studies

The overview of EQ-5D data in the national quality registries showed several examples of how routinely collected EQ-5D data have been used at an aggregated as well as at an individual level [5]. For example, EQ-5D data have been used in the follow-up of interventions, health economic studies, quality indicators, benchmarking, quality improvement, and at the individual patient level. Thus, there were several examples of how data could be used for decision-making at all

levels of the health care system. The examples cover use in individual consultations with patients at the micro level and the assessment of care or specific interventions, which may influence decisions at a regional or national level. Nevertheless, a relatively large proportion (19/41) of the national quality registries collecting EQ-5D data reported that the collected data were to their knowledge not being used for any of these purposes.

Within this theme, the research program initiated a collaboration with one of the three national quality registries collecting EQ-5D data in the area of psychiatry: the Swedish National Quality Registry for electroconvulsive therapy (Q-ECT). This registry has been collecting data on EQ-5D-3L since 2011. The aim of the collaboration was to explore the application of EQ-5D to follow-up health outcomes of patients with unipolar or bipolar depression after treatment with ECT and the influence of different components in the ECT treatment on HRQoL. Treatment with ECT has previously been seen to have a positive effect in patients with severe depression [10, 11]. However, it is also associated with cognitive side effects such as temporary memory loss [10]. Previous studies based on data from Q-ECT have investigated health outcomes after ECT using clinical and disease-specific measures [12-14]. Nevertheless, there were few studies applying generic outcome measures such as EQ-5D, which could contribute with a holistic perspective of the treatment, including both the impact of treatment effects as well as the impact of adverse events.

The collaboration with Q-ECT resulted in two research studies [15, 16]. First, the research program contributed with methodological support in one study, in which it was investigated how HRQoL changed after treatment with ECT and if there were any differences between sex and age groups [15]. The study showed that there were statistically significant improvements in EQ-5D index scores and EQ VAS after ECT in all patient groups. The average increase in EQ-5D index score varied between 0.31 and 0.46 and the average increase in EQ VAS varied between 28 and 40. These improvements in HRQoL were even larger than improvements in HRQoL observed after total hip replacement [17]. The improvements in EQ-5D index score and EQ VAS score were larger among older than among younger patients but there was no statistically significant difference in improvement between the sexes. Due to the lack of control group and the limited follow-up period, it remains to be further investigated how much of the improvements in HRQoL that may be explained by the treatment with ECT and if the improvements are maintained in a longer perspective.

In the second study, EQ-5D data for more than 5 000 individuals included in the Q-ECT were used to examine the association between the pulse width received in the first ECT session and HRQoL after ECT. Pulse width is one of the parameters that may be adjusted in the ECT treatment with the intention to maximize treatment effect and reduce cognitive side effects [18, 19]. However, there is relatively few studies regarding the influence of pulse width on the effect of ECT, especially in terms of the effect on HRQoL. As in the previously mentioned study in collaboration with Q-ECT, improvements in HRQoL after ECT were relatively large in all subgroups but no robust association was found between pulse width and patients' HRQoL after

ECT. It remains to be investigated if this is due to a lack of sensitivity of the EQ-5D-3L or if the level of pulse width has no impact on the effect on HRQoL resulting from the treatment. Other factors influencing the choice of pulse width should also be further investigated.

In an additional study based on data from the National Quality Registry Multiple Sclerosis (MS), a member of the research team provided methodological support regarding the analysis of EQ-5D data. The study was published in the international journal *Neurology* in 2020 [20]. The aim of the study was to evaluate quality of life in adults with pediatric-onset multiple sclerosis (POMS) or adult-onset multiple sclerosis (AOMS) and to explore determinants of quality of life in both these groups. In total, data on EQ-5D from 5,094 individuals and 22,357 individual EQ-5D scores were included in the study. The results showed that lower quality of life was associated with experiencing a relapse, severe neurologic disability, and higher Multiple Sclerosis Impact Scale (MSIS-29) psychological score. Thus, it provides support for a focus on reducing neurological disability and improving psychological status to improve the patients' quality of life.

Workshops and seminars

In 2018, a workshop and a seminar were organised by QRC Stockholm in collaboration with members of the EuroQol group (Bas Janssen, Nancy Devlin, David Parkin and Gouke Bonsel). The workshop was titled "How do we make better use of EQ-5D data?" and the target group were representatives from the national quality registries working with analysis and use of EQ-5D data from the registries. Representatives from eight registries participated in the workshop together with the Swedish research team and the EuroQol members. The purpose of the seminar was to increase knowledge about how PROMs can be used as outcome measures in quality improvement and the follow-up of health care. It was primarily directed to persons who was working with, or who were interested in the use of, PROMs within Region Stockholm, but also targeted persons working with PROMs in the national quality registries, or who were working with PROMs as a tool for follow-up of health care at a national level. A total of 110 persons signed up for the seminar which was also broadcasted at the website of QRC Stockholm.

End-user conference 2021

To summarize and disseminate the learnings from the Swedish PROMs program, an end-user conference was held on April 16th, 2021. The target group consisted of persons working in the national quality registry organisation or in the national system for knowledge management and other interested persons working within the health care regions. In total, 205 persons signed up for the conference (Figure 1). Of these, approximately 30 percent were from the national quality registries and approximately 40 percent were from the health care providers (health care regions).

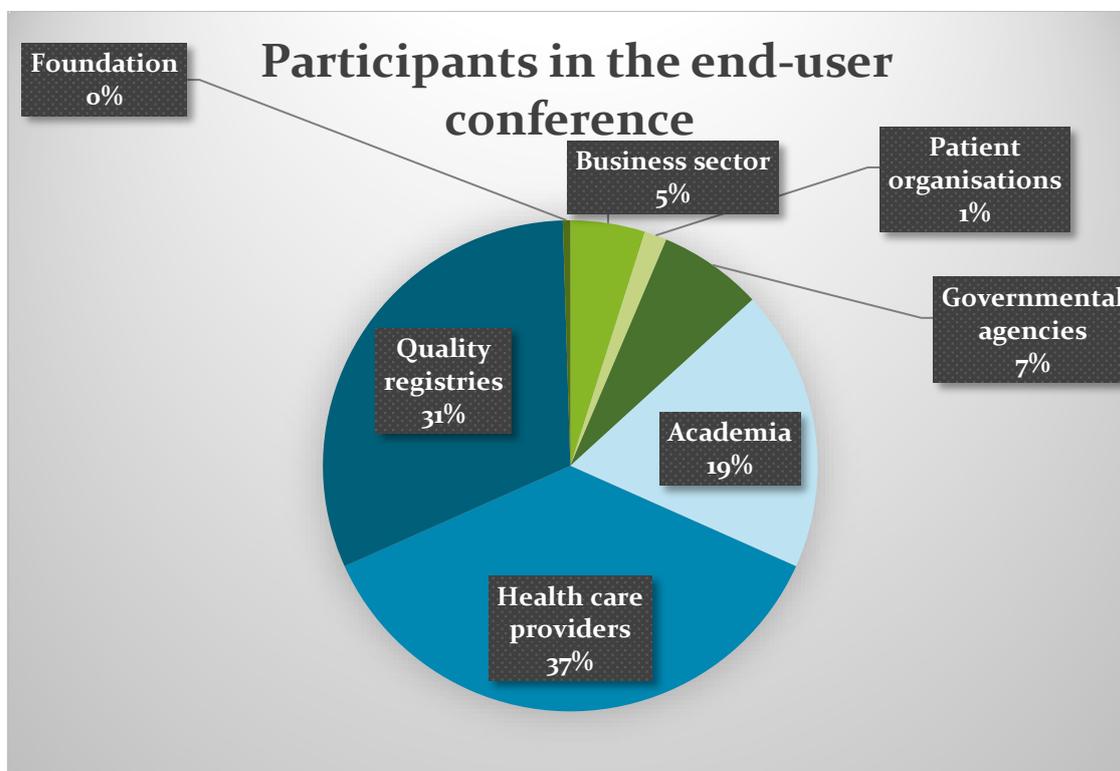


Figure 1. Participants in the end-user conference

Representatives from the Swedish PROMs program opened the conference and presented results from the research program. To complement the work and findings from the Swedish PROMs program, invited external speakers shared their experiences from working with PROMs and/or specifically EQ-5D. Professor Joanne Greenhalgh was invited as a keynote speaker to share her knowledge about when and how feedback of PROMs data can lead to improvements in patient care. Furthermore, two speakers having conducted studies on EQ-5D in the national quality registries were invited to share examples of how EQ-5D data can be used to assess the impact of a value-based reimbursement and of the usefulness of EQ-5D and the Paretian classification system among patients with chronic heart failure [21, 22]. Speakers from the Swedish Rheumatism Association and the Swedish Association of Local Authorities and Regions (SALAR) contributed with their perspective on the use of PROMs in Swedish health care. The EuroQol Research Foundation was also invited to present the organisation and introduce the audience to potential opportunities for collaborations with the organisation. The conference ended with a discussion about important findings, and necessary actions for future use and studies of PROMs in routine health care.

The audience was on several occasions during the conference invited to contribute with their experiences in different polls. At the beginning of the conference, they were asked about their experience of PROMs (Figure 2). Of 96 respondents, about 50 percent of the conference

participants responded that they had experience of analysing PROM data and about 45 percent that they had experience of collecting PROM data to a quality registry or a study. In addition, 30 percent reported that they had used PROM data from other sources in their own work and about 20 percent reported that they had used PROM data in consultations with patients. Further, about 40 percent of the participants reported that they had experience of responding to questionnaires regarding their own health.

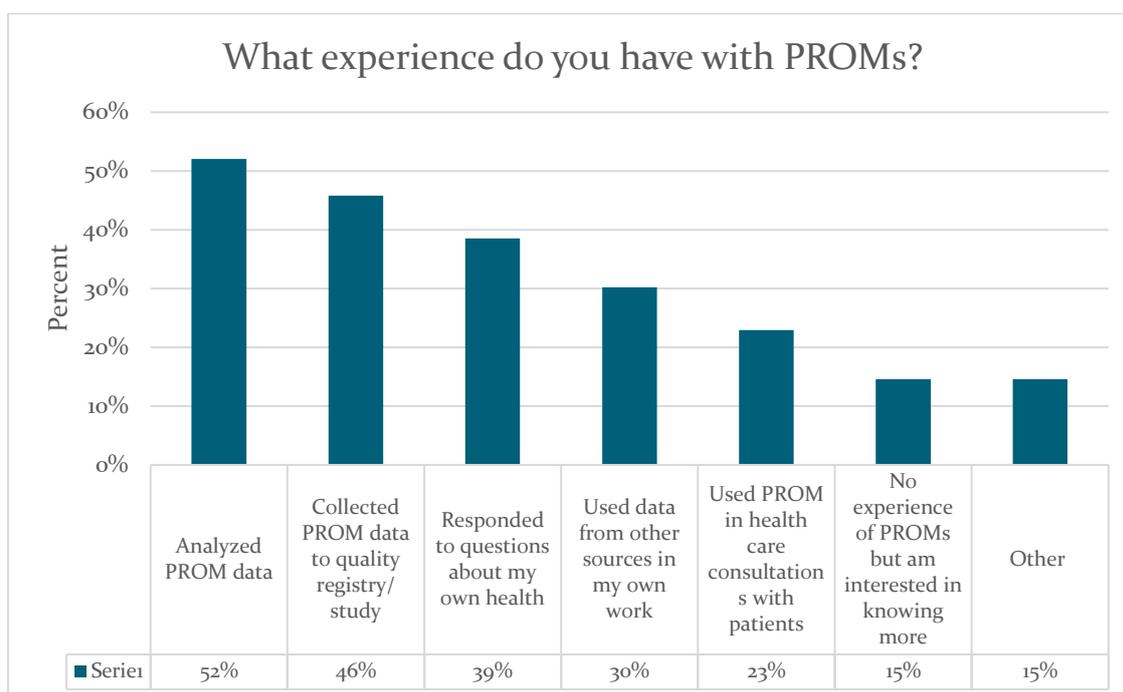


Figure 2. Audience response regarding experience of PROMs (96 respondents).

At the end of the conference, the audience was consulted regarding their view of what would be needed for an optimal use of PROMs in health care (Figure 3). Of 45 respondents, approximately 80 percent responded that there was a need for the involvement of users (patients, health care professionals, decision makers) in the selection of PROMs. Further, about 75 percent responded that there was a need for methodological support regarding analysis and interpretation of data and for tools for collecting and compiling PROM data. In addition, about 60 percent responded that there is a need for better coordination between stakeholders. More accessible PROMs and more knowledge about PROMs was requested by about 40 percent of the persons in the audience.

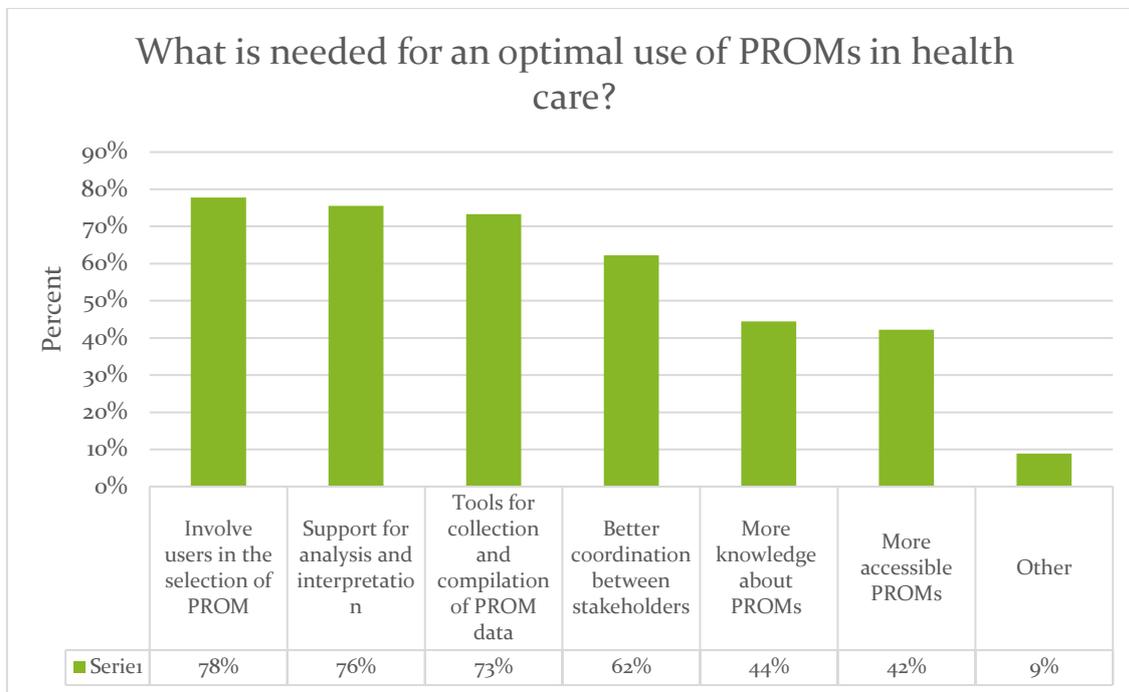


Figure 3. Audience response regarding needs for an optimal use of PROMs in health care (45 respondents).

Other studies related to the Swedish PROMs program

A study conducted by researchers in another research group at Karolinska Institutet was also funded by Region Stockholm within the agreement. This study was part of the research program before the shift of focus in 2018 and contained analyses of EQ-5D profile data and EQ VAS scores across patient groups in the national quality registries [23]. Further, Region Stockholm did, as part of the agreement, contribute with funding to a study with the purpose to create a Swedish value set for EQ-5D-5L. The study was conducted by Umeå University and co-funded together with the EuroQol Research Foundation. Approximately 800 individuals were recruited to the study through their membership in associations, such as sports associations, cultural associations, and associations for senior citizens. The interviews were conducted physically or digitally using the EQ VT protocol. The data collection for the study was finished during late Spring 2021 and a manuscript presenting the new value set is expected to be submitted to an international peer reviewed journal by the end of 2021.

International collaborations

The researchers in the research program had several international contacts with the purpose to exchange knowledge and experiences of routine outcome measurement with PROMs in health care.

Collaboration with Alberta PROMs and EQ-5D Research and Support Unit (APERSU)

The research management team visited the Annual APERSU End-user Conference in Edmonton October 2018 to present the Swedish national quality registries and the Swedish PROMs program and take part of the work by the APERSU team. This visit identified several common challenges and opportunities for collaboration. The visit resulted in a research exchange visit by a PhD student in the Swedish team. From August to November 2019, PhD student Olivia Ernstsson visited the APERSU team in Edmonton, Canada. The visit was made possible by a travel grant from the EuroQol Research Foundation and provided opportunities to present and discuss the research of the PhD student, as well as to participate in other research activities (e.g., meeting, workshops, journal clubs) together with researchers in the APERSU team. The research visit also provided opportunities to exchange experiences and ideas between the research groups in Stockholm and in Edmonton, for example regarding how the research groups work with large scale application of EQ-5D at different levels of the health care system. Furthermore, the PhD student attended the Annual APERSU End-user Conference, which covered interesting presentations and examples on the use of PROMs, and how it can stimulate quality improvement in health care. As a result of the visit, a senior researcher in the APERSU was invited to be a co-author of one of the papers in the PhD thesis. Furthermore, a member of the Swedish team was invited to present the Swedish PROMs program as part of a panel organized by APERSU at a meeting by the Canadian Association for Health Services and Policy Research (CAHSPR). The outputs of the collaboration are listed below:

- Presentation about the PhD project and the research program at APERSU, University of Alberta, Edmonton, Canada (October 2019)
- Oral presentation in a panel organized by APERSU at the 2019 Annual CAHSPR Conference in Halifax, Canada (May 2019). Title of panel: “Putting Patients at the Centre of Health Care: The use of patient-reported outcome measures (PROMs) in the Healthcare System
- Oral presentation of the Swedish National Quality Registries and the Swedish PROMs program at the 4th Annual APERSU End-user meeting in Edmonton, Canada (11-12th October 2018)

Collaborations with the EuroQol group

A member of the research management team was appointed a member of the Populations and Health Systems Working Group (previously Large-Scale Applications Working Group) in the EuroQol Group. This implied participation in activities related to the use of EQ-5D as a PROM, such as the development of a research agenda in this field and the review of applications for funding of studies. Further, the collaboration resulted in the following activities:

- Presentation (discussant) and poster presentation at the EuroQol Early Career Researchers meeting in Prague, Czech Republic (March 2020)
- Presentation about the research program at the International Meeting for Health System PROMs users at the EuroQol Plenary meeting (September 2019)
- Visit at QRC Stockholm by the co-chairs of the Large-Scale Application Working Group, Gouke Bonsel and Bas Janssen (March 2018)
- Representatives for the EuroQol Research Foundation were part of the SAC and participated in SAC meetings approximately two times per year. The SAC met physically in Stockholm twice during the active period of the program. The SAC had the opportunity to give feedback on activities within the program, study plans and the progress of the studies.
- The EuroQol members in the SAC contributed to the workshop directed to the national quality registries and the PROM seminar in 2018.

Examples of other international activities

The research team presented the Swedish PROMs program at several other international meetings listed below:

- Presentation about the results from the overview of EQ-5D in the national quality registries and the qualitative study on EQ-5D and TTO at the Institute of Health Economics, Edmonton, Canada (October 2019)
- Presentation of the national quality registries and the Swedish PROMs program at the Institute of Health Economics in Edmonton, Canada (10th October 2018).

- Presentation about the research program at meeting with representatives from the Norwegian quality registry centres (“Nasjonalt servicemiljø for medisinske kvalitetsregistre”) (June 2019)

Invited talks and conference contributions in Sweden

The research team was invited to present the program at several national meetings. During the active period of the program, the program and the findings of the studies were presented at several of the national quality registries’ board meetings or PROM meetings and at meetings with national agencies. The aim of attending these activities was to inform about the methodological support, the research program and to find possible collaborators.

Examples of presentations directed to national stakeholders

- Presentation about the collection and use of EQ-5D for research and follow-up of health care at a research conference organized by the Swedish Association of Local Authorities and Regions (“SKLs forskningskonferens”) (May 2019)
- Presentation about PROMs and the research program at the Swedish Agency for Health and Care Services Analysis (“Vårdanalys”) (February 2019)
- Presentation of the Swedish PROMs program at Swedish Agency for Health Technology Assessment and Assessment of Social Services (September 2018)

Examples of presentations directed to national quality registries

- Presentation about EQ-5D in the national quality registries at the National Quality Registry for Pain Rehabilitation (NRS) Research Meeting (November 2019)
- Presentation of the Swedish PROMs program at the annual meeting of the National Quality Registry for Neurological Care (February 2019)
- Presentation of the Swedish PROMs program for the directors of the six regional quality registry centers (January 2019)
- Presentation of the Swedish PROMs program at a meeting of the PROM group of the National Quality Registry for Cardiopulmonary Resuscitation (January 2019)
- Presentation of the Swedish PROMs program at a meeting of the national quality registries’ PROM network (December 2018)

Examples of other activities

The research team was also active in several other activities:

- An abstract for the SwedeAmp study (Study 3) was accepted for presentation at a conference organized by the Swedish Health Economics Association (March 2020). However, the conference was later cancelled due to the COVID-19 pandemic.
- Presentation about using EQ-5D to measure and value health in the doctoral course “Quality of Life as an outcome measure in care sciences” at Karolinska Institutet (January 2020)

- Presentation about EQ-5D in the national quality registries at the conference organized by the Swedish Health Economics Association (March 2019)
- Presentation of the Swedish PROMs program at seminar organised by Vinnvård and Region Stockholm (September 2018)
- Presentation of the Swedish PROMs program at the annual workshop of PMhealth – the national network for Psychometrics and metrology within health sciences (June 2018)
- Presentation of the Swedish PROMs program for colleagues at QRC Stockholm (April 2018)
- Presentation of the Swedish PROMs program at the Centre for Medical Technology Assessment, Linköping University, (February 2018)

Results from the Swedish EQ-5D Service Management Project

Within the responsibility of being a coordination center for the Swedish PROMs program, the Service Management Project had the assignment to:

- Coordinate the sub-licenses signed by the national quality registries.
- Distribute the different versions of EQ-5D to the quality registries. The sub-licensing agreement meant that the quality registries had access to the paper versions of EQ-5D-3L, EQ-5D-5L and EQ-5D-3L-Y (children's & youth version) in several different languages.
- Provide user support and methodological guidance to the end-users
- Provide a valid digital service for EQ-5D that was approved by the EuroQol Research Foundation to the national quality registries.
- Deliver a plan for the future service management of EQ-5D (after 2020).

This project was not a formal part of the research program but was expected to add additional value to the Swedish parties as well as the EuroQol Research Foundation. This was done by focusing on strategies for facilitating the use of EQ-5D in daily practice as well as building knowledge, competence, and IT to make it easy and patient safe to use the instrument for development and decision-making on micro, meso and macro level in the Swedish health care system. The project had the aim to increase the quality of the data collection within the national quality registries and facilitate the use of the instrument in the Swedish context.

Sub-licenses and administration of EQ-5D

At the end of 2020, 39¹ of the 106 national quality registries had signed a sublicense for the collection of EQ-5D data. Most of them collected data with EQ-5D-3L (n=30) but some of them also collected data with EQ-5D-5L (n=14). In addition, several registries were collecting data with EQ-5D-Y and the two proxy-versions (n=5). Apart from EQ-5D in Swedish, EQ-5D in the following 21 languages were used:

Arabic, Arabic (Israel), Arabic (Lebanon), Bosnian, Chinese, Croatian, Danish, English, Farsi, Finnish, French, German, Greek, Icelandic, Norwegian, Polish, Romanian, Russian, Serbian, Slovakian, Spanish, Swedish (Finland), and Turkish.

Upon the end of the licensing period December 31st, 2020, a routine was set up together with the EuroQoL Research Foundation in order to secure a good licensing process for the continuation of

¹ Discrepancies between the numbers reported here and in the results from the published overview reported in the section about the research program are explained by some licenses being signed after year 2018 and that the Swedish Neuro Registry has one license for all subregistries.

collection of EQ-5D data by Swedish national quality registries, as well as by Swedish health care providers. The routine has been implemented and is published on QRC Stockholm's web site.

User support and service management

One of the aims of the service management project was to increase the knowledge about EQ-5D by teaching and providing methodological support to the end-users (the national quality registries and Region Stockholm). This was done in collaboration with the research program. During 2018, the project team has:

- Created a web page with information about EQ-5D, the research program, support to end-users, and Frequently Asked Questions (FAQ)
- Introduced a support function for end-users of EQ-5D.
- Provided user support. The cases handled were customer inquiries regarding issues such as agreements, research, use of EQ-5D, and web services. The team also provided support to users who wants to use the Swedish digital EQ-5D.

The Swedish EQ-5D digitalization project

Prerequisites, design and future use of a Swedish digital EQ-5D client was investigated in collaboration with tech vendors of the Swedish quality registries and the Swedish national infrastructure for health care communication; Inera/1177. The digital EQ-5D client was prepared and developed together with Inera and put into production during Spring 2019. At the end of 2020, digital versions of EQ-5D-3L, EQ-5D-5L and EQ-5D-Y were available. The digital EQ-5D client was introduced through a pilot project, followed by workshops and user support. The service was at the time of writing this report managed by Inera/1177 through licensing by the EuroQoL Research Foundation.

Upon the end of the licensing period (December 31st, 2020), the routine and layout established together with Inera/1177 and the EuroQoL Research Foundation was documented and used as a template for digital EQ-5D versions developed by other vendors providing electronic forms to national quality registries as well as health care providers. The routines have been implemented and are published on QRC Stockholm's web site.

Implications and recommendations for future collection and research

The Swedish PROMs program had several implications for the collection and use of EQ-5D from the national quality registries. First, the service management project and the overview of the collection of EQ-5D data in the registries have contributed with increased knowledge of the current collection and use of EQ-5D in Swedish health care. The overview may facilitate future collaborations and inspire new research based on the available data. The service management project has also facilitated a correct use of the instruments by providing support regarding the license and administration of the instruments as well as methods for analyzing data. For example, the service management team has provided guidance regarding available versions of the instrument, choice of value sets and alternative ways of presenting data. Presentations and individual contacts with stakeholders have also led to increased knowledge about what the EQ-5D is and for what purposes it can be used. As supported by the audience engagement at the end-user conference, this kind of central methodological support would also be of value to improve the quality of the collection and analysis of other PROMs. Thus, further initiatives to support the use of PROM data from the national quality registries are recommended to consider the implementation of a continuous methodological support function for PROMs in general.

An important finding from the work within the program is that EQ-5D data from the national quality registries are used for several different purposes, at an individual as well as an aggregate level [5]. The EQ-5D was originally developed for use in economic evaluations but there has been an increasing interest in the use of EQ-5D as a PROM to follow-up quality of health care [24]. Thus, the use of EQ-5D data from the national quality registries in patient consultations, benchmarking and quality indicators may constitute interesting cases for further study. To improve the current use of EQ-5D data, alternative methods for analysis may be considered, such as focusing less on the index values and more on the five dimensions or EQ VAS as well as adjusting for case mix when comparing the results of different units or regions.

Another interesting finding was that almost 50 percent of the registries were unaware of any use of the EQ-5D data from the registry for quality improvement or decision-making. A possible explanation for this limited use of collected data can be that the quantity and quality of the collected data still need to increase for an analysis to be meaningful. However, there are established guidelines for how to successfully implement PROMs in clinical practice, which may be useful to increase the use of data from the national quality registries [25, 26]. The authors of the guidelines have identified practical challenges and barriers related to the implementation of PROMs and include recommendations for how to deal with these. An important starting point in their recommendations is to formulate a clear purpose of the collection that can be communicated to, and supported by, the involved stakeholders (patients, clinicians, administrative staff and others) [26]. For national quality registries that have not yet started the

data collection, this will be useful to guide the choice of PROM(s) and plan for analysis. In this case, it is recommended to involve patients and clinicians in the choice of PROM, which is also supported by the audience input at the program's end-user conference. For the registries that have already started the collection, it will still be useful to formulate a clear purpose to improve the collection of the data and motivate patients and clinicians to contribute to the collection. The guidelines also contain recommendations for what to consider when deciding on how often the questionnaires should be completed, how the PROMs will be administered and analysed, what tools to use to aid interpretation, to whom and how the data will be presented, how to respond to issues identified through the PROM assessments, and how the value of using PROMs will be assessed.

Another important consideration when choosing a PROM is the measurement properties of the instrument in the specific patient population [25, 26]. This is usually investigated by searching for previous studies of the feasibility, reliability, responsiveness, and validity of the outcome measure in the population of interest. However, the extensive collection of PROM data in the registries also constitute an important opportunity to investigate the measurement properties of EQ-5D and other PROMs in the patient populations covered by the registries. The Swedish PROMs program included one such study of EQ-5D based on data from the Swedeamp registry and two similar projects have been initiated in collaboration with SRQ and SWIBREG. Nevertheless, there are to our knowledge only a few previous studies of the measurement properties of EQ-5D based on data from the national quality registries [8, 9]. Thus, psychometric analyses of data from several of the other national quality registries could contribute to the evidence regarding the measurement properties of EQ-5D and inform the registries' own choices of PROMs. If the studies show that EQ-5D can be considered to have good measurement properties in the population, these results may strengthen the motivation to continue the data collection. In contrast, poor measurement properties may support the choice of another instrument.

As it is an important strength of EQ-5D that it enables the comparison of HRQoL across disease areas as well as the calculation of quality-adjusted life years (QALYs) for use in health economic evaluations, increased use of the collected data for these purposes should be encouraged. For example, the collection of EQ-5D data in the national quality registries may constitute an important input to the assessment of health economic consequences of the national large-scale quality improvement initiatives² that are developed within the National system for knowledge-based management. Yet, if the data is to be used for such purposes, the measurements properties of EQ-5D as well as the completeness and quality of the EQ-5D data must first be investigated.

In conclusion, the program has contributed to an increased understanding of the collection of EQ-5D in routine health care in Sweden and provided administrative and methodological support

² An example is the development of person-centered and coordinated care pathways in different disease areas.

support to the national quality registries and Region Stockholm. Nevertheless, it is recommended for future initiatives to support the use of PROM data from the registries to focus on the establishment of a more permanent methodological support function directed to the collection of PROMs in general. The studies included in the program have contributed to the scientific literature regarding measurement properties and applications of EQ-5D. Several areas for further study have been identified and the collection of EQ-5D data in the national quality registries may constitute an interesting case for further assessment of measurement properties in the populations covered by the national quality registries as well as of how different uses of EQ-5D may influence decision-making and improve patient health.

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Appendix A. The Swedish Research Program of Mutual Interest (SRPMI) (approved by EuroQol Research Foundation in February 2018)

Swedish Research Program of Mutual Interest (SRPMI)

The Swedish Research Program of Mutual Interest (SRPMI) will be conducted in 2016-2020, according to the Sweden-EuroQol Research Foundation (ERF) agreement about the use of EQ-5D within the Swedish PROMs Program (SPP), a program which supports the use of patient-reported measures within the Swedish National Quality Registries (NQR).

The Swedish NQRs have been developed in order to be used in an integrated and active way for continuous learning, improvement, research and management, to create the best possible health and care, together with the patient. Over 90% of the National quality registries include some form of patient-reported measures, and EQ-5D is the most common instrument used. There are just above 100 NQRs and about 35% of them use the EQ-5D, most commonly together with other patient-reported measures (12 use EQ-5D-5L, 26 use EQ-5D-3L, 3 use EQ-5D-Y). NQRs are obliged to include patient-reported measures to be certified at a high level (and obtain more funding). Some of this data is to some extent already being used to inform decision makers at different levels in the health care system. For example, patient-reported data are integrated in patient overviews used in clinical encounters for shared decision-making with patients regarding their further care and choices of treatments. However, there is still a great need of finding ways of using and presenting the collected EQ-5D data, if this rich data material is to reach its full potential in contributing to quality improvement and improved decision-making, especially at the managerial level.

EQ-5D is also a common instrument in Swedish health care in general. County councils, being the main health care providers in Sweden, may make agreements in accordance to the main Sweden-ERF agreement. As EQ-5D is the most common patient-reported outcomes measure in the Stockholm County Council (SCC) today, SCC is the first county council to have made such an agreement, regulating the use of EQ-5D within the county council in addition to the use regulated by the main agreement. All health care providers in SCC report information on care events, which is then registered in the SCC health databases. Thus, the SCC databases include data for follow up on medical information, including health outcomes measured by EQ-5D, and financial information of produced care in the Stockholm County Council.

The main scope of the SRPMI is to further explore ways of using EQ-5D data as a means for quality improvement in routine health care. Thus, the SRPMI has a focus on large scale application and use of health data for decision-making at different levels in routine health care. This area was chosen to be of mutual interest for Sweden and the international EuroQol research society.

The availability of large scale data through the NQRs and the SCC health data base provides a unique opportunity for investigation of PROMs and health state values, over time and between patient groups. The SRPMI will make use of this opportunity and focus on the validation and application of EQ-5D in this context. The project will meet the aims of the ERF Large Scale

Applications Working Group (LSA WG) to initiate requests for proposals that promote and examine large-scale health system applications for EQ products, to stimulate methodological and applied research relating to the use of EQ-5D in measuring local and system-wide performance, as well as its use in assessing population health, and to focus on applications within healthcare systems.

Organization

The SRPMI has a Principal Investigator (PI), M.F. (Bas) Janssen, PhD, (ERF, The Netherlands), assisted by a Swedish Research Management Team (RMT).

The Scientific Advisory Committee (SAC) will provide support regarding the focus, strategy, and projects within the SRPMI. The SAC consists of representatives from the ERF as well as from different Swedish stakeholders, and is chaired by the representative of the NQRs, Professor Jack Lysholm, the Office of the National Quality Registry Organisation, Stockholm, and Umeå University.

EQ-5D is distributed to the NQRs and to the users within SCC by the Quality Registry Center (QRC) Stockholm, SCC.

The PI is appointed by the head of QRC Stockholm on behalf of both the NQR organisation and the SCC. The appointment must be approved by the ERF to be effective. QRC Stockholm has the right to replace the PI, effective immediately, and the PI also has the right to leave its position with immediate effect. The ERF must be kept informed during the whole re-organisation process, and must approve of the new organisation for it to be effective.

The RMT is appointed by the head of QRC Stockholm after approval from the PI. Members of the RMT may vary in different phases of the SRPMI.

The members of the SAC are appointed in agreement by the head of QRC Stockholm and the ERF, and the work in the SAC is regulated by the SAC Terms of References.

Use of EQ-5D data from the Swedish NQRs and the SCC health databases to inform decision-making in the Swedish health care system

Project overview

The focus of the program is the use of large-scale application of EQ-5D data from the Swedish NQRs and the SCC health databases to inform decision-making in the Swedish health care system. The work within the program will be done in collaboration with the NQRs and/or other potential users of EQ-5D for decision-making in Sweden (county councils, the Dental and Pharmaceutical Benefits Board, National Board of Health and Welfare etc.).

All quantitative data to be used in the SRPMI is already collected by the NQRs and the SCC. All NQRs interested in using the EQ-5D have signed an agreement committing to supply EQ-5D data to the SRPMI without any fees. Similarly, EQ-5D data in the SCC is available through the SCC-EQF agreement. A list of the 34 NQRs currently using EQ-5D within the agreement can be found at the end of this document (Table 1). More registries may sign the agreement within the coming year. In addition, qualitative data on how patients think and reason when answering EQ-5D-5L and valuing own health using TTO will be collected through qualitative interviews.

The time that EQ-5D data has been collected varies between registries. However, several registries have collected data for at least three years. Thus, this constitutes a unique opportunity to investigate longitudinal data. In addition, the simultaneous collection of data on clinical measures and other PROMs enables the investigation of psychometric characteristics of EQ-5D (both 3L and 5L) and the mapping of other disease-specific and generic PROMs towards EQ-5D. Apart from EQ-5D, the NQRs contain data on many other outcome measures such as generic measures (e.g. RAND-36, SF-36), condition- or disease specific measures (about 100 different measures, e.g. EORTC QLQ-C30, HADS, Stroke Impact Scale-16, FSS, MSIS-29), patient reported experience measures (e.g. TSQ), as well as profession-reported and clinically relevant measures depending on the patient group. Several NQRs plan to implement and validate the Patient Reported Outcome Measure Information System (PROMIS), which is currently being translated into Swedish.

Below, there is an outline of the key areas of the program. The projects within the program will operate within the subthemes. However, they will, due to the limited time and resources, not be able to cover all of these. In addition, even though NQR and SCC data are known to be of high quality data, quality may vary between registries. Thus, there is a need to carefully examine the quality of the data before we decide on the specific research questions. Consequently, the work within the program will start with an overview of how PROMs data in the registries and data bases are currently collected, administered, and used by decision makers. This type of overview may also help other researchers or decision makers make better use of the data in the registries.

Criteria for prioritizing between projects based on data in the NQRs and the SCC health data base:

- Relevance to the NQRs and decision makers' interests and priorities
- Alignment with the ERF's interests and research priorities
- Coverage and data quality in the NQRs and the SCC database

Topics to be addressed in sub-projects during and/or after the agreement period

1. **Overview of PROMs data in the NQRs and in the SCC health data bases**
 - An overview will be conducted regarding how PROMs data in the registries and data bases are currently collected, administered, and used by decision makers in clinical practice and at a regional (county councils) and national level.
 - **Deliverables:**
 - A NQR PROM report in Swedish and English, presenting the results of the overview (2018)

2. **Use of PROMs data (with a special focus on EQ-5D) to support decision-making and quality improvement in health care**
 - **Subthemes:**
 - How to analyze, present and communicate EQ-5D data (and complementary health data) to better support decision makers and quality improvement in health care
 - Reported HRQoL, as measured by EQ-5D-3L and EQ-5D-5L, in specific patient groups, by sex, age, and disease severity (e.g. for the purpose of developing population/norms data for specific patient groups)
 - Mapping from non-preference-based PROMs to EQ-5D response levels
 - Use of NQRs and SCC health data bases to follow-up, complement, and/or validate costs and effects on HRQoL of specific health care interventions or programs
 - **Proposed methods:** These projects will be conducted in collaboration with the NQRs and/or potential decision-makers (e.g. the Dental and Pharmaceutical Benefits Board, the National Board of Health and Welfare, the county councils). There is already work in progress to better visualize NQR data at large. Thus, it will be possible to participate in that work and develop it further regarding patient-reported data, in collaboration with the NQRs. Relevant areas where EQ-5D data from the registries can be used to improve decision making will be identified together with the registries and decision makers. The analyses will be based on data from relevant NQRs and the SCC database.
 - **Deliverables:**
 - A minimum of two scientific papers (each covering one of the potential research questions above) submitted to peer reviewed journals (one in 2020 and one at latest 2021)
 - Two abstracts submitted to EuroQol meetings (one in 2019 and one in 2020)
 - A Swedish NQR PROM report (summary in English) with examples of how EQ-5D data from NQRs can be analyzed, presented and communicated to better support quality improvement in health care (2019)
 - 1-2 workshops on specific topics relating to large scale collection/use of EQ-5D data

3. **Psychometric properties of EQ-5D in specific disease areas and patient groups**
 - **Subthemes:**
 - Other factors than health status influencing patients' reporting of HRQoL using EQ-5D (qualitative study)
 - Validity and reliability of existing versions of EQ-5D in specific patient groups, or other subgroups

- The influence of additional dimensions (bolt-ons) on the validity of EQ-5D in the patient groups covered by the registries
- **Proposed methods:** The proposed research questions can be investigated using both qualitative and quantitative data. Patients with diabetes type I will be invited to participate in qualitative individual interviews that will be guided by a semi structured interview guide, and the collected data will be analyzed using qualitative content analysis. Quantitative data will be collected from the NQRs and SCC database. Validity and reliability of the current versions of EQ-5D may be investigated by analyzing EQ-5D data in relation to clinical measures, and in relation to disease-specific and other generic PROMs from National Quality Registries (NQRs). Further, different language versions may be investigated by comparison of Swedish data to collected EQ-5D data in other countries. The need for additional dimensions could be investigated by analyzing whether additional items would improve the sensitivity/responsiveness of EQ-5D to differences/changes in health status.
- **Deliverables:**
 - A scientific paper describing the results of the qualitative study submitted to a peer reviewed journal (submitted 2018)
 - A minimum of one additional scientific paper (covering one of the potential research questions above) submitted to a peer reviewed journal (at latest 2021).
 - Two abstracts submitted to EuroQol meetings (one in 2018/2019 and one in 2020)

Budget

The budget covers € 65.000/year according to the NQR-EQF agreement and additional € 30.000/year through the SCC-EQF agreement in accordance with the main agreement regarding the NQRs, i.e. the SRPMI is fully funded by Sweden. Costs mainly pertain to personnel costs (for the RMT, the PhD student, and supervision of the PhD projects). As the studies will be performed on existing data from the NQRs, it is expected that no additional funding is needed. However, the RMT will, in addition to the projects within the budget of the SRPMI, explore the possibility to initiate collaborations with interested members of the EuroQol Research Foundation on topics related to the program. For these studies, proposals for additional funding from the EuroQol Research foundation may be submitted.

Timelines

Several of the planned studies will be part of a PhD trajectory during the years 2016-2021 and the papers will be submitted to peer reviewed journals during this period. In addition, two NQR PROM reports will be delivered 2018-2019.

Specific project plans

Specific project plans will be developed by the PI and the RMT for each sub-project in cooperation with the SAC.

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