PRO-active; Digital Health literacy in Patient Reported Outcome Concepts

Background

Patient Reported Outcome (PRO) concepts – defined as "any report coming directly from the patient about a health condition and its treatment" (U.S. Department of Health and Human Services FDA 2006) - is increasingly becoming a part of routine health care services for a wide range of long term conditions (Chen, Ou, and Hollis 2013; Kotronoulas et al. 2014). Especially in the sense of standardized, validated questionnaires (either generic or disease specific) that measures patients' perception of their health situation (Kingsley and Patel 2017).

PRO measures in clinical practice can both serve as a 1) screening tool where it is anticipated to have the potential to detect patient complications, or as a 2) clinical monitoring tool used to monitor the impact of treatment and facilitate doctor-patient communication (Greenhalgh 2009; Valderas et al. 2008).

Both as screening tool and monitoring tool PRO measures is anticipated to facilitate patient involvement, support patients in self-managing chronic conditions, and increase health literacy (Greenhalgh 2009).

Digitalized PRO is utilized increasingly as more of our health care system is becoming digitalized. This enables the patients to answer questions about their experienced health situation without presence of a health care worker on a computer or smartphone (Chen, Ou, and Hollis 2013). This requires technical competence, patient independence and self-care, engagement and motivation, and altered expectation to the treatment (Norgaard et al. 2015).

While the use of digitalized PRO may give pronounced benefits with regards to patient empowerment and health care (Chen, Ou, and Hollis 2013; Kotronoulas et al. 2014) a limitation is that some patients seem to benefit from this approach to a larger degree than others onto the point where some patients don't engage in PRO at all (Schamber et al. 2013). This has the risk to enlarge the social gap in health care rather than close it (ViBIS 2016) The Danish Health Data Board has initiated a national implementation of PRO data (Finansministeriet, Danske Regioner, and Kommunernes Landsforening 2017)- One of the implementations are at Diagnostic Centre, University Research Clinic for Innovative Patient Pathways, Silkeborg Regional Hospital. Here, PRO data is used in a range of ways in routine practice. Patients with chronic inflammatory bowel disease get registered in the PRO set up. PRO data may replace a consultation, be used as preparation before arriving in the clinic, or as a way to contact the clinic if symptoms get worse.

Due to sparse evidence on active use of digitalized PRO there is a need for research and evaluation of the field. Especially, into patients for whom PRO is not immediately suitable and into what can be done to strengthen patients' use of PRO.

E-health literacy and readiness

To fully understand the users of health care technology, it is important to be able to differentiate between users with respect to their needs, resources and health technology readiness. A multidimensional tool, "Readiness and enablement index for health technology" (ReadHy), has been developed and validated and can be used to describe user's health technology readiness level and degree of enablement (Kayser, Rossen, et al. 2018). The READHY instrument offers a means to understand users of health technology and provides a measure of health technology readiness of the users

Aim of the project

This project will answer the following research questions:

> Which patients do not benefit from the current active use of the PRO system, and why?

How can non-users be recruited and retained by addressing their particular needs, knowledge, skills and perceptions, including trust and motivation?

Can the instrument ReadHy by itself be used as part of medical PRO data to offer health professionals insight into the patient's overall status?

Study Design
Action Research
The ph.d. project will consist of four studies, which will be conducted as action research, and in combination will answer the questions above, following this timeline:
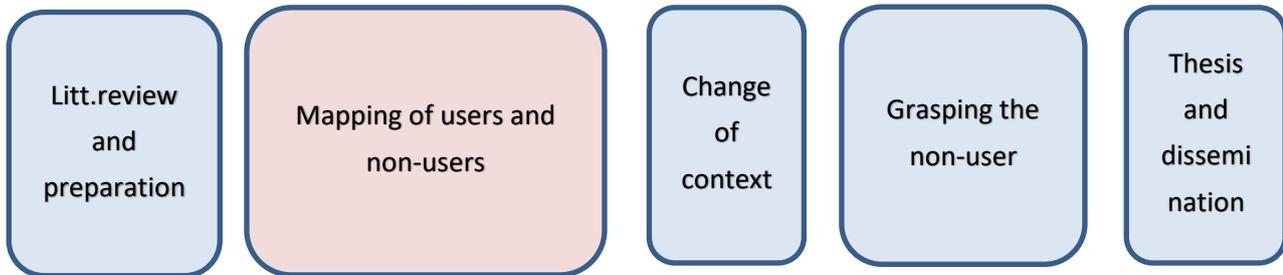
Action research is an iterative process, aimed to create cooperative learning, performed by practitioners and with researchers taking an active role in the project through the following steps; plan, action, observe, evaluate, reflect and then iterate. This means that the studies following the main study (study 2) might alter during the project. Action research demands a comprehensive mapping of current practice to be able to engage in change (Koshy, Koshy, and Waterman 2019). This is why the mapping-study is the core of the project.

Expected outcome
The project will consist of four studies; A literature review, an analysis of the current implementation, a comparison to a different environment and an introduction of Readhy into clinical practice.
The main result of this project will be to understand how different groups of patients can engage in the use of PRO with the provided benefits and to develop the eco-system around PRO to enhance inclusion of patients. The aim is to provide guidelines for a generic approach to provide better use of PRO for all patients with chronic conditions.

Study 1: Review of non-use of digitalized PRO
Objective
The objective of this scoping review is to understand 1) what is the proportion of non-users of digitalized PRO in empirical studies of routine healthcare for outpatients with long-term conditions, 2) what is the demographic characteristics of non-users, 3) what is mentioned about the patients (e-)health literacy and 4) what is the patients' reasons for non-use of digitalized PRO?
Methods
A scoping review is carried out using the Arksey and O'Malley framework and reported using the PRISMA-ScR reporting for scoping reviews (Tricco et al. 2018).
Material
Relevant articles are identified by searching PubMed, Embase/Ovid, Web of Science and PsycINFO databases.

Study 2: Analysis of current implementation

Objective

The first task of this project will be to map the eco-system of PRO by describing the current use of the PRO-platform (AmbuFlex 2018) at Diagnostic Centre at Silkeborg Regional Hospital and investigate the benefits and limitations regarding patients' health literacy, ability to participate in decision making and manage their condition with less physical meetings.

Using ReadHy (Kayser, Rossen, et al. 2018) this project will map the user, their engagement in their own health, their clinician's perception and the relation to the healthcare system to understand how the patient interacts with PRO and to what extent the eco-system around PRO contributes to patient empowerment and a change in patient-clinician-relationship (McAllister, Dunn, and Todd 2011; Kayser et al. 2015). This knowledge is important to be able to design and adapt the service to the needs of the users (Kayser et al. 2015).

To further optimize the PRO-eco-system and to understand who will benefit in which way, it is relevant to carefully consider how people interact with digitally provided measurement schemes, and to understand the particular barriers people with different e-health literacy encounter within the digital setting (Chan and Kaufman 2011); and which benefits emerge from utilizing digital media for measurement purposes.

The project will introduce ReadHy (Kayser, Rossen, et al. 2018), into a clinical setting and observe how it can be used to support the adoption of PRO data in a clinical setting and how the data will enable the health professionals to better educate, engage and empower their patients.

Methods

This study will be based on a mixed method approach using qualitative and quantitative methods, including different interview forms and validated questionnaires for "*the purpose of breadth and depth of understanding and corroboration*" (Johnson, Onwuegbuzie, and Turner 2007)*.*

Using a mixed method the researcher collects and analyze both qualitative and quantitative data in response to the research question. In this study a questionnaire is conducted and complemented by interviews with patients and clinicians. The two forms of data is then integrated and analysed in combination.

The rationale for this approach is to enlighten the answers from the questionnaire with interviews with the different clusters of patients that emerged from the questionnaire. Interviews is used to understand the cultural, social and psychological elements that might not reveal in the questionnaire. The questionnaire is given in advance as a validated tool – the answers emerging in the interview is not. In addition to that it is believed that the clinician's point of view and attitude towards the intervention could be of relevance to the patient perspective.

The focus will be on understanding the users and their capabilities to digitally fill out questionnaires using a ReadHy (Kayser, Rossen, et al. 2018) which is build on domains from three validated questionnaire (eHLQ, HeiQ, HLQ) (Kayser, Karnoe, et al. 2018; Kayser, Rossen, et al. 2018; Osborne et al. 2013) and semi-structured interview. This will form the basis of a study of how different well-defined patient groups use PRO schemas in a clinical context. Analysis will be done in relation to existing PRO data, both active and passive, and it will be evaluated whether other validated generic data sets can be involved and used to provide a better understanding of the patient by the clinician and a better opportunity to convey data relevant to the individual patient's perspective.

Also the system surrounding the use is of utmost importance to describe in this phase. The use of the platform can never be seen as an isolated event and is related to the interaction with the clinic, the clinician, the collection mode, and other context specific elements.

Material

600 patients with chronic inflammatory bowel disease (IBD) will be part of this analysis and 20 patients and 12 clinicians will be interviewed.

Study 3: Change of context

Objective

Building on the knowledge gathered in study 1 a second iteration is conducted; an analysis in a different clinical setting. Several of the domains in the used framework could be subject to cultural and organizational differences especially because of the action research approach to the development. Therefore the aim of study 2 is to gather the perspective of another clinical setting in another health care system and another culture to study the transferability.

Method

Using the (possibly adapted) ReadHy instrument on patients in another clinical context will provide a mapping of the users and the non-users through the domains described in table 1. A context specific comparison will be conducted.

Material

200 patients at Epworth Healthcare, Melbourne, Australia

Study 4: Grasping the non-user

Objective

The second iteration will have the goal to describe how the PRO-system can address the particular needs, knowledge, skills and perceptions among the current non-user and how the ReadHy by itself can be used as part of PRO data. The development of the eco-system prepared in study 1 and refined in study 2 will be performed in study 3. The aim of this evaluation is to establish how ReadHy-scores relate to contacts, how patients can be divided into different resource groups based on their scores and how they can be stratified.

Methods

Using the (possible adapted) ReadHy instrument a thorough evaluation will be conducted. Through an action research approach the evaluation will be context-specific, but with a comprehensive description of the context, the scientific aim of the evaluation is that it would be applicable on other similar uses of PRO-data for people with long term conditions. The collected data will be qualified with interviews and observational studies.

During this period the data collection will be continuously evaluated in relation to which domains that provides meaningful insight for the individual patient, and which may continue to be used as relevant PRO data. The results obtained will be supplemented by a mapping of which subjective and objective data types can complement ReadHy data and thus provide broader insight into both the physical, mental and social related health of the patient.

Material

200 patients with chronic inflammatory bowel disease (IBD) will be part of this analysis and 15 patients and 5 clinicians will be interviewed.

Publications

4 scientific, peer-reviewed publications will emerge from this study; a literature review, a comprehensive mapping of the users, the non-users and the barriers in the current implementation, and a final evaluation of the action research approach and the effect on the patients in relation to the ReadHY framework.

Significance

An interdisciplinary action research approach can ensure safe digital questionnaires and measurements in and easy understandable language with sufficient instructions, developed and tailored for specific conditions, patient types, adherence regimes and with the most appropriate multimodal combinations, and matched to user experiences. This will be a part of the Danish Health Data Board (Sundhedsdatastyrelsen) national effort on PRO to ensure best use of PRO, not only with patient with IBD, but for several chronic diseases.

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