

# A paradigm shift: Sharing Patient Reported Outcome via a National Infrastructure

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## Abstract

Digital solutions transform the way clinical services can be provided and make it possible for patients to participate in decisions concerning their own treatment. With the aim to support a better and more efficient healthcare system in Denmark, it has been agreed among authorities and care providers to establish a national infrastructure for sharing data between hospitals, municipalities, general practitioners and patients and concurrently develop standardized national digital cross-sector questionnaires for the purpose. Sharing data via the national infrastructure enables proactive involvement through patient reported outcome (PRO). The national infrastructure forms a paradigm shift 1) regarding cooperation by moving from a baton workflow to shared collaboration and 2) for the development of digital cross-sector questionnaires.

Cross-sector questionnaire definitions are stored in a national questionnaire repository, and are used in local PRO applications to capture the patients' responses.

## Keywords:

Patient reported information, national eHealth infrastructure, information sharing, cross-sector questionnaire definition, questionnaire response, HL7 CDA, IHE XDS

## Introduction

It is well known that history taking is the most important source of information in healthcare and patients are the best providers of information regarding their own health [1]. Normally it is a health professional interviewing the patient, that collects the information from the patient. However, health professionals do not collect all the relevant information from the patient, besides the task of documenting the patient history is time consuming and patients may even do a better job by filling out a standardized and validated questionnaire [2].

## Ask the patient – Patient Reported Outcome

Across health systems, a wide range of activities have been launched for using Patient Reported Outcome (PRO) PRO is a general designation for patients' responses to questions about their own state of health. According to FDA, PRO is defined as: "any report of the status of a patient's health condition that comes directly from the patient without interpretation of the patient's response by a clinician or anyone else" [3]. PROs take the form of carefully designed and validated questionnaires that can be used to capture and quantify the patient experience own health and of treatment impact. The patients' response to a questionnaire is denominated PRO-data. By systematically and actively using PRO-data in the dialogue with the patient, the planning and treatment of the care provided to the patient can

be personalized to meet individual needs and concurrently fulfill clinical guidelines. Further PRO-data may also support value-based health management and can be used to perform screening for side effects and reduce the number of unnecessary consultations. At the same time, PRO-data creates sound new data for research and quality development. Used correctly, PRO-data are just as essential to the quality of care as clinical data from other more accustomed sources. PRO-data should therefore in the future be an integrated part of data applied in clinical practice.

The Danish Health Data Authority has established a permanent PRO secretariat [4] that is responsible for development of standardized cross-sector questionnaires to be used in the healthcare sector nationwide. Standardized questionnaires, for cross sector use, are to be stored and accessed in a national questionnaire repository.

Focus is on using PRO-tools to support active patient participation and involvement. PRO-data are to be used in clinical encounters or as a substitution for outpatient contacts. The aim is to support and strengthen communication between patient and healthcare professional and concurrently ensure efficient processes. PRO-data reported by the patient can be used for clinical assessment before the clinical encounter, or as a dialogue support tool during the encounter; further PRO-data can be applied to support planning of treatment and as a tool for continuous health monitoring. PRO-data can be shared cross sectors, to all relevant healthcare providers including the patient, via the national infrastructure.

Development of cross-sector questionnaire specifications require involvement of all affected stakeholders including patient representation. Furthermore, it is crucial that the questionnaires are tested and validated in pilot projects before they are used in daily operation on a national level.

## Sharing data via a national infrastructure

To support new flexible ways of cross sector cooperation, that include patient involvement, requires concurrent development of IT-technologies as well as well validated standardized and structured questionnaires. A prerequisite is a generic and standardized IT infrastructure that can support easy interconnection to the many different IT-systems that are used by the various care providers in healthcare.

For more than 20 years, messaging has been the main technology applied in Denmark for exchanging of information among various healthcare organizations [5]. Messaging is easy to implement as the focus for the individual message (discharge letter, referral, lab result....) is well defined. The weakness in messaging is that information is only shared between the sender and the receiver.

Today, there is a high demand among care providers and patients to obtain access to relevant clinical data at the point of care independent of location. A common national infrastructure for the healthcare sector has therefore been established in Denmark to make it possible to share relevant eHealth data across all healthcare organizations as well as patients home. Furthermore, an agreement will be made in the 2020 finance act, which will oblige the parties to start connecting the local IT systems to the national infrastructure with the aim of exchanging PRO-data.

Use of PRO-data will be implemented across regions, municipalities and GPs to ensure sufficiently broad use in and across the healthcare sector based on the common infrastructure and the standardized questionnaires.

## Methods

### Development of standardized national questionnaires

A standardized method for development of national questionnaires has been developed and evaluated [6]. An overview of the development methodology is illustrated in Figure 1 **Fejl! Henvisningskilde ikke fundet.**

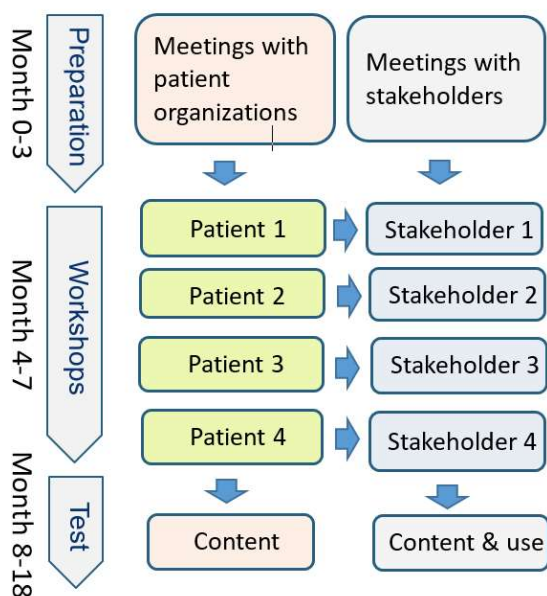


Figure 1. The development methodology for concerted national questionnaire definitions.

The design method builds on participatory design principles [7]. To support patient involvement a number of meetings and workshops with patient organizations are held to complement the questionnaire development meetings and workshops with the various stakeholders are prepared. The starting point in the development process is always a review of existing PRO material within the area, this is presented to the stakeholders and concurrently a discussion of the aim and practical application takes place.

Table 1. Fully developed areas for PRO in the program.

Area	Status
Apoplexy	Pilot testing
Arthrosis (knee and hip)	Pilot testing
Screening for depression in somatic patients	Pilot testing
Pregnancy and childbirth	Workshops completed
Heart rehabilitation	Workshops completed
Diabetes	Workshops completed

By March 2019, six national standardized questionnaires, as shown in Table 1, **Fejl! Henvisningskilde ikke fundet.** has been developed.

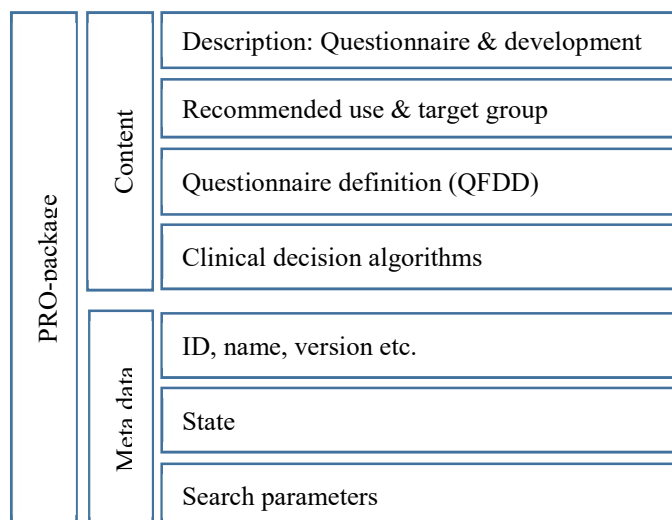


Figure 2. A PRO-package contains content and metadata.

### National questionnaire repository

A new national questionnaire repository contains PRO-packages that encompasses questionnaires, clinical algorithms and recommendations for use of PRO questionnaires and PRO-data. A PRO-package contains material as illustrated in **Fejl! Henvisningskilde ikke fundet.**

A PRO- package includes a description of the questionnaire and the intended use in several documents that support the technical implementation in the local IT-systems. Metadata are primarily data to be used to search for a specific PRO-package.

The PRO-packages are published via the national questionnaire repository and can be downloaded by healthcare organizations and software providers. However, if a user wants to download a PRO-package, the user must register in the questionnaire repository. As part of the registration, the user hand in an e-mail address, that is used to notify the user when the PRO-package is updated.

### Development of a national IT infrastructure

The national IT infrastructure builds on the Danish “Reference architecture for collecting health data from citizens” [8]. The reference architecture acts as the common reference for all business areas and IT solutions regarding collection of health data from citizens. The focus in the reference architecture is on data flow from individual citizens to healthcare systems. The data is collected from or provided by the citizen and is communicated to Cross-Enterprise Document Sharing (XDS) repositories in the national infrastructure. Healthcare professionals, that have a “care-relation” with a patient is cleared to look-up relevant data. The use of international standards for communication and content are important to ensure semantic interoperability. Furthermore, it improves quality, as it is the same standardized data set that is applied by all involved care providers.

Further, an important aim of applying an infrastructure based on a standardized reference architecture is to accelerate dissemination and thus implementation in practice.

Sharing PRO-data via the national IT infrastructure focuses on both mono-sectorial and cross-sectorial use of data, thus

supporting a smooth cooperation among the various care providers

The national infrastructure is built around a national service platform as shown on Figure 3. The platform among other things hold information on whether there is a ‘care-relation’ between any given care-provider and patient.

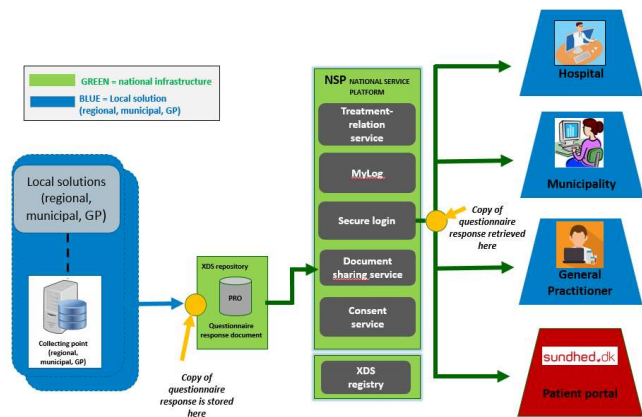


Figure 3. National Service Platform and services

### Document Sharing Service

The Document Sharing Service (DSS) is a national service for sharing documents among healthcare organizations. Documents can hold any kind of data, but they have to be expressed in an agreed standardized format. The DSS is based on the international standard for maintaining and sharing documents among health organizations; Cross-Enterprise Document Sharing (XDS). This is managed through federated document repositories and a document registry to create a longitudinal record of information about a patient within a given clinical affinity domain.

### Consent service

According to the Danish healthcare laws, health professionals has by default the right to access the citizens healthcare data, if it is relevant in relation to actual care situation and the patient has provided oral consent.

In order to restrict access to data a citizen can block:

- Access to all data for a specific period
- Access to data from a specific health organisation
- Access to data for a specific person

The consent service is linked to the DSS and will automatically filter out documents, if a citizen has blocked access to data.

### Standards for questionnaires

Two HL7 CDA v2 standards are used for questionnaires. The Questionnaire Form Definition Document (QFDD) describes how the questionnaire is constructed and organized. The QFDD includes information about the author, the version, a title, heading, text for sections and for each question; it is specified how the answer to any question can be given e.g. as free text, numeric values or multiple choice. It is also possible to add conditions where a specific response will open-up a new section with further questions. The QFDD is important to use, when receiving a populated questionnaire in order to understand and interpret the answer.

The Questionnaire Response Document (QRD) is the questionnaire filled by the patient (the PRO-data). The QRD has a link to the QFDD.

The QFDD and the QRD standards ensures that data can be integrated and re-used (semantic interoperability) in the numerous existing IT systems, that are used every day in the hospitals, municipalities and by the general practitioners.

Before the healthcare organizations, can begin to share data via the national IT infrastructure, the correct implementation of the QFDD and QRD standards are tested and certified. The tests and certification are mandatory to all users of the IT infrastructure.

### Testing and evaluation of the national standardized questionnaires

When a national questionnaire has been developed, a validation is carried out with approximately 20–30 patients, representing a broad diversity of potential responders, e.g. differing regarding age and sex as well as social and educational background. Questionnaire algorithms and usability are also tested in small-scale implementation and at several pilot sites. The pilot sites are cross-sectorial according to the relevant cross-sectorial workflows.

A research program has been set up to identify categories of eligible patients, benefits and disadvantages of using PRO-data and the effect application of a system for Patient Reported Information may have on clinical work. From previous experience, we know that the use of PRO-data will empower patients and improve efficiency and effectivity of care processes in some patient groups [9, 10] and it may even improve outcome [11].

## Results

### Dissemination

A new national IT infrastructure based on IHE XDS [14] and HL7 CDA standards has been established and tested. The use of international standards ensures that relevant data can be shared across hospitals, municipalities and general practitioners independent of which IT-providers and systems that are applied. The patients further have access to their own PRO-data as well as other health data via the Danish Public Healthcare Portal [12].

The IT infrastructure is in daily operation and is until now also used for sharing of patient appointments, patient master data, care plans and home monitoring as well as PRO-data.

### Maturity the infrastructure

On the Technical Readiness Levels (TRL) scale developed by National Aeronautics and Space Administration (NASA) [13] as a methodology to assess the maturity of critical technology solutions, the infrastructure is assessed to be on TRL 8 (in daily operation with real users) by March 2019.

As shown on Figure 4, TRL is based on a scale from one to nine, where nine is the highest maturity level of the technology solution. The use of TRL also provides the basis of a consistent description of the maturity level of the national infrastructure.

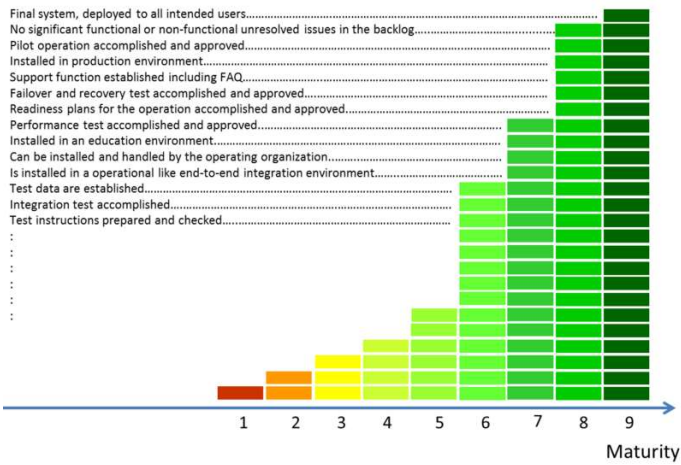


Figure 4. TRL scale to access the maturity.

### Questionnaire development

The most important findings during the first rounds of development and evaluation of questionnaire are listed in Table 2.

Table 2 The most important findings during the questionnaire development process

Area
1. Many issues need to be clarified by the patients before and between stakeholder workshops
2. Most patient pathways are cross sectorial, but cross sectorial workflows are complex and not well described
3. Most previous knowledge on patient reported information is derived from mono sectorial use in hospitals as digitalized Patient Reported Information only has been scarcely used in primary care
4. Use of Patient Reported information is a fundamental cultural transformation to health professionals
5. Legal clarification of who may have access to what kind of Patient Reported Information is important
6. Electronic questionnaire systems including algorithms are medical devices and thus must be CE marked in the EU

### Discussion

Currently there is a lot of ongoing work in Denmark to develop new IT-solutions that can involve and empower the patient and make the care provided more personalized and efficient. There are several strategies to address this challenge, one is to ensure efficient access to relevant patient data for all care providers in all of the various health organizations involved in the care process of a single individual.

### Messaging

For many years, messaging has been the preferred approach for communication of health data. Messaging is based on the premise that the sender and the receiver have knowledge of each other; e.g. a hospital is sending a discharge letter to the patient's general practitioner. This is a baton workflow, where

the diagnosing and treatment is done stepwise by handing over the patient and what is judged as relevant information from one care provider to another care provider. In the baton workflow process, there is a risk of not sending the relevant information or for loss of information, as the patient's data are only communicated as single messages between the sender and receiver.

### Collaboration via a national infrastructure

Today's technology allows the establishment of a national infrastructure where data are shared among many actors. Relevant data can be collected, shared and applied where and when it is relevant (the services in the National Service Platform - Figure 3 - ensures that there is legitimate right to access the data).

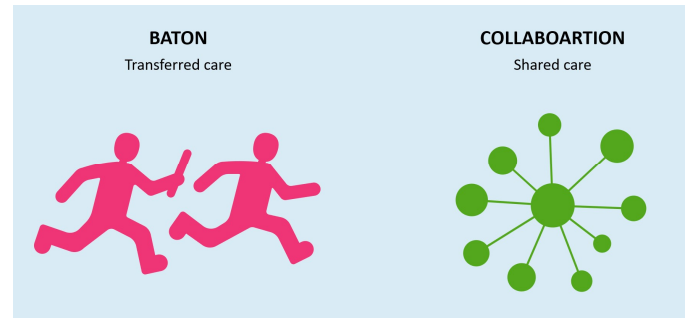


Figure 5. From baton to collaboration

Going from Baton to Collaboration provides a profound shift in the information exchange paradigm as well as in the possible ways to cooperate. Further introducing questionnaires filled by the patients and accessible whenever relevant provides a completely new set of possible ways to cooperate in the healthcare sector.

The national infrastructure is designed as a common generic infrastructure, which can be applied by all care providers, though we have found that it is a challenge that many small healthcare organizations do not have internal IT knowledge and capabilities to establish a smooth integration to the national IT infrastructure. Further legal issues have to be addressed and handled in the way questionnaires are designed and distributed as well as in the design of the infrastructure. It is however a benefit that the security issues are taken care of in the design of the IT infrastructure

In the development of questionnaires it is essential that, all stakeholders are represented in the process and that all stakeholders actively take part in the dialogue and teamwork to ensure a truly participatory process. Furthermore, as one of the central aspects in participatory design points out it is essential that stakeholders collaborate on equal terms [7]. This we have managed to support by conducting dedicated workshops for patients and for clinicians from the primary care sector as we found that they needed more support in the process, as clinicians from the hospitals have an advantage by their pre-experience in development and use of questionnaires with patient reported information.

### Conclusions

Based on our findings, we are convinced that the increased use of patient reported information involving patients and clinicians in the development, evaluation and implementation processes will be of great benefit both for the individual patients as well as for the entire healthcare system[11]. However, it requires a



thorough and exhaustive development program including tracks for both technical infrastructure, questionnaire development, evaluation and application as well as a research program.

Sharing data versus messaging is a major paradigm shift concerning technology, use of eHealth standards, clinical workflow, security and not to forget handling of legal challenges and privacy.

## Acknowledgements

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