

Health Information Technology to improve patient safety

Focus on medication reconciliation

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GLOSSERIES

Abbreviations	Definitions
ADE	Adverse drug event
AHRQ	Agency for Healthcare Research and Quality
App	Application
BPMH	Best Possible Medication History
CD	Chronic Disease
Clin Pharm	Clinical pharmacist
Com Pharm	Community pharmacist
CPOE	Computerized Physician Order Entry
DPP	Dossier Pharmaceutique Partagé
eHealth	Electronic Health
EHR	Electronic Health record
eID	Electronic identity card
eMedRec	Electronic medication reconciliation
EMR	Electronic medical record
eTool	Electronic tool
GP	General practitioner
HCP	Healthcare professionals
HIE	Health information exchange
HIT	Health information technology
IT	Information technology
MedRec	Medication Reconciliation
OTC	Over-the-counter
PADE	Potential adverse drug event
PCC	Primary Care Clinics (=Maison médicale)
PCP	Primary Care Provider
PHR	Personal Health Record
PS	Physician Specialist(s)
RSB	Réseau Santé Bruxellois
RSW = ReHN (for Chapter 4)	Réseau Santé wallon = Regional eHealth Network (for Chapter 4)
SEAMPAT ICT Platform	Seampat Information communication technology Platform
UCD	User-centered design
VIDIS	Virtual Integrated Drug Information System
MedRec app	Medication Reconciliation application
Patient app	Patient Application

French/Dutch abbreviations	Definitions
AFMPS/FAGG	Agence fédérale des médicaments et des produits de santé Federaal agentschap voor geneesmiddelen en gezondheidsproducten
AIM/IMA	Agence InterMutualiste InterMutuatlissch Agentschap
CBIP/BCFI	Centre Belge d'Information Pharmacothérapeutique Belgisch Centrum voor Farmacotherapeutische Informatie
INAMI/RIZIV	Institut national d'assurance maladie-invalidité Rijksinstituut voor ziekte- en invaliditeitsverzekering
SAMv2	Source authentique et validée des médicaments, version 2

Some helpful translations	Definitions
Features - Functionalities	Caractéristiques/Fonctionnalités
Requirements	Exigences
Specifications	Cahier des charges

FOREWORD

Mrs K. is admitted to the geriatric department for acute confusion and walking difficulties since 4 days. After a thorough clinical examination, we excluded the main causes of her problems. But when we came to her medications' list, we were somewhat confused. We received a list from her general practitioner with her prescribed medication. Mrs K. is also taking some over-the-counter medications her daughter bought a few days ago for her at the pharmacy. Additionally, she went 7 days ago to the cardiologist who added 3 new medications. Mrs K. started 2 of the 3 medications prescribed by the cardiologist. Unfortunately, she does not remember the name of these new medications.

It started with a usual patient story for a future geriatrician and it ends up with a hospital admission followed by a hospital stay of more than 10 days. Everybody has part of this puzzled medication list: the general practitioner, the patient, her daughter, the pharmacist, the cardiologist. Regular medication reconciliation may probably have avoided the hospitalization of Mrs K.

However, medication reconciliation is a not well-considered process by health-care professionals, especially by physicians. It is the process of obtaining and verifying a complete and accurate list of all patients' current medications to ensure that precise and comprehensive medication information is transmitted across transitions of care. It is a time-consuming and cognitive overloading process. Therefore, sensitizing professionals to the medication reconciliation process and finding solutions to support and optimize it is a healthcare priority.

I was given the opportunity to work on the SEAMPAT project that aims to define and develop an electronic tool for medication reconciliation (MedRec). This tool offers the possibility to the patient to document his medication list. Although, this project IS NOT specifically dedicated to older patients, I was really happy to be hired on it and to share and collaborate with the other researchers to address this splendid challenge of defining an electronic MedRec tool with a patient app.

Introduction

1. CONTINUITY OF CARE – CONTINUITY OF MEDICATION

1.1. WHAT IS CONTINUITY OF CARE?

From a **provider perspective**, continuity of care refers to continuity and consistency of clinical management, including the (1) sharing of information and communication about care-planning, (2) multidisciplinary teamworking, along with (3) integration and (4) care coordination¹. Patients and providers have two distinct perspectives of continuity of care. **Patients experience** continuity of care as a satisfying continuum of care^{2,3}. Both perspectives are complementary and important when studying continuity of care. Continuity of care is concerned with the quality of care over time, the ideal is the delivery of “**seamless care**”². Breakdowns in the healthcare continuum can have many repercussions: adverse events, laboratory abnormalities, unanticipated re-hospitalizations, unplanned visits to the emergency department/outpatient clinics/general practitioner or permanent disabilities. **Transition points** of care are the main **threat** to continuity. For example, evidence shows that about one in five patients has an adverse event after being discharged from hospital⁴.

Preventing discontinuity in care requires close collaboration between the different actors (all healthcare providers and the patient). Complete medical information – patients’ symptoms and complaints, patients current condition, medical history, essential diagnostic findings, abnormal laboratory results, results of examination and tests, tests pending, treatment plan and medications, future appointments, follow-up plan – but also non-medical information, such as the information given to the patient and his family, ethical wishes (organ donation, cardiopulmonary resuscitation) and patients’ life objectives, needs to be shared directly and timely^{5,6}. Sharing information calls for qualitative relationship between actors with respect and consideration for the work and knowledge of each involved stakeholder. Indeed, everyone has a piece of the puzzle and each has his own responsibilities.

1.2. CONTINUITY OF MEDICATION = A KEY COMPONENT OF CONTINUITY OF CARE

Continuity of medication is one component of this continuity of care⁷⁻¹⁰. But, it is a key component as discontinuity in medication can lead to many adverse drug events potentially harmful for the patient^{11,12}. Treatment plan modification, insufficient education of patients and deficits in information and communication to healthcare professionals (HCPs) are the main reasons for medication discontinuity^{6,12-14}. Following hospital discharge about 20% of patients experienced an adverse event, most frequently an **adverse drug event (ADE)**^{4,11}. Medication-related problems and adverse drug events are leading causes of preventable hospital admission^{15,16}.

1.3. TRANSITION POINTS: A RISKY SITUATIONS

These last years, the **number of transitions** per patient **is rising**. This rising because of the increasing number of elderly patients, the increasing number of chronically ill patients, the shortening of hospital stays, the constant pressure for increased productivity, the growing effort to deliver care in the community^{1,4}. **Transition points of care are a risky situation** where patients may experience **medication discrepancies**^{7,13}, which are unexplained differences between medication lists at these transition points¹⁷.

The **Best Possible Medication History (BPMH)** is generally considered as the gold standard to compare the different medications' lists and identify discrepancies. The BPMH, defined by the Institute for Safe Medical Practice in Canada, is a history created using (1) a systematic process of interviewing the patient/family; and (2) a review of at least one other reliable source of information to obtain and verify all of a patient's medication use (prescribed and non-prescribed). Complete documentation includes drug name, dosage, route and frequency^{18,19}. To gather the BPMH it is thus necessary to collect data on patients' medication adherence. Because the compared medication lists vary with the transition points of care, discrepancies are sometimes defined differently¹⁷. For example;

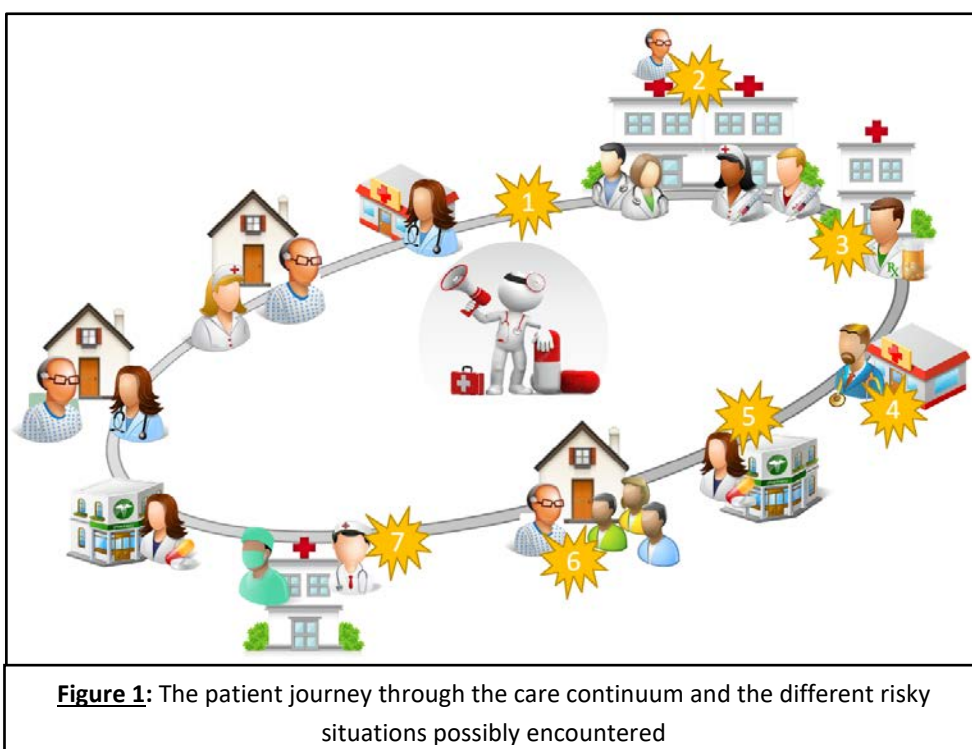
1. At admission: discrepancies are the differences between the BPMH and the admission orders.

2. During inpatient transfer: discrepancies are the differences between the BPMH and the pre-transfer medications and the transfer medications.
3. At discharge: discrepancies are the differences between the BPMH and current inpatient medications and the future discharge medication list.
4. At home or in long term care: discrepancies are the differences between the BPMH and the most current information found in the patient's recorded medication information sources.

In the context of our work, we will use discrepancies with a generic definition – differences between one or more lists of medication (no matter the transition point) and the BPMH. When taking a closer look at a patient's journey through the healthcare system (Figure 1), **numbers of discrepancies are frightening:**

1. Medication discrepancies are found in up to 67% of hospital admissions^{10,20-22} and the risk of discrepancies at admission increased for every additional drug²³.
2. A majority of discrepancies at hospital admission (11% to 59%) have a potential for harm¹⁰.
3. 10 to 30% of these discrepancies can potentially lead to deterioration of the patients' health and prolong their stay in the hospital^{10,24} and this proportion is even more important in regard to geriatric patients²².
4. Discrepancies can be found in up to 88% of patients in outpatient clinics²⁵⁻²⁷.
5. In Belgium, in 33% of patients discharge from hospital, community pharmacist identified one or more drug-related-problem²⁸.
6. At home, an Australian study compared the medication list in the electronic medical record of the GP with a BPMH. They found that 87% of patients' had one or more discrepancies and 62% had discrepancies of moderate to high significance²⁹. In the Netherlands, Tulner et al. identified at least one discrepancy for 86.7% of the geriatric outpatients when comparing the medications described by the patients and their caregivers with the drugs listed by their GP³⁰.
7. Finally, 25% of patients readmitted to hospital within 30 days (after discharge) are readmitted because of a suboptimal communication concerning their medication⁸.

	The patient		Family Relatives
	The nurse at home		The community pharmacist
	The general practitioner		Hospital caregivers
	The physician specialist		



Understanding the importance of the menace for patient safety, has wake up researchers and policymakers. International leading organizations, such as the World Health Organization, the Institute for Health Improvements, the International Joint Commission, etc. have underlined the importance of care across the continuum. Those organizations introduced patient safety goals³¹, elaborated strategies and guidelines for improvements³²⁻³⁴, developed books³² and toolkits^{35,36} to help institutions optimizing care transitions. Many research for path of improvements has been done these last years^{4,10,13,20,37-41}. However, improving continuity of medication is a challenging task and huge room for improvements remain⁴².

1.4. CONTINUITY OF CARE AND PARTICULARITIES FOR OLDER ADULTS

Older patients are a particular and interesting population. A recent German study found that a quarter of older patients are suffering from at least four **chronic diseases**⁴³. Which is similar to the proportion of older adults in the Belgian population where 25% are affected by at least three chronic diseases⁴⁴. They can suffer from many **impairment** (visual, hearing, motor, cognitive) that can lead them to frailty and dependency and consequently to changes in their place of living: home, nursing homes, assisted long-term care facilities, revalidation center, etc. Older frailty patients experience thus **frequent transitions**.

Besides, they are especially vulnerable because **many medications** are often used to treat multiple comorbidities^{22,45} and they are much more susceptible to develop adverse drug reactions (10–35% yearly), especially after transitions of care⁴⁶. They are supposed to follow complex medication plan which involves multiple medications prescribed by **different doctors** with variable dosages and frequencies⁴⁷. Moreover, some patients have cognitive disabilities and consequently great difficulties to recall their medications and the prescribed/recommended dosage^{48,49}.

Because of all these difficulties, elderly participating in their care is not always possible⁴⁹. Thankfully, some patients are well surrounded by family members and/or friends that can help to ensure continuity of care and more specifically continuity of medication. Concerning geriatric care, to the identified key actors of medication continuity (patients, physicians and pharmacist), we should certainly

add: **family members or contact resources**. Indeed, for the elderly, the professional or un-professional caregiver has a crucial role in continuity of care.

1.5. APPROACHES TO IMPROVE CONTINUITY OF CARE

Improving continuity of care requires theory- and evidence based interventions, targeted at specific behavioral and environmental factors⁵⁰. Because those interventions are very complex and resource-intensive to implement, a recent study provides a guiding framework with practical tools to support HCPs and policymakers in their efforts in improving transitions⁵⁰. Numerous factors related to the patients and the HCPs, the organizational and technical level have to be considered. For example: knowledge and understanding, skills, patient-centered attitude and culture, multidisciplinary teamwork, standardized working-processes, existing communication channels, shared electronic information exchange system⁵⁰. It is to highlight that the authors of the study, as other authors, emphasized the importance of continuity in medication and the urgent need for accurate medication reconciliation^{5,50,51}.

Efforts to improve medication safety comprise adapting the language and the vocabulary of the information for each interlocutor and sharing **exhaustive** information timely and directly: medication name, dosage, frequency, time of administration, route of administration, therapeutic intent, reason for introducing/changing/discontinuing a medication, start date, stop date⁵. Different actors are implicated in the process and each has a role to play:

- Patients (if needed with the help of family/contact resources) should discuss with HCPs on what medication they are taking, how they are taking these and why they are taking it this way to obtain a complete medication history and to find a consensus while reconciling medications.
- Physicians have the duty to ensure that correct and complete medication information is provided to the other HCPs and to the patients.
- Pharmacists, because they have been formally educated, are the best skilled individuals to interview patients about their medication histories. They are also experts in pharmacology (pharmacodynamics, pharmacokinetics, side effects, interactions, etc.).

Therefore, in order to achieve optimal results and preserve medication safety, physicians should collaborate with patients and pharmacists⁵.

Because improving continuity of care is very complex and resource-intensive and because discontinuity in medication is such an important threat to patient safety, **we decided to focus especially on the component “medication continuity” and thus “medication reconciliation”**.

2. MEDICATION RECONCILIATION

2.1. DEFINITION

Medication reconciliation (MedRec) is a formal and collaborative process of obtaining and verifying a complete and accurate list of all patient’s current medications – including the name, dosage, frequency and route – to ensure that precise and comprehensive medication information is transmitted consistently across transitions of care⁵². We believe there is only one type of medication reconciliation but it could be the first step of a clinical medication review⁵³. With or without reviewing the medication list, MedRec aims to enable prescribers making the most appropriate prescribing decisions for the patient⁵⁴. Several leading international healthcare organisations, such as the WHO, involved in patient safety have listed MedRec as a priority objective to improve healthcare^{31,37,55-57}.

2.2. PROCESS

The formal and collaborative process of MedRec consists of 3+1 STEPS^{19,52,58}:

1. **Verification:** The first step consists in gathering the Best Possible Medication History (BPMH). This is a particularly difficult step requiring medication information from multiple sources including data on patient adherence (general practitioner, community pharmacist, specialist, electronic medical record, patient, etc.). Several tools exist to support the clinician taking it^{18,59}.
2. **Identification:** In the second step the clinician compares different lists in order to identify discrepancies – unexplained differences between lists –

related to drug name, drug dosages, drug frequency and route of administration.

3. **Reconciliation:** Identified discrepancies are resolved in the third step. While reconciling the medication list, the opportunity to conduct a medication review (checking for appropriateness) can be taken.
4. **Communication:** The last step, and probably the most important, aims to communicate the, reconciled and eventually clinically reviewed, medications list. It is essential to document each taken decision and each modification. Finally, the documented list is shared with the patient and every patient's healthcare provider. Patient medication education should also be added to this particular step.

2.3. PROBLEM AND CHALLENGES

Improving medication reconciliation is a challenge because it is a complex process influenced by many factors.

First, reconciling medication is a **teamwork** including the patients and the different HCPs of the patients (physicians and pharmacists of the first and second line of care)⁶⁰. Every partner of the team needs knowledge, education, information and time to accomplish his role and fulfil his responsibilities. Second, MedRec is a **resource-intensive task**. Gathering the Best Possible Medication History is probably the most resource-intensive step of the MedRec process that can possibly last up to 46 minutes per patient and consequently being costly^{60,61}. Third, MedRec interventions **affect complex workflows**, which are very variable from one to another institution and even variable between wards in the same institution⁶¹⁻⁶³. Finally, because it is **difficult to measure accurately the benefits** of MedRec, evidence is lacking and institutions are hesitant to invest resources^{10,20,40,42}.

There are thus no easy solutions for implementing MedRec interventions matching the organizational strengths, workflows and goals based on institutional priorities⁴².

2.4. DIFFERENT APPROACHES CAN IMPROVE MEDREC BUT FURTHER RESEARCH IS NEEDED

Because MedRec interventions are complex interventions, influenced by many variables (workflow, leadership, staff skills and training, use of IT, existence of patient safety culture, ...), the clinical impact of these interventions is difficult to evaluate⁴². Recent systematic reviews^{10,20,40} found that MedRec in different setting has the potential to identify a high proportion of discrepancies and to reduce potential harm. Two of these reviews^{10,20} indicate that the most successful interventions relied heavily on pharmacists. Spinewine et al.¹³ showed that, additionally to pharmacists' intervention, patient education and counseling reduce the risk of adverse drug events and hospital readmissions in some studies. However, all authors conclude that strong evidence concerning **the actual impact on process measures, clinical outcomes as well as cost-effectiveness are lacking**^{10,13,20,40,41}. Besides pharmacies-led reconciliation and patient education/counselling, information technology (IT) seems equally an interesting approach to facilitate MedRec activities⁹. However, at the time of Bassi's review (2010), no application supporting the whole process of MedRec could be found and no evidence existed concerning relationship between specific IT features and the potential of MedRec improvements.

Further research is thus clearly needed to better understand the benefits of particular intervention components of MedRec interventions, alone and in combination, how best to implement them, the patients most likely to benefit and the actual impact on clinical outcomes improving patient safety.

Besides, it is important to notice that MedRec aims to improve continuity of care, but will not lead per se to improved prescribing. In this regards, MedRec is fully complementary to medication review (MedRev), and MedRev should always be done after obtaining a Best Possible Medication History^{38,40,60,64,65}.

3. PATIENT PARTICIPATION

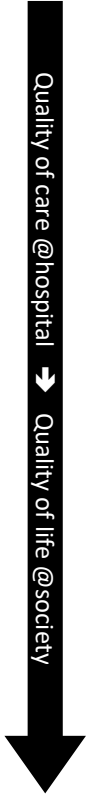
3.1. CLARIFICATION BETWEEN “PATIENT PARTICIPATION, PATIENT-CENTEREDNESS” AND “PATIENT EMPOWERMENT” AND DEFINITION⁶⁶

Patient participation, patient-centeredness and patient empowerment are trendy concepts for several years. Despite the popularity of these three terms, existing scientific literature offers no clear definitions for these concepts, and it is unclear how they are best measured. Therefore, Castro et al.⁶⁶ tried to define patient participation, patient centeredness and patient empowerment, clarifying patients' role (table 1) and proposed a process model linking the three concepts in healthcare. Patient participation could be considered as the “lowest” level of engagement even though it still improves quality of care. **In the context of this present work, we will stick to patient participation/involvement.**

Table 1: Definitions and characteristics of the concepts of patient participation, patient centeredness and patient empowerment⁶⁶

	Definition	Patients' role(s)	Consequences	Measurement scales (examples)
Patient participation, Synonymously with patient involvement	Individual patient participation revolves around a patient's rights and opportunities to influence and engage in medical decision concerning his care (dialogue, patient preferences, potential and a combination of his experiential and the professional's expert knowledge).	• Patients actively engaged in various activities • Patients taking part of medical decision that affects their lives • Patients working in partnership with HCPs	Informed patients improve quality of care (patient safety and patient satisfaction)	The Shared Decision Making Questionnaire – CollaboRATE – The Patient Participation Culture Tool – ...

Quality of care @hospital → Quality of life @society



Patient centeredness	Patient-centeredness = biopsychosocial approach and attitude that aims to deliver care that is respectful, individualized and empowering (individual participation, built on a relationship of mutual trust, sensitivity, empathy and shared knowledge)	• Patient = unique person • Biopsychosocial approach tailored to needs, values and beliefs of the patient • Patient-HCP = a sustainable and genuine relationship	Patient with good illness-related knowledge have better health behavior and adherence with improved health outcomes and improved quality of care	Client-centered care questionnaire – Kim Alliance Scale – Stanford Trust in Physician scale – ...
Patient empowerment	Individual patient empowerment = process that enables patients to exert more influence over their individual health by increasing their capacities to gain more control over issues they themselves define as important.	• Enabling process • Achieving personal change • Self-determination : right and ability to make their own choices (autonomy)	Patients gaining more control over their lives, achieve self-management in order to finally improve their quality of life	Patient empowerment scale – Partners in Health Scale – Patient Activation Measure – ...

Quality of care @hospital → Quality of life @society



Because no univocal definition exist concerning patient participation^{66,67}, it is hard to decide which tool matched the best with the desired and foreseen measures. As observed in this table, measurements scales and/or tool are not lacking^{66,68-74}, but few are reliable and valid.

3.2. FROM PATERNALISM TO PARTNERSHIP

In 1997, the World Health Organization Vienna wrote into their Recommendations “Promote patient-centered care across the world as a mean to achieve the highest possible level of health as the realization of a basic human right”⁷⁵. Since then, paternalistic healthcare approaches have gradually given way to patient-oriented approaches that take into account patients’ differences, values, and experiences. The **“patient as partner”** has been considered as a key component in the redesign of health care processes and is advocated as a means to improve patient safety^{76,77}. Many models emerged, the most famous being “the Montreal Patient Model”⁷⁷. In the Montréal Model, the patient as partner is a gradually enabled and enlightened to become a full member of the interprofessional care team. His ‘life-project’ constitutes the guiding principle according to which clinical decisions are to be made^{77,78}. Healthcare organizations, universities and institutions are increasing efforts to involve the patient, using different forms of engagement (participation, active engagement, empowerment,...), and seeing him as a partner at different levels of the healthcare system: in health education, in health care, in health research^{77,79-82}. The patient is an active actor of his care and a splendid source of experiential information by living with the disease⁷⁸.

Older patients, because suffering from multiple chronic diseases^{43,44}, have a rich experiential knowledge. But barriers to their engagement are much more substantial compared to other adults⁸³. Indeed, they often present impairments that hinder their participation and they have been passive “order takers” from HCPs for many years. Multiple hospitalizations and transitions of care are common with numerous HCPs that give them the feeling that no one is in charge of their care¹. Moreover, many elderly will not question HCPs, fearing it will negatively influence their care⁸³. However, because studies showed that older people’s daily lives are strongly influenced by the impact of the disease and ageing, elderly patients are still interested to be involved in their care management⁸³⁻⁸⁵. Older adults should be involved with their family caregiver and/or professional caregiver.

Patients and HCPs believe that **patient participation** in care can prevent medication errors⁸⁶. Patient participation in communication can also improve the

quality of patient transitions, reduce hospital readmissions⁸⁷ and so improve medication continuity⁸⁸.

Information technology is evolving very fast. Every day, new applications are being developed and launched on the market. The healthcare system is no exception and health information technology (HIT) is progressing unrestrained. Studies have been reporting the engagement of patients in their health through the use of HIT⁸⁹. Even though patients expressed some fears, they are generally positive about the use of HIT⁹⁰. However, the exact added benefit of patient participation in medication continuity by the use of electronic is still unclear^{88,90,91}.

3.3. CHALLENGES AND BENEFITS OF PATIENT PARTICIPATION

The potential for engaging patient in patient safety is huge⁹² but influenced by various factors^{49,76,92,93}. Patients' involvement is indeed related to the healthcare system, the activity of healthcare professionals' and the patients' capacity and motivation for participation.

In general, beliefs and knowledge largely influence patient involvement⁴⁸. While some patients present an excessive thrust in the healthcare system and their HCP^{48,93}, other patients are worrying about being considered as "difficult patient" and fearing embarrassment and negative judgmental reaction from HCPs⁹²⁻⁹⁴. Both patients and healthcare professional need basic information about how the healthcare system works and what is expected from patients to contribute to high quality of care⁴⁸.

While patient engagement seems to be a key component to improve patient safety and quality of care, the exact added benefit of patient participation is still unclear⁹³. Further research is thus essential to establish key determinants for the success of patient participation in improving patient safety and reducing medication errors^{76,88}, including for the frail older population.

4. DEVELOPMENT AND EVALUATION OF HEALTH INFORMATION TECHNOLOGY TOOLS

4.1. DEFINITIONS

a. Health information technology

The term "health information technology" (health IT or HIT) is a broad concept that encompasses an array of technologies to store, share, and analyze health information in an electronic environment⁹⁵.

b. Usability

Usability is a very popular concept used to discuss and evaluate information technology. Because various levels of information technology evaluation exist, many different definitions of usability are used. For example:

1. the restrictive ISO 9241-11 definition⁹⁶, usability is defined as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use”.
2. the Whitney Quesenberry’s definition⁹⁷, distilling usability into the following dimensions called the 5Es: effective, efficient, engaging, error tolerant, easy to learn.
3. Rubin and Chisnell’s⁹⁸ concept of usability, viewed as a 6 dimensions’ concept. To be usable, a product or service should be useful, efficient, effective, satisfying, learnable, and accessible.

Other definitions of usability also exist but these are the most commonly used. The three definitions agree that usability concerns: effectiveness, efficiency and satisfaction (~engaging). In Quesenberry’s definition and Rubin and Chisnell’s definition, the concept of learnability is added. A really interesting concept regarding sustained used and adoption of a tool. However, to evaluate correctly “learnability”, the same person or group of persons should use the tool repeatedly for several months. Something not easily possible in the context of our work. Other relevant concepts are added to the definitions such as “error tolerant” and “accessibility”. Concepts best measurable when an IT tool is implemented and used in routine. Therefore, **in the context of this work, we choose to work with the ISO 9241-11 definition of usability⁹⁶.**

c. Usefulness

To be usable, an IT tool should be useful, efficient, effective, satisfying, learnable, and accessible. In contrast, to usability, the different definitions concerning usefulness are very similar. Usefulness refers^{98,99} to the degree to which a product enables a user to achieve his or her goals while meeting specific needs. Usefulness is thus an **assessment of the user's willingness** to use the product at all. Interestingly, usefulness is probably the element that is most often overlooked during health IT evaluation studies.

d. Human-centered design

A human-centered design is an approach used to design and develop systems. This approach aims to make the interactive system more usable by focusing on the use of the system and applying human factors/ergonomics and usability knowledge and techniques¹⁰⁰. In practice, the terms “human-centered design” and “user-centered design (UCD)” are often used synonymously. UCD involves **understanding the needs, values, and abilities of users** to improve the quality of users' interactions with and perceptions of the technology^{101,102}. UCD contributes to improving the identification and definition of functional requirements¹⁰³. It also increases the likelihood of completing the project successfully and reduces the risk of the product failing to meet stakeholder requirements or being rejected by its users¹⁰⁰.

4.2. EXISTING GUIDELINES AND RECOMMENDATIONS TO DEVELOP HEALTH INFORMATION TECHNOLOGY (HIT) AND EVALUATE HIT USABILITY

Different guidelines and recommendations exist concerning the development and evaluation of health information technology. For example, **the Agency for Healthcare Research and Quality**¹⁰⁴ elaborated a guide for developers and system designers on “Designing Consumer Health IT”. The document presents 10 recommendations and highlights the key strategies that have been used to produce outstanding health IT products. The recommendations focus on the design methods and issues to consider throughout the development process and into commercialization. The AHRQ also present the ideal IT design process ending with the commercialization phase.

Table 2: Recommendations Mapped by Development Phases¹⁰⁴			
AHRQ Recommendations that should be followed during:		development	testing
1	Assemble and prepare a design team consisting of members with appropriate knowledge and skills for all product development phases.	X	X
2	Strive to understand customer needs within the environments that the product will be used throughout all product development phases.	X	X
3	Include a diverse set of customers when generating ideas for new products and when evaluating early product iterations.	X	X
4	Select and apply well-developed and established design methods in combination with intuition- or innovation-driven design approaches .	X	X
5	Use multiple approaches early to learn about customers and the market to inform the product's design.	X	Non applicable
6	Drive design decisions and modifications based on learning from prototyping and pilot testing activities.	X	X
7	Define and tailor success metrics based on the needs and contexts of unique customer segments.	X	X
8	Balance customer needs with product safety and privacy concerns specific to health IT products.	X	X
9	Build products based on established health data and transmission standards .	X	X
10	Incorporate successful marketing strategies to promote the product and be responsive to customers once the product is promoted and adopted.	Non applicable	Non applicable

Besides these recommendations, we consulted various **usability textbooks**. Two of them are considered as main reference by computer scientists^{97,98}. Both give similar advice concerning the development and evaluation of IT and these could be synthesized as follows:

1. Respect the lifecycle product (= IT development cycle) but **focus on the user** (not the product).
 - o Start by gathering requirements and assessing users' need

- o Design, develop and test the product: several times, using different type of tests at the different phases of the development cycle
 - o Launch the product on the market
- 2. Include end-users from the start of the project
- 3. Associate different type of tests at the different phases of the development cycle. Test usability (effectiveness, efficiency and satisfaction) during all phases.
 - o Exploratory or Formative testing are done early in the development cycle. These testing include few users with small testing. Focus on collaboration between participants and moderator, ask participants for ideas, collect “**qualitative data**” to answer “**why**”. Collect **quantitative** data to **examine the effectiveness** of preliminary design concept. If needed, repeat testing.
 - o Assessment or Summative testing are conducted either early or midway into the product development cycle, usually after the fundamental or high-level design or organization of the product has been established. The purpose of the assessment test is to expand the findings of the exploratory test by evaluating the usability of lower-level operations and aspects of the product: **efficiency and effectiveness - how well & how fast. Collect quantitative and qualitative data** to answer those questions.
 - o Validation/verification testing is conducted late in the development cycle and is intended to measure product usability against established benchmarks.
- 4. Test at least usability (effectiveness, efficiency and satisfaction) and when possible usefulness. Think about learnability and accessibility. Therefore use:
 - o An iterative design, very powerful to obtain the best results with the less resources
 - o several iterations to identify product flaws or deficiencies previously missed
 - o different prototypes
 - o different methods of evaluation: observations, focus groups, interviews, think-aloud, heuristics evaluation, create task-based scenarios
- 5. Test in the lab but also in the final/real setting

Kushniruk and Patel¹⁰⁵⁻¹⁰⁷ describe different methodological approaches applied and refined for the evaluation of health information systems. The focus of their paper is the assessment of human-computer interaction. The same key words are mentioned: iterative development, prototyping, UCD, quantitative and qualitative data, etc.

However, two recommendations seem important to highlight:

1. “Shift from a focus on the design of software and system components to gaining a better understanding of the interaction between health care information systems and end users in conducting day-to-day tasks”.
2. A sample as small as 5 end-users per iterative cycle can identify the majority of usability problems.

This last recommendation was discussed several years later by two different authors^{108,109}. They end-up with a much more nuanced advice. **“No one size fits all”**. Sample size depends of the complexity of the study and the precise objective of the study. Five to ten participants would be a basis to discover about 80% of usability issues. The more complex the study and the objectives, the more participants you should include with an upper limit of 25 participants. Including more than 25 participants would not permit to find more problems. Finally, you should never forget that the number of evaluators and their quality affects results considerably and probably more than participant group size.

Besides these examples, **the U.S. Department of Health & Human Services** proposes Usability Guidelines concerning web design and digital communications systems in general¹¹⁰. A group of **European experts** developed “Guidelines for good evaluation practice in health informatics (GEP-HI)”¹¹¹ and the **HIMSS Usability Task Force** provides critical information for organizational individuals and leaders on increasing awareness of usability and beginning the institutionalization of the user experience into health organizations¹¹². All these guidelines and recommendations¹¹⁰⁻¹¹² were similar to the recommendations we considered for development and evaluation^{97,98,104,107}.

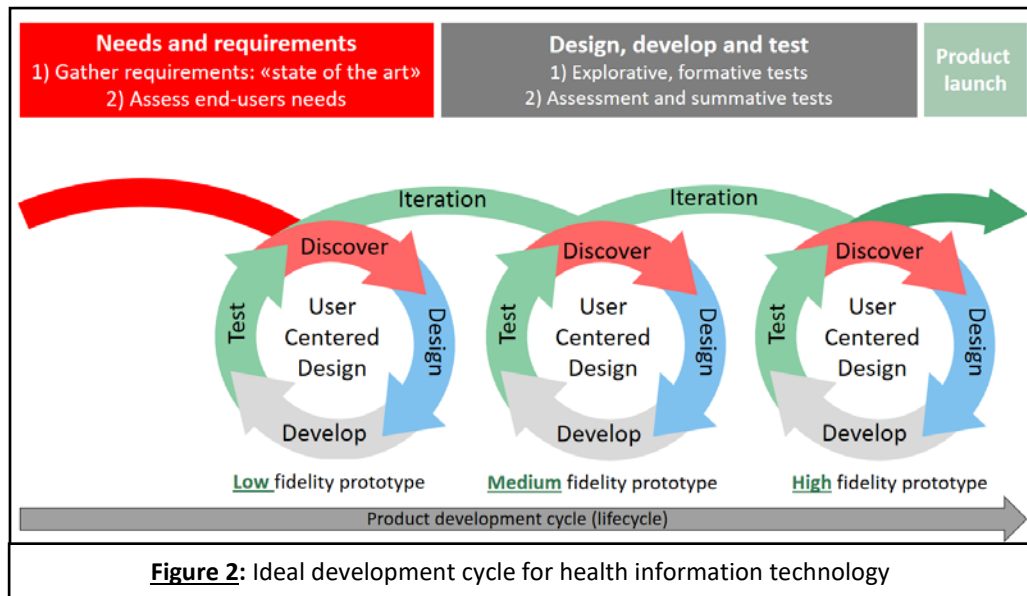
4.3. EXISTING GUIDELINES/RECOMMENDATIONS ON REPORTING OF EVALUATION STUDIES IN HIT

We examined different recommendations on reporting of evaluation studies in health IT, such as **STARE-HI**¹¹³, **CONSORT-eHEALTH**^{114,115} and guidelines for reporting of health interventions using mobile phones¹¹⁶. We summarized key recommendations (Table 3). These were followed when reporting results of the evaluations of the health IT tool.

Table 3: Checklist with a summary of the main items of STARE-HI and CONSORT-eHEALTH^{114,115} recommendations
<u>Title</u> : type of the evaluated system, study question, study design
<u>Abstract</u> : objective, setting, participants, measures, study-design, major results, conclusion
<u>Keywords</u> : EVALUATION , system, setting, outcome measure, study design
<u>Introduction</u> : detail scientific background, rationale for the study, objectives of the study
<u>Study context</u> : organizational setting, developers (names, affiliations, sponsors), system details, history of development, previous publications/prototypes, and system in use
<u>Methods</u> : ensure replicability , study design, clarify the level of human involvement, mode of delivery, features/functionalities/components of the intervention, theoretical background/framework, participants, study flow , outcome measures or evaluation criteria + instructions/co-intervention (education, training, support, incentives) given to users, methods for data acquisition and measurement, methods for data analysis
<u>Results</u> : demographic and other study coverage data, unexpected events during the study (positive or negative), study findings and outcome data, unexpected observations (positive or negative)
<u>Discussion</u> : answers to study questions, strengths and weaknesses of the study, results in relation to other studies, meaning and generalizability of the study (implications for various stakeholders), unanswered and new questions
<u>Conclusion</u> : main findings, impact of the findings and how they relate back to the “big picture”

4.4. OVERVIEW OF THE DEVELOPMENT AND EVALUATION PROCESS

Considering all these recommendations, we built an illustrative Figure of what should be tested at which moment of the development cycle.



This figure was inspired by Figure 3.1 from Rubin J and Chisnell D, Handbook of Usability Testing: How to plan, design and conduct effective tests? Second Edition. Wiley Publishing, Inc. Part I, Chapter 3: When should you test? An overview.⁹⁸ AND by Figure 3.1 from Barnum C, Usability Testing Essentials: Ready, Set... Test! Edition Morgan Kaufmann-Elsevier. Chapter 3: Big U and little u Usability.⁹⁷

The first step of a an IT tool development cycle should be gathering requirements by a review of the literature (“state of the art”) and assessing users’ need by using focus groups and/or individual interviews including different end-users. The second step should last a certain time in order to test the different prototypes of the future tool using an iterative user-centered design. Evaluation test should be slightly different according to the level of the prototype being tested. Quantitative and qualitative data should be collected using different approaches. Finally, the third and last step of the development cycle, should be the launching of the tool on the market.

4.5. ILLUSTRATION: DEVELOPMENT AND EVALUATION OF THE COLORADO CARE TABLET

In the context of this present work, we will focus on the **two first steps** of the IT development cycle. We therefore would like to present **the method used by a research team from the Colorado, USA**, to develop an IT tool on Tablet for older adults. Their publications illustrate the 2 first steps of the development cycle.

1. STEP 1: Needs analysis and requirements gathering: Published as *“Haverhals LM, Lee CA, Siek KA, Darr CA, Linnebur SA, Ruscini JM, et al. Older adults with multi-morbidity: medication management processes and design implications for personal health applications. JMIR 2011.”*¹¹⁷
 - o Aim of the project: To optimize personal health applications (PHA) to assist older people and their caregiver in their medication management
 - o Objective of the study: To understand the medication self-management issues faced by older adults and caregivers that can be addressed by an electronic PHA.
 - o Method of the study: A **qualitative analysis** of a series of individual and group **semi-structured interviews** was conducted. Participants were identified through purposive sampling to capture variations in education, ethnicity, income levels, and living arrangements. They started with two exploratory **focus groups** to refine the guide for semi-structured interviews. The exploratory FG were followed by 16 individual interviews and two confirmatory focus groups. In total, they encounter 32 older adults and 2 family caregivers. All interviews and focus groups were audio-recorded, transcribed for analysis by a transcriptionist, and reviewed for accuracy by a research assistant.
2. STEP 2: Design, develop and test: Published in two different articles: *“Siek KA et al. Colorado Care Tablet: the design of an interoperable Personal Health Application to help older adults with multimorbidity manage their medications. J Biomed Inform 2010”*¹¹⁸ and *“Siek KA et al. Colorado Care Tablet: the design of an interoperable Personal Health Application to help older adults with multimorbidity manage their medications. J Med System 2011”*⁶³

- o Aim of the project: To optimize personal health applications (PHA) to assist older people and their caregiver in their medication management
- o Objective of this paper: Presenting an overview of the design and development of the PHA, named the Colorado Care Tablet. In addition, the best way to implement each design requirement was explored.
- o Method of the study: **User-centered iterative design**. Six iterative cycles were used. A total of 22 patients and 9 caregivers participated to the development of the PHA. **Quantitative as well as qualitative** data were collected. The high-fidelity prototype was tested compared to another PHA. Each cycle had specific goals. For example,
 - Iteration 1: design and evaluate paper-based prototypes informed by participants' everyday reality.
 - Iteration 3, Refine the medication list management interface and evaluate alternate forms of input mechanisms.

5. THE BELGIAN CONTEXT

5.1. EHEALTH ARCHITECTURE IN BELGIUM

a. eHealth Platform, Hubs and Métahubs.

In Belgium, the eHealth platform is a public institution that aims to promote healthcare services as well as secured health information exchange (HIE) within the healthcare system by respecting confidentiality and privacy of health information.

The architecture is based on a “System-to-system” system also called “Hubs & métahubs”. One main characteristic of this system is the exchange of information between the different Hubs without any centralization of the data. Healthcare professionals (HCPs), currently mostly physicians, are affiliated to a chosen Hub. Five Hubs (also called network systems) exist:

1. Réseau Santé Wallon (RSW)/Intermed – Wallonia region
2. Collaborative Zorgplatform (CoZo) – Flanders region
3. Vlaams Ziekenhuisnetwerk KU Leuven (VznKUL)/Vitalink – Flanders region
4. Antwerpse Regionale Hub (ARH) – Flanders region
5. Abrumet/Brusafe – Brussels-Capital region

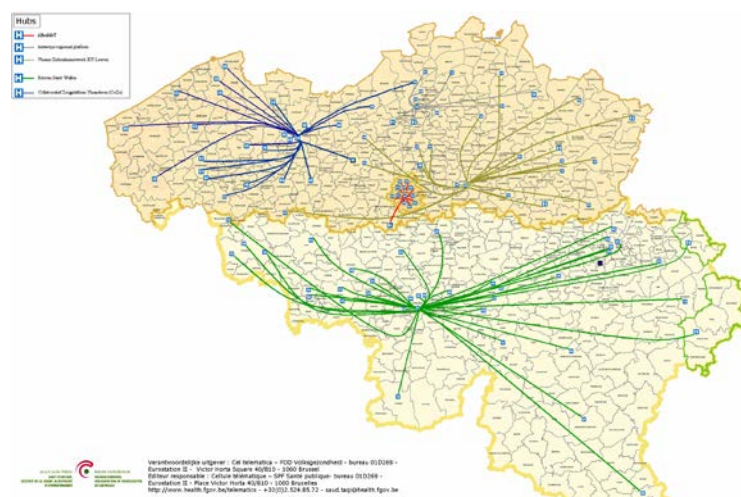


Figure 3: Belgium and the 5 Hubs

Each hub contains a reference register indicating where, in which electronic medical record, documents of a given patient can be found. The métahub system is there to support HIE. They help the hubs to find if a patient has documents registered on another hub, another network system. Patients' data are accessible through this "Hubs & métahubs" system only if the patients have given their eHealth consent, or PatientConsent. The PatientConsent is registered with the electronic identity card and the PIN code of the patient. The patients are supposed to receive clear and exhaustive information concerning their consent. Afterwards, they can give their PatientConsent through (1) the eHealthConsent application, (2) their GP, their community pharmacy, their health insurance fund, the hospital admissions service, or (3) the patient portals of one of the five eHealth networks.

For example, Docteur B working in Brussels area, as a general practitioner using a local software, consults for patient S (who has given his PatientConsent) the HUB "Abrumet". Thanks to the Hub "Abrumet" he learns that patient S has a set of documents in two different hospitals in Brussel. Thanks to the "métahub" he can also see that patient S went to the hospital in the KU Leuven where some documents concerning a recent hospitalization can be found thanks to the Hub "Vlaams Ziekenhuisnetwerk KU Leuven" (Figure 3).

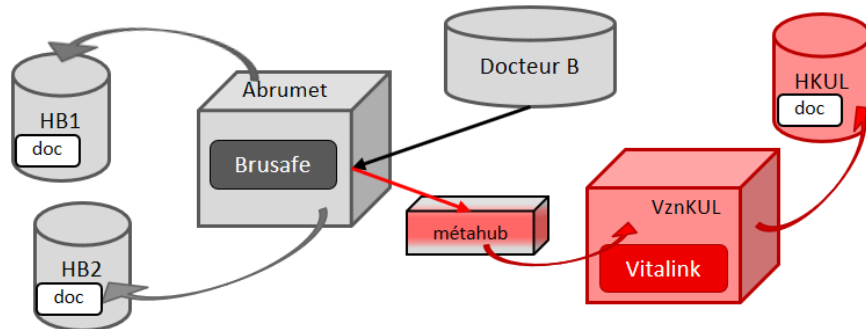


Figure 3: Docteur B, working in Brussel consulting the Hub "Abrumet" found documents (doc) in Hospital 1 (HB1) and Hospital 2 (HB2). The Hub through the métahub could also retrieve information from the KU Leuven (HKUL).

Some Hubs have also a safe or digital platform (Intermed, Vitalink, BruSafe) where some information concerning a given patient can be registered. The aim of this digital platform is to allow consultation of documents of an electronic medical

record temporarily disconnected from the Hub, for example because the computer is offline.

To facilitate communication and information interoperability between different healthcare sectors (general hospitals, general practitioners, private laboratories, medical centers,...), eHealth ask for standardization. In the context, of this work, two standardization systems are of interest.

1. Communication standards are based on the KMEHR (Kind messages for Electronic Healthcare Record) communication system.
2. The patient health summary, SUMEHR (Summarized Electronic Health Record), is a standard summary published exclusively by GPs. The SUMEHR corresponds to the minimum set of data that a physician needs to have a view of the medical situation of a patient. A SUMEHR, using KMEHR, is typically registered onto one of the Hubs' digital platforms.

Both standards (KMEHR and SUMEHRs) will be used in the context of this work.

On the 20th of November 2017, more than **6.6 millions of patients had given their PatientConsent**¹¹⁹ and more than 1,8 patients had at least one SUMEHR published on one of the 3 digital platforms. In total **end October 2017, 2.587.603 SUMEHRs had been published** (792.703 on Intermed, 1.596.382 on BruSafe and 1.596.382 on Vitalink)¹²⁰.

Apart from the Hubs, community pharmacists have also been working on health information exchange between the different community pharmacists, via a system called "DPP=dossier pharmaceutique partagé" or "GFD=gedeeld farmaceutisch dossier". If the patient has given his eHealth consent, pharmacists exchange drug delivery data: the exact name of the medication and the box that was bought by the patient. However, they do not exchange information concerning doses and frequency.

b. eSante Action Plan

The first version of this plan was elaborated during autumn 2012 as the "eSante Action Plan" 2013-2018. An update came out in 2015¹²¹. This plan was discussed with caregivers, members of patients' associations, of social security, of IT industry and authorities. The plan defines the IT objectives of the Belgian authorities for the Healthcare system. To fulfil his different objectives, the eSante roadmap has pointed out 20 fields of actions. The third field concerns the

“medication scheme”¹²², the sixth the “sharing to collaborate”¹²³ and the tenth the “patient access to his health information”¹²¹.

For end 2019, every **general practitioner** will have to use an electronic chart for each patients and will have to publish patients’ summaries (SUMEHR) on the corresponding “Hub”. An electronic medical record will have to be defined for other HCPs (physicians, pharmacists, physiotherapists, nurses, dentists, etc.). They will also be able to publish information on the different Hubs. **Every HCP** will have to be able to, at least, consult documents available via the different Hubs and, even better, integrate documents’ contents into their own electronic medical records (EMR). Every HCPs, including pharmacists will have to be able to create and modify “medication schemes” that will be published on the different digital platforms (Intermed, Vitalink, BruSafe). These medications’ schemes will be shared with physicians, pharmacists and nurses working inside or outside the hospital.

Concerning **the patient**, he will have access to all the available information concerning his health on the different Hubs and on the different digital platforms. He will be able to consult the content of the documents, but probably with some information filters (under discussion). He will access all his health data by using a secured authentication system on his computer as well as on his smartphone. The exact mechanism are still under reflection.

c. The medication list: what exactly can be communicated with who and how?

On January 2018, the situation is as follows. Information concerning the medication list of a given patient are available on the different digital platforms (Intermed, Vitalink, BruSafe) in a specific section of the SUMEHR (Figure 4). This information is published and registered by the general practitioner and is consultable by any other physicians connecting to the corresponding Hub. Information concerning medication are also available via the hospitalization reports or consultation reports published by the different hospitals. Information is available but, unfortunately, not always understandable (for example, see posology of the medications) and most of the time not integrable into the local electronic medical record used by physicians and thus into the electronic chart of

a given patient. This happens because interoperability between the different software is not optimal

Rapport résumé d'urgence - Fichier créé le 26/10/2017

Aperçu général | Intolérances médicamenteuses | Diagnostics | Antécédents | Médications | Vaccins

Patient
 NISS
 Nom
 Prénom
 Sexe
 Date de naissance
 Adresse

Auteur
 IJAMI 1.96510.12.004
 Profil Médecin
 Nom
 Prénom
 Adresse
 Téléphone
 Email

Gestionnaire du DMG
 IJAMI
 Nom
 Prénom
 Date

Intolérances médicamenteuses

Description	Début	Fin	Statut	Commentaire	Certitude	IBUI/ICPC/ICD
eruption cutanée type 0 sur lidocaine	04/03/2013					-/-

Diagnostics

Description	Début	Fin	Statut	Commentaire	Certitude	IBUI/ICPC/ICD
Pan sinusite chronique	18/01/2017		active			-/-/J32
bio ok atypiques en cours pas enceinte très mal aux sinus maxillaires avec irradiation dans les dents à D je propose simuto + 500 mg paracétamol et ibuprofène si néé + contraception	04/01/2017		active			-/-/J32
Sinusite maxillaire avec infection des voies respi sup et otite à G	03/01/2017		active			-/-/J01.0
Eruption > allergie à la lidocaine	08/09/2015		active			-/-/
Rhinosinusite maxillaire et ethmoïdale aigue	28/08/2015		active			-/-/
virose? Début angine?	24/08/2015		active			-/-/
syndrome grippal	04/03/2013		active			-/-/

Antécédents

Description	Début	Fin	Statut	Commentaire	Certitude	IBUI/ICPC/ICD
multiples fractures des membres entre 8 et 16 ans, toutes d'origine accidentelle	04/03/2013		inactive			-/-/
néant	04/03/2013		inactive			-/-/
accouchement par césarienne 2x 4/07/2013 et 3/08/2015	04/03/2013		inactive	césarienne pour siège		-/-/W92/O82.9
dent de sagesse	04/03/2013		inactive			-/-/
hypotension artérielle	04/03/2013		inactive			-/-/K88/I95.9
glaucome	04/03/2013		inactive			-/-/T61/E04.9
fragilité ORL angine à répétition fragilité ORL sinusite à répétition maxillaire	04/03/2013		inactive			-/-/
varicelle(s)	04/03/2013		inactive			-/-/K99/I86.8
enfance fracture multiples	04/03/2013		inactive			-/-/

Médications

Description	Début	Fin	Statut	Temporalité	Dosologie	Instructions	Cnk/Atc
Cataflam (c) 50mg - 30 compr. enrobé(s)	26/10/2017		prescribed	chronic	1 00005 1		0444165/M01A05
D-Cure (c) 25000 IU/ml - 4x1 ml amp. buvable(s)	09/06/2016		prescribed	chronic	1 00002 1	à prendre avec le repas le 2661163/A11CC05	
Cetirizine EG (c) 10mg - 50 compr. pelliculé(s)	09/06/2016		prescribed	chronic	1 00005 1	plus gras au coucher	1736248/R06AE07
Dafalgan (c) 500mg - 32 comprimés effervescents p.o.	04/03/2013		prescribed	chronic	1 00005 3	SN	0044545/N02BE01

Vaccins

Description	Indications	Date	Statut	Commentaire	Cnk/Atc
Navix 1440 (c)	hepatitis	30/08/2016	administrated		1149939/J07BC02

Avertissement : Les données présentes dans un SUMEHR ne peuvent être considérées comme exhaustives. Ceci est en concordance avec les principes du RSW. Ces données sont présentes à titre purement indicatif et ne dispensent jamais d'une anamnèse circonstanciée.

Figure 4: A SUMEHR viewed through the Hubs “Réseau Santé Wallon” or “Abrumet”

In Flanders, every pharmacist (community and clinical pharmacists) has access to the medication scheme and the vaccines published on Vitalink. In Brussels and Wallonia, community pharmacists do not have access to the different Hubs. Clinical pharmacist working in hospitals have access exclusively to the section “medication and vaccines” of the SUMEHRs of the patients. Besides, the only information shared currently between community pharmacists and physicians is done via Recip-E, which is a system allowing communication of prescribed medication exclusively. Currently very few hospitals are using Recip-E. This means that there is quasi no health information exchange between the community pharmacists and the hospital, except for phone call and private emails. Although, the need of electronic transfer of medication data between primary and secondary care was already underlined several years ago²².

5.2. PROMOTING MEDREC IN BELGIUM

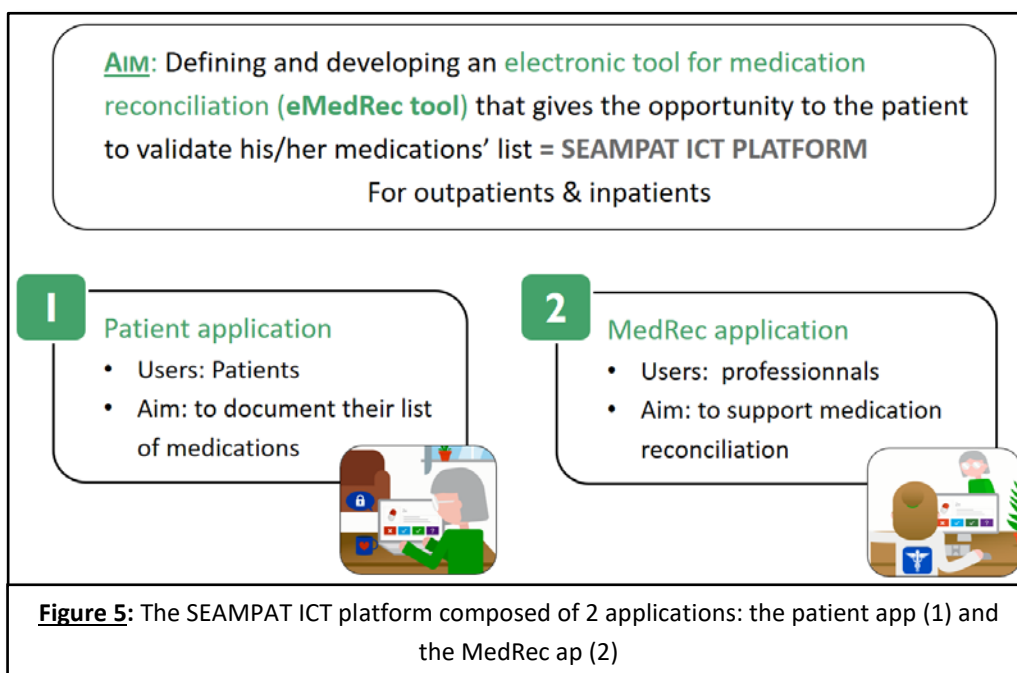
A report published by the Federal Center of Expertise of Healthcare in 2010, exhorted the launching of national campaigns on continuity of care focusing on medications. The same report asked for guidelines on optimizing continuity of care, financial incentives and improvement of electronic health care infrastructure.

Since then, national and regional campaigns have been set up. A lot of research projects and initiatives related to continuity of care were set up^{12,14,23,28,124-126}. The eSante Action Plan has been elaborated and first steps of the plan are under implementation. Some improvements are underway concerning the electronic healthcare infrastructure. But, the situation still needs to be ameliorated.

5.3. THE SEAMPAT PROJECT

The SEAMPAT research project emerged in this specific national and international context and received funding from the “Walloon Region” in 2014. The project aimed to define, develop and implement in Wallonia **an electronic tool to support/facilitate medication reconciliation (e-MedRec)** for all stakeholders of the MedRec process, those from the primary and the secondary care, including the patient. The initial idea of the project came from the multiple problems encountered in clinical practice, and the potential interest to have the patient documenting his medication intake. Therefore, the SEAMPAT information communication and technology (ICT) platform is composed of two applications: a first one for the patient, “the patient app”, and a second one for health-care professional, “the MedRec app” (Figure 5).

The project is led by UCL (Louvain Drug Research Institute, clinical pharmacy research group: LDRI/CLIP) and assembled researchers with various, appropriate



and complementary skills and knowledge (physician, pharmacist, computer scientists, lawyers, anthropologist/sociologist). The project includes 9 working packages (see appendixes). The present thesis project is embedded in the SEAMPAT project and I have worked on five working packages.

Different 'sponsors' are supporting the project and helped out at the diverse phases of the development cycle. In addition, an external expert panel including different physicians (general practitioners and specialists), pharmacists, nurses, patients and government leaders gave also comments at several time points of the project.

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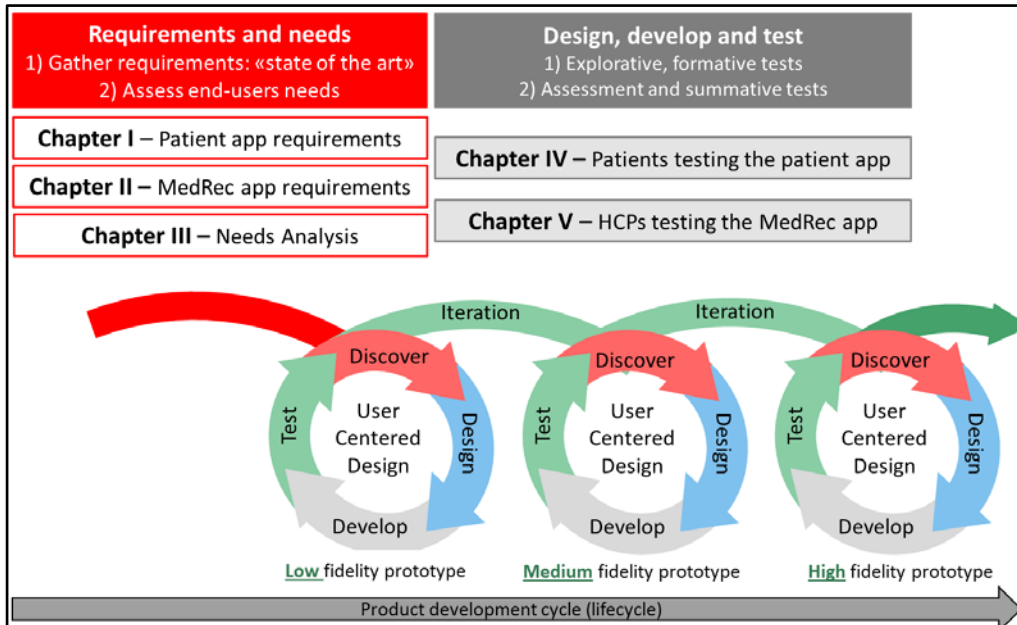
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Research Objectives & Thesis Overview

Research objectives

1. Objectives



In the context of this present work, we focused on the two first steps of the IT development cycle as we do not aim to launch any MedRec tool on the market. Each step of the development corresponds to one of my research objectives.

1.1. RESEARCH OBJECTIVE NUMBER ONE

The first research objective is to **identify requirements as well as users' needs and expectations** for an eMedRec tool composed of a patient app and a MedRec app.

We started by gathering requirements for the two applications that constitute the SEAMPAT ICT platform: the patient app and the MedRec app.

Firstly, we synthesized functional as non-functional requirements in order to aliment specifications (cahier des charges) for the design and development of both applications.

Chapter I, entitled "Most important requirements to build a patient app for MedRec", is a narrative review of the literature.

Chapter II, entitled “Most important requirements deemed by healthcare professionals (HCPs) to build an eMedrec tool with a patient app”, is a systematic review of the literature.

Secondly, a needs’ and expectations’ assessment analysis was done using different focus groups corresponding to the different end-users categories: patients, general practitioners, community pharmacist, physician specialist and clinical pharmacist. This assessment fulfilled functional and non-functional requirement in order to have exhaustive specifications for the computer scientists.

Chapter III, is entitled “What are the needs of patients and healthcare professionals concerning the use of IT for MedRec?”

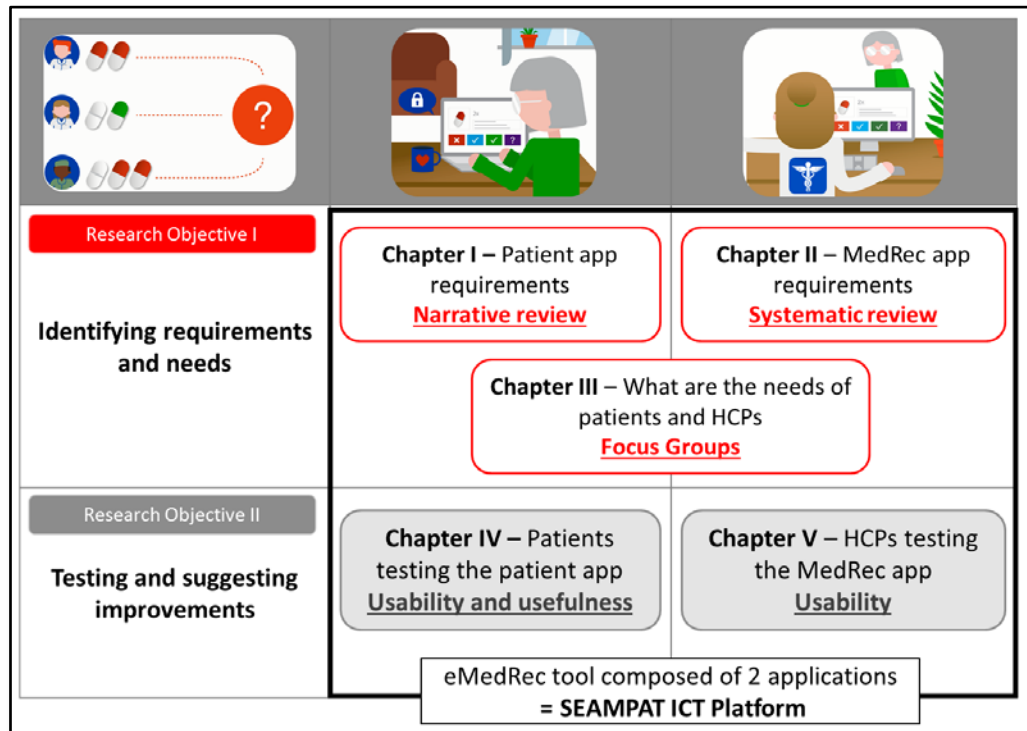
1.2. RESEARCH OBJECTIVE NUMBER TWO

The second research objective of my work is to **test and suggest improvements** concerning an eMedRec tool composed of a patient app and a MedRec app. Both applications have been tested using an iterative user-centered design with different prototypes (low-, medium-, high- fidelity prototypes). Findings are synthetized in two different chapters corresponding to the evaluation of the two applications.

Chapter IV, reports findings from the evaluation of the three different prototypes (low-, medium-, high- fidelity) of the patient application. The aim of this Chapter is to evaluate usability of the two first prototypes. Concerning the third prototype, we evaluate **usability and usefulness**. This Chapter is entitled “Patients testing the patient application”.

Chapter V, reports findings from the evaluation of the three different prototypes (low-, medium-, high- fidelity) of the MedRec application. The aim of this Chapter is again to evaluate **usability of the three prototypes**. This fifth Chapter is entitled “Healthcare professionals testing the MedRec application”.

2. Thesis overview



Research objectives

Results

Research objective I :

Identifying requirements as well as users' needs and expectations for an eMedRec tool composed of a patient app and a MedRec app

Chapter I – Most important requirements to build a patient app for MedRec

A narrative review

S. Marien, D. Legrand, A. Spinewine

Chapter I at a glance

What is already known about the subject?

- We know that patients are generally positive about being involved in their own health care.
- However, multiple factors influence patient participation.
- Patient participation can improve medication continuity.

What this chapter adds:

- We identified 14 systems involving the patient in medication reconciliation processes using or not using information technology
- Our literature review helped us identifying and categorizing factors influencing patient participation. The key influencing factors highlighted by authors are: patient-provider relationship, provider's attitude and education.
- This work enabled identification of factors influencing the use of eHealth: patients have an overall positive attitude about using health information technology, are worried about security, confidentiality and their ability to use information communication technology (ICT) regarding their health efficiently (and without unnecessary expense).
- We end by formulating recommendations and advice for the design and development of the patient application of the SEAMPAT ICT platform. These recommendations concern:
 - The development and designing of the patient app. Therefore, we elaborate a set of functional and non-functional requirements.
 - The identification of the target population for the evaluation of the patient application.

Related Publication

Part of the Lecture Notes in Computer Science book series (LNCS, volume 9758)

Authors' Contribution

Sophie Marien, main author of this chapter. Built up the research query, screened articles for inclusion, extracted data and elaborate implications for the patient app development and design.

Anne Spinewine validated each step of this work (building research query, article inclusion, data extraction, elaboration recommendations...) and in case of any doubt, helped to make a decision.

Delphine Legrand has helped for the screening of the results of the patients' database research, has helped writing the methodology section, and has read the whole chapter to verify consistency.

ABSTRACT

Introduction: Patient participation is increasingly recognized as a key component in the redesign of the healthcare process and considered as a means to improve patient safety. Indeed, patient participation could improve continuity of care and more specifically continuity of medication. However, multiple facilitators and barriers are influencing this participation. The use of information technology (IT) is considered a means to engage the patient in his or her health. But how to engage patients by using IT to improve medication continuity is still unclear.

Objective: the aim of this present work is double.

(1) Identifying existing systems that allow patients to participate in the medication reconciliation process.

(2) Identifying factors influencing patient participation (positively or negatively) in safety of care and in continuity of medication

Method: Two literature searches were conducted to answer both objectives. Boolean queries were built using associations of controlled vocabulary and free text. We searched Pubmed and Scopus but also international patents databases. Inclusion and exclusion criteria were specific to each objective. Identification, analysis and data extraction (using standardized extraction forms) were done by SM and validated by AS.

Results: We identified 10 electronic tools enabling the patient to participate in medication continuity. Four additional processes engaging the patient in MedRec without the use of IT were also identified.

Patients are willing to engage in their healthcare but this highly depends on their own ability, resources, preferences as well as healthcare endorsement and healthcare organization. Factors influencing patients' participation have been synthesized in Table 7.

Conclusion: The literature reviews delivered fruitful results and enabled us to formulate functional as non-functional requirement for the patient app of the SEAMPAT ICT platform. Results also helped defining the best target population for the future evaluation of the patient app.

KEYWORDS

Patient participation, medication reconciliation, continuity of care, information technology, patient portal.

1. INTRODUCTION

Patient engagement is increasingly recognized as a key component in the redesign of health care processes and advocated as a mean to improve patient safety and quality of care¹. Many different ways of engaging the patient have been explored²⁻⁴ and many factors can influence positively or negatively patient participation^{5,6}.

Information technology (IT) systems have been progressively replacing paperwork and the health system is no exception⁷. IT solutions seem to be promising to improve efficiency and accuracy of specific intervention. However, in many health activities the transition from paper to electronic is challenging.

There have been studies reporting the engagement of patients in their health through the use of IT⁸. However, the exact added benefit of patient participation in medication continuity by the use of electronic is still unclear. It is thus necessary to summarize existing data in order to correctly design IT tools that will be used by patients to improve medication continuity.

Therefore the aim of this present work is:

- 1) To identify existing system allowing the patient to participate in the medication reconciliation process
 - a. **Systems enabling electronic documentation** of the medication list by the patient or by a caregiver, whether or not these systems are linked to a tool allowing electronic medication reconciliation (MedRec) by the health care provider.
 - b. **Systems involving the patient** in the MedRec process **without** the use of **electronic**
- 2) To identify factors influencing patient participation (positively or negatively) in safety of care and in continuity of medication

Identification of systems engaging the patient in the MedRec process by the use of electronic or not and factors influencing patient participation will enable us to formulate recommendations and advices to inform design, development and evaluation of the patient app for medication reconciliation.

2. MATERIAL AND METHODS

The present work consisted in literature reviews. The results were used to generate recommendations for the patient application to be developed for the SEAMPAT ICT platform.

2.1. EXISTING SYSTEMS ALLOWING THE PATIENT TO PARTICIPATE IN THE MEDICATION RECONCILIATION PROCESS

We searched both patents' database as scientific literature (Pubmed and Scopus). The search in the international patents databases (FamPat) "Questel Orbit" and in the public international patents database "Espacenet" was performed with the help of Picarré propriété intellectuelle.

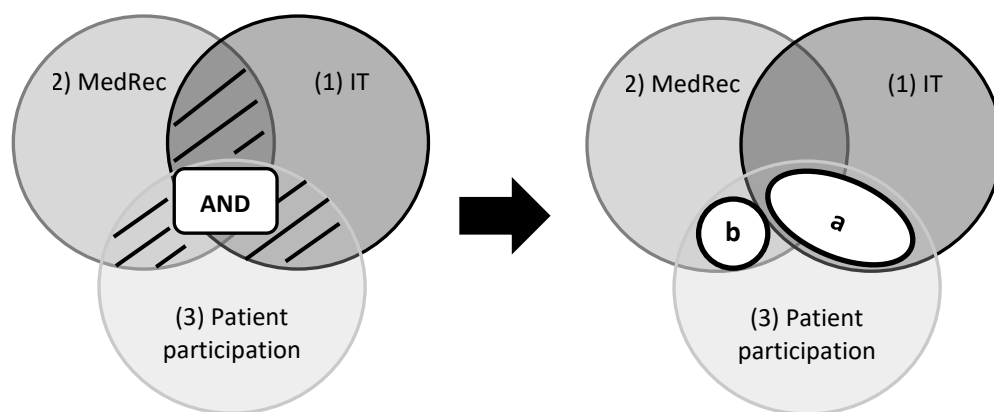


Figure 1a : Search strategy elaborated to identify tools (electronic or not) allowing the patient to participate in the MedRec process

Figure 1b : Studies were included in :
- group a when electronic was used
- group b when patient was engaged without the use of electronic

A first search was conducted in international patent databases in May 2013 with an update in June 2014. Several concepts were used to build up the research queries: drug reconciliation, electronic patient encoding, electronics and authors identified during the preparatory work. The research queries have combined the previously cited concepts with the authors and citations of the documents. The complete strategy can be found in Appendix I.

Regarding the scientific literature search, we developed a research query in Pubmed with controlled vocabulary ("MeSH") and free text combining three groups of words. The research query was built in June 2014 and translated into the controlled vocabulary of Scopus database at the same period. Because, combining the three groups of words by "AND" (Fig 1a and Appendix II) identified very few studies, words of group 1 and 2 were associated using "OR". Studies at the intersection of (group 1 OR 2) AND group 3 were screened for inclusion (Fig 1b). In addition, we checked the reference list of included studies and relevant reviews. An update was done in September 2017.

To be included a report had to describe the design and the functioning of the system as the development of the system or the evaluation of the system. Reports were categorized in two different groups:

- a. **Systems enabling electronic documentation** of the medication list by the patient or by a caregiver linked or not to a tool allowing electronic MedRec by the health care provider.
- b. **Systems involving the patient** in the MedRec process **without** the use of **electronic**

No exclusion criteria were applied concerning design of the study, date of publication or country. However, we did not include IT systems enabling encoding of general health information without a specific module or focus on medications. We did not include IT systems developed to improve medication adherence without a direct link to a MedRec tool or a MedRec process.

First inclusion was done by screening title and abstract. Inclusion was then confirmed by reading full text (article/patent). When several publications were related to the same system, these were grouped together. Authors of MedRec tools⁹⁻¹⁴ with a fully electronic process were contacted in order to get information about the actual use of the tool.

Data were extracted using a standardized extraction sheet based on (1) the Cochrane Effective Practice and Organization of Care data collection form, (2) form used in previous systematic reviews⁸, and (3) data needed to inform development of the SEAMPAT patient application. Data were extracted by main researcher (SM) and systematically verified by a second researcher (AS). Analysis of results is purely descriptive.

2.2. FACTORS INFLUENCING PATIENT PARTICIPATION (POSITIVELY OR NEGATIVELY) IN SAFETY OF CARE AND IN CONTINUITY OF MEDICATION

Based on several articles that were identified during the development of the SEAMPAT project during the year 2013, the literature search was extended by (a) hand-searching the references lists of these articles and (b) constructing a research query in Medline (via the Pubmed Central portal) based on the keywords assigned to the previously identified articles. Again a research query combining "MeSH Terms" (belonging to the thesaurus of Pubmed) and free text was build in June 2014. Two groups of terms were associated by an "AND":

- a. A first group, related to security of care and continuity of care. These include the following MeSH terms "Patient Safety", "Medication Reconciliation", "Continuity of Patient Care" and free text, such as "Medication Reconciliation", "Patient Safety" and "Patient Centered-Care".
- b. A second group, related to patient participation, using the MeSH term « patient participation » and the same free text as previously such as «patient engagement», «patient involvement» and «patient empowerment» and directly derived expression such as « patient engage », « engaging patients », « patient involved », etc.

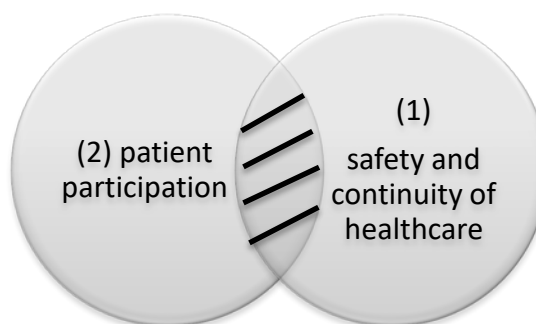


Figure 2 : Search strategy to identify articles dealing with factors influencing patient participation in safety, security and continuity of healthcare

The unstructured literature research at the beginning of the project showed that there was (1) a very large number of publications dealing with the active participation of patients in patient safety and/or quality of care, (2) a significant heterogeneity in the definitions of patient participation and the subjects treated, these subjects being sometimes quite remote from the Seampat theme (e.g. hand hygiene, prevention of ventilator-associated pneumonia, etc.), (3) few studies covering specifically patients' active participation in the MedRec process.

After several discussions between members of the SEAMPAT research team, it was decided:

- (a) **Concerning the active participation of patients in the safety** of their own care, to include only **systematic reviews and narrative reviews**.
- (b) Concerning patient **active participation in medication continuity**, to include **all type** of studies (including qualitative studies) assessing **facilitators and barriers** of patient participation.

The main researcher (SM) identified and included articles. Data were analyzed using standardized extraction forms organized into 4 subtopics: objectives, method, main results and conclusion. Articles inclusion and data extraction was validated by a second researcher (AS). Factors affecting patients' willingness to participate in the safety of their own care were organized using a slightly modified version of Rachel E. Davis categories of Table 1: Factors affecting patients' willingness to participate in improving the safety of their own health care⁶. Results were discussed within the SEAMPAT research team. Key messages to inform the patient app design and development were identified.

Table 1: Factors affecting patients' willingness to participate in improving the safety of their own health care	
<i>Categories by Davis RE</i>	<i>Categories adapted for SEAMPAT</i>
1. Patient-related	1. Patient-related
2. Illness-related	a. Factors related to patients' characteristics (profile, nature, temper, gender, age...) b. Factors related to people surrounding the patient, his/her social network c. Factors related to patients' illness (type and severity)
3. Health care professional-related	2. Health care professional-related
4. Health care setting-related	3. Health care setting-related
5. Task-related	

3. RESULTS

3.1. SYSTEMS ALLOWING THE PATIENT TO PARTICIPATE IN THE MEDICATION RECONCILIATION PROCESS

Forty-eight research queries were used in the patent databases of “*Picarré propriété intellectuelle*” in June 2014. From those 48 queries, the 9 most relevant queries identified 1146 patents (Figure 3). All were screened on title and abstract, and allowed us to identify 38 documents. After reading full text, 4 patents met our inclusion criteria: Tripoli L. (2 patents), Lesselroth Bl. (2 patents).

Thirty-one studies were included in the two different groups (Figure 3: flow chart): 24 articles in “group a” and 7 articles in “group b”. Studies from “group a” engaged the patient in the MedRec process by the use of electronic. In “group b”, we include studies actively engaging the patient in the MedRec process but without the use of electronic.

Both the systems of “group a” and of “group b” strongly encourages the patients to improve their knowledge about their medication plan and to actively participate in communicating medication information. Some studies¹⁵⁻¹⁷ showed that patient engagement and patient feedback improved the accuracy of the medication list and by this MedRec.

a. **Systems enabling electronic documentation** of the medication list by the patient or by a caregiver linked or not to a tool allowing electronic MedRec (eMedRec) by the health care provider (24 articles – 10 tools).

Table 2 describes the main characteristics of the 10 identified tools enabling electronic documentation of the medication list. We then provide a summary of each tool.

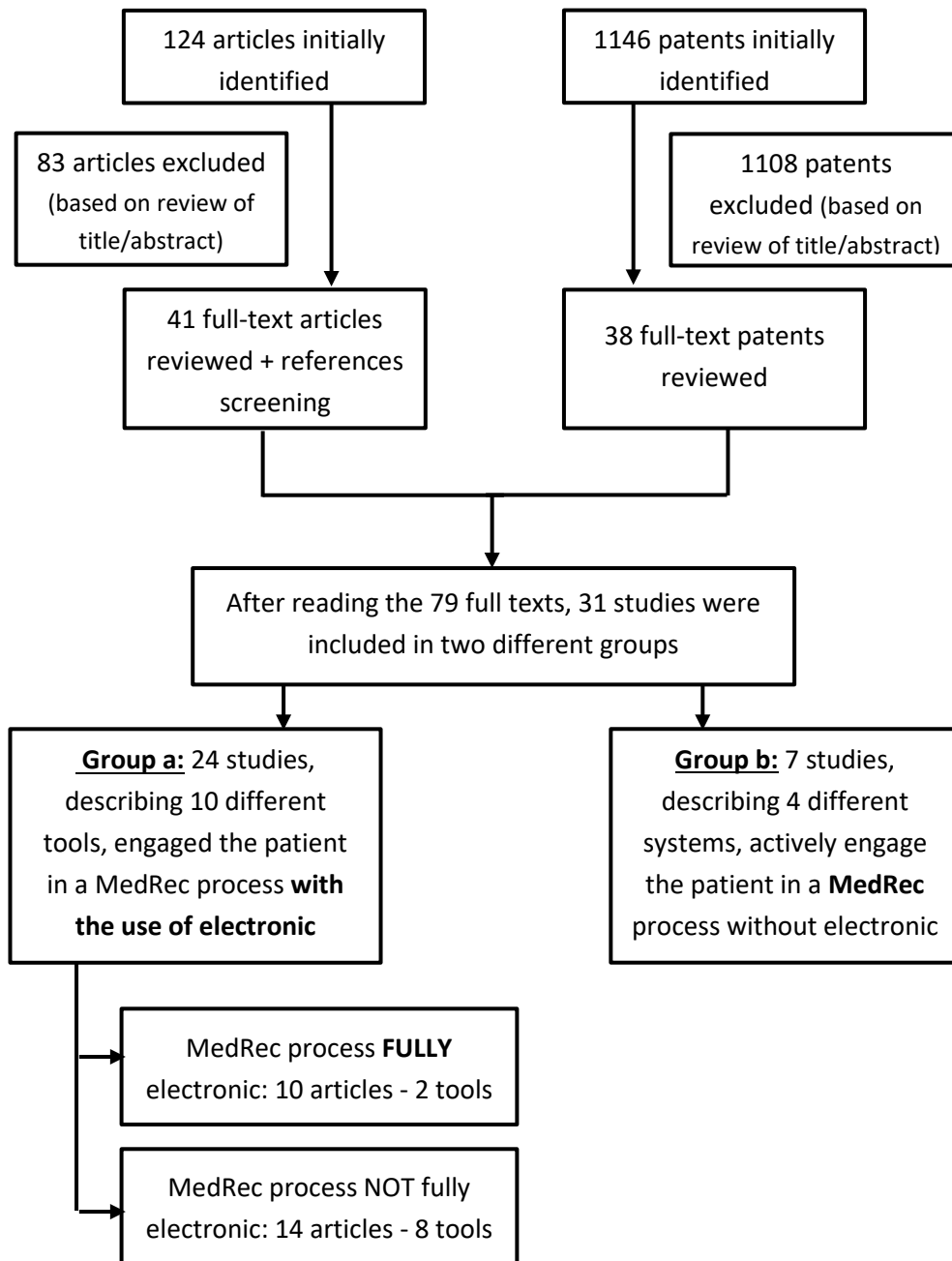
**Figure 3 :** Flow chart

Table 3: Characteristics of the 10 identified systems enabling electronic documentation of the medication list		
Countries	All identified electronic systems were developed in the US	
Health care organization	• Veteran Affairs health system^{13,18-20}: 3 • University/Tertiary hospital/Regional system^{15,17,21,22}: 3 • Not-for-profit organization¹⁶: 1	• Private insurance⁹: 1 • Family Practice²³: 1 • Unknown: 1
Setting	Except for the Interactive Patient Medication List, all systems were exclusively developed for outpatient clinic or ambulatory care.	
Medication sources	<u>No link to any medication source</u>: Iowa PHR¹⁷ and Heyworth SMMRT²⁰ <u>Multiples sources</u>: The Interactive Medication List^{9,10}	<u>One source</u>: The APHID^{13,14,18} (EMR), The Gateway^{15,22} (EMR), The Colorado Care Tablet¹⁹ (pharmacy fulfillment), The MedTable^{24,25} (EMR), Patient portal with secure messaging²¹ (EMR), MyGeisinger¹⁶ (EMR), a web-based application using artificial intelligence²³ (EMR)
Main functionalities	<u>Documenting medication</u> • Patients have 3 or 4 options to check + the possibility to add medications ± comments in free text^{13,16,22,23} • Patient checks Yes/taking or No/no longer taking⁹ and add medication/comments in free text²⁰ • Patients delete/modify medication schedule¹⁹ • Not clearly mentioned^{17,21,25}	<u>Other functionalities</u> • Asking for prescription refill^{9,16,22} • Viewing other health information into the EMR: lab results^{16,17}, physicians' notes, health summaries¹⁶ • Managing: administrative profile, medical appointments^{16,19,22} • Red flag symptoms¹⁹ • Health related educational resources or app recommendation^{17,22,23,25}, printing possibilities^{20-22,25}
Disadvantages	• Not accessible to everybody (without a specific health insurance, lack of computer knowledge, low socio-	• Some systems showed inconsistency in matching medication pictures which can confuse patients^{18,19}

	economic status...) • Most systems have maximum one source of medication^{13-16,18,19,21-25} • Most systems are not directly linked to the application allowing electronic MedRec by a HCP^{16,17,19,23,25} • Merge of the patient documented information into the EMR is not easily done or not possible, need for manual encoding by the HCP	• Some tools are not taking account of medication dosage • Very few systems describe safety culture¹⁷, patient education... necessary to reach system adoption by patients • Very few systems mentioned tutorials or support embedded into the tool¹⁷ • Few rigorous evaluation of the tools concerning effectiveness and efficiency^{15,25}

Abbreviations: APHID: automated patient history intake device; EMR: Electronic Medical Record; PHR: Patient Health Record; SMMRT: Secured Messaging for Medication Reconciliation Tool; US: United States of America.

Two MedRec tools had a fully electronic process, which means the 3 steps of MedRec (gathering the Best Possible Medication History, identifying discrepancies, resolving discrepancies) are performed thanks to electronic.

- In Portland, Oregon – USA, the Automated Patient History Intake Device (APHID)^{11-14,18,26,27} was elaborated for patients scheduled for an outpatient consultation and the kiosk is accessible only in the outpatient clinic. Usability and satisfaction were evaluated and patients' feedback was collected to improve the tool. This one appeared to be easy to use for the patients. A randomized controlled trial started in 2012 (RCT protocol) to evaluate the accuracy of the collected information but no results have been published yet.

- The Interactive Patient Medication List^{9,10} (San Diego, California – USA) enables patients to document their medication intake based on a consolidated medication list. It also offers additional functionalities: access to all medication sources available on the health network and identification of the differences, adherence evaluation, ordering in advance medication at the pharmacy, etc. According to the inventor of this patent, the tool is not yet implemented but has already been discussed in focus groups with HCPs.

Eight MedRec tools supporting patients' engagement in the update of their medication list by the use of electronic. Sharing the information updated by the patient, identifying discrepancies and/or resolving discrepancies were not performed electronically by the following tools.

- o Patients participate to the update of their medication list by the use of a specific module embedded into their patient portal or their personal health record. A patient portal is defined as a secure online website that gives patients convenient 24-hour access to personal health information from anywhere with an Internet connection. Using a secure username and password, patients can view health information²⁸. In the following MedRec systems, the input of the patient can not be used directly by the healthcare professional.
- The Gateway^{15,22} is a secure patient portal, developed by Partners HealthCare System (Massachusetts – USA) allowing patients to view the current active medication list from the local EHR (=LMR). The patient is asked to compare this list with what he/she thinks he's taking and to ask details regarding discrepancies. It was designed with a combination of structured information and free text boxes offering a certain freedom to the patient but still offering the possibility to easily import information from the Gateway into the LMR. The last publication was in 2012: reporting a reduction of unexplained discrepancies with potential for harm.
- Iowa personal health record (PHR)^{17,29} (Iowa – USA) is a web-based application that allows patient to view, print and modify medication information, allergies and health information. The PHR, developed using a participatory design, displayed medication safety messages such as

important laboratory monitoring (potassium monitoring when taking and ACE inhibitor) and drug-drug interactions. After adjustment for baseline differences, patients using the PHR showed a higher rate of reporting verbally stopping/starting a medication or modifying the dosage of a medication during the MedRec process at the time of the doctor's visit. The Iowa PHR can be considered as a tool improving patient education about the importance of reporting adherence and participating in the MedRec process.

- o A dedicated tool, independent of a patient portal or patient health record, was created to engage patients in their medication management.
 - The Colorado Care Tablet (CCT)^{19,30-32}, developed in the Colorado, USA, was iteratively designed using a participatory approach with patients aged 65 and above. It has a user-friendly interface. The application offers different functionalities such as encoding medications, accessing to information about medications (i.e. adverse events), preparing an appointment, etc. The researchers also provided some design guidelines useful for patient application developers.
 - A web-based application using Artificial Intelligence (AI)²³ was developed and tested in Austin in Texas, USA, to improve medication reconciliation. The patients' medication list is loaded by the app from the HCPs' connected EMR. The AI transformed prescription instruction in written natural language into coded information. The app proposed alternative medications (for example, cheaper medications) to the patient and identified duplications. The patient has different options to document his medications. The list reviewed by the patient is then reconciled by the HCP during the consultation using the same app on the same tablet. An observational pilot study and HCPs interviews permitted to conclude that the app is well accepted by patients and HCPs. The AI helps patients and HCPs to reconcile medications. But no rigorous evaluation of discrepancies reduction was done.
 - The MedTable^{24,25} a Patient-Provider Medication-Planning Tool, is a patient education tool, integrated with the EMR in primary care clinics for patients with type II diabetes. It was created in order to support collaboration between patients and health care provider concerning

medication planning. Patient initiated the medication reconciliation and then addressed discrepancies with the nurse which update the medication list in the EMR. A randomized controlled trial showed increased patient satisfaction concerning communication about medication during clinic visits but medication reconciliation and discrepancies were not measured.

- O The patient is engaged in the MedRec process based on a secured electronic messaging system
 - MyGeisinger personal health network (PHR)¹⁶, is part of the Geisinger Health System, Pennsylvania, USA. For the study, patients receive an electronic medication feedback form prepopulated with their current active-medication list according to the EHR. Patients documented their medication list which was then sent to a Geisinger Pharmacist who updated the medication record in the EHR. Patients' feedback ameliorated the accuracy of the medication list and the medication feedback form improved patient engagement, communication, and information sharing.
 - In Boston, USA, Heyworth et al.²⁰ designed a Secure Messaging for Medication Reconciliation Tool (SMMRT) within a patient web. Through a pilot study they evaluated medication safety improvements for patients recently discharged from hospital. Included patients received an SMMRT from the pharmacist 3 days after hospital discharge. This email allows the patient to check "yes" or "no" to each listed medication and to add free text comments. The patient sent his reply to the pharmacist which resolved discrepancies by several email replies or even by phone. The final reconciled medication list is posted in the electronic health record. More than 90% of patients were willing to continue using the system. Patients particularly appreciated their active engagement in the MedRec process.
 - In Arizona, USA, Raghu et al.²¹ developed a secure messaging system to update the medication list in ambulatory care setting. As Heyworth's system, this MedRec process relies on the pharmacist proactivity which sent an email (via the patient portal account) to the patient before an appointment in order to update the medication list. Patients who did not had a portal account were contacted by phone. At the time of appointment, the MedRec process is completed. Because, patients'

characteristics were very different when comparing answers to the secure messaging system or phone calls, authors conclude that mixed mode communication with patient will be needed to improve MedRec.

b. **Systems engaging the patient** in the MedRec process without the use of electronic (7 articles describing 4 systems).

- In Washington DC, USA, Hummel et al.³³ have studied workflow restructuring in 4 emergency departments of community hospitals to improve MedRec processes. Indeed, the final decision of the physician both in relation to diagnosis and in relation to therapeutic management is influenced by the patient's treatment list. Caregivers in the different emergency departments found that patient participation would make it easier to have an accurate and complete list. The authors, in reflection with the field teams, therefore proposed a restructuring of the emergencies' flow. They emphasized the importance of educating the patient to have a complete and accurate list of his or her treatment each time he goes to the emergency room. They then proposed to categorize patients and to designate some staff members who would have the responsibility to help patients complete their medication list when it is incomplete
- In Melbourne, Australia, Lingaraj et al.³⁴ have designed and tested a new partnership model "patient-HCP" towards effective MedRec comprised of four stages. Stage 1 occurred prior to admission, during an outpatient visit. Patients received a brochure they had to complete at home with information concerning their medication list and allergies. Stage 2 happened on admission. Ward nurse reviewed the brochure completed by the patient and discussed with them medication safety issues. Patients were also enhanced to be more active, more involved in their medication management. At discharge, as stage 3, patients received counselling with their discharge medication list from the pharmacist. Stage 4 consisted of a phone call, given to patients identified as "at risk", from the pharmacist 7 days post-discharge to ensure patient were managing well their medications. Number of reported medication errors and near-misses were compared using a before-and-after study. This study could demonstrate NO effectiveness of this new process on

reported medication errors and near-misses. However they advocated that patient education about medicines and the establishment of this kind of partnership (patient-HCP) should occur prior to admission.

- The VA Health Summary is available in the VA Patient Portal, My HealtheVet³⁵⁻³⁸. The content of this summary is the result of previous studies (JMIR 2015) and includes: allergies, history of encounters, history of procedures, immunizations, laboratory results, medications, problems/conditions, vital signs, and emergency contact information. Patients can view the summary but cannot modify it electronically. Turvey et al, trained patients in the intervention arm to print this VA Health Summary before an appointment with a non-VA provider. Comparing the VA and the non-VA providers' medication list did not significantly improve MedRec. This study is an example of how the technology platform promotes continuity, but only under certain contexts and clinical workflows.
- At the CHU UCL Namur, site Godinne, Belgium, Spinewine A. et al. encouraged active patient participation through a structured questionnaire on drugs. This questionnaire aims to obtain the complete medication list taken at home by the patient. The patient or his/her caregiver is invited to answer the question before admission to the hospital or before a consultation. HCPs were also sensitize to the problem through leaflets. The questionnaire was developed and evaluated using an iterative design. It was tested in several inpatient groups, in terms of both form and content. The results of these evaluations (available on request) made it possible to improve the questionnaire in order to increase its validity.

3.2. FACTORS INFLUENCING PATIENT PARTICIPATION (POSITIVELY OR NEGATIVELY) IN SAFETY OF CARE AND IN CONTINUITY OF MEDICATION

Four systematic reviews, three narrative reviews dealing with patient participation in safety and/or quality of care and four qualitative studies were included. Tables 4, 5 and 6 provide a summary of each of these publications.

Many factors influence patient participation, the literature shows that the level of education, understanding and knowledge of their disease and the functioning of the health system can promote patient participation. Patients well supported by their relatives (family or not) without being muffled by it and patients part of patients' associations are generally more likely to become involved. On the other hand, the influence of age, sex and personal characteristics (marital status, personality characteristics, patients' beliefs...) varies according to the type of participation requested to the patient and therefore does not lead to the conclusion of a specific association. As for the illness, suffering from chronic illness without being too sick and having already suffered themselves (or a relative) of a hospital readmission or an adverse event following discontinuity of care, strongly enhance patient participation in care.

One essential factor needs to be highlighted: "medical climate" defined as health care professionals support, interaction with health-care professionals or healthcare professional attitude regarding patient participation greatly influence patient involvement. Indeed, health care professionals' support, time dedicated to the patient, quantity and quality of the delivered information to the patient... are factors that influence patient participation as the quality or level of his involvement in care.

Those facilitators and barriers to patient active participation have been synthetized and are represented in table 7.

Besides, a systematic review focused on electronic patient portals and the evidence on satisfaction, efficiency and attitudes⁸. Although the heterogeneity of the studies and their poor quality do not allow to draw solid conclusions, results indicate a great willingness of the patients to use a "patient portal" and to engage in their process of care by this method. Race, ethnicity, level of education, health literacy as well as IT use, knowledge and literacy are all factors that hinder patient involvement through the use of an electronic portal.

Table 4: Factors influencing patient participation in patient safety, quality and continuity of care : Systematic Reviews					
	References	Year	Objective	Method	Main results/conclusion
1	Engaging patients as vigilant partners in safety: a systematic review ³⁹	2009	Assessing and summarizing the current evidence related to patient participation in error prevention	❖ Embase, Pubmed, CINAHL, Cochrane Library, Eric, PsychInfo ❖ Hand search of references lists of retrieved articles ❖ From 1995 to 2008 ❖ English, German and French articles	At general level, patient share a positive attitude about engaging in their safety. Patients' beliefs and perceptions have an important role in intention to engage and subsequent behavior. Patient involvement may be successful if: • Initiatives are based on patients' perspectives • These enhance complex behavioral changes • Their implementation are accompanied by serious efforts for cultural change in health care institutions
	Schwappach D - Medical Care Research and Review			❖ Exclusion of empirical studies, commentaries, reviews and theoretical analyses ❖ Evaluation of patient participation by assessment of attitudes/behaviors and evaluation of interventions	
2	Patients' willingness and ability to participate actively in the reduction of clinical errors: a systematic literature review ⁴⁰	2012	Identifying facilitators and barriers to willingness and ability to active patient participation	❖ Embase, Medline, PsychInfo, CINAHL, Cochrane, ISI Web of Knowledge ❖ Hand search of 10 key journals ❖ Organization websites related to patient safety (such as AHRQ) ❖ From 1999 to 2011	Numerous factors were identified (see Table 7). Main barriers are severity of illness and patients' perception of their role. Patients fear to being labelled "difficult".
	Doherty C, Stavropoulou C. Social Sciences & Medecine			❖ Exclusion: education programs, case-reports, literature reviews, comments and opinions.	

3	Electronic Patient Portals: Evidence on Health Outcomes, Satisfaction, Efficiency, and Attitudes ⁸	2013	Evaluating patient portals and evidence related to health outcomes, patient satisfaction, efficiency and attitudes	❖ Pubmed, Web of Science ❖ Hand search of key articles ❖ From 1990 to 2013	Lack of evidence due to heterogeneity and limited high-quality studies. Patients' attitudes are generally positive but use of patient portal may differ with patient-specific factors (ethnic group, race, literacy). Use of patient portal was associated with improved outcomes for patients with specific disease (e.g. hypertension, diabetes)
	Goldzweig, C. L. et al – Annals of Internal Medicine			❖ Exclusion of cases-reports, purely descriptive studies without report of barriers or facilitators ❖ Limited to English studies	
4	Promoting engagement by patients and families to reduce adverse events in acute care settings: a systematic review ²	2014	Studying how interventions encouraging patient engagement as patient safety practice have been implemented	❖ Embase, Medline, CINAHL, Cochrane ❖ From 2000 to 2012, English written ❖ Inclusion of systematic reviews and prospective controlled studies in hospital settings	Patient engagement in patient safety is an attractive approach. High-quality evidence regarding implementation is lacking to inform future patient safety practices. Further work should examine strategies to assess and overcome barriers to patient engagement. Studies should also clarify the added benefit of multifaceted approaches to improve patient safety.
	Berger Z. et al. - Making Health Care Safer II. BMJ Quality and Safety			❖ Various topics : hand hygiene, surgical site, prevention and monitoring of ventilator-associated pneumonia	

Table 5: Factors influencing patient participation in patient safety, quality and continuity of care : Scoping and/or narrative reviews					
	References	Year	Objective	Method	Main results/conclusion
5	Patients' preference for involvement in medical decision making: a narrative review ⁴¹	2006	Clarifying knowledge about the factors which influence patient preferences for involvement in medical decision making	❖ From 1975 to 2003 ❖ Qualitative and quantitative studies	❖ Factors influencing patient involvement in medical decision making are numerous, variable and highly complex ❖ Some factors are quite consistent across studies (e.g. being younger, being better educated, being a women). ❖ Involvement may not be acceptable or appropriate for everyone. ❖ Identifying those factors is important to sensitize HCP to individual patient preferences and improve patient centeredness ❖ Studies investigate very different variables so it is difficult to draw consistent conclusion
	Say R, Murtagh M, Thomson R. - Patient Education and Counseling.			<u>Factors affecting patient preference :</u> ❖ Demographic variables ❖ Experience of illness and medical care ❖ Health status ❖ Type of decision ❖ Information preferences	
6	Patient involvement in patient safety: what factors influence patient participation and engagement? ⁶	2007	Describing factors affecting patient participation in quality and safety issues of the patients own care	Drawing existing evidence for direct and indirect factors influencing patient participation.	❖ No one size fit all. ❖ Patients should be considered as safety safeguards, they are only a part of a much broader change to improve safety and quality. ❖ Patients and HCPs knowledge and belief have great influence on patient engagement ❖ Need for research on factors' clinical impact interactions
	Davis RE et al. - A literature review. Health Expectations			Conceptual framework, <u>5</u> <u>categories :</u> ❖ Patient-related	

			❖ Illness-related ❖ HCP-related ❖ Health care setting-related ❖ Task-related	⇒ advices to favor patient engagement: ❖ Building a partnership patient-HCP ❖ Multimodal approach are probably more likely to engage patients successfully
Patient Participation: Current Knowledge and Applicability to Patient Safety ⁵		Reviewing efficacy of patient participation in decision making in order to develop a	❖ Cochrane, Medline, CINAHL. ❖ From 1966 to 2008	Patient involvement is the key factor in the redesign of health care processes. Patient participation can be successful at different levels of care: decision-making, management of chronic

Table 6: : Factors influencing patient participation in patient safety, quality and continuity of care : Qualitative Studies

Y. Longtin, et al. - Mayo Clinic Proceedings	framework. Proposing an agenda for research.	Factors influencing patient participation in preventing errors: ❖ Related to HCPs. ❖ Related to patients ❖ Other non-modifiable factors (age, ethnicity ...)	Patient involvement can improve patient safety and prevent medical errors but barriers to engagement has to be thoroughly studied in order to overcome those and reach successful patient engagement!

	References	Year	Objective	Method	Main results/conclusion
8	Patients' attitudes toward electronic health information exchange: qualitative study ⁴²	2009	Exploring patients' view about sharing of electronic health information and patients' preferences about learning and participating electronic exchange of health information	❖ 64 patients, ❖ US Massachusetts	Most patients supports electronic health information exchange even though they were concerned about security and privacy, and this particularly if the amount of exchange data was huge. Therefore, they want clear and complete information concerning the communication and sharing of their medical data. They also wish to be able to ask questions and have the choice of accepting or not the exchange of their data (opt-in system rather than opt-out). Among community members, unanimous acceptance of the notion that health information exchange would improve quality and safety of care. But this study was done in the Massachusetts and results maybe not generalizable to other communities.
	SR Simon et al. Journal of Medical Internet Research			❖ 5 focus groups (=FG), ❖ Semi-structured questionnaire completed anonymously by each participants of the FG	
9	Beliefs and experiences can influence patient participation in handover between primary and secondary care--a qualitative study of patient	2012	Improving knowledge and understanding of patients' perspectives about their participation	❖ 23 Swedish patients, chronically ill, ❖ Handovers between: primary healthcare centers and emergency ward/room. ❖ Patients' stay of 48h	Patient active participation is related to their beliefs (current care = seamless care), lacked trusting relationship patient-HCP and past experience (previous experiences of poor communication). A redundant handover system that can effectively adjust to variation in patients' ability, resources and

	perspectives ⁴³		in handovers.	❖ Individual interviews done by the project nurse ❖ 1 to 7 weeks post-discharge ❖ Qualitative analysis	preferences for active participation in the handover may be the optimal solution to enhance patient safety. Patients need to know why and how participating in handovers. They also need to be made aware they can improve handovers.
10	The key actor: a qualitative study of patient participation in the handover process in Europe⁴⁴ M. Flink et al. British Medical Journal of Quality and Safety	2012	Exploring the patients' experiences and perspectives related to the handovers between their primary care providers and the inpatient hospital	❖ 90 patients, ❖ 5 European countries (Netherlands, Spain, Poland, Italy and Sweden) ❖ « HANDOVER » study ❖ Individual interviews and FG ❖ Semi-structured interview guide for both ❖ 3 to 4 weeks after discharge in patient native language ❖ Family member sometimes present during interviews	The patient's participation varies according to three "themes": his position - his prerequisites - his preferences. The position of the patient varies according to the health system where the patient is treated and the attitude of the healthcare professionals. In order to be able to engage, the patient needs certain prerequisites (a strong social network, a certain level of education, sufficient knowledge). Patients expressed preferring to be an actor or to be passive. They do not want the system to operate on the basis of shared responsibility. They also demand transparency of information as a tailored level of support (tailor to their resources and ability to participate).

Table 7: Facilitators and barriers to patients' participation in their own care.

	Facilitators	Barriers
Patient-related factors 1) Factors related to patients' characteristics (profile, nature, temper, gender, age,...)	- High level of education^{5,6,20,43}, better understanding⁴ / knowledge of pathology^{6,43 5} - High socio-economic status^{5,8} - <i>Younger patient</i>^{2,5,8}, women^{5,6,8} - <i>Previous experience demonstrating the need to participate in the management of its treatment: absence of engagement → information gaps</i>^{6,20,43,44} → need to engage - Need/feeling of control^{2,44} - List of medications brought from home⁴³ - Expansive character, extraverted personality^{2,43}, enthusiastic and motivated³⁹ Conclusion: In general patients want to participate but depends on: envy, the given means (ability and resources), the benefit/risk ratio³⁹	- Illiteracy^{5,39}, low level of education^{5,6,8,39,44}, poor communication due to lack of knowledge of the language of the country^{2,39,40}. - Low socio-economical status^{5,39}, particular ethnic group⁸, ethnic minority group with fewer questions^{39,40}. - Older patients^{2,5,6,8,39}, men^{6 5}, <i>younger patient</i> when it comes to marking the surgical site at marker². >< inconclusive about gender, age, level of education⁴⁰ - <i>Previous experience demonstrating need to participate in management of its treatment: lack of engagement did not seem to hinder recovering → reduce future participation</i>⁴⁰ - Patient lacking discipline⁴⁴, without knowledge of how/who to warn about adverse events⁴⁰ - Believes that the HCP must assume its responsibilities by informing colleagues during transitions³⁹ → feeling frustrated when patients are asked to do the work of HCPs in their place^{43,44} - Think that HCPs have all the information, that they have exhaustive information⁴³. - Patients fear negative reaction of HCPs to their engagement^{2,6}, fear of being labelled "difficult patient", fear of being rude or offending, fear of implying incompetence⁴⁰. - Fear of side effects because they have done badly their job of

		participation/engagement³⁹ - Afraid to have their trust to their HCP or to the health care system affected when observing medication/medical errors³⁹. - Excessive trust in their HCP and his “care behavior”² - Too long time between the information given regarding participation and the effective participation of the patient (marking the surgical site)². - Lack of information concerning disease and treatment, lack of clear written or verbal information given by an HCP⁴⁰. - Risk of complications if patient is educated to participate and the health care system where he is hosted can not answer him³⁹
2) Factors related to people surrounding the patient, his/her social network	- Presence of family or friends encouraging participation⁴⁴ - <i>The role of the family in the final decision related to ethnicity and culture: Americans and Afro-Americans decide themselves^{5,45}</i> - Patient Association Encouraging Participation⁵ - Comitee of quality and security of care publishing a journal encouraging patient participation⁵	- Absence of family members or carer⁴³. - <i>Role of the family participating in the final decision related to ethnicity and culture: Hispanic, Japanese patients make the family strongly involved, often so much that they sometimes leave the final decision to their family⁵.</i>
3) Factors related to patients' illness (type and severity)	- Complex decision in treatment management⁴⁴ - Type of disease: myocardial infarction, neoplasia...⁶ - Mild illness⁵	- Complex decision in treatment management⁴⁴, complex illness with difficulty in decision-making⁵ - Very ill/sick patient⁵ (bed-ridden, end of life⁴⁰) with multiple treatments, cognitive difficulties (memorizing with or without

	- Patient with severe chronic disease but not yet severely affected⁶ - Patient very ill with multiple treatments⁸, difficulties of memorization with or without difficulties of understanding^{43,44} - Personally (or in their circle) suffering of a severe infection resulting from a lack of hygiene of the hands²	- understanding difficulties)^{43,44}, dementia, confusion, severe depression, visual/auditory/motor impairment⁴⁰. - Lack of knowledge about their disease, low health literacy⁵. - Type of participation requested influences the decision: read an x-ray, bring his list of medications, decide for or against chemotherapy...⁵ - Allergies to more than 3 medications⁴⁰
Health care professional-related factors	- HCP enhancing patient to participate in medical decising and medical treatment⁴⁴ - Positive attitude towards patient participation: HCP ask a lot of questions⁴³, HCPs invite the patient to the discussion² - Caucasian HCPs (patients would be more likely to ask questions)⁵ - <i>Type of physician specialties</i> = obstetricians, oncologists, general practitioners, pediatricians...⁵ >< age and gender of the physician do not seem to have any influence - Greater use of secure messaging between patient and general practitioner⁸	- HCP referring to written or oral reports, electronic communication, shared medical data bank^{43,44} - HCPs that need to have and keep control⁴⁴ - HCP think that patient need less information due to their lack of literacy⁵, lack of information given by the HCP⁴⁰ - Implementation of a "rapid response system" with difficulties to obtain HCPs' participation because they had the feeling this system reduced their role and responsibilities², fear of the work overload linked to this system² - Lack of medical staff⁴⁰, patient/nurse ratio to high (lack of time)² - Conflict between the statements of certain clinicians (e.g. midwives) and the message promoted⁶ - Time-consuming²⁰, lack of time⁵. - Lack of training of the medical staff concerning the ideal patient-provider relationship and the evolution of it⁵ - Non Caucasian HCPs⁵

		- <i>Type of physician specialties=:</i> cardiologists ⁵ - Difference between what the HCP thinks he should do to do well and what he actually can do⁴⁰
Health care settings-related factors	- Positive climate/sphere/culture⁴⁴ - Enough time, adequate consultation room, HCP without time pressure and constraint⁴³ - Implementation of a "rapid response system": leadership, involvement of the physician, listening to and understanding of the patients ² - Adapted follow-up during patients' transition of care, alert symptoms, red flags² - Committee of quality and security of care publishing a journal encouraging patient participation⁵ - Patient with a business/trading insurance system⁸	- Negative climate/culture : HCP asking few questions and letting space for few questions, acute health status , HCP busy typing on the computer ...^{43,44 40}. - Gap of information between what the patient should know to understand continuity of care and what he is informed about^{43,44} - Reluctance of the administration of the hospital regarding the implementation of a "rapid response system"^{2,6}. - Work shift too short, lack of time to do their work⁴⁰ and inform the patient^{2,6} - Difficulty accessing the Internet or the MedRec module²⁰ - Pressure, business constraint on HCPs⁴⁰ - Patient participation in certain circumstances increases the risk of complication, e.g. active participation in the emergency department³⁹

NB: Influencing factors in italics are those found as both facilitators and barriers

Because this review was realized at the start of the SEAMPAT project in 2014, we did a recent and quick update in September 2017. Using the same research equation as before with two different filters, one allowing to identify reviews and the other filter specific to qualitative studies, we found over 140 supplementary articles related to patient participation in patient safety.

Based on title screening followed by abstract reading we identified 7 interesting articles⁴⁶⁻⁵². Five of the newly identified articles^{46,48-51} discussed the heterogeneity about the definition, terminology and outcomes around patient engagement. Therefore, Castro et al.⁴⁸ tried to define patient participation, patient centeredness and patient empowerment (see table 1 in the introduction section). Patient participation could be considered as the “lowest” level of engagement even though it still improves quality of care.

Kim et al.⁴⁶ published a review of patient and family engagement strategies to improve medication safety. Nearly all articles previously identified in our research were included in their review. They developed a framework to define the 5 levels of patient engagement, adapted from the Healthcare Information and Management Systems Society (HIMSS) Patient Engagement Framework. The two lowest levels of engagement correspond to informing about healthcare and engagement. Level 3 to 5 define various degree of engagement: empowerment, partnership and integration. They conclude that two strategies are essential to medication safety improvements: patient engagement and medication reconciliation. According to the authors, level 4 or 5 of patient engagement (partnership and integration) can be reached by using patient portals.

Concerning factors influencing patient participation: no supplementary factor compared to those mentioned in table 7 was identified. However, most authors^{46,49-52} strongly insisted on the importance of the patient-HCP relationship, the HCP attitude and on the need to educate both patients AND HCPs to patient engagement. Finally, Ariens et al.⁴⁷ published in September 2017 a qualitative paper concerning barriers and facilitators to eHealth use in daily practice. Compared to Simon et al.⁴² patients still have an overall positive attitude about the use of electronic in Health. Patients are still worried about security and confidentiality but new concerns emerged: IT literacy, eHealth literacy, eHealth education and training and last the financial aspects of daily eHealth use. Patients

are convinced about the need to take those factors into account to reach successful implementation and adoption of eHealth interventions.

4. DISCUSSION AND IMPLICATIONS FOR SEAMPAT

These complementary publications fruitfully support our thought concerning perspectives for the SEAMPAT project.

Besides being positive about engagement in their health care, we find out that the patients are equally positive about participation in the process of MedRec. Patient participation is all the more important as it improves the quality of care and as it is the first step before reaching patient empowerment, which improves quality of life. Patients are willing to use patient portals or electronic tools to support their active participation. We identified 10 electronic systems engaging the patient in medication continuity^{9,16-23,25}. Tasks assigned to the patients varied with the different systems. Most systems allowed the patients to document their medication list electronically but reconciling medications was still done by hand. Majority of publications come from North America, where health care systems and culture are very different from the Belgian situation. Interpretation of the data, particularly with regard to external validity, must therefore be done with great caution.

Patient portals are helpful means to reach the highest level of patient engagement in medication safety. However, to reach successful portal adoption by patients, fruitful implementation and optimal patient involvement, it is essential to work on the different factors influencing patient participation. Factors influencing patient participation are numerous: some support patient engagement while other deter patients to engage in their health. We noticed that level of engagement vary with the type of intervention asked to the patient. Severity and type of illness as patient human environment have also an impact on patient willingness to engage.

As mentioned previously, this is not a systematic review and therefore our work has some limitations. Firstly, we may have missed studies due to our lack of systematism and the many different ways in which the literature describes patient safety interventions. Secondly, we encountered great heterogeneity among studies (concept definitions, keywords, type of intervention, outcome, study

design...) and we identified only one systematic review specific to patient and family engagement strategies to improve medication safety, this thanks to our recent update. Thirdly, by focusing on “patient participation, involvement, engagement”, we have probably not sufficiently deepened “patient participation by the use of information technology” and have not investigated thoroughly enough patient portals (PP) and patient health records (PHR). Indeed, most of the publications related to PP and PHR are rarely using keywords such as “patient engagement” or “patient participation” and the MeSH term “patient portal” was introduced by PubMed central in 2017. However we used the MeSH term “electronic health record” which is situated above “patient portal” in the Mesh tree. Additionally, no articles related to PP or PHR are mentioned in the references list of articles dealing with patient participation in safety in general care. Finally, filing a patent in Europe ask for very different requirements than in the US. So e-MedRec tools engaging the patient may exist in Europe but have not been patented, neither have led to publications in the literature.

However, we did a research as exhaustive as possible by combining a patent research and research in the scientific literature. We hand-searched every references list of included articles and interesting articles related to the studied topic. By doing this, we encountered after a while always the same articles and so we could say we reach saturation of data. We can also argue that we have been, from a scientific point of view, both sensitive and specific. In fact, we have carried out a sensitive research since we first looked for all publications dealing with patient participation in patient safety and quality of care. We can also qualify our research as specific because we have refined our equations to find articles about patient participation, involvement, or engagement precisely in the medication reconciliation process.

This literature review will inform the development of the patient app prototype in the context of the SEAMPAT project, with respect to (a) non-functional requirements, (b) functional requirements and (c) evaluation of the patient app.

4.1. IMPLICATIONS CONCERNING NON-FUNCTIONAL REQUIREMENTS

All non-technological factors that were considered as essential to support patient participation and to reach the best possible results of this engagement, have been classified under this non-functional requirements section. In particular, we highlighted the need for patient education but also the necessity to educate and sensitize healthcare professionals and specifically physicians to patient participation/engagement, the need to study the workflow in which the patient app will have to be implemented and the need for identifying role and responsibilities of each stakeholder. We have detailed these elements by classifying them into three subgroups. The first concerns the information to be communicated to the patient, the second the training tools and methods that we must develop for the health care professionals, the third group includes all the elements that cannot be classified in one of the first two groups.

a. Important information to communicate to the patients before they start to use the patient app

- Your doctor may not have up-to-date information on your treatment. Your treatment has probably evolved since your last hospitalization/consultation.
- The aim of your participation is to improve communication and sharing information about your medication list. You will certainly not do the work of your physician, neither will you being labeled as “a difficult patient”. Your physicians are competent but your collaboration will improve the quality of care delivered by them.

b. Sensitization and education of health care professionals

- Persuade health care professionals of the importance of patient participation in MedRec
- Enhance health care professionals to encourage and promote patient participation as health care professionals support is a key factor for successful patient engagement in his care

c. Other

- Make the patient app easily accessible to patient (e.g. wifi in the waiting room) and from different IT support (e.g. computer, tablet...)

- Interface design of the patient app should be similar to applications patients are used to operate so that it is easy to use and easy to learn to use it even for non-IT experts.
-

4.2. IMPLICATIONS CONCERNING FUNCTIONAL REQUIREMENTS

Afterwards, we identified different characteristics to be integrated into the patient app of the SEAMPAT ICT platform in order to optimize use and acceptance of the tool. The previously included articles have helped establishing a list of functional requirements that offer important support to the patient. These recommendations have been classified into three groups.

a. Authentication features

- Patient identification should be certain and secure (e.g. national registry number, finger print + date of birth...)
- Allow access to the application by various computer supports: tablet, smartphone, kiosk, computer ...
- Enable access to the application from different locations: home, hospital, waiting room, pharmacy ...

b. Features for easier documentation of medication information

- Starting from a pre-populated medication list
- Presenting only one compiled medication list to the patient.
- Providing a self-completion system to add new medication
- Linking each medication to a picture of the pill and/or the pillbox
- Allowing printing a memo of the medication list

c. Features encouraging and supporting the use of the tool

- Allow patients to use a touch screen
- Find the right balance between text and icons
- The less clicks and the less time needed to perform a specific action, the best
- Favor options to check rather than free text boxes
- Offer the possibility to add comments in free text but in a second step
- Create user-friendly interfaces
- Allow documentation of medication allergy: type & severity
- Offer the possibility, in the same app, to manage medical appointments

A lot more features and functionalities have been encountered in the literature but we have decided to enumerate only the most important features and functionalities to inform the design and development of the patient app.

4.3. IMPLICATIONS FOR EVALUATION OF THE PATIENT APP

Finally, this work enabled us to better identify our target population to include in the design, development and evaluation of the patient app. Patients at highest risk of discrepancies (multimorbid, polymedicated, frail, non-adherent...) will the most benefit from a medication reconciliation process supported by the SEAMPAT ICT platform. Besides, we think it may be wiser to start with patients willing to participate into the medication reconciliation process and not totally reluctant to the use of IT in order to gather the richest feedback possible. Therefore, we decided to include patients belonging to both groups (at risk of discrepancies and interested in the project). We will recruit inpatients as outpatients and this with the help of general practitioners and specialists physicians in order to have a certain diversity.

Despite the limitations of this work, this review of the literature was particularly fruitful to formulate advice and recommendations for the progress of the SEAMPAT project and more particularly for the design, development and evaluation of the patient app.

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Chapter II - Electronic tools to support medication reconciliation

A systematic review

Most important requirements deemed by HCPs to build an
eMedrec tool with a patient app

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Chapter II at a glance

What is already known about the subject?

- Health information technology (IT) can reduce medication discrepancies by supporting the HCPs' cognitive burden and by reducing the time needed for medication reconciliation.
- Electronic medication reconciliation tools enable HCPs to compare the best possible medication history to inpatient/outpatient medication orders and to identify discrepancies by displaying medication lists and to resolve discrepancies by providing the following options: continue, change, or discontinue a medication.
- Bassi performed a scoping review in 2010 and found that IT was mainly used to obtain medication information, but very few systems at that time used a fully enabled eMedRec tool.

What this chapter adds:

- Since 2010, new electronic tools for medication reconciliation (eMedRec tools) have been developed. These eMedRec tools are effective if they include specific functionalities (Table 2). In addition to these functionalities, context and implementation must be carefully considered in order to maximize adherence and effectiveness, and should be more thoroughly reported.
- In this chapter, we systematically reviewed existing evidence about eMedRec tools that fully support MedRec. It therefore ends with a summary of the authors' key messages for the successful development and implementation of eMedRec tools.

Related Publications

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Authors' Contributions

S.M. and B.K. had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: All authors. Acquisition, analysis, and interpretation of data: All authors.

Drafting of the manuscript: S.M. Critical revision of the manuscript for important intellectual content: All authors. Final approval of the version to be published: All authors. Obtained funding: A.S. Administrative, technical, and material support: S.M., A.S. Study supervision: A.S.

ABSTRACT

Objectives: Medication reconciliation (MedRec) is essential for reducing patient harm caused by medication discrepancies across care transitions. Electronic support has been described as a promising approach to moving MedRec forward. We systematically reviewed the evidence about electronic tools that support MedRec, by (a) identifying tools; (b) summarizing their characteristics with regard to context, tool, implementation, and evaluation; and (c) summarizing key messages for successful development and implementation.

Materials and methods: We searched PubMed, the Cumulative Index to Nursing and Allied Health Literature, Embase, PsycINFO, and the Cochrane Library, and identified additional reports from reference lists, reviews, and patent databases. Reports were included if the electronic tool supported medication history taking and the identification and resolution of medication discrepancies. Two researchers independently selected studies, evaluated the quality of reporting, and extracted data.

Results: Eighteen reports relative to 11 tools were included. There were eight quality improvement projects, five observational effectiveness studies, three randomized controlled trials (RCTs) or RCT protocols (ie, descriptions of RCTs in progress), and two patents. All tools were developed in academic environments in North America. Most used electronic data from multiple sources and partially implemented functionalities considered to be important. Relevant information on functionalities and implementation features was frequently missing. Evaluations mainly focused on usability, adherence, and user satisfaction. One RCT evaluated the effect on potential adverse drug events.

Conclusion: Successful implementation of electronic tools to support MedRec requires favorable context, properly designed tools, and attention to implementation features. Future research is needed to evaluate the effect of these tools on the quality and safety of healthcare.

KEYWORDS

Medication reconciliation, health information technology, quality improvement, continuity of care, patient safety

1. INTRODUCTION

Medication management continuity is a worldwide patient safety concern and a very complex task^{1,2} requiring communication and information-sharing among providers, patients, and families across different settings.³ Patients are therefore at risk for medication discrepancies during transitions from one care setting to another.^{4,5} These discrepancies – unexplained differences among documented regimens across different sites of care⁶ – can lead to a prolonged hospital stay, early readmission, unplanned visits to the emergency department,⁴ and even death.⁷ Medication reconciliation (MedRec) is a formal and collaborative process of obtaining and verifying a complete and accurate list of a patient's current medicines⁸ to ensure that precise and comprehensive medication information is transmitted consistently across care transitions.⁹ Several leading organizations worldwide, such as the World Health Organization, The Joint Commission, the Institute for Healthcare Improvement, the National Institute of Clinical Excellence, and the Canadian Patient Safety Institute, have campaigned for the implementation of MedRec. Despite this, most healthcare organizations are struggling to develop efficient tools and effective implementation strategies.^{3,7,10,11} Successful MedRec is resource-intensive: it is time-consuming, requires multidisciplinary collaboration, and imposes a cognitive burden on clinicians that could be relieved by the use of technology.^{2,9,12} Efforts to reduce medication discrepancies using health information technology (IT) have recently emerged¹³ and different organizations have clearly indicated that technology to support the MedRec process will be essential for its successful implementation across the healthcare system. Electronic medication reconciliation (eMedRec) tools are computerized tools used to help support MedRec processes. These tools allow healthcare providers to compare the best possible medication history to orders and to identify discrepancies by displaying medication lists and to resolve discrepancies by providing the following options: continue, change, or discontinue a medication.¹⁴ Whereas previous systematic reviews summarized the available evidence on MedRec^{4,5} and a few narrative or scoping reviews have addressed the use of IT in MedRec,^{3,15,16} to our knowledge, there has been no systematic review of electronic tools (e-tools) to support MedRec. Bassi et al.³ performed a scoping

review of primary studies published up to March 2009 that looked at the use of IT in the MedRec process. They found that IT was mainly used to obtain medication information, but very few systems at that time used a fully enabled eMedRec tool. However, the authors reported that promising applications were being developed to support the entire MedRec process. Original studies have since described the development and evaluation of such tools.^{2,9,12,17,18} We therefore aimed to systematically review the evidence about e-tools that fully support MedRec, by (1) identifying tools; (2) summarizing their characteristics with regard to context, tool, implementation, and evaluation; and (3) summarizing key messages for successful development and implementation of eMedRec tools.

2. MATERIALS AND METHODS

2.1. DATA SOURCES AND SEARCHES

We performed a systematic search of articles published from database inception up to October 2014 using PubMed, the Cumulative Index to Nursing and Allied Health Literature, Embase, PsycINFO, and the Cochrane Library. We developed the search strategy in consultation with a medical librarian who is experienced in systematic review. We used an iterative process of building a search strategy, running the search, searching the relevant articles for additional terms, and then rebuilding the search strategy. Our search strategy consisted of a combination of subject heading terms and free-text words combining two groups of themes: (1) continuity of care – medication reconciliation, and (2) IT. The final search strategy for PubMed (see Supplementary Appendix I) was then adapted for each database. The other queries can be provided on request. To identify additional eMedRec tools (both those about which reports have been published and those that have not), we (1) scanned the reference list of included studies and relevant reviews; (2) searched patent databases, ie, the FamPat database (Questel Orbit) and the Espacenet database with the help of Picarre Intellectual Property; (3) searched recent grey literature reports referring to eMedRec;^{14,19} and (4) scanned the list of articles that subsequently referenced the papers included using Scopus (last search November 2015). More information is available on request.

2.2. STUDY SELECTION

Eligible reports included original full-text articles, proceedings, and patents describing e-tools that supported all three steps of the MedRec process, namely, (1) gathering the best possible medication history, (2) comparing the different lists in order to identify discrepancies, and (3) resolving those discrepancies. Reports had to contain both a description of the tool and some kind of evaluation, whether regarding a health outcome, provider satisfaction, adherence, utilization, or efficiency. Proceedings and patents were also included – in addition to original full-text articles – because these are frequent forms of publication for health IT tools. If several patents had been written for the same tool, we used the most recent. Because the information available in proceedings is limited, for potentially eligible proceedings, we contacted authors by e-mail to request additional information and/or clarification, using a standardized form and screenshots of the tool. This additional information was then used for study selection and data extraction. If three e-mails to the proceedings authors went unanswered, the proceedings were then excluded. We excluded reports that did not include a description of the tool, reports referring to an e-tool that only partially supports the MedRec process, reports on the reconciliation of specific drugs and classes, review papers and commentaries, and non-English-language reports. There were no restrictions regarding study type, setting, or type of care transition. Two reviewers (B.K. and S.M.) independently evaluated the eligibility of reports by first examining their titles and abstracts, and then the full text of reports identified as potentially eligible for this study. Disagreements were resolved by discussion, and, when consensus could not be reached, a third author (A.S.) was consulted and a decision was made. Eligibility was delayed for proceedings and for studies reporting data incompletely, pending author contact (see above).

2.3. DATA EXTRACTION AND QUALITY ASSESSMENT

A standardized data extraction form (Supplementary Appendix II) was created based on (1) the Effective Practice and Organization of Care data collection form,²⁰ (2) forms used in previous systematic reviews,^{3,4,21} and (3) reports from the gray literature on eMedRec.^{14,19} The form was piloted on four reports by 3 reviewers (A.S., B.K., and S. M.) to ensure completeness, clarity, and reliability.

Data extraction included study design (using a recently published categorization of improvement interventions²²) and description of context, tool, implementation and evaluation, and lessons learned as reported by the authors. Two reviewers (S.M. and B.K.) independently extracted data. Disagreements were resolved by consensus. For each report, we evaluated quality in two complementary ways. First, the quality of reporting of the context, tool, and implementation/evaluation was evaluated with the criteria used in a recent systematic review of patient portals.²¹ These criteria had been modified from criteria developed to assess patient safety strategies, which included health IT applications.²³ Second, based on the Canadian Paper to Electronic MedRec Implementation Toolkit¹⁴ and on the American Multi-Center Medication Reconciliation Quality Improvement Study (MARQUIS) toolkit to disseminate best practices in inpatient MedRec,¹⁹ we listed the main ideal features needed to for a user-friendly and efficient eMedRec tool, and, for each report, we evaluated whether each feature was present.

2.4. DATA SYNTHESIS AND ANALYSIS

Due to the large variation in study types and measurements, a meta-analysis of the studies considered was not possible. Instead, we constructed evidence tables showing the characteristics and results for all included reports and critically analyzed the data. Reports that referred to a single eMedRec tool were grouped together. Finally, we compiled a summary of recommendations made by the authors of the included studies for the successful development and implementation of eMedRec tools. We categorized these factors as being relative to the tool, context, or implementation and used them to draw conclusions.

3. RESULTS

3.1. STUDY SELECTION

Overall, the search strategy yielded 2143 reports following duplicate removal, of which 1991 were discarded after examining the title and abstract (Figure 1). Of the 152 reports that were selected for full-text screening (or screening of additional information sent by authors, in the case of proceedings) and 5

additional reports identified through reference list searching, 18 met our inclusion criteria (14 published articles, 2 proceedings, and 2 patents). The main reasons for exclusion were (1) the tools described did not support all three steps of the MedRec process, and (2) the report lacked a description of the tool.

3.2. DESCRIPTION OF STUDIES

The 18 reports included in this study were published over the last 10 years and describe 11 different eMedRec tools. Five reports were about the Automated Patient History Intake Device (APHID),^{10,11,24-26} three were about the PreAdmission Medication List Builder,^{1,27,28} two were about the Twinlist,^{9,12} and there was one report about each of the other tools. According to Portela's classification, eight reports were quality improvement projects,^{1,2,9,12,25,29-31} five were effectiveness observational studies,^{10,24,27,32,33} and three were randomized controlled trials (RCT)²⁸ or RCT protocols.^{7,11} Because the two remaining reports were patents, we could not classify them in one of these categories. Table 1 summarizes the characteristics and main results of the reports included in this study. The quality of the reports' description of the context, the tool, and the implementation are reported in Table 2.

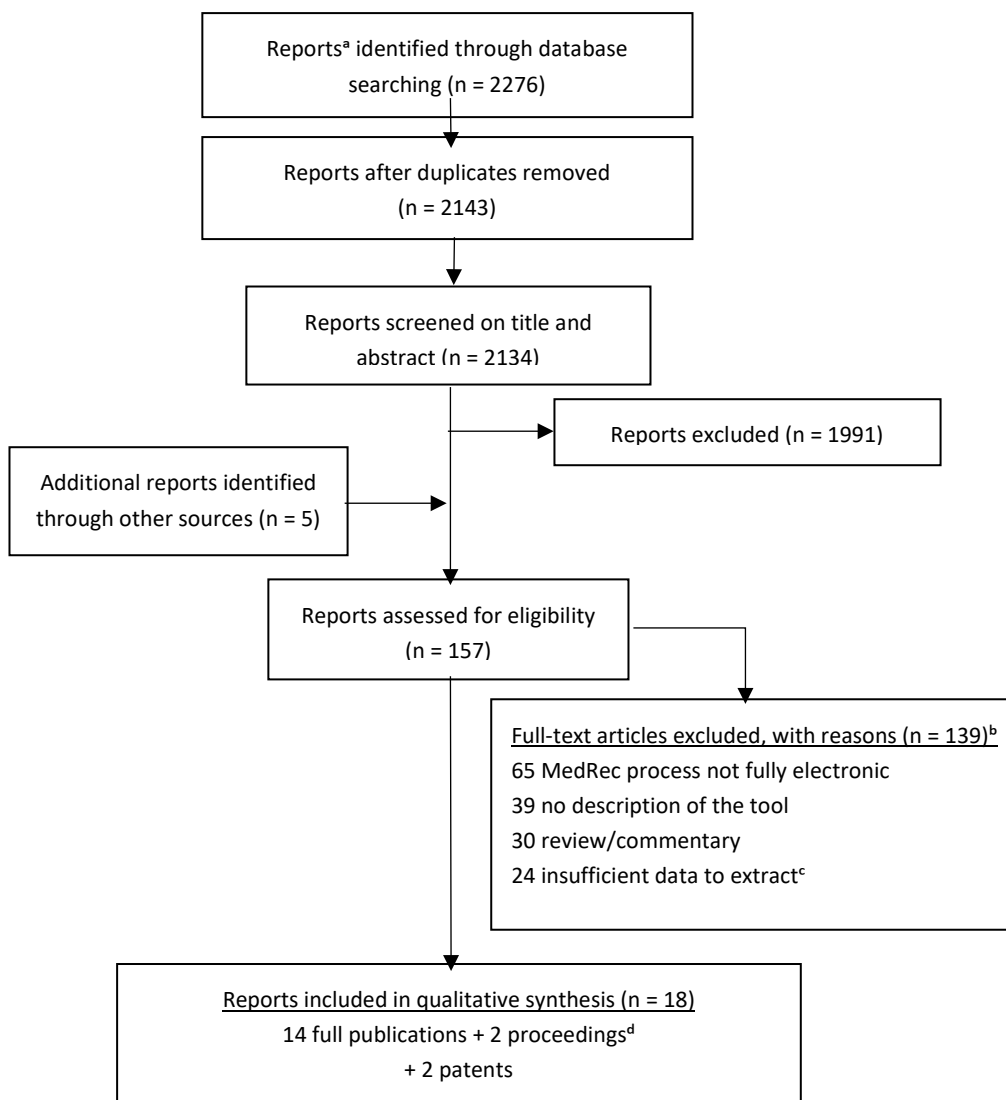


Figure 1 Search strategy and study selection

^a Reports include full-text articles, proceedings and patents.

^b Reports could be excluded for more than one reason.

^c Insufficient data means: full text not available or unanswered request by authors of proceedings.

^d Proceedings were included if authors could send us relevant additional information so that publication met inclusion criteria and that data could be extracted.

Table 1: Description of studies and main results

e-Tool	Author, country, year	Point of investigation	Objective(s) of the study	Study Class ^a	Main results of evaluation ^b
The PreAdmission Medication List (PAML) Builder	Poon, USA, 2006 ¹	Admission, Discharge	To describe the design of a novel application and the associated services that aggregate medication data from EMR and CPOE systems	QIP	A: 78% of patients had a PAML created. U: users found the interface intuitive and many were able to use it without any training. Clinicians found electronic juxta-position of the PAML with admission and or discharge order screens helpful.
	Turchin, USA, 2008 ²⁷	Admission, Discharge	To assess clinicians' attitudes toward eMedRec, their compliance and the factors that affect their efficiency and compliance	Eff OS	S: 39% of users satisfied, 50% of users thought eMedRec helpful, 64% of users agreed eMedRec improves patient care. A: A planned action was recorded on admission for 69% of the medications listed in the PAMLs; Users' prior compliance with using the tool was the main predictor of future compliance ($p < 0.0001$). U/E: 69% reported that it usually took them less than 10 minutes to build a PAML, users' experience and ease of use shortens the time to build a PAML.

	Schnipper, USA, 2009 ²⁸	Admission, Discharge	To measure the impact of an eMedRec intervention on medication discrepancies with potential for harm	RCT	O: significant decrease in potential adverse drug events (adjusted relative risk, 0.72; 95% CI 0.52-0.99); no significant difference in health care utilization (readmission and visit to the emergency department). A: For 99% of patients the PAML Builder application was used, a PAML was completed within 24 hours of admission for 46% and prior to discharge for 75%.
A tool within the EMR to facilitate MedRec after hospital discharge	Schnipper, USA, 2011 ³²	Post-discharge	To describe the design and implementation of the tool, attempts to improve use, informal feedback from clinicians and generalizable lessons learned to maximize the usability of the tool and its impact on patient safety	Eff OS	S: most clinicians were supportive of the tool, several clinicians asked for an interruptive reminder. A: the tool was used in 12% to 18% of eligible patients during the first 6 months and in 41% for the last 6 months after implementing a pop-up reminder, clinical outreach and education. U: users identified several usability issues (e.g. the way to invoke the tool was not obvious enough, confusion about whether they needed to act upon every medication discrepancy) and several actions were taken afterwards.
A tool for MedRec after hospital discharge with an (electronic) retrieval of community drugs and an (electronic) communication module	Tamblyn, Canada, 2012 ⁷	Discharge	To determine if electronically enabled discharge MedRec reduces the risk of adverse drugs events, emergency room visits and readmissions 30 days post-discharge compared with usual care	RCT protocol	O: adverse drug events, emergency visits, hospital readmissions 30 days post-discharge.

MedRec application	Cadwallader, USA, 2013 ²	Outpatient	To design a MedRec application that could incorporate multiple data sources and convey information about patients' adherence to prescribed medications	QIP	U: Feedback of clinicians, information-technology professionals, pharmacists and nurses were collected. Each prototype then underwent iterative revisions to incorporate their feedback. A final prototype was then created by incorporating the best features of each initial approach.
Twinlist	Markowitz, USA, 2011 ¹²	Post-discharge	To evaluate if a systematic user interface design process will dramatically improve the efficiency and quality of MedRec process	QIP	U/E: 3 tasks were analyzed via the KLM analysis: reconciling 2 identical medications, removing a medication and editing its dosage. The number of actions, the number of required mental operations, and overall task completion time were lower for the prototype than either LHS RxPad or PAML.
	Plaisant, USA, 2013 ⁹	Discharge	To describe Twinlist, an interface that provides cognitive support for MedRec. To describe a series of variant designs and discuss their advantages or disadvantages. To report a pilot study	QIP	U = Feedback from 20 users: the Twinlist spatial layout is a meaningful grouping and the multistep animation is helpful for learning (70%).

The Automated Patient History Intake Device (APHID)	Lesselroth, USA, 2009 ²⁵	Outpatient	To describe project design and implementation, review preliminary findings on feasibility, and discuss the barriers to adoption encountered by the development team	QIP	A: 1371 patients used the APHID during the 1st month; 47% of eligible patients (n=8170) used the APHID during the ensuing 6 months. S: most staff reported the APHID helped with history collection, providers also felt overwhelmed with the new responsibility of MedRec, some clinicians were reticent to address discrepancies that felt outside their content area. S/E: 67% patients believed the program improved their medication recall. U: many providers felt that the volume of medications to review and formatting of medication lists made it challenging to quickly identify discrepancies needing action. U: 75% patients thought the APHID was easy to use, 67% easy to navigate, 94% easy to understand.

Lesselroth, USA, 2009 ¹⁰	Outpatient	To describe how they developed and implemented a process for patients in the waiting room to use kiosk technology in providing their own medication histories	Eff OS	O: 91% of cases with discrepancy, average of 4,6 discrepancies per patient, average of 1,6 clinically significant or potentially lethal discrepancies. S: nurse agreed they possessed a more accurate drug-dispensing information, patient were occasionally dissatisfied when asked to review expired medications. A: 82% patients used the kiosk. U: patient said the kiosk was easy to use and medication pictures assisted with recall. E/U: the use of the APHID by patients represents a nearly 50% reduction in nursing time dedicated to reconciliation activities.
Lesselroth, USA, 2011 ²⁴	Outpatient	To describe the development, administration and findings of a survey intended to assess PCP perceptions of the tool in an effort to identify factors that can influence implementation	Eff OS	S: PCP have favourable attitudes toward MedRec and think it represent an important safety intervention but 43% did not believe they had the necessary resources to manage discrepancies, the majority of PCP favoured the tool over usual care. U: 58% of the PCP indicated that they were familiar with the technology and had seen the tool output.

	Lesselroth, USA, 2012 ¹¹	Outpatient	To evaluate the accuracy of the medication list produced using the software. To measure the incremental value of including medication pictures. To characterize the types and root causes of medication discrepancies detected using the software	RCT protocol	E: number of discrepancies, types, root cause and severity.
	Lesselroth, USA, 2014 ²⁶	Any	To describe the invention: APHID supporting medication reconciliation, clinic check-in, demographic and insurance data verification and allergy review	Patent	NA

A MedRec view within the EHR displaying two columns : inpatient and outpatient medications' list	Vawdrey, USA, 2010 ²⁹	Admission, Discharge	To assess the impact of adopting the eMedRec process at a large academic medical center	QIP	S: Clinicians complained about the 30-60 seconds required for adding a medication and about the technical limitation concerning the conversion of Outpatient medication profile medications into inpatient orders. A: Usage of the eMedRec process <40% before the "hard-stop" intervention and above 96% one month after. E: average number of medications contained in the Outpatient Medication Profile was <2 before implementing the eMedRec process and had increased to 4,7 after .
A MedRec application launched from within the EHR	Bails, USA, 2008 ³⁰	Admission, Discharge	To describe the interdisciplinary process undertaken at a large academic medical center, to develop a full online MR program	QIP	A: in phase 1, MedRec done for only 20% of patients. In phase 2, after providing feedback and making eMedRec mandatory, compliance rates achieved 95%.
Electronic pathway for MedRec	Lovins, USA, 2011 ³¹	Admission, Transfer, Discharge	To implement an eMedRec pathway to reduce medication errors happening after transitions of care	QIP	S: patient, family and staff presented high level of satisfaction. A: compliance rate was > 90%. E/U: Staff perceived improvements in workflow, efficiency and safety.

The Discharge Instruction element	Sherer, USA, 2011 ³³	Admission, Discharge	To determine the accuracy of the discharge medication list made with the Discharge Instruction element and given to the patient by comparing this list with the list dictated in the discharge summary	Eff OS	S: High level of provider satisfaction. A: Provider usage rates varied from 87% to 93%. E/U: 95% accuracy rate for information collected at admission, eMedRec implementation reduced time spent completing the discharge work by 7 minutes.
Interactive Patient Medication List	Tripoli, USA, 2014 ⁸	Not applicable	To describe the invention: system, methods and techniques for presenting a medication list to a patient and for maintaining updates to the medication list	Patent	U: feedback from pharmacists.

Abbreviations:

APHID = Automated Patient History Intake Device; CI = confidence interval; CPOE = computerized physician order entry; eMedRec = electronic medication reconciliation; EHR = electronic health record; EMR = electronic medical record; e-tool = electronic tool; Eff OS = Effectiveness observational study; KLM analysis = Keystroke-Level Model; LHS RxPad = Legacy Health system with RxPad record; NA = not

applicable; PAML = preadmission medication list; PCP = primary care provider; PVAMC = Portland Veteran Affairs Medical Center; QIP = Quality improvement project ;RCT = randomized controlled trial;

^a **Study Class:** According to Portela's published improvement interventions categorization²²

Quality improvement projects (QIP): Project is set up primarily as an improvement effort, to learn what works in a local context. It is typically motivated by a well-defined problem and oriented towards a focused aim. PDSA cycles are often applied, allowing for testing incremental, cyclically implemented changes, which are monitored through statistical process control.

Effectiveness studies:

1. RCTs
2. Quasi-experimental designs: The intervention is implemented and followed-up over time, ideally with a control.
3. Observational (longitudinal) studies: The implementation of the intervention is observed over time.

^b **Results:** O = health outcomes; S = satisfaction; A = adherence; U = utilization; E = efficiency

Table 2: Description of the context, system, implementation and presence of ideal features of eMedRec tools

e-Tool	Author, Country, Year	Context	Tool						Implementation / Evaluation						
		Description criteria ^a	Description criteria ^b	Integrated in the workflow?	Linked to other electronic systems? ^d	Automatic highlighting of discrepancies?	Reason for stopping medication written?	Different possibilities to organize medication lists?	Description criteria ^c	eMedRec, process with reminder or mandatory? ^e	Other specific features associated ^f	Use of different prototypes	Usability evaluated?	Routine use?	Evaluation of users' compliance to eMedRec?
The PAML Builder	Poon, USA, 2006 ¹	> 3	> 3	+	●	--			≥ 2		+	+	+	+	+
	Turchin, USA, 2008 ²⁷	> 3	> 3	+					≥ 2				+	+	+
	Schnipper, USA, 2009 ²⁸	> 3	> 3	+	●	--			≥ 2				--	+	+
A tool within the EMR for MedRec after hospital discharge	Schnipper, USA, 2011 ³²	> 3	2	+	⊙	+			≥ 2	⊙	+	+	+	+	+

e-Tool	Author, Country, Year	Context	Tool						Implementation / Evaluation						
MedRec after hospital discharge	Tamblyn, Canada, 2012 ⁷	> 3	> 3	+	●	+	+		≥ 1		+	--	--	--	--
MedRec application	Cadwallader, USA, 2013 ²	2	> 3	--	●	+		+	NA		+	+	+	--	--
Twinlist	Markowitz, USA, 2011 ¹²	0/1	2	--	○	+			NA			+	+	--	--
	Plaisant, USA, 2013 ⁹	2	2	--	○	+		+	NA			+	+	--	--
APHID	Lesselroth, USA, 2009 ²⁵	> 3	2	+	●	--			≥ 2			+	+	+	+
	Lesselroth, USA, 2009 ¹⁰	> 3	> 3	+	⊙	--			≥ 2				--	+	+
	Lesselroth, USA, 2011 ²⁴	> 3	0/1	+	●	--						+	+	+	--
	Lesselroth, USA, 2012 ¹¹	> 3	0/1	+	●	--							--	+	--
	Lesselroth, USA, 2014 ²⁶ - patent	NA	> 3	NA	●	+	+		NA		+	NA	NA	NA	NA

e-Tool	Author, Country, Year	Context	Tool						Implementation / Evaluation						
A MedRec view within the EHR displaying two columns	Vawdrey, USA, 2010 ²⁹	> 3	2		●					●		+	--	+	+
MedRec application launched from within the EHR	Bails, USA, 2008 ³⁰	> 3	2	+	●	--			≥ 2	●		+	--	+	--
Electronic pathway for MedRec	Lovins, USA, 2011 ³¹	> 3	NA	+	●/⊙	+		+	NA	⊙		+	+	+	+
The Discharge Instruction element	Sherer, USA, 2011 ³³	> 3	2	+	●/⊙	+		+	≥ 1	○		--	+	+	+
Interactive Patient Med List	Tripoli, USA, 2014 ⁸	NA	> 3	NA	●	+	+	+	NA		+	NA	NA	NA	NA

Abbreviations: eMedRec = electronic medication reconciliation; EMR = electronic medical record; CPOE = computerized provider order entry; NA = not applicable;

+ = YES -- = NO (as mentioned in the report by the authors)

An empty box = not reported by the authors

^a Description of the context: >3 criteria, 2 criteria, 0/1 criteria: Size, location or academic status; Financial status, or past information technology experience; Information about culture, teamwork and leadership; Existing external factors: for example, regulatory requirements, presence in the external environment of payments or penalties such as pay-for-performance or public reporting

^b Description of the tool is: >3 criteria, 2 criteria, 0/1 criteria: Different functionalities included; What/how the tool interfaces with the EMR; What is required for the consumer to operate it; description items had to be sufficiently detailed so that it could be 'replicated'

^c Description of the implementation: number of components beyond "staff education": ≥ 2 , ≥ 1 , 0

Possible components are: description of barriers and facilitators, audit and feedback, presence of 'champions' (quality improvement leaders) responsible for implementation, assessment of impact on workflow, and tailoring/change management.

^d Linked to ≥ 3 other systems = ●; Linked to 1 or 2 other systems = ⊙; Not linked to any other systems = ○ (for example: CPOE, EMR, pharmacy claim,...)

^e Mandatory = ●; **Reminder** = ⊙; **Nothing** = ○

^f Other specific features associated: review appropriateness of medication, post-discharge communication with patient and or with other health care provider (by email/printed list), possibility to reconcile only part of the medication list, decision support functionality (not specifically related to medication reconciliation), existing of different way of presenting medication regimen to the different users according to the needs of each (physician, patient, pharmacist,...), section for drug event report via email,

...

3.3. CONTEXT OF DEVELOPMENT

Ten of the tools reported on were developed in the United States and one was developed in Canada.⁷ Except for the Interactive Patient Medication List,⁸ all the tools were developed in academic environments (ie, academic hospitals or universities). Tools were almost equally implemented at admission and discharge^{1,27-31,33} or in outpatient clinics.^{2,10,11,24,25,32} Five of these tools^{1,10,11,24,25,27,28,30,31,33} were reported as having been developed in hospitals promoting patient safety culture, four reports^{2,7,29,32} did not include information about this culture, and, for the two last tools, this criterion was not applicable.^{8,9,12} When patient safety culture was mentioned, the quality improvement team insisted on the need for interdisciplinarity or teamwork for developing and implementing eMedRec. One study highlighted the importance of the context of development.²⁸ In that case, the intervention took place in two hospitals, and a statistically significant decrease in potential adverse drug events was reported in one of the two hospitals. The authors hypothesized that differences in context and implementation (level of publicity and nurses' involvement) probably contributed to the differences observed.

3.4. CHARACTERISTICS OF THE TOOLS

Seven^{1,7,10,11,24,25,27,28,30-33} of the tools reported on were integrated into the organization's/clinicians' workflow. All the tools, except the Twinlist,^{9,12} used electronic data from different sources, such as pharmacy claims data, electronic medical records, and computerized physician order entry (CPOE) to collect the medication history and identify discrepancies. Despite the fact that these characteristics are considered by the United States and Canadian toolkits as ideal features for eMedRec tools,^{14,19} only half^{2,7-9,12,26,31-33} of the 18 reports included in this study highlighted medication discrepancies, only 5 of the 18 reports^{2,8,9,31,33} offered various possibilities for organizing medication lists differently, and only^{7,8,26} documented reasons for stopping medication (Table 2). Other functionalities were implemented in order to reduce the time needed to complete tasks and cognitive burden: displaying medication lists side-by-side^{2,7,9,12,29,33} and using different filters^{2,8,9,31,33} for sorting unreconciled medications. Additional

functionalities to make the eMedRec process more efficient included gathering information from multiple sources;^{1,2,8,10,11,24,26,28-30} giving access to detailed information on prescribing, dispensing, etc.;^{7,8} communicating the reconciled medication list easily and quickly to other providers;^{7,8,25} linking decision support systems (eg, systems supporting decision to admit patients, supporting drug-drug interaction detection);⁸ and creating a link with an automatic input to the CPOE.^{8,24,30} Plaisant's team^{9,12} also developed animations to help novices master the tool they reported on. With regard to the availability of the tools on the market, Twinlist is available as an open-source program,⁹ the Discharge Instruction element is commercially available,³³ and the APHID^{10,11,24-26} team is working on a prototype for a national enterprise deployment within the Veterans Health Administration. In addition, a few tools can be embedded in electronic health record (EHR) products such as CERNER,³³ Eclipsy Sunrise EHR,²⁹ and Siemens EHR.³¹ Finally, two additional tools will probably be commercially available in the next few years.^{7,8} Lesselroth's team involved patients, considered as a group of specific users, in the MedRec process.^{10,11,25} Patients reviewed their composite list of medications with the eMedRec tool, using a kiosk situated in the lobby, and the program automatically charted patient response in the EHR. Cadwallader also planned to involve patients in this process.²

3.5. IMPLEMENTATION AND EVALUATION

To develop an eMedRec tool, most of the research teams used different prototypes with Plan-Do-Study-Act cycles to improve the tool and adapt it to users' needs and to workflow (Table 2). These were classified as quality improvement projects (Table 1). Although teams explained that they needed several years to develop the tool before it was finally put into routine use, none mentioned the number of prototypes they developed to arrive at the final tools. Due to the variability of the objectives recorded and to missing information, results were difficult to compare (Table 1). Nevertheless, the main measures of evaluation were related to usability,^{1,2,9,10,12,24,25,27,31-33} adherence to the tool,^{1,10,25,27-33} and user satisfaction.^{24,25,27,29,31-33} Usability was evaluated in different ways: time saved by clinicians,^{9,27,33} workflow improvement,^{10,31} ease of use,^{1,9,10,12,24,25,27} and understanding of the tool.^{9,24,25} In several quality

improvement projects, usability issues that were identified led to the implementation of improvements in a revised prototype of the tool. Regarding adherence, some authors^{1,28,30,32} looked at the number of patients with a medication list created or reconciled, while others measured the proportion of clinicians using the tool^{29,31} or the proportion of patients connecting to the tool.^{10,25} When tools were in routine use, several teams struggled with user adherence and therefore implemented specific incentives (Table 2). Three authors reported significant improvements in adherence after implementing a reminder^{31,32} or even a hard stop.^{29,30} Other steps taken in support of tool adoption included elaborating workflow models^{1,10,11,25,28} aimed at integrating the new e-tool in the most efficient way possible and defining the responsibilities^{1,7,10,11,25,28-30} of each actor. With regard to the impact of eMedRec on health outcomes, Schnipper reported that an eMedRec intervention significantly decreased the risk of potential adverse drug events.²⁸ In her RCT protocol, Tamblyn has planned to measure adverse events, emergency visits, and hospital readmissions.⁷ Finally, Lesselroth will evaluate the impact of eMedRec on medication discrepancies.¹¹

3.6. RECOMMENDATIONS FOR THE SUCCESSFUL DEVELOPMENT AND IMPLEMENTATION OF AN eMEDREC TOOL

Because objectives varied considerably from one report to another, the authors of the reports included in this study arrived at a variety of conclusions. Nevertheless, each team produced a list of recommendations for the successful development and implementation of an eMedRec tool. These are summarized in Box1.

Box 1: Recommendations made by authors for the successful development and implementation of eMedRec tools
Recommendations concerning the context of development
Adapt the tool workflow to the habits of frontline users^{1,7,24,25,27,28,30} Offer the possibility of invoking the application from multiple points in his or her workflow¹, regardless of the EMR medication list status³² Define the roles of each frontline user in the eMedRec process^{10,25,27,30} Ensure support from clinical/hospital leaders^{1,30} and a suitable organizational climate^{24,25,30} Persuade frontline users, especially clinicians, of the importance of MedRec³⁰ Engage patients in the medication reconciliation process^{2,25}
Recommendations concerning functionalities and development of the tool
<i>Concerning the tool in general</i>
Develop tool features and design interfaces in an iterative manner, driven by the clinical processes^{9,12,27} Use design guidelines for designing health information technology; identify and use individual design components (e.g. animation, groupings) Choose a design that matches the overall design philosophy of your EHR user interface⁹ Use prototypes and pilots²⁷ Involve patients as collaborative partners in developing the tool¹⁰ Do not anticipate users' needs¹ Medication information needs to be entered in coded format²⁷

<i>Gathering the best possible medication history</i>
• Use information from different sources^{1,2} and gather this information electronically by linking the eMedRec tool to medication lists of other systems (EMR, CPOE, EHR, pharmacy claims,...)^{24,29,30} • Aim for interoperability between different medication lists, with the possibility of automatically charting the reconciled list in the EHR/CPOE^{24,30} • Develop easy-to-use technology (drug pictures, prescribers' information next to each medication)^{10,24,29} • Do not over-automate the tool¹
<i>Identification of discrepancies</i>
• Develop robust detection of discrepancies¹⁰ • Develop technology that is easy to use and reduces the cognitive load: use animations and offer different filters for classification; help providers to recognize, contextualize, and manage medication discrepancies^{2,9,12,24,29}
<i>Resolving discrepancies</i>
• Explore and develop decision-support algorithms to help providers to identify clinically meaningful discrepancies^{2,10} • Develop easy-to-use technology: allow manual verification of all medication;³² allow partial reconciliation;²⁵ document reasons for all reconciliation actions taken,³² enable inter-facility provider communication of discrepancies¹⁰ foresee tight integration with the CPOE system^{27,29,30}

Recommendations concerning the implementation of the tool
Provide education and support: regularly train users and local leaders, provide on-site support^{1,7,24,27,32} To improve compliance: introduce reminders or hard-stop,^{27-30,32} reduce the time needed to reconcile medication,²⁹ have measurable compliance rates to enable ongoing feedback,^{28,30} collect users' suggestions^{1,24,27,30} Compare electronic lists to a gold-standard structured medication history^{11,25} Conduct usability testing^{2,12,29} and test the software (reliability + interoperability) in selected and disparate settings^{11,25} Focus on efficiency in addition to clinical improvements¹² Establish a process for referring recurrent errors and discrepancies for failure analysis and potential system-based intervention¹⁰ Assess the generalizability of your findings using comparable data from other hospitals using electronic medication reconciliation tools²⁹

4. DISCUSSION

4.1. MAIN FINDINGS

To our knowledge, this is the first systematic review of e-tools to support MedRec. We have identified 11 tools that support the entire MedRec process, 7 of which are in routine, daily use.^{1,10,11,24,25,27-33} This adds valuable information to recent literature reviews that identified a limited number of studies of IT support for MedRec. Most studies referred to e-tools that supported some, but not all, steps of the MedRec process.^{3,4} We mainly found quality improvement studies and observational effectiveness studies that showed positive results overall in terms of usability,^{1,2,9,10,12,24,25,27,31-33} satisfaction,^{24,25,27,29,31-33} and adherence.^{1,10,25,27-33} However, evidence remains insufficient about the impact of eMedRec tools on the quality and safety of healthcare.

4.2. IMPLICATIONS FOR PRACTICE

Recent reports summarized the ideal features and functions an eMedRec tool should include.^{14,19} None of the tools identified seem to include (or to have described whether or how it included) all of these features and functions, but these manuals were published after all of the reports we identified. Our data confirm that the success of developing and integrating technical solutions to support MedRec is strongly dependent on attention to implementation processes and extensive usability testing.

a. Implementation Processes

Successful eMedRec requires a concerted quality improvement effort, of which IT is but one component. To be embraced by most users, eMedRec tools need appropriate national and institutional environments. At the national level, all the tools identified were developed in the United States and Canada, where national campaigns and incentives have encouraged MedRec progress since 2005.^{34,35} Accordingly, the applicability of our results to other healthcare systems with different environments, cultures, and use of health IT, including those in Europe, cannot be guaranteed. Three studies carried out in Spain with one eMedRec tool

have been published recently,^{18,36,37} but additional studies will need to be conducted in environments outside the United States and Canada.

At the institutional level, we found that endorsement by quality improvement leaders,^{1,24,30} highly integrated care, past experience of technology, and a culture of fostering patient safety enhanced the adoption of eMedRec into routine use. Persuading frontline users and improving awareness among clinicians of the importance of eMedRec (eg, by specific clinical vignettes) is essential to successful implementation.³⁰ Staff education (eg, providing training on its use, educational handouts, or online materials) and on-site support were repeatedly recommended by researchers. Despite favorable organizational cultures, institutions have struggled to reach user compliance rates above 50%.^{14,29,30,32} Additional measures that were reported to be helpful in increasing compliance were (1) workflow redesign^{1,24,27} and precise definitions of roles and responsibilities,^{25,27,30} (2) equipping the tools with reminders^{31,32} or hard-stop systems,^{29,30} and (3) reducing the time needed to reconcile medication.²⁹ As with non-electronic processes, successfully implementing eMedRec requires multidisciplinary teamwork.^{31,38,39}

b. Extensive Usability Testing

Usability testing is the most commonly used evaluation method for assessing user interactions with health IT. Clinical processes have to drive IT development and design.²⁷ Usability tests ensure that clinicians and other healthcare professionals have an opportunity to evaluate and provide feedback on eMedRec systems' functionality, usability, and workflow.^{14,24,27,30,40} Most reports evaluated some components of usability.^{1,2,9,10,12,24,25,27,31-33} Evaluations of Twinlist were unique in that they purposively evaluated cognitive support of MedRec through interface design.⁹ In an experimental study⁴¹ published after we carried out our systematic search, the authors found that Twinlist could significantly improve the performance and safety of MedRec tasks. Their results should certainly help other developers and researchers, including EHR vendors, improve their own design.

c. Applicability to Commercially Available Tools

Three of the eleven tools that were identified in the present review are available as an open-source program (Plaisant⁹) or commercially available (Vawdrey²⁹ and

Sherer³³). Two additional tools are aiming to get into the market.^{7,8,26} Many other MedRec tools (either stand-alone or embedded in EHRs) are commercially available. Unfortunately, no eligible reports on these other tools were found by our search strategy. In order to explore the applicability of our results to these tools, we contacted 8 eMedRec software vendors referred to in the MARQUIS toolkit¹⁹ and 16 EMR vendors and asked them to provide information on their MedRec tools. Three reminders were sent. Seventeen vendors did not respond, and most responders did not want to share detailed information. In addition, we searched for information on the vendors' websites.⁴²⁻⁵⁹ It seems that many tools are clearly integrated in the clinician's workflow and tightly linked to CPOE and other decision support systems. Many vendors claim that users gain time and accuracy by using their MedRec tool. Nevertheless, information concerning the tool's characteristics – such as automatically highlighting discrepancies, making it possible to document the reason for stopping/modifying medication, offering different options for the organization of the medication list – was neither provided by vendors, nor found on their websites. At least nine EHRs had developed a patient portal^{48-50,52,54,56,58,59} but patient input is apparently not used to inform the MedRec tool's consolidated list (a synthesis table can be found in Supplementary Appendix III).

4.3. IMPLICATIONS FOR RESEARCH

As most of the tools reported on had only recently been implemented, the evaluations of these tools were mainly limited to measures of usability,^{1,2,9,10,12,24,25,27,31-33} user adherence^{1,10,25,27-33} and satisfaction.^{24,25,27,29,31-33} We found only one RCT that evaluated the impact of eMedRec on clinical outcomes, namely potential adverse drug events.²⁸ Future studies should correlate the specific features of MedRec tools to their efficacy in improving the identification and resolution of medication discrepancies. This could help with considering which features are the most important. Validated measures should be used to assess usability, such as the Questionnaire for User Interaction Satisfaction,⁶⁰ and these measures should also be correlated to efficacy. Moreover, future research should evaluate – using rigorous and, if possible, multicentric designs²² – to what extent eMedRec is able to achieve the goal of

improving patient safety and quality of care. A few such trials are currently ongoing.^{7,11} Outcome measures in future trials should include measures of adverse drug events and the number of unintentional medication discrepancies per patient. The latter measure has recently been endorsed by the United States National Quality Forum⁶¹. Such outcomes, together with selected process data, are worth considering in a core dataset. In addition, risks potentially introduced by eMedRec, such as over-reliance on electronic medication lists and technology induced errors, will need to be evaluated.

Quality of reporting should be improved. The present work has shown that many reports lack adequate information on the characteristics of the tools and of their implementation. Context, the characteristics of the tools, and implementation features all have an impact on effectiveness. Future researchers should carefully describe each component, and particular attention should be paid to describing features that have been listed as essential for the successful implementation of eMedRec.^{14,19}

Further research should investigate the quality of MedRec modules in EHRs and the incremental benefits of add-on MedRec software integrated with these EHRs. However, it should be noted that research on this topic might be hampered by a lack of scientifically rigorous data in peer-reviewed journals or patent databases, by a lack of information due to confidentiality considerations, and by difficulties in implementing direct comparisons, because no hospital is going to adopt more than one EHR at once. However, before/after studies by hospitals adopting different tools might be informative, as might be multihospital comparisons of adjusted discrepancy rates in institutions that use different EHRs. Increasing patient engagement as another strategy for enhancing eMedRec efficiency¹⁶ should be assessed by researchers. Patients can get involved, most often through patient portals, by providing their list of medications, by commenting on medication discrepancies between different lists, and by self-informing about nonadherence. For example, Siek et al.^{17,62} developed the Colorado Care Tablet, a Personal Health Application that older adults with limited computing experience (ie., a population for which obtaining the best possible medication history is especially challenging)^{17,36,38} could easily use. Except for the APHID tool,^{10,25} patient portal studies were excluded from the present review, due to the fact that portals were often not linked to an eMedRec tool or that description of the tool

was lacking. From our viewpoint, patient portals remain an interesting way of involving patients and improving medication reconciliation,⁶³ and such data could inform developers of future eMedRec tools.

4.4. LIMITATIONS

This systematic review has several limitations. First, it is likely that we missed some existing eMedRec tools, because we limited our selection to English-language reports, because we cannot exclude publication bias, and because eMedRec tools developed in countries other than the United States may not have been patented. In addition, the translation of our research query in the Embase database generated difficulties. Indeed, “emtree” (Embase controlled vocabulary) did not contain any specific term for “medication reconciliation” (it was translated as “medication therapy management”). Despite this, our search strategy was comprehensive and not limited to published full-text papers. In addition, we did not restrict our selection to experimental designs. This was certainly appropriate given the objectives of this review, and the data from ongoing quality improvement studies and observations studies were valuable. Second, we had to exclude possibly interesting reports due to absent or incomplete data on the tools they described. Efforts were made to collect additional data from proceedings – some requests were successful but others were not. We did not attempt to collect additional data from authors of full-text papers with no data on the tool. Third, to be included, eMedRec tools had to support the entire MedRec process; this decision was taken for reasons of homogeneity and because we considered it to be an essential feature of eMedRec tools. However, several reports on tools that support some, but not all, steps of the MedRec process have generated some useful data. For example, Agrawal et al. developed an eMedRec system for use on admission to an acute care hospital.^{39,64,65} Even though resolving discrepancies was not performed electronically, they reported a substantial reduction in medication errors, and the lessons learned from their experience were later used by many other research teams. More recently, Heyworth et al. found that enabling patients to conduct MedRec through a web portal was feasible during the transition from inpatient to outpatient care.⁶⁶

5. CONCLUSION

The transition is under way from paper to eMedRec¹⁴ and the proportion of healthcare organizations using a fully electronic system for MedRec-related activities is expected to increase in the future. E-tools that support the entire MedRec process have been developed and evaluated. In addition to the functionalities of the tools, context and implementation must be carefully considered in order to maximize adherence and effectiveness, and should be more thoroughly reported. Evidence from rigorous studies is needed to evaluate the effect of eMedRec on the quality and safety of healthcare.

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Chapter III – Patients and health care professionals point of view about medication reconciliation and the use of information technology for medication reconciliation

Short report

S. Marien, Q. Boucher, P. Vanmeerbeek, A. Spinewine

Chapter III at a glance

What is already known about the subject?

- Discrepancies are a threat to patient safety.
- The majority of eMedRec tools that were identified from the literature reviews come from North America, where health care systems and culture are very different from the Belgian situation. Interpretation of the data, particularly with regard to external validity, must therefore be done with great caution.
- When developing an electronic tool for medication reconciliation, patients' needs are different from healthcare professional needs but clear identification of these needs in the Belgian context hasn't been done yet.
- Literature studies reviewed emphasize the importance of taking into account factors related to the workflow, tool development and implementation climate. However, these factors may differ depending on the setting where tools are developed.

What this chapter adds:

- Patients and healthcare professionals were not familiar with the term "medication reconciliation = MedRec", except for clinical pharmacists who were very well informed about the subject. However, health care professionals (HCPs) and patients were participating unconsciously to the MedRec process.
- Discrepancies were experienced and identified by all participants. Depending on their "profile" (patients, general practitioners, physician specialists, community pharmacists and clinical pharmacists), they identified different types of discrepancies (omissions, commission, dosage, etc.).
- Most participants were using information technology in their professional life and thought it could be wise to use IT to improve MedRec, after having understood the concept of medication reconciliation.
- Specific functional and non-functional requirements were identified by participants as essential to reach tool adoption. For example, being able to use the tool everywhere on every support, linking the patient app to a

reminder system for adherence, linking the MedRec app to clinical decision systems in order to facilitate medication prescription.

- Participants also gave advice and recommendations concerning the tool implementation such as the location and the time period within workflow where the two apps should be accessible.

Related Publications

No related publication. No paper in preparation.

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Study concept and design: All authors.

S.M., Q.B. and P.V.M. acquired all the data and had full access to the data in the study.

S.M. and Q.B. take responsibility for the integrity of the data and the accuracy of the data analysis.

Interpretation of data and elaboration of specifications for SEAMPAT: Q.B. under revision of all authors.

Drafting of the chapter: S.M. Critical revision of the chapter for important intellectual content: A.S.

ABSTRACT

Background: In Chapter 1 and Chapter 2 we identified electronic systems allowing patients to contribute to medication reconciliation (MedRec) and/or healthcare professionals (HCPs) to reconcile medications. This work helped us to identify ideal features of an electronic MedRec tool with a patient app and a MedRec app. However, all identified tools were developed in North America, where health care systems and culture are very different from the Belgian situation. This emphasize the importance of a needs analysis in the Belgian context with potential end-users of both applications.

Objectives: The objective of this present work were first, to explore users' knowledge about MedRec and their participation in the MedRec process, and second to identify their views and expectations relative to the use of information technology (IT) for MedRec.

Methods: Data were collected during 11 focus groups (FG). A first round of 7 FG was held end 2014 with patients, physician specialists (PS), general practitioners (GP), clinical and community pharmacists and nurses. Four additional FG were organized during the summer 2015. FG were audiorecorded, transcribed and analyzed. A general inductive method was used to analyze transcripts.

Results: Six patients and 50 health care professionals (GPs, PS, pharmacists and nurses) participated to the FGs. (1) Most HCPs and some patients participated actively in the MedRec process, but the majority were doing it unconsciously. All participants recognized that transitions between care settings could lead to discrepancies. Different types and causes of discrepancies were noticed by each category of participants. (2) Although participants identified a list of barriers to the use of IT for MedRec, such as confidentiality and fear of hacking, general opinion about the use of IT was positive. Participants proposed some essential requirements to add to the tool to support, encourage and enhance the use of an electronic tool for MedRec. Participants also gave advice and recommendations concerning the tool implementation.

Conclusion: Requirements considered as essential by end-users and identified barriers will be considered when developing, designing and implementing the SEAMPAT platform with both applications.

KEYWORDS

Medication reconciliation; engaging the patient; end-users views and expectations; IT features.

1. INTRODUCTION

In Chapter 1 and Chapter 2 we identified 9 electronic systems engaging the patient in medication continuity¹⁻¹⁰ and 10 electronic medication reconciliation (eMedRec) tools allowing healthcare professionals (HCPs) to perform MedRec electronically^{8,11-19}. Among these tools, the APHID⁴ met inclusion criteria of Chapter 1 and 2. These reviews helped us to identify ideal features of an eMedRec tool with both a patient app as well as a MedRec app. We also identified barriers and facilitators with respect to the adoption of the system by both patients and doctors, enabling to define functional and non-functional requirements for their application.

All tools were developed in North America, where health care systems and culture are very different from the Belgian situation. This emphasized the importance of a Belgian needs analysis, already highly recommended by information technology (IT) experts²⁰⁻²⁴. End-users of both applications were included in this study.

The objectives of this present work were:

- 1) To explore users' knowledge concerning MedRec and their participation (conscious or unconscious) to the MedRec process.
- 2) To identify their views and expectations relative to the use of information technology (IT) for MedRec.

2. MATERIALS AND METHODS

2.1. PARTICIPANTS AND STUDY SETTING

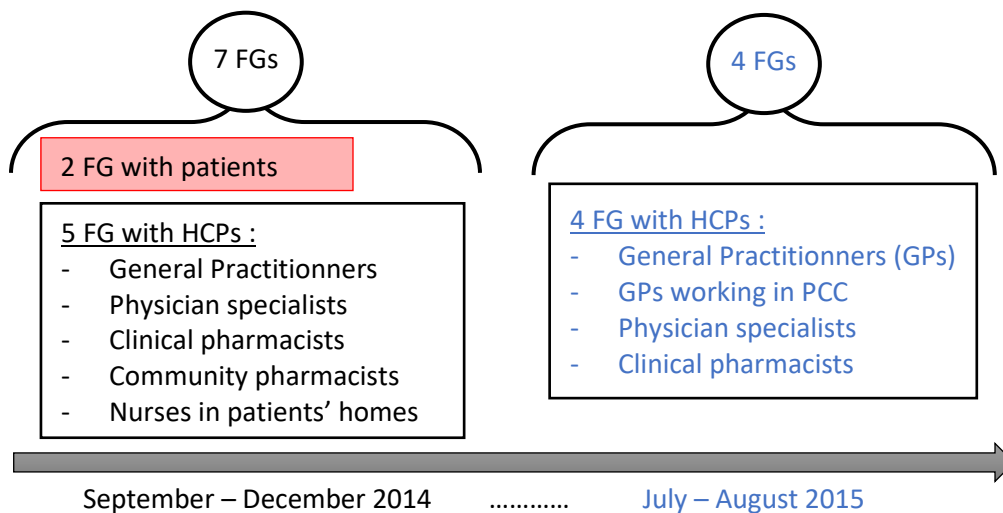
Participants were potential end-users of both applications. They were recruited via emails and/or phone calls using a "snowball procedure". Our sample included on purpose men and women of each group of users. **Patients** were all coming from the **region of Namur** and were outpatients as well as inpatients. They were recruited at the CHU UCL Namur and through patients' associations. They all had at least one chronic illness and were taking more than 5 medications on the day of inclusion. HCPs belonged to the four main groups performing MedRec in Belgium:

physician specialists (PS), general practitioners (GP), clinical pharmacists (ClinPharm), community pharmacists. Because nurses working at their patients' homes could be considered to be the patients' caregivers and because they also could be users of the patient app instead to help patients with various impairments, a focus group (FG) with nurses was also organized.

HCPs were recruited in the two regions where researchers had a network of potential participants: **Namur and Brussels**.

2.2. DATA COLLECTION

All the data was collected during FG discussions. In total 11 focus groups were organized. A first round of 7 focus groups was held between September and December 2014. We organized 2 focus groups with patients, one with PS, one with GPs, one with clinical pharmacists, one with community pharmacists and one with nurses visiting patients at home. Following data analysis from the first series of FGs, it became evident that we were lacking information concerning the MedRec app. So, we then organized 4 additional focus groups with HCPs during the summer of 2015. Two focus groups were conducted with GPs including one group of GPs working specifically in "Primary care Clinics" (PCC, "*Maison médicale*"). Two last focus groups were held with physician specialists and clinical pharmacists separately.



Three researchers of the SEAMPAT team participated to each focus group discussion with a defined role: 1 animator (QB), 1 observer (SM), 1 scribe (PVM). Discussion was based on a semi-structured questionnaire constructed in 3 sections: (1) introduction to the SEAMPAT project, (2) MedRec experience and knowledge (current situation), (3) expectations from an IT tool for MedRec (IT support to develop). Questionnaires were slightly adapted for each group of participants and were validated by all members of the SEAMPAT research team (see Appendix 1 Chapter 3). Each focus group lasted about 2 hours and was audio-recorded. The importance of speaking freely was emphasized: “all comments and questions are welcome, there is no negative feedback only information that should help us performing better”. Field notes were taken during discussion. Written consent was asked from each participant. Data saturation was reached.

2.3. DATA SYNTHESIS, ANALYSIS AND IMPLICATIONS FOR THE eMEDREC TOOL

Audio-recordings were transcribed. A general inductive method was used to analyze transcripts and field notes. Analysis was guided by the research outcome: the development of a list of functional and non-functional requirements (= exigences) for the two applications of the eMedRec tool to build two requirement specifications documents (= cahier des charges). One researcher (QB) analyzed transcripts and corresponding field notes and elaborated a summary of each focus group discussion. Summaries were divided into two main topics, in line with the two objectives: current situation and participants’ views and expectations concerning an IT tool for MedRec. Then, after several readings of all transcripts and field notes, categories and subcategories were identified for each topic. Summaries of each focus group discussion and the full list of categories and subcategories were reviewed by the two other researchers present during FG for completeness and accuracy (SM and PVM). When consensus was reached, results were sent to other team members of SEAMPAT for feedback and validation. After several iterations between team researchers, a computer scientist (QB) used the identified categories and subcategories together with the data from chapters 1 and 2 to build the first draft of the requirement specifications documents.

3. RESULTS

Six patients of whom 4 were women, and 50 HCPs (19 GPs, 10 PS, 15 pharmacists and 6 nurses) of whom 32 were women participated to the focus groups.

3.1. CURRENT SITUATION

Participants participate actively in the MedRec process but most of them are doing it unconsciously. Indeed, except for pharmacists, patients as well as most physicians and nurses had never heard the term “medication reconciliation”.

However, all participants recognized that transitions between settings of care could lead to differences in the medication lists (discrepancies) and so to medication errors. Different types and causes of discrepancies were identified by each category of participants. **Physicians** were complaining about medication omissions, additions and substitutions. According to them, most discrepancies were the consequence of inconsistency between medical reports and written prescriptions, and insufficient attention to patients’ adherence when taking medication histories. **Pharmacists** also mentioned discrepancies in medication dosages and pharmaceutical forms. **Patients** highlighted the lack of attention paid by HCPs to medication history, leading to “re-“prescription of medication previously tried without success. Moreover, some omissions were equally due to patients’ omission to mention particular pharmaceutical forms (e.g. eye drops, inhalers, patches, ointment, etc.) and certain medicinal products (e.g. alimentary complements, phytotherapy) as they did not consider these as medication.

Participants identified many problems in our actual healthcare systems favoring this discontinuity in care and thus in medication. Major problems were: lack of information sharing (within a given setting and across different settings), lack of rigor and procedures, lack of accuracy in information, lack of time dedicated by HCPs to medication, workflow interruptions, oral information without written information. Participants also mentioned problems more specifically linked to the use of IT: slowness of systems, lack of interoperability and need of doing duplicate work.

To overcome these difficulties, patients and HCPs have tried to find solutions. HCPs have developed “hotline” (privilege phone numbers) allowing easier and

quicker contact between HCPs and “communication forms” accompanying the patient during healthcare setting transitions. Patients use pill box or up to date, paper or printed medication lists they bring with them when consulting physicians or being hospitalized. Some patients with high health literacy are actively engaged in their care and control each change of medication done by HCPs.

3.2. PARTICIPANTS’ OPINION AND EXPECTATIONS CONCERNING AN IT TOOL FOR MEDREC

HCPs’ and patients’ **general opinion** about the use of IT was **positive**. HCPs thought IT could be particularly useful to improve information exchange to ameliorate the accuracy (precision and exhaustivity) of their patients’ medications list. For example, by improving their knowledge about the reason for stopping/modifying a medication. While the majority agreed that the patients’ input could help improving the precision of the medication list, most HCPs were skeptical about patients’ IT skills. GPs considered that less than 10% of their patients could reasonably document their medication list using IT. Community pharmacists and physician specialists were less pessimistic and spoke respectively about 33% and 50% of their patients able to use IT to document their medications list. Hospital HCPs insist on the importance of hearing patients’ voice because some patients do not tell everything to their GP fearing to disappointing someone they appreciate.

HCPs’ greatest fear was the time needed to use such a tool and the risk of duplicating their work. Some HCPs were also concerned about privacy, risk of hacking and the danger of spying on their work with the negative effect that some information could turn against them with nasty consequence. For example, when a therapeutic decision is taken based exclusively on clinical judgement and is slightly different of what is proposed in the evidence-based guidelines. Moreover, all HCPs worried about the large amount of data that could rapidly be available and the risk of being overwhelmed and being unable to prioritize easily information.

Compared to HCPs, **patients** were slightly more enthusiast about the idea of valuing their input with the use of IT. Patients appreciate the idea to have written information they could consult at any time from any place (even on holidays) using any IT support (computer, tablet, smartphone). As HCPs, patients believe IT

support could help improving the accuracy of their medication list across the different health setting. However, patients clearly expressed the need to be reassured about privacy, confidentiality, security and reliability of the system. Patients also mentioned the importance of the printing function because it would help them verifying or remembering information concerning their medication list. Some patients mentioned their lack of familiarity and knowledge concerning the use of IT and asked for an application easy to use (e.g. touch screen and structured information) but without making the tool too childish. **HCPs** emphasized this need. **Finally, HCPs and patients** feared reduced “eye/human contact” by overriding patient anamnesis to the benefit of the information recorded into the computer.

Patients and HCPs mentioned a list of features that would help convincing them to use an IT tool for MedRec. For example, **HCPs ask for** a tool so well designed that it could improve interoperability between the different softwares (e.g. inside and outside the hospital), present information coming from different sources (particularly the pharmaceutical delivery from community pharmacies), avoid duplicate work, support cognitive burden (e.g. recognizing duplicate medication, highlighting discrepancies) and reduce time needed for reconciling medication. **HCPs** thought also that such a tool should be linked to their computerized physician order entry (CPOE) and different clinical support systems (e.g. drug-drug interaction). Another example: a tool helping to save medication history and medication allergies for several months or years. Patients specified that the medication history should be visible only on demand and easy to consult by any one. **HCPs imagined that** the tool could help preventing inappropriate prescriptions of medications by using this historical information linked to a drug-drug interaction detection system. This tool could be linked to a notebook consultable and editable online by the patient and the HCPs taking care of the patient. It should help patients recalling medication by pictures of pill boxes and/or medication itself. It could also be customizable and tailor to users’ needs (e.g. medication reminders on smartphone, appointments’ alerts, fill-in forms for reimbursement). Finally, a tool supporting patient education by improving health literacy (e.g. with links to websites with consistent, valid and reliable information) would be very valuable and terminate to convince HCPs and patients to use IT for MedRec.

4. DISCUSSION

4.1. MAIN FINDINGS

All participants were aware that discrepancies can happen and that these can be a treat to patient safety. However, very few knew the process of MedRec, despite the previous work and sensitization campaigns done in Belgium²⁵⁻²⁷. Consistently with previous studies, patients and HCPs had an **overall positive attitude** about the use of health information technology²⁸⁻³⁰. However, participants expressed fears about the use of IT. These fears are well-known and similar to barriers we identified in the narrative review of chapter 1. During FG, participants mentioned **a set of desired features** that would enhance future tool adoption. Interestingly, the features deemed most important by participants such as medication reminders³¹, appointment alerts³¹, access to a notebook, links to reliable and valid scientific websites³², drug-drug interaction detection system³³, support for patient education and emergency support are not directly related to the process of MedRec. However, some of these features were offered as additional functionalities by some of the MedRec tools identified in chapters 1 and 2^{1,8,15,16,18,19,33}.

4.2. IMPLICATIONS FOR SEAMPAT

The first draft of the requirement specifications documents for both apps of the SEAMPAT IT platform was built on basis of results of chapter 1 to 3³⁴. Specifications were organized in functional and non-functional requirements (Appendixes). Functional requirements are for example details of the medication information that should be visible through the app for the patient and for HCPs. Non-functional requirements include for example, (1) sensitizing end-users about the process of MedRec, its importance to medication safety and their possible role in improving medication information sharing, OR (2) reassuring end-users about the privacy, confidentiality, security and reliability of the developed applications once users logged into the app. Requirements were then classified as

“essential” for an efficient eMedRec tool and “nice to have”. “Nice to have” requirements were placed under a “waiting room section” for a future version of SEAMPAT because these were not directly related to MedRec activities and were outside the main scope of the project.

Considering the literature, requirements reducing time needed for MedRec and improving accuracy of the reconciled list by reducing cognitive burden were judged as essential³⁴. Being well-integrated into the workflow and into the eHealth Belgian architecture with high interoperability will be key factors for adoption^{34,35}. Reminders, alerts, notebooks, drug-drug interactions system were considered as “nice to have” requirements. Because these “nice to have requirements” were specific to our needs analysis and because of results from previous needs analysis³¹⁻³³, we think they are worth considering for the SEAMPAT IT platform, at least in an ulterior version of SEAMPAT.

4.3. IMPLICATIONS FOR RESEARCH

It is really curious to notice that requirements deemed most important by participants had to be classified as “nice to have” by researchers. This should clearly be a path to explore for researchers. Should we develop tools specifically dedicated to MedRec. Or should eMedRec tools be part of a larger application? What type of application would improve MedRec most? A MedRec application perfectly functioning to support the 4 steps of MedRec with eventually some additional functionalities such as email commincation? Or an unperfected MedRec application to support discrepancies detection but associated with several hardly desired additional functionalities that would greatly improve tool adoption such as drug-drug interaction detection system, drug-laboratory detection system, a system preventing inappropriate prescription (e.g. if the patient has allergies), a system related to reimbursement forms for specific medications,... Future studies could assess relation between a particular set of features directly related or not to MedRec and MedRec improvements using patient safety outcomes (such as hospital readmissions, emergency visits,...).

4.4. LIMITATIONS

Our work clearly had some limitations^{36,37}. First, participants were volunteers, and numbers were relatively small (certainly with respect to patients), therefore we may have failed to collect a sufficiently wide range of opinions, including opinions that were more negative. Secondly, insufficient information was collected on health literacy and IT literacy of the participants. However, concerning HCPs, focus groups were held during meetings where physicians and pharmacists had to be present for accreditation.

Thirdly, identification of categories and subcategories was done by only one researcher, with the profile of a computer scientist (QB). However, data was audiorecorded, complemented by field's notes of the three researchers and all of them had very different and complementary profiles (QB = computer scientist, PVM = anthropologist, SM = medical doctor) and characteristics. So we hope it reduced bias. Moreover, because data analysis and interpretation were reviewed by all other team members of SEAMPAT with all different profiles, it enriched interpretation of results.

Finally, although most focus groups were held in the hospital setting, participants were all greeted in an auditorium outside the main building, where they were given a light snack, which may have helped them to feel they could speak freely. Moreover, because some participants (patients and HCPs) expressed strong unwillingness to use IT for MedRec, the researchers present during the FG had the impression participants spoke openly and frankly.

5. CONCLUSION

Building a system in which people want to engage requires knowing what their experiences are and what matters most to them.³⁵ Our results helped us identify what matters most to patients and healthcare professionals from the regions of Namur and Brussels. These results complemented findings of chapter 1 and 2 and allowed us to elaborate the requirement specifications documents. Identified barriers and essential requirements were then considered when developing, designing, implementing and testing the SEAMPAT platform with both applications.

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Research objective II :

Testing and suggesting improvements concerning an eMedRec tool composed of a patient app and a MedRec app

Chapter IV – Patient testing the patient application

IV.1. SEAMPAT: AN ICT PLATFORM FOR MEDICATION

RECONCILIATION WITH ACTIVE PATIENT INVOLVEMENT

Valéry Ramon, Ravi Ramdoyal, Sophie Marien, Quentin Boucher, Delphine Legrand, Christine Burnet, Perrine Vanmerbeek, Anne Spinewine

International Conference on Computers Helping People: Proceeding. 2016.

IV.2. A WEB APPLICATION TO INVOLVE PATIENTS IN THE

MEDICATION RECONCILIATION PROCESS: A USER-CENTERED

USABILITY AND USEFULNESS STUDY

Sophie Marien, Delphine Legrand, Ravi Ramdoyal, Jimmy Nsenga, Gustavo Ospina, Valéry Ramon, Benoit Boland, Anne Spinewine

Journal of the American Medical Informatic Association 2018 Aug; [Epub ahead of print]

This Chapter 4 represents an important part of the work accomplished in the context of my thesis. Therefore, it **has been divided into two different sections** IV.1. and IV.2. corresponding to two articles.

Section IV.1. has been published as “SEAMPAT: an ICT platform for medication reconciliation with active patient involvement”. It summarizes the global methodological approach giving a few results of Chapter 1 and Chapter 3 and it reports results of **the first and the second iterations** of the evaluation of the patient application.

Section IV.2. “A web application to involve patients in the medication reconciliation process: a user-centered usability and usefulness study” is under review. It reports methods and results of **the third iteration** of the evaluation of the patient application.

Chapter IV at a glance

What is already known about the subject?

- Medication reconciliation (MedRec) is a worldwide patient safety goal. Many organizations are struggling to implement effective processes.
- Information technology can help optimizing the MedRec process.
- Patient engagement is known to improve medication continuity. Most patients have an overall positive attitude about the use of information technology to engage in their care.
- Patient portals are becoming widely used and studied, but very few tools engaging patients in the MedRec process and/or directly linked to information technology softwares used by healthcare professionals, have been studied so far in the literature.

What this chapter adds:

- Patients are interested in the use of an electronic tool to take a more active part in their care but they find it difficult to understand the importance of MedRec and the role they can themselves play to improve the process.
- Usability testing showed positive results regarding the patient app, but at present, results are insufficient and the tool needs to be improved before it can be fully adopted and used sensibly in the long-term.
 - The patient app needs improvements: additional features, not directly related to MedRec but in line with patients' expectations have to be added to the tool.
 - Collaboration and concordance (including IT exchange) between patients and providers is essential, particularly because patients consider providers' endorsement as a fundamental factor of their engagement.
- Finally, collecting quantitative and qualitative data was the cornerstone to enable interpretation of results and translate those into a practical and usable interface.

IV.1. SEAMPAT: AN ICT PLATFORM FOR MEDICATION RECONCILIATION WITH ACTIVE PATIENT INVOLVEMENT

Related Publications

Valéry Ramon¹, Ravi Ramdoyal¹, Sophie Marien², Arnaud Michot¹, Jimmy Nsenga¹, Gustavo Ospina¹, Fabian Steels¹, Quentin Boucher^{1,3}, Delphine Legrand², Christine Burnet⁴, Perrine Vanmerbeek⁴, Anne Spinewine². SEAMPAT: AN ICT PLATFORM FOR MEDICATION RECONCILIATION WITH ACTIVE PATIENT INVOLVEMENT. International Conference on Computers Helping People with Special Needs - ICCHP 2016: Computers Helping People with Special Needs pp 269-276

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Authors Contribution

V.R., R.R. and S.M. had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: All authors.

Acquisition of data: V.R., R.R., Q.B. and S.M.

Analysis and interpretation of data: All authors.

Development of the patient app: V.R., R.R., J.N., G.O.

Drafting of the manuscript: V.R. and S.M.

Critical revision of the manuscript for important intellectual content: All authors.

Final approval of the version to be published: All authors.

Obtained funding: A.S.

Administrative, technical, and material support: S.M., V.R., R.R., A.S.

Study supervision: A.S.

IV.1.1. R&D Idea Introduction

The transitions across different health care settings, notably home and hospital, may be critical regarding the continuity of patient's medication. Some of the medication discrepancies occurring during these transitions are intentional and justified by the patient's clinical condition. Other ones are not and result from either imprecise information about current medications (indication, posology,...) or from unintentional information loss. These can potentially be harmful to patient's health (leading to extended hospital stay, early readmission, unplanned visits to the emergency department or even death) and therefore lead to increased use of healthcare resources and increased costs.

To obtain a complete and accurate list of all current medications, patient engagement is increasingly recognized as a key determinant. However, limited work addressed the value of patient empowerment and the benefit of using information and communication technologies (ICT) in this process.

The goal of SEAMPAT is to define, implement and evaluate an ICT-based medication reconciliation (MedRec) process in which the patient is actively involved in providing information about his/her current medications. MedRec is the formal and collaborative process of obtaining and verifying a complete and accurate list of patient's current medications. It aims at ensuring that no medication was added, omitted or modified by inadvertence during the transitions across multiple care settings. SEAMPAT develops a proof-of-concept prototype made of two web applications: one for the patients, usable at home or at hospital, and one for healthcare professionals (HCPs) (physicians, pharmacists) to help them perform MedRec. These two applications will be interconnected through the Walloon Regional eHealth network of Belgium (Réseau Santé Wallon). This paper mainly focuses on the patient's application which is at a more advanced stage of development.

SEAMPAT is an ongoing three-year (2014-2017) collaborative research project funded by the Walloon Region of Belgium. The multi-disciplinary partnership includes medical experts (physicians, pharmacists) as well as experts in ICT, experts in law and in anthropology. The research work is guided by an advisory board gathering a broad panel of stakeholders. It is also supported by the Réseau Santé Wallon, a medical software provider, a university hospital and a major Belgian health mutuality insurance.

IV.1.2. State of the art in this area (other projects, publications, ...)

Firstly, a literature review was performed, mainly in the PubMed bibliographic database, in order to identify existing ICT tools that support patient empowerment/engagement for medication reconciliation. It was completed by a search for patents in FamPat and Espacenet patent international databases. Several interesting tools were found. They allow the patients to validate their medications and give additional information about these medications. Additional references will be provided in the full paper. Hereafter are the most interesting:

- **the Colorado Care Tablet (CCT)** [1] has a user-friendly interface. It was iteratively designed with patients above 65 years old. The application offers different functionalities such as encoding medication, accessing to information about medication (i.e. adverse events), preparing an appointment, etc.. The researchers also provided some design guidelines useful for patient application developers.
- **the Automated Patient History Intake Device (APHID)** [2]-[3] is a tool that appears to be easy to use for the patients. It was first elaborated for patients before an outpatient consultation. Usability and satisfaction were evaluated and patients' feedback was collected to improve the tool. A randomized controlled trial is still ongoing.
- **the Interactive Patient Medication List** [4] offers a lot of different functions to the patient: access to all medication sources available on the health network and identification of the differences, adherence evaluation, ordering in advance medication at the pharmacy, etc. According to the inventor, the tool is not yet implemented.
- **the Patient Gateway Medication Module** [5]-[6] is a patient portal designed to improve the accuracy of medication lists within the electronic health record. The patient validates his medications and adds other information. A set of usability tests were done to refine the tool design.

In parallel, a literature search was performed, again in PubMed, to identify factors influencing patient participation in approaches to improve quality and safety of healthcare. Based on twelve relevant articles (systematic reviews, narrative reviews and qualitative studies), a table was built with facilitators and barriers to patient's participation.

Considering all those references, SEAMPAT innovates by providing the first ICT tool exploiting such a large set of patient medication sources to perform MedRec. As further explained later in this paper, these sources come from both inside and outside hospital and include the patient's input on an equal footing with HCPs sources. It is also the only tool accessible to the patient from home.

IV.1.3. Methodology

Firstly, a literature review and a search for patents were performed, as described above. In parallel, eleven focus groups were organized with patients and HCPs. They were composed of two to eight people with the same profile (patients, pharmacists, physicians including both general practitioners and specialists). The goal was to assess their experience about medication discrepancies as well as to identify their fears, needs and expectations of an ICT solution for MedRec in which the patient is actively engaged.

Relying on all information collected from the literature review and through those focus groups, a requirement specifications document has been elaborated and reviewed with all project associated stakeholders (i.e. members of the advisory board and representatives of the different institutions supporting the project). This document has then been used as a basis for the specification and design of the patient's application. The project stakeholders were again closely associated to the definition of the detailed architecture of the application, including its external interfaces and the format of the data flows. The data structures have been defined based on the Belgian standard KMEHR [7] used for the exchange of structured health information.

Based on the conclusions obtained in the literature review and also on discussions with some medical experts supporting the project, three target patient groups were selected for the evaluation phases: pulmonary transplanted patients, patients visiting their general practitioner at least once a month and patients hospitalized for a scheduled surgery. The focus is on patients at risk of discrepancies and taking at least 5 medications. At least half of the patients will be older than 65.

As far as the user interfaces are concerned, they are designed using the following methodology:

- by taking into account the ten major usability principles synthesized from recommendations from usability experts (such as [8]-[9]) and existing standards (such as ISO 9241 , ISO 14915 and AFNOR Z67-133.1);
- by considering the closest applications found in the literature search, namely the CCT of Siek K. and the APHID of Lesselroth B. et al.;
- and, very importantly, with an iterative approach actively involving the final users, based on the user-centred design presented in [10]. Bearing in mind the users' profile and context, it notably consists in associating the users throughout the development lifecycle, studying their behaviours and reactions and progressively refining the system based on their regular feedback. This leads to user interfaces which are more efficient, more user-friendly and satisfactory for their users while favouring the adoption of the final system.

In this iterative process, it was decided to foresee three main iterations, the first two ones being already accomplished at this time:

- static prototype (mock-ups): its objective was to evaluate the content rather than the form (relevance of the presented information, understandability of the considered flows and interactions, high-level structuration of the screens). The evaluation was performed through discussion groups with 15 users in total (5 users per target group) and via a satisfaction questionnaire. The user interfaces were adapted following to the users' feedback.
- interactive prototype with fake data: the objective of this second prototype was to put the users in a more realistic situation, allowing them to navigate through the different screens, in order to observe their take up of the application and identify problematic interactions. Due to external constraints, fake medication data were used. The evaluation, involving 30 users in total (10 users per target group), was performed through usability sessions guided by a reference scenario (add, modify, delete medications) and with a satisfaction questionnaire. Again, the user interfaces have been modified after those sessions.
- dynamic prototype with real data: the objective of this third stage is to offer to the users an entirely functional prototype connected to their real

medication data in order to make the final adjustments. The evaluation, which has not been started yet, will involve 45 to 60 users (15 to 20 per target group) and last a few months.

In parallel to the medical and technical works, a juridical analysis identifies the applicable laws or regulations which can lead to constraints or guidelines to the elaboration of the SEAMPAT tools. It also cares about the formalities necessary to the evaluation phase (e.g. declaration to ethical committee, patient and HCP informed consent forms). An analysis of the social acceptability of the project is also performed by an anthropologist to understand how the MedRec actually satisfies a social need.

IV.1.4. R&D work and results

Two web applications (using HTML5/Javascript technologies) are being prototyped and interconnected through the Réseau Santé Wallon (RSW):

- an application for the patients, usable on desktop, laptop or tablet at home or at hospital: it will allow the patients to consult and report the list of their current medication starting from the data communicated by healthcare professionals (HCPs) in primary as well as secondary care (pharmacists, physicians including both general practitioners and specialists) on the RSW. The patients will report whether they take each medication listed, how (posology) and possibly for what purpose (indication). They can mention additional medications. The information will be made available to HCPs through the RSW. The patients will be encouraged to update their medication list before any visit to a doctor.
- an application for HCPs to support the medication reconciliation (MedRec) process: for a given patient, it will highlight the medication discrepancies between the medication list a HCP has in his/her electronic patient record, the patient's list and the medications reported by other HCPs. Thanks to this information, the HCP will perform medication reconciliation and update his/her own list. The reconciled list will be made available to other HCPs and to the patient through the RSW. The application will be integrated as an additional module in the medical software commonly used by the HCP. Because at a lower stage of

development (its specifications are coming to an end), it is less discussed in this paper.

A conceptual scheme of the SEAMPAT system is shown below. This system is protected by high security mechanisms. Patient's authentication is performed with the Belgian electronic identity (eID) card and its associated PIN code. Data transfers over Internet only occur through secure connections (https, VPN IPsec tunnel) and data themselves are encrypted before their transfer (double encryption). Only patients who gave their consent for registration to the RSW are able to use the application. The juridical work identified the major applicable laws. They concern health data protection, the patient's rights (a.o. the right to be informed) and the exercise of regulated health professions. These texts provided various guidelines which were integrated into the architecture of the solution. Access rights to medication data available on the RSW follow the rules defined in the Privacy Policy of RSW, established from this legal framework.

At this stage of the project, as mentioned earlier, a second version of the patient's application (with fake data) has already been developed and evaluated with 30 users. Taking into account all patients' feedback collected so far, the application is now being enhanced to connect to the patients' real medication data available on the RSW.

IV.1.5. Scientific and practical impact or contributions to the field

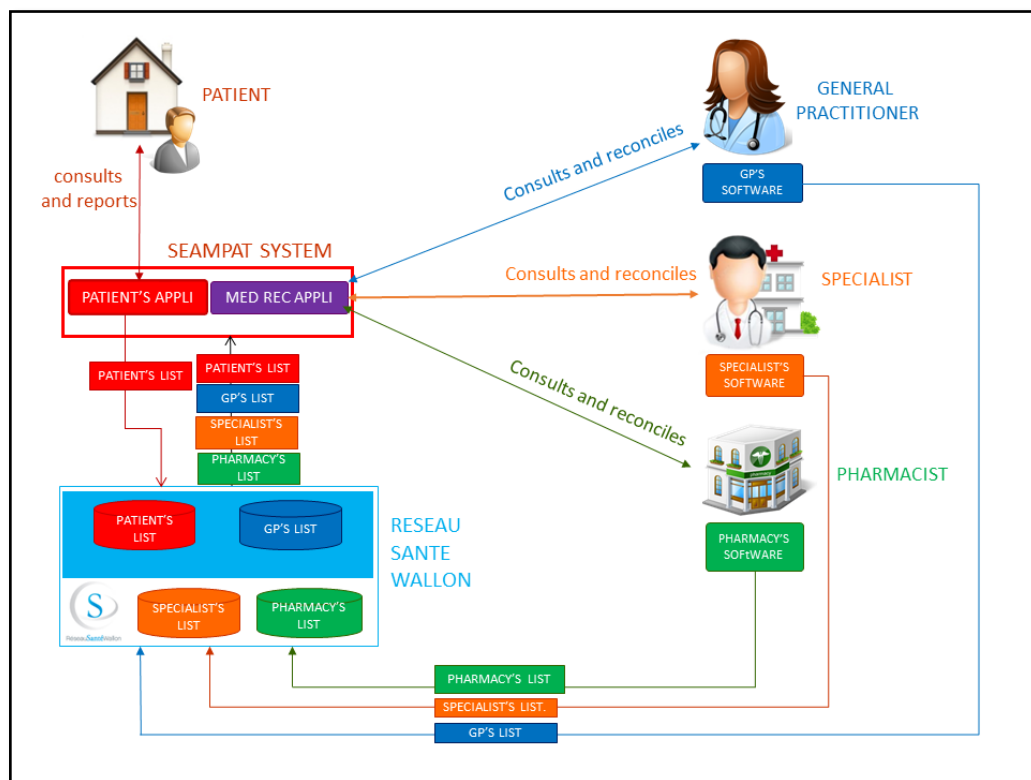
As already said above, unintentional medication discrepancies can potentially be harmful to patient's health (leading to extended hospital stay, early readmission, unplanned visits to the emergency department or even death) and therefore lead to increased use of healthcare resources and increased costs. The scientific literature claims that at least one potentially harmful discrepancy appears for 45% of patients. Moreover, 27% of prescription errors at hospital are due to an incomplete medication history at hospital admission. Also, 25% of hospital readmissions are due to poor communication relating to medication at hospital discharge. MedRec is one of the five priority axes of the World Health Organization (WHO) (High 5s project: <http://www.high5s.org>). It is also a usual requirement for hospital accreditation.

The project results may contribute to improve the quality of healthcare of Walloon patients, in particular elder and/or polymedicated chronic patients. They may also benefit to the project stakeholders and to enterprises developing medical software applications for patients, hospitals and physicians in private practice.

IV.1.6. Conclusion and planned activities

So far, the vast majority of patients involved in the project have shown tremendous enthusiasm and interest and are willing to continue to work with us. Their constructive feedback enabled to refine already twice the patient's application. The prototype is now being connected to the patients' real medication data available on the RSW. In about two months, it will be evaluated with 45 to 60 voluntary patients, 15 to 20 per target group. The application for HPCs, whose specifications are coming to an end, should also be developed and evaluated with potential users in the next few months.

IV.1.7. Conceptual scheme of SEAMPAT solution

**Figure:**

The patients consult the patient app and see their list of medications. Their list is a merged medication list with information available on the Réseau Santé Wallon (RSW) coming from the GP, the specialists, the pharmacy and the patient himself. Patients document their medication list (what and how they are taking their medication). A new patients' list is then published on the RSW.

The HCPs consult the MedRec app and see the information available on the RSW organized in 3 columns (see below) to support medication reconciliation. The HCPs reconcile the patients' medication list. The reconciled medication list is then available in their own local software. Afterwards, this reconciled and updated medication list is published on the RSW from their own software.

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IV.2. A WEB APPLICATION TO INVOLVE PATIENTS IN THE MEDICATION RECONCILIATION PROCESS: A USER-CENTERED USABILITY AND USEFULNESS STUDY

Related Publications

Sophie Marien^{1,2,3}, Delphine Legrand¹, Ravi Ramdoyal⁴, Jimmy Nsenga⁴, Gustavo Ospina⁴, Valéry Ramon⁴, Benoit Boland^{2,3}, Anne Spinewine^{1,5} A web application to involve patients in the medication reconciliation process: a user-centered usability and usefulness study. Journal of the American Medical Informatic Association 2018 Aug; [Epub ahead of print]

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Authors Contribution

S.M. had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: All authors. Acquisition of data: S.M. Analysis and interpretation of data: All authors

Development of the patient app: Ravi Ramdoyal, Valery Ramon, Jimmy Nsenga, Gustavo Ospina

Drafting of the manuscript: S.M. Critical revision of the manuscript for important intellectual content: All authors. Final approval of the version to be published: All authors. Obtained funding: A.S. Administrative, technical, and material support: S.M., V.R., R.R., A.S. Study supervision: A.S.

ABSTRACT

Background: Medication reconciliation (MedRec) can improve patient safety by resolving medication discrepancies. Because information technology (IT) and patient engagement are promising approaches to optimize MedRec, the SEAMPAT project aims to develop a MedRec IT platform based on two applications: the “patient app” and the “MedRec app”.

Objective: This study evaluates three dimensions of usability (efficiency, satisfaction, and effectiveness) and usefulness of the patient app.

Methods: We performed a four-month user-centered observational study. Quantitative and qualitative data were collected at different time points. Participants completed two questionnaires: one on usability (the system usability scale) and a second on usefulness. Effectiveness was assessed by measuring the completeness and correctness (i.e. medication discrepancies) of the medication list generated by the patient application. Qualitative data were collected from observations at different time points and from semi-structured interviews at the end of the study.

Results: Forty-two patients completed the study. Sixty-nine percent of patients considered the patient app to be acceptable (SUS Score ≥ 70) and usefulness was high. The medication list was complete for a quarter of the patients and there was a median of two discrepancies per patient. The qualitative data enabled the identification of several barriers (related to functional and non-functional aspects) to optimize usability and usefulness.

Conclusion: Our findings highlight the importance and value of user-centered usability testing of a patient application implemented in “real-world” conditions. To achieve adoption and sustained use by patients, the patient app should meet patients’ needs while also efficiently improving the quality of MedRec.

KEYWORDS

medication reconciliation; discrepancies; patient safety; personal health records; usability testing; user-centered design

IV.2.1. Introduction

Continuity of medication is a worldwide patient safety concern requiring information-sharing among providers, patients, and families across settings ¹⁻⁴. Medication discrepancies are unexplained differences between medication lists at different transition points of care ⁵. These discrepancies threaten patient safety ^{4,6,7}.

Medication reconciliation (MedRec) is the formal, collaborative process of obtaining and verifying a complete, accurate list of a patient's current medication to ensure that precise, comprehensive medication information is transmitted consistently across transition points of care ⁸. MedRec makes it possible to resolve discrepancies. Although several leading organizations worldwide ⁹⁻¹³ have campaigned for the implementation of MedRec, improving MedRec remains challenging ¹⁴.

The use of information technology (IT) seems a promising approach ^{3,15-18}. However, rigorous studies to evaluate the impact of electronic MedRec (eMedRec) are lacking ^{17,19}.

Patient engagement is increasingly recognized as a key component in the current redesign of health care processes. Accordingly, different research teams have developed electronic applications that allow patients to document medication lists ²⁰⁻²⁶. These applications are generally standalone ²⁶ or linked to a single source of information ^{20,22,25}. Moreover, all applications have been developed in the United States, where health systems, environments, and culture differ from Europe.

This study took place in Wallonia (a region in Belgium of about 3,600,000 inhabitants), where more than 1 million inhabitants are connected to the Regional eHealth Network (ReHN) ²⁷. The ReHN allows the exchange of eHealth documents between healthcare professionals (HCPs) caring for a particular patient. For example, a cardiologist in hospital A can access the Summarized Electronic Health Record produced by the general practitioner (GP) and the discharge letter from hospital B.

The SEAMPAT project is a multidisciplinary research project aimed at developing an eMedRec process. The project chose to actively engage patients and to support HCPs – both in primary and secondary care – through two specific eMedRec applications ^{18,19} interconnected with the ReHN: one for patients (“patient app”)

and one for HCPs (MedRec App). Both were developed according to recommendations by health IT experts²⁸⁻³². Requirements for the low-fidelity prototypes were defined on the basis of needs analysis and literature review^{19,33}. These then evolved to medium- and high-fidelity prototypes using an iterative user-centered design with three main iterations. Details of the development and the first two phases of evaluation are reported elsewhere³³.

In the present study, we report the results of the third iteration phase with the high-fidelity prototype (i.e. a working prototype connected to real eHealth data) of the patient app. Our objective was to assess the usability and usefulness from the perspective of different categories of patients, with the aim of making recommendations that could lead to increased adoption and sustained use of the patient app and inform further research in the field.

IV.2.2. Materials and methods

IV.2.2.1. System details

The patient app (using HTML5/JavaScript technologies), usable on a desktop or laptop at home or in hospital, lets patients document their medication lists. This IT system is protected by high-security mechanisms³³. Patient authentication is by the Belgian federal electronic identity (eID) card and its PIN code. Only patients registered with the ReHN can use the app. The app (Figure 1) presents patients with a list of medications compiled from different sources available on the ReHN, using a specific algorithm to prevent conflicting information: the GP's medication list, the hospital's medication list, and the patient's medication list (except for the first connection to the patient app). For each medication, patients indicate if and how they are taking it by choosing the appropriate option (taking as indicated, taking differently, not taking, unknown). Patients can also add medications and may also add indication and name of prescriber (Figure 1). The patient medication list (Figure 2) is then updated on the ReHN.

At the time of our study, the MedRec app was still under development. The working prototype was not available yet; therefore HCPs could not use the MedRec app to look at the medication documented by the patient and to perform MedRec.

Figure 1a

SEAMANT

21/11/2017

Valider et me déconnecter

SEAMANT

21/11/2017

21/11/2017 21:20

D'après les informations dont nous disposons, voici la liste des médicaments qui vous concernent.
N'oubliez pas de renseigner votre prise de médicament avant toute visite chez un médecin.

Besoin d'aide?

LES MÉDICAMENTS QUE JE PRENDS ACTUELLEMENT

La liste suivante reprend les médicaments que vous êtes probablement en train de prendre en ce moment.
Vous pouvez cliquer sur la photo de chaque médicament pour voir plus d'informations à son sujet.

	Prenez-vous actuellement ce médicament?			
 Dafalgan (C) 500mg - 32 Comprimés Effervescents P.O. Prendre 1 comprimé(s), 3 fois(s).	☒ NON Je ne prends pas/plus	☒ OUI Mais différemment	☒ OUI Comme indiqué	☐ DOUTE Je ne sais plus
 Cetirizine EG (C) 10mg - 80 Compr. Pelliculé(s) Prendre 1 comprimé(s), 1 fois(s).	☒ NON Je ne prends pas/plus	☒ OUI Mais différemment	☒ OUI Comme indiqué	☐ DOUTE Je ne sais plus
 FML LIQUIFILM 1 X 5 ML 1 goutte 2x/jj OD OG	☒ NON Je ne prends pas/plus	☒ OUI Je le prends	☒ OUI Comme indiqué	☐ DOUTE Je ne sais plus
 LIQUIFILM TEARS SOL OPHT 15 ML yeux	☒ NON Je ne prends pas/plus	☒ OUI Je le prends	☒ OUI Comme indiqué	☐ DOUTE Je ne sais plus
 PHYSIOMER JET FORT ADULTE 210ML 1 pharaline 1 x par jour (Soir)	☒ NON Je ne prends pas/plus	☒ OUI Je le prends	☒ OUI Comme indiqué	☐ DOUTE Je ne sais plus

LES MÉDICAMENTS QUE JE NE PRENDS PAS/PLUS

La liste suivante reprend d'autres médicaments que vous ne prenez probablement plus.

Figure 1b

SEAMANT

21/11/2017

Valider et me déconnecter

SEAMANT

21/11/2017

21/11/2017 21:20

AJOUTER UN MÉDICAMENT

Veuillez renseigner les autres médicaments que vous prenez actuellement et qui pourraient se présenter sous l'une des formes suivantes

 Comprimés

 Gélules

 Liquides Sirops

 Gouttes

 Inhalateurs Aérosols

 Sprays

 Patchs dermiques

 Injections (Vaccins et autres)

 Crèmes Pommades Onguents

 Suppositoires

 Phytothérapie / plantes

 Homéopathie

 Vitamines Compléments

 Médicaments de tous types

INFORMATIONS COMPLÉMENTAIRES

Veuillez fournir les informations complémentaires suivantes.

ANTIBIOTIQUES

Avez-vous pris des antibiotiques autres que ceux éventuellement précisés ci-dessus au cours des 3 derniers mois?

☒ NON ☒ OUI

Veuillez préciser si possible de quel(s) antibiotique(s) il s'agit.

Zinnat

ALLERGIES

Veuillez préciser le nom du (des) médicament(s) et décrire la (les) réaction(s) allergique(s)?

☒ NON ☒ OUI

DIVERS

Y a-t-il autre chose que vous souhaitez mentionner à propos de vos médicaments?

☒ NON ☒ OUI

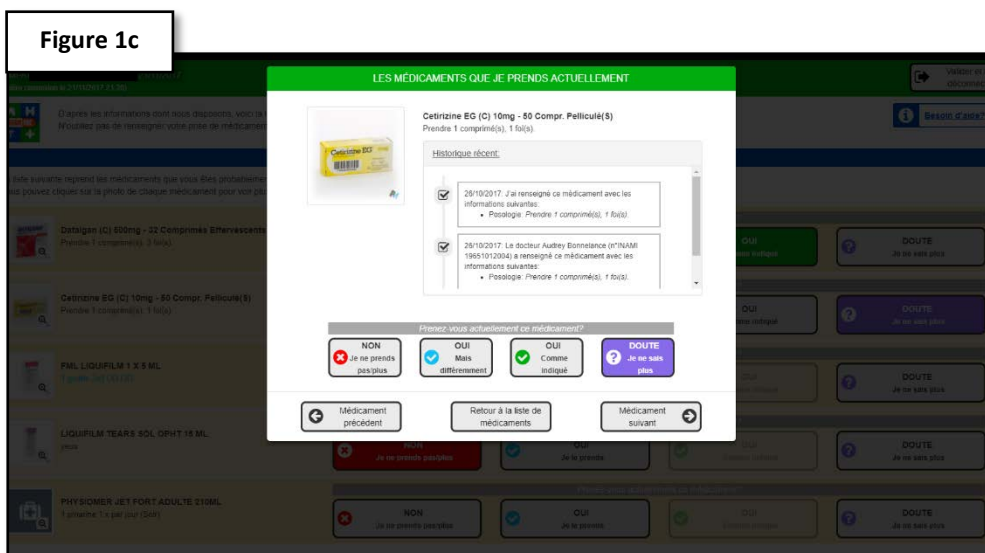


Figure 1a-e: Patient app screenshots

Upper row (Figure1a - 1b): Up: Patient medication list = list compiled from different sources available on the ReHN. For each medication, patients can choose the right option: No, Yes, etc. Down: Patients can also add medications to the list by clicking on one of the icons. Finally they can add information concerning recent antibiotic intake and allergies.

Middle row (Figure1c): If patients click on the magnifying glass, they can see details of date of prescription, indication, posology, larger pillbox picture, etc.

Lower row (Figure1d – 1e): Up: Patients can also add medications (prescription or over-the-counter). Once you start to type a medication's name, the system shows existing medications and box pictures. Down: Patients can indicate for what purpose (indication) they are taking the medication and who prescribed it.

Figure 1d

AJOUTER UN MÉDICAMENT

Vous souhaitez ajouter un médicament du type "Comprimés" à votre liste de médicaments «en cours».

Comment souhaitez-vous procéder?

☐ Choisir un autre type de médicament

☐ Je dispose de l'emballage

☒ Je connais son nom

☐ Je ne connais pas plus son nom

1. Chercher le médicament par son nom

Veillez entrer les premières lettres de son nom:

data

- DAFALGAN FORTE 1G COMP 16 (Belgium)
- DAFALGAN FORTE 1G COMP 50 (Belgium)
- DAFALGAN FORTE SEC COMP 10 X 1000 MG (Belgium)
- DAFALGAN ODIS COMP ORO DISP 16 (Belgium)



Figure 1e

AJOUTER UN MÉDICAMENT

Vous souhaitez ajouter un médicament du type "Comprimés" à votre liste de médicaments «en cours».

Comment souhaitez-vous procéder?

☐ Choisir un autre type de médicament

☐ Je dispose de l'emballage

☒ Je connais son nom

☐ Je ne connais pas plus son nom

1. Chercher le médicament par son nom

Veillez entrer les premières lettres de son nom: DAFALGAN ODIS COMP ORO DISP 16

2. Confirmer le médicament

Vous avez sélectionné le médicament suivant. Est-ce le bon médicament?

 DAFALGAN ODIS COMP ORO DISP 16

3. Renseignez la prise

Veillez préciser comment vous prenez ce médicament (combien, quand, comment).

Par exemple: "1 comprimé 3 fois par jour"

Renseignez ici votre prise:

4. Renseignez l'indication

Veillez préciser pourquoi vous prenez ce médicament.

Par exemple: "contre la douleur"

Renseignez ici l'indication:

5. Renseignez le prescripteur éventuel

Si ce médicament vous a été prescrit par un médecin, veuillez préciser le nom de l'éventuel prescripteur.

Par exemple: «Dr. Unter, mon cardiologue»

Renseignez ici le prescripteur éventuel:

Espace Privé « Patient »

retour au portail (déconnexion) Patients' name

Accueil Mes documents Mes autorisations d'accès Mon historique des accès Mon consentement

Documents

Vous trouverez ci-dessous la liste des documents qui ont été référencés par vos prestataires de soins sur le Réseau Santé Wallon. Ces documents ne sont accessibles qu'aux prestataires de soins autorisés (voir liste des prestataires de soins) et ce dans le cadre de votre prise en charge. Pour l'ajout ou l'exclusion d'un prestataire de soins autorisé à accéder à l'ensemble de vos documents, utilisez le menu « Autorisations d'accès ». Vous pouvez autoriser ou restreindre l'accès de certains documents médicaux en particulier en cliquant sur « gérer » dans la ligne concernant le document.

+ Ajouter une note dans le journal
+ Ajouter un résumé de santé

Tous | Laboratoire | Documents Psy | Sumehr | Autres | Journal

Filter par dates :

Date	Type	Auteur	Profil	Service	Site	Accès	Accès Patient	Traces
6/07/2017	Résultat laboratoire	WALLEMACQ Pierre	Médecin	Laboratoire	Cliniques universitaires Saint Luc	Gérer	Libérable l'auteur document	par du Voir
24/05/2017	Note journal		Médecin	-	-	Gérer	Accessible	Voir
24/05/2017	Note journal		Médecin	-	-	Gérer	Accessible	Voir
30/03/2017	Schema medication	MARIEN Sophie	Médecin	external	CHU Namur UCL	Gérer	Accessible	Voir
20/03/2017	Schema medication		Patient	-	-	Gérer	Accessible	Voir
20/03/2017	Schema medication		Patient	-	-	Gérer	Accessible	Voir
14/03/2017	applicationlink		-	-	-	Gérer	Accessible	Voir
3/03/2017	Schema medication		Patient	-	-	Gérer	Accessible	Voir
24/02/2017	Schema medication		Patient	-	-	Gérer	Accessible	Voir
14/02/2017	Schema medication		Patient	-	-	Gérer	Accessible	Voir

1 2 3 4 5 ... >>

Médications					
Description	Début	Fin	Statut	Posologie	
JANUVIA COMPR. PEL. 28X 25MG ()	15/09/2016	31/12/9999	Non	1 comprimé le matin	
ZESTRIL COMPR. 28X 5MG ()	15/09/2016	15/09/2016	Non	1 comprimé le matin , 1 le soir	
DICLOFENAC EG COMPR. GASTRO-RESIST. 30X 50MG ()	15/09/2016	31/12/9999	Non	1 comprimé le matin , 1 Å midi , 1 le soir Pendant les repas	
PANADOL (PIP) COMPR. 50X 1G ()	15/09/2016	31/12/9999	Non		
SOFRASOLONE 7800/0,5/2,5 SUSP. SPRAY NAS. 10ML ()	15/09/2016	15/09/2016	Non		
DAFALGAN COMPR. EFFERV. 40X 500MG ()	15/09/2016	27/09/2016	Non	1 comprimé le matin , 1 Å midi , 1 le soir	
DAFLON 500 MG COMP ()	01/11/2015	10/09/2016	Non	1 comp. 2 x par jour (Matin - Soir)	
D-CURE SOL. 12X 25000UI/1ML (time1x/mois)		03/10/2016	Oui, mais différemment	tous les 15 jours: 0	
FELDENE GEL TUBE 50G 0,5% (persphysicianmoi)			Oui, comme indiqué	à la demande	
CETIRIZINE EG 10 MG COMP ()		08/02/2017	Oui, comme indiqué	10 mg(s) - max: mg(s)/24h. - interval:	
CATAFLAM 50 MG DRAG ()		08/02/2017	Non	50 mg 2 x par jour (Matin - Soir)	
DAFALGAN 1G COMP ()			Non	1 comp.(s) - max: 3 comp.(s)/24h. - interval: 8h.	

Figure 2: Screenshots: a patient logged onto his/her Regional eHealth Network (ReHN) page

Upper row: Patient's welcome page with his name in the upper right part of the page. Patient's list of documents with patient's medication lists (i.e. "schema de medication") published on the ReHN by the patient app.

Lower row: Patient medication list published by the patient. The column status shows the option chosen by the patient to answer the question: "Are you currently taking this medication?"

IV.2.2.2. Study design

This was a four-month user-centered descriptive study of usability and usefulness. In the context of our study, usability was defined according to ISO 9241-11 as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.”³⁴.

- Satisfaction: How satisfied is the patient with the tool?
- Effectiveness: How complete and correct is the patient medication list?
- Efficiency: What is the level of patient effort required?

Usefulness was defined as the degree to which a product enables users to meet specific needs and as an assessment of users’ willingness to use the product³⁵. A table summarizing the different concepts evaluated, their definitions, and the measurement method is available in Appendix I.

This paper follows the recommendations of the Statement on Reporting of Evaluation Studies in Health Informatics³⁶. The study protocol was approved by the Ethical Committee of CHU UCL Namur.

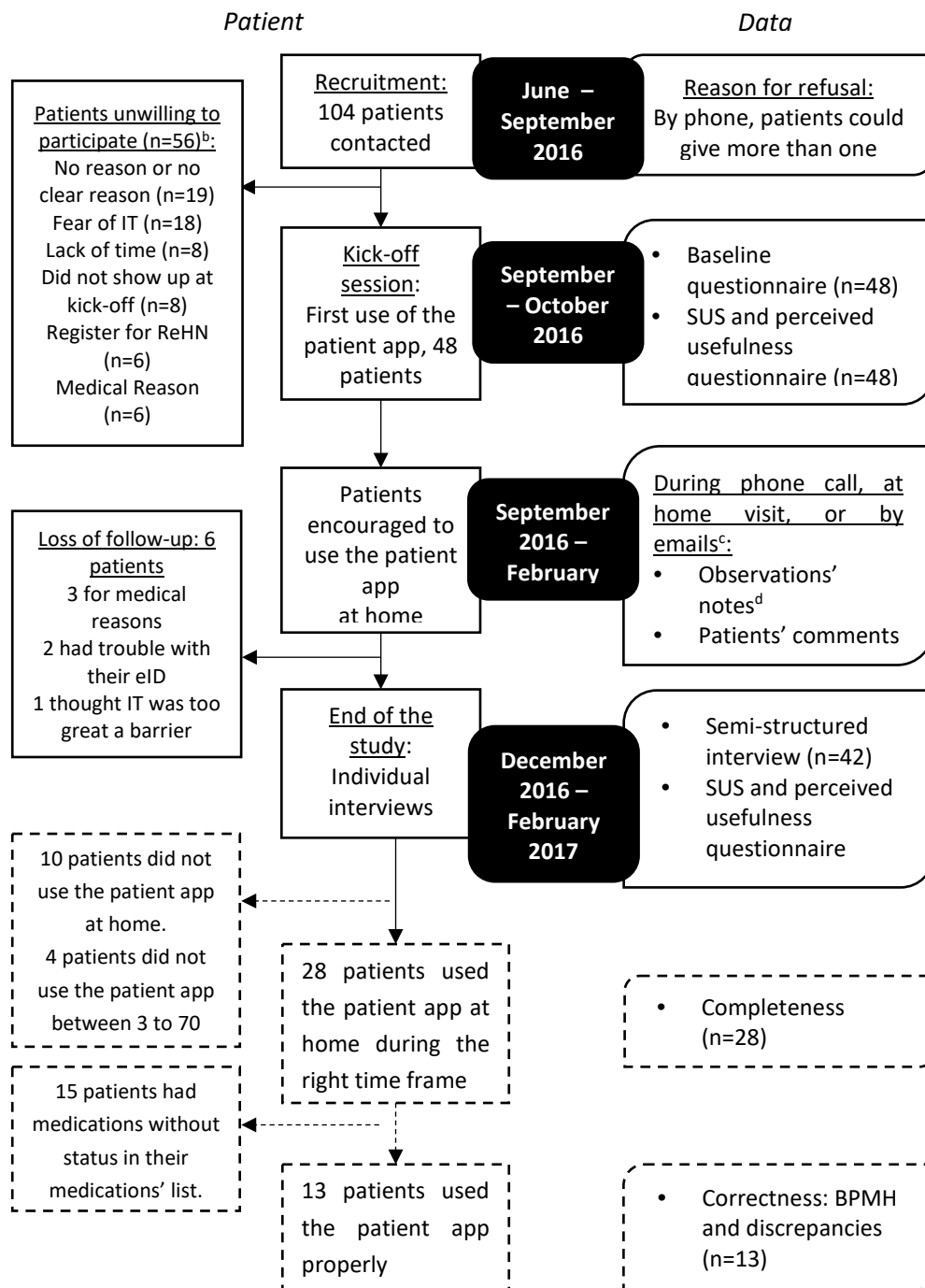


Figure 3: Patient flow and related measurements

Abbreviations: BPMH = Best Possible Medication History; eID = Electronic identity card; IT = information technology; PAM = Patient Activation Measure; ReHN = Regional eHealth Network; SUS = System Usability Scale

^aFor more information, please refer to appendix II.

^bThe percentage of patients who refused to participate was 43% for pulmonary transplant patients, 18% for outpatients recruited through their GP, and 39% for inpatients hospitalized for scheduled surgery.

^cThe observations during phone calls, home visits or by email were in response to patient's having questions or trouble with the application.

^dThe notes were entered by observers, not patients.

IV.2.2.3. Sampling/participants

We used a purposive sample of patients at high risk of medication discrepancies, who varied in terms of age, gender, education, illness, health literacy, computer literacy, setting, and medical encounters. Three groups of patients were defined: pulmonary transplant outpatients (who regularly have consultations with specialist physicians), outpatients visiting their GP at least once a month, and inpatients hospitalized for scheduled surgery. Eligibility criteria were: age older than 18 years; ability to speak and read French; use of ≥ 5 daily medications; and willingness to participate. Patients with cognitive or visual impairment were excluded unless they could be accompanied by a caregiver. Sociodemographic and computer knowledge data were provided by patients using questionnaires.

We aimed to recruit 15 participants per group. Pulmonary transplant outpatients and surgical inpatients were recruited in a rural teaching hospital (CHU UCL Namur, Belgium). Outpatients followed in primary care were cared for by GPs working in the same area as the teaching hospital and were recruited with their help. Patients were informed of the purpose and content of the study. A letter describing the study was sent to them and their principal physician. Every patient gave his/her informed consent. They were not compensated for their time, nor did they receive any incentive for participation.

IV.2.2.4. Study flow

Study flow proceeded in four steps (Figure 3). First, patients were contacted by phone for recruitment. Second, patients attended a “kick-off” session, for their

first use of the app. We grouped four to six patients per session, in the presence of three to five researchers (at least one physician and one IT scientist). After an introduction, patients were invited to log into the patient app and document their medication list. Field notes were taken by researchers to record issues and challenges regarding the tool's use. Critical usability issues were identified and immediately resolved. Third, patients could use the app at home over 3-4 months. They received a printed user guide and were instructed to use the app, if possible, before each new visit to any HCP. As their only reminder, patients received a phone call from the main researcher (SM) approximately 8 weeks after the kick-off. At any time, patients could ask for help by email or phone. For problems not solved remotely, a team member visited patients' homes. Finally, every patient met the main researcher, at home or at the hospital, for a one-hour semi-structured interview.

IV.2.2.5. Evaluation criteria

As recommended by the Agency for Healthcare Research and Quality ³² and by two usability textbooks ^{29,30}, quantitative and qualitative data were collected at different times in order to gain an in-depth understanding of the app's usability and usefulness (Appendix I).

a. Quantitative measures

Usability and usefulness were assessed after the first app use and at the end of the study, using two questionnaires. To evaluate usability, the system usability scale (SUS: ten statements, 5 positive and 5 negative, rated on a 5-point Likert scale) was selected because it has been successfully used in the medical domain, has been validated for a wide range of interface technologies, is quick to complete and easy to interpret, and can be applied to small sample sizes ³⁷⁻⁴¹. To evaluate usefulness, we developed a questionnaire based on previous publications ⁴²⁻⁴⁴. The seven statements were rated on a 5-point Likert scale.

Effectiveness was evaluated at the end of the study, by assessing the completeness and correctness of medication lists published on the ReHN using the patient app ⁴⁵. **Firstly, completeness** was analyzed in patients who used the app between 3 to 70 days before the final interview. This interval was selected in order to have a recent medication list updated by the patient. A shorter interval

was not chosen, as some patients may not have frequent medication changes. Completeness was defined as the presence of name, dose, frequency, and medication status. All four pieces of information needed to be present for all medications on the list for it to be considered complete for each patient. Medication status corresponds to the option chosen by the patient for the question: *“Are you currently taking this medication?”* When no option was selected, the medication was considered as “without status” and the list, thus, incomplete. Status was considered to be essential information, as the information presented by the patient app on name, dosage, and frequency could possibly come from a HCP and not always from the patient. **Secondly, correctness** was evaluated by analyzing medication discrepancies for patients who documented the medication status of each medication. Discrepancies were defined as differences between the list documented by the patient and the best possible medication history (BPMH, gold standard), performed by a trained clinician during the final interview. Types and causes (Appendix II) of discrepancies were analyzed, using a tool previously validated by our team ⁴⁶. Statistical analysis was performed using SPSS version 24 (e.g. continuous variables were compared between the start and the end of the study using a paired samples T-test, and between two groups using the Mann-Whitney U test, after assessing data normality; categorical variables were compared between groups using Pearson’s chi² test.) It was technically impossible to collect quantitative data on **efficiency**.

b. Qualitative measures

Qualitative data concerning usability and usefulness were collected during discussion with patients and observations of patients interacting with the system (Appendix 1). At the kick-off session, patients performed specific tasks (i.e. log-in, documenting medications status, adding medication if relevant, log-out). They were asked to describe their first perceptions by writing down three positive and three negative aspects of the app. When researchers had contact with patients during the study, they took written notes of patients’ comments. During the individual interview at the end of the study, the main researcher met patients, using an interview guide. This guide was based on the literature and experts’ advice ^{42-44,47}, was reviewed by the research team, and was tested with one patient (Appendix 3). The interview aimed to address user’s experiences and: (1)

usability, (2) usefulness, and (3) patient's usual medication organization (e.g. use of a pillbox, use of reminders) to understand how the app could fit in with the patient's habits. Interviews were not recorded. During interviews the main researcher wrote keywords to capture patients' comments. When very specific ideas were mentioned, these were transcribed verbatim.

Data were coded using a conventional qualitative content analysis approach. Interview notes, observation notes, and patients' emails were triangulated to develop initial codes. Data were analyzed by two independent researchers (SM and DL) and organized according to the initial codes. Codes were then sorted into categories and subcategories to create meaningful results^{48,49}. A third researcher (AS) then checked categories and coding. Discrepancies were resolved by discussion between researchers. No specific conceptual framework guided the approach.

IV.2.3. Results

IV.2.3.1. Participants

A hundred eligible patients were invited by phone to participate. Forty-four agreed to participate. Reasons for non-participation are listed in Figure 3. The caregivers of four participating patients who asked to take part in the study and who met the inclusion criteria were also included. In total, 48 patients agreed to participate and 42 completed the study. Patient characteristics are presented in Table 1.

Table 1: Characteristics of the study population at baseline (n=48)		
Sociodemographic variables		
"Subgroup" (n)		
Pulmonary transplants	16	33.3%
Ambulatory patients visiting their general practitioner at least once a month	20	41.7%
Patients hospitalized for scheduled surgery	8	16.7%
Caregiver of patient from another group	4	8.3%
Age (years; median [IQR])		
	65	[60-69]

Gender (n)		
Female	16	33.3%
Male	32	66.7%
Education		
Middle ^a	15	31.3%
High ^b	30	62.5%
Unknown	3	6.2%
Most frequent comorbidities		
Hypertension	29	60.4%
Sleeping troubles (disorder)	18	37.5%
Vascular disease	13	27.1%
Diabetes	11	22.9%
Medication variables at baseline per patient		
Number of medications (median [IQR])	8	[5-11]
Pulmonary transplants	11.5	[10-13.5]
Ambulatory patients visiting their general practitioner at least once a month	7	[5-8]
Patients hospitalized for scheduled surgery	5	[4]
Caregiver of patient from another group	6	[3]
Over-the-counter medication (n)	31	64.6%
Use of IT at home		
Regular use of a computer (>1x/week)	39	81.3%
Internet connection at home	45	93.8%
Knowledge of their eID PIN CODE	37	77.1%
Connected to other e-fgov applications (for example: Taxonweb to complete your tax form)	20	41.7%

Abbreviations: IQR = interquartile range; e-fgov application = electronic application of the federal government of Belgium. Definitions: Education in Belgium was divided into two groups: ^aMiddle education level: primary or secondary school education; ^bHigh education level: professional higher education or university.

From the kick-off to the end of the study, the patient app was used 2 to 4 times by 20 patients of the 42 (47.6%), ≥ 5 times by 12 (28.6%), and once (during the kick-off meeting) by 10 (23.8%). The 32 who used the app at home (76.2%) made 147 connections (median: 3; IQR= 1.25-5). The number of connections was not

significantly different between patient groups, except that the four caregivers tended to connect more frequently.

IV.2.3.2. Usability

a. The SUS questionnaire

The SUS questionnaire was filled in by 29 (91%) of the 32 patients who used the app at home. The median SUS score was 72.3 at the start and 75.0 at the end of the study. More than half of the patients (69%) rated the app above 70 both at the start and at the end ^{39,40} (Table 2).

Table 2: System Usability Scale (SUS) scores after first use (kick-off sessions) and at the end of the study (N=29)		At kick-off		At the end of the study	
		Mean	SD	Mean	SD
1.	I think that I would like to use the patient app frequently	3.14	0.639	3.14	1.026
2.	I found the patient app unnecessarily complex	3.00	0.886	2.90	0.939
3.	I thought the patient app was easy to use	2.93	0.704	2.79	1.101
4.	I think that I would need support from a technical person to be able to use the patient app	3.03	0.865	3.07	0.923
5.	I found the various functions in the patient app were well integrated	3.14	0.516	2.90	0.976
6.	I thought there was too much inconsistency in the patient app	2.93	0.799	3.07	0.799
7.	I would imagine that most people would learn to use the patient app very quickly	2.48	0.871	2.69	0.761
8.	I found the patient app very cumbersome to use	3.00	0.802	3.00	1.069
9.	I felt very confident using the patient app	2.69	0.891	3.00	0.845
10.	I needed to learn a lot of things before I could get going with the patient app	3.28	0.591	2.97	1.149
Calculated total score		74.1	12.3	73.71	15.49

Positive statement (1, 3, 5, 7, 9), scoring from 0 = totally disagree to 4 = totally agree. Negative statement (2, 4, 6, 8, 10), scoring from 4 = totally disagree to 0 = totally agree. Abbreviations: SD = standard deviation

No correlation was found between SUS scores and patients' age, sex, group, previous IT use, or availability of a medication list provided by the GP or the hospital. The SUS score at the end of the study was slightly correlated with the

number of connections, as high users (patients who used the app ≥ 4 times during the study) gave a median SUS score of 80 [70-83.8] versus 72.5 [67.5-75] for low users ($p=.04$).

b. Effectiveness : completeness and correctness

Completeness was evaluated for 28 patients (Table 3a). The medication list was complete for 7 of these 28 patients (25%). The main reason for incompleteness was the absence of medication status. This was mainly due to misunderstanding of the color code. For example, a patient viewing a green button – “Yes, I’m taking this medication as indicated” – did not realize the button was green (and the status, thus, already documented) because he/she had already selected this option during a previous connection. By clicking it again, the information on status was deselected and green changed to gray. Having a documented status for each medication was not influenced by patterns of use (high versus low) but it was influenced by the number of medications (the smaller the number of medications, the smaller the number of medications with undocumented status).

Correctness was evaluated for 13 patients (Table 3b). Ten patients had at least one medication with a discrepancy. For these 13 patients, 21 medications ($21/97 = 21.7\%$) with a discrepancy were found (i.e., 1.6 per patient). Table 3 shows the prevalence, types, and causes of discrepancies. The main causes were technology-related. No significant correlation was found between the number of discrepancies and age, sex, group, SUS score, previous IT use, number of medications, or patterns of use. The median number of discrepancies was higher for patients with a medication list provided by the GP or the hospital than for patients who had to enter all medications by themselves (median of 2 and 1 respectively) but the trend was not significant ($p=0.06$).

Table 3: Completeness and correctness	
3a. Completeness of the medication list for the 28 patients who had used the patient app between 3 and 70 days before the final interview (n=295 medications)	
Medication name documented	N= 279 (94.6%)
Dosage and frequency documented	N=255 (86.4%)
Status documented ^a	N=195 (66.1%)
3b. Correctness of the medication list: discrepancies between the list documented by the patient and the best possible medication history for the 13 patients who documented the status of each medication (n=97 medications) ^b	
Prevalence per patient (n=13 patients), n (%)	
Number of patients without discrepancies	3 (23.1%)
Number of patients having 1 medication with a discrepancy	4 (30.6%)
Number of patients having 2 medications with a discrepancy	4 (30.6%)
Number of patients having ≥3 medications with a discrepancy	2 (15.4%)
Prevalence per medication (n=97 medications), n (%)	
Number of medications with a discrepancy	21 (21.7%)
Types (n=21 discrepancies in total)	
Dosage and frequency	13 (61.9%)
Omission	5 (23.8%)
Other difference	1 (4.8%)
Therapeutic substitution	1 (4.8%)
Addition	1 (4.8%)
Generic-brand substitution	0%
Causes (n=21 discrepancies)	
Technology-level	13 (61.9%)
Technical bug with information documented by the patient not recorded by the patient app ^c	9
Mis-clicking, mis-documentation by the patient in the free text box, or medication mis-chosen by the patient due to lack of clarity in the app ^d	4
Duplicates	0
Patient-level	8 (38.1%)
Self-medication	3
Intentional non-adherence	4
Other	1
System-level	0%

^a Medication status corresponds to the option chosen by the patient for the question: “Are you currently taking this medication?”

^b Medications with no status (taking as indicated, taking differently, not taking, unknown) documented by the patient could not be evaluated for correctness.

^c Example: Operating the patient app, concerning “Medrol 4 mg 2 tablets a day”, a patient had chosen “I’m taking the medication differently” and added in the free text box: “once a day in the morning”. Because information indicated in the free text box did not appear in the patient medication scheme published on the ReHN, what appeared was “Medrol 4 mg – taking differently – 2 tablets a day” instead of “Medrol 4 mg – taking differently – once a day in the morning”.

^d Example 1: Operating the patient app, concerning “Spidifen 400 mg” without any frequency indicated by a clinician, a patient had chosen “I’m taking the medication as indicated”. For the patient, it was not clear he had to specify the frequency.

Example 2: Operating the patient app, concerning “Cellcept 500 mg tablets”, a medication added by the patient himself. The picture associated with Cellcept was not clear enough. Therefore, the patient inadvertently selected, “Cellcept ampoules for injection of 500 mg”.

c. Qualitative data

Table 4 describes the barriers and strategies to optimizing the app, based on patient interviews. Table 4a describes usability items related to different aspects of the app such as connection, on-screen display, information on past medication, and completion checks.

Table 4: Barriers and strategies to optimizing usability and usefulness, based on patient feedback

4a. Categories, subtopics, and quotes related to usability

Category	Subtopic	Sample quotes
Challenges for patients	Patients lack skills to connect to the patient app.	“The patient app requires better computer skills than I have.” (Patient 1)
		“I have never been able to connect to the patient app.... I'm not completely against the idea of using such a tool, but I would need much more support and more

		encouragement to use it.” (Patient 2)
		“I didn’t dare to connect to the patient app because I was afraid of doing stupid things” (Patient 3)
	Patients would like help of a caregiver or family member.	“The patient app is clearly needed, but maybe you should think about allowing someone other than the patient to document the medication list. For example, the caregiver, whether professional or not.” (Patient 19)
		“I would only use the patient app if my wife filled it in for me.” (Patient 22)
	Patients have difficulties using eID, but find it a reassuring security check.	“The ID card is a good level of security; I am reassured to have such a level of security.” (Patient 2)
On-screen display	Better overview of the medication list documented	“It should be possible to have an overview of your medication list before you log off. So you could check exactly what you noted.” (Patient 12)
	Need for “patient-friendly” medication names	“Improve the display of medication names. The patient doesn’t know details about boxes or types of generic. It is confusing to see too many details. It gives a feeling of insecurity.” (Patient 14)
		“I can’t always find the right box when adding medications [because the names are too long and confusing].” (Patient 25)
	Indications or reasons for stopping medication must be more clearly visible.	“It would be better to highlight the indication for which a medication has been prescribed, both for the patient and for other prescribers.” (Patient 15)

		"The start date and the end date, as well as the indication and the reason for stopping medication should be easier to see." (Patient 42)
	Viewing or editing mode: need for distinct modes	"Having an editing and a viewing mode would make it easier to see a medication's 'status' and whether you have already modified something or not." (Patient 15) "It would be nice if the patient were welcomed with a personal opening page. This is his home and it would put him at ease and establish trust. He should be asked what he wants to do: consult his medications list, make changes, or delete a medication." (Patient 14)
	Better highlighting of answers selected	"After selecting an answer, the other options should become gray, so we know we have already given an answer." (Patient 12)
Past medication history data	Hide past medication history by default (risk of misunderstanding when presented by default)	"It is disturbing to see medications which aren't taken. Archiving should be allowed, but optionally, by a specific button." (Patient 14)
	Need for exhaustive data	"It is important to be able to access the entire history of taking medication, with a system of archiving to avoid confusion when using the patient app but being able to know which medication has already been tested, which one works or not." (Patient 10)
		"Have a history of 6 to 12 months with access possible but not permanent, with

		the possibility of removing medications which aren't taken." (Patient 8)
Data exchange and connectivity	Add delivery data from the community pharmacy	"To be exhaustive, you should have all delivery data from the community pharmacy." (Patient 8)
Miscellaneous	More possibilities to edit medication list posology (removing/suspending medication, undoing an action, etc.)	"I would like it to be easy to cancel an action." (Patient 29) "I wish there was an option to definitively delete a medication from the list." (Patient 4)
	Completion check	"The system should warn us when an answer is missing." (Patient 24)
	Improve software functioning (performance, dependability, etc.)	"The waiting time to connect is too long. The cursor doesn't click on the button I want to click on." (Patient 21)
3b. Categories, subtopics, and quotes related to usefulness		
Additional functionalities, to enhance usefulness/added value for patients	Possibility of printing a medication list or schedule	"Print the medication list and have the opportunity to make attractive medication schedules." (Patient 38) "I would like to print my list by clicking on an icon or using a right mouse click." (Patient 29)
	Reminders to take medications	"Reminders, I think that's attractive, particularly for the day when I will have memory problems." (Patient 30) "I think a reminder system, after having synchronized the medication list with your smartphone, would be necessary." (Patient 33)
	Possibility of customizing the app to match patients'	"Reminders could be helpful for some patients. But I think it is necessary to be able to cancel those options if we don't

	needs	need them. Recurrent alerts will annoy us and make us ignore them!" (Patient 5)
		"Make the patient app more fun. The patient app has to be more user-friendly and maybe customizable for younger people!" (Patient 17)
	Reminder to log onto the app regularly	"Maybe also alerts to encourage people to log onto the patient app after several weeks of inactivity." (Patient 33)
	Add educational information on medication, to improve health literacy	"I suggest a small description of each medication.... This description should contain: (1) why the drug is usually prescribed, (2) the most serious side effects with an order of 'frequency', (3) possibly contraindications and major interactions." (Patient 5)
		"I think it could be useful to have links to popular websites containing information validated by health professionals about the expected effect, indications, and major side effects of medications." (Patient 40)
Data exchange and connectivity	Transforming the patient app into a connected tool	"I would like to synchronize information with my smartphone. Not only to have reminders, but also to have my entire medication list on my smartphone." (Patient 35)
	Offering suitable alternative electronic devices	"I would agree to use the patient app on a smartphone without the eID and eID card-reader, but not on a kiosk at the entrance to the hospital. I would rather opt for the employee at reception." (Patient 9)
		"I would have liked to indicate my entire medical history or to be able to import or

	integrate the one provided by my GP. I think it's a pity to separate the two (my work on the patient app and the documents from the GP)." (Patient 19)
	"I think a discussion forum (with other patients or healthcare professionals) could be nice." (Patient 39)
Allowing patients to communicate about their health	"Sharing information about allergy and medication intolerance with all physicians is essential." (Patient 15)
Giving feedback based on graphs and statistics to patients so they can adjust their behavior to prevent adverse events	"I also imagine a system of graphs of consumption/intake of medications that can be compared to our symptoms. It would be interesting to produce statistics, but especially to understand and to anticipate. For example, within ten days of chemo it is usual to have a decrease in the number of white blood cells, followed by weight loss ...so you could prepare yourself by a specific diet." (Patient 33)

IV.2.3.3. Usefulness

a. Questionnaire

Most patients thought the app could help them or their caregivers to save time and gain accuracy in keeping medication lists up to date. A large majority said the app could improve communication between HCPs (Table 4). No correlation was found between usefulness and patients' age, sex, group, or frequency of use.

Table 4: Patients' agreement on seven perception statements about the patient app after first use (kick-off sessions) and last use (interviews) (N=29)		At kick-off	At the end of the study
		% (n) of patients who agreed or totally agreed	% (n) of patients who agreed or totally agreed
1.	I think by using the patient app I could save some time when updating my medication list.	89.7% (26)	79.3% (23)
2.	I think by using the patient app I could help my HCPs save some time when updating my medication list.	93.1% (27)	96.6% (28)
3.	I think the patient app could help improve my understanding of my medication list.	86.2% (25)	79.3% (23)
4.	I think the patient app could help my HCPs to have an accurate medication list.	96.6% (28)	100% (29)
5.	I think the patient app could improve communication about my medications between my HCPs and myself.	100% (29)	89.7% (26)
6.	I think the patient app could improve communication about my medications between HCPs.	100% (29)	93.1% (27)
7.	I would advise a friend to use the patient app.	89.7% (26)	82.8% (24)
Percentage of patients who agreed or totally agreed with all seven statements		62.1% (18)	62.1% (18)

Percentage (and absolute number) of patients who agreed (score 4) or totally agreed (score 5) with the statement. Statement scoring: 1 = totally disagree, 2 = disagree, 3 = no opinion, 4 = agree, 5 = totally agree

Abbreviations: n = absolute number of patients; SD = standard deviation

The percentage of patients who (totally) agreed at the start and at the end of the study was compared for each item. P values were all >0.05.

b. Qualitative data (Table 4b)

The overall perception of the app's usefulness varied between patients. Some found it useful because it helped them to know their medication list better or to think about the reasons for their medications and because it gave them an

opportunity to regain control of their treatment. In contrast, 16 patients (38%) perceived no added value, for various reasons. Firstly, some considered their medication management was good and therefore did not log onto the app. These patients had developed personalized approaches to managing medication, such as pillboxes near a printed list and smartphone reminders. They felt the tool would more likely benefit less-organized patients with frequent medication changes or with problems recalling medication. Secondly, some patients reported that their physicians already had in their computer all information concerning their medications. Finally, some were unwilling to use the app because of a lack of interest in IT use or because they were uncertain about security and privacy.

Half of the patients (23/42=54.8%) were convinced the app could be useful under certain conditions. First, patients asked for various additional functionalities (e.g. possibility of printing the medication list, reminders to take medications). Second, patients insisted on the need for integration and connectivity. The app would be much more valuable if all stakeholders participated actively. The list, moreover, should be part of a more global and shared overview of essential information concerning the patient's health status. Finally, some patients thought the app should become a connected tool with possibilities for synchronization on smartphones, generating customizable and adjusted alerts (e.g. reminders).

IV.2.4. Discussion

Our main results showed that a majority of the patients were satisfied with the app and would be willing to use it under certain conditions. Our study design made it possible to identify these conditions (e.g. additional functionalities, improved on-screen display, customization, and connectivity). However, our results also suggest that there may be inherent limits to how much a patient can clean up their own medication list. While improvements to the application may decrease the number of discrepancies, they will never be eliminated. Patients should be encouraged to do the best they can and to review their list with their GP or community pharmacist. Prompts could be sent to patients (e.g. text reminders on their mobile phones) to increase use of the app. It would then be easier to keep the list up-to-date, share it, and annotate the list whenever needed.

The quantitative and qualitative data on **usability and usefulness** were somewhat contrasting but highly complementary. The scores derived from the two questionnaires showed that most patients were satisfied and that most believed the app could improve the accuracy of medication lists and communication and reduce the time spent on reconciling medications. Nonetheless, several scores slightly decreased between the beginning and end of the study. It is possible that some patients were disappointed because of technical errors that occurred and because HCPs did not use the list generated by patients. Moreover, more than a third said during interviews that they would not use the app but usefulness is crucial for the adoption and sustained use of a tool ^{28,31,50}. With regard to **effectiveness**, the medication list was complete for only a quarter of the patients and discrepancies were detected for approximately two-thirds. The types and causes of medication discrepancies differed from those reported in the literature ^{17,51-55}. Comparison must be made with caution, because the number of patients included in our study was low and because patients were updating their medication lists without any care transition triggering the process. The majority of discrepancies in the present study were technology-related. This confirms that IT approaches can introduce new types of errors and that analyzing the typology of errors is important when addressing usability.

Analyzing the quantitative and qualitative data, we identify four main **areas for improvement** for the future. The first is technology-related; the others apply to any approach to improving MedRec.

First, both the patient app itself and, to some extent, the eHealth network need improvement. For example, efficiency can be improved by decreasing the level of effort required to connect, without compromising security aspects. Such improvements are currently being implemented. Effectiveness could be improved through better on-screen display and editing features. Removing default statuses from a previous connection would probably greatly increase the number of medication statuses documented by patients. This would take a few more seconds of patients' time, but would probably be worthwhile. Importantly, in order to improve usefulness – and therefore adoption – the app should better meet patients' needs by offering additional features such as feedback, reminders, and appointment alerts. Such features were present in other similar applications ^{26,56,57}.

Second, raising patient awareness of the epidemiology and dangers of medication discrepancies is essential. Many were unaware that their HCPs might lack information^{58,59} and unaware of the harmful impact of medication discrepancies and of their own potential role in optimizing MedRec^{14,60,61}. Even though there have been previous efforts to raise patient awareness, greater efforts are needed, along with better communication on the roles and responsibilities of all stakeholders, including patients. We have now produced a video to contribute to meeting this need.

Third, better concordance between patients and physicians is required. Several discrepancies arose because patients documented the medication they were supposed to take rather than what they actually took. The main reasons were that patients did not want to be labelled as difficult or non-compliant or had previous experience with a prescriber not taking their perspective into account when (de)prescribing. Patient participation and shared decision-making are cornerstones of high-quality healthcare⁶². This also applies to MedRec.

Finally, because the MedRec app for HCPs was still under development, the patient medication lists available on the ReHN were rarely used by physicians to reconcile medications. This was perceived by patients as a lack of support from their HCPs and certainly hampered patient app adoption. Indeed, the literature identifies providers' endorsement as one of the most influential factors^{58,63,64} in patients' engagement with their health.

IV.2.4.1. Comparison with Previous Work

There have been several previous reports on the evaluation of applications whereby patients document their medication lists in the context of MedRec. The majority – and we followed the same approach – asked patients to document medications from an existing list. Our work differs in several respects. The environment is different. Existing tools were developed in North America, in health organizations with closed IT systems, and used either no source of medication data or a single one (most often, medication refills). Our tool is, to the best of our knowledge, the second reported from a European country^{51,52,65}. However, the design, development, and usability assessment of that Spanish MedRec tool were never reported in the literature.

SEAMPAT has been developed to link and manage data from different providers, using different electronic tools and patient records and various sources of information. The patient app was evaluated with real patients, real data in a real workflow. This therefore brings added value to the existing literature. Finally, many existing tools provide additional functionalities (such as reminders or information on medications). Our data suggest that such functionalities may be critical for usefulness and therefore tool adoption.

With regard to results from evaluations, data on usability are available for some reports, but not all ^{20,22,23,56,66-68}. Moreover, we found none for which quantitative and qualitative usability measurements were collected through various methods at different time points in different settings.

IV.2.4.2. Limitations

Our study had several limitations. First, the French version of the SUS questionnaire used in the present study has not been validated. Nevertheless, the French SUS questionnaire has been widely used, with conclusive results in many studies ^{69,70}. Second, a selection bias in the sample cannot be ruled out. About half of those approached refused to participate and we probably selected a sample with a greater interest in working with computers. However, we deliberately recruited patients from different groups of potential users and the study sample was quite diverse in age, sex, medical history, and IT use. In the context of a future study ⁶³, it would be useful to evaluate how patient health, eHealth, computer literacy, and levels and patterns of use influence research results. Third, interviews were not transcribed verbatim and most were done by just one researcher. We used reformulation to ensure that information was well understood by the researcher. Fourth, the interview guide was fairly close-ended, which could have influenced the kind of information we collected. Fifth, it was not feasible to evaluate efficiency in a quantitative way. This should be done in the future, as a tool will not be adopted if a burdensome number of clicks or too much time is needed to achieve the desired goal. Finally, there could be some debate about the definitions we used for usability and usefulness. Many different definitions exist. We selected definitions that are known worldwide, that have

been used in published papers, and that made sense for the research team, given the objectives of the study.

IV.2.5. Conclusion

Our findings highlight the value of a user-centered usability study in real-world conditions, collecting both quantitative and qualitative data. Our study also underlines the necessity of tailoring a patient application to patients' real needs, while keeping its features in line with its primary objective, i.e. optimizing MedRec. Our results show that the patient app has valuable potential for optimizing MedRec and that it is worth developing further into a more mature system. A larger study could then be conducted to evaluate the effect of this eMedRec approach, using both the patient app and the MedRec app, on carefully selected outcomes, such as adverse events and hospital admissions.

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Study concept and design: All authors

Development of the patient app: Ravi Ramdoyal, Valery Ramon, Jimmy Nsenga, Gustavo Ospina

Acquisition of data: Marien

Analysis and interpretation of data: All authors

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Chapter V – Healthcare professionals testing the MedRec application

A User-Centered design and usability testing of a web-based medication reconciliation application integrated in an eHealth network

Sophie Marien^{1,2,3}, Delphine Legrand¹, Ravi Ramdoyal⁴, Jimmy Nsenga⁴, Gustavo Ospina⁴, Valéry Ramon⁴, Benoit Boland^{2,3}, Anne Spinewine^{1,5}

Chapter V at a glance

What is already known about the subject?

- More than 80% of patients in outpatient clinics have discrepancies. At hospital admission, more than 50% of patients have discrepancies. Unfortunately, an important proportion of discrepancies (up to 59%) have a potential for harm.
- Therefore, Medication Reconciliation (MedRec) – the process that aim to resolve discrepancies – is a worldwide patient safety goal. Many organizations are struggling to implement effective processes.
- Information and communication technology tools have been developed to optimize the MedRec process. But
 - None possesses all the functionalities we recommended in Chapter 2.
 - Most were developed and evaluated in North America where patient safety culture and healthcare system and environment are different from Belgium.
- Adapting IT tools to the environment is highly recommended: technical architecture, workflow, institution structure and organization, etc.

What this chapter adds?

- This study confirms the importance of conducting usability assessments before investing time and resources in a large study evaluating the clinical impact of an eMedRec approach, with the patient app and the MedRec app.
- We underlined the need of testing prototypes in a real clinical setting, as evaluations in a real clinical environment created an additional set of requirements.
- Our findings will also hopefully increase chances of successful implementation, acceptability and sustained use over time by HCPs.
 - We learned that interoperability and workflow integration are key factors to reach a successful adoption of the tool.
- We believe developing tools supporting more than MedRec (for example MedRec + MedRev) should absolutely be explored

Related Publications

Sophie Marien^{1,2,3}, Delphine Legrand¹, Ravi Ramdoyal⁴, Jimmy Nsenga⁴, Gustavo Ospina⁴, Valéry Ramon⁴, Benoit Boland^{2,3}, Anne Spinewine^{1,5} A User-Centered design and usability testing of a web-based medication reconciliation application integrated in an eHealth network. Accepted with revision in the IJMI. Under 2nd review.

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Authors Contribution

Sophie Marien designed the study, acquired the data, analyzed and interpreted the data, and wrote the manuscript.

Anne Spinewine assisted in study design and in the analysis and interpretation of the data, revised the manuscript for important intellectual content, and approved the final version.

Ravi Ramdoyal (RR) and Valery Ramon (VR) developed the different prototypes, assisted in study design and in the analysis and interpretation of the data, revised the manuscript for important intellectual content, and approved the final version.

Delphine Legrand assisted in the analysis and interpretation of the data, revised the manuscript for important intellectual content, and approved the final version.

Jimmy Nsenga and Gustavo Ospina, developed the different prototypes with RR and VR, modified prototype when encountered important usability issues during assessments, revised the manuscript for important intellectual content, and approved the final version.

ABSTRACT

Background: Medication discrepancies, which are a threat to patient safety, can be reduced by medication reconciliation (MedRec). MedRec is a complex process that can be supported by the use of information technology and patient engagement. Therefore, the SEAMPAT project aims to develop a MedRec IT platform based on two applications. The application for the professionals is called: the “MedRec app”.

Objective: In the present study, we aimed to describe the development and usability testing of the MedRec app, reporting results of a three iterations user-centered usability evaluation.

Methods: We used a three phase iterative user-centered study spread over 16 months. At each phase, the usability evaluation included several methods (observations, questionnaires, and a follow-up discussions with participants) to collect quantitative and qualitative data in order to improve the current prototype and evolve to the next prototype.

Results: In total, 48 healthcare professionals (25 general practitioners and 23 hospital clinicians) participated to the MedRec app evaluation. There were 14, 32 and 5 participants for phases 1, 2 and 3 respectively. At each phase, many design modifications were done to strengthen usability. Concerning usability, participants considered the prototypes as an acceptable interface with a median System Usability Score of 73 at phase 2 and 75 at phase 3. Participants emphasized the need for improvements concerning workflow integration, usefulness and interoperability.

Conclusion: Our study describes the importance of conducting usability assessments before investing time and resources in a large study evaluating the effect of an eMedRec approach on carefully selected clinical outcomes. Our findings may also increase the chances of acceptability and sustained use over time by clinicians.

KEYWORDS

Medication reconciliation; health information technology; web-application; iterative user-centered design; usability testing; continuity of care; inpatient and outpatient care

1. INTRODUCTION

Medication discrepancies are unexplained differences between medication lists at different transition points of care¹. They are found in up to 88% of patients in outpatient clinics²⁻⁴ and 71% of hospital admissions⁵. An important proportion of discrepancies (11% to 59%) have a potential for harm⁶. Medication Reconciliation (MedRec) is a formal and collaborative process of obtaining and verifying a complete and accurate list of a patient's current medicines⁷ to ensure that precise and comprehensive medication information is transmitted consistently across transitions of care. MedRec aims to resolve discrepancies and several leading organizations worldwide have promoted MedRec to improve patient safety⁸⁻¹². However, successful MedRec interventions require important resources and integration in complex workflows with variation of multiple factors (leaders' endorsement, patient safety culture, health information technology systems, clinicians' education, clinicians' and patients' expectations, etc.). Therefore, wide implementation of MedRec remains difficult^{13,14} and user-centered design (UCD) approaches are particularly interesting as they enabled to integrate numerous of these factors. However, successful MedRec interventions require important resources and integration in complex workflows with variation of multiple factors (leaders' endorsement, patient safety culture, health information technology systems, clinicians' education, clinicians' and patients' expectations, etc.). Therefore, wide implementation of MedRec remains difficult^{13,14} and user-centered design (UCD) approaches are particularly interesting as they enabled to integrate numerous of these factors.

Information technology (IT) has been presented as a promising approach to move MedRec forward. In a recent systematic review, we identified 11 IT tools supporting the entire MedRec process¹⁴. Studies showed positive results overall in terms of usability, satisfaction and adherence.¹⁵⁻²⁶ The use of IT for MedRec might also reduce time spent and clinicians' cognitive burden^{27,28}. However, all tools were developed in North America in academic environments, and limited information was available on the context of development and implementation of the tool. Data on the effect of electronic MedRec (eMedRec) on quality and safety outcomes were lacking. In another recent systematic review²⁹, Mekonnen et al

included studies reporting data related to the effectiveness of electronic MedRec. Interventions had to start in the hospital with the use of electronic but the whole MedRec process did not need to be electronic. Authors found that eMedRec was able to minimize the incidence of medications with unintended discrepancy. The ten included studies were performed in the US and Spain, and well-designed studies were lacking.

The present study took place in Wallonia (a French-speaking region in Belgium, of about 3,600,000 inhabitants). The Regional eHealth Network (ReHN), known as the “Réseau Santé Wallon”, allows the exchange of eHealth documents between healthcare professionals (HCPs) caring for a particular patient. For example, a cardiologist in hospital A can access the Summarized Electronic Health Record produced by the general practitioner (GP), the discharge letter from hospital B, and a cardiac echography from hospital C. Currently, 91.9% of the hospitals, 73% of the general practitioners (GPs) and 35% of the inhabitants of Wallonia are connected to the ReHN^{30,31}.

Bearing this in mind, the SEAMPAT project, supported by the Walloon Region, aims to develop an electronic MedRec (eMedRec) process to improve continuity of care. It is a multidisciplinary research project led by a research team of computer scientists (including usability experts), physicians, pharmacists, one sociologist and one lawyer. The SEAMPAT MedRec ICT platform, developed for ambulatory care as for inpatient care, is made of 2 applications: the patient application (patient app)³², designed specifically for patients, and the medication reconciliation application (MedRec app), designed for HCPs. These 2 applications are interconnected with the ReHN. The methodological approach to develop both applications followed recommendations of health IT experts³³⁻³⁷. In the present study, **we specifically describe the development of the MedRec app, reporting results of the three iterations.**

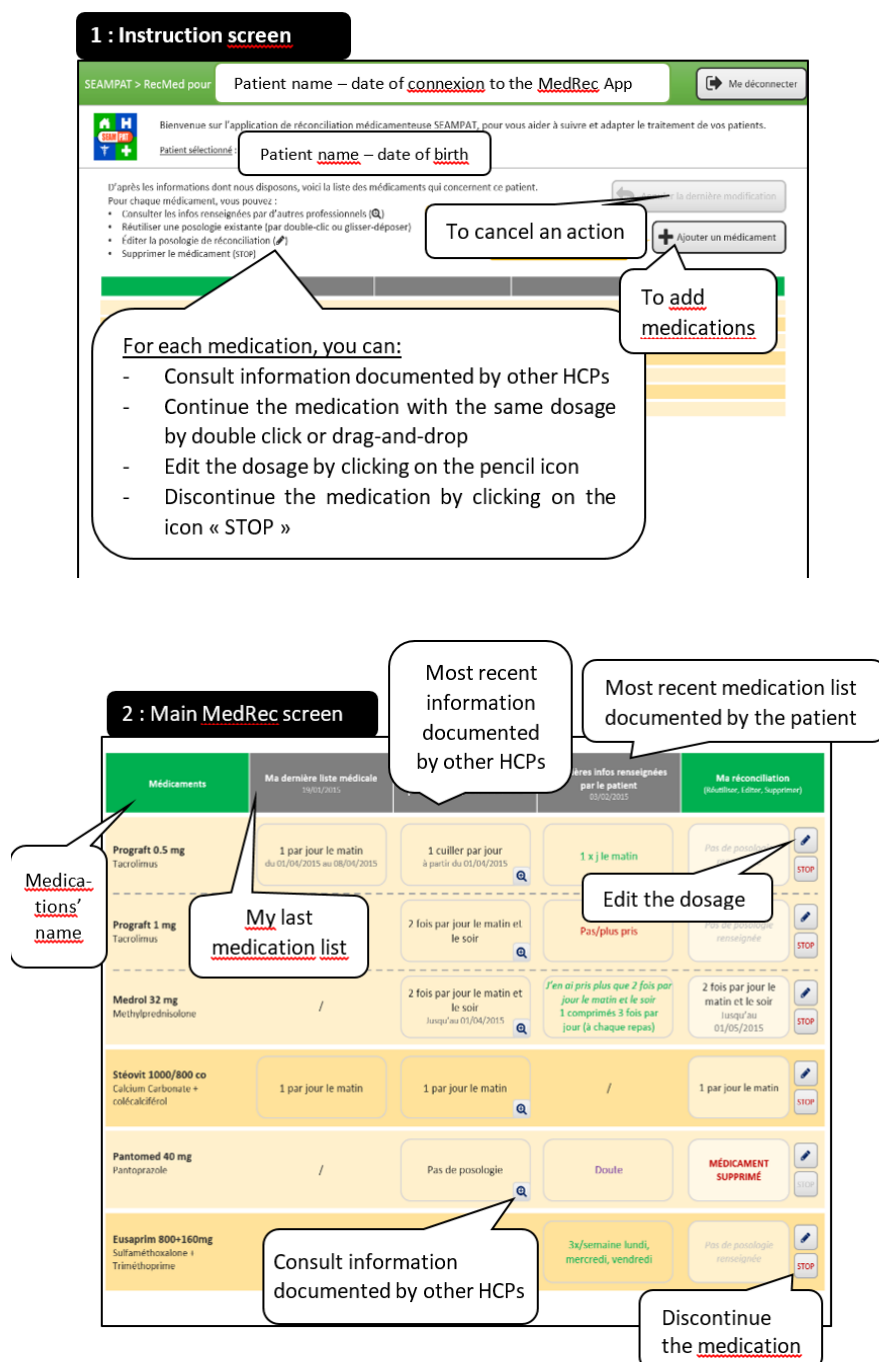
2. MATERIALS AND METHODS

2.1. SYSTEM AND DETAILS

The MedRec app (using HTML5/Javascript technologies), usable on a desktop or laptop is accessible for every clinician through the ReHN. HCPs' authentication is done through secured log-in and password which are personal and mandatory. Data transfers occur through secure connections and data themselves are encrypted before their transfer³². The app can only be used for patients registered to the ReHN by a HCP taking care of the patient.

The MedRec app allows the HCP to compare three "medication lists" (Figure 1): (1) the "reference" medication list (the most recent list edited by the GP – when the app is used by GPs, or by the hospital where the HCP is working – when the app is used by physician specialists (PS) or clinical pharmacists (ClinPharm)), (2) a compiled medication list presenting the most recent and complete information documented by other HCPs – this was done by an algorithm developed by the research team, that took into account various data such as date, ATC code, specialty code, identity of HCP, dosage,...), (3) the medication list documented by the patient, using the patient app. All information used is initially retrieved from the ReHN.

In order to relieve cognitive burden and support clinicians, we followed advices from Plaisant et al.^{27,38} As examples: the MedRec app highlights differences and similarities of medications' name, dosage, etc. between the three lists; the app uses spatial grouping of medications and offers the possibility to modify medications' classification. The column with the patient's documented list uses the same color codes as for the patient app so that clinicians can easily show the main screen to the patient and start reconciliation discussion. Information such as reason for starting or stopping medication and prescribers' name are visible through tooltips. The HCP can stop, continue or modify each medication of the list. He can also add new medications. The aim is to publish the reconciled medication list on the ReHN.

Figure 1: Four screen shots of the static prototype (December 2015-January 2016)

3 : Screen to edit posology

EDITER LA POSOLOGIE

Médicament	Ma dernière liste médicale 19/01/2015	Dernières infos renseignées par d'autres professionnels	Dernières infos renseignées par le patient 03/02/2015	Ma réconciliation (Réviser, Editer, Supprimer)
Prograft 0.5 mg Tacrolimus	1 par jour le matin du 01/04/2015 au 08/04/2015	1 cuillère par jour à partir du 01/04/2015	1 x j le matin	Pas de posologie renseignée

Veuillez préciser comment prendre ce médicament.

Posologie:

Date de début:

Date de fin:

Indication:

Editing a posology, in free text

4 : Detailed view of information provided

INFORMATIONS RENSEIGNÉES PAR D'AUTRES PROFESSIONNELS

Médicament	Ma dernière liste médicale 19/01/2015	Dernières infos renseignées par d'autres professionnels	Dernières infos renseignées par le patient 03/02/2015	Ma réconciliation (Réviser, Editer, Supprimer)
Prograft 0.5 mg Tacrolimus	1 par jour le matin du 01/04/2015 au 08/04/2015	1 cuillère par jour à partir du 01/04/2015	1 x j le matin	Pas de posologie renseignée

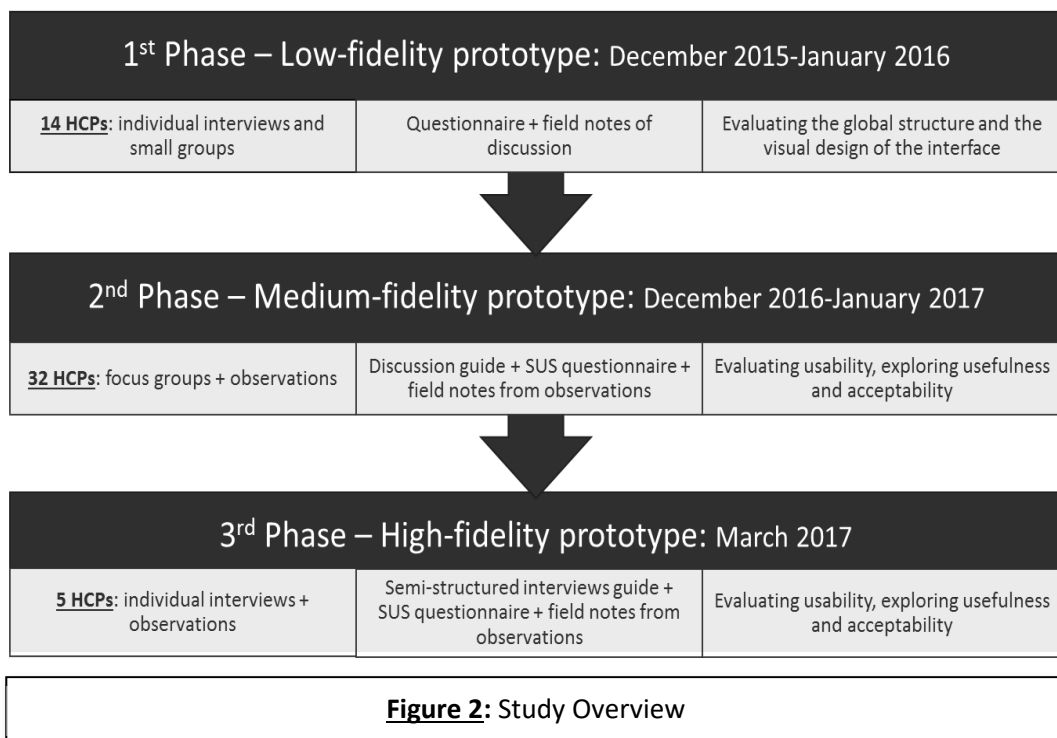
Historique récent (double-cliquer ou glisser-déposer pour réutiliser):

- 14/03/2015 : Le Dr Carol a renseigné ce médicament avec les informations suivantes:
 - Posologie : 1 cuillère par jour
 - Date(s) de traitement : à partir du 01/04/2015
- 12/03/2015 : La Pharmacie Pharmacie du Coin a délivré ce médicament.
- 12/03/2015 : Le Dr Alice a renseigné ce médicament avec les informations suivantes:
 - Posologie : 1 par jour
 - Date(s) de traitement : Dr Carol /2015
 - Indication : Anti-rejet N°INAMI 5678901
- 10/03/2015 : Le Dr Carol a renseigné ce médicament avec les informations suivantes:
 - Posologie : 1 cuillère par jour
 - Date(s) de traitement : à partir du 01/04/2015
- 07/03/2015 : Le Dr Dave a renseigné ce médicament.

View of the information documented by other HCPS after clicking on the magnifying glass

2.2. STUDY DESIGN AND SAMPLING OVERVIEW

We performed a three phase iterative user-centered study spread over 16 months, with low-, medium- and finally high-fidelity prototypes (Figure 2).



At each phase, several methods (observations, questionnaires, and interviews/group discussions) were used to collect quantitative and qualitative data on usability. Results and more specifically areas of improvement were discussed within the research team (research clinicians, computer scientists and other team members). Modifications were decided and implemented in the next prototype.

Participants belonged to three groups of potential end-users of the MedRec app: general practitioners (GP), physician specialists (PS) and clinical pharmacists (ClinPharm). GP were recruited from three local GP associations in Walloon Region and Brussels. PS and ClinPharm were recruited in a teaching hospital (CHU

UCL Namur, Godinne site, Belgium). All participants were volunteers and were contacted by email. They were selected in order to have a diverse sample in terms of age, gender, number of years of professional experience and information technology knowledge. We aimed to recruit 5 participants of each group for each iteration. The sample sizes are typical for usability studies and research has demonstrated that they are sufficiently large to elicit the vast majority of usability issues.^{39,40} The protocol was approved by the Ethical committee of CHU UCL Namur (reference number B039201421687).

2.3. PHASE 1: LOW-FIDELITY PROTOTYPE

The aim of phase 1 was to evaluate usability and more specifically, the global structure and the visual design of the interface of the MedRec app. The low-fidelity prototype was a static mock-up designed on Powerpoint. Functional and non-functional requirements had been defined on the basis of needs analysis and literature review conducted by the research team^{32,41}.

After an introduction on the project and the session objectives, participants were shown the low-fidelity prototype. They were allowed to interrupt in order to ask questions and make comments. Field notes of the discussion were taken by the main researcher (SM). At the end of the presentation, participants completed a close-ended 12-item questionnaire, developed on basis of literature^{16,26,42} and advice from usability experts from the research team (Appendix I). Descriptive quantitative analysis was done using Excel. Qualitative data was analyzed using a conventional content analysis approach⁴³.

2.4. PHASE 2: MEDIUM-FIDELITY PROTOTYPE

The aim of phase 2 was to evaluate usability, to explore usefulness and acceptability. The medium-fidelity prototype was an interactive tool using a prespecified scenario with a mock patient. Using a computer, each participant accessed the web-based prototype and reconciled the patients' medication list. The scenario was adapted to each HCP group (GP, anesthesiologist, internist, surgeon, ClinPharm).

Participants were invited to a session of one to two hours with colleagues from the same group. The sessions were organized as follows: (1) introduction about

the project and the aim of testing; (2) presentation of the mock patient scenario; (3) interactive medication reconciliation for the mock patient by each participant using the prototype; (4) discussion about usability, usefulness and acceptability of the tool; (5) filling the System Usability Scale (SUS) questionnaire (10 statements rated on a 5-point Likert-scale). The SUS was selected because it is successfully used in the medical domain, validated for a wide range of interface technologies, quick to complete, easy to interpret and can be applied to small sample sizes⁴⁴⁻⁴⁸. In reference to the qualification “good product” of Bangor’s adjective rating scale, we considered a SUS score above 70 as acceptable^{44,45,48}.

During the MedRec session (part 3), observation notes were taken by at least 3 researchers (IT experts and clinicians, and in some cases a sociologist). The discussion (part 4) was organized following a guide developed (Appendix II) by the research team based on literature review^{16,26,41,42,49} and pilot-tested with 3 external experts. Discussions were audio-recorded and transcribed. Subsequently, interview transcripts and observation notes were analyzed by two independent researchers (SM and DL) using a conventional content analysis approach to develop first themes^{43,50}. Themes were matched with coding categories based on previously published coding schemes⁵¹⁻⁵³. Discrepancies in the coding were resolved by discussion to achieve a consensus.

2.5. PHASE 3: HIGH-FIDELITY PROTOTYPE

The objective was similar to phase 2. The high-fidelity prototype was a functional prototype linked to real patient data through the ReHN. Given the timing constraints and the variety of EMR softwares used by participants, the MedRec app was not accessible through each software. Hence, the prototype was tested using a web-application link available from the ReHN.

Eligible participants had to be connected to the ReHN and had to have at least one patient having participated to the development of the Patient-App (see Chapter 4). During an individual session in the presence of 2 to 3 researchers, each participant used the MedRec app to reconcile medications of one or two of their participating patients. Written consent was asked to these patients but for practical reasons, the patient was not present during this MedRec session. Therefore, it had been decided not to publish the reconciled list on the ReHN.

Observation notes were taken by researchers during the MedRec session. Subsequently, a semi-structured interview was performed with each participant, using an interview guide derived from phase 2 and reviewed twice by usability experts (Appendix II). Interviews were audio-recorded. Finally, participants completed the SUS questionnaire. Observation notes and interview transcripts were analyzed using the themes developed during phase 2.

3. RESULTS

3.1. POPULATION DESCRIPTIVE STATISTICS

In total, 48 clinicians participated in one of the three iterations of the MedRec app: 25 GPs, 18 PSs (anesthesiologists, internists and surgeons) and 5 ClinPharms (Table 1 and Figure 2). Three clinicians (2 PS and one ClinPharm) tested both the medium- and the high-fidelity prototype. Half of the participants (56%) had 10 or more years of professional experience.

Table 1: Sociodemographic characteristics of the participants (n=48)		
“Subgroup” (n)		
General Practitioners	25	52.1%
Physician Specialists (<i>6 anesthetists, 10 medical internists, 1 surgeon and 1 intensive care physician</i>)	18	37.5%
Clinical Pharmacists	5	10.4%
Gender (n)		
Female	25	52.1%
Male	23	47.9%
Number and types of participants at each phase of the study (n)		
Phase 1,	14	
General Practitioners	8 (57.1%)	
Physician Specialists	6 (42.9%)	
Phase 2	32	
General Practitioners	15 (48.3%)	
Physician Specialists	12 (34.5%)	
Clinical Pharmacists	5 (17.2%)	
Phase 3	5	
General Practitioners	2 (40%)	
Physician Specialists	2 (40%)	
Clinical Pharmacists	1 (20%)	

3.2. LOW-FIDELITY PROTOTYPE

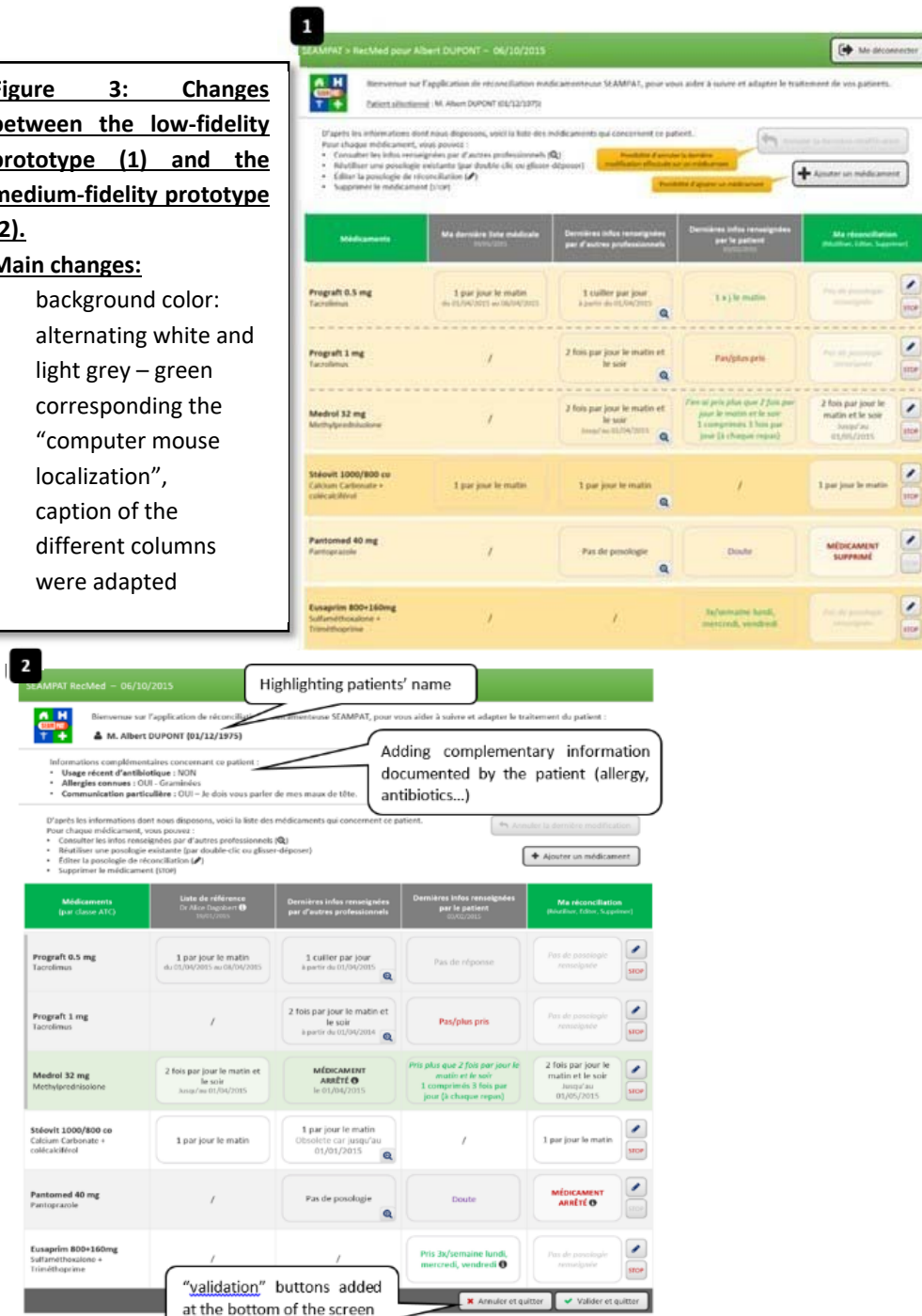
Figure 1 shows 4 screen shots of the low-fidelity prototype. All participants (n=14), except one, were positive about the global structure and the visual design of the static MedRec app. Five participants, 4 GPs and 1 PS (35.7%) commented on the background color. They thought alternating light and dark yellow was confusing, as they did not understand it stood for grouping medications per therapeutic class. Furthermore, they found it too different from the EMR design they were used to. Four of the 6 PS preferred to have the most recent medication list as reference, whoever did it, while GPs rather choose for the last medication list documented by a caring GP, even if less recent.

Participants thought it was easy to use drag-and-drop, double clicks, the “pencil” icon (to edit) or the “STOP” icon (to discontinue a medication) but they wished to have a button allowing to confirm and validate the reconciled medication list. Physicians (6 GPs, 1 anesthetist, 1 cardiologist) appreciated the possibility to access “history details” for each medication (Figure 1, section 4). Ten (71%, 5 GPs and 5 PS) preferred encoding medication posology in a structured way. Half of them asked for default values: frequency, duration, start date, end date. They stressed the need to highlight important information such reason for starting or stopping a medication and medical specialty of the prescriber. Finally, they emphasized on improving the clarity of icons, minimizing the text to read and the number of clicks needed to accomplish a task. All participants wished to reduce time spent performing MedRec by using the app. Figure 3 illustrates evolution from low- to medium-fidelity prototype.

Figure 3: Changes between the low-fidelity prototype (1) and the medium-fidelity prototype (2).

Main changes:

- background color: alternating white and light grey – green corresponding the “computer mouse localization”,
- caption of the different columns were adapted



3.3. MEDIUM-FIDELITY PROTOTYPE

Thirty-two professionals tested the medium-fidelity prototype. The medium-fidelity prototype seemed relatively intuitive and participants gave it a median SUS Score (range: 55 – 92.5) of 73 (IQR=65-79).

Qualitative feedback indicated an overall positive feeling about the MedRec app and also revealed a set of possible enhancements of the prototype. These enhancements were organized in seven categories: Visibility, Content, Understandability, Navigation, Workflow, Usefulness and Interoperability (Table 1). Improvements concerning workflow integration, usefulness and interoperability clearly appeared to be crucial to achieve users' acceptability. Figure 4 illustrates evolution from medium- to high-fidelity prototype.

3.4. HIGH-FIDELITY PROTOTYPE

Two GPs, 2 PS and 1 ClinPharm tested the high-fidelity prototype. Median SUS score was 75 (IQR= 65-79). Qualitative data revealed that MedRec app clarifications and enhancements were appreciated by participants. Continuing, discontinuing and modifying medications seemed a relatively intuitive task. One GP that had not seen the previous prototypes of the MedRec app had some difficulties with the icons. Participants emphasized the importance of having as few clicks as possible. Participants testing the high-fidelity prototype in a real clinical setting expressed more concerns about usefulness and workflow integration (table 1). Main suggestions for further improvements are listed in Table 1.

Screen shot 1

SEAMPAT RecMed – 06/10/2015

Bienvenue sur l'application de réconciliation médicamenteuse SEAMPAT, pour vous aider à suivre et adapter le traitement du patient :

M. Albert DUPONT (01/12/1975)

Informations complémentaires concernant ce patient :

- Usage récent d'antibiotique : NON
- Allergies connues : OUI - Graminées
- Communication particulière : OUI - Je dois vous parler de mes maux de tête.

D'après les informations dont nous disposons, voici la liste des médicaments qui concernent ce patient.

Pour chaque médicament, vous pouvez :

- Consulter les infos renseignées par d'autres professionnels (Q)
- Reaffirmer une posologie existante (par double-clic ou glisser-déposer)
- Éditer la posologie de réconciliation (P)
- Supprimer le médicament (STOP)

Cette section et ses sous-sections ne sont affichées que lorsqu'il y a du contenu pertinent à y afficher (p.e. réponses non vides).

Annuler la dernière modification

+ Ajouter un médicament

Médicaments (par classe ATC)	Liste de référence Dr Alice Dagobert 19/01/2015	Dernières infos renseignées par d'autres professionnels	Dernières infos renseignées par le patient 01/02/2015	Ma réconciliation (Modifier, Éditer, Supprimer)
Prograft 0.5 mg Tacrolimus	1 par jour le matin du 01/04/2015 au 08/04/2015	1 cuiller par jour à partir du 01/04/2015	Pas de réponse	Pas de posologie renseignée STOP
Stéovite 1000/800 co Calcium Carbonate + colécalciférol	1 par jour le matin	1 par jour le matin Obsolète car jusqu'au 01/01/2015	/	1 par jour le matin STOP
Pantomed 40 mg Pantoprazole	/	Pas de posologie	Doute	MÉDICAMENT ARRÊTÉ
Eusaprim 800+160mg Sulfaméthoxazole + Triméthoprim	/	/	Pris 3x/semaine lundi, mercredi, vendredi	Pas de posologie renseignée STOP

Annuler et quitter Valider et quitter

Figure 4: Changes between the medium-fidelity prototype (screen shots 1 and 3) and the high-fidelity prototype (screen shots 2 and 4)

Screen shot 2

SEAMPAT RecMed – 06/10/2015

Bienvenue sur l'application de réconciliation médicamenteuse SEAMPAT, pour vous aider à suivre et adapter le traitement du patient :

M. Albert DUPONT (01/12/1975)

Informations complémentaires renseignées par le patient :

- Prise d'antibiotique durant les 3 mois précédant la date du 03/02/2015 : NON
- Allergies connues : OUI - Graminées
- Communication particulière : OUI - Je dois vous parler de mes maux de tête.

Allergies aux médicaments mentionnées dans le dossier résumé d'urgence :

- Pénicilline
- Sulfamides

D'après les informations dont nous disposons, voici la liste des médicaments qui concernent ce patient.

Aide rapide Annuler la dernière modification Ajouter un médicament

Médicaments Triés par Classe ATC	Dernière liste publiée par un généraliste 04/04/2015	Dernières infos renseignées par d'autres professionnels 04/04/2015	Dernières infos renseignées par le patient 04/04/2015	Ma liste à jour (Modifier, Éditer, Supprimer)
Prograft 0.5 mg Tacrolimus	1 par jour le matin du 01/04/2015 au 08/04/2015	1 cuiller par jour à partir du 01/04/2015	Pas de réponse	1 fois par jour le matin du 01/04/2015 au 08/04/2015 Dates à préciser
Stéovite 1000/800 co Calcium Carbonate + colécalciférol	1 par jour le matin	1 par jour le matin Obsolète car jusqu'au 01/01/2015	/	1 par jour le matin Dates à préciser
Pantomed 40 mg Pantoprazole	/	Pas de posologie	Doute	Pas de posologie renseignée
Eusaprim 800+160mg Sulfaméthoxazole + Triméthoprim	/	/	3x/semaine lundi, mercredi, vendredi	MÉDICAMENT ARRÊTÉ

Quick help appears with a tooltips

Icons are different

Screen shot 3

EDITER LA POSOLOGIE

Médicament	Liste de référence Dr Alice Dagobert 19/01/2015	Dernières infos renseignées par d'autres professionnels	Dernières infos renseignées par le patient 03/02/2015	Ma réconciliation (Réviser, Editer, Supprimer)
Prograft 0.5 mg Tacrolimus	1 par jour le matin du 01/04/2015 au 08/04/2015	1 cuiller par jour à partir du 01/04/2015	1 x j le matin	Pas de posologie renseignée STOP

Renseigner la prise conseillée Entrer une posologie en texte libre

Veuillez préciser comment prendre ce médicament.

Posologie à prendre fois tous les jour(s)

Prise pendant le repas

☒ En cas de

A partir du

Arrêt normal ☒ Durée jour(s)

☐ Date de fin

☐ Médicament chronique (pas de date de fin)

Arrêt alternatif si

Indication pour le patient

Note complémentaire

Annuler Confirmer

Screen shot 4

EDITER LA POSOLOGIE

Médicament	Dernière liste publiée par un généraliste 19/01/2015	Dernières infos renseignées par d'autres professionnels 21/01/2015 - 01/02/2015	Dernières infos renseignées par le patient 03/02/2015	Ma mise à jour (Réviser, Editer, Supprimer)
Prograft 0.5 mg Tacrolimus	1 par jour le matin du 01/04/2015 au 08/04/2015	1 cuiller par jour à partir du 01/04/2015	1 x j le matin	Pas de posologie renseignée STOP

Renseigner la prise conseillée Entrer une posologie en texte libre

Veuillez préciser comment prendre ce médicament.

Posologie * à prendre fois tous les jour(s)

Prise pendant le repas

☒ En cas de

A partir du

Arrêt normal * ☒ Durée jour(s)

☐ Date de fin

☐ Médicament chronique (pas de date de fin)

A arrêter si

Indication

Instruction pour le patient

Note complémentaire

Annuler Confirmer

Highlighting essential information concerning medication dosage

Table 1: Coding categories with corresponding themes and examples after testing the medium- and high-fidelity prototype

Category	Definition	Themes	Examples
Visibility	Ability to quickly recognize key messages and instructions provided by the MedRec app	Visibility improves when clarifying titles and names	Column titles are long, confusing and lack clarity (medium-fidelity prototype) .
		Visibility improves when instructions and information are appropriately located and highlighted	Medication names should similar to the one of my software. (high-fidelity prototype)
			Button to add medication seems on the right place but the icon used was not clear enough and many clinicians did not understand why it stood for (medium-fidelity prototype) . Stopped medication should be easier to identify and the reason for stopping a medication should be visible directly on the main screen (medium-fidelity prototype) . Molecule name, date of initiation of prescription and first prescriber should easily visible somewhere (high-fidelity prototype) .
Content	Medical accuracy or appropriateness of the MedRec app (patient information, documentation)	Content improves when information optimization of MedRec	Physicians “contact information” should be accessible (specialty, phone number) to easily reach prescriber for explanation about one medication (medium- and high-fidelity prototype) . Having access to pharmacy deliveries is essential (medium- and high-fidelity prototype) .

		Content improves when available information helps supporting actions beyond MedRec: for example appropriate prescribing	It could be an added value to have access to older historical data up to several years. For example to remember which medications have already been tested for a patients' epilepsy (medium- and high-fidelity prototype). Manage complex posologies (such as regimen) should be possible (medium- and high-fidelity prototype).
Understand-ability	Ability to quickly comprehend meaning of text, instructions and the purpose of the MedRec app	Using common medical terminology and the standard icons, and providing clear instructions improves understandability	Vocabulary such as "alternating stop" were not understandable by majority of clinicians (medium-fidelity prototype). The trash icon, to cancel an action was confused with the "STOP" icon, to discontinue medication. (medium-fidelity prototype) To facilitate posology editing, there is a real need to prioritize information... it is important to highlight which information is mandatory and which is nice to have (medium- and high-fidelity prototype)..
Navigation	Ability to move easily through the CDS tool	Tooltips and tips should appear on the right location at the appropriate moment to ameliorate	The text explaining how to reconcile medication and why each icon stand for should be visible only on demand (medium-fidelity prototype). Therapeutic intent and condition for taking a medication could be additional information visible

		navigation	with a tooltip on the main screen (medium-fidelity prototype) .
			Little video tutorials could be accessible in order to help users to operate efficiently the MedRec App. (medium- and high-fidelity prototype)
Workflow	Ability of the MedRec app to fit into the natural order of events in a patient encounter	To prevent workflow disturbance, the MedRec app should be accessible at any moment on various devices and provide additional functionalities	The MedRec app user interface should be adapted to be usable on smartphone and tablets (medium-fidelity prototype). Access should be possible 7 days a week, 24 hours a day (high-fidelity prototype). We should being able to print the medication list in a “patient-friendly” format so patients could receive a resume of the reconciliation process (medium- and high-fidelity prototype). The MedRec app should be totally integrated with other existing systems such as CPOE, CDSS (prescribing error and drug-interaction detection system, e.g. drug-drug interaction detection, drug-disease interaction detection) and the EMR (medium- and high-fidelity prototype).
Usefulness	Ability of the app of Improving MedRec	Implementing supplementary	To gain time, it would be great to be able to reconcile several medication together (medium-

	speed, decreasing cognitive burden and/or improving accuracy of MedRec	functionalities are essential to improve usefulness and so acceptability of the app	and high-fidelity prototype) The reconciled medication list should automatically replace the medication previous list in our software and on the ReHN to avoid errors and double work (high-fidelity prototype).
Inter-operability	Ability of the MedRec app to easily share information with other medical softwares	Structured data is fundamental for interoperability and information sharing	Editing posology should be by default in a structured way so data exchange would be facilitate in the future (medium-fidelity prototype). Interoperability and information sharing are a key for usefulness and utility (high-fidelity prototype).

4. DISCUSSION

4.1. MAIN RESULTS

In this study, we conducted an iterative user-centered usability evaluation of a MedRec web-application for HCPs. Participants considered the medium- and high-fidelity prototype as acceptable interfaces (SUS score > 70). However, no significant change was observed in the SUS score (73 vs. 75). This is likely because the number of participants was too small, because not all usability issues of the medium prototype indicated by participants were implemented and because testing the high-fidelity prototype in a near real environment created an additional set of requirements^{51,52}, particularly concerning workflow integration and usefulness.

Because workflow integration as well as usefulness and interoperability are crucial to achieve user's acceptability^{54,55}, the high-fidelity prototype should undergo some essential improvements before being evaluated in a larger study. Results of the low- and medium-fidelity prototype testing enabled identification of different usability issues mainly related to four of the seven categories identified during the two last iterations: visibility (e.g. highlighting information), content (e.g. access to older historical data), understandability (e.g. alternating colors for grouping medications), and navigation (e.g. tooltips and tips on the right location at the appropriate moment). Most remaining issues related to these 4 categories and pointed by participants during phase 3 were modifications that were not implemented in the high-fidelity prototype. These issues (e.g. using medication names similar to the one of the usual software²⁷, managing complex posologies, having access to pharmacy deliveries^{56,57} and prescribers' contact information^{24,26}, embedded video tutorials⁵⁸, etc.) should be addressed in priority as they were already identified as essential for successful implementation in previous studies¹⁴. Finally, researchers should pay attention on the number of clicks needed to fulfil a specific action²⁵, as emphasized by participants.

Supplementary functionalities to improve usefulness and design modifications related to workflow integration and interoperability, essential for sustained used over time, should be deepened when the MedRec app is implemented.

4.2. STRENGTHS

We used a user-centered design with a purposive and diverse sample that can be considered as a valuable design as it ensures that the final product is desirable and suitable for whom it was created⁵⁴. Even though, samples were small we had rich and meaning full discussions. Secondly, being a team composed of members with different knowledge and skills (IT experts, the clinicians, the sociologist and the usability experts) was ideal to prepare and observe testing of the different prototypes³⁷ as understanding and translation of results into functional or non-functional requirements^{54,55,59}. Besides, working in close collaboration with the ReHN gave us the possibility to work with real data, coming from multiple sources– unlikely most eMedRec tools^{5,23,49,60-62} – and in a real clinical setting to test the high-fidelity prototype. It guaranteed the compatibility of the MedRec app with the standards used by the ReHN (message format, data exchange mechanism, security...) and will greatly facilitate integration into the Belgian eHealth landscape and interoperability with EMRs. Both factors are known to be highly fundamental to translate the tool interface into a practicable and usable user-interface^{54,55} and to reach acceptability of the tool, optimal users' compliance and sustained use over time^{26,51,63}.

4.3. IMPLICATIONS FOR RESEARCH

Future evaluation of the usability of the MedRec app should be performed on a larger sample of participants and evaluate, in addition to the SUS score, the three aspects of usability as defined by the ISO 9241-11⁶⁴. First, effectiveness could be evaluated by measuring discrepancies, for example by using safety probes as published recently⁶⁵ and the HCPs' cognitive burden⁶⁶. The potential risk of technology-induced errors introduced by the MedRec app should also be evaluated^{13,57,67}. Second, efficiency could be studied by the number of clicks, scrolls and the time needed to reconcile medication³⁸. Finally, to assess satisfaction and to increase chances of successful adoption, the MedRec app should be used in routine in a real clinical setting for a few weeks so that usability issues related to workflow integration and interoperability can be deepened as well as user experience of different HCPs' subgroups³⁴.

In a later stage, an experimental study measuring the effect of the app on patient outcomes (e.g. reduction of adverse event, emergency visits) and users' performance^{54,68} will be needed and may reveal improvement concerning patient safety.

4.4. LIMITATIONS

Our study has several limitations. Firstly, although a user-centered design with a purposive and diverse sample can be considered as a valuable design, we recruited volunteers, who maybe more interested in the tool and more experienced in health informatics. Therefore comments may have been more positive or more negative than if participants were randomly selected⁵². Moreover, during testing researcher(s) were present, which could have an impact on behavior and reported observation as a result of being observed (Hawthorne effect)^{52,56}.

Secondly, in phase 1, field notes were recorded by the primary researcher which could also have introduced some biases.

Thirdly, in phase 3, due to time-constraints, a limited number of HCPs reconciled the medication list in absence of a participating patient. However, many suggestions and comments emerged from discussion and identified usability issues confirmed the importance of addressing some design modifications before conducting a larger study. Finally, the MedRec app in phase 3 was not accessible via the local EMR. However, given the compatibility of our tool with the standards used by the ReHN, such integration will be facilitated, though it should still be realized on a case-by-case basis.

5. CONCLUSION

This study assessed usability of an implemented MedRec app that uses electronic information from multiples sources including the medication list as documented by the patient.

Our study describes the importance of conducting usability assessments before investing time and resources in a large study evaluating the effect of an eMedRec approach on quality and safety of healthcare outcomes. Our findings will also hopefully increase chances of successful implementation, acceptability and sustained use over time by clinicians.

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General Discussion

In the following chapter, we summarize the principal findings of this thesis work and discuss the validity of our results. We underline the added value of this thesis and the perspectives for further work. Finally, because of my profile of future geriatrician, we also highlight some lessons learned that could be valuable for geriatricians and general geriatric care.

1. WHAT WE DID AND WHAT WE FOUND: A BRIEF OVERVIEW

Medication reconciliation (MedRec) is the systematic process used to resolve medication discrepancies. Discrepancies, defined as differences in medication lists at different transition point of care, can lead to deleterious consequences for the patient. Moreover, these discrepancies have an indirect but important impact on healthcare system costs. Therefore, national and international leading institutions have defined MedRec as an essential patient safety goal.

However, implementing effective MedRec processes and reaching measurable improvements in clinical practice remains a challenge. During this thesis, we explored two approaches supporting MedRec: the use of information technology (IT) and the patient participation. These approaches were conducted in the context of the SEAMPAT project that aimed to develop an information and communication technology (ICT) platform made of two applications: the patient app and the MedRec app. The objectives of our thesis were: (1) To identify requirements and users' needs for an eMedRec tool composed of a patient app and a MedRec app, and (2) To test and suggest improvements concerning this eMedRec tool, for both the patient app and the MedRec app.

1.1. RESEARCH OBJECTIVE I: IDENTIFYING REQUIREMENTS AND USERS' NEEDS

In *Chapter 1*, through a narrative review, we identified essential requirements concerning a patient app for MedRec. A patient app mainly requires patient participation, a key element in the redesign of healthcare that involves the patient in medical decisions. We learned that not every patient desires the same degree of engagement. Patient participation is influenced by many different factors at various levels (Chapter 1, Table 7). Simon et al.¹ and Ariens et al.² conclude that patients were generally positive about the use of IT to support participation in their healthcare but that many barriers and fears exist (Chapter 1). We identified 10 electronic systems involving the patient in medication continuity. However most publications were conducted in North America where patient safety culture and the healthcare system are different from ours.

In *Chapter 2*, we report on 11 electronic tools supporting the entire MedRec process (systematic review). Nine electronic tools were found and added to the two tools involving the patient in the process that we already mentioned in the first Chapter of this thesis^{3,4}. In addition to the description of the characteristics of these 11 tools, we built a box entitled “Recommendations made by authors for the successful development and implementation of eMedRec tools” (Chapter 2, Box 1). The recommendations’ box was divided into 3 sections where we highlight that attention should be paid to particular functionalities of the tools, and even more to the context of development and the implementation of the tool. This box has now been integrated in the second edition of the Canadian toolkit: “Paper to Electronic MedRec Implementation Toolkit”⁵. Finally, we asked for further research, using rigorous studies, to evaluate the effect of eMedRec on the quality and safety of healthcare.

The results of *Chapter 3*, constitute the “missing link” between our 1st (requirements) and 2nd research objectives (testing and suggesting improvements). After having identified requirements for the patient app and the MedRec app and before starting development of the SEAMPAT MedRec ICT platform, we deepened users’ needs in a specific geographical context: the Brussels and Wallonia regions in Belgium. Results taught us how to prioritize requirements for both applications and made us write a “nice to have requirements” section. Finally, these results helped us elaborate the study design of the patient app and the MedRec app evaluations.

1.2. RESEARCH OBJECTIVE II: TESTING AND SUGGESTING IMPROVEMENTS

Chapter 4 concerns the patient app. We report that the vast majority of patients involved in the evaluation of the low- and medium-fidelity prototypes were enthusiastic and interested in continuing using the patient app in the future. Their constructive feedback enabled us to refine the prototypes in order to get a high-fidelity prototype easier to use than the two previous ones. Testing the high-fidelity prototype raised the same enthusiasm among the patients. Some results were surprising. Indeed, the primary objective of the patient app – i.e. participating in the MedRec process – let some patients in doubt’. The patient app

functionalities did not exactly meet the patients' expectations. However, they said the app had valuable potential for optimizing MedRec.

Chapter 5 concerns the healthcare professionals (HCPs) app (MedRec app). We describe the three iterations of testing and improving the MedRec app prototypes (low-, medium-, and high-fidelity prototypes). HCPs considered this app as valuable and interesting to support MedRec. The modifications made, to the low- and the medium-fidelity prototypes following HCPs' suggestions, improved its usability. According to HCPs' expectations, the app should be linked to the computerized physician order entry (CPOE) and thus to various clinical decision support systems. When improving the MedRec app, the following key words should be kept in mind: time, cognitive burden, flexibility and availability, workflow integration and interoperability. Indeed, health information technology (HIT) is only useful when it helps doing more than what we usually do without HIT or if it helps doing it quicker and/or more accurately.

2. STRENGTHS AND LIMITATIONS OF THIS WORK

2.1. MAIN STRENGTHS OF THE THESIS

a. Methodological approach

In the evaluation of this electronic tool, we have produced rigorous work by following recommendations (1) from the Agency for Healthcare Research and Quality⁶ and (2) from two usability textbooks^{7,8}. As illustrated in Figure 1, successful implementation of the applications and their sustained use over time requires an analysis of needs and requirements (Chapter 1 to 3), followed by an iterative process of design, development and evaluation (Chapter 4 and 5)⁷⁻¹³.

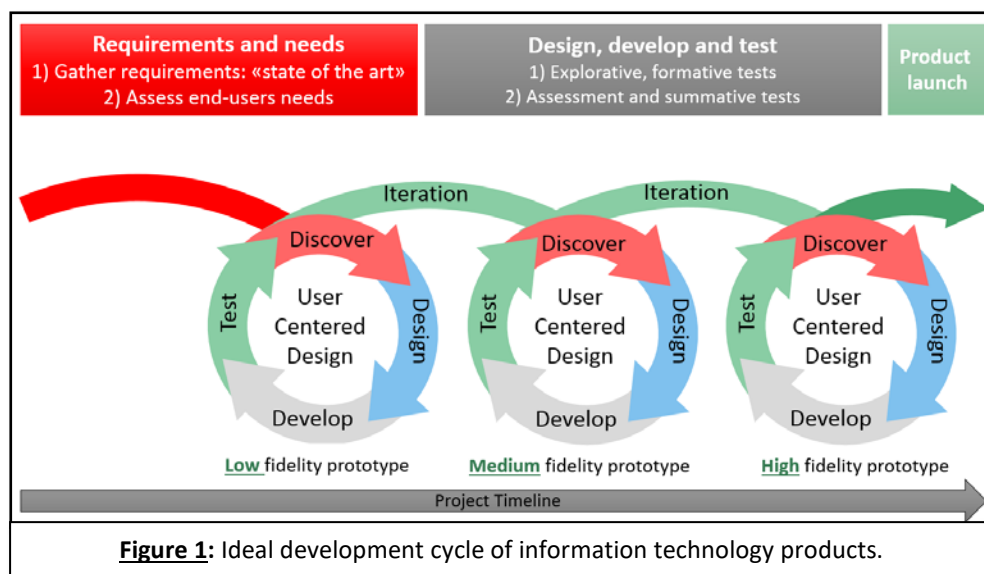


Figure 1: Ideal development cycle of information technology products.

Evaluation and development of the SEAMPAT ICT platform was performed using 3 prototypes of each app, which evolved from low-fidelity to high-fidelity. Usability was evaluated as part of a **user-centered iterative development** process because it is a powerful and effective process that greatly strengthens usability and adoption of the final IT tool^{7,14,15}. Besides usability, we evaluated perceived **usefulness** and potential **acceptability** of the patient app. We explored both concepts (usefulness and acceptability) concerning the MedRec app in order to

anticipate and prepare the possible next steps of the lifecycle of the SEAMPAT ICT platform (SEAMPAT 2.0)⁷. Following recommendations, we performed the appropriate tests (informative and summative) at the appropriate moment^{7,8}. The use of different approaches to collect qualitative and quantitative data clearly enriched the interpretation of the results by providing a multi-faceted understanding of the facilitators and barriers to the tool's adoption¹⁶⁻¹⁸. Reporting evaluation was done following the **STARE-HI** – Statement on reporting of evaluation studies in Health Informatics¹⁹ with slight modifications inspired by guidelines for reporting mobile health interventions²⁰ and the subitems' checklist expanding **CONSORT-eHEALT** item 5²¹.

Moreover, the whole SEAMPAT research team was composed of researchers with different and appropriate knowledge and skills and validated every step of the development and the evaluation processes. Looking at the same data from a different perspective helped identifying limits and risk of bias of the studies as well as improving the security and safety of both applications^{6,12,13,22}.

Although validation by comparison should be performed carefully because it can lead to pseudo-validation by replication of “unrigorous methods”, our design, development and testing method were similar to previous robust studies published in valid and reliable journals^{14,22-25}.

b. A user-centered approach (including health care professionals and patients)

Testing prototypes with a user-centered design (UCD) by including end-users from the start, particularly patients, is currently infrequent within the health care literature¹⁶. Of the 19 tools identified in both Chapter 1 (10 eMedRec processes involving the patient) and Chapter 2 (9 electronic tools supporting the whole MedRec process), only two clearly mentioned having used a user-centered design approach^{15,26}. For some tools end-users' feedback was collected during the tools' assessment or usability evaluations. However end-users never seemed to have been involved from the beginning in gathering requirements and assessing needs^{4,27-30}.

Yet, using **UCD from the beginning** is advantageous. Firstly, because by involving patients and HCPs in gathering requirements and assessing needs (Chapter 3) we received input that increases the probability of developing a tool that

corresponds to end-users real needs and expectations^{14,16,31}. Secondly, working with end-users for evaluation of both applications (Chapter 4 and Chapter 5) maintained the focus on patients' and HCPs' perspectives and avoided the danger of experts thinking "instead of patients and HCPs"¹⁴. Finally, a new group of end-users was recruited for each iterative session (in Chapter 4 and in Chapter 5), which enlarged the range of possible outcomes because each prototype was new to at least some participants¹⁴. Because of the great potential of UCD, many recent studies (2016 and after) developed tools using this approach^{12-16,22,31-36}. Only one of these studies²⁶ concerns an eMedRec tool.

Additionally, during evaluations but also during discussions with the SEAMPAT research team and the steering committee including patients and HCPs, we were several times surprised how patient input could be valuable to keep real patient safety goals as the main direction³⁷.

c. The two lines of care (community and hospital care)

Belgium has a scattered healthcare system with suboptimal information sharing and communication between primary and secondary care, for various reasons and despite many efforts from HCPs of both lines of care³⁸⁻⁴⁰. Our strength was to involve patients, general practitioners (GPs) and community pharmacists as well as physician specialists (PS) and clinical pharmacists from the start. Most studies are focusing on MedRec at hospital transitions or post-discharge from hospital^{41,42}. Very few studies evaluated discrepancies and/or MedRec in the primary care sector^{43,44}. In Belgium, a qualitative study (including patients, HCPs and policymakers) classified problems related to care transitions into 5 categories³⁹: Three categories concern problems that may happen outside the hospital setting (linked to HCPs, to patients and their families, or to processes). In Chapter 3, we confirm the importance of including the primary care sector because patients and HCPs mentioned that discrepancies could for example be due to the lack of information sharing between a PS and their GP or the inaccuracy between their prescriptions (to buy medication at the pharmacy) and their written medication scheme (at home) completed by professional or unprofessional caregivers.

The developed ICT platform is innovative as the MedRec systems developed in the literature are meant for inpatients²³ OR for outpatients^{45,46} but, to our knowledge, never for both together.

d. The same information (for the patient and the HCP applications)

Both applications being integrated into the current eHealth architecture (applications integrated into the Hub of the RSW) and being linked together, are presenting the same information to the patients and the HCPs. Except for the APHID developed by Lesselroth et al.⁴ none of the implemented tools mentioned in the literature is directly using patients' input to complete HCPs' electronic medication record (EMR) information. In Belgium, Vitalink authorized patient access to medication data but the patients are not allowed to modify or add information. The large majority of available commercial applications are not integrated into the Belgian eHealth architecture. In Chapter 1, as confirmed by Chapter 4, we found that HCPs' endorsement of the electronic tool is a crucial factor to patient participation.

e. A collaborative multidisciplinary research

MedRec is a collaborative process, requiring researchers with different skills and knowledge working together (see General Introduction, section 5.3. "The SEAMPAT Project"). Following literature a minimum set of criteria should be followed to successfully obtain results⁴⁷⁻⁴⁹ such as shared goals and vision, team strengthening, leadership and communication structures. The topics treated during the research project were complementary and related to different domains (medical, pharmaceutical, IT, ethical, etc.). However, improving patient safety remain a clear purpose and vision for the team during the whole project. An external expert panel supported the researchers for keeping the direction as defined at the start of the project. Personal professional and emotional skills of researchers participated to the success of the project. As future geriatrician, a specialist in complexity working in multidisciplinary teams, we were particularly skilled to enhance communication, keep the patient in the center and adapt to the current situation (for example, delayed work of another group).

2.2. LIMITATIONS

Some limitations of this research work need to be mentioned and discussed.

a. All recommendations were not fulfilled

In Chapter 2, we created a box assembling the main recommendations made by authors for the successful development and implementation of eMedRec tools. Recommendations were organized according to (1) the context of development, (2) the functionalities and the development of the tool and (3) concerning the implementation of the tool. Because both applications were not used in practice outside of our study' protocols, most recommendations concerning the implementation of the tool are not yet applicable.

In Box 1 we aim to reflect upon which recommendations were followed (partially or completely) in the context of our work.

<u>Box 1: Recommendations made by authors for the successful development and implementation of eMedRec tools</u>	<u>Fulfilment</u>
1. Recommendations concerning the context of development	
▪ Adapt the tool workflow to the habits of frontline users^{4,23,50-54} ▪ Offer the possibility of invoking the application from multiple points in his or her workflow⁵⁰, regardless of the EMR medication list status²⁹ ▪ Define the roles of each frontline user in the eMedRec process^{4,51,53,55} ▪ Ensure support from clinical/hospital leaders^{50,53} and a suitable organizational climate^{4,52,53} ▪ Persuade frontline users, especially clinicians, of the importance of MedRec⁵³ ▪ Engage patients in the medication reconciliation process^{4,27}	- ❶ - ❷ +/- ❸ + +/- ❹ +
2. Recommendations concerning functionalities and development of the tool	
<i>Concerning the tool in general</i>	

- o Develop tool features and design interfaces in an iterative manner, driven by the clinical processes^{30,51,56} - o Use design guidelines for designing health information technology; identify and use individual design components (e.g. animation, groupings) - o Choose a design that matches the overall design philosophy of your EHR user interface³⁰ - o Use prototypes and pilots⁵¹ - o Involve patients as collaborative partners in developing the tool⁵⁵ - o Do not anticipate users' needs⁵⁰ - o Medication information needs to be entered in coded format⁵¹	+ + + + + + +/- ⑤
<i>Gathering the best possible medication history</i>	
• Use information from different sources^{27,50} and gather this information electronically by linking the eMedRec tool to medication lists of other systems (EMR, CPOE, EHR, pharmacy claims,...)^{52,53,57} • Aim for interoperability between different medication lists, with the possibility of automatically charting the reconciled list in the EHR/CPOE^{52,53} • Develop easy-to-use technology (drug pictures, prescribers' information next to each medication)^{52,55,57} • Do not over-automate the tool⁵⁰	+/- ⑥ +/- ⑦ + +
<i>Identification of discrepancies</i>	
• Develop robust detection of discrepancies⁵⁵ • Develop technology that is easy to use and reduces the cognitive load: use animations and offer different filters for classification; help providers to recognize, contextualize, and manage medication discrepancies^{27,30,52,56,57}	+ +
<i>Resolving discrepancies</i>	

• Explore and develop decision-support algorithms to help providers to identify clinically meaningful discrepancies^{27,55} • Develop easy-to-use technology: allow manual verification of all medication;²⁹ allow partial reconciliation;⁴ document reasons for all reconciliation actions taken;²⁹ enable inter-facility provider communication of discrepancies⁵⁵ foresee tight integration with the CPOE system^{51,53,57}	+/- ❸ +/- ❹
3. Recommendations concerning the implementation of the tool	
▪ Provide education and support: regularly train users and local leaders, provide on-site support^{29,50-52,54} ▪ To improve compliance: introduce reminders or hard-stop,^{23,29,51,53,57} reduce the time needed to reconcile medication,⁵⁷ have measurable compliance rates to enable ongoing feedback,^{23,53} collect users' suggestions⁵⁰⁻⁵³ ▪ Compare electronic lists to a gold-standard structured medication history^{4,24} ▪ Conduct usability testing^{27,56,57} and test the software (reliability + interoperability) in selected and disparate settings^{4,24} ▪ Focus on efficiency in addition to clinical improvements⁵⁶ ▪ Establish a process for referring recurrent errors and discrepancies for failure analysis and potential system-based intervention⁵⁵ ▪ Assess the generalizability of your findings using comparable data from other hospitals using electronic medication reconciliation tools⁵⁷	Not applicable Not applicable +/- +/- Not applicable Not applicable Not applicable

Legend:

+ when recommendation was totally fulfilled; - when recommendation was not fulfilled;

+/- when recommendation was partially fulfilled

The BOX contains more than 20 recommendations (without taking into account the 7 recommendations concerning implementation). Of these, nine could not be perfectly fulfilled: number ❶ to ❹ in the box. This is mainly for 4 reasons:

1. No time and motion study was performed because the tool is not yet implemented in practice.
2. We had to adapt to the current Belgian IT landscape and situation. For example, medication data were not always available in coded formats or interoperable formats.
3. The SEAMPAT ICT platform was not implemented for routine use.
4. The future place of SEAMPAT in the Belgian eHealth architecture is not well-established.

Interestingly, the “not followed recommendations” correspond to what users insist on during application evaluations (see section results and discussion of Chapter 4 and 5). This is particularly important, as it will inform future perspectives concerning the SEAMPAT ICT platform. The identification of the requirements (Chapter 1 and 2) and needs (chapter 3), enabled computer scientists to take them into account. The development of the SEAMPAT ICT platform was designed such that it can easily be adapted to different software and IT architectures.

b. Some possible “use-cases” were not included in the evaluation of the apps

In the context of the SEAMPAT project, none of the applications was made accessible on tablet or smartphone due to the authentication process: electronic identity card (eID) with PIN code + eID reader and viewer. The patient app could also have been accessible on a kiosk at the entrance of the hospital or in the consultation waiting room.

The use of a tablet in the waiting room to prepare the MedRec process to be completed with the physician during consultation was well accepted by patients³⁶ and by HCPs³². Tablets allow to enlarge the target population and even help young children to participate in their healthcare as shown in a recent study¹⁴. Many studies evaluating the usefulness of applications on **smartphone** to help in the management of several chronic disease(s) showed promising results^{13,25,31,33,58-60}. Lesselroth et al.^{4,61} showed good patient acceptance of a **MedRec kiosk** in the lobby of an outpatient clinic. Developing and evaluating those three additional use-cases (SEAMPAT’s applications available on smartphones, tablets and kiosks) answers to a recommendation of Chapter 2, BOX 1 “Offer the possibility of

invoking the application from multiple points in the workflow⁵⁰ which is applicable to the MedRec app but could also be applicable to the patient app^{6,16}. Having access to the application from everywhere, at every moment, on every device also fulfills expectations raised by patients and HCPs at different phases of the SEAMPAT ICT platform development cycle (Chapter 3; Chapter 4, table 4; and Chapter 5, table 1). Moreover, we learned from previous studies that convincing HCPs to use eMedRec tools is difficult. Increasing ease of access to the tool may improve compliance and prevent addition of MedRec reminders^{29,62} or mandatory steps^{53,57} in the workflow process.

Concerning the SEAMPAT ICT platform, we did not assess these potentially interesting use-cases because of the technical and security constraints of authentication (PIN code and eID). However, I am convinced that a future version of SEAMPAT would be able to fulfill this expectation as the secured authentication by the application “itsme”¹ is available since November 2017 for the Belgian eHealht services.

c. Participants selection bias

Firstly, pulmonary transplanted patients were chosen because of their specific profile: at high risk of discrepancies (taking many medications, having multiple comorbidities), particularly enthusiastic (curious and involved in their health, thankful and so they easier offer their help to research) and member of the “Oxygene asbl” (representing the patient’s voice). Therefore, they may have introduced a bias in the results. However, this group of 16 patients (33% of the total sample) represented already a large diversity of patients concerning sociodemographic data and they had less IT skills than other included patients. They gave more suggestions to improve the patient app, which is important to adapt the app to patients’ needs. All their suggestions were at least supported by two patients belonging to the three other groups. So, if pulmonary transplanted

¹ Itsme is an application (available on Play store and App Store) that can prove your identity and approve transactions in a safe, easy and reliable way. You can login anywhere and anytime with just one password on your mobile phone.

patients would have influenced results they have done it in a positive way by helping to improve the app.

Secondly, we did not include frail older patients even though medication discrepancies are frequent and have more adverse consequences in frail older patients compared to the general population. Frail older patients were not our target group as many of them are limited by cognitive, visual or physical impairment making the use of the patient app difficult or impossible. However, in the future, caregivers of geriatric patients should be allowed to use the patient app in the name of the patient with legal rules and conditions clearly defined.

Finally, included patients and HCPs were all volunteers. This may have had an impact on the results, as participants could have been excessively positive and enthusiastic or in contrast more negative than if participants would have been randomly selected¹⁸. However, we deliberately recruited patients and HCPs with different profiles (age, gender, literacy, medical history, health literacy, IT use and knowledge, profession, ...). At each phase of the study, we have been tried to include less enthusiastic participants and we encourage free speaking during FG and interviews. At each time-period of the development cycle of SEAMPAT, we met with patients and HCPs that were not in favor of the use of IT for MedRec and with several "claims". Even so, in the future (SEAMPAT 2.0) it would be very interesting to collect a wider range of opinions.

d. The gold standard used, the Best Possible Medication History, could be criticized

The Best Possible Medication History (BPMH) is a medication history collected using a systematic process of interviewing the patient/family; and a review of at least one other reliable source of information to obtain and verify all of a patient's medication used (prescribed and non-prescribed). Complete documentation includes the drug name, dosage, route and frequency⁶³⁻⁶⁵. Gathering the BPMH is the first step of the MedRec process.

When evaluating the patient app, a BPMH performed by the PhD student was used as gold standard. The information provided by BPMH is not always 100% accurate^{66,67}. The patient does not always tell everything^{68,69} because of fear (results of Chapter 3). Moreover, the medication history was collected by a

physician, who is doing less well than a pharmacist^{41,67,70-73} and the community pharmacy was not called for every patient. Nevertheless, the BPMH remains the best available reference and the gold standard recommended in the literature^{66,67,70,74}. The physician (SM) had been trained to collect a medication history, most interviews were done at home where patients discuss more freely than in the hospital setting⁷⁵. A validated structured questionnaire⁷⁶ for collecting the BPMH was used and for each patient, at least 2 medication resources (GP's medication list and PS medication list) were consulted, in addition to the patient interview.

e. No generalizability to the Belgian and international context

The SEAMPAT ICT platform as it was designed in the context of the research project, is not generalizable for use at the national or international level. Findings from focus groups and individual interviews are barely generalizable to another context. However, providing that our methodological approach used was rigorous, credible and valid^{12,77}, we think that the results are transferable to the Belgian and international context. Moreover, since some of our results are in line with previous results (e.g. functional/non-functional requirements and recommendations), we believe these could be used as a basis to build any electronic MedRec tool in any other context⁵.

3. ADDED VALUE AND PERSPECTIVES

3.1. INFORMATION TECHNOLOGY SUPPORT FOR MEDREC: “MORE THAN JUST A GADGET”

a. Information technology can be an added value

Concerning MedRec, information technology is not a gadget. Information technology may be very useful as it can support HCPs’ work in the 4 steps of the MedRec process.

- (1) Evidence shows that **IT helps gathering the BPMH** by prepopulating automatically the medication list with information coming from multiples sources (the patient, the primary care provider, the outpatient clinics, the community pharmacy, the inpatient chart,...)^{42,78}. A recent study confirms that access to pharmacy claims reduces potential medication error by more than 30%^{79,80}. Electronically gathering the BPMH is clearly less time-consuming than phone calls to every patient’s carer²⁶. The prepopulated medication list then only needs to be further documented, particularly concerning dosage and instructions (frequently missing in data claims⁷⁹) and validated during a face-to-face interview with the patient and/or his/her family. IT is not meant to replace patient-provider discussion, nor clinical judgement.
- (2) **IT helps identifying medication discrepancies** by facilitating alignment of identical medications, highlighting similarities and discrepancies, grouping them by therapeutic class, alphabetical order or patients’ answers, and can reduce the HCP’s cognitive burden^{30,56,81,82}. Comparing medications’ lists and identifying discrepancies is indeed a difficult task causing cognitive overload and resulting in inaccuracies of the reconciled list, particularly in a context of multiple work interruptions, usual for many HCPs⁸³.
- (3) **IT provides the options that HCPs do mentally** (i.e. continue, change or discontinue a medication) In addition, IT prevents forgetting to resolve discrepancies by blocking the next action when reconciliation is incomplete^{29,53,62,84,85}. Because there are significant differences in the MedRec mental process among HCPs and variances in the way of

interacting with electronic devices, eMedRec tools will have to be particularly well-designed for second and the third steps of the MedRec process to be really helpful⁸⁶.

- (4) And most importantly, if systems are highly interoperable and data is systematically structured, IT allows sharing information between HCPs instantly without any data loss.

Even if all eMedRec studies, including the very recent ones^{26,87-91}, show that the use of electronic supports the HCPs in reconciling medication, none has currently been able to demonstrate a positive impact on patient safety outcomes (reduction of adverse drug events, unplanned visits, hospital readmissions, etc.) and cost savings^{26,42,87-91}.

Recent publications suggest that future work should develop and evaluate MedRec tools concomitantly with **tools supporting patients' adherence and/or medication review**^{43,92-94}. In our work, during the evaluation of the patient app, some patients asked if they should document the medications they were supposed to take or those they actually were taking. This question underlines that collecting consciously the BPMH requires assessing patients' adherence. Many applications have been developed to support and/or monitor patients' adherence⁹⁴⁻⁹⁶. We believe IT may help interoperability and information sharing between adherence applications and MedRec applications and so improve the reliability of the BPMH.

Our results from the needs assessment (Chapter 3) and results of the MedRec app evaluation (Chapter 5) showed a strong wish of the HCPs to have various applications and decision support system coupled, as previously reported in the literature^{43,92,93}. Specifically, HCPs emphasized the importance of **linking the MedRec app to the computerized physician order entry (CPOE)** system with integrated clinical decision support systems (CDSS): such as drug-drug interactions, drug-disease interaction, drug-lab abnormalities alerts, etc. In a previous Belgian study, GPs asked for the integration of STOPP&START criteria in a CDSS⁹⁷ to improve the appropriate prescribing for older adults. If well designed, well calibrated in order to reach high alerts' specificity and to avoid alert fatigue⁹⁸, it could be interesting to implement and evaluate those MedRec and MedRev tools together. However, the risk of over reliance on IT by HCPs exists⁵⁰. HCPs will always have to remain critical and to rely on their clinical judgement.

b. Challenges

Although users (patients and HCPs) recognize that e-tools can support the MedRec processes⁹⁹, and can be useful and valuable¹⁰⁰, their long term acceptance is not straightforward. Indeed, designing health IT (HIT) adjusted to users' needs and effectively beneficial for HCPs' practice in terms of patient safety and medical costs is not a piece of cake.

Firstly, IT introduces **new types of errors** such as data being lost or incorrectly entered, displayed or transmitted^{79,101}. Results of the third iteration of our patient app showed that the first cause of discrepancies was technology related. Probably by usability difficulties and by lack of training to use their app, the patients did not document the "status" of some medications. This fact resulted in an unintentional lack of information (Figure 2). Newly installed systems are followed by an initial increase in errors^{102,103}. These errors and the decisions resulting from these errors, increase the risk of patient harm¹⁰¹.

Figure 2: On this print screen the patient did not choose any option to answer the question “Are you currently taking this medication?” for the last medication of the list (Physiomer). This medication was then considered as “without status”. When the HCP consults his MedRec application, he will not know if the patient is taking or not the Physiomer.

Secondly, the **danger of fatigue** due to many alerts or triggers is always pending and HCPs may end up bypassing essential alerts without even looking at

them^{102,104}. Coupling decision support systems to CPOE and/or MedRec tools is not the right solution to improve patient safety but it should be one component of a complex multifaceted solution.

Thirdly, HCPs show considerable **resistance to organizational change**¹⁰⁵. Most of them fear the plethora of data that would lead to difficulties of finding the desired information and of information prioritization. Overwhelming information in healthcare is not due to IT¹⁰⁶, which just make it worse.

Fourthly, IT always raises **the question of responsibilities**. Who is responsible for what and when? One of the work packages of the SEAMPAT project aimed to evaluate the legal aspects related to both applications, and this work was performed by researchers from CRIDS (centre de recherche information droit et société) at UNamur (see Appendixes, section 7.1.). In the context of the SEAMPAT project, the use of the MedRec app by HCPs and the patient app by patients, do not modify their responsibilities. The information coming from the patient should be added besides pre-existing information. It should not modify or delete the information written by HCPs, neither their responsibilities. Physicians are responsible for the appropriateness of their own prescriptions (drug-drug interaction, drug-disease interaction, drug-lab interaction, adequate posology, etc.). Pharmacists are responsible about what they deliver to the patient. While reconciling medication, HCPs are facing the whole medications list. Some physician specialists do not feel comfortable to express their opinion concerning medication there are not used to prescribe. Different options have been studied to overcome these difficulties: partial MedRec⁴, and an additional option “continue as previous”²⁶.

Fifthly, HIT needs to fulfil thoroughly a set of **technical requirements** such as intuitive design, structured information, workflow compatibility, high interoperability, high security (preventing hacking). Current IT is therefore most of the time not profitable to every user¹⁰³. Evaluation of both applications of the SEAMPAT ICT platform confirmed this absolute need for complete and structured information associated with high interoperability. Indeed, identical medications were not always correctly identified and recognized by both applications (the MedRec app and the patient app). Actually, physicians’ local softwares did not always assign an ATC/CNK code to each patients’ medication. Therefore, patients encountered duplicate medications corresponding to the same medication (for

example “paracetamol 1g, one tablet 2x times a day” prescribed by two different physicians). HCPs on their interface saw unaligned medications. Belgian healthcare authorities (CBIP/BCFI, INAMI/RIZIV, AFMPS/FAGG, AIM/IMA) are working since several years on an authentic and validated medication source, currently named SAM² version 2 or SAMv2¹⁰⁷ (SAM: source authentique des médicaments). Such a unique medication database for all Belgian softwares would in the future reduce these technology-induced errors.

Besides well-designed technology, users deeply need **constant training, repeat education and on-site support** to use IT in the most optimal way^{26,29,50,99}. Finally, network coverage and web connection speed need to be optimal so that IT tools/software still work quicker than the HCPs and their pencils.

3.2. PATIENT PARTICIPATING IN MEDREC USING IT: WORTHWHILE, UTOPIA OR DANGER?

a. Why to involve the patient in the IT based-MedRec process?

We believe for several reasons that patients should be involved in the process of MedRec. Firstly, patients recognize facing potentially **harmful medication errors** and are **willing to participate** in care^{28,108-110}. Patients having participated to the SEAMPAT project reported that having experienced, themselves or their relatives, adverse drugs events, they are strongly motivated to participate in medication continuity. Moreover, the patient is the only person knowing exactly what medication he/she is taking and how it is taken⁹⁴. Secondly, there is an increase in the number of persons suffering from **chronic diseases** and thereby from **polymedication** prescribed by various HCPs^{111,112}. The “greying” of the population affected by more chronic diseases and the consequently augmentation of frail patients experiencing **many transitions** across care settings¹¹³, are well-known risk factors for medication discrepancies^{114,115}.

Thirdly, even if some patients (in our research 17%: 18/104; nine men and nine women) feared the use of IT and for this reason refused to participate to the evaluations of the patient app, the literature shows that most patients have an overall **positive attitude** towards HIT^{1,116}.

² SAM = source authentique et validée des médicaments

Results of the patient app evaluation showed that **being an active user of IT** was the main facilitator to IT use which concurs with the literature^{11,117,118}. Age is not a barrier except that, currently, older people have been less active user of IT in their youth. Finally, the upcoming generations have been using IT for years and are engaged in many domains through IT. Because we are today building eHealth systems for tomorrow, we should involve the patient in the IT-based MedRec process.

b. How best involving the patient in the MedRec process with the use of IT?

Some **patient's skills** are needed in order for them to participate successfully and efficiently in their health¹¹⁹. Indeed, factors as health literacy, high level of education, enthusiasm and motivation (see table 7 of Chapter 1) are important facilitators to patient participation. Moreover, patients' education and counseling have been showed to reduce the risk of adverse drug events (ADE) and hospital readmissions¹²⁰. Because some patients rather delegate or have to delegate their health management for different reasons (lack of skills, unwillingness, impairments ...), **involving caregivers** in the MedRec process should be possible in the near future. Caregivers (professional or not) should identify themselves using their own eID in order to preserve patients' privacy.

Most authors¹²¹⁻¹²⁵ equally insisted on the importance of the **patient-HCP relationship**, the HCPs' attitude and the need to educate both patients and HCPs to patient involvement in his health. Finally, patients should also be supported in the use of IT. Training and education are important facilitators to reach IT adoption for HCPs^{29,50-52,54} and patients are certainly no exception. Our 4 month-evaluation of the high-fidelity prototype of the patient app indicated the need for **support to the patients**. Giving them helpful answers at the right time clearly contributed to their motivation for continuing using the patient app and going until the end of the study.

For all these reasons, we believe it is worth involving patients in the IT-based MedRec process provided patients and caregivers are **educated, advised and supported**. Reluctant patients should never been forced to engage and patients' preferences should be respected. Systems such as pay for performance or pay for quality could be an option but should not been given priority. Patients'

participation should be considered as an opportunity (and not a duty) for the patients to improve their own safety. Indeed, when the influencing factors (facilitators as barriers) are not considered, patient participation can become a danger (e.g. monitoring alarms stopped by mothers in neonatology, misuse of internet misleading patients to dangerous options if there are not guided by their HCPs)^{126,127}.

c. Which patients should be involved in IT-based MedRec?

Although it would make sense to focus on the patients at high risk of medication discrepancies^{111,114,120}, the latter patients are usually not the ones who involve spontaneously in their healthcare. Indeed, factors as age, disease severity, and low health literacy are barriers to patient's participation.

Our literature review indicated that caregivers and family support are important facilitators to participation (see Chapter 1). Additionally, we observed during evaluations that older age¹²⁸ is not a blocking factor to the IT use. Literature confirms that eHealth literacy and IT literacy^{11,117,118} are more important factors than age in determining the patient's ability and willingness to use technology. Finally, patient participation improves safety of care and patient portals are considered as a potential support to reach the highest level of patient engagement^{116,123}.

Therefore, to deliver the same quality of care to every patient, we should not target any specific population. **All patients** should be offered the possibility to become an actor of his/her care and to participate in the IT-based MedRec process. Patients should be encouraged, helped and possibly assisted by a caregiver in their involvement.

To successfully involve patients in this process, MedRec should be embedded into a **patient portal** which should be designed and developed as a dynamic component of the patient-provider relationship¹¹⁷. Patient portals should be seen and developed as part of whole integrated HIT system¹¹⁷ supporting patient empowerment and therefore including feedback systems allowing patients to understand and to anticipate their health problems. Patient portals features should also be aligned with patients' and HCPs' information needs and expectations¹¹.

3.3. MEDREC IS ESSENTIAL BUT NOT SUFFICIENT FOR PATIENT SAFETY

a. Why would MedRec still be needed in a national medication scheme system?

We will forever have to reconcile medication. Even if we try to build a central “medication scheme” as currently foreseen by the Belgian Healthcare authorities, we will still face differences between what the patient was prescribed, what he bought at the pharmacy, what he is actually taking or what he had to take during his hospital stay.

In the pharmacy, the patient can buy medications for someone else that can be recorded under his own name. Evidence show that patients buy many over-the-counter medications (OTC medications)⁹⁴ as painkillers, sleep pills, pills for cough/cold/allergies, pills for gastrointestinal disorder¹²⁹ and other medicinal supplement (phytotherapy, vitamins, aromatherapy, homeopathy). These medicinal products can also lead to adverse drug events, especially when products are unknown by the HCP. Oppositely, it is not because the patient does not buy a medication that he is not taking it. Finally, the quality and accuracy of the BPMH can be deteriorated if providers over-rely on pharmacy claims data^{130,131}.

Patients have many reasons, and sometimes very good reasons, not to follow the prescribed treatment. Up to 69% of medication-related hospitalizations are due to **medication non-adherence**¹³². Even though it is difficult to measure, non-adherence is an interesting modifiable risk factor¹³². Successful interventions to improve adherence are usually complex, targeting on all important barriers and tailored to individual characteristics of the patient (one size does not fit all). Moreover, interventions should be applied over a period of time¹³³.

During the hospital stay, prescribers have to adapt their medication prescribing to the limited hospital formularies and many therapeutic interchanges thereby happen¹³⁴. These interchanges elevate the risk of potential medication errors during or after hospitalization. Patients see also their medication regimen intentionally modified during their stay. Unroe et al. found that nearly all patients left the hospital with changes in their medication regimens¹³⁵ and up to 77% of patients did not receive adequate medication instructions at discharge¹³⁶. Another study showed that 14.3% of the patients who experienced medication discrepancies were rehospitalized at 30 days¹³⁷.

b. What is the place of MedRec, does it need to be the center of an IT system?

In Belgium, MedRec is not well known and well considered by most HCPs (Chapter 3 and Chapter 5). Some HCPs participating in our project were uncertain about the usefulness of the current MedRec app version 1.0 (Chapter 5). Answering users' needs is crucial for usefulness, tool adoption and sustained use over time^{10,138}. HCPs expected **additional features** favoring time gain, improving accuracy of the medication list, avoiding duplicate work and improving communication with other HCPs. Schnipper et al²³, observed that tight integration of the MedRec tool and the **CPOE** favored eMedRec usefulness and increased its completion rates. HCPs testing Cadwalladers' tool²⁷ considered it particularly useful because it was related with the **pharmacy dispensing data** which clearly helped gathering the BPMH but also assessing patients' adherence. The physicians interviewed by Long³² were satisfied because **patients' electronic input** improved the accuracy of the reconciled medication list. Reaching HCP's adoption of an eMedRec tool and high MedRec completion rates is hard^{53,57,62}. Thus, optimizing medication continuity in order to improve patient safety should consist in a wider approach than just improving MedRec^{43,92,93}.

Therefore, a MedRec tool should not be developed as a standalone module it should be seen as a dynamic component of "a patient medication path". An electronic medication path that followed the patient's journey through the entire health system with flashing flags each time a specific action needs to be executed by the HCP or the patient: adherence evaluation, medication reconciliation, medication review. Of course, not every action will need to be done at every consultation with every patient. Further research should focus on determining which set of criteria will make flash the flags and when these flags should appear in the workflow. Future studies could also evaluate this "electronic patient medication path" by comparing it to usual care (usual care would be in this context a better Gold standard than the BPMH), and using patient safety goals as outcomes.

3.4. SEAMPAT 2.0: IMPORTANT CONSIDERATIONS FOR BOTH APPLICATIONS

a. Educating front-line users on MedRec and health IT

In 2008, Bails⁵³ underlined the need of persuading front-line users, especially physicians, about the importance of MedRec. Nine years later, at least in Belgium, most encountered HCPs and patients in the context of this work are still not convinced about **the importance of MedRec** and ignorant of their specific role in the process. This even though, Belgian Health care authorities are aware of the problem^{40,139} and sensitization campaigns have been held. Therefore, I think we should start putting MedRec forward, notably by **informing future HCPs during their graduate programmes** about continuity of care and medication (importance, processes, challenges...). We should also **educate patients** about MedRec and health IT: (1) improve their knowledge of the MedRec process but also their potential role to improve it and (2) clarify the positive and negative aspects concerning the use of health IT. The eHealth consent should for example, only be given after exhaustive information. Knowledge could be improved by short videos appearing when patients' log into their patient portal, on screens in the community pharmacies, in waiting rooms of physician consultations, on facebook, etc. Besides, we should encourage the patients to participate in their health and we should absolutely train HCPs to enhance **patient participation** and collaboration in his care. Indeed, patient participation hindered by HCPs not responding to patients' willingness to participate could become a risk for patient safety¹⁴⁰.

In the context of our work but also during informal meetings, we were surprised by HCPs ignorance concerning **HIT and IT**. Many are still not using technology in their professional environment, some are seeing IT as a way to "spy" and being controlled for all what they are doing. Most of the HCPs who are using medical softwares in their practice are using them inefficiently and exploiting it far under their functional capacities. Some HCPs know little concerning the Belgian eHealth environment. For example, some physician specialists working in hospitals had never heard about regional networks. However, they were connected to the regional eHealth network through their hospital. Yet, we know training, education and on-site support are one of the key factors to implement successfully eMedRec

tools^{29,50-52,54} but actually to implement IT in general. So, additionally to eMedRec sensitization, we should focus on HCPs' education and information about patient participation as well as the use of IT and its potential support to improve patient safety. However, informing and sensitizing HCPs would probably not be enough to effectively improve the use of HIT and their participation to the MedRec process. Other incentives may include decisions relative to pay for performance or pay for quality, benchmarking data, etc.

b. Both applications of the SEAMPAT ICT platform need technical improvements

Technical improvements would further improve efficiency and perceived usefulness. Table 1 includes main suggestions for technical improvements for SEAMPAT 2.0. according to patients (patient app) and HCPs (MedRec app). Another table in the "Appendixes section" proposes an agenda for further testing of both applications including suggestions for a Randomized Controlled Trial.

Table 1 : Proposed agenda for the technical improvements of SEAMPAT 2.0	
Concerning the patient app	• Make authentication easier. Allow use of the app on different supports (smartphone and tablets). • Include dispensing data coming from the community pharmacy • Focus on the disappearing of duplicated medications by improving medication identification and interoperability (SAMv2 probably helpful) • Link each medication with a picture of the pill boxes but also of the medication (during medication history taking patients are generally referring to the pharmaceutical form, shape and color of the medication) • Offer the possibility to have an overview of the complete medication list • Make alerts appear to the patient when he/she has not documented the medication status (when no answer has been given to the question: "Are you currently taking this medication?") • Add in priority the additional features asked by patients (Table 4 Chapter 4)
Concerning the MedRec app	• Make the MedRec app accessible through the usual software of the HCP • Include delivery data coming from the community pharmacy • Make the reconciled medication list directly usable in order to prescribe medication for outpatients and for inpatients (WITHOUT COPY-PASTE) and to populate the "patients' home medication list" • Couple the MedRec app to at least 4 clinical decision support systems: dosage checking/drug-drug interactions/drug-lab interactions/cheaper molecule(s) • Consider implementation of partial reconciliation (solution proposed by Tamblyn²⁶) • Consider additional "fine-tuning" (see Table 1 of Chapter 5)

c. How could we best integrate SEAMPAT 2.0 into the workflow?

No easy solution exists. Indeed, workflows are different in the primary care and in the hospital setting. Workflows also differ from one hospital to another and even between different wards in the same hospital. In addition, physicians' and pharmacists' workflow differ greatly. Therefore, each workflow will have to be studied carefully by a **time and motion study** before implementing SEAMPAT2.0. However, attention on the possibility of invoking the application at different points in the workflow should certainly be kept. Another fundamental element is avoiding duplicate work by improving interoperability and sharing information.

d. Where and how should both SEAMPAT 2.0 applications be accessible?

The patient app should be accessible through a **patient portal** and totally integrated into that portal. The patient portal should fulfil requirements deemed as essential by patients (Chapter 1, 3, 4). To support utility and functionality, patients' input should be directly usable by HCPs (without copy-paste) using their own medical softwares. The patient portal should be **consultable anywhere at any time**: at home, in waiting rooms GP/hospital, during hospitalization, at the pharmacy. Because **smartphones and tablets** have showed promising results to involve patients in their healthcare^{13,25,31-33,36,58-60}, patients should be able to consult their patient portal on both devices. The association of the patient app with a tablet application as 3S Homecare might be studied¹⁴¹. 3S Homecare offers many of the functionalities deemed as important by patients (reminders, agenda, connecting book shared with HCPs). It also presents an emergency button and records temperature, blood pressure, etc.

Concerning **the use of a Kiosk** in the waiting room of the GP, at the entrance of the hospital, or in the community pharmacy, even if Lesselroth's kiosk for MedRec was well-accepted by patients⁶¹, it should be first more thoroughly studied. Indeed, during focus groups and interviews, patients mentioned several times that a kiosk might not feel sufficiently confidential and private. Finally and yet importantly, apps should be highly **secured** and with an easy authentication system.

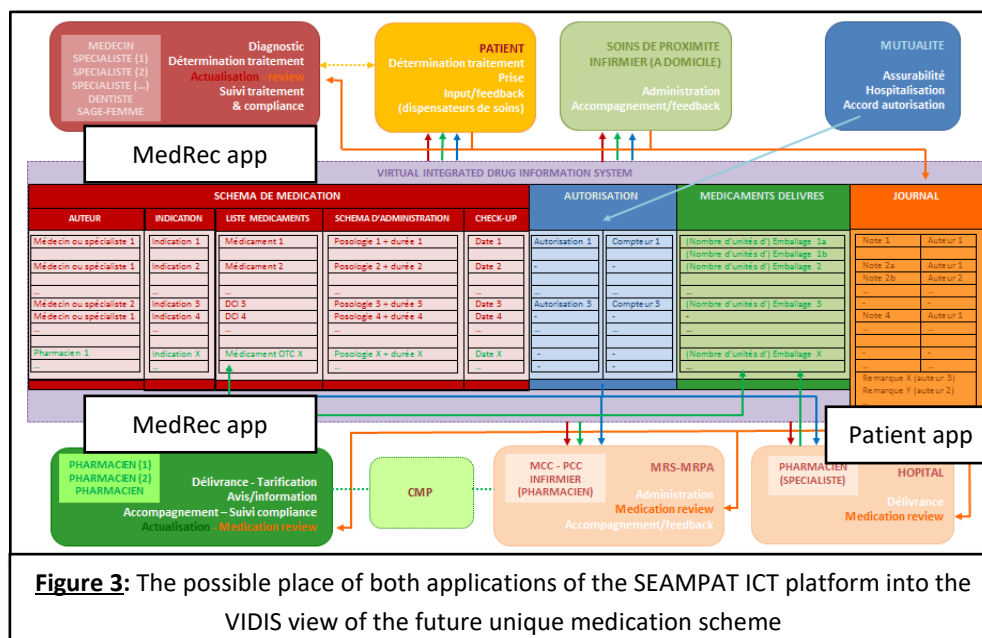
e. Which place for SEAMPAT 2.0 in the future Belgian ehealth architecture?

The SEAMPAT ICT platform has already a place in the present eHealth Belgian architecture. However, considering future evolution of Belgian's eHealth architecture (Introduction, section 5.1.b "eSante Action Plan")¹³⁹, the SEAMPAT ICT platform will have to adapt to be usable and useful for all patients and all HCPs. The roadmap of the Action Plan has pointed out 20 fields of actions. The third¹⁴², sixth¹⁴³ and tenth field of action¹³⁹ are currently under implementation and closely related to the present work.

The third field of action concerns the "medication scheme" including the **VIDIS** project. VIDIS (Virtual Integrated Drug Information System) aims to build IT rules and standards to improve interoperability between HCPs' softwares to reach a "unique medication scheme" shared by every concerned actor (patients, prescribers, pharmacists, nurses, hospitals, nursing homes). This "Medication Scheme" will be linked to the SAMv2 database as will have to be all softwares of the different actors. Because healthcare authorities foresee to pay HCPs for their contribution to the "Medication Scheme" based on **qualitative indicators**, we believe HCPs might be interested in a tool helping them to improve the quality of their input¹⁴² by facilitating the comparison of (Figure 3):

- 1) Their reference medication list (last updated list in their local software including for the hospital setting)
- 2) The VIDIS medication scheme
- 3) The medication list documented by the patient

Concerning the patient app, it could be linked to the "Journal section" of VIDIS and integrated in the personal health record (PHR) that is foreseen in the **tenth field of action** (Figure 3). Our experience with the patient app could also be considered in Flanders where the "unique medication scheme", developed by **Vitalink**, is presently visible to the patients but not modifiable. As the patient-app was designed (after a few technical modifications) it could even be directly integrated in its present state to the Vitalink platform.



Belgian authorities foresee **patients' access** to all his health data (tenth field of action)¹³⁹. We think this access is a huge step forward to improve patient safety. However, we should go further than simply “allowing access”. When looking at medical applications available on Google Play Store, more than four hundred are related to medications and more than one hundred specifically to continuity of care. Among the 24 mHealth projects selected and the 10 approved at the evaluation of October 2017 by the Belgian authorities, two^{144,145} are clearly allowing the patients to document/add information and to share their data with HCPs.

Regarding the **sixth field of action**, “**sharing to collaborate**”, the way of sharing “patients' input” is vague. Yet, results taught us HCPs' endorsement is crucial for patient participation. Therefore, we believe the patients should be able to give input that could be integrated directly and effectively by HCPs in their local softwares. Besides, improving patient safety asks also for sharing to collaborate between the patient's HCPs. Because reconciling and reviewing medication cannot be done properly if you do not know the whole patient picture – medications' indication and patients' medical history as well as current context

(medical, social,...) and patients' preferences – the entire SUMEHR should be visible to physicians but also to clinical and community pharmacists.

Instead of improving health information exchange, some countries (e.g. Estonia¹⁴⁶, Denmark¹⁴⁷) opt for a national eHealth system. Such a unique central system might be a solution to improve seamless care for the patient as it would reduce information loss. However, it might introduce new challenges (e.g. standardization of workflows and care processes throughout the country) and undesirable consequences (e.g. mismatch between local needs and national objectives)^{148,149}.

3.5. RESEARCH PERSPECTIVES

Medication continuity is essential to patient safety. Although many leading health organizations are promoting and supporting MedRec implementation for several years, healthcare institutions and HCPs are still struggling to implement effective processes¹⁰³. To improve the understanding of the challenges and to help find solutions to overcome them, we believe researchers should explore different paths.

Firstly, **the path of the most important features of an eMedRec tool**. The eMedRec tool^{15,150} should be studied to assess which features induce the highest discrepancies detection rate. Organizations with a small budget could start implementing first the most effective features.

Secondly, **the association of MedRec with other e-tools**. We are convinced by the high potential of coupling an eMedRec tool with electronic tools supporting other key elements of medication continuity. As adherence assessment is usually done when the BPMH is gathered, studying the association of eMedRec tools and applications supporting patients' adherence to medications should be investigated. Because tight integration with CPOE programs improves MedRec completions' rate²³ and thus adoption over time of eMedRec tools, we think that eMedRec tools should be studied together with CPOE and CDSS in order to improve appropriate prescribing. Two STOPP&START CDSS are currently being studied in two large European studies (SENATOR¹⁵¹ and OPERAM¹⁵²). If those ongoing studies show that CDSS reduces the number of drug-related adverse events, it will be interesting to link these with an eMedRec tool and to study the

impact on patient's safety outcomes. Other CDSS (such as drug-drug interaction detection, drug-lab interaction detection, drug-disease interaction detection) could also be evaluated with eMedRec tools. It would also be interesting to compare the clinical effects of the different CDSS, in order to understand which is to be implemented. Indeed, we should not forget the risk of alert fatigue as well as the risk of over reliance on IT^{50,102,104}.

Finally, **the path of the partner's behaviors**. We believe that the development of medical IT applications will be much more useful and reach wider adoption if the development process is thought using another perspective. We should thoroughly analyze the actual and current behavior concerning MedRec of general practitioners, of physicians specialists, of community pharmacists, of clinical pharmacist, of nurses at home, of patients. When behaviors are clearly established and when desired behavior is clearly defined, the application/tool should be adapted to tailor the required behavior changes^{153,154}.

3.6. RECOMMENDATIONS FOR POLICYMAKERS

Our results showed that it is feasible to use IT for MedRec and to include the patient in the process. However, to reach successful implementation of eMedRec in Belgium, education should be provided to every participant of the MedRec process (the HCPs and the patients). National and or regional campaigns concerning MedRec/MedRev and eHealth networks should be continued and enhanced. The benefit of patient participation in his health and more particularly in medication reconciliation could be highlighted during these campaigns. HCPs' education should concern MedRec/MedRev/Adherence, patient participation and HIT. Education should start during their graduate programs and being pursued through "les concertations medico-pharmaceutiques". Elaboration of graduate programs should be done interdisciplinary (with nurses, physicians, pharmacists, computer scientist) in collaboration between the different regions of Belgium. Some part of the program should be given by bringing students from different disciplines together.

"Les concertations medico-pharmaceutiques"¹⁵⁵ (e.g. « Vers une bonne collaboration entre le médecin généraliste et le pharmacien: disponibilité et communication ; accords concernant la prescription ; prescription sous DCI et

substitution ») could be useful to clearly define local processes between GPs and “le pharmacien de reference” to improve MedRec. The hospital sector could be highly encouraged to participate in those “concertations” as well as physician specialists working outside the hospital as they all have a role to play in the MedRec process. The patient should also have a place in the process. Additional incentives could be given to “concertations’ group” when they have defined and implemented in routine systematic processes for MedRec, for example:

- Before each programmed hospital admission.
- At hospital discharge
- Post-discharge after a visit to the GP or the PS

Additional incentives could also be given when reconciliation is associated to a medication review and a medication adherence assessment. The “pharmacien de reference” should be supported¹⁵⁶. His “patient medication schemes” should be used for reconciling medication as patients are often speaking more freely with a HCP different from their physician. Support should be given to patients bringing complete and precise information concerning their medication at hospital admission. Rewards could also be distributed to patients asking their HCPs to reconcile their medication list and patients using patient portals to manage their medications.

Finally, policymakers should continue supporting the implementation of labelled eMedRec tools. Labelled commercial softwares should be reevaluated regularly. Criteria concerning MedRec should be added to the section CPOE of the GP softwares criteria¹⁵⁷. A “core criteria” concerning a MedRec module could be added in the Belgian Meaningful Use Criteria for hospitals electronic health records¹⁵⁸. A set of mandatory functionalities in regard with box 1 of Chapter 2 could be defined for the MedRec module which should be strongly integrated into the software with high interoperability between CPOE, the national medication scheme (VIDIS) and the five ReHN.

4. WHAT THIS WORK BROUGHT TO GERIATRIC CARE AND MYSELF

4.1. GERIATRIC CARE

Older patients are a very high risk group for medication discrepancies because they suffer from multiple chronic conditions, have many medications prescribed by different doctors with variable dosages and frequencies. They are also more susceptible to “transit” across various care settings and it has been shown that unintended medication discrepancies in older patients during transition moments are common¹⁵⁹. Therefore, particular efforts should be made in this specific population towards seamless pharmaceutical care. The patient app could be of great support for frail older patients.

However, because older patients frequently have various impairments and because current elderly are not always very familiar with the use of informatics, one or multiple caregiver(s) should be allowed to use the patient app on behalf of the patient. A “framework” outlining the access, the possibility of reading and documenting the medications should be studied and defined.

Finally, we believe MedRec should be done systematically and certainly be coupled with MedRev and adherence assessment for each patient hospitalized in geriatric care. But also for older patients hospitalized outside the geriatric ward and for elderly at home.

4.2. A FEW THOUGHTS OF WHAT THIS WORK LEARNED ME

As a medical doctor, trainee in geriatrics, I particularly appreciate patients’ contacts and encounters. I am very sensitive to people’s distress and people’s hidden demand. In my work but also in my daily life with my relatives, I am trying to listen to people, trying to understand what is on their mind. Still, I think this work could never have done better than to remind me that one never can think instead of someone else. “What you think they think is most probably wrong”. I also learned that behind each patients’ action is a reason and generally a good reason that just needs to be understood and integrated to deliver better care to your patients.

I thank my colleagues and particularly the pharmacists for having shown me what exactly is rigor in your work. I discovered how much knowledge have pharmacists, how rigorous is their work and how they always think and act based on evidence. I realized that phytotherapy and OTC medications are at least as important as prescribed medications. Especially because these health products can also be responsible of important adverse events.

Finally, I have learned that adopting another position than the the physician's one when taking care of the patient could provide more information. Interviews or anamnesis need to be done questioning your patient with humility without any judgement. I cannot count the number of patients having told me "do not tell this to my doctor, I do not want to disappoint him/her". Most physicians still seem very difficult to reach for patient. Once more I have to thank the patients who have participated to SEAMPAT.

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EPILOGUE

After 10 days of hospitalization, Mrs K. recovered from her acute confusion and is again able to walk as 2 weeks before her admission. During her hospitalization, a medication review was done with the help of a trained clinical pharmacist. It is now time to think about going back home. To prepare her discharge, the geriatrician or the clinical pharmacist working on the geriatric ward could use the MedRec app available through his local software. He would reconcile the medication list of Mrs K. comparing what she was prescribed by the GP, what we learned at admission (over-the-counter medications and medications from the cardiologist) and what she was prescribed during her hospitalization. Those three lists would be compared by the geriatrician or the clinical pharmacist with support of the app. Discrepancies would be identified and resolved. Every action taken would clearly be documented. The reconciled medication list would automatically be integrated into the hospital discharge letter. A copy would be printable for the patient, the nurse at home, the community pharmacist and the GP.

After sensitization campaigns addressed to HCPs and to patients and their caregivers, the reconciled medication list makes part of the usual discharge paper at the hospital. The development of the MedRec app supports the reconciliation process and facilitates the publication of the reconciled medication list on the different eHealth Networks in Belgium. Using the patient app instead of the patient, the caregiver at home can instantly check the reconciled medication list and if needed document some changes. These modifications are then instantly available for the community pharmacist who delivers the medications and if required uses the MedRec app to document some changes (for example, switch from generic to brand). Afterwards, when the GP visits Mrs K. at home he once again opens the MedRec app and sees every modification done to the medications list since the hospital discharge. Keeping the pieces of the puzzle together by regularly reconciling medications will hopefully prevent Mrs K of being hospitalized.

Appendixes

1. APPENDIX OF THE INTRODUCTION

The 9 work packages of the SEAMPAT project	
WKP 1	Patient participation: state of the art and needs analysis
WKP2	Patient application: specifications, architecture and development
WKP3	Patient application: impact evaluation
WKP4	MedRec application: state of the art and needs analysis
WKP5	MedRec application: specifications, architecture and development
WKP6	Integration of both applications
WKP7	MedRec application: impact evaluation Evaluation of both applications together
WKP8	Legal, sociological, ethical analysis
WKP9	Communication and dissemination activities

2. APPENDICES OF THE CHAPTER 1

2.1. APPENDIX I:

Concepts	Mots-clés
Réconciliation médicamenteuse	MEDICATION+ S RECONCIL+
Encondage électronique du patient	PERSON?AL+ S HEALTH+ S RECORD+, MEDICATION+ S HISTOR??? S GATHER+, MEDICATION+ S LIST+, MEDICATION+ S KIOSK+
Électronique	+ELECTRONI+
Auteurs	Sociétés
Blake Lesselroth	/
Katie Siek	
Slagle	

2.2. APPENDIX II

Table 3 : Research strategy, MeSH terms and free text related to 3 topics, combined with an “AND”		
(1) Information Technology (IT)	(2) Medication reconciliation	(3) Patient participation
"Medical Records Systems, Computerized"[Mesh] OR "Electronic Health Records"[Mesh] OR "Wireless Technology"[Mesh] OR "User-Computer Interface"[Mesh] OR "Text Messaging"[Mesh] OR "Electronic"[Title/Abstract] OR "Electronics"[Title/Abstract] OR "user-computer interface"[All fields] OR "medical records"[Title/Abstract] OR "medical record"[Title/Abstract]	"Continuity of Patient Care"[MeSH Terms] OR "Medication reconciliation"[all fields] OR Reconciliation[Title/Abstract] OR (((((((medication[Title/abstract]) OR medications[Title/abstract]) OR medicated[Title/abstract]) OR medicine[Title/abstract]) OR medicines[Title/abstract]) AND reconcil*[Title]))	"patient engagement"[Title/Abstract] OR "engaging patients"[Title/Abstract] OR "engaging patient"[Title/Abstract] OR "patient engage"[Title/Abstract] OR "patients engagement"[Title/Abstract] OR "patient involvement"[Title/Abstract] OR "patient involved"[Title/Abstract] OR "patients involved"[Title/Abstract] OR "patients involvement"[Title/Abstract] OR "Patient participation"[MeSH Terms] OR "Patient centered-care"[MeSH Terms]

3. APPENDIXES OF THE CHAPTER 2

3.1. APPENDIX I: PUBMED SEARCH STRATEGY (28 10 2014)

Theme IT

1. "Medical Records Systems, Computerized"[Mesh]
2. "Electronic Health Records"[Mesh]
3. "Wireless Technology"[Mesh]
4. "User-Computer Interface"[Mesh]
5. "Text Messaging"[Mesh]
6. "Patient Discharge/methods"[Mesh]
7. "Patient Discharge/organization and administration"[Mesh]
8. "Patient Discharge/standards"[Mesh]
9. #1 to #8 OR ((((((("Medical Records Systems, Computerized"[Mesh] OR "Electronic Health Records"[Mesh]) OR "Wireless Technology"[Mesh]) OR "User-Computer Interface"[Mesh]) OR "Text Messaging"[Mesh]) OR "Patient Discharge/methods"[Mesh]) OR "Patient Discharge/organization and administration"[Mesh]) OR "Patient Discharge/standards"[Mesh])
10. electronic tool[title/abstract] AND (all[sb] NOT MEDLINE[sb])
11. "electronic device"[title/abstract] AND (all[sb] NOT MEDLINE[sb])
12. Electronic design
13. "Electronic"[Title/Abstract] OR "Electronics"[Title/Abstract]
14. (((("Electronic"[Title/Abstract]) OR "Electronics"[Title/Abstract]) AND (all[sb] NOT MEDLINE[sb]))
15. ((((((("Electronic"[Title/Abstract]) OR "Electronics"[Title/Abstract]) AND (all[sb] NOT MEDLINE[sb])))) AND reconciliation
16. "User-Computer Interface"
17. "User-Computer Interface" AND (all[sb] NOT MEDLINE[sb])
18. "medical record""[Title/Abstract] OR "medical records""[Title/Abstract]

-
19. ("medical record system" OR "medical records system") AND (all[sb] NOT MEDLINE[sb])
 20. #1 OR.... until #8 OR #13 OR #16 OR #18
-
- ((((((((((("Medical Records Systems, Computerized"[Mesh]) OR "Electronic Health Records"[Mesh]) OR "Wireless Technology"[Mesh]) OR "User-Computer Interface"[Mesh]) OR "Text Messaging"[Mesh]) OR "Patient Discharge/methods"[Mesh]) OR "Patient Discharge/organization and administration"[Mesh]) OR "Patient Discharge/standards"[Mesh]) OR "Electronic"[Title/Abstract]) OR "Electronics"[Title/Abstract]) OR "user-computer interface"[All fields]) OR medical records[Title/Abstract]) OR medical record [Title/Abstract]

Theme "Continuity of Care"

21. "Medication reconciliation"[all fields]
 22. Reconciliation[title/abstract]
 23. Reconciliation[Title/Abstract] OR "medication reconciliation"[all fields]
 24. "Primary Health Care"[Mesh]
 25. "Primary Health Care"[Mesh] and "medication reconciliation"
 26. "Primary Health Care"[Mesh] AND #20
 27. "Primary Health Care"[Mesh] NOT ((reconciliation[Title/Abstract]) OR "medication reconciliation"[all fields])
 28. # 25 AND #20
 29. "Continuity of Patient Care"[Mesh]
 30. #29 NOT #23
 31. #30 AND #20
- ("Continuity of Patient Care"[MeSH Terms] NOT ("Medication reconciliation" OR Reconciliation[Title/Abstract])) AND (((((((((((("Medical Records Systems, Computerized"[Mesh]) OR "Electronic Health Records"[Mesh]) OR "Wireless Technology"[Mesh]) OR "User-Computer Interface"[Mesh]) OR "Text Messaging"[Mesh]) OR "Patient Discharge/methods"[Mesh]) OR "Patient

- Discharge/organization and administration"[Mesh]) OR "Patient Discharge/standards"[Mesh]) OR "Electronic"[Title/Abstract]) OR "Electronics"[Title/Abstract]) OR "user-computer interface"[All fields]) OR "medical records"[Title/Abstract]) OR "medical record"[Title/Abstract])
32. #29_AND #20
33. #29_AND #1
34. #21 OR #22 OR #29 = (("Continuity of Patient Care"[MeSH Terms]) OR "Medication reconciliation") OR Reconciliation[Title/Abstract]

Conclusion 28/10/2014:

((("Continuity of Patient Care"[MeSH Terms]) OR "Medication reconciliation") OR reconciliation[Title/Abstract]) OR (((((((medication[Title/abstract]) OR medications[Title/abstract]) OR medicated[Title/abstract]) OR medicine[Title/abstract]) OR medicines[Title/abstract]) AND reconcil*[Title/abstract]))

AND

1166 articles

3.2. APPENDIX II: DATA EXTRACTION FORM

Legend:

1. *Elements in italic bleu* : delete as appropriate
2. *Elements in italic grey* : examples to help complete the form
3. X (=present)/0 (=absent)/F (=foreseen)

The yellow color of the table means this is an important factor for a successful implementation (see lessons learned for eMedRec implementation, ISMP, Canada)
The purple color Quality criteria evaluation inspired on the article of Goldzweig

Paper attributed number:

1. GENERAL INFORMATION

Publication date	
ID of person extracting data	

Appendixes

Report title (<i>title of paper/ abstract/ report</i>)	
Report author contact details	
Study funding source (<i>including role of funders</i>) and financial status if mentioned	
Possible conflicts of interest (<i>for study authors</i>)	
Notes:	

2. CONTEXTUAL INFORMATION

Setting of development/ implementation of the tool	Country		
	Academic + size	YES/NO	
	Point of investigation	Preadmission/admission/transfer inside hospital/discharge/post-discharge/outpatient Other:	
	Network (describe)		
	Setting and "Partnership" between who and who	For which patient is the tool designed?	
		For which professional is the tool designed?	
		Where can you find the tool? (Consultation, hospitalization, both,...)	
Which phase of the project is reached as	Piloting/design development in progress (e.g. Tamblin) - describe		

described in the paper?	Evaluation/Routine use <i>(e.g. Poon 2006) - describe</i>		
Length of study (as stated by the authors)			
Information about patient safety culture, teamwork and leadership	YES/NO	Past information technology experience	YES/NO
External factors	Regulatory requirements: YES/NO Presence in the external environment of payments or penalties such as pay-for-performance or public reporting: YES/NO		
Description of the Contexts	<i>Describes ≥ 3 domains // Describes 2 domains // Describes 1 or 0 domains</i> - size, location or academic status - financial status, or past information technology experience - information about culture, teamwork and leadership - existing of external factors		

3. DESCRIPTION OF THE TOOL

Evaluation of the workflow before starting the project?	YES/NO			
Workflow	a. Actors involved in the use of the tool and their responsibilities if it is defined	YES/NO	Actors involved	Responsibilities defined and exact role given
			Patient: active (encoding his treatment)/passive (answering questions/carrying his drugs)	
			Family/caregiver	
			Nurse	
			Pharmacist	
			Physician : GP	
			Physician : Specialist	
			Research assistant	
		Other:		
		If responsibilities are defined, are their different steps defined for the medication reconciliation process and are those steps systematically the same? YES/NO		
b. IT landscape – to		Electronic prescription associated/CPOE (describe)		
		EMR associated or EHR (describe)		

Coding medication data	which other system is the tool linked?		Automatic link to an EXTERNAL drug database with full information about drugs and possible <i>automatic or manual</i> substitution of the drug name to the brand or generic name and vice-versa
			Pharmacy claim or pharmacy dispensing data (officinal pharmacy)
			Electronic administrative data associated
			Communication with other providers
			Other:
	c. Structured?		Fully structured
			Fully structured + possibility to have free text for comments
			Hybrid system
	d. Drug regimen detail available (in free text or structured)		Drug name
			Drug dosage
			Drug frequency administration
			Route administration
			Administration method
			Allergies/intolerances - <i>with/without</i> – description
			Indication/diagnosis
			Prescription date
			Purchase date
			Drug state (active/expired/discontinued)
			Prescriber's name
			Drug information's source (pharmacist DB, patient input, hospital's ER,)

		What happen if the information about each medication is not available in all the different lists? Did they think a solution to match those lists' information?		<i>If yes, describe :</i>					
	e. To make it easy		Recognized different terms used for the same medicament						
			When typing the first letters of a drug, the system suggests different names						
			Free voice text						
			Pictures of the medication						
			Tools that can take pictures						
Identification of medication discrepancies	f. How many lists are used to obtain the BPMH?								
	g. Whose lists are compared?	YES/NO	Whose list?	PA	A	Transfer	Disch	P-D	Outpatient
	h. When are they compared?		Primary care : pharmacist dispensing data						
	i. Which list is used systematically and		Primary care: GP EMR						
			Primary care: GP prescription issued						

	which one is used optionally (S/O = systematic/optionally)?		Primary care: other						
			Secondary care: specialist physician, list in EMR + <i>describe</i>						
			Secondary care: specialist physician, prescription issued (CPOE) + <i>describe</i>						
			Secondary care: other						
		Non electronic source:							
	j. Are those lists electronically interoperable?	<i>FULLY/PARTIALLY/Not described</i> Describe if possible							
	k. Lists presented side by side?	<i>YES/NO</i>							
	l. Filters for organization and/or	✓ <i>Only 1 manner to organize the medication lists/More than one "filter" to organize the medication list</i>							
✓ Classification items									
Drug classes				Initiation datum					

	categorization drugs		Drug indication		Stop datum
			Brand name		Suspended medication
			Generic name		Other:
			Prescriber's name		
	m. To facilitate the discrepancies identification and the comparison?		Existing of a timeline to present stopped medication information into eBPMH?		
			Reason for stopping or modifying the medication recorded?		
			Ability to move electronic sources of medication information into a eBPMH		
			Ability to add new medication into the eBPMH based on other sources (non-electronic) of information		
			Ability to update the medication list at any time		
			Automatically identify a patient at high risk for medication problems (eg. based on the number or classes of mdc or changes or...)		
			Displays dates prescribed/ordered as appropriate for each source		
			Highlight differences in doses frequencies, routes and formulations for each medication		
	n. Specific features		- w or w/o proposals for correction - w/ or w/o validation of the correction proposed <i>Describe :</i>		
			Automatic reconciliation for identical drugs		
			Red flags/alarming symptoms		
			Patient counseling		
			Medication Information (adverse events, pharmacokinetics, pharmacodynamics,...)		
			Track compliance/therapeutic adherence		

Components of the eMedRec intervention	o. What?		Other :
			Continue
			Stop/discontinue
			Modify/substitute
			Add
			Undecided button/unable to verify
	p. Specific features	Existing of alerts/reminders/mandatory for eMedRec for providers : <i>YES/NO</i>	
			Review appropriateness of medication
			Post-discharge communication with patient (email/printed list)
			Communication content: list with or without explanation about changes
			Possibility to reconcile only part of the medication list (<i>some specialists may only reconcile a part the medications they want to prescribe > eg rheumatologist and methotrexate</i>) > with possibilities to delay the full eMedRec)
			Decision support functionality (not specifically related to medication, e.g. decision to admit a patient, decision to define a level of care, automatic detection of drug-drug interaction, computer-assisted diagnosis, disease treatment and management,...)
			When reconciliation done, medication regimen presented differently for the different users according to the needs of each (physician, patient, pharmacist,...)
			Section for drug event report via email
			Other :
Staff education	<i>YES/NO</i>		
	- Who was conducting the training?		

	- Who they trained?	
	- What kind of training was provided?	
	- In what format?	
	- For how long?	
	- And how the training was expected to affect the specific behaviors of those trained?	
Incentives to motivate medical staff and/or patients	YES/NO (barriers and facilitators) <i>Describe,</i>	
Description of the system	Adequate (3 points described)// Partial (2 points described)// Insufficient (1 or 0 point described) <i>Measuring implementation process and how the context influences the process</i> - functionalities included described - what/how the system interfaces with the EMR (+/- response time) - what is required for the consumer to operate it	

Description of Implementation	<i>≥ 2 components beyond “staff education” // ≥ 1 component beyond “staff education” // Nothing beyond “staff education”</i> <i>Other possible components: barriers and facilitators description, tailoring or change management, dedicated time for feedback +/- measuring, key stakeholders/individuals responsible for implementation, assessing the impact on the workflow, measuring of users performance,</i> See : file:///C:/Users/mariens/Downloads/EDS-Evaluation-Final-Report-August-2011.pdf + Shekele (ref 5 Goldzweig), Agency for Healthcare Research and Quality + http://www.effectivehealthcare.ahrq.gov/ehc/products/60/318/CER-Methods-Guide-140109.pdf

4. EVALUATION OF THE TOOL

Focus of the evaluation <i>(described in the paper)</i>	
Study Design	✓ Quality improvement project
	CQI/PDCA (Plan-Do-Check-Act) List precise design:
	✓ Effectiveness studies
	RCT
	(quasi-)Experimental (more control over the intervention but less over the confounding factor)

	Control group List precise design: (<i>Retrospective cohort, case-control, pre-post, cross-sectional, case-report...</i>)		
	Observational (longitudinal) studies (implementation of the intervention is observed over time) and ideally prospective		
Study Sample	Which users are/were included in the study/ies?		Number of “participants” included in the evaluation? <i>What was evaluated through their participation? (IT considerations – RCT - ...)</i>
	Physician/Physician resident		
	Pharmacist/pharma resident		
	Nurse		
	Patient		
	Caregiver		
	Other:		
	Patient representative of a national or large regional (multistate) population		
	Patient representative of a smaller geographic population or a specific clinical population at the national or large regional level		
	Selected sample, such as that in a specific clinical setting or enrolled in a randomized trial		
	Response/participation rate : <i>≥80% // ≥60% but < 80% // <60% or not stated // Not Applicable</i>		
Usability evaluated	✓ Use of different prototype? YES/NO If yes, how many?		

and prototype evolution	✓ Usability evaluated? <i>YES/NO</i>	
	What has been evaluated?	
	Who has it been evaluated? (FG, interview, observation, feedback sessions...)	
	✓ Users' suggestions about usability :	
Additional components of the intervention	Feed-back to users? <i>YES/NO</i> Describe : <i>(E.g. educational sessions, audit + feedback, workflow modifications...)</i>	
Process measures (e.g. only 70% of the patients had a PAML build)		
Outcomes		Describe

	Clinical impact of medication reconciliation evaluated? YES/NO (Discrepancies, readmissions < 30 days, post-discharge emergency visits...)	
	Evaluation of users' satisfaction? YES/NO Quantitative evaluation? Qualitative evaluation?	
	Other : (Time saving...)	

5. OTHER INFORMATION

	Description as stated in report/paper	Location in text (pg. & ¶/fig/table)
Key conclusions of the study authors		

Appendixes

Main counselling of the study authors		
Main perspectives as stated by the authors <i>(in terms of development and evaluation)</i>		
References to other relevant studies		
Correspondence required and asked for further study information <i>(what and from whom)</i>		

Correspondence received (<i>from whom, what and when</i>)	
Notes:	

3.3. APPENDIX III (ONLY FOR EDITORS): DESCRIPTION OF THE CONTEXT, SYSTEM AND IMPLEMENTATION OF COMMERCIALY AVAILABLE E-MEDREC TOOLS.

Description of the context, system, implementation and presence of ideal features of commercially available e-MedRec tools			
Company and/or Product	Context	System	Implementation

Appendixes

	Patient Portal linked to EHR?	MedRec Tool?	Integrated in the workflow?	Linked to other electronic systems?	Automatic highlighting of discrepancies?	Reason for stopping medication written?	Different possibilities to organize medication lists?	e-MedRec, process with reminder or mandatory?	Other specific features associated with Use of different notations?	Existing of a patent?	Routine use?	Point of investigation?	
EPIC	Lucy	own tool	+	+	+	+	+	only on discharge	+	?	1	we suppose every tool is used in routine	A/T/D
CERNER	Cerner Patient Portal	own tool Cerner Medication History	+	+	+	?	+	?	+	?	3		A/T/D
MCKESSON	MyCarePlu s	IntegrateRx MedRec RelayHealth	+	+	?	?	?	?	+	?	not found		?
ALLSCRIPT	Follow Myhealth	HCS Med Rec tool from HCS clinical Solution	NOT APPLICABLE										

MEDITECH	MEDITECH's web-based Patient and Consumer Health Portal	own tool MEDITECH's comprehensive medication reconciliation	+	+	+	?	?	?	+	?	not found	we suppose every tool is used in routine	?
NEXTGEN	NextGen Patient Portal	own tool	+	+	?	?	?	?	+	?	not found		?
HEALTHLAND	InteliChart Patient Portal	RCOPIA ACUTE CARE - Dr First or PDRX - latric or ExitCare - Elsevier	NOT APPLICABLE										
COMPUTER PROGRAMS & SYSTEM, Inc	?	Trubridge	+	+	?	?	?	?	+	?	not found	we suppose every	?

Appendixes

SIEMENS	?	INVISION MedsConnect	+	+	most probabl y not	most probabl y not	most probabl y not	-	+	?	2	tool is used in routine	A/T/ D
ECLINICALWORKS	?	Exit-Writer (Krames- staywell)	NOT APPLICABLE										
CARE360	MyQuest Patient Portal	?	INFORMATION NOT FOUND ON THE WEBSITE and NO ANSWER RECEIVED										
GREENWAY (the only ones who filled in the template)	Greenway Health's patient portal		+	+	+	-	-	-	+	-	?	we suppos e every tool is used in routine	A/T/ D
First Databank	?	fdb MedsTracker	+	+	?	?	?	?	+	?	not foun d		A/T/ D
RCOPIA ACUTE CARE Dr First	?	Meditech Healthland	+	+	?	?	?	?	+	?	Not foun d		?
EXIT-WRITER Krames staywell	?	Allscripts - Cerner - EpicCare - MediTech -	+	+	?	?	?	?	+	?	Not foun d		?

		eClinicalWorks											
PDRX Iatric	?	Meditech - MedHost - Siemens - McKesson - CPSI - EpicCare - Cerner - Healthland	+	+	+	+	+	?	+	?	Not found		?
HCS Med Rec HCS Clinical Solutions	?	Allscript	+	+	?	?	?	?	+	?	Not found		T/D
ExitMeds Med Rec Exitcare - Elsevier	ExitCare OnCall®	Healthland	+	+	?	?	?	?	+	?	Not found		?
RxReconcile Healthtek (no access to the rxreconcile.com website from Belgium - information gathered only from the MARQUIS toolkit)	?	integrates with existing clinical systems	+	+	+	?	+	?	+	?	Not found		?

Appendixes

MediREC Mediware	?	with major health information system	+	+	?	?	+	?	+	?	2		A/T/ D

Abbreviations: A= Admission, D = Discharge, eMedRec = electronic medication reconciliation; EMR = electronic medical record;
T= Transfer; + = PRESENT; - = NOT PRESENT; ? = DOUBT

4. APPENDIXES CHAPTER 3

4.1. APPENDIX I

QUESTIONNAIRE MEDECINS GENERALISTES

A. Situation actuelle

1. Dans quelle mesure la réconciliation médicamenteuse vous concerne-t-elle ? Quelle est la proportion de patients qui ont des incohérences/erreurs dans leur liste de médicaments à prendre ?
2. Sous quelle forme vos patients gardent-ils trace de leur liste de médicaments et des changements effectués ?
3. Comment les aidez-vous à mettre de l'ordre dans cette liste et comment les encouragez-vous à procéder pour que des incohérences/erreurs ne se reproduisent plus (ou dans une moindre mesure) ?
4. Y a-t-il une catégorie de patients plus à risque ? Si oui, comment agissez-vous avec eux ?
5. De votre côté, dans quelle mesure pensez-vous que vous disposé d'une information exhaustive et correcte ? Autrement dit, quelle est la fréquence (approximative) des incohérences ?
6. Les patients sont-ils « transparents » par rapport à leur traitement ? Osent-ils vous dire lorsqu'ils ont arrêté un traitement de manière volontaire ? (Sans doute difficile à estimer). Mentionnent-ils les traitements de comptoir ? Le « shopping médical » et les modifications de traitements faites par des spécialistes qu'ils ont consultés sans vous en parler ?
7. Une fois cette information recueillie, comment gardez-vous une trace de celle-ci ?

B. Solution à développer

1. Quelle serait « votre » solution idéale ? pour diminuer les discordances/erreurs médicamenteuses ? ? Sous quelle forme se présente-t-elle ?
2. Quel rôle vous voyez-vous jouer dans une solution informatisée de réconciliation médicamenteuse ?
3. Quelle est la personne qui est la plus à même de collecter cette information ?
4. Quels obstacles voyez-vous à la mise en place d'un tel système ?

- i. En ce qui vous concerne ?
 - ii. En ce qui concerne le patient ?
 - iii. En ce qui concerne les hôpitaux ?
 - iv. En ce qui concerne d'autres intervenants ? Lesquels ?
- 5. Au contraire, quels seraient les avantages d'une telle solution pour les acteurs susmentionnés ? En particulier pour vous ?
- 6. Avez-vous connaissance d'une telle solution mise en place ailleurs? Ou à l'étude ?
- 7. L'encodage dans le système informatique :
 - i. De quelle manière imaginé vous l'encodage du patient ?
 - 1. Patient modifie directement le schéma de médication présent dans le système, comme une sorte de mise à jour des données avec une possibilité de voir qui a fait les dernières mises à jour ?
 - 2. Patient encode son traitement dans une « nouvelle fenêtre » qui lui est propre. L'encodage pouvant se faire en texte libre ou par « cochage » (sera discuté avec les patients). Et alors, lors de la réconciliation médicamenteuse, le professionnel de la santé, voit la fenêtre du patient et la fenêtre contenant le dernier schéma de médication encodé dans le système. Le professionnel réconcilie alors le traitement.
 - ii. Après encodage, qui pourrait avoir accès à cette information ?
 - iii. Qui serait autorisé à la mettre à jour ?
- 8. Le patient peut-il remplir ces données seul (moyennant validation) ?(l'assistance d'un professionnel est-elle toujours requise ?)
- 9. Quelle information l'outil doit-il vous fournir? (nom du médicament, molécule, fréquence de prise, date de première prescription, prescripteur,...)
- 10. Outre la réconciliation médicamenteuse, quelles autres fonctions cet outil pourrait-il remplir ?

QUESTIONNAIRE PATIENTS

A. Introduction.

Ce focus group se situe dans le cadre du projet « Seampat » qui a pour objectif de définir et de mettre en œuvre un processus électronique de réconciliation médicamenteuse dans lequel le patient participe activement à fournir de l'information concernant ses traitements médicamenteux. Le but final est de produire un prototype de plate-forme de réconciliation médicamenteuse qui englobe une application pour le patient permettant l'encodage de ses traitements médicamenteux et un module de réconciliation médicamenteuse pour permettre la comparaison des données encodées par le patient avec celles encodées par d'autres professionnels de la santé.

Nous sommes dans la première phase du projet qui vise à récolter un maximum d'information quant au type d'outil attendu et au type d'outil qui serait facilement et volontiers utilisé par les professionnels de la santé (médecins, pharmaciens,...) et les patients. Pour cette raison, différents focus groups et interviews de patients, de médecins généralistes, de médecins spécialistes, de pharmaciens cliniciens et de pharmaciens d'officines sont organisés.

Le but de ce focus group est donc de discuter avec vous en vue de mieux comprendre votre expérience actuelle en ce qui concerne la réconciliation médicamenteuse, votre sentiment par rapport à un outil informatique relatif à cette problématique, vos besoins,... Nous avons une liste de questions que nous aimerions aborder avec vous au cours des deux prochaines heures. Celles-ci serviront surtout à guider le focus group mais nous sommes ouverts à toute autre question.

B. Situation actuelle

1. Comment faites-vous à l'heure actuelle lorsqu'une liste de vos médicaments vous est demandée ?
 - i. Connaissez-vous par cœur la liste de vos médicaments (nom, posologie, prescripteur, raison,...) ?
 - ii. L'aide d'un tiers (ex. personnel médical) est-elle requise ?

- iii. Gardez-vous une trace écrite/physique (ex. pilulier) de cette liste? Utilisez-vous des moyens mnémotechniques ?
- 2. Dans le sens inverse, lorsque vous quittez l'hôpital, la liste des médicaments à prendre est-elle claire pour vous ?
 - i. Une telle liste « physique » vous est-elle fournie par le médecin/pharmacien ?
 - ii. Si pas, sous quelle forme vous est donné la liste ?
 - iii. L'information fournie est-elle claire pour vous ?
- 3. De manière générale avez-vous l'impression de prendre tous vos médicaments en temps et en heure? (sur une échelle de 1 à 10)
- 4. Avez-vous déjà fait face à une situation dans laquelle votre liste de médication ne correspondait pas à celle du médecin ? Si oui, quelle a été votre réaction ? Comment expliquez-vous ces possibles discordances ?
- 5. Selon vous, qu'est-ce qui pourrait contribuer à améliorer l'exactitude de votre traitement ?
- 6. Dans quel contexte une liste de vos médicaments vous est-elle demandée ? (pharmacie, généraliste, hôpital,...)
- 7. A quelle fréquence votre liste de médicament évolue-t-elle ? Cette liste de médicament est-elle fréquemment revue et modifiée par les médecins et/ou pharmaciens ? A combien par semaine évaluez-vous le nombre de changements qui sont faits ?

C. Solution à développer

- 1. Que pensez-vous d'une solution informatique qui permettrait de mieux gérer et consolider l'information relative à vos médicaments ?
 - i. Quelles sont vos craintes vis-à-vis d'une solution informatisée ?
 - ii. Au contraire, qu'est-ce qui vous rassurerait dans une telle approche ?
 - iii. Qu'est-ce qui vous inciterait à utiliser un outil informatique ?
- 2. Quelle serait « votre » solution idéale ? Sous quelle forme se présente-t-elle ?
- 3. Donnez votre avis sur les solutions suivantes:

-
- i. Encoder votre liste de médicaments seul à la maison avant une consultation ou une hospitalisation programmée ?
 - ii. Encodage seul à l'hôpital avant un rendez-vous ?
 - iii. Idem points i et ii mais assisté de personnel médical ?
 - iv. Voyez-vous d'autres possibilités ?
 4. Quelle est la personne qui connaît le mieux votre suivi médicamenteux et qui serait la plus à même de vous accompagner dans cette tâche ? En d'autres termes, avec qui seriez-vous le plus rassuré d'encoder de telles informations (votre médecin traitant, votre pharmacien, un médecin spécialiste, l'infirmière du domicile, un de vos enfants/petits-enfants/proche,seul) ?
 5. De quel œil voyez-vous une responsabilisation accrue dans la réconciliation de vos médicaments ?
 6. Si on suppose qu'une telle solution est mise en place :
 - i. Quelle serait la plateforme idéale : un ordinateur, un smartphone, une tablette, un écran tactile,... ?
 - ii. Oseriez-vous indiquer qu'une information à disposition du logiciel (et donc du médecin) est erronée ou auriez-vous peur de le contredire ?
 - iii. Quel flux vous semble le plus approprié :
 1. Le logiciel vous fournit une liste de médicaments dont il a connaissance et, dans cette liste, vous confirmez les médicaments correctement inscrits, corrigez les erreurs et ajoutez les éléments manquants
 2. Vous partez de zéro et indiquez vous-même l'ensemble des médicaments que vous prenez. Cette information est ensuite confrontée aux données disponibles dans le logiciel.
 3. Ou peut-être auriez-vous une idée basée sur votre manière actuelle de procéder ?
 - iv. Quels aides visuelles pourraient faciliter l'élaboration de la liste des médicaments dans ce logiciel ? (ex : photos des médicaments, photos des boîtes, explication du rôle du

médicament, suggestions de médicaments commençant par les premières lettres tapées, encodage basé sur les différents moments de la journée,...)

7. De manière générale, quelles sont vos attentes par rapport à un tel système ?
8. Est-ce qu'un tel logiciel pourrait remplir d'autres rôles qui faciliteraient votre suivi médical ? Par exemple, une fois votre schéma de médication encodé et validé, serait-il intéressant pour vous d'en recevoir une copie ? Si oui, sous quelle forme ? Par exemple, gestion de l'agenda ? Par exemple, des alertes avec les symptômes à suivre (effets secondaires de certains médicaments) ?
9. Avec qui seriez-vous prêts à partager cette information ? (ex. uniquement le médecin chez lequel vous aviez rendez-vous, votre médecin généraliste, un hôpital en particulier, l'ensemble des hôpitaux, votre pharmacien, l'ensemble des pharmaciens,...)

4.2. APPENDIX II

Table 1: Detailed list of functional requirements concerning			
The patient app		The MedRec app	
1F	Authentification des patients	1F	Authentification des professionnels de la santé
2F	Informations médicamenteuses à afficher	2F	Affichage des informations médicamenteuses
		2.1F	Information médicamenteuse à afficher
2.1F	Initialisation des données	2.2F	Historique d'un médicament
2.1.1F	Importation des données relatives à la liste de médicaments à partir du SUMEHR d'un patient	2.2.1F	Données de contact
2.1.2F	Importation des données relatives à la liste de médicaments à partir du DPP	2.3F	Arrêts et modifications

	<i>d'un patient</i>		
2.1.3F	<i>Importation des données relatives à la liste de médicaments à partir du DMIh d'un patient</i>	2.4F	Import des données
2.1.4F	<i>Importation des données relatives à la liste de médicaments précédemment encodée par le patient à partir du RSW</i>	2.4.1F	<i>Import des données relatives à la liste de médicaments à partir du SUMEHR d'un patient</i>
		2.4.2F	<i>Import des données relatives à la liste de médicaments à partir du PCDH d'un patient</i>
2.2F	Récupération des informations médicamenteuses	2.4.3F	<i>Import des données relatives à la liste de médicaments à partir du DMIh d'un patient</i>
2.2.1F	<i>Affichage des photos des médicaments</i>	2.4.4F	<i>Import des données relatives à la liste de médicaments validée par le patient</i>
		2.5F	Tri de la liste de médicaments
3F	Information médicamenteuse à collecter	3F	Réconciliation médicamenteuse
3.1F	Information complémentaire pour les médicaments non pris	3.1F	Processus de réconciliation
3.2F	Information complémentaire à collecter (allergies)	3.2F	Sources pour la réconciliation
3.3F	Médicaments obtenus sans ordonnance	3.3F	Mise en évidence des discordances
4F	Gestion de l'information par le patient	3.4F	Liste réconciliée
4.1F	Validation de la liste de médicaments par le patient	3.4.1F	<i>Copie d'un médicament dans la liste réconciliée</i>
4.2F	Indication de doutes par rapport à un médicament	3.4.2F	<i>Edition d'un médicament</i>

4.3F	Modification de la liste de médicaments par le patient	3.4.3F	<i>Ajout d'un médicament</i>
4.4F	Ajout de médicaments par le patient	3.4.4F	<i>Suppression d'un médicament</i>
4.4.1F	<i>Encodage de l'information médicamenteuse via un clavier</i>	3.4.5F	<i>Indication d'un doute</i>
4.4.1.1F	<i>Mécanisme d'auto-complétion</i>	3.4.6F	<i>Justification de réconciliation</i>
4.4.2F	<i>Encodage de l'information médicamenteuse via un code-barres</i>	3.5F	Réconciliation partielle
4.5F	Récapitulatif des informations encodées		
4.6F	Vérification de la complétude		
4.7F	Encodage des formes galéniques		
4.8F	Vérification de la correspondance forme galénique/médicaments encodés		
4.9F	Exportation des données relatives à la liste de médicaments sur le RSW		
5F	Fonctionnalités additionnelles	4F	Intégration de l'application de réconciliation
5.1F	Affichage du schéma de médication	4.1F	Export de la réconciliation
5.2F	Exclusion des notices, effets secondaires et interactions		
6F	Mécanisme d'aide intégré à l'application	5F	Mécanisme d'aide intégré à l'application

Table 2: Detailed list of NON-functional requirements concerning the patient app and the MedRec app

1NF	Structure de l'interface	1NF	Structure de l'interface
2NF	Aspect visuel proche des applications existantes	2NF	Flux de traitement du patient
		2.1NF	Disponibilité de l'application
3NF	Supports informatiques	3NF	Supports informatiques
4NF	Faible apprentissage requis	4NF	Apprentissage
5NF	Facilité d'utilisation	5NF	Interactivité
6NF	Explication du rôle du patient	6NF	Attention des utilisateurs
7NF	Feedback en fin de processus	7NF	Facilité d'utilisation
8NF	Etat d'avancement	8NF	Motivation des patients

Table 3: Detailed list of requirements concerning the patient app and the MedRec app in the "waiting room".

1SA	Carnet de suivi de pathologie chronique (ex : diabète, anticoagulation,...)	1SA	Détection d'interactions entre les médicaments d'un patient
2SA	Agenda de prise de médicaments et de rendez-vous (avec rappels)	2SA	Signalisation de fin de boîte de médicaments (renouvellement)
3SA	Carnet de communication		

5. APPENDIXES CHAPTER 4

5.1. APPENDIX I:

Appendix 1: Additional Table 1: Concepts evaluated, definitions and methods of measurements			
Concept	Definitions	Measurements performed/ data collected	
		Quantitative data	Qualitative data
1. Usability	Usability was defined according to ISO 9241-11 as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use[1].	Assessed through the System Usability Scale (SUS) questionnaire	Qualitative data were collected concerning usability (including satisfaction, effectiveness and efficiency) and usefulness. Data were collected at the start of the study, during the study and at the end of the study. This was done through:
a. Satisfaction	Satisfaction: The positive associations and absence of discontent that user experience during the performance[1]. ⇒ How satisfied is the patient with the tool?	Assessed through the SUS questionnaire	
b. Effectiveness	Effectiveness: To what extent the user can achieve a goal with accuracy and completeness[1].	Assessed through the SUS questionnaire	

	⇒ How complete and correct is the patient medication list?		- Semi-structured interviews (end of the study) - Observations of patients using the patient app (at study start, and during the study). Research took written notes. No video recording was performed. - Comments and questions raised by patients (during the study)
- Completeness	Completeness was defined as the presence of all four pieces of information (name, dosage, frequency, and medication status) on the medication list documented and published by the patient on the regional ehealth network.	Presence of the four pieces of information (name, dosage, frequency, and medication status). Medication status corresponds to the option chosen by the patient for the question: <i>“Are you currently taking this medication?”</i>	
- Correctness	The medication list documented and published by the patient on the regional ehealth network was considered to be correct if the list documented corresponded to the medications taken by the patient according to the best possible medication history (i.e. if there were no discrepancies).	Discrepancies were defined as differences between the list documented by the patient using the patient application and the best possible medication history (BPMH, gold standard) evaluated by a trained clinician during the final interview.	
c. Efficiency	Efficiency: The level of effort and resource usage which is required by the user in order to achieve a goal in relation to accuracy and completeness[1]. ⇒ What is the level of patient effort	Not assessed	

Appendixes

	required?		
2. Usefulness	Usefulness is the degree to which a product enables users to meet specific needs and as an assessment of users' willingness to use the product[2].	7 items questionnaire (see table 2)	

References

1. International Organization for Standardization, 9241-11:1998, Ergonomics of human–system interaction — Part 11: Guidance on Usability. Geneve: ISO;1998.
2. Tullis T, Albert B. Measuring the User Experience - Collecting, Analyzing, and Presenting Usability Metrics. 2013 July 17, 2013.

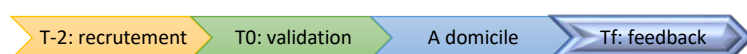
5.2. APPENDIX II: CODING OF TYPE AND CAUSES OF DISCREPANCIES

Some discrepancies could have more than one cause.	
Some Definitions: comparing the electronically documented medication list and the BPMH	
If the medication has every "brick" of information (name, dosage, frequency) BUT no status, it was considered as 1 discrepancies receiving the coding 33 (see below) When each line of medication was complete (name, dosage, frequency, status) but that a medication was lacking in comparison to the BPMH, the medication list was considered as NON complete Medication taken only on demande were considered in discrepancy analysis only if they were on average taken once a day	
Classification of discordances (causes)	
Code number	Patient-level
1	Adverse drug event
1	Didn't have time to fill the prescription
1	Money/financial barrier
1	Unintentional nonadherence
1	Self-medication
1	Intentional nonadherence
Code number	System-level
2	Conflicting information from different informational sources
2	Confusion between; - Brand/generic names - Medication hospital formulary/Equivalent medication
2	Instructions to patient at transfer incomplete/inaccurate/illegible
2	Instructions between prescribers at transfer incomplete/inaccurate/illegible
2	Medication history incomplete/inaccurate
2	Prescription error
2	Dispensing error
2	Inadequate quantity
2	Patient barriers not taken into account; - Cognitive impairment - Vision/hearing/dexterity impairment - Swallowing difficulties - No caregiver/need for assistance not recognized - Literacy/language barrier

2	Administrative problems
2	Other
Code number	Technology-level
31	Medication name, dosage, frequency or other modification done by the patient that the tool did not registred
32	Lack of clarity that had for consequence wrong information entered by the patient. For example: mismatching of picture of the pillbox and medication, medication dosage/frequence not understand by the patient, information on the ReHN differing from information into the Patient-App, etc.
33	Medication status not documented by the patient
34	Duplication of a medication

5.3. APPENDIX III: SEMI-STRUCTURED INTERVIEW GUIDE

Guide for semi-structured interview



In Mont-Godinne or at home : interview lasting about one hour

PATIENT CODE

- a. Analyse des discordances (FOCUS PRINCIPAL)
- a. Etes-vous d'accord que nous regardions ensemble la liste encodée que vous avez encodée via SEAMPAT et que nous comparions cela à ce que vous prenez et aux informations en provenance du médecin/pharmacien ?

Tableau 1. Questionnaire pour l'Anamnèse Médicamenteuse Structurée (SHIM)

Questions posées pour chaque médicament figurant sur la liste des médicaments fournie par le pharmacien d'officine:

1. Utilisez-vous ce médicament comme prescrit (dose, fréquence, forme galénique)?		Oui
		Non

2. Ressentez-vous des effets indésirables? Si oui, lesquels ?		Oui
		Non
3. Pourquoi prenez-vous ce médicament autrement que prescrit (dose, fréquence, forme galénique) ou pas du tout?		
4. Utilisez-vous d'autres médicaments sur ordonnance qui ne figurent pas sur cette liste (regarder les emballages des médicaments pris par le patient)?		Oui
		Non
5. Prenez-vous des médicaments achetés sans ordonnance?		Oui
		Non
6. Utilisez-vous des médicaments homéopathiques ou des médicaments à base de plantes (p.ex. à base de millepertuis)?		Oui
		Non
7. Utilisez-vous des médicaments qui sont ceux d'un membre de votre famille ou d'un ami?		Oui
		Non
a. Si oui, lesquels ?		
b. A quelle occasion, dans quelles circonstances ?		
8. Utilisez-vous des médicaments « en cas de besoin »?		Oui
		Non
a. Lesquels ?		
b. A quelle occasion, dans quelles circonstances ?		
9. Utilisez-vous des médicaments qui ne vous sont plus prescrits?		Oui
		Non
a. Lesquels ?		
b. A quelle occasion, dans quelles circonstances ?		
<i>Questions au sujet de l'utilisation des médicaments:</i>		
10. Prenez-vous vos médicaments de manière indépendante (sans aide d'une autre personne)?		Oui
		Non
a. Si non, qui est la personne qui vous aide généralement ?		
b. Qui et comment vous prépare-t-on vos médicaments ?		
11. Utilisez-vous un pilulier?		Oui
		Non

a. Expliquez-moi		
12. Rencontrez-vous des problèmes pour prendre vos médicaments?	☐	Oui
	☐	Non
13. Si vous utilisez des médicaments à inhaler dans les poumons: a. Quel type de dispositif d'inhalation utilisez-vous ?		
b. Rencontrez-vous des problèmes dans l'utilisation de ce dispositif?	☐	Oui
	☐	Non
14. Si vous utilisez des gouttes ophtalmiques: Rencontrez-vous des problèmes dans l'administration de ces gouttes ophtalmiques?	☐	Oui
	☐	Non
15. Est-ce que ça vous arrive d'oublier de prendre vos médicaments?	☐	Oui
	☐	Non
a. Si oui, quel médicament et pour quoi?		
b. Que faites-vous si vous remarquez que vous avez oublié de prendre votre/vos médicament(s)?		
<i>Autres</i>		
16. Souhaitez-vous faire un commentaire ou poser une question au sujet d'un de vos médicaments?		

b. Pouvez-vous m'expliquer ces différences (Cleays)?

Tableau 2. Instrument to Characterize Unintentional Medication Discrepancy					
	Mdc 1	Mdc 2	Mdc 3	Mdc 4	Mdc5
NAME OF THE MEDICATION INVOLVED					
Anatomical Main Group (A – B – C – D – G – H – J – M – L – N – P – R – S – V)					
Type of unintentional medication discrepancy identified					
Omission	☐	☐	☐	☐	☐
Addition	☐	☐	☐	☐	☐
Duplication	☐	☐	☐	☐	☐

Substitution	☐	☐	☐	☐	☐
Dose différente	☐	☐	☐	☐	☐
Fréquence d'adm différente	☐	☐	☐	☐	☐
Durée de traitement	☐	☐	☐	☐	☐
Autre					
Cause					
1. Patient level					
1. Adverse drug event	☐	☐	☐	☐	☐
2. Didn't have time to fill the prescription	☐	☐	☐	☐	☐
3. Money/financial barrier	☐	☐	☐	☐	☐
4. Unintentional nonadherence	☐	☐	☐	☐	☐
5. Self-medication	☐	☐	☐	☐	☐
6. Intentional nonadherence	☐	☐	☐	☐	☐
7. Other: Cliquez ici pour entrer du texte.					
2. System level					
1. Conflicting information from different informational sources	☐	☐	☐	☐	☐
2. Confusion between; - Brand/generic names (BG N) - Medication hospital formulary/Equivalent medication (Form)	☐	☐	☐	☐	☐
3. Instructions to patient at transfer incomplete/inaccurate/illegible	☐	☐	☐	☐	☐
4. Instructions between prescribers at transfer incomplete/inaccurate/illegible	☐	☐	☐	☐	☐
5. Medication history incomplete/inaccurate	☐	☐	☐	☐	☐
6. Prescription error	☐	☐	☐	☐	☐
7. Dispensing error	☐	☐	☐	☐	☐
8. Inadequate quantity	☐	☐	☐	☐	☐
9. Patient barriers not taken into account; - Cognitive impairment - Vision/hearing/dexterity impairment - Swallowing difficulties - No caregiver/need for assistance not recognized - Literacy/language barrier	☐	☐	☐	☐	☐
10. Administrative problems	☐	☐	☐	☐	☐
11. Other:					

b. Questions générales

a. Consommation des soins de santé

i.	Entre T0 et Tf, combien de fois avez-vous rencontré votre médecin généraliste?	
ii.	Entre T0 et Tf, combien de fois avez-vous rencontré un spécialiste en milieu hospitalier?	
iii.	Entre T0 et Tf, combien de fois vous êtes-vous rendu à la pharmacie?	
iv.	Entre T0 et Tf, combien de fois avez-vous été hospitalisé?	
	a. Hospit n°1 était-elle programmée? 1=oui, 0=non	☐ Oui ☐ Non
	b. Hospit n°2 était-elle programmée? 1=oui, 0=non	☐ Oui ☐ Non
	c. Hospit n°3 était-elle programmée? 1=oui, 0=non	☐ Oui ☐ Non
v.	Entre T0 et Tf, combien de fois avez-vous consulté en salle d'urgence ?	

b. Sur le portail du RSW, j'ai vu que vous avez publié fois votre liste de médicaments :

i. Dans quel contexte avez-vous fait cela (endroit, moment) ?

☐	1. Avant une consultation chez.....
☐	2. Après une consultation chez.....
☐	3. Après un passage à la pharmacie
☐	4. Après une modification de mon traitement conseillé par téléphone par le médecin/pharmacien
☐	5. Avant une hospitalisation
☐	6. Après une hospitalisation
☐	7. Autre.....

c.	Si vous avez vu un médecin depuis	☐	Oui

notre rencontre, le médecin a-t-il regardé la liste de médicaments que vous aviez publiée sur le RSW ?	☐	Non
i. Si oui, « qu'en a-t-il pensé ? »	Cliquez ici pour entrer du texte.	
d. Si vous avez vu un pharmacien depuis notre rencontre, lui avez-vous montré l'application ?	☐	Oui
	☐	Non
i. Si oui, « qu'en a-t-il pensé ? »	Cliquez ici pour entrer du texte.	
e. Avez-vous montré l'application à quelqu'un d'autre ?	☐	Oui
	☐	Non
ii. Si oui, « qu'en a-t-il pensé ? »	Cliquez ici pour entrer du texte.	
f. Avez-vous eu l'impression que SEAMPAT répondait à des difficultés rencontrées au quotidien ?	☐	Oui
	☐	Non
g. Avez-vous l'impression que SEAMPAT vous complique la vie ?	☐	Oui
	☐	Non

c. Feedback relatif à la qualité – sécurité des soins

a. Au niveau de votre compréhension de vos médicaments, avez-vous constaté un changement avec l'application SEAMPAT ?		
i. Comprenez-vous mieux la raison pour laquelle vous prenez vos médicaments ?	☐	Oui
	☐	Non
i. Si oui, auriez-vous un exemple d'amélioration ? <i>neurofen est pr la D+, fait des trous ds l'estomac ➔ se prend en mangeant</i>		
ii. Est-ce que l'application vous a aidée ? Comment ?		
b. Avez-vous changé d'attitude vis-à-vis de vos médicaments suite à l'utilisation de SEAMPAT ?	☐	Oui
	☐	Non

Exemple ? <i>par exemples : (1) Changé de pharmacie ? Eté plus souvent dans la même ? Achter +/- de mdc sans prescription ? (2) Ne plus apporter sa liste de mdc sous format papier chez le médecin ? (3) Parler plus facilement de vos mdc ? Au contraire, ne plus en parler car vous estimez qu'il a toute l'information sur l'ordinateur ?</i>		
i. Y a-t-il des médicaments que précédemment vous n'auriez pas mentionnés à votre médecin car vous les pensiez sans importance ? <i>ex : « produits non considéré » comme des mdc vrais (gouttes, patch, crème)</i>		Oui
		Non
Exemple ?		
c. Avez-vous constaté une modification de l'attitude de votre médecin vis-à-vis de votre liste de traitement ? <i>(par exemple : Posait-il plus/moins de questions ? Posait-il des questions différentes, plus spécifiques?)</i>		Oui
		Non
d. Avez-vous l'impression que votre médecin vous a donné des conseils différents grâce à SEAMPAT ? <i>(par exemple, vous a-t-il conseillé d'arrêter un mdc que vous achetez en vente libre à la pharmacie ? Vous a-t-il conseillé de modifier la dose d'une vit, d'un complm^t alimentaire ? Vous a-t-il référé à un autre soignant par rapport à un mdc spécifique ? A-t-il demandé conseil à un collègue concernant un mdc spécifique,...A-t-il modifié le dosage d'un « mdc » en vous expliquant que cela est suite à une interaction avec un autre mdc ?)</i>		Oui
		Non
e. En quoi l'application SEAMPAT vous a-t-elle été utile ?		
f. Vous avez utilisé SEAMPAT..... autant de fois. Selon vous, qu'est-ce qui vous encouragerait à utiliser plus souvent l'application ? Par exemple		
i. Le fait de pouvoir se connecter sans carte d'identité électronique et sans code PIN		Oui
		Non
ii. Le fait d'avoir une tablette dans la salle d'attente		Oui
		Non
iii. Le fait d'avoir une borne à l'entrée de l'hôpital		Oui
		Non
iv. Le fait que votre médecin vous		Oui

	encourage à l'utiliser		Non
v.	Le fait que votre médecin prenne plus de temps pour discuter de vos médicaments		Oui
			Non
vi.	Le fait que votre médecin ait pris plus de temps pour discuter avec vous d'autre chose que vos médicaments		Oui
			Non
vii.	Le fait que vous compreniez mieux à quoi servent vos médicaments....		Oui
			Non

d. Feedback relatif à la technologie (ease-of-use/suggestions)

CODE

a. Avez-vous eu des problèmes de connexion ?		Oui
		Non
i. Quelqu'un a-t-il pu vous aider à les résoudre ?		Oui
		Non
ii. Qui ?		
b. Vous avez eu des difficultés pour :		
	i. pour modifier une posologie ?	
	ii. Ajouter une information précise ?	
	iii. Ajouter un médicament ?	
	iv. Supprimer un médicament ?	
c. Y a-t-il des « choses » que vous auriez souhaitez faire avec SEAMPAT qui n'ont pas été possible?		Oui
		Non
i. Exemples		
d. Continueriez-vous à utiliser SEAMPAT en dehors du projet de recherche ?		Oui
		Non
i. Pourquoi ?		

5.4. APPENDIX IV: SOCIODEMOGRAPHIC VARIABLES CONCERNING THE PATIENTS WHO REFUSED TO PARTICIPATE TO THE EVALUATION OF THE PATIENT APP

Table 1: Sociodemographic variables of the patients contacted by phone for the evaluation of the patient app				
	patients accepting to participate(n=48)		patients refusing to participate (n=56)	
"Subgroup"	(n)		(n)	
Pulmonary transplants	16	33.3%	10	17.8%
Ambulatory patients visiting their general practitioner at least once a month	20	41.7%	24	42.9%
Patients hospitalized for scheduled surgery	8	16.7%	22	39.3%
Caregiver of patient from another group	4	8.3%	0	0%
Age (years; median [IQR])				
	65	[60-69]	67	[57-73]
Gender (n)				
Female	16	33.3%	32	57.1%
Male	32	66.7%	24	42.8%

Table 2: Patients refusing to participate (n=56)						
Reason for refusing to participate	Fear of IT (n=18)	Lack of time (n=8)	Did not show up at kick-off (n=8)	Register for ReHN (n=6)	Medical Reason (n=6)	No reason or no clear reason (n=19)
By "Subgroup"						
Pulmonary transplants	4	2	2	0	1	2
Ambulatory patients visiting their general practitioner at least once a month	8	2	4	5	1	6
Patients hospitalized for scheduled surgery	6	4	2	1	4	11
Caregiver of patient from another group	0	0	0	0	0	0
By age (years; median [IQR])	67 [60-74]	65 [59-74]	68 [66-70]	? (lack data)	61 [52-69]	65 [45-74]
By Gender (n)						
Female	9	4	6	4	4	12
Male	9	4	2	2	2	7

6. APPENDIXES CHAPTER 5

6.1. APPENDIX I : LOW-FIDELITY PROTOTYPE EVALUATION QUESTIONNAIRE.

Quelques consignes pour intro pr soph :

- Evaluation informelle
- Description du déroulement du test

But :

1. exposition identique à chaque participant
 2. commentaires notés au vol, observation – notes indirectes
- Professionnel mais amical – court mais clair, précis et complet
 - Ce qu'on test : L'OUTIL ⇒ Sommes-nous partis dans la bonne direction ?

Introduction :

Pour rappel, le **projet SEAMPAT** a pour but de développer un **outil électronique de réconciliation médicamenteuse** composé de deux modules :

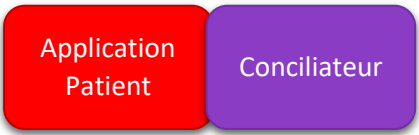
(1) L'application-patient permet au patient de valider la liste des traitements médicamenteux qu'il prend probablement. **(2) Le conciliateur**

permet la comparaison des données encodées par le patient avec celles encodées par d'autres professionnels de la santé (médecins, pharmas) afin d'avoir la liste de médicaments la plus à jour possible et la plus précise possible.

Si vous êtes là aujourd'hui, c'est pour nous aider à développer un conciliateur qui soit le plus adapté possible à l'utilisation des médecins. Nous voulons voir si les premières idées, les premiers « écrans » vont dans la bonne direction et si l'outil est compréhensible, clair et complet.

Il n'y aucune bonne ou mauvaise réponse, question, suggestion et/ou commentaire. L'important c'est de nous faire part de tous les commentaires tant négatif que positif. Ce n'est probablement pas facile, mais l'idéal serait d'essayer de vous projeter comme si vous deviez utiliser cet outil par vous-même et pour vous-même. De cette manière, vous pourrez nous dire tout ce qui vous passe par la tête. Comme cet outil vous est destiné, nous souhaitons pouvoir l'améliorer grâce à vos suggestions !

Est-ce que tout vous semble clair ? Avez-vous d'autres questions avant de commencer ?



Application
Patient

Conciliateur

Questionnaires :**1) Questions pour les médecins lors de la visualisation des interfaces**

1. Quelle a été votre première impression lors de la visualisation de cet outil ? Sur une échelle de 1 à 10, quelle note donnez-vous au visuel de cet outil ? (entourez votre réponse)

Mauvais visuel								Excellent visuel		
1	2	3	4	5	6	7	8	9	10	

2. Dans l'ensemble, l'outil vous semble-t-il compréhensible/facile à utiliser ? (Le vocabulaire est-il adéquat ? Les phrases et les questions formulées sont-elles claires et compréhensibles ?) oui/non
3. Percevez-vous clairement l'intérêt du conciliateur ? Oui/non
4. Comprenez-vous l'intitulé des différentes colonnes ? oui/non
 - Auriez-vous fait le même choix ? oui/non
 - Si non, qu'auriez-vous fait ? Expliquez :.....
5. Passez-vous en revue la liste de traitement :
 - pour chaque patient ? oui/non
 - pour chaque patient que vous estimez «à risque » ? oui/non
 - à chaque consultation ? oui/non
6. Trouvez-vous que la manière de réconcilier un médicament est intuitive ? oui/non
7. Appréciez-vous l'utilisation des icônes (crayon = éditer/ stop = arrêter un médicament /...) ? oui/non
8. Ces images/icônes sont-elles toutes compréhensibles pour vous ? oui/non
9. Appréciez-vous le choix des couleurs ? oui/non
 - Y a-t-il des couleurs que vous remplaceriez ? Si oui, lesquelles ?
10. Etes-vous intéressé par l'historique des médicaments ? oui/non
 - Cette présentation vous convient-elle ? oui/non
 - Jusqu'à combien de temps en amont souhaiteriez-vous remonter ? 3 mois/6 mois/12 mois
11. Utiliseriez-vous cet outil ? oui/non

12. Avez-vous des suggestions pour améliorer cet outil ?
Expliquez :.....

2) *Questionnaire d'informations générales (temps remplissage +/- 2-3 min)*

- a. Sexe : homme/femme
b. Age : ans
c. Quel logiciel informatique utilisez-vous :

d.

Allez-vous régulièrement sur votre eHealthBox ?	
☐	Au moins 1x/semaine
☐	Au moins 1x/mois
☐	Moins d'1x/mois

e.

Etes-vous connecté à MediBridge?	
☐	Non
☐	Oui,

f.

Avez-vous déjà entendu parler du réseau de santé bruxellois – abrumet (RSB) ?	
☐	Non
☐	Oui

g.

Si oui, avez-vous donné votre consentement au RSB – abrumet ?	
☐	Non
☐	Oui

h.

Savez-vous ce qu'est un SUMEHR ?	
☐	Non
☐	Oui

i.

Allez-vous sur le RSB pour consulter les données de vos patients (bio, radio, SUMEHRs,...) ?	
☐	Non
☐	Oui

j.

Quand vous avez consulté le RSB, avez-vous trouvé les informations qui vous intéressaient ?	
☐	Non
☐	Oui

k.

Connaissez-vous le code pin de votre carte d'identité ?	
☐	Non
☐	Oui

l.

Avez-vous déjà essayé de vous connecter sur le RSB avec votre carte d'identité?	
☐	Non
☐	Oui

3) Grille d'observation

a. Identification des difficultés rencontrées

i. Lors de la connexion au logiciel

ii. Lors de la suppression d'un médicament

iii. Lors de l'ajout d'un médicament

iv. Lors de la modification d'une posologie

b. Identification des remarques orales et des réactions marquantes (comportement)

i. Remarques orales

-
-
-
-
-

ii. Réactions marquantes

-
-
-

6.2. APPENDIX II: HIGH-FIDELITY PROTOTYPE EVALUATION QUESTIONNAIRE

I Informations générales

Médecin généraliste (2)/médecin spécialiste (2)/pharmacien clinicien (1)	
Quel âge avez-vous ?	
Depuis combien d'années exercez-vous votre métier (année de formation de spécialités y comprises) ?	
Depuis combien d'années utilisez-vous un ordinateur au quotidien dans le cadre des soins aux patients ?	Toujours
	> 20 ans
	≤ 20 ans
	≤ 10 ans
	≤ 5 ans
Autre point qu'il vous semble important de mentionner ?	

II Guide de discussion

1. Dans l'ensemble, l'outil vous semble-t-il compréhensible? (Par exemple : vocabulaire est-il adéquat, phrases et questions formulées de manière claires et compréhensibles ?)

☐	Oui	
☐	Non	
Pourquoi?		

2. L'intitulé de chacune des colonnes est-il suffisamment clair ?

☐	Oui
☐	Non
Commentaire(s) ?	

3. Avez-vous eu des difficultés pour mettre à jour la liste de médicaments de vos patients ?

☐	Oui
☐	Non
Commentaire(s)?	

4. Détails de la liste de médicaments :

Les informations présentées pour chaque médicament sont-elles pertinentes/utiles?	☐	Oui
	☐	Non
Y a-t-il d'autres informations que vous jugez utiles et qui n'apparaissent pas ?		
Autre commentaire :		

5. Avez-vous compris la signification des différentes icônes utilisées (la « loupe », le « crayon », le « sens interdit », le « i »,...) ?

☐	Oui
☐	Non

Quelle(s) suggestion(s) avez-vous?	

6. Avez-vous rencontré des difficultés pour ajouter un médicament ?

☐	Oui
☐	Non
Pourquoi?	
Quelle(s) suggestion(s) avez-vous?	

7. Que pensez-vous que doit devenir le résultat de votre mise à jour (=la liste réconciliée) ? Autrement dit la liste « réconciliée » pourrait-elle par exemple « écraser » la liste de médicament que vous avez dans votre dossier médical ?

8. Que pensez-vous de l'édition d'une nouvelle posologie/modification d'une posologie existante ?

	oui	non
Intuitive ?	☐	☐
Préférez-vous introduire la posologie de manière structurée ?	☐	☐
➤ Trouvez-vous important d'avoir les deux possibilités ?	☐	☐
Structuration des items agréables ?	☐	☐
Avez-vous des conseils, des suggestions, des remarques éventuelles :		

9. Avez-vous rencontré des difficultés pour annuler une action (par exemple non désirée)?

☐	Oui
☐	Non

10. La raison d'arrêt d'un médicament est notifiée par le médecin qui réconcilie la liste de médicament

	oui	non
Cette raison doit-elle TOUJOURS être communiquée aux autres professionnels de santé ?	☐	☐
Selon vous, quelle est la meilleure manière de communiquer cette information aux différents professionnels de santé qui soignent votre patient ?		

11. Que recommanderiez-vous à l'équipe SEAMPAT pour que l'outil aie le plus de chance possible d'être adopté par tous les cliniciens (médecins, pharmaciens) ?

12. Si vous deviez conseiller l'utilisation de SEAMPAT à vos patients, quels arguments utiliseriez-vous pour susciter leur intérêt ?

13. Avez-vous des suggestions, conseils, des remarques ?

SUS et échelle visuelle

Quelle a été votre première impression lors de la visualisation de cet outil ? Sur une échelle de 1 à 10, quelle note donnez-vous au visuel de cet outil ? (entourez votre réponse)

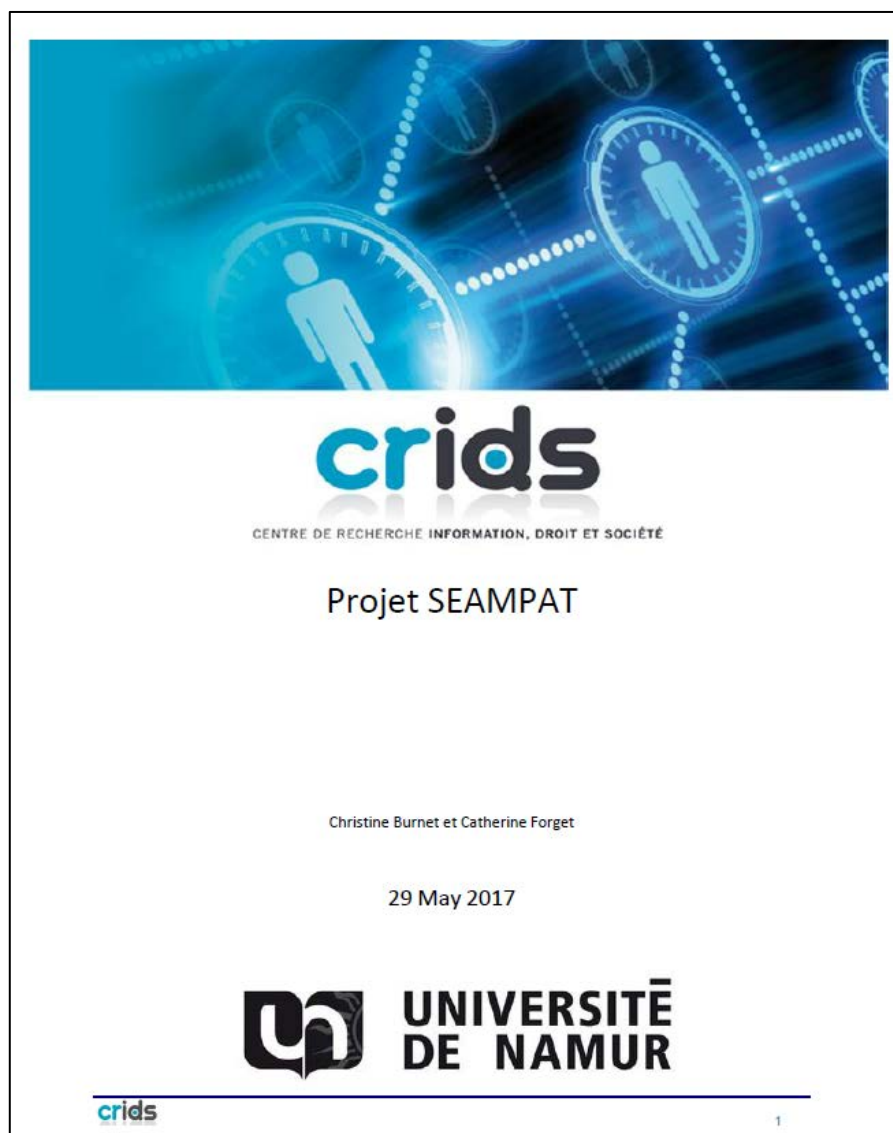
Mauvais visuel**1****2****3****4****5****6****7****8****Excellent visuel****9****10**

System Usability Scale (Brooke)		Disagree strongly	Disagree	Sans opinion	Agree	Agree strongly
1	Je pense que j'aimerais utiliser SEAMPAT fréquemment					
2	J'ai trouvé SEAMPAT trop compliqué					
3	J'ai trouvé SEAMPAT facile à utiliser					
4	Je pense que j'aurai besoin de l'aide d'un informaticien pour être capable d'utiliser SEAMPAT					
5	J'ai trouvé que les différentes actions possibles avec SEAMPAT étaient faciles à réaliser (ajouter un médicament, supprimer un médicament, modifier le dosage d'un médicament....)					
6	J'ai trouvé beaucoup d'incohérences dans SEAMPAT					
7	J'imagine que la plupart des cliniciens (médecins – pharmaciens) seraient capables d'apprendre à utiliser SEAMPAT très rapidement					
8	J'ai trouvé SEAMPAT fastidieux à utiliser					
9	Je me sentais très sûr(e) de					

	moi en utilisant SEAMPAT					
10	J'ai dû apprendre beaucoup de choses au niveau informatique avant de pouvoir utiliser SEAMPAT					

7. APPENDIXES DISCUSSION

7.1. APPENDIX I



8. Quid des responsabilités des professionnels de soin de santé en cas d'utilisation d'un outil de réconciliation médicamenteuse ?

a. Le médecin ?

Conformément au Code de déontologie médicale et à la réglementation applicable, dans le cas où le médecin traitant fait usage des applications telles que développées dans le cadre du projet SEAMPAT, il devra également tenir compte de nouvelles informations qui lui sont fournies par l'application « conciliateur » par exemple, avant de prescrire un médicament. Sa responsabilité n'est donc pas aggravée dans le sens où, il n'est pas tributaire de nouvelles obligations. Il reste par contre tenu de faire un choix tel que l'aurait fait « un médecin normalement prudent et diligent placé dans les mêmes circonstances de fait » et pour lequel l'exercice abusif de la médecine sera forcément sanctionné⁹.

b. Le pharmacien ?

Conformément à la loi coordonnée du 10 mai 2015 relative à l'exercice des professionnels de soins de santé, si un pharmacien de manière générale et donc également s'il fait usage d'une application « conciliateur » telle que développée dans le cadre du projet SEAMPAT, il est tenu, en cas de doute suffisant, de ne pas délivrer le médicament au patient. Cependant, le pharmacien ne pourra refuser de délivrer purement et simplement, il devra directement prendre contact avec le médecin généraliste ou spécialiste ayant délivré le médicament afin de remédier à l'erreur qui aurait été constatée.

De même constate par le biais de l'application « conciliateur » que le patient prend par lui-même des médicaments lui paraissant peu compatibles avec les médicaments prescrits

⁹ Nous reprenons ici les situations exemplifiées sur le site de la Commission de la protection de la vie privée. Voy. <https://www.privacycommission.be/fr/node/7109>

¹⁰ C. DELFORGE, « La responsabilité civile du médecin au regard de la prescription de médicaments », *R.G.D.B.*, Bruxelles, Kluwer, 2003, p. 373.

par le médecin, il doit informer le patient mais ne peut refuser de lui délivrer le médicament ou critiquer ouvertement le médecin traitant.

Veuillez noter qu'un approfondissement de cette question est prévu à la section 6 de la partie II du présent document.

9. Quid des droits et responsabilités de l'entourage du patient et/ou de son représentant légal ?

A domicile, le patient peut se faire aider par son entourage. Il va de soi que l'utilisation de l'application SEAMPAT par le patient ne modifie pas les responsabilités civiles de son entourage.

L'entourage peut comprendre la personne de confiance et son représentant légal. Les notions de personnes de confiance et de représentant légal ne doivent pas être confondues.

Le représentant légal est identifié comme suit :

- si le patient est mineur: les parents exerçant l'autorité sur le mineur ou son tuteur¹¹
- si le patient majeur est incapable¹² ou, si le patient majeur n'est pas en mesure d'exercer ses droits lui-même :
 - un mandataire désigné par le patient¹³
 - l'époux cohabitant, le partenaire cohabitant légal, le partenaire cohabitant de fait¹⁴

Le représentant légal n'intervient que si le patient n'est pas capable d'exercer ses droits alors que la personne de confiance intervient concurremment avec ou au nom du patient, capable d'exercer ses droits.

Leurs rôles sont donc distincts, la personne de confiance peut exercer un droit à l'information et à la consultation du dossier tandis que le représentant légal peut en principe exercer l'ensemble des droits accordés par la loi au patient.

Veuillez noter qu'un approfondissement de cette question est prévu à la section 2.1 de la partie II du présent document.

¹¹ LDP, article 12, §1er.

¹² LDP, article 13.

¹³ LDP, article 14, §1er.

¹⁴ LDP, article 14, §2.

7.2. APPENDIX II

Table : Proposed agenda for further testing of both applications	
Further testing	1) To implement improvements for both app 2) To test these improvements of each app, using at least one more pilot focusing on usability: effectiveness, EFFICIENCY and satisfaction 3) To map workflow of the HCPs in the different settings (hospital, primary care, community pharmacy) where the MedRec app will be implemented 4) To test the SEAMPAT ICT platform (both app together) using a randomized controlled trial lasting at least one year, with the following PICO: a. Population: i. inclusion criteria (+/- targeting patients at risk of ADE): adults taking 5 medications or 3 with at least 1 medication at high risk for ADE and one OTC medication + no exclusion if cognitive impairment but consent asked to caregiver ii. recruitment: continuously following patient admission at the hospital b. Intervention⁴: i. For patients: tailored health education/training in the use of the patient app, according to their health literacy and IT literacy ii. For HCP: tailored education/training in the use of the MedRec app according to their MedRec knowledge and IT literacy iii. Define role of each frontline users. Allow MedRec as multidisciplinary teamwork (partial reconciliation possible versus continue as previous).

	c. Comparison : usual care (ideally a cluster RCT by wards to avoid contamination between the two arms) d. Outcomes: tool use; MedRec completion rates; number of discrepancies; adverse drug events; readmissions within 30 days; emergency visits (ED or GP). And costs related to the primary outcomes

CURRICULUM VITAE

PERSONAL INFORMATION

Name : Sophie Marien

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Current position: Geriatrician at Cliniques universitaires Saint-Luc

EDUCATION

2015-2018	Docteur en sciences médicales
2012-2018	Master complémentaire en gériatrie
2009-2012	Master complémentaire en médecine interne
2005-2009	Diplôme de docteur en médecine
2002-2005	Diplôme de candidat en médecine

AWARD AND SPECIAL ACTIVITY

Ma thèse en 180 secondes – édition mars 2016 : Quand les médicaments s’emmêlent, la technologie s’en mêle! (vidéo sur youtube : <https://www.youtube.com/watch?v=8OXnQY0bHwQ>)

Prix Junior de la Société Belge de Gériatrie et de Gériatrie pour le meilleur poster, Ostende 2017.

COMMUNICATIONS IN RELATIONSHIP WITH THIS THESIS

1.1. SCIENTIFIC PUBLICATIONS

Marien S, Krug B, Spinewine A. Electronic tools to support medication reconciliation: a systematic review. *J Am Med Inform Assoc*. 2017 Jan;24(1):227-240. doi: 10.1093/jamia/ocw068. Epub 2016 Jun 14. Review.

Marien S, Delphine L, Ravi R, Nsenga J, Ospina G, Ramon V, Boland B, Spinewine A. A web application to involve patients in the medication reconciliation process: a user-centered usability and usefulness study. *J Am Med Inform Assoc*. 2018 Aug 17. doi: 10.1093/jamia/ocy107. [Epub ahead of print]

Ramon V, Ramdoyal R, Marien S, Michot A, Nsenga J, Ospina G, Steels F, Boucher Q, Legrand D, Burnet Ch, Vanmerbeek P, Spinewine A. Seampat an ICT platform for medication reconciliation for active patient involvement. ICCHP 2016, Linz, Austria, July 13-15, 2016, Proceedings, Part I; Pages: pp 269-276

1.2. BOOK CHAPTER

Petrovic M, Sommers A, Marien S, Spinewine A. Optimization of drug use in older adults: a key factor for a successful ageing. In *CAMBRIDGE HANDBOOK OF SUCCESSFUL AGING*. Editors: Rocío Fernández-Ballesteros, Jean-Marie Robine, Athanase Benetos 2018 (under printing)

1.3. POSTER/ORAL PRESENTATION AT NATIONAL AND INTERNATIONAL MEETINGS

Congrès IFGG (CIPG) : Liège, 14-16 mai 2014

- Fibrillation atriale du patient âgé: aide à la décision par les scores CHADS₂ et HEMORR₂HAGES – Benoit Boland, Sophie Marien, Frédéric Maes, Olivia Dalleur, Anne Spinewine, Christophe Scavée.

- Traitements anti-coagulant (AC) et anti-plaquettaire (AP) chez des patients âgés en fibrillation atriale (FA): fréquence, profil clinique, et risque hémorragique. – Sophie Marien, Olivia Dalleur, Frédéric Maes, Anne Spinewine, Benoit Boland (**oral presentation**)

Congrès SBGG : L iège, automne, octobre 2015

- Empowering older patients to document their medication list: preliminary results on the use of an electronic tool (e-tool) in order to help them validating their own medication list – Sophie Marien, Ravi Ramdoyal, Quentin Boucher, Anne Spinewine (**oral presentation**)

IHI International Forum on quality and safety in Healthcare: Göteborg, avril 2016

- SEAMPAT: improving continuity of medication use through patient empowerment and use of information technology. Sophie Marien, Christine Brunet, Quentin Boucher, Delphine Legrand, Ravi Ramdoyal, Valery Ramon, Perrine Vanmeerbeek, Anne Spinewine

Congrès SBGG : L iège, automne, octobre 2016

- SEAMPAT: Engaging older patients to document their medication list by the use of an electronic tool to facilitate medication reconciliation: study protocol. Sophie Marien, Ravi Ramdoyal, Valery Ramon, Anne Spinewine

BVGG Congress: Oostende, Février 2017

- SEAMPAT: Engaging older adults to validate their medication list through the use of an electronic tool : preliminary results. Sophie Marien, Delphine Legrand, Pierre Pagazc, Ravi Ramdoyal, Valery Ramon, Anne Spinewine

Informatics for Health: Manchester, 24 – 26 April 2017

- SEAMPAT: Improving medication reconciliation through patient electronic input: preliminary results. Sophie Marien, Catherine Forget, Patrick Heymans, Delphine Legrand, Pierre Pagazc, Ravi Ramdoyal, Valéry Ramon, Anne Spinewine