



Health care trajectories in chronic illness : using routine data to support care coordination and shared decision-making

Luiza Siqueira Do Prado

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Health care trajectories in chronic illness: using routine data to support care coordination and shared decision- making

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*To Victor and Maria Flor,
My home away from home.*

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Foreword

This work is a doctoral thesis organized by published works, or an article thesis. It presents a general introduction, three articles – one reporting on the protocol of a systematic review, one reporting the review itself, and one reporting on a qualitative study, followed by a general discussion and, finally, a conclusion and perspectives of future work.

This thesis has followed best practice recommendations for eHealth development. It is based on a registered and protocol-based literature review and a qualitative study involving both healthcare professionals and patients, the key-stakeholders of eHealth development and usage. The general introduction presents the key concepts of chronic conditions and chronic care, such as chronic conditions management, shared decision-making, and health literacy, and of health information technology, electronic health records, electronic and mobile health applications, data visualization, and its role in mediating decision-making in chronic care. In addition, it presents results and information specific to the French context concerning chronic conditions, particularly on the condition targeted in the qualitative study, and concerning the use of health information technology. These concepts describe the context for the subsequent sections. The last section presents the research problem, the main objectives of the thesis and how the text is organized in further detail.

The three articles have a conventional structure: introduction, methods, results, and discussion. Supplementary materials are included after each manuscript. They are accompanied by a summary of the topics developed to highlight its most important results. The review has been submitted to a peer-reviewed journal, and the qualitative study prepared for submission. The protocol was published on the BMJ Open in February 2020.

The general discussion summarizes the main results of each article and makes the connection to the general objectives. Strengths and limitations are also discussed, followed by perspectives for future work. A conclusion ends this report.

The annexes present two previously published articles that have helped structure this work, and all the documents concerning the qualitative study.

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Abbreviations

AACTT	Action, Actor, Context, Target, Time
AGP	Ambulatory glucose profile
ALD	Affection de longue durée
ANS	Agence du Numérique en Santé
APPS	Applications
ASALEE	Actions de SANTé Libérale En Equipe
ASIP-Santé	Agence des systèmes d'information partagés en santé
BCT	Behavior change technique
BHLS	Brief health literacy screen
CCM	Chronic care model
CCP	Comité de protection des personnes
CDP	Care delivery pathway
CDSS	Clinical decision support system
CGM	Continuous glucose monitoring
CICI	Context and Implementation of Complex Interventions
CIM	Clinical information modelling
CIMP	Clinical information modelling processes
CNIL	Comission nationate de l'informatique et des libertés
COREQ	Consolidated Criteria for Reporting Qualitative Research
DALY	Disability-adjusted life years
DMP	Dossier Médical Partagé
DNS	Délégation ministérielle du numérique en santé
ECG	Electrocardiogram
EHD	Electronic healthcare database
EHR	Electronic health record
ENS	Espace numérique de santé
FFD	Fédération française des diabétiques
GDP	Gross domestic product
GP	General practitioner
HbA1c	Glycated hemoglobin
HCP	Healthcare professional
HIS	Hospital information systems
HIT	Health information technology
HL	Health literacy
NCD	Noncommunicable disease
OECD	Organisation for Economic Co-operation and Development
PEMAT-A/V	Patient Education Material Assessment Tool for audiovisual materials
PHR	Personal health record
PRISMA	Preferred Reporting Items for Systematic review and Meta-Analysis
PRISMA-P	Preferred Reporting Items for Systematic review and Meta-Analysis Protocols
PwD	People/person with diabetes
PwT1D	People/person with type 1 diabetes
PwT2D	People/person with type 2 diabetes

QATSDD	Quality assessment tool for reviewing studies with diverse designs
REALM	Rapid estimate of adult literacy in medicine
SDM	Shared decision-making
SI-DEP	Système d'information de dépistage
SISRA	Plateforme Système d'Information de Santé Rhône Alpes
S-TOFHLA	short test of functional health literacy in adults
T1D	Type 1 diabetes
T2D	Type 2 diabetes
TIR	Time in-range
TPE	Therapeutic patient education
WHO	World Health Organization

Résumé

La gestion des maladies chroniques est un défi de santé, du point de vue individuel et populationnel. Cela implique des interactions régulières avec de multiples professionnels de la santé, pour des périodes pouvant aller jusqu'à la durée d'une vie. Les systèmes de santé actuels nécessitent de trouver des solutions pour offrir des soins intégrés, tout en améliorant leur efficacité et en réduisant les coûts. Des stratégies importantes étudiées et testées sont la coordination de soins, la collaboration interprofessionnelle et la décision partagée. Ces stratégies peuvent être améliorées par des solutions numériques, qui peuvent, à la fois, optimiser la communication et fournir des informations de santé précises et au bon moment également aux patients et aux professionnels de la santé. Une possibilité pour permettre cet accès aux informations médicales, ou de santé de manière plus générale, simplifiée et facile à comprendre est de générer des visualisations des trajectoires de soins, composées d'épisodes de soins (consultations, procédures, etc.) et de leurs résultats (prescriptions et changements de traitement, ordonnances et résultats d'examens, etc.) extraits de bases de données de santé, pour être utilisées au moment de la prise de décision ou pour fournir des réflexions sur la pratique courante et comment l'améliorer.

Parmi les maladies chroniques, le diabète a un des plus grands impacts de santé publique : c'est encore une des premières causes de complications et de morts prématurées entre les adultes âgés de 20 à 79 ans dans le monde. En France, plus de 3,5 millions de personnes étaient traitées pour un diabète en 2020. Il s'agit aussi d'une des maladies le plus étudiées dans la littérature scientifique, souvent utilisée comme champ d'expérimentation pour des innovations de la pratique de soins, comme l'éducation thérapeutique, ou encore des innovations technologiques. En partant de l'attention donnée actuellement aux solutions de eSanté, cette thèse a pour objectif d'investiguer l'offre courante et l'usage des solutions numériques utilisant des données de santé collectées en routine pour étayer la coordination de soins et la décision partagée en soins chroniques, plus particulièrement en diabétologie. Nous avons développé, en utilisant une approche interdisciplinaire utilisant des éléments de la santé publique, de l'informatique médicale et de la psychologie de la santé, un protocole d'une revue systématique, la revue en soi et une étude qualitative. Nous avons considéré trois domaines complémentaires : clinique, technologique et comportemental.

Ce travail est composé donc de 3 articles : un protocole d'une revue systématique décrivant et synthétisant des méthodes de visualisation des parcours de soins chroniques extraits de bases de données, la revue systématique en soi et une étude qualitative investiguant comment les trajectoires de soins des personnes vivant avec un diabète sont construites en vie réelle, et comment les solutions eSanté sont utilisées pour favoriser la coordination de soins et la décision partagée en France. Comme plusieurs méthodes ont été proposées les dernières années pour quantifier et visualiser les trajectoires de soins, les deux premiers articles avaient l'objectif de décrire leur contenu et développement, et aussi de créer des recommandations communes pour la construction des parcours de soins chroniques dérivées de données de santé. Le protocole a suivi les *Preferred Reporting Items for Systematic review and Meta-Analysis Protocols* (PRISMA-P). Il a décrit la recherche dans la littérature des publications en anglais révisées par comité de lecture dans des bases de données comme PubMed (MEDLINE), Scopus, IEEE, CINAHL et EMBASE, sans restriction de date. L'extraction de données et l'analyse de contenu déductive-inductive des articles sélectionnés ont aussi été décrites. La revue systématique, à son tour, a suivi les *Preferred Reporting Items for Systematic review and Meta-Analysis* (PRISMA). Les données portant sur les informations et les objectifs cliniques, le développement technologique et les caractéristiques principales des méthodes, et aussi les comportements des utilisateurs illustrés dans les articles ont été présentées de façon narrative et résumées en tableaux. Des 2920 articles identifiés, 14 ont été inclus (une évaluation et 13 rapports descriptifs). Les objectifs cliniques étaient axés sur la prise de décision (6 articles), la coordination de soins (7 articles) ou l'interprétation de données (1 article). Le développement technologique a suivi un processus similaire partant de la définition de la portée jusqu'à la validation de l'outil, avec des niveaux de détails variables. Trois articles ont décrit des comportements des utilisateurs faisant référence à : l'accès aux outils, la planification des soins, l'adaptation du traitement, ou le support à l'adhésion thérapeutique. Les résultats montrent que l'utilisation de bases de données de santé électroniques pour quantifier et visualiser des parcours de soins chroniques est un domaine émergent. Des rapports standardisés et plus détaillés des aspects cliniques et technologiques sont nécessaires. Une attention limitée a été donnée à comment ces visualisations de parcours de soins seraient utilisées, validées, et mises en place en pratique courante.

Le troisième article présente une étude qualitative, VOIES-D-ql, composée d'entretiens semi-dirigés avec un échantillon choisi à dessein de 15 professionnels de la santé en diabétologie, 12 personnes vivant avec un diabète de type 1 et 6, avec un diabète de type 2. L'objectif de cette étude était d'investiguer l'usage des outils de eSanté pour faciliter la coordination de soins et la décision partagée en diabétologie, à la fois du point de vue des professionnels et des personnes vivant avec un diabète. Les guides d'entretien ont été développés, testés, et incluaient des questions sur les mêmes 3 domaines (clinique, technologique et comportemental). Les entretiens ont été retranscrits et analysés en utilisant la méthode de *framework* en suivant la structure des guides d'entretien. Les résultats de cette étude ont montré que la communication et la transmission de données entre professionnels et avec les patients ont été signalées encore comme très dépendantes des patients eux-mêmes. La plupart de l'information transmise était composée de résultats d'analyse de sang et de comptes-rendus de consultation. Les deux groupes ont décrit une ambivalence par rapport à l'utilisation d'outils technologiques. Les professionnels ont décrit une augmentation du fardeau cognitif et des tâches chronophages. Les personnes vivant avec un diabète ont décrit un manque important d'usabilité et de capacité d'adaptation des applis de eSanté et également des systèmes hospitaliers dédiés aux patients. Les outils eSanté doivent se focaliser particulièrement sur l'intégration des systèmes et sur l'entrée automatique de données. Les fonctions les plus importantes ressorties lors des entretiens étaient celles qui facilitaient l'envoi et la réception des données et la communication entre professionnels, et entre professionnels et patients.

Pour conclure, ce travail présente un ensemble de recommandations au développement et à la mise en place des outils eSanté en général, et, en particulier, d'un outil qui proposerait la visualisation de parcours de soins chroniques pour fournir des informations faciles à lire pour augmenter la documentation et le processus de décision partagée dans le cadre des maladies chroniques. Les résultats rapportés dans cette thèse apportent des contributions à la littérature scientifique sur les caractéristiques des outils technologiques développés dans le monde pour visualiser les parcours de soins chroniques, ainsi comme sur l'expérience de soins des personnes vivant avec un diabète, et l'usage d'outils eSanté pour assister la coordination de soins et la décision partagée en diabétologie en France.

Executive summary

Managing chronic conditions is a health challenge, both from an individual and from a populational perspective. It involves periodic interactions with multiple healthcare providers for up to a lifetime. Healthcare systems currently work toward integrated care to improve care and efficiency while reducing costs. Some important strategies that have been studied and tested are care coordination, interprofessional collaboration and shared decision-making. These can be enhanced by digital solutions, that can potentially improve communication and provide accurate and timely health-related information to both patients and healthcare professionals. One possibility to provide simple and easy access to medical and health-related information is to generate visualizations of care trajectories composed of healthcare events and its results, extracted from electronic healthcare databases, to be used at the point of care, or to provide insights into current practice and ways of improving it. These trajectories can be constructed by linking multiple data sources and extracting time-stamped healthcare utilization events (e.g., consultations, procedures, and its results such as prescriptions of medications or tests, test results, etc.) and other medical data related to individual or groups of patients over a specific time.

Among chronic conditions, diabetes has one of the biggest public health impacts: is still a leading cause of serious complications and premature deaths among adults aged 20-79 years in the world. In France, more than 3.5 million people were treated for diabetes in 2020. It has also been extensively studied and been used as an experimentation field for care practice or technological innovation. Building on the contemporary attention given to eHealth solutions, this thesis aimed to investigate the current offer and use of eHealth solutions using routine collected data to support care coordination and shared decision-making in chronic care, diabetes care in particular. We have elaborated, with an interdisciplinary approach putting together elements from public health, health informatics and health psychology, a protocol for a systematic review, the systematic review, and a qualitative study. We considered three complementary domains, clinical, technological, and behavioural.

This work is, thus, composed of 3 articles: a protocol for a systematic review describing and synthesizing methods of visualization of data-driven chronic care delivery pathways, the systematic review, and a qualitative study investigating how care trajectories of people with diabetes are currently being constructed in real life, and how eHealth technologies are being used to assist care coordination and the shared decision-making process in France. As several methods have been proposed in recent years to quantify and visualize care trajectories, the first two articles aimed to describe their content and to derive common recommendations for data-driven chronic care delivery pathways construction. The protocol followed the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P). It described a literature search for peer-reviewed publications in English in databases such as in PubMed (MEDLINE), Scopus, IEEE, CINAHL and EMBASE, without date restrictions. Data extraction and a deductive-inductive content analysis of the selected records were also described. The systematic review followed the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA). Data on clinical information and aims, technological development and characteristics, and user behaviors presented were summarized in tables and presented narratively. Of 2920 records identified, 14 studies were included, all descriptive reports. Clinical aims focused on treatment decision making (6 records), care coordination (7 records) or data interpretation (1 record). Technological development followed a similar process from scope definition to tool validation, with various levels of detail in reporting. Three articles described user behaviors, that referred to: accessing tools, planning care, adjusting treatment, or supporting adherence. Results show that using electronic healthcare databases for quantifying and visualizing chronic care delivery pathways is an emerging field. Detailed and standardized reporting of clinical and technological aspects is needed. Limited consideration was given to how chronic care delivery pathways would be used, validated, and implemented in clinical practice.

The third article presents a qualitative study called VOIES-D-ql, composed of semi-directed interviews with a purposive sample of 15 healthcare professionals involved in diabetes care, 12 people with type 1 diabetes and 6 people with type 2 diabetes. It aimed to investigate the uses of eHealth tools to facilitate care coordination and shared decision-making in diabetes care from the perspectives of healthcare professionals and people with diabetes. Interview guides were developed, tested, and included questions on the same three domains (clinical,

technological, and behavioral). Interviews were transcribed verbatim and analyzed using the framework method, following the structure of the interview guides. Results have shown that communication and data exchange between providers and with patients was reported as still highly dependent on patients themselves. Most exchanged information were blood test results and summary letters exchanged between physicians. Both groups described ambivalence towards the use of eHealth and other technological tools. Professionals described an increase in cognitive burden and time-consuming tasks. People with diabetes described a substantial lack of usability and adaptability of both mHealth apps and patient-dedicated hospital systems. Data sharing with and among providers was viewed as necessary, if patients are informed, give consent, and confidentiality and data security are ensured. Healthcare professionals valued interprofessional collaboration but described a lack of time to exchange with other providers and set common goals for patients. In conclusion, several improvements are needed to adapt the eHealth tools offer to the current needs of healthcare professionals and of people with diabetes. eHealth tools development should focus particularly on system integration and automatic data feeding, and on features that facilitate data exchange and provider-provider and patient-provider communication.

This work is ended by a set of recommendations to the development and implementation of eHealth tools in general, and particularly of a tool that would propose chronic care delivery pathways visualization to provide easily readable information to enhance healthcare documentation and the shared-decision making process in the context of chronic conditions. In closing, the results reported in this thesis bring contributions to the scientific literature on characteristics of technological tools developed to visualize chronic care delivery pathways worldwide, as well as the healthcare experience of people with diabetes, and the use of eHealth tools to assist shared decision-making and care coordination in diabetes management in France.

1. General introduction

The adequate management of chronic conditions is one of the biggest contemporary health challenges worldwide (*WHO / Noncommunicable Diseases*). Despite decades of research, many issues on how to best support patients are still current, and many patients do not get the care they want or need (Coleman et al., 2009). Many strategies have been studied to improve chronic care, such as care coordination, interprofessional collaboration, shared decision-making, among others, and eHealth solutions have been tested and implemented to either support these strategies or deliver interventions (Baysari & Westbrook, 2015; Bond, 2014; Carayon et al., 2019; Chaudhry et al., 2006; Davis et al., 2017; De Raeve et al., 2017; Vrijhoef et al., 2017). Diabetes, either type 1, type 2, or gestational diabetes, is one of the most commonly studied chronic conditions and has been used as an experimentation field for many of these strategies (Avery et al., 2012; Brzan et al., 2016; Busetto et al., 2016; Chatterjee et al., 2018; Cotter et al., 2014; Holmen et al., 2017). Practices have changed and much progress has been made, but challenges remain - diabetes is still a leading cause of serious complications and premature deaths among adults aged 20-79 years (*WHO / Noncommunicable Diseases*). In France, in 2020, more than 3.5 million people were treated for diabetes and complications are still very frequent (*Le diabète en France*). One axis of action is to enhance the therapeutic decision-making process by providing accurate and timely health-related information to both patients and healthcare professionals (HCP). In this direction, the new national health strategy puts a special focus on digital health. This thesis is set out to investigate the current use of eHealth solutions to mediate care coordination and the shared decision-making process between patients and HCP in the context of chronic care, particularly solutions including visualizations of care delivery pathways (CDP) (in French, *parcours de soins*). The sections below present the key-concepts used in the thesis.

Chronic conditions

The most prominent cause of disability and premature death worldwide, representing the highest number of disability-adjusted life years (DALYs) in the Global Burden of Diseases, are non-communicable diseases (NCD), also known as chronic conditions (*Global Burden of Disease (GBD)*, 2014). Seventy-one percent of annual deaths globally are attributable to NCD. According to the World Health Organization (WHO), cardiovascular diseases account

for most deaths, followed by cancers, respiratory diseases, and diabetes – together, these four groups cause 80% of premature deaths related to chronic conditions (*WHO / Noncommunicable Diseases*). The rise in prevalence of such conditions is highly related to unhealthy lifestyles and population aging. Evidence shows, however, that 15 million annual deaths related to chronic conditions occur between the ages of 30 and 69 years (defined as premature deaths). The definition of chronic condition applied in this work is any condition requiring medical attention over 12 months (Goodman, 2013).

In France, in 2019, 18 % of people covered by the government health insurance lived with a chronic condition (in French *affection de longue durée*, ALD) (*Les résultats de la sécurité sociale en 2019 / Cour des comptes*, 2019). This represents more than 11 million people. According to the French Court of Auditors, in 2016, chronic conditions represented 60 % of the costs in the health insurance reimbursement system, close to 90 billion € per year. In addition, the increase in the number of people covered for a chronic condition is steep: more than 10 times superior to the growth of the general population in the last 20 years (*Sécurité sociale 2016 / Cour des comptes*, 2016).

The management of chronic conditions

Most of the time, the management of chronic conditions requires a long-term and multidisciplinary approach, including therapeutic education and lifestyle changes, to prevent the aggravation of symptoms and the occurrence of complications, loss of quality of life, and, ultimately, death. Chronic care is focused on multi-professional teamwork and usually involves many health care professionals (HCP). Considering the long-term aspect of chronic care, going up to a lifetime, and its configuration, healthcare becomes more and more complex and costly (Hamine et al., 2015).

To improve chronic care, Wagner et al. have proposed, in a series of articles starting in 1998, the chronic care model (CCM) (Bodenheimer et al., 2002a, 2002b; E. Wagner, 1998; E. H. Wagner, 2001; Wagner EH et al., 2002) to provide a structure for redesign and reform of primary care to adapt its offer to patients' needs. This model is composed of 6 essential and interrelated healthcare components: self-management support, clinical information systems, delivery system redesign, decision support, healthcare organization, and community support.

The goal behind the elaboration of such a model, and of other initiatives to improve chronic care (Ouwens et al., 2005), is essentially improving patient outcomes by the interaction of a prepared and proactive multi-professional team with informed and active patients (Figure 1-1). Essential aspects of chronic care that are targeted are continuity of care and care coordination (Chen & Ayanian, 2014; Haggerty et al., 2003), which have been described to decrease care fragmentation, health care costs, medical errors, hospital readmissions, and avoidable emergency visits (Chen & Ayanian, 2014; Hussey et al., 2014).

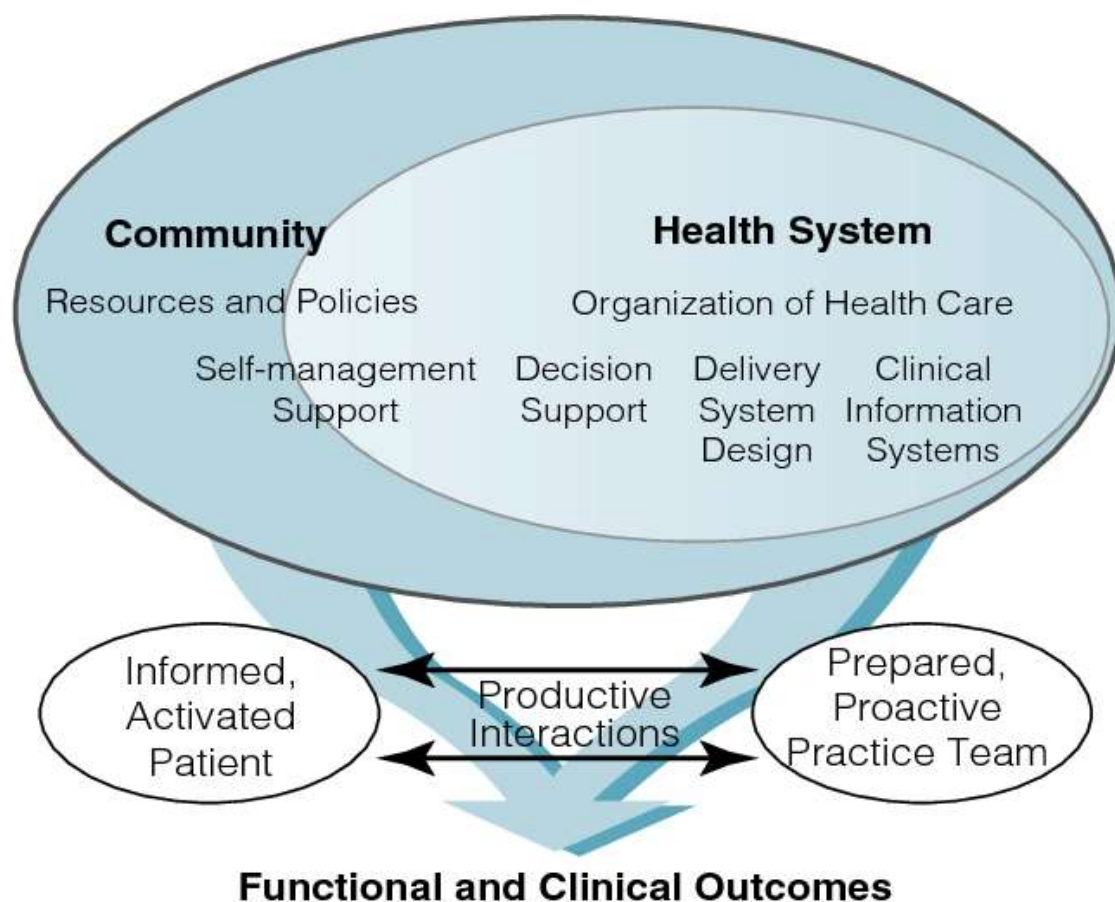


Figure 1-1 – Model for improvement of chronic illness care (E. Wagner, 1998)

In a study from 2009, Coleman et al. (Coleman et al., 2009) have shown accumulated evidence supporting the effectiveness of the CCM in improving chronic care. Evidence is stronger when most or all six components are acted upon, but studies examining the relationship between the presence of CCM elements and quality of care have also shown improvements, measured by process or outcome measures.

Care coordination and interprofessional collaboration

Care coordination has been seen in the last 20 to 30 years as necessary for effective primary and chronic care, with benefits ranging from decreasing costs by reducing hospital admissions (Hussey et al., 2014) to improving the quality of chronic disease management and improved patient satisfaction (Friedman et al., 2016). Although international consensus recognizes its essential role in providing high-quality person-centered care, it is a large and poorly defined concept. Schultz and McDonald (2014) reviewed the published definitions of the term 'care coordination' to identify common themes and provide a clearer working definition. They have stated five core elements of care coordination: participants (at a minimum the patient and a physician, but normally involving multiple providers and family or caregivers as well), interdependence (each participant provides specialized knowledge, skills, and services, and they are dependent upon each other to carry out the patients' care), roles and resources (participants must be aware of each other's roles and actions), information exchange (coordination depends on the exchange of critical information about patients, which inform participants of each other's actions and help guide decision-making), articulation of a goal (the aim is to ensure patients receive appropriate healthcare services, at the right order, at the right setting) (Schultz & McDonald, 2014).

Coordinated care is viewed in opposition to fragmented care, and it is commonly measured by the concept of 'continuity of care' (Chen & Ayanian, 2014). To define 'continuity', Haggerty et al. (2003) reviewed the literature and proposed that it represents how single healthcare events are experienced as coherent and consistent with patients' needs and contexts. They also stated its two core elements: care of an individual patient (continuity is related to the individual patient's care experience), and care over time.

Interprofessional collaboration, in turn, is defined as cooperation between different HCP to ensure the best use of resources, by combining complementary competencies and skills (Supper et al., 2015). Although the concepts of care coordination, interprofessional collaboration, and continuity of care have been used interchangeably in the literature, in this work, interprofessional collaboration is considered an integrative part of care coordination, especially in the case of chronic care, and continuity of care as an outcome of care coordination.

Health information technology

Health information technology (HIT) is a term that covers a wide range of tools used to store, share, and analyze health information, from electronic health records (EHR) and personal health records (PHR) to electronic prescribing tools (Buntin et al., 2011; Chaudhry et al., 2006; Kruse & Beane, 2018). The introduction of such technologies started in the 1960s, but a steady increase in HIT adoption was observed in the years 2010-2020, coinciding with government policies prioritizing EHR implementation with the objective of supporting integrated care, improving information exchange, reducing costs, medical errors, paperwork, among others (Adler-Milstein et al., 2015, 2017; Blumenthal, 2010; Shekelle et al., 2006). At the point of care, such technologies allow for improving the decision-making process, either by providing access to essential information or by embedded clinical decision support systems (CDSS) that alert and/or advise on diagnosis and treatments (Häyrynen et al., 2008).

There are, however, multiple challenges associated with the adoption and use of HIT, especially EHR. Studies have shown the use of EHR to more than double HCP's cognitive efforts and increase workload (Dunn Lopez et al., 2021), decrease consultation time dedicated to talking to patients (Sinsky et al., 2016), increase the number of tasks executed by physicians, who also must adapt to continuously changing systems and interfaces (Arndt et al., 2017; Benda et al., 2016). It has also been shown that design flaws and usability issues can decrease clinicians' efficiency in executing daily tasks (Ariza et al., 2015), cause patient harm (Howe et al., 2018), and are associated with increased rates of burnout (Melnick et al., 2020). Solutions proposed by the authors of several studies include certification requirements and testing standards (Ratwani et al., 2015), compliance with usability requirements and focusing on specific high-cognitive workload clinical tasks during systems design (Ariza et al., 2015).

In the absence of interoperable HIT and easily accessible actionable health-related information, patients themselves are often left to store and ensure information exchange between providers (Melnick et al., 2020), and clinicians have to integrate information themselves using oral accounts, paper, and different software to guide health-related decision-making.

The French eHealth context

In France, two main governmental programs have been created by the French Ministry of Health to accelerate the adoption of HIT and particularly EHR. The first one, called Digital Hospital (in French *Hôpital numérique*) (*Le Programme Hôpital Numérique - Ministère Des Solidarités et de La Santé*) was implemented in 2012-2017 and aimed to develop and modernize hospital information systems (HIS). The second, My Health 2022 (in French *Ma santé 2022*), announced in 2018, is a much larger program aiming to reorganize and transform the French healthcare system. It puts a particular focus on the governance of health data, with actions such as the creation of specialized institutions such as the Health Data Hub and the Agency of Digital Health (in French *Agence du Numérique en Santé* (ANS)), and more broadly on the acceleration of implementation, adoption, and use of health-related digital services and platforms (DICOM_Lisa.C, 2017; *Feuille de route « Accélérer le virage numérique en santé »*).

Electronic healthcare databases and the DMP

The French healthcare system offers high-quality care, average health outcomes are good, and France invests more than 11% of its GDP in healthcare (Goujard, 2018). Yet, some areas are still underdeveloped when compared to other OCDE countries. One of these areas is the use of eHealth, particularly the digitalization of health data and its utilization in current practice, and it has been an important bottleneck over the last two decades. Currently, two main types of EHD co-exist in France, the EHR focused on service provision and administration such as physicians' health records (in French, *logiciels métier*), hospital records, health networks' patients' records, pharmacy records, and the claims reimbursement databases, such as the one from the national public health insurance system (in French, *Assurance Maladie*), and others from the private insurances. The main attempt at integration is the national electronic medical record, also called personal or shared medical record, the DMP (Odeh, 2016). Other initiatives such as health networks (in French, *réseaux de santé*) composed of different local and regional actors also exist.

The beginning of the DMP project was the passing of a law in August 2004 (n° 2004-810, on the government health insurance). The intention was to implement the record nationally in only 3 years, by July 2007. The first version of the DMP, called at that time in French "*Dossier*

Médical Personnel” (in English, Personal Medical Record) was a distributed region-wide record containing personal health information entered by HCP and stored in a server approved and controlled by the ministry in charge of health, aiming to allow easy and fast access to medical information, to facilitate care coordination, and to improve care quality and continuity. After an abrupt interruption following a joint report by three ministries, the Ministry of Economy, Finances and Labor, the Ministry of Budget, Public Accounts and Civil Service, and the Ministry of Health, Youth and Sport (in French, *Ministère de l’Économie, des Finances et de l’Emploi, Ministère du Budget des Comptes publics et de la Fonction publique, and Ministère de la Santé, de la Jeunesse et des Sports*), a second attempt (DMP 2) was initiated in 2009 and launched in December 2010, with a slower approach aiming to implement it nationally in a decade. The uptake, however, was once again not as expected: the government expected 2 million users by the end of the first year (2010) and 13 million by the end of 2014, but only 150 thousand people opened a DMP account by July 2012 (Burnel, 2018; Odeh, 2016; Séroussi & Bouaud, 2017). In 2014 the name of the record was changed to “*Dossier Médical Partagé*” (in English, Shared Medical Record) (Odeh, 2016), particularly to focus on its role to support care continuity and information sharing between care teams (Séroussi & Bouaud, 2017), more than a record mainly managed by patients themselves. Unlike the first time, in 2009, during the second attempt, the government opted for a nationally centralized configuration instead of region-wide records. This means health-related information is centrally stored in purpose-built platforms and care records are specifically created to allow information sharing (Séroussi & Bouaud, 2017). The information contained in such care records is not as exhaustive as on EHR such as physicians’ health records, but HCP have access to the essential information needed to support coordinated management (Séroussi & Bouaud, 2017) – ideally, after each interaction with the healthcare system, HCP or health organizations should upload into the DMP, if applicable, hospital reports, lab results, x-ray results, prescriptions, primary care summaries, and all other relevant information (Figure 1-2). It is important to point out that the DMP is not intended to replace physicians’ health records or HIS, it is intended to be an intermediary tool, interoperable with available software and other systems. Currently, the data in the DMP are document-based, with no structured medical data or metadata, which prevent further analyses, for research or routine performance monitoring purposes. Important advantages

of the DMP 2, as it was thought, are that it has been developed to be person-centered, in an opt-in model (to benefit from DMP, each individual had to open an account, or authorize a HCP to open one for them), and controlled by the patients themselves, meaning they are the ones to authorize and control the access of HCP to their data. However, this was not without controversy: Seroussi et al (2016) describe the difficulties HCP have had to accept the DMP, as many have considered that patients could potentially hide important medical information.

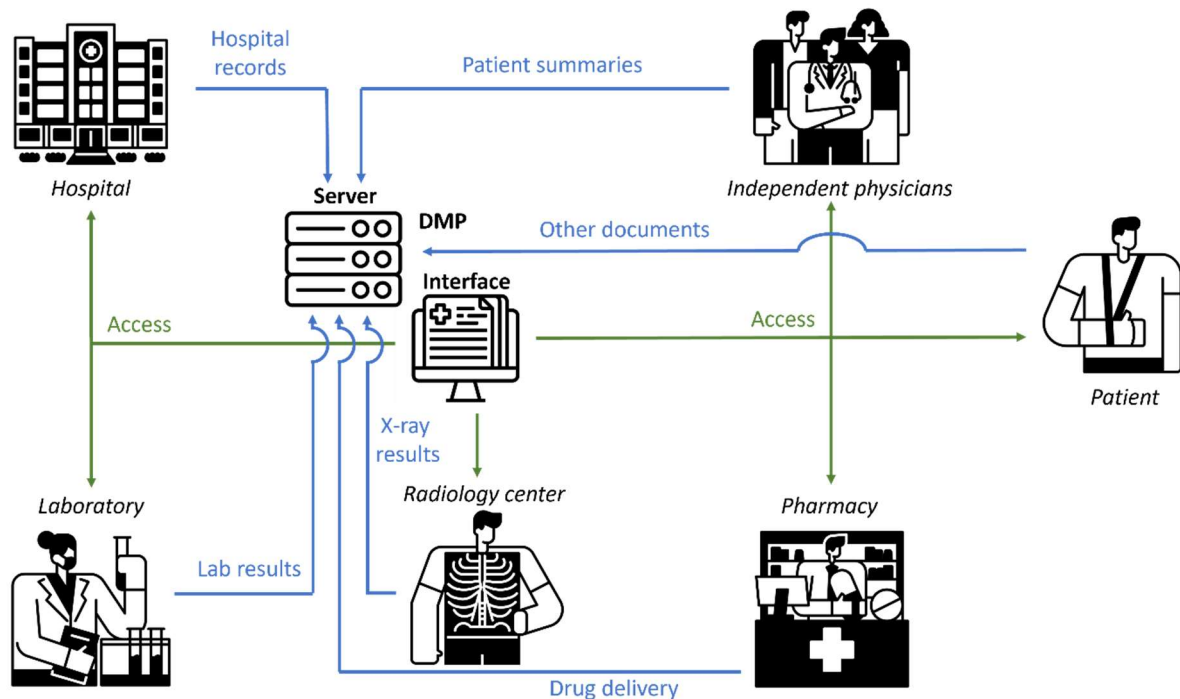


Figure 1-2 - DMP data input and access

Barriers and facilitators to the implementation of the DMP

In the study performed by Serroussi et al in 2016, ordered by the French ministry in charge of health, a working group with the involved stakeholders (physicians, patients, and administrators) was set up and several meetings were carried out to investigate the reasons for the poor adoption of the DMP and generate recommendations to increase its uptake. According to the authors, the reasons for its slow adoption were both cultural and technical: no clear political support, no culture of medical information sharing among health practitioners, no education of patients and citizens, and the persistence of technical difficulties. They described the measures that had been adopted to facilitate the implementation of the DMP, like patients being able to open their own accounts without a HCP involved, and the transfer of the responsibility of the project from the ASIP-Santé, the

Agence des systèmes d'information partagés de santé (in English, Agency of shared health information systems) to the government health insurance, which was able to, for instance, offer financial incentives and promote the DMP use among private physicians. Burnel (2018) also discussed the difficulties related to HCP being responsible for creating DMPs, which can be time-consuming in short consultations, and the fact that HCP only see the benefit of using the DMP once enough HCP and patients are using it, since it is a cooperative tool.

The new health national strategy My Health 2022 and its implications

After the launch of the strategy My Health 2022, the acceleration of the digitalization of healthcare data, also called the health digital turn (in French, *virage numérique*), became a priority. The DMP was then embedded into a larger project, in French the “*Espace Numérique de Santé*” (ENS) (in English, Digital Health Space), also called “*Mon Espace Santé*” (in English, My Health Space). The participation model has been changed to opt-out (all users have an account unless they explicitly express the desire to close it). A new important feature added to the DMP is the automatic feeding by the government health insurance of the healthcare history of the previous 24 months, instead of the information being fed by HCP. Other than the DMP, this personal digital space will include a calendar (Agenda), a secure messaging system (MSSanté professionnels et citoyens, in English MSHealth professionals and citizens), an electronic prescription system (e-prescription), care coordination tools (e-parcours), and other eHealth applications that will be made available to users, who will be able to download them according to their individual needs. For HCP, a package of services (in French, “*Bouquet de Services*”) has been created to and will be launched in 2022, aiming to provide access to the current offer of eHealth applications (*Doctrine du numérique en santé*). In 2019, the ASIP-Santé became the *Agence du numérique en santé* (ANS) (in English, Agency of digital health), under the recently created *Délégation ministérielle du numérique en santé* (DNS) (in English, Ministerial delegation of digital health) (*L'ASIP Santé devient l'agence du numérique en santé*). This was the result of a roadmap following the new health strategy, in an effort to create conditions to develop and regulate digital health, to promote innovation to benefit professionals and patients, and to assist public authorities to conduct digital projects of national interest (*Feuille de route « Accélérer le virage numérique en santé »*). This agency is responsible for creating toolkits concerning data security and systems interoperability and implementing basic services essential to

developing eHealth in the country, such as authentication services and cyber surveillance, and promoting the use of secure messaging systems. A timeline of the DMP project up to 2022 is presented in Figure 1-3.

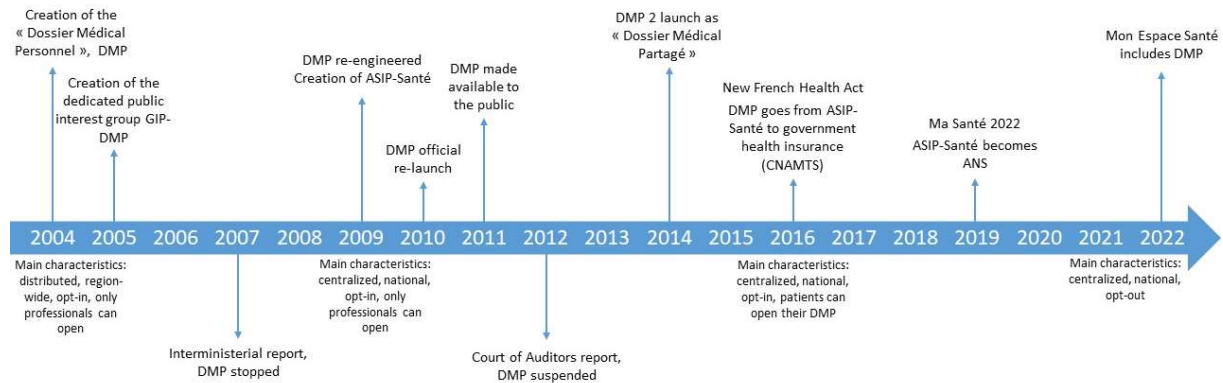


Figure 1-3 - DMP project timeline

Other important points of the My Health 2022 strategy are the promotion of the use of EHR nationally to serve as data entries for several eHealth platforms, the creation of the nationwide data platform Health Data Hub to allow for the exploitation of large healthcare datasets, and the promotion of telemedicine and telehealth services.

In 2020, the ANS has published a technical policy framework (in French, *doctrine du numérique en santé*), an annually updated document with a set of principles to guide the development of eHealth projects by different actors (*Doctrine du numérique en santé*), and a roadmap to accelerate the digitalization of healthcare data including 30 actions and the correspondent time frames (Pon & Létourneau, 2020). The roadmap presents 5 main directions, listed below.

- Strengthen the governance of digital health;
- Increase security and interoperability of health information systems;
- Accelerate the implementation of essential digital services;
- Implement nationally the digital health platforms;
- Support innovation and promote stakeholder engagement.

The agency also published in 2019 and 2020 documents with the results of the actions performed concerning the health digital turn (*Feuille de route « Accélérer le virage numérique en santé »*).

During the Covid-19 global pandemic, several digital projects were carried out by the French government, like the app TousAntiCovid, open to the general public, and the *Système d'information de dépistage* (SI-DEP) (in English, Screening information system). This system was designed to receive the Covid-19 test results, monitor the number of cases, and, in case of a positive test, make the connection to the government health insurance, and inform the person of the test result. The pandemic has increased the acceleration of the digitalization of health-related data and services, already underway before 2020. For example, the implementation of the SI-DEP system has triggered an important increase in the number of e-CPS, which will, in turn, permit the use of other platforms by HCP (*Feuille de route « Accélérer le virage numérique en santé »*).

Although the DMP project has had an arduous path, recent data show that about 9.7 million DMP were created up to November 2020 (*Feuille de route « Accélérer le virage numérique en santé »*). The public policies resulting from My Health 2022 and the eHealth technical policy framework are based on stakeholder participation and transparency, through council meetings and the periodic update of the pivotal guidelines. This is, however, very recent, and yet to be evaluated. The implementation of the ENS occurred in the beginning of 2022, and the package of services for HCP has not yet been implemented at the time this thesis is being written. The eHealth applications that will be integrated to the ENS will be made available in an “application store” model, and industrial actors will be responsible for the needs assessment, and application development and launch.

Electronic healthcare data visualization

One way to improve the usability of EHR and the actionability of the presented information is to generate health data visualizations (Park et al., 2022; Stadler et al., 2016). These visualizations can be temporal (presented with timelines) and context- or disease-oriented. Different types of data points, such as medical consultations and other encounters with HCP, treatments, procedures histories, etc., can be presented in user-friendly dashboards or interfaces for both HCP and patients to, for example, retrace chronic care delivery pathways.

Examples of health data visualization, with different objectives and applications, are LifeLines (tool providing general visualization of personal histories, applied to medical and court records) (Plaisant et al., 1996), AdhereR (A. Dima et al., 2019; A. L. Dima & Dediu, 2017)(tool to visualize medication histories and estimation of medication adherence), EventFlow (Monroe, Lan, Lee, et al., 2013; Monroe, Lan, Morales del Olmo, et al., 2013) (tool to visualize temporal event sequences and healthcare discovery), amongst others.

Information visualization enhances the understanding of data and provides insights into abstract information by leveraging the human visual system (Patterson et al., 2014). It has been shown to reduce missing information, facilitate the spotting of anomalies and trends, and the recognition of visible patterns. At the population level in healthcare, the identification of disease trajectories can provide useful information to adapt health services to patients' needs (Jensen et al., 2014).

eHealth, mHealth, and chronic diseases

Electronic and mobile health (eHealth and mHealth) tools have the potential to mediate the process of patients' active engagement in self-management behaviors adapted to their specific context. Such tools can help promote therapeutic patient education (TPE), provide feedback on patient-generated data and symptom monitoring, provide health information, and give instructions on actions needed in life-threatening situations and other emergencies (Brzan et al., 2016; Darlow & Wen, 2016; Gustavell et al., 2018; Khairat & Garcia, 2014; Licskai et al., 2013; Maguire et al., 2015).

Several studies have shown, however, that mHealth applications (apps) intending to promote lifestyle changes such as weight loss or increase physical activity, or for the self-management of chronic conditions, are lacking behavior content (Direito et al., 2014) and have low levels of understandability and actionability (Prado et al., 2019), and therefore the potential to facilitate self-care behaviors might be currently underexploited.

One of these studies was published in 2019 by our research group (see Annex 1). We have systematically searched electronic databases to identify peer-reviewed articles assessing health apps for the self-management of chronic conditions, and we searched for top apps in the "Medicine" category on the Google Play store using 12 keywords related to the four

most common chronic conditions (cardiovascular diseases, cancer, respiratory diseases, and diabetes). Only apps in French were included. We then extracted background characteristics (star, ratings, etc.) and assessed the presence of behavior change techniques (BCT), and we evaluated their content using the Patient Education Material Assessment Tool for audiovisual materials (PEMAT-A/V) to compute understandability and actionability levels. Our results have shown the apps targeted few behaviors and included few BCT; levels of understandability were considerably low and of actionability, were close to null (ranging from 0 to 100).

Shared decision-making in chronic care

Historically, medical decision-making was based on a paternalistic approach, with physicians making the decisions themselves and merely presenting them to patients. During the 20th century, a novel approach based on patient autonomy was introduced, and in the 21st century, the shared decision-making (SDM) model was introduced and widely supported across the world. This model is not binary, but a continuum, potentially adaptable to different contexts (Figure 1-4) and always based on the patient-provider relationship, ethical principles, and patient preferences (Kon, 2010).

Five formats of SDM are possible (Figure 1-4): patient-driven, when the patient has strict autonomy and the physician only presents options and the patient makes the choice; physician recommendation, when the physician explains options and makes a recommendation, ideally based on the patient's values previously known by the physician; equal partners, when the physician and the patient work together to reach a mutual decision, but the physician ensures patient's values guide the decision; informed nondissent, when the physician determines the best course of action and fully informs the patient, always guided by the patient's values; and physician-driven, when the physician independently makes decisions, which, ideally, only apply for value-neutral situations.

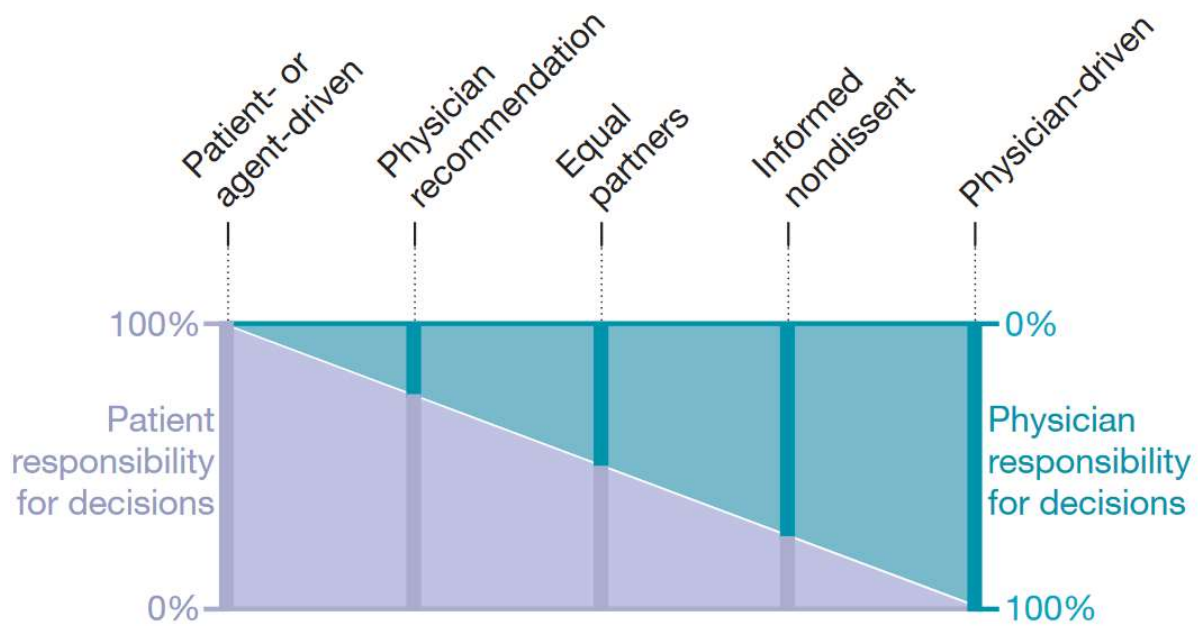


Figure 1-4 - Shared decision-making continuum (Kon, 2010)

In chronic care, SDM is particularly important because, unlike in emergency or hospital care, patients themselves are the ones to carry out any medical or health-related decision made during the consultation. The paradigm of decision-making in chronic care is, however, different from acute care: decisions can be revisited and reversed during periodic encounters without life-threatening consequences. Interventions targeting patients aiming to increase patient participation and promote active involvement have been shown to improve important outcomes, such as HbA1c – an indicator of blood glucose levels over 3 months – in the context of diabetes. Such participation is considered to be essential to put in place the decisions made during the consultation, resulting in better self-management (Montori et al., 2006).

A few studies have investigated the potential role of HIT – particularly PHR, in SDM. A scoping review carried out by Davis et al. in 2017 has introduced an integrated SDM-PHR conceptual framework (Figure 1-5). The most studied condition in the 38 papers they have reviewed was diabetes, and the most common patient activity for SDM was “access to health information”. Most research was focused on informing PHR implementation, and the studied outcomes were affective-cognitive (related to patient-provider communication), behavioral (related to decision-making, medication management, and adherence to adapted

behaviors), and health-related (physiological measures, quality of life, and symptom management). They have concluded that, although the use of HIT such as PHR is advocated as an instrument to facilitate SDM, research is yet to prove its effectiveness as a mechanism to improve patient outcomes. In addition, they proposed that EHR and PHR have to be designed on an interconnected architecture to create a complete and shareable account of the patient's profile, to allow personalized decision-support – which, in turn, adds value to HIT and would potentially increase its adoption and integration into routine practice.

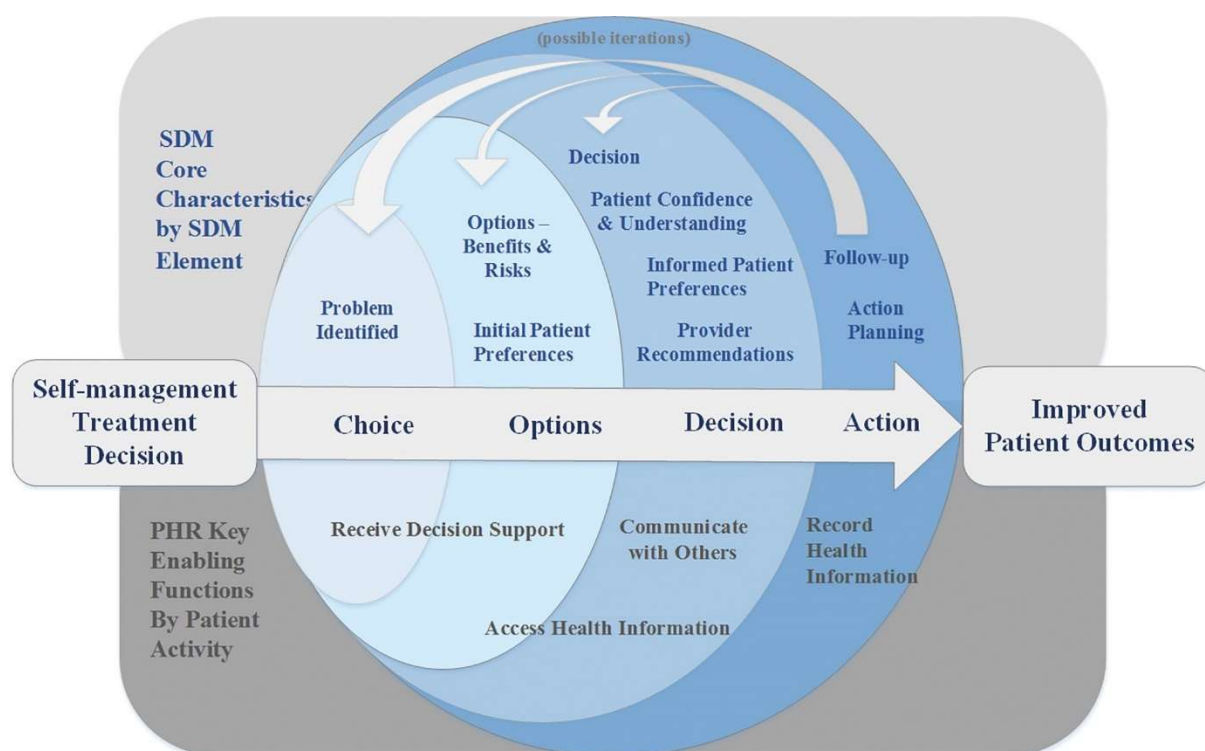


Figure 1-5 - SDM-PHR conceptual framework (Davis et al., 2017)

Health literacy

Health literacy (HL) is a concept that has been more and more used in public health and healthcare in recent years. It was introduced more than fifty years ago, and Sorensen et al., in 2012, have performed a systematic literature review of its multiple definitions and created an integrated model to facilitate its application to research and practice (Figure 1-6). They also present a broad and comprehensive resulting definition: *“Health literacy is linked to literacy and entails people's knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in*

everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course”.

Low levels of HL are associated with worse health outcomes in general (Paasche-Orlow & Wolf, 2007), and, in the context of chronic conditions, have a consistent association with poorer disease-related knowledge and self-efficacy, as well as playing a role in affecting behaviors necessary for the development of self-management skills (Mackey et al., 2016).

Different authors have proposed different dimensions for HL (Baker, 2006; Medicine et al., 2004; Paasche-Orlow & Wolf, 2007; Speros, 2005). The work by Nutbeam et al. (2008), reviewed by Sorensen et al., proposed 3 dimensions for HL, the first being functional health literacy, which refers to basic skills in reading and writing to function in everyday situations, the second, interactive health literacy, that are more advanced cognitive and social skills to participate in everyday situations, extract information and derive meaning from communication, and the third, critical health literacy, more advanced cognitive and social skills that can be applied to critically analyze information and be used to exert greater control over life situations.

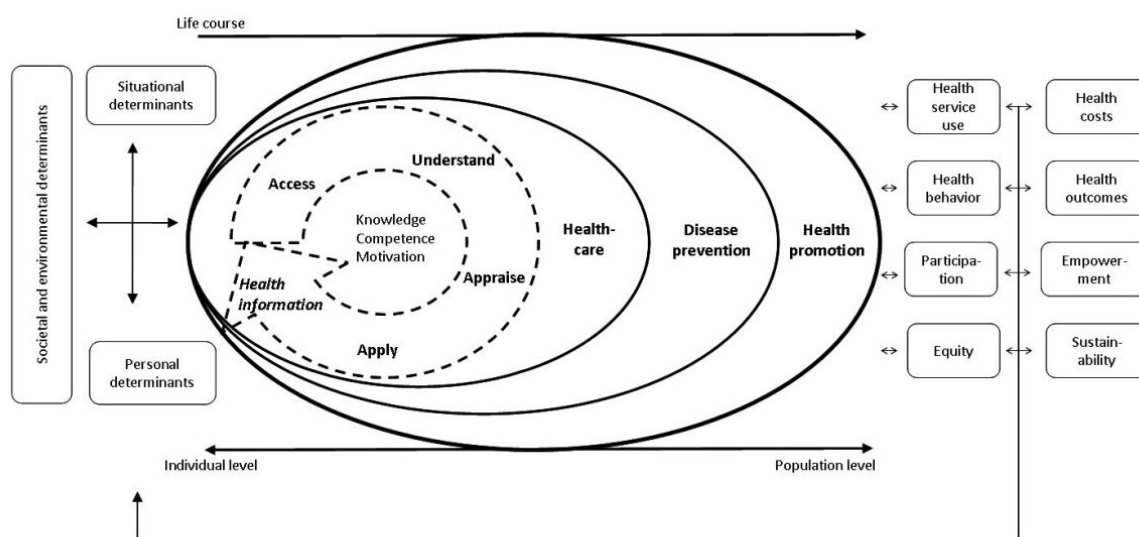


Figure 1-6 – The integrated model of health literacy (Sørensen et al., 2012)

HL has both been conceptualized as a risk factor for health outcomes, such as the association of low HL and a range of health conditions, and as a personal asset, or a set of skills that can

be worked on to improve health decision-making (Nutbeam, 2008). In the context of chronic conditions, HL is of particular importance (Mackey et al., 2016; Paasche-Orlow & Wolf, 2007), since patients need to interact with HCP and the healthcare system, addition to the need to be able to grasp condition-related oral and written information on diagnosis and treatment, adequate self-management behaviors, lifestyle changes, more recently, digital solutions such as health information websites, patient platforms, mHealth apps and PHR. For healthcare services and individual HCP, to assess patients' HL levels provides a way to adapt communication. Several instruments to measure HL exist, the most applied in research being the rapid estimate of adult literacy in medicine (REALM) and the short test of functional health literacy in adults (S-TOFHLA).

One of the instruments applied in the qualitative study VOIES-D-ql, part of this work and detailed in Paper 3, was a questionnaire called the brief health literacy screen (BHLS). The BHLS is a 3-item self-reported questionnaire with response options based on a 5-point Likert scale intended to measure functional HL, with similar performance to detect low levels of HL as the REALM or the S-TOFHLA. Our research group has carried out a content validity study with patients and HCP of the French version of the BHLS in hospital settings (see Annex 2). This study used cognitive interviews and qualitative analysis to evaluate the questionnaire and showed that, however still in need of improvement in French terms to increase adaptation to chronic care settings, it was understandable, easy, and quick to administer (Perrin et al., 2021).

The applied case: diabetes mellitus

The study VOIES-D-ql focused on type 1 and type 2 diabetes mellitus. The three main reasons these chronic conditions were chosen were: first, their importance to public health - diabetes was directly responsible, globally, for 1.5 million deaths in 2019 – 70 % of which occurred before 70 years, and is a major cause of blindness, kidney failure, heart attacks, stroke, and lower limb amputation, among other significant complications (*WHO / Noncommunicable Diseases*); second, because of it being widely studied and used as an experimentation field for technological and therapeutic innovations (Adaji et al., 2008; American Diabetes Association Professional Practice Committee, 2021b; Arnhold et al., 2014; Avery et al., 2012; Gæde et al., 2009; Greenwood et al., 2017; Holmen et al., 2017; Lepard et

al., 2015; Yu CH. et al., 2015); and third, because I have been a person with diabetes (PwD) for more than 15 years.

In France, almost 4 million people were being treated for diabetes in 2019, corresponding to a prevalence of 5.3 % of the population, with an annual average increase in prevalence of 2.23%. More than 5% of all healthcare costs are attributable to these conditions, with an annual average increase in costs of 2.83% (*Fiche « Diabète » | L'Assurance Maladie; Le diabète en France; Prévalence et Incidence Du Diabète; Sécurité sociale 2021 | Cour des comptes*).

In addition, the choice of diabetes as the target condition led us to study two considerably different patient populations, people with type 1 diabetes (PwT1D) and people with type 2 diabetes (PwT2D). Type 1 diabetes (T1D) is characterized by deficient or absent insulin production, requires daily administration of insulin, and its onset is generally early in life (childhood, adolescence, and early adult life), even if its incidence amongst older people is increasing (*Diabète de Type 1 · Inserm, La Science Pour La Santé; WHO | Noncommunicable Diseases*). It represents around 5% of all PwD worldwide. In general, this population has lived with the condition for many years, and much of the diabetes technology, such as insulin infusion pumps or continuous glucose monitoring (CGM) systems, is developed specifically for them. Type 2 diabetes (T2D) is related to the body's ineffective use of insulin, often linked to excess body weight and physical inactivity, and, even if currently more and more common in younger populations, its onset is more common at older ages (*Diabète de type 2 · Inserm, La science pour la santé; WHO | Noncommunicable Diseases*). In contrast with PwT1D, this population is generally older, less prone to technology usage and experimentation, and might only use medication, and no insulin, in addition to lifestyle changes to manage the condition.

Healthcare delivery pathways

As explained above, best practices in diabetes management – as for other chronic conditions– are based on interprofessional (or team-based) care and collaboration (American Diabetes Association Professional Practice Committee, 2021a). Generally, the core care team is composed of the patient, specialist and primary care physicians (endocrinologist, general practitioner (GP), pediatrician if patients are children or

adolescents, or geriatrician if patients are elderly), specialized nurses, and dieticians or nutritionists (Aschner et al., 2010). For the periodic screening of potential diabetes complications, ophthalmologists, dentists, cardiologists, and neurologists are included on the team. Other HCP, depending on availability and on the organization of the healthcare system, such as specialized physical educators, specialized diabetes educators, psychiatrists or psychologists, podiatrists, among others, can also be included on the team (*ALD n°8 - Diabète de type 1 chez l'adulte; ALD n°8 - Diabète de type 1 chez l'enfant et l'adolescent; ALD n°8 - Diabète de type 2*; Szafran et al., 2019).

In France, according to the document *Actes et Prestations – ALD N° 8 “Diabète de type 1 et diabète de type 2”* from March 2014 by the *Haute Autorité de Santé* (HAS) (*ALD n°8 - Diabète de type 2*), the basic follow-up is ensured by a GP or pediatrician (children or adolescents), and for eye screening patients should see an ophthalmologist once or twice a year, or a nurse, or an orthoptist, and a dentist once a year. Other HCP included in the follow-up when needed are endocrinologists, geriatricians (when frailty is observed), ophthalmologists (for medical or surgical treatment of eye complications), cardiologists (for heart tests like ECGs when not performed by the GP, other functional tests), nephrologists, neurologists, psychiatrists, nurses, dieticians (for specific cases), podiatrists, physical therapists, etc. Several other HCP might intervene for very particular situations such as psychologists, addiction specialists, specialized physical educators, expert patients, among others.

The encounters with HCP (care events) and their results, such as prescriptions of medications or tests, procedures, referrals, etc., compose what will be called hereafter care delivery pathways (in French, *parcours de soins*). Other terms such as clinical pathway, care pathway, care planning, care map, etc. (Kinsman et al., 2010) are also used to describe the standardization of care for a specific clinical problem, procedure, or episode of healthcare in a specific population. We will also use the term healthcare trajectories to refer to care encounters from the patients' point of view.

In this thesis, we hypothesize that HCP and patients themselves need access to important information about e.g., previous encounters, test results histories, and other interactions with the healthcare system over time to be able to make informed decisions. Easy access to such information has the potential to not only retrace encounters and provide a general

view of the care context, but also to avoid test and medication prescription duplication, to access medication histories and allow medication reconciliation, and potentially improve self-management if patients have timely access to their own health-related data. With this in mind, this work is organized around 3 different, but equally important, domains: 1) health-related (clinical) information essential to the decision-making process, 2) the technology itself and how it is used, and 3) the behaviors and interactions between the key actors (providers, patients, families) of the decision-making process (between providers in the context of collaboration and care coordination and between providers and patients in the context of shared decision-making).

Research problem, general objectives, and how this work is organized

eHealth solutions have the potential to facilitate care coordination and enhance the shared decision-making process in chronic care. In France and in diabetes care, this has not been explored so far from the interdisciplinary perspective described in this thesis. Therefore, the main objectives of this work were 1) to describe and synthesize how visualizations of chronic care delivery pathways built from electronic healthcare databases (EHD) (data-driven chronic care delivery pathways) are currently being generated and used in the context of chronic conditions and 2) to investigate how eHealth is currently used in diabetes management to inform shared-decision making and to promote care coordination in the Auvergne-Rhone-Alpes region in France. As such, the present work builds on the following research questions:

1. How are data-driven chronic care delivery pathways currently developed and used?
 - a. How do existing methods address clinical outcomes, what technical characteristics do they have, and what behaviors and interactions do they promote?

To answer these questions, a protocol for a systematic review of quantification and visualization methods of chronic care delivery pathways has been elaborated, registered, and published (Paper 1), as required by best practices for reviews of the literature, and a review of the literature was carried out (Paper 2). The Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) guidelines (Moher et al., 2015) and the Preferred Reporting Items for Systematic review and Meta-Analysis (PRISMA)

(Moher et al., 2009) were followed for the elaboration of the protocol and the reporting of the review, respectively.

2. How are healthcare trajectories constructed in real-life medical settings for people living with diabetes in Auvergne-Rhone-Alpes, France?

The qualitative study VOIES-D-ql was proposed to answer this question. Semi-directed interviews with HCP involved in diabetes care and with PwD (both T1D and T2D) and content analysis using the framework method were performed. The interview guides addressed the information they considered essential to the decision-making process, the use of diabetes technology and eHealth in current practice or daily life, and the decision-making process itself, between providers and the relationship patient-provider. Paper 3 presents the main results of this study, and all the other documents (in French) such as the protocol, the ethics committee approval, the information on the study presented to HCP and PwD, the initial questionnaires, and the integral content of the transcribed interviews are presented as annexes.

3. Can an eHealth tool with a patient care delivery pathway visualization be integrated into healthcare facilities and healthcare practices in the current context?

A synthesis of the state-of-the-art of eHealth and current governmental policies in France is presented in the section eHealth in France. Building on it, together with the results of the literature review and the qualitative study, in the General discussion a set of recommendations to the development and implementation of eHealth tools in general is proposed, and particularly of a tool that would propose chronic care delivery pathways visualization to provide easily readable information to enhance healthcare documentation and the shared-decision making process in the context of chronic conditions.

Therefore, the main contributions of these studies and of the thesis are 1) the identification of key data elements critical to chronic conditions management (applied to diabetes) for patients and providers alike, and 2) the creation of a comprehensive framework for assessing existing or new eHealth tools, comprising care delivery pathways visualizations in particular, and for supporting the integration of new tools into clinical practice.

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2. Article 1 - Quantification and visualization methods of data-driven chronic care delivery pathways: protocol for a systematic review and content analysis

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Abstract

Introduction Chronic conditions require long periods of care and often involve repeated interactions with multiple healthcare providers. Faced with increasing illness burden and costs, healthcare systems are currently working towards integrated care to streamline these interactions and improve efficiency. To support this, one promising resource is the information on routine care delivery stored in various electronic healthcare databases (EHD). In chronic conditions, care delivery pathways (CDPs) can be constructed by linking multiple data sources and extracting time-stamped healthcare utilization events and other medical data related to individual or groups of patients over specific time periods; CDPs may provide insights into current practice and ways of improving it. Several methods have been proposed in recent years to quantify and visualize CDPs. We present the protocol for a systematic review aiming to describe the content and development of CDP methods, to derive common recommendations for CDP construction.

Methods and analysis This protocol followed the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P). A literature search will be performed in PubMed (MEDLINE), Scopus, IEEE, CINAHL and EMBASE, without date restrictions, to review published papers reporting data-driven chronic CDPs quantification and visualization methods. We will describe them using several characteristics relevant for EHD use in long-term care, grouped into three domains: 1) clinical (what health-related events it includes and for what clinical aims?), 2) data science (how is the method developed and what data infrastructure it relies on?), and 3) behavioral (what behaviors and interactions does it promote in users and through what methods?). Data extraction will be performed via deductive content analysis using previously defined characteristics and accompanied by an inductive analysis to identify and code additional relevant features. Results will be presented in descriptive format and used to compare current CDPs and generate recommendations for future CDP development initiatives.

Ethics and dissemination Ethical approval is not required for this review. Results will be disseminated in peer-reviewed journals and conference presentations.

PROSPERO registration CRD42019140494

Keywords clinical decision support systems; medical informatics application; data visualization; clinical pathway; delivery of health care, integrated; electronic healthcare databases.

Strengths and Limitations

- While most reviews of health technology tools focus on clinical objectives and technical characteristics, we will also consider behaviours of and interactions between users to describe the selected methods.
- We will perform both deductive and inductive content analysis to fully describe the methods.
- We will focus on methods described in peer-reviewed papers and exclude conference proceedings and other types of reports, to obtain detailed validated descriptions; this may limit our access to more recent studies due to the fast-paced development in the field.
- Lack of completeness in methods descriptions may limit our ability to assess all characteristics, such as the stages of development, the involvement of stakeholders or experts prior to data acquisition and analysis.
- As this is a relatively new field of health technology, there are no guidelines for reporting and no consensus on quality criteria for the studies we will evaluate; our work will also contribute to the development of such recommendations.

Introduction

Effective delivery of integrated care is a priority for healthcare systems worldwide and has been the focus of considerable efforts in recent years, particularly in response to the increasing demands of chronic care (Bodenheimer et al., 2002b; Ouwens et al., 2005). Long-term conditions may require lifetime care, which may consist of multiple interactions with a variety of healthcare providers at variable time intervals (Bodenheimer et al., 2002a; Pham et al., 2009). When service delivery is fragmented, the overall effectiveness of these interactions in terms of long-term quality of life and health-related outcomes is reduced, and risk of harm is increased (Campbell et al., 1998; Wagner, 2001). Centralizing patient information produced by different providers in electronic healthcare databases (EHD) has the potential to help implementing new ways of service delivery to improve outcomes

(Gooch & Roudsari, 2011). Several attempts have been made to link multiple data sources to generate comprehensive descriptions of patients' healthcare journeys in long-term conditions. These descriptions are produced by constructing longitudinal trajectories from various time-stamped healthcare utilization events and related medical data (J. H. Bettencourt-Silva et al., 2015; Gotz et al., 2014; Huang et al., 2013, 2014; Jensen et al., 2014; Perer et al., 2015; Y. Zhang et al., 2015; Yang & Su, 2014; Zhang et al., 2015; Zhang & Padman, 2016). For example, Zhang et al. have produced longitudinal trajectories using electronic health records (EHR) and cost pathways (Y. Zhang et al., 2015; Zhang et al., 2015; Zhang & Padman, 2016) of people living with chronic kidney disease to inform patient engagement and to detect common pathways. Bettencourt-Silva et al. (2015) have reported on the development of a patient-centric database from multiple Hospital Information Systems (HIS) (J. Bettencourt-Silva et al., 2012) and on building data-driven pathways from routine hospital data on people living with prostate cancer to explore their potential use in biomedical research (J. H. Bettencourt-Silva et al., 2015). However, generating these informative trajectories from disparate and often incompatible data sources proves challenging (J. Bettencourt-Silva et al., 2012; Denaxas & Morley, 2015). As various initiatives have been developed independently, with distinct methodologies and objectives, it is essential to examine systematically the proposed solutions in order to derive principles of action to stimulate convergence of methods.

In the context of chronic conditions, the way patient trajectories are established may be subject to multiple influences and analyzing routine care data can provide insights on how they have been drawn over time and their potential sources of variation (Vanasse et al., 2018; Zhang et al., 2015). In the literature, trajectories within healthcare systems have been described using many terms, which makes it challenging to build consensus on terminology and practical meaning (Bleser et al., 2006; Kinsman et al., 2010). We will use the term data-driven 'care delivery pathway' (CDP) to group several terms we will find in the selected studies to designate retrospective trajectories obtained from EHD. To describe the methods proposed for synthetically displaying objective measures or assessments of health status or healthcare utilization (e.g., quantifying) and graphically showing the temporal elements of chronic CDP (e.g., visualizing), we will assess how they addressed three domains:

- 1) The selection of relevant clinical and health-related events.

This domain will examine how the methods define health status and evaluate disease progression or stabilization, and how they show transitions between health status and acute manifestations (Jensen et al., 2014). Usually, the trajectory timeline begins at diagnosis and involves more than one provider (J. H. Bettencourt-Silva et al., 2015; Jensen et al., 2014; Zhang et al., 2015). Treatment decisions are generally based on health status (indicated by biomarkers, clinical examination, self-declared levels of quality of life, etc.), care units and settings, treatment availability (medication, procedures, etc.), and patient-provider preferences (Vanasse et al., 2018).

- 2) The technological development itself and considering issues related to data quality and exchange.

This domain aims to describe how the method is built, which data sources and analyses are used, and the necessary infrastructure surrounding its implementation. Digitalization of health-related data is a global trend (Adler-Milstein et al., 2015; Ben-Assuli, 2015) and highly detailed data are being collected daily in diverse settings and healthcare services. Such methods may apply a range of techniques from basic algorithms to advanced statistical and machine learning models (Zhang & Padman, 2015), which can provide useful insights into care delivery processes. Technological developments in this field also need to meet strict criteria of data security, accuracy of models and predictions, openness of development and validation processes, among others (J. H. Bettencourt-Silva et al., 2015; Liaw et al., 2013).

- 3) Considering behaviours of actors and interactions between them with the aim of effectively improving care delivery.

Integrated care depends on multiple actions and decisions made collaboratively by patients, healthcare providers, administrative staff and other actors concerning patients' course of treatment (Peikes et al., 2009). To inform these decisions, technological solutions must have access to clinical exams and provide key actors with relevant information, such as the patients' past interactions with other providers, the medical procedures performed, the medications prescribed (Stille et al., 2005). To have a positive impact on improving care delivery, visualizations and quantitative indicators of the patient's prior care need to be

adapted to the user's needs at specific points in the trajectory, like after acute events or hospitalizations. This domain will examine what behaviors and interactions the methods promote (who are its target individuals, what actions need to be performed, in what context, when, and by whom) (Francis & Presseau, 2019; Presseau et al., 2019), and what strategies are proposed to encourage this performance.

Aims and objectives

We aim to identify and describe the methods that have been proposed to quantify and/or visualize data-driven CPDs of people living with chronic conditions. Given the complexity of their context of use, more than only reviewing technical methods, we aim to investigate how these tools have considered the three domains described above.

For this end, we propose the following research questions:

1. What clinical information does the method use and how was it considered relevant?
2. What are the method's development and implementation characteristics?
3. Which behaviours and interactions does the method aim to promote among users and how?

Methods

The Cochrane Handbook (*Cochrane Handbook for Systematic Reviews of Interventions*) and the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) (Moher et al., 2015) were used to write this protocol and the systematic review will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al., 2009). The review will be performed by one primary reviewer (LSP) and three secondary reviewers (AD, MV and SA) and will follow 6 steps: literature search, records screening and pre-selection (title and abstract), full-text screening and final selection, extraction of data, quality assessment, analysis and synthesis of data.

The studies expected to be analyzed in this work will likely be descriptive and not follow standard methodology (i.e., experimental or observational, method validation), yet considering the manuscripts as a qualitative corpus allows for coding the narratives according to the conceptual structure we propose (Gooch & Roudsari, 2011; Moreno-Conde et al., 2015). Content analysis has been used in many studies in health sciences (Elo &

Kyngäs, 2008) and an inductive content analysis applied in a systematic review of clinical information modeling processes (Moreno-Conde et al., 2015) has developed descriptive categories in a context similar to the one we propose here. As we consider them relevant to the studies we will review, they will be included in our coding framework, as detailed below.

Searches

A literature search will be performed in the following electronic databases: PubMed (MEDLINE), Scopus, IEEE, CINAHL and EMBASE. The search will be adapted to each database, and the resulting search strategies are provided as supplementary material. The terms searched will be related to three main categories, connected by the AND operator: “data-driven” (MeSH terms like “Electronic health record”, “data mining”, etc.), “clinical pathways” (MeSH terms like “clinical pathway”, “disease management”, etc.), and “chronic conditions” (MeSH term “chronic diseases”). Searches will be performed with MeSH terms or with keywords in Title/Abstract in PubMed; MeSH terms will be adapted for the databases that do not permit their usage or use different indexed terms. Bibliographies and citation tracking of relevant literature will be hand searched to identify additional relevant studies. A first selection will be performed using abstracts and titles, followed by full-text examination of entries selected.

Types of publications/studies and eligibility criteria

We will consider CDPs to be a series of time-stamped events describing the sequence of care of users with a diagnosed chronic condition (conditions requiring medical attention for a period longer than 12 months) (Goodman, 2013). These events can be the diagnosis itself, routine, non-scheduled or emergency consultations with a general practitioner and/or specialist, therapeutic education sessions and other health-related interventions. These can result in prescriptions of medications, medical procedures and tests, which may also appear in the trajectory. Data-driven CDP analyzed here will need to be composed of at least two time-stamped events recorded in EHD from people with the diagnosis of a chronic condition, with no duration restrictions (e.g., CDP may cover periods from days or few months to several years).

We will consider peer-reviewed publications (1) reporting methods for visualization or quantification of data-driven chronic CDP (including protocols and reports of study results),

(2) using data from people living with chronic conditions retrieved from EHD and (3) published in English. No restrictions on publication date, study design, population characteristics, type of healthcare facility and level of care will be applied.

We will exclude studies that aim only to assess healthcare utilization over a specific period as part of a single research study, for example as an outcome to evaluate health-related interventions, to describe populations or disease prevalence, or as a proxy measure of disease aggravation risk. We will also exclude studies that do not mention population or data characteristics or do not state they analyze data from people living with chronic conditions, papers with full-text not written in English, conference abstracts, systematic or narrative reviews, meta-analyses, and grey literature.

Screening

We will use Covidence, an online systematic review management software, for records screening. After duplicates removal, titles and abstracts in the remaining records will be screened independently by two reviewers for full text appraisal. If reviewer discordance arises, consensus will be reached through discussion and arbitration with one of the secondary reviewers not involved in the selection of the record. Studies selected in the first step will go through full text screening using the same process to establish eligibility. Inter-rater reliability (Cohen's Kappa) between primary and secondary reviewers will be computed and reported.

Data management

We will report the number of included and excluded articles as well as the number of full-text papers obtained and assessed. Reasons for exclusion of screened full-text studies will also be stated in the final review. The data will be managed using Covidence and Microsoft Excel spreadsheets.

Data extraction and analysis

We will use both deductive and inductive content analysis (Elo & Kyngäs, 2008) to appraise the selected studies: deductive when relying on pre-defined frameworks such as the categories previously described by Moreno-Conde et al. (2015) (Moreno-Conde et al., 2015) to describe the technical characteristics of the proposed solutions and on the AACTT framework (Francis & Presseau, 2019; Presseau et al., 2019) (action, actor, context, target,

time), to describe the behavioural domain, and inductive when additional relevant characteristics need to be described.

Data from included studies will be extracted using a customized electronic data extraction form. Information on study characteristics (authors, title, type of study, year and country of study, objective, and research questions); population characteristics (number of patients, age, gender, condition) will be extracted directly from the included studies.

Deductive-Inductive content analysis

We will perform a deductive content analysis following existing theories, as described below, and inductive analysis for observed relevant characteristics not yet covered by existing literature. If more than one selected record describe development, validation and/or implementation of the same method, we will extract basic paper characteristics, as described above, but the content analysis will be performed per method.

1) For the clinical domain, we will extract information on clinical or cost outcomes the method might target (if reported and which ones) and on how the outcomes were considered relevant (e.g., involving experts, final users, or other stakeholders).

2) For method development and data processing, we will analyze and compare to what has been proposed by Moreno-Conde et al. (2015) (Moreno-Conde et al., 2015). The categories detailed in the study are briefly described below.

- Scope definition leading to selection of the domain and selecting relevant experts: identifying the domain and expected uses of the method through the creation of a group of experts.
- Analysis of the information covered in the specific domain: creation of definitions, identification of clinical scenarios, workflows, users, guidelines, literature, etc., so the method meet the requirements of clinical practice or other intended usages.
- Design of the tool: detailing the set of attributes associated with the method, domain terminologies, ensuring compatibility across domains.
- Definition of implementable tool specifications: description of implementable technical specification.

- Validation: use of techniques to validate the method, such as peer-review validation or creation of prototype screens.
- Publishing and maintenance: availability in public repositories.
- Governance: description of the organization responsible for developing and maintaining the tool.

Other information extracted from studies regarding this domain will be healthcare utilization characteristics (type of event, e.g., consultation, test, procedure) and data characteristics (sources of data, data preparation, data analysis).

3) To describe behaviour and interactions the method might promote or facilitate, we will apply the AACTT (Francis & Presseau, 2019; Presseau et al., 2019) framework. Other information extracted from studies will be output characteristics like intended final users, purpose and use scenarios. We will also code the presence of strategies planned or performed to achieve these behavioural change objectives, such as training, organizational changes, evaluation of the performance of the method in routine care, if implemented, and other initiatives studies might present.

The primary reviewer and one secondary reviewer will pilot data extraction independently for a subset of 10% of selected records to compare and discuss data extraction process. If necessary, we will repeat the pilot extraction process (outlined above) until agreement is reached. Disagreements will be solved with the help of a third reviewer and piloting may consist of several interactions between reviewers to compare and reach consensus regarding relevant information to be extracted from full-text analysis. After this first step, a codebook will be developed, and data extraction of the remaining records will be performed by the primary reviewer.

Quality and bias assessment

As most quality assessment tools are developed for commonly-used study designs and there is no consensus regarding tools for generic use, we propose to evaluate quality from a different perspective. We will evaluate if main stakeholders (patients and/or family, healthcare professionals, administrative personnel) were involved at any stage of the development of the method. Research shows the importance of involving patients, the

public and other stakeholders in health-related research to obtain experiential knowledge, setting research priorities and focus on practical questions (Hoffman et al., 2010; Ocloo & Matthews, 2016; Selby et al., 2012; Staley, 2015). Also, it has been shown that trials funded by for-profit organizations can positively bias interpretation of trial results (Als-Nielsen et al., 2003), and research in data usage can be funded by companies interested in selling their own methods. To assess potential bias, we will evaluate declared conflicts of interest and sources of funding. Quality assessment will be discussed in the review, but no study will be excluded from the analysis based on quality criteria.

Data synthesis

The technical methods will be synthesized using the content analysis described above and the studies will be categorized and described using the 3 domains, depending on study type and reporting. We will present the results in tables along with method and study identification and summarize via descriptive statistics. We will compare the different characteristics within the 3 domains to identify common, infrequent, or missing features of these tools, and extract recommendations for future initiatives.

Patient and public involvement

A representant of a patients' association was involved in reading and approving of this protocol. This systematic review is part of a larger project that will be developed closely with patients and healthcare providers.

Ethics and dissemination

Ethical approval is not required. Results will be disseminated in peer-reviewed journals and/or conference presentations. Data used in this review will be made available through supplementary materials and open trusted repositories.

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In summary

This first paper is the protocol of a systematic review following the PRISMA-P guidelines. It was also reviewed by a patients' association representative (in French, *representant des usagers*), to improve the pertinence of the research. The objective of the systematic review was to describe the content and development of methods aiming to quantify or visualize CDP in the context of chronic conditions. These methods were described under three complementary aspects 1) the selection of relevant clinical and health-related events to construct the CDP, 2) the technological development itself and implementation characteristics, and 3) the behaviours of actors and interactions between them the methods aimed to promote. The choice of these 3 aspects is based on the need to put health technology into the context of care and of care organizations.

The paper has been published in February 2020 on the BMJ Open, the first database searches were performed in August 2020, and updated in April 2021 and in April 2022. Extracted data included basic characteristics (authors, title, type of study, year, country, objective,), population characteristics (number of patients and condition), clinical data included in the methods (data points and description of relevance assessment), development characteristics (architecture, database linkage, included interfaces, participation of stakeholders). As described in the protocol, we expected the reported items in the selected records to vary significantly, so we have chosen to perform a deductive-inductive content analysis using as a basic framework the categories developed by Moreno-Conde et al to describe clinical information modelling processes (CIMP).

The value of the protocol publication is to ensure that a systematic search has been carried out and all the details are available for further inspection. As in other technology-related areas, this is a fast-evolving field in which developments are not often evaluated using research methods, and only in recent years this type of literature review is becoming possible. eHealth is also an interdisciplinary field, and we have tried to encompass this characteristic by analyzing the records from the 3 different dimensions described above to add to the efforts to standardize research and development in this area. The resulting literature review is presented in the next paper.

Supplementary File 1 – Search strategy

Table 2-1 - Terms and indexed key-words applied in the databases search

Category	Medical Subject headings (MeSH) – MEDLINE (PubMed)	CINAHL Search	EMBASE	Keywords
Data-driven	Electronic health record; data mining; machine learning; clinical decision support systems; analysis, cluster; medical informatics application	MH Electronic Health Records OR MH Data Mining OR MH Nursing Informatics OR MH Machine Learning OR MH Decision Support Systems, Clinical OR MH Cluster Analysis OR MH Medical Informatics OR MH Computer Graphics OR MH Algorithms OR TI Data-driven OR TI visualisation OR TI computer graphics OR TI process mining OR TI data mining OR TI visualization OR TI supervised learning OR TI unsupervised learning OR TI practice based OR TI modelling OR TI mapping OR TI cluster* OR TI data analys* OR AB Data-driven OR AB visualisation OR AB computer graphics OR AB process mining OR AB data mining OR AB visualization OR AB supervised learning OR AB unsupervised learning OR AB practice based OR	(Electronic health record or data mining or machine learning or clinical decision support systems or analysis, cluster or medical informatics application).sh. or (Data-driven or visualisation or computer graphics or process mining or data mining or visualization or supervised learning or unsupervised learning or practice based or modelling or mapping or cluster* or data analys*).ti. or (Data-driven or visualisation or computer graphics or process mining or data mining or visualization or supervised learning or unsupervised learning or practice based or modelling or mapping or cluster* or data analys*).ab.	Data-driven OR visualisation OR computer graphics OR process mining OR data mining OR visualization OR supervised learning OR unsupervised learning OR practice based OR modelling OR mapping OR cluster* OR data analys*

		AB modelling OR AB mapping OR AB cluster* OR AB data analys*		
Clinical pathways	Clinical pathways; delivery of health care, integrated; clinical practice pattern; disease management; care management, patient	MH Critical Path OR MH Health Care Delivery, Integrated OR MH Practice Patterns OR MH Disease Management OR MH Patient Care Plans OR TI Clinical course OR TI integrated care OR TI care map OR TI care pathway OR TI care plan OR TI treatment plan OR TI patient journey OR TI patient flow OR TI clinical redesign OR TI integrated care OR AB Clinical course OR AB integrated care OR AB care map OR AB care pathway OR AB care plan OR AB treatment plan OR AB patient journey OR AB patient flow OR AB clinical redesign OR AB integrated care	(Clinical pathways or delivery of health care, integrated or clinical practice pattern or disease management or care management, patient).sh. or (Clinical course or integrated care or care map or care pathway or care plan or treatment plan or patient journey or patient flow or clinical redesign or integrated care).ti. or (Clinical course or integrated care or care map or care pathway or care plan or treatment plan or patient journey or patient flow or clinical redesign or integrated care).ab.	Clinical course OR integrated care OR care map OR care pathway OR care plan OR treatment plan OR patient journey OR patient flow OR clinical redesign OR integrated care
Chronic conditions	Chronic diseases; chronic illness	MH Chronic Disease OR TI Integrated chronic care OR AB Integrated chronic care		Integrated chronic care

MEDLINE search string

((data-driven[Title/Abstract] OR health information[Title/Abstract] OR data analys*[Title/Abstract] OR computer graphics[MeSH Terms] OR visualization[Title/Abstract] OR machine learning[MeSH Terms] OR data mining[MeSH Terms] OR clinical decision support systems[MeSH Terms] OR medical informatics application[MeSH Terms] OR algorithm[MeSH Terms] OR supervised learning[Title/Abstract] OR unsupervised learning[Title/Abstract] OR analysis, cluster[MeSH Terms] OR practice-based[Title/Abstract] OR electronic health record[MeSH Terms] OR clinical decision support systems[Title/Abstract] OR process mining[Title/Abstract] OR data mining [Title/Abstract] OR machine learning [Title/Abstract] OR medical informatics application[Title/Abstract] OR cluster*[Title/Abstract] OR modeling[Title/Abstract] OR mapping[Title/Abstract]))

AND

(chronic diseases[MeSH Terms] OR chronic illness[MeSH Terms] OR integrated chronic care[Title/Abstract])

AND

(delivery of health care, integrated[MeSH Terms] OR clinical practice pattern[MeSH Terms] OR clinical pathway[MeSH Terms] OR critical pathway[MeSH Terms] OR clinical course[Title/Abstract] OR integrated care[Title/Abstract] OR care map[Title/Abstract] OR care pathway[Title/Abstract] OR care plan[Title/Abstract] OR treatment plan[Title/Abstract] OR disease management[MeSH Terms] OR disease management[Title/Abstract] OR care management, patient[MeSH Terms] OR patient journey[Title/Abstract] OR patient flow[Title/Abstract] OR clinical redesign[Title/Abstract] OR integrated care[Title/Abstract]))

Scopus search string

(TITLE-ABS-KEY("data-driven") OR TITLE-ABS-KEY("health information") OR TITLE-ABS-KEY("data analys*") OR INDEXTERMS("computer graphics") OR TITLE-ABS-KEY("visuali*ation") OR INDEXTERMS("machine learning") OR INDEXTERMS("data mining") OR INDEXTERMS("clinical decision support systems") OR INDEXTERMS("medical informatics application") OR INDEXTERMS("algorithm") OR TITLE-ABS-KEY("supervised learning") OR TITLE-ABS-KEY("unsupervised learning") OR INDEXTERMS("cluster analysis") OR INDEXTERMS("practice-based") OR INDEXTERMS("electronic health record") OR TITLE-ABS-KEY("clinical decision support systems") OR TITLE-ABS-KEY("process mining") OR TITLE-ABS-KEY("data mining") OR TITLE-ABS-KEY("machine learning") OR TITLE-ABS-KEY("medical informatics application") OR TITLE-ABS-KEY(cluster*) OR TITLE-ABS-KEY("modelling") OR TITLE-ABS-KEY("mapping"))

AND (INDEXTERMS("chronic diseases") OR INDEXTERMS("chronic illness") OR TITLE-ABS-KEY("integrated chronic care"))

AND (INDEXTERMS("integrated delivery of health care") OR TITLE-ABS-KEY("clinical practice pattern") OR INDEXTERMS("clinical pathway") OR INDEXTERMS("critical pathway") OR TITLE-ABS-KEY("clinical course") OR TITLE-ABS-KEY("integrated care") OR TITLE-ABS-KEY("care map") OR TITLE-ABS-KEY("care pathway") OR TITLE-ABS-KEY("care plan") OR TITLE-ABS-KEY("treatment plan") OR INDEXTERMS

("disease management") OR TITLE-ABS-KEY("disease management") OR INDEXTERMS("patient care management") OR TITLE-ABS-KEY("patient journey") OR TITLE-ABS-KEY("patient flow") OR TITLE-ABS-KEY("clinical redesign") OR TITLE-ABS-KEY("integrated care"))

IEEE search string

((((((((((((((((((((((((((("Index Terms":electronic health records) OR "Index Terms":data mining) OR "Index Terms":machine learning) OR "Index Terms":clinical decision support systems) OR "Index Terms":cluster analysis) OR "Index Terms":medical informatics) OR "Index Terms":computer graphics) OR "Index Terms":algorithm) OR "IEEE Terms":medical information systems) OR "IEEE Terms":electronic medical records) OR "Author Keywords":healthcare practices) OR "Publication Title":data-driven) OR "Abstract":data-driven) OR "Publication Title":machine learning) OR "Abstract":machine learning) OR "Publication Title":cluster analys*) OR "Abstract":cluster analys*) OR "Publication Title":data mining) OR "Abstract":data mining) OR "Author Keywords":electronic health record) OR "IEEE Terms":Guidelines) OR "IEEE Terms":Data mining) OR "IEEE Terms":Algorithm design and analysis) OR data mining) OR data-driven) OR electronic health record) OR algorithm) OR visualization) OR clustering) OR algorithm)

AND (((((((((((("Index Terms":clinical pathway) OR "Publication Title":clinical pathway) OR "Abstract":clinical pathway) OR "Author Keywords ":clinical pathway) OR "Author Keywords":healthcare practices) OR "Author Keywords ":Pathway) OR clinical path*) OR care pattern) OR care plan) OR care map) OR critical path*)

AND (((("Index Terms":chronic disease) OR "Publication Title":chronic disease) OR "Abstract":chronic disease) OR "IEEE Terms":Diseases) OR chronic*

Supplementary File 2 – PRISMA-P Checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Table 2-2 – PRISMA-P checklist

Section and topic	Item No	Checklist item	Reported Item		Page No
			YES	NO	
ADMINISTRATIVE INFORMATION					
Title:					
Identification	1a	Identify the report as a protocol of a systematic review	X		44
	1b	If the protocol is for an update of a previous systematic review, identify as such	X		
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	X		45, 47
Authors:					
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	X		43
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review		X	
	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	X		
Amendments					
Support:					
Sources	5a	Indicate sources of financial or other support for the review		X	
Sponsor	5b	Provide name for the review funder and/or sponsor		X	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol		X	
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	X		45, 46, 47
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	X		45, 47
METHODS					
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	X		48
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	X		47, 48
Search strategy	10	Present draft of search strategy to be used for at least one	X		Supplementary

		electronic database, including planned limits, such that it could be repeated		File 1
Study records:				
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	X	50
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	X	48, 49, 50
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	X	48, 49, 50
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	X	49
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	X	
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	X	
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	X	
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	X	
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	X	
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	X	50
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	X	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	X	

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

3. Article 2 - Quantification and visualization methods of data-driven chronic care delivery pathways: a systematic review

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Abstract

Objective Electronic healthcare databases (EHD) are increasingly used for informing clinical decision-making. In chronic care, linking and accessing information on healthcare delivered by different providers could improve coordination and health outcomes. Several methods for quantifying and visualizing this information into data-driven care delivery pathways (CDP) have been proposed. We aimed to describe the content and development of CDP methods and propose recommendations for future work.

Materials and Methods We conducted a systematic review following PRISMA. We searched peer-reviewed publications in English reporting CDP methods using chronic care data, and extracted data on clinical information and aims, technological development and characteristics, and user behaviors described. Data were summarized in tables and presented narratively.

Results Of 2921 unique records identified, 14 studies were included, 13 descriptive reports and one validation study. Clinical aims focused on treatment decision making ($n = 6$), care coordination ($n = 7$) or data interpretation ($n = 1$). Technological development followed a similar process from scope definition to tool validation, with various levels of detail in reporting. User behaviors ($n = 3$) referred to accessing CDPs, planning care, adjusting treatment, or supporting adherence.

Discussion Using EHD for quantifying and visualizing CDPs is an emerging field. Detailed and standardized reporting of clinical and technological aspects is needed. Limited consideration was given to how CDPs would be used, validated, and implemented in clinical practice.

Conclusion As the field expands, it would benefit from developing common standards of development and reporting that consider clinical, technological, and behavioral aspects.

Keywords: chronic care, patient pathway, data visualization, systematic review

Background and significance

Secondary use of patient data recorded as part of healthcare delivery in electronic healthcare databases (EHD) has the potential to improve healthcare quality and reduce costs (Meystre et al., 2017). As chronic care consists of interactions with many healthcare

providers for long periods of time (Bodenheimer et al., 2002; Pham et al., 2009), EHD data can be particularly useful for supporting decisions related to improving chronic care delivery (Meystre et al., 2017). With the increased prevalence of chronic conditions worldwide, healthcare organizations show a growing interest in methods to link and transform EHD data from multiple sources into comprehensive descriptions of patients' recent health status and healthcare utilization history (Samal et al., 2011; Zhang & Padman, 2015, 2016). These descriptions, which we refer to as data-driven *care delivery pathways* (CDP), may apply numeric (quantification) or graphical (visualization) methods to synthesize information on the often-fragmented patients' healthcare journeys (Do Prado et al., 2020). The aim of CDP may be to provide relevant clinical and contextual information to assist healthcare professionals (HCPs) and patients in making shared decisions on the course of treatment, or to investigate sources of variation in healthcare utilization at the organization or system levels to inform quality improvement decisions. Providing feedback from routine care delivery via CDP shows promise in reducing fragmentation and improving decision making (Samal et al., 2011). Evaluating with patients retrospectively the care pathways obtained from their electronic records, in relation to their care goals and experiences, may help assess and work towards improving person-centered integrated care in long-term conditions (Berntsen et al., 2018).

Several attempts to build such descriptions in different settings exist (Bettencourt-Silva et al., 2015; Gotz et al., 2014; Huang et al., 2013, 2014; Jensen et al., 2014; Perer et al., 2015; Yang & Su, 2014; Zhang, Padman, & Patel, 2015; Zhang, Padman, Wasserman, et al., 2015; Zhang & Padman, 2016). These initial efforts highlight the many challenges of developing CDPs that support clinical care in meaningful, reliable, and actionable ways, which can be grouped into three domains: clinical, technological, and behavioral. First, the complexity of clinical situations may require information on multiple parameters relevant for a diverse range of decisions in the care process; CDPs require careful selection of key information depending on evidence-based clinical processes and treatment options, as well as data availability (Kinsman et al., 2010; Yang & Su, 2014). Second, developing the technology to access, link, clean, and produce comprehensible descriptions of these data to make them available at the point of care is a complex task; CDPs visualization and quantification methods need to meet standards of data quality criteria of completeness, consistency,

accuracy, reliability, and timeliness, among others (Liaw et al., 2013). Third, the aims of these methods can only be reached if their intended users act on this information in ways that optimize patients' interactions with their HCPs and the decisions taken; thus, CDPs visualization and quantification methods should be designed to facilitate concrete actions by patients and HCPs in specific contexts and moments in time (Presseau et al., 2019). While these three domains have been considered in part in these initial efforts, no agreed approaches exist to deal with all the clinical, technical, and human aspects of developing, evaluating, and implementing data-driven CDP visualization and quantification methods in chronic care. As health systems embark on similar projects accessing data from EHD to guide optimization of chronic care services, they would benefit from learning from the methods developed in recent years and how they considered these three domains. The insights gained could represent a basis for specifying minimal procedures to follow in project planning, conduct and reporting future projects and thus ensure more streamlined evidence synthesis in this field.

Objective

The objective of this review was to describe and synthesize the different characteristics of quantification and visualization methods of data-driven chronic CDP published in scientific literature. Description focused on research questions corresponding to the above-mentioned domains: 1) what clinical information does the method use and how was it considered relevant? 2) what are the method's development and implementation characteristics? and 3) which behaviors and interactions does the method aim to promote among users and how?

Methods

The protocol for the present review was registered in PROSPERO (registration CRD42019140494) and published (Do Prado et al., 2020). The review followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al., 2009) (see checklist in Supplementary File 1). It followed 7 steps: literature search, records screening, and pre-selection (title and abstract), full text screening and final selection, data extraction, deductive-inductive analysis, critical appraisal, and data synthesis. We did not assess interrater reliability in article screening, disagreements were discussed between the

two initial reviewers and, if an agreement was not reached, a third reviewer made the final decision. In addition to the points mentioned in the protocol (involvement of stakeholders, source of funding, and conflicts of interest), critical appraisal was performed using the quality assessment tool for reviewing studies with diverse designs (QATSDD) (Sirriyeh et al., 2012), a 16-item quality assessment tool designed to be applied to quantitative, qualitative, or mixed-method studies. Items receive a note varying 0 (no mention at all to the item) to 3 (complete explanation). Considering the variability of our sample and the fact that the studies were not purely quantitative or qualitative, we noted the items present on the studies and attributed a NA (not applicable) label to the items that did not apply. We calculated a score by adding the note given to each item individually and dividing by the total possible considering the sum of the noted items (score ranged from 0 to 1). No other modifications were brought to the initial protocol.

A literature search was performed in the electronic databases PubMed (MEDLINE), Scopus, IEEE, CINAHL and EMBASE. The terms searched were related to three main categories: “data-driven” (MeSH terms like “Electronic health record”, “data mining”, etc.), “clinical pathways” (MeSH terms like “clinical pathway”, “disease management”, etc.), and “chronic conditions” (MeSH term “chronic diseases”). The complete search strategy is available as supplementary file to the published protocol (Do Prado et al., 2020). We considered peer-reviewed publications that (1) reported methods for visualization or quantification of data-driven chronic CDP (including protocols and reports of study results), (2) used data from people living with chronic conditions retrieved from EHD and (3) were published in English. No restrictions on publication date (up to March 2022), study design, population characteristics, type of healthcare facility and level of care were applied. Record screening was done using the online systematic review management software Covidence. After duplicates removal, titles and abstracts were screened independently by two reviewers, followed by full text screening. Disagreements were discussed with a third reviewer until consensus was reached. We then checked reference lists to find additional relevant studies.

Data from included records were extracted using an electronic data extraction form. We have extracted information on characteristics of study (authors, title, type of study, year and country of study, objective, and research questions), population (number of patients, age,

gender, chronic condition), clinical and cost outcomes, method development and validation, and stated users and use case scenarios. We also extracted data on the clinical information presented on the proposed interfaces, if present, or data summaries, along with the description of how authors evaluated the relevance of the information (e.g., consulting with experts). In the technological domain, we performed a deductive-inductive content analysis to appraise methods' development and validation (Do Prado et al., 2020; Moreno-Conde et al., 2015). Inductive analysis includes open coding and creating categories directly from the analyzed text, while deductive analysis uses existing data applied to a new context (Elo & Kyngäs, 2008). In this work, to perform the deductive analysis, we used the framework proposed by Moreno-Conde et al (Moreno-Conde et al., 2015) for describing projects defining Clinical Information Models (CIM) for supporting semantic interoperability of electronic health record systems. Based on an inductive analysis, they identified seven non-mutually exclusive categories after tagging and categorizing the extracted information of CIM processes: "Scope definition leading to selection of the domain and selecting relevant experts", "Analysis of the information covered in the specific domain", "Design of the tool", "Definition of implementable tool specifications", "Validation", "Publishing and maintenance", and "Governance" (Do Prado et al., 2020; Moreno-Conde et al., 2015). While this review focused on a different type of technology, we considered the development process similar to that of CDP methods and adopted this framework as our starting point. The inductive analysis consisted of coding the data extracted into new categories if initial categories were insufficient for its description. The resulting updated framework was discussed among two coders until consensus was reached.

In the behavioral domain, considering the usage of health information systems, such as hospital information systems (HIS) and other clinical software as health-related processes, we applied the AACTT (Action, Actor, Context, Target, Time) framework to analyze the use case scenarios presented in the selected records to describe user behaviours. AACTT is a behaviour specification framework applicable to implementation interventions in healthcare to clarify the behaviours of stakeholders across multiple levels of the health system. An action is the behaviour that needs to change, in terms that can be observed or measured; an actor is the person (or persons) that does or could do the actions targeted; a context is the physical location, emotional context or social setting in which the action is performed; a

target is the person (or persons) with or for whom the action is performed, and time specifies when the action is performed (time, date or frequency) (Presseau et al., 2019).

Results

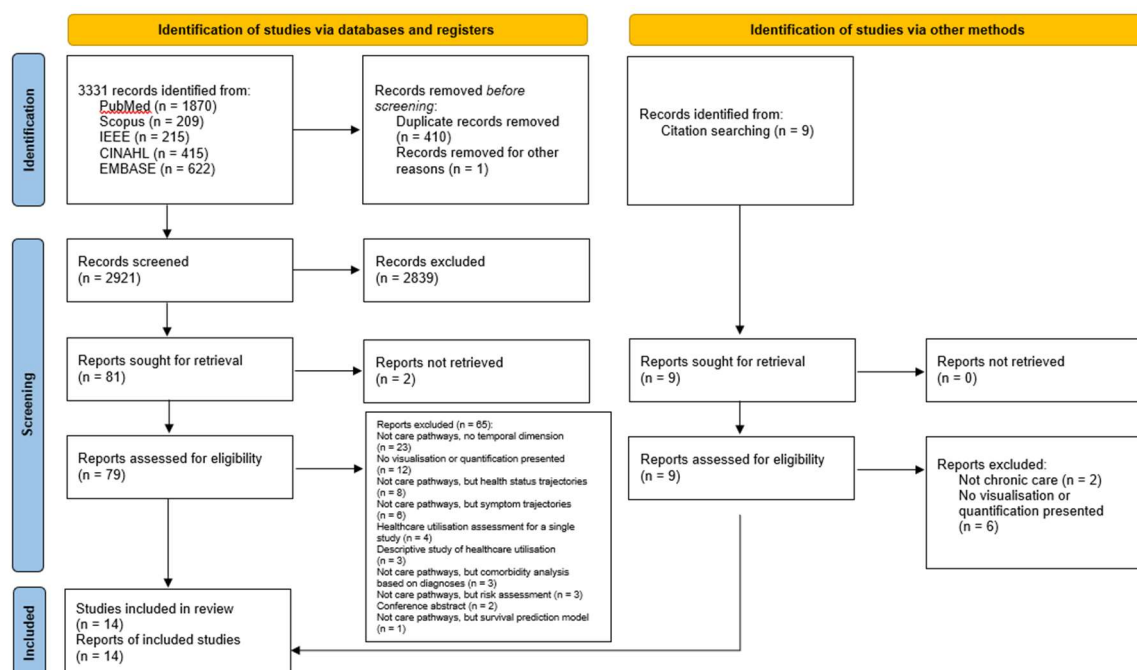


Figure 3-1 – Flow diagram

Of the 14 studies included in this review (Figure 3-1), 10 were performed in English-speaking countries (5 in the US (Hsu et al., 2012; Sun et al., 2014; Zhang, Padman, Wasserman, et al., 2015; Zhang & Padman, 2016; Zhang Y. & Padman R., 2017), 3 in the UK (Bettencourt-Silva et al., 2015; Husain et al., 2012; Litchfield et al., 2018), one in Australia (Warren et al., 1999), and one in New Zealand (Mabotuwana & Warren, 2010); the other 3 were performed in Italy (Panzarasa S. et al., 2004), China (S. Guo et al., 2019), Finland (Umer et al., 2019), and Germany (Richter et al., 2021) (Table 3-1). Most articles (n = 11) were published after 2011 (Bettencourt-Silva et al., 2015; Hsu et al., 2012; Husain et al., 2012; Litchfield et al., 2018; Richter et al., 2021; S. Guo et al., 2019; Sun et al., 2014; Umer et al., 2019; Zhang, Padman, Wasserman, et al., 2015; Zhang & Padman, 2016; Zhang Y. & Padman R., 2017). Three articles were published by the same group (Zhang, Padman, Wasserman, et al., 2015; Zhang & Padman, 2016; Zhang Y. & Padman R., 2017). One article was a protocol (Litchfield et al., 2018), 12 were descriptive studies (Bettencourt-Silva et al., 2015; Hsu et al., 2012; Husain et al., 2012; Litchfield et al., 2018; Mabotuwana & Warren, 2010; Panzarasa S. et al., 2004; S. Guo et al., 2019; Sun et al., 2014; Umer et al., 2019; Warren et al., 1999; Zhang, Padman,

Wasserman, et al., 2015; Zhang & Padman, 2016; Zhang Y. & Padman R., 2017), and one was a validation study (Richter et al., 2021). All but one study had descriptive objectives, i.e., to present a quantification or visualization method and its development. Although all of them focused on support systems for chronic care, the objectives presented by the studies focused on different topics or components of these systems: clinical decision support system (n = 1) (Umer et al., 2019), decision support system focused on care planning (n = 1) (Warren et al., 1999), data aggregation from different sources in the continuum of care (n = 1) (Richter et al., 2021), care coordination (care flow management) system (n = 1) (Panzarasa S. et al., 2004), linkage system between different datasets (n = 1) (Husain et al., 2012), system to predict health-status transitions (n = 1) (Sun et al., 2014), framework and ontology for chronic disease management (n = 2) (Hsu et al., 2012; Mabotuwana & Warren, 2010), and systems to build and visualize clinical pathways (n = 6) (Bettencourt-Silva et al., 2015; Litchfield et al., 2018; S. Guo et al., 2019; Zhang, Padman, Wasserman, et al., 2015; Zhang & Padman, 2016; Zhang Y. & Padman R., 2017). Eight studies and the protocol reported a process of validation of the reported methods (Bettencourt-Silva et al., 2015; Hsu et al., 2012; Husain et al., 2012; Litchfield et al., 2018; Mabotuwana & Warren, 2010; S. Guo et al., 2019; Sun et al., 2014; Umer et al., 2019). Only one study reported evaluation in real-life clinical settings, with patients and clinicians (Richter et al., 2021). The studies targeted different chronic conditions: type 1 and type 2 diabetes (n = 1) (Panzarasa S. et al., 2004), type 2 diabetes and hypertension (n = 1) (Litchfield et al., 2018), ankylosing spondylitis (n = 1) (Husain et al., 2012), glioblastoma multiforme (n = 1) (Hsu et al., 2012), prostate cancer (n = 1) (Bettencourt-Silva et al., 2015), traumatic brain injury (n = 1) (Umer et al., 2019), chronic kidney disease (n = 1) (Zhang, Padman, Wasserman, et al., 2015), rheumatoid arthritis (n = 1) (Richter et al., 2021), hypertension (n = 2) (Mabotuwana & Warren, 2010; Sun et al., 2014). Four studies targeted patients with multiple chronic conditions (n = 4) (S. Guo et al., 2019; Warren et al., 1999; Zhang & Padman, 2016; Zhang Y. & Padman R., 2017).

Table 3-1 - Characteristics of selected studies

Study	Title	Country	Type of study	Objectives	Studied population	
					Number of patients	Conditions
Warren et al, 1999 [1]	Chronic Disease Coordinated Care Planning: Flexible, Task-Centered Decision Support	Australia	Descriptive	descriptive: Care Planning On-Line (CPOL), a decision support system for chronic care planning at SA HealthPlus by integrating relevant information flows at the point-of-care user interface and architecture	4000	High-use patients in South Australia in ten groups including diabetes, cardiac, aged care, and lung disease
Panzarasa et al, 2004 [2]	A careflow management system for chronic patients	Italy	Descriptive	descriptive: Infrastructure (Careflow Management System; CfMS) for enabling the cross-organizational communication process of chronic disease management in diabetes care	-	Type 1 and type 2 diabetes
Mabotuwana et al, 2010 [3]	ChronoMedIt – A computational quality audit framework for better management of patients with chronic conditions	New Zealand	Descriptive and validation	descriptive: ChronoMedIt (Chronological Medical audit), a framework that takes temporal considerations into account when formulating and executing audit criteria in chronic disease management validation: To apply the framework to two practices' datasets to detect patients with suboptimal management	1286	Hypertension
Husain et al, 2012 [4]	HERALD (Health Economics using Routine Anonymised Linked Data)	UK	Descriptive	descriptive: Procedures linking patient-derived questionnaire data with routinely collected information and secondary care clinical datasets to conduct health economics analyses	715	Ankylosing Spondylitis

				validation: To map patients journeys in an Ankylosing Spondylitis cohort in 3 different settings (general practitioner, outpatients, inpatients)		
Hsu et al, 2012 [5]	Context-Based Electronic Health Record: Towards Patient Specific Healthcare	US	Descriptive	descriptive: AdaptEHR, a context-based EHR using biomedical ontologies and (graphical) disease models as sources of domain knowledge to identify relevant parts of the free-text record to extract, aggregate, map on ontologies and display in the patient record for different users depending on their information needs to inform medical decision-making validation: To implement the framework in a system called AdaptEHR to present and synthesize information from neuro-oncology patients	283	Glioblastoma multiforme (brain cancer)
Sun et al, 2013 [6]	Predicting changes in hypertension control using electronic health records from a chronic disease management program	US	Descriptive and validation	descriptive: Approach for predicting the risk and timing of transitions (deterioration/improvement) in hypertension control using all available clinical information from electronic health records (demographics, diagnoses, medications, laboratory results) and physician judgment of hypertension control status, using a feature selection strategy to identify relevant predictors validation: To evaluate the prediction approach on a patient cohort in a chronic disease management program, the Vanderbilt MyHealthTeam (MHT)	1294	Hypertension

Bettencourt-Silva et al, 2015 [7]	Building Data-Driven Pathways From Routinely Collected Hospital Data: A Case Study on Prostate Cancer	UK	Descriptive and validation	descriptive: To propose a framework for building and visualizing individual data-driven patient-centric pathways from routinely collected hospital data for prostate cancer validation: To evaluate the completeness and utility of the generated pathways for investigating biomarker trends.	1904	Prostate cancer
Zhang and Padman, 2015 [8]	On Clinical Pathway Discovery from Electronic Health Record Data	US	Descriptive	descriptive: Iterative, practice-based clinical pathway development process that integrates health IT and domain knowledge and includes elicitation of practice patterns (candidate clinical pathways) from Electronic Health Records data about the sequence of patients' visits to the clinic represented by a one-dimensional Markov chain	1624	Chronic kidney disease (CKD)
Zhang and Padman, 2016 [9]	Data-Driven Clinical and Cost Pathways for Chronic Care Delivery	US	Descriptive	descriptive: Approach to incorporate medical costs in the clinical pathways of patients with multiple chronic conditions validation: To compare a cost-centered perspective and a clinically focused perspective to show similarities and differences in the categorization of pathways and patient subgroups	288	CKD stage 3, diabetes, and hypertension
Zhang and Padman, 2017 [10]	An interactive platform to visualize data-driven clinical pathways for the management of multiple chronic conditions	US	Descriptive	descriptive: Prototype of an interactive visualization platform on treatment of patients with multiple chronic conditions (clinical pathways) - design, development, and implementation	1084	CKD, hypertension, and diabetes

Litchfield et al, 2017 [11]	Can process mining automatically describe care pathways of patients with long-term conditions in UK primary care? A study protocol	UK	Protocol	<p>descriptive: Algorithms for automated process mining for senior practice staff and commissioning groups to understand care delivery processes - method and development;</p> <p>validation: To compare the results of automated process mining with traditional process mapping methods in patients with hypertension or type 2 diabetes mellitus (T2DM) at four primary care practices.</p>	4000 (estimated)	Type 2 diabetes and hypertension
Guo et al, 2019 [12]	Visual Progression Analysis of Event Sequence Data	China	Descriptive and validation	<p>descriptive: EventThread 2 (ET2) a visual progression analysis technique and system, including a stage analysis algorithm and a system for visual query and interrogation;</p> <p>validation: To evaluate effectiveness of ET2 in identifying evolution through stages with real-world data compared to known ground truth; collect expert feedback on whether the output is meaningful, informative, easy to use, interpretable, readable.</p>	145	Cardiovascular disease
Umer et al, 2019 [13]	A decision support system for diagnostics and treatment planning in traumatic brain injury	Finland	Descriptive and validation	<p>descriptive: Decision support system for diagnostics and treatment planning in traumatic brain injury - modules and their functionalities, architecture, and development (requirement elicitation, implementation);</p> <p>validation: To evaluate the usability of the decision support systems in two clinical settings.</p>	400 (training data) + 60 (validation study)	Traumatic brain injury

Richter et al, 2021 [14]	The PICASO cloud platform for improved holistic care in rheumatoid arthritis treatment—experiences of patients and clinicians	Germany	Validation	validation: Evaluate an information and communication platform using an evaluation framework, in a 6-month proof-of-concept study in clinical routine care with rheumatoid arthritis patients and providers.	30	Rheumatoid arthritis
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Clinical domain: What information was used and how was it considered relevant?

The most common clinical aim was providing a visualization of longitudinal healthcare utilization data to optimize clinical pathways (Table 3-2) (Bettencourt-Silva et al., 2015; Husain et al., 2012; Zhang, Padman, Wasserman, et al., 2015; Zhang & Padman, 2016). Most studies used data from multiple EHD, including EHR and other HIS. The most common relevance criteria for data selection were consultation with experts (Bettencourt-Silva et al., 2015; Hsu et al., 2012; Litchfield et al., 2018; Mabotuwana & Warren, 2010; S. Guo et al., 2019; Sun et al., 2014; Umer et al., 2019; Warren et al., 1999) and the guidelines for the targeted chronic condition (Panzarasa S. et al., 2004; Warren et al., 1999). One record (Richter et al., 2021) reported an evaluation in clinical practice with patients and clinicians, and the evaluated outcomes were both clinical (patient-reported outcome measures such as functional ability and disease activity) and related to user experience (acceptability, usability, user satisfaction, clinical relevance of the platform). Some records proposed real-life evaluation criteria for future work, ranging from comparing HCPs performance with/without the proposed system (Hsu et al., 2012; Umer et al., 2019; Warren et al., 1999), comparing care maps produced by the system to the ones produced using traditional process mapping methods (Litchfield et al., 2018), to using qualitative methods such as think-aloud and focus groups (Zhang Y. & Padman R., 2017). While one record reported that the system gave feedback on cost (Warren et al., 1999) and one built care pathways using EHR and medication cost data (Zhang & Padman, 2016), none reported any cost outcome for evaluation.

Table 3-2 - Clinical aspects of the CDP quantification and visualization methods selected

Record	Clinical aim	Clinical information used	Relevance criteria	Evaluation criteria*
Warren et al 1999	To provide guideline-based elements to help clinicians formulate care plans for patients with complex and chronic illness	<p>Summary display: patient identification data, diagnoses, allergies, and key observations. The key observations vary from project to project. For example, in the cardiac project these are the cardiac risk factors of blood pressure, cholesterol, weight, smoking status and diabetes status.</p> <p>Services display: Patient's goals, all services available, individualized schedule of services, reminders of cost.</p>	Clinical guidelines: care mentors (specialists, GPs, nurses, and other health professionals) selected 5 key observations to emphasize the most critical information (per project).	Formulation of care plans by care coordinators to fictionalized cases using the system or paper. Quality of the care plan to be assessed by specialists and scored considering key health risks. Use assessed by automatic logging of GPs use of system features. User satisfaction assessed using a validated questionnaire.
Panzarasa et al 2004	To help coordinate care in diabetes by enabling primary care actors to communicate between them and with clinical service providers, and handle the overall communication process underlying chronic disease management	Medical history, physical examination, laboratory evaluation (lipid assessment, foot and eye examination, microalbuminuria, others), management plan (including insulin treatment, self-management program including blood glucose monitoring, control visits with GPs, diabetologists, nurses, dieticians, psychologists, and pharmacists).	Example on management of diabetes, relevance is decided following guidelines by the American Diabetes Association, translated into a process model using Workflow Management Coalition (WfMC) standards	-

Mabotuwana et al 2010	To help clinicians detect patients with suboptimal management by enabling them to perform quality auditing using disease-specific criteria, to support assessment of quality improvement programs or to act as a tool to support immediate follow-up	The extracted dataset consisted of demographics (age in years, ethnicity, and gender), prescribing (but not dispensing) details, classifications (diagnosis codes based on Read Clinical Codes, and some procedure codes), relevant laboratory test results, and blood pressure measurements.	Collaboration with two New Zealand general practices; series of iterative discussions with an expert panel from one of the clinics (practice manager, three GPs and two nurses)	-
Husain et al 2012	To improve diagnostic and referral pathways by 1) Retrospective and prospective tracking of patient pathways, 2) Validation of patient-reported recall data, 3) Objective measure of the cost of illness, 4) Healthcare pathways and referral history, and 5) Profiling of patients	Linking with GP data systems provides healthcare utilization history including previous diagnoses, referrals, presenting symptoms, investigation results and previous medications, associated conditions and use of co-medications; linkage with IP data provides hospital visits, surgery and hospital treatment; linkage with mortality datasets ensure dataset remains relevant; linkage with A&E give information on emergency visits; patient completed questionnaires and trial data.	Not detailed	Possible assessment of the impact of specific healthcare interventions on subsequent healthcare utilization (e.g., A&E visits or hospital admission) thanks to the longitudinal routine data.
Hsu et al 2012	To help decision making by selecting relevant information in the patient's EHR	Radiology reports (with images), pathology, oncology notes, consultation letters, surgical notes, admission/discharge summaries, and laboratory results.	All information reported for a given disease, iterative development process with physicians.	Performance of physicians is compared when using AdaptEHR versus existing means (e.g., manually generated slide presentation) while reviewing a case at a tumor board conference. Evaluation metrics will include time spent to prepare the case, ability to answer questions posed by board members (e.g., precision/recall of information

				retrieved from the patient record), and overall satisfaction with the interface.
Sun et al 2013	To enable intelligent care delivery and the detection of patient-specific risk factors within a care coordination system designed to empower a collaborative workforce to improve the health and care for patients with hypertension, heart failure, or diabetes.	Demographics, diagnoses, medications, laboratory results, BP measurements; traditional data from electronic health records supplemented with physician judgement of hypertension control status.	The model uses all available clinical information and physician inputs on BP control, a feature selection strategy is applied to identify characteristics relevant to the transition prediction algorithm.	-
Bettencourt-Silva et al 2015	To select high quality data for clinical studies and decision making; enable (re)design, management, and optimization of pathways	Patient-centric data conveyed in in workflow logs produced by multiple hospital information systems or EHR, and local cancer registry; a holistic representation of the patients, including their demographics, comorbidities, test results, or other information, and is limited by the availability of electronic information in the hospital information systems. In the case study on prostate cancer, the operational data store contains information from the following systems: administration, cancer waiting times, histopathology, radiology, biochemistry, operating theater, orthopedics, oncology, and radiotherapy.	Selection of specific data elements from the operational data store to form a pathway performed later in consultation with the domain experts (urology consultant, prostate cancer geneticists, a consultant oncologist, a histopathologist, and a chemical pathologist).	-

Zhang and Padman 2015	To provide visibility into ways to improve patients' experience during treatments, examine treatment approaches and quality of care, and foster innovative care models in healthcare practices based on treatment data	Multidimensional EHR data about patients' visits to the clinic, including the visit purpose, procedures, medications, and diagnoses, transformed into a sequence of visits represented by a one-dimensional Markov chain; combinations of the medication, visit purpose, procedure, and diagnosis nodes form super nodes representing the visit content	Developed in collaboration with a specialist/clinic; no further details	-
Zhang and Padman 2016	To achieve accurate predictions of anticipated future events and costs following different clinical and cost pathways for improved shared decision making	Previous studies: a) encounters; b) diagnoses as International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes; c) procedures as Current Procedural Terminology (CPT) codes; and d) prescriptions of medications summarized by drug classes. This study combines statistical machine learning and data visualization by specifically incorporating costs associated with medications.	Information from previous studies by the same authors developed in collaboration with a specialist/clinic and addition of costs	-
Zhang and Padman 2017	To support shared decision making in the context of multiple chronic conditions	Encounter types, diagnoses, and interventions, all recorded at different points in time	Developed in collaboration with a specialist/clinic; no further detail	Evaluation of the platform with actual users in a formal experimental setting, such as through think-aloud protocol and focus groups, is considered by the authors to be important future work. To accommodate this task, they will work on adding human computer interaction capabilities, such as recording the number of times a node is clicked

				by a user in order, to understand what features users are most interested in.
Litchfield et al 2017	(Protocol) To understand and optimize organizational performance in the management of two chronic conditions (hypertension and type 2 diabetes)	Coded information on patient contact with the service including consultations, diagnoses, prescriptions and laboratory tests, events (prescriptions, referrals, appointments, etc.) recorded with a date.	Existing algorithms as a starting point for process mining, iterative interaction with experts to validate results; focus groups with clinical and non-clinical staff and patients for process mapping.	Automatization of care patterns by comparing process models generated by process mining techniques in primary care settings to process maps generated using traditional process mapping methods.
Guo et al 2019	To improve data interpretation by providing visualization of event sequences	Application of the method to a public critical care dataset (MIMIC), containing de-identified electronic health records with timestamped events organized into seven categories (admission and discharge, death, ICU admission and discharge, prescriptions, infusions, laboratory tests, and microbiological tests)	Authors' experience in the field, a review of the existing features and limitations of existing tools, and interviews with domain expert users	-
Umer et al 2019	To help improve clinicians' confidence when deciding whether a decision suggested by a decision support system is appropriate by providing visualizations and predicting probable patient outcomes	Six core data entities: patient, injury, situation, condition, measurement and treatment related to each other with one-to-many relationship; and many specialized sub-types/entities, like CT, MRI and Glasgow Coma Scale measurements (measurement entities) or pharmacology and surgery	Specifically designed with clinicians to address data analytics challenges in clinical practice in an iterative process of design and development	Comparison of predicted outcomes (unfavorable/favorable outcome) by clinicians with/without the DSS

		(treatment entities)		
Richter et al 2021	To enable a more efficient and effective use of available data by the orchestration of available information for a patient in the continuum of care—consisting of hospitals, outpatient departments, practices, non-physician health-service providers, home monitoring—into a comprehensive view	Data from multiple sources such as hospitals, medical practices, insurance companies, and research facilities - no further detail.	User requirements were identified in focus groups comprising various stakeholders (e.g., patients, physicians, study nurse, health care insurance) and patient interviews.	Functional capacity (Functional Ability Questionnaire (FFbH)), and its values were derived to Health Assessment Questionnaire (HAQ). Self-reported disease activity (RA Disease Activity Index (RADAI)). Disease Activity Score (DAS) 28 CRP, and medication were recorded at baseline and follow-up visits (after 3 and 6 months).

* Note: Evaluation criteria were proposed for future work and not included in the research reported in the selected studies (except for Richter et al, 2021).

Technological domain: how were the methods developed and implemented?

Six of the seven initial categories proposed by Moreno-Conde et al (Moreno-Conde et al., 2015) were maintained for describing technological characteristics, referring to *scope definition*, *analysis of available information*, *tool design*, *specifications definition*, *method validation*, and *governance* (Table 3-3). However, only one study reported on the last category, and none on *publishing and maintenance*. Two new categories were identified through inductive content analysis, *Dataflow and transformation* and *Data protection*. Each of these 9 categories included up to 3 subcategories, resulting in a total of 14 technological characteristics; the 14 studies reported information referring to a median of 6.5, ranging from 3 to 11, subcategories.

- *Scope definition leading to selection of the domain and selecting relevant experts.* All studies included information on the domain to be covered and whether the scope of the presented system was geographically local or wider. Ten studies mentioned involving a group of experts or discussing with clinicians during the method development (Bettencourt-Silva et al., 2015; Hsu et al., 2012; Litchfield et al., 2018; Mabotuwana & Warren, 2010; Richter et al., 2021; S. Guo et al., 2019; Umer et al., 2019; Warren et al., 1999; Zhang & Padman, 2016; Zhang Y. & Padman R., 2017). Two of them (Litchfield et al., 2018; Umer et al., 2019) provided details about how expert feedback would be obtained and applied. Umer et al (2019) performed interviews with 11 specialists to develop a first version and later undertook an iterative process of feedback and development with 5 specialists (Umer et al., 2019); Litchfield et al (2018) reported in the protocol that the development stage would be iterative with a clinical expert and the informatics lead (Litchfield et al., 2018).
- *Analysis of the information covered in the specific domain.* Four studies (Bettencourt-Silva et al., 2015; Hsu et al., 2012; Panzarasa S. et al., 2004; Umer et al., 2019) presented clinical scenarios and workflows. Characteristics of existing systems, such as how they were implemented and documented, were also present in 4 studies (Bettencourt-Silva et al., 2015; Panzarasa S. et al., 2004; S. Guo et al., 2019; Umer et al., 2019).
- *Design of the tool.* Most studies (n = 11) detailed the set of attributes associated with the method (Bettencourt-Silva et al., 2015; Hsu et al., 2012; Litchfield et al., 2018;

Mabotuwana & Warren, 2010; Panzarasa S. et al., 2004; Richter et al., 2021; S. Guo et al., 2019; Sun et al., 2014; Umer et al., 2019; Warren et al., 1999; Zhang Y. & Padman R., 2017).

- *Definition of implementable tool specifications.* Implementable technical specifications were presented in 8 studies (Bettencourt-Silva et al., 2015; Hsu et al., 2012; Mabotuwana & Warren, 2010; Panzarasa S. et al., 2004; Richter et al., 2021; S. Guo et al., 2019; Umer et al., 2019; Zhang Y. & Padman R., 2017).
- *Method validation.* Validation or testing were performed using different strategies: application of the developed tool to a cohort of patients and evaluation of key performance indicators (n = 4) (Bettencourt-Silva et al., 2015; Husain et al., 2012; Mabotuwana & Warren, 2010; Sun et al., 2014), comparison between using the tool versus not using the tool (n = 2) (Litchfield et al., 2018; Umer et al., 2019), adding the system to an existing EHR system and collecting expert feedback through an initial usability test (n = 1) (Hsu et al., 2012), or through showing the tool to experts and performing qualitative interviews (n = 1) (S. Guo et al., 2019). One study performed a real-life evaluation (Richter et al., 2021).
- *Governance.* One study reported on the evaluation of a platform held by a consortium of European actors from 7 countries, responsible for developing and maintaining the method (Richter et al., 2021).
- *Dataflow and transformation.* The tools described in this work used datasets from different EHD, that were subsequently processed by system components to create visualizations. Explicitly describing how different datasets were linked or linkage algorithms used is important to trace the final data items and to understand how these tools could be integrated to existing EHR (Bettencourt-Silva et al., 2015; Hsu et al., 2012; Husain et al., 2012; Mabotuwana & Warren, 2010, 2010; S. Guo et al., 2019) and to consider interoperability. Also, providing the architecture or a conceptual model of the systems enables understanding of how it is structured and how the different components interact (Bettencourt-Silva et al., 2015; Mabotuwana & Warren, 2010; Sun et al., 2014; Umer et al., 2019; Warren et al., 1999). System architecture and data models, expressed in UML, XML or as ontologies, were reported in 6 studies (Bettencourt-Silva et al., 2015; Mabotuwana & Warren, 2010,

2010; Panzarasa S. et al., 2004; S. Guo et al., 2019; Umer et al., 2019). Only the work of Bettencourt-Silva et al (2015) described and discussed data quality in EHR (Bettencourt-Silva et al., 2015). One study mentioned using the HL7/FHIR standards to enable data exchange with other systems (Richter et al., 2021).

- *Data protection.* During development, measures taken to protect patients' data, like anonymizing (Bettencourt-Silva et al., 2015; Husain et al., 2012; Mabotuwana & Warren, 2010; Sun et al., 2014; Zhang, Padman, Wasserman, et al., 2015; Zhang & Padman, 2016; Zhang Y. & Padman R., 2017) or pseudo anonymizing patient data (Litchfield et al., 2018), need to be described explicitly for readers to be able to ascertain how the tool ensures protection of private or sensitive data. In one study, a publicly available anonymized dataset was used (MIMIC) (S. Guo et al., 2019) and in one study the platform was cloud-based following European standards to ensure data security (Richter et al., 2021).

Table 3-3 - Technological characteristics of the CDP quantification and visualization methods selected

Categories		[1]	[2]	[3]	[4]	[5]	[6]	[7]	[8]	[9]	[10]	[11]	[12]	[13]	[14]
Scope definition leading to selection of the domain and selecting relevant experts	Information on the domain to be covered and whether the scope is local or wider are presented	x	x	x	x	x	x	x	x	x	x	x	x	x	x
	The study involved a group of experts based on the care setting, healthcare activities and clinical requirements	x		x		x		x		x	x	x	x	x	x
	Expected uses or use case scenarios are presented		x	x							x		x	x	
Analysis of the information covered in the specific domain	Clinical scenarios, workflows and users are understood to determine the data items to be used in the method		x			x		x						x	
	Existing systems are described (how they have been implemented and documented)		x					x					x	x	
Design of the tool	The set of attributes associated with the method is detailed	x	x	x		x	x	x			x	x	x	x	x

Definition of implementable tool specifications	Implementable technical specification is described		x	x		x		x			x		x	x	x
Validation	The study presents prototype screens	x		x		x	x	x	x	x	x		x	x	x
	The method is validated (e.g.: training/testing data, pilot study, implementation test, etc.)			x			x	x				x	x	x	x
Governance	There is an organization responsible for developing and maintaining the method														x
	If applicable, this organization is in charge of quality review, publication, and relationships with other projects working on the same domain														x
Dataflow and transformation	Linkage between datasets is described	x		x	x	x		x					x		x
	The architecture of the tool is presented	x	x	x			x	x						x	x
Data protection	Data protection for the development is described			x	x		x	x	x	x		x	x		x
Number of subcategories mentioned (of 14)		6	7	10	3	7	6	11	3	4	6	5	10	10	11

Behavioural: actions and interactions to improve care delivery

Three studies presented use case scenarios with enough detail to identify who will use the method, in which activities, contexts, moments and with whom (Table 3-4). Other studies mentioned intended uses in general terms (eg, “improve shared-decision making” or “help clinicians in making decisions”). In addition, three articles did not specify who were the intended end-users (Husain et al., 2012; Litchfield et al., 2018; Sun et al., 2014), 6 stated the end-users were physicians (primary care providers or specialists) (Bettencourt-Silva et al., 2015; Hsu et al., 2012; Mabotuwana & Warren, 2010; S. Guo et al., 2019; Umer et al., 2019; Warren et al., 1999), and 5 included patients and families as end-users, in addition to physicians and/or managers (Panzarasa S. et al., 2004; Richter et al., 2021; Zhang, Padman, Wasserman, et al., 2015; Zhang & Padman, 2016; Zhang Y. & Padman R., 2017).

Panzarasa et al (2004) described two scenarios (Panzarasa S. et al., 2004). One referred to a scenario in which a physician uses the warning generated by a care flow management system from home monitoring of blood glucose defined to detect treatment response and intervene to modify treatment with the patient, if needed. The second scenario described how patients and physicians may use suggestions for periodic medical visits issued by the care flow management system based on integrated guidelines and healthcare utilization data to plan their care.

Mabotuwana et al (2010) described three scenarios (Mabotuwana & Warren, 2010). In the first, the system detects patients out of supply of a given medication and warns the physician to either address the non-adherence or provide a prescription in the next consultation. The second scenario described how the system allows the physicians to become aware of patients with whom they might have to improve communication and engage in a “problem-solving” approach, also by detecting patients with poor supply profiles. In the third, they described how a set of audit criteria and the data provided by the system would allow for an assessment of physicians’ adherence to guidelines and compare practices.

Warren et al (1999) described a scenario in which the system alerts users (physicians) to review guidelines through different warns and flags (Warren et al., 1999).

Table 3-4 - Behavioral elements present in the CDP quantification and visualization methods selected

Panzarasa et al 2004	Scenario 1: "An important task performed by the Cf is the automatic evaluation of home monitoring data, as soon as they are sent to the diabetes management center, in order to detect potential critical situations that should be notified to the care providers or that could require further clinical investigations. This analysis calculates several descriptive statistics (i.e., arithmetic means, standard deviations and the highest and lowest values in a given period of time), performs data interpretation through the extraction of patterns of clinical importance and consistency checking. If the Cf notices that the patient is not responding in the expected way to the therapy (e.g., hyperglycemia and hypoglycemia are too frequent) it generates a guideline-based suggestion to the physician about the need of a therapy modification."				
	Actor	Action	Context	Time	Target
	Physician	To modify treatment	Patient's home	After system alert	Patient
	Scenario 2: "In order to help physicians and patients in the management of the long-term screening, the CfMS schedules periodic visits based on the patient's care process history."				
	Actor	Action	Context	Time	Target
	Patient	To schedule medical visit	Patient's home	Periodically	Patient
Mabotuwana et al 2010	Scenario 1: "Awareness of immediate cases – identification of those patients that, at a particular moment in time, are out of supply of an indicated medication. In the first instance, the action is to treat the non-adherence as inadvertent and recall the patient and/or simply prescribe as indicated at the next opportunity. This includes not just patients with lapsed medications, but also those whose circumstances have changed (e.g., due to development of a co-morbidity) and thus require additions to previous therapy."				
	Actor	Action	Context	Time	Target
	GP	Treats nonadherence or add new treatments	Consultation	When identified	Patient
	Scenario 2: "Opportunity for communication with those with poor supply profiles – at some point it becomes logical to look to a lack of concordance between doctor and patient, and/or to the ability of the patient to achieve adherence for other reasons. Low Medication Possession Ratio over an extended				

	<i>time period and repeated lapses in medication supply indicate the need for improved communication between GP and patient; possibly the clinician needs to engage the patient more in a joint “problem-solving” approach in relation to underlying adherence barriers.”</i>				
	Actor	Action	Context	Time	Target
	GP	To engage in 'problem-solving' approach	Consultation	Not clear	Patient
	Scenario 3: <i>“Opportunity to critique GPs on their adherence to established guidelines and compare practices on specified criteria – for example, the JNC7 hypertension guideline recommends ACEi/ARB medication as compellingly indicated therapy for patients with comorbid hypertension and chronic kidney disease. If an agreed set of audit criteria can be established, this form of reporting also provides an opportunity to compare GP practices (as we have done here with two practices) in an attempt to provide feedback to the GPs to improve the management of their patients with chronic conditions.”</i>				
	Actor	Action	Context	Time	Target
	Not identified	To give feedback to GPs on guideline adherence	Not identified	Not identified	Patient
Warren et al 1999	Scenario 1: <i>“Users are actively alerted to review relevant guidelines through the several mechanisms: 1) Flags on observations. Right-clicking these observations or the flags will invoke the relevant guideline. Relevant guidelines will appear where observations are recorded (such as in the Initial Medical Assessment form) and in the “heads up” patient summary. 2) Flags on services. 3) Explicit save-time warnings. In some specific cases like vaccination the user will be prompted to consider a particular guideline before exiting the client application.”</i>				
	Actor	Action	Context	Time	Target
	User (GPs)	To review guidelines (not specified)	Software usage	When flags and warnings are shown	Patient

Critical appraisal

Eight records involved stakeholders at some point during the development (Bettencourt-Silva et al., 2015; Hsu et al., 2012; Litchfield et al., 2018; Mabotuwana & Warren, 2010; Richter et al., 2021; S. Guo et al., 2019; Umer et al., 2019; Warren et al., 1999). Two records declared to have received public and private funding (Sun et al., 2014; Warren et al., 1999), four did not declare funding (Bettencourt-Silva et al., 2015; Litchfield et al., 2018; Zhang,

Padman, Wasserman, et al., 2015; Zhang Y. & Padman R., 2017), and 7 declared to have received public funding (Hsu et al., 2012; Husain et al., 2012; Mabotuwana & Warren, 2010; Panzarasa S. et al., 2004; Richter et al., 2021; S. Guo et al., 2019; Umer et al., 2019), and one declared to have received no funding (Zhang & Padman, 2016). No record declared a conflict of interest – 6 included a section “Conflicts of interest” with none declared (Bettencourt-Silva et al., 2015; Husain et al., 2012; Litchfield et al., 2018; Richter et al., 2021; Sun et al., 2014; Zhang & Padman, 2016), and 8 did not include the section (Hsu et al., 2012; Mabotuwana & Warren, 2010; Panzarasa S. et al., 2004; S. Guo et al., 2019; Umer et al., 2019; Warren et al., 1999; Zhang & Padman, 2015; Zhang Y. & Padman R., 2017).

We have applied the QATSDD to the 14 studies. Only four items were applicable to all or most of the reviewed records: “Statement of aims/objectives in main body of report”, “Clear description of research setting”, “Evidence of user involvement in design”, and “Strengths and limitations critically discussed”. The assessed items and the respective notes are presented in Supplementary File 2. Calculated scores varied between 0.33 and 1 (mean = 0.64, SD = 0.16).

Discussion

Tapping into the potential of routinely collected healthcare delivery data for improving chronic care is a rapidly evolving area of research. One type of innovation that has been gathering interest is represented by methods to quantify and visualize care delivery pathways (CDPs). This review takes stock of pioneering CDP work and describes characteristics of resulting tools and their development from three key perspectives: clinical, technological, and behavioral. We identified 14 studies that targeted different chronic conditions and clinical settings in 8 countries, indicating the international reach of this emerging area. From a clinical perspective, the main aim and expected benefit of these methods was to improve physicians’ decision making by enhancing interpretation of individual-level data; to this end, clinical guidelines and collaborating clinicians provided the relevant input for method development. From a technological perspective, most studies presented details on technological development, system architecture and data sources. Few provided information on validation processes, and only one real-life evaluation was performed. Most papers reported stakeholder involvement before or during development.

From a behavioral perspective, three of 14 studies mentioned possible actions intended to follow from accessing CDP data or visualizations, essentially referring to adjusting treatment, care planning, supporting treatment adherence or reviewing prescribing behaviors according to clinical guidelines. All but one studies were descriptive reports of early development work, 11 of them published in the past 10 years and describing largely similar development steps. Critical appraisal has shown that conflicts of interest and sources of funding are stated in only about a half of the records, and instruments to assess quality do not directly apply to the type of study analyzed here. Nevertheless, the substantial variation in types of information reported indicates that the time is right for structuring common methodological standards for this emerging area for guiding future projects and facilitating evidence synthesis.

From a clinical perspective, the adoption of clinical pathways has been shown to improve outcomes such as in-hospital complications and clinical documentation, but evidence on other patient outcomes, like length of stay and hospital costs, is still unclear (Rotter et al., 2010). One way to generate practice-based clinical evidence and to detect care patterns, innovative care sequences and unwanted care variations, is to visualize care trajectories. However, we believe that, to fulfill this potential, possible uses and use case scenarios must be clearly defined in a preliminary phase of needs assessment, along with the clinical settings in which these visualizations would be applied. The reviewed studies presented views or prototype screens, but clinical aims and use case scenarios were, for the most part, insufficiently described to ascertain applicability to clinical contexts. The studies reported systems that were not evaluated in real-life settings to assess the impact of their implementation on care organization, quality, or effectiveness. Our search for subsequent articles describing further evaluation of the analyzed methods did not identify additional records.

From a technological perspective, although clinical information is readily available in current EHR systems, the diversity in patient data and the lack of interoperability between different health care organizations health information systems are still a challenge to secondary use of patient data (Meystre et al., 2017; Zhang & Padman, 2015). In this work, the main data source for most studies was EHR, but, when other HIS were used, data acquisition processes

and linkage methods were not always presented. Other systems characteristics such as architecture and data security measures were not available in all reports. Another important point is that even though essential to enable the selection of quality data for clinical investigation, data quality indicators were only reported and discussed in one paper (Bettencourt-Silva et al., 2015).

From a behavioral perspective, our work shows that the technological innovations analyzed here did not clearly specify actions or use case scenarios and, more importantly, did not always identify end-users. This is commonly the case in health services research and explains in part why, despite the potential benefits of uptake of innovations to care organization and practice, sub-optimal clinical practices persist and are associated with avoidable morbidity and mortality (Presseau et al., 2019). In this context, the AACTT framework can help describe behaviors of individuals and teams as they contribute to health care. This represents a starting point for identifying barriers and facilitators of these behaviors (at individual, team, and system level), and specific strategies or techniques to promote behavior change in the agreed direction, by features integrated in the tool or by additional user training. For example, using longitudinal health care visualizations and decision support systems, care coordination can be promoted at healthcare professional level through functions such as messaging systems to provide cues for action, or feedback on behavior from encounters history (Marchibroda, 2008). None of the selected studies mentioned strategies to promote intended behaviors or user training, which suggests that integration into clinical care was not envisaged yet by CDP developers. Moreover, system developers need to go beyond individual approaches of healthcare professionals as users and take into account the complex interactions between professionals or teams, and between professionals and patients. In the studies included in our review, patients were not systematically considered as possible users, even when aims included improving shared-decision making process at the point-of-care. Considering that access to actionable information can lead to better chronic disease management (Klein et al., 2015; Mohsen & Aziz, 2015), including patients as end-users and integrating their preferences in the development phase of such tools have the potential to improve the shared-decision making process.

As the subject of this review is relatively new – most papers selected were published after 2010 – there is a need for a common reporting structure as the field evolves. The methodological approach and data sources were found to be similar across studies, but the items reported differed. Moreno-Conde et al (2015) suggested that the common steps they identified in the development of CIMs they reviewed could define a unified process to guide their definition (Moreno-Conde et al., 2015). The steps, derived from the categories found in an inductive content analysis, were (1) scope definition and domain and team selection, (2) domain analysis, (3) CIM design, (4) definition of implementable CIM specifications; (5) validation, and (6) publication and maintenance, all encompassed by (7) a general governance process. Similarly, the studies reviewed in this work provide a set of common types of information and technological development steps that can be used as a minimal shared structure. Thus, following our data extraction framework, we propose that new data-driven CDP visualization and quantification methods development projects could consider reporting clinical aspects (aim, information used, relevance and evaluation criteria), technological aspects (which could be followed sequentially in the methods development), and behavioral aspects (identifying end users and their actions expected following the AACTT framework). CDPs visualization and quantification methods could follow a similar process with CIM development, including (1) defining scope and the work team comprising potential end-users (HCPs, patients, managers), (2) performing a domain analysis, (3) designing the tool, (4) defining implementable tool specifications, (5) detailing dataflow and transformation, (6) describing data protection, (7) performing validation by end-users; and eight step would consist in publishing the resulting data-driven CDPs visualization methods. Moreover, we consider that the development of data-driven CDPs frameworks could benefit from following established frameworks for developing complex health interventions (MRC (Skivington et al., 2021), IM (Fernandez et al., 2019), CEHRES (van Gemert-Pijnen et al., 2011)), which would improve the design and reporting of such system-level innovations.

Strengths and limitations

This review is the first to examine systematically research published in the emerging field of data-driven CDP visualization and quantification methods and propose ways to structure the conduct and reporting of such studies in the future. It is thus opening new directions for further interdisciplinary work in this field, in particular for taking into account clinical,

technological and behavioural aspects of such complex innovations equally, with a view to sustainable implementation in clinical care. Our review presents several limitations that would need addressing in future work. First, although we employed several keywords and terms in different databases, it is likely that our search might have missed some publications. This is due mainly to the diversity of terminologies employed in describing CDPs and highlights the importance of developing common terms and definitions for this type of work. We propose “*data-driven chronic CDPs*” as a unifying term, and welcome further clarifications and agreement on terminology. Second, since healthcare technology is a fast-evolving field not all technologies developed are disseminated to scientific audiences; our review did not include CDPs visualization and quantification methods not published as peer-reviewed papers. By selecting only peer-reviewed work, we have focused on CDP development projects that aimed to produce scientific evidence to support their tool and therefore our results should be interpreted as a synthesis of best available evidence. Future work could a review other types of literature to identify a broader range of methods developed in more diverse contexts.

Conclusion

Data-driven chronic CDP quantifications and visualizations add value to EHD use in clinical settings by providing contextual information to inform shared decision-making. This has the potential to improve care quality and, ultimately, patient outcomes. This review synthesized published work on constructing longitudinal healthcare utilization descriptions and proposed a set of reporting items to stimulate the convergence of methods.

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Conflicts of interest

None declared.

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In summary

The systematic review identified 14 studies reporting data-driven chronic CDPs quantification and visualization methods. We described the selected methods considering 3 complementary domains: clinical, technological, and behavioral. The main findings are summarized below.

- 1) Clinical: the studies targeted different chronic conditions and clinical settings. The most common clinical aim was to improve physicians' decision making by providing visualizations to enhance data interpretation, and authors relied mostly on guidelines and collaborations with experts to select relevant data points to exhibit.
- 2) Technological: although reporting varied, most studies presented details on technological development, system architecture and data sources. Fewer provided information on validation processes, as no common framework exists, and no real-life evaluation was performed. Most papers reported stakeholder involvement before or during development.
- 3) Behavioral: Some studies did not specify end-users or possible actions, and, in most studies, patients were not considered as end-users nor were part of consulting committees during development. No method included visualizations specifically developed to support decisions made by patients, even though some stated that support of shared-decision making at the point of care is an objective of the proposed views. Moreover, the selected studies did not provide tool integration strategies nor mentioned training to HCPs before using the tools. These characteristics suggest these systems were mostly designed as clinical research tools, or as technological innovations, and their integration into clinical care settings and existing HIS was likely not envisaged at the time.

One important contribution of this work is the assessment of the behavioral domain. During the development of eHealth tools, clinical and technological aspects are essential to define their feasibility and applicability to the current practice and to the data infrastructure available. Our findings show interactions between users that could be beneficial to care and could be promoted by these tools are often not considered during development, which shows that the potential for mediating care coordination or collaboration between providers, and patient-provider communication is not yet fulfilled. The participation of patients as experts in the development of such tools is also lacking in the reviewed studies. The next article addresses these issues and highlights the importance of patient input in eHealth tools development from the conception phase.

Supplementary file 1 - PRISMA 2020 Checklist

Table 3-5 – PRISMA Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	65
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	66
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	67,68
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	68
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	69,70 and protocol
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	69 and protocol
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	69,70, and protocol
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	69,70,71 and protocol
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	69,70,71 and protocol
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	70,71 and protocol
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	70,71 and protocol
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	69
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	NA
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	70, 71 and protocol

Section and Topic	Item #	Checklist item	Location where item is reported
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	NA
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	NA
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	70
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	NA
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	NA
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	69
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	NA
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	71
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	71
Study characteristics	17	Cite each included study and present its characteristics.	71,72,73, 74, 75, 76,77,78
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	93,94 and Supplementary file 2
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	74-78,80-85,89,90,92,93
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Supplementary file 2
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	NA
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	NA
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	NA
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	NA
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	NA
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	93-97

Section and Topic	Item #	Checklist item	Location where item is reported
	23b	Discuss any limitations of the evidence included in the review.	96,97
	23c	Discuss any limitations of the review processes used.	96,97
	23d	Discuss implications of the results for practice, policy, and future research.	95-97
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	67
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	67
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	68
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	97
Competing interests	26	Declare any competing interests of review authors.	97
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Supplementary files

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71

For more information, visit: <http://www.prisma-statement.org/>

Supplementary file 2 – Critical appraisal – application of the QATSDD

Table 3-6 – QATSDD critical appraisal

QATSDD item	Warren et al 1999	Pansara za et al 2004	Mabotuwana et al 2010	Husain et al 2012	Hsu et al 2012	Sun et al 2013	Bettencourt-Silva et al 2015	Zhang and Padman 2015	Zhang and Padman 2016	Zhang and Padman 2017	Litchfield et al 2017	Guo et al 2018	Umer et al 2019	Richter et al 2021
Explicit theoretical framework	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Statement of aims/objectives in main body of report	3	3	3	3	3	3	3	1	3	3	3	3	3	3
Clear description of research setting	3	3	3	3	3	3	3	3	3	3	3	NA	3	2
Evidence of sample size considered in terms of analysis	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1
Representative sample of target group of a reasonable	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1

size														
Description of procedure for data collection	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	3
Rationale for choice of data collection tool(s)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0
Detailed recruitment data	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1
Statistical assessment of reliability and validity of measurement tool(s) (Quantitative only)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Fit between stated research question and method of data collection (Quantitative)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	2

Fit between stated research question and format and content of data collection tool e.g. interview schedule (Qualitative)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0
Fit between research question and method of analysis	NA	NA	NA	3	NA	NA	NA	NA	NA	NA	NA	NA	NA	1
Good justification for analytical method selected	NA	NA	NA	3	NA	NA	NA	NA	NA	NA	NA	3	NA	1
Assessment of reliability of analytical process (Qualitative only)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0	NA	0
Evidence of user	3	0	1	0	1	0	3	0	0	0	3	1	3	3

involvement in design														
Strengths and limitations critically discussed	0	1	3	0	0	2	3	0	3	2	3	2	2	3
Score	0.75	0.58	0.83	0.66	0.58	0.66	1	0.33	0.75	0.66	1	0.6	0.58	0.47

4. Article 3 - eHealth uses in care coordination and shared decision-making in diabetes care in France: a qualitative study with people with diabetes and healthcare professionals

[Prepared for submission, not yet published]

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Abstract

Background Diabetes care is complex and costly, and its success in preventing disease aggravation and premature death has been described to be dependent on several components. Two important ones are care coordination and patient active involvement in care, often through shared decision-making. The use of eHealth and other technological tools can enhance these processes, by, among other uses, providing essential medical information in a timely manner. Also, diabetes is a chronic condition that has been used as an experimentation field for technological innovation given its public health importance. This study, thus, aimed to investigate the uses of eHealth tools to facilitate care coordination and shared decision-making in diabetes care by obtaining in-depth reports through qualitative interviews with both healthcare professionals and people with diabetes.

Methods We recruited a purposive sample of 15 healthcare professionals involved in diabetes care, 12 people with type 1 diabetes and 6 people with type 2 diabetes. Two interview guides, one for professionals and one for people with diabetes, were developed and tested, with questions focusing on three different yet complementary perspectives: clinical, technological, and behavioral. We performed and recorded semi-directed interviews, that were subsequently transcribed verbatim and analyzed using the framework method using the interview guides as basic structure.

Results Communication and data exchange between providers and with patients is still highly dependent on patients themselves. Most exchanged information are blood test results, HbA1c in particular, and summary letters exchanged between physicians. Both groups described ambivalence towards the use of eHealth and other technological tools, professionals described an increase in cognitive burden time-consuming tasks, and people with diabetes described a substantial lack of usability and adaptability of both mHealth apps and patient-dedicated hospital systems. Data sharing with and among providers is viewed as necessary, if patients are informed, give consent, and confidentiality and data security are ensured. Healthcare professionals value interprofessional collaboration but described a lack of time to exchange with other providers and set common goals for patients.

Conclusion The results of this study show several improvements are needed to adapt the eHealth tools offer to the current needs of healthcare professionals and of people with

diabetes. eHealth tools development should focus particularly on system integration and automatic data feeding, and on features that facilitate data exchange and communication provider-provider and patient-provider.

Keywords: eHealth, chronic care, diabetes care, care coordination, shared decision-making

Introduction

Diabetes is among the four priority noncommunicable diseases (NCDs) defined by the World Health Organization (WHO) and is one of the major causes of premature death, disability, and multimorbidity worldwide (*Non Communicable Diseases*). Because of its impact on public health, it has also been a model for experimentation and improvements in chronic care, such as therapeutic education, eHealth interventions, or mHealth applications development, and has been a testing field for telemedicine (Adaji et al., 2008; American Diabetes Association Professional Practice Committee, 2021b; Chatterjee et al., 2018; Costa et al., 2009; Holtz & Lauckner, 2012; C. L. Jackson et al., 2006; S. L. Jackson et al., 2018; Kaufman, 2010; Marcolino et al., 2018; Nobel, 2006; Siriwardena et al., 2012; Wyne, 2008). However, despite decades of developments in health care organization and technology, research shows that people with diabetes (PwD), and more generally people with chronic conditions, still face several challenges in getting the care they want or need (Coleman et al., 2009).

The approach to diabetes care, as to chronic care in general, should be interprofessional and based on ongoing collaborative communication (American Diabetes Association Professional Practice Committee, 2021a). Evidence shows it should be aligned with the Chronic Care Model (CCM) (Wagner, 1998) the framework of reference for efforts to structure and facilitate the restructuring of healthcare systems, primary care in particular, towards a collaborative, integrated, and person-centered operation. In the CCM, collaboration between informed patients and a prepared, proactive care team is essential for improving health outcomes. The model identifies 6 essential elements: community resources and policies, healthcare organization, self-management support, delivery system design, decision support, and clinical information systems (Bodenheimer et al., 2002).

In France, the interprofessional team responsible for diabetes care is generally composed of a general practitioner (GP), an endocrinologist, a nurse, and a dietician. For type 2 diabetes (T2D), the follow-up can be done by the GP only, while for type 1 diabetes (T1D) an endocrinologist is, most of the time, the physician responsible for the management of the condition. Other physicians such as geriatricians and other healthcare professionals (HCP) can be involved as stipulated by the *ALD n°8 - Diabète de type 1 chez l'adulte; ALD n°8 - Diabète de type 1 chez l'enfant et l'adolescent; ALD n°8 - Diabète de type 2*, such as adapted physical activity (APA) specialists, or nurses specialized in therapeutic patient education (TPE) within the ASALEE program. ASALEE (*Actions de Santé Libérale En Equipe*, French acronym for Actions in Liberal Health in Teams) is a program developed in France to establish interprofessional collaboration between GPs and nurses, working physically in the same places, to ensure the follow-up of some chronic conditions, namely T2D (Fournier, 2018).

Such interprofessional teams are intended to ensure continuity of care and care coordination (Chen & Ayanian, 2014; Hussey et al., 2014; Kianfar et al., 2019), which have been described to decrease care fragmentation, health care costs, medical errors, hospital readmissions, and avoidable emergency visits (*NQF: Preferred Practices and Performance Measures for Measuring and Reporting Care Coordination*). Care coordination has been shown to improve patient-provider and provider-provider communication, and patient satisfaction (Chen & Ayanian, 2014; Hussey et al., 2014), and technology has been extensively explored in recent years as a way to enhance it in several related domains such as eHealth, health information technology (HIT), or yet mHealth apps, for multiple of health conditions (Bates, 2010; Baysari & Westbrook, 2015; Burton LC. et al., 2004; Carayon et al., 2019; Cipriano et al., 2013; Darkins et al., 2008; David Bates, 2015; Falconer et al., 2018; Rigby et al., 2015; Smaradottir et al., 2015).

eHealth is a broad term that encompasses the organization and delivery of health services using the Internet and related technologies (Boogerd et al., 2015; Eysenbach, 2001; Mea, 2001; Oh et al., 2005). Examples of eHealth solutions are web-based platforms, patient portals, mobile health applications (mHealth apps), and other digital health interventions. HIT is information technology applied to health and healthcare, and these terms eHealth has

also been defined as the application of information and communication technology to health (Peterson et al., 2016). The term diabetes technology is used to describe hardware, devices, and software that PwD use to help manage the condition, varying from devices to administer insulin – syringe, pen, or insulin pumps, to blood glucose monitoring (BGM) or continuous glucose monitoring (CGM), and the dedicated software that allow visualizing the patient-generated data. More recently, the term started to cover other types of technology, such as hybrid closed-loop insulin infusion systems or automated insulin delivery systems (American Diabetes Association Professional Practice Committee, 2021b; Castle et al., 2017). In addition to the disease-specific technology, eHealth tools and HIT such as electronic health records (EHR) complete de range of technologies that health care professionals (HCP) and PwD interact with in diabetes management (Adaji et al., 2008; Aikens et al., 2014; Nobel, 2006).

HIT, which refers to the processing, storage, and exchange of health information in an electronic environment (Shekelle et al., 2006), is an important component of health decision-making in chronic care. Access to information on HIT such as health information systems or EHR is crucial for health-related decision-making, as it is based on the ability to read and act on information within specific contexts. However, just having access to such tools is not enough to improve care. Several studies have shown using systems such as EHR increases the cognitive burden among HCP (Dunn Lopez et al., 2021; Melnick et al., 2020). Other studies (Park et al., 2022; Stadler et al., 2016) have also shown the way information is presented matters to how people perceive its utility and are able to act accordingly to what has been presented. Moreover, questions for patients arise on data sharing, data ownership, data security, and data selling (Bani Issa et al., 2020; Blobel et al., 2016). Specifically in the French context, it is important to mention the personal medical record (DMP, *Dossier Medical Partagé*, in French), a centralized patient-controlled record, created to ensure information sharing among HCP according to the opt-in consent model. After a series of problems and several relaunches from 2004 to 2017, it has been embedded into the new initiative My Health Space (*Mon Espace Santé*, in French) in 2021 (Burnel, 2018; Séroussi & Bouaud, 2017).

From the patient's perspective, important practices that have been described and extensively studied in the last two decades are shared decision-making and patient access to

their own medical data (Kon, 2010; Légaré & Witteman, 2013; Mohsen & Aziz, 2015). Patient involvement, and more specifically shared decision-making in chronic care, have been shown to improve population and individual health outcomes (Légaré & Witteman, 2013; Shay & Lafata, 2015). However, the use of technology such as EHR and other software intended to facilitate access to medical information and the decision-making process in healthcare is complex and may be beneficial but also detrimental to the care process – while it increases access to medical histories and oftentimes allows more informed decisions (Ben-Assuli, 2015), it also increases the cognitive burden and does not decrease consultation time (Mishuris & Linder, 2013). Therefore, the objective of this study was to understand the current place of clinical information systems and other technological tools in chronic care delivery, more specifically diabetes care, as well as decision-making and care organization, from both patient and HCP perspectives. We aim to offer a comprehensive description of the context in which new or existing technologies can be used for person-centered care in diabetes, focusing on interprofessional and patient-provider communication and information storage, access, and exchange in diabetes care, to gain insights on what could be proposed to improve the availability of essential health-related information, and to enhance its comprehension by both HCP and patients. Qualitative methods and three complementary perspectives regarding eHealth and chronic care were chosen, 1) clinical aspects, such as which information is important to health-related decision-making, 2) behavioral aspects, such as how decisions regarding diabetes management are currently being made and how managements goals are being set, and 3) technological aspects, such as which and how eHealth and diabetes technology are currently being used.

Methods

We conducted semi-structured interviews with HCPs involved in interprofessional diabetes care and with PwD to obtain in-depth reflections on communication, information exchange, and the use of eHealth, HIS or software showing patient-generated data such as continuous glucose monitoring (CGM), for instance, to inform the process of shared-decision making in diabetes care.

In this qualitative descriptive study, we used inductive framework analysis (Gale et al., 2013). The Consolidated Criteria for Reporting Qualitative Research (COREQ) (Tong et al., 2007)

checklist is provided as Supplementary File 1. The protocol of this study was reviewed by a HCP and a patients' association representative.

Participants

A purposive sample of HCPs and PwD was recruited. We aimed to recruit 15 participants per group or stop when data saturation was reached. HCPs were recruited through contact with diabetes care departments in hospitals and medical associations in Lyon and Grenoble areas. Eligible participants were physicians (endocrinologists, pediatric endocrinologists, general practitioners (GPs), interns, geriatricians), nurses, dieticians or nutritionists, physical educators, or professionals specialized in therapeutic education, with at least one year of experience in diabetes care.

PwD were recruited through patients' associations such as the Diabetics French Federation (in French, *FFD – Fédération Française des Diabétiques*) and the Diabetic Women's French Association (in French, *Association Française des Femmes Diabétiques*). Snowball sampling was applied, by asking participants to suggest other potential participants to be contacted. Eligible participants were 1) more than 18 years old, 2) diagnosed with type 1 or type 2 diabetes for at least one year, 3) having had at least one consultation with a HCP in the last 12 months, 4) able to communicate in French, 5) affiliated to the government health insurance, and 5) having given consent to participate and to the audio recording of the interview.

Before the interviews, participants answered several questions including, for HCPs, year of birth, gender, profession, type of practice (independent versus employed), years of experience with diabetes care (for T1D and T2D), and frequency of diabetes consultations. For PwD, other than gender and year of birth, questions inquired about time since diagnosis, presence of diabetes-related complications, and socioeconomic status. PwD also answered the Brief Health Literacy Screening (BHLS) (Chew et al., 2004, 2008), a 3-item instrument on a 5-point response Likert scale to measure functional health literacy. Scores of the BHLS range between 3 and 15 (Wallston et al., 2014), with scores superior to 9 indicating an adequate level of health literacy (Perrin et al., 2021).

All participants received verbal and written information about the study and agreed to participate. The institutional review board Committee for the Protection of Persons participating in biomedical research (in French, *Comité de Protection des Personnes* (CPP)), approved the study protocol (number: 20.02.14 / SI CNRIPH 20.01.31.57642). The study data management plan was reviewed and approved by the French commission in charge of reinforcing the General Data Protection Regulation (GDPR) of the European Union (in French, *Commission Nationale de l'Informatique et des Libertés* (CNIL)).

Interviews

Two interview guides were developed, one for HCPs and one for PwD (see Supplementary File 2). The first was reviewed by an endocrinologist that did not participate in the study and was pilot tested with another HCP; the latter was reviewed by a representative of a patients' association and adapted following data analysis of initial interviews and participants' suggestions. Questions in the interview guides concerned three main categories: 1) storage, access, and exchange of medical information, 2) the decision-making process, and 3) current use of technological tools such as EHR and other software, including software providing access to patient-generated data from blood glucose sensors and insulin pumps. We chose these three categories to obtain reports related to the three perspectives previously presented (clinical, behavioral, and technological). With the first (clinical), we aimed to obtain descriptions of which medical or health-related information was considered by HCP as essential to learn the health status of a patient in an adequate manner and how such information is currently produced and attained. Concerning PwD, we wanted to understand which information they considered relevant to transmit to HCP and the extent of their responsibility in storing and communicating it. With the second (behavioural), we aimed to understand the roles and actions of different HCP and patients in the process of making decisions in diabetes management. This includes interactions between HCP working in team-based care or not (who does what in care coordination and interprofessional collaboration) and between HCP and patients (sharing the decision-making process, respecting patients' preferences and values). And with the third (technological), the objective was to understand the reach and value of technological tools in the current practice in diabetes management, concerning HCP, and, for patients, the place these tools have in their daily lives with the condition.

The interviews lasted between 30 and 80 minutes and were conducted in person, by phone or using videoconference software between January and June 2021. They were all done by the same interviewer, LSdP, who is female, a PhD candidate, trained in interviewing methods, and a PwD herself for more than 15 years, which all interviewees were aware of. When conducted in person, interviews with HCP were undertaken at their workplace and with PwD, at their home.

Analysis

All interviews were recorded and transcribed verbatim. We performed a semi-inductive analysis, with the structure of the interview guides as a basic framework. The analysis was carried out with NVivo 12 by LSdP, discussed with AD, and reviewed by A-MS. For the interviews with PwD, two coders worked together on a third of the interviews to generate the first version of the codebook, and subsequently coded the other interviews and reviewed each other coding to come to an agreement. For HCP, coding was led by one analyst and reviewed by a second. Codes were grouped around the main topics used to develop the interview guide, also used to build the analytical framework that was then applied to all the interviews. Illustrative segments of each theme were selected and grouped in tables for discussions with the research team. All co-authors reviewed the final codes and text segments used as quotes.

Results

Fifteen HCPs and 18 PwD (12 PwT1D and 6 PwT2D) agreed to participate. Data saturation was ensured by progressive analysis of interviews and checking no new codes or themes were generated from the data. Two participants with T2D answered the initial questionnaire but decided not to do the interview. The reasons were believing the language of the mandatory items concerning the local legislation in the study information letter were too complex for patients to understand and preferring to have a face-to-face interview during the period of COVID-19 health restrictions.

HCPs were physicians (endocrinologists, general practitioners (GPs), and geriatricians), specialized nurses, specialized physical activity educators, and dieticians (Table 4-1). They had experience with both diseases ranging from less than 5 years to more than 30 years and

consulted from less than one patient per month to more than one per week. Three HCPs did not consult PwT1D, and one did not consult PwT2D.

Among the PwD participating, 9 were men (50%) and 9 women, with diverse professional backgrounds and different income levels (Table 4-2). PwD ages ranged from 33 to 74 years, and they had lived with diabetes for 10 to 59 years. All participants had adequate levels of health literacy according to the BHLS.

Table 4-1 - HCP demographics and other professional characteristics

	Levels	n
N		15
Age (years)	30 to 39	5
	40 to 49	3
	50 to 59	4
	60 to 69	1
	> 69	1
	NA	1
Gender	Female	11
	Male	4
Profession	Dietician	2
	APA professional	1
	Nurse	3
	Asalee nurse	1
	Endocrinologist	3
	Pediatric Endocrinologist	1
	GP	3
	Geriatrician	1

Type of practice	Employed	10
	Independent	4
	Retired	1
Experience T1D (years)	< 5	1
	5 to 10	1
	10 to 19	4
	20 à 29	3
	> 30	3
	No experience	3
Experience T2D (years)	< 5	1
	5 to 10	3
	10 to 19	4
	20 à 29	3
	> 30	3
	No experience	1
Frequency T1D	< 1 patient per month	5
	> 1 patient per week	7
	No patients	3
Frequency T2D	1 to 3 patients per month	3
	> 1 patient per week	10
	1 patient per week	1
	No patients	1

Table 4-2 - PwD demographics

	Levels	n
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N		18
Gender	Female	9
	Male	9
Age (years)	30 to 39	2
	40 to 49	2
	50 to 59	2
	60 to 69	8
	> 70	4
Diabetes type	Type 1	11
	Type 2	6
	Other	1
Time since diagnosis (years)	> 30	8
	15 to 30	5
	< 15	5
Living situation	With partner or with children	13
	Alone	5
Education level	High school	5
	Bachelor's or equivalent	1
	Master's or equivalent	9
	Does not want to reply	3
Professional activity	Active	5
	Incapacitated	3
	Retired	10
Monthly income (€)	< 1500	2

	1500 to 2000	1
	2500 to 3000	4
	> 3000	6
	Does not know or does not want to reply	5
Has complications	No	14
	Yes	4
BHLS score	12	1
	13	2
	14	7
	15	8

Healthcare professionals

Six themes were generated from the interviews with HCP (Table 4-3), presented below by main category (clinical, technological, and behavioral aspects).

Clinical aspects

Finding the data, knowing the person

Participants described a process of searching for different types of data from multiple sources to understand the patient's physical health, its evolution in time, the care their received, as well as their views of their condition and treatments and their life context.

To assess patients' physical health, they relied on biomarkers such as the HbA1c values (the most cited), creatinine and albumin rates to evaluate kidney function, eye fundus exams to assess the presence of diabetic retinopathy and other microvascular damage, cholesterol rates, etc.

This information was described as sometimes difficult to obtain, and risked omissions. These difficulties were perceived as caused by different systems not being integrated and by lack of time to exchange with other HCP for the management of specific cases. The actions described to overcome the barriers to access information were to call laboratories to ask for blood test results, to call colleagues to ask for information or summary letters, to ask

patients to bring test results in paper, or to call other healthcare organizations to get medical histories. The data from HIS and test results were not integrated with patient-generated data from insulin pumps or CGM software. Other important information such as therapeutic education sessions attended by the patient and consultations with paramedical professionals do not systematically appear in HIS.

Patient-reported data about the history and experiences with the disease were usually collected verbally and recorded in free text.

Collecting information from patients verbally in the consultation was seen as important for providing missing information and building the patient-provider relationship.

Technological aspects

Ambivalence towards technology

All participants have reported using several types of technology in their daily practice: HIS with EHR, different CGM- and insulin pump-dedicated software, and other regional health information systems such as SISRA (*Plateforme Système d'Information de Santé Rhône Alpes*, in English, Health Information System in Rhone Alpes). Although using software seems to be essential to the process of decision-making in diabetes care, especially for T1D, the relationship HCP have with all the programs they use simultaneously is a complicated one. The HCP we interviewed outline having issues coping with how fast things evolve in this field. They also say being compelled to use multiple software consumes a lot of time they believe should be spent on talking to patients. Other issues involve the use of electronic cards, multiple codes, and passwords to be able to access health information systems.

Adopting and using technologies mentioned was facilitated by perceiving technology as essential for the decision-making process, especially for T1D, and by the easier access to patient-generated information such as insulin dosage and blood glucose measurements. Concerning the use of EHR and HIS, facilitators were hospital policy, the perception of their professional role and social influences.

HCPs reported several difficulties with technology adoption and use. The rapid evolution of technology required familiarization with new hardware and software. The access to increasing amounts of data from multiple users required increasing amounts of time to read

and interpret. The lack of integration resulted in increasing time and effort spend using different access procedures (e.g., electronic cards, multiple passwords and access codes). Participants expressed the need for system and data integration. This was seen as having information in the same location (systems integration), and as operating a selection of relevant information in relation to the process of clinical care (integration in care).

Existing systems lack features and usability

Participants reported on their interactions with current technologies in their daily practice. They valued positively functions such as easy or automatic access to test results and the centralization of medical information on HIS, being able to exchange messages with other HCP through HIS or SISRA.

Several reported suboptimal experiences when mainly having to use multiple screens to see different interfaces at the same time, lack of interoperability between the dozens of software used by GPs and HIS, having to change computers to use specific software installed only on some machines, having to keep multiple passwords, or having to use an electronic card to ensure secure access to specific systems. The lack of integration between patient-generated data and HIS was also frequently mentioned.

They expressed interest in several functions which were not currently available, such as having real-time communication with patients and access to blood glucose measurements for specific cases, systems that integrate teleconsultations platforms and that allow for easy information editing and validation. These functions would help them have a more accessible communication channel with patients and reduce the time spent on improving documentation.

Sharing data is of utmost importance

Participants viewed sharing data with patients and other HCP as a way to improve communication, decrease costs due to fragmentation, and lead to better care processes and outcomes. They considered the management of access rights as essential: patients need to be informed and give explicit authorization as they believe access to patient data for purposes other than care can lead to issues such as selling data to private insurance companies. They declared they do not use the DMP. Reasons mentioned were lack of

knowledge or interest, usability issues, limitations in access from hospital settings, and the perception that it serves only to store documents and they already have it on paper or on their dedicated software.

Behavioral aspects

HCP communicate with each other primarily to exchange information – working towards shared objectives is less common

HCP described the process of communication and information exchange between them and with patients. The actors involved in this process are patients themselves, specialists (endocrinologists, cardiologists, ophthalmologists, neurologists), GPs, nurses, dieticians and, less often, other support professionals like psychologists, adapted physical activity educators, and pharmacists. They exchange essentially summary letters, test results and, in the case of professionals working in the same physical location, they meet and work together on the definition of common therapeutic or dietetic goals. Other HCP, particularly between hospital and community services, did not describe discussing specific cases and/or defining common goals.

There were differences, however, between T1D and T2D. PwT2D rarely see HCP other than physicians (GP, endocrinologists, or other specialists), while PwT1D commonly see specialized nurses, dieticians, and other paramedical professionals such as podiatrists. For both diseases, though, one physician, GP, or endocrinologist for PwT2D and always the endocrinologist for PwT1D, is the professional responsible for centralizing all patient information.

One important point to note is the role of the specialized nurse Asalee. The interviewed nurse described working on the same computer as the GP, having access to all their systems and patient information with the GP credentials.

On the one hand, HCP described their relationships with colleagues as satisfactory, and collaboration was often mentioned as enabling them to obtain the missing information necessary to provide good care. The described feeling reassured by communicating with other providers and feeling like part of a community. On the other hand, the provider-provider communication was described as restricted to summary letters after consultations, often only one way (e.g., endocrinologist to GP or cardiologist to endocrinologist), without

follow-up. They also described it as time-consuming and said that sometimes patients do not agree with sharing information with other professionals.

HCPs work towards patient health and life goals by supporting multiple patient behaviours

From a behavioral perspective, participants described their role as supporting patient goals related to multiple interacting behaviours (eating, physical activity, monitoring blood glucose, medication administration, attending appointments), in order to improve glycemic control (time in range, HbA1c) and quality of life. To achieve these goals, participants mentioned aiming to improve knowledge, motivation and to adapt strategies to the patients' contexts. Specific therapeutic goals were often not formalized in the consultation. Participants mentioned formulating achievable goals on different timeframes: short-term evaluated biweekly when patients were part of a telehealth program, and mid-term evaluated every consultation (typically twice a year). Opinions varied regarding the relative importance of these goals, for some participants the most important is to be present and available for the patients, for others setting quantifiable small goals, like increasing the number of times patients measure their blood glucose levels or patients being sure they take long-action insulin every day, is an essential part of every consultation.

Participants highlighted the importance of person-centeredness and shared decision-making, which they expressed as supporting patients elaborate goals themselves, taking time to understand the person's life context, taking into account patient's preferences when applying diabetes management guidelines to their situation. Motivational interviewing, in-depth open conversations, and regular follow-ups were described as instrumental for achieving person-centeredness.

Table 4-3 - Themes generated from interviews with HCP

Theme	Sample quote(s)
Clinical aspects	
<i>Finding the data, knowing the</i>	"We need information to know the person: their age, their life context, their history with the disease, their current treatment, we need information on their biological indicators, notably HbA1c. That's why we ask people coming to the association to bring their blood test

<i>person</i>	<p>results. And after that we work a lot around the person's lived experience,". P1 (endocrinologist)</p> <p>"Well, for me, the central element, in a first contact with the person, is to know a little about how they live diabetes on a day-to-day basis, how they manage their situation, at the health plan and at the professional, family, plan... all the aspects of their social and psychological life, how they feel and how they manage the treatments and medications, how they feel about the medications..." . P14 (GP)</p> <p>"At the nurse level, when it's a new patient, before they arrive, I like to take a look at their record, start to know more about their medical history [...]. If it's a new patient that will be followed here, at the hospital, there's the education diagnosis, we look, we ask general questions about where they are in the follow-up, how they experience the follow-up... how they live with their diabetes, as well, is super important, this will allow us to give a direction to care". P8 (nurse)</p>
Technological aspects	
<i>Ambivalence towards technology</i>	<p>"We are completely surrounded by digital data. [...] We have to have data, and technology makes us invaded by data. The challenge is to integrate these data to care, I mean, get all these information and have our own algorithm that will allow us to analyze it all. Are we good or do we need to adjust something? And how to interpret and help the person interpret it all? The danger is exactly to have all this information on the phone and have indicators 'it's good', 'it's bad'... without having a kind of supervision, of help... the connected devices are awesome, but only if they are integrated to interprofessional care" P11 (endocrinologist)</p>

	<p>“The more we share, the more information we have, and we need to have time to get to know all this information. What we have seen with Covid... I work with several physicians, everyone is sending what they have found, I have to read it all... And this multitude of information sources makes us saturated at some point”. P13 (Asalee nurse)</p>
<p><i>Existing systems lack features and usability</i></p>	<p>“When it’s a new patient [...] They either come with their health record, but often it’s a very long PDF file, [...] 60, 70 pages long, and often it has all the consultations, all the prescriptions... what I need is the last prescription in the first place, if it’s in the file they give me, if not I ask for it. [...] Notably the last summary letters, the last blood test results. But I don’t necessarily have proof of what they tell me, especially if it’s already a bit old.” P6 (GP)</p> <p>“[...] these new tools have helped a lot, but [using them] it’s also time-consuming. I mean, downloading the pump data and the sensor data together so we can see it all at the same time, it takes time for the nurse or the physician doing it. And also, we don’t always have it on our screens, at the hospital we change desks, we are not always in the same room, and then ‘oh, here I can’t download this pump’. [...], when we don’t have two screens [...], if the nurse has downloaded the pump and the sensor data to the file, I can’t open it, I open the one, close it, open the other, I need two different places. Sometimes it’s hard to get people to understand that until I have seen the patient, things must be in two different places so I can pass from one to the other without losing too much time. It’s not optimal yet”. P10 (endocrinologist)</p> <p>“The little problem is that it [the messaging system] does not warn of an incoming message, so we have to really go to the specific tab to see if we have messages. At first, we don’t really think of it, we don’t</p>

	<p>have that reflex, so we have to tell ourselves to do it every morning when we open the session in the software to see if there are replies or demands”. P9 (dietician)</p> <p>“Most of the time, if it’s a patient I’m seeing for the first time, the only data available comes from the patient, who comes with blood tests printed on paper, or, sometimes now, in a flash drive with, in the best of cases, an export of their medical record. Sometimes they come with nothing at all – more often than not, on the illusion that we have access to it all”. P15 (GP)</p>
<i>Sharing data is of utmost importance</i>	<p>“I think there’s a big dysfunction... sometimes I prescribe blood tests twice because I don’t have access to the results of tests a colleague has prescribed, for example. So, these are useless health costs, I believe if we optimize, having a place to centralize all patients’ medical and health information, and patients could have access, but also the ensemble of professionals involved in their care pathway, we could save a lot of money”. P1 (endocrinologist)</p> <p>“I think it’s interesting to share information with all providers [the patients] see so we have a kind of global view. For me, it’s interesting, for instance, to see the consultations they might have had with the physician, and I think the physicians are also happy to see my feedback”. P13 (Asalee nurse)</p>
Behavioral aspects	
<i>HCP communicate with each other primarily to exchange</i>	<p>“The eye fundus, for instance, the ophthalmologists don’t write a lot, it’s getting better, but we can have a hard time accessing these data. Sometimes when we have liberal professionals that don’t systematically write to the endocrinologist, you know, people get operated on for something, appendices, or something, not related to diabetes, these specialists will write to the GP but not to the</p>

<p><i>information</i> – <i>working</i> <i>towards</i> <i>shared</i> <i>objectives is</i> <i>less common</i></p>	<p>endocrinologist. And then we miss this information. And also, when people are followed up by several specialists, it's not always easy [...].</p> <p>We have people that see a cardiologist, a nephrologist, a rheumatologist, for these people, prescriptions are modified, someone adds on or takes out a treatment, and sometimes we can't know exactly what treatment the patient is taking.”. P10 (endocrinologist)</p> <p>“When I prescribe a blood test I get the results, if it wasn't me, I don't get it. I don't see why I'm not in copy or if there isn't an option 'with a copy to the GP' when the labs do it. When the patient is hospitalized, I'm not necessarily informed. I think we should have a status in the file, for example, but it should be coordinated, 'hospitalized', if the person is in the hospital so I know of it, or if the person passes away, so I don't have to wait for a letter or for someone to call me”. P6 (GP)</p> <p>“We are a big community, the community of healthcare professionals, we help each other a lot. When we are looking for information and we reach to a colleague, there's no problem, we communicate, and we exchange. It takes energy and time, but it works – it's a kind of B system”. P1 (endocrinologist).</p> <p>“Generally, the summary letter is addressed to the endocrinologist, and it's scanned to the digital record. For example, if the patient has the appointment with a dietician before the appointment with the [endocrinologist], we have the summary letter from the GP in the file”. P9 (dietician)</p>
<p><i>HCPs work</i> <i>towards</i> <i>patient</i> <i>health and</i> <i>life goals by</i></p>	<p>“Well, we try to... in theory, to set goals that are accepted and shared. So, we say 'it would be nice to do that, what do you think?'. 'Sure, that's right, but how do we do to get there?', 'let's see how to better calculate things', so it goes through these goals”. P11</p>

<i>supporting multiple patient behaviours</i>	<p>(endocrinologist)</p> <p>“I’d say it’s not me who fixes the goals, it’s the patients – I just make them reflect on what they could do during our conversations [...]. The objective is to bring them to reality, where at some point they’ll do a lot of things for a week, and then they’ll get tired and stop it all. So, the objective is to be consistent over time because it's chronic”. P8 (nurse)</p> <p>“Generally, we do not start with an HbA1c goal. We see where the patient is and, oftentimes, I explain what the HbA1c is because the patients don’t really get it [...]. We rarely have a goal, actually. We set small goals according to what I can explain to them. If I talk to them about healthy eating, we see how they can change their eating habits. And progressively, with more visits, every time we have lab test results, we talk about it, we see if it’s going up, or down, and we try to see together why and how”. P13 (Asalee nurse)</p>
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People with diabetes

Six themes were generated from interviews with PwD (Table 4-4). There were significant differences between T1D and T2D, especially between the HCP involved in their care, as described in the first theme.

Clinical aspects

Biographies in dates, diagnoses, and test results – a whole life in memory and paper

Participants declared to keep important amounts of clinical data and they reported adopting different strategies to store and transmit them to HCP. Most participants with T1D reported having either a folder with papers (test results, prescriptions, and summary letters) they use themselves and/or bring to consultations or not having any paper and keeping everything online (laboratory and hospital systems). Some said they do not worry because they believe the GP has all the results and summary letters. They declared that the most important information to store were diagnoses and dates, treatments, and procedures, along with HbA1c results over time.

Concerning participants with T2D, except for one participant, they all reported to keep everything organized on paper in a folder. Participants with T2D were much less likely to use computers and access files online. They declared the most important were time since diagnosis, medications, and HbA1c.

History told in summary letters

Communication and data exchange between providers from the point of view of patients was described as mainly summary letters, many times on paper, after consultations or at referral to a new physician. They declared summary letters usually go one way - from the endocrinologist to the GP. They also stated that sometimes other providers (cardiologist, ophthalmologist) send summary letters to endocrinologists after the consultation. No participant described physicians discussing their cases or being aware of any other form of communication or data exchange other than summary letters.

Technological aspects

Ambivalence towards technology is even stronger among PwD

Participants reported on their current usage of eHealth and mHealth applications, such as apps to count carbohydrates, CGM apps for smartphone or computer-based, insulin pump software, and other systems like hospital systems, the DMP, or telehealth platforms. Most PwT1D described enjoying using new technology and having tried new technologies for years, like new insulin infusion systems. They reported putting a lot of hope in the improvement of diabetes management by the new technological systems that are made available such as data integration platforms or hybrid closed-loop insulin infusion systems. Some participants expressed their experience could be improved by integrating pump and CGM data automatically into their electronic health data, to have test results and patient-generated data in the same place and analyze all information together. mHealth apps were often cited as being used in the past or having been downloaded onto their smartphone, but none has been described as consistently used over time. All participants with T1D used either the CGM computer-based or smartphone app to follow blood glucose levels and to create Ambulatory Glucose Profiles (AGP) reports to discuss with physicians during consultations. These reports generally presented the TIR, average blood glucose during chosen time periods (day, week, month), and variability indicators.

Concerning PwT2D, they mostly described having difficulty using computers and preferred to keep information on paper.

Sharing data is important, but consent, respect of data ownership and security are even more. With few exceptions, patients declared to be interested in having access to their own data. They also declared they would share any health-related or medical data with HCP involved in their follow-up, especially GPs. Most of them would like to be able to access their health care utilization history and be able to analyze how their follow-up and/or disease has progressed over time. Some of them also say they would like to get rid of all the papers they have accumulated over the years, especially because it is difficult to decide when to throw away old test results, prescriptions, and summary letters. Some of them declared using the patient-dedicated hospital system, but they also described coming across inconsistencies with HCP reports, as they are responsible for the information declared in the summary letters and for the documents stored in the system.

Most patients declared to see benefits in potentially having access and using their own data to analyze healthcare utilization, test results trends over time, and being able to share it with other providers when needed. Some have, however, said they wanted to keep all their information on paper and preferred to choose who could have access to their medical information directly - only showing the file to providers they decide to. Beliefs and attitudes regarding shared electronic records were ambivalent: while they declared to believe it increases care quality and safety, allowing for providers in urgent care to have access to their medical data, for example, they were also afraid of data leakage, data selling to private insurance companies, targeted marketing, or improper access by unauthorized HCP.

All participants reported to not use the DMP, with only one exception. Many had never heard of it nor had any HCP propose to open an account for them, as set by the national policy. The participant who declared to use the DMP described a negative experience with the system in general, saying it had poor usability and it was time-consuming to upload files into the record.

Behavioral aspects

Differences between PwT1D and PwT2D

All participants were currently being seen by at least one HCP; all PwT1D are being seen by an endocrinologist or, in the case of PwT2D, either a GP or an endocrinologist.

Concerning PwT1D, most participants reported consulting the same endocrinologist for many years. Endocrinologists were, without exception, the central HCP in T1D management. All of them had a declared GP, which they reported not being involved in diabetes management. They reported consulting periodically an ophthalmologist and a cardiologist, with some exceptions, following guidelines and what they have been taught during therapeutic education sessions.

Participants described pharmacists as not being involved in diabetes management – with some exceptions, in which the pharmacists were also PwD themselves – and they reported that they do not consider pharmacists in general as having a potential active role. Nurses and dieticians were not spontaneously mentioned as part of the interprofessional team. Sometimes their role was described as very narrow, mostly to download patient-generated data from insulin pumps and sensors before consultations with physicians or to conduct TPE sessions. When participants were also participating in a telehealth program in addition to conventional care, they described nurses and dieticians as having a more important role as they reviewed goals every 15 days, but they are still not spontaneously included in the interprofessional care team unless explicitly asked. The insulin pump provider company was also included sometimes as being part of the care team.

All PwT2D had a declared GP, which was described to have a more important role in diabetes management than for T1D. When participants were seen by an endocrinologist, however, the decisions concerning treatment were described to be made by them, and participants reported, in this situation, having experienced conflictual situations with GPs. One reason participants mentioned having chosen a specific GP was that they declared not having a problem with the fact that they also consulted an endocrinologist.

In general, they also declared to see cardiologists periodically. Nurses and dieticians were not spontaneously mentioned. When specifically asked, the reactions to seeing a dietician

were particularly strong, participants declared to have healthy eating habits and that they have never felt the need to see a dietician.

For PwD, the ability to listen and to offer support to patients is the most important characteristic of HCP

The decision to keep seeing a specific HCP was described as being mostly based on their ability to listen to participants' preferences and choices. Eleven out of 12 PwT1D and four out of six PwT2D said they take part in decision-making concerning diabetes management. The remaining three patients declared they prefer the decisions to be made exclusively by physicians.

Many participants declared not to have any quantifiable therapeutic or dietetic goal defined with providers, even though many providers have declared they try to set goals at each consultation. Most participants for whom HbA1C and/or TIR were within target declared to keep seeing providers only to renew prescriptions for medications and to do blood or other periodic tests. For them, the decision to go see a specialist (ophthalmologist, cardiologist, etc.) was described as mainly based on guidelines and what has been taught during TPE sessions throughout their life with diabetes. For those with complications, they reported physicians decide themselves on the periodicity of consultations.

It is important to highlight that, even for those with indicators within the target, participants described seeking support from HCP, either with technology or with therapeutics more broadly. They said sometimes providers could not offer support, for example when they used hybrid closed-loop or automated insulin delivery systems, available commercially or do-it-yourself.

Table 4-4 - Themes generated from interviews with PwD

Theme	Sample quote(s)
Clinical aspects	
<i>Biographies in dates, diagnoses, and test results - a</i>	"I tell everything orally. But I don't start from scratch, my follow-up has been done at the hospital for quite a while [...]. With the cardiologist, I changed cardiologists, I told them

<p><i>whole life in memory and paper</i></p>	<p>orally". P4 (woman, T1D)</p> <p>"Int: Would you like to have access to all your past appointments, blood test results, all your medical history?</p> <p>Part: Yes, it would make get me a lot of space in my home. When I see a new provider, I have my medical file on paper... it takes a lot of space, I don't like it.</p> <p>Int: Do you have a lot of paper?</p> <p>Part: Too much for my taste. And I never know when to throw it away, if it will be important in 15 years... so I keep it". P6 (woman, T1D).</p> <p>"At first, it's just orally. Afterward, if more precise information is really needed... sometimes I keep my blood test results. The history is in my head. And it's the most important things." P7 (woman, T1D)</p> <p>"I have a paper version of the file and I make myself print the documents and add them to the pile. That's how I do it. I have a lot of histories – going back 150 years I think – in a file, all the treatments. I've never had any other filing, for 30 years, and I put it all in the pile". P9 (man, T1D)</p> <p>"I rarely see new healthcare professionals, but, for example, when I had the cataract surgery, I went to see the surgeon with my file. For the admission to the clinic, I went with my papers as well because they asked me for my blood test results, for the anesthesiologist and all. So, yes, I have a paper file and I take it with me". P13 (man, T2D).</p>
<p><i>History told in summary letters</i></p>	<p>"She [the GP] has the updated list of medications, she gets the summary letters of everyone else... but does she read it?</p>

	<p>I'd be surprised, honestly. She must read it. Because she has it all organized on her computer... I must never leave a paper with her; she scans it all. I think if I call her, she'll go see in her record." P2 (woman, T1D)</p> <p>"[When seeing a new GP] I bring the summary letters from the specialist and this makes the summary, actually.</p> <p>Int: You only bring with you the summary letters from the specialists? No other results?</p> <p>Part: Only the summary letters." P4 (woman, T1D)</p> <p>"Since my follow-up started at the hospital, everything is internal to the hospital. I only have the summary letters." P5 (man, T1D)</p> <p>"They [the GP] get the summary letters, so they take a look at the report from the hospital, the annual summary, with no particular opinion, saying 'it's good' or 'it's not good, your HbA1c is a bit high, you have to bring it down'... Well, yes. 'You have to pay attention to what you eat'... Well, yes." P9 (man, T1D)</p> <p>"Every time, the endocrinologist writes a summary letter that he sends to the GP, and the GP has never changed the treatment recommended by the endocrinologist. But he's doing my prescription renewals, so I see him every three months, give or take". P13 (man, T2D)</p>
Technological aspects	
<i>Ambivalence towards technology is even</i>	"I am very comfortable with technological tools, yes. And currently, for the follow-up, I use [name of the CGM in the cloud project]. So, I have this server and it's extraordinary: I

<p><i>stronger among PwD</i></p>	<p>have my blood glucose, the insulin, I'm doing sports, all the history is there, I generate the statistics, that I print and give to the physician, she scans and puts it in my file. This thing, it's extraordinary, everything is there! The insulin, what we eat, blood glucose, physical activities... It's really THE tool for diabetes care. I go to the hospital and 'ah, no, we can't access your external website'. I have a tool I can share with the provider and the provider can't use it". P9 (man, T1D).</p> <p>"It's something really good [the shared electronic health record, DMP]. When they told me about it I said, 'I have to do it soon, because it must take time', and I'm having trouble retrieving information. It's true that I can scan the summary letters and put them in the DMP [...]. I can bring papers if they ask me years of papers [on bringing information to new providers]. Now everything is digitalized. The other solution would be put it all in a flash drive, but well... for me, the DMP is like the social security card. On the card we should have a direct link to open the DMP". P5 (man, T1D)</p> <p>"I told you [on medical data sharing], I'm not in favor of making them public, or giving information to which hackers could have access. And considering the analyzing techniques, marketing techniques that target us using cookies or other methods, to know our interests... I'm not in favor. I'm not really into social networks neither, even if I do have a profile... I use it to talk to my grandchildren. I have concerns about the shared medical record, maybe they're unjustified, but I don't want to have a record like that". P14 (man, T2D)</p> <p>"Ah, no [on using mHealth apps or patient online forums]. That, really, I don't feel like focusing myself on that. For some</p>
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	<p>people, it helps, but for me, on the contrary, it makes me focus on the disease. Very few people know I'm a diabetic. I do the follow-up, everything is going well, I'm not at all focused on my disease, so I won't go see online forums or things like that". P18 (woman, T2D)</p> <p>"Honestly, I don't have the need [on having an electronic health record]. I understand that for someone who can't follow, as I can, the things – I'm very meticulous by nature – it could be very useful, it could make them save a lot of time and it would avoid the paper. Considering what I already have, it's practical to keep it, for the moment I don't see any value. But well, at my age, we're not really into technological tools... Maybe if I see, one day, a friendly enough document that can be easily accessed and where I can find all the series of medical tests I'm currently noting down, I'd stop noting them down... maybe, I have to see. But there's my first reflex at my age". P16 (man, T2D)</p>
<p><i>Sharing data is important, but consent, respect of data ownership and security are even more</i></p>	<p>"I don't want it [her medical data] to go to the United States. This is the first point. I'm not against sharing my medical data with the providers I see or with researchers for statistical analyses. But if health data is wandering around, I care a lot more, and especially if it reaches insurance companies [...]. My goal would be to improve my care or my quality of life. I'm quite selfish at these moments, and I give my health data only if it brings me something. If I have nothing in return, I'm not giving it." P6 (woman, T1D)</p> <p>"I agree 100% [with medical data sharing], I see no problem of confidentiality or any other concern... anyway, I don't see the difficulties it could bring, on the contrary. It can only be</p>

	<p>of value, to me, to be able to share it". P11 (man, T1D)</p> <p>"I tell myself that we are already controlled enough and having all my summary letters... since I don't read them even when they come on paper, I couldn't care less about having them on a shared hospital record. I haven't created an account [on the patient's hospital record]. It's still a computer application with all the excesses it might have, so I don't want it."</p> <p>"It [the shared electronic record, DMP] can be interesting when we need healthcare anywhere, so we can have... let's say I have an accident, I'm unconscious. It's not written on my face I'm diabetic, I don't have a card saying I'm diabetic on my wallet. The only thing I have on my wallet is my social security card. You see there's the DMP, the healthcare professional in charge can see what I have. That's useful. The sharing of medical data between healthcare providers, I don't care. But the shared electronic record in the advent of the need for care is interesting. At least you have it all. No matter the state the patient is in, you can have access to all these information". P12 (woman, T1D)</p> <p>"For me, if they tell me why, I don't bother [sharing her medical data with providers and researchers]. But if it's hidden from me, I don't want it. I've been on trials, with my cardiologist... I've participated in another research project for two years. I'm always ready to help with research, but I need to give my consent, and not have my data taken like that, without telling me. I'm always ready to take part". P17 (woman, T2D)</p>
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Behavioral aspects	
<i>Differences between T1 and T2D</i>	<p>"I see my endocrinologist every six months. But I also do the classic follow-up with the cardiologist, ophthalmologist, when needed. Very precisely I don't know... Ophthalmologist every year, cardiologist... I had Covid, so I saw many cardiologists, but normally it wasn't the moment. And that's all. I have a GP, but I don't see her for my diabetes." P4 (woman, T1D)</p> <p>"My GP is, I'd say, for basic treatments. Because I have high blood pressure, high cholesterol... And the current diseases, not more than that. If I have a cold... So yes, nothing more." P7 (woman, T1D)</p> <p>"[...] an annual appointment to take stock, with something relatively stable for many years now and is always accompanied by this specialist [the endocrinologist].</p> <p>Int: Do you also see a GP?</p> <p>Part: Every time, the specialist wrote a summary letter and sent it to my GP, and my GP has never once modified the treatment prescribed by the specialist. But he did the follow-up for my prescription renewal, so I saw him every 3 months, give or take." P13 (man, T2D)</p> <p>"Int: Do you also see an endocrinologist?</p> <p>Part: No. First, I have never asked him, and, apparently, my diabetes is controlled. My last HbA1c was 7.7 but I'm normally around 6.5. So, no endocrinologist. I have only my GP, whom I trust." P14 (man T2D)</p>
<i>For PwD, the ability</i>	"There's an actual dialog. That's why, by the way, I like my

<p><i>to listen and to offer support to patients is the most important characteristic of HCP</i></p>	<p>endocrinologist and it has been 10 years that I keep seeing her. I couldn't have a top-down information that I'd have to apply. Honestly, it gives me a rash. Normally, I expose the details of the problem that, for me, are the most important. And then there's a dialog and we decide." P6 (woman, T1D)</p> <p>"It's her approach [on why she likes the endocrinologist she sees]. To begin with, she doesn't have a guilt-creating approach. She has never told me 'your HbA1c is a catastrophe', 'you're diabetic, you smoke, it's not good'. [...] She tells me things, but she makes the distinction between the protocol and the human being". P12 (woman, T1D)</p> <p>"One day, I remember telling my GP 'I heard that when we take more than 4 medications at the same time there are possible side effects', and she said, 'it's good to spread a little, but we can't do anything either'. We trust each other, there's this simplicity, I'd say". P16 (man, T2D).</p> <p>"In medicine, I'm trusting the young generation. She must be 40 years old [the new GP she sees]. It's good, they have a new approach to medicine, to the patient as well, maybe. Or maybe I found someone with a good approach. Also, the fact that there isn't a war between the endocrinologist and the GP, I think it's good. Because I have right away set the limits, I told her 'I am being followed for diabetes but it's...' and she said, 'on the contrary, the specialists, they're here for that. Now they say the GP can assure diabetes care, no problem. But I think the same way when there's the specialist, they know exactly, they know better how to handle treatments". P18 (woman, T2D)</p>
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Discussion

This study described HCP and PwD experiences and perceptions of current technology use in shared-decision making in diabetes care. We focused on three complementary perspectives to report on their experiences: clinical, technological, and behavioural. From a clinical perspective, participants described which information they believe to be essential to make decisions in diabetes care; HCP described the need to have easy, if not automatic, access to periodic clinical test results to evaluate glycemic control and organ function, but also to keep track of subjective patient information, such as the history with the disease and the treatment, and life objectives. PwD described to store clinical test results and summary letters produced by different providers on paper over the years, and they believed the important information to share with HCP are mainly, but not restricted to, diagnoses, dates, and current treatments. From the technological perspective, the use of diabetes technology and eHealth was mostly perceived as essential to decision-making, but also as time-consuming and an increase in cognitive burden by HCP. PwD described two different relationships with technology. PwT1D, in general, were prone to technology use have been experimenting with new treatments and other innovations for years. The second profile, mainly PwT2D, described to mainly use computers and phones to perform very basic tasks and declared to prefer to keep all medical information on paper. Data sharing with and between providers, and researchers, was viewed by both groups as useful and important, with the condition that patients give explicit and informed consent. Important functions of technological tools cited by both HCP and PwD were easy access to health information (blood and imaging tests results), a user-friendly interface, integration with patient-generated data from diabetes technologies, electronic communication with and between providers and patients, and, very importantly, the possibility to exchange information between hospital and community services. These findings show both HCP and most PwD are willing to use eHealth tools to help diabetes management and decision-making, but improvements in the current tool offer are necessary to cover their needs. From a behavioral perspective, barriers and facilitators to care coordination and shared decision-making were outlined. HCP described to want to exchange with other providers and to set common care goals, but this is hindered by their current lack of time. They also declared to attach importance to patients' preferences and values, and to believe they should be actively

involved in care decisions. From the patients' point of view, although most participants declared to take part in care decisions, some said they preferred to let the providers make treatment decisions, particularly concerning medications. All PwD declared, however, to value the ability of HCP to listen and to take their needs into account. The setting of quantifiable therapeutic goals was not straightforward: while many HCP have declared to try to set small goals at each consultation, most patients said they do not usually have explicit goals to attain and review with the providers they consult.

Concerning access to clinical data, our results show that keeping track of biomarkers, such as HbA1c, is of particular importance both to HCP and PwD. Yet, important barriers are mentioned by both groups and access to medical information over time is not facilitated by the available tools. HCP often rely on patients to bring blood test results on paper, and other important information such as diagnoses, and procedures are mainly transmitted orally. Although verbal transmission of information is considered essential to establish the patient-provider relationship, it can also be unreliable (Richter et al., 2021). In addition, the tracking of patient-reported subjective information over time is mainly done through free text. Reading notes and transmitting them to other HCP can be time-consuming and laborious, but research has shown being unable to write freely and having to tick boxes is also considered laborious and repetitive by HCP (Mishuris & Linder, 2013). Therefore, technological solutions could be linked to context- or disease-oriented eHealth that provide templates to facilitate entering information without losing important details. Another point is that diabetes technology is not integrated into the current HIS, which prevents keeping automatic histories of parameters such as time in range (TIR – the percentage of time spent within blood glucose targets), which, alongside HbA1c, has been used in the past years as a key indicator of treatment success, especially for T1D (Vigersky & McMahon, 2019).

Concerning the use of technology in current practice, although HIT is currently ubiquitous and its use is unavoidable for HCP, it has been shown to increase documentation burden (Moy et al., 2021), and it has been criticized for its role in increasing complexity in medical practice (Mishuris & Linder, 2013). Our results show HCP view the use of multiple software as time-consuming and as one of the reasons patient-provider communication during consultations can be jeopardized, and this can be a barrier to eHealth utilization. Other

important barriers related to using technological tools in diabetes care were the lack of automated integration of patient-generated data to HIS, the fast-evolving nature of diabetes technology, the lack of understanding of how to use the different systems available – or possibly lack of training on how to use these systems appropriately. For PwD, the mentioned barriers were the lack of understanding of how the systems work – such as how information is integrated into EHR or the inconsistency regarding documents made available by different providers, and concerns about privacy and data security, which confirmed previous research results (Bani Issa et al., 2020; Blobel et al., 2016). The French national health strategy My Health 2022 (*Ma Santé 2022*, in French) puts a special focus on the digitalization of health data and the broad adoption of the My Health Space platform. The French personal medical record (DMP) is not known, however, by many participants, HCP and PwD alike. In a systematic review of systematic reviews, Ross et al. (2016) have analyzed factors influencing the implementation of eHealth. Their findings show knowledge and beliefs act as facilitators and barriers to the implementation and acceptance of eHealth systems. In our study, we found HCP have positive attitudes toward data sharing and the implementation of a shared patient record, which is contradictory to their attitudes toward the DMP – they have unanimously declared it is not useful. Other important factors contributing to the failure of eHealth adoption by HCP shown by Ross et al. are the lack of adaptability to fit the local context (closely related to interoperability, the ability of systems to exchange information with systems already in place), and high complexity. The HCP interviewed in this work described a high level of complexity, having to deal with multiple software at the same time and putting together data by themselves, and a very low level of adaptability and interoperability of the HIS in place. The case of the regional database SISRA, created with the intention to decrease fragmentation between hospital and community services, is one example. Most HCP could have access to the service, but it was described as not being integrated with the hospital record, and they declared having issues accessing their accounts. Barriers mentioned were the multiple passwords and the need for a professional card – which is intended to ensure data security but also prevents the adequate use of the service.

PwD we interviewed had stopped using mHealth apps or other systems, such as the DMP when they did not perceive its usefulness or ease of use, as stated by the technology

acceptance model (Davis, 1989) and confirmed by Ross et al. findings (Ross et al., 2016). In France, mHealth apps for the self-management of chronic conditions lack behavioral content and have low understandability and actionability levels (Prado et al., 2019). This likely influences long-term usage of mHealth apps and other eHealth tools by the referred population, but further research is needed to investigate which characteristics of such tools are the most effective in helping make daily decisions regarding diabetes management.

From a behavioral perspective, one important result of our study is that, although interprofessional collaboration has been shown to be a facilitator in diabetes care (Raaijmakers et al., 2013) and the delegation of tasks by GPs to other professionals such as nurses or pharmacists has been proven effective to improve diabetes outcomes such as HbA1c or glycaemic control in the context of T2D (Supper et al., 2017), PwD interviewed did not spontaneously see nurses or pharmacists as part of the diabetes care team. Equally, information exchange was largely restricted to physicians and the participation of other support HCP in care was dependent on information obtained in medical consultations and they were not included as recipients of summary letters or test results. Regarding care coordination, the sharing of knowledge and information was described as essential and beneficial to care. HCP have, however, expressed that the general lack of time prevents them from further exchanging with other providers to discuss cases and establish common care objectives. Available HIS and other regional health systems like SISRA seem to have improved HCP's ability to communicate via direct messaging or the possibility to leave notes on patients' records within the software, but this seems to be mainly restricted to hospital settings. As shown in previous research (Or & Gandré, 2021), fragmentation of care between hospital and community services is also observed in our study, and current technological tools do not offer a comprehensive solution to this problem. As the storage of medical and other health data, our results show information exchange and communication between providers is, many times, insured by the patients themselves.

Most PwD valued being actively involved in medical and treatment decisions, which has been shown in several previous studies (Degner et al., 1997; Milliat-Guittard et al., 2007; Ndjaboue et al., 2020). One of the most cited reasons by PwD to change physicians was the perceived lack of ability to listen to patients' concerns. All HCP interviewed clearly stated the

intention to consider patients' contexts, life experiences, and disease histories, and to discuss all aspects of treatment with patients not only to make decisions but also to change medications regimen and reduce the number of drugs to improve adherence when needed (more specifically for PwT2D). Although shown not to improve biomedical outcomes by itself (Heisler et al., 2002; Peikes et al., 2009), the involvement of patients in health-related decisions is widely accepted (Heisler et al., 2002), viewed as essential for improving chronic care (Barry & Edgman-Levitan, 2012), and has been increasingly important to patients (Hahlweg et al., 2020; Marahrens et al., 2017). This work demonstrates that, although HCP and PwD are actively using eHealth tools to make health-related decisions, their potential to enhance shared-decision making in diabetes care is dependent on several important improvements.

To guide eHealth tools development, we suggest the focus be placed on adaptability and compatibility between existing software to allow for information exchange and integration of data from different sources. One important result of this would be that tools would then have the possibility to generate easy-to-read graphical visualizations of health histories. This would allow HCP and PwD to keep track of health-related information, such as test results, procedures, treatments, and healthcare utilization, and potentially enhance the decision-making process. Behavioral interventions targeting patients to increase the uptake of patient electronic records such as My Health Space could focus on effective communication regarding privacy, confidentiality, and data security, as this has been the most common barrier to sharing health data mentioned in the interviews.

Strengths and limitations

This study has several strengths. It is a qualitative study that allowed us to obtain in-depth accounts of both HCP and PwD experiences. The recruitment of PwD was done mainly through patient associations, which ensures their participation was an act of their own will. Many interviews were performed by telephone or video call, which can limit the pressure to provide socially acceptable answers compared to face-to-face interviews. In addition, the fact that only one interviewer (LSdP), also a PwD, did all the interviews assures the same approach was kept throughout the work. This study also has some limitations. First, we have interviewed only 6 PwT2D, which is usually not sufficient to ensure data saturation.

Nevertheless, since the focus of this study was technology usage and all the participants we interviewed in this group had a similar discourse and reported to not tend to use eHealth or mHealth applications, nor diabetes technology, we have therefore considered data saturation was obtained. Second, we had a purposive sample, which can be both a strength and a limitation. A strength because participants were probably interested by the subjects proposed and had well-reflected answers; and a limitation because their answers might or might not represent well the populations of interest to this study. And, finally, the fact that all the HCP interviewed were aware the interviewer is a PwD may have introduced a social desirability bias, especially concerning answers about patient involvement and shared-decision making. We believe, however, that having a PwD carry out the interviews to be a strength that outweighs this limitation, as it allows a strong interpersonal link to be rapidly established between interviewer and interviewees.

Conclusion

The present study shows there are several areas of improvement in the use of eHealth to mediate care coordination and shared decision-making in diabetes care. Developers and policymakers must take into account the needs of HCP and patients alike. The active participation of patients in health-related decisions, especially concerning health data, is bound to be magnified in the coming years with the increasing use of eHealth and mHealth tools, and the further digitalization of health data. Implementation studies are needed, adapted to the local cultural and social context, to investigate the strategies that will facilitate the uptake of technological solutions by HCP and patients.

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Conflicts of interest

None declared.

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In summary

Article 3 presents the results of the study VOIES-D-ql, a qualitative study performed using semi-directed interviews with both HCP and PwD (T1D and T2D). We have followed the same structure of investigation used in Paper 2: we developed interview guides addressing clinical, technological, and behavioral aspects regarding the use of diabetes technology and eHealth to inform shared decision-making and to support care coordination in the context of diabetes management. The main goal was to describe the experiences and current use of technological tools of the interviewed groups. For HCP, the main objective was to understand which health-related information was crucial to care, how they accessed this information and, if they had problems to obtain such data, how they managed to overcome the possible barriers, and how they currently used the available tools to communicate and exchange information with other HCP. For PwD, we gathered descriptions of the current organization of care, how they obtained, stored, and transferred their own health-related information, and if and how they used eHealth or mHealth in their daily lives. In addition, we obtained in-depth descriptions of the shared-decision making process and of how both groups perceived sharing health-related data through eHealth such as personal medical records.

We then performed a thematic analysis of the transcribed interviews using the framework method. This method allows summarization and structuration of the interviews in matrices (see Supplementary File 3), in order to identify patterns within the data. One important advantage of this method is to easily present information obtained from the interviews to other members of the research team and thus facilitate interactions and the process of creating themes.

Several themes were identified. The most important findings for HCP were that obtaining and tracking subjective information was just as, or even more, important than objective information (medical history, blood test results, etc.), technology was ubiquitous but still not completely adapted to their current needs, data sharing was considered as essential to care, care coordination when HCP were not working in the same physical space was restricted to exchanging summary letters, and person-centered care was considered by all interviewed HCP as the best care.

For PwD, we observed important differences between T1D and T2D, regardless of the age of the patient. With few exceptions, PwT1D were prone to technology and/or innovation use, while PwT2D generally preferred to keep out of using technological tools. Most patients kept paper records and brought them to consultations when needed, but most information was transmitted orally. They were mostly favorable to sharing their health-related information with the care team but were specially concerned about data ownership and security. The perception of the provider's ability to listen was the most important criteria to maintain the patient-provider relationship.

With regard to the tools themselves, the most important characteristics were to be interoperable (the automatic exchange of data between systems), to integrate patient-generated data from insulin pumps and CGM, to have a user-friendly interface, to allow provider-provider and patient-provider direct communication, and to permit interaction with the data to generate graphical and/or temporal views and enable other analyses (current systems only provide PDF files).

COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Table 4-5 – COREQ checklist

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal Characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	116,117
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	116,117
Occupation	3	What was their occupation at the time of the study?	116,117
Gender	4	Was the researcher male or female?	116,117
Experience and training	5	What experience or training did the researcher have?	116,117
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	116,117
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	116,117
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	116,117
Domain 2: study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	114
<i>Participant selection</i>			

Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	115
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	115
Sample size	12	How many participants were in the study?	117
Non-participation	13	How many people refused to participate or dropped out? Reasons?	117
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	117
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	116,117
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	118,119,120
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	116
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	NA
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	117
Field notes	20	Were field notes made during and/or after the interview or focus group?	-
Duration	21	What was the duration of the inter views or focus group?	117
Data saturation	22	Was data saturation discussed?	115,117,146,147
Transcripts returned	23	Were transcripts returned to participants for comment and/or correction?	-
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	117
Description of the coding tree	25	Did authors provide a description of the coding tree?	Supplementary file 3
Derivation of themes	26	Were themes identified in advance or derived from the data?	117
Software	27	What software, if applicable, was used to manage the data?	117
Participant checking	28	Did participants provide feedback on the findings?	NA

<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	124-130, 135-140
Data and findings consistent	30	Was there consistency between the data presented and the findings?	117-140, Supplementary File 3
Clarity of major themes	31	Were major themes clearly presented in the findings?	117-140
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	117-140

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Supplementary File 2 – Interview guides (HCP and PwD)

Healthcare professionals

VOIES-D-qi

Guide d'entretien pour les professionnels

Préambule :

- Vérifier la disponibilité du(de la) participant(e) pour les 30 prochaines minutes
- Obtenir l'accord écrit du(de la) participant(e) pour l'enregistrement de l'entretien, ou bien vérifier qu'il a été obtenu auparavant, et l'informer qu'il/elle peut passer des questions s'il/elle le souhaite (les sujets peuvent être discutés à partir d'expériences personnelles et à un niveau plus général). Un exemplaire du consentement doit être conservé par le(la) participant(e) et un exemplaire sera conservé dans le classeur investigateur de l'étude.
- Informer que l'entretien est confidentiel et que les réponses seront traitées en respectant son anonymat (pour cela, ne pas recueillir de données identifiantes. Se contenter de recueillir les données essentielles à l'étude)
- Une fois l'enregistrement démarré, indiquer le code attribué au(à) la participant(e) (N° d'inclusion, initiales) et la date du jour (ne pas mentionner de nom).

Introduction :

“Durant cet entretien, je souhaiterais parler avec vous sur vos échanges avec d'autres professionnels de santé et les informations que vous jugez importantes sur les patients pour être bien informé(e) pendant les consultations. Cela va nous aider à comprendre comment nous pouvons développer des outils de visualisation du parcours d'utilisation de soins pour vous aider à prendre les décisions les plus adaptées aux besoins des professionnels et des patients, avec les professionnels que vous soutiennent. Il y a des points précis que je souhaiterais aborder avec vous.”

À propos des informations médicales

- Si vous avez un nouveau patient, de quelles informations avez-vous besoin pour connaître son état de santé général ? *** (pour les non spécialistes, proposer un cas spécifique, par exemple : un homme, 65 ans, en surpoids, avec un diabète de type 2 depuis 10 ans OU une femme, 35 ans, avec un diabète de type 1 depuis 30 ans) ***
- Comment avez-vous accès aux informations médicales de vos patients ? Comment le partage avec d'autres professionnels se fait ? (envoi et réception, etc., avec médecin traitant, spécialiste, laboratoire d'analyse)
- Est-ce que vous rencontrez des problèmes dans ce partage d'informations ?

À propos de la prise de décision

- Qu'est-ce que vous visez dans le suivi du patient dans le court-moyen terme ?
- Comment vous fixez un objectif thérapeutique avec le patient ? (Des exemples d'objectifs – maigrir, améliorer l'adhérence, améliorer l'insulinothérapie fonctionnelle, etc.)
- Et à quelle fréquence vous jugez nécessaire de fixer ces objectifs ?
- De quoi avez-vous besoin comme information (ou interlocuteur – professionnels avec qui échanger) pour y arriver ?

À propos de l'utilisation des outils technologiques (comme des logiciels dédiés, l'accès à des bases de données, des plateformes pour la prise de rendez-vous, des logiciels pour l'analyse des données des objets connectés, etc.)

- Pouvez-vous m'en dire plus sur votre usage des logiciels dans votre pratique courante ? Utilisez-vous le DMP ?
- Que pensez-vous du partage de données de santé numérisées avec d'autres professionnels ou avec des chercheurs ?

Évaluation globale

- À votre avis, dans tout ce que nous venons de discuter, qu'est-ce que marche déjà bien aujourd'hui ? Dans un monde idéal, qu'est-ce que vous aimeriez faire différemment ?

Fin de l'entretien :

- *Remercier le(la) participant(e) pour le temps dédié à l'entretien et pour sa contribution à l'étude*
- *Laisser le(la) participant(e) poser des questions s'il(elle) le souhaite*
- *Vérifier sa disponibilité et le délai pour recevoir plus de détails concernant sa participation ultérieure à l'étude de faisabilité*
- *S'engager à partager les résultats finaux de l'étude*

People with diabetes

VOIES-D-qi

Expériences individuelles de soins : Guide d'entretien pour les patients

Préambule :

- *Vérifier la disponibilité du(de la) participant(e) pour les 60 prochaines minutes*
- *Informar que l'entretien est confidentiel et que les réponses seront traitées en respectant son anonymat (pour cela, ne pas recueillir de données identifiantes. Se contenter de recueillir les données essentielles à l'étude)*
- *Obtenir l'accord écrit du(de la) participant(e) pour l'enregistrement de l'entretien, ou bien vérifier qu'il a été obtenu auparavant, et l'informer qu'il/elle peut passer des questions s'il/elle le souhaite (les sujets peuvent être discutés à partir d'expériences personnelles et à un niveau plus général). Un exemplaire du consentement doit être conservé par le(la) participant(e) et un exemplaire sera conservé dans le classeur investigateur de l'étude.*
- *Une fois l'enregistrement démarré, indiquer le code attribué au(à) la participant(e) (N° d'inclusion, initiales) et la date du jour (ne pas mentionner de nom).*

Introduction :

“Durant cet entretien, je souhaiterais parler avec vous sur vos échanges avec des professionnels de santé pour vous aider à mieux gérer votre diabète et les informations que vous jugez importantes à partager avec eux pendant les consultations. Cela va nous aider à comprendre comment nous pouvons développer des outils de visualisation du parcours d'utilisation de soins pour vous aider à prendre les décisions les plus adaptées à vos besoins, avec les professionnels qui vous soutiennent. Je commencerai avec des questions précises sur certains points, après nous échangerons plus librement”

Questions générales

- Pourriez-vous m'en dire plus sur comment votre maladie est prise en soins ? (Traitement, professionnels impliqués, services spécialisés, éducation thérapeutique)
- Est-ce qu'il y a un professionnel avec lequel vous faites un point de temps en temps sur vos besoins de santé (ou de soins – état de santé, objectifs de traitement ou de vie) ?
 - Quel est le rôle de votre médecin traitant ? De votre pharmacien ?

À propos des informations médicales

- Comment faites-vous part de vos informations médicales aux professionnels de santé impliqués dans la prise en soin de votre diabète ?
- Est-ce que vous rencontrez des problèmes dans ce partage d'informations ?
- Imaginez que vous avez une consultation la semaine prochaine avec un nouveau médecin traitant, comment se passerait pour vous ce premier rendez-vous ?
 - Quelles informations pensez-vous être nécessaires de leur faire part ? (Situation fictive de changement de professionnel, déménagement, etc.)

À propos de l'utilisation des outils technologiques

- Utilisez-vous des portails dédiés aux patients ou d'autres outils, comme des applis, dans votre vie quotidienne ?
 - Utilisez-vous le Dossier Médical Partagé ?
- Que pensez-vous du partage de données numérisées de santé avec des professionnels de santé ou avec des chercheurs ?
 - Avec qui êtes-vous confortable de les partager et avec quel objectif ? Aimeriez-vous les avoir vous-même ?
- Concernant l'utilisation des outils numériques, vous diriez que c'est facile ?
 - Moyennement facile, difficile ou très difficile

À propos de la prise de décision

- *Changement de professionnel* : Avez-vous changé de service, de médecin traitant ou de spécialiste récemment ? Comment ça s'est passé ?
- *Décision partagée* : Si vous avez changé de traitement récemment, comment cela se passe-t-il généralement ? Comment souhaiteriez-vous que cela se passe ? Comment vous définissez les objectifs de votre traitement ? Vous sentez-vous en capacité de faire valoir vos besoins, attentes et contraintes par vos interlocuteurs en santé ?
- Comment voyez-vous les prochains 12 mois du point de vue de votre santé ? (Quelles types de soins, quels types de consultations, d'examen, etc., la personne pense faire)
- S'il y eu des décisions pendant la consultation comment les mettez-vous en place par la suite ? (Des changements de traitement ou des nouvelles consignes)

Fin de l'entretien :

- *Remercier le participant pour le temps dédié à l'entretien et pour sa contribution à l'étude*
- *Laisser le participant poser des questions s'il le souhaite*
- *Vérifier sa disponibilité et le délai pour recevoir plus de détails concernant sa participation ultérieure à l'étude de faisabilité*
- *S'engager à partager les résultats finaux de l'étude*

Supplementary File 3 – Framework matrices (HCP and PwD)

Table 4-6 - HCP summary matrix

Interview		Medical (and other) information					Technological tools				
		Description	Access/Support	Barriers to access	Quality criteria	Role of guidelines	Description	Current use	Determinants	Opinion on data sharing	DMP*
1	Physician 1 (endocrinologist, association)	Personal characteristics (age, life context, treatments, biomarkers like HbA1C), BG measurements; personal experience with diabetes; physical symptoms; other HCPs the patient might have seen	Patients bring test results on paper	No access to electronic medical records, patients might not have any previous test results; patients sometimes have no BG measurements; patients with no or too much information on paper; electronic information still exclusive to some HCPs Actions: in therapeutic education sessions, work on the importance of having			Software to analyze pump and CGM data, EHR hospital system. At the association they do not have a software.	At the association they constitute a paper record.			Never used. Under the impression they do not have access to it.

				<p>biomarkers tested</p> <p>periodically ask the lab for the test results,</p> <p>work on why the patient does not want to measure BG</p>							
2	Physician 2 (geriatric specialist, hospital)	<p>Health history, current treatments, HCPs patients see, hospitalization history; HbA1c, BG for hospitalized patients, presence of cardiovascular complications, vascular exams, ophthalmology exams, nephrology exams</p>	<p>Orally, electronic medical record for those seen at the hospital, summary letters from other HCPs; scanned documents from GPs</p>	<p>Shared medical record (DMP) rarely used, patients without summary letters, patients hospitalized in other institutions, patients who come without current prescriptions</p>		<p>Guidelines to avoid negative interactions between medications</p>	Hospital EMR		<p>Hospital EMR allows access to tests results history, has a messaging system, generates alerts in some situations</p>	<p>Agrees if it is justified, with explicit patient authorization and if it goes through ethics committees.</p>	<p>Does not use it.</p>

3	Dietician 1 (association)	Health history, current treatments, HCPs patients see at what frequency, weight history, how patients eat, if they practice physical activities; blood test results with HbA1c, cholesterol, triglyceride, liver enzymes, glomerular filtration rate,	Eating habits told orally, some patients fill in a meal notebook before consultation; test results on paper	No access to electronic medical records, summary letters not addressed to dietitians, test results not addressed to dietitians even if asked, patients do not systematically bring test results		Guidelines are harder to apply when it comes to patients' eating habits	Uses platforms for scheduling appointments (Doctolib), regional medical information platform (SISRA), gestational diabetes smartphone application (MyDiabby). At the association there is no software, at the liberal practice there is no specific software for dietitian consultations		Platforms like Doctolib allow HCP to ask patients to bring specific documents before consultations; SISRA has a secure messaging system because HCP cannot send confidential patient information by regular e-mail; MonSisra has a teleconsultation platform; MyDiabby allows remote access to BG and HCP can communicate with patients in real-time.	Thinks it can help care improve, but patients need to know about it and give explicit authorization.	Does not use it ("pas du tout").
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4	Nurse 1 (association)	Age, gender, height, weight, HbA1c, current treatments, other diseases; personal experiences, feelings, social and family context, contact person, self-management assessment (do the patient feel able to self-manage?), motivations, lifestyle	In best case scenario they receive a summary letter from the endocrinologist, normally patients tell them orally and bring test results on paper; access to SISRA with physician authorization	Patients come without any previous clinical test results; some women do not want to get weighed; no access to electronic medical records Action: call GP to get test results			Regional medical information platform (SISRA), no software at the association		Be able to easily edit information, that would be validated by someone	Thinks it can improve communication between HCP, but data security needs to be ensured.	Thinks they do not have access to it.
5	Physical educator (association)	HbA1c, comorbidities, current treatments, BMI, smoking status, care delivery pathway, other HCPs the patient sees at which frequency, perceived health status, effort test results, questionnaires	Summary letters, papers patients might bring to consultations,	Only has access to information physicians decide to write and share, patients might not bring prescriptions or test results for several appointments,		Works to bring patients up to date on guidelines to avoid or detect complications	Regional medical information platform (SISRA), at the liberal practice uses different software to download actimeter data and to communicate			Thinks it would improve care and decrease care fragmentation specially for multimorbidity; it needs to be automatic; people need to be reassured that their	Does not use it.

		about self-reported physical activity level (liberal practice, not at the association)					e with other HCP.			data would not be used commercially so it would be done more easily.	
6	Physician 3 (GP, health center)	Smoking status, alcohol consumption, date of the last blood test, weight, height; sociodemographic characteristics, literacy levels, blood test results, surgery history, family history, stroke and cardiac arrest history, other chronic conditions; address	Pdf medical histories patients might ask previous GPs;	Medical histories in pdf extremely long; test results might not be addressed if they are not the prescriber; death is not automatically informed (it takes time for the letter to arrive); test results not always available, self-monitoring data often not available; difficulties to access current software (Zepra	Only consider s last 2-3 summary letters	Suggest patients over 65 see a cardiologist every one or two years, but ultimately the cardiologist decides	Uses several scheduling appointments platforms (Doctolib, avecmondoc), regional medical information platforms (Zepra, SISRA, myHCLpro), software to send prescriptions to patients (Ordolic), physician software "logiciel métier" (Weda), other			Thinks it should be done within the same structure but patients need to be informed; GPs should have access to all medical data unless patients explicitly remove permission; thinks authorizations could be given with the GP declaration to social security; HCPs	Has tried as patient, not as HCP

				and SISRA)			specific software like Trajectoire, Whatsapp to communicate with coworkers			should be able to filter information they consider too sensitive to be seen by other HCPs; ER services should have limited access (no access to psychiatric diagnoses); patients should have alerts if someone without authorization has access to their records	
7	Nurse 2 (specialized center)	Education assessment, life context, personal experiences, how patients handle glucometers, insulin injections, emergencies, hypo and hyperglycemia	Electronic medical record, perceptions told orally; self-monitoring data transferred by a telehealth application				Hospital EMR, telehealth platform, e-mail				Does not use it, does not know of it ("Je ne connais même pas")

8	Nurse 3 (specialized center)	Care delivery pathway, reasons to come to the center, current treatments, education assessment, personal experiences with HCPs and with the disease, life context, physical activity level	Studies electronic medical records, if available, before consultations;				Hospital EMR, telehealth platform, systems to download pump and sensor data			Thinks big pharma companies are not to be trusted even if they say how they are using the collected data (CGM data)	Does not use it
9	Dietician 2 (specialized center)	Health history, time since diagnosis, type of diabetes, presence of complications, cardiovascular risk, if the patient has any pain or other factors altering quality of life, other chronic conditions, allergies, food intolerance, special diets, weight history; if	Electronic medical record, medical prescriptions, summary letters (scanned into the electronic medical record)	Sometimes summary letters are not scanned into electronic medical records; missing information in summary letters from GPs			Hospital EMR, telehealth platform	Puts in writing in the EMR all the information about patients' eating habits, behavioural aspects, family aspects, physical activities, weight and height, and also diet goals and	Uses the messaging system embedded in the hospital EMR because of data security.		

		patient has seen a dietitian before						what is expected of the patient to put it into practice. Looks at ancient dietitian encounters to see what has been done with the patient. Sends messages through the hospital EMR to other HCP (at the same hospital). Uses the telehealth platform to check BG graphs, insulin doses or insulin pump parameters, and eating information input by patients			
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								(pictures of meals with date and time)			
10	Physician 3 (endocrinologist, specialized center)	Medical summary, presence of complications, biomarkers (fundoscopic examination, blood tests - creatine levels, cholesterol, - urine albumin, current treatments, life context, sociodemographic, diabetes management assessment,	Electronic medical record for patients already seen at the hospital, for other patients, summary letters on paper, less frequently by e-mail, from GP or previous endocrinologist; history told orally by patients; by phone for emergencies; patients send information by e-mail	Difficulty to access ophthalmological test results (ophthalmologists often do not write summary letters); some liberal HCPs do not address summary letters to the endocrinologist, only to GP; patients sometimes see several specialists and it might be difficult to know exactly what is the current treatment, specially for older patients			Hospital EMR, software to analyze pump and CGM data, telehealth platform	Nurses or themselves download pump and CGM data, then they use it to analyze patients' self-management skills and have discussions about how to adapt the treatment. Tries to couple different software data (pump and CGM) to analyze results with patients. Make decisions	The regional platform (SISRA, MonSISRA) do not communicate with the hospital EMR system (Easily)	Agrees if patients give authorization	Thinks they do not have access at the hospital, or they do not know how to access it.

								remotely based on CGM data sent by patients by e-mail or using the CGM software (LibreView).			
1 1	Physician 4 (endocrinologist, specialized center)	Life context and goals, everything other than subjects related to BG; after the first consultation clinical context, time since diagnosis, other diseases, presence of complications; performance indicators	Orally, patients or family members come with paper files; paper letters from other HCPs	Family members that monopolize information on paper; for 90% of patients during the current week other HCPs did not address summary letters Action: re-construct the record from pieces of information			Uses multiple platforms and software during consultations (hospital EMR - written information and test results intra-hospital, software for BG analysis, message systems)	Access to test results (retina screening for example), BG indicators to guide consultations, but does not let the computer "guide" the consultation. Data is downloaded at the center and then they see the patient in a	Gets multiple messages from the different platforms, sometimes in duplicate - "Je vois qu'il y a un truc, vaut mieux pas se connecter"		Hospital EMR communicates automatically with the DMP, but says it's the 'liberal world' that uses it

								different room where they can analyze the numbers together. The data input by patients in the telehealth platform can also be analyzed remotely and HCP can put comments or suggestions to patients according to alerts within the system.			
1 2	Physician 5 (pediatric endocrinologist , hospital)	Weight, height, physical symptoms, disease history, blood pressure, puberty state, growth curve, family history, social context; capillary HbA1C	Health record (carnet de santé), orally				Uses multiple platforms and software during consultations (hospital EMR - written		Cannot log in to some platforms, has problems with the CPS card		Uses the "carnet de santé", the DMP is automatically connected to the hospital EMR, but sees no

							information and test results intra-hospital, software for BG analysis, message systems)				utility to using it
1 3	Nurse 4 (Asalee, liberal)	Clinical test results, consultations history, patient contact, therapeutic goals, life goals, feelings, personal experiences, social context,	Electronic medical record from partner GPs; oral exchanges with GPs,	Often no summary letter from ophthalmologists Action: Prepares a file with current information and asks patients for missing information at the subsequent appointment		Guidelines guide their practice, they are who will explain to patients why and when to get blood tests and see specialists	Uses different physicians' software ("logiciel métier des médecins") and the Asalee platform	Access to medical information (prescriptions, summary letters, test results) and puts in notes about encounters with patients, including when patients did not come to the consultation so physicians can follow up. Puts anonymized patient information			Does not use it.

								in the Asalee platform for subsequent studies.			
1 4	Physician 6 (GP, liberal)	Above all, social and psychological aspects, questions about therapeutic adherence and how the person managed when diagnosed; difficulties in relation to disease acceptance; assessing the person's state of mind and trusting them; personal experience with diabetes	Test results on computer, otherwise patients bring them on paper				Risk calculators, SISRA (also as a messaging system), physician software 'logiciel metier'	Uses risk calculators to show patients how biomarkers improvements can impact their cardiovascular risk, SISRA as a messaging system and to centralize information (all summary letters at the same place)			Never used
1 5	Physician 7 (GP, liberal)	Time since diagnosis, diabetes knowledge and personal experience assessment,	Patients bring the extration of their electronic medical record in a	Patients come without any previous clinical test results Action: update patient record during first		Suggest patients have their HbA1c tested every 3 or 4 months, see an ophthalmologi	SISRA used in AURA region, 'logiciel metier', platforms to schedule		SISRA - decrease the number of messages on inboxes, improves communicatio		"Coquille vide qui ne sert, actuellement , à pas grand-chose" Uses rarely

		medications, HbA1c; BG measurements; assess what other HCPs might have explained to patient	flash drive	consultation		st and have a foot exam once a year, talk about the importance of physical activities	appointments		n, more and more HCPs using it DMP - no classifying or hierarchy of information		as a physician and has never used as a patient
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Table 4-7 - HCP summary matrix (continuation)

Interview		Decision-making		Care coordination			Evaluation		
		Approach	Goals (description)	Description	Determinants	Assessment	Difficulties	Positive aspects	Improvement aspects
1	Physician 1 (endocrinologist, association)	Person-centered: tries to understand why patients might not have done blood tests when recommended and works in therapeutic education; asks the person where she wants to go and how; asks the needs and preferences of patients and builds propositions from there; explore situations to find people's resources to reach therapeutic or life goals; crosses information from patients' perceptions and indicators (such as BG	Increase physical activity, better understand the connection between eating habits and BG or the importance of periodic blood tests; improve stress management; identify when to ask for help in case of hypoglycemia;	Receives and sends summary letters in paper from and to the physician that addressed the patient to the association. Believes the patient is still the main mean of information sharing between HCPs.	The association cannot work without summary letters to understand why patients have been referred.	Thinks care is not optimal because there are still problems in coordination, which causes extra costs for the healthcare system.	Not enough time to exchange with other HCPs.	HCPs help each other a lot, they pass on information when needed even if it is time consuming. The hospital system and the direct access to test results. Teamwork.	To have an actual shared and universal electronic record. Improve information sharing between HCPs, and also with other health organizations like clinical labs.

		tests) to have conversations and assess goals; writes summary letters with patients, who validate the content, to send to other HCPs with patients' authorization	other goals concerning behaviours, weight management or HbA1c Assessment and frequency: proposes an evaluation appointment						
2	Physician 2 (geriatric specialist, hospital)	Mixed approach: patients might have significant cognitive impairment, so tries to explain treatments to family/carer	Mostly linked to interactions between medications or physiological limitations (often impaired renal function)		Thinks the lack of time makes it difficult to talk to other HCP, like pharmacists, to improve care to older people.	Says often GPs renew old prescriptions, that have been updated, after patients are released from hospital. Believes pharmacists can play a key role to help patients follow prescriptions und understand treatments.		Electronic records are only getting better	Would like to have more time to discuss with patients and explain the importance of treatments. Improve communication with liberal nurses, and the communication hospital-community in general. Have HCP working at the same time at the hospital and with their independent practice

3	Dietician 1 (association)	Person-centered: asks patients why they are there and what they expect from the consultation; discusses and validates with patients what can be done to put what has been decided into practice	Small goals related to improving eating habits (like eating less cheese), regular physical activity, weight loss, improving quality of life Assessment and frequency: if HCP is the referent of the patient, they see them 2 or 3 times individually and multiple times in group sessions depending on the patient needs; at the liberal practice sees patients once a month	All HCP at the association agree on what to write to GPs and specialists about therapeutic goals and other activities (ETP, advice, etc.). Each professional fills in a record after seeing a patient so the others can see what has been done.	Says dietitians are rarely included in the information exchange. Also says defining shared objectives with other HCP can be time consuming. Feels reassured when sees other HCP share the same issues with specific patients.	Coordination between HCP exists at the association, but at the liberal practice HCP are still isolated.	Dietitians are not reimbursed by social security, so patients have to pay themselves.	Networks created around the association with independent HCPs and GPs. When it works, having access to electronic records allows accessing verified and secure information.	Having coordination meetings with multiple HCPs.
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4	Nurse 1 (association)	Person-centered: asks patients what they want to change (what they are able and are willing to do) and help them formulate goals	Patients decide the goals and how to put it into practice, normally linked to understanding care, having and using a glucometer, talking to physicians about how to improve glycemic control Assessment and frequency: Labels goals as "reached", "partially reached", "not reached". Assess goals between the second and third appointments at the association	Receives at the association HbA1c results, hospitalization summaries, treatments, comorbidities, etc.				Have difficulties to access SISRA because of connection problems.		Having a common record where different HCP can input data and complete missing information.
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5	Physical educator (association)	Person-centered: focus on ETP and allowing patients to be autonomous and self-manage	Tries to establish "micro-goals" patients' feel they can accomplish (mainly related to stop smoking, improving eating habits and increasing physical activity levels) Assessment and frequency: Random frequency depending on patient needs. In the liberal practice assesses goals based on actimetry and self-reported questionnaires.	Receives at the association HbA1c results, hospitalization summaries, treatments, comorbidities, etc.			Believes a lot of tests are repeated because HCPs are not informed. Not all HCPs are comfortable with technology.		Ideally the DMP would be actually used by HCPs and patients.
6	Physician 3 (GP, health center)	Person-centered: focus on explaining the disease and its implications (complications, why see HCPs and do blood tests	For people with type 1 diabetes the main goal is to keep them motivated;	Receives and sends summary letters to other HCP. Does not send therapeutic	Believes summary letters without a clear	Does not think care coordination or shared objectives between HCP exist, at least from their side.	Feels a lot of information does not gets to them. Information	More and more HCPs using computers to share information and	Patients should have a record like the DMP, but more dynamic and

		with a given frequency, etc); asks life goals to try and define therapeutic goals,	HbA1c inferior to 7.5%; get HbA1c levels testes at least twice a year (for some just having it done once is already enough); blood pressure control and weight management. Assessment and frequency: Every time they see the patient for diabetes follow up.	goals to other HCP, but sometimes receives them in the summary letters, like from cardiologists. Specialists define objectives and send them, who will then talk to the patient.	structure cause a lost of time, but says their own summary letters are too succinct and miss half the information.		hierarchy and classifying is difficult, specially for people with multimorbidity. Has several duplicate test results and other documents in patients files.	communicate.	easily accessible. Improve communication community-hospital. Communicate with people in a trustworthy manner so patients know their data is protected and not being sold. Create new jobs to have people that would periodically clean records and put files in order. Have an european policy of data sharing.
7	Nurse 2 (specialized center)	Person-centered: patients elaborate goals themselves, thinks patients need to be as autonomous as possible	Mid-term goal is to live better with the disease and long-term to improve glycemic control; establish small	Sends endocrinologists a telehealth summary at 3 and 6 months after the beginning of the program.		Does not have any interaction with HCP outside the hospital.		Team work.	Improve hospital-community communication. Would like to stop running after profits and have more time to do

			goals through exchanges in the telehealth platform Assessment and frequency: with the telehealth platform they try to assess goals once a week or two weeks; larger goals are assessed every 6 months during the medical appointment.						things well.
8	Nurse 3 (specialized center)	Person-centered: focus on patients' strenghts; spends 1-2 hours talking to patients during the first consultation to make a global assessment; thinks it is not their role to define goals, patients elaborate goals themselves; adapts instructions to people's life contexts	Increase the number of BG checks and better manage insulin injections (number or time of day) Assessment and frequency: likes to call the patient to ask how			Believes nurses have no interactions with GPs or other HCP outside the hospital; thinks coordination existis between physicians but not other HCPs.	Receives too many e-mails and feels overwhelmed by the amount of information.	Having a telehealth platform avoids leaving patients alone to self-manage. Having other HCPs on the team, like psychologists, and working with patients to improve services.	Create bonds with the independant world. Being able to actually offer a care pathway adapted to patients' needs and preferences, not adapted to budgetary

			modifications in treatment have been put in place and if they seem to be working; keeps a sheet with results at 1, 3 and 6 months but prefers to have patients subjective perceptions. The telehealth program is evaluated by patients every 6 months.						constraints.
9	Dietician 2 (specialized center)	Person-centered: checks patients have established goals themselves, asks why patients have come; starts by asking people what they are able to do concerning their eating habits (if patients do not feel ready they just end the consultation or ask the patient to describe their eating habits); asks patients' opinion about	Increase the number of rapid insulin injections a day and BG checks; diet goals are secondary. Goals related to eating habits are normally related to reducing fat or sugar intake, if	Information is passed on by physicians, feels it is less appropriated for dietitians to ask patients their histories. Also has access to summary letters from GPs. Talk directly to endocrinologists		Dietitian encounters are not summarized nor sent to GPs.		Information sharing at the hospital. The telehealth platform improved communication with patients and augmented the frequency of interactions, specially with real-time	Systems should send alerts when new messages or replies arrive. Improve information sharing concerning dietitian consultations.

		<p>situations and tries to understand BG results</p>	<p>it is not effective to reduce hyperglycaemia they talk to physicians to adjust insulin dosage. Assessment and frequency: ideally every month, the telehealth program helps keep in touch with patients and allows asking them how they feel modifications are going. Can also talk to physicians to check if insulin changes have made an effect, but most diet-related goals are assessed by discussing with patients.</p>	<p>to explain goals set with patients or to ask for further explanations as to why patient has been referred (orally or by messaging system).</p>				<p>exchanges.</p>	
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10	Physician 3 (endocrinologist, specialized center)	Person-centered approach: tries to combine patients' preferences, needs and skills with diabetes care guidelines	Therapeutic goals during consultation not necessarily formalized (thinks it is normally done in ETP sessions); tries to propose small goals for the next consultation (reduce insulin doses to avoid hypoglycaemia, increase BG tests, etc); goals are often linked to HbA1c around 7% for people with type 1 diabetes and to increasing physical activity levels, improving eating habits or stop smoking for people with type 2 diabetes	Receives test results from labs, ans summary letters from other HCP in paper or in electronic format in the hospital EMR.		Says at the hospital they have a real team work.	Sometimes medical devices, specially the old ones, are difficult to operate and it may take a lot of consultation time. The hospital infrastructure is not always adapted to the use of specific pump and CGM software, sometimes they can only use one room. Different devices, software and new rules to improve data security make their job complicated.	Access to data generated by new medical devices is easier. Technology helps lose less information, repeat less tests, hospital systems work well.	Improve information sharing with community medicine. Would like to have single software solutions that would have all the medical information at the same place.
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			<p>and frequency: goals assessed during discussion with patients or test results, asks when patients want to see them again</p>						
11	Physician 4 (endocrinologist, specialized center)	Person-centered approach: during the first consultation tries not to talk about BG or modify treatments, but about life projects and get to know the person; adapts therapeutic goals to patients' skills and preferences; shows the patients' availability to help without imposing things to do	<p>Tries to establish acceptable and shared goals; combines time in range (TIR) and HbA1c (the objective is to have na HbA1c inferior to 7 with about 4% of time in hypoglycemia)</p> <p>Assessment and frequency: checks time in range (TIR)</p>	Sends and receives summary letters to other HCP.		Thinks coordination with other HCP only exist in serious and urgent cases.	Operating all the different software, accessing messages, placing documents, etc., is very time consuming. Community software ('logiciel metier') do not communicate with the hospital system.	Interprofessional teams react faster and think better together; care is being organized around data generated by connected objects.	Believes data providers should not be data owners, and it would facilitate interactions and interoperability between systems. Work on the idea of sharing information in a trustworthy manner, to avoid that patients feel

									invaded.
12	Physician 5 (pediatric endocrinologist, hospital)	Person-centered approach: tries to see what is possible for patients and parents, always prioritizing patients' security (not possible to stop taking insulin injections, for example); adapts goals to patients' and parents skills - smaller goals to make it more manageable	Goals are specific to each patient (for example eat less between meals, improve BG at one specific time range) Assessment and frequency: Asks patients how it went and uses indicators to objectively assess glycemic goals; performs a HbA1c test during consultation. Ideally patients should be seen every 3 or 4 months, but sees so many patients the intervals need			Says the communication with GPs happens only in one way, GPs almost never send them summary letters.	Has so many patients it is impossible to see them at the ideal frequency. Does not have the professional card (CPS) to use MonSisra.	Teamwork.	Would like all data to be at the same place, easily accessible.

			to be longer						
13	Nurse 4 (Asalee, liberal)	Person-centered approach: asks patients why they decided to have a consultation	Normally linked to managing weight, understanding and taking medication Assessment and frequency: Patients decide the frequency of appointments, Asalee defines a frequency of once a trimester	Talks directly to physicians to set shared goals; makes summaries to GPS every week concerning consultations	Oral exchanges with physicians are simpler and faster.				Would like the Asalee software to be improved.
14	Physician 6 (GP, liberal)	Patient-centered approach: asks about the beginning - how the person has lived the diagnosis is an indication of adherence; asks about family history with type 2 diabetes; assesses motivation to adapt the	Small goals related to physical activity, weight and eating habits	Has been in a diabetes network with different HCP (endocrinologists, dietitians, nurses, pharmacists, etc). Sends regularly patients to ETP		Thinks the network fulfills coordination needs (addresses patients to nutritionists/dietitians, fills in a medical file and the specialists have their own file). Says it is a global			Different records need to be interconnected so information appears in other places easily without HCP

		means to help patients self-manage; asks about physical activity and eating habits (thinks it is important for physicians to learn about nutrition); goes slowly with small goals to increase physical activities and improve eating habits; trusts patients, avoids an "adherence police" approach; asks about secondary effects when in doubt about adherence (when observes no change in biomarkers); focus on quality of life and values small beneficial changes		services, works with an Asalee nurse. Normally does not manage people with type 1 diabetes (most are followed by hospital services)		approach with mid and long-term assessments of patients evolution. Describes a difference in approach by some endocrinologists: "Parce que bon, certains diabétologues ont tendance, dès que l'hémoglobine glyquée franchit des zones de turbulence... On rajoute des médicaments, donc les patients se retrouvent avec des listes de médicaments – dont, entre nous soit dit, je pense qu'ils choisissent, des fois, les médicaments – et il y a un problème d'observance, après, qui se met en place."			intervention. GPs could benefit from harmonizing medical software, which would be connected to hospital and network systems. Believes there should be a minimum set of common characteristics to all medical software. Using international terminologies could also help share information and perform research and evaluation on primary care.
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15	Physician 7 (GP, liberal)	Patient-centered approach: asks about patients' perception of diabetes and family history; focus on small goals (specially physical activity and eating habits); asks indirect questions about taking medication, asks about secondary effects,	Does not think the idea of short-term goals apply to diabetes, tries motivational interviewing to define long-term goals	Thinks GPs are the health care goalkeepers and managers of coordination; talks to patients to ask if they would like to see other HCP. Likes to be informed in a synthetic format of activities patients might have done with other HCP.	Some patients do not want to see other HCP, specially dietitians	Believes the different programs that exist can be used as a guide to coordinate efforts, but does not have the time to systematically put it into practice (also thinks other HCPs do not do it systematically either). Sometimes can feel left out of important information, like when they do not know the patient is already in a diabetes network.		Shared-decision making; writes more detailed information to keep track of what happens to patients; shares information with colleagues at the same office.	Believes the amount of information produced surpasses the human brain capacity to understand. Also believes the amount of information vectors (cell phone, phone, messaging systems, secretary messages, patients, mail, e-mail) lead to cognitive saturation and impair clinical reasoning
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Table 4-8 - PwD summary matrix

Interview		Health care			Health information			
		Description	Perception	Care coordination	Description	Storage	Issues	Transmission
1	Female, 68 yrs, T1D (30 yrs since	Follow up done by an independent physician (endo), goes to the		Says GP and endo interactions are limited to sending each other	Says she does not keep information on paper and all		Declares never having had any problem with	

	diagnosis)	hospital if needed because she uses an insulin pump since 2002. Regular care includes visits to the endo twice a year, visits to GP every 3 months, blood and urine tests. Pharmacist knows she is a PwD, but says she interacts with them just to give flyers of the association she is a part of. Seems to be comfortable with both the endo and the GP.		summary letters on paper.	information is given orally to new care providers. According to her, if they want more information, they should talk to her GP or endo.		information transmission.	
2	Female, T1D (43 yrs since diagnosis)	Sees her endo every 6 months, follow up completely done at the hospital. Never sees the GP unless she needs a referral. Has a good communication with the endo, everything goes through them (central HCP). Also sees a psychiatrist once a month, a cardiologist and an opthtalmologist every 6 months. Declares to have friends who are also	Says she does not like to be treated in a condescending way: "Mais elle est nouvelle, et je suis nouvelle aussi, et j'ai pas bien pris la première fois où elle m'a dit « il faut que je vous voie souvent parce que vous avez du diabète dans les yeux », j'ai dit « vous me parlez pas comme ça. Ça veut dire quoi avoir du diabète dans les yeux ? – Bah oui, vous êtes		She is seen in the same hospital for many years, so she has not had the need to share information with new providers in a while. She knows dates, diagnoses and names of insulins and medications, can easily tell her medical history.	Keeps all her papers, declares to have a pile of papers with her medical history.		Tells orally her story (diagnostic, complications, etc) to new HCP.

		<p>endocrinologists, to whom she goes to when in need. The pharmacist does not have a role in her treatment.</p> <p>She's on an insulin pump for 10 years, likes to try new treatments (feels pride to have tried new insulins right after they were put on the market)</p>	<p>diabétique. – Oui mais j'ai une rétinopathie. Elle est comment ? Vous me parlez en français, parce qu' « avoir du diabète dans les yeux », je ne sais pas ce que c'est ». "</p> <p>Has been instructed when young to not have kids by her mother and by HCP.</p>					
3	Male, other (pancreactomy)	<p>Declares to see a GP, a endocrinologist, and a pharmacist only to get medications. Does not see a cardiologist.</p> <p>Frequency is decided by the provider "Mais sinon, pour avoir une consultation pour dire « est-ce que tout va bien ? », je ne sais pas si elle va ouvrir la porte... Parce que donc elle m'a donné un rendez-vous en janvier 2022. Dans sa tête... Voilà"</p> <p>Declares to have neglected the prescription to see an</p>	<p>Feels lonely and abandoned by the providers. Blames them for his diabetes, as it was the result of a surgery. Declares "je gère mon affaire tout seul".</p>	<p>Says there is no communication between providers, and there should be a way to assemble providers and share information. Also declares to have had HCP say incoherent things about diabetes.</p>	<p>Makes reference to blood tests results. History mainly told orally, has a USB flash drive he left with the GP with his surgical history.</p>	USB flash drive	<p>Declares he would like a provider to look at his blood test results and explain what is going well or not.</p>	<p>Oral and using a USB flash drive</p>

		ophthalmologist.						
4	Female, T1D	Sees the endocrinologist every 6 months, once a year the cardiologist and the ophthalmologist. Sees a GP but declares she has no role in diabetes care. Also is seen by the company that provides the pump and the sensor (prestataire). Normally does one blood test per year. Central provider is the endocrinologist. Declares the pharmacist has no role.			Declares to have no complications, so her history is easily told to the providers.	Has everything on her e-mail account.		Sends information by e-mail (not encrypted) or explains orally. Also says, if needed, she puts together older summary letters to show new providers.

5	Male, T1D (60 yrs since diagnosis)	<p>His follow-up has mostly been done at hospital services. His current follow-up is done at a specialized center, with a telemedicine service (interactions with a specialized nurse and a dietitian every 15 days, and periodic e-mails to the endocrinologist). Sees the endocrinologist every 6 months in general, but declares that it is possible to have shorter intervals between visits (3 months). The GP, who he sees once or twice a year, is responsible for prescribing all the blood tests: the participant says he's the "pilot" and asks the GP periodically to prescribe them <i>"Je suis suivi par mon généraliste, qui me fait faire tous les examens autres : glycémie, contrôle général lié au diabète... Tout ça, c'est</i></p>	<p>Seems to be generally satisfied with current care, specially with the new center and the telemedicine service. Declares to see no interest in having a pump provider (prestataire), a common observation among PwT1D. Thinks a pharmacist would be able to provide the same level of care with a decrease in costs.</p>	<p>Essentially referral between physicians. All reports and summary letters are sent to the endocrinologist. The GP has a central role in everything not diabetes-related, while the endocrinologist receives all the medical information. At the specialized center, communication/coordination between the interprofessional team is ensured.</p>	<p>Everything is in the electronic health record at the hospital.</p>	<p>Has a DMP and tries to scan all his files into it.</p>	<p>The hospital system does not communicate with the DMP, declares to lose a lot of time by scanning documents.</p>	<p>Since his files are all on the same system, declares not to bring anything in paper, only if the provider asks for it.</p>
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		<p><i>mon généraliste qui pilote ça. C'est moi qui le pilote, je lui dis « il faut qu'on fasse ça, ça, ça... ». Ça va faire soixante ans que je suis diabétique, donc il y a une petite expérience à ce niveau-là.".</i> The GP is also responsible for the follow-up of a diabetes complication (neuropathy). He also declares to see a cardiologist once a year (the physician is responsible for scheduling the next appointment after each consultation). Declares to see an ophthalmologist every year, and has few contacts with his pump provider (prestataire).</p>						
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6	Female, T1D (30 yrs since diagnosis)	Sees the endocrinologist twice a year or more, the GP has no role in diabetes management. Her follow-up is done at the specialized center within the hospital. Sees the ophthalmologist once a year for examination of the eye. Has never seen a cardiologist, but the nurses at the diabetes center do an ECG during day hospital admissions (hospitalization de jour). Sometimes is able to do all tests (blood tests, ophthalmological tests, heart tests) at the center. Sees the pump provider nurse twice a year, and declares to have a good relationship with the pharmacist. Is very active at the association of diabetic women, and says the association has an important role in her diabetes management	Declares to be specially satisfied with the possibility to do all medical procedures at the same place. Says her relationship with the GP is not easy (declares to be the daughter of a GP, so her relationship with them is not the same as everyone else).		Makes a summary orally to new providers, sometimes bring summary letters from the endocrinologists to consultations. The most important information for her is the diagnosis (type 1 diabetes), time since diagnosis, and the current treatment. Also says her disease is controlled, and has always been, but complications were recently diagnosed (makes a list of the diagnoses)	Declares to keep a lot of papers and to have no clue when or if to throw them away.	Says when she forgets something the provider asks and " <i>fait son job</i> ".	Orally (tells the last 2 or 3 years) and sometimes brings summary letter from the endocrinologist on paper.
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		and other " <i>Quand tu parlais d'interlocuteurs liés au diabète sur les interrogations, les projets de vie, ce genre de choses... Ces questions-là... Alors je vois ma diabète sur des aspects médicaux, mais plus sur du ressenti, l'aspect psy, c'est plus via cette association.</i> "						
7	Female, T1D (29 yrs since diagnosis)	Since the diagnosis she has been followed-up by an interdisciplinary team including a cardiologist and a dietitian. She declares to have developed an eye complication and thus seeing an ophthalmologist became even more important. Sees the endocrinologist every month to make pump adjustments (new pump).	Says that the endocrinologist she sees is young and technophilic, so she has to follow. Declares also to feel the need to see a psychologist, specially in the beginning, which she had never had access to. She is active in na association and helps organize support groups. She has no provider with whom she shares her life goals or talks about other	Says the ophthalmologist, the endocrinologist and the cardiologist used to send each other summary letters.	She tells orally her medical history			Essentially orally, if needed she provides the last blood tests results in paper.

		<p>She currently sees an endocrinologist, a cardiologist once a year, an ophthalmologist three times a year, a podiatrist, by her own will, three times a year. Also sees a GP for everything else, non diabetes-related. Pharmacist has no role. Has participated in all therapeutic education sessions she could.</p>	<p>subjects.</p>					
8	Male, T1D (25 yrs since diagnosis)	<p>His follow-up was always been done in hospital services, currently at the specialized center. Is part of the telemedicine service and communicates with the nurse and the dietitian every 15 days. Sees an ophthalmologist every year and declares to not see any other provider outside the center.</p>	<p>Seems very pleased with the follow-up at the center and the telemedicine service.</p>		<p>For him, the most important information concerns his habits and way of seeing the disease. All other information he considers important is provided by the sensor graphs.</p>	<p>Declares to not keep anything.</p>		<p>Declares all prescriptions and summary letters are automatically sent to the providers involved in his care.</p>

9	Male, T1D (35 years since diagnosis)	Has always been followed-up at hospital services, normally every 6 months. The periodic tests are usually done in a day hospitalization (hospitalisation de jour). Every three or four years he used to be hospitalized for a week to do all the therapeutic education workshops. The central professional is the endocrinologist, all other professionals are transitory (change at each consultation). For a while, the GP renewed his prescriptions and he only saw an endocrinologist every one and a half years. Currently, the GP has no role in diabetes management and he sees him very rarely. Pharmacist has no role either. Was seen by the pump provider every three months instead of six because he wanted	When the follow-up was done by a team of endocrinologists (a different endo at each consultation) he believes care was erratic. Says he felt and still feels like he has to justify his blood glucose results to providers <i>"Et en général, il fallait justifier, vis-à-vis des diabétoques, pourquoi j'étais en hyper, et qu'est-ce que j'avais fait, et pourquoi j'étais en hypo, et qu'est-ce que j'avais fait... c'était un peu cette phase de « justifiez-moi pourquoi... »... c'est un peu ça le souvenir des rencontres que j'avais avec le diabétoque."</i> He thinks the providers propositions regarding treatment, only related to pump and insulin to carb parameters, are not the central element in diabetes		Has a pile of papers and the hospital also sends him summary letters and test results on paper.	He has a folder with all the papers <i>"mis em vrac"</i> , he prints everything.	To avoid issues with storage (different types of documents like imagery or test results in pdf) he prints it all so he has easy access to all his files. Declares to have no communication channel with providers, specially the endocrinologist, with whom he would like to share information on real time, if needed. The pump provider has a communication channel, so he would go through them to send information to the endocrinologist. Says the hospital system he can access is somehow "random", he cannot see all the summary letters	Providers at the hospital service have access to all his files through the HIS, and the lab sends test results directly to the hospital. He prints the server reports to show them to providers at the hospital.
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		to, but now they are back to every six months.	management. With more consultations (every six months instead of 18 months), he thinks follow-up is easier and more adapted this way. However, since he has decided to implement a closed loop system, he feels the endocrinologist cannot "help" him anymore.				and cannot understand why some are there and some are not. He thinks it is still very provider-dependent, that the documents end up in the system or not. He uses a free server to store all his patient-generated data (insulin doses, physical activity, etc.) but at the hospital they cannot access it due to security restrictions.	
10	Male, T1D (53 yrs since diagnosis)	His follow-up is done at the hospital. He sees an endocrinologist and an ophthalmologist twice a year, a cardiologist once a year. Used to be hospitalized for a week every year for ETP sessions and to do all the tests (eye, heart, lungs, etc.), but now he	Seems to have conflictual relationships with HCPs. He says when diagnosed they instructed him to be very restrictive about his lifestyle (very common in people diagnosed more than 20-30 years ago). Has a history of treatment		Says he has some documents, but he does not need to keep anything. <i>"Je vous parle, j'ai quelques éléments que j'avais gardés, notifiés, mais sans plus. J'ai besoin de rien. Il y a tellement</i>	Describes having an organized folder with prescriptions, summary letters, procedures, that his wife is also familiar with. His wife		Brings the folder with all his medical information on paper to appointments, but says he does not need it and that he know by heart his HbA1c results and other

		<p>makes the appointments himself when he wants. He has eye complications (retinopathy), treated with injections and laser. Sees a GP for other things, no role in diabetes management. Pharmacist has no role. No mention to nurses or dietitians.</p>	<p>fatigue and renouncement. He tells having to impose seeing his ophthalmologist twice a year instead of one, against her advice, and he was proven right when he got eye hemorrhage.</p>		<p><i>longtemps que je l'ai sur le dos, cette maladie chronique, et tous les jours, toutes les heures, vingt-quatre heures sur vingt-quatre... Mon livre est dans ma tête."</i> He describes later, however, being very organized and keeping all summary letters, prescriptions and other medical-related information on paper. He says important information are the summary letters, diagnoses, treatments and procedures.</p>	<p>also scans all his papers to keep it on the computer.</p>		<p>important data.</p>
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11	Male, T1D (10 yrs since diagnosis)	<p>He declares to treat his type 1 diabetes with his GP. Sees the endocrinologist twice a year and by email if needed.</p> <p>Ophthalmologist once a year, podiatrist twice a year, cardiologist once a year. The GP makes na ECG once a year.</p> <p>Dentist once a year and blood tests every three months. Says, however, that the key HCP is the endocrinologist.</p> <p>Pharmacist has no role.</p> <p>Has been to ETP sessions right after being diagnosed.</p>	Describes having a really good relationship with the endocrinologist.			Keeps a folder with test results and summary letters. Says it could be digital, but it would be less practical.		Test results sent directly by the lab to physicians, for other tests, like heart tests, he keeps it and brings it to the consultation. Summary letters are made by the endocrinologist and sent to all the other providers involved in his care. Other information is transmitted orally.
12	Female, T1D (11 yrs since diagnosis)	<p>Sees an endocrinologist and a GP, which has no role in diabetes management, only prescriptions renewal whenever needed.</p> <p>Pharmacist also lives with type 1, she sees them as a peer helper.</p> <p>She exchanges messages with nurses from the specialized</p>	<p>She describes having had a bad experience with the diagnosis and at the beginning of diabetes care. She had to see 3 physicians to find one she felt comfortable with. Says the GP she sees does not understand a thing about diabetes "<i>En général, quand je</i></p>		<p>She says she does not see hospital mail, keeps her prescription in her backpack. Does not keep summary letters, she thinks she does not need them as the GP also gets it.</p> <p>She believes the most important</p>			

		center every week, and periodically does an ECG and an eye exam at the center as well. Does not see an ophthalmologist nor a cardiologist.	<i>ressors de l'hôpital, elle me met sous la surveillance de mon médecin traitant, qui n'y connaît absolument rien. Parce qu'à part pour faire les ordonnances... il comprend rien, c'est une quiche."</i>		information to have access to are blood test results, all the other information, like dates, diagnoses, etc., she knows by heart. Also says integrating sensor data and blood test results could be helpful.			
13	Male, T2D	Has been diagnosed and saw na endocrinologist at first, but since then has been followed up by a GP every three months. Sees the endocrinologist once a year. The GP has never made any changes to treatment. Pharmacist is a person with type 1 diabetes, sometimes they talk about treatments. Has seen a dietitian but says the last time he saw them, they had nothing to say.		Talks about summary letters being sent by the endocrinologist to the GP, but not the other way around.	Thinks the most important information is the HbA1c, all his exchanges with physicians are around this outcome.	Has all his files organized in the computer.		Says blood test are sent directly by the lab to the prescriptor, but when the GP or the endocrinologist does not have a copy he sends it himself. He makes sure both physicians are informed.

14	Male, T2D (20 yrs since diagnosis)	Sees a GP every one and a half months or three months maximum. Makes general blood tests once a year, HbA1c every three months. Says he talks about physical activity and diet regularly with the GP. The last time he saw a cardiologist was two years ago, and they told him he had nothing to fear. Has never seen an endocrinologist, nor a nurse or a dietitian. Pharmacist has no role.				Has a file with all his papers, does not like the computer.		Brings the folder with all his medical information on paper to appointments.
15	Female, T2D (5 yrs since diagnosis)	Sees only the GP, the physician is responsible for her diabetes management. Has done an ETP session at the hospital. Sees an ophthalmologist every 6 months because she has lost na eye - not diabetes-related. She goes to an association that promotes physical activities for people with obesity, has seen a	She seems pleased with current care. Declares not to consider diabetes a disease, it is just something she has to take an injection every two weeks for.	Not mentioned as she only sees the GP.		Declares not to store nor manage any information, says all of her medical data is online. Does not keep prescriptions.		

		dietitian there but they do not discuss diabetes.						
16	Male, T2D (19 yrs since diagnosis)	Sees a GP, who is responsible for his diabetes treatment, but has changed treatments when he met a new physician by his GP advice. Declares to see a cardiologist less than he should, every 2 years. Sees an ophthalmologist once a year. Did not like the experience he had seeing a dietitian. Pharmacist has no role.			Says the GP he sees has everything on the computer.	Keeps a health notebook with all his medical information. Also keeps test results in paper.		Says he has his health notebook with him at all times, but the providers have never asked to look at it.
17	Female T2D (11 yrs since diagnosis)	Has been followed up for severe asthma, then diabetes and heart issues at the same hospital for the same specialists for several years. Since she has a new asthma treatment and is doing better, she sees providers once or twice a year. Diabetes management is done by an endocrinologist. The	Says she is not ashamed of being sick, has been seen by the same providers, including the pharmacist, for many years.	GP gets summary letters from the specialists.	Believes it is important the providers know she lives with diabetes, severe asthma, hypertension.	Keeps tests results and other papers in a - very organized, as she says - folder.		

		GP has no role in diabetes management, she declares they are aware of everything but, for every disease she has, she sees a specialist. Has done several ETP sessions and has seen dietitians multiple times. The pharmacist has a special role, she can count on them for reassurance, explanations, etc.						
18	Female, T2D	Declares to see the endocrinologist every 6 months, and, in case of problems, every 3 months. The role of the GP is limited to being aware of what the endocrinologist has decided. Also declares to do blood tests every 6 months, and to see an ophthalmologist and a cardiologist once a year. Has never been to an ETP session, the endocrinologist explains what she has to do, and she also asks the	Says she did not like the previous GP because they did not like that she was also being followed up by an endocrinologist.		Says the physician has everything he needs on the computer. Declares the most important information to pass on to new providers is the fact that she lives with diabetes, the current treatment she is under, the medication she currently takes, and showing blood tests results over one or two years.		Says she has always made the connection between GP and endocrinologist. She tells orally the GP when there is a change in treatment or other significant event.	Says she tells the GP orally about treatment modifications and blood test results. Also says summary letters are becoming more and more rare.

		pharmacist if she encounters any problems.						
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Table 4-9 - PwD summary matrix (continuation)

Interview		Technological tools				Decision-making			
		Description	Current use	Determinants	Opinion on data sharing	DMP*	Description	Role played by technology	Choice of professional
1	Female, 68 yrs, T1D (30 yrs since diagnosis)	Declares to use the computer, tablet and smartphone.	Uses LibreLink and LibreView for CGM data, brings her smartphone to the consultation so her endo can see her BGs.		Says she travels a lot so it could be easier to have a shareable electronic health record. For her, all of the care providers she sees could have access to her record; at the pharmacy it could be a solution for when a prescription is not available (in case she forgets or does not have it for any reason). Sees no reason to use it herself, does not have	It has been opened, but she never used it. Sees no need or usefulness.	Says she has not had any recent changes and had nothing to say about the shared-decision making process. Says she would accept any decision made by the providers she sees "Pour ça, je fais confiance aux médecins, au diabétologue, tout ça, aux professionnels de santé. C'est pas du tout mon domaine, j'y connais rien, donc je fais confiance. S'ils me disent de		Says she changed GPs and her criterion was flexibility: the physician needed to agree to do home visits in case she could not go physically to the physician's office, like if she had a low blood glucose.

					any important changes in treatment and is currently happy with the amount of information she has access to.		changer d'insuline, je changerai d'insuline". Says she has no particular goal, and none is set by any HCP; she is happy with her HbA1c and her weight.		
2	Female, T1D (43 yrs since diagnosis)	Uses apps like Glucicheck and LibreView	Shares her BG history on LibreView with a friend, not with her endocrinologist.		Is favorable but says she believes it would be difficult to share too much information without context to providers.	Declares to have one but has never opened it.	Decides with her friend which medication to take and if/how to make changes to treatment, then talks to the endo to have a second opinion and asks them to provide a prescription. Or her friend suggests a new treatment/change in treatment. (friend is a retired endocrinologist)	Talks to endo by e-mail, thinks sending HCP BG information would be overwhelming for them - specially without context (what was made when)	Wanted someone with "du recul", does not want her endo friend to be her physician. "Elle me connaît différemment, parce qu'on a souvent fait des choses ensemble, donc elle me connaît 24h/24. Lui me connaît un quart d'heure dans son bureau d'hôpital. Mais je voulais avoir quelqu'un qui avait le recul."

3	Male, other (pancreatectomy)	Declares to not use any app or platform diabetes-related.			Would share data with any provider in the care team. Also declares to have the need to access his medical history easily, to help him decide which treatment to take.	Has it but does not use it.	Declares to make all decisions himself, concerning insulin and the medication he takes. "...en deux mots, je me démerde tout seul".		Says he used to see a GP that had a burnout and it was not easy to find a new one. Also declares to have changed endocrinologists because the one he used to see reprimanded him for traveling. The new one knows how to listen and would receive him between patients if needed.
4	Female, T1D	Uses apps like Glucicheck and a forum for women with diabetes	Only to count carbs.		Would share data with any provider in the care team (only sees physicians, no nurses or dietitians).	Does not use it. Declares to have concerns on its security, thinks private insurances will have access in the future to patients data. Also says it took her hours to open hers.	Declares not to propose any changes, the providers make the propositions. Says she does not have any measurable goal.		Is seen at the same hospital for 15 years, has changed endocrinologists because she felt pressure to accept a sensor.

5	Male, T1D (60 yrs since diagnosis)	Uses the telemedicine platform, an app to count carbs, the DMP.	Uses the DMP to keep track of his healthcare utilization, uses an app to count carbs and the telemedicine platform to upload his pump and sensor information and to communicate with the team at the center.	Likes to test new technology (pumps, sensors, DMP, etc.) and asks the endocrinologist to assess his eligibility to clinical trials regularly.	Is open to data sharing with all providers and would like to have access himself to all of his medical data (tests results, healthcare use, summary letters, etc).	Has one and is trying to use it. However, the lack of communication between systems and the DMP's limitations are a problem to have access to tests results, for example.	The endocrinologist proposes treatment modifications, and he accepts them or not. Asks the GP for periodic blood tests himself.	All his data (pump and sensors) are used to make decisions about treatment and to keep track of therapeutic goals (based mainly on 'time in range').	Did not give much detail, but says he needs to change GP because the current one he sees is "getting old". Has been followed-up at two different hospitals in two different cities and seems to be satisfied with care at the hospital setting.
6	Female, T1D (30 yrs since diagnosis)		Uses the sensor app, have tried using an app to count carbs but did not keep using it, and uses a computer application to send her pump and sensor data to the endocrinologist.	Declares to be married to a geek and to have no problems using software or other technological tools.	Declares to be favourable to sharing her data with all the providers involved in her care, but has concerns when it comes to data security, or that it could end up being used by insurances. Says she would share her data if it	Declares to not have it because no provider has talked about it or offered to open one for her.	She explains the problems to the endocrinologist and they have a conversation, she asks the endocrinologist to write down any changes in treatment so she can keep track of the modifications in case she forgets. Keeps a question list for	Having the sensor makes changes in insulin dosages less frequent, she takes less time to assess her data compared to when she did not have it (used to do it 3 or 4 times a year, and after the sensor twice a year).	Declares to have changed GPs because she did not feel the GP was able to correctly diagnose the cause of her pain. Says she likes the endocrinologist that follows her up because she is not authoritarian and allows an

					brings her an advantage, if not, she is not interested. She would like to have access herself, says it could save her a lot of physical space at her home.		the next consultation with the endocrinologist. Declares not to have specific therapeutic goals, only broader ones like decrease amount of hypoglycemia and improve quality of life. When she saw a physical educator (educatrice en activité physique adaptée) at the center, the provider gave her specific instructions on how to deal with blood glucose during physical activities, such as the blood sugar level she should start an activity with.		actual dialog to take place.
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7	Female, T1D (29 yrs since diagnosis)		Gluci-check and Foodvisor to count carbs, the sensor app to see her blood glucose levels		Thinks data should be shared, but the patient should have access to it all and be the proprietary. Thinks it should be shared with the diabetes team, the GP and the labor physician.	Does not have nor use it.	The physician proposes changes and they discuss to decide whether to do it or not. For insulin dosage, the physician analyses her graphs and proposes changes to the pump configuration. Therapeutic goals are mainly non specific and HbA1C-related.		Has changed GPs because the one she used to see got retired. Same thing with the endocrinologist. Says she likes the endocrinologist a lot because he listens to her, does not judge and takes her opinion into account.
8	Male, T1D (25 yrs since diagnosis)	Uses the sensor app and the telemedicine platform.		Says tools have to help him in his daily life, otherwise he sees no point.	Says he has no problem with data sharing: " <i>Je ne fais pas partie des gens que ça choque</i> ". Believes it allows research and treatments to evolve. Would share it with all providers involved in diabetes care. Says a platform that would summarize all his	Never heard of it.	Keeps the same treatment he had as a child, when the physician proposed to change the treatment, he said he considered it was not convenient and did not change. Declares to have established some therapeutic goals with the nurses at the center, but did	All decisions are currently made based on sensor graphs and the interactions on the telemedicine platform.	Has seen only two endocrinologists, one as a child and one as an adult. The referral was done by the first hospital service and he has never change providers.

					medical history would be very useful, would like to have access to the data himself.		not specify which ones.		
9	Male, T1D (35 years since diagnosis)		Uses a server to storage all his patient-generated data and generates reports he prints to show providers, also uses the sensor app, the closed loop app.						
10	Male, T1D (53 yrs since diagnosis)	Has everything scanned on the computer and says the physicians at the hospital have access to everything on the hospital system.	Scanned papers kept on the computer.			Says he does not know the DMP.	Describes having to make decisions himself regarding medications and follow-up. Says he has lived 53 years with diabetes and has nothing to learn. Seems to have a 'shared decision-making' process with the endocrinologist. He says he feels able to share and talk to physicians,		He is very clear that he chooses HCPs based on their capacity to have what he considers a true dialog, to have empathy, to listen.

							say if he agrees or not. Currently he feels listened to and respected.		
11	Male, T1D (10 yrs since diagnosis)		Uses a sensor and its app to regularly analyze his blood glucose graphs. Follows conferences on a website created specifically to discuss COVID-19 and diabetes.		Says he agrees 100%, sees a clear interest for patients. Would share his data with any HCP and researchers. Would also like to have access himself, specially to blood tests filtered by type and time period.	He was one of the first users of the DMP, during the first implementation attempt. Says he currently has a DMP but makes no usage nor sees any utility.	Exchanges by email with the endocrinologist to make decisions that could not otherwise wait for a regular consultation. He feels he can talk to them to discuss and accept or not treatment modifications.		Describes having seen at least 4 or 5 to choose one he felt comfortable with. Says that their approach did not suit his needs. When asked for more details, he explains that they did not listen or did not practice shared-decision-making, or he did not feel he could trust them,
12	Female, T1D (11 yrs since diagnosis)				Does not like to use any system to share her medical data, not even the hospital patient system. Says she did not want her file to be digitalized.	Has opened one, but says the endocrinologist cannot access or upload documents, they do not have the necessary card	She explains how she feels to the endocrinologist and they make adjustments so things get more manageable. She does not feel pressure to		She asked to change endocrinologists because, as she said, the first one was " <i>une handicapée des relations humaines</i> " and

					Says, however, that she would like to have a shared electronic file, like the DMP, to which every HCP she sees could have access to, specially in case of emergencies. Sees no use for herself.	(carte CPS).	modify treatments when she is not comfortable and feels listened to and respected. She also says that before seeing the physician she already knows what she has and the treatment she wants to take, and it annoys some of them.		the second had not seen her file nor took an interest in her. The third, she says, corresponds completely to what she expects concerning empathy and the ability to listen.
13	Male, T2D	Says he is favorable, if everything is well regulated. He thinks confidentiality issues have to be addressed and is afraid some type of deviation could happen and data could end up with insurance companies. <i>"Ça peut être intéressant en</i>					Has approached the physician to modify treatments that made him feel pain, and the physician agreed to change. Calls it a "negotiation".		Thinks it is important that the HCP makes an effort to talk simply and be pedagogic to stablish a trust-based relationship with patients.

		<p><i>fonction des sécurités qui sont posées".</i></p> <p>He believes his current electronic health record, within the hospital, does not need to be shared with the GP as he already has access to test results. He also thinks it would not be useful to him to have every test or other medical information about himself, as he does not have the knowledge needed to interpret the information.</p>								
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14	Male, T2D (20 yrs since diagnosis)			Does not like using computers, is afraid his information on the computer will be stolen or used for marketing purposes.	Says he does not know.	Never heard of it.	Says treatment has never been modified and he only changed GPs because the previous one retired. Also says he does not ask questions about the treatment and accepts what has been proposed by the physician. He explains, however, that he likes is curious and ask questions to understand what is happening to him.		
15	Female, T2D (5 yrs since diagnosis)		Declares not to use any diabetes-related technology.		Says she has no problems with data sharing and believes the GP should have access to all of her medical information. Would also like to have access herself.	Has a DMP that has been open by the pharmacist. She thinks it is important to have all of her medical information in one place so when she is old HCP can easily access it. Also	Says she decided herself to increase the amount of physical activities she does. For diabetes treatment, declares she accepts anything the physician says she has to do, she say she does not		

						says the DMP is not currently useful as the providers at the hospital do not have access.	need to have a say in it.		
16	Male, T2D (19 yrs since diagnosis)			Used the computer daily, used Doctolib, teleconsultation platforms, etc.	Believes it is important to avoid test prescription duplicates. Would be comfortable sharing his medical data with any provider involved in his care. Does not see how it would be useful for him to have individual access.	Does not have a DMP.	Says he has proposed changes in medication type (sachet to pill) to the GP after discussing with the pharmacist, also proposed changes in regimen (time of day).		Lives in a small town and sees the GP available.

17	Female T2D (11 yrs since diagnosis)		Does not use any diabetes-related technology.		Likes the idea of sharing her data with researcher and all providers involved in her care. Believes it helps knowledge advance. Says she would not see the utility of having it herself, she is more comfortable with papers.	Does not have it yet because she has a computer issue. She says the GP centralizes all of her medical information, so she does not need the DMP.	Says the specialist proposes treatment modifications and, if well explained, she usually accepts.		
18	Female, T2D	Says she does not like to use any app or portal diabetes-related as it makes her think she is sick.	Does not like using the computer.		Believes data should be centralized and available to all health care providers involved in her care.	Has heard of it but does not really understand. Says she has given the authorization to the social security to open hers.	Trusts the endocrinology to make all the decisions regarding treatment. She feels however heard and respected. For starting insulin, for instance, he has waited as long as possible because she was afraid of having to take injections.		Has chosen a new GP closer to her home. Likes that the new GP is young, thinks young people know new techniques and have a new way of doing medicine.

5. General discussion

This thesis aimed to investigate the role of eHealth use in current practice to facilitate care coordination and inform shared decision-making. We applied an interdisciplinary approach with elements from Health Services Research, Health Psychology and Health Informatics, and considered three complementary domains, clinical, technological, and behavioural, in an effort to describe technology uses and applications in chronic care in a comprehensive manner. In particular, we aimed to cover the multiple aspects of providers and patients' interactions with technology and with each other. This work is composed of a literature review describing and synthesizing methods of visualization of chronic care delivery pathways, and a qualitative study investigating how care trajectories of PwD are currently being constructed in real life, and how eHealth technologies are being used to mediate the shared decision-making process in France. We have elaborated and published a protocol for a systematic review, submitted the review for publication, and prepared a qualitative study for publication. The results reported in this thesis bring contributions to the scientific literature on characteristics of technological tools developed to visualize CDP in chronic care worldwide, as well as the healthcare experience of PwD, and the use of eHealth tools to mediate shared decision-making and care coordination in diabetes management in France.

Concerning the first objective (Papers 1 and 2), we have shown that the topic of visualization of healthcare trajectories is contemporaneous and relevant. As health-related data become available to developers, more and more platforms allowing access to care histories and easy-to-read display formats, like graphs and other visual aids, will be created. The use of the analyzed tools, however, was mainly restricted to testing settings. This shows the complexity of obtaining data from EHD, developing, and implementing eHealth tools, and evaluating them in real-life conditions. The records we reviewed did not evaluate clinical outcomes, but some presented indicators to be formally evaluated in the future. Technical characteristics were disparate, and reporting varied considerably. Very few records discussed interoperability between systems, or data security – both of which were shown in the qualitative study to be very important to both patients and providers. Some records presented use case scenarios describing behaviors and interactions between users; patients were not commonly considered as final users.

Concerning the second objective (Paper 3), we have shown care trajectories in real-life are guided by guidelines PwD are presented with during TPE sessions. PwT1D, in general, saw several HCP periodically for complications screening or follow-up when complications are already present. PwT2D most of the time see only one physician, the GP or the endocrinologist, who is responsible for centralizing information, referral to other providers if needed, and making most therapeutics-related decisions. Our results show that support professionals, like nurses and dieticians, do not have the place that previous research has shown to be effective in improving health outcomes (Raaijmakers et al., 2013; Supper et al., 2017). They also, in general, do not have access to the same amount of data physicians do, and are highly dependent on them to access patient-related information. The use of eHealth tools is of particular importance to the management of T1D, but HCP and PwT1D alike have ambivalent relationships with the tools available, as has been shown by Ross et al., 2016. HCP are willing to coordinate care and collaborate, but the definition of common objectives regarding specific patients is not yet a common practice. Existing health information systems, such as HIS, are a means for HCP to communicate within the same healthcare setting. In contrast, communication is still very limited between hospitals and community healthcare services, even if a dedicated regional platform exists. In our study, shared decision-making was considered important by all HCP and most PwD, in accordance with the results of several studies (Degner et al., 1997; Milliat-Guittard et al., 2007; Ndjaboue et al., 2020).

Considering the French context specifically and the information presented in the section “French eHealth Context” in the Introduction, we believe that to generate comprehensive visualizations of care trajectories in the context of chronic care it would be necessary to have access to EHD containing exploitable raw data in structured format. This would be, however, not a simple task. First, the results of the VOIES-D-ql study show that the number of technological tools HCP and patients deal with daily, most not interoperable, make it difficult to add a new application without integrating and simplifying the existing ones. Second, data are currently made available in a non-editable format (only a few data are included in health-related documents such as laboratory results or primary care summaries as metadata: patient name and age, date, type of document and provider responsible for the document). According to Seroussi et al (2016), the document structure is bound to be

changed soon to offer more information as metadata, and it would allow to generate graphical and temporal visualizations of data within the available HIS, including the DMP. Analyses of populational data (de-identified) are already possible through the National System of Health Data (Système National des Données de Santé, SNDS) and through other EHD, but this does not apply to treatment decisions made at the point of care with specific patients. Being able to generate personalized visualizations of healthcare trajectories would add value to the existing solutions (Park et al., 2022; Patterson et al., 2014).

We consider the overall scenario of eHealth development in France, however, to be highly favorable to technological innovations. The changes proposed since the launch of the My Health 2022 strategy have created an ecosystem of actors and allowed for the development of solutions in record time during the Covid-19 pandemic. Technological innovations in other areas in France, such as energy, are also being developed in this same model of boosting private medium and small enterprises projects (AMI *“Socle Numérique et Émergence de Nouveaux Services Énergétiques,”* 2022). Although this type of market might spur innovation, it can also create a disorderly market such as the mHealth app market. The advantages are the rapid changes and solutions made available to users, but it can also mean an important loss in quality and the emergence of multiple incompatible standards, which in turn could increase the interoperability issues.

With this in mind, we propose to developers and policy makers the following framework to assess eHealth tools such as care trajectories visualization tools already in use, and guide the development of new ones, based on the results of this work, both the systematic review and the VOIES-D-ql study, and on previous literature (specified at each item):

1) Clinical aspects

- a. Include only relevant data and apply data protection measures following current legislation (from the results of Article 2). All used data need to be described (aim, information used, relevance criteria) so patients are aware of what data are used (Articles 2 and 3).
- b. Develop context-based tools (Hsu et al., 2012) guided by clinical scenarios or care processes to avoid displaying a large amount of potentially irrelevant information. For chronic care, the construction of care trajectories must only

include events related to the chronic condition, so it can be useful to the decision-making process in that specific context (Articles 2 and 3).

- c. Consider patient-generated data and how this can be integrated into eHealth tools (from the results of Article 3). The use of connected objects and mHealth apps are more and more common, but the existing information systems lack the ability to accommodate this important information and to merge it with lab test results or medication histories, for example. This would make possible the analysis of the impact of the introduction of specific medications or other management strategies with more detail, and our results show this integration is considered essential to care by both patients and providers.
- d. When reporting on development or evaluation, report on data source, integration, and quality (Article 2).

2) Technological aspects

- a. From the results presented in the systematic review, we propose the following steps (Article 2):
 - i. define scope and the work team comprising potential end-users
 - ii. perform a domain analysis
 - iii. design the tool
 - iv. define implementable tool specifications
 - v. detail dataflow and transformation
 - vi. describe data protection
 - vii. perform validation by end-users
 - viii. publish the resulting tool and its evaluation
- b. In addition to objective health outcomes and usability, it would be beneficial if the evaluation of eHealth tools considers other indicators such as patient and provider satisfaction, perceived usefulness and ease of use (Article 3).

3) Behavioural aspects

- a. Consider applying established frameworks for developing complex interventions such as the MRC (Skivington et al., 2021), the IM (Fernandez et al., 2019), and the CEHRES (van Gemert-Pijnen et al., 2011)

- b. Involve a group of potential end-users, and other stakeholders such as managers, if possible, in the development of the tool since the initial phases to enhance relevance and adaptation (Articles 2 and 3).
- c. Perform an extensive needs assessment study with patients and providers alike. Understanding how services function and how they differ from one another, and how patients are using their own data to make decisions and to interact with providers is crucial for technology adoption (Article 3).
- d. Clearly define who are the end-users and how they will interact within the tool. Consider not only the individual behaviors the tools might promote, but also how users will use the tool to interact (data-sharing, leaving notes, messaging) (Articles 2 and 3).
- e. Specify end-users' behaviours within the tool, or promoted by it, using consolidated frameworks such as the AACTT framework to provide details and to allow for further evaluation of the tool impact on current practices (Article 2).
- f. Consider the existing eHealth tools and the attitude providers, in particular, have towards them. The cognitive and documentation burdens must be taken into account, and it is important to avoid the addition of new tools that are not interoperable with the existing ones. Multiplying the offer of technological tools is not necessarily beneficial and might prevent users from wanting to use technology altogether (Article 3).

Limitations

This work has some limitations. Concerning the review, we have focused only on quantification and visualization methods of chronic CDP and not on other types of eHealth tools such as personal medical records, for example. This might have restricted our results and analysis, but it also has enabled to focus on one type of technology development. In addition, we considered the methods could also be embedded in larger systems or platforms including other functions. Concerning the VOIES-D-ql study, in addition to the limitations already described in the article, we also had an important delay in approval and recruitment due to the COVID-19 pandemic. The interviewing format, from in person to video or telephone, had to be adapted to respect the health restrictions in place. Finally, we have

performed only an initial context analysis of the French eHealth environment. We believe this is a starting point that describes the current situation, and a thorough investigation of the context should be carried out as future work.

Conclusion and perspectives

This thesis has applied the best available practices to synthesize knowledge by performing a systematic review with a published protocol, and a qualitative study with PwD and multiple HCP involved in diabetes care, many working in interprofessional teams. We also consulted patient representatives and HCP to prioritize research objectives and improve the relevance of the work.

Building on the results presented here, a context inquiry of the French eHealth environment applying the CEHRES framework (van Gemert-Pijnen et al., 2011) would be an important contribution to the literature. This would provide more details on who are the stakeholders involved, their role and how they interact, and the strong and weak points to understand how new eHealth solutions can improve the current practices in chronic care.

Another important work would be to analyze the development of the different attempts to implement the DMP nationally using a framework such as the CICI (Context and Implementation of Complex Interventions) (Pfadenhauer et al., 2017), to learn from the previous experiences and build culturally adapted implementation strategies to enhance the impact and uptake of eHealth solutions. This framework comprises three dimensions with their corresponding domains: context (geographical, epidemiological, socio-cultural, socio-economic, ethical, legal, political), implementation (implementation theory, process, strategies, agents and outcomes), and setting (physical location in which the intervention takes place).

Finally, a study including a platform with temporal views of chronic care trajectories, applied to a chronic condition such as diabetes and initially to a hospital service, would be the obvious next step. First, a platform including a graphical display of care trajectories reconstructed from EHD and other functions that can facilitate interprofessional collaboration would be developed following the framework described in this thesis. Then, it would be tested in a hospital setting, such as a specialized center, and evaluated based on its

role in promoting provider-provider and patient-provider communication, information exchange and comprehension, and improvements in the shared-decision making process.

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Annexes

Annex 1 – Article
Behavior Change Content, Understandability, and Actionability of
Chronic Condition Self-Management Apps Available in France:
Systematic Search and Evaluation

Original Paper

Behavior Change Content, Understandability, and Actionability of Chronic Condition Self-Management Apps Available in France: Systematic Search and Evaluation

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Abstract

Background: The quality of life of people living with chronic conditions is highly dependent on self-management behaviors. Mobile health (mHealth) apps could facilitate self-management and thus help improve population health. To achieve their potential, apps need to target specific behaviors with appropriate techniques that support change and do so in a way that allows users to understand and act upon the content with which they interact.

Objective: Our objective was to identify apps targeted toward the self-management of chronic conditions and that are available in France. We aimed to examine what target behaviors and behavior change techniques (BCTs) they include, their level of understandability and actionability, and the associations between these characteristics.

Methods: We extracted data from the Google Play store on apps labelled as *Top* in the *Medicine* category. We also extracted data on apps that were found through 12 popular terms (ie, keywords) for the four most common chronic condition groups—cardiovascular diseases, cancers, respiratory diseases, and diabetes—along with apps identified through a literature search. We selected and downloaded native Android apps available in French for the self-management of any chronic condition in one of the four groups and extracted background characteristics (eg, stars and number of ratings), coded the presence of target behaviors and BCTs using the BCT taxonomy, and coded the understandability and actionability of apps using the Patient Education Material Assessment Tool for audiovisual materials (PEMAT-A/V). We performed descriptive statistics and bivariate statistical tests.

Results: A total of 44 distinct native apps were available for download in France and in French: 39 (89%) were found via the Google Play store and 5 (11%) were found via literature search. A total of 19 (43%) apps were for diabetes, 10 for cardiovascular diseases (23%), 8 for more than one condition in the four groups (18%), 6 for respiratory diseases (14%), and 1 for cancer (2%). The median number of target behaviors per app was 2 (range 0-7) and of BCTs per app was 3 (range 0-12). The most common BCT was *self-monitoring of outcome(s) of behavior* (31 apps), while the most common target behavior was *tracking symptoms* (30 apps). The median level of understandability was 42% and of actionability was 0%. Apps with more target behaviors and more BCTs were also more understandable ($p=.31$, $P=.04$ and $p=.35$, $P=.02$, respectively), but were not significantly more actionable ($p=.24$, $P=.12$ and $p=.29$, $P=.054$, respectively).

Conclusions: These apps target few behaviors and include few BCTs, limiting their potential for behavior change. While content is moderately understandable, clear instructions on when and how to act are uncommon. Developers need to work closely with health professionals, users, and behavior change experts to improve content and format so apps can better support patients in

coping with chronic conditions. Developers may use these criteria for assessing content and format to guide app development and evaluation of app performance.

Trial Registration: PROSPERO CRD42018094012; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=94012

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KEYWORDS

mHealth; mobile phone; app; self-management; chronic conditions; target behaviors; behavior change techniques; understandability; actionability

Introduction

Chronic conditions are the main cause of disability and premature death worldwide, representing the highest number of disability-adjusted life years in the Global Burden of Disease project [1]. More specifically, four groups of diseases—cardiovascular diseases, cancers, respiratory diseases, and diabetes—cause 80% of premature deaths related to chronic conditions [2]. The rise in prevalence of such conditions, while being determined by multiple causes, is highly related to unhealthy lifestyles and population aging. Treatment requires a long-term and multidisciplinary approach, including therapeutic education and lifestyle changes, to prevent further aggravation and/or premature death; treatment focuses on modifiable behavioral risk factors, such as insufficient physical activity or inadequate diet [2]. Achieving and maintaining satisfactory quality of life is strongly dependent on the patient's ability to reduce behavioral risks and to regularly perform specific self-care activities defined together with health care providers (ie, self-management behaviors). This process of active engagement in obtaining skills and taking part in health-related decisions is also called patient empowerment [3]; this may be mediated by technology that facilitates self-awareness and understanding how and when to take action regarding measured physiological parameters, to prevent or react to deterioration in health status.

Currently, mobile health (mHealth) mobile phone apps can support patients in performing behaviors such as symptom monitoring and medication intake, among others [4]; therefore, they have the potential to help improve population health and reduce health care costs. By the end of 2017, mobile broadband subscriptions were expected to reach 4.3 billion worldwide [5]. In 2012, one in five mobile phone users had at least one health-related mobile app on his or her phone [6]; in 2015, over half of that population had downloaded at least once a health-related app [7]. In addition, numbers of mHealth apps downloaded are similar between individuals with and without chronic conditions [8]. The availability of mHealth apps and people's tendency to carry their devices with them at all times mean they can also be used for delivering behavioral interventions to large populations [9]. Yet, despite the increasing number of studies and reviews on the use of such apps on health outcomes, evidence for effectiveness is still unclear [10,11]. Furthermore, in the fast-paced technology culture, few mHealth interventions are designed in collaboration with patients, clinicians, or behavioral scientists or are subject to rigorous testing [4,12]. The result is a wide and heterogeneous range of

offerings that differ in their objective, content, and user experience [13].

To assess the potential of self-management apps to improve individual and population health, it is useful to consider them as technology-mediated health behavior change interventions. For such interventions to be effective, they need to intervene on the causal behavioral pathways relevant to the health of their user group (ie, to target specific behaviors causally linked to the desired outcomes). Moreover, from a psychological perspective, they need to include behavior change techniques (BCTs), which are the *active ingredients* of behavior change interventions: reproducible and irreducible components of these interventions that can trigger change in the psychological determinants of these behaviors and, consequently, improve health [14]. In recent years, health behavior theorists and intervention developers have been building consensus on methods to identify BCTs present in existing interventions, which resulted in a 93-BCT taxonomy that is currently used as a shared framework for intervention evaluation and development [15]. The presence of behavioral change content has been shown to increase the effectiveness of mHealth and Internet-based interventions [16,17]. Examining the mHealth app offerings in terms of occurrence of target behaviors and BCTs can be informative regarding the current state-of-the-art on behavior change; it can also highlight opportunities for improvement [18], for example, by studying links between usage patterns of individual behavior change content and changes in health outcomes.

The presence of relevant behavior change content does not by itself guarantee that users will be able to interact with it and potentially change their behaviors. These tools need to present information in an accurate, comprehensible, and actionable way; they must also consider different communication competencies, styles, and health literacy levels to optimize their reach and enhance health decision making [19]. Evidence shows that most educational materials are too complex for patients with low health literacy [20]. To assess the suitability of mHealth apps for diverse audiences, it is useful to consider them as health-related materials. The Patient Education Material Assessment Tool for audiovisual materials (PEMAT-A/V) is a commonly used method in this domain; this tool evaluates the extent to which health-related materials are understandable (ie, understandability) and give clear instructions regarding actions that users may take to apply the information presented (ie, actionability) [20]. Presenting relevant behavior change content in a suitable manner is therefore important for ensuring that the intended users achieve the goals the app is supposed to facilitate. Apps with richer behavioral content may also present it in a

more understandable and actionable way, and this can be seen as an indicator of app quality and of the level of expertise of the developing team. Yet, to our knowledge, no examination of both content and suitability of apps was performed to date. Understanding the links between content and format in the current app offerings in a specific territory may provide insights into the rapidly evolving app development phenomenon and recommendations for improvement.

As mHealth develops worldwide, evaluations of app content and format are increasingly common and necessary to inform policy discussions on achieving the potential of mHealth to improve public health [21]. For example, BCTs were shown not to be widely implemented in top-ranked physical activity apps in the United States [22]. In New Zealand, in physical activity and dietary apps, BCTs associated with increased effectiveness in modifying these behaviors were more common in paid apps [23]. In Canada, theory-based cognitive-behavioral content was found to be present in only 10% of apps for depression [24]. Although app use is a global phenomenon, research is normally limited to apps in English, while the available offerings in commercial marketplaces are restricted to geographical regions. The French Health National Strategy 2018-2022 has forecasted a generalization of digital services in health care and put special interest in promoting favorable health behaviors and fighting social inequities in access to health care [25]. It is thus important to assess the current mHealth app offerings in France and in French, especially for self-management of chronic conditions. To our knowledge, no review with these characteristics has been published to date worldwide, and the potential of these tools to support behavior change for self-management of chronic conditions has not yet been fully examined. Such evaluation is instrumental for orienting the development of this expanding field in a way that best serves the interests of all stakeholders, including patients, health care professionals, app developers, payers, and the health care system.

Therefore, this systematic review of mHealth apps for chronic condition self-management in France aimed to answer the following questions: (1) What behaviors are targeted in these apps, and by which BCTs?; (2) What levels of understandability and actionability characterize these apps?; and (3) Are apps with more behavioral change content also easier to understand and act upon?

Methods

Overview

We developed a systematic review protocol based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guidelines, an evidence-based minimum set of items for reporting systematic reviews [26]. We registered the protocol with the International Prospective Register of Systematic Reviews (PROSPERO), an international database of prospectively registered systematic reviews (registration number: CRD42018094012). The PRISMA checklist [26] is available in Multimedia Appendix 1.

Apps were identified through two different approaches: (1) a search of peer-reviewed articles reporting on development or validation of mHealth apps for self-management of chronic conditions and (2) a search in the Android commercial marketplace for mobile phones. We used the Android marketplace Google Play store as it represents 88% of the global mobile phone market [27] and most apps are developed for both operating systems (ie, Android and iOS).

A systematic search of PubMed (ie, MEDLINE), IEEE, and Web of Science electronic bibliographic databases was conducted; all search terms are available in Multimedia Appendix 2. We searched for peer-reviewed articles and conference papers published between 2012 and 2018 concerning mHealth self-management interventions for the previously stated chronic conditions. Articles and papers had to report on empirical research on the development or validation of mHealth tools, pilot studies, or randomized controlled trials, both protocols and reports of study results. Articles and papers were assessed independently by two investigators (LSdP and CC) based on title and abstract, followed by full-text examination to identify available apps in France, in French, and for Android from the Google Play store.

Subsequently, a list of the first 500 free apps labelled as *Top* in the Google Play store in the *Medicine* category and the first 55 paid apps available in the same category was extracted (n=555). The number of paid apps was limited by the marketplace. Another search was performed using 12 keywords in French related to the four groups of diseases: cardiovascular diseases, cancers, respiratory diseases, and diabetes. The keywords were as follows: “maladie cardiaque,” “maladie coeur,” “AVC accident vasculaire cérébral,” “infarctus,” “maladie pulmon,” “asthme,” “BPCO,” “maladie respiratoire,” “cancer,” “diabète,” “diabète type 1,” and “diabète type 2.” For each keyword, the first 20 apps shown in the marketplace (n=240) were extracted. The complete list (n=795) was assessed independently by two investigators. After screening, selected apps were divided into five groups: four according to the conditions they targeted—*cancers*, *diabetes*, *respiratory diseases*, or *cardiovascular diseases*—and one generic group (ie, *other*) for apps that targeted behaviors like medication adherence and physical activity, irrespective of medical condition (ie, they did not specifically reference a disease within the previous four groups).

All searches, data extraction, and coding were done between March and April 2018. Coding was performed a second time in October 2018 by a different investigator, along with interrater reliability, reconciliation, and coding review. A Samsung J7 mobile phone with Android, version 6.0.1, was used for downloading and evaluating all selected apps.

Eligibility

All native apps available for download in France and in French at the Google Play store designed for patients for the self-management of cardiovascular diseases, cancers, respiratory diseases, and diabetes were eligible. There was no restriction considering price or the source of for-profit or not-for-profit funding. The following apps were excluded: apps that were clearly not for chronic conditions (ie, apps that did not state their main purpose or were designed for other users or purposes,

such as training health professionals or students, hospitals, or medical laboratories; making medical appointments; reaching emergency services; or geographical localization of defibrillators or pharmacies); apps for chronic conditions other than those in the four groups studied in this work; apps for chronic conditions in the four groups that were not for self-management (ie, offering general health information or risk assessment); apps that required additional hardware, like special glucometers; apps with descriptions in French but content in English or with different names and same content; and, finally, apps that were no longer available in October 2018.

Eligible apps may describe their objective as chronic disease self-management or target only specific behaviors relevant for these conditions, such as medication adherence, trigger management, exacerbation management, physical activity, dietary behaviors, and archiving health information. Apps that targeted only preventive behaviors, such as physical activity and diet, with no reference to chronic condition management were also excluded.

Screening and Selection

The reference management software, Zotero (Corporation for Digital Scholarship), was used to identify and remove duplicate records in the literature search. Titles and abstracts of remaining records were screened by two independent reviewers to establish eligibility. If two reviewers recommended study or app inclusion, the full text of the study or the app availability was sourced for review and appraisal in order to determine eligibility for this study. If reviewer discordance arose, consensus was reached through discussion and arbitration with a third investigator.

Data Extraction and Analysis

The following app characteristics were extracted from the Google Play store, along with app's name and available description: information on the presence of sales on the app (ie, paid app or free app with or without paid features), number of downloads (ie, from 10+ to 10,000,000+), user ranking (ie, from 1 to 5 stars), number of ratings, version, last update, and developer information. Developers were then categorized into three groups: (1) *private company*, comprising single-app developers and dedicated app-developing companies; (2) *nonprivate*, comprising nongovernmental organizations, public institutions, or European projects; and (3) *pharmaceutical and medical device companies*, comprising bigger players in the market, such as pharmaceutical laboratories and other medical technology companies.

Target Behaviors and Behavior Change Content

Target behaviors were coded following detailed examination of app content and further functions, like sending notifications to users to perform tasks such as drinking water, exercising, etc. Each target behavior present was coded once per app; one app could contain several target behaviors. Behavior change content was coded by a trained investigator (LSdP) using the BCT taxonomy [15]. This taxonomy represents a consensus of hierarchically structured techniques developed to specify behavioral interventions. Each BCT present was coded once for each app; one app could contain multiple BCTs. A second

trained coder (ALD) evaluated a subset of 8 selected apps out of 44 (18%); interrater reliability was computed with bias-adjusted kappa.

Understandability and Actionability Assessment

Material is understandable and actionable when users of different health literacy levels can “process and explain key messages” and “identify what they can do based on the information presented” [20]. Understandability and actionability levels were evaluated using the PEMAT-A/V [20], which is a systematic method to evaluate understandability and actionability of patient education materials. It includes 13 items in five topics—Content, Word Choice & Style, Organization, Layout & Design, and Use of Visual Aids—to evaluate understandability (eg, “The material makes its purpose completely evident,” “The material uses common, everyday language,” etc) and four items for actionability (eg, “The material clearly identifies at least one action the user can take”). Each item was rated with 0 (If Disagree) or 1 (If Agree), while items that were not applicable received N/A. Item scores were added and divided by the maximum score possible, excluding items that were not applicable, and the result multiplied by 100 to get a percentage score. A second coder assessed understandability and actionability scores for the same subset of apps used for BCT coding; interrater reliability was computed using the intraclass correlation coefficient.

Data Analysis

Coding was done using Microsoft Excel and all statistical analyses were performed using RStudio, version 1.1.383. We examined app characteristics, behavioral content, and PEMAT-A/V scores via descriptive statistics. We performed nonparametric tests to compare groups and to investigate the correlation between the variables of interest, given their distribution properties. Associations between behavioral content and PEMAT-A/V scores were investigated via bivariate correlations (the Spearman rank correlation coefficient, ρ). Additional exploratory analyses regarding relationships between app characteristics and these content and format properties are reported in Multimedia Appendices 3-6 for interested readers.

Results

Search

Of the total 704 unique apps identified in the Google Play store, 167 (23.7%) had descriptions in languages other than French; 104 apps (14.8%) were considered as targeting chronic conditions in general and 50 apps (7.1%) focused on chronic conditions in the four groups of diseases included in this review. Other chronic conditions, not considered in this work, were back pain, migraine and headache, sleep apnea, and depression, among others. For app selection, agreement between reviewers was substantial ($\kappa=.62$). Reconciliation was done by a third reviewer when agreement was not reached after discussion between the first two. A total of 50 apps out of 704 (7.1%) met the inclusion criteria. Nonetheless, 3 of the selected apps required other connected objects (eg, connected glucometer, blood glucose sensor, or smart watch), 3 had descriptions in French but app content was entirely in English, and 2 pairs of

apps had different names but the same content, so 1 app from each pair was removed; the number of excluded apps was 8. When the second round of coding of BCT content and understandability and actionability scores was performed in October 2018 for calculation of interrater reliability and score revision, 3 apps were no longer available on the marketplace and were removed from the analysis.

The literature search yielded 1344 abstracts, and 234 manuscripts were assessed based on full text. The kappa indicating interrater reliability was .33 (ie, fair agreement), and a third reviewer did reconciliation by checking all records disagreed upon by the first two reviewers. Many of the manuscripts found through the literature search were reviews, as well as reviews of reviews ($n=282$). No peer-reviewed or conference papers from French institutions were selected for full-text screening. A total of 7 [28-34] out of 234 (3.0%)

manuscripts selected mentioned at least one native app for Android available in France and in French; these were included in our review. Of the 7 apps, one was present in two different articles and one required a glucometer connected to the mobile phone, which prevented app use. This resulted in 5 distinct apps downloaded from the Google Play store. Apps found through the literature search were not present in the list of apps extracted previously from the Google Play store. Finally, we analyzed a list of 44 unique native apps: 5 from the literature search and 39 from the marketplace search (see Figure 1).

Sample Characteristics of Apps

A total of 44 apps were downloaded and analyzed, most of them targeting diabetes (19/44, 43%). The least-represented category was cancer (1/44, 2%). Table 1 shows the main characteristics of the apps analyzed.

Figure 1. Flowchart of the screening process.

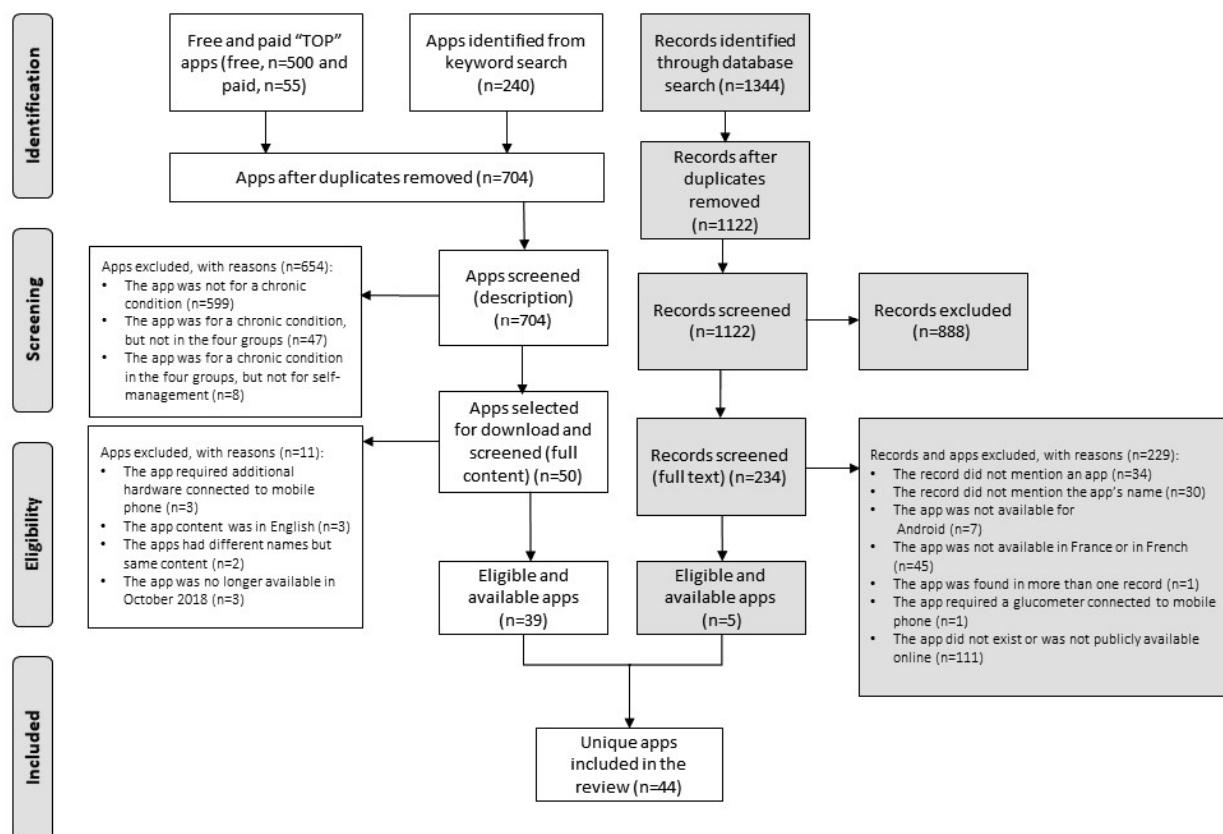


Table 1. Characteristics of apps sample.

Characteristics	Apps (N=44)
Disease category, n (%)	
Cancers	1 (2)
Respiratory diseases	6 (14)
Cardiovascular diseases	10 (23)
Diabetes	19 (43)
Other	8 (18)
Number of stars, mean (SD)	4.18 (0.48)
Number of stars, range	3-5
Number of user ratings, mean (SD)	16,140.1 (61,401.6)
Number of user ratings, range	2-374,462
Downloads, n (%)	
50+	1 (2)
100+	3 (7)
500+	4 (9)
1000+	4 (9)
5000+	4 (9)
10,000+	6 (14)
50,000+	3 (7)
100,000+	10 (23)
500,000+	3 (7)
1,000,000+	3 (7)
5,000,000+	2 (5)
10,000,000+	1 (2)
Gratuity, n (%)	
Paid app	1 (2)
With paid features	14 (32)
Without paid features	29 (66)
Developer, n (%)	
Nonprivate organization ^a	4 (9)
Pharmaceutical or medical device company	13 (30)
Private app-development company	27 (61)

^aNongovernmental organizations, public institutions, or European projects.

Target Behavior and Behavior Change Technique Characteristics

We identified the presence of 10 target behaviors and 21 BCTs in our app sample (see Table 2). The maximum number of target behaviors observed per app was 7 in 2 apps; the median number was 2. A total of 5 apps did not present any target behaviors. A

total of 4 apps had no BCTs present and another 4 had only 1 BCT, while only 1 app had more than 10 (n=12). The median number of BCTs per app was 3 (range 0-12).

The kappa for interrater reliability in BCT coding was .68 (ie, substantial agreement); the reconciliation process was used to revise coding in the whole app sample.

Table 2. Prevalence of target behaviors and behavior change techniques (BCTs) in the app sample.

Target behaviors and BCTs	Occurrence in apps (N=44), n (%)
Target behavior	
Tracking symptoms	26 (59)
Medication adherence	13 (30)
Tracking diet	12 (27)
Tracking weight	11 (25)
Archiving health information	9 (20)
Physical activity	6 (14)
Attending medical appointments	3 (7)
Tracking emotional symptoms	3 (7)
Drinking water	2 (5)
Tracking sleep	2 (5)
BCT	
Self-monitoring of outcome(s) of behavior	31 (70)
Feedback on outcome(s) of behavior	25 (57)
Self-monitoring of behavior	19 (43)
Prompts and cues	17 (39)
Information about health consequences	14 (32)
Goal setting (outcome)	11 (25)
Graded tasks	5 (11)
Action planning	4 (9)
Biofeedback	3 (7)
Feedback on behavior	3 (7)
Social support (practical)	2 (5)
Social comparison	2 (5)
Instruction on how to perform the behavior	1 (2)
Demonstration of the behavior	1 (2)
Credible source	1 (2)
Monitoring of emotional consequences	1 (2)
Social reward	1 (2)
Goal setting (behavior)	1 (2)
Social support (unspecified)	1 (2)
Social support (emotional)	1 (2)

The most common target behaviors were *tracking symptoms* (eg, in the case of apps for hypertension, these included measuring blood pressure and recording the values in the app journal) (26/44, 59%); *medication adherence* (eg, recording medication name and dosage and setting alarms to remember taking them) (13/44, 30%); *tracking diet* (eg, in the case of diabetes apps, these included noting food quantities in an app journal) (12/44, 27%); *tracking weight* (11/44, 25%); and *archiving health information* (eg, recording clinical test results in an app journal) (9/44, 20%). For BCTs, the most common were *self-monitoring of outcome(s) of behavior* (31/44, 70%), followed by *feedback on outcome(s) of behavior* (25/44, 57%), *self-monitoring of behavior* (19/44, 43%), *prompts and cues*

(17/44, 39%), *information about health consequences* (14/44, 32%), and *goal setting (outcome)* (11/44, 25%). All target behaviors and BCTs mentioned above were encountered in more than 20% of analyzed apps.

Figure 2 shows examples of target behaviors and BCTs. The left-hand screenshot shows a blood glucose journal, corresponding to the target behavior *tracking symptoms* and the BCT *self-monitoring of outcome(s) of behavior*. The middle screenshot shows a graph with blood glucose level variation through a period of one week along with the blood glucose target range defined by the user and his or her health care provider, corresponding to the BCTs *feedback on outcome(s)*

of behavior and goal setting (outcome). The right-hand screenshot shows a food journal corresponding to the target behavior *tracking diet* and the BCT *self-monitoring of behavior*. This specific app is designed for people with type 1 diabetes and knowing the amount of carbohydrates in meals is essential for adjusting insulin dosage.

Understandability and Actionability Scores

Out of the 44 apps, 2 (5%) had an actionability score of 100%. The mean understandability score was 43.50% (SD 22.24), the median was 42% (interquartile range [IQR] 28), and the values ranged from 9% to 92%. For actionability, the mean score was 23.50% (SD 36.86), the median was 0% (IQR 50), and values ranged from 0% to 100%. A total of 30 apps out of 44 (68%) had null actionability (ie, they had no clearly stated actions the user could take regarding the self-management behaviors the app targeted). Figure 3 shows the co-occurrence of understandability and actionability scores in the sample.

The kappa for interrater reliability for understandability scores was .65 (ie, substantial agreement) and for actionability scores

was .02 (ie, poor agreement). Both coders rated actionability as low for most apps. Differences were mostly related to an interpretation ambiguity in the first item of the actionability assessment—"The material clearly identifies at least one action the user can take"—upon which all three other actionability items were dependent. The fact that there were only four items to evaluate also influenced the different scores. Disagreements were discussed and the process of reconciliation led to revising the scores for the other apps in the sample.

Understandability and actionability scores were positively correlated ($p=.67$, $P<.001$) and so were the number of BCTs and target behaviors per app ($p=.62$, $P<.001$). Understandability had a positive correlation to the number of BCTs per app ($p=.35$, $P=.02$) and number of target behaviors per app ($p=.31$, $P=.04$). This may suggest that apps with more target behaviors and BCTs also tended to present this content in a way that is easier to understand. Actionability had moderate positive correlations to target behaviors per app ($p=.24$, $P=.12$) and BCTs per app ($p=.29$, $P=.054$), which were not statistically significant.

Figure 2. Screenshots from the Gluci-Check app from the Google Play store. The screenshots show examples of target behaviors and behavior change techniques (BCTs) used in apps. The left-hand screenshot corresponds to the target behavior *tracking symptoms* and the BCT *self-monitoring of outcome(s) of behavior*; the middle screenshot corresponds to the BCTs *feedback on outcome(s) of behavior* and *goal setting (outcome)*; the right-hand screenshot corresponds to the target behavior *tracking diet* and the BCT *self-monitoring of behavior*.

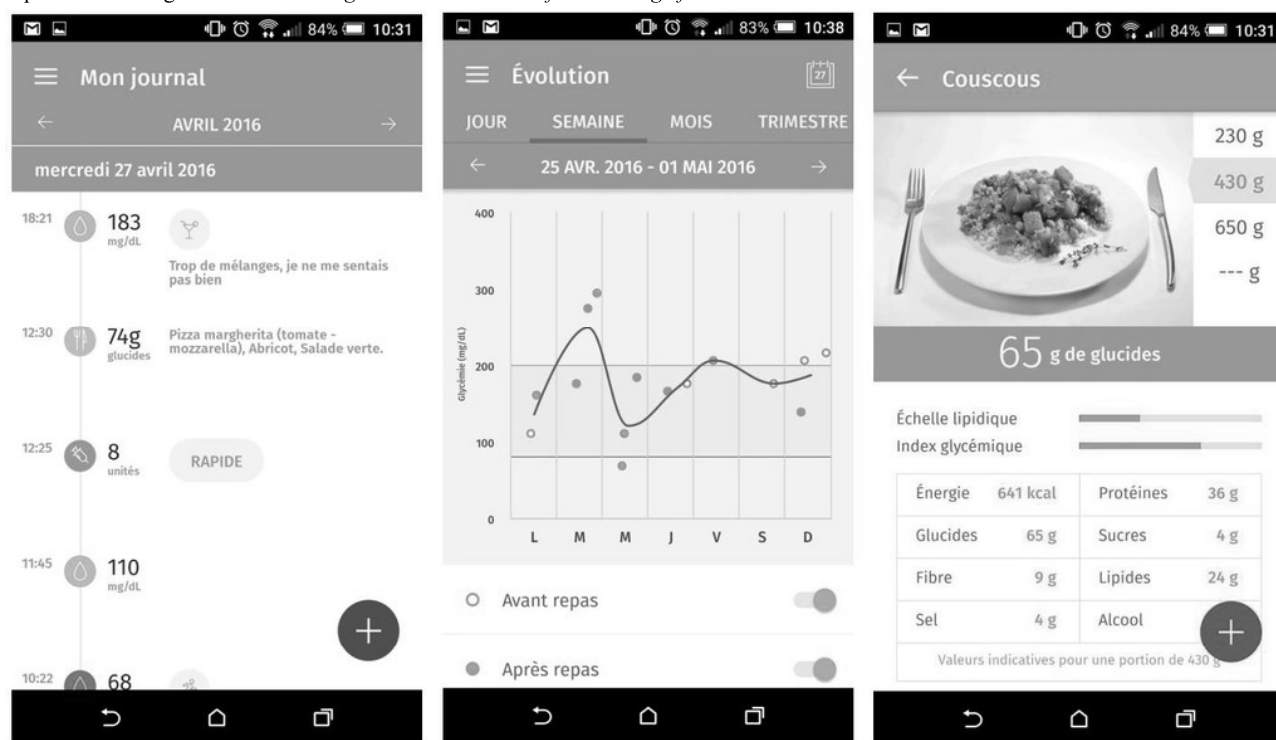
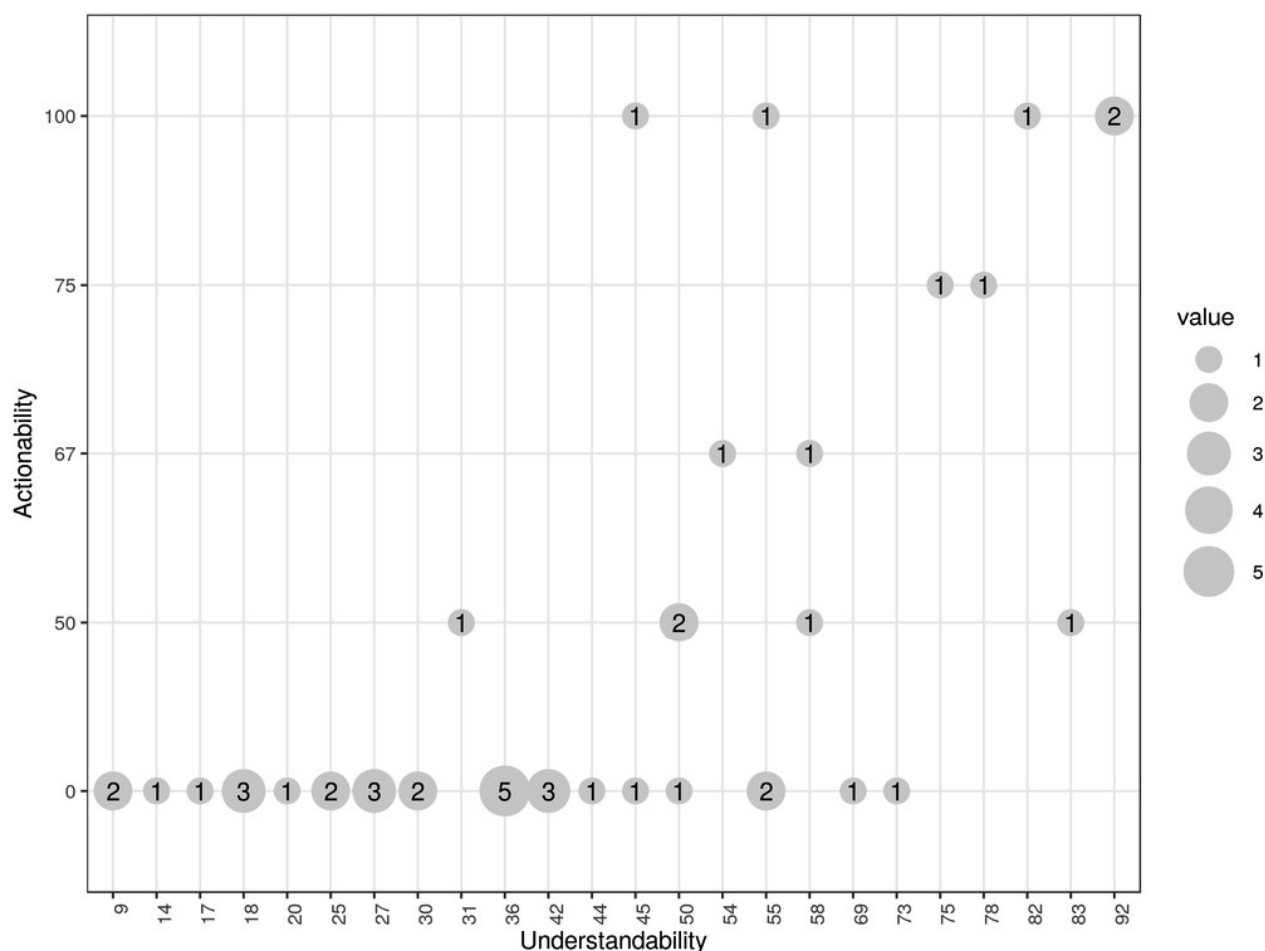


Figure 3. Understandability versus actionability; the circle size and label indicate the number of apps with the corresponding two scores.



Discussion

Principal Findings

The use of mHealth apps for supporting health-related behavior change and patient empowerment is being widely discussed as a solution to health care challenges worldwide, particularly for chronic conditions. This review showed that in 2018 in France, the potential of mHealth is far from being achieved. The apps available for download on Google Play had relatively limited behavior change content and, although moderately easy to understand for diverse audiences, they did not commonly point to clear actions users may take to self-manage the condition targeted. To better support patients with chronic conditions, apps can be improved by building on more solid behavior change research and applying it in ways that are easier to understand and act upon.

By searching directly on Google Play, among 704 apps with different purposes and languages, we found only 39 apps available in French targeting self-management in the four groups of chronic conditions with the highest mortality rates—cardiovascular diseases, cancers, respiratory diseases, and diabetes. This suggests that, for a patient or health care professional interested in using apps to manage a chronic condition, finding an appropriate app can be challenging. Moreover, our literature search identified only 5 apps available in France and in French. In another review with similar

methodology performed in Canada with mHealth apps in English, of the total of 107 apps for depression analyzed, 48 were found through a literature search [24]. This highlights the variability of mHealth apps offerings worldwide, in terms of both availability and research, and the importance of studying the evolution of this domain in different countries and languages.

Targeting specific key behaviors in interventions and combining active components (ie, BCTs) that are potentially effective for behavior change in the context of chronic conditions is crucial to achieve the intended change and, consequently, improve and maintain quality of life [35,36]. In our sample, the most common target behavior was *Tracking symptoms*, and an important prevention behavior, *Physical activity*, was present in only 6 apps. The median number of target behaviors per app was 2, ranging from 0 to 5. The modifiable behaviors described as priorities by the World Health Organization as risk factors increasing mortality rates, such as tobacco use, alcohol consumption, and excessive salt intake, were not addressed in any of the analyzed apps. There was substantial variation in the number of BCTs present and the majority of the apps focused on self-monitoring, confirming the focus on monitoring behaviors as previously shown in the literature. We observed 20 BCTs in our sample and the median number of BCTs per app was 3, ranging from 0 to 12. Conroy et al [22] observed 26 BCTs in total and the most top-ranked apps for physical activity incorporated less than 4 BCTs, ranging from 1 to 13. Direito et al [23] found 26 BCTs in total, with an average of 8.1 BCTs

per app, ranging from 2 to 18; free apps, such as most of the apps evaluated in our study, presented a slightly smaller average (ie, 6.6, ranging from 3 to 14). In both studies, *provide instruction* was the most common BCT, which was not observed in the case of chronic condition mHealth apps in our study. Similar to the results of Martínez-Pérez et al [37] regarding mHealth apps for the most prevalent conditions by the World Health Organization, we found more assistive and monitoring characteristics in the apps in our sample than informative and educational ones, also reinforced by the most common target behavior *tracking symptoms*. *Demonstration of the behavior* was an uncommon BCT, and videos or illustrations to clarify the use of measurement equipment, such as blood glucose or pressure monitors, were rare. Furthermore, only a third of apps presented *information about health consequences*, which is indispensable for understanding complications related to the chronic conditions discussed here. *Goal setting (outcome)* was also frequent (>60%) in physical activity apps [22], while in our work, it was present in less than one-fourth of apps. Goal management BCTs (ie, *goal setting* and *goal review*) were found to be effective in physical activity and dietary behavior change interventions [38–41]. Also, the combination of self-monitoring techniques with at least one other self-regulation technique (ie, intention formation, feedback on performance, specific goal setting, and review of behavioral goals) is shown to be more effective than other interventions [40]. Moreover, *action planning*, which is highly related to actionability and overcoming emergencies, was present in only 5 apps. We were thus able to identify limited behavioral change content and a focus on monitoring rather than goal management or education.

The apps in our study were to a large extent not suitable for low literacy audiences. The median understandability and actionability scores were 42% and 0%, respectively. In a previous study that applied the PEMAT-A/V to 43 apps intended for parent education (ie, parenting, child health, or infant health) [42], 30 apps had understandability scores between 76% and 100%, while for actionability, 19 apps had scores in this range. We found most apps had hard-to-read text (ie, small font and too much text). In previous work with a different methodology, Meppelink et al [43] showed that almost 80% of Dutch health information websites were over the recommended B1 reading level: B1 reading level means 95% of the population can understand the information. In addition, the predominantly low actionability of the apps in our study shows that we are still far from fulfilling the potential of mHealth tools to increase patient autonomy. More than half of the analyzed apps did not present any clearly stated action and they did not have any suggestions concerning the data recorded by users on health-related events. For mHealth apps to fully achieve their potential to support chronic condition treatment, clearly indicating actions is imperative (eg, diabetes apps need to indicate that patients need to intervene immediately if high or low blood glucose is recorded and give concrete physical activity suggestions to users). In our study, apps with more target behaviors and BCTs were also more understandable, indicating that developers who consider behavioral content may also be more careful with making sure apps are comprehensible for users; levels of actionability were low irrespective of behavioral content. We therefore highlight actionability as a priority to address in app

development: stating actions users can take, addressing users directly when describing actions, presenting actions in short explicit steps, and explaining how to use data visualization to take action [20].

Strengths and Limitations

First, our study used a three-pronged search strategy to identify apps relevant for our research questions: two strategies likely employed by users to identify apps in the marketplace (ie, top-ranked mHealth apps and active keyword search) and one strategy to identify apps that have been subject to scientific research (ie, a literature search). However, only the Android app marketplace was examined in this study and, although Google has the largest portion of the mobile app market and most apps are present in both marketplaces, not considering the second-most popular app marketplace (ie, Apple App Store) can lead to omission of relevant apps. Nonetheless, we believe our search strategies enabled us to obtain a representative sample to describe the current state-of-the-art in mHealth self-management support. Second, we only considered peer-reviewed papers and conference articles published in English, even though we were looking for apps available in France and in French. A future study of the iOS marketplace and French databases may be useful to complement our findings. We have also downloaded and assessed both behavioral content as well as understandability and actionability by two independent coders interacting directly with the apps, not only the descriptions available in the commercial marketplace. Thus, we were able to obtain a comprehensive assessment of the properties examined and reflect also on the assessment tools used.

We identified several issues for further improvement. First, while the BCT taxonomy enables systematic coding with good intercoder reliability, there is no consensus to date on classifying target behaviors apart from broad domains [44]. We have followed commonly used terminology to describe target behaviors in this study, yet our descriptions would have certainly benefited from standardized labels. Target behavior definition and selection is a key step in behavior change [45] and working toward a consensus on target behavior classification would further facilitate evidence synthesis. Second, since PEMAT-A/V was developed for educational materials using audio and video resources, we encountered a few difficulties when applying its criteria to apps. For example, app names and descriptions are commonly less informative in apps than what is expected for other health-related educational materials, names may be unrelated to the condition, and descriptions do not necessarily contain all app features. These characteristics may be interpreted as low understandability but may also be due to different design conventions in apps, which may have to be considered as an underestimation of understandability in our sample. PEMAT-A/V was selected after careful review of several tools, as it was considered best suited to app assessment by the research team. However, we would support a future adaptation of PEMAT-A/V for apps, which could aim to reconcile the usual brevity of the app medium with the requirements of effective communication for different audiences. Third, our study focused on the content and format of apps and excluded other criteria for judging app quality, from user engagement

and functionality [46] to data security and ethical and legal standards [47]. A comprehensive evaluation was beyond the scope of our review and would need to consider multiple dimensions.

Conclusions

Our findings suggest that mHealth apps available in France could be improved in terms of content and format. They also illustrate how two readily available tools—the BCT taxonomy and the PEMAT-A/V—can provide useful insights into the potential of an app to support patient empowerment. These tools can be used by different stakeholders in app development or to assess the existing offerings to ensure an effective contribution

of apps to patient care; we would recommend their inclusion in broader app development and evaluation guidelines. Given the prevalence of the chronic conditions considered here, it is essential to make sure different levels of health literacy are considered when developing health-related materials. Also, the development of mHealth apps should involve users and consider their behavioral support needs and be accompanied by research on whether their content and use are able to effectively change behavior. Apps could also benefit from integrating more instructions for intended users on actions to perform, more modifiable behavioral risk factors, and more behavior change content, especially BCTs associated with increased effectiveness in modifying target behaviors.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.

[PDF File (Adobe PDF File), 67KB-Multimedia Appendix 1]

Multimedia Appendix 2

Search strategy in the Google Play store and in PubMed (ie, MEDLINE), IEEE, and Web of Science databases.

[PDF File (Adobe PDF File), 44KB-Multimedia Appendix 2]

Multimedia Appendix 3

App sample with data extracted from the Google Play store.

[XLSX File (Microsoft Excel File), 12KB-Multimedia Appendix 3]

Multimedia Appendix 4

Dataset used to perform analyses.

[XLSX File (Microsoft Excel File), 17KB-Multimedia Appendix 4]

Multimedia Appendix 5

R markdown script.

[TXT File, 32KB-Multimedia Appendix 5]

Multimedia Appendix 6

R markdown report with descriptive statistics and inferential statistical and exploratory analyses.

[PDF File (Adobe PDF File), 235KB-Multimedia Appendix 6]

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Abbreviations

BCT: behavior change technique

IQR: interquartile range

mHealth: mobile health

PEMAT-A/V: Patient Education Material Assessment Tool for audiovisual materials

PRISMA-P: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols

PROSPERO: International Prospective Register of Systematic Reviews

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Annex 2 – Article
Using the Brief Health Literacy Screen in Chronic Care in French
Hospital Settings: Content Validity of Patient and Healthcare
Professional Reports



Article

Using the Brief Health Literacy Screen in Chronic Care in French Hospital Settings: Content Validity of Patient and Healthcare Professional Reports

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Abstract: Person-centered care has led healthcare professionals (HCPs) to be more attentive to patients' ability to understand and apply health-related information, especially those with chronic conditions. The concept of health literacy (HL) is essential in understanding patients' needs in routine care, but its measurement is still controversial, and few tools are validated in French. We therefore considered the brief health literacy screen (BHLS) for assessing patient-reported HL in chronic care settings, and also developed an HCP-reported version of the BHLS with the aim of using it as a research instrument to assess HCPs' evaluation of patients' HL levels. We assessed the content validity of the French translation of both the patient-reported and HCP-reported BHLS in chronic care within hospital settings, through cognitive interviews with patients and HCPs. We performed qualitative analysis on interview data using the survey response Tourangeau model. Our results show that the BHLS is easy and quick to administer, but some terms need to be adapted to the French chronic care settings. Health-related information was observed to be mainly communicated orally, hence a useful direction for future literacy measures would be to also address verbal HL.

Keywords: health literacy; chronic care; content validity; BHLS



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1. Introduction

Limited health literacy (HL) is associated with worse health outcomes in general [1]. According to the World Health Organization (WHO), HL is defined as “the cognitive and social skills that determine the motivation and ability of individuals to gain access to, understand and use information in ways that promote and maintain good health” [2]. For people living with chronic conditions, HL is particularly important [1] since managing chronic conditions involves interacting with illness-related information such as diagnoses, medical treatments, or lifestyle changes required, as well as interacting with healthcare professionals (HCPs) and the healthcare system. From HCPs point of view, care has shifted from professional- or facility-centered medicine to person-centered, i.e., care that is respectful of and responsive to preferences, needs, and values of individuals, and ensures that values of individuals guide all decisions [3]. Shared decision-making is thus being put at the center of the consultation [4] to promote person-centered care. In this context, HCPs must be able to detect patients' HL needs to improve communication and allow effective patient participation in the care process [5,6]. Therefore, HL has emerged as an important field of research in chronic care [7]. Its assessment becomes increasingly advocated to support services and HCPs adapting written and oral communication to individual needs [8,9].

However, assessing HL in routine care is a complex issue, as many definitions and measurement instruments are available; it may be difficult to know which one to apply to the broad range of situations encountered, especially in chronic care [10]. At present, there is no standard instrument to be used in current practice and HCPs adapt communication to their subjective perception of patients' understanding. Nutbeam et al. [11] proposed three dimensions for HL: functional (the ability to read and understand written information), interactive (more advanced cognitive literacy and social skills that enable active participation in health care), and critical (the ability to critically analyze and use information to participate in actions that overcome structural barriers to health). Available instruments align different definitions of HL covering one or more of these dimensions [10], measure either objective (performance-based) or subjective (self-perceived) HL, vary in length and administration mode. While lengthy multidimensional and performance-based measures are often preferred for research purposes, short subjective measures are more adapted to the time constraints of routine care. One such measure is the brief health literacy screen (BHLS), a 3-item questionnaire with response options based on a 5-point Likert scale that takes approximately 1 min to complete and is either self- or orally administered. It was developed in 2004 by Chew and others to measure functional HL [12], validated in English and applied in different contexts [9–15]. Its performance for detecting low levels of functional HL is similar to that of the rapid estimate of adult literacy in medicine (REALM) [16] and the short test of functional health literacy in adults (S-TOFHLA) [17], which have been used in the large majority of empirical HL research [10] and are highly correlated with each other [12,15,18]. In addition, to our knowledge, there is no instrument dedicated to HCPs to assess how they perceive patients' HL levels. As HCPs' perceptions of patients' HL level during clinical interactions are instrumental for appropriate tailoring of communication, this approach could be convenient, especially for research purposes, to evaluate whether HCPs correctly appraise patients' HL levels during patient-HCP interactions.

In France, the use of the BHLS has been limited so far to online surveys [19,20]. Although a version in French has been produced by Delanoë et al. [21] for use in Quebec (Canada), currently there is no standard validated version to be applied in clinical and hospital settings in France. Such a version would be useful both for research and for routine use to assess patients' HL and adapt interventions. For these purposes, it is necessary to continue the psychometric validation process following current standards, i.e., to investigate whether the French translation meets the three key criteria of content validity-relevance, comprehensiveness, and comprehensibility as recommended by the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) guidelines [22,23].

Thus, the objective of this study is to perform content validity testing for patient-reported and HCP-reported versions of the BHLS in chronic care within French hospital settings, through cognitive interviews. Assessing to what extent the construct of HL as defined by the BHLS corresponded to the way patients and HCPs interpreted the questions would allow a more nuanced understanding of the suitability and potential uses of this instrument and identify ways of improving measurement of HL in these settings.

2. Materials and Methods

We conducted a qualitative study using semi-structured cognitive interviews, a method to investigate if a survey question corresponds to its intended purpose, to assess the content validity of the French version of the BHLS in chronic care within hospital settings. This study followed the COSMIN Guidelines [23] to test if the questionnaire measurement was an adequate reflection of the construct to be measured (HL). The interview guides followed the 4-stage Tourangeau model [24] as theoretical basis; this model states that survey responses involve the following four stages: (1) comprehension of the terms/questions, (2) retrieval of relevant information from memory, (3) judgement/estimation processes, and (4) response processes regarding answer modalities [25]. The BHLS in English is presented in Table 1.

Table 1. Questions and response options for the brief health literacy screen (BHLS).

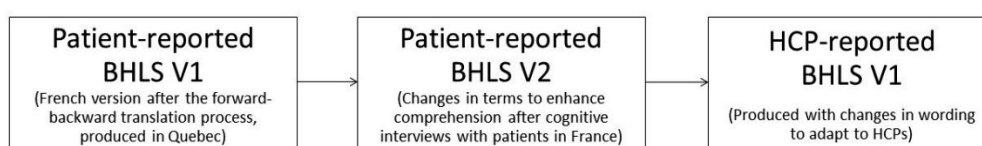
Question	Response Options
1. How confident are you filling forms by yourself?	Not at all confident, a little bit confident, somewhat confident, quite a bit confident, extremely confident
2. How often do you have someone help you read hospital materials?	Never, occasionally, sometimes, often, always
3. How often do you have problems learning about your medical conditions because of difficulty reading hospital materials?	Never, occasionally, sometimes, often, always

Following recommended best practices, all participants were informed orally on the study objectives and their oral consent was collected before inclusion. In accordance with French legislation, study-specific ethical approval was not required as due to the nature of the study objectives, i.e., understanding how participants perceived a questionnaire, and not directly improving their own health and care. No identifiable data were collected, and data processing followed recommended procedures at the research site.

2.1. Development of the BHLS in French

The first version of the BHLS in French (Supplementary Material S1) was developed by Delanoë et al. [21] as a part of a previous work conducted with French-speaking patients (patient-reported BHLS V1). It was designed using a forward-backward translation procedure (from English to French to English). As required by COSMIN guidelines [23], two translators produced a first version of the English text in French, then other two translators produced a new version of the translated text in English, which was compared to the original text. Consensus on questions wording was then reached after revision by a committee composed of researchers, healthcare professionals, and translators.

To assess the content validity of the French patient-reported BHLS (V1) in hospital settings, we conducted interviews with a sample of patients living with chronic conditions. A second version of the patient-reported BHLS was produced after the analysis of patients' interviews results (V2). After that, a version based on the patient-reported BHLS V2 dedicated to interviewing HCPs was created by a group of experts in HL, public health, and social psychology. We then performed the content validity assessment of the resulting HCP-reported BHLS V1 through interviews with HCPs (Figure 1).

**Figure 1.** Development of the different versions of the BHLS used in this study.

2.2. Recruitment of Participants

Patients were recruited in May 2019 using convenience sampling at a respiratory diseases department at the university hospital Hospices Civils de Lyon (HCL), France. Inclusion criteria were: (1) being at least 18 years old, (2) having an appointment in the outpatient clinic of the participating hospital for the respiratory follow-up of a chronic disease during the study period, (3) being able to give consent, and (4) being able to communicate in French.

HCPs were recruited between January and June 2020 in the departments of cardiology and psychiatry of the HCL and diabetology of the Centre Hospitalier Universitaire Grenoble-Alpes (CHUGA). The inclusion criterion was to work in a hospital facility in chronic care. Sampling aimed for a diversity of professions: physicians, nurses, and assistant nurses.

We aimed to recruit at least 12 participants in each group (patients and HCPs), expecting to reach data saturation with this sample size following recommendations on qualitative interviews [26].

2.3. Interview Methods

The BHLS was self-administered in a separate room (patient-reported BHLS V1 and HCP-reported BHLS V1) and the cognitive interview was undertaken. Three investigators (A.P., L.S.d.P., and A.D.) led the interviews after being trained in interviewing methods and having practiced with the interview guide with members of the research team. The interviewer asked a series of questions to obtain specific information on the process by which the participant answered each BHLS question [25].

We designed two interview guides, one for patients and one for HCPs. Patients were invited to think about different experiences throughout the care process, and HCPs were prompted to recall a patient living with a chronic condition who had recently been in care. These guides investigated the reasoning that leads to answering the questions and identified problematic items to subsequently drive the necessary modifications to enhance content validity [27]. The interview guide for patients' interviews (summary presented in Table 2) was drafted first, the HCP guide derived from the patient guide after improvement and adaptations to fit with the profiles of HCPs. For the first question, HCPs were asked how confident they believed the patient was to fill in forms by him/herself. We were interested not only in how they perceived the terms, but also in how they perceived patients would fill in forms by themselves. In the second question, we were interested in understanding how HCPs observed and described the frequency of aid requested by patients to read hospital or health-related documents. In the last question, professionals were asked how often they believed the patient had problems learning about their medical condition because of difficulty reading hospital materials.

2.4. Qualitative Analysis

All interviews were recorded with participants' permission and transcribed in summary tables for qualitative analysis. The summary table template followed the 4-stage Tourangeau model [25]. Analyses were performed following recommended procedures for cognitive interviews [25,28] and were conducted separately for patients and HCPs.

First, two independent coders (A.P. and A.D. for patients; A.P. and L.S.d.P. for HCPs) extracted information from the recordings to fill in the summary tables, then quotes were compared to define categories from similar responses to establish an analysis codebook (each code was followed by a code definition and instructions on how to code); it was then tested by both coders in one interview for each group; categories were extensively discussed and later reviewed by A.L.D. and J.H. Each coder then applied the codebook to half the interviews and coders reviewed all the summary tables together. Two synthesis tables, one for patients and one for HCPs (Supplementary Materials S2 and S3), were generated from the summary tables; key findings were analyzed to determine how participants had understood the terms in the questions and if the elements and items were interpreted as intended by the instrument.

Table 2. Summary of the interview guide for patients.

Stage	Topic
Comprehension of the terms/questions	
Question 1	Understanding of the term “forms” Suggestions to replace the term “forms” Understanding of the expression “to be confident”
Question 2	Understanding of the expression “to have someone help you” Understanding of the term “hospital materials”
Question 3	Understanding of the expression “problems learning” Understanding of the expression “medical conditions” Understanding of the expression “difficulty reading”
Retrieval of relevant information from memory	
Question 1	Last time they recalled having filled in forms Examples of forms
Question 2	Situation(s) used to estimate frequency of having someone help them
Question 3	Situation(s) recalled appraising difficulties learning about medical conditions
Judgment/estimation processes	
All 3 questions	Effort made to recall situations experienced Feeling influenced in replying to the questionnaire Feeling a “right” or “wrong” answer was expected
Response processes regarding answer modalities	
Question 1	Meaning of each response option Reason to have chosen a specific response option
Questions 2 & 3	How many times having had someone help them or having had problems learning because of difficulty reading
General questions	Understanding of the topic addressed by the questionnaire Assessing difficulties to answer to the questions presented Opinion on the title and presentation of the questionnaire

3. Results

We conducted cognitive interviews with 13 patients attending outpatient consultations for a chronic disease and 12 HCPs to assess content validity of the French version of the BHLS. For both groups, the number of participants was sufficient to reach data saturation [26,28].

3.1. Patients Results

Eight of the interviewed patients were men. Over half of them were between 60 and 69 years old ($n = 7$) and 6 had a high level of education. There were as many active ($n = 6$) as retired patients ($n = 6$). None self-reported a low level of health literacy (Table 3).

Results are reported according to the stages of Tourangeau’s model for each of the three questions (Q1, Q2, and Q3) of the patient-reported BHLS V1.

3.1.1. Comprehension of the Questions and Terms

In Q1, the term “forms” was interpreted in two ways; either it was associated with administrative forms (e.g., taxes or administrative forms in English, “impôts” or “formulaires administratifs” in French) ($n = 7$), or it was understood as medical forms ($n = 6$). Eight of the thirteen respondents thought the question was about questionnaires. When asked about

the meaning of “to be confident,” in the French translation “être confiant,” respondents mainly referred to being self-confident ($n = 8$) but it was sometimes seen as trusting the doctor or the people administering the questionnaire ($n = 5$).

Table 3. Patients characteristics.

Characteristic	<i>n</i> (%)
Sex, <i>n</i> (%)	
Male	8 (61.5)
Female	5 (38.5)
Age in years, <i>n</i> (%)	
30–39	1 (7.7)
40–49	2 (15.4)
50–59	2 (15.4)
60–69	7 (53.8)
>75	1 (7.7)
Education level, <i>n</i> (%)	
No school	2 (15.4)
Middle school	3 (23.1)
High school	2 (15.4)
College/University	6 (46.2)
Professional status, <i>n</i> (%)	
Unemployed	1 (7.7)
Employed	6 (46.2)
Retired	6 (46.2)
Medical condition, <i>n</i> (%)	
Asthma	6 (46.2)
Leukemia	3 (23.1)
Spinal cord transplant	1 (7.7)
Allergy	1 (7.7)
Unknown	2 (15.4)
Health literacy level, <i>n</i> (%)	
Low (BHLS score ≤ 9)	0
Adequate	13 (100)

Regarding Q2, most participants ($n = 12$) considered that “have someone help you” (“demander de l’aide” in French), was related to asking for HCPs help, while two patients referred to their relatives. Ten patients associated “hospital materials” (“documentation remise à l’hôpital” in French), to written materials and two patients also considered oral information. Furthermore, the majority linked it to documentation related to illness and care (results of biological or radiological exams) while the others thought it would refer to more general medical documentation (information leaflets).

Regarding Q3, five patients interpreted “have problems learning” as having difficulty understanding terms or words employed in health documents that they considered too technical or specific. Two patients pointed out that in general health documents or information leaflets were incomplete in order to fully understand the information. The term “medical condition” was mainly associated with health status (“état de santé,” in French) but three patients also referred to “medical record,” “treatment or care” or even “comprehensive support.” This expression was considered too vague. Complex medical terms were unanimously interpreted as terms with which they have “trouble understanding,” but two patients also talked about the concept of readability of manuscript documents, i.e., “the doctor’s handwriting.”

To improve comprehension and adapt to cultural specificities, in the first question the term “form” was replaced by “medical form” (“formulaire médical”) and in the third question the expression “medical condition” was replaced by “health status” (“état de santé”), according to suggestions made by the respondents.

3.1.2. Retrieval of Relevant Information from Memory

All participants referred to outpatient consultations at the hospital to fill in the BHLS, and especially the consultation of the day just before the interview. However, regarding the term “forms,” some patients referred to other situations of their daily life, unrelated to health and care.

3.1.3. Judgment/Estimation Processes

With regard to the decision-making process for the entire questionnaire, respondents declared that they did not have to make a considerable effort to recall personal situations. Their answers were intuitive and spontaneous. In addition, they indicated that they did not feel influenced or even guided in their choice of response.

Q1 made good reference for most patients ($n = 8$), to situations experienced in consultation, concerning treatments or forms to be filled in for the pathology. Although the interpretation of the term “form” itself remains confusing.

Q2 mostly referred to situations of care at the hospital and the examinations to be carried out. However, almost all patients referred to hospital HCPs and did not think about their relatives (spouse, child, neighbor) or other HCPs when approaching the subject asking for help.

Lastly, for Q3, the patients referred to situations related to the management of their chronic pathology. Most of them referred to written documents because of the complexity of the terms or the difficulty in reading the doctors’ writing. On the other hand, one patient understood the question in terms of oral comprehension. The little variability in response meant that the subjects were considered to have had similar interpretations among themselves and in accordance with what the question required.

3.1.4. Response Processes Regarding Answer Modalities

For Q1, answers modalities were from “extremely confident” to “not at all confident.” Only the first two response modes (quite a bit confident, extremely confident) were given. “Extremely confident” was interpreted on the one hand as being entirely sure (“flawless,” “ten on a scale of ten”) and on the other hand, as quite sure (“90%,” “possible problem but rare”). While “somewhat confident” was explained as “not totally sure” or “sometimes a doubt.”

Q2 and Q3 asked about frequency of the situation (never, occasionally, sometimes, often, always). The answer mode “never” was defined as “0 times” or “a few times” while the answer mode “occasionally” implied “from time to time” or “infrequently.” “Sometimes” was also explained as “from time to time.” Answers modalities were sometimes explained in the same way although they were supposed to express nuances, which shows variability between individuals’ comprehension.

The BHLS was judged as easy to complete by almost half of the respondents ($n = 5$), while other 5 respondents considered the last question hard to understand.

3.2. HCPs Results

Seven HCPs were women, a third were between 40 and 49 years old and a third were trained physicians (Table 4).

3.2.1. Comprehension of the Questions

Regarding Q1, “to be confident” was understood in two different ways: to be sure and to be able to fill in the forms ($n = 10$), and to trust the professionals and institutions they would hand over the forms to ($n = 2$). All HCPs understood the term “medical forms,” but four of them said it was not used in their work setting. When asked for examples of medical forms, HCPs mentioned consent forms for research or invasive procedures ($n = 6$), medical history forms ($n = 2$), hospital admittance/discharge forms ($n = 4$), questionnaires for research studies ($n = 1$), satisfaction forms ($n = 1$), insurance forms ($n = 1$), and suicidal

risk forms ($n = 1$). Three HCPs also cited prescriptions, although they are filled in by physicians, and two did not provide any example.

Table 4. HCP characteristics.

Characteristic	<i>n</i> (%)
Sex, <i>n</i> (%)	
Male	5 (41.7)
Female	7 (58.3)
Age in years, <i>n</i> (%)	
20–29	1 (8.3)
30–39	5 (41.7)
40–49	4 (33.3)
50–59	2 (16.7)
Profession, <i>n</i> (%)	
Physician	4 (33.3)
Intern	3 (25)
Nurse	3 (25)
Assistant nurse	2 (16.7)

Regarding Q2, for seven HCPs “have someone help” meant the patient would ask questions orally to friends or family, while two referred to asking questions orally to HCPs, and two referred to asking questions both to friends or family and HCPs. Concerning the help provided, HCPs said it meant asking questions about the documents ($n = 7$), health care ($n = 1$), or the disease itself ($n = 2$), one said it meant calling the hospital service after discharge to ask for help understanding the course of treatment. One HCP did not give a clear answer. When asked how they understood hospital or health-related documents, five referred to documents related to health care or the specific disease the patient had, two referred to general documents delivered by the hospital to all in-patients, and five said either general or disease-specific documents.

Regarding Q3, “problems learning” was perceived as a lack of general literacy by one HCP and “difficulty reading” was perceived likewise by five HCPs. For the remaining HCPs, both expressions were perceived as related to the complexity of medical terminology in the delivered documents. Eight HCPs understood that “health status” was about the disease itself, while three of them understood it meant the health care the patient had undertaken. One HCP did not give a clear answer.

3.2.2. Retrieval of Relevant Information from Memory

For Q1, only three HCPs provided a description of an actual situation they had experienced. Nine said they had not experienced any situation where the patient had to fill in forms, so they recalled mentally possible forms patients could be asked to fill in or projected onto the specific patient other experiences they generally had with other patients, mainly related to difficulties reading documents or understanding information given orally. For Q2, five HCPs were able to recall a real situation and six for Q3.

3.2.3. Judgment/Estimation Processes

To answer Q1, most HCPs assessed the patient’s confidence based on the situations not related to filling in medical forms, e.g., having seen them reading documents, or based on their knowledge of the patient’s educational background.

For Q2, HCPs answered based on how patients asked them for help, or on how they had seen patients interact with their families. The phrase “at what frequency” (“à quelle fréquence”), translation of “how often,” was perceived as too vague. Q3 was the most challenging, many said they did not relate patients’ difficulties apprehending a specific medical condition to problems reading, instead they said it was mainly related to the disease complexity or to a substantial lack of motivation (which they often called “denial,” “déli” in French).

Eight HCPs considered the questionnaire easy to answer, three said it was difficult, and one said the third question was long and confusing. Many said they were aware that their answers may not reflect the patient's reality, but their perception of it.

3.2.4. Response Processes

For Q1, HCPs' answers varied more than patients. Five HCPs chose the response option "quite a bit," four "somewhat," two "not at all," and one "a little bit." "Quite a bit" was mainly associated with perceived higher educational levels, while "somewhat" was associated with patients who were able to cope but had doubts or forgot important information. One HCP stated to have chosen "somewhat" because it appeared to be more neutral than the others. "A little" was associated with a recent diagnosis and "not at all" with patients that needed help reading.

For Q2, three HCPs chose the option "a little of the time," three chose "most of the time," and "none of the time," "some of the time" and "all of the time" were each chosen by two HCPs. One HCP explained having chosen the "a little of the time" because "every time we saw the patient, he had additional questions to ask." "Most of the time" was associated with patients that asked questions repeatedly. "None of the time" was associated with patients who had higher educational levels, "some of the time" with a perception that the patient could have problems understanding documents or the choice was based on the perception of the response option being neutral, and the "all of the time" was associated with patients with a low autonomy degree, e.g., they generally have a close relative present during consultations.

For Q3, four HCPs chose the option "most of the time" and it was associated with patients that had problems understanding written documents but did not have problems systematically; three chose "a little of the time," which was associated with patients that understood correctly but could have doubts. "None of the time" was chosen by three HCPs and "some of the time" by two, and both were associated with the same characteristics as for the second question (the first to higher educational levels and the latter to a perception of neutrality).

Table 5 presents the key findings for both groups.

Table 5. Key findings from cognitive interviews following the Tourangeau survey response model.

Respondent	Question	Comprehension	Retrieval	Judgement	Response
Patients	Q1	"To be confident" not always perceived as self-confidence "Forms" is a too broad term	Situations with administrative forms not related to healthcare		The first two response options were chosen by different respondents giving the same justification for their choices
	Q2	"Have someone help you" perceived as mainly related to HCPs help "Hospital materials" perceived as imprecise and referring to general documentation about disease or care		Responded spontaneously	
	Q3	"Have problems learning" perceived as mainly referring to medical jargon "Medical condition" not always perceived as health status "Trouble understanding" perceived as referring to misunderstandings between patient and HCPs	Outpatient consultations		"Never" perceived as not once to a few times "Sometimes" explained as from time to time

Table 5. Cont.

Respondent	Question	Comprehension	Retrieval	Judgement	Response
HCPs	Q1	“To be confident” not always perceived as self-confidence “Medical forms” described as a rarely used term	Imagined situations	Judged mainly based on educational background	“Quite a bit” for higher education levels “Somewhat” for patients who missed information or to indicate a neutral response “A little” for recent diagnosis “Not at all” for help needed with reading
	Q2	“Have someone help” perceived as mainly related to family or friends “Hospital materials” was perceived as imprecise and referring to general documentation about disease or care	Outpatient consultations or hospitalization	Judged based on frequency of asking for HCPs or family for help	“None of the time” for higher educational levels “A little of the time” for high autonomy, but also explained as every time “Some of the time” for problems understanding documents or to indicate a neutral response
	Q3	“Problems learning” perceived as related to medical jargon or to an important lack of motivation “Health status,” term replacing “medical condition,” understood as denoting the disease or care		Judged based on disease acceptance	“Most of the time” for patients who repeatedly asked questions “All of the time” for patients with low autonomy

4. Discussion

The BHLS was translated to French, yet no validation has been performed specifically for use in hospital settings. In addition, little is known about how professionals perceive and evaluate patients’ literacy levels to adapt their communication in clinical interactions, and whether the BHLS could be used to measure HCP appraisal of patients’ HL. Therefore, in this study we have developed an HCP-report version of the instrument and examined the content validity of the French version of the BHLS for patients and the HCPs version introduced here, in chronic care within hospital settings in France through cognitive interviews and qualitative analysis of patients and HCPs reports. Our findings suggest several uses are possible for the BHLS in French hospital settings. According to participants in our study, the BHLS was overall quick and easy to administer, which supported its applicability in clinical practice. However, we also identified limitations to its validity in the studied context, especially related to the terms used in the questions, which highlight several directions for further improvement.

HL is an evolving concept, changing with factors internal and external to health care systems. Therefore, measurement instruments like the BHLS need to be accompanied by a continuous process of psychometric evaluation and improvement to suit the needs of both patients and HCPs in current practice. Some limitations identified in the current versions are likely due to cultural or healthcare system-specific factors such as terms culturally adapted to the United States [12,13,15,18,29] that were not perceived the same way in France. For example, participants struggled with connecting the term “forms” with health-related situations and associated it rather with public administration. This may be due to the fact that the healthcare system in France does not systematically require patients to fill in forms by themselves, as most information is obtained orally by HCPs and procedures vary greatly from service to service. Therefore, it would be useful to add to the BHLS questions about verbal HL, i.e., the ability to understand and act on verbally communicated health information [15]. Sand-Jecklin and Coyle [15] have added

two questions addressing the understanding of verbal health information to the three screening questions proposed by Chew et al. [12], which might be a starting point for further studies to investigate whether this dimension of HL can prove more adapted to the French healthcare system. A second example refers to the term “confident”; while in English the meaning is unambiguously referring to the respondent’s perceived self-efficacy, in French the term also denotes “trust” and therefore was sometimes interpreted in this context as trust in the patient-provider relationship. A more appropriate term in French would be equivalent to “capable” (“se sentir capable”), which can be tested in further work. A third example refers to Q1 and Q3 being perceived as the most difficult to understand in our study. This finding contrasts to previous results supporting the validity of these questions and indicating strong correlations between the English BHLS and S-TOFHLA, a widely used measure of functional HL [12,30]. Although the BHLS has been extensively validated in the United States [12,13,15,30], in other languages it has not always shown similar results. Mantwill et al. [31], showed that in five countries (Hungary, Italy, Lebanon, Switzerland, and Turkey), the BHLS items were not related with the S-TOFHLA and argued that qualitative studies should be performed outside the United States to investigate cross-cultural differences.

Rapid screening of patients with potential difficulties to understand their medical condition is essential to adapt communication and possibly improve adherence to treatments and self-care behaviors. Participating HCPs were equally positive about the potential application of BHLS in routine care but were, in most cases, aware their answers corresponded to their own perceptions and likely not the patient’s estimation of their own HL level. This shows the HCP-reported BHLS could be useful in further studies, to compare patients’ self-perceived HL levels against HCPs’ perceptions, if applied to the same patient population. Another useful application of HCP-reported BHLS could be for training purposes, to raise awareness on the importance of HL and its assessment to adapt communication. However, given the HCPs expressed concern with potential mismatch between their perceptions and patients’ own assessments, we would not recommend its use as a proxy measure of patients’ HL level until further improvements and testing are performed. To expand the toolbox for assessing HL in clinical settings, other questionnaires such as the recently developed Conversational Health Literacy Assessment Tool (CHAT, [32]) need to be adapted to French and could help HCPs better understand patients’ HL challenges and resources and thus make health care decisions more effectively and responsively.

The concept of HL is bound to evolve with future changes in healthcare systems. Currently, there is increasing attention to HL in France, and we expect that with further training of HCPs on identifying HL-related patient needs and strengths in the consultation HCPs will feel more equipped to assess HL levels accurately and intervene appropriately. It can be envisaged in this case that the potential mismatch between patient-reported and HCP-reported BHLS would reduce, which could be an indicator of successful HCP training in HL. To increase content validity and also concordance between HCP and patient reports, the evolution of HL measurement would also need to follow changes in how consultations take place, in particular what common experiences of obtaining, processing and understanding information occur in patient-HCP interaction that can be indicative of patients’ HL. Moreover, in France, as worldwide, information is obtained more and more from the internet or mHealth apps instead of information brochures or hospital materials. Therefore, an important dimension to consider for future development of short HL assessments for use in clinical care is digital HL, i.e., the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem [27].

This study has some limitations. First, the patient population was a convenience sample recruited in a single hospital department, which can impact the generalizability of our results. To strengthen the results presented here, further studies can recruit patients from different hospital departments to have a more diverse population. Second, we noticed that HCPs often based their answers on situations that they had not experienced with

the patient. This may be due to recall bias, since they were not interviewed immediately after a patient visit; however, an alternative explanation may be that situations evoked in the BHLS less frequently occur in HCP-patient interactions in these settings. Third, we interviewed patients after outpatient visits but not after hospitalizations. We believe that this might have led to differences in the type of situations patients and HCPs recalled to answer the BHLS questions, particularly in relation to the term “hospital materials” which were associated with a greater diversity of situations for patients compared to HCPs. One way to address these points would be to recruit both patients and HCPs in the same hospital departments during hospitalization. Finally, we believe the patient-reported BHLS V2, proposed here following the content validity examination, is yet to be tested using qualitative methods with a new patient population.

5. Conclusions

This study adds to the understanding of how patients and HCPs go through the BHLS response process to assess patients’ HL levels. The questionnaire was well-received by participants, and the interviews conducted led to further improvement of the patient-reported BHLS and propose several improvements of the HCP-reported BHLS. The present findings converge with previous work indicating that HL is not an easy translatable concept across cultures and healthcare systems. Interactions between patients and HCPs or health systems may manifest in different ways and require different indicators in different settings. Therefore, further work could be focused on identifying the main categories of interactions in a specific setting and formulate items adapted to the setting that target these categories. We also show that the concept of HL needs to be further discussed in HCP initial and continuous education, so that HCPs develop their skills to identify barriers in patients’ comprehension and develop strategies to enable efficient communication.

Supplementary Materials: The following are available online at <https://www.mdpi.com/1660-4601/18/1/96/s1>. Table S1: Comparison of the 2 BHLS versions and propositions of changes in English and in French. Table S2: Synthesis of patients cognitive interviews in French. Table S3: Synthesis of HCPs cognitive interviews in French.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available in Supplementary Materials S2 and S3.

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Annex 3 – Protocol – Study VOIES-D-ql



Hospices Civils de Lyon
Direction de la Recherche
Clinique et de l'Innovation

Document type

PROTOCOLE

***Recherche impliquant la personne humaine mentionnée au 3
de l'article L.1121-1***

***Étude qualitative sur l'expérience individuelle d'utilisation et de planification de
soins des personnes ayant un diabète et des professionnels de santé en diabétologie
VOIES-D-ql***

Protocole impliquant la personne humaine non interventionnel du 3°

Version 2 du 16/03/2020

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Avis favorable du CPP Ouest III le : 20/03/2020

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RESUME

TITRE	Étude qualitative sur l'expérience individuelle d'utilisation et de planification de soins des personnes ayant un diabète et des professionnels de santé en diabétologie - VOIES-D-ql
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VERSION DU PROTOCOLE	2 du 16/03/2020
JUSTIFICATION / CONTEXTE	<p>La prise en soins des maladies chroniques reste fragmentée et le transfert d'informations entre les professionnels de santé impliqués reste souvent à la responsabilité du patient et de ses proches. Il existe une tendance croissante à l'utilisation des données de santé recueillies systématiquement dans les services de soins. En France, la mise en place du Dossier Médical Partagé (DMP) représente un effort considérable pour centraliser les informations médicales et les rendre disponibles pour le patient et les professionnels. Cependant, des initiatives de valeur ajoutée sont nécessaires pour exploiter le potentiel de cet outil. Des projets réalisés à l'international montrent l'importance de la communication simple et visuelle des événements de soins pour la compréhension globale du parcours et de la planification des étapes ultérieures, selon les objectifs de santé et de vie définis en collaboration entre patients et professionnels. Pour l'objectif d'élaboration d'un outil pertinent et adapté à la pratique centrée sur la personne, il est nécessaire de décrire de façon élaborée et précise les expériences individuelles de soins des personnes concernées, tout comme les besoins informationnels des professionnels de santé et de ces personnes, conjointement, au moment de la prise de décision partagée dans le contexte spécifique de la maladie chronique. Cette étude vise à réaliser cette description par des entretiens semi-directifs avec des personnes atteintes de diabète de type 1 ou type 2 et des professionnels impliqués dans la prise en soins des personnes atteintes de diabète sous trois domaines : clinique (les critères cliniques pertinents pour les personnes impliquées), technologique (l'utilisation des outils technologiques dans la pratique médicale courante et dans le quotidien des patients), et comportemental (les interactions conductrices du parcours, les stratégies utilisées par les personnes dans la prise de décision en santé et les stratégies de communication entre professionnels de santé). À partir de ces informations, un prototype d'outil pour visualiser l'historique d'épisodes de soins dans le contexte du diabète sera développé avec la participation des patients et des professionnels participants.</p>
OBJECTIFS	<ul style="list-style-type: none"> • Objectif principal : Décrire la construction de l'expérience individuelle de soins des personnes ayant un diabète. • Objectif(s) secondaire(s) :

	<ul style="list-style-type: none"> • Objectif secondaire 1 : Décrire la prise de décision dans la perspective des patients menant à la visite chez le professionnel de santé en fonction des caractéristiques sociodémographiques et du niveau de littératie en santé • Objectif secondaire 2 : Décrire les besoins informationnels des professionnels de santé sur le parcours de soins des patients, au moment de la prise de décision partagée • Objectif secondaire 3 : Evaluer la faisabilité d'un prototype d'outil de visualisation d'utilisation de soins pour l'aide à la décision partagée entre les professionnels et les personnes ayant un diabète
METHODOLOGIE / SCHEMA DE LA RECHERCHE	<p>Il s'agit d'une étude descriptive, transversale, non-interventionnelle, qualitative au moyen d'entretiens individuels semi-directifs et/ou collectifs (focus groups) auprès de personnes ayant un diabète et des professionnels de santé impliqués dans leur prise en soins.</p> <p>Les professionnels de santé seront recrutés dans les unités de diabétologie de la région Auvergne-Rhône-Alpes, notamment sur les villes de Lyon et Grenoble. Ils rempliront un questionnaire initial et seront contactés pour programmer un entretien d'environ 30 minutes. À la fin de cet entretien, ils seront interrogés sur leur intérêt pour participer à un deuxième entretien d'environ 30 minutes dans les 6 mois suivants pour évaluer le prototype de visualisation développé.</p> <p>Les patients seront repérés dans les associations de la région, comme la Fédération Française des Diabétiques de la région Auvergne-Rhône-Alpes (AFD AURA), et au sein des mêmes unités de diabétologie. Ils rempliront un questionnaire initial pour permettre aux investigateurs d'évaluer les critères d'inclusion et d'échantillonnage théorique. Après cette étape de sélection, les investigateurs rentreront en contact dans les 6 mois suivants pour programmer un entretien d'environ 1h. À la fin de cet entretien, ils seront interrogés sur leur intérêt pour participer à un deuxième entretien d'environ 30 minutes dans les 6 mois suivants pour évaluer le prototype de visualisation développé.</p>
CRITERES DE JUGEMENT	<ul style="list-style-type: none"> • Critère principal : Description des expériences des patients dans la construction de leurs parcours d'utilisation de soins et les interactions conductrices du parcours. • Critère(s) secondaire(s) : • Critère secondaire 1 : Description de la prise de décision dans la perspective des patients menant à la visite chez le professionnel de santé en fonction des caractéristiques sociodémographiques et du niveau de littératie en santé • Critère secondaire 2 : Description des besoins informationnels des professionnels de santé sur le parcours de soins des patients, au moment de la prise de décision partagée • Critère secondaire 3 : Description de la faisabilité du prototype d'outil de visualisation d'utilisation de soins développé
POPULATION CIBLE	Personnes adultes atteintes de diabète de type 1 ou de type 2 et de professionnels de santé impliqués dans la prise en soins de personnes ayant un diabète dans les régions de Grenoble et Lyon.
CRITERES D'INCLUSION	<u>Patient(e)</u>

	<ul style="list-style-type: none"> . Agé(e) de 18 ans ou plus ; . Atteint(e) de diabète de type 1 ou type 2 selon les critères de l'Haute Autorité de Santé et confirmé par un endocrinologue depuis au moins 1 an ; . Ayant eu au moins une consultation avec un professionnel de santé dans les 12 derniers mois ; . Capable de communiquer en français ; . Apte à participer à un entretien ; . Personne affiliée à un régime de sécurité sociale ; . Ne s'opposant pas à participer à l'étude. <p><u>Professionnel(le) de santé</u></p> <ul style="list-style-type: none"> . Ayant au moins 1 an d'expérience professionnelle dans la prise en charge des personnes ayant un diabète ; . Médecin endocrinologue, diabétologue ou généraliste, interne, infirmier(e) ou diététicien(ne), professionnel spécialisé en éducation thérapeutique.
CRITERES DE NON INCLUSION	<p><u>Patient(e)</u></p> <ul style="list-style-type: none"> . Personne institutionnalisée ; . Personne sous mesure de protection juridique. <p><u>Professionnel(le) de santé</u></p> <ul style="list-style-type: none"> . N'étant pas impliqué(e) dans la prise en charge des personnes ayant un diabète.
CRITERES DE SORTIE D'ETUDE	<i>Non applicable.</i>
NOMBRE DE SUJETS	<p>Il est prévu d'inclure 15 patients pour chaque sous-groupe de la pathologie (type 1 et type 2), soit 30 entretiens au total. Si la saturation n'est pas obtenue lors du 15^{ème} entretien, le nombre pourra être augmenté jusqu'à 20 entretiens par sous-groupe, soit un effectif de 40 patients maximum. Pour les professionnels de santé, le recrutement va cibler un échantillon représentatif des équipes spécialisées et un effectif d'environ 15 professionnels est attendu.</p> <p>Au total, l'effectif de personnes interrogées sera de 55 maximum.</p>
DUREE DE L'ETUDE	<p>Durée de la période d'inclusion : 12 mois</p> <p>Durée de la participation pour chaque sujet : 12 mois (dont 1 entretien de 1h et 1 entretien de 30 minutes pour les patients et 2 fois 30 minutes pour les professionnels)</p> <p>Durée totale de l'étude : 24 mois</p>
LIEU DE LA RECHERCHE	Établissements de soins primaires et secondaires, et associations de patients dans la région Auvergne-Rhône-Alpes, principalement dans les villes de Lyon et de Grenoble
RETOMBES ATTENDUES	<p>Les retombées attendues sont la description des expériences des personnes atteintes de diabète dans la construction de leurs parcours d'utilisation de soins, des interactions conductrices du parcours, ainsi que des besoins informationnels des professionnels de santé, sous 3 domaines déterminés (clinique, technologique et comportementale). Cette description va guider le développement d'un prototype d'outil de visualisation des épisodes de soin (consultations, séances d'éducation thérapeutique, etc.) et des actes résultants (prescriptions de médicaments ou d'examen, résultats d'examen, orientation vers un spécialiste, etc.), visant à aider la prise de décision partagée pour la planification des étapes ultérieures du parcours de soins.</p>

LISTE DES ABREVIATIONS

AFD AURA	Fédération Française des Diabétiques de la région Auvergne-Rhône-Alpes
ANSM	Agence Nationale de Sécurité des Médicaments et des produits de santé
BHLS	Brief Health Literacy Screen
CNIL	Commission Nationale Informatique et Liberté
CPP	Comité de Protection des Personnes
DMP	Dossier Médical Partagé
HCL	Hospices Civils de Lyon
MR	Méthodologie de Référence
NHS	National Health Service
NHSX	National Health Service user eXperience

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1 INFORMATIONS GENERALES

1.1. Titre

Étude qualitative sur l'expérience individuelle d'utilisation et de planification de soins des personnes ayant un diabète et des professionnels de santé en diabétologie - VOIES-D-ql

1.2. Identifiants du projet et historique des mises à jour

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1	27/01/2020	Rédaction initiale
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2 **JUSTIFICATION SCIENTIFIQUE**

2.1 **Etat actuel des connaissances - Rationnel**

Le vieillissement de la population et l'augmentation de la prévalence des maladies chroniques posent des enjeux importants à l'organisation des soins [1]. La prise en soins de ces conditions médicales reste fragmentée [2] et le transfert d'informations entre les professionnels de santé impliqués reste souvent à la responsabilité du patient et de ses proches. Il existe une tendance croissante à l'utilisation des données de santé recueillies systématiquement dans les services de soins pour prédire des états de santé futurs, calculer de risques d'aggravation, etc. [3, 4], mais la plupart de ces systèmes ne prennent pas en compte le contexte du patient ou de la pratique médicale.

En France, la mise en place du Dossier Médical Partagé (DMP) représente un effort considérable pour centraliser les informations médicales et les rendre disponibles pour le patient et les professionnels [5]. Cependant, le DMP est encore peu adopté et des initiatives de valeur ajoutée sont nécessaires pour exploiter le potentiel de cet outil. Plus largement, le virage numérique comprendra, en plus du DMP, un espace numérique en santé pour chaque citoyen [6] et un *Health Data Hub* a été créé [7]. D'autres initiatives se sont développées récemment dans d'autres pays pour améliorer l'organisation des soins et/ou mieux accompagner les patients en exploitant les données disponibles. Au Royaume Uni, par exemple, l'unité gouvernementale NHSX s'engage depuis début 2019 à développer des politiques publiques et des bonnes pratiques pour la transformation numérique du NHS [8]. Aux États-Unis, des groupes de travail comme le *Health Information Technology Working Group*, dans le *National Institute of Diabetes and Digestive and Kidney Diseases* [9], développent des plans de suivi électroniques utilisant des données du dossier médical électronique pour la maladie rénale chronique. Ces projets, entre autres, montrent l'importance de la communication simple et visuelle des événements de soins pour la compréhension globale du parcours et de la planification des étapes ultérieures, selon les objectifs de santé et de vie définis en collaboration entre patients et professionnels.

Dans le contexte de l'amélioration des services en soins chroniques, une des maladies les plus étudiées est le diabète. Les services de diabétologie ont été le lieu d'expérimentation de plusieurs innovations en soins chroniques, comme pour l'éducation thérapeutique et l'auto-gestion [10, 11], les soins participatifs [12] et les soins centrés sur la personne [13], l'implémentation des systèmes de télémédecine [14, 15], entre autres. Le diabète est une pathologie présentant un risque d'aggravation et de multimorbidité important qui nécessite une prise en charge interdisciplinaire et des interactions avec des multiples services de santé, et l'état de santé des personnes ayant un diabète est évalué par des critères cliniques objectifs [16]. C'est une pathologie à forte prévalence et avec un impact économique très important : en France, plus de 3,3 millions de personnes sont traitées pour un diabète selon Santé Publique France [16], et, selon la Caisse Nationale de l'Assurance Maladie, environ 19 milliards d'euros par an sont remboursés à des personnes ayant un diabète, soit 15% des dépenses individualisables pour tous les assurés [17]. En se concentrant sur les deux types principaux de diabète, type 1 et type 2, cette étude pourra avoir deux populations avec des profils sociodémographiques ou cliniques différents, mais pour lesquelles l'évaluation des résultats de santé le mode de suivi interprofessionnel pourraient présenter des défis similaires.

Pour l'objectif futur d'élaboration d'un outil pertinent et adapté à la pratique centrée sur la personne, il est nécessaire de décrire de façon élaborée et précise les expériences individuelles de soins des personnes concernées, tout comme les besoins informationnels des professionnels de santé et de ces personnes, conjointement, au moment de la prise de décision partagée dans le contexte spécifique de la maladie chronique. La méthode la plus adaptée pour décrire ces expériences subjectives et obtenir la contribution de la population concernée pour la construction de l'outil est la méthode qualitative, par des entretiens semi-directifs. Cette étude vise à réaliser cette description sous trois domaines : clinique (les critères cliniques pertinents pour les personnes impliquées), technologique (l'utilisation des outils technologiques dans la pratique médicale courante et dans le quotidien des patients), et comportemental (les interactions conductrices du parcours, les stratégies utilisées par les personnes dans la prise de décision en santé et les stratégies de communication entre professionnels de santé). En plus des entretiens, des données socioéconomiques seront recueillies et le *Brief Health Literacy Screen* (BHLS) sera appliqué pour mesurer le niveau de littératie en santé

des patients, pour évaluer si les expériences individuelles de soins varient en fonction de ces caractéristiques [18].

À partir de ces informations, un prototype d'outil sera développé pour visualiser l'historique d'utilisation de soins dans le contexte du diabète, ayant pour objectif principal de faciliter la communication entre les équipes multidisciplinaires de soins et aussi entre professionnels et personnes atteintes de diabète. Ce prototype sera présenté à des patients et à des professionnels en entretiens semi-directifs ou des focus groups pour identifier des freins et des leviers à son utilisation dans la pratique courante.

2.2 Hypothèse de la recherche

La description des expériences des personnes atteintes de diabète dans la construction de leurs parcours d'utilisation de soins, des interactions conductrices du parcours, ainsi que des besoins informationnels des professionnels de santé, permettrait de développer un outil d'aide à la prise de décision partagée pour la planification des étapes ultérieures du parcours. Cet outil permettrait la visualisation des épisodes de soin (consultations, séances d'éducation thérapeutique, etc.) et des actes résultants (prescriptions de médicaments ou d'examen, résultats d'examen, orientation vers un spécialiste, etc.), visant à aider la communication entre les différents professionnels des équipes multidisciplinaires et entre professionnels et patients.

Cette étude propose de répondre aux questions : (1) Quelle est l'expérience de construction du parcours d'utilisation de soins du patient du point de vue des 3 domaines décrits ? (2) Est-ce que cette expérience varie selon le statut socioéconomique et/ou le niveau de littératie en santé ? (3) Pour les professionnels, quels sont les besoins informationnels dans le moment de prise de décision ? (4) Comment ces besoins varient-ils en fonction de l'activité exercée, du temps d'expérience, de la structure de soins ? (5) Quelle est l'acceptabilité d'un outil de visualisation d'utilisation de soins dans la prise de décision partagée dans la pratique courante en diabétologie ?

2.3 Justification des choix méthodologiques

La méthode de recherche qualitative choisie pour cette étude se justifie par le besoin de rapprocher la recherche de la pratique clinique courante et de la réalité des personnes atteintes de diabète. Les méthodes de recherche en services de soins se développent de plus en plus en collaboration avec les personnes concernées. Dans cette perspective, la présente étude commence par interviewer les utilisateurs finaux (personnes atteintes de diabète et professionnels de santé) dans une démarche participative [19] pour tracer les scénarios idéaux et réels, pour planifier des solutions en connexion avec les points de vue des parties prenantes.

Des entretiens semi-dirigés sont la méthode de choix pour obtenir des données reflétant des expériences et besoins individuels, et sont appropriés pour générer des modèles théoriques et des questionnaires pertinents. L'analyse thématique est une méthode qualitative adaptée aux situations d'exploration des représentations et préférences individuelles. Enfin, la méthode de comparaison constante permet l'identification d'éléments distincts ou similaires entre sous-groupes, permettant le développement d'un modèle avec des paramètres pouvant être ajustés à la situation étudiée [20].

Les données suivantes seront recueillies :

Pour les patients, avant l'entretien :

- Année de naissance ;
- Genre ;
- Type d'affection de longue durée (diabète de type 1 ou type 2) ;
- Date de diagnostic (mois et année) ;
- Complications liées au diabète ;
- Questionnaire littératie santé (BHLS) ;
- Adresse (ville).

Durant l'entretien :

- Statut socio-économique (situation familiale, niveau d'études, situation professionnelle et revenu mensuel).

Pour les professionnels, avant l'entretien :

- Année de naissance ;
- Genre ;
- Profession ;
- Type de pratique (libéral ou pas) ;
- Temps d'expérience en prise en soins des patients avec un diabète de type 1 ou de type 2 ;
- Fréquence de consultation avec cette population.

Les données de contact et préférences pour organiser l'entretien seront demandées avant l'entretien.

2.4 Population cible

La population cible est constituée de personnes adultes atteintes de diabète de type 1 ou de type 2 et de professionnels de santé impliqués dans la prise en soins des personnes atteintes de diabète dans les régions de Grenoble et Lyon. Ce sera une étude qualitative avec l'objectif d'obtenir des points de vue divers et de décrire des expériences individuelles distinctes.

2.5 Retombées attendues

Les retombées attendues sont la description des expériences des personnes atteintes de diabète dans la construction de leurs parcours d'utilisation de soins et les interactions conductrices du parcours, ainsi que les besoins informationnels des professionnels de santé, sous 3 angles déterminés (clinique, technologique et comportementale). Cette description va guider le développement d'un prototype d'outil de visualisation des épisodes de soin (consultations, séances d'éducation thérapeutique, etc.) et des actes résultants (prescriptions de médicaments ou d'examens, résultats d'examens, orientation vers un spécialiste, etc.), visant à aider la communication entre les différents professionnels des équipes multidisciplinaires et entre professionnels et patients, pour faciliter la prise de décision partagée dans la planification des étapes ultérieures du parcours.

3 OBJECTIFS DE LA RECHERCHE

3.1 Objectif principal

L'objectif de cette étude est de décrire la construction de l'expérience individuelle de soins des personnes ayant un diabète de type 1 ou de type 2.

3.2 Objectifs secondaires

- Objectif secondaire 1 : Décrire la prise de décision dans la perspective des patients menant à la visite chez le professionnel de santé en fonction des caractéristiques sociodémographiques et du niveau de littératie en santé ;
- Objectif secondaire 2 : Décrire les besoins informationnels des professionnels de santé sur le parcours de soins des patients, au moment de la prise de décision partagée ;
- Objectif secondaire 3 : Evaluer la faisabilité d'un prototype d'outil de visualisation d'utilisation de soins pour l'aide à la décision partagée entre les professionnels et les personnes ayant un diabète ;

4 CONCEPTION DE LA RECHERCHE

4.1 Type d'étude

Étude qualitative consistant d'entretiens avec des personnes atteintes de diabète de type 1 ou type 2 et des professionnels de santé.

Cette étude est une recherche impliquant la personne humaine (RIPH) de type 3.

4.2 Critères de jugement

Pour cette étude, les expériences individuelles d'utilisation de soins sont considérées comme la description par l'utilisateur de son parcours dans le système de santé (parcours de soins). Le parcours de soins est défini ici comme la totalité des interactions entre un usager et le système de santé sur une période de temps, comprenant des consultations avec des professionnels de santé individuels ou en équipe multidisciplinaire, des séances d'éducation thérapeutique, la prescription des traitements, ou des tests cliniques réalisés; un parcours de soins peut être caractérisé par le type d'interactions et interventions qui ont eu lieu et leur périodicité, les types de professionnels de santé impliqués, leur comparaison aux interactions recommandés par les guides de bonne pratique en vigueur, et l'évolution de l'état de santé bio-psycho-sociale en lien avec ces interactions. Les expériences individuelles représentent la narration et l'évaluation subjective de ces interactions par rapport à leurs objectifs de santé et de vie.

4.2.1 Critère de jugement principal

Le critère de jugement principal de cette étude qualitative est la description des expériences des personnes atteintes de diabète de type 1 ou type 2 dans la construction de leurs parcours d'utilisation de soins, et des interactions conductrices de ce parcours. Pour atteindre cet objectif, des guides d'entretien semi-dirigés ont été rédigés, les entretiens réalisés seront enregistrés et les transcriptions seront analysées par analyse thématique au moyen du logiciel NVivo. Cette analyse sera déductive dans un premier temps, en suivant les trois domaines décrits précédemment (clinique, technologique et comportemental), et inductive à partir des thèmes qui susciteront des récits des personnes interviewées.

4.2.2 Critères de jugement secondaires

Les critères secondaires seront :

- Critère secondaire 1 : Description de la prise de décision dans la perspective des patients menant à la visite chez le professionnel de santé en fonction des caractéristiques sociodémographiques et du niveau de littératie en santé. Cette description sera faite à partir des questionnaires appliqués en amont (*Brief Health Literacy Screening* - BHLS) et de statut socioéconomique et de l'analyse thématique des récits des personnes interviewées.
- Critère secondaire 2 : Description des besoins informationnels des professionnels de santé sur le parcours de soins des patients, au moment de la prise de décision partagée. Cette description sera faite à partir de l'analyse thématique des récits des professionnels interviewés.
- Critère secondaire 3 : Description de la faisabilité du prototype d'outil de visualisation d'utilisation de soins développé. Les expériences et préférences des patients et professionnels seront utilisés pour développer et améliorer un prototype de visualisation des épisodes de soin enregistrés dans des bases de données médico-administratives.

5 CRITERES D'ELIGIBILITE

5.1 Critères d'inclusion

Patient(e)

- Agé(e) de plus de 18 ans ;
- Atteint(e) de diabète de type 1 ou type 2 selon les critères de la HAS et confirmé par un endocrinologue depuis au moins 1 an ;
- Ayant eu au moins une consultation avec un professionnel de santé dans les 12 derniers mois ;
- Capable de communiquer en français ;
- Apte à participer à un entretien ;
- Personne affiliée à un régime de sécurité sociale ;
- Ne s'opposant pas à participer à l'étude.

Dans la population présentant les critères ci-dessus, un questionnaire initial sera appliqué avec d'autres critères d'échantillonnage théorique pour constituer un panel de participants représentatifs de la multiplicité de profils de la population diabétique. Les critères seront :

- Genre ;
- Tranches d'âge (18-39, 40-65, >65) ;
- Niveau de littératie en santé (faible et haut) ;
- Temps depuis le diagnostic (inférieur et supérieur à 10 ans).

Professionnel de santé

- Ayant au moins 1 an d'expérience professionnelle dans la prise en charge des personnes ayant un diabète ;
- Médecin endocrinologue, diabétologue ou généraliste, interne, infirmier(e) ou diététicien(ne), professionnel spécialisé en éducation thérapeutique.

5.2 Critères de non inclusion**Patient(e)**

- Personne institutionnalisée ;
- Personne sous mesure de protection juridique.

Professionnel de santé

- Professionnel de santé n'étant pas impliqué dans la prise en charge des personnes ayant un diabète.

Aucun critère d'exclusion n'est prévu pour cette recherche.

5.3 Modalités de recrutement et faisabilité

L'étude sera menée dans la région Auvergne-Rhône-Alpes, principalement dans les villes de Lyon et Grenoble. Les professionnels de santé seront recrutés au sein des unités de diabétologie de l'Hôpital Lyon Sud et du Centre Hospitalier Universitaire Grenoble-Alpes. Les patients seront repérés au sein des mêmes unités et dans des associations de patients de la région, comme la Fédération Française des Diabétiques de la région Auvergne-Rhône-Alpes (AFD AURA). Des informations sur l'étude seront fournies à ces organisations (notamment la Notice d'information et questionnaire initial) avec les contacts des investigateurs de l'étude pour que les personnes intéressées remplissent le questionnaire initial avec les critères d'inclusion et d'échantillonnage théorique. Une fois le questionnaire rempli, les investigateurs rentreront en contact avec chaque patient pour programmer l'entretien individuel qui pourra se dérouler par téléphone, à leur domicile ou à proximité (bibliothèque ou tout autre local public convenant aux personnes), dans les locaux des associations ou de l'équipe de recherche.

Il est attendu de recruter entre 15 et 20 personnes atteintes de diabète de type 1, 15 et 20 personnes atteintes de diabète de type 2 et 15 professionnels de santé.

Pour l'étude de faisabilité, le prototype d'outil de visualisation sera montré à des personnes ayant manifesté l'intérêt d'y participer, pendant un deuxième entretien individuel d'environ 30 minutes ou des focus groups d'une durée d'environ 1h, selon la disponibilité des participants et à un endroit convenable.

6 ORGANISATION GENERALE

6.1 Calendrier de l'étude

Durée de la période d'inclusion : 12 mois

Durée de la participation pour chaque patient/sujet sain : 12 mois (à partir de la réalisation du questionnaire initial et contact postérieur pour programmer l'entretien d'environ 1h pour les patients ou 30 minutes pour les professionnels dans les 6 mois suivants. Pour les patients et professionnels intéressés, un deuxième entretien de 30 minutes aura lieu 6 mois après pour évaluer la faisabilité du prototype développé)

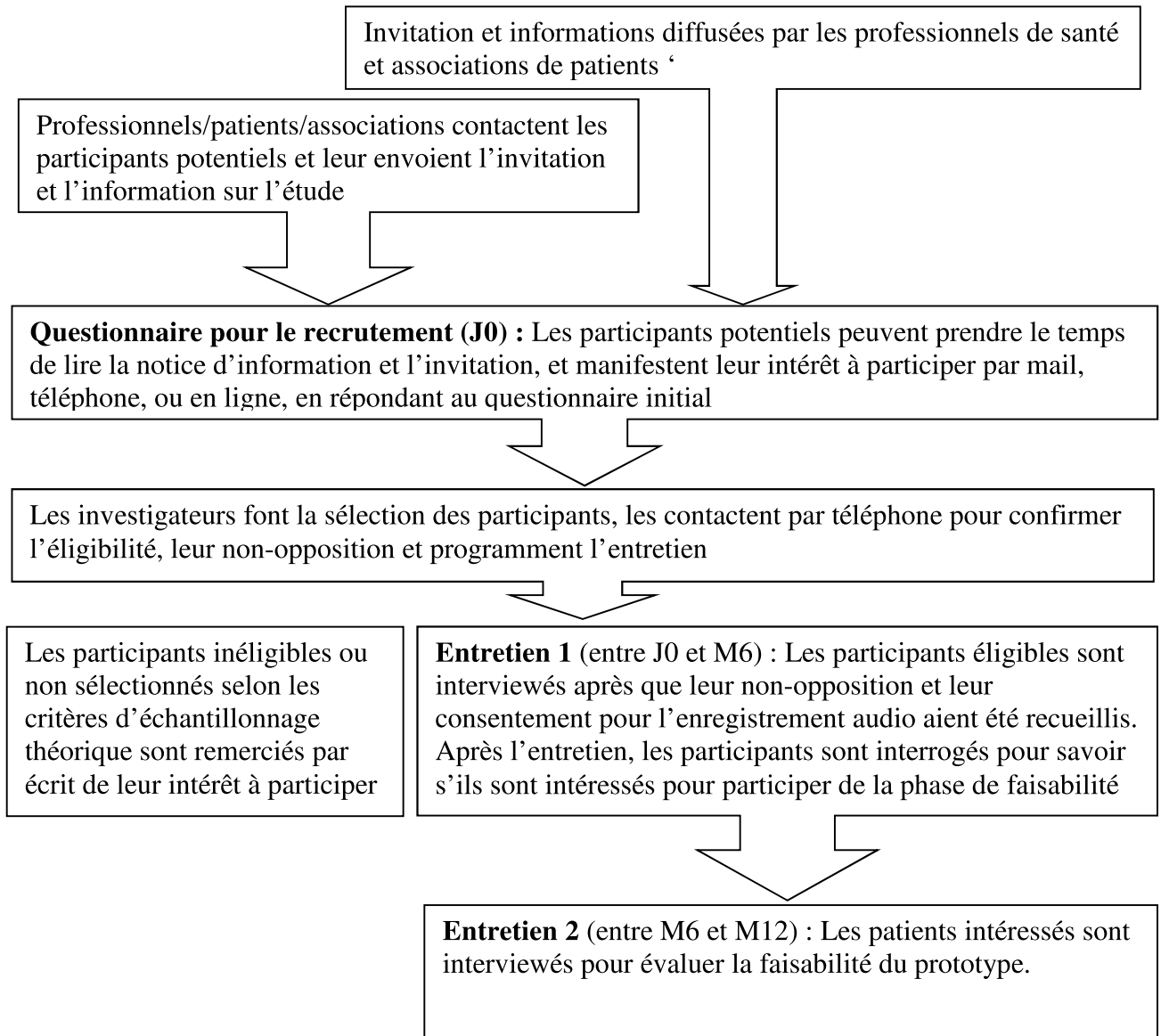
Durée totale de l'étude : 24 mois

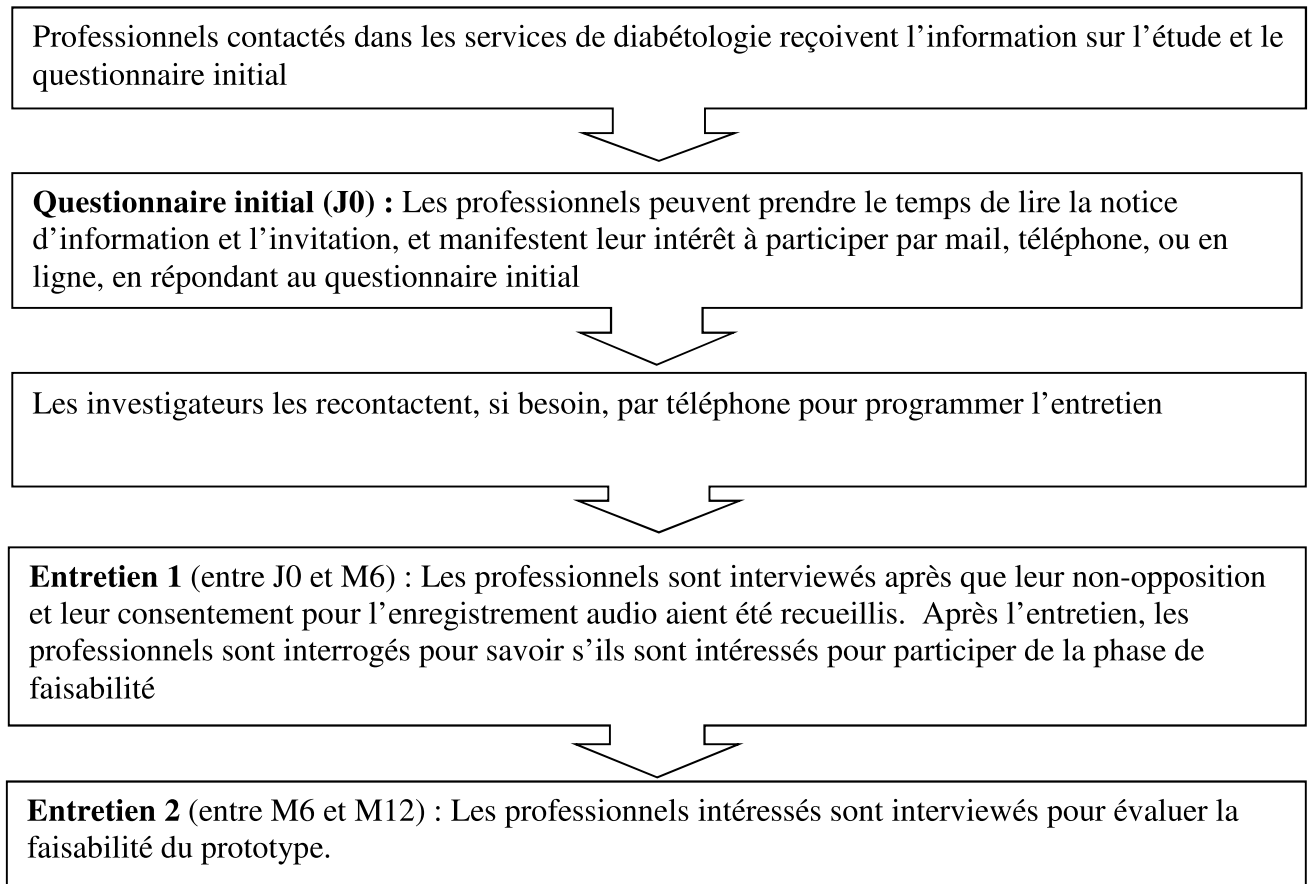
Début des inclusions : Dès l'obtention des autorisations réglementaires, prévision pour le 2^{ème} trimestre 2020.

Dès la première inclusion, le promoteur doit informer sans délai le CPP de la date effective de démarrage de l'étude (date effective de démarrage = date d'inclusion du premier patient).

La date de fin d'étude sera transmise par le promoteur au CPP dans un délai de 90 jours. La date de fin de la recherche correspond au terme de la participation de la dernière personne qui se prête à la recherche, ou le cas échéant, au terme défini dans le protocole.

6.2 Schéma général et tableau récapitulatif





6.3 Règles d'arrêt temporaire ou définitif

- Arrêt de participation d'une personne à la recherche :

Les sujets pourront demander à sortir de l'étude à n'importe quel moment, sans avoir à se justifier, et quelle qu'en soit la raison. En cas de sortie prématurée, l'investigateur doit en documenter les raisons de façon aussi complète que possible.

- Arrêt d'une partie ou de la totalité de la recherche :

Les Hospices Civils de Lyon se réservent le droit d'interrompre l'étude à tout moment, s'il s'avère que les objectifs d'inclusion ne sont pas atteints.

En cas d'arrêt prématuré de l'étude pour des raisons de sécurité, l'information sera transmise par le promoteur dans un délai de 15 jours au CPP.

7 EVALUATION DE LA SECURITE

Un événement indésirable est une réaction nocive et non voulue.

D'après l'article L1123-10, les dispositions relatives aux vigilances de chaque produit ou pratique faisant l'objet de la recherche sont applicables.

L'investigateur devra signaler tout événement indésirable selon les procédures de gestion de la qualité et des soins de son établissement.

D'après l'article L1413-14, tout professionnel ou établissement de santé ayant constaté une infection nosocomiale ou tout autre événement indésirable grave lié à des soins réalisés lors d'investigations, de traitements ou d'actions de prévention doit en faire la déclaration au directeur général de l'agence régionale de santé.

Les événements indésirables sanitaires sont à signaler sur le portail de signalement des événements indésirables sanitaires : www.signalement-sante.gouv.fr

Il n'est prévu dans cette étude qualitative aucun examen biologique, dispositif médical, médicament ou autre procédure diagnostique ou thérapeutique susceptible de présenter un risque pour la santé ou la sécurité des patients.

8 ASPECTS STATISTIQUES

8.1 Nombre de sujets nécessaires

Les méthodes qualitatives prévoient d'inclure des participants jusqu'au moment où les nouveaux entretiens individuels n'apportent plus d'informations nouvelles et/ou essentielles sur la question de recherche (saturation de données) et selon le contexte de faisabilité de la recherche[20]. Pour cette étude, il est prévu d'inclure 15 patients pour chaque sous-groupe de la pathologie (type 1 et type 2), soit 30 entretiens au total. Si la saturation n'est pas obtenue lors du 15^{ème} entretien, le nombre pourra être augmenté jusqu'à 20 entretiens par sous-groupe, soit un effectif de 40 patients maximum.

Pour les professionnels de santé, le recrutement va cibler un échantillon représentatif des équipes spécialisées et un effectif d'environ 15 professionnels est attendu.

Au total, l'effectif de personnes interrogées sera de 55 maximum.

8.2 Description des méthodes statistiques

Aucun test statistique ne sera réalisé dans le cadre de cette étude qualitative. L'analyse de données sera une analyse thématique du contenu des retranscriptions des entretiens individuels enregistrés, à l'aide du logiciel NVivo.

L'analyse sera déductive, selon les 3 angles définis dans le guide d'entretien, puis inductive, selon les thèmes abordés durant les récits des personnes interviewées. Pour les critères de jugement secondaires, la stratégie d'analyse sera faite à partir de l'élaboration de catégories spécifiques et par analyse comparative des données en sous-groupes établis selon les caractéristiques socioéconomiques et le niveau de littératie en santé. Les besoins informationnels pour la prise de décision partagée (angle clinique et technologique des guides d'entretien) guideront le développement du prototype d'outil de visualisation.

Le codage de données sera fait au fur et à mesure de la réalisation des entretiens (comparaison constante), pour adapter les guides d'entretien, si besoin, les catégories de l'arbre de codage initial et pour vérifier l'obtention progressive de la saturation des données.

L'analyse sera réalisée par Luiza SIQUEIRA DO PRADO sous la supervision de la Dr Alexandra DIMA et l'interprétation des résultats sera discutée avec les membres du comité scientifique de l'étude. Un rapport écrit sera envoyé aux participants intéressés, avec une invitation à contribuer ou rectifier l'analyse. Les commentaires, suggestions ou autre, formulés par les participants, seront intégralement annexés au rapport final de l'étude.

8.3 Méthode de prise en compte des données manquantes

Non applicable

8.4 Gestion des modifications apportées au plan d'analyse

Non applicable

8.5 Responsable des analyses et logiciel utilisé

Le responsable des analyses est l'investigateur principal de l'étude, Dr Alexandra DIMA, qui supervisera l'analyse thématique réalisée par Luiza SIQUEIRA DO PRADO à l'aide du logiciel NVivo.

9 DROITS D'ACCES AUX DONNEES ET DOCUMENTS SOURCES

9.1 Accès aux données

- le promoteur est chargé d'obtenir l'accord de l'ensemble des parties impliquées dans la recherche afin de garantir l'accès direct à tous les lieux de déroulement de la recherche, aux données sources, aux documents sources et aux rapports dans un but de contrôle de qualité et d'audit par le promoteur ;

- les investigateurs mettront à disposition des personnes chargées du suivi, du contrôle de qualité ou de l'audit de la recherche impliquant la personne humaine, les documents et données individuelles strictement nécessaires à ce contrôle, conformément aux dispositions législatives et réglementaires en vigueur (articles L.1121-3 et R.5121-13 du code de la santé publique).

9.2 Documents sources

Les documents sources sont définis comme tout document ou objet original permettant de prouver l'existence ou l'exactitude d'une donnée ou d'un fait enregistrés au cours de l'étude clinique. Ils seront archivés pendant 25 ans par l'investigateur ou par l'hôpital s'il s'agit d'un dossier médical hospitalier.

Dans le cadre de cette étude, les documents sources seront les enregistrements audio des entretiens, les retranscriptions écrites et anonymisées, et le questionnaire initial décrivant les caractéristiques socioéconomiques et de niveau de littératie en santé.

9.3 Confidentialité des données

Conformément aux dispositions concernant la confidentialité des données auxquelles ont accès les personnes chargées du contrôle de qualité d'une recherche impliquant la personne humaine (article L.1121-3 du code de la santé publique), conformément aux dispositions relatives à la confidentialité des informations concernant notamment les essais, les personnes qui s'y prêtent et les résultats obtenus (article R. 5121-13 du code de la santé publique), les personnes ayant un accès direct aux données prendront toutes les précautions nécessaires

en vue d'assurer la confidentialité des informations relatives aux essais, aux personnes qui s'y prêtent et notamment en ce qui concerne leur identité ainsi qu'aux résultats obtenus.

Ces personnes, au même titre que les investigateurs eux-mêmes, sont soumises au secret professionnel (selon les conditions définies par les articles 226-13 et 226-14 du code pénal).

Pendant la recherche impliquant la personne humaine ou à son issue, les données recueillies sur les personnes qui s'y prêtent et transmises au promoteur par les investigateurs (ou tous autres intervenants spécialisés) seront rendues anonymes.

Préalablement aux entretiens, les données identifiantes des participants (Nom, prénom et coordonnées renseignées sur le document d'invitation seront transmises aux investigateurs de l'étude pour qu'ils puissent les contacter et programmer l'entretien. Un code d'identification leur sera ensuite attribué (N° et Initiales). A la fin de la recherche, les données identifiantes transmises aux investigateurs pour contacter les patients (nom, prénom, coordonnées) seront détruites et les données analysées seront codées (N°/initiales). Seule la liste de correspondance (nom, prénom, date de naissance et code d'identification attribué) sera conservée dans le classeur investigateur de l'étude, archivé dans une armoire fermant à clé pendant la durée d'archivage.

Pendant la retranscription des entretiens, des mentions à des données identifiantes tels que des noms/prénoms, lieux, etc., seront remplacées par un terme général non-identifiant (par exemple, [nom de l'hôpital], [nom de la ville], [nom de la personne]). Pour l'écriture des rapports, les citations seront accompagnées de noms génériques et seules les caractéristiques importantes du participant seront gardées, i.e., « Mme Unetelle, atteinte de diabète de type 2 » ou « M Untel, diététicien ».

Pour coder ces caractéristiques des participants, chaque participant recevra un code (N°/Initiales), inclus dans le classeur de l'étude. Les mêmes codes seront utilisés pour enregistrer l'entretien respectif des participants. Des données personnelles dans le dossier source seront gardées séparées des retranscriptions des entretiens et ne seront accessibles qu'aux investigateurs de l'étude pendant la collecte de données.

10 CONTROLE ET ASSURANCE DE LA QUALITE

Les investigateurs s'engagent à accepter les audits d'assurance qualité effectués par des personnes mandatées par le promoteur ainsi que les inspections effectuées par les Autorités Compétentes. Toutes les données, tous les documents et rapports peuvent faire l'objet d'audits et d'inspections réglementaires sans que puisse être opposé le secret médical.

11 CONSIDERATIONS ETHIQUES

11.1 Autorités compétentes

Le protocole, la notice d'information, le cahier de recueil de données de l'étude et le cas échéant le(s) questionnaire(s) seront soumis pour avis au Comité de Protection des Personnes *Ouest III*.

La notification de l'avis favorable du CPP sera transmise à l'ANSM.

Le promoteur s'engage à ce que le démarrage de l'étude ne se fasse qu'après obtention de l'avis favorable du CPP.

11.2 Modifications substantielles

En cas de modification substantielle apportée au protocole par l'investigateur, elle sera approuvée par le promoteur. Ce dernier devra obtenir préalablement à sa mise en œuvre un avis favorable du CPP.

11.3 Information du patient

Les patients seront informés de façon complète et loyale, en des termes compréhensibles, des objectifs, de leurs droits de refuser de participer à l'étude ou de la possibilité de se rétracter à tout moment.

Toutes ces informations figurent sur un formulaire d'information remis au patient, la non-opposition du patient sera recueillie par l'investigateur avant le début de la recherche et sera notifiée dans le classeur de l'étude.

11.4 Déclaration de conformité

Le promoteur et l'investigateur s'engagent à ce que cette recherche soit conduite :

- conformément au protocole,
- conformément aux dispositions législatives et réglementaires actuellement en vigueur en France et au niveau international.

12 GESTION ET CONSERVATION DES DONNEES

12.1 Cahier d'observation

Le cahier d'observation ne comportera que les données nécessaires à l'analyse en vue de publication. Ce seront les données collectées dans les questionnaires initiales, les enregistrements audio et les retranscriptions des entretiens. Aucune autre donnée ne sera recueillie. La précision des informations renseignées dans le questionnaire initial sera assurée en début des entretiens individuels.

12.2 Gestion des données

Les entretiens seront enregistrés et retranscrits, toute donnée identifiante comme des noms/prénoms, lieux et institutions sera supprimée. La précision des transcriptions sera vérifiée pendant l'analyse de données, en comparant parallèlement l'enregistrement audio à la retranscription pour un échantillon des entretiens. Les enregistrements audio et les retranscriptions, avec l'analyse respective, seront sauvegardés à des endroits différents avec accès protégé par mot-de-passe et sécurisés pendant la durée d'archivage (comme décrit dans la section 12.4).

12.3 CNIL

Cette recherche a obtenu l'autorisation de la Commission Nationale de l'Informatique et des Libertés (CNIL).

12.4 Archivage

Pour toutes les recherches sur la personne humaine, la durée d'archivage est de 25 ans.

Les documents suivants seront archivés par le(s) centres investigateurs jusqu'à la fin de la période d'utilité pratique.

Ces documents sont :

- Protocole et annexes, amendements éventuels,
- Formulaires d'information
- Données individuelles
- Documents de suivi et courriers relatifs à la recherche

Le promoteur conserve la totalité des documents de l'étude :

- Protocole et annexes, amendements éventuels,
- Formulaires d'information (trames)
- Documents de suivi et courriers relatifs à la recherche
- Analyses statistiques
- Rapport final de l'étude

Le promoteur conservera l'ensemble des données de l'étude pendant 25 ans.

Aucun déplacement ou destruction ne pourra être effectué sans l'accord du promoteur. Au terme des 25 ans, le promoteur sera consulté pour destruction. Toutes les données, tous les documents et rapports pourront faire l'objet d'audit ou d'inspection.

13 REGLES RELATIVES A LA PUBLICATION

Les communications et rapports scientifiques correspondant à cette étude seront réalisés sous la responsabilité de l'investigateur principal de l'étude avec l'accord des investigateurs associés. Les coauteurs du rapport et des publications seront les investigateurs et les cliniciens impliqués, au prorata de leur contribution à l'étude, ainsi que le biostatisticien et les chercheurs associés.

Les règles de publications suivront les recommandations internationales (N Engl J Med, 1997; 336 :309-315). L'étude sera enregistrée sur un registre des essais cliniques en libre accès (clinicaltrials.gov) avant l'inclusion du 1^{er} patient.

14 REFERENCES BIBLIOGRAPHIQUES

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Annex 4 –Avis favorable comité de protection des personnes (CPP)
Study VOIES-D-ql

Comité de Protection des Personnes

OUEST III

Agréé par arrêté ministériel en date du 16 mai 2018,

Constitué selon l'arrêté du Directeur Général de l'ARS Nouvelle Aquitaine en date du 31 mai 2018.

C.H.U. La Milétrie

Bâtiment Vie La Santé – Entrée n°4 - 1er étage

2 rue de la milétrie – CS 90 577 - 86021 POITIERS CEDEX

Tél : 05.49.45.21.57

E-mail : cgp-ouest3@chu-poitiers.fr

Valérie Plattner

Direction de la Recherche

Clinique et de l'Innovation

3 quai des Célestins

69002 LYON

Poitiers, le 20 mars 2020

Objet : Avis Favorable

Référence Comité : 20.02.14 / SI CNRIPH 20.01.31.57642 (à rappeler dans toute correspondance)

Domaine thérapeutique : Endocrinologie / Diabétologie

Date de tirage au sort : 31/01/2020 – Recevabilité : 05/02/2020

Avis : 24/02/2020

Réponse promoteur : 17/03/2020

Madame,

Le Comité a étudié lors de sa séance plénière du 19 février 2020, le projet de protocole suivant :

Numéro de l'essai : 69HCL19_0897

Titre de l'essai : " Étude qualitative sur l'expérience individuelle d'utilisation et planification de soins des personnes ayant un diabète et des professionnels en diabétologie - VOIES-D-ql "

Identité du promoteur : Hospices Civils de Lyon - 3, quai des Célestins - B.P. 2251
69229 LYON CEDEX 02

Adresse électronique de contact du Promoteur : drcli_promo@chu-lyon.fr

Identité du Coordonnateur : Dr Alexandra DIMA - Laboratoire HESPER
Université Claude - Bernard Lyon 1

Numéro d'identification : 2020-A00210-39

Catégorie : 3

Versions :

Lettre de saisine : 30/01/2020

Lettre de réponse : 17/03/2020

Document de réponse : 17/03/2020

Formulaire de demande d'avis : version n° 1 (non daté)

Protocole : Version 2 du 28/02/2020

Résumé en français : version 2 du 16/03/2020

Notice d'information patient : version 2 du 16/03/2020

Note d'information à l'attention des professionnels de santé : version 2 du 16/03/2020

Liste des investigateurs : version 2 du 16/03/2020

Recueil de données nominatives : 30/01/2020

Formulaire de réponse invitation patients : Questionnaire initial et invitation à participer à un entretien dans le cadre de l'étude : version 1 du 27/01/2020

Formulaire de réponse invitation professionnels : Invitation à participer à un entretien dans le cadre de l'étude : version 1 du 27/01/2020

Guide d'entretien faisabilité du prototype : version 1 du 27/01/2020:

Guide d'entretien pour les patients Expériences individuelles de soins : version 1 du 27/01/2020

Guide d'entretien pour les professionnels besoins informationnels : version 1 du 27/01/2020

Le quorum étant constaté,

M.	L.	LACOSTE	Qualifié en matière de recherche biomédicale	(T)
Mme	N.	RABAN	Qualifiée en matière de recherche biomédicale	(S)
Mme	E.	GAND	Biostatisticienne	(S)
M.	J.	DELIGNE	Médecin Généraliste	(T)
Mme	C.	AIGRIN	Pharmacienne	(T)
Mme	A.	GIRAULT	Infirmière	(T)
Mme	D.	CHUILLET-MOREAU	Qualifiée en matière éthique	(T)
Mme	V.	BONNAUD	Psychologue	(T)
Mme	A.	RANGER	Qualifiée en matière juridique	(T)
M.	D.	MAROUBY	Représentant d'association de malades	(T)
Mme	E.	RABOIS	Représentante d'association de malades	(T)

après avoir entendu le rapporteur et l'avis du méthodologiste, les membres du CPP ont délibéré puis après avoir obtenu les informations et corrections demandées, la Vice-Présidente ayant reçu mandat des membres, un **avis favorable** a été émis à la mise en œuvre de cette étude, en application des dispositions du Code de la Santé Publique et de la réglementation en vigueur applicable aux recherches impliquant la personne humaine présentée **au 3° de l'article L.1121-1 du CSP.**

Soyez assurée, Madame, de mes sentiments les meilleurs.

Adeline RANGER
Vice-Présidente



*Selon l'article R1123-34 du CSP, Le promoteur informe sans délai l'autorité compétente et le comité de protection des personnes **de la date effective de commencement de la recherche**, correspondant à la date de la signature du consentement par la première personne qui se prête à la recherche en France.*

Annex 5 – Formulaire invitation patients
Study VOIES-D-ql

Questionnaire initial et invitation à participer à un entretien dans le cadre de l'étude :

***Étude qualitative sur l'expérience individuelle d'utilisation et de planification
de soins des personnes ayant un diabète et des professionnels
de santé en diabétologie - VOIES-D-ql***

Date : |_|_| / |_|_| / |_|_|_|_|

Nom et prénom : _____

Année de naissance : |_|_|_|_|

Genre : F ☐ M ☐ Autre ☐

Quel est votre affection de longue durée (ALD) ?

Diabète de type 1 ☐
Diabète de type 2 ☐

Depuis quand êtes-vous diagnostiqué ? |_|_| / |_|_|_|_|

Est-ce que vous avez des complications liées au diabète ? (Exemples : rétinopathie
diabétique, néphropathie diabétique, neuropathie diabétique, etc.)

Oui ☐ Non ☐

Précisez :

.....
.....

Observation libre :

.....
.....
.....
.....
.....

Littératie en santé – BHLS patient

	Pas du tout confiant	Un peu confiant	Moyennement confiant	Assez confiant	Très confiant
1. A quel point êtes-vous confiant(e) lorsque vous complétez des formulaires médicaux par vous-même ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Jamais	Occasionn ellement	Parfois	Souvent	Toujours
2. À quelle fréquence vous arrive-t-il de demander de l'aide (famille, amis, voisins, médecins, pharmaciens...) pour lire la documentation remise à l'hôpital ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. À quelle fréquence vous arrive-t-il d'éprouver de la difficulté à comprendre votre état de santé à cause de difficultés à lire les documents qui vous sont remis ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Nous souhaitons organiser un entretien avec vous à un moment et à un lieu à votre convenance. Pour cela, pourriez-vous répondre aux questions suivantes :

Préférence pour entretien : ☐ téléphonique ☐ face-à-face

De façon générale, quand seriez-vous disponible pour un entretien ?

Adresse - ville : _____

Adresse complète (si vous préférez que l'entretien se déroule à votre domicile) :

Numéro de téléphone : _____

Adresse email : _____

Avez-vous des commentaires ou questions que vous souhaiteriez partager :

Annex 6 – Note d'information patients
Study VOIES-D-ql



Hospices Civils de Lyon
Direction de la Recherche Clinique
et de l'Innovation

NOTE D'INFORMATION A L'ATTENTION DES PATIENTS

Étude qualitative sur l'expérience individuelle d'utilisation et de planification de soins des personnes ayant un diabète et des professionnels de santé en diabétologie VOIES-D-ql

Version 2 du 16/03/2020

PROMOTEUR :

Hospices Civils de Lyon

Direction de la Recherche Clinique et de l'Innovation (DRCI)
3, quai des Célestins
BP 2251 69229 Lyon Cedex 02
EA 7425 HESPER Health Services and Performance Research
Université Claude Bernard Lyon 1
Domaine Rockefeller- 4eme étage (aile CD)
8 avenue Rockefeller
69373 Lyon 8
Tél : 06 32 86 82 37
Email : alexandra.dima@univ-lyon1.fr

Madame, Monsieur,

Mme SIQUEIRA DO PRADO Tél 04 26 68 82 22 vous a proposé de participer à l'étude VOIES-D-ql, une étude qualitative sur les expériences individuelles d'utilisation et de planification de soins des personnes ayant un diabète.

Ce document a pour objectif de vous donner toutes les informations relatives à cette étude de façon à vous permettre d'exercer au mieux votre liberté de décision. Ce document est obligatoire et son contenu est défini par le Code de la Santé Publique, article L 1122-1.

Merci de prendre le temps de **lire attentivement les informations qui suivent**. Vous avez le droit de prendre le temps de réfléchir, de discuter de cette étude et de poser toutes les questions que vous souhaitez sur cette étude, à qui vous voulez (médecin traitant, association de patients, etc...).

La présente notice d'information vous sera remise pour que vous puissiez bénéficier de l'ensemble des informations.

Votre participation à l'étude est entièrement libre et volontaire. Si vous ne désirez pas y participer, vous continuerez à bénéficier de la prise en charge médicale habituelle.

Quel est l'objectif de cette étude ?

Vivre avec une maladie chronique exige, dans la majorité des cas, de multiples interactions avec des professionnels de santé et le système de santé pour garder la meilleure qualité de vie possible. Ces interactions génèrent une grande quantité de données médicales. Cependant, le transfert de ces données entre les différents professionnels de santé impliqués reste souvent à la responsabilité du patient et de ses proches, tout comme la reconstitution du parcours d'utilisation de soins. Le partage de ces informations est nécessaire pour aider à la prise de décision entre patients et professionnels, sur les prochaines étapes de la prise en soins. Des outils de visualisation pourraient être développés pour aider professionnels et patients dans ce processus.

L'objectif de cette étude est de décrire les expériences individuelles dans la construction du parcours d'utilisation de soins des personnes ayant un diabète sous 3 angles : clinique (les informations cliniques considérées comme essentielles pour la prise de décision en santé et la planification des étapes ultérieures du parcours), technologique (l'utilisation d'outils technologiques comme des portails destinés aux patients ou des applications mobiles pour obtenir ou stocker des informations), et comportementale (le processus de prise de décision en santé et les interactions conductrices du parcours de soins).

➤ Déroulement de l'étude et nature des données recueillies

Nous vous proposons de remplir un questionnaire initial et de vous rencontrer d'ici 6 mois en face à face ou par téléphone lors d'un entretien d'environ 1 heure. Dans les 6 mois suivant cet entretien, et si vous le souhaitez, vous pouvez participer à un deuxième entretien d'environ 30 minutes pour évaluer et améliorer le prototype d'un outil qui sera développé à partir des préférences des personnes interviewées dans cette première phase. Nos échanges seront enregistrés, avec votre accord, afin de recueillir le plus d'informations possible. Des entretiens téléphoniques seront privilégiés, mais cela pourra aussi se dérouler à votre domicile ou à proximité, dans les locaux de l'équipe ou dans tout autre lieu public qui vous arrangerait.

Les enregistrements seront transcrits mot-à-mot, sauf les noms des personnes, des lieux ou des institutions (pour garder la confidentialité des participants aux entretiens). Ils seront utilisés pour décrire la manière dont la collaboration entre les différents participants aux soins a lieu, ainsi que les différents points de vue sur les solutions d'amélioration des soins collaboratifs.

Ces transcrits seront conservés en toute sécurité pendant 25 ans dans les locaux de l'investigateur principal où la recherche a eu lieu, en conformité avec la réglementation en vigueur.

En revanche les enregistrements ne seront conservés que jusqu'à l'analyse des données de l'étude afin de pouvoir les écouter à nouveau dans le cas où le transcrit ne serait pas assez claire ou s'il y a besoin de plus d'informations (pause, intonation, etc.). Ils seront ensuite détruits.

A cet effet, nous vous demandons de nous notifier par e-mail votre accord pour l'enregistrement audio. En cas d'impossibilité de réponse par e-mail, il est également possible de compléter et signer l'encadré situé à la fin de cette notice d'information et de nous renvoyer le document par la poste, ou de nous le remettre en main propre en cas d'entretien en face-à-face. . Vous devrez en conserver un exemplaire..

➤ Participation volontaire

Votre participation à cette étude est volontaire et vous avez le droit de réfléchir avant de prendre votre décision. Vous êtes libre de vous opposer à votre participation à cette étude et ce à tout moment et sans avoir à vous justifier.

Si vous choisissez de ne pas participer à cette étude vous conserverez tous vos droits garantis par la loi et recevrez les soins nécessaires appropriés.

De même, si vous décidez de participer à cette recherche, mais que vous changiez d'avis au cours de celle-ci, vous pouvez à tout moment demander d'interrompre votre participation à l'étude sans aucun préjudice, sans justification de votre part et sans que votre responsabilité ne soit engagée. Dans ce cas, vos données recueillies jusque-là seront utilisées dans les résultats de l'étude.

Si vous décidez d'arrêter votre participation à l'étude, vous devrez en informer votre médecin ou Mme SIQUEIRA DO PRADO. Celui-ci est également en droit d'arrêter votre participation à l'étude à n'importe quel moment, s'il considère que ceci est dans votre intérêt.

Durant votre participation à l'étude, vous serez informé de toute découverte importante et qui pourrait affecter votre décision de continuer à participer à cette étude.

Si vous participez actuellement à un autre protocole de recherche sur la personne humaine, merci d'en informer votre médecin.

➤ **Confidentialité et protection des données**

Un traitement informatique de vos données personnelles va être mis en œuvre pour permettre d'analyser les résultats de la recherche au regard de l'objectif de cette dernière. Le responsable du traitement des données est le promoteur, dont les coordonnées figurent sur la première page, conjointement avec l'Université Claude Bernard de Lyon (UCBL). Ce traitement des données a pour fondement juridique l'article 6 du Règlement Général sur la Protection des Données (RGPD) à savoir l'exécution d'une mission d'intérêt public dont est investi le responsable de traitement et les intérêts légitimes poursuivis par lui. De plus, au titre de l'article 9 du RGPD le responsable de traitement peut de manière exceptionnelle traiter des catégories particulières de données, incluant des données de santé notamment à des fins de recherche scientifique.

Préalablement aux entretiens, votre identité (nom, prénom) et vos coordonnées renseignées sur le document d'invitation de participation seront transmises aux investigateurs de l'étude pour qu'ils puissent vous contacter et programmer l'entretien. Un code d'identification vous sera attribué (N° et Initiales). A la fin de la recherche, les données identifiantes transmises aux investigateurs (nom, prénom, coordonnées) seront détruites et seuls des données codées seront conservées pour l'analyse.

Par ailleurs, sauf opposition de votre part adressée à l'investigateur principal dont les coordonnées figurent sur la première page de ce document, vos données recueillies dans le cadre de cette étude pourront être transmises ailleurs dans le monde et réutilisées par des partenaires publics ou privés lors de recherches ultérieures exclusivement à des fins scientifiques. En cas de transfert de données à caractère personnel hors de l'Union Européenne et/ ou vers un pays ne garantissant pas un niveau de protection suffisant par rapport à l'Union Européenne ou à une organisation internationale, le promoteur et/ou le responsable de traitement mettront en place des garanties appropriées pour ce transfert (Clauses Contractuelles Spécifiques). Si vous souhaitez obtenir une copie des Clauses Contractuelles Spécifiques, vous pouvez vous adresser au Délégué à la Protection des Données (DPO) :

- du promoteur à l'adresse suivante : dpo@chu-lyon.fr.
- ou de l'UCBL à l'adresse suivante : donnees.personnelles@univ-lyon1.fr.

Si vous avez des questions ou des réclamations au sujet du traitement de vos données au cours de cette étude, vous pouvez contacter le DPO par voie électronique ou par courrier postal :

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Si vous estimez, après avoir contacté les DPO, que vos droits sur vos données ne sont pas respectés, vous pouvez adresser une réclamation (plainte) à la CNIL : <https://www.cnil.fr/fr/webform/adresser-une-plainte>

Les données personnelles se rapportant à cette étude pourront être accessibles aux personnes mandatées par le Promoteur (responsable de la recherche) ainsi qu'aux Autorités de santé. Toutes les personnes participant à la réalisation de l'étude ou à l'analyse de ses résultats sont tenues au plus strict secret professionnel.

Conformément à la réglementation française et européenne, les données de l'étude ne seront pas conservées plus de 2 ans après la publication des derniers résultats ou, en l'absence de publication, au-delà de la signature du rapport final de l'étude et seront archivées durant 25 ans.

➤ **Exercer vos droits**

Le registre des patients contenant le code d'identification composé d'un numéro et des initiales de votre nom et votre prénom sera conservé uniquement par l'investigateur. Vous pourrez, à tout moment, exercer votre droit d'accès, de vérification, de correction, de limitation, d'effacement et d'opposition au traitement et à la transmission des données vous concernant en en faisant la demande auprès du médecin de votre choix ou auprès d'un investigateur de l'étude. Si vous souhaitez exercer votre droit à l'effacement de vos données, le responsable de traitement peut au titre des Articles 17.3.c et 17.3.d. du RGPD ne pas faire droit à cette demande si celle-ci est susceptible de rendre impossible ou de compromettre gravement la réalisation des objectifs de la recherche. Ainsi, vos données recueillies préalablement au retrait de votre consentement pourront ne pas être effacées et pourront continuer à être traitées dans les conditions prévues par la recherche.

Si les résultats de cette étude devaient être présentés dans des communications et/ou des publications scientifiques médicales, votre identité n'apparaîtra d'aucune façon.

A l'issue de l'étude, les résultats globaux de la recherche pourront vous être communiqués sur simple demande auprès du coordonnateur de l'étude. La base de données de l'étude rendue totalement anonyme pourra être transmise à d'autres chercheurs qui travailleraient sur le même sujet.

➤ **Aspects éthiques et réglementaires**

La présente étude est conduite conformément à la législation et à la réglementation en vigueur.

Le Comité de Protection des Personnes Ouest III a émis un avis favorable à la réalisation de cette étude le 20/03/2020. Cette recherche a obtenu l'autorisation de la Commission Nationale de l'Informatique et des Libertés (CNIL).

➤ **Qui contacter pour toute question ?**

Si vous avez des questions sur l'étude ou des inquiétudes, ou si vous ressentez une gêne ou un handicap résultant de votre participation à cette étude, vous pouvez à tout moment contacter le médecin qui assure votre prise en charge :

Nom / Prénom : SIQUEIRA DO PRADO Luiza

Adresse : Laboratoire HESPER EA 7425

Téléphone : luiza.siqueira-do-prado@univ-lyon1.fr

L'ensemble de l'équipe HESPER et les Hospices Civils de Lyon vous remercient d'avoir pris le temps de lire ce document, et le cas échéant, vous remercie pour votre participation à cette étude.

➤ **Autorisation enregistrement de la voix**

Prénom, NOM :

J'ai bien noté :

- L'enregistrement audio des entretiens
- Que l'enregistrement
 - sera transcrit mot à mot, sauf les noms des personnes, des lieux ou des institutions.
 - sera conservé jusqu'à analyse des données et sera ensuite détruit à la fin de l'étude

☐ **J'accepte l'enregistrement audio des l'entretiens.**

☐ **Je n'accepte pas l'enregistrement audio de l'entretien.**

Date : __/__/__

Signature

Annex 7 – Formulaire invitation professionnels
Study VOIES-D-ql

Invitation à participer à un entretien dans le cadre de l'étude :

***Étude qualitative sur l'expérience individuelle d'utilisation et de planification
de soins des personnes ayant un diabète et des professionnels
de santé en diabétologie - VOIES-D-ql***

Date : |_|_| / |_|_| / |_|_|_|_|

Nom et prénom : _____

Année de naissance : |_|_|_|_|

Genre : F ☐ H ☐ Autre ☐

Quelle est votre profession ?

- ☐ Infirmier(e)
- ☐ Diététicien(ne)
- ☐ Interne
- ☐ Diabétologue
- ☐ Chef de service
- ☐ Aide-Soignant(e)
- ☐ Autre :

Pratiquez-vous en libéral ? ☐ Oui ☐ Non

Depuis combien d'années suivez-vous des patients avec ces maladies ?

Durée	Diabète de type 1	Diabète de type 2
Je ne suis pas ce type de patients	<input type="checkbox"/>	<input type="checkbox"/>
Moins de 5 ans	<input type="checkbox"/>	<input type="checkbox"/>
5 à 10 ans	<input type="checkbox"/>	<input type="checkbox"/>
10 à 19 ans	<input type="checkbox"/>	<input type="checkbox"/>
20 à 29 ans	<input type="checkbox"/>	<input type="checkbox"/>
30 ans et plus	<input type="checkbox"/>	<input type="checkbox"/>

À quelle fréquence avez-vous vu des patients avec ces maladies au cours des dernières 12 mois ?

Durée	Diabète de type 1	Diabète de type 2
Plus de 1 patient par semaine	<input type="checkbox"/>	<input type="checkbox"/>
1 patient par semaine	<input type="checkbox"/>	<input type="checkbox"/>
1-3 patients par mois	<input type="checkbox"/>	<input type="checkbox"/>
Moins de 1 patient par mois	<input type="checkbox"/>	<input type="checkbox"/>

Annex 8 – Note d'information professionnels
Study VOIES-D-ql



Hospices Civils de Lyon
Direction de la Recherche Clinique
et de l'Innovation

NOTE D'INFORMATION A L'ATTENTION DES PROFESSIONNELS DE SANTÉ

Étude qualitative sur l'expérience individuelle d'utilisation et de planification de soins des personnes ayant un diabète et des professionnels de santé en diabétologie VOIES-D-ql

Version 2 du 16/03/2020

PROMOTEUR : **Hospices Civils de Lyon**
Direction de la Recherche Clinique et de l'Innovation (DRCI)
3, quai des Célestins
BP 2251 69229 Lyon Cedex 02
Tel : 04 72 40 68 52 Fax : 04 72 11 51 90

INVESTIGATEUR PRINCIPAL: **Dr Dima Alexandra Lelia**
EA 7425 HESPER Health Services and Performance Research
Université Claude Bernard Lyon 1
Domaine Rockefeller- 4eme étage (aile CD)
8 avenue Rockefeller
69373 Lyon 8
Tél : 06 32 86 82 37
Email : alexandra.dima@univ-lyon1.fr

Madame, Monsieur,

Vous avez été invité.e à participer à une recherche intitulée VOIES-D-ql, qui pourrait vous intéresser du point de vue de votre expérience dans la prise en soins des patients ayant un diabète de type 1 ou de type 2.

Ce document a pour objectif de vous donner toutes les informations relatives à cette étude de façon à vous permettre d'exercer au mieux votre liberté de décision. Ce document est obligatoire et son contenu est défini par le Code de la Santé Publique, article L 1122-1.

Merci de prendre le temps de **lire attentivement les informations qui suivent**. Vous avez le droit de prendre le temps de réfléchir, de discuter de cette étude et de poser toutes les questions que vous souhaitez sur cette étude, à qui vous voulez (votre association professionnelle, par exemple).

La présente notice d'information vous sera remise pour que vous puissiez bénéficier de l'ensemble des informations.

Votre participation à l'étude est entièrement libre et volontaire.

Quel est l'objectif de cette étude ?

Vivre avec une maladie chronique exige, dans la majorité des cas, de multiples interactions avec des professionnels de santé et le système de santé pour garder la meilleure qualité de vie possible. Ces interactions génèrent une grande quantité de données médicales. Cependant, le transfert de ces données entre les différents professionnels de santé impliqués reste souvent à la responsabilité du patient et de ses proches, tout comme la reconstitution du parcours d'utilisation de soins. Le partage de ces informations est nécessaire pour aider à la prise de décision entre patients et professionnels, sur les prochaines étapes de la prise en soins. Des outils de visualisation pourraient être développés pour aider professionnels et patients dans ce processus.

L'objectif de cette étude est de décrire les expériences des professionnels dans la construction et planification du parcours de soins des personnes ayant un diabète sur 3 angles : clinique (les informations cliniques considérées comme essentielles pour la prise de décision en santé et la planification des étapes ultérieures du parcours), technologique (l'entrée de données et l'utilisation d'outils technologiques comme des logiciels pour obtenir ou stocker des informations), et comportementale (le processus de prise de décision partagée et les interactions avec les autres professionnels).

➤ Déroulement de l'étude et nature des données recueillies

Nous vous proposons de remplir un questionnaire initial et de vous rencontrer d'ici 6 mois en face à face ou par téléphone lors d'un entretien d'environ 30 minutes. Dans les 6 mois suivant cet entretien, et si vous le souhaitez, vous pouvez participer à un deuxième entretien d'environ 30 minutes pour évaluer et améliorer le prototype d'un outil qui sera développé à partir des préférences des professionnels interviewés dans cette première phase. Nos échanges seront enregistrés, avec votre accord, afin de recueillir le plus d'informations possible. Ces entretiens pourront se dérouler par téléphone, à votre lieu de travail, dans les locaux de l'équipe ou dans tout autre lieu public qui vous arrangerait.

Les enregistrements seront transcrits mot-à-mot, sauf les noms des personnes, des lieux ou des institutions (pour garder la confidentialité des participants aux entretiens). Ils seront utilisés pour décrire la manière dont la collaboration entre les différents participants aux soins a lieu, ainsi que les différents points de vue sur les solutions d'amélioration des soins collaboratifs.

Ces transcrits seront conservés en toute sécurité pendant 25 ans dans les locaux de l'investigateur principal où la recherche a eu lieu, en conformité avec la réglementation en vigueur.

En revanche les enregistrements ne seront conservés que jusqu'à l'analyse des données de l'étude afin de pouvoir les écouter à nouveau dans le cas où le transcrit ne serait pas assez claire ou s'il y a besoin de plus d'informations (pause, intonation, etc.). Ils seront ensuite détruits.

A cet effet, nous vous demandons de nous notifier votre accord par e-mail pour l'enregistrement audio. Si vous ne souhaitez pas répondre par e-mail, il sera également possible de compléter et signer l'encadré situé à la fin de cette notice d'information, et de nous la remettre en main propre en cas d'entretien en face-à-face. Vous devrez en conserver un exemplaire.

➤ Participation volontaire

Votre participation à cette étude est volontaire et vous avez le droit de réfléchir avant de prendre votre décision. Vous êtes libre de vous opposer à votre participation à cette étude et ce à tout moment et sans avoir à vous justifier.

Si vous choisissez de ne pas participer à cette étude vous conserverez tous vos droits garantis par la loi et recevrez les soins nécessaires appropriés.

De même, si vous décidez de participer à cette recherche, mais que vous changiez d'avis au cours de celle-ci, vous pouvez à tout moment demander d'interrompre votre participation à l'étude sans aucun préjudice, sans justification de votre part et sans que votre responsabilité ne soit engagée. Dans ce cas, vos données recueillies jusque-là seront utilisées dans les résultats de l'étude.

Si vous décidez d'arrêter votre participation à l'étude, vous devrez en informer l'investigateur principal de l'étude dont les coordonnées figurent sur la première page de ce document.

Celui-ci est également en droit d'arrêter votre participation à l'étude à n'importe quel moment, s'il considère que ceci est dans votre intérêt.

Durant votre participation à l'étude, vous serez informé de toute découverte importante et qui pourrait affecter votre décision de continuer à participer à cette étude.

➤ **Confidentialité et protection des données**

Un traitement informatique de vos données personnelles va être mis en œuvre pour permettre d'analyser les résultats de la recherche au regard de l'objectif de cette dernière. Le responsable du traitement des données est le promoteur, dont les coordonnées figurent sur la première page de ce document, conjointement avec l'Université Claude Bernard de Lyon (UCBL). Ce traitement des données a pour fondement juridique l'article 6 du Règlement Général sur la Protection des Données (RGPD) à savoir l'exécution d'une mission d'intérêt public dont est investi le responsable de traitement et les intérêts légitimes poursuivis par lui. De plus, au titre de l'article 9 du RGPD le responsable de traitement peut de manière exceptionnelle traiter des catégories particulières de données, incluant des données de santé notamment à des fins de recherche scientifique.

Préalablement aux entretiens, votre identité (nom, prénom) et vos coordonnées renseignées sur le document d'invitation seront transmises aux investigateurs de l'étude pour qu'ils puissent vous contacter et programmer l'entretien. Un code d'identification vous sera attribué (N° et Initiales). A la fin de la recherche, les données identifiantes transmises aux investigateurs (nom, prénom, coordonnées) seront détruites et seuls des données codées seront conservées pour l'analyse.

Par ailleurs, sauf opposition de votre part adressée à l'investigateur principal dont les coordonnées figurent sur la première page de ce document, vos données recueillies dans le cadre de cette étude pourront être transmises ailleurs dans le monde et réutilisées par des partenaires publics ou privés lors de recherches ultérieures exclusivement à des fins scientifiques. En cas de transfert de données à caractère personnel hors de l'Union Européenne et/ ou vers un pays ne garantissant pas un niveau de protection suffisant par rapport à l'Union Européenne ou à une organisation internationale, le promoteur et/ou le responsable de traitement mettront en place des garanties appropriées pour ce transfert (Clauses Contractuelles Spécifiques). Si vous souhaitez obtenir une copie des Clauses Contractuelles Spécifiques, vous pouvez vous adresser au Délégué à la Protection des Données (DPO) :

- du promoteur à l'adresse suivante : dpo@chu-lyon.fr.
- ou de l'UCBL à l'adresse suivante : donnees.personnelles@univ-lyon1.fr.

Si vous avez des questions ou des réclamations au sujet du traitement de vos données au cours de cette étude, vous pouvez contacter le DPO par voie électronique ou par courrier postal :

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de limitation, d'effacement et d'opposition au traitement et à la transmission des données vous concernant en en faisant la demande auprès du médecin de votre choix ou auprès d'un investigateur de l'étude. Si vous souhaitez exercer votre droit à l'effacement de vos données, le responsable de traitement peut au titre des Articles 17.3.c et 17.3.d. du RGPD ne pas faire droit à cette demande si celle-ci est susceptible de rendre impossible ou de compromettre gravement la réalisation des objectifs de la recherche. Ainsi, vos données recueillies préalablement au retrait de votre consentement pourront ne pas être effacées et pourront continuer à être traitées dans les conditions prévues par la recherche.

Si les résultats de cette étude devaient être présentés dans des communications et/ou des publications scientifiques médicales, votre identité n'apparaîtra d'aucune façon.

A l'issue de l'étude, les résultats globaux de la recherche pourront vous être communiqués sur simple demande auprès du coordonnateur de l'étude. La base de données de l'étude rendue totalement anonyme pourra être transmise à d'autres chercheurs qui travailleraient sur le même sujet.

➤ **Aspects éthiques et réglementaires**

La présente étude est conduite conformément à la législation et à la réglementation en vigueur.

Le Comité de Protection des Personnes Ouest III a émis un avis favorable à la réalisation de cette étude le 20/03/2020.

Cette recherche a obtenu l'autorisation de la Commission Nationale de l'Informatique et des Libertés (CNIL).

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Nom / Prénom : SIQUEIRA DO PRADO Luiza

Adresse : Laboratoire HESPER EA 7425

Téléphone : luiza.siqueira-do-prado@univ-lyon1.fr

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➤ **Autorisation enregistrement de la voix**

Prénom, NOM :

J'ai bien noté :

- L'enregistrement audio des entretiens
- Que l'enregistrement
 - sera transcrit mot à mot, sauf les noms des personnes, des lieux ou des institutions.
 - sera conservé jusqu'à analyse des données et sera ensuite détruit à la fin de l'étude

☐ **J'accepte l'enregistrement audio de l'entretien.**

☐ **Je n'accepte pas l'enregistrement audio de l'entretien.**

Date : __/__/____

Signature