Parcours en santé : épistémologie et pratiques de modélisation

Benjamin Du Sartz de Vigneulles

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Université Claude Bernard Lyon 1

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Parcours en santé : épistémologie et pratiques de modélisation

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Résumé

Les sociétés contemporaines traversent une transition épidémiologique et démographique où l'essor des maladies chroniques, la fragmentation de l'offre et le cloisonnement des acteurs exacerbent les tensions sanitaires et financières. Pour restaurer la cohérence organisationnelle, le concept de « parcours en santé » s'est imposé comme cadre fédérateur soutenant la coopération interprofessionnelle. Mais la complexité inhérente à cette approche multidimensionnelle en limite le déploiement. La modélisation constitue un levier essentiel pour réduire cette complexité et éclairer les démarches organisationnelles, à condition de sélectionner la technique la plus appropriée. Cette thèse cherche à optimiser la conception d'une modélisation de parcours en santé. Elle s'articule en quatre parties : (i) un état de l'art des méthodes de modélisation ; (ii) l'identification de déterminants invariants susceptibles d'influencer un parcours ; (iii) la modélisation systémique du parcours du patient hémophile ; (iv) la modélisation du parcours du patient douloureux aux urgences.

Les résultats montrent la possibilité de constituer un répertoire des méthodologies utilisées pour modéliser des parcours, l'influence déterminante de certains facteurs sur les parcours mis en place, l'identification précise de critères organisationnels prioritaires pour une équipe de soins, et l'apport de l'analyse de criticité pour repérer les étapes les plus à risque de défaillance dans un parcours.

Ces contributions associées à d'autres permettent de proposer une démarche de réflexion favorisant la conception pertinente d'une modélisation d'un parcours en santé.

Mots clés : parcours de soins, parcours en santé, méthodologie, modélisation, santé publique

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Title

Healthcare pathways: epistemology and modeling practices

Summary

Contemporary societies are going through an epidemiological and demographic transition, in which the rise of chronic diseases, the fragmentation of services and the compartmentalization of actors are exacerbating health and financial tensions. To restore organizational coherence, the concept of the “healthcare pathway” has emerged as a unifying framework supporting inter-professional cooperation. But the inherent complexity of this multidimensional approach limits its deployment. Modeling is an essential lever for reducing this complexity and informing organizational approaches, provided the most appropriate technique is selected. This thesis seeks to optimize the conception of healthcare pathway modeling. It is divided into four parts: (i) a state-of-the-art review of modeling methods; (ii) identification of invariant determinants likely to influence a pathway; (iii) systemic modeling of the hemophiliac patient's pathway; (iv) modeling of the painful emergency patient's pathway.

The results show that it is possible to compile a repertory of the methodologies used to model care pathways, the decisive influence of certain factors on the care pathways implemented, the precise identification of priority organizational criteria for a care team, and the contribution of criticality analysis in identifying the stages most at risk of failure in a care pathway.

These contributions, combined with others, provide an approach for thinking about the relevant conception of modeling healthcare pathways.

Keywords:

care pathways, healthcare pathways, methodology, modeling, public health

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Liste des abréviations

AMDEC : Analyse des Modes de Défaillances, de leurs Effets et de leur Criticité

ANAP : Agence Nationale d'Appui à la Performance sanitaire et médico-sociale

ARS : Agence Régionale de Santé

CC : Chemin Clinique

CIF : Classification Internationale du Fonctionnement, du Handicap et de la Santé

CLS : Contrat Local de Santé

CDSI : Caractéristiques décisives en santé d'un Individu

CNSA : Caisse Nationale de Solidarité pour l'Autonomie

COP : Critères Organisationnels Primordiaux

CPTS : Communauté Professionnelle Territoriale de Santé

CTS : Conseil Territorial de Santé

DAC : Dispositifs d'Appui à la Coordination

DIPS : Déterminants Invariant de Parcours en Santé

DPS : Déterminant de Parcours en Santé

DS : Déterminant de santé

EBM : Evidence Based Medicine (médecine fondée sur les preuves)

ETP : Education Thérapeutique du Patient

HPST : Hôpital Patient Santé Territoire

IA : Intelligence Artificielle

MAIA : Méthode d'Action pour l'Intégration des services d'Aide et de soins dans le champ de l'autonomie

MCDA : Multi Criteria Decision Analysis (analyse décisionnelle multicritères)

MNT : Maladies Non Transmissibles

MSP : Maisons de Santé Pluridisciplinaire

NPM : New Public Management (nouvelle gestion publique)

OMS : Organisation Mondiale de la Santé

PAERPA : Personnes Âgées En Risque de Perte d'Autonomie

PCO : Plateformes de Coordination et d'Orientation

PPCS : Plan Personnalisé de Coordination Santé

PREMs : Patient-Reported Expérience Measures (mesures de l'expérience rapportée par les patients)

PROMs : Patient-Reported Outcome Measures (mesures des résultats rapportés par les patients)

PRS : Projet Régional de Santé

RAI-HC : Resident Assessment Instrument – Home-Care (questionnaire d'évaluation de soins à domicile)

UE : Union Européenne

1. INTRODUCTION

1.1 Le contexte d'émergence de la cohérence organisationnelle en santé

Par le passé, la maladie était essentiellement définie comme un dysfonctionnement temporaire, principalement causé par des affections aiguës, telles que les infections bactériennes et virales, ou les traumatismes physiques (1). Cependant, les sociétés modernes, notamment du fait d'un essor scientifique et technologique, ont été marquées par une transition épidémiologique et démographique, appelée aussi « transition sanitaire » (2).

D'un côté, depuis la révolution industrielle, une nouvelle ère s'est ouverte dans laquelle les actions humaines (pollution par exemple) ont entrainées des conséquences nuisibles à la santé, pouvant engendrer l'apparition de pathologies et de décès prématurés (3). De plus, les nouveaux modes de vie, majoritairement urbains, caractérisés par une sédentarité et une alimentation riche en graisses et en sucres, ont induit le développement de nouveaux risques sanitaires (syndrome métabolique par exemple) dans les populations (4). Aujourd'hui, ce sont donc principalement les maladies non transmissibles (MNT), telles que les pathologies cardiovasculaires ou respiratoires, les cancers, ou les pathologies métaboliques, qui représentent un problème majeur de santé publique, à l'origine d'environ 75% des décès dans le monde (43 millions) en 2021 (5). Au sein de l'Union Européenne (UE), les MNT sont à l'origine de 90% des décès (6) et leur prévalence continue d'augmenter. Par exemple, le nombre d'adultes vivant avec un diabète dans le monde est de 537 millions et devrait atteindre 783 millions d'ici 2045 (7). Les MNT font peser une lourde charge sur les personnes qui en sont atteintes et sur leurs familles, ainsi que sur les systèmes de soins de santé, les économies nationales. Les MNT représentent en effet 80 % de la charge sanitaire dans les pays de l'UE (8). Cette évolution de la situation sanitaire dans le monde est caractérisée par l'Organisation Mondiale de la Santé (OMS) comme une « épidémies de maladies non transmissibles » (9).

D'un autre côté, les avancées scientifiques ont permis de réduire considérablement certaines pathologies et leurs impacts. Par exemple, les progrès en matière de techniques de diagnostic, le développement de l'imagerie médicale notamment, ont permis des prises en charge plus précoces des MNT (10). De nouvelles options thérapeutiques, comme l'immunothérapie ou les thérapies ciblées, ont amélioré les perspectives vitales (11). Ces innovations ont permis d'améliorer les pronostics pour des millions de patients, transformant des pathologies autrefois incurables en maladies chroniques, comme pour certains cancers par exemples. Ceci est également le cas pour les maladies transmissibles telles que le SIDA, l'hépatite virale ou la syphilis, qui affectent encore des millions de personnes dans le monde chaque année (12). Par exemple, le recours précoce a des solutions thérapeutiques

innovantes a transformé le pronostic de l'infection par le VIH d'une maladie rapidement progressive et finalement mortelle en une condition chronique ayant un impact limité sur l'espérance de vie (13).
Ces avancées dans les soins se traduisent également en une baisse du taux de mortalité en général, et en une transition démographique favorable à un vieillissement des populations (14). Il y a donc de plus en plus de personnes ayant une ou plusieurs pathologies chroniques. Une pathologie chronique entraine généralement un recours permanent ou régulier à de multiples services en santé (soins médicaux, aide psychologique, aide sociale,…) (15).

Cette transition sanitaire a entrainé des conséquences économiques et sociales majeures (16). Elle est apparue dans de nombreux pays, comme le Pérou (17),le Qatar (18), la Chine (19), l'Australie (20), mais aussi en Afrique (21) et en Asie du sud par exemple (22) ; ainsi qu'en France (23). Les systèmes de santé ont dû prendre en compte la pluralité et la durabilité de nombreuses pathologies et adapter leurs organisation afin répondre à des besoins de soins plus longs et continus, qui sont venus peser comme une épreuve sur nos sociétés (24). La croissance rapide des coûts médicaux a ainsi posé de sérieux défis aux Etats. Par exemple, il a été montré que dans certains pays, une meilleure gestion de la santé et des MNT pourrait sauver plus de 8 millions de vies et générer près 350 milliards de dollars de bénéfices d'ici 2030 (25). Pour minimiser les coûts de soins et épargner les ressources en santé d'une surcharge, tout en garantissant la qualité des soins, les systèmes de santé ont dû évoluer (26).

Cette transition sanitaire s'est développée dans le contexte de fragilités économiques globales des années 1970-1980 (27) (dont essentiellement les « chocs pétroliers »). Dans ce cadre, les gouvernements de nombreux pays occidentaux ont cherché à réduire les dépenses publiques et à améliorer l'efficience des administrations. Ainsi, le concept de « New Public Management » (NPM), traduit en français par « nouvelle gestion publique », a émergé, principalement dans les pays occidentaux basés sur les principes de économie libérale (28). Il s'agit d'un ensemble de réformes administratives ayant pour but de moderniser le secteur public en introduisant des principes issus de la gestion privée. Une des principales caractéristiques du NPM est l'évaluation de la performance. Les administrations publiques ont alors eu comme nouvelle norme de gestion de se fixer des objectifs précis et d'évaluer régulièrement les résultats par des indicateurs quantifiables, comme par exemple la réduction des délais et durées de prises, en charge en France (29) comme dans d'autres pays (30).

Ainsi, face aux nouvelles exigences imposées par la transition sanitaire et par la recherche d'efficience, les systèmes de santé, dont celui de la France, ont été contraints de réformer leurs organisations. Ces réformes institutionnelles ont affecté plusieurs aspects du système de santé, de la gestion des hôpitaux à l'organisation des soins primaires (premier niveau de contact entre les individus

et le système de santé : médecins généralistes, infirmiers ou pharmaciens), en passant par l'intégration des nouvelles technologies dans les pratiques.

Les décideurs politiques du monde entier expérimentent depuis longtemps des modèles de financement des hôpitaux afin d'améliorer la performance des systèmes (31). Ainsi par exemple, les financements aux résultats ou à la performance ont été développés en plus ou en remplacement du paiement forfaitaire ou de la capitation globale (32). En France, le financement des établissements de soins a été réformé. Plutôt que de recevoir un budget global fixe, ces établissements ont été financés proportionnellement à l'activité réelle de soins (33). C'est alors l'essor du principe de la « tarification à l'activité » (T2A) dans le but de rendre les établissements plus compétitifs entre eux, induisant ainsi l'atteinte de rentabilité (34). En parallèle, une démarche de redéfinition des hospitalisations a été initiée dans plusieurs pays comme au Canada (35), aux Etats-Unis (36), en Autriche (37), en Suisse (38), en Allemagne (39), en Russie (40) et en France, par le principe de « virage ambulatoire » (41). Il s'agit d'une stratégie de réorganisation des soins visant à privilégier les prises en charge qui évitent les hospitalisations traditionnelles complètes. Ainsi, de nombreux actes médicaux (diagnostics ou interventions chirurgicales par exemple) peuvent être réalisés sans nécessiter un séjour prolongé à l'hôpital. Cela permet de réduire les coûts, d'optimiser les ressources hospitalières, d'améliorer l'expérience des patients et de s'adapter aux avancées technologiques (42). D'autres révisions des politiques de financements ont pu être mises en place, telles que la rémunération sur objectifs de santé publique pour les soins primaires en France (43). En parallèle, des réformes de fonctionnements ont été instaurées afin de favoriser une gouvernance de proximité par décentralisation, de favoriser une organisation territoriale efficiente, ou de mutualiser les ressources afin de générer des économies d'échelle. Ainsi, en France, plusieurs lois se sont succédées en quelques années telles que : la loi n° 2009-879 du 21 juillet 2009 portant réforme de l'hôpital et relatif aux patients, à la santé et aux territoires (HPST), la loi n° 2016-41 du 26 janvier 2016 de modernisation de notre système de santé, la loi n° 2019-774 du 24 juillet 2019 relative à l'organisation et à la transformation du système de santé, la loi n°2023-1268 du 27 décembre 2023 visant à améliorer l'accès aux soins par l'engagement territorial des professionnels. Concrètement, cela s'est traduit par l'émergence des agences régionales de santé (ARS) (44), les maisons de santé pluridisciplinaires (MSP) et les communautés professionnelles territoriales de santé (CPTS), ou les groupements hospitaliers de territoires par exemple (45).

Toujours dans le but de réduire les tensions sur les systèmes de santé, ces changements se sont accompagnés de redéfinitions des rôles et des activités de certains professionnels de santé, avec par ailleurs l'introduction de nouvelles compétences et la définition de nouveaux métiers. Les infirmières, par exemple, jouent un rôle de plus en plus central dans le suivi des patients atteints de pathologies chroniques, et cela s'est traduit par la mise en place du statut d'infirmière en pratiques avancées (46),

ou chez les pharmaciens la possibilité de prescrire et d'administrer des vaccins (47). On parle dès lors de mesures permettant les délégations de tâches (48), libérant ainsi du temps médical. Également, le métier d'assistant médical a été déployé, avec pour mission d'effectuer des tâches à la fois administratives, organisationnelles, mais aussi de préconsultation (prises de constantes, …) (49). En outre, le métier de coordinateur de regroupements pluriprofessionnels de soins primaires (MSP ou CPTS) a été créé, avec pour mission d'effectuer des tâches de gestion administrative et financière, gestion d'équipe (mobilisation, planification et animation de réunions, suivi des décisions…), gestion des relations (internes et externes), gestion d'actions de santé publique, … (50)

Les transformations conceptuelles et organisationnelles des systèmes de santé cherchent à répondre aux mutations profondes liées notamment aux évolutions épidémiologiques en santé et sociétales. Elles ont été accompagnées par des évolutions dans les pratiques professionnelles en santé. En effet, la diversité des maladies et la chronicisation de nombreuses pathologies ont conduit aux phénomènes de division (ou répartition) du travail et d'hyperspécialisation (51). La division du travail est une caractéristique clé du fonctionnement d'une société en vue de maximiser la production et l'efficacité, en permettant aux individus de se concentrer sur des tâches spécifiques, au lieu de devoir accomplir l'ensemble des tâches nécessaires (52). Ainsi, la division du travail a participé au développement de l'hyperspécialisation et a conduit à une dépendance mutuelle entre différents individus, car les différentes étapes de production dépendent des compétences des uns et des autres pour aboutir à un résultat final. Cela s'est traduit par un cloisonnement des secteurs d'activité : soins de ville, soins hospitaliers, soins médico-sociaux… (53). Ce cloisonnement s'est caractérisé par une fragmentation de l'offre de soins dans de nombreux pays, comme la Colombie (54), les Etats-Unis, le Canada, Singapour (55), le Japon (56),ou la Chine (57) par exemple. En France, cela s'est traduit par plus de 180 métiers dans le domaine de la santé et près de 150 spécialités médicales (58), une segmentation des législations, et une dispersion des repères et dispositifs. Un tel cloisonnement du système de santé a finalement compliqué la prise en charge de patients, notamment en raison de barrières structurelles, logistiques et culturelles (59). Il est apparu comme étant un véritable obstacle à la continuité, à la qualité et à la cohérence des soins et des autres services en santé, et un obstacle dans la lutte contre la progression des inégalités d'accès aux soins (60). Ce cloisonnement est également apparu comme étant un obstacle à l'efficience économique en santé (61). Par conséquent, opérer un décloisonnement des organisations de santé est devenu une nécessité (62).

La recherche de cohérence organisationnelle a été initialement basée sur la gestion de la production de prestations et la gestion de l'organisation des soins. La gestion de la production de prestations s'est appuyée sur un phénomène de standardisation par le développement de l'« evidence based medicine » (EBM), décliné en France sous le terme de « pratique fondée sur des données

probantes », ou de « médecine fondée sur les preuves » (63). Il s'agit d'une approche de la prise de décision où les praticiens de santé utilisent les meilleures données disponibles issues de la recherche (essais cliniques ou études scientifiques) pour mettre en application les pratiques ayant démontré une efficacité clinique et un niveau de sécurité considéré comme acceptable. Ces meilleures données disponibles peuvent être utilisées pour élaborer des guides de recommandations dites de « bonnes pratiques », ou de « protocoles de prise en charge », contribuant à la mise en œuvre de plan de gestion des maladies partagés par tous. Bien que critiquable sous certains aspects, cette approche de performance a permis de contrôler les coûts médicaux et d'améliorer la qualité des soins (64).

La gestion de l'organisation des soins s'est appuyée initialement sur le principe de coordination des tâches (65). Il s'agissait d'abord d'ordonner les interventions. Puis la coordination s'est développée par la gestion des interactions entre acteurs afin d'harmoniser leurs différentes actions. La coordination se définit comme une action conjointe des professionnels de santé et des structures en vue d'organiser la meilleure prise en charge des patients notamment en termes de programmation des étapes diagnostiques et thérapeutiques, dans une logique dite de « juste recours aux soins » (66). La coordination relève alors d'une dimension fonctionnelle (67), et elle est le corollaire d'une démarche volontariste de coopération entre acteurs, qui elle relève d'une dimension stratégique et répond en premier lieu à une demande de prise en compte de la complexité. Cette approche d'efficience vise la juste articulation entre les prestations. Dans ce sens, des concepts organisationnels ont émergé.

> Par exemple, à un niveau macro du système, la méthode du patient traceur est un outil d'évaluation de conformité aux procédures de soins, et des effets de la coordination. Elle consiste à suivre le parcours d'un patient (réel ou fictif) au sein du système de santé. L'objectif est d'analyser les interactions entre les professionnels et avec les patients, en termes structurels et de processus pour identifier d'éventuels dysfonctionnements (retards, redondances, manque de communication,…) (68).
>
> A un niveau micro du système, il y a la « gestion de cas », mission au cours de laquelle un professionnel dédié centralise les informations concernant un patient en situation complexe, organise les interventions des professionnels de santé et assure leurs liens (69). Il personnalise donc la coordination pour un patient donné en mobilisant de façon cohérente toutes les ressources nécessaires à ses besoins. Il s'agit d'un accompagnement intensif de proximité (70).
>
> Mais la coordination suppose une clarification des tâches de chacun pour une gestion adéquate des interactions entre acteurs. C'est sur cette notion de gestion des tâches que va émerger le concept de parcours en santé.

1.2. Le parcours en santé : une dynamique organisationnelle et un principe fonctionnel

1.2.1. La théorie : un concept multidimensionnel

Le parcours en santé est d'abord un concept, c'est-à-dire un objet abstrait, mental, constitué d'idées, issues principalement de connaissances et de raisonnements (71). Le parcours en santé est un concept qui s'est construit progressivement sur la base de deux approches différentes, complémentaires, qui se sont développées parallèlement : « l'approche processuelle du soin » et « l'approche biopsychosociale de la santé ».

1.2.1.1. Le concept de parcours issu d'une organisation basée sur l'offre : « l'approche processuelle du soin »

La gestion de la qualité des soins a été considérée comme relevant de la standardisation des processus de prise en charge (72). Un processus est une série d'activités ou d'actions ordonnées et interconnectées, visant à atteindre un objectif précis, dont chaque étape est conçue pour transformer des ressources (matérielles, humaines, ou informationnelles) en résultats qui contribuent au but final (72). Les processus sont souvent perfectionnés pour assurer la cohérence, l'efficacité, et la qualité d'une production. Ainsi, un processus de soins est une séquence d'étapes, une planification d'activités cliniques et administratives destinées à fournir un traitement à un patient, depuis sa première interaction avec le système de santé jusqu'à la fin de sa prise en charge. Chaque étape de ce processus vise à diagnostiquer, traiter et accompagner le patient pour, en premier lieu, favoriser son rétablissement. Chacune d'entre elles est alors productrice d'une contribution précise qu'il convient d'identifier en termes d'enjeux, de contenu et de qualité-sécurité (73).

Inspirée des sciences du management dans le cadre de la production manufacturière Outre-Atlantique, les techniques de clarification des activités de transformation processuelle d'éléments entrants en éléments sortants se sont développées (74). Au début du XX^{ème} siècle, Frederick Taylor a appliqué la méthode scientifique à l'industrie manufacturière pour déterminer « la meilleure façon de faire chaque travail » (75). Ce type de management a favorisé l'émergence d'une culture organisationnelle reposant sur des principes tels que l'analyse des tâches, leur standardisation, la séparation entre conception et exécution, le contrôle strict, la rémunération au rendement, et la formation et la sélection. Par cette rationalisation forte du travail, il s'agit de résoudre les défaillances inhérentes à toutes les réalisations de l'Homme, et principalement d'augmenter la productivité en réduisant les gaspillages. Cette méthode taylorisme a largement diffusé dans de nombreux milieux professionnels, y compris dans la sphère médicale (76).

Ainsi, l'ordonnancement détaillé en séquences successives de tâches prévues s'est développé autour de la notion de « critical pathway », décliné en France sous le terme de « chemin critique », dans le cadre de la gestion de processus en général(77). Il s'agit d'une méthode qui met en évidence les interrelations entre les activités et permet de visualiser la gestion des tâches. Cette visualisation rend les dépendances claires, améliore la planification et facilite l'identification des relations entre les activités et leurs durées. Elle aide également à détecter les réponses optimales et les éléments inconsidérés dans l'organisation du travail. Cela permet de mettre en évidence les activités les plus importantes et d'optimiser l'allocation de ressources (78). Les chemins critiques se concentrent donc sur la standardisation des soins pour des diagnostics spécifiques afin de réduire la variabilité, les coûts et les délais. L'appellation « ciritical pathway » va progressivement évoluer à la fin des années 1980 pour correspondre davantage au domaine spécifique du soin avec le terme « clinical pathway » (79), décliné en France par le terme « chemin clinique » (CC) (80).

Une intervention peut être ainsi considérée comme un chemin clinique s'il s'agit d'un plan de soins multidisciplinaire structuré, si elle est utilisée pour traduire des recommandations basées sur les données probantes dans des structures locales de prise en charge, si elle détaille les étapes du traitement ou des soins dans un inventaire d'actions (plan, protocole, algorithme, …), si elle vise à normaliser les soins pour un problème clinique spécifique pour une population cible (81). Cependant, l'efficacité de la mise en œuvre des CC dans des environnements réels a été remise en cause. Par exemple, la mise en œuvre d'un CC nécessite une combinaison de connaissances pluridisciplinaires et un consensus entre les membres de l'équipe de soins, ce qui peut être difficilement réalisable. Ces difficultés de réalisation peuvent entrainer une utilisation non optimale des ressources matérielles et financières, et une gestion insatisfaisante des équipes soignantes , rendant nécessaire le principe de coordination (82).

Cette notion d'organisation standardisée des activités cliniques concernait à l'origine essentiellement la pratique médicale dite « au chevet du malade » (83), souvent dans des structures de type hôpital. C'est ainsi sur cette base que le terme « care pathway », traduit en français par « parcours de soin », va se développer à partir du milieu des années 1990 (84), et se retrouve dans le monde entier (Brésil (85), Etats-Unis (86), Italie , Norvège (87), Bénin (88), Maroc (89), l'Inde (90), Pakistan (91), Chine (92), Japon (93), Australie (94)).
Le concept s'est élargi pour englober également l'offre de soins non médicaux (soutien social par exemple), et la prise en charge hors des murs d'un hôpital (soins de ville par exemple).

1.2.1.2. Le concept de parcours issu d'une organisation basée sur la demande : « l'approche biopsychosociale de la santé »

En parallèle de « l'approche processuelle du soin », d'autres courants de pensée et postures se sont développés, davantage portés sur l'atteinte de résultats qui comptent pour la personne ayant une pathologie.

L'habitus, terme développé par Bourdieu, désigne un ensemble de dispositions innées et acquises qui structurent les pensées et les actions des individus, d'après les conditions sociales et économiques dans lesquelles une personne grandit et vit (95). Cette notion permet de comprendre comment les individus intègrent et reproduisent les structures sociales dans leurs pratiques quotidiennes, et cela peut s'étendre aux comportements en santé (96). Le sociologue y associe la notion de capital personnel élargi, avec le capital économique (les ressources financières et matérielles), le capital culturel (les connaissances, les compétences, les goûts culturels et les diplômes), le capital social (les réseaux de relations et les alliances), et le capital symbolique (le prestige, le statut et le pouvoir dérivé de la reconnaissance sociale). Il y associe également la notion de champs sociaux (économique, politique, culturel…), vus comme des espaces structurés propices à l'élaboration de règles et hiérarchies spécifiques qui influencent les comportements des individus.

Engel a quant à lui proposé de dépasser l'approche biomédical traditionnelle, qui jusqu'à lors se concentrait essentiellement sur les aspects biologiques et pathologiques des maladies, en considérant la santé et la maladie comme le résultat d'interactions entre trois dimensions : biologique, psychologique et sociale (Figure 1).

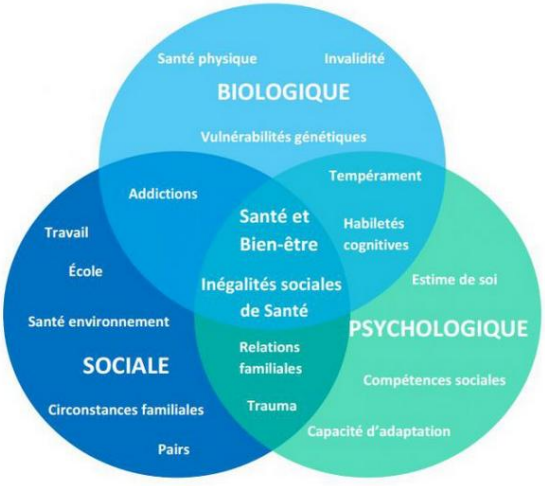


Figure 1. Schéma sur les contextes et enjeux de la santé en regarde du modèle Biopsychosocial d'Engel (97)

Le modèle biopsychosocial d'Engel induit un changement de perspectives : d'une structuration de causalités simples et linéaires, il s'attache aux causalités multiples et réciproques, ce qui a pour corollaire de les rendre plus difficilement identifiables et donc contrôlables (98).

Autour de ce modèle, « l'approche biopsychosociale » s'est développée dans de nombreux pays d'Amérique (comme les Etats-Unis (99) ou le Canada (100)), d'Europe (comme l'Irlande (101) ou l'Allemagne (102)), d'Orient (comme la Turquie (103) ou l'Inde (104)), d'Extrême-Orient (comme la Chine (105) ou le Japon (106)), et en Australie (107).

En France, cette approche s'est également imposée, et a eu comme corollaire une transposition culturelle marquée par des textes législatifs, tels que :

- La loi de bioéthique du 29 juillet 1994, qui visait à protéger les droits fondamentaux des personnes et qui a marqué une prise de conscience collective sur les enjeux éthiques posés par les progrès scientifiques (108).
- La charte du patient hospitalisé, publiée par la circulaire du 6 mai 1995 (puis circulaire du 2 mars 2006), qui a posé des jalons pour garantir le respect et la dignité des patients dans les établissements de santé et a introduit des principes essentiels tels que le droit à l'information et le respect de l'intimité (109).
- La loi du 9 juin 1999 sur le droit à l'accès aux soins palliatifs, qui a marqué une avancée dans le respect de la dignité humaine avec la recherche de la réduction des souffrances physiques et psychologiques pour les personnes en fin de vie (110).
- La loi du 4 mars 2002, relative aux droits des malades et à la qualité du système de santé, qui a introduit le concept de « démocratie sanitaire » et de « consentement libre et éclairé » du patient et a encouragé la mise en place d'une relation plus égalitaire entre soignant et soigné (111).
- La loi Hôpital, Patients, Santé et Territoires (HPST) de 2009, qui a introduit le concept d' « empowerment » ("autonomisation du patient") de la personne malade à travers le développement de l'éducation thérapeutique du patient (ETP). Cette approche vise à donner aux patients les compétences et les connaissances nécessaires pour mieux gérer leur santé et participer activement aux décisions concernant leur traitement. En renforçant l'autonomie et la responsabilisation des patients, elle vise à améliorer les résultats de santé tout en adaptant le système de santé aux attentes des usagers (112).
- La loi de modernisation de notre système de santé de 2016, qui fixe un cadre pour garantir la pérennité de notre système de santé grâce à des leviers organisationnels et innovants axés sur la réduction des risques par la prévention, le renforcement des soins de proximité et l'élargissement de la démocratie sanitaire (113).

A l'échelle internationale, l'OMS a promu plusieurs cadres de références mondiales, tels que :

- La Charte d'Ottawa de 1986 qui initie le développement du principe de promotion de la santé : « donner aux individus davantage de maîtrise de leur propre santé et davantage de moyens de l'améliorer ». Elle incite à intervenir autant sur les facteurs environnementaux de la santé que sur les facteurs individuels, en associant les populations concernées (114).
- La Classification Internationale du Fonctionnement (CIF), du Handicap et de la Santé de 2001 (115), dans le but de fournir un cadre et un langage pouvant être appliqués de manière universelle pour faire avancer le développement des politiques et des services dans le sens d'une meilleure prise en compte des besoins des personnes (Figure 2). Fonctionnement et handicap y sont vus comme des concepts multidimensionnels qui permettent de mettre en avant l'interaction dynamique entre plusieurs composantes :
    - Les activités que font les individus et les domaines de la vie auxquels ils participent
    - Les facteurs environnementaux qui influencent leur participation
    - Les fonctions organiques et les structures anatomiques des individus
    - Les facteurs personnels

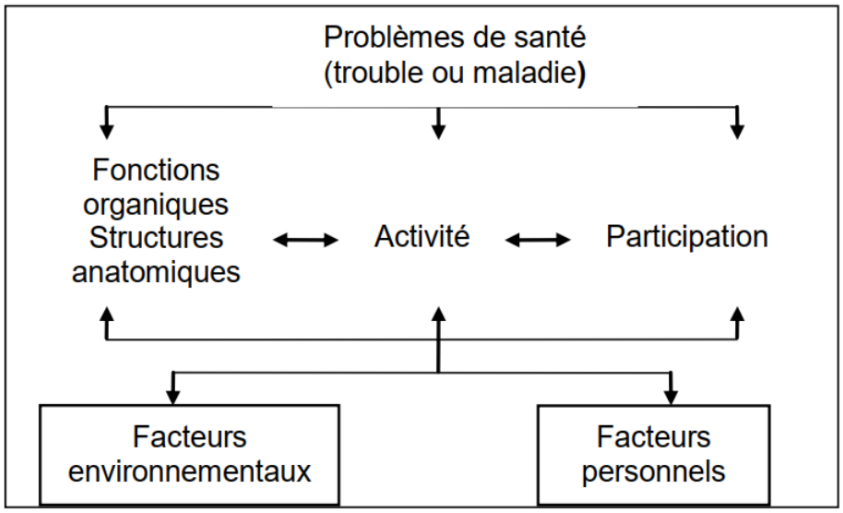


Figure 2. Interactions entre les composantes de la CIF, selon l'OMS (2001) (116)

Il est très souvent admis aujourd'hui que la santé d'une personne est influencée par divers déterminants dont l'environnement et les conditions sociales (circonstances dans lesquelles les individus naissent, grandissent, vivent, travaillent et vieillissent). Les déterminants de santé sont également les systèmes mis en place au cours du développement d'une société et qui peuvent permettre de faire face à la maladie. Ces circonstances sont déterminées par des forces politiques, sociales et économiques (Figure 3) (117).

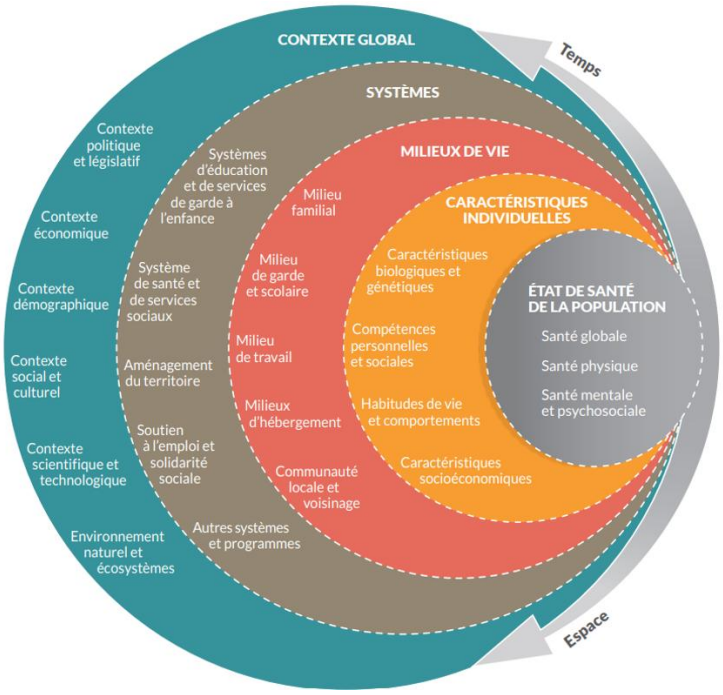


Figure 3. Vue d'ensemble des catégories de déterminants de la santé, selon le Gouvernement du Québec (117)

Selon l'OMS, prendre en considération les déterminants sociaux et agir sur eux, c'est réduire les inégalités en matière de santé, et c'est renforcer l'infrastructure essentielle qui permet aux sociétés de prospérer, pour une meilleure cohésion sociale (118).

C'est dans cette dynamique de pensée « d'approche biopsychosociale » que les soins ont été considérés comme devant être interconnectés aux autres dimensions de la vie. C'est ainsi qu'à la fin des année 1990 émergent les concepts de « chronic care model » (119) (« modèle de soins pour maladies chroniques ») et d'« integrated care pathway » (120) (« parcours de soins intégrés » pour toute maladie), dans lesquels la coordination entre professionnels doit être élargie à toutes les interventions réalisées dans le milieu de vie des personnes et non uniquement aux acteurs des soins.

Il alors possible de considérer l'existence d'un continuum santé, composé de différentes dimensions d'intervention, interdépendantes et reliées dans un même ensemble homogène, diffus dans l'espace (de populations à individus) et progressif dans le temps (de la promotion de la santé à la fin de vie) (Figure 4) (121).

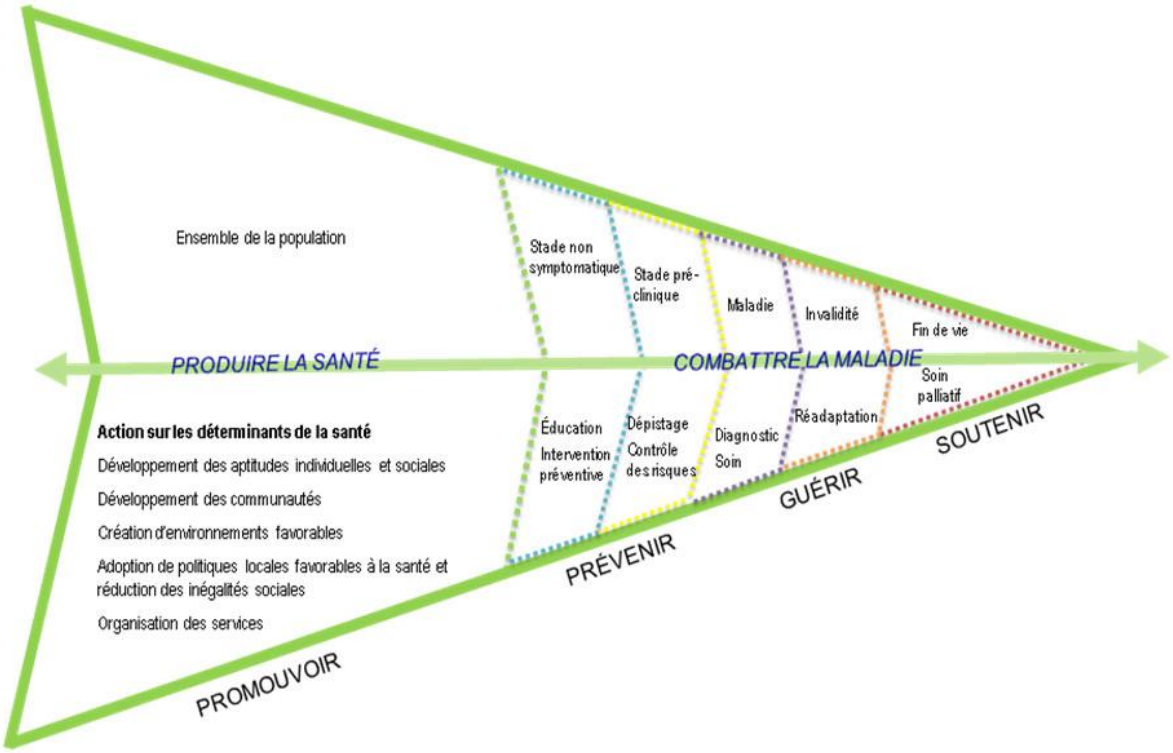


Figure 4. Continuum d'interventions de santé selon Le Consortium Initiative sur le partage des connaissances et le développement des compétences (2012) (121)

En parallèle, l'attention portée à l'individu-patient va changer. Celui-ci ne va plus être perçu comme un acteur passif, mais va devenir la composante centrale, tout autant que cible, d'une démarche pour la santé et non uniquement pour le soin (122). L'individu présentant une pathologie va collaborer avec les professionnels de santé, sociaux, et médico-sociaux pour définir ses besoins de santé et déterminer les solutions les plus adaptées pour y répondre. Cela va se traduire par la recherche de décisions partagées, où les personnes sont encouragées à participer aux choix et aux actions qui concernent leur santé. Dans ce cadre, les soins dits « centrés sur le patient » sont définis par le patient mais réalisés par le professionnel. C'est passer d'une approche "faire pour" à une approche "faire avec" (123). Ceci inclut non seulement les aspects médicaux, mais également les aspects de la vie quotidienne qui peuvent influencer le traitement, comme l'alimentation, l'activité physique ou la gestion du stress.

Dans le prolongement de la réflexion sur la santé biopsychosociale, une nouvelle approche s'est développée en complément de la médecine conventionnelle. Il s'agit de rechercher une articulation cohérente entre différentes pratiques thérapeutiques, qu'elles soient issues de la médecine classique ou de méthodes complémentaires, afin de favoriser le bien-être global et à maintenir la qualité de vie des individus. C'est dans ce cadre qu'est apparu le concept d'« integrative health » (124), décliné en France sous le terme de « santé intégrative » (125). Cette approche repose sur une coordination entre les soins médicaux conventionnels et les pratiques non conventionnelles ou traditionnelles (comme

l'acupuncture, la méditation, la phytothérapie, etc.), dans une logique de prise en charge globale, centrée sur la personne.

En outre, toujours dans cette démarche d'une plus grande considération portée à l'individu-patient, les professionnels de santé vont chercher à connaitre davantage les points de vue des usagers au sujet de leurs interactions avec les systèmes de soins et de santé. Un vaste déploiement de l'analyse des perceptions va être opéré dans de nombreux pays, atour de trois principaux types de mesures :

- Les *Patient-Reported Outcome Measures* (PROMs) pour le résultat des soins,
- Les *Patient-Reported Expérience Measures* (PREMs) pour l'expérience des soins,
- Les questionnaires de satisfaction des patients pour la réponse à leurs attentes.

Une déclinaison française de cette démarche se retrouve au sein du « e-Satis », qui est le dispositif national de mesure en continu de la satisfaction et de l'expérience des patients (126). Ces éléments d'enquête constituent de bons outils de participation des usagers à l'amélioration personnelle ou collective de leurs parcours de soins (127).

1.2.1.3. Le développement du concept de parcours en santé en France

Initialement, le terme de « parcours de soins coordonné » apparait de façon officielle dans la loi de Financement de la Sécurité Sociale du 13 août 2004 relative à l'Assurance Maladie (128). Mais à cette époque, il recouvre surtout la notion d'origine anglosaxonne de « gatekeeping » (129), dans laquelle le médecin traitant joue le rôle de « gardien » de l'accès aux services de soins spécialisés, et filtre les orientations vers les autres professionnels grâce à un courrier permettant le remboursement des frais de prise en charge. La logique associée à la notion de parcours reste ici la maîtrise des dépenses.

En 2009, dans la loi HPST (44), la notion de parcours de soins apparait comme étant un élément servant à positionner l'activité des biologistes et la place de l'ETP. De plus, cette loi renforce le rôle du médecin généraliste de premier recours en stipulant qu'il doit s'assurer de la coordination des soins nécessaire à ses patients.

C'est essentiellement en 2013, avec la « Stratégie Nationale de Santé », que le concept de parcours en santé se développe (130). En effet, l'allocution officielle du gouvernement, représenté par Marisol Touraine, Ministre de la santé, précise : « c'est dorénavant à partir du parcours de la personne, patient, personne âgée, personne handicapée, que doit s'organiser le système de santé, pour supprimer peu à peu les ruptures dans la prise en charge provoquées par les cloisonnements. Il s'agit de structurer le système de santé autour de la notion de parcours de soins » (131).

En 2014, la notion de parcours est considérée comme étant la « réponse à la nécessité de modifier notre système de santé face à l'augmentation des maladies chroniques et l'évolution des besoins de la population » (132).

Aujourd'hui, selon le Ministère de la santé (133) :

« *Un parcours s'entend comme la prise en charge globale, structurée et continue des patients, au plus près de chez eux.*

- *Les parcours de soins, qui permettent l'accès aux consultations de 1er recours et, quand cela est nécessaire, aux autres lieux de soins : hospitalisation programmée ou non (urgences), hospitalisation à domicile (HAD), soins de suite et de réadaptation (SSR), unité de soins de longue durée (USLD) et établissements d'hébergement pour personnes âgées dépendantes (EHPAD)*

- *Les parcours de santé, qui articulent les soins avec, en amont, la prévention en santé et sociale et, en aval, l'accompagnement médico-social et social, le maintien et le retour à domicile*

- *Les parcours de vie, qui envisagent la personne dans son environnement : famille et entourage, scolarisation, prévention de la désinsertion professionnelle, réinsertion, logement »*.

Du fait de ces différents aspects conceptuels, dans ce travail, le terme « parcours **en** santé » est alors utilisé pour généraliser et englober ces dimensions.

Toujours selon le Ministère de la santé : *« L'objectif de cette approche globale et graduée est de permettre aux Français de recevoir « les bons soins par les bons professionnels dans les bonnes structures, au bon moment ». Cela, en bénéficiant d'un égal accès à la santé, de prises en charge lisibles, accessibles, complètes et de qualité, ainsi que d'une organisation sanitaire et sociale rationalisée et plus efficiente. Et surtout, satisfaire à la demande des patients et de leurs proches en faisant évoluer les soins et les services. En effet, la médecine de parcours amène à un changement de paradigme profond : l'adaptation de la prise en charge, des relations entre professionnels, des structures et des moyens autour des malades, de leur entourage et de leurs besoins… et non plus l'inverse. En effet, les parcours sont une révolution, qui place les patients au centre de la prise en charge. Ce ne sont plus eux qui doivent s'adapter au système de santé – organisations ou structures – mais au système de s'organiser pour répondre à leurs besoins* ».

Cette présentation issue de l'État incarne une volonté louable. Mais elle reste une déclaration d'intention politique qui privilégie les notions consensuelles (« égal accès », « qualité », « efficience »), sans les caractériser précisément. Ce texte se contente de généralités et ne propose pas de mécanismes

concrets pour transformer les pratiques et pour lever réellement les résistances structurelles qui entravent la coordination. Cela d'autant plus en citant le terme « médecine de parcours » qui renvoie essentiellement à une approche réduite aux aspects cliniques et curatifs, et qui semble marquer un manque de reconnaissance réel des déterminants non médicaux (logement, éducation, culture…). Ce positionnement officiel ressemble à un vœu pieux, mais vague. Pour les acteurs du parcours, il peut entretenir une représentation floue du concept de parcours.

Toutefois, ce texte laisse aussi entrevoir le fait qu'au-delà de l'uniformité, de la normalisation des pratiques et de la seule coordination des tâches professionnelles, la cohérence organisationnelle, par le concept de parcours, doit tendre vers une « universalité discernante » : devant s'appliquer de façon adaptée à tous. L'accompagnement en santé doit alors prendre en compte à la fois la standardisation et la singularité : c'est le principe de la singularité standardisée (134).

Ainsi il peut être recherché pour chaque usager du système de santé a un parcours particulier (135). Afin d'assurer un cadre de réflexion partagé sur la notion de parcours adapté à chaque individu, la Conférence Nationale de Santé a réalisé une charte (136). Celle-ci est destinée aussi bien aux usagers qu'aux professionnels de santé, et s'applique à l'ensemble des étapes du parcours de santé (prévention, soins, rééducation-réadaptation, accompagnement ; à domicile, en ville ou en établissement ; dans les champs sanitaire, médico-social et social). Elle repose sur trois principes et répond à quatre objectifs :

- Principes :

1. Usagers et professionnels sont dans une relation partenariale
2. Tout usager prend, avec le professionnel de santé, les décisions concernant sa santé
3. Usagers et professionnels partagent des responsabilités collectives vis-à-vis de notre système de santé et de solidarité.

- Objectifs

1. Agir pour la promotion de la santé, l'éducation pour la santé, la prévention et le maintien de la santé tout au long du parcours de santé
2. Assurer l'accès de tout usager aux professionnels, aux établissements et services de santé, quelle que soit sa situation sociale, économique, géographique, d'état de santé, de handicap et de dépendance
3. Élaborer le parcours de santé personnalisé dans une démarche de co-construction entre usager et professionnel de santé

4. Garantir la qualité, la continuité et la sécurité de la prise en charge et de l'accompagnement tout au long du parcours de santé personnalisé de l'usager.

1.2.1.4. Vers une définition universelle du parcours

Le concept de parcours en santé s'est élargi progressivement, incorporant de multiples éléments constitutifs différents, voire opposés. En 2006, une revue de littérature a recensé 84 définitions différentes de la notion de parcours. Ces divers définitions ont entrainé comme conséquence un manque de clarté sur la nature de ce concept, et une confusion sur sa signification (137).

Une étude a été mené en 2022 sur la conceptualisation du parcours de soins (138). Gartner et al. ont identifié 22 objectifs différents pour lesquels un parcours en santé a été mis en place : amélioration de la qualité et de la sécurité, amélioration de l'efficacité dans la prestation des soins, optimisation du processus de prestation du point de vue de la gestion des opérations, intégration des meilleures pratiques par respect des guidelines et de l'EBM, amélioration de l'expérience du patient, développement des soins centrés sur le patient, amélioration des résultats pour le patient, amélioration de la coordination de la prestation des services, standardisation de la prestation des soins, réponse aux besoins du patient, amélioration de la collaboration interprofessionnelle, accompagnement aux changements, aide à la prise de décision clinique, amélioration de la communication, prise en compte des besoins des professionnels de la santé, amélioration du système d'orientation, définition des buts communs et d'objectifs significatifs, contrôle de la conformité du personnel, soutien à la gestion des connaissances, amélioration de l'accès à l'information pour les patients et les aidants, adoption d'une approche systémique, compréhension de la dynamique du pouvoir et des facteurs relationnels. Les auteurs soulignent que les objectifs qui apparaissent le plus souvent au cours des dernières années (les plus dynamiques sur l'intervalle de temps récent) visent avant tout « l'amélioration de l'expérience et du vécu du patient » et « la recherche de réponse aux besoins du patient ». De plus, s'appuyant sur les articles analysés, afin de rassembler les différentes perspectives concernant le concept de parcours appliqué à la santé, les auteurs ont proposé la définition suivante :

Un parcours est « *une intervention managériale complexe, qui adopte à long terme une approche systémique, pour un groupe de patients bien défini qui couvre l'ensemble du continuum de soins, depuis la prévention et le dépistage jusqu'au rétablissement ou aux soins palliatifs. Cette intervention :*

- donne la priorité aux patients et aux soignants en analysant l'expérience du patient à travers ses besoins et ses attentes, en tenant compte du besoin d'information, d'éducation, d'engagement et d'implication et en intégrant les relations avec le patient comme un besoin fondamental,

- soutient les rôles des acteurs professionnels impliqués dans le parcours de soins en développant l'adhésion à l'approche de soins centrés sur le patient ; en travaillant sur l'interdisciplinarité par le développement des compétences, à la fois techniques et surtout relationnelles ; la clarification des rôles et des responsabilités ; et en prenant en compte l'expérience des professionnels à la fois dans la compréhension des contraintes organisationnelles et dans leur bien-être au travail,

- intègre une approche de processus de soins par la modélisation et l'amélioration du parcours de soins en intégrant en permanence les connaissances et les informations les plus récentes pour soutenir la prise de décision clinique et en définissant des boucles de rétroaction pour améliorer en permanence les processus cliniques et non cliniques soutenus par la gestion des opérations dans le cadre d'approches méthodologiques d'amélioration des processus,

- met en place des structures de coordination grâce à la mise en œuvre des meilleures pratiques et à la transposition des lignes directrices dans la pratique quotidienne, au soutien de la continuité de l'information par l'intégration des services au niveau systémique, à la mise en œuvre de la gestion des connaissances tout au long du continuum des soins et à l'identification des responsables à chaque étape du parcours de soins,

- s'adapte aux contextes des structures physiques et sociales en intégrant les contraintes liées aux ressources humaines, matérielles, économiques et financières, ainsi que la dynamique sociale des relations de pouvoir et de confiance,

- s'appuie sur des systèmes d'information et de gestion des données, rendus possibles par la numérisation, qui garantissent la circulation de l'information dans le bon contexte, au bon moment et au bon endroit, et permettent l'intégration continue des connaissances les plus récentes dans le flux de soins et la gestion de données accessibles en temps réel pour suivre et évaluer les écarts dans les pratiques et les résultats,

- promeut le développement d'un système de santé apprenant pour soutenir le parcours de soins.

Le but et l'objectif commun d'un PS est de répondre aux besoins et aux attentes des patients par l'amélioration continue de l'expérience et des résultats des patients, de la qualité et de la sécurité, tout en tenant compte des réalités opérationnelles et sociales du système ».

Les auteurs rendent ainsi compte de la dimension holistique du concept : le parcours consiste à prendre en compte la personne dans sa globalité et dans son contexte de vie.

1.2.2. La structuration : les éléments essentiels

1.2.2.1. Le « cadre conceptuel » et ses attributs

Gartner et al.(138) ont proposé un cadre conceptuel du parcours autour de la notion de « patient-centered care pathway », en identifiant ses principaux « attributs », c'est-à-dire les caractéristiques essentielles devant idéalement être présentes dans chaque démarche visant à structurer un parcours (Figure 5).

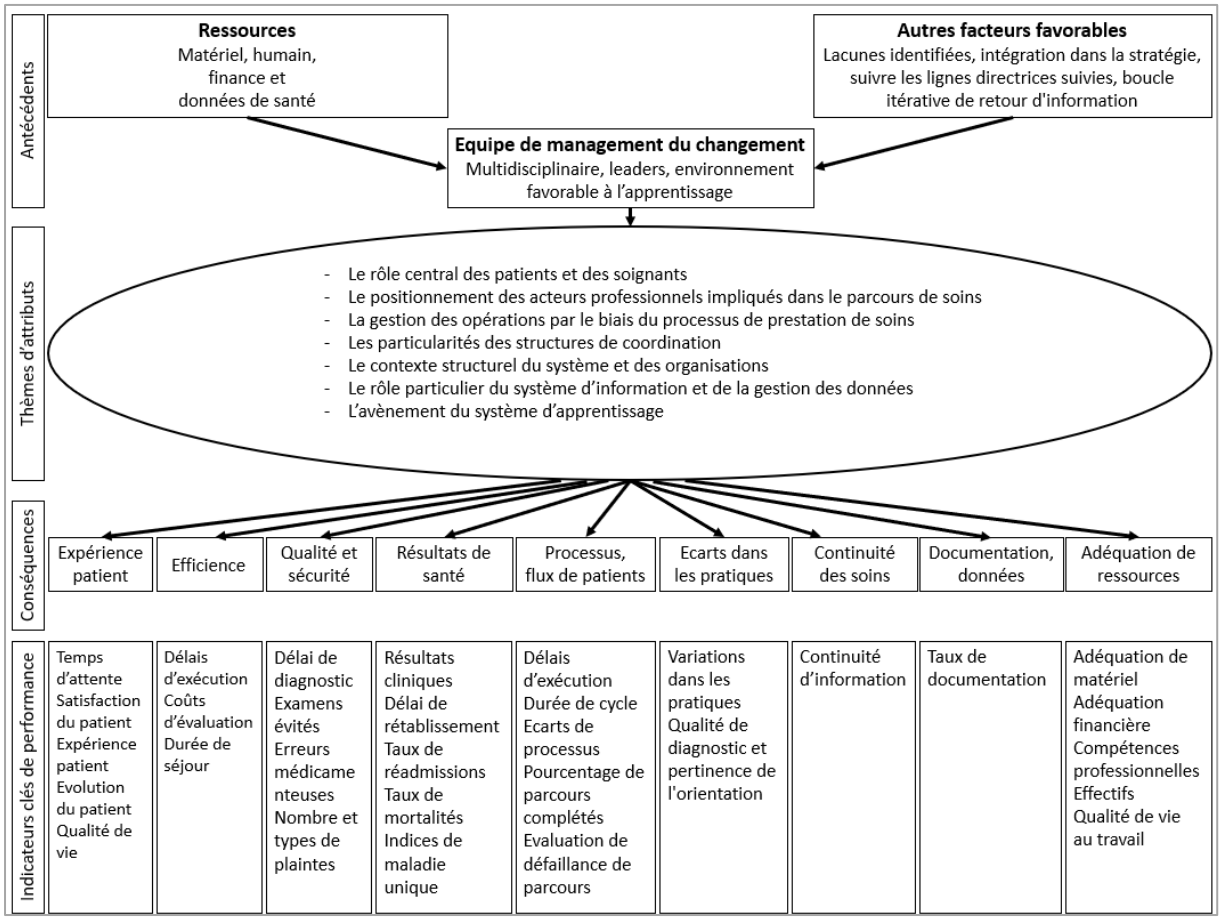


Figure 5. Cadre conceptuel de la notion de parcours en santé, selon Gartner et al. (138)

Les 28 attributs ont été regroupés en sept thèmes d'attributs :

- Le rôle central des patients et des soignants. L'expérience du patient s'est imposée progressivement comme étant un pilier de la qualité des soins, au même titre que l'efficacité clinique et la sécurité. Elle est influencée positivement ou négativement par plusieurs dimensions telles que des dimensions spatio-temporelles (l'accessibilité et le temps d'attente) et des dimensions sociales, cognitives et émotionnelles. Le respect et le développement du

niveau de littératie en santé (capacité de gestion de l'information) du patient est vue comme étant un aspect essentiel à son adhésion, à son engagement et à une prise de décision véritablement partagée. La qualité de la relation patient-soignants, basée sur la confiance, semble être une condition fondamentale. Les interactions doivent se faire dans un format flexible pour mieux s'adapter aux besoins spécifiques et favoriser l'individualisation des soins. La présence d'un soutien psychosocial et l'inclusion des proches sont également importantes.

- Le positionnement des acteurs professionnels impliqués dans le parcours de soins. Il est nécessaire de considérer la participation de toutes les catégories professionnelles impliquées directement ou indirectement dans le parcours de soins à toutes les étapes. La recherche d'une compréhension commune est indispensable (partage des connaissances). L'engagement multidisciplinaire est une condition préalable obligatoire à la réussite des programmes de parcours. Les compétences interpersonnelles sont alors considérées comme critiques. Enfin, le bien-être du personnel est directement lié à l'engagement et à la performance.
- La gestion des opérations par le biais du processus de prestation de soins. L'approche processus reste au cœur de la notion de parcours dans l'ensemble de la littérature. Il devient impératif de coconcevoir à la fois les parcours de soins et les activités de prise de décision. Pour les concepteurs de services de santé, les méthodes de construction des parcours de soins sont des considérations importantes. Le changement dans les parcours est inévitable et la gestion du changement est une nécessité.
- Les particularités des structures de coordination. L'intégration des guides de pratique clinique basée sur les preuves dans les parcours est une évidence, et une opportunité de bonne utilisation. Ainsi, cela peut aider à surmonter deux limites de l'utilisation des recommandations : (i) elles ne doivent pas être suivies aveuglément, mais elles doivent être contextualisées et appliquées de façon appropriées, (ii) elles doivent être connues, et le fait de les intégrer aux parcours permet une meilleure diffusion et partage. Cela améliore la collaboration interprofessionnelle et clarifier les rôles. De plus, la continuité de l'information est un facteur clé, et la présence d'un support d'information tout au long du parcours, accessible aux patients et aux soignants, est importante. De même, la présence d'un responsable de la coordination est nécessaire. En outre, au-delà du soin, la coordination doit être ouverte à tous les services liés à la santé. Enfin, l'ensemble des connaissances contextuelles doit être intégré au parcours.
- Le contexte structurel du système et des organisations. Le contexte géographique local (nombre, diversité et positions des offres de services) est un élément essentiel pour une bonne intégration des organismes officiels et informels, ainsi que la disponibilité des ressources (humaines, matérielles et financières). De plus, la structure sociale (règles, normes, valeurs, croyances, coutumes, habitudes, schémas comportementaux) peut façonner l'action des gens.

- Le rôle particulier du système d'information et de la gestion des données. Cela permet une meilleure analyse des parcours et donc leur amélioration par la génération de mesures correctives opportunes. Un système d'information peut favoriser la responsabilisation. Il soutient la communication, appuie l'apprentissage, et aide à la prise de décisions. Cela réduit les erreurs et améliore la qualité. Il fournit la connectivité fondamentale entre les silos de groupes professionnels.
- L'avènement du système d'apprentissage. Moins développée que les autres pour le moment, cette caractéristique de parcours consiste à mettre au point un système permettant d'apprendre de lui-même et de son expérience passée et d'améliorer l'efficience grâce aux boucles de rétroaction, dans une démarche continuelle. Les données sur les résultats peuvent être utilisées comme rétroaction pour déterminer les possibilités d'amélioration à diverses étapes du processus ou dans des interfaces spécifiques entre les intervenants. Le système d'apprentissage favorise « la compétence individuelle, la pensée systémique, une vision cohérente, l'apprentissage en équipe et l'intégration de différentes perspectives ».

Ces sept thèmes d'attributs illustrent bien l'interdépendance entre les systèmes de soins, de santé, social, culturel, économique, politique et juridique (139). Ces interdépendances peuvent engendrer des synergies mais aussi des tensions, des télescopages et des antinomies, reflétant la nature multidimensionnelle et complexe des enjeux liés à la santé, à l'échelle tant individuelle que populationnelle.

1.2.2.2. L'« approche parcours » et ses leviers

Bloch regroupe l'ensemble des leviers pouvant structurer la réflexion parcours dans ce qu'elle nomme l'« approche parcours » (140). Celle-ci s'organise selon trois catégories de leviers :

- Leviers organisationnels : approche populationnelle sur le territoire (ex : système d'orientation partagé), gouvernance partagée (ex : au niveau décideurs/financeurs et au niveau opérateurs), place des usagers et de leur entourage au niveau individuel et collectif (ex : prise de décision), adaptation du système de financement (rémunération incitative), outils et un système d'information partagé (plan de soin), déploiement d'une offre de service interstitielle/ intermédiaire/ complémentaire (ex : équipes mobiles).
- Leviers professionnels : fonctions dédiées à la mise en œuvre du parcours (ex : coordinateurs), qualification et formation des professionnels (y compris à l'interprofessionnalité)

- Leviers d'accompagnement : diagnostic partagé (ex : vision d'ensemble des ressources disponibles), conduite de projet globale (ex : gestion des risques), pilotage de la dynamique de changement adaptée au contexte territorial (ex : clarification des rôles).

1.2.3. L'application : la territorialisation

1.2.3.1. Des dispositifs de mise en œuvre locale

Une fois structuré, le concept peut devenir un principe fonctionnel et trouver une traduction organisationnelle concrète, une mise en œuvre effective. Les interventions qui vont façonner un parcours seront pratiquées selon des conditions opérationnelles, des réalités de terrain, des spécificités contextuelles (offres et demandes en santé). En France, le mot « filière » est un terme utilisé pour traduire une organisation de l'offre dans un domaine de santé spécifique, dans un secteur géographique donné. C'est alors l'expression d'une mise en réalisation, qui généralement prend son origine dans un mode d'organisation interne à un établissement de soins, et qui se prolonge en externe à travers un réseau structuré ou informel (141). Sur son territoire d'implantation, une filière doit donc proposer les dispositifs de soins couvrant l'intégralité des parcours possibles.

Au niveau d'un territoire, plusieurs dispositifs peuvent être déployés pour rendre effectif le concept de parcours, tels que :

- Les Plateformes de coordination et d'orientation (PCO) qui sont en appui du parcours de bilan et d'intervention précoce pour enfants avec des troubles du neurodéveloppement (142),
- Les Pôles de compétences et de prestations externalisées qui permettent de prévenir les ruptures de parcours, à tout âge, en organisant un accompagnement adapté aux besoins des personnes, quel que soit leur handicap, par une mobilisation collective de tous les acteurs (143),
- Les « Communautés 360 » qui apportent une réponse inconditionnelle et de proximité à toutes les personnes en situation de handicap ainsi qu'à leurs familles (144).

Un exemple particulièrement emblématique de démarche parcours est celle mise en place pour les personnes âgées. Tout d'abord, dans une volonté de construire une démarche de coordination de proximité, au service de la personne, adaptée à ses attentes et ses désirs, à l'opposé d'un modèle unique de coordination reproductible dans tous les territoires, les CLIC (Centres locaux d'information et de coordination en gérontologie) ont été instaurés en 2000 (145).
Puis, le dispositif « MAIA » (initialement pour Maisons pour l'Autonomie et l'Intégration des malades Alzheimer, remplacé par Méthode d'action pour l'intégration des services d'aide et de soins dans le

champ de l'autonomie) fut conçu en 2009 dans le cadre du troisième Plan Alzheimer (146). Il était destiné à guider la structuration d'un travail partagé, mis en œuvre par les institutions et les professionnels d'un territoire, au service de la continuité des parcours des personnes âgées de 60 ans et plus en perte d'autonomie. Il était présenté comme étant un cadre organisationnel national s'adaptant aux diversités locales, et permettant d'élaborer un cheminement cohérent et coordonné pour la santé des personnes en y incluant les divers services de soins, médico-sociaux et sociaux (147). Puis, en 2014, l'expérimentation PAERPA (Personnes Âgées En Risque de Perte d'Autonomie) (148), également appelé « parcours de santé des aînés », a été mis en place avec pour objectif de maintenir la plus grande autonomie le plus longtemps possible pour les personnes de plus de 75 ans dans leur cadre de vie habituel, en partant de leurs besoins et des besoins des aidants.

En parallèle, en 2019, pour tout individu ayant une pathologie, quel que soit son âge, ont été déployés le Plan (ou Projet) personnalisé en santé et le Plan personnalisé de coordination santé (PPCS) (en cas de situation individuelle complexe) (149). L'objectif est alors de favoriser la diffusion généralisée d'une culture de la coordination, en matérialisant par un outil spécifique des bonnes pratiques collectives. Ils sont destinés à aider les professionnels à planifier et à personnaliser l'accompagnement de la personne après une analyse concertée de ses problèmes et de ses besoins non couverts, avec la prise en compte de ses attentes et de ses projets. Les professionnels sont invités pour cela à accorder une égale importance aux dimensions médicale, psychologique, sociale et environnementale.

Les dispositifs MAIA et PAERPA ont finalement été intégrés progressivement au début des années 2020 au sein des « Dispositifs d'Appui à la Coordination » (DAC), organisations territoriales destinées à soutenir la coordination de l'ensemble des professionnels de santé pour toute personne en situation dite complexe, et de faciliter l'accompagnement de ces personnes (150). Parmi les missions d'un DAC, une fait office d'observatoire de ruptures de parcours (celles-ci pouvant être entendues comme un désajustement, progressif ou soudain, entre les besoins d'une personne et le système d'aides et de soins) (151). Cet observatoire a pour objectif d'analyser les difficultés repérées dans les accompagnements afin d'apporter des pistes d'amélioration et des réponses aux professionnels qui soient concertées, adaptées et durables. Il doit permettre d'objectiver des défaillances systémiques et d'identifier plus finement le caractère structurel de certaines ruptures sur un territoire si elles sont récurrentes.

Cette succession de réformes successives, impulsées par les pouvoirs publics, illustre la volonté de l'Etat d'apporter des solutions favorisant un décloisonnement des divers secteurs concernés par la santé. Mais elle illustre tout autant la superposition de divers mécanismes organisationnels et dispositifs, induisant un manque de lisibilité quant à leurs missions, entrainant de plus des difficultés

d'ajustement des diverses postures professionnelles vers une cohérence globale d'action et de service (152).

1.2.3.2. La mobilisation des acteurs de proximité

Selon Bloch (140), la réussite de ce type d'interventions territoriales organisationnelles dédiées à la coordination dépend des contextes de mise en application. Une des conditions de mise en œuvre efficiente est inscrite dans le principe de la « responsabilité populationnelle » (153). L'ensemble des acteurs de santé d'un territoire est responsable du maintien et de l'amélioration de la santé de la population de ce territoire ainsi que de la prise en charge optimale des patients de ce territoire (154). Ils doivent se fédérer autour d'un projet commun, favorable à un décloisonnement territorial. Cette démarche collective relève d'un principe organisationnel car il porte sur une stratification des besoins de santé des populations au travers d'un diagnostic partagé, sur une élaboration et une réalisation de programmes d'actions, et sur une évaluation régulière pour réajustements. Il vise un quadruple objectif : une meilleure santé pour la population sur le territoire, une meilleure prise en charge pour chaque patient dans cette population, une meilleure utilisation des ressources du territoire et une meilleure attractivité du territoire pour les professionnels (155). Cette responsabilité populationnelle n'est que de portée purement déclaratoire (156). Selon Janus (2023), c'est une approche sincère de soins centrés sur la relation, qui, en s'appuyant sur les interactions humaines et des forces sociales, propose des leviers très puissants sur la motivation et le sens au travail des professionnels (155). Cette démarche contribue à un alignement de valeurs entre acteurs, à un partage culturel favorable à la co-construction pour une meilleure gestion de la santé des populations (157).

En lien avec la responsabilité populationnelle se décline le principe de subsidiarité des actions en santé. Il s'agit de la capacité des acteurs à confier de manière autonome une responsabilité d'action à un autre acteur ayant le meilleur ratio proximité/compétences et au plus près de la personne. Ce principe implicite est en fait une posture professionnelle, qui vise à garantir que les décisions soient prises au niveau le plus adapté aux besoins de la personne, sans intervention inutile d'une autorité sauf en cas de nécessité (158). Ce principe est complémentaire de celui de délégation de gestion ou de tâches, qui lui est formalisé à propos d'une ou plusieurs tâches précises entre une autorité délégante et un acteur délégué. Ces deux principes favorisent les interactions au sein de groupes d'acteurs, génératrices d'intelligence collective (159).

Pour accompagner cette territorialisation, des concertations spécifiquement locales sont menées (de type « conférence régionale de la santé et de l'autonomie ») (160), et chaque ARS organise l'élaboration de son propre Projet régional de santé (PRS) depuis la loi relative à l'organisation et à la transformation du système de santé de 2019 (161). Il s'agit alors du principal instrument de pilotage

régional des politiques de santé, visant à améliorer l'approche transversale à l'échelle territoriale au profit de l'organisation des parcours de santé (162). Chaque PRS comprend notamment le Schéma régional de santé, établi sur la base d'une évaluation des besoins sanitaires, sociaux et médico-sociaux. Il détermine pour l'ensemble de l'offre de soins et de services de santé des prévisions d'évolution et des objectifs opérationnels (163). Dans chacun des territoires de santé d'une région, le Directeur général de l'ARS constitue un Conseil territorial de santé (CTS). Ce conseil est composé de représentants des différentes catégories d'acteurs du système de santé. C'est une instance locale au service de la démocratie sanitaire (164) qui regroupe, dans un esprit de dialogue et de concertation, les partenaires locaux professionnels, institutionnels et associatifs, dans le but de mieux cerner les besoins des territoires en matière de santé (165). C'est sur cette base qu'est exprimée une volonté de diagnostic populationnel partagé, de gouvernance équilibrée et de pilotage organisationnel adapté.

Pourtant, malgré les initiatives nationales, réformatrices, et locales, organisationnelles, pour le décloisonnement des services en faveur de la cohérence et optimisation des parcours de santé, il a été reconnu que le système de santé n'évoluait ni spontanément, ni uniformément, ni rapidement dans le sens attendu ; faciliter des mises en œuvre rapides et pragmatiques est devenu par conséquent une nécessité (166). Ainsi, par exemple, le dispositif « Article 51 » (167), qui vise à expérimenter des organisations innovantes faisant appel à des modes de financements inédits permettant de décloisonner les services en santé et d'inciter à la coopération entre les acteurs locaux. Une modification du cadre législatif est survenue en 2024 pour renforcer ce dispositif et encourager la mise en place d'organisations dites de « parcours coordonnés renforcés », grâce au financement collectif d'équipes déployées entre la ville, l'hôpital et le secteur médico-social autour d'un épisode donné de soins. Le dispositif « Article 51 » n'a pas vocation à se substituer aux parcours et dispositifs de coordination existants, le parcours coordonné renforcé aidant à mettre en place des solutions pour les patients aujourd'hui les plus difficiles à prendre en charge.

Signe d'une volonté d'ancrer un engagement territorial commun, le Contrat local de santé (CLS) introduit par la loi HPST est l'expression de dynamiques locales partagées entre acteurs et partenaires de terrain pour mettre en œuvre des actions, au plus près des populations. Les signataires sont les collectivités territoriales et les ARS (168). Les préfets, les services de l'Etat, les acteurs de santé et les associations peuvent être associés au dispositif. Il est destiné à inscrire dans la durée une démarche de cohérence autour d'un programme de santé local et de mutualiser les moyens pour répondre aux besoins.

En substance, introduire une démarche de parcours en santé au sein d'une structure, la mettre en application et l'évaluer constituent une intervention complexe.

1.3. La complexité : une caractéristique des parcours en santé

1.3.1. La théorie des systèmes complexes

Il s'agit d'un cadre conceptuel qui vise à comprendre des systèmes composés d'un grand nombre d'éléments (169). Une des spécificités est que chaque élément peut influencer et être influencé par les autres. Cela crée des boucles dites de « rétroaction » provoquant des effets réciproques. De plus, une action peut avoir des répercussions à différents niveaux du système. Une caractéristique spécifique est que ces interactions peuvent créer de l'émergence, c'est-à-dire un phénomène pouvant engendrer une nouvelle dynamique ou une nouvelle propriété au système, faisant ainsi que le tout est plus que la somme de ses parties. L'un des principaux exemples est celui de l'apparition de la vie.

Ces systèmes complexes sont composés d'éléments en interaction et sont interactifs avec leurs environnements. En lien avec la notion d'homéostasie, ils peuvent s'adapter et réorganiser leurs composants de manière à maintenir une certaine stabilité ou fonctionnalité interne face à des perturbations liées au milieu extérieur. Ces systèmes sont donc adaptatifs, et leur comportement global ne peut donc être déduit à partir seulement des propriétés de ses éléments pris individuellement. La quantité d'informations et d'interactions à prendre en compte complique par ailleurs fortement la caractérisation d'un système complexe donné (170).

Treize caractéristiques de la complexité d'un système peuvent être recensées (171) :

1. Frontières indéterminées ou floues,
2. Possibilité d'être ouvert,
3. Possibilité d'avoir des sous-systèmes imbriqués,
4. Dynamisme dans le réseau de relations avec différentes échelles d'interconnectivité,
5. Phénomènes émergents,
6. Relations non linéaires,
7. Boucles de rétroaction,
8. Points de levier,
9. Dépendance dite « au sentier »,
10. Sensibilité aux conditions initiales,
11. Robustesse,
12. Diversité et hétérogénéité,
13. Interconnexion et interactions.

Mais bien qu'il soit donc possible de concevoir généralement la complexité selon plusieurs aspects, elle correspondra aussi spécifiquement à des propriétés intrinsèques au système considéré.

1.3.2. La complexité inhérente à la santé

La théorie des systèmes complexes, initialement développée dans les domaines de la physique et de la biologie, s'applique maintenant à de nombreux autres secteurs, dont celui de la santé (172). Selon Sturmberg (173) : « Il ne fait aucun doute que la santé et les soins de santé sont complexes, mais ce que cela signifie n'est pas toujours clair, ni pour ceux qui décrivent ou discutent de la complexité dans le domaine de la santé, ni pour ceux qui doivent gérer ces complexités ». Selon Rouse (174) : « La complexité de la santé ne peut être expliquée de manière adéquate par une représentation qui ne saisit qu'un seul niveau d'abstraction de l'écosystème. Plusieurs niveaux d'abstraction sont nécessaires pour comprendre l'ensemble des forces qui affectent la santé d'une population. Ces niveaux sont décrits et vont des cellules à la société, des aberrations de la signalisation du système immunitaire aux valeurs et normes de la société ».

La complexité en santé peut s'inscrire dans l'élargissement de la pensée holistique (175). Par exemple, dans son programme de recherche et d'innovation pour la période 2021-2027, la Commission Européenne souhaite développer les approches de santé humaine dans le cadre de la santé planétaire (176). Celle-ci est définie comme « la réalisation du niveau le plus élevé possible de santé, de bien-être et d'équité dans le monde entier, grâce à une attention judicieuse portée aux systèmes humains - politiques, économiques et sociaux - qui façonnent l'avenir de l'humanité et aux systèmes naturels de la Terre qui définissent les limites environnementales sûres à l'intérieur desquelles l'humanité peut s'épanouir. En d'autres termes, la santé planétaire est la santé de la civilisation humaine et l'état des systèmes naturels dont elle dépend » (177). Dans cette perspective, les acteurs du premier recours et plus largement tous les professionnels engagés dans la santé, sont particulièrement concernés. Certains auteurs considèrent également le développement de la littératie en santé planétaire comme pouvant être l'un des principaux leviers de l'indispensable virage civilisationnel vers un avenir durable et sain (178). L'OMS se réfère quant à elle à la logique de « One Health », entendue comme étant une approche intégrée et unifiée qui vise à équilibrer et à optimiser durablement la santé des personnes, des animaux et des écosystèmes (179).

La santé publique est un domaine complexe, composé de nombreux aspects, et en perpétuelle évolution, qui nécessite une analyse multidimensionnelle (180). Si la mise en œuvre de la démarche parcours a montré des résultats encourageants en termes de réduction de la variation des prises en charge, d'amélioration de l'accessibilité, de la qualité, de la durabilité et de la rentabilité des soins, il demeure toutefois une sous-utilisation de ce mode organisationnel (181). Selon Jabbour, la qualité

effective des parcours peut être limitée par le manque de rigueur et d'expertise dans la conception de ces parcours (182). La mise en œuvre des parcours en santé se confronte à de grands défis par manque de compréhension partagée et d'appropriation au niveau opérationnel, notamment due à leur complexité inhérente (183).

Il est ainsi nécessaire de clarifier ce que signifie la complexité et de prendre en compte celle-ci lorsqu'il s'agit de décider de quelle manière évaluer les interventions (184). Les administrateurs, régulateurs, praticiens doivent, dans leur tâche de description et d'analyse des parcours, pouvoir s'appuyer sur des outils d'extraction de connaissances à partir de données (185). Il est alors nécessaire de disposer de méthodologies qui permettent de gérer les interactions dynamiques et l'émergence, qui prêtent attention à l'interconnexion et intègrent une compréhension de la façon dont les systèmes s'assemblent dans leur ensemble à partir de différentes perspectives (186). Des outils pour visualiser la structure et les interdépendances d'un système deviennent nécessaires, tout autant pour évaluer la dynamique du système dans des conditions évolutives (173). La modélisation est ici un outil particulièrement pertinent.

1.4. La modélisation : une ressource puissante face au défi de la complexité

Savoir ce qu'est un parcours en santé est une base fondamentale pour penser la cohérence organisationnelle. Mais cette connaissance seule est insuffisante pour appréhender les dynamiques complexes d'un parcours et juger de sa pertinence. L'évaluation est un processus de mobilisation spécifique de connaissances permettant d'établir les relations existantes de cause à effet (187). L'évaluation cherche à expliquer comment et pourquoi les choses fonctionnent afin de préconiser des améliorations ou des adaptations. Pour une évaluation performante, la modélisation peut être un outil puissant (188). De façon générale, les outils d'évaluation traditionnels, souvent limités par leurs hypothèses statiques et linéaires, ne parviennent pas à capturer suffisamment le réseau complexe constitutif d'un système, ce qui se traduit par une mauvaise estimation de l'impact des mesures prises pour atteindre les objectifs préalablement fixés (189). Le manque de compréhension claire des effets dynamiques entre les éléments entrants dans un processus systémique, les sortants et les résultats, ainsi que les estimations des effets voulus et non voulus des interventions, posent des problèmes aux gouvernements et aux financeurs (190).

1.4.1. Le principe de la modélisation

La modélisation est une méthode permettant de créer une représentation simplifiée d'un système complexe afin de mieux comprendre ses dynamiques et interactions (191). Il s'agit d'un codage de notre compréhension d'un système naturel à l'aide de symboles et de règles d'un formalisme choisi,

pour faire des déductions permettant de mieux le comprendre. Alors que le système de santé est caractérisé par une multitude d'interactions entre différents agents (patients, professionnels de santé, institutions, etc.), la modélisation permet de représenter ces interactions. En créant un modèle abstrait du système, il devient ainsi possible d'identifier des schémas récurrents, des difficultés ou des défaillances. Le principe de modélisation est directement dérivé de la méthode scientifique : des données empiriques sont collectées et analysées pour découvrir des corrélations qui peuvent être décrites par des causalités. Une hypothèse est formulée qui permet de décrire l'observation et d'expliquer les corrélations observées pour expliquer le système observé. Des expériences peuvent être menées pour tester davantage l'hypothèse jusqu'à ce qu'elle soit acceptée par l'ensemble de la communauté scientifique et devienne une théorie. Une fois qu'un modèle est construit, il peut être utilisé pour simuler différentes hypothèses ou scénarios.
La modélisation est donc un outil très utile pour la compréhension et l'analyse des systèmes complexes, tel que ceux liés à la santé.

1.4.2. La modélisation appliquée à la santé

Selon l'Agence Nationale d'Appui à la Performance sanitaire et médico-sociale (ANAP) (192), la modélisation d'une filière a pour objectif l'amélioration de la prise en charge des patients avec une adaptation des soins selon la gravité et les besoins du patient. De façon générale, la modélisation peut aider à identifier les territoires où les divers services en santé sont encore trop cloisonnés et où des efforts de coordination sont nécessaires (193). Elle peut faciliter la visualisation des flux de patients à travers le système (représentation quantitative de la circulation des patients dans un système de soins, axée sur la gestion des entrées, des sorties et des transitions entre les services). Puisque les systèmes de santé sont confrontés à des limites en ressources humaines, matérielles et financières, la modélisation peut aider à optimiser la répartition des ressources. La modélisation va ainsi permettre aux décideurs d'envisager certaines variables (comme l'introduction de nouvelles technologies, une réduction du personnel ou une augmentation de la demande de soins) comme pouvant affecter l'ensemble du système. En tendant vers la simulation, la modélisation va s'attacher à réduire l'imprévisibilité, l'incertitude, l'incomplétude et la versatilité qui caractérisent des systèmes complexes adaptatifs comprenant l'humain. Elle va en particulier permettre d'anticiper des risques potentiels (médicaux ou organisationnels) et d'orienter vers une juste élaboration de mesures d'évitement ou réduction de ces risques. Par exemple, la crise sanitaire liée à la Covid-19 a été une période de recours significatif à l'utilisation d'approches de modélisation, notamment pour produire des simulations concernant la propagation du virus et ainsi orienter les interventions politiques : 340 articles ont été publiés en langue anglaise sur une période de 2 ans sur cette seule thématique (194).

1.4.3. Les risques liés à la modélisation

Cependant, la crise liée à la Covid-19 a également mis en lumière la vulnérabilité des modèles utilisés face à des biais génériques et spécifiques qui pouvaient compromettre la validité et l'interprétation de leurs résultats. En effet, les processus de choix méthodologiques pour modéliser peuvent être influencés par des contraintes cognitives (195). Certaines études se sont basées essentiellement sur des hypothèses pour fonder leurs architectures de modélisation (196). Ainsi, l'utilisation du « Ferguson Imperial Model » comme outil de gestion de la crise a pu être critiquée (197), et la place des modèles au sein des décisions politiques a pu être discutée (198,199). Cette situation a mis en lumière que les résultats peuvent surtout dépendre du choix du modèle utilisé, et pas seulement de la façon dont il est appliqué. Pour le Comité Consultatif National d'Éthique, la crise épidémique Covid-19 s'est alors associée à une crise structurelle et à une crise morale, aboutissant à une crise globale, systémique, sources de différents types de souffrances, dont la « souffrance éthique » (200) ; cela peut-être en lien avec le choix de stratégie de modélisation utilisé.

Selon Woermann (201), dès que nous nous engageons dans la complexité, nous devons faire certains choix de modélisation pour décrire les phénomènes. Questionner l'éthique de la complexité permet d'éclairer la nature des choix de modélisation. Selon Cilliers (202), face aux systèmes complexes, il est essentiel de tenir compte de la diversité des perspectives et des incertitudes, et les décisions ne peuvent être prises de manière simplifiée. Les réflexions sur ce qui oriente et motive nos actions doivent être développées, et la gestion des systèmes complexes doit adopter une approche flexible et elle aussi adaptative.

Puisque la modélisation s'attache à décrire ou identifier les aspects essentiels d'un système (dans sa structure et ses dynamiques fondamentales), certaines variables ou interactions peuvent être négligées ou sous-estimées. Cela peut conduire à des représentations imprécises ou trop simplistes. De plus, la collecte de données les plus exhaustives possibles dans un système de santé complexe est souvent difficile et coûteuse, ce qui peut limiter la capacité des modèles à refléter fidèlement la réalité. Si par ailleurs les données utilisées pour construire le modèle sont biaisées, obsolètes, ou incomplètes, le modèle sera peu fiable. Enfin, les systèmes complexes adaptatifs sont en perpétuelle évolution, et les modèles développés à un moment donné peuvent rapidement devenir obsolètes.

Ellison a présenté ces limites de la modélisation comme étant au cœur de tensions épistémologiques (203). Selon lui, la capacité des modèles de produire des projections précises d'événements est sévèrement limitée par leurs aptitudes à refléter réellement les mécanismes et processus sous-jacents impliqués. Ainsi, la valeur épistémologique des modèles dépend de la réflexion, de la diligence et des compétences des personnes impliquées dans leur application, leur interprétation et leur diffusion

(204). Des faiblesses substantielles dans ces trois domaines constituent un défi important et durable pour la santé et pour l'application de nouvelles techniques centrées sur les données où le risque de partialité, d'interprétation erronée, de malentendu et de fausse représentation demeure, avec de grandes difficultés à les éliminer.

1.5. L'épistémologie : une voie pour réduire les risques liés à la modélisation

1.5.1. L'épistémologie

Le mot « épistémologie » est issu de la combinaison de deux mots grecs, *épistèmè* signifiant science, connaissance, savoir, et *logos* signifiant discours, langage, jugement. L'épistémologie est alors assimilable à l'étude sur la *science* ou l'étude sur la *connaissance*. De manière générale, l'épistémologie interroge la nature et la valeur des principes, des concepts, des méthodes, et des résultats des sciences. Elle suppose donc une démarche réflexive et critique afin de discuter du *bien-fondé* et de la *portée* des méthodes scientifiques employées et des propositions qui en résultent (205). Selon Charmillot (206), l'épistémologie chercher à exercer une fonction de vigilance critique et à garantir la production de l'objet scientifique. Selon Jotoba (207), elle permet de structurer un corps théorique et pratique autour d'un concept donné, ce qui permet de l'étudier sous diverses perspectives et, ainsi, d'en débattre rationnellement. Selon Joyce, elle aide à combler le fossé entre la recherche et la pratique à prévoir ce qui peut fonctionner dans un contexte spécifique (208). Enfin, selon Carter (209), elle oriente la méthodologie à mettre en œuvre. Une méthodologie est ici définie comme une théorie de la manière dont la recherche doit se dérouler, c'est une étude (description et explication) des principes qui vont être employés. La méthodologie justifie ainsi les méthodes d'un projet de recherche, qui peuvent être considérées comme un plan de mobilisation de techniques de collecte de preuves ou des procédures-actions de recherche. Par conséquent, l'épistémologie guide la méthodologie, la méthodologie justifie la méthode, la méthode organise la mobilisation de techniques, les techniques produisent des données, et l'analyse de ces données permet de créer de la connaissance (Figure 7).

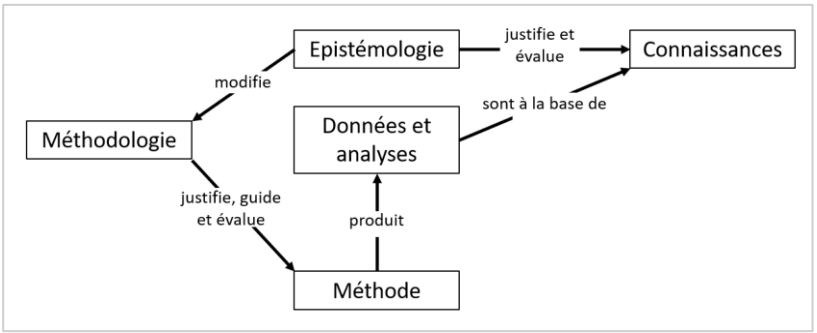


Figure 6. Relations entre épistémologie, méthodologie et méthode. Tiré de Carter, Little / Epistemologies, Methodologies, and Methods (209)

1.5.2. L'épistémologie appliquée à la santé

L'épistémologie appliquée aux sciences de la santé analyse les fondements théoriques, méthodologiques et pratiques qui portent la construction, l'évaluation/validation et l'application du savoir en santé. Elle interroge la manière dont les connaissances en santé émergent d'une articulation complexe entre les données empiriques (résultats d'essais cliniques, observations cliniques), les cadres théoriques (modèles conceptuels) et les savoir-faire pratiques (210).

Cependant, ces connaissances sont souvent fragmentées et incomplètes, et les professionnels doivent prendre des décisions dans des contextes d'incertitude. Selon Wyer, « les soins de santé contemporains sont de plus en plus complexes et manquent d'une compréhension unifiée de l'épistémologie, de la méthodologie et des objectifs (211). Le manque de cohérence conceptuelle dans des notions telles que les « soins centrés sur le patient » illustre la discordance qui règne dans l'ensemble du système ». L'épistémologie aide ici à clarifier la façon dont différents types de connaissances interagissent et comment les incertitudes peuvent être prises en compte. Une étude a montré par exemple qu'une démarche épistémologique de nature biopsychosociale était associée à une réduction des réactions de stress face à l'incertitude chez les médecins de premier recours (212). Plus globalement, elle pose la question de savoir jusqu'à quel point les résultats obtenus à un niveau individuel peuvent être généralisés à une plus large population, ou comment les biais d'observation dans un contexte donné peuvent affecter les conclusions médicales et/ou politiques (213).

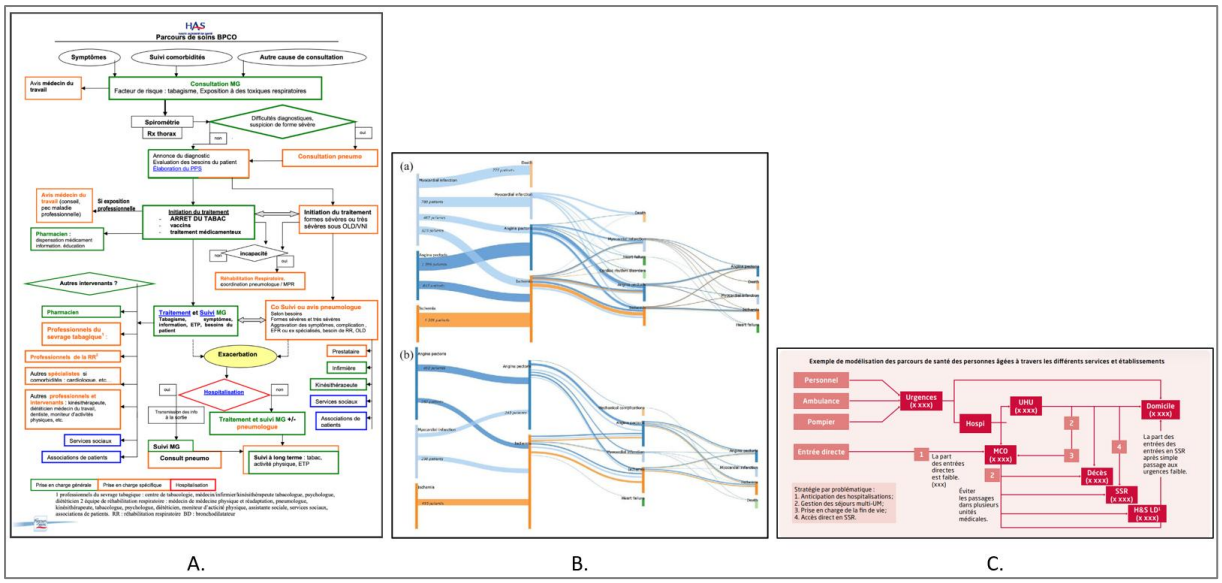
L'épistémologie cherche la transparence méthodologique, par l'explicitation des limites des données et des conflits d'interprétation, contribuant ainsi à contrer les simplifications excessives qui contournent les nécessaires ajustements méthodologiques. L'épistémologie appliquée aux sciences de la santé constitue donc un puissant levier pour renforcer la rigueur des pratiques et la légitimité des décisions prises en contexte d'incertitude (214). Djulbegovic fait un lien entre épistémologie, prise de décision et éthique en matière de santé (272). Il précise par exemple que les questions éthiques et épistémologiques portent sur les méthodes à utiliser pour prendre en compte les données existantes avant qu'un essai clinique soit conçu : les chercheurs ont l'obligation morale d'utiliser les meilleures méthodes disponibles pour évaluer les connaissances existantes avant qu'une recherche clinique puisse être menée.

1.5.3. L'épistémologie appliquée à la modélisation

Selon Rosen (215), « *La modélisation est l'essence de la science et l'habitat de toute épistémologie* ». La particularité de la modélisation est que le système étudié est étudié indirectement. Selon Langemann (216), travailler sur le processus de modélisation par des études épistémologiques

est une démarche largement admise. Selon Graebner (217), une démarche épistémologique doit aider à clarifier la manière dont on souhaite générer des connaissances sur la réalité au moyen de son modèle. Elle doit permettre de répondre à des questions telles que : "Quelles sont les conditions nécessaires et suffisantes de la connaissance ?", "Quelles sont les sources de la connaissance ?", "Comment pouvons-nous générer des connaissances sur le monde réel ?" ou encore "Qu'est ce qui fait qu'un modèle peut être une représentation pertinente d'une réalité ? ". L'intérêt est de réfléchir à la manière dont les modèles sont liés à la réalité et donc destinés à créer des connaissances fiables sur le système étudié ; le processus de mise en relation d'un modèle avec la réalité étant lié à l'objectif visé et à l'interprétation du modèle. Enfin, une démarche épistémologique doit être spécifique à une discipline, et un manque d'explicitation à ce niveau constitue un obstacle potentiel au travail interdisciplinaire. En effet, un cadre épistémologique clair peut aider les chercheurs à réfléchir à leurs pratiques en les obligeant à être très précis sur la manière dont leur modèle est censé améliorer la compréhension du système étudié. En outre, les cadres épistémologiques peuvent mettre en évidence les compromis à réaliser entre différents souhaits de modélisation. Ils peuvent ainsi aider à faire des choix de conception explicites et fondés, et suggérer des perspectives complémentaires et mettre en relation les résultats que l'on peut obtenir avec différentes méthodes (218). Le choix du bon cadre de modélisation et du bon modèle nécessite ainsi une réflexion sur leurs forces et leurs faiblesses. Et il peut parfois ne pas y avoir de "bon" modèle, rendant alors judicieux le fait d'utiliser plusieurs « moins bons modèles » afin d'examiner le système étudié sous différents angles (219). Par ailleurs, un choix équilibré des méthodes est particulièrement important dans le contexte d'un travail interdisciplinaire.

Au regard de l'intérêt d'appréhender de manière pragmatique et efficiente une notion telle que le parcours de santé, la modélisation devient un outil incontournable. Puisque la modélisation permet d'incarner finement des idées, tout objet de représentation utilisé pour réfléchir à un processus ou à un système peut être considéré comme un modèle. Il existe alors une variété de formats qui remplissent la fonction de modélisation (220) et l'on peut trouver ainsi plusieurs approches de modélisation des parcours de santé comme par exemple l'utilisation de la technique « Business Process Model and Notation » pour les parcours de soins des patients ayant une bronchopneumopathie chronique obstructive ou diagramme de Sankey pour les parcours de soins de syndromes coronariens (Figure 8).



A. B. C.

Figure 7. Exemples de différentes approches de modélisation des parcours en santé

Exemples de différentes approches de modélisation des parcours en santé. A : Modélisation du parcours de soins des patients ayant une bronchopneumopathie chronique obstructive (BPCO) selon la Haute Autorité de Santé (221)*. B : Modélisation des parcours de soins de syndromes coronariens selon Pinaire et al.* (222)*. C : Modélisation du parcours de santé des personnes âgées selon l'ANAP.* (192)*.*

L'existence de divers types de modélisation des parcours en santé interpelle quant au choix de méthodes les plus adaptées pour modéliser, et ainsi apporter au mieux des éléments de compréhension et d'évaluation. Il ne semble pas exister de réflexion précise concernant la sélection judicieuse de techniques de modélisation, adaptées à l'objectif et/ou à la situation, alors qu'il existe des risques liés à une modélisation inappropriée.

1.6. Démarche de recherche

- **Portée**

La dynamique organisationnelle des parcours, basée sur une approche processuelle du soin (l'offre) et sur une approche biopsychosociale de la santé (la demande), est destinée à décloisonner au mieux acteurs et activités au service d'une population ou d'un individu, et elle est ancrée au cœur de la cohérence des systèmes de santé et de la pérennité des sociétés, notamment en termes épidémiologiques, économiques et éthiques (Figure 9).

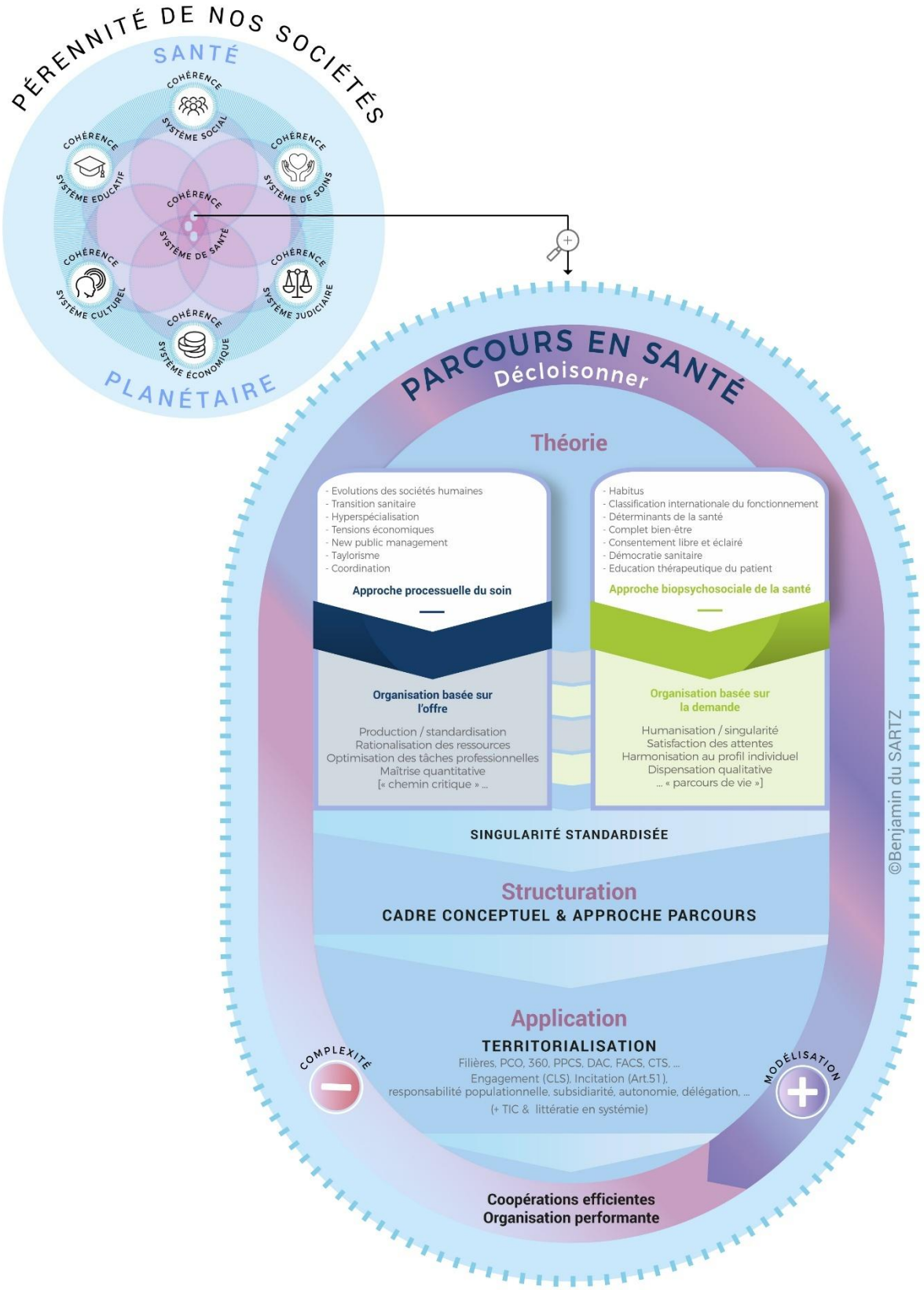


Figure 8. Ancrage de la dynamique organisationnelle de parcours au cœur de la cohérence des systèmes de santé et de la pérennité de nos sociétés.

- **Problématique**

La complexité inhérente aux parcours en santé entrave leur conception théorique ainsi que leur mise en œuvre, rendant difficiles les coopérations efficientes entre acteurs et la performance organisationnelle. Si une modélisation des parcours en santé adaptée peut réduire ou prendre en compte au mieux cette complexité et favoriser les interventions pertinentes, au contraire une modélisation inadéquate peut générer des éléments d'analyse insuffisants, voire trompeurs. Cependant, pour favoriser une juste utilisation des méthodes et techniques disponibles pour modéliser les parcours, il n'existe pas de consensus robuste.

- **Question de recherche**

Comment optimiser la conception d'une modélisation de parcours en santé ?

- **Objectif**

Proposer une démarche de réflexion favorisant la conception pertinente d'une modélisation d'un parcours en santé.

- **Hypothèse**

Une démarche épistémologique devrait permettre de comprendre les façons dont les connaissances sur la modélisation des parcours en santé sont produites, structurées, utilisées et utilisables.

- **Méthode**

Le travail de recherche a été développé selon quatre parties :

- Etat de l'art sur les méthodologies de modélisation des parcours en santé. Cette partie porte sur l'examen des connaissances disponibles dans la littérature scientifique. Elle repose sur un article publié de revue de la portée.
- Identification des déterminants invariants de parcours en santé. Cette partie porte sur les points de vue de différents experts. Elle repose sur un article publié de protocole d'étude et sur un article soumis de résultats.
- Modélisation du parcours du patient hémophile : une approche systémique. Cette partie porte sur la complémentarité de différentes approches pour analyser un parcours. Elle repose sur un article publié d'identification de critères organisationnels, sur un article publié de protocole d'étude pour recueillir les points de vue de patients, et sur un article publié de résultats.

- Modélisation du parcours de soins du patient douloureux aux urgences : une approche mixte. Cette partie porte sur l'association d'une méthode qualitative et d'une méthode quantitative pour modéliser un parcours. Elle repose sur un article soumis de résultat.

2. RESULTATS DES TRAVAUX DE RECHERCHE

2.1. Partie 1- Etat de l'art sur les méthodologies de modélisation des parcours en santé (article 1)

Afin de réaliser un état de l'art des modélisations de parcours utilisées, la méthode de scoping review (ou examen de la portée) a été choisie, particulièrement propice pour explorer des sujets peu couverts. Elle fournit une vue d'ensemble qui aide à orienter des recherches futures ou des actions dans le domaine concerné. Elle offre une clarification des concepts présents dans la littérature et identifie leurs principales caractéristiques, y compris les aspects méthodologiques (223).

Cet article intitulé "Improving care pathways through evidence-based modeling strategies: a scoping review" a été publié. Son objectif était de répondre à la question de recherche suivante : « Parmi les différents systèmes de santé quelles sont les méthodologies les plus efficaces pour modéliser les parcours de soins afin d'améliorer la qualité des soins, l'optimisation des processus et les améliorations durables du système de santé ? ».

Pour répondre à cette question de recherche, les critères de la grille PRISMA-ScR (Preferred Reporting Items for Systematic reviews and Meta-analyses for scoping review) ont été respectés. La sélection des publications a été effectuée dans 3 bases de données électroniques (PubMed, Web of Science et Embase). Les critères d'inclusion étaient les suivants : (i) publications en anglais ; (ii) études humaines, (iii) publiées lors des cinq dernières années (entre le 1 janvier 2019 et le 3 avril 2024) et (iv) utilisation de la modélisation pour analyser les PC. Les critères d'exclusion étaient les suivants : (i) les revues systématiques, (ii) les études sur les tissus humains et les animaux, (iii) les études qui n'utilisent pas la modélisation ou qui ne décrivent pas clairement leur méthodologie, (iv) les études qui ne se concentrent pas sur les parcours de soins, (v) les publications autres que les articles scientifiques évalués par les pairs (par exemple, les articles de conférence, les extraits de livres, les rapports institutionnels, les résumés de congrès, les commentaires).

Pour chaque publication incluse, les données ont été extraites et classées suivant une démarche de taxonomie originale composée notamment de 5 catégories « mères » : objectif de modélisation, méthode utilisée, objectif de la technique utilisée, fonction de la technique utilisée, et caractéristique opérationnelle de la technique utilisée.

41 articles ont été inclus. Les résultats ont d'abord montré que les objectifs de modélisation portaient sur la qualité des soins pour 46,3% (19/41) des études, l'amélioration continue pour 31,7% (13/41) ou l'optimisation des processus pour 22,0% (9/41). Quant aux méthodes utilisées, elles étaient qualitatives

pour 41,5% (17/41) des études, quantitatives pour 34,1% (14/41) ou mixtes pour 24,4% (10/41). Les objectifs des techniques utilisées étaient la description pour 48,8% (20/41), l'aide à la décision pour 36,6% (15/41) ou la prédiction pour 14,6% (6/41). Les fonctions recherchées par les techniques utilisées étaient basées sur le comportement et l'interaction dans 51,2% des cas (21/41), le processus et le flux dans 34,2% (14/41), ou l'analyse dans 14,6% (6/41). La caractéristique opérationnelle de la technique la plus utilisée était phénoménologique pour 39 % (16/41), suivie de dynamique pour 19,5% (8/41) et de simulation pour 17,0% (7/41). Aucune étude n'a utilisé les caractéristiques ethnographiques, d'apprentissage automatique ou de terrain (0%). Dix études ont combiné deux techniques à caractéristiques opérationnelles différentes : simulation et phénoménologique (dans 12,2% des cas), dynamique et phénoménologique (4,9%), intelligence artificielle (IA) et contenu (2,4%), statistique et phénoménologique (2,4%) ou statistique/mathématique et thématique (2,4%).

Ensuite, après ce premier niveau d'analyse, les résultats ont permis d'observer la nature des combinaisons de ces catégories utilisées par les articles. En effet, grâce à l'utilisation de tris croisés dans un fichier Microsoft Excel, il est possible de prendre connaissance de la construction méthodologique des études publiées, à partir de n'importe quelle catégorie. Par exemple, en prenant comme catégorie d'intérêt l'objectif de modélisation des PS, on peut voir que lorsqu'il s'agissait de la qualité des soins (46,3% des cas), alors la principale méthode qui a été utilisée était la méthode qualitative (68,5%), le principal objectif de la technique utilisée visait la description (68,5%) et la principale fonction de la technique utilisée était comportementale et basée sur l'interaction (68,5%). En revanche, lorsque la modélisation avait pour objectif l'amélioration continue (31,7% des cas), alors les principales méthodes qui ont été utilisées étaient les méthodes quantitatives et mixtes (38,5% chacune), les principaux objectifs des techniques utilisées visaient soit la description, soit l'aide à la décision (38,5% chacune), et la principale fonction de la technique utilisée était comportementale et basée sur l'interaction (46,0%). Parmi les 41 articles inclus, 30 avaient alors des combinaisons méthodologiques uniques : leurs associations de catégories et de sous-catégories ne se retrouvaient pas dans les autres études. Par conséquent, 11 articles ont partagé des combinaisons similaires dans au moins deux études différentes.

En outre, l'étude propose une analyse des techniques utilisées et montre des variations dans leurs applicabilités, leurs forces et leurs limites.

La proposition de catégorisation des processus de modélisation fournit un cadre méthodologique aux chercheurs qui cherchent à analyser et à améliorer les parcours en santé. Elle peut servir de répertoire organisé des méthodologies et des techniques utilisées, servant ainsi d'outil d'aide à la conception pour les initiatives de modélisation des parcours.

Toutefois, la conception de modèles de PC n'est pas sans poser de problèmes, notamment en ce qui concerne les données et les obstacles à l'acceptation. À mesure que nous avançons, il est clair que la modélisation des parcours en santé doit être intégrée dans un plan stratégique plus large, prenant en compte l'ensemble du système dans lequel les parcours opèrent. Si cette étude fournit un cadre cohérent aux chercheurs et aux professionnels de la santé, il reste encore beaucoup à faire pour affiner ces modèles, surmonter les obstacles identifiés et explorer de nouvelles méthodologies.

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Review Article

Improving care pathways through evidence-based modeling strategies: a scoping review

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ABSTRACT

Objectives: Noncommunicable and communicable diseases represent significant public health problems, heavily straining healthcare systems. The care pathway (CP) concept has emerged as a promising framework to improve care coordination and delivery, but its complexity often hinders implementation. Modeling, with its various methodologies, represents a valuable approach to address this challenge. Systematizing these methodologies is essential for enhancing CPs. This scoping review aims to describe and analyze CP modeling methodologies.
Study design: Scoping review.
Methods: Following PRISMA-ScR guidelines, searches were performed in PubMed, Web of science and Embase. Inclusion criteria were: (i) publications in English; (ii) human studies, (iii) published between January 1, 2019 and April 3, 2024 and (iv) use of modeling to analyze CPs. For each publication included, data were extracted and categorized based on modeling goals, methods used, functions of the techniques and their respective strengths and limitations.
Results: Analysis of the 41 included articles revealed that the main goals of CP modeling were quality of care (46.3 %), continuous improvement (31.7 %), and process optimization (22.0 %). The methods used for modeling were qualitative (41.5 %), quantitative (34.1 %), or mixed (24.4 %). Technical goals were description (48.8 %), decision support (36.6 %), and prediction (14.6 %). Qualitative methods (68.5 %) were common in studies focused on quality of care. Only 11 articles shared similar methodologies across at least two studies. Key weaknesses of CP modeling were data availability and implementation acceptance.
Conclusions: This scoping review identified key categories and commonly used methodologies in CP modeling, offering a framework to help researchers and healthcare professionals improve CP design and implementation, leading to better patient outcomes and more efficient healthcare systems.

1. Introduction

Noncommunicable diseases (NCDs) and communicable diseases represent a major public health burden, contributing to morbidity, mortality, and economic costs. NCDs such as cardiovascular diseases, cancer, chronic respiratory diseases or diabetes kill 41 million people each year, accounting for 74 % of all deaths worldwide.[1] Meanwhile, communicable diseases like AIDS, hepatitis or syphilis remain persistent global health challenges, affecting millions of people worldwide each year.[2] Although, chronic patients' survival time is increasing, their quality of life may deteriorate,[3–5] resulting in an increasing demand for medical and health services.[1] The management of these diseases requires a major mobilization of health and social resources, and accounts for a significant part of the pressure on healthcare systems.[6,7] Therefore, it is essential to optimize the organization of care. For some countries, better management of prevention and treatment could save more than 8 million lives and generate $350 billion by 2030 for NCDs alone.[8]

In this context, the concept of patient-centered care pathways (CPs)

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Table 1
Inclusion/Exclusion criteria and rationale for choice of criteria.

Type of criteria	Criteria	Justification
Inclusion Criterion 1	Publications in English.	English is the most widely used language in scientific literature, ensuring accessibility and broader applicability of findings.[27]
Inclusion Criterion 2	Human studies.	Human studies are essential for understanding clinical pathways, as they reflect the full complexity of patient care, which cannot be captured by animal or tissue-based researches.[28]
Inclusion Criterion 3	Published during the last 5 years (between January 1, 2019 and April 3, 2024).	This time frame ensures that the research is current and relevant to modern healthcare practices and modeling techniques.[29,30]
Inclusion Criterion 4	Use of modeling to analyze clinical pathways (CPs).	Modeling is a proven and powerful tool for analyzing CPs, as it allows for simulation of real-world scenarios and prediction of patient outcomes.[15–19]
Exclusion Criterion 1	Systematic reviews.	Systematic reviews summarize existing evidence but do not present new data or modeling results; the goal of this review was to focus on original research.[31]
Exclusion Criterion 2	Human tissue and animal studies.	These studies do not provide direct insights into human clinical pathways and may not model the full scope of patient care.[31]
Exclusion Criterion 3	Studies that do not use modeling or did not clearly describe their methodology.	These studies do not fall within the aim of this scoping review and are therefore irrelevant.[31]
Exclusion Criterion 4	Studies that do not focus on CPs.	These studies do not contribute to understanding the modeling of CPs and are therefore irrelevant.[31]
Exclusion Criterion 5	Publications other than peer-reviewed scientific papers (e.g., conference papers, book extracts, institutional reports, congress abstracts, commentaries).	Non-peer-reviewed publications often lack rigorous scientific evaluation and can not meet the methodological standards of peer-reviewed articles.[32]

has emerged as a promising framework for improving the quality and economic burden of healthcare delivery, mainly based on interprofessional coordination. CP are designed to address the needs and expectations of patients through continuous improvements in patient experience, outcomes, quality and safety.[9] By integrating the operational and social dynamics inherent in healthcare systems, CPs aim to streamline the patient journey through the healthcare system, ensuring that patients receive timely and appropriate care at the right cost at each stage of their treatment.[10] This approach not only improves the quality of care, but also the efficiency of healthcare delivery, ultimately benefiting both patients and healthcare providers.[10]

However, implementation of CPs in practice faces a number of challenges. The complexity of CPs in healthcare systems[11] often hinders the realization of their full qualitative and quantitative potential.[12] Organizational and cultural barriers, privacy and security issues, ethical and legal considerations, as well as financial and resource constraints, collectively pose significant obstacles to the effective application of the CP concept.[13] These challenges require a holistic approach to the design and implementation of CPs, taking into account the multiple and often competing demands in the healthcare systems.[14]

To address these challenges, modeling of CPs has emerged as a robust and valuable approach. Modeling involves the creation of simplified representations of healthcare systems to understand and anticipate their dynamics under various conditions.[15] Through modeling, it is possible to analyze the impact of different factors on health outcomes and identify areas for improvement in healthcare delivery and costs. By providing crucial insights into patient flows, resource requirements, and potential bottlenecks in the care delivery process, modeling enables healthcare providers to develop efficient healthcare systems.[16]

However, it is important to note that CPs modeling does not refer to a single approach, but encompasses a variety of methodological frameworks, each with its specific applications and benefits.[17] This diversity of modeling methods allows for a more targeted approach to the analysis and improvement of CPs, ensuring that the specific needs of different patient populations and healthcare contexts are effectively addressed.[18,19]

Furthermore, the improvement of CPs requires methodological systematization to ensure that the most appropriate and effective methods are used.[20] Comprehensive knowledge of existing modeling methods and their contexts of application is essential for selecting the appropriate methodology for analyzing and improving CP. This systematic approach can lead to more efficient and effective healthcare systems, capable of addressing the challenges posed by NCDs and communicable diseases.

Several literature reviews have examined CP modeling techniques and tools in healthcare. Aspland et al. (2021)[21] highlighted the benefits of methods such as stochastic modeling, optimization heuristics, data mining, and simulation for improving patient flow and resource use, but noted a lack of integration between these approaches. Kassim et al. (2022)[22] focused on Business Process Model Notation (BPMN), identifying its potential to visualize patient trajectories while pointing out its complexity and the training required for healthcare professionals. Bogale et al. (2024)[23] explored visual modeling languages like Unified Modeling Language and BPMN, emphasizing their value in enhancing multidisciplinary team communication but also noting the challenges of adapting these tools for clinical environments.

While previous reviews have advanced CP modeling, significant gaps remain in understanding the diverse methodologies and their application in healthcare systems. This scoping review addresses these gaps by systematically classifying CP modeling approaches from the past five years, focusing on their role in quality improvement, process optimization, and continuous care enhancement. By integrating qualitative, quantitative, and mixed-method approaches, it offers a comprehensive framework that not only refines CP design and implementation across clinical settings but also guides researchers and healthcare professionals in evaluating and applying CPs to enhance patient outcomes and promote more sustainable healthcare systems.

2. Methods

2.1. Study design

A literature review was conducted using scoping review guidelines to provide an overview of the available research data[24,25] and followed the Preferred Reporting Items for Systematic reviews and Meta-analyses for scoping review (PRISMA-ScR) criteria[26] (Supplementary file 1). The scoping review format allows for the inclusion of all types of studies and follows five steps: (i) determination of a precise research question and search strategy, (ii) identification of appropriate publications, (iii) classification of publications, (iv) data extraction, and (v) synthesis, analysis and report of results.

2.2. Identification of research questions

The research question, based on PCC format, was: Among diverse

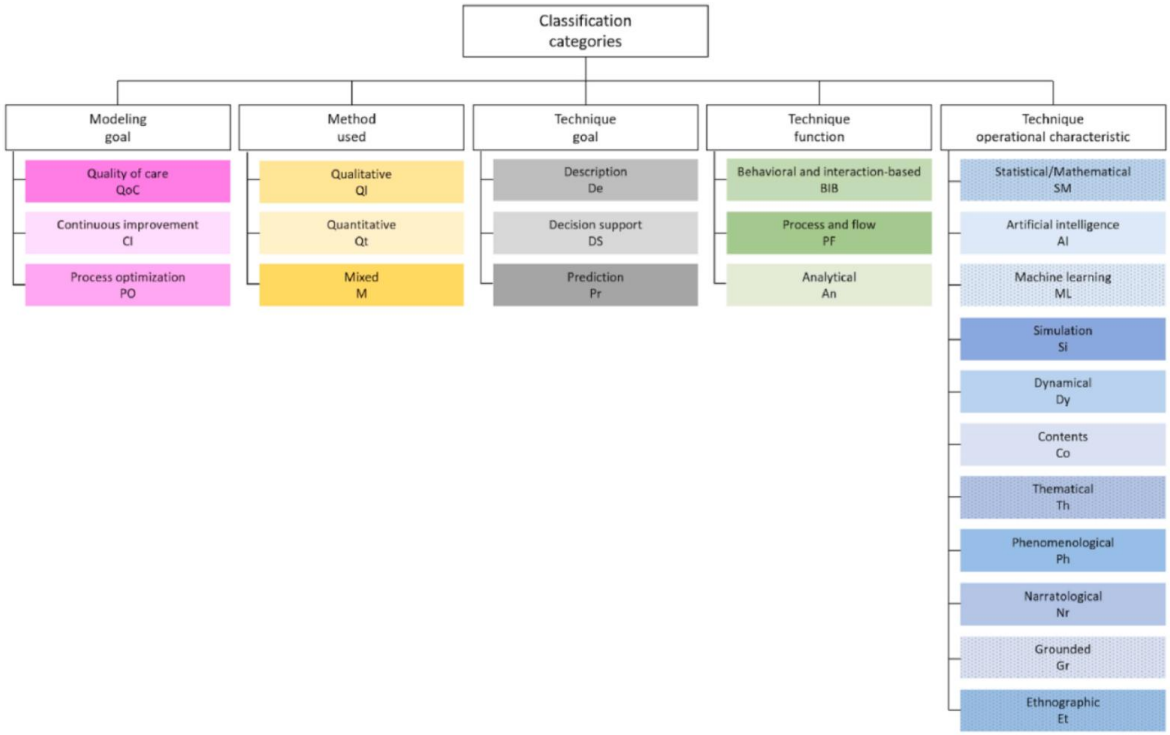

Fig. 1. Classification scheme to analyze articles AI: Artificial intelligence, An: Analytical, BIB: Behavioral and interaction-based, CI: Continuous improvement, Co: Contents, De: Description, DS: Decision support, Dy: Dynamical, Et: Ethnographic, Gr: Grounded, M: Mixed, ML: Machine learning, PF: Process and flow, Ph: Phenomenological, PO: Process optimization, Pr: Prediction, Ql: Qualitative, QoC: Quality of care, Qt: Quantitative, Si: Simulation, SM: Statistical/Mathematical, Th: Thematical, Na: Narratological.

healthcare systems (Population), what are the most effective methodologies (Problem) for modeling care pathways to improve quality of care, process optimization, and sustainable health system improvements (Context)?

2.3. Selection of publications

Electronic research was organized in PubMed, Web of science and Embase in April 2024. The search strategy was developed with the assistance of a specialist librarian, who helped in selecting appropriate terms from the Medical Subject Headings (MeSH) thesaurus: ("clinical pathway" OR "patient pathway" OR "care pathway" OR "Health pathway" OR "Health care pathway" OR "Healthcare pathway") AND ("modeling" OR "modelling" OR "Simulation" OR "model").

Inclusion and exclusion criteria are presented in Table 1.

First, a selection based on titles and abstracts was made by two reviewers (B.D. and G.M.). Then, a second selection was carried out by two reviewers (B.D. and F.C) based on a full assessment of the text. In case of disagreement, they debated at each stage until a consensus was reached.

2.4. Data extraction and analysis of modeling methodologies

Firstly, data were extracted for each included publication by two reviewers (B.D. and F.C). The data were reported according to the goal and context of the study (health domain), the techniques and tools used for modeling, and the limitations and interests of the modeling used.

Secondly, the data analysis was conducted using the thematic analysis method in five steps proposed by Braun and Clarke[33] for qualitative data, which consists of six key steps:

1. Familiarization with the data: Initially, two authors (B.D. and R.L.) read and re-read the collected data to fully understand the content and immerse themselves in the information.
2. Generating initial codes: During this phase, we applied the keywording technique, based on taxonomy studies[34] and literature reviews,[10,35] to identify key terms and concepts that emerged from the data.
3. Searching for themes: The keywords, determined in the previous step helped to organize and categorize the data in a systematic way. The keywords were grouped into relevant themes by researchers (B.D. and R.L.).
4. Reviewing themes: The identified themes were refined and reviewed (B.D. and R.L.) by comparing them against the entire data set to ensure their relevance and coherence. This step allowed us to consolidate some themes and discard others that were less relevant.
5. Elaboration of the classification: Finally, the results of the analysis were synthesized, presenting them in a structured manner.

3. Results

3.1. Selection of articles included

The Fig. 2 presents the flowchart of the study. From the three database searches, 6280 articles were identified. After applying the inclusion and exclusion criteria and deleting duplicates, 1029 articles remained and were screened at the title and abstract level. Then, 83 articles were retained for full-text evaluation. Among them, 42 articles were excluded. Indeed, nine were literature review (exclusion criterion 1), 31 did not use modeling or did not clearly describe their methodology

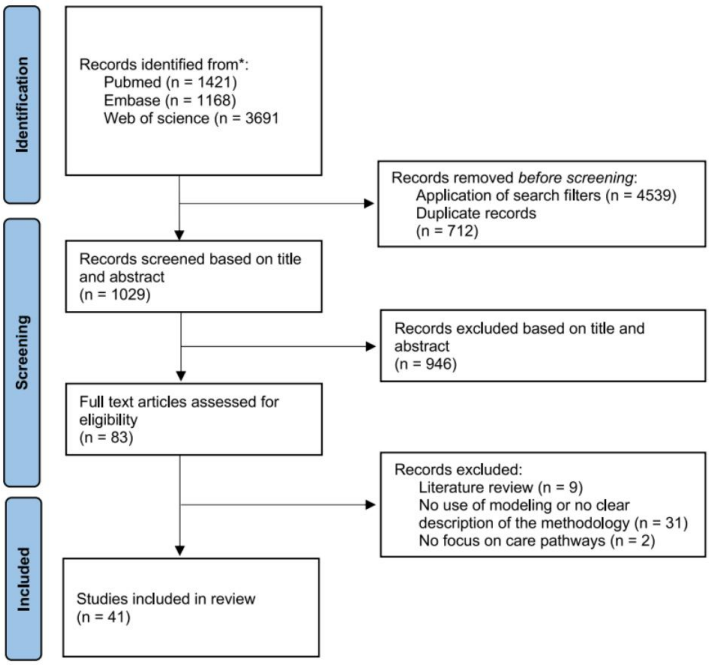

Fig. 2. Flowchart of the scoping review.

(exclusion criterion 3) and two did not focus on CPs (exclusion criterion 4). Finally, 41 articles met the inclusion criteria and were included.

3.2. Analysis of articles

3.2.1. Keyword-based classification scheme for analyzing articles

The classification scheme obtained by keywording technique is presented in Fig. 1. The modeling methodologies were classified according to five categories and their subcategories. The category "modeling goal" was divided into three subcategories (Quality of care (QoC), Continuous improvement (CI) and Process optimization (PO)). The category "method used" was divided into 3 subcategories (Quantitative (Qt), Qualitative (Ql) and Mixed (M)). The category "technique goal" was divided into 3 subcategories (Description (De), Prediction (Pr) and Decision support (DS)). The category "technique function" was divided into 3 subcategories (Process and flow (PF), Behavioral and interaction-based (BIB), and Analytical (An)). The category "technique operational characteristic" was divided into 11 subcategories (Statistical/Mathematical (SM), Machine learning (ML), Artificial intelligence (AI), Simulation (Si), Dynamical (Dy), Contents (Co), Thematical (Th), Grounded (Gr), Phenomenological (Ph), Narratological (Na), Ethnographic (Et)). The categories and subcategories are defined in Supplementary File 2. This taxonomy is an original approach developed for this research work. It was constructed through an iterative process that combined existing theoretical models, the multidisciplinary expertise of the research team, and ongoing refinement during article analysis. The structure aimed to capture a broad range of modeling strategies and was designed to be both comprehensive and adaptable. Consequently, some techniques were identified before articles analysis as being potentially useable for modeling, such as certain qualitative techniques.

3.2.2. Classification of articles

The main characteristics of included articles are described in the Supplementary file 3. Table 2 presents the classification and Fig. 3 the repartition of the 41 included articles according to the method of analysis chosen, considering modeling goal, method used, technique goal, technique function and technique operational characteristic (see Table 3).

The modeling goals were quality of care for 46.3 % (19/41) of studies, continuous improvement for 31.7 % (13/41) or process optimization for 22.0 % (9/41). The methods used were qualitative for 41.5 % (17/41) of studies, quantitative for 34.1 % (14/41) or mixed for 24.4 % (10/41). The technical goals were description for 48.8 % (20/41), decision support for 36.6 % (15/41), or prediction for 14.6 % (6/41). The technique functions were behavioral and interaction-based for 51.2 % (21/41), process and flow for 34.2 % (14/41), or analytical for 14.6 % (6/41). The most technical operational characteristic used was phenomenological for 39 % (16/41), followed by dynamical for 19.5 % (8/41) and simulation for 17 % (7/41). No studies used ethnographic, machine learning or grounded (0 %). Ten studies combined two technical operational characteristics: simulation and phenomenological (12.2 %), dynamical and phenomenological (4.9 %), artificial intelligence and contents (2.4 %), statistical and phenomenological (2.4 %) or statistical/mathematical and thematical (2.4 %).

3.2.3. Cross-analysis of subcategory combinations according to modeling goals

Fig. 4 presents the combinations of subcategories based on the modeling goals. When the main goal of the CPs modeling was quality of care (46.3 %), the main method used was qualitative (68.5 %), the main technique goal was description (68.5 %), and the main technique function was behavioral and interaction-based (68.5 %). When modeling for continuous improvement goal (31.7 %), the main methods used were quantitative and mixed (38.5 % each), the main technique goals were description and decision support (38.5 % each), and the main technique function was behavioral and interaction-based (46.0 %).

Table 2
Classification of 41 articles included [35–52].

Author (1st), year, ref	Modeling goal	Method used	Technique goal	Technique function	Technique operational characteristic
Beny et al. 2022 [35]	Continuous improvement	Qualitative	Description	Behavioral and interaction-based	Phenomenological
Ardito et al. 2020 [36]	Continuous improvement	Qualitative	Description	Process and flow	Dynamical
Mochamat et al. 2023 [37]	Continuous improvement	Qualitative	Description	Process and flow	Phenomenological
Tax et al. 2019 [38]	Continuous improvement	Quantitative	Decision support	Analytical	Simulation
Alahmar et al. 2020 [39]	Continuous improvement	Quantitative	Decision support	Analytical	Statistical/Mathematical
Bernardi et al. 2019 [40]	Continuous improvement	Quantitative	Decision support	Process and flow	Dynamical
Allam et al. 2021 [41]	Continuous improvement	Quantitative	Prediction	Process and flow	Artificial intelligence
Funkner et al. 2022 [42]	Continuous improvement	Quantitative	Prediction	Process and flow	Artificial intelligence
van Delft et al. 2021 [43]	Continuous improvement	Mixed	Decision support	Behavioral and interaction-based	Simulation and Phenomenological
Yakutcan et al. 2022 [44]	Continuous improvement	Mixed	Decision support	Behavioral and interaction-based	Simulation and Phenomenological
Fan et al. 2022 [45]	Continuous improvement	Mixed	Description	Behavioral and interaction-based	Artificial intelligence and Contents
David et al. 2021 [46]	Continuous improvement	Mixed	Description	Behavioral and interaction-based	Statistical/Mathematical and Thematical
Trevena et al. 2022 [47]	Continuous improvement	Mixed	Prediction	Behavioral and interaction-based	Simulation and Phenomenological
Iglesias et al. 2022 [48]	Process optimization	Qualitative	Decision support	Process and flow	Dynamical
Zhang et al. 2019 [49]	Process optimization	Quantitative	Decision support	Analytical	Artificial intelligence
Mu et al. 2021 [50]	Process optimization	Quantitative	Description	Process and flow	Dynamical
Crozes et al. 2023 [51]	Process optimization	Quantitative	Description	Process and flow	Statistical/Mathematical
Wood et al. 2020 [52]	Process optimization	Quantitative	Prediction	Behavioral and interaction-based	Statistical/Mathematical
De Oliveira et al. 2020 [53]	Process optimization	Quantitative	Prediction	Process and flow	Dynamical
Allen et al. 2022 [54]	Process optimization	Mixed	Decision support	Analytical	Simulation and Phenomenological
Boareto et al. 2022 [55]	Process optimization	Mixed	Decision support	Behavioral and interaction-based	Simulation and Phenomenological
Aissaoui et al. 2022 [56]	Process optimization	Mixed	Decision support	Process and flow	Dynamical and Phenomenological
Kazak et al. 2019 [57]	Quality of care	Qualitative	Decision support	Behavioral and interaction-based	Contents
Sooter et al. 2019 [58]	Quality of care	Qualitative	Decision support	Process and flow	Dynamical
Bilò et al. 2020 [59]	Quality of care	Qualitative	Decision support	Process and flow	Phenomenological
Bediang et al. 2022 [60]	Quality of care	Qualitative	Description	Behavioral and interaction-based	Contents
Cherif et al. 2020 [61]	Quality of care	Qualitative	Description	Behavioral and interaction-based	Narratological
Fitzgerald et al. 2019 [62]	Quality of care	Qualitative	Description	Behavioral and interaction-based	Narratological
Forde et al. 2022 [63]	Quality of care	Qualitative	Description	Behavioral and interaction-based	Narratological
Choukair et al. 2021 [64]	Quality of care	Qualitative	Description	Behavioral and interaction-based	Phenomenological
Depreitere et al. 2020 [65]	Quality of care	Qualitative	Description	Behavioral and interaction-based	Phenomenological
Lee et al. 2023 [66]	Quality of care	Qualitative	Description	Behavioral and interaction-based	Phenomenological
Talarico et al. 2020 [67]	Quality of care	Qualitative	Description	Behavioral and interaction-based	Phenomenological
Leach et al. 2022 [68]	Quality of care	Qualitative	Description	Behavioral and interaction-based	Thematical
Morales-Contreras et al. 2020 [69]	Quality of care	Qualitative	Description	Process and flow	Phenomenological
Allihaibi et al. 2021 [70]	Quality of care	Quantitative	Decision support	Behavioral and interaction-based	Artificial intelligence
Ajmi et al. 2019 [71]	Quality of care	Quantitative	Decision support	Behavioral and interaction-based	Simulation
Yang et al. 2023 [72]	Quality of care	Quantitative	Description	Analytical	Artificial intelligence
Cascini et al. 2021 [73]	Quality of care	Quantitative	Prediction	Analytical	Statistical/Mathematical
Payedimarri et al. 2021 [74]	Quality of care	Mixed	Description	Behavioral and interaction-based	Phenomenological and Statistical
Calabrese et al. 2024 [75]	Quality of care	Mixed	Description	Process and flow	Dynamical and Phenomenological

When modeling was process optimization (22.0 %), the main method used was quantitative (56.0 %), the main technique goal was decision support (56.0 %), and the main technique function was process and flow (56.0 %).

Among the 41 included articles, 30 reported unique combinations of subcategories. Therefore, only 11 articles shared similar combinations in at least two studies (Table 2). The most frequently observed combination, found in four articles, involved quality of care as the modeling objective, qualitative method, description as the technique objective, behavioral and interaction-based technique function, and phenomenological technique operational characteristic. Despite these similarities, variations in context, techniques, and tools were noted across studies.

3.2.4. Strengths and weaknesses in the modeling methodologies of the included studies

The analysis of the modeling methodologies used in the 41 articles revealed weaknesses that could concern any of the methods or techniques used (Supplementary file 3). Firstly, modeling could be challenged by technical difficulties such as limited availability data. In addition, the data may be too specific. This can lead to mistrust in the ability of a model to correctly or completely capture a complex system and real-world dynamics. Thus, these challenges can affect the accuracy of a model and the relevance of its applicability, making generalization difficult. Secondly, implementation challenges relate to the obstacles encountered in operationalizing modeling within existing healthcare frameworks. The implementation of organizational models may encounter resistance from caregivers or institutions. It requires their cooperation, which can be hampered by communication deficits. Moreover, healthcare models are often difficult to implement into existing systems and require significant validation to ensure they work as intended.

The systematic comparative analysis of the CP modeling techniques

Table 3
Identical classification combinations for 2 or more articles, with variations in contexts or techniques and tools used.

Author (1st), year, ref	MG	MU	TG	TF	TOC	Context	Techniques and Tools used
Allam et al. 2021 [41]	CI	Qt	Pr	PF	AI	General Hospital Care	Data Processing: AI-based trajectory analysis AI solutions, data from patient trajectories (Dynamic features) and baseline variables (Static features) that describe risk factors at the patient level
Funkner et al. 2022 [42]	CI	Qt	Pr	PF	AI	Emergency and Acute Care Coronary syndrome	Data-driven approach based on knowledge discovery algorithms, optimized by a surrogate-assisted approach. Evolutionary algorithms. The multi-objective optimization problem (MOOP) is used (a) as an object of modeling and optimization; (b) as a tool to solve an optimization problem
van Delft et al. 2021 [43]	CI	Mi	DS	BIB	Si&Ph	Lung Cancer Care	Timed automata-based model, experts' meetings, data from a cohort of patients, Markov techniques
Yakutcan et al. 2022 [44]	CI	Mi	DS	BIB	Si&Ph	Chronic obstructive pulmonary disease	Discrete event simulation model, literature, data from the hospital, semi-structured interviews, questionnaire, group meetings
Cherif et al. 2020 [61]	QoC	Ql	De	BIB	Na	Breast cancer care	Observational research. Thematic and lexicometric content analysis techniques. Patients' comments from a specific Internet forum
Fitzgerald J et al. 2019 [62]	QoC	Ql	De	BIB	Na	Dementia	The "voice of consumers" concept and the Ideal State Consumer Journey Model, using a healthcare-specific transformational change methodology. A consumer-centric visual approach using the storyboard design
Forde et al. 2022 [63]	QoC	Ql	De	BIB	Na	Pediatric Hospital - Somatic symptom disorders	Biopsychosocial (BPS) model, interviews and whiteboard: 'developmental history'
Choukair et al. 2021 [64]	QoC	Ql	De	BIB	Ph	Rare Diseases	Graphical visualization, discussion in groups with representatives of all disciplines involved in diagnosis, treatment and care
Depreitere et al. 2020 [65]	QoC	Ql	De	BIB	Ph	Low back pain and radicular pain	Consensus-based common sense, data visualization, literature study, medical guidelines, focus group, questionnaire
Lee et al. 2023 [66]	QoC	Ql	De	BIB	Ph	Gastrointestinal surgery	Process mapping developed by the research team (clinical experience of the research team), consensus within the team of experts
Talarico et al. 2020 [67]	QoC	Ql	De	BIB	Ph	Rare diseases	RarERN Path method, questionnaires, individual interviews or working groups; by face to face or virtual meeting, Delphi

AI: Artificial intelligence, An: Analytical, BIB: Behavioral and interaction-based, CI: Continuous improvement, Co: Contents, De: Description, DS: Decision support, Dy: Dynamical, MG: Modeling goal, Mi: Mixed, MU: Method used, Na: Narratological, PF: Process and flow, Ph: Phenomenological, PO: Process optimization, Pr: Prediction, Ql: Qualitative, QoC: Quality of Care; Qt: Quantitative, Si: Simulation, SM: Statistical/Mathematical, TF: Technic function, TG: Technic goal, Th: Thematical, TOC: Technic operational characteristic.

used in the included articles is summarized in Table 4 and detailed in Supplementary file 3. The analysis of techniques highlighted significant variations in their applicability, strengths, and limitations. Business Process Model and Notation (BPMN) and Value Stream Mapping (VSM) were widely used for process visualization and optimization, offering clarity and standardization but lacking adaptability to dynamic decision-making. Process Mining and Fuzzy Process Mining provided data-driven insights into real-world care pathways, yet they were highly dependent on data availability and quality. Discrete Event Simulation (DES) and Markov Chain Models enabled scenario testing and probabilistic forecasting but required specialized expertise and extensive computational resources. Agent-Based Modeling (ABM) effectively captured complex stakeholder interactions but demanded high calibration efforts. Ontology-based Modeling and Graph Theory (DAGs) enhanced interoperability and relationship mapping, though they faced challenges in integration with existing healthcare systems. AI-based approaches showed promise in predictive analytics, yet their interpretability and reliance on large datasets limited their widespread adoption. Stochastic approach improves service efficiency but requires specific expertise. System Dynamics captures system behavior but limits fine-tuned analysis. Petri Nets formalizes workflow logic but is less suited to highly complex situations. Delphi and action research are oriented

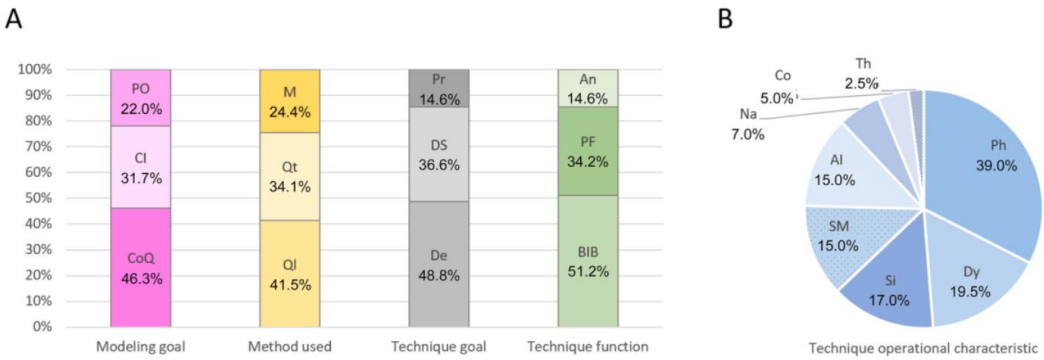

Fig. 3. Distribution of articles by categories of classification. A: Modeling goal, Method used, Technique goal and Technique function. B: Technique operational characteristics. AI: Artificial intelligence, An: Analytical, BIB: Behavioral and interaction-based, CI: Continuous improvement, Co: Contents, De: Description, DS: Decision support, Dy: Dynamical, Mi: Mixed, Na: Narratological, PO: Process optimization, Pr: Prediction, Ql: Qualitative, QoC: Quality of Care; Qt: Quantitative, PF: Process and flow, Ph: Phenomenological, Si: Simulation, SM: Statistical/Mathematical, Th: Thematical.

towards a quality perspective with a collaborative approach using repeated cycles of feedback for consensus but they consume resources (time) and may be subject to bias.

4. Discussion

In the health domain, the benefits of relying on CPs are fundamental because they concern safety and quality of care, the knowledge regarding real-world activities and the guidance of professional interventions, finally the resources used or subsequent costs. However, improving CP encompasses great complexity and numerous challenges, and remains a difficult concept to grasp,[78] requiring a holistic consideration. Recent initiatives provide several attempts to clarify this concept.[10,79] Indeed, implementation of CPs must be considered as a strategy to be mastered.[77] Such a strategy must promote solutions that harmonize stakeholders perspectives.[80] Numerous theoretical frameworks have been developed to enhance the understanding of the concept of CPs,[81] integrating both theoretical concepts and practical applications. The gap between the two is problematic, and can be even dangerous.[82] Health care providers make decisions every day in the context of incomplete information and uncertainty, which can lead to various shortcomings such as diagnostic errors, practice variability, and noncompliance with guidelines.[64] Solutions are needed to identify and reduce some relevant and frequent uncertainties.[71] Process modeling has emerged as a powerful tool serving healthcare organizations with a focus on performance or efficiency improvement.[63] However, modeling methodologies are not sufficiently adopted for designing, integrating and managing processes in the healthcare domain.[60] The use of an inappropriate modeling method can moreover hinder the proper handling of the activity interactions found in healthcare systems.[76] The choice of a relevant modeling thus requires careful consideration. Although the literature provides numerous articles on the topic, the methodology used to model the care pathway varies widely. Particularly, the lack of a standardized classification could result in inconsistencies due to ambiguous and varied descriptions.[83] The ability to classify methodologies according to their design elements would increase efficiency. Taxonomy is particularly well-suited to complex situations,[34] because this information management strategy improves knowledge sharing, facilitates research and policy initiatives, and provides guidance.[84] In the present study, a taxonomical approach was based on a classification with 5 categories and 23 subcategories.

Our results showed that the most frequently used method was qualitative (41,5 %), followed by quantitative (34,1 %) and mixed (24.4 %). However, a mixed methodology that combined these two methods brings greater benefits to the understanding of a research topic than the use of one alone.[85] The triangulation of data obtained by quantitative and qualitative methods provides a deeper and more complete picture of the phenomenon observed in healthcare.[86] Therefore, for a topic as complex as modeling of CPs, the use of mixed methods should be prioritized whenever possible. Our results also demonstrated that prediction through modeling was understudied. However, in the context of CP modeling, prediction is set to increase with the development of innovative digital solutions and the concept of the digital twin.[87]

Moreover, our categorical analysis of the modeling processes described in the included articles provides a methodological framework for researchers seeking to analyze and improve CPs. Our study focuses on cases where the researcher has defined his or her modeling objective. However, other perspectives can also be considered, such as cases where the researcher wishes to use a technical objective and examine the associated modeling structures. Thus, the present review provides an organized repertory of methodologies and techniques used, serving as a design support tool for CP modeling initiatives.

Other literature reviews have also explored CPs modeling,[88,89] but they are frequently monothematic, focusing on a single modeling technique such as process or data mining or simulation or stochastic modeling. The Emma Aspland's (2019) study,[21] which focused on a taxonomical demonstration, aimed to clarify the broad scope of "clinical pathway" by classifying research data.[21] This study highlighted the research interactions between mapping, modeling and improving pathways. Modeling methods were classified into four groups: stochastic modeling (7,5 % of papers), optimization heuristics (15,8 %), data mining or machine learning (20,8 %), and simulation (55,8 %). It also analyzed the relationship between these methods and six outcome measures: cost, legal (fraud or medical negligence), pathway mapping, patient progression (survival or disease progression), resource (capacity or staffing levels), and time (length of stay or waiting and traveling times). Although modeling was not the main focus of such work and the classification categories were limited, this study may provide insights for expanding the taxonomy of CPs modeling methodologies.

Our study has several limitations. Firstly, categories and subcategories chosen are not exhaustive. For example, for AI in our classification, machine learning and AI were selected, and AI could be more detailed with neural networks, deep learning, or generative AI. Secondly, the choice of a taxonomic approach to categorization can present a number of challenges,[90] including finding the right level of detail in the classification.[91] Thus, in our categorization, three defined subcategories (machine learning, anchoring and ethnography) were not used and, conversely, it is also possible that subcategories may be missing. Thirdly, the inclusion criteria such as publication date may have excluded some relevant publications. The five-year timeframe for

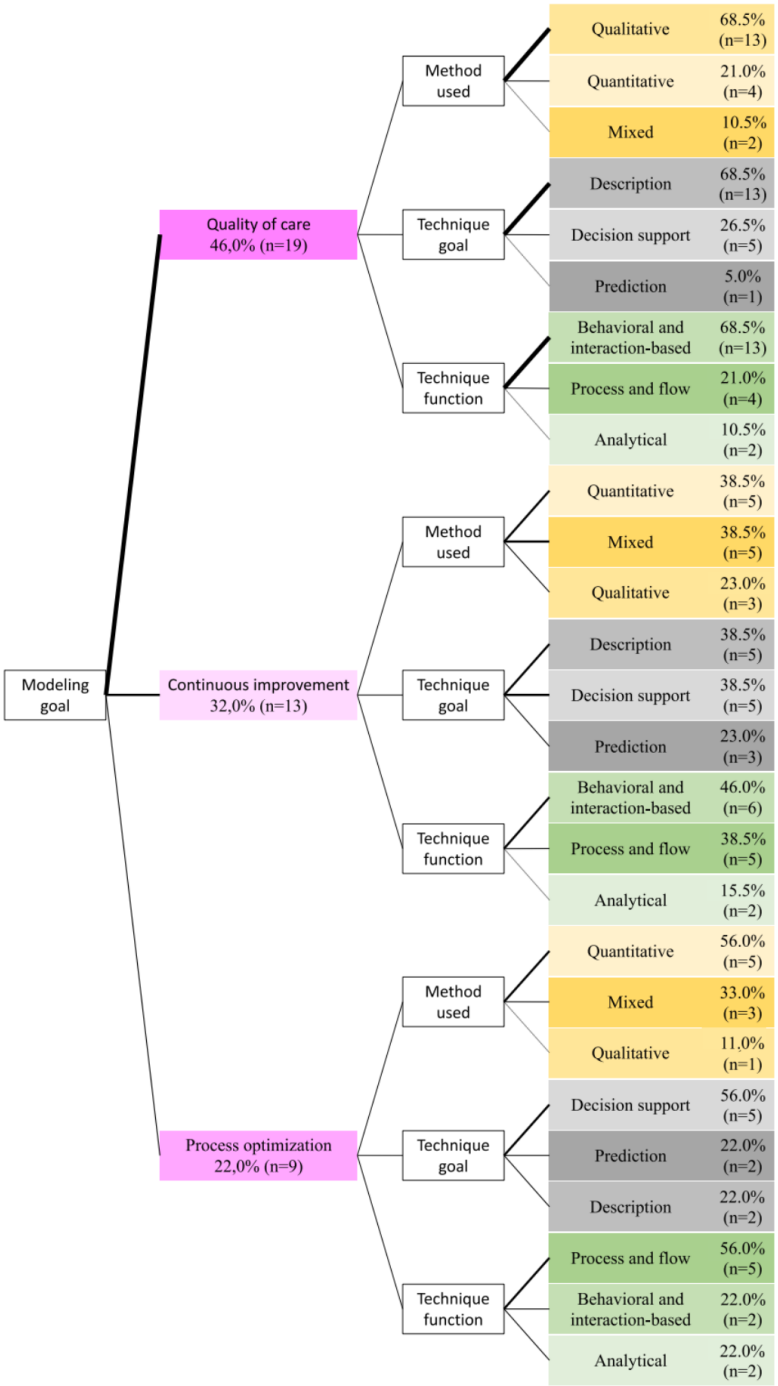

Fig. 4. Combinations of subcategories based on the modeling goals.

inclusion of articles, which, while aiming to manage excessive results and focus on recent studies, inherently excludes potentially valuable older research that could provide important insights into long-term trends or fundamental developments in the field, thus limiting the depth of the review and omitting significant results still relevant today. Fourthly, the search strategy across three databases aimed to provide a comprehensive overview, but it may have missed some sources, particularly those in the grey literature, not included in the data search.

Table 4
Comparative analysis of care pathway modeling methodologies.

Techniques	Description	Advantages	Limitations
ABM[53,54]	Simulation based on autonomous agents representing healthcare system actors	- Represents complex interactions between actors. - Useful for modeling patient-staff flows.	- Difficult calibration. - Requires many input parameters.
Action research[55,56]	Problem-solving through collaboration and reflection.	- Iterative improvement, integrates stakeholder feedback, fosters collaboration.	- Time-intensive, results not generalizable, requires institutional buy-in.
AI-based modeling[57,58,59]	Uses AI and predictive algorithms to improve CP	- Enhances forecast accuracy. - Can be integrated into hospital systems.	- Requires large and high-quality datasets. - Interpretability issues with AI models.
BPMN[60,61,62,63,64,56]	Graphical modeling of CP	- Clear and standardized representation. - Easy to interpret for healthcare professionals. - Can be combined with other methods (e.g., VSM, Process Mining).	- Limited in managing dynamic events. - Difficult to model complex decision-making processes.
Delphi[65,66]	Iterative feedback rounds	- Achieves expert consensus.	- Potential selection bias, time-consuming, lacks patient input.
DES[57,68,59,69]	Modeling hospital processes through event simulation	- Allows risk-free scenario testing. - Provides precise quantitative data.	- Requires expertise in modeling. - Does not always account for human interactions.
DMN[61,64]	Standardizes clinical decision-making to improve automation	- Complementary to BPMN. - Easily implementable in digital systems.	- Lacks flexibility for complex decisions. - Requires extensions to model clinical data.
Fuzzy Process Mining[70]	Modeling based on fuzzy values to represent uncertainty in pathways	- Accounts for process variability. - Useful for complex medical processes.	- Implementation complexity. - Difficulty in interpreting results.
Graph Theory & DAG[53]	Uses graphs to model complex relationships in care pathways	- Effectively visualizes event relationships. - Helps predict clinical outcomes.	- Difficult integration into hospital software. - Requires high-quality data.
Markov Chain & Monte Carlo Simulation[71,68,59]	Probabilistic modeling of state transitions	- High precision in medical process modeling. - Allows robust forecasting.	- Dependent on data for calibration. - Complex result interpretation.
MCDM[62]	Helps in multi-criteria decision-making in healthcare	- Robust and objective evaluation of alternatives. - Considers multiple factors.	- Methodological complexity. - Requires expertise in decision analysis.
Ontology-based Modeling[57,72,73]	Structuring and formalizing knowledge on CP	- Enhances system interoperability. - Useful for decision-support systems.	- Development complexity. - Difficult integration with existing systems.
Process Mining[74,75,62]	Analysis of hospital information system data to reconstruct pathways	- Based on real data. - Identifies bottlenecks.	- Dependent on data quality. - Implementation difficulties.
Petri Nets[76]	Graphical, for concurrent system modeling.	- Formalizes workflow logic and resource utilization.	- Limited expressiveness for complex clinical pathways, requires technical expertise.
Stochastic approach[69,77]	Randomness of optimization processes in CP	- Addresses uncertainty in resource allocation, improves service efficiency.	- Requires mathematical expertise, context-specific results, scalability challenges.
VSM[63]	Visual tool used to analyze, design, and optimize CP	- Highlights inefficiencies. - Helps restructure processes. - Complementary to BPMN.	- Less effective for complex or unpredictable processes.

ABM: Agent-based Modelling, AI: Artificial Intelligence, An: Analytical, BIB: Behavioral and interaction-based, BPMN: Business Process Model and Notation, CI: Continuous improvement, DAG: Directed Acyclic Graphs, De: Description, DES: Discrete Event Simulation, DMN: Decision Model and Notation, DS: Decision support, Dy: Dynamical, MCDM (Multicriteria Decision-Making), MG: Modeling goal, MU: Method used, PF: Process and flow, PO: Process optimization, Pr: Prediction, Ql: Qualitative, QoC: Quality of Care; Qt: Quantitative, Si: Simulation, SM: Statistical/Mathematical,TF: Technic function, TG: Technic goal, TOC: Technic operational characteristic, VSM: Value Stream Mapping.

Fifthly, this study did not have a pilot test phase with assessment of inter-rater agreement via Cohen's κ statistic to validate the selection process. Sixthly, this literature review provides essentially descriptive and useful information to guide healthcare providers, but the effectiveness of these choices remains questionable given the lack of information in the articles analyzed. Sixthly, this literature review provides essential descriptive insights to guide healthcare providers. However, its ability to assess the effectiveness of these choices is limited due to the lack of robust data in the analyzed studies. While some articles highlight technical limitations, many do not, making it difficult to evaluate the benefits and drawbacks of the proposed approaches. A rigorous assessment of a modeling methodology would require comparative studies across different contexts, ensuring its applicability and relevance. Modeling offers a structured perspective on complex systems, where the choice of approach should be based on the alignment between objectives and available resources. This scoping review contributes to this reflection by facilitating the search for methodological congruence, but further research is needed to strengthen and expand these findings.

In conclusion, understanding the complexity of CPs is essential, and modeling them is a key solution when designed with a clear strategy. This scoping review has identified some key categories of CP modeling and the most commonly used methodologies. However, the design of CP models is not without its challenges, including data-related issues and barriers to acceptance. As we move forward, it is clear that the modeling of CPs must be integrated into a broader strategic plan, taking into account the entire system in which the CP operates. While this review provides a coherent framework for researchers and healthcare professionals, there is still much to be done in terms of refining these models, addressing the identified barriers, and exploring new methodologies. Future research should focus on overcoming data limitations, fostering greater stakeholder engagement, and enhancing the adaptability of CP models to different healthcare contexts. By continuing to build on this foundational work, we can ensure the better implementation and evaluation of CPs, ultimately leading to improved patient outcomes and more resilient healthcare systems.

Author statements

Ethical approval

This scoping review utilizes existing published studies and ethical approval was therefore not required.

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Competing interests

The authors declare that they have no competing interests.

Authors' contribution

BD: Conceptualization, Methodology, Investigation, Data curation, Writing – original draft. RL: Investigation, Data curation, Writing – original draft. GM: Investigation, Data curation, Writing – review & editing. CD: Conceptualization, Writing – review & editing. FC: Conceptualization, Methodology, Investigation, Data curation, Writing – original draft. RL: Investigation, Data curation, Writing – original draft. All authors have read and agreed to the published version of the manuscript.

Availability of data and materials

All data generated or analyzed during this study are included in this published article and its supplementary information files.

Use of generative AI

The authors declare that they have not made use of generative AI and AI-assisted technologies in the writing process of this manuscript.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.puhe.2025.105751.

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Supplementary file 1: Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	1-2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	3-4
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	4
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	NA
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	4
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	4
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	4
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	4-5
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	4-5
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	4-5
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this	NA

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
		information was used in any data synthesis (if appropriate).	
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	4-5
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	6
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	Supplementary File 2
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	NA
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	6-11, Supplementary File 2
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	6-11
DISCUSSION			
Summary of evidence§	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	11-12
Limitations	20	Discuss the limitations of the scoping review process.	12
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	13
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	13

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.
* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.
† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).
‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.
§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

Supplementary file 2: Definitions of categories and subcategories

- The modeling goal

The goal pursued by using care pathway modeling has been classified into three categories: quality of care, process optimization, and continuous improvement.

- Quality of care

It's about ensuring that patients receive care that is effective, safe and based on the best available evidence. This involves standardizing clinical practices to minimize unnecessary variation and improve patient outcomes. This is expected to lead to greater consistency in care, fewer medical errors, and improved health outcomes. This includes striving to improve the patient experience by reducing waiting times, facilitating transitions between services, and making care more personalized and coordinated. It aims to increase patient satisfaction, improve treatment compliance and create a positive perception of the care received.

- Process optimization

It's about mapping care processes to identify inefficiencies. This involves streamlining workflows to improve coordination between different healthcare services. This includes identifying sources of waste and opportunities to reduce costs without compromising the quality of care. It aims to optimize the use of human and material resources.

- Continuous improvement

It's about an approach based on a culture of ongoing progress. The emphasis is on continual assessment of performance and adaptation of practices to meet changing needs. It aims for progressive and sustainable improvements in the organization's processes and overall results. This includes informing decision-making. It aims to ensure that patients receive the right care at the right time.

The point of this categorization is to be able to identify the types of methods and techniques used in the literature according to the main objective sought when setting up a care pathway modeling approach.

- The method used

A method is an intellectual concept designed to coordinate a set of operations. It is a way of thinking, following principles and a certain order of reasoning. It is an organizational strategy used to trace the way to be followed. Its implementation requires the use of techniques.

The method used to model the care pathway has been classified into three categories: quantitative, qualitative and mixed.

- Quantitative

A quantitative method is a research approach used to collect and analyze numerical data in order to identify relationships between variables. This method is characterized by the use of standardized measurement techniques and statistical tools.

- Qualitative

Research approach used to gather non-numerical data in order to understand complex phenomena, behaviors, experiences and social interactions. It is characterized by the collection of rich, detailed data through techniques such as interviews, observations, document analysis and focus groups. The main aim is to explore and describe in depth the perceptions, motivations, attitudes and experiences of participants, often in their natural context. Qualitative methods favor an inductive approach to data analysis, developing theories and concepts.

- Mixed

Research approach that combines qualitative and quantitative data collection and analysis techniques to obtain a richer, more complete understanding of the phenomena under study, drawing on the strengths of each method while compensating for their respective weaknesses.

These methods are based on specific research considerations. They are approaches that can mobilize different philosophical conceptions. The point of this categorization is to be able to identify the goals sought and the techniques used according to the method chosen.

- The technique goal

A technique is the application of a practical process to accomplish a task. Its implementation requires the use of tools (instruments, resources, objects used).

The goal pursued by using a type of technique to model care pathway has been classified into three categories: description, prediction, and decision support.

- Description

For techniques to provide an in-depth understanding of data, to identify patterns, links, relations and underlying structures, and to summarize and represent the essential characteristics of the data. Used to describe the current or past state of care pathways. Such as exploratory data analysis, descriptive statistics or data visualization.

- Prediction

For techniques to predict future or unknown values, to develop accurate models for reliable forecasts. Used to describe the future state of care pathways. Such as logistic regression models, neural networks, decision tree algorithms (e.g., Random Forest, Gradient Boosting), or support vector machines (SVM).

- Decision support

For techniques to provide optimal recommendations for decision-making, optimize processes and resources, and support strategic and operational planning. Used to help making choices by optimizing resources and interventions.

The point of this categorization is to be able to identify possible matches between the goals sought by modeling and the goals of the techniques used.

- The technique function

The function allows to indicate the determined activity that is entrusted to the technique, the role that is assigned to it, the duty that it must perform. The functions to which a care pathway modeling technique may be attached have been classified into three categories: process and flow, behavioral and interaction-based, and analytical.

- Process and Flow

For techniques to visualize and optimize business processes, improve workflow efficiency and coordination, identify inefficiencies and bottlenecks. Use of standardized diagrams and notations to represent steps, decisions, and information flows. Analysis of sequences of activities and control points.

- Behavioral and interaction-based

For techniques to understand the dynamics and interactions between the actors of the system, to study emerging behaviors and responses to interventions, to simulate complex scenarios to predict the impacts of changes. Use of models simulating interactions between individuals or entities. Modeling of individual behaviors and effects of interactions at the systemic level.

- Analytical

For techniques to analyze the economic impacts and long-term outcomes of decisions, optimize resources and strategies based on quantitative analysis, support informed decision-making through data and predictive models. Use mathematical and statistical models to analyze data and predict results. Modeling of complex systems with feedback loops to study long-term effects.

The point of this categorization is to refine the overall coherence and to check the adequacy between the goals sought and the tools used.

- The technique operational characteristic

The operational characteristic of a technique makes it possible to distinguish it according to its application framework and its specific properties of implementation. The operational characteristics identified are 11.

- Statistical / Mathematical

Analytical techniques, whether statistical or mathematical, are essential for collecting, organizing, interpreting and presenting data, enabling conclusions to be drawn and informed decisions to be made. Both approaches provide a richer, more comprehensive understanding of the phenomena under study, facilitating the resolution of complex problems through robust theoretical tools and empirical analysis. Statistical techniques use probabilistic tools to infer properties of populations, and rely on assumptions about the distribution of data and relationships between variables. Mathematical

techniques use deductive tools to prove theorems and solve equations, and rely on arithmetic and algebraic operations, as well as differential and integral analysis.

- Machine learning

For algorithm-based techniques enabling computer systems to learn and improve automatically from data. They include supervised, unsupervised and reinforcement-based approaches to classification, prediction, pattern recognition and decision-making. The aim is to learn from data to make predictions or classifications without being explicitly programmed for each task. Focused on using data to train algorithms to recognize patterns and improve their performance over time. Includes supervised, unsupervised and reinforcement learning, decision tree, feature engineering, ...

- Artificial intelligence

For algorithm-based techniques enabling machines to simulate human cognitive functions, using different approaches to create intelligent systems (logical, symbolic, heuristic...), promoting reasoning and decision-making. Includes: fuzzy logic, knowledge representation, expert systems, automated reasoning, ...

- Simulation

For techniques based on a process of creating a computer model, to reproduce the behavior of a real system in order to analyze its operation, predict its performance, and test different scenarios without intervening on the real system. Includes: Monte Carlo simulation, discrete-event simulation, continuous simulation, agent-based modeling (ABM)...

- Dynamical

For techniques based on an approach for describing and analyzing the behavior of a dynamic system, whose state evolves over time, such as systems whose variables change continuously, or discrete systems whose changes occur at specific time intervals. Includes: block diagram modeling, hybrid simulation models, ...

- Contents

For techniques based on coding and interpretation of textual and visual content to identify patterns. To describe and quantify content and identify trends. Coding text or images, categorizing information, analyzing theme frequencies. Example: Analysis of interview transcripts to identify participants' main concerns.

- Thematical

For techniques based on the identification, analysis and reporting of patterns (themes) within data. To discover and interpret recurring and significant themes. By reading and rereading data, searching for themes, defining and naming themes.

- Grounded

Generates theories from data, rather than testing pre-existing hypotheses. Data collection and analysis take place simultaneously. The coding of results is stratified: open, axial and selective. On a non-random, but theoretical sample, for empirical understanding.

- Phenomenological

For techniques that focus on the study of lived experiences and the subjective meanings that individuals attribute to these experiences. This approach seeks to understand how people perceive and interpret their own reality, using description rather than explanation. They aim to reveal the fundamental structures of these experiences to offer a profound understanding of human perceptions and meanings.

- Narratological

For techniques that focus on the different ways in which stories are told and the elements that make up those stories. The aim is to examine the internal mechanisms of narratives to understand how they produce meaning and how they affect the participant. They may involve analyzing the internal structures of stories.

- Ethnographic

For immersive techniques enabling the study of cultures and communities by observing and participating in their daily lives, in order to understand the behaviors, values and practices of an individual or group in context.

Supplementary file 3: Characteristics of included studies

BPMN: Business Process Model and Notation; BPS: Biopsychosocial; CMMN: Case Management Model and Notation; CP: Care pathway; DAG: Directed Acyclic Graph; DES: Discrete event simulation: DMN: Decision Model and Notation; HIS: Health Information Systems; DES: Discrete Event Simulation; MCDM: Multicriteria Decision-Making Methods; PM: Process Mining; UML: Unified Modeling Language; VSM: Value Stream Mapping; LOS: Length Of Stay; ICP: Integrated Clinical Pathway; OM: Optimal Matching; TP: Task Planning; PCCP: Psychosocial Clinical Care Pathways; SCM: Shared Care Model

Author Year Country	Context	Techniques used Tools used	Interests	Limitations
Aissaoui et al. [48] 2022 Tunisia	Hospital and CPs Multidisciplinary outpatient clinics	Systematic BPMN-VSM based process analysis approach: - BPMN: "life cycle", "AS-IS", "TO-BE" - VSM: from the Lean Management concept Case study approach, Five-why analysis, Root cause analysis	BPMN and VSM complement each other in enhancing clinical management and continuous improvement. GV: Provides tools for detecting failures and supporting continuous improvement. BPMN: Uses simple graphical elements to improve clinical processes, useful for modeling clinical pathways and hospital processes. VSM: Maps process flows as timelines, addressing patient needs through visualization and resource quantification. It restructures processes in four steps, aiding in patient care delivery and supporting work processes. Together, BPMN and VSM effectively visualize, quantify, and improve clinical processes and patient care delivery.	- BPMN and VSM have limitations noted in academic literature. - These limitations have led to extensions and combinations with other tools. - Some limitations are related to their general structure, while others are domain-specific. - This study involved a unique case study and data collection period was short.
Ajmi et al. [63] 2019 France	Emergency	Multi-agent system, Agents' behavior and communication protocols, INGENIAS methodology: to allow an efficient transition from the specification to the code and allow different settings to test the system with a low cost Performance Indicators, a scheduling and (re)-orchestration algorithms.	- To establish a direct real-time link between required performances and effective actions to reduce overcrowding. - **Multi-agent approach:** - Used for modeling and resolving complex problems where centralized approaches are limited. - Allows a decentralized system representation via autonomous, rational, and interactive entities called "agents." - Agents are software entities that can perform multiple roles and behaviors, and can represent human beings (e.g., medical staff agents) with mobility. - Facilitates discussion on the relevance of metrics to select the best ones for a given study context. - **Focus on three performance indicators**: - Remaining Patient Care Load: Estimates what remains in care within the complete patient care process. - Cumulative Waiting Time. - Length of Stay.	- Agent-based models can be complex to implement and calibrate. - Model accuracy heavily depends on the quality of available input data. - Results may not be generalizable to other contexts or healthcare systems.

Alahmar et al. [31] 2020 Canada	Emergency and Acute Care Length of Stay of stroke patients	CP automation by ontology method and machine learning algorithms, statistical analysis Electronic Health Record, Health Information Systems (HIS), Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT), Laboratory Information Systems software systems, Health Level 7 messaging functionality, R programming language - "RStudio"	- To reduce data missingness problems, enabling detailed statistical analyses on CP data, and improving the results of data analytics algorithms. **- SNOMED CT-based automation framework:** - Digitizes CPs. - Makes e-CP systems central components in HIS. - Enables detailed statistical analysis of CP interventions. - Maximizes data extraction from CPs. **- Addressing missing data in HIS:** - Achieved by fully digitizing and integrating CPs with HIS. - Generates rich datasets. - Improves the performance of data analytics algorithms in healthcare. - **Key contribution:** - Complete digitization and automation of e-CPs capture all CP data. - **Results:** - Demonstrated improved prediction results compared to LOS prediction using traditional EHR-based datasets.	- **Main focus:** Nursing services as a factor affecting stroke patients' Length of Stay (LOS). - **Other influencing factors:** Comorbidity, diabetes…
Allam et al. [33] 2021 Switzerland	General Hospital Care	Data Processing: AI-based trajectory analysis AI solutions, data from patient trajectories (Dynamic features) and baseline variables (Static features) that describe risk factors at the patient level	- To estimate the likelihood of future health outcomes, cluster the patient cohort while accounting for the longitudinal form of patient trajectories, detect clinically meaningful sub patterns in patient trajectories. - **Benefits:** - Understanding how and why health measurements change over time - AI-based trajectory analysis enhances existing computational approaches for: Disease prevention, detection, diagnosis and treatment	- **High barriers of entry:** - Complexity in using AI-based trajectory analysis methods **- Limits of use:** - Complexity Data access and sharing issues in medicine - **Communication challenges:** - Difficulty in communication between AI developers and medical experts - **Involvement of multiple actors:** - Requires collaboration between regulation, law, data science, and medicine professionals
Allen et al. [46] 2022 UK	Emergency and Acute Care Stroke and thrombolysis	Machine learning (Turing Way and Monte Carlo simulation models) and interviews Data on hospital admissions, STRESS guidelines (Strengthening the Reporting of Empirical Simulation Studies), TRIPOD guidelines (Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis)	- **CP Simulation:** - Used to model effects of changing pathway performance. - **Qualitative Research:** - Assessed clinician attitudes toward the simulation methods. - **Three Changes Modeled:** 1. Arrival-to-treatment time in 30 minutes. 2. Proportion of patients with determined stroke onset times set to at least the national upper quartile 3. Thrombolysis decisions made based on the majority vote of a benchmark set of hospitals. - **Outcomes:** - Identified ways to improve care process management. - Clinicians engaged well with the modeling.	- **Data Limitations:** - Individual case decision-making should not rely solely on these tools due to the limited data available per individual. - **Hospital Variability:** - Significant variation in care depending on local patient population. - Each hospital should establish its own targets. - **Clinician Attitudes:** - Clinicians from hospitals with lower care process use were more cautious about the methods. - Confident thrombolysing physicians, who needed the methods least, were more open to the influence of machine learning and quality improvement techniques. - **Machine Learning Model:**

				- Predicts the use of thrombolysis but does not directly predict patient outcomes.
Allihaibi et al. [62] 2021 Australia	Emergency and Acute Care	Stochastic Simulation-Optimization approach, by using statistical distributions techniques, the stochastic optimization mixed integer programming (SOMIP) approach, and the Discrete Event Simulation model Stochastic variables, such as patient interarrival times and treatment time, a hybrid evolutionary algorithm (Genetic Algorithms)	- Serve more patients in specific time windows - Provide the same quality of the service using fewer medical resources.	- Requires development of a prospective mathematical model for integrated medical units - Utilizes hybrid metaheuristic techniques - Addresses large scale size problems.
Ardito et al. [28] 2020 Italy	CP	A meta-model based on a General Purpose Description Language Business Process Modeling Notation (BPMN2.0) language, UML class diagram, IDEFx (Integration Definition for Function Modelling), Chatbot	- To ensure high degree of automation in process execution - Execution engine implemented as a chatbot integrated with social media - Acts as a virtual assistant during the entire ICP execution - Gathers patient's health data - Does not require the medical community to adopt a complex process-modelling language - Knowledge from the graphical ICP process model using GPDL flows easily into the meta-model - Alternative to AI and NLP-based approaches	- Dialogue text is constructed to vary for the same context - Prevents static dialogue by using different phrasing - Achieves dynamic dialogue through an appropriate selection algorithm.
Bediang et al. [52] 2022 Switzerland	CP	Knowledge engineering -Ontology-based semantic model. "Shareable and Reusable CP Ontology (ShaRE-CP)", developed according to a modular approach. The Uschold et al. approach Literature, the ontology editor Protégé, The Web Ontology Language Second Edition (OWL2), Web services (OWL-S), the ontology of time and the Dublin Core ontology	- To improve quality and efficiency of care through the support of health professionals in the design, development and use of CPs, taking into account the evolution of knowledge and the context, like other ontologies. - Promotes sharing and reusability of CPs across different contexts - Useful for reasoning to detect inconsistencies and generate new knowledge before, during, and after CP execution - Serves as a basis for developing decision support systems for planning, managing, and optimizing patient care, especially in resource-limited settings - Iterative process identified main concepts and relations for developing the domain ontology - Enables formal description of knowledge domains (classes and relations) - Facilitates inconsistency detection and new knowledge generation via a reasoning engine.	- Complexity in integrating ontologies - Extensive validation needed to ensure accuracy - Limitations in practical application - Requires specific adaptation to healthcare institutions - Potential compatibility issues with existing systems and data formats.

Beny et al. [27] 2022 France	Rare diseases Haemophilia	Mapping Face-to-face interviews of health professionals, work observations	- Data used for social network analysis and structural/functional modeling of the hospital network - Highlights specific elements within the network - Identifies obstacles and barriers - Reveals structural weaknesses, aiding in recommendations and improvements - Interview methodology (individual or group with health professionals) effectively assesses and characterizes unique influencers	- Selection bias: identification and recruitment of participants.
Bernardi et al. [32] 2019 Spain	Hospital and CPs Orthopedic Department	Healthcare System Specification based on Unified Modeling Language profile. With timed and Stochastic Petri Net bounding techniques (Stochastic Well-formed Net model) Petri Net model (a Stochastic Well-formed Net model), a software platform (HEAT)	- Simple graphical modeling language with few primitive elements for introducing CPs for specific diseases - Specifies three essential aspects: Patient flow, Resource utilization and Information interchange - Utilizes basic elements from Unified Modeling Language (UML) activity diagrams, which are easy for medical doctors to understand - UML extensions include tagged values for activity nodes and edges - Provides transformation patterns from UML elements to Stochastic Well-Formed Nets for formal CP modeling	- Parallel activities cannot be modeled - Decision support systems need rigorous validation for reliability and effectiveness - Dependence on specific hospital or regional data limits result generalization - Implementation and adoption may encounter resistance within healthcare institutions
Bilò et al. [51] 2020 Italy	General Hospital Care Hymenoptera venom allergy (HVA)	The 8 steps method of Lodewijckx et al 2012, data visualization by flow diagram Literature review, face to face meeting of experts	- Identifies key interventions (rational and core activities) and process indicators - Develops a set of indicators to assist clinicians and healthcare organizations - Helps assess the quality of care based on evidence-based recommendations	- Multidisciplinary expert group is essential - Limited by lack of patient involvement - Indicators must be verified through specific clinical audits
Boareto et al. [47] 2022 Brazil	Emergency and Acute Care Stroke patients	Combination of: - Process Mining (PM) - Discrete Event Simulation (DES) - Multicriteria Decision-Making Methods (MCDM) ROMETHEE II technique: an outranking method) Data visualization with BPMN Technique Literature, data available in the event log, interactions with domain experts, SimPy (a python library for DES), Nurses interviews, A BPMN software	- Identifying activities ensures statistical accuracy of improvements and eliminates the need for on-site testing. - PM: Transforms event records into process models. - DES: Explores and simulates alternative scenarios. - MCDM: Provides robust, mathematically-based decisions considering various criteria. - Combining PM and DES enables agile process simulation with process specialists using a common language. - Combining DES and MCDM strengthens decision-making for process improvement, addressing multiple scenarios and indicators while avoiding patient risks from on-site testing. - Methodology could be used to optimize bed distribution in hospitals.	- Research does not cover root cause diagnosis for activity improvement - Simulation is limited by its level of granularity - Hospital and healthcare environments may not be sufficiently mature for data-dependent process improvement initiatives

Calabrese et al. [67] 2024 Italy	Emergency and Acute Care Transient loss of consciousness	Service design and action research methodologies, embedded within the overarching framework of a digital transformation initiative. Process mapping based on BPMN technique. Processes simulation approach Literature, Semi-structured interviews, Bizagi Process Modeler software, BPMN 2.0	- Service design and action research use iterative phases, alternating between action and reflection to drive change and learning - Action research is effective for developing, implementing, and troubleshooting new processes, and for documenting factors affecting problem-solving - Service design focuses on end-user needs and experiences, making it suitable for developing new digital processes - Combining service design and action research provides a holistic framework for digital transformation of CPs - Process simulation measures key performance indicators and tests for improvements - Digital transformation is proposed as a comprehensive solution for detecting bottlenecks and optimizing diagnostic CPs - The approach enhances patient care and advances the digitalization of diagnostic CP management, offering valuable insights into healthcare management.	- Extending the solution to support CPs involving surgical interventions adds complexity
Cascini et al. [65] 2021 Italy	Hospital and CPs	Data-driven approach: Data collection procedure, analytical-descriptive model, predictive model, customizing the model Clinical records	- Supports organizational and clinical decision-making through a predictive model - Evaluates clinical risks at each stage of the patient journey - Records and calculates variables and behaviors affecting healthcare safety and quality over time - Enhances understanding of healthcare processes and their complexity - Assists healthcare professionals in selecting optimal care strategies, managing interventions, and reducing hospital stay length - Provides information to refine CPs by highlighting patients' health risks and undesired outcomes related to their intra-hospital journeys	- Requires a stand-alone information system or an extension of existing systems in the healthcare facility - Needs a developmental phase with multidisciplinary collaboration among medicine, healthcare, data science, and information systems experts
Cherif et al. [53] 2020 France	Cancer Care Breast cancer	Observational research based on nethnography method. Thematic and lexicometric content analysis techniques Patients' comments from a specific Internet forum, Tropes® software	- Nethnography adapts traditional ethnography to the characteristics of online communities - Qualitative research methodology for using, collecting, analyzing, and interpreting publicly available online information - Offers original modeling of the patient pathway - Provides insights into patient typology - Suggests practical improvements for the healthcare pathway	- Only one source: information publicly available online. - Passive patients not included.

Choukair et al. [56] 2021 Germany	Rare Diseases	Graphical visualization, Clinical Test Discussion in groups with representatives of all disciplines involved in diagnosis, treatment and care, pdf, cvs file, SSP26	- The chart displays various event courses based on diagnostic results and expert clinical decisions - The checklist documents the patient's CP in a concise yet comprehensive manner - Details each process step with required actions or information - Captures what has been done in response to each item - Combines a generic CP with evidence-based guidelines - Allows disciplines to adhere to their specific guidelines and documentation needs - Creates a unified set of information essential for evidence-based clinical decision-making	- Nationwide application necessitates resolving major issues related to digital interoperability and data protection
Crozes et al. [43] 2023 France	Emergency and Acute Care After acute stroke	Retrospective observational study based on statistical method and sequential analysis (Optimal Matching and clustering), multinomial logistic regression, gamma regression and Generalized Linear, data visualization by Tempograms Hospital data and electronic medical records. Ecological index of deprivation (European Index of Deprivation). Chi test and ANOVA test (Fisher's exact test and the KruskalWallis test)	- Optimal Matching (OM): Identifies all possible sequences of chronological states based on defined time steps - Measures sequence similarity and distances using operations like insertion, deletion, or substitution with associated costs - Hierarchical ascending classification: Clusters typical paths from the dissimilarity matrix established by OM - Multinomial logistic regression: Analyzes the impact of socioeconomic characteristics on healthcare providers using an ecological deprivation index - Gamma regression model: Assesses healthcare costs - Identified 4 typical hospital CPs, revealing user needs, particularly for disadvantaged groups, and resources for comprehensive care - Demonstrates that healthcare costs vary with deprivation levels - Provides practical guidelines for coordinating care pathways among different health system stakeholders	- Focused exclusively on in-hospital pathways, where data is denser and sequences are more defined - Limitation: Selection of participants through the Hospital Information System may not fully represent the population - Expected under-representation of comorbidities
David et al. [38] 2021 Zimbabwe	Hospital and CPs Prenatal care	Care Pathway Modelling theory (Schrijvers G 2012) and systems thinking theory Literature, Retrospective medical record data, clinician interviews, checkland and Poulter's (2006) Soft System Methodology (SSM), Network Tools for Intervention Modelling with Intelligent Simulation [NETIMIS] ('spaghetti' visualization).	- A well-planned CP can educate patients on danger signs, symptoms, and risk factors - Facilitates early intervention to prevent adverse effects from diseases	- Modeling relies on data from the central hospital, which may not represent other contexts or hospitals - Quality and accuracy of the data can limit the modeling - Results may not be generalizable beyond the studied context

De Oliveira et al. [45] 2020 France	General Hospital Care	Process mining method, Mathematical formulation, Ascending representation and time-dependent features (grid process model, Petri net unfolding and time grid process model). Spring search (greedy heuristic) and Tabu search (with optimized edges) procedures Literature, data including events, traces and event logs. The fitness measure. A tablet application developed by the company HEVA	- Process Mining: Discovers, monitors, and improves actual processes by extracting knowledge from event logs in IT systems - Positioned between Big Data/Data Mining and Business Process Modeling/Analysis - Three main areas: Process discovery, Conformance checking and Model extension - Ascending representation: Avoids loops and backward transitions; considers time patterns of event logs during optimization - Tabu search algorithm: Determines the optimal process model to maximize replayability while adhering to node and arc constraints - Fitness measure: Assesses how well a process model captures causal relations in event logs - Process model optimization: Aims to determine an optimal grid process model - Defines descriptors to characterize process model structure and event log complexity - Grid structure, time patterns, and frequent event displays: Provide interpretative insights for medical staff and decision-makers	- Tabu Search with Optimized Edges: More efficient with low event diversity - May require specific constraints to produce a comprehensible and visually interpretable model - Current classification methods use only "flattened data" (feature vectors) as input
Depreitere et al. [57] 2020 Belgium	General Hospital Care Low back pain and radicular pain	Consensus-based common sense, data visualization Literature study, medical guidelines, focus group, questionnaire	- A multidisciplinary approach is crucial in all studied pathways - The current pathways have been positively received by both the Belgian national health insurance and the government	- The process required urgency, goodwill, and perseverance - Training and change management were crucial for successful pathway initiatives in larger regions.
Fan et al. [37] 2022 China	Chronic Diseases Diabetes	Ontology: the management process of diabetes is divided into 9 management tasks, and the Diabetes Care Pathway Ontology is constructed to represent the knowledge contained in this pathway model, retrospective study Literature, evidence-based medical guidelines and expert recommendations, data records extracted from a telehealth system, SPSS software, SpringBoot+MyBatis+MySQL design architecture	- Guides the timing and content of interactive interventions between physicians and patients - Regulates physicians' medical service behavior - Formulates distinct management plans for physicians and patients - Ontology represents domain knowledge in a machine-readable and formal format - Can be integrated into a clinical decision support system as a knowledge base.	- The 3 compared ontologies were limited to comprehensive diabetes management for patients - Management plans primarily focused on patients, overlooking physicians' responsibilities and the importance of their interventions.

Fitzgerald et al. [54] 2019 Australia	CP	The “voice of consumers” concept and the Ideal State Consumer Journey Model, using a healthcare-specific transformational change methodology. A consumer-centric visual approach using the storyboard design (Essomenic™ approach) Discussions groups within participatory workshops, DXC’s Essomenic software to map participants’ journeys	- The study concentrated on consumer needs and wants within the healthcare system - Developed “storyboards” offer clear insights into consumer experiences, highlighting effective initiatives and areas needing improvement - Findings will aid policymakers, healthcare providers, and researchers in better planning and addressing the needs of people with dementia and their caregivers - Identified issues include: - Long lead times to diagnosis - Varied experiences with treatment and support - Poor care coordination and insufficient consideration of its impact on consumers	- Information about services, their purpose, and eligibility criteria was hard to obtain - Potential CPs were often poorly explained - Most carer support was reactive rather than proactive
Forde et al. [55] 2022 Norway	General Hospital Care Paediatric - Somatic symptom disorders	Biopsychosocial (BPS) model literature, Interdisciplinary team, Interviews and whiteboard: ‘developmental history’	- The BPS model uses assessment and treatment of complex conditions, integrating information from diagnostic tools while evaluating phenomena beyond their scope - Guides the development of holistic, interdisciplinary healthcare at all levels - Identifies key factors: - Predisposing factors - Sensory and emotional vulnerability - Triggering factors - Reinforcing factors - Provides new insights into the interplay of factors contributing to symptoms, supporting treatment and rehabilitation	- Requires an interdisciplinary approach with patients and caregivers at the center - Begins with a thorough medical examination for accurate assessments - Success depends on a shared understanding among patients, caregivers, and professionals - Evaluates the significance of individual factors in the context of overall causal factors and symptoms.
Funkner et al. [34] 2022 Russia	Emergency and Acute Care Coronary syndrome	Data-driven approach based on knowledge discovery algorithms, optimized by a surrogate-assisted approach. Electronic health records (EHRs), Evolutionary algorithms. The multi-objective optimization problem (MOOP) is used (a) as an object of modeling and optimization; (b) as a tool to solve an optimization problem.	- Knowledge discovery algorithms: Data-driven algorithms aimed at extending knowledge about specific objects or problem domains - Forms of knowledge include functional dependencies, robust groups, predictive models, and optimization results - Surrogate models (metamodels): Approximate computationally expensive models to support complex tasks - Used for predicting outcomes or characteristics of existing models - Areas of surrogate modeling include: - Constrained and unconstrained global optimization - Multi-objective optimization - Design space exploration	- Predictions rely on data characteristics, emphasizing the need to store runs across various datasets to cover the data parameter space - Patients with comorbidities may be transferred to different departments during their hospitalizations

Iglesias et al. [40]
2022
Spain
	Hospital and CPs
	Infection
		Data visualization with:
		- BPMN
		- Task Planning standard notation
		
		openEHR, raw.io5 tool with the VML libraries, RESTful API
			- Clinical-oriented process representation standards address specific needs of clinical workflows:
			  - Case Management Model and Notation (CMMN): Extends BPMN for multi-activity cases handling unpredictable situations
			  - Decision Model and Notation (DMN): Defines complex business logic through process rules
			- BPMN-based process models: Handle time constraints such as task and edge durations
			- Temporal Processes (TP): Models future orders or actions, including parallelism and time references, and supports ad-hoc modifications during execution
			- TP is effective for representing time dependencies in clinical processes
			- Extended BPMN diagrams were successfully translated into the TP specification
			- These methods facilitate the identification and comparison of key temporal features
				- Challenges in modeling complex time constraints with current standards
				- Need for improvements to enhance compatibility and adaptability to clinical scenarios
				- Current models lack the expressiveness to capture all nuances of clinical processes

Kazak et al. [49] 2019 USA	Pediatric Care Hematopoietic stem cell transplantation	Collecting points of view techniques Interviews of caregiver, focus group with parents and multidisciplinary clinicians; interview guide, Altas.ti qualitative analysis software	- Developed with input from key stakeholders: patients, families, physicians, and psychosocial staff - Emphasis on including all family members has increased the pathway's acceptability - PCCP provides a roadmap for psychosocial care, ready for implementation and integration into clinical practice	- Limited transferability due to participant selection - Sample size was small - One focus group did not provide enough time to explore all relevant ideas - Concerns of patients and families at highest risk may be underrepresented.
Leach et al. [60] 2022 Australia	chronic nonspecific low back pain	A modified nominal group technique to a multistage needs-driven evidence-based health workforce model Group of seven experts, review of clinical guideline recommendations	- Develops a needs-based integrative service delivery model to apply a biopsychosocial approach to disease management in primary care - Creates a high-level CP to enable the operationalization of a comprehensive, responsive, and integrative healthcare model for managing CLBP	- Absence of direct consumer involvement - Despite being informed by best practices and shaped by consumer preferences, consumer input might have further refined the CP.
Lee et al. [58] 2023 Canada	General Hospital Care Gastrointestinal surgery	Process mapping Literature, a first representative case scenario, as a guide, developed by the research team (clinical experience of the research team), consensus within the team of experts, Microsoft PowerPoint	- Process mapping: Visually breaks down pathways into individual components - SCMs (Service Chain Models): Theoretically and mathematically grounded in queueing theory to improve timeliness and equity in care - Illustrates the number and nature of additional queues a patient encounters in a Complex Adaptive System - Provides a visual description of pathway breakdowns	- Discussions included a focus group of multidisciplinary providers using existing SCMs, potentially introducing bias into the findings - The patient encounter map does not depict queues outside the surgeon's control, such as delays for imaging and specialist consultations

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Mochamat et al. [29] 2023 Germany	Rehabilitation and Palliative Care Fatigue	Medical Research Council Model, the first of the five steps: the concept of developing an intervention, based on the evidence base identification, theory identification/development, and process/outcomes modelling Literature, focus groups with healthcare professionals, interviews of representatives of self-help groups, Zoom sofwtware	- CPs are cost-effective, enhance care quality, and ensure standardized outcome-oriented care - Pathways facilitate efficient resource management, provide comprehensive patient information, and serve as a clinical audit tool - Developing a CP is essential for implementing structured burden management	- Reliance on specific hospital or regional data limits generalization - Practical implementation is complex across different contexts - Compatibility and integration issues with existing healthcare systems
Morales-Contreras et al. [61] 2020 Spain	General Hospital Care Hip fracture	Action research (AR) based on the Lean techniques: Data gathering, data feedback, data analysis, action planning, implementation, and evaluation Literature review, collaboration within expert in Lean, process innovation, and healthcare, and hospital management and professionals (doctors, nurses, technicians)	- Qualitative Case Study: Explores the "how" and "why" of phenomena, focusing on contemporary events; theory derived from cases has strengths like novelty, testability, and empirical validity due to its connection with empirical evidence - Uses diverse data sources: interviews, documentation, quantitative data, and direct observations - Action Research (AR): Facilitates collaboration between researchers and stakeholders to define objectives, formulate research questions, and apply findings for positive social change; aims to generate action while building related knowledge - Lean Management Systems: Analyzes production processes to identify and enhance activities that add value to the customer, while minimizing or eliminating wasteful activities	- Data limitations: Cannot be generalized due to its qualitative nature - Context specificity: Findings are applicable only to the particular context studied
Mu et al. [42] 2021 China	Chronic diseases Foot of people with diabetes mellitus	Mathematical approach within the "lean thinking" concept, based on regression model and multivariate Generalized Linear Models IBM CPLEX optimizer, R software	- The obstetric ward planning problem is modeled using a mixed-integer programming approach - Positive and negative correlation factors were identified, leading to improved care capacity - Provides decision variables and a flowchart forward allocation post-planning - GLM regression analysis helped identify correlation factors to enhance departmental performance and patient capacity - Benefits include improved caregiver efficiency and rest time, and more detailed medical services for patients - The model is user-friendly, providing insights on ward types and maximum patient flow with given input parameters	- Model Limitations: May not capture all nuances of actual clinical processes - Context-Specific Results: Findings are specific to the parameters and data of the studied context and may not be generalizable - Implementation Challenges: Practical application in different hospital environments can be complex
Payedimarri et al. [66] 2021 Italy	Rare diseases Myasthenia Gravis	CP design by literature review and CP validation by Delphi method AGREE II tool, questionnaires	- Identifies the care process, key interventions, and relevant process indicators - Helps clinical teams organize timely diagnoses and deliver high-quality, accessible, and cost-effective treatments and care	- The CP is based on international and national evidence and is not organization-specific - Expert input may lead to the development of new quality indicators and metrics, though they are not yet validated

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Sooter et al. [50] 2019 United States	CP for Contraception	BPMN et Decision Model and Notation (DMN) Data visualization with flowcharts Guidelines, Trisotech modeler, eXtensible Markup Language (XML) format and imported in other tools such as for instance Camunda, True/False (Boolean) values, SNOMED CT codes	- Bridging the gap between narrative guidelines and digital models requires translating clinical processes and decisions - Using DMN (Decision Model and Notation) and BPMN (Business Process Model and Notation) models standardizes the format, making it understandable for both clinicians and software engineers - BPMN and DMN are open-source standards with defined semantics and multiple modeling tools available - These models offer a clear description of processes and decisions and can be used as executable “microservices” - As interoperability advances, the use of BPMN and DMN models as microservices may become increasingly significant	- BPMN and DMN models lack built-in mechanisms to organize and provide metadata about data objects - Integration of a “data dictionary” into BPMN and DMN models is not yet part of the standards, requiring a separate modeling approach - They struggle with modeling complex series of questions, often resulting in complicated models
Talarico et al. [59] 2020 Italy	Rare diseases	A specific methodology was created, based on qualitative and semi-qualitative methods, called the RarERN Path method, for the integration of the perspectives of large communities of European stakeholders Questionnaires, individual interviews or working groups; by face to face or virtual meeting, Narrative Medicine approach (Rita Charon), Delphi	- The RarERN Path method aims to offer a practical approach for implementing and developing a reference organizational model for PCP (Primary Care Pathways) - Applying RarERN Path across various disease-specific and geographical contexts aims to ensure improved, cost-effective, and patient-centered care for rare diseases and conditions throughout Europe	- Limited by the specificity of data and contexts for the rare diseases studied - Requires validation and adaptation of methods for other clinical contexts - Results may vary depending on the expertise of the users
Tax et al. [30] 2019 Netherlands	General Hospital Care Nonmalignant lesion of pancreas	Decision-analytical model using decision trees and comparison of medical procedures Literature, deterministic and probabilistic sensitivity analyses (Monte Carlo analysis)	- Conducts cost-effectiveness analysis of a care process by identifying relevant and irrelevant uncertainties - Provides guidance for making informed decisions	- Nondifferentiating variables were excluded from the analysis - Provides relative differences in cost-effectiveness, without offering absolute results for each strategy

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Trevena et al. [39] 2022 United States	General Hospital Care Support Intensive Care Delivery	Modeling Agent Behaviors based on structured expert rule representation technique, using directed acyclic graph (DAG), computational simulation model: a digital twin prototype simulating actions and interactions Granular electronic health record (EHR) data, and the support of multiprofessional clinical experts, spreadsheet, CSV file, Graph database management system (Neo4j)	- The Digital Twin is designed to simulate and predict a patient's future state based on current conditions and treatments, rather than for diagnosis. - Directed Acyclic Graphs (DAGs) offer a flexible and interpretable way to represent and understand relationships, such as interactions between organ systems and their clinical effects. - Storing expert rules in a graph database provides three key benefits: 1. Allows medical practitioners to update rules without altering application code 2. Reduces application size and storage requirements 3. Enhances application speed by offloading rule determination to the database	- Management of multiple DAGs and their use in patient simulations presents a significant challenge. - While DAG models are effective for developing new drugs and medical devices, their use as decision support tools in clinical settings (e.g., critical care) remains limited. - The performance of these models is constrained by data availability, and clinicians may be skeptical of "black-box" models due to a lack of transparency in the underlying rules. - Data-driven models may underperform in live clinical environments and may not fully translate to clinical utility at the bedside. - Models that do not explicitly incorporate known causal pathways can produce results that are counterintuitive, uninterpretable, or even detrimental, limiting their practical value for clinicians.
van Delft et al. [35] 2021 Netherlands	Cancer Care Lung cancer	Mathematical description and scenario analysis, using a timed automata-based model, and experts’ meetings, Markov or DES techniques The UPPAAL software, data from a cohort of patients, ggplot2 package (version 3.2.1) in R statistical software version 3.6.1, meetings with multidisciplinary team	- UPPAAL software utilizes a distributed modeling paradigm, allowing systems to be modeled with networks of timed automata. - It enables modeling of independent processes asynchronously and uses synchronization channels to manage process interruptions in subroutines. - Substructures can be created for specific aspects of the pathway, enhancing interdisciplinary communication with individual templates in a graphical interface. - The model-checking engine in UPPAAL allows developers to verify the reachability of states or pathways. - Model calibration improves diagnostic accuracy by comparing model outputs with real-world patient data, ensuring internal validity. - Markov and DES models use events or timing of events to control patient flow, with DES providing a more flexible approach, potentially reflecting independent subroutines depending on software capabilities.	- Evaluating all options in a trial-based setting is impractical and potentially unethical. - High-test frequency reduces the impact of changes in test sensitivity on model outcomes by limiting the effect of false-negative results. - The model outcome measure does not fully capture the direct effect of test sensitivity, as low sensitivity might only delay detection of immune-related adverse events.

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Wood et al. [44] 2020 UK	General Hospital Care Delays to transfer and discharge caused by blocking after service.	Mathematical description, the Markov chain stochastic process: the movement to future states of the chain is dependent only on the current state and not of those visited previously. A simple example of a continuous-time Markov chain is the birth death process. Plus discrete event simulation (DES) technique: "Markov DES approach". The Erlang distribution: a special case of the gamma distribution Statistical softwares: “R” and “AnyLogic”	- Stochastic queuing systems can be analyzed either analytically, through exact or numerical methods, or via simulation to understand inefficiencies and blockages. - The system is modeled as a continuous-time Markov chain with state transitions for patient arrivals, transfers, and discharges, using the Erlang distribution for length of stay. - This approach can model real-life scenarios, such as bacterial growth or patient flow in single-bed units. - Markov DES differs from traditional methods by using the Markov chain to determine both event timing and state transitions, rather than a fixed scheduler. - The Erlang distribution also accounts for delays at external service points not included in the model’s capacity, capturing realistic delays.	- Discrete Event Simulation (DES) is used due to tractability issues preventing an analytical solution to the Markov chain, focusing on capacity rather than individual patient journeys. - The model assumes Erlang-distributed Active Length of Stay (LOS), which offers flexibility but lacks the versatility of some phase-type distributions. - Instantaneous transfers between service points are assumed, which may underestimate capacity if significant travel times between points are not considered. - Time homogeneity is assumed for patient arrivals, ignoring potential seasonality and time-of-day variations. - It is assumed that patients cannot leave the queue except through admission, which may not reflect real-world scenarios.
Yakutcan et al. [36] 2022 UK	Chronic diseases Obstructive pulmonary disease	Discrete event simulation (DES) model Literature, data from the hospital, semi-structured interviews, questionnaire, group meetings, Simul8 software, Microsoft SQL Server	- Extensive research on COPD has explored cost-effectiveness, disease burden, and treatments using methods such as Markov modeling, Monte Carlo simulation, agent-based simulation, system dynamics, and increasingly, Discrete Event Simulation (DES). - DES models the disease course by tracking patients individually and addressing organizational issues in healthcare settings, helping decision-makers improve efficiency. - General uses of DES in healthcare include: - Disease progression modeling: Conceptualizing disease pathways to compare interventions. - Health and care systems operation: Understanding system mechanisms and relationships. - Screening modeling: Projecting the impact of earlier disease detection. - Health behavior modeling: Evaluating effective interventions considering individual behavior changes. - Entities in DES can include features like age, gender, and disease states, enhancing the model’s flexibility and detail. - DES provides insights into the impact of scenarios such as activities and resources, and helps assess the effects of redesigning COPD services and managing readmissions.	- Discrete Event Simulation (DES) models systems where state variables change only at discrete time points. - Simulation models represent systems but cannot capture every detail, requiring cautious interpretation of results. - Assumptions and simplifications are inherent in both mathematical and simulation models.

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Yang et al. [64] 2023 China	Hospital and CPs Pancreatitis	Fuzzy process mining method a multi-level expert classification system with fuzzy values a categorization of medical events into long-term and temporary events a hierarchical clustering method Electronic medical records, process mining tools	- Preserves important details in medical procedures by including both common and uncommon patient treatment patterns in the process model. - Modeling process is simple and understandable, offering a comprehensive representation of medical intricacies. - Process mining technologies such as alpha algorithm, fuzzy miner, heuristic miner, and inductive miner are used to support specific medical processes, with inductive miner being the most widely utilized. - Visualization tools like ProM generate graphical representations of medical event sequences, enhancing clarity. - Avoids the spaghetti effect in traditional models by effectively showing simultaneous medical operations.	- Clustering Window Events: Use hierarchical clustering to group Window Events into Aggregate Events. - Clustering Parameter "t": This parameter is crucial for the effectiveness of clustering. - Clustering Effect: The quality of the clustering significantly impacts the overall quality of the process model.
Zhang et al. [41] 2019 Singapore	Hospital and CPs	Process design, and modularization method, Sequencing approach, Combination of Design Structure Matrix technique and Genetic algorithms-based procedure, "DSM-based modularization method for healthcare process design". Literature review, Sequencing algorithm, Genetic algorithms, A square matrix	- Standardization and Flexibility: Standardizing process modules improves efficiency, while their flexibility allows for customization. - Modularization Benefits: Reduces process complexity by grouping related healthcare activities into modules and improves coordination by combining modules to address diverse medical needs. - Optimal Clustering: Aims to minimize interaction between modules while maximizing interaction within each module. - Decision Support: DSM-based modularization and sequencing algorithms offer effective decision support in designing modular care pathways (CPs). - Streamlined Pathway: Process mining helps in clustering related healthcare services into modules, supporting the mass customization of healthcare services through flexible configuration.	- Future Work: Develop alternative algorithms for identifying process modules. - Comparative Studies: Conduct studies to compare different algorithms. - Computational Tools: Create effective tools for large-scale process design. - Healthcare Context: Focus on improving practical healthcare service delivery.

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2.2. Partie 2 - Identification des déterminants invariants de parcours en santé (articles 2 et 3)

Certains facteurs influencent le parcours d'un patient dans l'écosystème de santé et peuvent avoir un impact sur la qualité des soins. Ces facteurs clés peuvent être appelés « déterminants de parcours en santé » (DPS) par comparaison avec les concepts de « déterminants de la santé » ou de « déterminants de la qualité et de la sécurité des soins dans les établissements de santé ». Ces DPS peuvent être vus comme étant des éléments clés du processus de parcours. Ils peuvent être des indicateurs du risque de rupture des soins ou, au contraire des leviers pour des changements positifs en matière de santé. Parmi ces DPS, certains sont systématiquement présents, quel que soit le domaine de santé. Ce sont des « déterminants invariants de parcours en santé » (DIPS), et peuvent être considérés comme l'une des premières briques dans la recherche d'un équilibre entre standardisation et singularité des soins. Le fait de caractériser les DIPS peut être considéré comme une étape fondamentale vers une meilleure compréhension et une plus grande appropriation d'une situation complexe.

L'objectif de l'étude était d'identifier et de développer une liste de DIPS basée sur une analyse qualitative d'entretiens semi-structurés avec des professionnels de la santé.

Un article de protocole intitulé « Systemic Modeling of Care Pathways by Identifying Invariant Determinants: A Qualitative Study Protocol » présente la méthodologie de recherche. Un échantillonnage intentionnel a été proposé pour inclure dans l'étude des professionnels de santé issus de différents secteurs : des praticiens de terrain, des professionnels académiques et des décideurs institutionnels. Le nombre de participants a été estimé a priori à 6 ou 7 experts par catégorie de professionnels, en vue de l'obtention d'une saturation des données. Une note d'information et un recueil de consentement destinés aux candidats avaient été prévus. Un plan de respect de l'éthique a été rédigé et approuvé par un comité de surveillance de l'éthique dans la recherche.

Un guide d'entretien a été élaboré par consensus au sein de l'équipe de recherche. La première partie du guide a été conçue pour recueillir les perceptions sur la notion de parcours en santé. La deuxième partie du guide portait sur la définition et l'identification des déterminants invariants de parcours en santé. La troisième partie du guide portait sur la modélisation des parcours en santé.

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Systemic Modeling of Care Pathways by Identifying Invariant Determinants: A Qualitative Study Protocol

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Abstract

Background: Care pathways are useful for optimizing patient or disease management. However, in practice, the implementation of this concept remains below its potential. Probably because it is a complex intervention in complex systems. In such cases, modeling is beneficial. Thus, facilitating the representation of care pathways can go through the formalization of a standardizable part. Indeed, certain structural elements of care pathways are systematically present, whatever the area of healthcare. The objective of the present study will be to identify and develop a list of these key factors, called "invariant determinants of care pathways". **Methods:** This qualitative study will adopt a descriptive design. Semi-structured interviews will be conducted with different types of health experts: practitioners, academics, and institutional representatives. An interview guide was designed in 3 research sections: identifying the main key elements of the care pathway concept, defining the main determinants considered as pathway invariants, projecting the interviewee into a broader perspective of systemic pathway description. Once collected, data will be anonymized, transcribed and analyzed according to a thematic approach. The analysis report will follow the COREQ checklist. This research project has been validated by the ethics committee of Lyon (n°2022-05-19-003). **Discussion:** The results of our research will enable us to use a systems approach to gain a better understanding of the concept of care pathways and, in the longer term, to model these pathways. This study will make it possible to identify and characterize the invariant determinants of care pathways. However, although these factors are systematically present, their influence on the care pathway varies. Methods for calculating the power of impact will be used to assess this variability. Then, for a more exhaustive approach, specific factors known as variant determinants will be identified. Determining the invariant and variant determinants will enable each care pathway to be modelled.

Keywords

care pathway, invariant determinants, modeling, study protocol, qualitative study

Background and Study Justification

Worldwide, non-communicable diseases (NCD) are the leading cause of disability and death. Of the 55 million deaths worldwide in 2019, around 71% (almost 41 million) were due to NCDs (World Health Organization, 2023). This burden of NCDs has led to a reorientation of the organizational approach of the healthcare system. Specific policies for the management of these diseases have been implemented (Haro et al., 2014). Care pathways represent an effective and efficient way of standardizing treatment progress, reducing the pressure on the healthcare system and

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problems associated with the areas that decision-makers need to address (Aspland et al., 2019). They have some advantages: (i) shortening the duration of the care production process, (ii) increasing the consistency of care, (iii) reducing the risk of errors, (iv) lowering the cost of the care production process, (v) increasing the satisfaction of professionals and patients (Hall et al., 2006; Schrijvers et al., 2012).

However, in practice, the implementation of the concept of care pathways in public health remains below its potential, both qualitatively and quantitatively (Jabbour et al., 2018). Probably because it is a tricky concept to grasp. Indeed, establishing a consensual definition proves difficult (De Bleser et al., 2006). It brings together many different ways of formulating and approaching (Aspland et al., 2019), and it requires a holistic consideration (Gartner et al., 2022). This is a field calling for systemic perspectives (Beleffi et al., 2021): care pathways are complex interventions (Seys et al., 2019) in complex systems (Kuziemsky, 2016). Faced with a complex system, modeling helps to understand its structure and operation. The modeling highlights the relationships between its components and also makes it possible to simulate different parameter configurations and predict system behavior (Salleh et al., 2017). By clarifying the situation, models facilitate informed choices and support clinical decision making (Elbattah & Molloy, 2015). However, there are many issues surrounding the application of modeling that can contribute to its misuse, such as the selection and adoption of inappropriate models (Teerawattananon et al., 2022). This is why a standard formalization for the representation of care pathways in general could be useful (Elbattah & Molloy, 2015). A common baseline, as a first step towards modeling care pathways, could facilitate initiatives to understand complex situations.

At the basic modeling level, a straightforward manner to represent pathways is using sequences of events, as a step-by-step representation of common medical practices. This approach makes it possible to analyze the different pathways (Trajano et al., 2021), and thus to identify the variant features (Rosa et al., 2022). Nevertheless, before looking for variations between care pathways, it is essential to characterize the typical fixed structure as precisely as possible, that is to define the elements common to all care pathways.

Some factors influence a patient's journey through the healthcare ecosystem (Nestrigue et al., 2019), and may impact the quality of care (Anderson et al., 2013; Elmusharaf et al., 2017). These key factors can be called "determinants of care pathways" (DCP) by comparison with the concepts of health determinants (Dyar et al., 2022) or determinants of the quality and safety of care in healthcare institutions (Haute Autorité de Santé, 2022). DCP can refer to guiding principles for healthcare delivery that focus on key elements of the pathway process. They could hence be indicators of the risk of a breakdown in care, or on the contrary levers for positive changes in health (Zelka et al., 2022). Among these DCP, certain structural factors of care pathways are systematically present, whatever the area of healthcare, such as organizational characteristics (Beaussier et al., 2015). They can be called "invariant determinants of care pathways" (IDPC), and can be seen as one of the first building blocks in the search for a balance between standardization and customization (Benzer et al., 2015) of care. Mastering IDCP (Sloman, 2005) may be a way of reducing undesirable flexibility, to encourage the desired variation (Melin & Axelsson, 2005). Thus, specifying IDCP can be seen as a fundamental step towards a better understanding and greater appropriation of a complex situation. This approach can find a broad echo in any type of health system and field of care.

The objective of the present study will be to identify and develop a list of IDCP based on a qualitative analysis of semi-structured interviews with health professionals.

Materials and Methods

Justification of the Method

The choice of a qualitative study via interviews is justified because this methodological approach allows « to understand the world from the subjects » point of view, to discover their lived world before the scientific explanations (Sayrs, 1998). In addition, qualitative research interviews will gather subjective information about a particular subject or experience. The focus is generally on the experiences of interviewees and how they perceive the world (DeJonckheere & Vaughn, 2019). Thus, semi-structured interviews allow the analysis and the comparison of the participants responses (McIntosh & Morse, 2015). This qualitative methodology permit specific areas to be addressed while giving interviewees the opportunity to reflect on their experiences and perspectives in defining, identifying and presenting the research gaps that concern them and that may not have been analyzed or anticipated by the researchers (Britten, 1995). Semi-structured interviews will allow to obtain new exploratory data in relation to IDCP, triangulate other data sources or validate findings through member verification (comments of participants about the results of the research).

Study Design

This qualitative study will adopt a descriptive design focusing on different health pathway approaches. Data will be collected through semi-structured interviews that will be organized in France from May to July 2024.

The report of this qualitative analysis will follow the consolidated criteria for reporting qualitative research (COREQ) guidelines as recommended by the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) network for qualitative research (Tong et al., 2007). The results will also be compared to the literature (Figure 1).

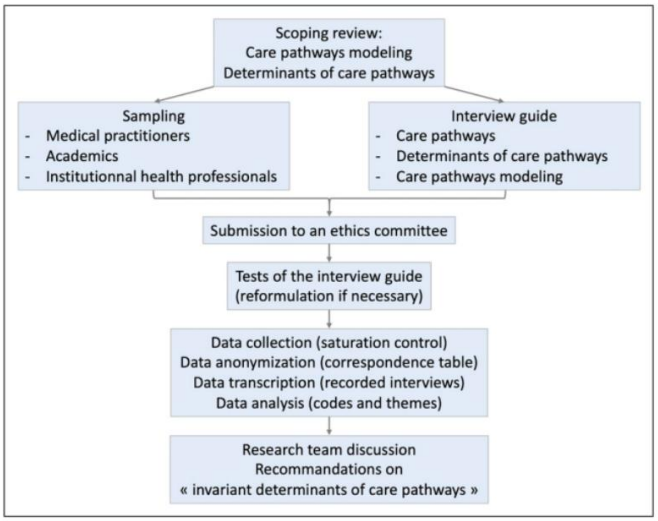

Figure 1. The flow chart of the study design.

Study Sample

To work widely on the subject, to be equally precise in research, and to tend towards consensus, it is expected that all participants will be professionals directly involved in health pathways and representative of the various approaches to them. Purposive sampling will be used to ensure that the insights of all identified groups are considered. This methodology is extensively used in qualitative research to identify and select information-rich cases (Setia, 2016).

Three groups of experts will be interviewed:

1) Health professionals in the field from the health, medico-social and social sectors: practitioners of the pathways, confronted in their daily practice with the priority notion of performance (ability to achieve set objectives), in direct contact with individuals, in the various dimensions in health, in a territorial ecosystem.
2) Academic health professionals: researchers, analysts, designers, ideologists and educators, confronted with the notion of relevance (link(s) between set objectives and identified needs (added value and service rendered), in a global way in supra-territorial health ecosystems (region, country, international).
3) Institutional health professionals: regulators, whether funders or decision-makers, confronted with the notion of efficiency (relationship between allocated resources and results: performance at the lowest cost).

To be included, participants must: (i) be professionals in the field from the health, medico-social and social sectors or Academic health professionals or Institutional health professionals; (ii) be over 18 years old, (iii) have professional experience in the field of pathways; (iv) have knowledges or competences in the health pathway; and (v) have understood, accepted and given written agreement to participate in the study.

Exclusion criteria for the study will be: (i) lack of consent form or; (ii) inability to participate in the interviews.

Sampling

Recruitment will be carried out via contacts or by sending an email to (i) the secretariats of health care structures (hospitals, nursing homes, …), representatives of professionals (Regional Unions of Health Professionals, …), health supervisory agencies (Regional health agencies, …), educational institutions (University of advanced studies in public health, …), (ii) to people recommended by peers (snowball method) and, (iii) to people identified on the LinkedIn professional network. This message will include a recruitment announcement, a study information sheet, and a consent document. Individuals interested in participating will be asked to indicate their intention by sending an e-mail to the person in charge of this research. In the email response, the participant will be asked to specify: the professional status (active or retired); the position related to the theme of the pathways held and; the duration of his/her experience related to the theme of the pathways. This will ensure that the sample is representative of the workers in

the field. This will also make it possible to generate an anonymous identification code (which will be sent to the participant by return e-mail, along with the interview appointment information). This will enable anonymization of the content. A correspondence table will be created.

Sample Size

In qualitative research, the number of interviewees is not a determining factor in the significance of the results. Data saturation through redundancy will be the main indicator. Thus, an initial sample size is estimated but the final sample size will be determined by data saturation (Hennink et al., 2019).

Given that it is recognized that, in the case of a homogeneous sample, (i) the first five–six participants produce the majority of new information in the dataset, while little information is obtained from subsequent participants, and (ii) that data from the first 10 participants identify 80%–92% of the information (Guest et al., 2020), and that when the sample size is around 20 interviews then little new information will be collected (Baker & Edwards, 2012), Thus, about 6–7 experts per group of health professionals should make it possible to achieve data saturation, that is the point at which the new data does not lead to a more complete understanding of the phenomenon studied but replicates previous findings (Saunders et al., 2018) and also to achieve a range of answers from each stakeholder group. Throughout the study, several parameters will be analyzed: study objective, sampling strategy, population, data quality, code type, and saturation. Semi structured interviews will be discontinued when data saturation is reached, according to the parameters defined by Hennink et al. (Hennink et al., 2017).

Development of the Interview Guide

The guide could not be developed on models pre-used or validated in previous studies because an analysis of the literature did not reveal any. Therefore, it was designed by the research team on the basis of consensus. The consensus methods are defined as a way to synthesize information and compare contradictory opinions, with the aim to define the degree of agreement within a group of selected individuals. The Delphi method is used to obtain a final, unique, convergent opinion of the group (Romero-Collado, 2021; Waliski et al., 2017). In this research team, the group was composed of specialists in public health and healthcare pathways. Each member established a list of questions that seemed relevant to determine the IDCP. Then, the members pooled all their proposals and they organized a first round of rating to determine if the questions should be included in the guide of interview. Each question was rated from 1 (totally disagree) to 9 (totally agree) with 5 to express indecision. The ratings were analyzed according to Table 1. When a question was deemed appropriate, then it was included in the guide of interview. When a question was deemed inappropriate, then it was excluded. When a question was considered to be uncertain or when a value missed, the group of experts discussed and rated it for a second round. If an agreement was still not reached, then the question was rejected.

This guide will be tested during three individual interviews, by telephone, with professionals working in healthcare pathways who will not participate in our study. These interviews will allow us to collect suggestions on the questions and adapt the guide. The questions included in the interview guide are described in Table 2.

The interview guide is structured in three sections (Table 2). The first section deals with the important elements of health care pathways. The objectives will be to identify the main key elements of the concept of care pathway for all the professionals, to obtain a classification of the elements of this concept according to their importance and to compare this classification according to the professionals. The second part deals with the determinants of care pathways. The objectives will be to identify the main determinants considered as invariants of the pathway by all types of professionals and to define them as precisely as possible. The third part deals with the modeling of care pathways. The objective will be to project the professional in a broader perspective of systemic description of the pathways.

Table 1. Conditions for Obtaining an Agreement Between Experts According to Median Value and Distribution of the Quotations.

Proposal estimated	Degree of agreement	Median	Minimum; maximum
Appropriate			
	Strong	≥7	7; 9
	Relative	≥7	5; 9
Inappropriate			
	Strong	≤3	1; 3
	Relative	≤3.5	1; 5
Uncertain			
	Indecision	4 ≤ median ≤6.5	1; 9
	No consensus	All other situations	All other situations

Table 2. Semi-Structured Interview Guide.

Topics	Objectives	Questions
Care pathways	Identify: - The main key elements of this concept for any type of professional, - The order in which the elements related to the subject of the study appear, if any, - The characteristics of the comparison of responses between the different professional statuses of the participants.	- What does the notion of a "care pathway" mean to you? - How can this concept be useful for our health care system? - What do you think are the main keywords frequently associated with the concept of care pathways? • Barrier to the pathway • Break in the pathway • Pathway fluidity • Health determinants • Pathway determinants • Complex pathway • Territorial coordination • Health project • Territorial health organization (GHT, CPTS, etc.) • Episode of care • Care trajectory • Care pathway • Clinical pathway • Patient tracer
Determinants of care pathways	- Identify the main determinants considered as pathway invariants by all types of professionals - Define them as precisely as possible	- What does the concept of care pathway determinants/key factors mean to you? - What differences do you see between the concepts of "health determinants" and "care pathway determinants"? - What do you think are the most important pathway determinants? - In your opinion, which pathway determinants can be described as invariant (i.e., key pathway orientation factors, regardless of the areas concerned)? Could you classify them according to their importance, and explain why? - Why is it relevant to consider pathway determinants? - Why is it relevant to consider the so-called invariant pathway determinants?
Care pathway modeling	Project the professional in a broader perspective of systemic description of the pathways	- What does the notion of "care pathway modeling" mean to you? Do you think that care pathway modeling is possible or illusory? • What is the purpose of a care pathway model? • What do you think are the key characteristics of such a model? • In your opinion, what is the role of so-called invariant determinants in care pathway modeling? • In your opinion, what is the place of variable/inconsistent determinants in care pathway modeling?

Description of the Interview and Data Collection

The semi structured interviews will be conducted by one researcher (B.D.), who is used to this kind of interview, using tele-conference or phone, according to the participant's availability and preference. For ethical reasons and respect for confidentiality, the research manager (F.C.) will be the only person to be aware of personal data and to know the table of correspondence. The researcher that will conduct the interviews will not know the identity of participants. The correspondence table showing the link between the identification code and the socio-demographic criteria of the participants will be kept within the research team.

The interview will begin with an introduction of the facilitator and a reminder of the objective of the interview. The interview will last approximately 1 hour. The guide will be used as sparingly as possible, only, when necessary, in such a way as to obtain spontaneous answers and to reduce the risk of

directing the respondents' answers. Recalls or requests for rephrasing will be proposed as a priority to expand the investigation. The audio recording will be deleted after this operation is completed.

Data Analysis

The analysis of the qualitative data will follow the methodological framework proposed by Braun and Clarke (2006) (Braun & Clarke, 2006), which consists of a thematic analysis. First, the recordings of the conversations will be transcribed verbatim and checked, tracking the exact course of the interview and indicating all components of the communication to understand the interactions (including laughter, hesitations). Second, two researchers will carry out open coding with an in-depth reading of each verbatim transcription. They will use a mixt content analytic method: inductive and deductive. Third, the two researchers will discuss the initial codes until they reach an agreement and draw up a first codebook. In case of divergent opinions, a third researcher, member of the research team, will be solicited. Fouth, researchers will use the structure of this code to analyze the remaining answers, remaining open to the inclusion of new codes or to the refining of existing ones. Fifth, the final structure with themes and subthemes will be finalized and occurrences will be measured to weigh the results.

Reliability during thematic data analysis will be guaranteed by systematically storing raw data, reporting detailed notes on the development and organization of concepts and themes, the establishment of a consensus on the themes, the provision of precise descriptions of the context and the description of the coding and analysis process (Kastner et al., 2016; Whittemore et al., 2014). The NVivo® software (QSR International) will be used for data analysis.

Ethical Approval

Ethical approval was obtained from the Research Ethics Committee of the University of Lyon (n°2022-05-19-003 on 27 october 2022) and a declaration (MR004) to the National Commission for Computing and Liberties (CNIL) (2226244 v zero was made on 5 May 2022. Written informed consent will be obtained from eligible participants before data collection.

Discussion

The implementation of care pathways is associated with better outcomes for patients and teams, and better organized care processes (Seys et al., 2017). At patient level, fewer post-operative complications are reported, with shorter lengths of stay (Austin et al., 2015; Kalmet et al., 2016; Rotter et al., 2010) and lower hospitalization costs (Barbieri et al., 2009). In addition, at team level, communication and relationships are improved, and the risk of burnout is reduced (Ahmed et al., 2013; Deneckere et al., 2013; Rotter et al., 2010). When a care pathway is put in place, staff feel the need to collaborate within the hospital and with primary care, leading to better organization of care processes (Furåker et al., 2004). Other examples of better organization of care are standardization of the care process, improved documentation and communication with patients and healthcare professionals, better monitoring of the care process and greater confidence in the performance of tasks (Ahmed et al., 2013; Allen et al., 2009; Clark et al., 2012; Rotter et al., 2010).

This study of the organizational dimensions of health will have a systemic approach. It will provide a better understanding of the system with a view to improving it. Based on a qualitative analysis of interviews with health professionals, this study will permit to identify and define a list of IDCP. They will be classified into facilitators or barriers (Tavender et al., 2016). Thanks to them, it will be possible to start modeling and to obtain a view of the main structure of all care pathways. However, identifying and describing is only a first step in the relevance of this systemic approach. Although these IDCP are systematically found in the care pathways, their impact differs from one care pathway to another. The second step will be to assign importance scores or situational impact weights to these IDCP, in order to clarify the implementation of specific strategies. Then, as each care pathway has its own characteristics, the third step will be to explore specific factors: the variant determinants.

Author's Note

This study protocol will be conducted in partial fulfilment of the first author's PhD in Education science and Public Health at Lyon University, under the supervision of the last author (50%) and the third author (50%), and under the local sponsorship of the fourth author. The first author will independently conduct all aspects of the study protocol, as indicated by the use of the first pronoun therein, unless otherwise specified.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Les résultats de notre étude sont présentés dans l'article intitulé « Identification of Invariant Determinants to Improve Care Pathways: A Qualitative Study among Healthcare Professionals » qui a été soumis pour publication.

Les critères d'inclusion étaient : (i) des professionnels français des secteurs sanitaire, médico-social et social ou des professionnels de santé universitaires ou institutionnels ; (ii) plus de 18 ans ; (iii) une expérience professionnelle quotidienne et de longue durée dans le domaine des parcours en santé ; (iv) des connaissances ou une expertise liées au système de santé ; et (v) avoir compris, accepté et donné son consentement oral pour participer à l'étude. L'intention était de sélectionner des professionnels fortement impliqués dans l'organisation des soins tant au niveau individuel que collectif, ainsi que des représentants d'organisations structurantes ou décisionnelles et d'entités publiques. Les critères d'exclusion étaient les suivants (i) moins de 10 ans d'expérience professionnelle, (ii) retraité, (iii) incapacité à participer aux entretiens.

Vingt-et-un entretiens ont été réalisés, avec une répartition de sept participants par catégorie d'experts (praticiens, académiques, institutionnels). La durée moyenne des entretiens était de 45 minutes. Les données recueillies ont été analysées en utilisant un modèle hypothético-déductif et des méthodes de codage. Le cadre méthodologique en cinq étapes proposé par Braun et Clarke pour l'analyse thématique a été appliqué.

Il en ressort que la distinction initiale entre déterminants de parcours en santé (DPS) et déterminants de la santé (DS) n'a pas été spontanément aisée. Cela était le signe d'une proximité entre ces deux notions, qui finalement ont présenté des différences. En effet, les résultats ont montré que d'un côté, les DS sont associés aux facteurs épidémiologiques, démographiques, sociologiques et environnementaux qui influencent directement la santé physique et mentale des individus ou des populations. Les participants ont perçu les DS comme des indicateurs statiques et descriptifs. D'un autre côté, les participants ont perçu les DPS comme des facteurs clés qui modulent la qualité et l'adéquation des soins et des services reçus par les individus, comme des facteurs dynamiques et explicatifs axés sur les organisations, les processus et les interactions au sein du système de santé. Les DPS pourraient alors servir d'indicateurs de risques de ruptures de soins ou, à l'inverse, de leviers pour des changements positifs en matière de santé. En résumé, la notion de DPS englobe une approche systémique, qui va au-delà des DS classiques. Il en ressort que les DS et les DPS opèrent à différents niveaux et étapes du continuum de soins, et qu'ils sont complémentaires pour comprendre et améliorer les résultats en matière de santé. Ainsi, il l'analyse des DS va aider à définir les caractéristiques du parcours en santé à mettre en place, alors que l'analyse des DPS va aider à comprendre les facteurs qui peuvent impacter les solutions mises en place.

Ainsi, la majorité des participants ont considérés les DPS comme des éléments clés de stratégies de modélisation des parcours en santé.

De plus, l'analyse des résultats a permis d'identifier les déterminants invariants de parcours en santé (DIPS), c'est-à-dire les facteurs qui influencent les interactions entre l'individu et le système de santé et qui sont systématiquement présents quelle que soit la situation. Les DIPS identifiés se répartissent en quatre catégories : état de santé, déterminants systémiques et organisationnels, déterminants sociaux et environnementaux, déterminants individuels et psychologiques.

Cependant, si ces DIPS sont des facteurs systématiquement présents, leurs poids d'influence peuvent varier d'un individu à un autre, d'une situation à une autre, ou d'un moment à un autre. En outre, la considération de ces DIPS peut être soumise à la subjectivité des acteurs du parcours.

Identification of Invariant Determinants to Improve Care Pathways: A Qualitative Study among Healthcare Professionals

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Abstract

Background:
Chronic diseases account for 71% of global deaths, straining healthcare systems. Care Pathways (CPs) have emerged as a strategy to enhance care coordination and delivery. However, further optimization is needed to address system vulnerabilities. This study aimed to define Determinants of Care Pathways (DCPs) and identify the Invariant Determinants of Care Pathways (IDCPs) influencing patient CP.

Methods:
A qualitative study was conducted using semi-structured interviews with 21 French healthcare professionals, including clinicians, academics, and institutional stakeholders. Using purposive sampling, data were thematically analyzed. The study adhered to COREQ guidelines and explored participants' conceptualizations of DCPs, their differentiation from Health Determinants (HDs), and identification of IDCPs.

Results:
DCPs were identified as dynamic, systemic factors affecting care processes, while HDs were viewed as static. Four categories of IDCPs were identified: health status, systemic and organizational determinants, social and environmental determinants, and individual and psychological determinants. IDCPs influenced CPs across contexts, affecting care quality and continuity. Participants highlighted the utility of heuristic and diachronic approaches in identifying DCPs.

Conclusions:
IDCPs provide a new framework for analyzing and optimizing CPs. Integrating IDCPs with HDs and CP characteristics can help healthcare systems anticipate disruptions and enhance interventions, offering valuable insights for public health policy.

Keywords:
care pathways; determinants of care pathways; invariant determinants of care pathways; healthcare system optimization; health outcomes

Statements and Declarations:

Competing interest

The authors declare that they have no competing interests.

1 Introduction

Chronic diseases (CDs) represent a major public health problem, accounting for approximatively 71% of deaths worldwide (41 million) in 2019 [1]. The management of CDs, particularly cardiovascular diseases, cancers, diabetes, and chronic respiratory diseases, is increasingly complex and poses significant challenges in terms of care coordination, economic costs, and disparities in access to healthcare [2–6].

In response to this growing burden, healthcare systems has had to evolve, leading to the development of new CD management strategies [7]. One such strategy was the concept of care pathways (CPs), defined as "a complex intervention for the mutual decision-making and organization of care processes for a well-defined group of patients during a well-defined period" [8,9]. This concept has gained in importance, particularly in Western countries. CPs represent a practical and efficient approach to standardizing treatment, alleviating pressure on healthcare systems, and addressing key issues for decision-makers [10]. The benefits of CPs are manifold: (i) reduced duration of care delivery, (ii) improved consistency of care, (iii) minimized risk of errors, (iv) reduced cost of care and (v) improved satisfaction of healthcare professionals and patients [9,11]. However, optimizing CPs remains necessary [12,13], as the COVID-19 pandemic highlighted persistent vulnerabilities in healthcare systems and underscored the need to improve the efficiency and adaptability of patient care [14–17].

Determinants of care pathway (DCPs) can be considered as systemic factors that shape the interactions between individuals and the healthcare system, both in terms of temporal dimensions (effective sequencing of care) and spatial dimensions (person's environment, including human and technical resources) [18]. Despite the diversity of CPs according to geographical contexts, pathologies and available care structures, certain DCPs can be identified as key non-variable conditions that significantly influence CPs, which can be termed "invariant determinants of care pathways" (IDCPs) [19]. Identifying these IDCPs will enable healthcare professionals to better manage critical points and recurrent patterns in patient care, thereby enhancing the performance and efficiency of care management [20]. Subsequently, more precise care recommendations and public health policies, tailored to patient needs and healthcare system resources, could be developed. Therefore, the analysis IDCPs could provide valuable information for strengthening the resilience of healthcare systems and ensuring adequate individual care.

The aim of this study was to define the concept of DCPs and identify the main IDCPs. To this purpose, a qualitative analysis was conducted. Semi-structured interviews were carried out with various French healthcare professionals actively involved in different aspects of CPs, including patient

care (physicians and non-physicians, in home settings and hospitals), professional and methodological evaluation, healthcare policy and healthcare funding.

2 Methods

This study presents a part of the results from a previously published research protocol [19]. A qualitative methodology was used to extract and analyze complex data from various dimensions, uncovering phenomena not previously detected [21]. The research was performed in accordance with the COnsolidated criteria for REporting Qualitative research (COREQ) guidelines [22](Supplementary File 1).

2.1 Sample recruitment

A purposive sampling method was used to ensure the inclusion of information from all identified professional categories [23]. Participant selection began within the professional networks of the research team members, and was supplemented by snowball sampling. The minimum sample size was set at 15 participants, which was expected to allow data saturation [24]. Selected participants received an email containing the recruitment announcement, a study information sheet (including ethics approval references), and a consent form. Prior to participation, each participant gave oral informed consent for their interview to be recorded, transcribed in full verbatim, and for the data to be published anonymously.

2.2 Inclusion and exclusion criteria

Participants were professionals directly involved in various domains of CPs and were classified into three categories: practitioners, academics, and institutional professionals. The first category included practitioners from the health, medico-social, and social sectors who are engaged in the day-to-day management of CPs and directly involved “in the field” with individuals, such as general practitioners. The second category included academic health professionals, comprising researchers, analysts, designers, ideologists, and educators, who focus on the relevance of CPs, and assess the alignment between set objectives and identified needs (e.g., added value and service provided) within broader, supra-territorial health ecosystems (regional, national, and international levels). The third category included institutional regulators of the healthcare system, such as funders and decision-makers, who work on the efficiency of CPs and evaluate the adequacy of resource allocation in relation to outcomes, with the aim of minimizing cost.

Inclusion criteria were: (i) French professionals from the health, medico-social and social sectors or academic health professionals or institutional health professionals; (ii) over 18 years of age; (ii) daily and long-term professional experience in the field of CPs; (iv) knowledge or expertise related to the healthcare system; and (v) having understood, accepted and given oral consent to participate in the study. The intention was to select professionals deeply involved in the organization of care at both individual and collective levels, as well as representatives of structuring or decision-making organizations and public entities. Exclusion criteria were: (i) less than 10 years of professional experience, (ii) retired, (iii) inability to participate in interviews.

2.3 Interview guide

The interview guide was composed of three parts [19]. This article presents the results of the second part of the interview guide, which consisted of 7 questions on the perceived meaning of the DCP concept, its relevance, differences with health determinants (HD), and identification of the most important DCPs. The aim was to identify the main determinants of CPs considered invariants (IDCPs) and to define them.

2.4 Data collection phase

Data collection was carried out through interviews in France between September 13, 2023 and June 6, 2024. All interviews were conducted by the same author (BD, male, PhDc), trained in qualitative studies, by videoconference or phone. Each interview began with an explanation of the procedure, data protection and anonymization measures, and the purpose of the interview. The interviewer guided the discussions according to the interview guide, using prompts or requests for rephrasing to probe topics further. Each interview was recorded and transcribed verbatim.

2.5 Qualitative data analysis

Data analysis was carried out by two authors (BP, female, a sociocultural anthropologist trained in qualitative analysis, and BD) using a hypothetico-deductive model and coding methods. The five-step methodology framework proposed by Braun and Clarke for thematic analysis was applied [25].

1. Familiarization with the data: This step involved reading and rereading the data in order to fully immerse and familiarize with their content (BP, BD).

2. Generating initial codes: This step involved transforming raw data (verbatim transcripts) into initial meaningful codes, which were then organized into themes to address the research questions and hypotheses. The first decontextualization stage involved isolating extracts from the interviews in order to make them semantically independent, with the aim of creating themes grouping all related extracts. The second stage of recontextualization involved pooling the previously decontextualized codes and themes in order to restore their meaning (BP).

3. Searching for themes: This step involved rearranging the data to identify themes through a hierarchical organization of concepts into more generic themes, which were then further deepened, enriched, and linked through continuous comparison. A final level of analysis articulated these themes (according to relationships of continuity, causality, concomitance, coexistence or overlap) around the initial research questions in order to structure the analysis (BP).

4. Reviewing of themes: The resulting themes were discussed and refined (BP, BD).

5. Defining and naming themes: Finally, finer coding was used to illustrate the themes with specific examples (BP, BD).

2.6 Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki and approved by the Research Ethics Committee of the University of Lyon, France (n◦2022-05-19-003, June 27, 2022).

All participants received written and oral information about the study and provided oral informed consent to participate because the interview was conducted by videoconference or phone. The results were anonymized and presented in this study as quotes accompanied by an anonymization code, such as "(Cx-y)", where “x” denotes the participant's professional category number (1=practitioners, 2=academics, and 3=institutional professionals), and “y” was an identification number. When several quotes from the same participant are presented, the anonymization code is followed by a number in order of appearance. For example, the second quote from the 7th academic participant was noted as follows: quote C2-7.2

3 Results

Thirty-one professionals were initially selected. While no one refused to participate, 10 individuals did not respond to the request for participation. Thus, twenty-one interviews were carried out. Among the participants, 8 were females, 13 were males, 4 were aged between 40 and 49, 3 were aged between 50 and 59, 14 were over 60. Three had between 10 and 19 years of professional experience in the healthcare sector, while 18 had over 20 years of experience. Each category of

178 healthcare professionals was represented by 7 participants. All interviews covered the entire scope of
179 the interview guide. The total duration of the interviews was 951.3 minutes, with an unequal
180 distribution among the three categories of healthcare professionals. Indeed, the total duration of the
181 interviews was 361.3 minutes for academic professionals, 291.4 minutes for practitioners and 298.1
182 minutes for the institutional professionals. The average duration of the interviews was 45.28 minutes,
183 with a median of 43.4 minutes (range: 24.3 to 80.0 minutes). It was not possible to identify any
184 significant differences in viewpoints between the three categories of participants.

185 The analysis revealed two main themes: (i) the characteristics of the DCPs concept, which were divided
186 into three sub-themes, and (ii) the identification of specific IDCPs, which were divided into four sub-
187 themes (Table 1).

188 ### 3.1 Characteristics of the concept of care pathway determinants

189 Regarding the definition of DCPs, participants initially found it challenging to differentiate
190 them from HDs, perceiving the two concepts as closely related and overlapping (Table 2, quotes C2-4).
191 However, upon deeper reflection, they acknowledged that while DCPs and HDs are interconnected,
192 they are indeed distinct (Table 2, quotes C1-13). Participants emphasized that DCPs, although not
193 directly influencing individual health, are critical in shaping the quality and continuity of care (Table 2,
194 quotes C3-7). They observed that HDs are static and descriptive, focusing on the structural aspects of
195 the healthcare system, whereas DCPs are dynamic, highlighting the processes and interactions within
196 the system (Table 2, quotes C2-7, C1-7).
197
198 Given the distinct roles and complementarities of HDs and DCPs, participants unanimously agreed on
199 the importance of focusing specifically on DCPs (Table 2, quotes C3-7, C2-9, C1-15, C1-3, C2-7, C3-3).
200 The identification of these determinants could enhance the understanding and analysis of individual
201 healthcare trajectories, ultimately improving the quality of care. On one hand, this focus facilitates the
202 standardization of CPs (Table 2, quotes C3-7, C2-9, C1-15); on the other hand, it provides a framework
203 for tailoring care pathways to better address individual needs. Understanding these determinants thus
204 offers a comprehensive perspective on the factors influencing population health and can inform public
205 policy decisions (Table 2, quotes C1-3, C2-7, C3-3).
206
207 Participants further highlighted that DCPs are key components in CP modeling strategies. DCPs were
208 seen as a practical solution for bridging the gap between theoretical models and real-world practice
209 (Table 2, quotes C3-6). By offering a structured framework for analyzing diverse patient trajectories
210 within the healthcare system, DCPs play a critical role in strengthening CP modeling and simulation

strategies (Table 2, quotes C2-8, C2-4, C2-9). While the majority of participants (n=18) expressed support for the integration of DCPs in CP modeling, three participants remained skeptical about the value of modeling approaches and the role of DCPs within them.

3.2 Identification of invariant determinants of care pathways

According to participants, IDCPs can be grouped into four categories: health status, systemic and organizational determinants, social and environmental determinants, and individual and psychological determinants (Figure 1). The IDCPs related to institutions was the least frequently mentioned theme (2 occurrences), while healthcare offer, socio-economic conditions and cognitive access to care were always addressed. After the seventh interview, no new determinants were identified.

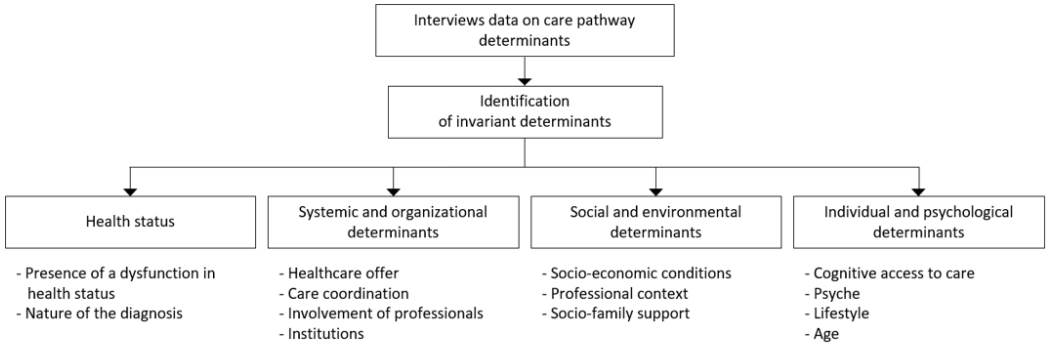

Figure 1. Identification of invariants determinants of care pathways

Concerning the health status, participants described the presence or absence of a dysfunction in health status as an IDCP (Table 3 quotes C3-5 and C3-1). Beyond this, the medical diagnosis of the disease emerged as a critical factor (Table 3 quote C3-6).

Concerning systemic and organizational determinants, the presence and accessibility of healthcare services are critical for enabling individuals to effectively engage with the health system (Table 3 quote C3-7). Coordination among healthcare professionals is essential to prevent gaps in individual care (Table 3 quote C1-7), while their engagement and commitment are vital for delivering effective care (Table 3 quote C1-13). Additionally, institutions, particularly management and regulatory entities, can play a key role in establishing a framework that shapes these interactions (Table 3 quote C2-9.1).

Concerning social and environmental determinants, socioeconomic status impacts access to and utilization of healthcare services (Table 3 quotes C2-7.1 and C2-9.2). Individuals with lower incomes may struggle with costs of medication or consultations, leading to potential delays or gaps in

237 care (Table 3 quote 2 C2-7). Employment status and working conditions can affect health management
238 and adherence to treatment plans (Table 3 quote 2 C2-7.2). Additionally, the presence or absence of a
239 supportive network can influence an individual's care (Table 3 quote 2 C1-13).
240 Concerning individual and psychological determinants (Table 3), patients' ability to manage
241 and utilize health information is essential (Table 3 C2-5). Their attitudes, beliefs, and personal history
242 impact how they engage with their health and treatments (Table 3 C3-7). Daily habits and personal
243 choices play a key role in adherence to treatment and the overall care experience (Table 3 C2-1).
244 Additionally, age can significantly impact individual care pathways (Table 3 C3-3).
245

246 ## 4 Discussion

247 To our knowledge, this study is the first that aims to define the concept of DCPs and to identify
248 the main IDCPs, based on twenty-one semi-structured interviews with various categories of health
249 professionals. Identifying IDCPs as potential barriers or facilitators could support the adoption of a
250 systemic approach to their implementation, which is currently limited, and therefore enhancing
251 patient care outcomes [26]. Previous studies identified factors that impact on the implementation of
252 CPs focusing on a specific CP [14,27,28] and underlined the need to take into account DCPs while
253 describing or modeling CPs. Our study extended beyond a single CP by examining CPs holistically and
254 employing a systemic approach to CPDs and care processes.
255 Firstly, DCPs were defined as a set of factors and conditions that influence an individual's
256 health trajectory over lifetime. Participants underlined that the concept of DCPs encompasses a
257 systemic approach, extending beyond the classical HDs. They noted that HDs and DCPs operate at
258 different levels and stages in the continuum of care, and are complementarity for understanding and
259 improving health outcomes. First, participants associated HDs with epidemiological, demographic,
260 sociological and environmental factors that directly influence the physical and mental health of
261 individuals or populations [29,30]. This is in accordance with Nutbeam's (1998) definition of HDs as
262 "the range of personal, social, economic, and environmental factors which determine the health status
263 of individuals or populations" [31]. Second, participants explained that HDs are static and descriptive
264 indicators. Sayers described that a static view of the relationship between these determinants and
265 their effects is often adopted, but it is crucial to account for time dependency [32]. Therefore, the
266 pathways that determine health should be understood in dynamic, continuous terms [32]. In this
267 context, DCPs are key factors of CPs because they were considered by participants as not directly
268 affecting individual health, but rather modulating the quality and adequacy of the care and services
269 received by individuals, as previously described [33–36]. DCPs are thus considered as dynamic and
270 explanatory factors focusing on organizations, processes and interactions within the healthcare

system. Considering the various dimensions of DCPs may shape the development of optimal CPs whatever their specificity regarding a disease: at the systemic and organizational level. DCPs could serve as indicators of potential care breakdowns or conversely as levers for positive health changes [37] or as guides for appropriate links between home setting and hospital professionals after hospital discharge [33–36]. or at the social and environmental level by taking into account social interactions between professionals in a local context [14].

Secondly, participants underlined that identifying DCPs requires two complementary approaches to CPs: heuristic and diachronic. The heuristic approach systematically analyzes the characteristics and structure of CPs as supported by previous studies [38–41]. Complementing this, the diachronic approach examines the temporal evolution of CPs, exploring how interactions between patients, healthcare professionals and the healthcare system evolve over time [42–45]. Together, these approaches, underlined by the concept of DCPs, offer a comprehensive view of CPs, taking into account both their static and dynamic aspects. Integrating DCPs supports a holistic and integrative approach to care, improving the quality and patient experience by tailoring care to individual needs and anticipating specific challenges [45], as previously demonstrated [46]. Additionally, this approach optimizes the organization of healthcare resources and services and the coordination of professionals [28], enhancing equity of access [47].

Thirdly, concerning the identification of IDCPs that consistently and systematically influence all CPs, this study showed that IDCPs can be classified into four major themes: health status, systemic and organizational determinants, social and environmental determinants, individual and psychological determinants. These results are in accordance with several factors identified in various specific CPs [36,48]. Salome et al [36] analyzed the CP of psychotrauma patient and identified factors leading to different clinical perspectives such as care provider's viewpoint on clinical guidelines, screening tools, and treatment options, but also by structural and organizational factors. Gartner et al [48], in a systematic review, analyzed CP definitions and identified several attributes of a fluid and effective pathway, that correspond to what we referred to as IDCP: (i) the cognitive access to care, psyche and lifestyle and socio-family support; (ii) the involvement of professionals; (iii) the care coordination and institutions; (iv) the care coordination; (v) the healthcare offer, institutions, care coordination; (vi) the care coordination. Thus, individual’s HDs help characterize predetermined attributes of individual’s CP, guiding from the start the implementation of appropriate solutions. Meanwhile, DCPs help identify factors that continuously impact these solutions throughout the course of CP and must be considered to optimize health outcomes and answers to specific individual needs.

Fourthly, identification of IDCPs could offer a novel framework for concretely analyzing the organization of care programs that accompany patients throughout their healthcare trajectory within

a specific territory. This approach, focused on the interactions between individuals and the healthcare system, has long been sought, particularly in France, where analyses have traditionally emphasized resource availability and predefined procedures, as suggested for example by the study of Crozes et al concerning CPs after ischemic stroke [28]. By adopting the perspective of a dialectic balance between ICPDs, it becomes easier to differentiate between system-dependent, inflexible elements that can however evolve, and human-dependent, adaptable factors regarding individual interactions but that can be resistant to change at the individual level. This aligns with the World Health Organization's perspective, which emphasizes the importance of conceptualizing a broad spectrum of potential improvement methods and interventions, while ensuring that policy accounts for key determinants of the quality of care regardless of the country and its healthcare system [49].

While IDCPs are always present, their impact on an individual care trajectory could vary - whether favorable or unfavorable, strong or weak - depending on the context or even within a given context over different periods [26,48]. Moreover, considering IDCPs does not overcome the variability of CPs depending on the subjectivity of actors involved in a given healthcare pathway in a given context. To consider and reduce the impact of this subjectivity, impact measurement techniques could be used [50], as well as artificial intelligence within data-matching algorithm [51].

Finally, this study presents several limitations. First, as with any qualitative study, it was difficult to know whether data saturation has actually been reached [52]. However, the participants' professional experience testifies to a high level of expertise and theoretical and practical knowledge, which legitimizes the relevance of the results. Furthermore, no significant differences in viewpoints between the three categories of participants were noted, reinforcing the power of the results. The implementation of focus groups with different samples of professionals could reinforce the results. Second, this study gathers the points of view of professionals only. To fully address the DCPs and their impact, the individual or patient's points of view are important [45,53]. To this end, data collection methods during the various stages of CPs, such as “the shadowing”, could be of interest [54]. Indeed, it is noteworthy to be able to have direct feed-back information from inside the system and during patient trajectory [55], a methodological choice that also engages and motivates health-care staffs to improve patient-centered care [54]. Third, this study relies on improving the process of care and finally the efficiency of it, which are universal concerns. The results based on the French context may not fully correspond to that seen in other Western countries, where the organization of the healthcare system is different, but the concept of DCPs and IDCPs can be universally applied, eventually with required adaptations (48).

5 Conclusion

Understanding the factors that shape CPs is essential for improving healthcare management and patient outcomes. This study has emphasized the importance of DCPs, which influence interactions between individuals and the healthcare system. The identification of IDCPs marks the first step in understanding how systemic and dynamic factors systematically impact care processes. By considering together HDs, CP characteristics and IDCPs, the link between theoretical models and practical healthcare interventions in real-world conditions can be strengthened. This comprehensive approach not only helps to improve the organization and coordination of healthcare interventions, but also informs public health policies, ultimately leading to more efficient and patient-centered care. This study offers a foundational framework for future research on optimization of CPs across diverse healthcare systems, incorporating techniques to evaluate the impact of CPDs and enhance modeling strategies.

6 Declarations

6.1 Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Research Ethics Committee of the University of Lyon (n◦ 2022-04-19-003on 27 June 2022). All participants were given written and oral information about the study and gave informed consent to participate.

6.2 Consent for publication

Not applicable.

6.3 Availability of data and materials

All data generated or analyzed during this study are included in this published article and its supplementary information files.

6.4 Funding

Not applicable.

6.5 Acknowledgements

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541 patient care: implementing cybernetics, Stud Health Technol Inform 107 (2004) 70–73.
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544 **Table 1.** Overview of major themes and sub-themes associated

Major themes	Characteristics of the concept of DCPs	Identification of IDCPs
Sub-themes	• Differences between health determinants and DCPs • Usefulness of DCPs to better understand CPs • DCPs as part of CPs modeling strategies	• Health status • Systemic and organizational determinants • Social and environmental determinants • Individual and psychological determinants

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547 **Table 2.** Participants' perception regarding the concept of care pathway determinants

Key emerging aspects	Illustrative quotes
HDs and DCPs	• "*It is not obvious to me, like that, a priori, I have never thought of attaching the term oh care pathway determinant. So, obviously, there is a link with the determinants of health, because the determinants of health are so broad, finally, that I am not sure which determinants might not be* health determinants *and would be determinants of care pathways*" (C2-4) • "*They're linked, but there are still a lot of differences. For me, health determinants are more about what causes pathologies [...] This is very epidemiological. The pathway will incorporate this as one of the elements, but it will be much broader. The approach is going to be much more systemic and much broader than just the pathological aspect*" (C1-13) • "*I would have said that health determinants are specific to the individual and that care pathway determinants involve interaction with others*" (C3-7) • "*It's difficult because care pathways have a diachronic aspect, a dynamic aspect, finally it is a trajectory, and health determinants are more static*" (C2-7) • "*in terms of health, we're looking at a point in time, a snapshot. A situation report, a stage. The pathway is part of the dynamic of development that will enable us to support*" (C1-7)
DCPs enhance understanding CPs	• "*But I do think it would be really interesting to be able to see if there are any key determinants [...] Identifying them can change things*(C3-7) • "*The determinants of care pathway, we are there in an approach [...] heuristic. That is understanding the mechanisms underlying a concept*" (C2-9) • "*I think that some of them are common to several pathways and that, by working on them in a slightly broader way, we'll be able to help several situations*" (C1-15) • "*This will also enable us to define the care pathways a little more clearly and adapt them to suit life and demand*" (C1-3) • "I*n relation to a... rather panoptic view, I would say, of the conditions that make good health possible, somewhere, in a society, it seems to me that it would be very interesting to think about the determinants of health pathways*" (C2-7) • *I think that the more we know about these determinants, the more we can perhaps act upstream. And again, coming back to my question about the efficiency of the system, I think in terms of public policy, it may perhaps lead to choices that are relevant, because informed by these determinants*" (C3-3)
DCPs enhance CPs modeling	• "*It's putting practice into theory. For me, that's what it's all about, if you work on it, you put practice into theory*" (C3-6) • "*What we need to look at is the determinants that will be favored and the determinants that will be antagonistic or may be a brake on the implementation of the pathway, the management of the pathway, the acceptance of the pathway*" (C2-8) • "*we must progress in this ability to think things. And to think about complexity, because if we think about simplification and standardization, I think we're missing the point. [...] I think we need to come up with some kind of more theoretical [...] modeling framework that nevertheless enable us to think about these pathways, and probably in these models we can try to include something more specific to take account of the differences in people's needs and expectations. And I think that perhaps certain models can respond to this, i.e. go beyond the standard pathway*" (C2-4) • "*it allows us to have... a framework with which we can work to forecast, predict, organize, improve, innovate. Modeling also allows us to compare an ideal pathway with real pathway and to think about improvement so that reality tends towards the ideal. […] It's a tool to manipulate a number of elements, which are determinants of care pathway, and organize them so that we can, again, build typical pathways and compare them with real pathways*" (C2-9)

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550 **Table 3.** Participants' perception regarding Invariant determinants of care pathways

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IDCPs categories	IDCPs sub-categories	Illustrative quotes
Health status	Illness	1. "*It's the illness. When it is unique or when they are combined. The illness determines the pathway*" (C3-5) 2. "*And then you have the pathway in the healthcare system for someone whose health resource is impacted by health events, illnesses etc.... [...] Because their health situation, in the sense of more than just illness, requires several partners*" (C3-1)
	Diagnosis	3. "*So, in the pathway, very often the tag... Very often the tag laid by the diagnosis, [...] the word posed... [...] this is really a very, very important thing*" (C3-6)
Systemic and organizational determinants	Healthcare offer	4. "*So, typically, the place and the offer of care around it is a determinant of the pathway because the pathway is going to be more or less complex*" (C3-7)
	Care coordination	5. "*Inter-knowledge of partners around a given theme, so that each knows what the other has to do, and how the other can intervene and help in the person's situation*" (C1-7)
	Professional Involvement	6. "*The availability and also... the involvement of these professionals. You can have a SIAD that's present, a SIAD that's available, but a SIAD that's exhausted*" (C1-13)
	Institutions	7. "*In the medical world, there is an institution that does not move and imposes on professionals, it is the medical association called the order of doctors. Professionals have ethical obligations that are supervised and therefore sanctioned by this medical association. And it imposes a behavior towards the person cared for. This behavior must be about the same according to all professionals. And so, this behavior has a role to play in the choices, in how people receive their therapy, how they are explained their therapy*" (C2-9.1)
Social and environmental determinants	Socio-economic conditions	8. "*Social integration is fundamental (ties of citizenship, filiation, work, and affinities) [...] we could say that the determinants of the health pathway... are, I would say, the effects of position [editor's note: social position] in addition to the usual health determinant*" (C2-7.1) 9. "*So in the social level, I mean by that, first and foremost, wealth. You don't organize your care pathway the same way when you have no money at all or when you have a lot of it*" (C2-9.2)
	Professional context	10. "*So it's clear that in terms of health, professional activity and, in any case, the social status it gives and the socio-economic conditions are absolutely fundamental [...] People with irregular working hours may find it difficult to follow consistent treatment*" (C2-7.2)
	Socio-family support	11. "*Some carers who are more or less carers. It's not just a question of knowing whether there's a spouse, but actually knowing what the relationship is between them, what the person's ability to help is, and so on*" (C1-13)
Individual and psychological	Cognitive access to care	12. "*Health literacy you see, is what I put first. Literacy is the evaluation of literacy. For me, it's an invariant. You can't start a course if you don't know who you're going to be working with*" (C2-5)
	Psyche	13. "*It's also linked to history. I'd even add that part, in fact, in the end, what relationship we have to health that's been built up, by our genetic heritage, by what we've seen, etc. [...] in the end, it's also linked to the fact that, well, life experiences, how we've seen things, people evolve around us, and what relationship we have to health*" (C3-7)
	Lifestyle	14. "*And then there's the vision of the user, of the patient, which is his health and life path, his trajectory, with his choices, his aspirations, his lifestyle habits*" (C2-1)
	Age	15. "*Because for me, my health path is obviously not the same, it may be one day, as an elderly person over 75 who is frail and gradually heading towards a loss of autonomy*" (C3-3)

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2.3. Partie 3- Modélisation du parcours du patient hémophile : une approche systémique

2.3.1. Identification des principaux critères organisationnels de l'offre de soins (article 4)

L'organisation autour d'une situation pathologique chronique, comme l'hémophilie, est complexe. Elle comprend une multitude d'acteurs différents impliqués dans la prise en charge du patient. Cette organisation est susceptible d'être significativement modifiée par des facteurs, comme par exemple l'introduction de nouvelles solutions thérapeutiques. Dans l'article publié intitulé « Multiple criteria decision analysis for therapeutic innovations in a hemophilia care center: A pilot study of the organizational impact of innovation in hemophilia care management », les objectifs étaient de définir les principaux critères qui sous-tendent l'organisation de soins et d'évaluer l'impact d'une innovation thérapeutique sur cette organisation.

En effet, l'hémophilie est une maladie génétique qui touche environ 1,1 million de personnes dans le monde, dont environ 418 000 cas sévères (224). Jusqu'au début du 21e siècle, le traitement de l'hémophilie se limitait essentiellement à l'import intraveineux du facteur de coagulation déficient. Cependant, des thérapies innovantes, avec de nouveaux mécanismes d'action et des modalités d'administration plus simples, comme les anticorps monoclonaux, sont apparues. Ces innovations peuvent transformer l'organisation des soins en éloignant les patients des structures hospitalières traditionnelles et en introduisant de nouveaux acteurs dans le parcours. Cependant, l'impact organisationnel de ces innovations reste peu étudié, alors que cela est essentiel pour anticiper les changements dans les parcours en santé et pour éviter les ruptures dans la continuité des soins. En ce sens, l'évaluation de l'impact organisationnel des innovations est cruciale pour adapter l'organisation des soins tout en garantissant la sécurité et l'efficacité du traitement.

Pour cette étude, un groupe d'experts multidisciplinaire a été constitué. Les critères d'inclusion étaient : (i) l'implication dans la prise en charge des patients hémophiles, (ii) la connaissance de l'organisation des soins, et (iii) le fait d'être un professionnel de santé médical ou non médical. Dix membres d'une même équipe hospitalières ont participé : trois médecins, trois infirmières, deux pharmaciens, un kinésithérapeute, et un psychologue.

L'étude a été basée sur une analyse décisionnelle multicritères (dite MCDA pour Multi criteria decision analysis) (225). A partir d'un répertoire de critères organisationnels adapté au secteur du soin composé de cinq domaines (activités, personnes, structure, technologie et environnement), la première étape a été de sélectionner les principaux critères organisationnels pour cette équipe de soins, grâce à une recherche de consensus. Sept principaux critères organisationnels ont été retenus. Puis chaque critère

identifié a été associé à une échelle de performance à plusieurs grades (comme par exemple : faible, moyen, élevé). Il a été ensuite possible de déterminer un poids d'importance à ces critères en utilisant une technique de révélation de préférences (PAPRIKA pour Potentially all pairwise rankings of all possible alternatives) (226). Cela a permis d'identifier les critères organisationnels primordiaux, soit de façon générale à l'équipe, soit par métier des membres. Enfin, une étape de cotation, individuelle puis en groupe, a permis de scorer les alternatives thérapeutiques innovantes selon les critères organisationnels, et de définir des mesures d'impacts. Ainsi, la thérapie génique a obtenu un score reflétant un impact organisationnel important, en grande partie dû à sa complexité et à une acceptabilité moindre.

Par conséquent, cette étude a mis en évidence la capacité d'identifier des principaux critères qui constituent le processus de prise en charge. Les perceptions des soignants sur leur propre organisation des soins ont été exprimées de façon robuste. Elle a également mis en évidence la capacité de calculer un score d'impact organisationnel suite à l'introduction d'une innovation thérapeutique. Cette méthodologie peut donc aider à optimiser les parcours en santé en tenant compte des spécificités organisationnelles locales et des acteurs impliqués dans la gestion des patients.

PLOS ONE

RESEARCH ARTICLE

Multiple criteria decision analysis for therapeutic innovations in a hemophilia care center: A pilot study of the organizational impact of innovation in hemophilia care management

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Abstract

Background

Several innovative drugs liable to lead to changes in healthcare organization are or soon will be available for the management of hemophilia. Analyzing their implementation can shed further light on healthcare decision-making, to anticipate changes and risk of breakdown in the patient's care pathway.

Methods

Multiple criteria decision analysis (MCDA), based on ISPOR recommendations, was used to assess the organizational impact of innovation in hemophilia care management. The MCDA process designed for this specific context involved ten French experts in hemophilia care management (physicians, nurses, pharmacist, physiotherapist and psychologist) in the hemophilia care center of Chambéry, in the Rhône-Alpes Region of France. This pilot study involved seven steps: (i) defining the decision problem; (ii) selecting and structuring criteria; (iii) assessing the relative weight of each criterion with software-assisted simulation based on pairwise comparisons of different organizational change scenarios; (iv) measuring the performance of the selected innovations; (v) scoring alternatives; (vi) calculating aggregate scores; (vii) discussion. The endpoint was to determine the expected overall organizational impact on a 0–100 scale.

Results

Seven organizational criteria were selected. "Acceptability for patient/caregiver/association" was the most heavily weighted. Factor VIII by subcutaneous route obtained the highest

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aggregate score: i.e., low impact on care organization (88.8 out of 100). The innovation with strongest organizational impact was gene therapy (27.3 out of 100).

Conclusion

This approach provided a useful support for discussion, integrating organizational aspects in the treatment decision-making process, at healthcare team level. The study needs repeating in a few years' time and in other hemophilia centers.

Introduction

Until the turn of the 21st century, hemophilia treatment basically consisted in repeated intravenous replacement of the deficient coagulation factor [1]. For some years now, new therapies have been emerging with different, non-replacement action mechanisms, less burdensome administration route (subcutaneous), longer action duration and, in the case of gene therapy, a curative aim [2–5]. Some are real technological innovations liable to disrupt care organization and/or patients' care pathways. Management of hemophilia, which is a rare condition, is highly structured and governed by guidelines for treatment and care organization. Patients are managed in specialized structures ensuring global multidisciplinary care. In France, the structures are hospital-based and the clotting factor concentrates are available only in hospital pharmacies. The patient's pathway is thus highly hospital-centered; but this is expected to change, as, in France, new treatments become available in community pharmacies, closer to the patient. These less burdensome treatments and accompanying clinical improvements are liable to move care away from specialized structures and to involve new actors in patient management [6]. To maintain optimal secure care, these organizational impacts need to be studied to accompany the changes in pathway.

Introducing an innovation impacts both the organization governing it and its environment [7]. The organizational aspect is still not fully taken into account, but is emerging as one of the key aspects of the decision-making process, alongside the clinical and medico-economic aspects. Assessment of therapeutic innovations (healthcare products, acts, care organization) does not at present take account of all aspects of healthcare organization, and this can lead to irrational decisions and non-optimal use of resources. A study with 53 European hospital managers showed that organizational aspects of new treatments were considered among the most relevant information for decision-making, with safety, clinical and economic aspects [8].

This finding has led to a need for effective decision support tools to enable a systemic approach to decision-making issues [9]. According to a special task force, to identify, collect and structure information required by those making judgments to support the deliberative process, particularly in the field of health, using a multiple criterion decision analysis (MCDA) is a correct route to go down [10]. Developed in the 1970s and widely used in non-medical fields such as agriculture, energy and marketing [11–13], MCDA approaches have spread to the health field since the 2000s [14]. MCDA is especially appropriate to questions requiring a range of relevant but often heterogeneous criteria to be taken on board. It facilitates strategic and operational decision-making in fuzzy or unstable settings, identifying the decision-making problem and shedding useful light on complex issues by implementing a number of alternatives. It also has the advantage of taking account of all relevant aspects (systemic approach), in a multidisciplinary setting, stimulating exchange in a structured decision-making process and enhancing the transparency and rationality of the decisions. To cite different examples of the

value of using this methodology: the Latin American Federation of the Pharmaceutical Industry (FIFARMA) stated that MCDA should strongly be considered as a tool to support Health Technology Assessment (HTA) [15]; and MCDA has been recognized as a relevant approach by the independent expert advisory committee of the Canadian Health Ministry in the context of drug reimbursement decision-making [16]. Recently, the French National Authority for Health (HAS) published, in December 2020, a methodology guide about organizational impact map for health technology assessment based on an MCDA approach [17]. In the MCDA method, the revelation of preferences can be obtained via the discrete choice approach (DCE) or via the Potentially all pairwise rankings of all possible alternatives (PAPRIKA) approach. The DCE method compares scenarios composed of four to six criteria on average [18], whereas the PAPRIKA method compares pairs of scenarios by evaluating two criteria at a time [19]. In the DCE method, the comparison of two alternatives by evaluating more than two criteria can lead to a bias if the user concentrates on one part of the criteria. The analysis conducted is then not exhaustive and can lead to uncertain results [18]. Conversely, the PAPRIKA method allows to simplify the choice of the users. Implicit pairs are automatically eliminated, which reduces the number of pairs to be compared and avoids inconsistencies in classification and the risk of redundancy [18]. This PAPRIKA method is integrated with an online software 1000minds® [20] which has the advantage of generating a random order of comparisons thus reducing the risk of bias related to the order. Moreover, the system does not involve any additional calculation and generates the global (mean or median) and individual weights for each criterion.

In the case before us, the MCDA approach has already been used in the evaluation of the organizational impacts of a therapeutic innovation, such as in acute pain management in an emergency department [9]. Despite some limitations of modeling, this demonstration provided conclusive results. To our knowledge, only one study has used MCDA in the setting of hemophilia. Gourzoulidis et al. (2021) determined' the value of prophylaxis versus on-demand treatment in hemophilia A and emicizumab versus replacement therapy in the Greek healthcare setting [21].

Hemophilia management requires complex structured organization comprising specialized multidisciplinary teams with numerous interfaces with the various actors involved in patient management. Many parameters are relevant to treatment decision-making: type of hemophilia, severity, comorbidities, age, and the patient's personal experience [22]. Introducing several innovations in this context is liable to induce changes in care management organization.

This context appears appropriate to develop the MCDA methodology for the assessment of the organizational impacts of a therapeutic innovation. In our view, this seems relevant because the more complex the system, the greater the uncertainty, especially in biopsychosocial models [23]. Moreover, working to reduce uncertainty will also improve the accompaniment of innovation-induced change, and make greater use of the benefits for improved health.

Thus, we conducted a pilot study in a single hemophilia care center to evaluate the organizational impact of innovation, using MCDA.

Materials and methods

The Scientific and Ethical Committee of Hospices Civils de Lyon IRB n° 00013204 (Lyon, France) examined the protocol registered under file number 21_322 and waived the requirement for ethics approval. According to French regulations and General Data Protection Regulation, all participants are informed and given the right to object. Since no medical or personal data was collected, informed oral consent was collected during the first meeting and documented in the meeting report.

The study methodology conformed to that of Lvovschi et al. [9]. The good practice guidelines of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) for the implementation of MCDA by health professionals were followed. Quantitative MCDA was used, as its methodology is well described, it is mainly used in the health field, and it has the advantage of providing aggregate scores that facilitate decision-making.

Seven steps, following the ISPOR quantitative MCDA approach, were followed: (i) defining the decision problem, (ii) selecting and structuring criteria, (iii) weighting criteria, (iv) measuring performance of alternatives, (v) generating a performance score, (vi) calculating aggregate scores, (vii) and deliberation [24, 25].

Defining the decision problem

The main study objective was to assess the impact of an innovation on the organization of care management of hemophilia patients. Secondary objectives were to define the main criteria underlying this organization and to collect the opinions of those involved regarding the interest of the MCDA approach. The analysis was performed from the point of view of health professionals specializing in hemophilia. Through this procedure organizational impact scores were produced to determine the impact of an innovation on the organization of care: weak impact, requiring minor changes, or strong impact requiring considerable changes.

A multidisciplinary expert group was set up. Inclusion criteria comprised (i) involvement in patient management in the center, (ii) familiarity with care organization, and (iii) being a medical or non-medical health professional. Individuals recruited were identified following an initial study on the care pathway of patient with hemophilia [26]. Among the 11 health professionals previously identified, only the biologist declined to participate. This led to 10 inclusions: 3 physicians, 3 nurses, 2 pharmacists, 1 physiotherapist and 1 psychologist. The study was conducted by a research team with experience in MCDA.

The study took place in the hemophilia treatment center of Chambéry in the Auvergne-Rhône-Alpes area of France, from January to June 2021, with 2 face-to-face meetings of 2 hours each and a remote individual work session (Fig 1).

In the first meeting, the MCDA approach and its interest for assessing the organizational impact of innovations were presented to the group, which then chose to score the organizational impact of the 6 therapeutic innovations shown in Table 1 [2, 3, 5, 27, 28].

Selecting and structuring criteria

Organizational criteria were selected by the group from a list based on a review of the literature, and grouped in 5 domains: task, surrounding, peoples, structure and technology [29]. Each expert consulted the criteria for each domain to select those that seemed relevant with respect to the predetermined issue. If the proposed criteria did not seem adequate, they could add one in a "free text" field. They were asked to select at least 1 per domain and not more than 8 criteria per domain.

Criteria were validated by consensus after this individual selection stage in the first meeting. The performance levels for each criterion was then established by consensus.

Weighting criteria

Weighting used the PAPRIKA method (*Potentially all pairwise rankings of all possible alternatives*), a method to reveal preferences integrated in an on-line software (1000minds Ltd, Dunedin, New Zealand) [19]. The principle is based on pairwise comparison between scenarios, assessing two criteria at a time and assuming all others to be equal. Before weighting a criterion, particular attention should be paid to performance level: low, intermediate, high. For the

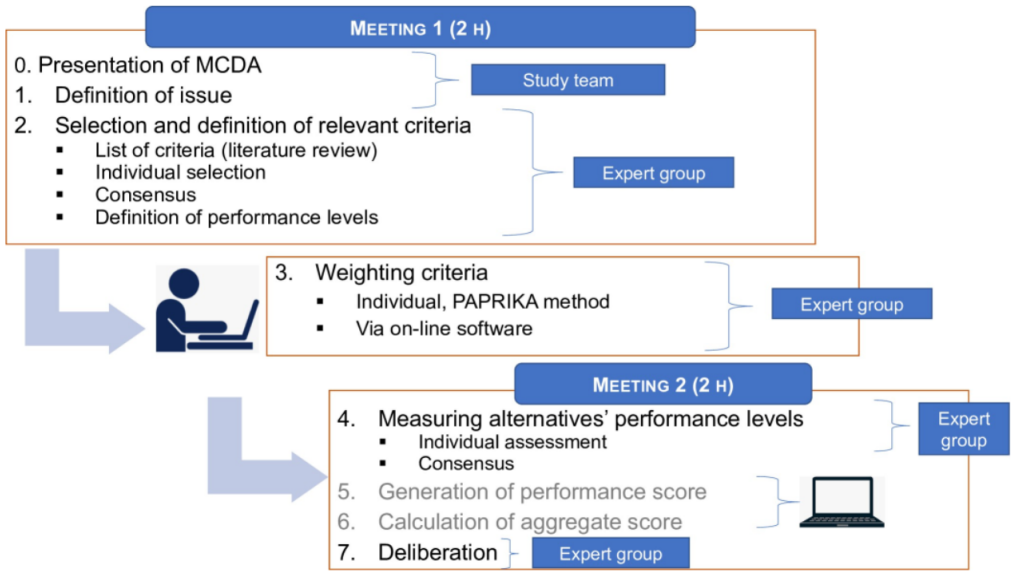

Fig 1. Description of the MCDA process assessing the organizational impact of innovations.

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study, each expert chose the situation they would prefer, answering the following question: "In the context of a novel hemophilia treatment, which situation would you prefer (in terms of

Table 1. Alternatives selected by the expert group.

THERAPY	TYPE OF THERAPY	INNOVATIVE CHARACTERISTIC	ACCESS TO THERAPY
BIVV001	Replacement (recombinant factor VIII)	Fusion protein with XTEN polypeptides to extend half-life	Clinical trial (phase III) (hemophilia A)
OCTA101	Replacement (recombinant factor VIII)	Subcutaneous anti-hemophilia factor	Clinical trial (phase I/II) (hemophilia A)
emicizumab	Non-replacement (bispecific antibodies mimicking factor VIII action)	Action mechanism: enhancing coagulation. Long half-life. Subcutaneous route	Marketed (hemophilia A including patients with inhibitors)
concizumab	Non-replacement (anti-TFPI monoclonal antibodies)	Action mechanism: rebalancing coagulation. Long half-life. Subcutaneous route	Clinical trial (phase III) (hemophilia A and B including patients with inhibitors
fitusiran	Non-replacement (RNA interference against antithrombin)	Action mechanism: rebalancing coagulation. Long half-life. Subcutaneous route	Clinical trial (phase III) (hemophilia A and B including patients with inhibitors)
volactocogene roxaparvovec giroctocogene fitelparvovec fidanacogene elaparvovec etranacogene dezaparvovec	Gene therapy	Healthy gene introduced in a single administration	Clinical trial (phase III) (hemophilia A and B including patients with inhibitors)

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impact on the organization of care)?" The upper limit thus corresponded to the lowest-impact situation and the highest weighting.

An explanatory notice was drawn up to optimize use of the tool. The experts provided their individual preference via the software. The mean weighting was used to calculate the aggregate score.

Measuring performance of alternatives

The second meeting reviewed the main characteristics of the innovations according to the current state of knowledge. The performance level of the alternatives was then assessed by consensus after a step of individual assessment.

Scoring alternatives and calculating aggregate scores

The performance scores and aggregate score of each innovation were calculated automatically by the PAPRIKA software after entering the performance levels validated by the expert group.

The method for aggregating weightings and performance levels most often used in the health field is the weighted sum method:

$$S(a) = \sum_{i=1}^{n} w_i s_i(a)$$

where S(a) is the aggregate score, w the relative weight of the criterion, and $s_i(a)$ the performance score for alternative A for criterion *i*.

Results

Choice and description of criteria

Eight criteria were identified as priorities in the first meeting: 2 in the "task" domain, 1 in "surrounding", 1 in "peoples", 1 in "structure" and 2 in "technology"." The "structure" criterion (innovation matching network objectives) was eliminated in the assessment meeting; at care-unit level, it is rather a precondition for introducing an innovation rather than a criterion that varies with department organization depending on the innovation in question. Performance levels per criterion ranged between 3 and 4; Table 2 shows criteria and performance levels.

Weightings of criteria

The experts made between 46 and 84 explicit comparisons in a median 14 minutes (range, 9–120 min). Those who took longest (55 and 120 minutes) did not complete the analysis, due to interruption: 1 nurse (who began again), and 1 physiotherapist; the physiotherapist's partial analysis was not taken into account in weighting the criteria.

The 3 criteria with the strongest weightings were "acceptability for patient/care-giver/association" (weight: 31.4%), "number of emergency or unscheduled consultations" (weight: 20.3%) and "complexity of the innovation and informed choice" (weight: 16.6%). Fig 2 shows criterion weightings.

Assessment of organizational impact of innovations

Alternatives were assessed by 4 of the experts: 1 physician, 2 nurses and 1 pharmacist. Responses varied according to profession and individual factors of understanding the criteria and knowledge of the innovation. After compiling individual results, discrepancies were discussed and consensus was reached for all innovations. The "number of emergency or

Table 2. Criteria for evaluation of the organizational impact.

Field	Criteria	Items	Item definitions
Task	Number of emergency or unscheduled consultations	Strong increase	Increase in number of emergency and unscheduled consultations
		Increase	Increase in number of unscheduled consultations
		No change	No change
		Decrease	Decrease in number of emergency consultations
		Strong decrease	Decrease in number of emergency and unscheduled consultations
	Change in patient recruitment	Complexification	Need for additional decision criteria
		No change	No change
		Simplification	Innovation meeting non-covered therapeutic need
Surrounding	Number of pathway or interface actors	Increase	New actors along pathway
		No change	No change
		Decrease	Fewer actors along pathway
Peoples	Medical and non-medical personnel training	Considerable	Very complex theoretical and practical training requiring development of several supports; long training (several days)
		Classical or standard	Complex theoretical and practical training requiring development of a single support accessible to all types of health professional; duration <1 day.
		Lightened	Simple theoretical and practical training requiring no new support; duration negligible (<1h)
		None	No training required
Structure	Acceptability for patient/care-giver/ association	None	No contribution in terms of efficacy, tolerance, practicality, adherence
		Weak	Improves 1 criterion of efficacy, tolerance, practicality, adherence
		Moderate	Improves 1 or 2 criteria of efficacy, tolerance, practicality, adherence
		Strong	Improves several criteria of efficacy, tolerance, practicality, adherence
Technology	Supply (product, associated devices)	Very complex	Several ordering procedures for products and devices, different supply procedures and supply times
		Complex	One additional step, easy to include in current procedures
		Simple	No change
	Complexity of innovation and informed choice	Very complex	Action mechanism hard to understand even for professionals; difficult to popularize
		Complex	Action mechanism more difficult to popularize
		Simple	Action mechanism easy to explain

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unscheduled consultations" criterion had the same score for all innovations (13.3 points) except for gene therapy (18.7 points). This was accounted for by the small number of emergency or non-scheduled consultations in everyday practice, leaving little room for improvement on this criterion. Treatments were presumed to be effective in the light of the state of knowledge at the time of the study. Thus, no deterioration in this criterion was expected. Responses to the "supply" criterion revealed a need for better definition, taking account of the laboratory supplying the treatment. For treatments still at the stage of clinical trials, supply modalities were difficult to determine. Obviously, the experts assessed this criterion taking account of the laboratory's expertise: hindsight on the knowledge of the pathology and patients' needs in terms of associated devices and the ability to set up emergency supply routes. One innovation could not be assessed on all criteria, as the experts lacked knowledge of the treatment. The 2 innovations with the highest aggregate scores (i.e., low impact on care organization) were subcutaneous recombinant anti-hemophilia factor (87/100) and very long action recombinant anti-hemophilia factor (88.8/100). Low scores (i.e., strong impact) were attributed to gene therapy (27.3/100) and anti-antithrombin RNA (21.9/68.3); their acceptability was deemed low and the innovation was considered difficult to explain in securing informed patient choice. Table 3 shows aggregate scores per innovation.

Fig 2. Mean and individual weighting per criterion.

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Discussion

This study was conducted in the field of hemophilia care. And as it took place in France, some local conditions and standards of care must be taken into account. For example, while France has implemented all 10 principles of hemophilia care (while other European countries have not), it is recognized that various aspects of the French hemophilia patient's care need to be improved (aging, psychosocial support, etc.) [27, 30, 31]. All the more so with regard to the therapeutic innovations that are coming.

Therefore, this study shows that the use of a structured analysis method helps to formalize the essential organizational criteria in the management of a pathology and to become aware of the possible impacts in the event of a breakthrough innovation in therapies. Thus, therapeutic innovations can induce organizational innovations, and recognizing this early and precisely can make it possible to prepare adequate support for change for care teams.

Then, the MCDA method, used in this study, allowed an expert group to attribute organizational impact scores for each study innovation. The method assessed the organizational impact

Table 3. Organizational impact scores per innovation.

	BIVV001	OCTA101	emicizumab	concizumab	fitusiran	gene therapy
Acceptability	31.4	31.4	31.4	19.3	8.6	8.6
Number of consultations	13.3	13.3	13.3	13.3	13.3	18.7
Complexity	16.6	16.6	8.1	8.1	0.0	0.0
Supply	11.7	11.7	6.1	11.7	0.0*	0.0
Training	7.7	7.7	7.7	7.7	0.0*	0.0
Recruitment	3.9	5.7	0.0	0.0	0.0*	0.0
Number of actors	2.4	2.4	0.0	0.0	0.0*	0.0
Aggregate score	87	88.8	66.6	60.1	21.9	27.3

* In the absence of sufficient data in the current state of knowledge

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of innovations and identified useful points for reflection for a subsequent more qualitative analysis of the nature of such organizational changes. An innovation that is complex to explain may require setting up new explanatory tools, impacting care-unit organization. In contrast, innovations consisting in replacement showed the least organizational impact, although this is to be read in the context of the study situation and cannot be directly extrapolated to other hemophilia centers. Although hemophilia management is highly structured and coordinated, there may be organizational differences between centers according to their geographic situation and history. It would be useful to repeat the present study in other centers, to analyze variations in choice of relevant organizational criteria and possible differences in impact according to care organization and geographical region. This could complement pathway analysis, with optimization according to organizational specificities, and also a greater consideration of complementary actors, like city caregivers. For example, in France, since June 15, 2021 (after this study), the pharmaceutical product emicizumab has had a dual dispensing circuit: hospital pharmacy and city pharmacy. This is the first hemophilia treatment available to patients in private practices. This dispensing is accompanied by additional risk-reduction measures, like a new organizational chart [32], an optimized information flow and a full training on the disease and treatments.

A better understanding of the nature and strength of the organizational impact of a therapeutic innovation should allow for a better match between therapeutic choice and individual's health determinants (biological characteristics, family environment, local health system, cultural context, etc.), to understand the most suitable patient support, and to ensure an optimal healthcare pathway, reducing the risk of dropouts.

From the point of view of the experts, the acceptability for patients/caregiver/association, the number of emergency and unscheduled consultations and the complexity of the innovation were the main criteria determining organizational impact. Gene therapy and anti-antithrombin RNA were the innovations with the greatest organizational impact, notably due to poor acceptability and high complexity hindering shared informed decision-making. Acceptability is a multifactorial criterion that may be related more to the patient and their experience and life than to the innovation itself. Thus, for example, not taking into account a good match between individual capacity for acceptability and the complexity of the innovation, which may lead to difficulties in understanding its usefulness or usability, could lead to a risk of poor therapeutic adherence. In this case, having already planned a specific work to increase the patient's level of health literacy could be a key success factor. Poor therapeutic adherence could also result from supply difficulties inherent to a therapeutic innovation if these were not clearly envisaged beforehand.

At patient level, individual variation in organizational impact score can be expected due to the strong weighting of this criterion. In a qualitative study in 20 hemophilia patients, 40% were very favorable and 35% favorable toward gene therapy, after information delivered ahead of the interview [33]. This study underlined similarities in the organizational impact from gene therapy and anti-antithrombin RNA related to their mechanism of action. It was estimated as very complex by this expert group. The organizational impact of these two therapeutic innovations differed in terms of the number of emergency or unscheduled consultations. This criterion was considered favorable only for gene therapy because of its effectiveness in treating hemophilia. New tools or process need to be implemented in order to bring appropriate information at patient for shared-decision. This need is not specific to this team since other studies stressed the need to develop means of training or communication to facilitate shared decision-making [34–37], in agreement with the present expert group's opinion regarding the importance of information for shared decision-making in hemophilia management. In this sense, it has already been demonstrated elsewhere that gene therapy brings a different therapeutic value chain than

traditional pharma, and involves new capabilities and requirements [38]. It calls for a rethink of current collaboration: additional roles of a hemophilia treatment centers could be implemented, and 'hub-and-spoke' models are thought out (prescription and management in national hubs; monitoring in spokes centers) [39]. This makes it crucial to educate patient and health care personnel, essential to define new quality and safety criteria [38].

The present study contributes to the early phase of assessment of MCDA in organizational impact in the health field. The MCDA method aims to facilitate the identification of the optimal solution [40]. It is particularly appropriate for problems that require taking into account a set of relevant and often heterogeneous criteria. It facilitates strategic or operational decision-making in an imprecise or unstable environment, objectifies a decision-making problem, and analyzes complex problems by implementing several possible alternatives. This method has several advantages. It allows (i) to take into account all relevant aspects (systemic approach), (ii) to be part of a multidisciplinary approach, (iii) to stimulate exchanges within the framework of a structured decision-making process, and (iv) to improve the transparent and reasoned character of decision-making. However, the MCDA method has several drawbacks [24, 41]. First, sufficient material and human resources (time, expertise, commitment) must be available and planned. In addition, training and familiarization of professionals are prerequisites for the efficient implementation of these methods. On the other hand, the limitations of multi-criteria methods are mainly related to reliability (accurate and complete data), variability and level of evidence of the input data, and structural uncertainty, such as disagreement on the weighting method. In this regard, several limitations are to be borne in mind.

The composition of the group immediately follows the starting point of any multi-criteria method, the definition of the problem may present biases in this study. It has an impact on the choice of alternatives, criteria and performance levels that structure the problem. Moreover, the group, composed of individuals from different backgrounds, is at the origin of the weighting of the criteria and their performance levels. Variations are expected; the aggregation of individual results with or without (average value) group consensus allows participants to express their point of view. Its composition is a crucial element of the multi-criteria method [10]. It is a source of heterogeneity which must be controlled via sensitivity analysis (study of subgroups, exploration of uncertainties and disagreements with other groups) [24].

A single workshop with participants may not be sufficient to ensure a representative evaluation, and multiple workshops or surveys may be necessary [24]. In this exploratory work, two workshops were held and the individual preference revelation step was conducted remotely.

Regarding the number of experts in the group, two other studies were performed with the same method, comprising 8 and 7 experts respectively [9, 40]. However, studies need repeating to test the method in larger groups so as to resolve issues of heterogeneity and assess varied alternatives.

No patients were included in the group, although patients play a growing role in decisions affecting their health. Including them in the decision-making process is coherent with the development of pathway-based approaches and of interactions with professionals to achieve transverse dialogue. The present study will be followed up by a qualitative study in patients regarding their perception of the impact on their care organization [42]. Finally, training participants is essential, and in the present study the experts received no specific training, although the MCDA method was presented at the outset of the study.

Regarding the PAPRIKA weighting method, several authors reported that users could find it difficult to decide about certain scenarios. They find it difficult to choose between two alternatives while setting aside important criteria not involved in the proposed scenarios. The present expert group did not raise this issue. Goetghebeur et al. also reported that some users found it hard to express their own point of view rather than projecting into an institutional or

social perspective. The perspective in the present study was that of the treatment center. PAPRIKA is an ordinal method, more robust than those used in grading scales for decision aid such as EVIDEM (Evidence and Value: Impact on DEcisionMaking) or Matrix4Value® [43–45]. It avoids several biases inherent to grading scales and makes comparison of weightings more reliable. The problem of individual perception of the scale is circumvented. And comparing two alternatives strictly in terms of two criteria prevents the user concentrating on only one part of the criteria.

The individual preferences expressed by the experts were seen as homogeneous by the group as a whole. However, individual weightings were closer for the criterion with the greatest weight (acceptability). Other authors likewise reported comparable weightings between assessors for the criteria judged more important; in the present study, individual weightings for criteria judged to be of intermediate importance (training and supply) were more divergent. This was also found by Goetghebeur et al. and Martelli et al.. According to Goetghebeur et al., divergences in weighting corresponded to varying individual perceptions and representations, and were not an obstacle; rather, they contribute to the exchanges generating consensus. These methods are interesting as they reveal disagreements between participants.

The same experts determined the weightings of the criteria and assessed the alternatives on these criteria. Other authors proceeded in the same way; however, Sampietro-Colom. et al. suggested that this could introduce bias. The Matrix4value® method uses two groups of experts; but this requires having sufficient human resources.

A question arises concerning maintaining non-discriminating criteria in assessing alternatives. In the present study, number of consultations was non-discriminating between the innovations with the exception of gene therapy. However, these criteria still have an impact. Increasing the number of performance levels for these criteria could confirm or discount their non-discriminating character. Moreover, in case of doubt regarding a difference in performance between several alternatives for a given criterion, the same score was attributed, and the criterion became non-discriminating, without, however, being canceled. Opinions differ on this point. Martelli et al. and Sampietro-Colom et al. attributed a score of zero in case of doubt, whereas Goetghebeur et al. attributed a low score in the EVIDEM model.

No sensitivity analysis was performed in the present study. Our MCDA model had several sources of uncertainty, affecting all components [24, 41]. Structural uncertainty was presumed to be low, as the weighting method and criterion value tree were established consensually. Uncertainty mainly came from using expert opinions as entry data. If a performance measure had been used, the choice between introducing an uncertainty criterion or an uncertainty analysis could have been discussed [24]. Oliveira et al. reported that different approaches to uncertainty analysis are used in MCDA to assess health technologies [46]. Moreover, the present low level of structural uncertainty could be confirmed by scenario analysis [24]. Finally, heterogeneity of preference could be studied by calling upon other expert groups [24].

In the absence of any prior assessment of the impact of the selected innovations on the organization of hemophilia care, no comparison could be made between a previous assessment process and the present method, as proposed by Martelli et al. and Goetghebeur et al. [43, 44]. Simulations could be set up to this end.

Conclusion

The interest of studying organizational impact is now recognized and including it in health technology assessment is a goal for the coming years. The idea of cost-effectiveness is now well understood by decision-makers. However, what choice should be made about an innovation of clear clinical efficacy but requiring changes in pathway organization and relations between

actors? The distinction between medico-economic and organizational evaluation needs to be retained; but the study of organizational impact can enrich medico-economic evaluation. The question of level of evidence arises for the organizational dimension. Moreover, taking organizational impact into account complexifies the evaluation of innovations. Methods must be chosen that respect a balance between simplicity of implementation and methodological rigor. It is also important to decide at what point in the cycle of an innovation organizational impact can most usefully be assessed.

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2.3.2. Analyse du parcours du point de vue des patients (article 5)

L'article publié intitulé « Patients' Perception of the Impact of Innovation on Hemophilia Care Management Organization: A Qualitative Study Protocol (INNOVHEMO Study) » avait pour objectif l'analyse des perceptions des patients concernant l'organisation de leurs soins et les impacts sur celle-ci dus aux innovations thérapeutiques.

Pour garantir une collecte de données homogène, le recrutement des participants a été envisagé sur un seul territoire, dans un réseau de soins typique de la prise en charge de cette pathologie en France. La diffusion de l'appel à participation a été assigné au comité régional de l'association de patients porteurs de cette pathologie et à deux centres régionaux de traitement de l'hémophilie.

Les critères d'inclusion étaient : (i) adulte (>18 ans) ou adolescent (12- 18 ans) atteint d'hémophilie congénitale A ou B avec traitement anti-hémophilique à la demande ou prophylactique (facteur VIII, facteur IX, concentré de complexe prothrombique, facteur VII activé, anticorps monoclonaux bispécifiques), (ii) parent adulte soignant (>18 ans) impliqué dans la prise en charge thérapeutique d'un enfant (<18 ans) atteint d'hémophilie congénitale A ou B avec un traitement anti-hémophilique à la demande ou prophylactique (facteur VIII, facteur IX, concentré de complexe prothrombique, facteur VII activé, anticorps monoclonaux bispécifiques), (iii) patient ou soignant ayant une expérience préalable du traitement de l'hémophilie.

Les critères d'exclusion étaient : (i) les patients ou parents sans traitement anti-hémophilique spécifique régulier (à la demande ou prophylactique), (ii) les patients venant pour une première consultation, (iii) les patients de moins de 12 ans, (iv) ainsi que les personnes ayant des difficultés avec la langue française.

Afin recueillir les perceptions des personnes porteuses de l'hémophilie ou de leurs aidants par des entretiens individuels semi-directifs, deux guides d'entretiens (patients / aidants) ont été conçus. Pour les patients, la première partie du guide a été conçue pour recueillir leurs perceptions sur leur parcours de soins et l'impact sur l'organisation des soins de leur traitement en cours. La seconde partie de ce guide se concentrait sur la notion d'innovation, d'abord avec la notion de changement en général puis plus précisément sur l'organisation des soins.

Pour couvrir ces différentes notions, l'élaboration du guide d'entretien s'est basée sur (i) différentes observations recueillies précédemment auprès de professionnels de santé, lors de visites dans les centres de traitement de l'hémophilie, (ii) le protocole national de diagnostic et de soins de l'hémophilie et (iii) une revue de la littérature qui a permis d'identifier des études qualitatives traitant des perceptions portées sur les parcours de soins par des patients atteints de différentes maladies.

A l’instar de notre recherche, une autre étude a mené également des entretiens auprès de patients et a pu décrire le parcours de soins des personnes asthmatiques (227). Cette analyse a décrit la perception des patients sur les acteurs de la prise en charge et leurs implications. Elle a mis en évidence la perception d'un manque de communication et de coordination dans la prise en charge.

Notre étude pourrait aider à identifier les risques de rupture dans le parcours de soins du patient hémophile et être utile aux patients, aux soignants ainsi qu'aux nouveaux acteurs impliqués dans le parcours de soins. Elle pourrait également faciliter le processus de prise de décision lorsqu'il existe différentes options thérapeutiques en incluant une dimension organisationnelle. Dans cette maladie chronique, où les patients deviennent acteurs voire partenaires de leur prise en charge, il est essentiel de recueillir leurs points de vue : cela peut améliorer notre compréhension de leurs comportements et de leurs motivations.

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STUDY PROTOCOL

Patients' Perception of the Impact of Innovation on Hemophilia Care Management Organization: A Qualitative Study Protocol (INNOVHEMO Study)

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Background: New therapies provide a favorable evolution in the care management of persons with hemophilia. However, the impact of these new therapies on patient care organization remains to be determined. A qualitative study will be implemented to analyze patients' perception regarding the impact of innovation on the organization of their care management. Secondary objectives will include refining specific factors related to persons with hemophilia (barriers or facilitators, especially the place of treatment) to consider within an organizational impact analysis.

Patients and Methods: Semi-structured individual interviews will be conducted via videoconferencing or by phone by two researchers using an interview guide. Participants will be recruited from the Rhône-Alpes region, in France. Physicians from two hemophilia treatment centers will identify eligible patients. Moreover, a call for volunteers will be launched by the Rhône-Alpes committee of the French hemophilia association. Interviews will be conducted with adult patients, adolescent patients or parents of a minor with hemophilia regularly treated prophylactically or on demand. Data analysis will be performed with NVivo® software. Each interview will be analyzed by two researchers using an inductive content analytic method.

Discussion: The INNOVHEMO study is an original study analyzing the way patients perceive the impact of an innovation on their care management organization. The resulting patient-specific factors, identified as barriers or facilitators, will need to be integrated into a more comprehensive analysis of the impact of innovation on care management organization.

Keywords: therapeutic innovation, hemophilia, care pathway, qualitative research, organizational aspect, patient experience data

Introduction

Hemophilia is a rare chronic genetic disorder due to deficient or absent coagulation factors (factor VIII in hemophilia A and factor IX in hemophilia B). It leads to spontaneous or traumatic bleeding; its main complication is hemophilic arthropathy. The worldwide incidence of hemophilia is one boy per 5000 male births for hemophilia A and one boy per 30,000 male births for hemophilia B.[1] In the past decades, the organization of hemophilia care has greatly evolved. One reason was the development of replacement therapies for the treatment and prophylaxis of

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hemorrhages; another was the structuring of specific care networks to optimize the management of this rare, severe and chronic disease.

In the seventies, the development of whole blood fractionation and emergence of the first clotting factor concentrates (CFCs), promoted care pathway advances with a shift from exclusive hospital-based care to the possibility of home-based treatment administration.[2–4] The contaminated blood products, in the eighties, made hemophilia care management more complex with a disastrous impact on the quality of life of persons with hemophilia (PWH). Afterwards, improved blood product safety and the development of recombinant CFCs helped promote the dissemination of prophylactic treatments.[5,6] All these advances contributed to an increased life expectancy in PWH, and transformed the disease into a chronic condition. However, CFCs are not curative and should be administered several times per week via infusion. One CFC-related complication is the development of inhibitors. The management of patients with inhibitors is more burdensome (increased CFC dosage, treatment with by-passing agents (less effective, shorter half-life, longer infusion duration), implementation of immune tolerance induction protocol).[7,8] Acute pain (eg infusion-related), chronic pain (joint pain), treatment burden (eg reconstitution problems, venous access difficulties, infusion rejection in children) impairs quality of life for PWH and their caregivers. As such, quality of life improvements in PWH and caregivers represents a real challenge.[9–15]

In parallel, specific care networks have become more organized over the years. On an international level, the world federation of hemophilia (WFH), created in 1963, has developed actions to promote optimal hemophilia care around the world.[16] Since the creation of the first specialized care center for persons with hemophilia in the United Kingdom in the late forties, hemophilia comprehensive care centers have been developed all around the world.[17,18] In France, regional centers for the treatment of hemophilia (CRTH) were created in the late eighties. Since 2005, national plans have been implemented to improve the care management of persons with rare diseases. This led to the labeling of a reference center on hemophilia and other constitutional hemorrhagic diseases (CRH) in 2006. Rare diseases networks were also set up to reinforce coordinated actions, such as the French network on inherited bleeding disorders (MHEMO). Specialized treatment centers are disseminated over the entire French territory (CRH, Constitutional Hemorrhagic Diseases Resource and Competencies Center (CRC-MHC) and Center for Hemophilia Care (CTH)). This contributed to a structured care pathway for PWH to improve their care management. Nowadays, hemophilia care management is articulated within this dedicated network encompassing various structures and different healthcare professionals, for the specific care management of the disease and its associated disorders (osteoarticular complications, infectious conditions). PWH are very involved in their care management (self-treatment). Expert patients and parents during therapeutic education training courses, French Hemophilia Association (AFH), school-based physicians, companies providing at-home care services are also implicated. The patient care pathway is punctuated with transition landmarks (childhood, adolescence, adult) and ruptures (city-hospital). This French care pathway is very hospital-centered. CRH, CRC-MHC and CTH are structures integrated within public hospitals. Patients regularly go to the hospital for their follow-up consultations. The early care management, right from childhood, associated with regular follow-up visits result in a very strong link between patients and specialist healthcare teams. The dispensing of CFCs by hospital pharmacies strengthens this closeness with the hospital. However, the accessibility of CFCs needs to be improve, especially in an emergency context.[19] Therefore, in France, the evolution of the drug distribution system represents a real challenge for patient care.

Today, new therapies are or will be implemented to improve hemophilia care. They represent new therapeutic approaches via 1) extending the circulating half-life of CFCs to reduce infusion frequency, 2) non-substitutive mechanisms of actions (mimicking Factor VIII function, acting on other pathways of hemostasis), 3) subcutaneous administration mode, and 4) gene correction.[20–23] Some therapies are already available (extended half-life CFCs, bispecific monoclonal antibody restoring the hemostatic activity) and promoted quality of life improvements in PWH.[24–27]

In addition to this favorable evolution in hemophilia care, several changes are to be expected. First, in patients' care pathway. Indeed, a reduction in treatment-related constraints and clinical improvements could drive patients away from specialized structures and involve new actors in the management of these patients. Furthermore, in France, to improve this care pathway, some new therapeutics could be available in community pharmacies, closer to patients. This will lead to a shift from hospital-center care pathway

to outpatient care pathway. In light of scarce data on long-term adverse events and efficacy, management of emergencies and surgeries with a high hemorrhagic risk, and the biological monitoring of these new therapeutics, a sustainable follow-up in expert centers remains essential for quality care.[28–31] Thus, the use of these new therapies must be properly secured and coordinated while training all new actors involved.

Second, an evolution of patient care organization is to be expected (new therapeutics protocols, new formation programs, variation in frequency of consultation). In a complex healthcare system, the clinical and medical-economic evaluations of healthcare innovations, essential to their marketing and financing, are no longer sufficient. The financing and evaluation of healthcare innovations represent a major Public Health issue. Since many therapeutic innovations will become available, studying the organizational impact of these new therapies could bring additional elements and facilitate healthcare decisions.[32]

Consequently, the impact of innovation on care pathway and on care organization needs to be clearly identified and analyzed. This makes it possible to study how to improve the care pathway and the experience of care for PWH while maintaining a high level of safety. Given that patients are at the heart of the care pathway, it is essential to consider their point of view on changes at these different levels (individual and institutional).

Patients and Methods

Objectives

The main objective of this study is to analyze patient perceptions regarding the impact of innovation on the organization of their care management.

Secondary objectives are:

- Analyzing the place of treatment in this care organization.
- Highlighting specific factors related to patients with hemophilia (barriers or facilitators), which should be taken into account when analyzing the impact of innovation on the organization of care management.

Type of Study

Several parameters are involved in the patient care pathway: patient characteristics, access to care, characteristic of the disease, and patient environment. Since sociological or cognitive factors can influence the care pathway,[33] we aimed to implement a qualitative study, best suited to collecting participants' experiences and perceptions on the organization of their care management.

Semi-structured individual interviews will be conducted by two researchers, one woman and one man, both trained in the qualitative study methodology. KB is a hospital pharmacist working on her PhD, BdSdV graduated in Public Health and Political Sciences and is an associate researcher in a university research lab. The interview-based analytic method is geared to explore disease-related behaviors, attitudes and experiences.[34] It is designed to analyze patients' perception on the impact innovation could have on the organization of their care management.[35] This method is indeed the best suited to guarantee the feasibility of this study. Hemophilia being a rare condition, patients sometimes reside far away from their care setting and it can be difficult to organize group meetings, whereas one-on-one interviews are more adapted to the patients' constraints. Even though face-to-face interviews are more effective, these will be conducted remotely to limit risks related to today's COVID-19 pandemic context.

Inclusion Criteria

The objective is to collect patients' perspectives on innovations at large but also on therapeutic innovations, since most future innovations in hemophilia will be therapeutic drugs. Thus, interviewed participants must be regularly treated for their hemophilia, in prophylaxis, or on demand.

In order to explore the greatest patient diversity, the cohort must include patients with associated comorbid conditions, patients with inhibitors, patients who participated in a clinical study, patients who experienced a change in treatment, patients who had issues with treatment adherence, and patients of all ages. This is an essential point, since the perception of the care pathway can vary according to one's experience.

Consequently, inclusion criteria are:

- Adult patient (>18 years) or adolescent patient (12–18 years) with congenital hemophilia A or B with on-demand or prophylactic anti-hemophilic treatment (factor VIII, factor IX, prothrombin complex concentrate, activated factor VII, bispecific monoclonal antibodies),
- Adult parent caregiver (>18 years) involved in the therapeutic management of a child (<18 years) with congenital hemophilia A or B with on-demand or

prophylactic anti-hemophilic treatment (factor VIII, factor IX, prothrombin complex concentrate, activated factor VII, bispecific monoclonal antibodies).
- Patient or caregiver with prior experience in hemophilia care

Exclusion Criteria

Exclusion criteria: patients or parents without a regular specific anti-hemophilic treatment (on demand or prophylactic), patients coming for a first consultation, patients under the age of 12, as well as persons having difficulties with the French language.

Recruitment and Sample Size

To ensure effective recruitment, with the required number of participants to meet the above listed criteria, participants will be recruited within one unique territory, the Rhône-Alpes, where the care pathway network is similar, ensuring homogenous data collection.

Participants will be recruited from a call for volunteers through the Rhône-Alpes committee of the French hemophilia association (AFH). Eligible participants will also be identified by physicians from two hemophilia treatment centers: Lyon and Chambery.

The Lyon center is the hemophilia national reference center on hemophilia with the higher number of patients for the region. The Chambery center is characterized by its history. In the sixties, a boarding school for patients with hemophilia opened in a nearby town called St Alban Leysse, attracting a population of patients with hemophilia to the region. It is one of the region's largest centers.

A first contact by phone will be followed by sending out an information letter and consent form.

We must include a sufficient number of patients to explore the greatest patient diversity. An initial sample is estimated at 15 participants per center, ie a total of 30 persons interviewed. Reaching representativeness of this population is not the objective. The topics for which a saturation need to be reached have not been previously identified. In this exploratory study, the collection of multiple perceptions will be prioritized. The final sample size could be adapted if the diversification of patient characteristics is not sufficient to yield enough exploitable data.

Description of the Interviews

The interviews will preferably be conducted by videoconferencing, to collect non-verbal visual communication elements (posture, voice, facial expression, gestures), when impossible it will be done by phone adapting to the agenda of the patient or parent.

The two researchers, KB and BdSdV, using an interview guide, will conduct semi-structured individual interviews. Each interview will be conducted one-on-one by one of the two researchers (according to their schedule). Each time the researcher deems it necessary he or she can prompt participants, reformulate an answer or even do a synthesis during the interview.[36,37] These interviews will be recorded on a voice recorder. If possible, additional elements, especially non-verbal attitudes, could be noted on paper.

The interview guide is structured gradually to bring participants to progressively change dimensions. The 1st part of the guide is designed to collect patients' perceptions on their care pathway and the impact of their ongoing treatment on care organization. The second part of this guide focuses on the notion of innovation with first the notion of change in general followed by the care organization.

To cover these different notions, the interview guide elaboration were based on: 1) different observations previously collected from healthcare professionals, during visits to the hemophilia treatment centers (actors identified, coordination, involvement of the different actors, identification of rupture points); 2) national hemophilia management and diagnostic protocol (PNDS);[38] and 3) a review of the literature that identified qualitative studies on patients with cancer or asthma and their care pathway perceptions.[39,40] A qualitative analysis, conducted on patients with hemophilia and caregivers, explored patients' knowledge and perceptions regarding their treatment. This analysis contributed to the interview guide framework.[14]

The guide starts by presenting the research and detailing the objective of the interview as well as reminding the patient of the study's confidentiality and anonymity parameters. Then it contains one introductory question which is followed by transition questions and examples of rephrasing and prompting (Table 1).

Sociodemographic, disease and treatment characteristics are collected at the end of the interview. Since these data could influence one's care pathway and perception of innovation, they are needed for the study analysis.

Beforehand, the interview guide will be tested on two participants per center: these four test participants will be part of the initial sample if the guide does not undergo major modifications.

Table 1 Interview Guide Used to Conduct Semi-Structured Individual Interview

Topics/ Subtopics	Questions
This interview will last about an hour and its objective is to explore the organization surrounding the care management of your condition, as well as your perception of innovation.	
Introductory question **Place of the treatment in your daily life** **Care pathway, care management organization** Actors Place of these actors in the care management Coordination, interaction between actors involved in the patient's care management	First, could you tell me about your/your child's hemophilia (diagnosis, care management) Overall, how do you feel about the place of your/your child's treatment in your daily life? How would you describe the organization of your/your child's care management? Who are the persons involved in the management of your/your child's condition? In your opinion why is a person more (or less) involved in the management of your/your child's condition? Could you tell me about the relationships between the different actors involved in your/your child's care management? In your opinion, what facilitates/limits the organization of your/your child's care management?
Place of the treatment in the care management organization	In your opinion, how does treatment influence this care organization? How did you perceive the different changes in treatment?
Innovation Perception of change Patient's/parent's definition Impact, barriers, facilitators	What do you think of these changes? More generally in the way you/your child's care management is organized? In your opinion, which changes could help facilitate your care? When I say innovation: what does it mean to you? More precisely regarding innovation in hemophilia management. If one speaks of a new innovative treatment, what does it mean to you? Describe one element you would absolutely like to change in your/your child's care management, conversely what is the thing you would not want to change in your/your child's care management?

Data Analysis and Validity

There will be verbatim transcriptions of the interviews, following the exact course of the interview and mentioning all communication elements, including non-verbal cues, to fully comprehend the interactions (laughs, hesitations, attitudes). Interviews will be transcribed by a company specialized in verbatim transcriptions.

Data collection and analysis will be done simultaneously. After the interview, each researcher will proceed with a thorough reading of each verbatim transcription. The NVivo® software is used for data analysis. Each interview will be analyzed by two researchers using an inductive content analytic method[41–44] following the steps described in Figure 1. A confrontation of results will be done after coding to reach a consensus. In case of divergent analysis, a third researcher opinion will be required. After reaching a consensus on the identified categories and themes, occurrences will be measured to weigh the results.

At the end of the analysis, we plan to conduct 2 or 3 additional interviews with study participants to present the emerging concepts and discuss their coherence to corroborate our results.

Ethics

Anonymity is mandatory. This point is underlined at the beginning of the interview and in the information letter distributed to eligible PWH or caregivers. Participants are invited to read this letter and a signed consent form is collected before the beginning of the interviews. The participant is free to terminate the interview at any time. Email exchanges with the transcription company are digitally secured. The downloadable files (recording and transcriptions) are protected with passwords sent via a separate channel.

This study will be conducted in accordance with the Declaration of Helsinki. This study was declared at the French national data protection agency CNIL on March 4, 2021. The Ethics Committee of the Lyon University Hospital reviewed this research project and approved the study on April 18, 2021.

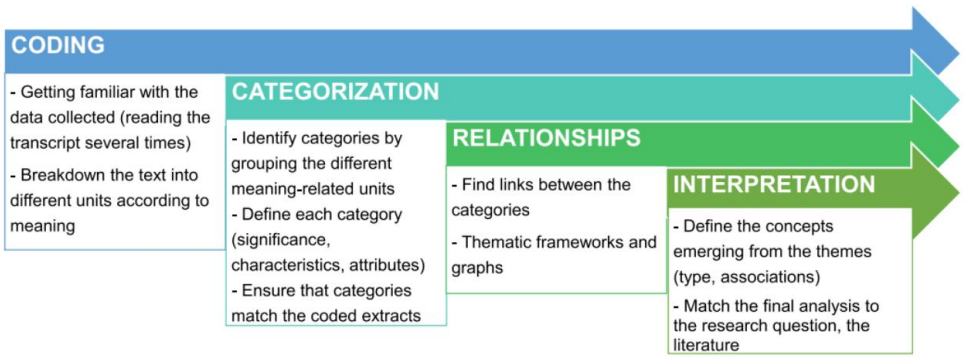

Figure 1 Steps from the inductive content analysis method.

Discussion

To our knowledge, this is the first study evaluating the perception of the impact of innovation on the organization of hemophilia care from a patient's perspective. Several qualitative studies were conducted to integrate the patient's perspective into the decision-making process for using innovative therapies. These studies highlighted acceptability criteria involved in shared decision making, such as treatment ease of use, efficacy on bleeds, safety and impact on daily life.[45,46] Another study underlined the importance for patients to communicate with a clinical team from an expert center in hemophilia to implement a new patient-centered care approach.[47] This confirms the relevance to explore patient perceptions regarding the impact of new therapies on care organization. This approach could help identify risks of rupture in the patient care pathway and be useful to patients, caregivers and healthcare teams along with new actors involved in the care pathway. It could also facilitate the decision-making process when there are different therapeutic options by including an organizational dimension. In this chronic condition, where patients become actors or even partners of their care management, it is essential to collect their perspectives.

In this study, we will focus on patients' perception of innovation at large, then medical innovations followed by therapeutic drug innovations. In fact, future innovations in hemophilia management will be therapeutic ones. In the past, new therapies led to organizational and medical innovations.[48] One can expect similar consequences in the upcoming years. Evolutions of the care pathway could lead to the implementation of innovative tools (ie to improve care coordination with expert centers) or innovative organizations (ie to develop the competencies of new actors in the management of this rare condition). It seems important not limit the analysis to therapeutic innovations.

The relevance of an interview-based qualitative analysis methodology lies in collecting a large amount of data while giving participants the opportunity to share their perspectives and feelings.[36] It can improve our understanding of participants' behaviors and motivations. Proposing two interview modalities (videoconference or phone) can lead to a data collection bias. It will be impossible to collect non-verbal cues if the interview is conducted by phone. The analysis is mainly centered on speech content analysis. Non-verbal communication cues are added elements in this study, knowing that they remain limited via video-conferencing in comparison with in person interview. However, it will be essential to take this element into account when interpreting the results.

There are biases with this type of study such as interviewer's characteristics (gender, experience, academic rank), relationships between the interviewer and study participant, which could influence data collection.[49] Having two different interviewers could limit biases related to the individual's characteristics. Using an interview guide and testing it beforehand is necessary to limit data collection dispersion. One of the difficulties in this study is collecting the perception of the person interviewed in the right dimension. In fact, our objective is to determine the perception of the impact on the care organization. It is important to avoid generating some confusion during

the interview between the impact of innovation on the patient's life vs on the patient's care pathway. The order of topics was determined to drive the participant through the various topics from 1) the place of treatment in his/her daily life, 2) perception of the care organization, 3) place of treatment in this organization, 4) perception of innovation, and finally 5) perception of innovation on this care organization. The implementation of a qualitative study via semi-structured interviews is a good method to describe the care pathway and care organization. Hannane et al, described the care pathway of asthmatic patients, by conducting interviews on 30 patients.[40] This analysis described the perception of patients on actors of their care management and their involvement. This highlighted the perception of a faulty communication and coordination in care management.

The INNOVHEMO study can propose a method for increasing the accountability of patient perception in organizational impact studies. This preliminary exploratory study is also designed to test the adequation of our study method. The objective was not to extrapolate the results. However, method reproducibility will enable to replicate this analysis in other regions or even other countries where the issue of innovation-related organizational impact is relevant. The resulting patient-specific factors, identified as barriers or facilitators, will need to be integrated into a more comprehensive analysis of the impact of innovation on care management organization.

Abbreviations

CFCs, clotting factor concentrates; CRC-MHC, constitutional hemorrhagic diseases resource and competencies center; CRH, reference center on hemophilia and other constitutional hemorrhagic diseases; CTH, center for hemophilia care; HIV, human immunodeficiency virus; PWH, persons with hemophilia.

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Disclosure

Mr Benjamin du Sartz de Vigneulles reports being an employee until march 2019, Oncology Department for Pierre Fabre Laboratories. The authors report no other conflicts or competing interests in this work.

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Cette étude n'a pu être conduite à terme, par manque de recrutement. Seulement quatre patients et un aidant ont pu être interviewés, rendant inexploitable le peu de données recueillies.

2.3.3. Elaboration d’un modèle du parcours hémophilie (article 6)

L’article publié intitulé « Haemophilia in France: Modelisation of the Clinical Pathway for Patients » visait à analyser, modéliser et fournir des systèmes d'aide à la décision aux acteurs institutionnels et de terrain impliqués dans les processus de soins et la prise en charge hospitalière systémique globale des patients hémophiles en France. Son objectif était d'établir un état des lieux des différents acteurs rencontrés par les patients hémophiles tout au long de leur parcours de vie, classés par famille (hôpital, ville, etc.), et d'identifier des zones de rupture potentielles ou avérées dans le parcours de vie pour améliorer les connaissances sur le parcours de soins d’un patient hémophile.

Il s'agissait alors d'une étude qualitative de recherche exploratoire. Les services spécialisés dans le diagnostic et le suivi des maladies hémorragiques et thrombotiques constitutionnelles de quatre hôpitaux ont participé. L'étude a été basée sur des entretiens semi-structurés avec 31 professionnels de la santé : 13 médecins, 3 pharmaciens, 1 biologiste, 6 infirmières diplômées, 1 kinésithérapeute, 1 psychologue, 3 attachés de recherche clinique, 1 chef de projet et 2 assistants employés dans le système de santé français. Les réponses des personnes interrogées ont été analysées à l'aide d'une analyse de contenu.

Une analyse des résultats a permis la réalisation d’une modélisation visuelle de la structure et du fonctionnement du réseau hospitalier. Ainsi, une cartographie du parcours de soins du patient hémophile au sein des différentes institutions et/ou services a été proposée, avec identification des zones de rupture.

De plus, des obstacles majeurs à une bonne prise en charge des patients atteints ont été identifiés, comme par exemple :

- Isolement des patients vis-à-vis des équipes soignantes, en raison des traitements prophylactiques de longue durée.

- Mauvaise reconnaissance des patientes féminines atteintes d'hémophilie, souvent considérées uniquement comme "porteuses" alors qu'elles peuvent être aussi affectées.

- Manque de coordination entre les différents services hospitaliers, notamment les urgences, où les patients hémophiles ne sont pas toujours correctement orientés.

- Perte de vigilance des patients, qui peuvent sous-estimer leur maladie à cause de l'espacement des traitements, ce qui entraîne des comportements à risque.

Par conséquent, cette étude permet de visualiser la situation relative à parcours de soins, de mieux la comprendre, et de mieux l’analyser. Elle met alors en évidence des points de fragilité dans le parcours de soins, comme le lien entre les soins hospitaliers et la vie quotidienne des patients qui est parfois insuffisant et le manque de prise en charge psychosociale, soulignant la nécessité d'une meilleure

coordination, tant au sein qu'en dehors des hôpitaux. Cela met en exergue les défis liés à la personnalisation des soins tout en maintenant des standards.

Ainsi, les points de fragilité dans les parcours de soins mis en évidence par de telles démarches de modélisation sont autant d’opportunités d’amélioration.

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Article

Haemophilia in France: Modelisation of the Clinical Pathway for Patients

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Abstract: Process-of-care studies participate in improving the efficiency of the care pathway for patient with haemophilia (CPPH) and rationalize the multidisciplinary management of patients. Our objective is to establish a current overview of the different actors involved in the management of patients with haemophilia and to provide an accurate description of the patient trajectory. This is a qualitative exploratory research based on interviews of the principal health professionals of four haemophilia services, between November 2019 and February 2020, in France. Mapping of the CPPH processes within the different institutions and/or services, as well as the rupture zones, were identified. Treatment delivery and biological analyses were carried out exclusively in healthcare institutions. The main liberal health professionals solicited were nurses, physiotherapists and general practitioner. Obstacles and barriers within the specialized service, with other hospital services and external hospital or private services, community health care providers et community environment and individual one was complex and multiples. Our research identified potential concerns that need to be addressed to improve future studies to identify influential elements. Similarly, other qualitative studies will have to be conducted on the perceptions and literacy of patients with haemophilia to develop a global interactive mapping of their trajectories.

Keywords: haemophilia; healthcare management; trajectory; course; modeling

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1. Introduction

Haemophilia A and B (ICD9: 286.0 and 286.1; ICD-10-CM code D66) encompass congenital deficiencies of the intrinsic pathway coagulation factors VIII (FVIII) and IX (FIX), respectively, with a variable risk for bleeding based on the type of haemophilia and the extent of factor deficiency [1]. Approximately 1.1 million of patients are affected by haemophilia worldwide, of whom approximately 418,000 have severe haemophilia [2]. Estimated prevalence is 24.6 cases per 100,000 males for all severities of haemophilia A. It is 9.5 cases per 100,000 males for severe haemophilia A, 5.0 cases per 100,000 males for all severities of haemophilia B, and 1.5 cases per 100,000 males for severe haemophilia B. In 1999, the World Federation of Haemophilia Annual Global Survey identified 78,629 people with haemophilia; this number has since increased to 210,454 in 2018 [3,4]. Since the start of the AGS (Annual Global Survey), there has been a tripling in the number of people identified with all rare bleeding disorders reported. The overview of trends and patterns in haemophilia and its treatment from the World Federation of Haemophilia's Annual Global

Survey Report, between 1999 and 2018, points to an increase in the number of people identified of 267% (210,414 cases in 2018), 295% for Haemophilia A (78,547 cases in 2018)) and 316% for Haemophilia B (78,547 cases) [2]. The global mean (standard deviation) per capita consumption of Factor VIII was 1.57 IU (3.65) in 2002 and 3.91 (1.85) in 2018, while that of Factor IX per capita was 1.57 IU (3.65) in 2002 and 3.91 (1.85) in 2018. America (46%) and Europe (33%) were the highest consumers [3]. The lowest average annual cost per person was reported in Bulgaria (EUR 6660) and the highest in Germany (EUR 194,490) [5]. In France, the median cost of hospitalization for a patient with haemophilia was EUR 30,073 not including the cost of long-acting antihemophilic factors [6]. In 2017, 42,000 people were treated for haemophilia or severe haemostasis disorders, with EUR 565 million allocated to their care. The average annual costs for Haemophilia A management per patient were EUR 72,209.60 [7].

Haemophilia care is complex, often requiring health management beyond the prevention and treatment of bleeding [8]. Over the past twenty years, the therapeutic management of patients with haemophilia has significantly evolved, both with the development of self-treatment and prophylaxis, and the emergence of recombinant drugs and evolution of treatments regarding efficacy and safety. With advances in care, increasing numbers of people with haemophilia achieve near-normal life expectancies [1]. These manifestations are associated with significant direct and indirect costs to individuals, their families, and society that increase in parallel with disease severity [9].

Integration, the coordination and alignment of tasks, has been promoted widely in order to improve the performance of hospitals [10]. Integrated care model is usually delivered by comprehensive haemophilia reference, competence or treatment centre for constitutional haemorrhagic diseases, which provide all components of care including consultation, prophylaxis, technical assistance, medication delivery, and home treatment supervision through geographically co-located and coordinated multidisciplinary teams. Specialized care centres organize care coordination, support technical services, administer finance, provide professional education and participate in the process of collection and reporting of data [8].

The healthcare process of a patient with haemophilia is complex: it is dynamic, variable and multidisciplinary [11]. The phases of the process involve several elements: the specialties of the provider(s), the procedures performed, the diagnoses observed, the therapeutic treatments and the biological analyses [12]. The starting point and end point of the process generally correspond to the beginning and end of the patient's care. Finally, it corresponds to the overall trajectory of the patient [13]. Management of patients with haemophilia necessarily follows clinical trajectories depending on specific situations [14]. Modelling the clinical pathways of people with haemophilia is part of the process of analysing and providing decision support systems to institutional and field actors involved in the overall and systemic care of patients. Based on the modelling of industrial processes and applied to more diversified and heterogeneous care paths, this is an original and essential step in improving the quality of health care [11]. This approach will make it possible to organize, rationalize and standardize the multidisciplinary management of patients to improve the performance of systems. Process-of-care studies are important to participate in the consideration of improving the efficiency of the haemophilia care pathway as the future of this disease is likely to change with the development of new innovative treatments [15]. Today, research on modelling the care trajectory of patients with haemophilia in specialized reference centres is rare.

This research aims to analyse, model, and provide decision support systems to institutional and field actors involved in the care processes and the global systemic hospital management of haemophilia patients established by the medical system in France. Its objective is to establish a current overview of the different actors encountered by patients with haemophilia throughout their life course, classified by family (hospital, city, etc.), and to identify potential or proven areas of disruption in the life course to improve knowledge of the trajectory of a patient with haemophilia.

2. Materials and Methods

2.1. Study Design

This is a qualitative exploratory research study. It is based on interviews of the principal actors in the organization of the patient course: health professionals from the hospital teams of four haemophilia services, located in three different regions between March 2019 and February 2020 in France. Using a mixed method, data were collected from the observations and interview manager and staff surveys to collect data on organizational, social, and clinical process integration, at four organizational levels: practice site, physician organization, health system, and outside health systems. Data were used to perform a social network analysis and a structural and functional modelling of the hospital network.

2.2. Setting

In France, the haemophilia Care Network is organized into haemophilia treatment centres (HTC). Consultations and care of patients are essentially performed in a haemophilia reference centre (HRC), or a resource and competence centre—constitutional haemorrhagic diseases (CRC-MHC), or a treatment centre for Constitutional haemorrhagic Diseases (CT-MHC). Drugs can be dispensed by hospital pharmacies (retrocession) and since 2021 by city pharmacies.

Four selected Hospital for our study were selected. Each centre specializes in the diagnosis and follow-up of constitutional haemorrhagic and thrombotic diseases:

- Hospices Civils de Lyon (HCL), Groupement Hospitalier Est, is a coordinator site from the HRC and the French network on inherited bleeding disorders (MHEMO) with 3000 consultations per year.
- Assistance Publique des Hôpitaux de Paris (APHP)—Hôpital Bicêtre is a reference centre for haemophilia and other constitutional coagulation protein deficiencies. Nearly 600 patients with haemophilia are followed in this reference centre for rare haemophilia diseases.
- The Lille University Hospital—Lille Regional Haemophilia Treatment Centre (CTL) is one of the five French sites labelled national reference centre for haemophilia and other rare coagulation deficiencies. This centre is composed of several functional units: (i) biological haemostasis; (ii) cardiological haemorrhagic pathology; (iii) haemorrhagic pathology Jeanne de Flandre; (iv) thrombotic pathology; (v) Willebrand UF, vi/Transfusion Safety & Hemovigilance; (vi) immuno-haematology. It should be noted that there is no doctor assigned to each patient, which favours the versatility of medical professionals. It is the doctor on duty who manages, with shared advice.
- The Metropole Savoy Hospital Centre in Chambery (CHC, France) is a CRC-MHC. It should be noted that it is relatively rare to have a haemophilia service in a general hospital, as is the case here. The geography (mountains) partly explains this situation. The number of populations increases by a factor of 100 during the winter vacations (skiing).

2.3. Data Collection

A multidisciplinary research team composed of researchers with backgrounds in pharmacy, ergonomics, and public health policy was formed to enrich the free interviews, limit individual interpretations, and strengthen the analyses to meet with several haemophilia services. The planned organization of the day included:

- Interview with the head of the department or his/her representative, who was able to explain the context and history of the organization.
- Visits to the departments concerned: 30 min–1 h.
- Interviews with the different actors of the pathway (collective or individual): doctor, nurse, paediatrician, haematologist, biologist, physiotherapist, pharmacist, etc.: 30 and 45 min.
- Work observations (free time involved) (secretarial/consultation/team meeting, patients, others): observations 1 h or more.

– Debriefing with the Head of Department: 15 min or more depending on availability.

Face-to-face interviews were conducted with physicians, pharmacists, nurses, secretaries, physiotherapists, psychologists, clinical research officers, and nursing assistants. It should be noted that in two cases, the field conditions made it necessary to set up a group interview. A total of 31 people were interviewed. A team meeting was also observed as well as five consultations of patients with haemophilia.

2.4. Network Validation

In order to validate, between August 2018 and November 2018, the social network by task was discussed face-to-face with four hospital staff members who also participated in observations and interviews. Some hospital staff members known to perform specific tasks were interviewed via email to obtain details about those tasks. A validation report was prepared to record the comments of the hospital staff.

Two initial pilot interviews were conducted to assess the items for content and conceptual clarity. Results suggested that these items could be used in the specific context of haemophilia care. The study was based on semi-structured interviews with 31 health care professionals: 13 physicians, 3 pharmacists, 1 biologist, 6 registered nurses, 1 physiotherapist, 1 psychologist, 3 clinical research associate, 1 project manager and 2 assistants employed in the French health care system. The interviewees' responses were analysed using directed content analysis. Maximum variation sampling inside professions were used to achieve diversity in size and performance. The process was set up and coordinated by an ergonomist specialized in the analysis of health trajectories. Individual interviews were conducted by authors (K.B., C.D., B.d.S.d.V.) on behalf of the ergonomist.

An inductive approach was applied using questions based on the existing literature on organizational process and patient trajectories and concerned participants' experiences and perceptions of the structural organizations they considered to impact their care of patients with haemophilia. The different interviews conducted in these four haemophilia services were followed by discussion meetings within the research team. For each site, the specialist prepared a synthesis, the authors (K.B., C.D., B.d.S.d.V.) meeting to enrich and validate the synopsis. A report of each site visit was written in a collaborative manner. Then, an overall analysis was formulated.

2.5. Outcomes

The principal objective was to identify the different actors involved in the management of patients with haemophilia and to determine the similarities between them to provide an accurate description of the patient trajectory.

The secondary objective was to determine any specificities, and their rationale, if applicable.

2.6. Sample Size

The number of cases to be included in the study is defined by data saturation and not by a calculation of the number of subjects necessary a priori. Data saturation is achieved when no new concepts emerge from the interviews. In our study, we confirmed data saturation with two additional interviews that did not bring any new concept.

2.7. Analysis

The process describes all actors involved in the care of patients with haemophilia. It is described from the point of view of the hospital actors and the intra-site analyses. The weight of each actor is qualitatively weighted, by focusing on the first three sites visited (Lyon/Lille/Paris). The objectives of qualitative analysis were to define concepts, mapping range and nature of process, creating typologies, to identify associations, providing explanations. Framework analysis has been used. Mapping and interpretation involved analysis of key characteristics. This mapping provided a schematic diagram of the event, thus providing guidance to the researcher in their interpretations of the data package.

3. Results

Mapping of the "Care Pathway of Patient with haemophilia" processes within the different institutions and/or services, as well as the rupture zones, were identified (Figure 1).

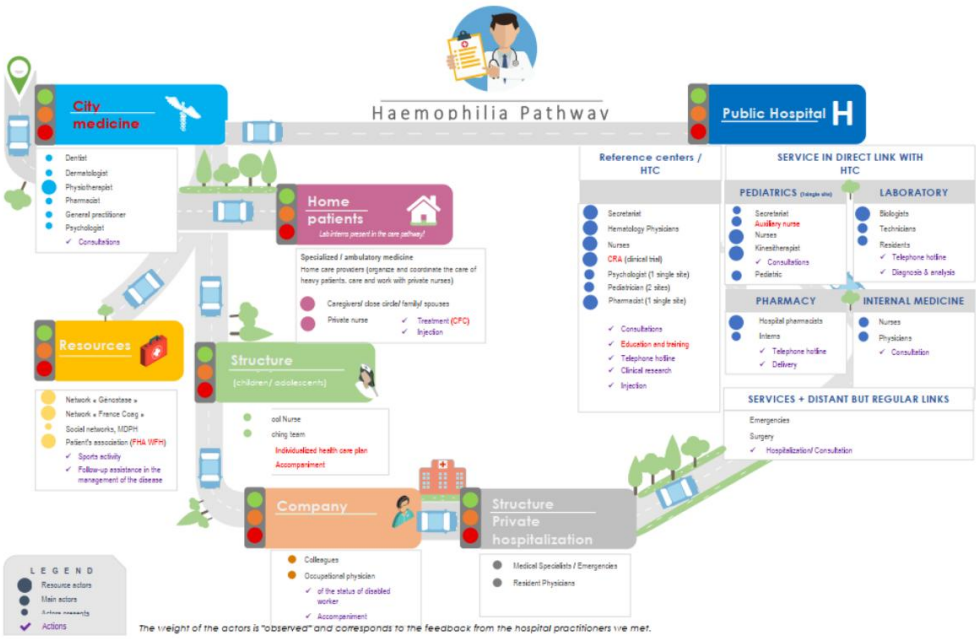

Figure 1. Modelisation of the health course of patients with haemophilia. FHA: French Haemophilia Association; CFC: Clotting Factor Concentrate; CRA: Clinical research associate; HTC: haemophilia treatment centres; mDPH: Departmental homes for disabled people; WFH: World Federation of Haemophilia.

Following the visits to the four haemophilia hospital services, the following specificities emerge from this representation. For their haemophilia, patients receive support from healthcare professionals, most of whom are hospital-based: medical consultations, treatment delivery and biological analyses are carried out exclusively in healthcare institutions, and in some centres only. The main liberal health professionals solicited were

- Nurses: mainly for treatment injections for patients who do not practice self-injection, or who do not have a caregiver for this practice.
- Physiotherapists: although their role is recognized by caregivers in haemophilia services for managing the consequences of hemarthrosis, they are not very present in the institutions.
- General practitioner is not very present; his or her interactions with the specialized service are very rare.
- Patient's close family and friends are particularly concerned by the disease, and even involved in its management.

3.1. Several Specific Elements Have Emerged

- The estrangement in the relationship between patients and health care teams due to the development of prophylaxis with long-acting treatments.
- Questions about the risk of patients escaping if new treatments are dispensed in pharmacies.

- The haemophilia service sometimes has difficulty getting along with certain other services, particularly emergency rooms, where patients are occasionally poorly recognized and misdirected.
- Poor recognition of women with haemophilia: not only "carriers" but also "affected": 1/3 of them have factor 8 deficiency. Additionally, 90% of these women are not believed in the emergency room.
- A loss of awareness of the disease on the part of patients, due to the lengthening of the time between treatments or easier administration methods, leading to risky behaviours (such as non-adapted physical activity, non-management of joint pain, etc.).
- The importance of therapeutic education of the patient, and of his entourage, to maintain an awareness of the disease and a good management of it.
- The importance of broad-based support for haemophilia patients, including both physiotherapists and psychologists.
- The link between hospital nurses and private nurses is almost non-existent.
- The link between city doctors and hospital doctors is almost non-existent.
- Adherence to medication was defined as satisfactory in children, average in adolescents, and poorer in adults.

3.2. Obstacles and Barriers

3.2.1. Within the Specialized Service

The processes are highly dependent on the organization of the team, the geographical situation, such as the location of centres on several sites, and the spatial location—proximity of the stakeholders. The factors for improving the trajectory are linked to the coordination of the actors because of the possible breakdown in access and the sharing of useful information regarding the patient between internal actors. The levers of multidisciplinary meetings within the CTHs organized around patients, therapeutic indications, and cross-referencing of different types of information are highlighted.

3.2.2. With Other Hospital Services

Historically, relationships are more or less marked and have an impact on the structuring of the service and its organization, for example with the paediatric service at Kremlin Bicêtre. Other services are more in the forefront, such as the analysis laboratory in Lille, where referents participate in team meetings, and the pharmacy in Lyon, where a pharmacist is attached to the service. Relations with other hospital departments are strongly rooted in their collaborative work, depending on the number of staffs, profiles, historical functioning, organization, availability and facilitation of formal or informal exchanges. The aim of these close links is to improve patient care and to optimize it, such as "same-day factor VIII dosage". In Lille, numerous meetings between manufacturers, pharmacists and doctors for the presentation of treatments have facilitated the work of both, and their collaboration "has simplified referral" and delivery methods based on simulations.

The links with "more distant" services such as emergency services or with centres of complementary and necessary medical expertise (stomatologists) are complex. Difficulties arise from maintaining the skills of people who change and who do not "practice" haemophilia on a regular basis. In Lyon, for example, the CTH participated in the training of emergency physicians, but this action was not sustainable over time (multiple actors/turnover). Protocols were then put in place that necessarily involved the patients ("make us call"). In Chambery, before the implementation of an on-call duty, training was organized every 6 months. Since then, there have been some difficulties maintaining an adequate level of knowledge for emergency residents. In Lille, a briefing is planned every 6 months with the emergency physicians. Similarly, in KB, special orthopaedic consultations for patients with haemophilia are held; in Lille, stomatology consultations are held (once a month) to compensate for the lack of links with the outside world ("some dentists in town refuse to take patients with haemophilia").

3.2.3. With External Hospital or Private Services

The same necessary relations as with remote intra-hospital services are developed, with the additional difficulty of distance and the organization of processes (who is in charge/thinking about it/checking). Patients are regularly reminded to call the haemophilia service when they go to another institution (travel, surgery or emergency). Patients with haemophilia also sometimes voluntarily hide their disease so as not to extend the length of their stay, for example.

3.2.4. With Community Health Care Providers

The pathway depends on the presence, training and knowledge of those involved in haemophilia and patient care, but also on the patient's pathway.

Many factors impact on good liaison between these players: distance, lack of training or collaborative tools, involvement in patient follow-up, knowledge of the specificities of haemophilia care.

The distanced role of the general practitioner in relation to the patient's course and the number of hospital consultations, for example (depending on the type of haemophilia), making the patient think that their general practitioner is less useful; this would be even more pronounced for women with haemophilia, as highlighted. This raises the question regarding the tools used between the city and hospital actors, via the injection follow-up booklet, the health booklet and the very variable methods of liaison (reports, etc.). For example, in Lille, the service receives two to three calls from general practitioners per year.

There are some exceptions depending on the site, notably in Lille, with physiotherapists (specific list of private physiotherapists—history and proximity link with a Belgian team which has developed many links with physiotherapists). This is not the case with psychologists, with whom attempts at cooperation envisaged in the past have not been satisfying. The avenues envisaged concern a potential mutualization with the rare diseases network.

In Lyon, links are being created between associations of hospital practitioners (nurses, doctors, pharmacists) and associations of community practitioners, while emphasizing the absence of computer links and the digitization of the care record of patient with haemophilia, which is currently underway. For dental, dermatology and colonoscopy care, compliance with protocols is imperative.

The measures envisaged include the mobilization of professional societies and the production and distribution of dedicated documents.

3.2.5. Between the Stakeholders in General Practice

The organization of the care pathway within the general medical practice should be developed in the questioning of patients.

3.2.6. Links between Patients with Haemophilia and Existing Support Structures

The important coordination and weight of the various associations and network organizations around patients and professionals were emphasized. However, although many associations exist, they are not always well identified by patients neither by community practitioners nor other hospital services.

3.2.7. School Care

Difficulties related to a lack of knowledge about haemophilia, difficulties in providing care (school trips, transporting injections, etc.), stigmatization, choice of sports, etc., penalize the children's trajectory. In Lille, a concern extends to the siblings of patients with haemophilia.

3.2.8. Professional Structures

There are weak links with health professionals, particularly occupational physicians. In Lyon, their importance was underlined, particularly in their necessary involvement in

the constitution of files for persons with disabilities. Finally, the impact is weak and may raise the question of keeping patients with haemophilia in employment.

3.2.9. The Immediate Environment—Family

The same level of requirements are necessary for education, and lifelong maintenance of skills is necessary. The understanding of one's disease, the way one lives with it, beyond the cognitive capacity to understand it, is also an element that influences the course of the disease. The place where one lives and access to care are also parameters that influence the course of treatment. Some patients with haemophilia hide their disease to avoid prolonging a hospital stay when they are in an institution where they are not usually followed up. There is a need to educate the people around them in the same way as the patients, with a similar requirement, and to keep them competent to carry out the injections in the event of difficulty for the patient.

3.2.10. The Impact of Therapeutic Innovations

Therapeutic innovations will have an impact on the treatment pathway, its structure and its actors, and both will have an effect at several levels. First, on the work of practitioners, particularly their medical and professional practices, as well as on dosages and analyses. Second, on hospital-city coordination and possible ambulatory risks linked to the distance of patients from hospitals, as the pathway is considered today. This refers to the structuring of ambulatory care, its coordination, its development, as well as the accessibility of treatments and care in case of delivery of treatments in city pharmacies. The necessary reinforcement of outpatient services and their reorganization so that they can respond to needs would be a real lever in the fight against areas of breakdown. The accessibility of information and the improvement of knowledge about haemophilia, and the resource people to whom one can turn, are issues. Similarly, the impact of the network on the territory may accentuate the disparities in patient care.

Finally, in terms of the impact on patients' lives and their apprehension of haemophilia, their "feeling" will be different, and their quality of life will be improved. For example, patients affected with a mild case of haemophilia may forget that they have this condition, and joint pain may not be caused by the disease. Other impacts may concern specific cases, such as patients with inhibitors.

4. Discussion

To the best of our knowledge, no literature has been published to date on the use and impact of clinical pathways on the quality of care for patients with haemophilia in healthcare settings. The present article provides a qualitative synthesis of the implementation of clinical pathway initiatives for patients with haemophilia in specialized French healthcare services. Its objective was to establish a current picture of the players encountered by patients with haemophilia throughout their life course, classified by family (hospital, city, etc.), and to identify potential or proven areas of disruption in the course. The method was to get a group of people to work on this picture, to have the elements that can vary the pathway of patients with haemophilia and, if fine, to identify all the impacts of therapeutic innovations on the trajectory.

Centres of expertise reference networks for rare diseases, including haemophilia, are fundamental to EU health policy (Article 12) [16]. Standards for the designations of two distinct levels of European health centres and delivery of optimal haemophilia care were introduced in 2008: (i) European Haemophilia Treatment Centres (EHTCs), should normally care for at least 10 people with severe haemophilia, delivering routine local care, and (ii) European Haemophilia Comprehensive Care Centres (EHCCCs), should normally care for at least 40 people with severe haemophilia, delivering multidisciplinary, specialized care and operating as a tertiary centre of reference [17]. Three of the four centres in our study were in the last category. At that time, the 10 guiding principles of haemophilia treatment were defined to provide a benchmark for the treatment of the disease [18]. France

has subscribed to these EHCCCs principles. As our study highlights, the trajectories of patients with haemophilia are based on an integrated approach to comprehensive multidisciplinary care. The itinerary described all the stakeholders involved in the management of patients with haemophilia. It is described from the perspective of the hospital professionals and intra–extra-site analyses. This concept of a course is claimed to provide a coherent organization of care and a veritable global service, considering the patient as a whole being, and not just one or several symptoms-diseases to be cared for [19].

The 2018 survey to assess the extent to which the 10 principles of haemophilia care were applied highlighted the principles of haemophilia treatment, and were generally applied across Europe [20]. Our study validates this information for France, whereas for some countries, aspects of national organization of care, centralization, paediatric care, and prophylaxis for adults can be optimized. However, there are still unmet needs in several dimensions of patient care as in general preparation for the ageing haemophilia patient and population psychosocial care [21].

Our research targets care processes, which are certainly restrictive in relation to health or life pathways, but which are the response to health needs on a territory in relation to risk factors and diseases [22]. They involve ambulatory and hospital care, comprising primary care and hospitalization, home hospitalization, follow-up and rehabilitation care, and long-term care units. Contextual analysis should consider the stakeholders who may impact or be affected by the health service, as well as the physical, social, political, and economic environments that may enable or hinder the standardization of the service [23]. Early identification of these elements, including how they relate or interact to one another, is a major first step in the process to develop effective strategies and interventions to strengthen the health service implementation [24].

Whereas until the 1960s, the median life expectancy for a patient with haemophilia was 30 years, the development of effective treatment based on prophylactic replacement of the missing factor, as well as a better knowledge of the disease, has changed the paradigm. Today, the quality of life and life expectancy for individuals with haemophilia is virtually normal [25].

In France, a national pharmacosurveillance system for FVIII and factor IX products administered to haemophiliacs was founded by the public health authorities in 1994 [26]. Renamed FranceCoag in 2003, its competence was also extended to other inherited bleeding disorders [27]. The high observed average prevalence of haemophilia A at birth (23.3 cases per 100,000 male live births between 1991 and 2008) compared with prevalence in other industrialized countries supports the exhaustiveness of this registry [27]. The median age of a cohort of 599 individuals at the time of diagnosis from 1980 to 1994 was 7.7 months. This age differed significantly between the different subgroups: 28.6 months in the mild forms, 9.0 months in the moderate ones and 5.8 months in the severe forms. In the severe forms, a trend towards earlier diagnosis was observed for three consecutive time periods [28].

In 1999,1234 people affected had been registered in 39 haemophilia centres. At the time of admission, 50.2% of them were younger than 15 years of age [26]. In 2005, diagnoses of haemophilia for the 4018 patients included in the 1994–2005 cohort comprised haemophilia A (n = 2901), of which 1306 were severe, and haemophilia B (n = 605), of which 229 were severe. The median age of patients was between 20 and 26 years according to the type of coagulation disorder, with a median age at diagnosis of 0.7 and 0.8 years for patients with severe haemophilia A and B, 1.7 and 3 years for patients with moderate haemophilia A and B, and 7.6 and 6.7 years for minor forms [29].

The French cohort provided in 2016 data from 9504 patients with hereditary bleeding disorders indicated that 60.5% were affected by haemophilia A and 13.7% by haemophilia B. Median age was 32 years (IQR: 18–50 years). At that time, a serum and plasma sample was available for 27.1% patients [30].

Our research identified four potential concerns that need to be addressed to improve future studies to identify influential elements:

- The importance of the hospital in the current course with the predominance of its actors, who may differ from one site to another, and the close links occasionally difficult to establish with the patient's life outside the hospital. This is a constant observed in industrialized countries. Procedures, rules for collaboration between EHTCs and EHCCCs must be written, shared and made available to the public [31]. While the implementation of the haemophilia treatment centre model is dependent on the availability of a relevant range of medical and paramedical services, states and territories depending on resources, patient population demographics, centralization and organization of services, most people with haemophilia receive care through specialized centres [32]. For example, in Australia, these centres were established in 1998 to play a leading role within their hospital, city and outlying areas to ensure optimal care and equitable distribution of professional and therapeutic resources [33].
- Links outside the hospital of various categories. The links are occasionally not strong enough to be maintained in the long term, reinforcing the importance and the necessary autonomy of the patient in the management of their illness. The links are occasionally non-existent or created on the basis of opportunities or historical configurations and often dependent persons. Certainly, the World Federation of Haemophilia recommends that patients with haemophilia be managed in a specialized comprehensive care centre [34]. However, sharing best practices with other healthcare professionals external to hospitals allows for better patient-centred approaches, and improved adherence and health outcomes [35]. Today, individuals with haemophilia can look forward to a virtually normal life expectancy and quality of life [25]. In France, 131 national reference centres for rare diseases must organize partnership in the delivery of care and the coordination of the health and social care network. Patient education, information and training of professionals, patients and their families are also among their missions. This raises the question of the extent to which the care of specific diseases or highly specialized interventions are restricted to a limited number of specific centres or health care providers. The treatment of haemophilia is evolving and changed the role of external stakeholders [36]. As a result of progress in disease management, healthcare professionals who are not haemophilia specialists are more likely to encounter people with haemophilia [37]. Nurses, for example, are the first point of contact for people with haemophilia and provide more care to patients and their families than any other specialist on the team [38,39]. They are to place greater emphasis on psychosocial support, therapeutic education, shared decision making, and patient support and advocacy [40].
- Intra-hospital interactions linked to opportunities, specific historical organizations and collaborative choices that are not always possible (limited flexibility) in terms of time, human or financial resources, availability, etc. The mission of French clinical networks of reference centres is to structure and coordinate the activities between the national and regional centres, the technical platforms, or any other structure involved in care for patients. EHTC must have access to multidisciplinary support, locally or in conjunction with EHCCCs as orthopaedics and physiotherapy, dental care, surgery, obstetrics and gynaecology, hepatology, infectious diseases, paediatric, clinical psychology and social worker [17,19,32].
- There is considerable variability despite a willingness to describe a "meta-course", a "standardized" description that makes it possible to visualize all of the participants who revolve around the patient and the places where patients with haemophilia go. Through daily self-management, patients with haemophilia become experts and partners in their own care. As such, they should be considered as separate essential members of the comprehensive care team [11]. However, main risks of disruption in this process target parameters such as patient typology, geographical accessibility, characteristics of the patient's disease, non-medical environment and therefore the patient's environment. The necessary search for balance between standardization of the care action and adaptation to the specificity of each situation, and the precious

pursuit of "standardized singularity": the personalization of standardized steps will contribute to the reduction in health inequalities [31].

Certain points in this research have identified structural weaknesses that provide guidance and decision-making aids for the recommendation or improvement of operational axes. The so-called "specialty" reference centre is the guarantee of quality care for haemophilia, a rare disease that requires a concentration of the necessary targeted financial human resources for a country, France, whose hospital-centred health organization allows for territorial coverage and quality geographic access for patients. This, where the health actors do not have for this disease problems of financing care for the patients, is the state taking in its account the totality of the treatments.

Within these reference centres, the complementarity between the expertise of the professionals and the experience of the patient accumulated through life with his or her health or psychosocial problems, the disease and its repercussions on his or her personal life and that of his or her families must be reinforced: personalizing care, developing and strengthening the patient's skills in sharing decisions with caregivers, knowing how to pay special attention to the physical and psychosocial health of patients, and continuity of care over time are the principles that guide the patient-centred approach. Improving the training and awareness of a multi-professional and, if necessary, multi-disciplinary team, as well as those of associated professions outside the reference centre, remains a challenge. The priority is to ensure a fluid and secure reception of patients at the right time in a relationship within the emergency services.

The expectation is that all members of the core team should be skilled and experienced in the treatment of bleeding disorders, but this must be accompanied by an awareness that patients with haemophilia do not have the same level of awareness/concern or perfusion capacity. Professionals need to be aware of the physical and psychosocial health of patients. As such, written management protocols are essential to ensure continuity of care, even if clinical staff changes. These protocols should be as personalized as possible, depending on age, venous access, bleeding phenotype, activity, and the availability of clotting factor concentrates. Recommendations for the management of patients with haemophilia are updated and disseminated by the various scientific societies identified.

Continuity of care over time requires awareness and education of other health care providers who are not specialized in haemophilia care [37]. It is a response to the need to improve quality of life, accessibility to treatment and the performance of management for patients treated chronically over the long term. It is in this context, for example, that the members of the Reference Centre for Haemophilia and Other Coagulation Proteins have contributed to the design of various tools made available to the entire community of health-care professionals, such as the introduction of a dual dispensing circuit for HEMLIBRA® (emicizumab), effective June 2021 [41]. In practice, if a patient wishes to have this drug dispensed in a community pharmacy, an e-learning course called "HEMOPHAR" for the retail pharmacist must be followed. The retail pharmacist must have completed the training modules. Tool sheets will be provided to facilitate the link between the CRC-MHC team members and the pharmacist.

At least, improving recognition of the condition in women is a sensitive issue, especially when the screening is conducted in the office of a community health care provider who is unlikely to consider haemophilia simply because the patient is a woman [42,43]. One-third of female drivers may have factor VIII or IX levels <40% and report bleeding events comparable to men at the same level, with the added risk of menorrhagia and postpartum haemorrhage [44]. Initial training in general medicine, gynaecology, obstetrics, and dentistry, continuing education for external health care providers relayed by academic societies, and awareness-raising among women under the authority of haemophilia patient associations must be reinforced. The management of women with low levels of haemophilia or with haemophilia should be identical to that of men with haemophilia: provision of a haemorrhagic disease card and booklet, regular consultations, correction of haemostasis

for trauma or before surgery or dental extractions. Special attention should be given to gynaecological and obstetrical events.

This study presents strengths. The baseline assessment of quality performed in this review attempted to provide a quality minimum as well as identified a large range of items that may influence the course implementation. The methodology of interviews, whether conducted individually or in groups with health professionals, is adequate to assess and characterize a variety of unique influencers. Qualitative methodology may affect the type of barriers/facilitators identified, but it is more likely that the aims of the studies included, their population of interest, and/or the particular service/subject addressed by the study had a stronger impact on the type of obstacles or facilitators identified. This work was deliberately limited to the French context, which allows for directly relevant and applicable results. Thus, focusing only on France appears to be a wise decision and not a limitation because it allowed us to obtain data in a context of particular interest.

A key limitation of this study was the selection bias associated with the identification and recruitment of participants. Volunteers may have been more positive about the expanding role of community professionals.

5. Conclusions

This study has been a positive exercise in enabling a greater understanding of the current haemophilia care landscape in France. The identification of barriers and facilitators, including how they relate to or interact with each other in the trajectory care of patients with haemophilia, is a key step for developing suitable strategies and interventions to enhance health service performance. The best knowledge of the care processes of patients among the key stakeholders will help to optimize clinical outcomes while enhancing patient quality of life. The Principles of Haemophilia Care were generally applied in France. Some aspects of national organization of care, interrelationship between key stakeholders—healthcare professionals, patients and their caregivers, managed care professionals—may be improved. Future studies could explore the opinions of a wider range of patients and broaden the scope of research to health and life-course pathways.

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2.4. Partie 4 - Modélisation du parcours de soins du patient douloureux aux urgences : une approche mixte (article 7)

L'article soumis intitulé « Improving pain management through care pathway modeling, criticality assessment and root cause analysis: a new strategy in the emergency department environment » avait pour objectif de modéliser le parcours d'un patient aux urgences afin de dépasser les schémas classiques de sous-évaluation de l'intensité de la douleur.

L'oligoanalgésie est la gestion insuffisante, par les professionnels du soin, du ressenti douloureux d'un patient qu'ils prennent en charge (228). C'est un problème fréquent dans les services d'urgence (SU), où la douleur aiguë est la raison la plus fréquente passage (229), y compris l'intensification de la douleur chronique (230). Ainsi, l'oligoanalgésie pourrait être considérée comme une défaillance du processus de soins attendu, indiquant des défauts dans la mise en œuvre des interventions appropriées.

L'analyse des modes de défaillance, de leurs effets et de leur criticité (AMDEC) est une technique habituelle d'amélioration de la qualité (231), basée sur l'identification de 4 éléments clés de compréhension : l'environnement de la défaillance, sa présence, sa puissance et sa nature. L'AMDEC a été développée au travers des six étapes :

1. Formuler un processus à enjeux élevés : en s'appuyant sur une revue de littérature et sur l'expérience « au lit du malade » de certains e ses membres, l'équipe de recherche a d'abord cartographié le parcours d'un patient adulte aux urgences en repérer les moments susceptibles de conduire à l'oligoanalgésie, autrement dit des situations à risque de défaillance dans le processus de soins de la douleur.

2. Mettre en place d'une équipe d'analyse des risques : sept experts (médecins et infirmières) ont été sélectionnés pour leur expertise en médecine d'urgence et en gestion de la douleur.

3. Repérer les situations à risque : une technique de recherche de consensus (Delphi modifiée) entre les experts a été utilisée pour préciser et valider le parcours d'un patient adulte aux urgences et l'identification des situations à risque de défaillance dans le processus de soins de la douleur.

4. Identifier la criticité : des caractéristiques de criticité ont été attribuées à la défaillance selon trois critères : fréquence de survenue de la défaillance, gravité de la défaillance et difficulté à résoudre le problème lié à la défaillance. A ces critères ont été assignées des échelles de Likert pour graduer la caractéristique de défaillance.

5. Calculer des niveaux de risque : individuellement, les experts ont renseigné les échelles de criticité sur les trois critères. Une attribution de points puis l'application d'une formule mathématique ont permis de calculer score de criticité par situation à risque de défaillance, de leurs assigner un numéro de priorité d'après le risque, et de les classer.

6. Révéler les causes profondes du risque : une analyse sur les facteurs sous-jacents aux défaillances a été réalisée pour les situations à haut risque.

Ainsi, l'étude a révélé 17 situations à risque d'oligoanalgésie dans le parcours de soin aux urgences. Celles-ci sont réparties sur cinq moments clés du parcours : triage, attente, prise en charge clinique, séjour aux urgences et départ des urgences. Parmi ces situations, six ont été identifiées comme étant à très haut risque de défaillance, réparties sur l'ensemble du parcours.

Les résultats de l'analyse des causes profondes ont montré que les facteurs organisationnels, comme le manque de protocoles adaptés et les difficultés de communication entre les soignants, jouent un rôle majeur dans l'apparition de la défaillance qu'est l'oligoanalgésie. Ils montrent également que des stratégies de résolution de défaillance peuvent être menées de façon globale (en agissant sur un facteur qui concerne plusieurs situations) ou de façon ciblée (en se concentrant sur une seule situation précise mais en considérant tous ses facteurs).

Cette étude montre que l'oligoanalgésie est souvent due à des erreurs dans le processus de soin, plutôt qu'à une sous-évaluation systématique de la douleur. L'analyse a permis d'identifier des moments critiques dans le parcours de soin, qui sont parfois négligés dans la littérature, notamment la période d'attente et le séjour aux urgences, qui sont souvent vus comme des interruptions du processus de soin plutôt que des étapes à part entière. Elle montre également que seulement 35% des situations à risque sont très critiques et peuvent maximiser la défaillance dans le processus de soins. Par conséquent, cela permet de cibler les stratégies de résolution de problème et de concentrer avec justesse les ressources pour améliorer le processus. Enfin, l'étude montre également l'intérêt d'équilibrer la standardisation des protocoles avec une certaine flexibilité dans la gestion individualisée de la douleur pour une meilleure adaptation aux caractéristiques spécifiques de chaque situation.

Improving pain management through care pathway modeling, criticality assessment and root cause analysis: a new strategy in the emergency department environment

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Abstract

Background: Pain management remains inadequate despite numerous studies on pain undertreatment. Addressing this issue in the emergency department (ED) requires an organizational perspective. This study aimed to model the pain journey of an ED patient, and perform a risk analysis using a failure modes, effects, and criticality analysis (FMECA) method adapted to the ED pain management process. **Methods:** A team of seven experts participated in the study. A six steps process helped to model an adult pain journey, perform a critical analysis, and conduct a Root Cause Analysis (RCA). **Results:** The ED care pathway was modeled into five care management phases, identifying 17 situations and four repetitive mechanisms at risk for oligoanalgesia. The situations were classified according to three levels of criticality and incorporated into a risk map, with six very high-risk situations dispersed throughout the care pathway. For each high-risk situation, the RCA highlighted redundant contributing factor themes and key factors of failure in pain management, such as "communication", "decision support and protocolization," and "pain education." These contributory factors are affordable management issues. **Conclusions:** The study suggested that, although there are numerous high-risk situations along ED journey, only a few situations required prioritization, underscoring the endless challenge of pain assessment, but also the need for individualized pain treatment in the ED and to go beyond improvement of pain-intensity scoring at triage. In care areas with high organizational constraints, the FMECA approach offers a reproducible methodology that can precede an action plan in addition to protocolization.

Keywords: Pain management; oligoanalgesia; emergency medicine; FMECA; risk map; care pathway; modeling; process failure

1. Introduction

Pain management is a critical and complex process [1–3], especially in care areas where it is in close interaction with the care pathway as Emergency departments (ED)[4]. Acute pain is the most frequent reason for adults visits to the ED [5], including chronic pain intensification [6]. ED experience is a crucial segment of patients' pain trajectory [7]. Some Key moments of the adult ED journey are already recognized as risks for inadequate pain management, as patient arrival, triage, discharge, sedation procedures, and evaluation times after drug action [8,9].

Despite incentive measures worldwide to improve pain management, pain intensity in the ED remains high, analgesics are underused, and treatment delays are frequent. This results in a high risk of undertreated pain, known as oligoanalgesia [10–13].

Several factors contribute to oligoanalgesia, including patients' medical histories, the nature of their pathologies, cultural and socio-economic aspects, perceptual biases [14,15]. Moreover, delays in treatment or inappropriate analgesic selection after under-evaluation of pain intensity highly contribute and organizational factors (long reassessment times, prolonged ED stays, insufficient pain management training) degrade pain management[16–18], as high patient flow in ED[11,19]. Procedural pain also remains insufficiently managed[20,21].

Thus, oligoanalgesia could be viewed as a failure in the expected care process, indicating flaws in the implementation of appropriate interventions. Given the complexity of care pathways in Eds [22], integrative frameworks incorporating the concept of failure could lead to a better understanding of the pain care pathway and of the analgesic care processes from admission to discharge [23]. This should be a relevant strategy for risk prevention and patient outcomes improvement [24].

Failure modes, effects, and criticality analysis (FMECA) [25,26] is a usual method for improving quality, based on the identification of 4 key components of understanding: the failure environment, its presence, its power and its nature [27,28]. FMECA has previously been applied successfully to patient pathways, in order to revise protocols [29] and to design risk maps for ED various contexts [30,31].

This study aims to move beyond the conventional patterns of pain intensity under-evaluation by implementing a risk reporting system and a root cause analysis. Our hypothesis was that oligoanalgesia represents a failure in pain management within the ED care pathway. FMECA method had been used to identify and understand moments of risk during the adult ED journey.

2. Methods

To examine the management of pain within a specific care pathway, considering oligoanalgesia as a failure in the care process within the adult ED, the FMECA method was used in six steps[32] (Fig 1), and the SQUIRE guidelines were followed to report data[33] (Supplementary file 1). Ethical approval was obtained from the Local Research Ethics Committee of the University Hospital Center of Rouen, France (n°E2023-19 on 5 April 2023). Oral informed consent was obtained from participants before data collection.

The first three steps involved modeling of the pain journey experienced by an adult patient, with the objective of identifying key moments and mechanisms most susceptible to lead to oligoanalgesia during the patient's circuit in the emergency room. These steps were based on a Delphi method and expert consensus [34,35]. In the final three steps, an analysis of criticality and a search for contributing factors were conducted using root cause analysis (RCA)[36,37].

2.1. Step 1: Formulating a high-stakes process

In order to prepare for the analysis of this failure, the research team initially focused on the processes of care in the ED. The aim was to formalize the structuring of activities that represented the environment in which oligoanalgesia could emerge. Based on a synthesis between literature and French bedside experience, an expert on emergency analgesia (VEL) and a specialist in health communication (PM) provided a graphical illustration of the emergency care pathway over the course of a one-month first step. The aim was to provide a model that could be adapted to all national contexts and hospital typologies. This was voluntarily restricted to the in-hospital setting, despite the existence of pre-hospital pain management because the patient's journey before arriving at the emergency department varies significantly by country. Particular, in France, severe pain management often involves multiple stakeholders, including emergency medical services, the fire department, private ambulance services, and others, creating a complex and sometimes fragmented pathway to care.

2.2. Step 2: Setting up the risk analysis team

The recruitment of team members was proposed within the "Pain board" of the French learned society of emergency medicine, an organization that represents a key source of expertise in pain management in emergency medicine (EM). Seven experts consented to participate in this research project. The research team comprised four doctors and three nurses from five different hospitals. These practitioners were emergency physicians and/or pain management specialists, including the ED heads (Supplementary file 2).

Problems and objectives were presented to them. Then, in the following steps, experts were encouraged to describe their perceptions of pain management during several opinion-

gathering moments, including group meetings, individual interviews, and digital questionnaires (Supplementary file 3). The experts were contacted four times between May 2021 and June 2022.

2.3. Step 3: Spotting the risk situations

To develop a functional analysis of the care process, the research team was augmented by a specialist in care pathway modeling (CD). The continuation of the research work made it possible to identify situations at risk of failure, with the aim to integrate them into the first scheme.

Then, this third step was carried out using a modified Delphi method, widely utilized for developing quality indicators in healthcare, including performance indicators for EM[38], following a structured process using a series of rounds (whose number is not predefined) until a consensus is reached (Supplementary file 4).

2.4. Step 4: Identifying the criticality

To elaborate the protocol for identifying criticality, the research team was supplemented by two additional members: a researcher in pharmacological emergency analgesia (CF) and a researcher in care pathway modeling (BdSdV).

The aim of this step was to characterize the failure impact. A high level of criticality required preventive measures as a priority. This allowed to deduce a priority ranking of risk situations. Numerous situations require classification by risk level for effective management, and to prioritize objectives in a busy ED.

It was decided to represent the criticality of the situations at risk of oligoanalgesia by three criteria: Frequency (F), Severity (S), and Difficulty in resolving (D). Each criterion had to be evaluated on a 4-point scale (very easy, easy, difficult, very difficult), with a criticality value assigned (Supplementary file 5).

2.5. Step 5: Calculating the risk levels

A new anonymous digital questionnaire (Supplementary file 6) was created to review the risk situations of oligoanalgesia and requested the seven experts to rate them using the associated 4-point scale (about half an hour).

Once answers had been collected and weighted by coefficients, the search for each situation of the Risk Priority Numbers (RPN) was carried out using the formula: F x S x D.

This was intended to identify the different levels of power of failure. A high level of RPN was considered as a high level of criticality. Thus, the final priority ranking was not decided a priori, but rather a posteriori, based on scores and spontaneous groupings.

2.6. Step 6: Revealing the root causes of risk

This step aimed to determine "the nature of the failure" [39] through a RCA conducted by seven experts. It was based on the London Protocol (LP), recognized for enabling comprehensive investigation and facilitating formal reporting [40]. The analysis used a matrix based on seven contributing factor themes (CFTs) that influence clinical practice (i.e., task and technology factors, individual (staff) factors, work environment factors, team factors, organizational and management factors, institutional context, and patient characteristics). Following the recommendations of French national health authority, based on the process of the Association of Litigation and Risk Management (ALARM), the "ALARM grid" was used as a digital double-entry table, allowing the identification of crossings (intersections) between each of the six high-risk situations (x-axis) and each of the seven CFTs (y-axis), resulting in 42 crossings [41,42]. The experts received this grid along with instructions to provide comments in free text, specifying the main perceived contributory factors of failure (Supplementary file 7).

Two members of the research team (CF and BdSdV) examined the answers according to a three-phases analysis.

Firstly, they began with a macro-analysis that involved of identifying [Situation / CFT] crossings that were particularly consensual and potentially highly explanatory, excluding crossings that contained at least three abstentions from respondents. Then, they selected crossings that received responses from at least five of the seven experts. Secondly, for these selected crossings, researchers proceeded with a micro-analysis to more precisely identify contributing factors by analyzing the text of the written responses. CF and BdSdV extracted useful data from the experts' responses independently, pooled them for comparison, and reached a consensus. After that, useful data were classified as explanatory causes of failure independently. These results were again pooled for comparison and consensus. Thirdly, to synthesize macro- and micro-analyses, CF and BdSdV summarized the causes into factor keywords. Two distributions of factors were finally provided.

3. Results

3.1. Pain journey and key moments at risk of oligoanalgesia

The first two components of the FMECA method ("environment of failure" and "presence of failure") were used to model the care pathway.

Based on the literature on the ED, the experience of the research team and the opinions of the group of experts, a first modeling of the care pathway was carried out. The use of Delphi

method allowed for agreement on the terminology, color coding, and the care management times, leading to a chronological and didactic graph. Five care management times emerged, each encompassing several moments of care: triage, waiting, clinical pathway, stay in the ED, and ED departure (Fig 2). Initially, 16 risk situations (or key moments) were identified, then a 17th moment was added by consensus. Experts decided to highlight four associated "mechanisms": pain assessment; transmission of information, prescription/availability of a protocol, and application of prescription/protocol (Fig 2). These mechanisms were structuring factors of this process, elementary constituents of activity, and present throughout the continuum of care.

3.2. Achievement of the risk map for pain management

The 3rd component of the FMECA method, "the power of failure", was used to achieve the risk map.

3.2.1. Critical analysis and Risk levels

For each situation the critical analysis of Risk Priority Numbers (RPN) was obtained using the formula: F x S x D (Supplementary file 8). Based on the distribution of results, the research team decided by consensus to classify the risk level as follows: (i) high risk (RPN > 20), (ii) moderate risk (RPN 15-20) and, low risk (RPN < 15). Therefore, six situations were considered high-risk (Supplementary file 9).

The situation with the highest criticality, RPN = 24.43, was number 10 ("Analgesic choice delayed because it depends more on the etiological diagnostic approach than on the pain intensity (e.g. NSAIDs and renal colic)"). It did not get the highest score in any of the three criteria (F=3, S=3, D=2.71). The second situation, with an RPN=23.88, was number 4 ("No rating scale adapted to the patients who cannot communicate"). This situation obtained the highest score for the frequency criterion (F=3.71, tied with situation 15; S=3, D=2.14). The third situation, with a RPN=23.65, was number 15 ("Unsystematic reassessment of pain"). It had the highest severity score (S=3.43) and the highest frequency score (F=3.71, tied with situation 4). But this situation also obtained the smallest score on the criterion of difficulty in resolving the problem (D=1.86, tied).

In addition to these three situations, there were three others with a RPN higher than 20: (i) "Insufficient time dedicated to pain assessment" (RPN=23.62); (ii) "Lack of anticipation of the analgesic relay" (RPN=22.53); (iii) "Reassessment of pain not carried out" (RPN=20.85).

Ten other situations have a RPN between 15 and 20, indicating a moderate risk. One situation had a RPN under 15 (number 14), corresponding to a low risk.

3.2.2. Final modeling of the risk map for pain

With the measurement of RPN, the care pathway modeling was completed by integrating the three levels of failure criticality (Fig 3).

3.3. Root cause analysis of very high-risk situations

RCA was performed following the London Protocol by the ALARM grid for the 6 high-risk situations (Fig 4). Macro-analysis allowed for the selection of 23 crossings out of a possible 42. Micro-analysis was performed on the all 23 crossings, leading to the identification of redundant factors for each CFT (min: 1, max: 5) and key factors for each situation (min: 6, max: 19).

Therefore, the analysis allowed the results to be interpreted in two ways (by CFT or by situation) and at two levels of granularity (globally or precisely).

3.3.1. Macro-analysis

The macro-analysis provided a global view of the link between CFTs and situations.

Regarding CFT, three of seven were involved in at least 4 of the 6 high-risk situations for oligoanalgesia (Fig 4).

The "task and technology factors" theme was present in the all six high-risk situations analyzed. This theme concerns protocols and procedures that define tasks and processes (eg, decision support, task definition, programming/planning, etc.). The "individual (staff) factors" theme was present in five of the six situations. This theme concerned the knowledge, qualifications, skills, and experience of each team member, which could affect their clinical practice. The "team factors" theme was present in four of the six situations. This theme concerned communication between professionals, communication with patients and their families, written information, transmission and identification of priorities for care, task allocation, etc. To implement a broad strategy to prevent the onset of failure throughout the care pathway, prioritizing these three CFTs could be a key step in optimizing the mobilization of resources.

As another way of interpreting results, this macro-analysis allowed observation of the composition of each situation in terms of CFT. Three of the six situations were affected by at least four of the seven CFTs. Situation 3 "Insufficient time dedicated to pain assessment" was concerned with all the themes except the institutional context. Situation 9 "Reassessment of pain not carried out" was also concerned with all the themes except the institutional context. Situation 15 "Unsystematic reassessment of pain" was concerned with task and technology factors, work environment factors, team factors, and

organizational and management factors. To implement a specific strategy to prevent the onset of failure, resources could be adequately focused on a special point of the care pathway. For example, if the departure was a strategic stage in the fight against oligoanalgesia (S16) for an ED, efforts can be prioritized on only two of the seven CFTs. Moreover, the situation with the highest criticality (S10: RPN=24.43) was mainly concerned with three CFTs of the seven (the three most present).

3.3.2. Micro-analysis

Micro-analysis provided a precise view of the link between CFTs and situations (Supplementary file 10: an example of the micro-analysis process).

Beyond identifying themes, the results highlighted the contributing factors, which are the causal agents at the root of the nature of the failure and the key explanatory elements that could form the basis of problem-solving approaches. These results can be read in two ways: by situation and by CFT.

Regarding CFTs, the results showed redundant factors within the 3 CFTs involved in at least four of the six high-risk situations. First, for the CFT "task and technology factors", the redundant factors included a lack of appropriate protocols, suitable tools, communication, organization, and culture. Second, for the "individual (staff) factors" CFT, the redundant factors were cognitive bias, lack of knowledge, experience, and skills. Third, for the "team factors" CFT, the redundant factors were a lack of a common culture and management.

Regarding high-risk situations, the results showed the completeness of key factors leading to oligoanalgesia.

4. Discussion and conclusions

To our knowledge, this study is the first to model risk situations in a pain management pathway. Addressing the question of poor pain management in EM requires a comprehensive approach that extends beyond pharmacology, to encompass all dimensions of organizational strategy, including management, education, and clinical pathways. Understanding errors is complicated by human or cultural factors, their interactions with systems, variable human perceptions in therapeutic decision-making, and the practical limits of anticipation in complex systems [43,44]. The FMECA method was chosen for its reliability. FMECA has been previously used for ED-based stroke diagnostics, pediatric EDs, and sickle cell care [30,31,45]. For criticality analysis, three criteria are often used: occurrence, severity, and detection [25]. However, FMECA evaluates failures related to practitioner experience, so alternative clinical terminologies can be used [46] and other risk prioritization models for ranking failure modes considered. We have therefore replaced "detection" by "difficulty to solve" because failure detection has already been addressed in our step 3 "Identify risk situations". Furthermore, the lack of oligoanalgesia detection is

well documented in the literature (Miner et al., 2006). Given the lack of similar studies, a standardized approach was adopted, ensuring a balanced assessment. The relative importance of each criterion was intentionally neutralized by using a single scale with four equal-weight gradients. Future research could explore weighting criteria [47–49] to reduce bias.

Applying the FMECA method to oligoanalgesia purpose in the ED highlighted five moments in the ED care pathway and identified 17 situations scattered across these moments. Previous studies identified fewer interruptions in pain management [50,51]. Moreover, Literature regularly amalgamates moments and situations into four key times: arrival, triage, discharge, sedation procedures. This simplification risks poor care management [50,51]. Our study distinguished "waiting" and "stay in the ED" as distinct care moments rather than breaks in care time. The concept of "Boarding" has been explored previously but not specifically for pain management [52]. In our study, the "boarding" time corresponded to the "stay in the ED" care moment and was confirmed as a point of interest.

The 17 situations identified represented high-risk moments of new or worsening pain. There were associated with four repetitive mechanisms promoting oligoanalgesia. Notably, difficulty in assessing pain was reported in a lower number of situations (4/17) as expected [53], and almost exclusively at triage (first ED care moment). The availability of a prescription (standardized or not) seems to be the main mechanism involved and observed at every stage of care.

According to RPN scores, six situations (35%) were classified as very high risk, potentially leading to critical failures in the care process. This aligns with the Pareto principle [54], suggesting that a minority of the causes produce a majority of effects.

The analysis of these six very high-risk situations revealed several insights.

First, 4 of these situations were related to pain assessment, and their localization along the care pathway confirms the need to evaluate pain status not only at the beginning of the ED clinical pathway [11,55]. The interest of our model is to have underlined two barriers of pain assessment at triage: insufficient time for pain evaluation and lack of scales for non-communicating patients. While addressing time constraints may be a focus in an overcrowded context [19], new pain scales are now available for this specific population (e.g., algoplus [56] or BOS 3 [57]) and could be implemented as routine evaluation in case of NRS failure. The lack of pain assessment realization was also highlighted twice, in the care areas without diagnostic or specific therapeutic procedures, suggesting the need of applicable protocols in "waiting" or "ED stay" areas.

Second, one of the very high-risk situations that we identified (S10) in the core of the ED care pathway is rarely described in literature. This related situation was particularly interesting as it underlined that prescribing decisions also involve delays due to an etiological diagnostic approach. Therefore, lack of pain assessment at triage and overcrowding are not the only risk factors for delayed analgesia [19,58]. Some delays might be justified by the need to adhere to recommendations and the need to prevent opioid-related toxicity and other adverse events linked to analgesic classes [59–61]. Furthermore,

346 when a chronic pain intensifies, or in the elderly, selecting appropriate analgesics can
347 become more challenging, contributing to additional delays [62,63]. Thus, despite a small
348 number of very high-risk situations, this study underscores various aspects of pain
349 management linked to different ED actors (pluriprofessional team) and the challenge of
350 individualized pain management.

351 Third, regarding the repetitive mechanisms associated with the 6 very high-risk situations,
352 the same tendencies than for the overall high-risk situations were observed. However,
353 failures related to transmission of information (situations S1, S12 and S17) were not
354 selected. Communication difficulties between caregivers were not associated with a high
355 criticality score, despite an ED organization based on multiple actors, successive work
356 shifts. Likewise, doctor-patient miscommunication had a RPN <15. The low score for the
357 criterion "difficulty of resolve" mainly explains this unexpected result. A discharge plan
358 based on standardized writing-support or mobile health technology are simple procedures
359 which are known to improve communication [64–66]; experts may have indirectly integrated
360 these data to their scoring. In the same line, the prevention of procedural pain (situation
361 S13) did not rank among the six high-risk situations, despite recommendations [67]. Once,
362 discrepancy was due to a low "difficult to resolve" score. Moreover, an unweighted
363 calculation that treated each criterion equally boosts this effect.

364 Nevertheless, these results should be compared with the RCA findings. The macro-analysis
365 identified three CFTs consistent with the conclusions after the first steps of FMECA.
366 However, mechanisms initially deemed of low priority had to be reconsidered as data were
367 reinforced, completed, or balanced by the RCA micro-analysis. LP's results thus provided
368 complementary data on the "transmission of information". Micro-analysis brought precise
369 elements linked to relationship between actors giving to the phenomenon of
370 communication a systemic dimension [68,69]. Moreover, despite seven CFTs planned in the
371 LP, many unexpected recurring elements were found in the raw data extractions and
372 communication was one of the cross-cutting concepts. Conversely, while the first steps of
373 the FMECA suggested that reinforcing the protocolization of pain management might be
374 an obvious solution, RCA seems to invalidate this concept. After detecting the presence of
375 the failure and calculating its power by criticality, an RCA by the LP provides a better
376 understanding of the nature of the failure and helps to detect supplementary key
377 contributing factors. In this study, classical barriers to managerial issues as culture, beliefs,
378 and attitudes [70] were only retrieved using RCA.

379 This study had several limitations. First, our study exclusively examines adult hospital care,
380 overlooking, pre-hospital settings, primary care, and self-medication. Similarly, pain
381 trajectory after ED discharge was not studied (recurrence and chronicization). Second, our
382 linear analysis oversimplified the emergency care system, which is actually more complex
383 and iterative, potentially amplifying oligoanalgesia by introducing other failures. Third, the
384 Delphi protocol, even with a representative panel of experts [71], presented challenges in
385 conceptualizing issues, leading to unexpected results. Future studies should consider these
386 potential biases. Fourth, the criticality analysis methodology may prioritize situations that
387 are not ethical priorities. Therefore, while criticality analysis provides valuable insights, it
388 should not be used as an exclusive tool for prioritizing actions against oligoanalgesia in
389 EDs. It needs to be supplemented with other strategies to ensure a comprehensive approach

to pain management. For example, incorporating patient input on pain management would be beneficial (shadowing technique [72], patient partner [73]…).

Our study has shown the complexity of pain management in systemic environments and demonstrated the relevance of using risk analysis methods to overcome this issue. In the case of ED pain journey, it is revealed that each care time can lead to poor management and analgesics prescriptions delay, but only a few situations are very high-risk ones that should be prioritized. Moreover, there are few contributory factors, linked to manageable issues. Considering oligoanalgesia as a process failure led to a multi-dimensional model, beyond conventional schemes only based on pain-intensity scoring. It underlined specific pain assessment barriers and highlighted the need to balance standardized protocols and individualized pain management. This study proposes a reproducible method and pragmatical tools for addressing care process failures in pain management, before developing or test an action plan.

Ethical Statement

Ethical approval was obtained from the Local Research Ethics Committee of the University Hospital Center of Rouen, France (n°E2023-19 on 5 April 2023). Oral informed consent was obtained from eligible participants before data collection.

Data availability statement

The data are fully accessible on request to the corresponding author.

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Conflicts of interest

None declared

Word counts 3950

Contribution of authors

VE.L., P.M., C.D. and B.dSdV designed the study. P.M., VE.L., and B.dSdV performed the experiments. P.M., VE.L., C.F. and B.dSdV analyzed the data and all authors critically examined the results. VE.L. had a primary role in preparing the manuscript, which was edited by P.M., C.D., F.C., C.F., and B.dSdV. All authors have approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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Figures

Fig 1. Methodology for managing oligoanalgesia in the emergency department based on the Failure Mode, Effect, and Criticality Analysis (FMECA) method.

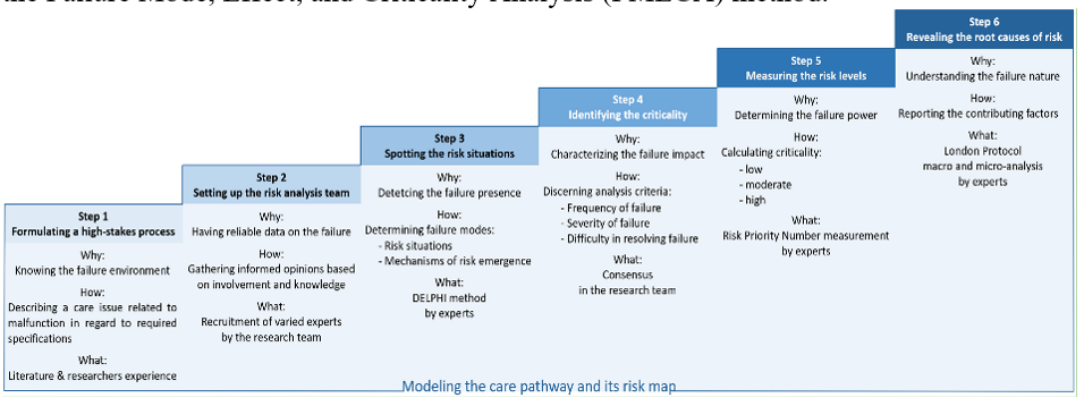
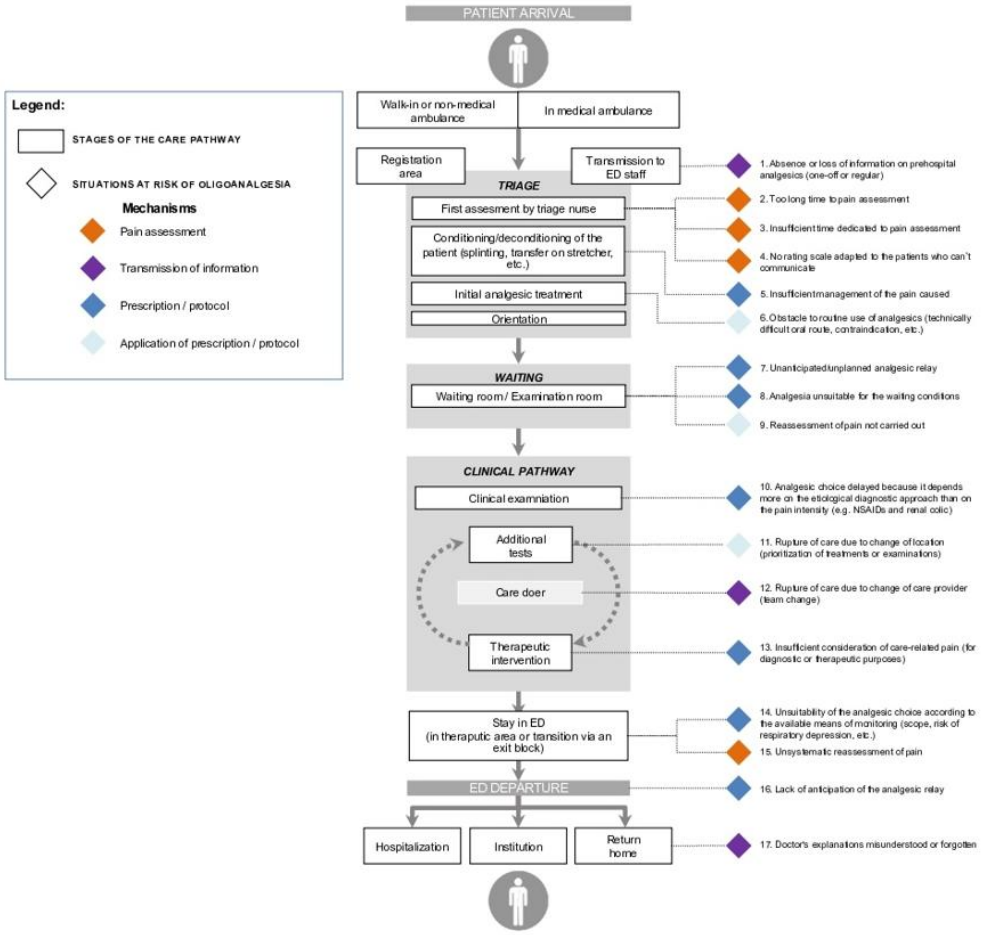
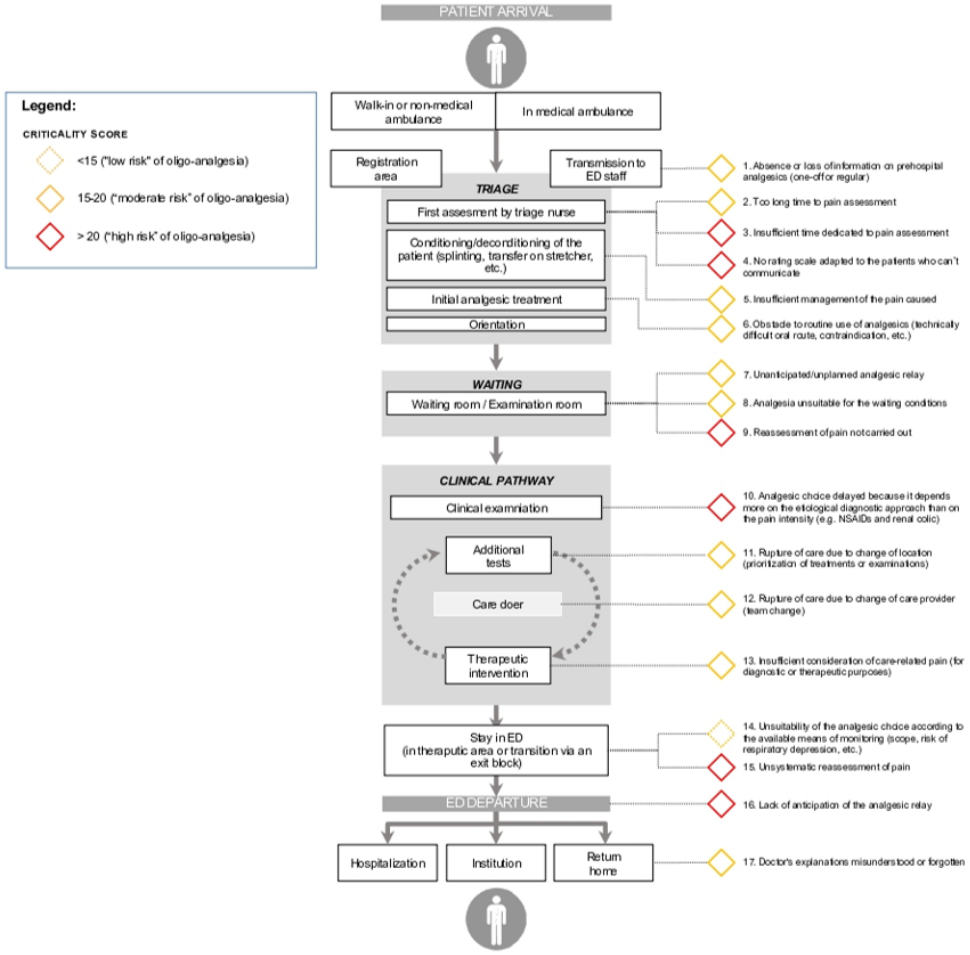


Fig 2. Situations at risk of oligoanalgesia in the ED care pathway of patient with acute pain and their associated mechanisms.



674 Fig 3. Criticality score for each situation at risk of oligoanalgesia in the ED care pathway
675 for a patient with acute pain.



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685 Fig 4. Results of the ALARM analysis.

Failure	High risk situations RPN > 20	Thems of contributing factors: Task and technology factors	Individual (staff) factors	Team factors	Work environment factors	Organisational and management factors	Patient characteristics	Institutional context	Summary of key factors
Underevaluation or/and undertreatment of pain (oligoanalgesia) in the care pathway of emergency department (ED)	3. Insufficient time dedicated to pain assessment Pathway Stage: Triage Mechanism: Pain assessment	✓	✓	✓	✓	✓	✓		Lack of: protocols, tools, assessment, organization, empathy, motivation, decision-making capacity, teambuilding, shared values, common culture, human resources management, prevention, communication ; and: unfavorable emotional state, impairment of working capacity, skill deification, communication barriers, complexity of health condition, inappropriate personal beliefs
	4. No rating scale adapted to the patients who can't communicate Pathway Stage: Triage Mechanism: Pain assessment	✓	✓						Lack of: appropriate protocol, suitable tools, specific skills, training, knowledge; and: cognitive bias
	9. Reassessment of pain not carried out Pathway Stage: Waiting Mechanism: Application of prescription / protocol	✓	✓	✓	✓	✓	✓		Lack of: specific protocol, global vision, knowledge and skills, workspace organization, management organization, communication, digital solutions, political commitment; and: inappropriate: human resources management, caregivers' beliefs or attitudes, patients' attitudes; and: heavy workload
	10. Analgesic choice delayed because it depends more on the etiological diagnostic approach than on the pain intensity (e.g. NSAIDs and renal colic) Pathway Stage: Clinical pathway Mechanism: Prescription / protocol	✓	✓	✓					Lack of: situational awareness, information, organization, knowledge, skills, culture, communication, tools, experience, foresight, supervision; and: unsuitable protocols, cognitive biases, inappropriate personal beliefs
	15. Unsystematic reassessment of pain Pathway Stage: Stay Mechanism: Pain assessment	✓		✓	✓	✓			Lack of: protocol, knowledge, culture, communication, organization, education, management commitment; and: inappropriate personal beliefs, unsuitable work environment
	16. Lack of anticipation of the analgesic relay Pathway Stage: Departure Mechanism: Prescription / protocol	✓	✓						Lack of: protocol, patient involvement in task completion, knowledge (caregivers and patients), appropriate tools, organization, communication, foresight, education, culture, experience
	Main redundant factors	Lack of: appropriate protocols, suitable tools, communication, organization, and culture	Cognitive bias, lack of knowledge, of experience and skills	Lack of a common culture and management	Lack of organization	Lack of: commitment, organization, culture and communication	Inappropriate beliefs or attitudes (caregivers and patients) and communication barriers		

Macroanalysis
Microanalysis
Priority target in the fight against failure

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3. DISCUSSION

Au cours de l'existence d'un individu surviennent des inflexions dans le cheminement de sa vie liées à la rencontre de l'individu avec un événement. Lorsque cette interaction induit une altération de l'état de santé (maladie, accident, …), elle constitue un point d'entrée dans un parcours en santé, associé à une modification de l'équilibre personnel en rapport direct avec une modification de l'intégrité physique ou morale. En fonction de l'évaluation de ce nouvel état de santé, diverses interventions thérapeutiques vont être mises en œuvre afin de restaurer une stabilité maîtrisée, reconfigurant alors les modalités de l'existence. Différents épisodes de soins vont ainsi jalonner ce parcours en santé en fonction de l'atteinte d'objectifs de prise en charge et des nouveaux besoins identifiés, caractérisés autant par la performance de l'offre déployée que par la qualité des services offerts perçue par l'individu. Un parcours en santé représente donc un processus dynamique marqué par des interactions continues entre la réponse donnée à des besoins (de soins et de vie) et la réponse perçue à des attentes (de soins et de vie). L'enjeu, tant pour les professionnels que pour l'individu, est d'intégrer ces deux aspects dans une logique de soins et d'accompagnement adaptée, cohérente, bienveillante et efficiente, et d'assurer une conjonction réciproque. Ce parcours peut être ainsi segmenté en divers épisodes de soins (hospitalisation, suivi ambulatoire, etc.), eux-mêmes ponctués de points d'étape (1, 2, 3…), qui sont des moments propices à l'évaluation de l'état de l'individu à un moment donné de son parcours. Chaque épisode de soins proprement dit est une dynamique caractérisée par un objectif principal (ex : stabiliser l'évolution d'une pathologie, réhabiliter une fonction altérée), un décours temporel, un collectif d'acteurs impliqués, un contexte de déploiement (personnel, social, géographique) et une organisation spécifique (le système de santé).

Dans le cas des personnes présentant une pathologie chronique ou un handicap, le parcours en santé est directement intégré au cheminement de la vie. Cet ensemble ne suit ni une ligne droite ni un tracé uniforme, mais s'apparente à un fil sinueux, progressant dans un système de santé cloisonné et souvent peu lisible, peu compréhensible, comparable à un labyrinthe complexe au sein duquel se dressent divers obstacles systémiques (Figure 9). Les filières de soins, agencements ou organisations optimaux de soins et d'accompagnement spécifiques à une pathologie donnée (par exemple le diabète) ou à une typologie de personnes (par exemple en situation de handicap neurologique), sont des guides faisant office de véritables fils conducteurs afin que les parcours suivent une trajectoire considérée comme idéale ou la plus adaptée dans un territoire donné dont les offres de services sont bien identifiées. La modélisation d'un parcours de santé, à l'instar de la solution d'Ariane, ne simplifie pas le labyrinthe que constitue le système de santé, mais donne, de façon générique, les moyens de s'y orienter et d'y cheminer au mieux, c'est-à-dire de la façon la plus avantageuse pour la personne et les professionnels.

Il s'agit ainsi d'un dispositif stratégique de repérage et d'analyse, permettant une vision clarifiée des enjeux, des moyens à déployer, des dynamiques de mise en œuvre, et des leviers d'amélioration à envisager en fonction d'une évaluation régulière des objectifs atteints et des modalités d'actions choisies pour les atteindre.

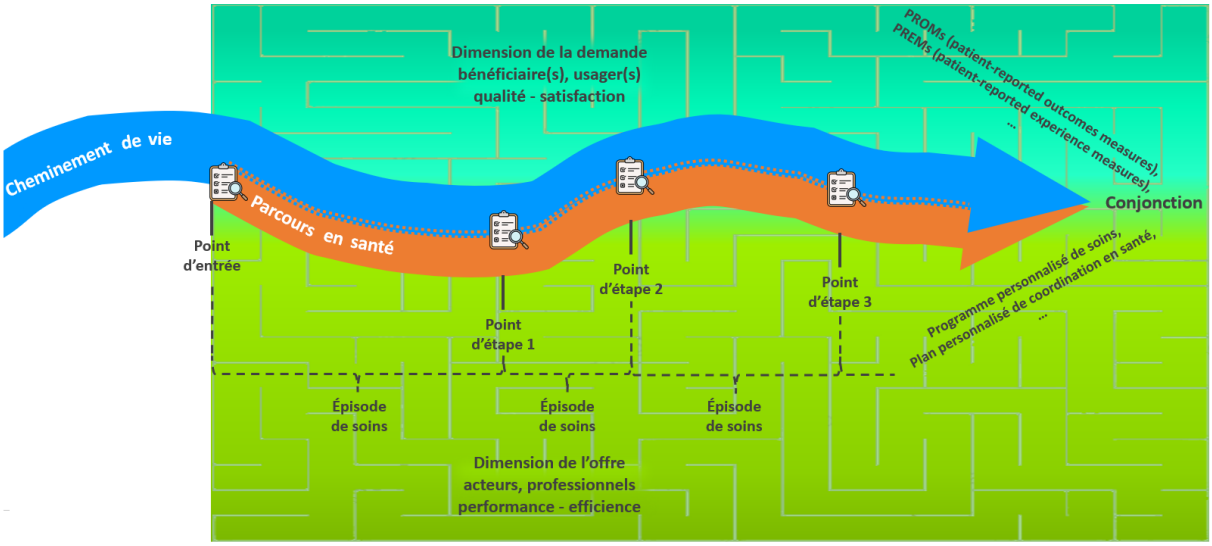

Figure 9. Représentation schématique du parcours en santé.

3.1. Démarche de réflexion pour la modélisation d'un parcours en santé

3.1.1. Penser un parcours en santé comme un système : apports de l'approche systémique

Afin d'examiner les connaissances disponibles dans la littérature scientifique, une revue de la portée de 41 articles a été réalisée (article 1). Le principal apport de ce travail est la proposition d'une *catégorisation originale pour l'analyse des méthodologies utilisées pour modéliser des parcours* en santé, pour en décrire la structuration. Bien que ce travail ait montré l'absence de standardisation dans les démarches de modélisation publiées, il a permis de mettre en évidence plusieurs tendances assez marquées dans ces démarches, comme par exemple le principal recours (cependant non exclusif) à des méthodes qualitatives lorsque l'objectif de modélisation visait la qualité des soins. Dans l'esprit d'une démarche de modélisation d'un parcours, la catégorisation réalisée constitue ainsi un outil permettant de tenir compte des diverses caractéristiques des méthodologies existantes, de s'en inspirer ou non selon les objectifs choisis et les moyens disponibles pour cette démarche.

Afin d'identifier les *déterminants invariants des parcours en santé* (DIPS), c'est-à-dire les éléments clés d'un parcours qui sont systématiquement présents quel que soit le domaine en santé considéré, une analyse de points de vue a été réalisée auprès de 21 professionnels de trois catégories professionnelles différentes (praticiens, chercheurs, institutionnels) (articles 2 et 3). A la différence des

déterminants de la santé qui permettent de définir les caractéristiques du parcours en santé à mettre en place, les DIPS aident à comprendre les facteurs qui impactent systématiquement les solutions mises en place, à toujours prendre en compte lors d'une démarche de modélisation. L'analyse de ces DIPS (comme l'analyse du poids de leur nature décisive) inscrit ainsi une démarche de modélisation dans une dimension systémique.

Afin de déterminer les *critères organisationnels primordiaux* (COP) au sein d'une équipe soignante pluridisciplinaire impliquée dans la mise en œuvre d'un parcours de santé dans ou pour une situation donnée (pathologie, offre, système, …), une étude de révélation de préférences a été réalisée (article 4). Bien que cette étude ait été réalisée dans le cadre d'un parcours en hémophilie, cette démarche est déclinable quel que soit le domaine de santé. En effet, cette étude a permis de caractériser des priorités organisationnelles partagées au sein d'une équipe et de distinguer les inclinations spécifiques aux divers métiers représentés. Cette étude a également permis de calculer les poids d'impacts d'innovations thérapeutiques sur les COP. L'analyse de ces COP confère une compréhension précise des diverses caractéristiques de l'offre de soins à mettre en place lors d'une démarche de modélisation d'un parcours. De plus, elle peut permettre une caractérisation des transformations potentielles en cas de nouvelles interventions en santé, pour un meilleur accompagnement au changement.

Afin de considérer les *perceptions et représentations des individus à propos de leur parcours en santé*, un protocole de recherche qualitative a été réalisé (article 5). L'article montre l'intérêt de recourir aux perceptions et représentations des patients pour décrire un parcours, de façon générique, et pour révéler des défaillances dans la prise en charge en comprenant comportements et motivations des acteurs, afin d'éclairer les processus de prise de décision. Dans le cas d'une volonté d'entreprendre une démarche de modélisation d'un parcours, du fait de l'intrication entre parcours en santé et cheminement de vie, l'analyse de la dimension de la demande ainsi décrite est un apport précieux.

Afin de mettre en application des modalités pratiques issues des diverses connaissances acquises, une étude de modélisation de parcours a été réalisée selon une démarche qualitative (article 6). Les rôles des différents acteurs en jeu ont été précisés, et les obstacles majeurs à une bonne prise en charge des patients identifiés. Une proposition graphique permet de visualiser la situation décrite, en mettant notamment en évidence des points de fragilité. La méthodologie utilisée éclaire ainsi la description d'un parcours de soins en prenant en compte divers points de vigilance à systématiquement considérer.

Enfin, afin de compléter la réflexion sur une mise en application d'une modélisation, une seconde étude de modélisation de parcours a été réalisée selon une démarche mixte (article 7). Bien que cette étude ait été réalisée dans le cadre du parcours d'un patient douloureux reçu aux urgences, la démarche est déclinable quel que soit la situation de santé considérée. En effet, elle a portée sur

l'analyse d'une défaillance dans les processus de soins au travers du calcul des risques de criticité et de l'identification des causes possibles. Les résultats montrent que seules certaines situations dans le processus ont un très haut niveau de criticité, explicable par des raisons clairement identifiables. Ce travail éclaire ainsi sur les différents types de mobilisation de ressources à envisager pour optimiser un parcours de soins en prenant en compte les facteurs de vulnérabilité organisationnelle.

3.1.2. Approches de la complexité et structuration méthodologique pour la modélisation des parcours en santé

Entreprendre une démarche de modélisation d'un parcours, c'est entre autres prendre conscience des façons dont la complexité opère pour altérer la performance d'un système dynamique tel qu'un parcours en santé. Selon Larrain et al. (189), il existe neuf aspects de la complexité pouvant être représentés au travers d'approches de modélisation (simulation dans le cas des auteurs, mais applicable à d'autres approches) :

- 1) Les *interactions*. Cet aspect se concentre sur les relations (directes ou indirectes) entre les composants d'un système ou d'une organisation, en cherchant à expliquer quel composant influence lequel sans pour autant expliquer comment leurs relations réciproques évoluent dans le temps. Certaines techniques de modélisation tiennent compte de ces interactions, telle que le Markov Model. On considère ici les dépendances des effets causaux entre composants d'un système. Soit directement : si le composant A représente un patient et le composant B une intervention médicale, l'effet d'une intervention sur le patient dépend des caractéristiques spécifiques du patient (âge, comorbidités…). Soit indirectement : la dépendance des effets causaux entre A et B peut ne pas être isolée et être influencée par un troisième composant C (soutien familial du patient par exemple), qui agit sur A (232). Le succès d'une intervention médicale (B) sur la santé du patient (A) peut être influencée par le soutien familial (C) : s'il est faible ou absent, l'intervention médicale pourrait avoir un effet moindre, même si elle est scientifiquement efficace.

- 2) Le *dynamisme*. Cet aspect complète le précédent en cherchant à expliquer comment les interactions évoluent. Il se concentre sur les changements d'états qui surviennent avec le temps et du fait de diverses modulations contextuelles : les composants du système peuvent changer leurs comportements non seulement avec le temps mais aussi en fonction de ce qui se passe autour d'eux. Certaines techniques de modélisation peuvent tenir compte de ce dynamisme, telles que les modèles basés agents. Ici, les relations ne sont pas linéaires, elles s'auto-renforcent cycliquement, créant des boucles de rétroactions. Celles-ci émergent dans la

durée, et leur analyse nécessite de suivre des cycles causaux dans le temps. Dans une relation entre les composants A et B d'un système, où A a un effet causal sur B, un composant tiers C va moduler A et influencer la manière dont A interagit avec B, et donc, à mesure que le système avance, modifier l'effet de A sur B sans interaction directe entre C et B (233). Dans un hôpital par exemple, une augmentation du nombre de patients (A) à soigner peut induire une diminution de la qualité des soins (B) délivrés, ce qui à son tour peut réduire la fréquentation des patients (A) dans le futur, créant une boucle de rétroaction négative. Mais une augmentation du volume de patients pris en charge peut dans le même temps augmenter les recettes de l'hôpital, et faciliter l'optimisation de la prise en charge.

- 3) *L'interférence*. Cet aspect complète également celui concernant les interactions en cherchant à expliquer comment les interactions évoluent mais ici selon une temporalité très courte, dite par perturbation. Certaines techniques de modélisation peuvent tenir compte de ce type d'interférences, telles que la simulation d'événements discrets. Dans une relation entre les composants A et B d'un système, où A a un effet causal sur B, un composant tiers C va directement perturber B et affecter la relation entre A et B, et influencer A. Mais si l'interférence est brève, elle n'implique pas de cycles causaux étendus. Elle repose alors sur des interactions simples et ponctuelles. L'impact est ici immédiat et ne revient pas de manière circulaire ; il est linéaire, même s'il peut être complexe (234). Par exemple, dans un hôpital, si une salle (B) est occupée par un patient (C), les autres patients (A) doivent attendre avant d'être pris en charge. Cette attente dépend donc de l'état actuel de la salle ("libre" ou "occupée").

- 4) *L'adaptation*. Cet aspect concerne la capacité d'un système à s'ajuster face à diverses situations grâce à des adaptations logiques (basées sur des règles et des conditions) de ses composants. Certaines techniques de modélisation peuvent tenir compte de ces adaptations, telles que les modèles dits « basés agents ». Il s'agit de s'intéresser aux réactions des composants dynamiques qui peuvent modifier leurs comportements, leurs manières d'agir en fonction des changements, en particulier des aléas survenant dans leur environnement. Cette adaptation est basée sur des décisions conditionnelles du type « Si…, alors… ». Cela permet de définir le comportement des composants en prenant en compte non seulement les actions d'autres composants mais également les conditions dans lesquelles ils agissent (235).

- 5) *Les données dites « soft »*. Cet aspect porte sur l'intégration de données appelées « souples » ou « molles », qualifications issues des approches qualitatives, par opposition aux données dites « dures » issues des approches quantitatives. Certaines techniques de modélisation peuvent intégrer ce type de données, telles que la simulation des dynamiques

des systèmes. Le choix des données soft est proposé quand la complexité rend difficile la mesure de variables par des démarches mathématiques, ou quand l'exactitude statistique n'est pas adaptée à la description de la structure du système ou de son comportement. Cela apporte une flexibilité conceptuelle permettant de mieux comprendre l'influence de variables importantes (236), mais une limite en est la difficulté de prouver la puissance de significativité des résultats obtenus.

- 6) *L'individualisation*. Cet aspect porte sur la considération des propriétés des systèmes complexes que sont l'hétérogénéité et la diversité. Il s'agit d'inclure des particularités individuelles, et de définir des attributs spécifiques pour les composants du système (237). Certaines techniques de modélisation intègrent cette notion, comme la microsimulation.

- 7) *La simultanéité des événements*. Cet aspect considère la survenue en parallèle de deux ou plusieurs événements au sein d'un même composant d'un système. Elle renvoie simplement à l'observation concomitante de plusieurs sous-systèmes. Une technique de modélisation particulièrement adaptée à ce type d'approche est la simulation d'évènements discrets (238).

- 8) *Les occurrences historiques*. Cet aspect porte sur l'observation de l'influence des états passés sur la nature des relations dans l'état actuel du système. La simulation de dynamiques de systèmes est une technique de modélisation prenant en compte une telle observation (239).

- 9) Les *émergences*. Cet aspect concerne enfin l'observation des caractéristiques d'un système susceptible de développer de nouveaux comportements, différents et nouveaux au regard de ceux issus de la somme de ses parties. Les interactions entre les divers composants peuvent ainsi créer des dynamiques inattendues à l'échelle de l'ensemble du système. Certaines techniques de modélisation, telles que les modèles basés agents, sont adaptées à cette approche (240).

De plus, dans le cas d'une démarche de modélisation d'un parcours, savoir tenir compte précisément des caractéristiques décisives en santé d'un individu (CDSI) peut être utile. Selon Busnel (241), pour pouvoir apporter des réponses adaptées et ciblées aux personnes sollicitant des soins, notamment à domicile, il est essentiel d'évaluer régulièrement leurs besoins. À cette fin, le questionnaire d'évaluation « Resident Assessment Instrument – Home-Care » (RAI-HC) a été élaboré. De nombreuses versions ont été développées sur cette première base, dont RAI-Santé mentale, RAI-Soins aigus gériatriques et RAI-Soins palliatifs par exemple. Le RAI-HC est ainsi composé de 19 domaines regroupant 280 items permettent une description globale de l'individu en matière de santé. Les

données issues de cette évaluation peuvent être utilisées à différents niveaux et moments dans le parcours d'une personne au sein d'un système de santé, afin d'éclairer les décisions en matière de soins et d'accompagnement. Les 19 domaines considérés sont :

1. Données sociodémographiques,
2. Admissions et historiques,
3. État cognitif,
4. Communications – Vision – Audition,
5. Humeur, comportement,
6. Bien-être psychosocial,
7. État fonctionnel dont activités de la vie quotidienne, activités instrumentales de la vie quotidienne et locomotion,
8. Continences,
9. Diagnostics médicaux,
10. Problèmes de santé (dont chute, douleur, fatigue, dyspnée, santé perçue),
11. État nutritionnel et buccodentaire,
12. État de la peau et des pieds,
13. Médicaments,
14. Mesures de prévention, traitements et programmes d'aide de soins,
15. Responsabilité juridique,
16. Soutiens sociaux (dont support social, état de santé des aidants),
17. Environnement, habitat et conditions financières,
18. Perspectives d'évolution,
19. Les données de sortie d'un épisode de soins.

Des sous-ensembles d'items permettent d'identifier les personnes susceptibles de bénéficier de soins et d'aides bien définies, et des appariements d'items permettent de révéler des populations d'individus arborant certaines caractéristiques en santé.

Enfin, lors d'une démarche de modélisation d'un parcours, savoir structurer méthodologiquement sa réflexion conceptuelle est essentiel. Gräebner (217) propose une grille dite « épistémologique » invitant tout modélisateur à préciser les arguments en faveur de la pertinence du modèle qu'il construit, tant en termes de démarche que de conception puis d'usage de l'outil (Annexe 1). Une fois remplie, la grille proposée permet de rendre lisible la démarche et ainsi de l'expliciter et de la mettre en œuvre avec des partenaires, puis de l'évaluer, enfin d'offrir des perspectives de comparaison avec d'autres démarches, ou bien de réplications avec ou sans adaptations. Initialement, l'auteur a répertorié huit attributs, ou concepts clés, qui doivent être explicables par un modélisateur au cours de sa démarche : *la cible du modèle, l'expressivité du modèle, la description du modèle, le scope de la cible, l'affectation du modèle, la concordance de propriétés, les propriétés imputées* et *le type d'explications*. Nous proposons d'y associer un attribut complémentaire : la *fonction du modèle*. Pour chacun de ces attributs, afin de guider le modélisateur dans sa réflexion de construction de la

connaissance pour sa démarche, nous proposons un exemple de démarche (le diabète de type 2), ainsi que des exemples de questions auxquelles un modélisateur doit pouvoir répondre, telles que : comment décider qu'il existe une correspondance suffisante entre la cible définie et la réalité observée ? Comment le choix du langage de modélisation affecte-t-il l'interprétation par les différentes parties prenantes ? Quels risques découlent de l'abandon de composantes jugées non essentielles ?

3.1.3. Cheminer vers la modélisation d'un parcours : association d'éléments pour une réflexion structurée

En associant les divers éléments pertinents issus des études menées dans le cadre de cette thèse à d'autres outils conceptuels, méthodologiques, ou métrologiques existants par ailleurs décrits ci-dessus, il est possible de développer une réflexion structurée sur la démarche de modélisation d'un parcours en santé. Ce processus de réflexion générique peut être mis à disposition des équipes souhaitant s'engager dans la modélisation d'un parcours indépendamment du domaine concerné.

D'un point de vue conceptuel, l'association de ces éléments génère une synergie de perspectives favorisant l'émergence d'une conception de modélisation qui englobe autant le « cheminement de vie » que le « parcours en santé » dans les dimensions de l'offre (institutions, professionnels) et de la demande (personne/patient bénéficiaire de l'offre) (Figure 10).

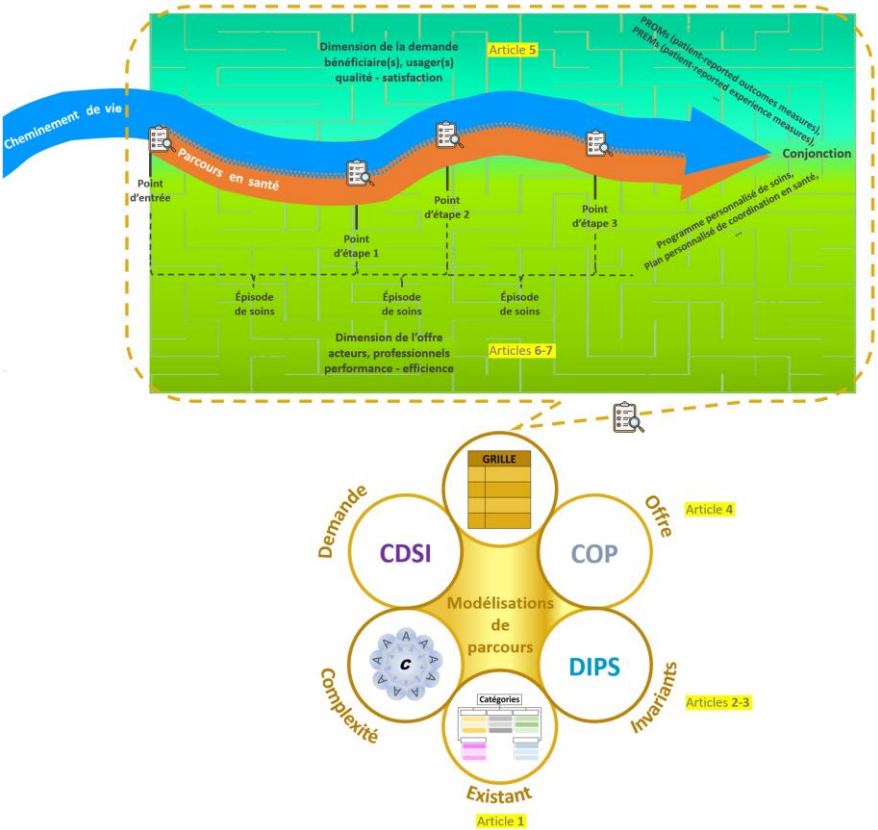

Figure 10. Synthèse conceptuelle des éléments méthodologiques proposés pour une démarche de modélisation de parcours. DIPS : déterminants invariants de parcours en santé. COP : critères organisationnels primordiaux. CDSI : caractéristiques décisives en santé d'un individu.

De façon opérationnelle, une approche progressive structurée en plusieurs étapes est proposée afin de conduire la démarche de réflexion pour la conception d'une modélisation (Figure 11).

En première étape, cibler les aspects de la *complexité* propres à la situation étudiée permet d'obtenir une macro-observation des directions potentielles et de définir une intention globale qui va orienter la réflexion de modélisation.

Ensuite, en deuxième étape, renseigner la *grille épistémologique* permet de diriger la réflexion. Répondre à des questions destinées à construire la connaissance permet de faire émerger une liste d'informations ou d'instructions à prendre en compte pour modéliser.

Dans une troisième étape, une combinaison de trois actions doit permettre d'accompagner la réflexion de modélisation dans le cadre large du concept de parcours en santé.

Tout d'abord, l'action d'analyser les poids relatifs à la situation des *déterminants invariants de parcours en santé* permet de comprendre l'influence de divers facteurs sur les caractéristiques du parcours mis en place.

Ensuite, il peut être considéré deux éléments de réflexion basés sur l'offre et la demande. L'offre étant caractérisée par l'approche processuelle du soin, peut elle-même être abordée selon deux modalités : 1) la catégorisation des méthodologies de modélisation des parcours existantes, issue de l'article 1, afin de repérer les démarches précédemment réalisées et surtout leurs résultats ; 2) repérage des *critères organisationnels primordiaux* afin de connaitre les propriétés qui composent le socle structurel des interventions de soin ou de santé concernées par la démarche de modélisation. La demande étant caractérisable selon une approche biopsychosociale, elle peut être investiguée par l'identification des *caractéristiques décisives en santé d'un individu* (ou d'une population si appariements), afin de faire émerger des spécificités éventuelles précisant le contexte de la démarche. Associer à l'analyse des DIPS, une réflexion combinant l'offre et la demande permettra ainsi d'inscrire la démarche dans la perspective de la *singularité standardisée*.

Dans une quatrième étape, il s'agit de finaliser la réflexion par la sélection des méthodes, techniques et outils de modélisation à privilégier. L'article 1 de cette thèse propose des repères caractérisant différentes techniques de modélisation (dont intérêts et limites).

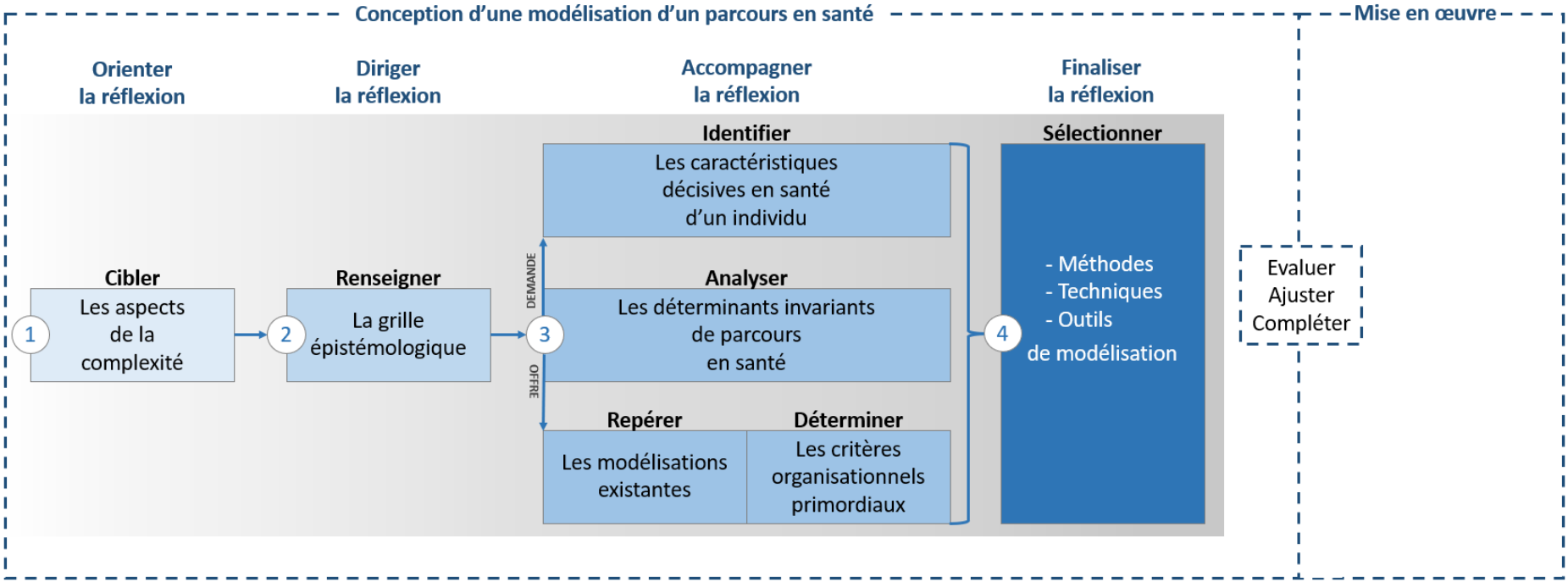

Figure 11. Synthèse de la démarche de réflexion pour la modélisation d'un parcours en santé.

3.2. Forces et limites du travail de recherche

3.2.1. Les points forts

Le travail présenté cherche à clarifier l'articulation entre deux notions essentielles que sont les parcours en santé et la modélisation. Il en propose une approche originale. D'une part, par une approche combinée théorique et pratique, les démarches d'analyse améliorent tant la production du savoir requis que du savoir-faire à mettre en œuvre. D'autre part, des données et apports innovants, comme l'identification de déterminants de parcours en santé ou la proposition d'une démarche de réflexion méthodologique multidimensionnelle pour la modélisation d'un parcours, sont mobilisés. Il s'appuie enfin sur la publication d'articles dans des revues scientifiques à comités de lecture.

3.2.2. Les limites

Les points de vue « usagers du parcours », représentants de patients, et/ou aidants n'ont pas été considérés autant qu'attendu : une tentative de recueil de perceptions des patients hémophiles a été envisagée, mais le manque de participants n'a pas permis la poursuite de l'exploration.

La démarche méthodologique proposée pour favoriser la conception pertinente d'une démarche de modélisation d'un parcours en santé n'a pas été testée, émergeant comme résultat synthétique de notre recherche. Afin d'éclairer de futures initiatives de modélisation de parcours, des comparaisons entre ou usage combiné des diverses démarches de modélisation publiées et celle proposée ici pour un même type de parcours, sont un complément à réaliser.

Les deux approches pratiques de modélisation présentées au travers des articles de thèse n'ont pas porté sur le même objet d'étude (une sur l'hémophilie et une sur l'oligoanalgésie), et l'évaluation des impacts de ces travaux sur l'évolution de la gestion des prises en charge n'a pas été réalisée dans la suite de ces travaux.

3.3. Prospectives

La démarche méthodologique favorisant une conception pertinente d'une modélisation d'un parcours en santé devrait être testée, de façon progressive. Une première étape consisterait à conduire une étude pilote monocentrique sur un parcours bien documenté et relativement stable (diabète de type 2 par exemple) en ayant recours à plusieurs techniques de modélisation (trois par exemple, issues de méthodes qualitative, quantitative et mixte). Les résultats issus de la modélisation pourraient être confrontés à des indicateurs de performance réels (délais, coûts, réadmissions) et à une évaluation qualitative des parties prenantes (par entretiens semi-directifs ou focus groups par exemple). Une

seconde étape pourrait prévoir une extension à plusieurs organisations de santé et à d'autres domaines de santé (cancer colorectal par exemple). Cela permettrait de pouvoir implémenter un référentiel général de modélisation des parcours servant de méta-analyse méthodologique.
Dans cette optique la justification de l'adéquation entre la démarche méthodologique de conception d'une modélisation selon une situation donnée et la sélection d'une technique de modélisation devra être consolidée.

De plus, dans le cadre d'une évaluation des impacts organisationnels induits par une innovation thérapeutique (une nouvelle technologie ou une nouvelle intervention), une démarche méthodologique structurée pour choisir puis évaluer la modélisation d'un parcours peut clarifier le cadre organisationnel, les dynamiques organisationnelles et les arbitrages multicritères, améliorer le test de scénarios et faciliter l'accompagnement au changement le cas échéant.

Enfin, les avancées technologiques offrent des perspectives pour l'avenir de la santé. L'essor des technologies portables (montres ou bagues connectées par exemple), voire greffées, devrait s'accentuer, favorisant ainsi le recueil objectif, en situation naturelle et instantané de données individuelles en santé. Le développement de l'IA et de l'apprentissage automatique permet déjà une analyse de ces données, tant à l'échelle individuelle que populationnelle, à des fins de prédiction optimisée pour des choix de comportement, d'ajustement ou d'intervention les plus adaptés. Il va devenir possible de produire des jumeaux numériques intégrés dans des réalités simulées reprenant l'ensemble des déterminants de la santé d'une personne et permettant de tester plusieurs variations concernant les déterminants de parcours (243). Au-delà de la prévention des risques, ces perspectives tendront vers davantage de proactivité et de création d'opportunités. Elles s'accompagnent cependant de défis techniques et éthiques à relever.

CONCLUSION

Face au défi de la cohérence organisationnelle et de l'efficience des systèmes de santé, l'enjeu que représente la mise en œuvre des parcours en santé peut être abordé au travers de la modélisation. Afin de favoriser les initiatives de coopérations et d'articulation adéquate entre acteurs en santé, il est nécessaire de guider les démarches d'analyse des situations individuelles en particulier complexes, qui éclairent sur les difficultés rencontrées en conditions naturalistes. Pour optimiser la conception d'une modélisation pertinente d'un parcours en santé, notre travail de recherche propose ainsi une démarche de réflexion méthodologique : (i) cibler les aspects de la complexité, (ii) renseigner une grille épistémologique, (iii) analyser les déterminants invariants de parcours en santé, repérer les modélisations existantes et déterminer les critères organisationnels primordiaux, identifier les caractéristiques décisives en santé d'un individu (ou d'une population), (iv) sélectionner les méthodes, techniques et outils de modélisation adéquats vis-à-vis des paramètres identifiés préalablement. En parallèle de la mise en œuvre de la modélisation élaborée, une évaluation de la démarche devra être réalisée pour l'ajuster et/ou la compléter.

Les démarches de modélisation devront se structurer d'autant plus afin de relever de nouveaux défis engendrés par l'augmentation de la variété et de la quantité de données exploitables avec l'essor de l'IA dans sa capacité et sa vitesse d'analyse, et dans son autonomie. Si l'IA peut apporter des avantages cybernétiques dans la régulation d'un système multidimensionnel dynamique, tels que les parcours de vie d'individus formant une population, sa prééminence dans la gestion des données pourrait cependant modifier notre manière de comprendre la santé et le monde. Les mécanismes d'interprétation des données par l'IA pourraient alors devenir de plus en plus opaques pour l'humain, et rendre incompréhensibles les processus de raisonnement et les solutions proposées, voire celles qui sont mises en œuvre. Un corolaire en est une redéfinition des principes de subsidiarité et de responsabilité dans les prises de décisions en santé, et une modification de la façon dont la réalité est perçue, définie et considérée d'une façon à la fois individuelle et collective. Face à la complexité croissante de nos sociétés, l'épistémologie humaine devra donc être davantage évolutive et adaptative. Le principe de réflexivité faisant référence à la capacité d'un système ou à celle de ses agents à s'observer et se transformer en fonction de cette observation, il implique une réflexion constante sur les méthodes de raisonnement, d'analyse et de validation de la connaissance. C'est cette réflexivité qui devra se retrouver au cœur des comportements de tous les acteurs de notre système de santé, le plus représentatif parmi les fondamentaux dans la construction d'une société juste et bienveillante.

Considérant que l'optimisation des parcours en santé des individus est un facteur de pérennité de nos sociétés, la modélisation de ces parcours est donc bien plus qu'une manipulation d'outils techniques : c'est une volonté de participer à la construction d'un sens commun.

Annexe 1. Proposition de grille consolidée des attributs épistémologiques d'un modèle, inspirée de Gräebner (217).

Attributs	Définitions	Compléments	Exemples	Exemples de questions épistémologiques
La cible du modèle	Préciser le système que le modèle est censé représenter, réel ou fictif. Il peut être spécifique, général ou hypothétique.	La cible du modèle peut être un phénomène réel, un système abstrait, un processus social, etc. Elle peut être un parcours en santé d'un individu ou celui d'une population type.	Modéliser le parcours d'un patient diabétique de type 2, depuis le diagnostic jusqu'au suivi annuel, en intégrant les interactions avec les médecins généralistes, diabétologues, et infirmiers Cible : patients adultes en milieu urbain avec accès à un réseau de soins structuré. Exclusion : patients pédiatriques ou atteints de diabète de type 1.	- Comment décider qu'il existe une correspondance suffisante entre la cible définie et la réalité observée ? Quels critères permettent de définir si la cible est suffisamment représentative de la réalité ? - Comment justifier les exclusions sans introduire de biais systémique ? - En quoi le niveau de spécificité de la cible affecte-t-il sa transférabilité à d'autres contextes ?
La fonction du modèle	Définir l'activité que le modèle doit accomplir en vue d'un résultat déterminé.	La fonction du modèle peut être la communication, la compréhension, l'évaluation, l'aide à la décision, …	Évaluer (ou simuler) l'impact de la fréquence des consultations (téléconsultations et présentiel) sur la prévention des complications aiguës : les hypoglycémies sévères Optimiser le calendrier des suivis pour réduire les hospitalisations non programmées de x%.	- Quelle question de connaissance (description, prédiction, explication...) le modèle doit-il prioritairement résoudre ? - Comment s'assurer que la fonction choisie réponde aux besoins réels des acteurs du parcours de soins ? - Dans quelle mesure la fonction du modèle influence-t-elle sa capacité à être utilisé dans d'autres contextes ? - La fonction déclarée est-elle compatible avec les données disponibles et la méthode envisagée ?
L'expressivité du modèle	Identifier des critères de fidélité permettant d'évaluer la capacité d'un modèle à représenter sa cible.	Les critères peuvent être divisés en deux catégories : - La suffisance structurelle : critères permettant de définir le degré de sophistication structurelle qu'un modèle doit avoir pour produire un résultat raisonnablement similaire à celui de sa cible, avec des normes d'erreurs acceptables. - L'adéquation causale : critères permettant de définir le degré de sophistication structurelle qu'un modèle doit avoir pour imiter de manière adéquate la causalité de sa cible, avec des normes de fidélité de représentation des mécanismes de la cible. L'expressivité du modèle dépend des formes de language utilisées (mathématiques, diagrammes, agents...).	Le modèle doit pouvoir rendre compte de la variabilité des profils patients et refléter les parcours réels mesurés (via données de santé). Suffisance structurelle : Le modèle doit intégrer un délai moyen entre consultation généraliste et spécialiste de x jours, avec une tolérance d'erreur de ± y jours. Adéquation causale : l'absence d'éducation thérapeutique peut entraîner une mauvaise observance des traitements, augmentant les risques de complications.	- Comment rendre le modèle suffisamment détaillé pour être fidèle à la réalité, tout en restant assez simple pour être compris et utilisé par les professionnels concernés ? - Comment vérifier que les causes et effets dans le modèle correspondent vraiment à ceux de la réalité ? - Quels critères permettent de distinguer une causalité réelle d'une corrélation artificielle dans le modèle ? - Comment justifier l'abandon de certaines dimensions de la réalité au profit d'une représentation plus maniable ?
La description du modèle	Décrire la manière dont le modèle peut être exprimé : mots, équations mathématiques, codes informatiques, graphiques, images…	Un même modèle peut être décrit de plusieurs manières différentes. Les descriptions peuvent ne pas décrire un modèle dans tous ses détails. La description du modèle va influer sur la lisibilité, la transférabilité et la communicabilité du modèle.	- Cartographier les étapes clés par BPMN, - Prédire les transitions entre états de santé "stabilisé", "à risque", "hospitalisé" par chaine de Markov, - Estimer l'impact des ressources limitées (disponibilité des endocrinologues) par équations logistiques. (Si simulation : utilisation d'un modèle multi-agents représenté sous forme de diagramme de flux et règles décisionnelles de type Petri nets).	- Comment le choix du langage de modélisation affecte-t-il l'interprétation par les différentes parties prenantes ? - Dans quels cas la description du modèle devient-elle trompeuse en masquant les lacunes du modèle ? - Comment assurer la cohérence entre différentes descriptions d'un même modèle ? - En quoi la description influence-t-elle la reproductibilité et l'utilisation pratique du modèle ?

Le scope de la cible	Délimiter les aspects de la cible à modéliser, en précisant ce qui doit être inclus ou ignoré (éléments spatiaux, temporels, sociaux ou organisationnels).	Scope de la cible et affectation du modèle cherchent à décrire la relation entre un modèle et une cible. Permet de dresser une convention d'utilisation de la modélisation d'après des précisions énoncées de façon spécifique par le modélisateur. Cela permet de clarifier ce que le modèle doit ou ne doit pas prendre en compte, et de s'assurer que les modèles ne sont pas utilisés ou jugés sur des points d'applications pour lesquelles ils n'ont pas été conçus (et pour lesquelles ils ne sont peut-être pas bien adaptés). Cela fait que le modèle devient une représentation de l'intention du modélisateur, et non pas de la nature réelle.	x mois suivant le diagnostic, incluant les consultations trimestrielles chez le généraliste et les ateliers d'éducation thérapeutique Exclusion : les complications à long terme (ex. rétinopathie) et les interactions avec les services d'urgence hors hypoglycémies sévères.	- Sur quelles bases éthiques ou méthodologiques justifier les exclusions/inclusions ? - En quoi la délimitation du scope affecte-t-elle les propriétés modélisables ? - Comment éviter que les limites du scope ne rendent le modèle inadapté à des contextes imprévus ? - Comment communiquer les limites du scope pour éviter les mésusages du modèle ?
L'affectation du modèle	Préciser la partie du modèle qui va correspondre à la partie de la cible identifiée pour modélisation (le scope). Peut préciser également les parties du modèle qui ne vont pas correspondre, et qui peuvent être ignorées.		- Les étapes clés : 1ère consultation avec un spécialiste, bilan de suivi,... - Les délais entre les étapes. (Si simulation : les agents du modèle représentent les patients, les médecins, les pharmaciens ; les flux modélisent les interactions : consultations et délivrances).	- Comment valider que les éléments modélisés reflètent fidèlement les mécanismes réels du système ? - Quels risques peuvent survenir si le modèle ne correspond pas bien à la réalité ? - Quels risques découlent de l'abandon de composantes jugées non essentielles ? - En quoi l'affectation influence-t-elle l'interprétation des résultats par les utilisateurs finaux ?
Concordance de propriétés	Décrire les principales propriétés pertinentes que le modèle cherche à reproduire et la manière dont elles doivent correspondre aux propriétés de la cible.	La concordance concerne aussi la validation empirique ou statistique du modèle.	Fréquence de suivi Taux d'HbA1c moyen = x% (±y%) Taux d'observance des traitements = x% Taux de complications = x% Nombre d'hospitalisations évitables = x	- Quelles méthodes et techniques permettent de valider la concordance entre modèle et réalité ? - Comment traiter les écarts entre propriétés modélisées et observées ? - Comment prioriser les propriétés à vérifier en premier si les ressources sont limitées ? - En quoi une concordance partielle affecte-t-elle la crédibilité globale du modèle ?
Propriétés imputées	Décrire les propriétés que le modèle impute (réellement ou faussement) à la cible désignée.	Ce sont les attributs que l'on suppose pertinents pour la cible via le modèle. Les propriétés imputées sont souvent hypothétiques, parfois non directement observables.	Le nombre de consultations a un effet causal sur le contrôle glycémique, même si des facteurs tiers (adhésion, mode de vie) ne sont pas directement mesurés. Les mesures glycémiques sont systématiquement reportées dans un dossier médical électronique, même si des omissions sont possibles en pratique.	- Sur quels arguments (théoriques, empiriques, pragmatiques) repose l'imputation de ces propriétés ? - Quelles conséquences découlent d'une imputation erronée et que le modèle se base sur des hypothèses fausses ? - Comment informer clairement les utilisateurs du modèle sur les hypothèses risquées ou incertaines qu'il contient ? - 5. Comment distinguer les propriétés imputées fondées sur des preuves de celles reposant sur des hypothèses ?

Le type d'explications	Spécifier la nature de la relation causale ou logique que le modèle établit entre les éléments. Principalement dans le cas d'une fonction de modèle basée sur la compréhension.	Types d'explications que le modèle peut donner : - Explication complète, l'histoire causale : le modèle doit montrer comment un phénomène concret s'est produit. Il va chercher à identifier la raison pour laquelle un certain fait s'est produit, à un moment donné et d'une manière particulière. Porte sur la description de tous les facteurs de causalité qui ont produit le fait. - Explication partielle : le modèle va chercher à isoler certains facteurs jugés importants et idéaliser les autres. Porte sur la description du rôle de certains facteurs explicatifs sous-jacents à la survenance d'un fait. Mais la fiabilité du modèle à fournir une explication grâce à certains facteurs peut être discutée. - Explication potentielle : le modèle cherche à représenter les mécanismes qui auraient pu en principe provoquer le phénomène en question. Également utilisable pour illustrer le fonctionnement de mécanismes purement théoriques.	Explication complète : une hospitalisation pour hyperglycémie peut être due à une erreur de dosage ou à une absence de suivi. Explication probabiliste : plus la fréquence de suivi est élevée, plus la probabilité de complications diminue. Explication partielle : des ateliers éducatifs peuvent avoir un impact positif sur la réduction des erreurs d'automesure glycémique. Explication potentielle : une application de suivi glycémique en temps réel peut avoir un impact positif sur l'observance.	- Quel type d'explication est le plus adapté aux objectifs de décision ou de communication ? - Dans quels cas une explication potentielle peut-elle être considérée comme une preuve théorique suffisante ? - Quels critères permettent de juger si ne explication fournie par le modèle est satisfaisante ? - En quoi le type d'explication influence-t-il l'utilisation pratique par les professionnels de santé ?

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