Qualité et organisation des soins du diabète de type 2

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Federaal Kenniscentrum voor de gezondheidszorg
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PREFACE

Le nombre de patients diabétiques ne cesse de croître dans le monde. Bien que le diabète ne soit pas de nature infectieuse, ce phénomène est bien dénommé « épidémie de diabète ». Celle-ci va de pair avec l'épidémie de l'obésité, dont la vitesse de croissance est jugée alarmante par l'OMS. Le diabète de type 2, sujet de ce rapport, n'est plus une maladie de la personne âgée : de plus en plus d'adultes jeunes y sont confrontés.

Le diabète constitue médicalement une cause importante de morbidité et de mortalité précoce, avec un impact financier majeur pour la société. Suivant les estimations internationales, le diabète consommerait 5 à 10% des ressources des soins de santé.

L'augmentation de l'espérance de vie, les habitudes alimentaires et le style de vie sédentaire actuels ne laissent en rien présager un ralentissement à court terme de l'accroissement du nombre de patients diabétiques. La Belgique peut être fière de son système de « convention du diabète », initialement créée pour les patients diabétiques de type 1. Ils peuvent bénéficier à vie d'un suivi et d'un traitement des complications dans des centres hospitaliers spécialisés. La médecine évolue et une partie des patients diabétiques de type 2 sont également traités par insuline et suivis durant de nombreuses années. Le système classique de convention avec les hôpitaux ne pourra plus faire face à l'affluence de patients évoquée ci-dessus. Sur le plan politique, cette constatation pose un réel défi à notre système de soins de santé. Quelle est la forme d'organisation la plus efficiente pour cette maladie chronique qui demande une collaboration régulière entre différentes disciplines de santé ? Et comment la qualité des soins peut-elle être assurée, sachant que la prise en charge du diabète ne se limite pas au suivi de la glycémie mais exige également la prise en charge d'autres facteurs de risque cardio-vasculaire et complications ?

Une telle question de recherche, relative à l'organisation à grande échelle de soins de qualité, exigeait également une étude de large envergure. Celle-ci comprend une revue systématique approfondie de la littérature, la description des initiatives actuellement en place et une étude relative à l'organisation de la prise en charge du diabète dans d'autres pays avec les leçons potentielles subséquentes. Le KCE se félicite de la collaboration multidisciplinaire fructueuse entre les quatre équipes universitaires et l'association flamande pour le diabète (Vlaamse Diabetes Vereniging). Le résultat est un rapport remarquablement concret construit sur une base scientifique. Tous nos remerciements sont également adressés aux nombreux experts de terrain qui y ont apporté leur contribution tout en veillant à ce que le contenu reste en harmonie avec la réalité. Un fil conducteur émerge en particulier de cette recherche : les futurs changements dans l'organisation des soins du diabète, changements pour lesquels ce rapport offre diverses options, doivent être positionnés dans un plan global comprenant une vision à long terme avec des objectifs clairs, mesurables et centrés sur le patient.

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Directeur général adjoint

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INTRODUCTION

Dans le monde entier, on observe une prévalence croissante du diabète, en particulier du diabète de type 2, qui représente actuellement 85% de l'ensemble des cas. Alors que dans le diabète de type 1, les personnes ne produisent (presque) pas d'insuline, les patients diabétiques de type 2 en produisent mais leur organisme ne peut l'utiliser correctement. Les principales causes sont l'obésité et un type de vie sédentaire, raisons pour lesquelles la prévalence du diabète de type 2 augmente avec l'âge. La prévalence croissante du diabète de type 2 représente un fardeau considérable pour l'organisation des soins de santé en Belgique. Actuellement, on estime que le pourcentage de la population belge atteinte de diabète se situe entre 4 et 5 % et une hausse considérable est prévue dans un proche avenir. Le diabète représente chez les adultes la première cause de cécité et de maladie rénale en phase terminale et il engendre une mortalité cardiovasculaire plus que doublée. Cela entraîne non seulement des souffrances humaines mais également un impact majeur sur les dépenses en soins de santé. Il est urgent d'élaborer un plan réunissant des stratégies pour la prévention, le diagnostic précoce et le traitement approprié du diabète.

L'approche multifactorielle, indispensable à la prévention des complications du diabète, constitue un défi majeur dans le traitement du diabète de type 2 : contrôle glycémique, prévention cardiovasculaire et en particulier, modifications du mode de vie afin de développer l'exercice physique et d'assurer la maîtrise du poids.

La présente étude vise à établir des recommandations au sujet de la qualité et de l'organisation des soins du diabète en Belgique. Elle se concentre sur le diabète de type 2, en raison de son impact social croissant. Le traitement de cette pathologie implique plusieurs acteurs et la coordination des soins constitue un objectif difficile. Le présent projet a été mis en œuvre par un consortium multidisciplinaire d'endocrinologues-diabétologues et de médecins généralistes appartenant à quatre universités, en collaboration avec l'association flamande du diabète (VDV). Trois questions ont été étudiées :

1. Dans la littérature indexée et les recommandations internationales pour la pratique clinique, quels sont les indicateurs de qualité en matière de soins du diabète ?
2. Quels sont les effets, liés ou non à la santé, des différents modèles de prise en charge sur le résultat des soins ?
3. Comment les soins du diabète sont-ils organisés dans neuf pays occidentaux (forces et faiblesses des systèmes) ?

Les niveaux de soins ont été définis comme « micro », « méso » et « macro ». Le niveau de soins « micro » est le niveau où se situe l'interaction individuelle entre le patient et son prestataire de soins (= niveau du patient). Le niveau de soins « méso » est le niveau où collaborent différentes organisations régionales de soins de santé ou plates-formes interdisciplinaires (= niveau population d'une pratique et/ou régional). Le niveau de soins « macro » (= niveau politique) est le niveau où se rencontrent les responsables politiques, les compagnies d'assurances, les organisations professionnelles, les enseignants et les chercheurs.

I PREMIERE PARTIE : INDICATEURS DE QUALITE (PROCESSUS ET RESULTAT) POUR LES SOINS DES PATIENTS DIABETIQUES DE TYPE 2

Une recherche exhaustive basée sur des données probantes, d'indicateurs de qualité des soins destinés aux patients diabétiques de type 2 a été réalisée, pour l'essentiel, à partir des recommandations de bonne pratique belges et celles de huit pays sélectionnés (Canada, Danemark, Estonie, France, Allemagne, Espagne, Pays-Bas et Royaume-Uni).

L'analyse de la littérature a été réalisée en plusieurs phases successives. Dans une première phase, la question de recherche a été formulée en suivant la stratégie « PICO ». Dans une seconde phase, la stratégie de recherche a produit une liste exhaustive des recommandations de bonne pratique existantes. Ces recommandations ont ensuite été évaluées pour leur qualité scientifique et leur pertinence. Finalement, les indicateurs de qualité potentiels identifiés dans ces recommandations de bonne pratique ont été analysés et évalués. Les indicateurs relatifs aux processus et ceux relatifs aux résultats ont été rassemblés: des spécifications ont été définies et des valeurs-cibles attribuées.

Grâce à cette méthode, 64 indicateurs de qualité potentiels ont été identifiés à partir de 104 recommandations de bonne pratique (sélectionnées pour leur qualité scientifique et leur pertinence). Une liste définitive de 29 indicateurs relatifs aux processus et aux résultats a été obtenue en ne retenant que les indicateurs strictement basés sur des données probantes. Ces indicateurs potentiels ont été classés suivant cinq aspects majeurs de la maladie et de sa prise en charge: le contrôle de la glycémie, le dépistage précoce des complications (hypoglycémie, hyperglycémie, rétinopathie, néphropathie, problèmes aux pieds), le traitement des complications, celui des maladies cardiovasculaires (macrovasculaires: infarctus du myocarde, accident vasculaire cérébral, …) et la qualité de vie.

Au niveau « micro », des valeurs-cibles (pour les indicateurs relatifs aux résultats) et des spécifications (pour les indicateurs relatifs aux processus) ont été attribuées aux 29 indicateurs potentiels. Le présent projet s'est concentré exclusivement sur les indicateurs, mais la même procédure pourrait être appliquée à l'avenir pour définir les normes de qualité (niveau « méso ») et les critères d'évaluation (niveau « macro »).

L'examen de la littérature a montré que la transposition directe des indicateurs entre pays caractérisés par des systèmes de soins, des pratiques et des cultures médicales différents ne pouvait s'effectuer sans adaptation. Cet ajustement requiert des informations complémentaires sur les préalables essentiels permettant l'usage, non seulement des indicateurs mais aussi des normes et des critères d'évaluation, dans un contexte de soins de santé donné. Dans le cadre de ce projet, les spécifications et valeurs-cibles des indicateurs ont été extraites (quand elles étaient disponibles) des recommandations belges pour la pratique clinique relatives au diabète de type 2. Par conséquent, les 29 indicateurs potentiels reflètent les valeurs et spécifications basées sur des données probantes les plus pertinentes dans le système de santé belge.

La liste des indicateurs, normes et critères d'évaluation (avec leurs exigences appropriées) ne reflète pas seulement la qualité des soins mais également les actions ou les préalables nécessaires pour assurer la qualité des soins aux niveaux « micro » (patient), « méso » (population d'une pratique et/ou niveau régional) et « macro » (niveau politique).

Ce projet a permis de dégager certaines suggestions relatives à l'élaboration et l'utilisation des indicateurs de qualité, notamment :

- évaluer, valider et définir de manière continue les priorités dans la liste des indicateurs potentiels relatifs aux processus et aux résultats ;
- assurer une mise à jour régulière basée sur des données probantes ;
- définir les spécifications et les valeurs-cibles souhaitables des indicateurs de qualité pour lesquels les données sont actuellement insuffisantes. Ceci peut être effectué soit en utilisant les données d'autres recommandations de bonne pratique (quand elles sont disponibles), soit en préparant ou créant les conditions préalables nécessaires à cet effet (cf. partie 3: analyse de l'organisation des soins du diabète dans la littérature et les pays étrangers) ;
- créer les conditions nécessaires afin de permettre la transposition des indicateurs potentiels en normes et critères d'évaluation ;
- répéter aux niveaux « méso » et « macro » le processus suivi au niveau « micro » (patient), afin de générer des listes de normes ou de critères d'évaluation avec leurs spécifications et valeurs-cibles.

2 DEUXIÈME PARTIE : MODÈLES DE PRISE EN CHARGE POUR LES PATIENTS DIABÉTIQUES DE TYPE 2

La seconde partie du projet visait à analyser les effets des différents modèles de prise en charge sur les résultats (liés ou non à la santé) de ces soins chez les patients diabétiques de type 2.

L'analyse systématique de la littérature a permis d'identifier cinquante-neuf (59) études, dont douze (12) ont été classées comme modèles de prise en charge en milieu hospitalier et quarante-sept (47) comme modèles de prise en charge en première ligne, en consultation externe et dans des centres communautaires ('community settings'). Finalement, cinquante-quatre (54) articles ont été sélectionnés, qui ont généré douze (12) modèles de prise en charge pour le milieu hospitalier et quarante-deux (42) modèles de prise en charge pour les soins de santé primaires, l'hôpital et les 'community settings'.

2.1 IDENTIFICATION DE SIX MODÈLES DE PRISE EN CHARGE POUR LE DIABÈTE

Dans la littérature analysée, la typologie des modèles de prise en charge était déterminée par le prestataire de soins, défini comme la personne responsable des décisions médicales prises dans le continuum des soins. Les modèles de prise en charge à l'hôpital, en première ligne, en consultation externe et dans les centres communautaires ont été analysés. Toutefois, il n'y a pratiquement aucune étude sur le terrain comparant l'efficacité des modèles de prise en charge pour le diabète en milieu hospitalier et en soins de santé primaires.

Six modèles de prise en charge pour le diabète ont été identifiés:

- Le médecin généraliste en soins de santé primaires,
- Les soins partagés avec rôle central du médecin généraliste en soins de santé primaires,
- Les soins partagés avec rôle central de l'infirmier éducateur en soins de santé primaires,
- Le rôle central du spécialiste en soins de santé primaires,
- Les soins partagés en milieu hospitalier,
- Le rôle central du pharmacien.

2.2 BASE CONCEPTUELLE DE LA CLASSIFICATION DES MODELES DE TRAITEMENT CHRONIQUE

La littérature analysée offre une grande variété en matière de soins dispensés : ces modèles ont été comparés aux résultats qualitatifs des interventions (résultats au niveau du processus de soins et/ou du patient). La présente étude a utilisé le modèle conceptuel développé par Wagner (2001) en vue de classer, réunir et regrouper les différentes interventions relatives à un traitement chronique. Les quatre constituants de base de ce modèle sont l'aide à la décision (outils destinés aux professionnels médicaux), l'aide à l'autogestion pour les patients et leurs familles, la conception du système par lequel les soins sont dispensés (organisation des soins) et les systèmes d'information clinique. Ce travail a identifié 19 interventions relatives au traitement chronique liées à ces quatre dimensions.

2.2.1 Une définition opérationnelle de la qualité des soins : la qualité synonyme d'efficacité

L'analyse de la littérature n'a apporté qu'une réponse partielle à la question de l'effet des différents modèles de prise en charge en milieu hospitalier et en soins de santé primaires sur la qualité des soins des patients diabétiques de type 2. Toutes les études évaluées ont défini la qualité des soins en termes d'efficacité. Néanmoins, l'efficacité ne représente pas l'unique composante de la qualité des soins. La présente analyse de la littérature n'a trouvé aucun article proposant un modèle adéquat pour d'autres dimensions de la qualité des soins telle que définie par Campbell et al. (2000) notamment l'accessibilité, la disponibilité et le coût (une composante clé de l'accessibilité). Cette recherche dans la littérature n'a pas non plus trouvé d'analyse, en termes de coût-bénéfice, de la mise en oeuvre de différents modèles de prise en charge chronique du diabète.

2.3 FACTEURS CLÉ POUR L'EFFICACITÉ DES MODÈLES DE PRISE EN CHARGE DU DIABÈTE

L'une des principales conclusions de cette étude est qu'aucun modèle n'offre de meilleurs soins que les autres si l'on considère l'efficacité au niveau du patient et/ou au niveau du processus de soins. L'efficacité des différents modèles de prise en charge était fonction du type d'intervention et de son intensité, indépendamment des autres caractéristiques. Toutefois, les programmes de soins pour le diabète n'impliquant qu'un type d'intervention se sont avérés moins efficaces que les programmes d'intervention comprenant plusieurs approches, même si aucune n'a semblé plus efficace qu'une autre. Les soins multidisciplinaires dans le cadre d'un programme d'intervention opérant selon différentes approches s'est révélée efficace, tant au niveau du patient que du processus de soins. Comme mentionné plus haut, l'étude n'a pas mis en évidence d'information concernant l'accessibilité des différents modes d'intervention et n'a révélé que des données limitées concernant les aspects coût-bénéfice.

2.4 AUCUNE INTERVENTION N'EST APPARUE COMME ESSENTIELLE POUR L'EFFICACITÉ

Le nombre limité d'études permet difficilement de déterminer si un plus grand nombre d'interventions lors d'un traitement chronique ou des combinaisons spécifiques d'interventions ont plus de chances d'être efficaces que lorsqu'il y a moins d'interventions. Toutefois, il a été constaté que les études qui comportent les quatre types d'interventions du modèle de prise en charge chronique amélioraient le résultat au niveau du patient. La plupart des études reprenant moins d'interventions concluent parfois aussi à une certaine efficacité.

L'aide à la décision pour les professionnels de la santé (ex. matériel éducatif et formation post-graduée) a montré son efficacité sur les résultats du processus de soins. La distribution de matériel éducatif (recommandations de bonne pratique) aux médecins et les réunions de formation continue (formation post-graduée) ont montré leur efficacité au niveau du processus (fréquence du contrôle de l'HbA1c) en combinaison avec d'autres interventions, telles que les consensus locaux, les audits, les rappels, les feedbacks, l'évaluation par des pairs ou la combinaison de ces actions. Dans toutes les études où le niveau initial des soins était insuffisant, des améliorations ont été constatées. L'effet au niveau du patient (ex. les valeurs de HbA1c) était moins clair, vu que la plupart des études n'évaluent pas ces résultats. Néanmoins, celles qui ont rapporté des résultats au niveau des patients montraient en général des améliorations.

L'aide à l'autogestion destinée aux patients et à leurs familles s'est avérée efficace, à la fois au niveau du patient et du processus de soins. L'ajout d'une intervention orientée vers le patient - telle que la distribution de matériel éducatif, l'éducation, l'aide au suivi, les rappels et les contrats de type comportemental - a généralement engendré des améliorations chez le patient, en plus d'une amélioration des résultats au niveau du processus de soins. Il convient de noter toutefois que l'éducation du patient est définie

de nombreuses manières, depuis les conseils diététiques individualisés jusqu'à un éventail complet de services.

Des procédures intensives pour assurer le suivi et la révision des rôles professionnels constituaient deux interventions fréquentes dans l'organisation des soins. Les procédures intensives pour assurer le suivi ont exercé un impact positif sur les résultats des processus. Elles ont amélioré le processus de soins en termes de programmation des visites et de fréquence des examens, indépendamment du type et de l'intensité des méthodes utilisées. Le suivi des patients a été réalisé par des systèmes informatisés ou par des infirmières qui contactaient régulièrement les patients (initiatives de type éducatif). Les appels téléphoniques destinés à reprogrammer les visites manquées combinés à l'éducation du patient se sont avérés plus efficaces que l'envoi de rappels aux patients. Comparés aux rappels uniques, les rappels multiples ont affecté les résultats au niveau des processus mais seulement à court terme. L'efficacité d'un suivi intensif sur les résultats au niveau du patient reste incertaine.

L'efficacité de la révision des rôles professionnels en tant qu'unique modalité d'intervention reste hypothétique. Combinée à une partie orientée vers le patient, la révision des rôles professionnels était associée à un effet favorable minime sur le contrôle de la glycémie. Les résultats de ces études doivent être interprétés avec prudence en raison de leur qualité méthodologique limitée. Néanmoins, les études dans lesquelles les infirmières remplaçaient en partie les médecins ont généralement montré un impact positif sur les résultats des patients (contrôle de la glycémie), spécialement lorsque l'intervention faisait partie d'une stratégie d'intervention plus complexe.

Enfin, l'introduction de systèmes d'information clinique a exercé un effet favorable sur les résultats au niveau du processus, en particulier les changements dans le système relatif au dossier médical. Les résultats suggèrent que les systèmes de rappel informatisés améliorent l'adhésion au traitement recommandé, davantage en facilitant des informations au sujet des résultats cliniques et de la mise en œuvre des procédures recommandées qu'en fournissant au clinicien des informations spécifiques au patient en rapport avec le respect des recommandations de bonne pratique. L'impact sur les résultats des patients des systèmes d'information clinique reste indéfini.

3 TROISIEME PARTIE : ORGANISATION DES SOINS DU DIABETE DANS NEUF PAYS OCCIDENTAUX

L'étude de l'organisation des soins du diabète en Belgique et dans huit autres pays visait trois objectifs, à savoir l'analyse de l'organisation des soins du diabète dans chaque pays (avec les tendances actuelles), l'identification des lignes de force et des faiblesses des différents types d'organisation et, lorsque possible, une évaluation de la qualité et des coûts des soins du diabète dans chaque pays.

Les pays ont été sélectionnés pour leur pertinence par rapport à la situation belge (pays voisins : France, Allemagne, Pays-Bas et Royaume-Uni) ou leur représentativité géo-politique : Estonie (pays postcommuniste), Danemark (Europe septentrionale), Espagne (région méditerranéenne), Canada (pays d'Amérique dont le système de santé est similaire aux systèmes européens).

Une première recherche a été réalisée dans la littérature indexée et non indexée. Les informations collectées ont été soumises à quatre experts de chaque pays, à savoir, deux experts en soins de santé de première ligne, un expert en soins de santé de seconde ligne et un expert en santé publique. Ils ont validé les résultats, comblé les lacunes et exprimé leur opinion au sujet des lignes de force et des faiblesses de la prise en charge du diabète dans leur pays.

3.1 EVOLUTION VERS UNE PRISE EN CHARGE DU DIABÈTE PLUS GLOBALE, INTÉGRÉE ET BASÉE SUR DES DONNÉES PROBANTES

Dans tous les pays étudiés, la plupart des patients diabétiques de type 2 sont suivis en soins de santé primaires, le médecin généraliste étant le prestataire de soins principal. Les prestataires de soins de seconde ligne sont généralement impliqués dans la prise en charge des patients traités par insuline ou présentant des complications. Tous les pays montrent une même tendance vers une prise en charge plus globale du diabète, intégrée et basée sur des données probantes. A l'heure actuelle, chaque pays a développé pour le diabète de type 2 ses propres recommandations de bonne pratique basées sur des données probantes. Elles sont de plus en plus souvent écrites par des groupes d'experts multidisciplinaires (médecins et autres soignants des soins de santé primaires et secondaires).

Cette tendance se reflète également dans l'émergence de soins multidisciplinaires plus structurés, avec l'introduction de protocoles de soins partagés (shared care protocols). Ces protocoles englobent le contenu des recommandations de bonne pratique et définissent les rôles des professionnels. Ils soulignent l'autonomie du patient et l'importance d'une éducation à la santé structurée. Malheureusement, l'impact de ces protocoles sur le résultat des soins du diabète n'est pas encore clair.

La prise en charge globale basée sur des données probantes comprend également le développement de systèmes de contrôle de qualité. Tous les pays développent des systèmes de contrôle de la qualité, soit au niveau de la pratique, soit aux niveaux régional ou national, bien que leur degré de réalisation varie largement. Le Royaume-Uni a le système le plus avancé et son audit national du diabète démontre que le contrôle de qualité au niveau national peut exercer un impact considérable sur le processus de décision politique. En outre, le « Quality and Outcomes Framework » montre que la surveillance au niveau du patient a le pouvoir d'améliorer la qualité des soins. Cela nécessite un contexte d'équipes multidisciplinaires de première ligne très bien structurées, un soutien informatique solide ainsi que des incitants financiers. En Allemagne, les caisses d'assurance-maladie sont supposées fournir des feedbacks aux médecins sur la qualité de leur prise en charge du diabète. Toutefois, la réalisation de ces rapports de qualité soulève de nombreux problèmes pratiques, tels que la validité des données ou la capacité de certaines caisses d'assurance-maladie à s'acquitter de cette tâche.

Finalement, le développement d'une prise en charge plus large, basée sur des données probantes, doit être soutenu par la technologie de l'information. Celle-ci facilite la

communication entre les professionnels de la santé et permet de contrôler la qualité. Plusieurs pays développent un dossier médical électronique commun (notamment en Andalousie ou la carte de santé électronique en Allemagne). Au Royaume-Uni, la médecine générale utilise un système informatique qui permet une collecte centralisée des données destinée au contrôle de la qualité.

3.2 IDENTIFICATION DES CONDITIONS PREALABLES POUR UNE EVOLUTION VERS UNE PRISE EN CHARGE PLUS GLOBALE ET INTEGREE DU DIABETE, BASEE SUR DES DONNEES PROBANTES : ANALYSE DES PAYS SELECTIONNES

Deux éléments pourraient expliquer les différences dans l'organisation des soins du diabète : la mesure dans laquelle les changements visés ont déjà été mis en œuvre et les caractéristiques de l'organisation globale des soins de santé. Plusieurs conditions préalables aux niveaux « macro », « méso » et « micro » semblent importantes pour une mise en œuvre efficace de ces changements.

3.2.1 Conditions préalables au niveau macro

3.2.1.1 Une organisation des soins de santé qui favorise la prise en charge des maladies chroniques

L'organisation des soins de santé primaires exerce un impact évident sur l'organisation des soins du diabète. Il semble pertinent de distinguer les systèmes de santé par la manière dont ils essaient de trouver un équilibre entre la demande des patients et les besoins de santé publique. En Belgique, au Canada, en France et en Allemagne, la liberté de choix du patient individuel revêt traditionnellement la plus haute importance. Le Danemark, l'Estonie, les Pays-Bas, l'Espagne et le Royaume-Uni ont développé une organisation des soins de santé alternative basée sur des listes de patients, un rôle de "gatekeeping" pour le médecin généraliste (limitation de l'accès aux soins spécialisés) et des systèmes globaux de paiement des médecins. Dans ces pays, les équipes de première ligne sont plus souvent multidisciplinaires, fournissant un large éventail de compétences, nécessaires à la prise en charge des maladies chroniques. Les sessions d'éducation à la santé, les cliniques spécialisées en diabète, les registres du diabète et les systèmes d'appel/rappel sont fréquents. La Belgique, la France et l'Allemagne évoluent lentement dans la même direction avec l'introduction d'incitants financiers qui soulignent le rôle du médecin généraliste et des paiements forfaitaires partiels (en Belgique).

3.2.1.2 Un financement adéquat de la gestion des maladies chroniques

Coordonner les soins, s'assurer que la médecine générale a la capacité d'améliorer la pratique clinique et évaluer la qualité du traitement nécessite des ressources humaines et financières. Aux Pays-Bas, la chaîne de diagnostic-traitement du diabète finance les protocoles de soins partagés (« shared care protocols »): les paiements sont liés à la qualité des soins. Au Royaume-Uni, le « Quality and Outcomes Framework » comprend également des paiements basés sur la qualité, bien qu'ils ne soient pas liés à un protocole de soins partagés.

En Allemagne, le "Disease Management Programme" (programme de prise en charge des Maladies) englobe des recommandations de bonne pratique et des protocoles de soins partagés. Ce programme fournit des moyens financiers additionnels, principalement pour les caisses d'assurance-maladie et dans une moindre mesure pour les médecins. Il oblige les médecins à suivre le protocole grâce à une collecte précise d'information sur leur pratique mais ceci n'a pas d'effet sur leur paiement. Il sera intéressant d'analyser l'impact du modèle allemand de soins partagés sur la qualité des soins.

3.2.1.3 Support national pour le développement de systèmes de technologie de l'information

Les technologies de l'information utilisées par les différents professionnels et organisations de la santé doivent être compatibles afin de garantir une communication productive entre les prestataires de soins et une collecte optimale de données sur la qualité des soins. Ceci requiert des initiatives au niveau national.

3.2.1.4 Placer le diabète à l'ordre du jour national

Les changements dans l'organisation des soins du diabète trouvent souvent leur origine dans des initiatives locales. Il est très important que ces initiatives s'étendent au niveau national. Les associations de patients exercent généralement un impact significatif sur les politiques en matière de diabète – en particulier en collaboration avec les organisations des professionnels de la santé. Un coordinateur national ou un comité de pilotage national peut également jouer un rôle important en maintenant les soins du diabète dans l'agenda national.

3.2.1.5 Disponibilité de recommandations de bonne pratique acceptées au niveau national et régulièrement actualisées

Des recommandations de bonne pratique nationales actualisées restent la pierre angulaire d'une prise en charge optimale du diabète. Tous les acteurs doivent participer à l'élaboration des recommandations de bonne pratique afin d'assurer une mise en œuvre efficace.

3.2.1.6 Recherche en matière d'organisation de la prise en charge du diabète

Il existe actuellement un manque de données valables et fiables sur l'organisation de la prise en charge du diabète sur le terrain, à l'exception du Royaume-Uni (et des Pays-Bas dans une moindre mesure). Ces deux pays présentent également des modèles de prise en charge du diabète plus développés que dans la plupart des autres pays.

3.2.2 Condition préalable au niveau « méso »

3.2.2.1 Disponibilité de structures qui soutiennent, coordonnent et supervisent la prise en charge du diabète au niveau local.

Dans plusieurs pays, les structures au niveau « méso » sont importantes pour l'intégration horizontale des programmes de prise en charge des maladies chroniques au niveau local, comme par exemple les caisses d'assurance-maladie en Allemagne et aux Pays-Bas et les organisations de soins de santé primaires (Primary Care Organisations, PCO) au Royaume-Uni. Elles créent souvent un forum où les professionnels de la santé peuvent initier des protocoles de soins partagés et contrôler la qualité des soins. Au Royaume-Uni, les PCO disposent même d'une plus grande autonomie pour organiser la prise en charge du diabète : ils établissent des registres du diabète, organisent des formations à l'attention des professionnels de la santé, appuient la première ligne (par ex. en employant un diététicien, en organisant des systèmes d'appel / rappel, des bilans annuels, en mettant sur pied des programmes de contrôle pour la rétinopathie).

Ces structures au niveau « méso » peuvent jouer un rôle important dans la mise en œuvre des politiques en matière de santé. Leur force réside dans l'implication de tous les acteurs locaux. Les futures « Samenwerkingsinitiatieven Eerstelijnsgezondheidszorg» (initiatives de collaboration en soins de santé de première ligne) en Flandre pourraient assumer ce rôle, pour autant qu'elles soient correctement financées et gérées de manière professionnelle.

3.2.3 Conditions préalables au niveau « micro »

3.2.3.1 Disponibilité d'équipes multidisciplinaires où le médecin généraliste joue un rôle central.

La composition de l'équipe de médecine générale diffère entre et au sein des pays, depuis les pratiques isolées avec des collaborations informelles (par ex. avec des diététiciens et podologues) jusqu'aux équipes multidisciplinaires, impliquant des assistants et infirmiers attachés à un cabinet médical et parfois même des infirmiers spécialisés en diabétologie, des diététiciens et podologues. L'équipe de soins de santé secondaires se compose idéalement d'un diabétologue ou endocrinologue, d'un infirmier spécialisé en diabétologie, d'un diététicien et d'un podologue. La multidisciplinarité de l'équipe améliore la communication entre les prestataires de soins et la globalité de la prise en charge du diabète.

3.2.3.2 Implication des infirmiers dans les équipes multidisciplinaires

Des infirmiers sont de plus en plus souvent inclus dans les équipes de soins de santé primaires et secondaires. Leurs titres, qualifications et fonctions diffèrent d'un pays à l'autre bien que deux catégories principales se distinguent. Certains infirmiers bénéficiant d'une formation réduite en diabétologie travaillent généralement en médecine générale. Ils dispensent une éducation à la santé et réalisent les suivis cliniques (aux Pays-Bas, au Royaume-Uni, en Espagne en Estonie et – dans une moindre mesure – au Danemark). D'autres infirmiers disposent d'une formation post-graduée plus étendue (« infirmiers spécialisés en diabétologie »). Ils travaillent généralement dans les soins de santé secondaires mais sont parfois impliqués dans les soins de santé primaires. Leurs fonctions varient considérablement, de l'éducation à la santé exclusive au suivi clinique, formation du personnel, liens entre les soins de santé primaires et secondaires (en Belgique, au Canada, au Danemark, en Allemagne, aux Pays-Bas, en Espagne et au Royaume-Uni).

L'implication des infirmiers est cruciale pour dispenser au niveau individuel une éducation structurée en matière de santé. Ils peuvent soulager la charge de travail des médecins, en particulier dans les soins de santé primaires. Les infirmiers spécialisés en diabétologie et les infirmiers attachés à un cabinet médical ont été spécialement désignés comme une force des systèmes britannique et néerlandais, où ils assument davantage de responsabilités que dans d'autres pays.

3.2.3.3 Une éducation à la santé structurée

De nombreux experts et politiques nationales soulignent l'importance de l'éducation à la santé mais il est difficile de trouver des données permettant de définir dans quelle mesure celle-ci est réellement dispensée dans la pratique quotidienne. Plusieurs pays, dont l'Allemagne, ont développé des programmes d'éducation collective en matière de santé mais l'efficacité de ces programmes n'a pas encore été suffisamment évaluée.

4 CONCLUSIONS

Ce rapport répond à l'urgence de réfléchir à la prise en charge chronique d'une population croissante de patients diabétiques de type 2 qui engendre une augmentation des besoins et des dépenses en matière de soins de santé. L'épidémie croissante de diabète pousse les décideurs politiques en matière de santé à définir des objectifs clairs en vue de traiter de la manière la plus rentable cette maladie chronique et toutes ses conséquences.

Ce projet a analysé l'organisation et la qualité des soins du diabète à l'aide de trois approches complémentaires, à savoir la recherche d'indicateurs de qualité basés sur des données probantes, une analyse systématique de la littérature sur l'organisation des soins du diabète et une analyse de l'organisation des soins de santé dans des pays européens.

Le développement, le choix et l'usage judicieux des indicateurs de qualité sont importants pour contrôler la qualité des soins du diabète. Cette étude conclut que la définition des indicateurs diffère largement selon les auteurs. Ce travail a opté pour la définition d'un indicateur proposée par la référence anglaise « Measuring General Practice » (M. Marshall et al) : « a measurable element of practice performance for which there is evidence or consensus that it can be used to assess the quality of care provided, and hence change it » (un élément mesurable de la performance de la pratique pour laquelle il existe une preuve ou un consensus qu'elle peut être utilisée pour évaluer la qualité des soins dispensés, et par conséquent la changer). Dans ce projet, des recommandations de bonne pratique ont, dans un premier temps, été sélectionnées sur base de critères de qualité spécifiques, vu le nombre élevé de recommandations de bonne pratique trouvées dans la recherche exhaustive de littérature. Il est apparu que les indicateurs identifiés dans les recommandations de bonne pratique et dans les listes d'indicateurs faisaient généralement référence aux processus de soins et que seuls quelques-uns faisaient référence aux résultats (intermédiaires) de la prise en charge. Les principaux indicateurs sont cités dans la récente directive belge (WVVH, 2005): ils ont été validées par des essais cliniques majeurs comprenant différentes interventions (ex. UKPDS).

La recherche d'indicateurs de qualité basés sur des données probantes a soulevé plusieurs problèmes. Premièrement, le nombre élevé « d'indicateurs valables » (appuyés par des données probantes) implique l'établissement de priorités pour certains d'entre eux. Néanmoins, aucune donnée probante ne permet d'effectuer un choix. Les utilisateurs d'indicateurs potentiels (clinicians et autres personnes impliquées) doivent par conséquent garder l'esprit ouvert afin de sélectionner un nombre optimal d'indicateurs de qualité reflétant différents domaines des soins du diabète. Deuxièmement, des indicateurs importants au niveau « micro » (patient) sont particulièrement utiles lorsqu'ils peuvent être traduits aux niveaux « méso » (population d'une pratique/régional) et « macro » (politique nationale) comme par exemple les indicateurs relatifs aux complications du diabète. Il convient enfin de s'efforcer d'adapter en permanence les valeurs-cibles des indicateurs en fonction des derniers développements mentionnés dans les études scientifiques (ex : valeur-cible pour l'HbA1c, fréquence du contrôle de la microalbuminurie, …).

La première conclusion tirée de la revue de la littérature sur l'organisation des soins du diabète est que son efficacité n'est pas influencée par le contexte : les modèles basés sur l'hôpital et sur la médecine générale engendrent des résultats similaires au niveau du patient et des processus de soins. Les informations complémentaires extraites de l'étude européenne ont souligné le rôle essentiel du médecin généraliste dans la prise en charge des patients diabétiques de type 2 dans tous les pays. La seconde conclusion tirée de l'analyse de la littérature est que des programmes d'intervention unique sont moins efficaces que les interventions comprenant plusieurs approches, bien qu'aucune intervention ne se soit avérée plus efficace qu'une autre. L'importance des interventions comprenant plusieurs approches a effectivement été identifiée dans l'organisation de différents systèmes de soins de santé européens, avec l'introduction des protocoles de

soins partagés (« shared care protocols »), comme au Danemark, aux Pays-Bas, en Allemagne et au Royaume-Uni.

La revue de littérature a également analysé l'organisation des soins du diabète à l'aide des quatre composantes d'un modèle relatif au traitement chronique : l'aide à l'autogestion, les méthodes d'information clinique, la réorganisation des soins et l'aide à la décision. Les études qui comprennent tous les types d'intervention du modèle de prise en charge chronique montrent les meilleurs résultats au niveau du patient, alors que celles qui comprennent moins d'interventions s'avèrent efficaces aussi mais dans une moindre mesure. Aucune intervention du modèle de prise en charge chronique n'est apparue comme essentielle (ou superflue) à l'efficacité des soins du diabète.

La plupart des études montrent que le processus de soins est favorablement influencé par les quatre points susmentionnés.

- Le matériel d'aide à la décision (recommandations de bonne pratique et formation post-graduée) exerce un effet positif sur les résultats liés au processus en combinaison avec d'autres interventions telles que les processus de consensus local, les audits, les rappels, les feedbacks, les évaluations par les pairs ou les combinaisons de ces interventions. En pratique, l'étude européenne a confirmé une tendance vers les pratiques cliniques davantage basées sur des données probantes, vu que la plupart des pays européens ont élaboré des recommandations de bonne pratique. Leur diffusion et mise en œuvre varient selon les pays. Certains pays ont organisé des groupes d'évaluation médicale (notamment la Belgique, l'Allemagne). La formation médicale continue s'avère plus fréquente, parfois liée à un diplôme (Estonie, Allemagne). Le projet d'Audit National du Diabète (National Diabetes Audit) au Royaume-Uni est l'unique projet européen qui analyse la qualité des soins du diabète au niveau national.
- L'aide à l'autogestion (à savoir l'éducation des patients, l'aide au suivi, les rappels et les contrats de type comportemental) exerce également un impact sur le processus de soins. L'étude européenne a découvert que peu de pays ont organisé l'éducation des patients aux niveaux « méso » (régional) ou « macro » (politique nationale). Néanmoins, des programmes éducatifs sont disponibles (localement) dans la plupart des pays.
- La redéfinition du système d'organisation des soins représente la troisième intervention susceptible de modifier le processus des soins. Elle englobe des dispositifs de suivi intensif dont la mise en œuvre varie selon les études comme par exemple : des visites programmées, un enregistrement des patients par un système informatisé, des contacts réguliers avec des infirmiers, des appels téléphoniques pour reprogrammer les visites manquées. Le suivi est facilité par certaines initiatives, comme la mise en place de registres du diabète en médecine générale (Estonie et Royaume-Uni). Les systèmes de contact et de rappel existent également au Royaume-Uni et aux Pays-Bas.
- Le développement de systèmes d'information clinique (comme les systèmes de rappel informatisés) représente la quatrième intervention qui exerce un effet sur les résultats au niveau du processus de soins. Les experts européens nourrissent également de grands espoirs concernant le rôle de l'informatique pour faciliter la communication entre les prestataires de soins et le contrôle de qualité des soins du diabète. Néanmoins, l'analyse sur le terrain montre que le Royaume-Uni constitue le seul système européen bénéficiant d'un système de technologie de l'information commun à toutes les pratiques de médecine générale.

L'effet des quatre composantes décrites ci-dessus en termes de bénéfice pour le patient est moins explicite dans la littérature. Deux types d'interventions sont susceptibles d'exercer un impact favorable sur le résultat des soins, notamment les interventions au niveau du patient (décrites ci-dessus comme l'aide à l'autogestion) et la redéfinition des rôles des professionnels. En l'occurrence, l'implication des infirmiers dans les soins des patients diabétiques en collaboration avec d'autres prestataires de soins exerce fréquemment un impact positif sur les résultats au niveau du patient, en particulier en combinaison avec d'autres stratégies d'intervention. L'analyse des systèmes européens montre qu'il existe effectivement un rôle croissant des infirmiers spécialisés en diabétologie (« diabeteseducatoren » en Belgique). Néanmoins, il est difficile de tirer des conclusions définitives concernant leur place optimale, vu que leur formation et leur fonction varient largement selon les différents systèmes de soins de santé européens.

Il est indispensable de contrôler la qualité afin d'évaluer dans quelle mesure ces interventions exercent un effet au niveau des processus et au niveau du patient. Ce contrôle de qualité existe au Royaume-Uni, en Allemagne, aux Pays-Bas et au Danemark. En Belgique, il concerne uniquement les patients relevant de la convention diabète. La stratégie de recherche utilisée (à savoir principalement la littérature médicale) permet généralement de tirer des conclusions quant à l'efficacité relative au traitement du diabète mais aucune conclusion ne peut être tirée concernant l'accessibilité et le coût des différents modèles de prise en charge.

Les systèmes de soins de santé européens s'orientent actuellement vers une meilleure prise en charge des maladies chroniques et en particulier du diabète de type 2. Si la littérature montre des résultats thérapeutiques similaires en milieu hospitalier et en première ligne, les pays européens optent généralement pour cette seconde option : le médecin généraliste est défini comme le principal coordinateur des soins, en collaboration étroite avec une équipe multidisciplinaire. Les systèmes de soins de santé européens montrent que plusieurs conditions doivent être remplies à tous les niveaux pour obtenir une prise en charge optimale des patients diabétiques :

- Au niveau « macro » : une organisation globale des soins de santé qui favorise la gestion des maladies chroniques (comme au Royaume-Uni), notamment un financement adéquat, une aide nationale au développement de systèmes de technologie de l'information, un leadership national et une recherche dans le domaine de l'organisation des soins du diabète ;
- Au niveau « méso » : la disponibilité de structures qui soutiennent, coordonnent ou supervisent les soins du diabète au niveau local et l'implication de toutes les parties prenantes dans le développement des protocoles de soins partagés ;
- Au niveau « micro » : l'existence d'équipes multidisciplinaires et une éducation à la santé structurée.

Chaque condition mentionnée ci-dessus contribue à optimiser la prise en charge de la population de patients diabétiques de type 2. Leur mise en pratique nécessite d'être soigneusement étudiée dans le contexte du système de soins de santé belge.

5 RECOMMANDATIONS

Sur base de la présente littérature scientifique, le KCE formule les recommandations suivantes pour la qualité et l'organisation de la prise en charge des patients diabétiques de type 2 en Belgique :

- Le KCE recommande une nouvelle organisation des soins pour la population croissante de patients diabétiques de type 2. La prise en charge traditionnelle orientée vers les symptômes doit évoluer vers une prise en charge globale, proactive, centrée sur le patient et intégrée, comprenant l'éducation, le suivi systématique et la prévention secondaire ou tertiaire des complications.

- En particulier, le « patient empowerment » et le soutien de sa famille sont les pierres angulaires pour atteindre une amélioration objective des résultats chez le patient. Ceci implique que le patient adhère à certains critères de compliance en ce qui concerne le processus de soins, tels que la fréquence des visites, le changement du mode de vie et l'ouverture d'un dossier médical global (DMG). Des interventions synchronisées destinées à aider le patient sont nécessaires pour augmenter la probabilité de résultats significatifs (ex. suivi intensif, rappel, éducation du patient, éducation en groupe …). Ces initiatives pourraient bénéficier des structures existantes, telles que les associations belges du diabète.

- La seconde modification dans la prise en charge du patient réside dans l'évolution des soins dispensés par un seul médecin vers une action concertée au sein d'une équipe multidisciplinaire intégrée dans le système des soins de santé primaires. Ces équipes doivent bénéficier des réseaux préexistants, tels que les cercles, les groupes locaux d'évaluation médicale (Glems) ou les réseaux diabète afin d'éviter la multiplication des structures.

- Le KCE propose que le médecin généraliste du patient joue un rôle central dans la coordination des soins du diabète de type 2 et des comorbidités associées. Cette position suppose que la formation universitaire et continue des médecins généralistes fournisse les compétences nécessaires pour le suivi du traitement du diabète. La réorganisation des tâches au sein de l'équipe multidisciplinaire permettra aux autres prestataires de soins (par exemple les infirmiers spécialisés en diabétologie, les pharmaciens, les diététiciens) de contribuer à ce suivi complexe par le biais de leurs compétences propres. En l'occurrence, le rôle d'un éducateur pour le diabète est essentiel dans le contexte d'un traitement combinant diverses approches, depuis les conseils sur le mode de vie aux techniques de traitement par insuline. A court terme, la profession d'éducateur pour le diabète ("diabeteseducator") devra être officiellement définie et reconnue par la législation belge. La description du profil, de la formation, de la fonction et de la reconnaissance doit prendre en compte les initiatives actuelles qui existent déjà sur le terrain. Il convient également de prendre en considération les ressources humaines déjà disponibles, à la fois dans les soins ambulatoires et en institution. Les infirmiers et diététiciens exerçant dans des maisons de repos et institutions similaires, où la prévalence des patients diabétiques de type 2 continuera à augmenter, devraient être encouragés à se former et se préparer à la prise en charge des patients diabétiques.

- Il convient de définir le rôle explicite des spécialistes du diabète (endocrinologues-diabétologues). Il se concentrera de préférence sur l'encadrement et la formation de tous les membres de l'équipe

multidisciplinaire impliqués dans les soins des patients diabétiques de type 2. Il y a lieu de convenir de recommandations de bonne pratique explicites pour l'orientation d'un patient individuel vers le spécialiste. En l'occurrence, les patients complexes et les patients qui n'atteignent pas les objectifs thérapeutiques des indicateurs doivent être pris en charge à la fois par le médecin généraliste et le spécialiste.

- Le KCE se prononce en faveur du développement de protocoles de soins partagés au sein de l'équipe multidisciplinaire, comprenant entre autres la définition des rôles professionnels, la stratégie de communication et le contenu de la prise en charge clinique basé sur les données probantes les plus récentes. En Belgique ont été élaborées récemment des recommandations de qualité pour la pratique clinique, relatives aux soins des patients diabétiques de type 2 en médecine générale. Des efforts doivent assurer leur mise en œuvre effective par les médecins généralistes et doivent élargir leur champ d'action à d'autres prestataires de soins, en rapport avec des objectifs clairs.
- Le KCE recommande le développement de systèmes d'information clinique exhaustifs pour la prise en charge globale des patients diabétiques de type 2. Les réseaux d'information et de communication doivent être utilisés en vue d'un suivi optimal des patients, de la disponibilité d'informations basées sur des données probantes et d'une communication efficace entre les prestataires de soins dans et hors de l'équipe multidisciplinaire. L'accessibilité de la partie clinique du dossier médical électronique à tous les prestataires de soins impliqués est essentielle pour la prise en charge intégrée du patient.
- Le KCE recommande le développement de systèmes de contrôle de qualité pour mesurer le résultat des soins à l'aide d'indicateurs, de normes et de critères d'évaluation appropriés. Ce contrôle de qualité doit se concentrer à la fois sur les soins de santé primaires et secondaires. Il doit reposer sur l'expérience des systèmes de collecte de données existants [notamment via l'Initiative pour la Promotion de la Qualité et Epidémiologie du Diabète sucré (IPQED) et via l'Agence Intermutualiste]. Ce projet de recherche fournit une série d'indicateurs de qualité basés sur des données probantes qui pourront être utilisés dans un système de contrôle de qualité. La définition des cibles et spécifications au niveau national requiert des discussions et l'implication de toutes les parties concernées (notamment les prestataires de soins et les acteurs de santé publique). Ce système de contrôle de qualité est essentiel pour évaluer l'effet des interventions multiples recommandées dans le cadre du présent projet. Il permettra d'identifier les domaines cliniques ou géographiques nécessitant une amélioration et, ultérieurement, de surveiller les actions entreprises.
- Les réformes futures doivent prendre en compte la prise en charge partagée en soins de santé primaires et le rôle central du médecin généraliste pour le diabète de type 2. L'actuelle convention diabète encourage clairement l'orientation des patients diabétiques de type 2 traités par insuline vers les soins spécialisés dans les hôpitaux, en vue notamment d'obtenir le remboursement des tigettes pour mesurer la glycémie. Vu l'augmentation estimée du nombre de patients diabétiques à un niveau épidémique, ces services seront inondés et sur-sollicités, alors que leur principale préoccupation devrait se concentrer sur les patients diabétiques de type 1, sur les soins de santé de seconde ligne et le traitement des complications ainsi que sur les patients diabétiques de type 2 qui nécessitent un schéma complexe d'insulinothérapie. Les patients diabétiques de type 2 qui ne présentent pas de complications majeures et ne nécessitent pas de schéma complexe d'insulinothérapie devraient accéder à l'aide dont ils ont besoin (éducation, matériel) au niveau des soins de santé primaires, pour autant que ce type de prise

en charge partagée réponde à certains critères d'organisation et de qualité.

L'ensemble de ces initiatives nécessite une politique nationale cohérente pour appuyer et coordonner les interventions. Actuellement, de nombreuses initiatives intéressantes existent pour améliorer les soins du diabète. Ces projets disséminés devraient être remplacés par des initiatives nationales qui s'inspirent des projets existants locaux/régionaux. Une plate-forme de communication centrale et les organisations de diabète existantes doivent s'harmoniser en une action concertée pour assurer une mise en œuvre efficace des interventions aux niveaux régional, local et au niveau du patient. L'aide financière doit prendre en considération les exigences minimales de l'organisation des soins et leurs résultats . A court terme, une aide est requise pour mettre sur pied des équipes dont les activités diffèrent du système de paiement traditionnel des honoraires à l'acte (notamment éducation collective, technologie de l'information, conseils sur le mode de vie par un éducateur pour le diabète). La définition du profil de la tâche est une condition préalable à ce financement. Il pourrait en outre être associé ultérieurement à des incitants liés à des résultats spécifiques évalués par le système de contrôle de qualité.

Ces conclusions et recommandations correspondent à celles de l'Union européenne (Diabetes, the policy puzzle: towards benchmarking in the EU 25). Leurs recommandations formulées pour le niveau national comprennent la nécessité d'élaborer des politiques nationales, des systèmes de collecte de données, des objectifs mesurables et des systèmes d'évaluation, une approche globale pour la gestion du traitement du diabète et des investissements dans la formation spécifique de tous les prestataires de soins.

Les recommandations du KCE relatives à la prise en charge du diabète s'appliquent à celle d'autres maladies chroniques, isolées ou comorbidités du diabète. Le rôle coordinateur du médecin généraliste dans le contexte d'une équipe multidisciplinaire en collaboration avec des spécialistes, le « patient empowerment », les systèmes d'information clinique et un contrôle de qualité donneront naissance à la prise en charge globale et intégrée des cas complexes de patients atteints de maladies chroniques.

INTRODUCTION

This study aims to analyse the literature on the quality and organisation of diabetes care in order to formulate recommendations for the Belgian health care system. Diabetes mellitus, especially type 2, is a disease with a growing impact on society and health care expenditure. Type 2 diabetes treatment involves many players and the organisation of care is a challenge, taking into account the limited health care resources. This study was performed by a consortium of endocrinologists-diabetologists and general practitioners from four Belgian universities in collaboration with the Flemish Diabetes Association (VDV).

This scientific report is structured according to the three main research questions:

1. What are the quality indicators of diabetes care as described in referenced literature and international guidelines? (chapter one)
2. What are the effects of different care models on health and non-health related outcomes of care? (chapter two)
3. How is diabetes care organised in 9 western countries? (chapter three)

The focus of this project is type 2 diabetes, considering its growing social impact. Several points deserve further attention. The organisation of care was analysed at the micro, meso and macro levels using the three following definitions. The micro level of care is the level of care where the individual interaction between the patient and the health care provider takes place (= patient level). The meso level is the level of care where different regional health care organisations or interdisciplinary platforms are working together (= practice level and/or regional level). The macro level of care is the level of care where policy makers, insurance companies, professional organisations, teachers and researchers meet (policy level).

Scientific summary

Table of contents

Chapter 1: Quality indicators (process and outcome) for diabetes care (type 2 diabetes mellitus): Literature analysis

1 INTRODUCTION

This part of the study contains the description and results of the literature search and analysis concerning (process and outcome) quality indicators for type 2 diabetes mellitus care, as published in existing guidelines since 1993.

The following limitations was applied to the literature search:

- Guidelines published since 1993. This year coincides with the publication of the DCCT (Diabetes Control and Complications Trial), the year where important changes in the diabetes care were introduced.
- Limited to guidelines concerning Western countries. The guidelines and their conclusions have to be relevant in view of the Belgian Healthcare System.
- Guidelines primarily from scientific guideline providers and major (diabetes) organisations, including those from Belgium and the 8 scope countries (Canada, Denmark, Estonia, France, Germany, Spain, The Netherlands, and UK). These studies were selected for the comparison study described in part 3.

2 MATRIX FOR DIABETES CARE QUALITY INDICATORS

In order to classify and provide a clear overview of potential quality indicators, the working group decided to put them into a predefined matrix (see appendix part 1.1). While the rows of this matrix would represent different diabetes topics (such as e.g. cardiovascular risk assessment, diabetic foot), the columns would reflect upon the severity of the diabetes problem, based on different treatment schedules (e.g. patients treated with life style interventions alone or also receiving oral antidiabetic drugs). However, it became clear during the project that the selected guidelines often failed to allow the potential indicators to be classified into this matrix. Especially classifying them according to disease severity (proposed columns of the matrix) was often impossible. For this reason the working group decided to abandon this matrix structure, as it would only result into a very arbitrary classification of the indicators.

The potential indicators were therefore classified in a more practical way, following several steps:

- inventory of all potential quality indicators
- "redistribution" of the (resulting) indicators over 5 major diabetes topics (at the appropriate level of care):
    - control of glycaemia,
    - early detection of glycemic complications (hypoglycaemia, hyperglycaemia, retinopathy, nephropathy, feet problems),
    - treatment of glycaemic complications,
    - cardiovascular disease (macrovascular: AMI, stroke, ...)
    - quality of life
- assignment of appropriate target values or further indicators specifications to these quality indicators.

3 PHASES IN THE LITERATURE ANALYSIS

The literature analysis was performed in five phases.

First phase: definition of the research question according to the 'PICO' principle[1].

PICO is an abbreviation or acronym that means: P: population or patient, I: intervention or indicator, C: comparison or control and O: outcome. PICO is a framework to translate the defined problem or practical question into a good answerable research question. This is the first basic need to a successful search and it allows finding sources of directly usable and relevant data which offer a rational and well founded answer to the research question.

Second phase: explanation of the search strategy.

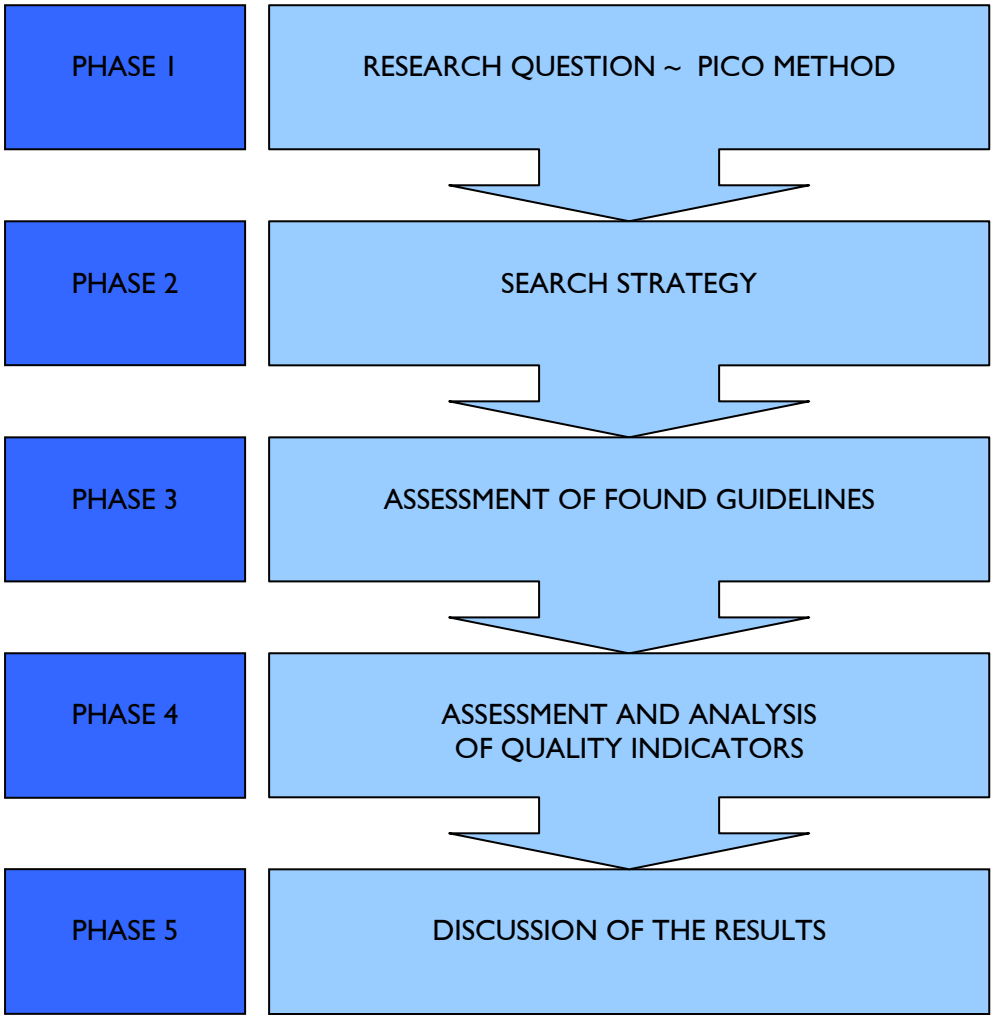
Third phase: assessment and evaluation of the resulting guidelines on their scientific quality and their relevance for answering the proposed research question (by two independently scoring researchers/reviewers), including documenting reasons for not including guidelines.

Fourth phase: assessment and analysis of the quality indicators found within the selected guidelines. During this phase the quality indicators were inventoried, situated and redistributed at the appropriate level of care and received specific target values (outcome indicators) or further indicator specifications (process indicators).

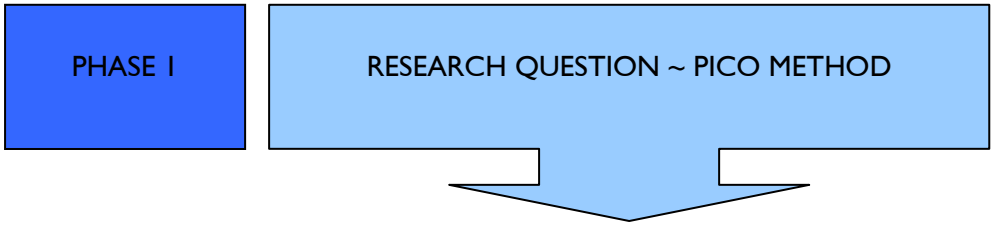
Fifth phase: description and discussion of the results.

The different phases of the literature analysis are graphically presented below.

[1] Van den Bruel A, Chevalier P, Vermeire E, Aertgeerts B, Buntinx F. EBM: otitis media in children: how to formulate a PICO question. Rev Med Liège 2004; 59: 671-5



3.1 PHASE 1: RESEARCH QUESTION ACCORDING TO THE 'PICO' PRINCIPLE



The research question is constructed according to the PICO principle.

P Participant/population

I Intervention

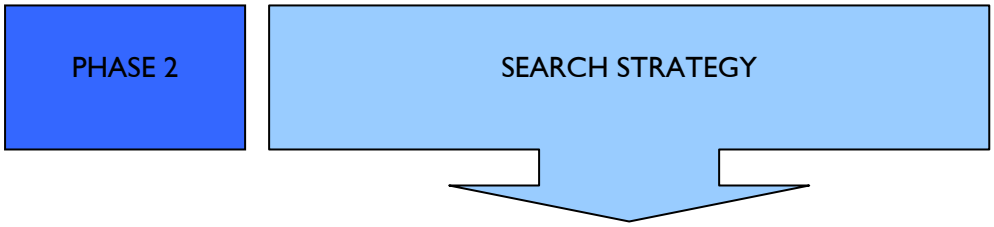
C Comparaison

O Outcome

Research question

With relation to type 2 diabetes mellitus patients (=P), which indicators have been described in existing guidelines, published since 1993 (=I/C), to evaluate the quality of care (process and outcome) (O)?

3.2 PHASE 2: SEARCH STRATEGY



3.2.1 Background: definitions of quality and quality indicators

As no universal definitions of "quality" or "quality indicator" are available, the project working group decided to adopt the definitions mentioned in the book "Measuring General Practice" (© The Nuffield Trust, 2003 – ISBN 1-8330-3425-1: http://www.npcrdc.man.ac.uk/Publications/MGP_book.pdf). This project refers to the quality of care of patients in general practice. This is the report of a demonstration project to develop and test a set of primary care clinical quality indicators. It has been commissioned as part of a collaboration between the Nuffield Trust, London (UK), one of the largest independent health policy charitable trusts in the UK (http://www.nuffieldtrust.org.uk/) and the RAND Corporation, Santa Monica, California (USA), a non-profit research organisation providing objective analysis and effective solutions that address the challenges facing the public and private sectors around the world (www.rand.org). The project itself was conducted in partnership with the National Primary Care Research and Development Centre (NPCRDC), based at the University of Manchester in the UK.

Diabetes type 2 patients are frequently treated in the first line of care (see chapter 3). The definitions proposed by the authors of the project mentioned above were therefore chosen for the present research.

*** Definitions**

Quality of care	There is no universal definition of this concept. Often it is described in terms of different dimensions of care, e.g. accessibility, effectiveness... (for an operational definition of quality of care, see part 2, "results of the search")
Guideline	Systematically developed statement to help practitioners and patients make decisions in specific clinical circumstances; in essence the "right thing to do".
Indicator	A measurable element of practice performance for which there is evidence or consensus that it can be used to assess the quality of care provided, and hence change it.
Quality Indicator	An indicator inferring a judgement about the quality of care being provided.

Although the literature provides several options to further define indicators, the working group decided to make the following distinction only:

- **Process** indicators ("who does what when and how often?"): a quality indication on the process or intervention delivering diabetes care
- **Outcome** indicators ("which interventions should deliver which results?"):
  a quality indication on the outcome of a process or intervention of diabetes care

This distinction aimed at avoiding possible misunderstandings or interpretations (as an illustration, terms like "primary" or "secondary" indicators might unintentionally give the impression of assigning importance amongst indicators).

3.2.2 Search strategy for guidelines on type 2 diabetes care

The project working group listed major guideline finders and (diabetes) organisations in collaboration with KCE after internal consultation and discussion. The composition of the working group (university GPs and diabetologists) allowed an optimal coverage of all potential sources.

The entries "diabetes" and/or "diabetes mellitus" and/or "diabetes type 2" and/or "diabetes care" were combined into the following major guideline finders:

- Guideline International Network, GIN (international initiative) - http://www.g-i-n.net/index.cfm?fuseaction=homepage
- National Guideline Clearinghouse (USA) - http://www.guideline.gov/
- National Health Service (NHS) guideline finder (UK) - http://libraries.nelh.nhs.uk/guidelinesFinder/

And into the medical search engines:

- SumSearch - http://sumsearch.uthscsa.edu/
- TRIP Database - http://www.tripdatabase.com/

The following sites of major (diabetes) organisations were consulted as well:

- WHO (http://www.who.int/topics/diabetes_mellitus/en/)
- International diabetes organisations
    - American Diabetes Association, ADA (http://www.diabetes.org/home.jsp), (USA)
    - European Association for the Study of Diabetes, EASD (http://212.144.4.93/easd/) (international initiative)
    - International Diabetes Federation, IDF (http://www.idf.org/home/) (international non-governmental organisation in official relations with the World Health Organisation and the Pan American Health Organisation)
    - Federation of European Nurses in Diabetes, FEND (http://www.fend.org/) (international initiative)
    - Primary Care Diabetes EUROPE, PCDEurope (http://www.pcdeurope.org/en/home.htm) (international initiative)

Finally, websites of important (diabetes) organisations within Belgium and the 8 scope countries (Canada, Denmark, Estonia, France, Germany, Spain, The Netherlands, and the UK) were also screened. If not found or referred to on the above mentioned websites, these links were searched for in general search engines such as www.google.be, by using the above mentioned entries (also including "guideline", "recommendation" etc) combined with the country's name.

3.2.3 Assessment and selection of the guidelines

The guidelines were assessed independently by two researchers, KD and JW. A first screening of the title and short description of the guideline allowed guidelines without relevance towards answering (part of) the research question (including relevance towards the Belgian Healthcare System) to be rejected (e.g. guidelines concerning the classification of diabetes). The investigators focused afterwards on two criteria, elements of the Appraisal of Guidelines Research and Evaluation (AGREE) instrument from the AGREE Collaboration (http://www.agreecollaboration.org/), to select guidelines:

- rigour of development (used methodology and the use of levels of evidence)
- clear presentation of the guideline

Major criteria to select guidelines were (1) the scientific value of the guidelines (including content, quality assessment and level of evidence) and (2) the relevance towards answering (part of) the research question (including relevance towards the Belgian Healthcare System). Other or more specific reason(s) for rejection were recorded as well.

3.2.4 Search for quality indicators on type 2 diabetes care

Based on the definition of a quality indicator, the selected guidelines were screened for potential process and outcome quality indicators.

To prevent bias, no further additional information on quality and/or quality indicators for diabetes care were looked up, implemented or used during this search.

3.2.5 Assessment of the quality indicators

The potential quality indicators found in the guidelines were assessed independently by two researchers, KD and JW.

During this phase the indicators were inventoried, situated and redistributed at the appropriate level of care and got assigned specific target values (outcome indicators) or further indicator specifications (process indicators), the latter being more detailed explanations of the exact process or intervention at hand, as defined within each of the different guideline texts.

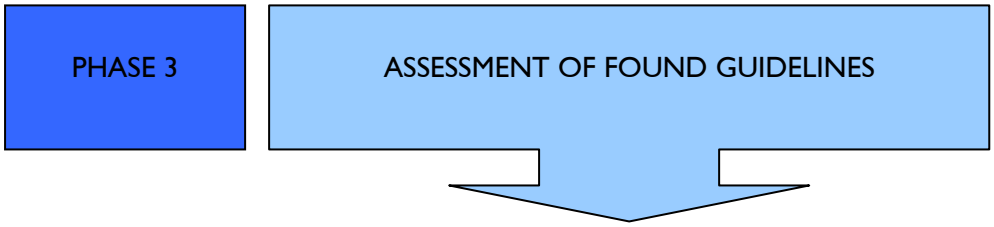
The inventory of indicators was furthermore compared with already available lists of quality indicators on diabetes care, to check whether any major indicator of care had been missed. The list was also made by the GPs, diabetologists and KCE researchers from the working group. After internal consultation and discussion the following websites were selected:

- the Organisation for Economic Co-operation and development (OECD) - health technical paper N 15 :"Selecting Indicators for the Quality of Diabetes Care at the Health Systems Level in OECD Countries" http://www.oecd.org/dataoecd/28/34/33865546.pdf
- the National Quality Measures Clearinghouse http://www.qualitymeasures.ahrq.gov/
- the Diabetes Quality Improvement Project (DQIP), under the sponsorship of a coalition of public and private entities (the American Diabetes Association, Foundation for Accountability, Health Care Financing Administration, National Committee for Quality Assurance), and joined by the American Academy of Family Physicians, American

College of Physicians, and Veterans Administration (USA) http://journal.diabetes.org/diabetesspectrum/00v13n1/pg5.htm

- Assessing Care of Vulnerable Elders (ACOVE), a RAND Health (independent private non-profit organisation) and Pfizer collaboration http://www.rand.org/health/tools/acpvedocs/table_indicators.pdf
- Institute for Clinical Systems Improvement, ICSI http://www.icsi.org/knowledge/detail.asp?catID=29&itemID=182
- International Diabetes Federation http://www.idf.org/webdata/docs/International%20standards.pdf
- Oxford Centre health outcomes http://nchod.uhce.ox.ac.uk/diabetes.pdf
- NHS FP clinical indicators http://nchod.uhce.ox.ac.uk/diabetes.pdf
- Prestatie-indicatoren RIVM https://webcollect.rivm.nl/deverbetermeter/index.htm
- links to QI websites by the German Quality Institute http://www.aezq.de/qualitaetsindikatoren/0index/3links/view

3.3 PHASE 3: RESULT OF THE GUIDELINES ASSESSMENT



The two investigators selected 176 diabetes guidelines. After a thorough screening using the AGREE elements mentioned before, the investigators held back 104 guidelines (59.1%) to search for potential (process and outcome) quality indicators (the details of this selection are in the appendix part 1.2).

Of the 104 accepted guidelines, 18 presented levels of evidence within the guideline text (17.3%). As no universal definition for "Levels of Evidence" was used, the definitions of the "levels of evidence" used by each of these 18 guidelines, were recorded as well to illustrate the scientific evidence each potential indicator is based on.

The levels of evidence used in the different guidelines are presented in appendix part 1.3.

3.4 PHASE 4: RESULT OF THE ASSESSMENT AND ANALYSIS OF THE QUALITY INDICATORS

3.4.1 Inventory

The two investigators identified 64 potential quality indicators (in appendix part 1.4). The comparison of these 64 indicators with those found within the pre-mentioned available lists did not result in any indicator having to be added to this list. The list presented in appendix still reflects the original matrix structure because it was only

decided later on in the project to abandon the predefined matrix as a classification system.

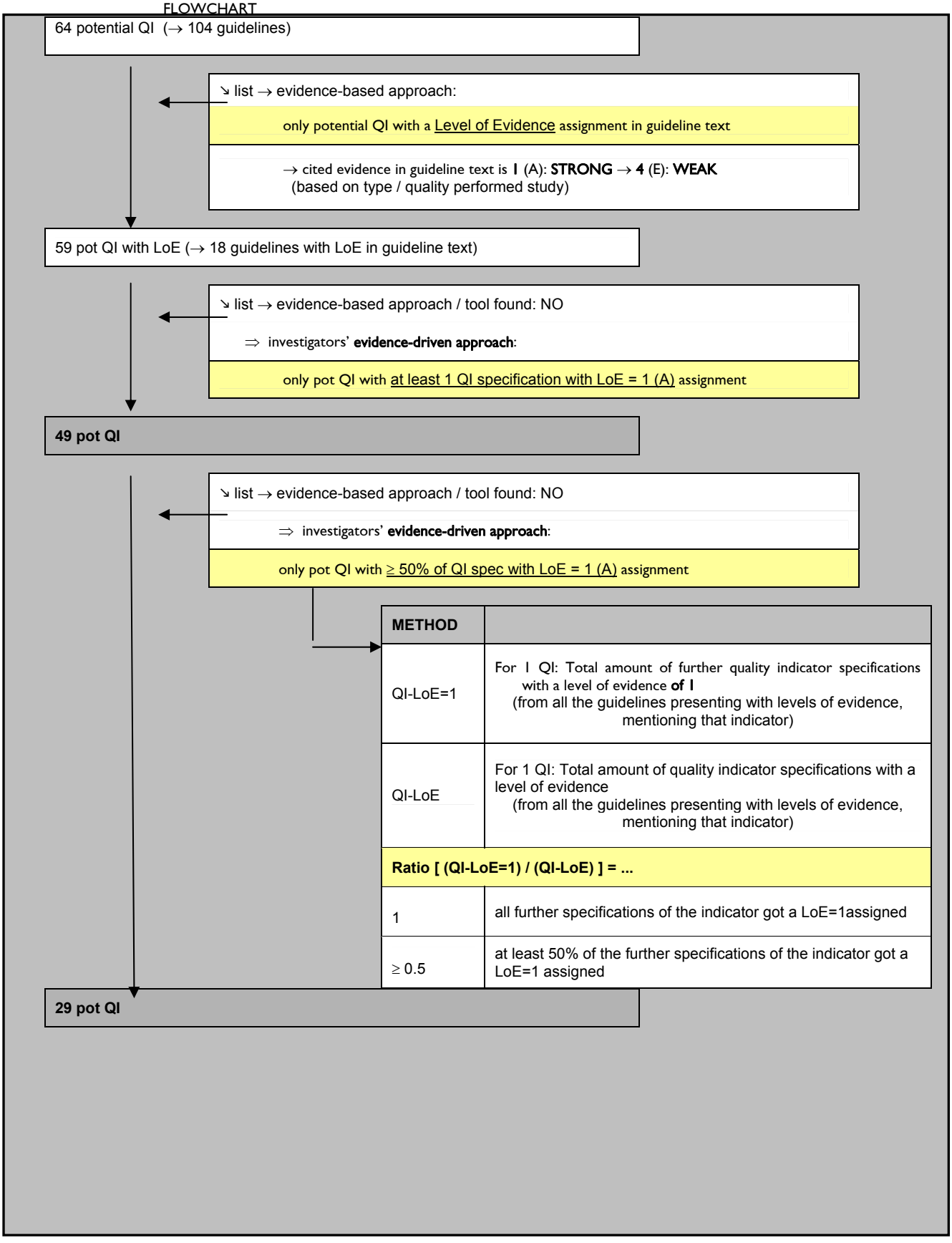
The appendix part 1.4 also specifies for each potential quality indicator (1) in how many of the guidelines it was mentioned, and (2) how many further specifications (= further detailed explanations of the indicator) were given (if given). The last two columns of this table present these data when only the 18 guidelines that specifically mentioned levels of evidence within their texts, were considered.

After internal consultation and discussion the project working group decided to "transform" the original list of 64 potential quality indicators into a list with evidence-based indicators only. The investigators therefore retained all potential indicators which had no level of evidence whatever assigned to them within the guidelines. This resulted in a list of 59 potential quality indicators. The investigators selected those with at least one further specification with a level of evidence of 1 or the equivalent A ("best evidence"). Following this procedure the list decreased to 49 potential quality indicators.

One could present this list of 49 indicators and leave to the indicator user (e.g. the care providers) to choice to select an optimal quality indicator set for his or her individual patient. However, this "pick-and-choose" random method would undoubtedly lead to non arbitrary and non comparable sets of indicators, hampering e.g. more generalised quality control.

The working group therefore decided go one step further, by reducing this list of 49 to a more workable list for the health care professional in the field. The flowchart on the following page presents all steps taken to reduce the list of evidence-based indicators. The resulting list of **29 potential indicators** is presented in the table thereafter. An illustration of the entire process can be found in appendix part 1.5 (using the first quality indicator of the resulting list of 29 as an example).

FLOWCHART



METHOD	
QI-LoE=1	For 1 QI: Total amount of further quality indicator specifications with a level of evidence **of 1** (from all the guidelines presenting with levels of evidence, mentioning that indicator)
QI-LoE	For 1 QI: Total amount of quality indicator specifications with a level of evidence (from all the guidelines presenting with levels of evidence, mentioning that indicator)
Ratio [(QI-LoE=1) / (QI-LoE)] = ...	
1	all further specifications of the indicator got a LoE=1assigned
≥ 0.5	at least 50% of the further specifications of the indicator got a LoE=1 assigned

Resulting 29 potential quality indicators.

#	Potential Quality Indicators	P / O	[QI-LoE=1 / QI-LoE] ratio
1	Patients should have a target HbA1c concentration	O	0,60
2	Patients should have a regular measurement of their HbA1c concentration	P	0,50
3	Patients should have (at least) annual disease review	P	0,75
4	Patients should receive lifestyle advice	P	0,69
5	Patients should receive regular lifestyle control / assessment	P	1,00
6	Patients should receive smoke cessation counselling	P	0,58
7	Patients' smoking status should be monitored	P	0,50
8	Patients who don't reach their target HbA1c under optimal OAD mono-treatment, should receive OAD combination therapy	P	0,53
9	Patients who don't reach their target HbA1c under optimal OAD combination therapy, should receive (combined OAD and) insulin treatment	P	0,75
10	Efforts to avoid severe hypoglycaemia should be made	P	0,50
11	Patients who don't reach their target HbA1c under optimal OAD combination therapy, should receive (combined OAD and) insulin treatment	P	0,52
12	Insulin therapy should be considered in certain circumstances	P	1,00
13	Patients on insulin therapy should receive education on blood glucose monitoring and self-management	P	0,50
14	Patients should have a target blood pressure	O	0,60
15	Patients with hypertension should receive appropriate antihypertensive treatment	P	0,60
16	Patients should have a regular screening for cardiovascular risk factors and disease (+/- risk classification)	P	0,57
17	patients with certain cardiovascular risk should receive appropriate (medical) treatment	P	0,71
18	Patients with cardiovascular disease should be on lipid lowering therapy	P	0,89
19	Patients should receive intensive insulin treatment following an acute MI	P	0,67
20	Long term treatment should be considered after an AMI (such as beta-blocking agents, ACE-I, lipid lowering drugs, and anticoagulation therapy)	P	0,82
21	Patients with CVD should receive appropriate treatment	P	0,86
22	Patients with (at least) microalbuminuria should receive appropriate medical treatment	P	0,59
23	Patients should have an eye risk (factor) classification	O	0,67
24	Patients with diabetic retinopathy should receive appropriate treatment (depending on eye risk - problem: conservative treatment, laser coagulation, vitrectomy, cataract extraction)	P	0,56
25	Patients should have a regular diabetic foot exam (interval depending on foot risk/problem)	P	0,57
26	Patients should receive foot care education	P	0,55
27	Patients with diabetic foot / Charcot foot should receive appropriate treatment (pressure release, revascularisation, antibiotics, resection of necrotic tissue, amputation, „,)	P	0,67
28	Health care professionals should be aware of potential effects of life events on stress and self-care behaviour	P	1,00
29	Patients should receive diabetes education on an ongoing basis	P	0,67

If one would consider ranking this list for importance, one could consider a strictly evidence-based approach, such as a ranking according to the proposed ratio [(QI-LoE=1 / QI-LoE) ≥ 50%]. However this does not reflect the indirect, not evidence-based

importance attributed by the selected guidelines to them (e.g. how often they mentioned or further specified these potential indicators). As such the investigators decided NOT to rank these 29 potential indicators for importance.

Different procedures can be used for the ranking of indicators using levels of evidence. The interested reader will find two examples in appendix part 1.6.

3.4.2 Redistribution at the appropriate level of care

The following definitions were adopted and used throughout the study:

- Micro level of care: level of care where the individual relationship between the patient and his/her health care provider takes place (= patient level)
- Meso level of care: level of care where different regional health care organisations or interdisciplinary platforms are working together (=practice level and/or regional level)
- Macro level of care: level of care where policy makers, insurancy companies, professional organisations, teachers and researchers meet (policy level)

As such the adopted definition of indicator (as described in chapter 3.2.1) only complies with the **micro level of care**. At this micro level of care the 29 potential indicators were regarded in view of 5 major aspects of diabetes and diabetes care selected by the working group. Each potential indicator was assigned to the most suitable aspect by the 2 investigators, KD and JW:

1. control of glycaemia,
2. early detection of glycaemic complications (hypoglycaemia, hyperglycaemias, retinopathy, nephropathy, feet problems),
3. treatment of glycaemic complications,
4. cardiovascular disease (macrovascular: AMI, stroke, ...)
5. quality of life

This resulted in the following "distribution" of the 29 potential indicators (see the table below), generating 5 workable "mini-lists":

1. control of glycaemia: 9 potential indicators
2. early detection of glycaemic complications: 2 potential indicators
3. treatment of glycaemic complications: 7 potential indicators
4. cardiovascular disease: 10 potential indicators
5. quality of life: 1 potential indicator

Aspect	#	Potential Quality Indicator	P / O
1	1	Patients should have a target HbA1c concentration	O
	2	Patients should have a regular measurement of their HbA1c concentration	P
	3	Patients should receive lifestyle advice	P
	4	Patients should receive diabetes education on an ongoing basis	P
	5	Efforts to avoid severe hypoglycaemia should be made	P
	6	Patients should have (at least) annual disease review	P
	7	Patients on insulin therapy should receive education on blood glucose monitoring and self-management	P
	8	Patients should receive regular lifestyle control / assessment	P
	9	Insulin therapy should be considered in certain circumstances	P
2	1	Patients should have a regular diabetic foot exam (interval depending on foot risk/problem)	P
	2	Patients should have an eye risk (factor) classification	O
3	1	Patients with (at least) microalbuminuria should receive appropriate medical treatment	P
	2	Patients who don't reach their target HbA1c under non-pharmacological treatment, should receive OAD mono-therapy	P
	3	Patients who don't reach their target HbA1c under optimal OAD combination therapy, should receive (combined OAD and) insulin treatment	P
	4	Patients with diabetic retinopathy should receive appropriate treatment (depending on eye risk - problem: conservative treatment, laser coagulation, vitrectomy, cataract extraction)	P
	5	Patients should receive foot care education	P
	6	Patients with diabetic foot / Charcot foot should receive appropriate treatment (pressure release, revascularisation, antibiotics, resection of necrotic tissue, amputation, ,,,)	P
	7	Patients who don't reach their target HbA1c under optimal OAD mono-treatment, should receive OAD combination therapy	P
4	1	Patients should have a target blood pressure	O
	2	Patients should receive smoke cessation counselling	P
	3	Patients with hypertension should receive appropriate antihypertensive treatment	P
	4	Patients should have a regular screening for cardiovascular risk factors and disease (+/- risk classification)	P
	5	patients with certain cardiovascular risk should receive appropriate (medical) treatment	P
	6	Patients with CVD should receive appropriate treatment	P
	7	Patients should receive intensive insulin treatment following an acute MI	P
	8	Long term treatment should be considered after an AMI (such as beta-blocking agents, ACE-I, lipid lowering drugs, and anticoagulation therapy)	P
	9	Patients with cardiovascular disease should be on lipid lowering therapy	P
	10	Patients' smoking status should be monitored	P
5	1	Health care professionals should be aware of potential effects of life events on stress and self-care behaviour	P

It is important to clear which views are being represented (different stakeholders have different perspectives of quality of care and although one is not more valid than another, this should be clarified). However, as indicators can only be used at the micro level of care, two supplementary concepts were introduced i.e., "**standard**" and "**(review) criterion**" (also adopted from the book "Measuring General Practice" from

The Nuffield Trust; 2003 as described in chapter 3.2.1). As a result, the indicators can be operationalised at the meso and the macro level.

At the meso level:

Standard	The level of compliance with a criterion or indicator. A target standard is set prospectively and stipulates a level of care that providers must strive to meet. An achieved standard is measured retrospectively and details whether a care provider met a pre-determined standard

At the macro level:

(review) Criterion3	Systematically developed statement relating to a single act of medical care that is so clearly defined it is possible to say whether the element of care occurred or not retrospectively in order to assess the appropriateness of specific health care decisions, services and outcomes

Example of a "translation" from an indicator into a standard and a criterion:

Patients should have a target HbA1c concentration		
Micro level (patient)	indicator	Patients should have a HbA1c < 7.0% [2]
meso level (practice / region)	standard	x % of the patients in a practice should have a HbA1c < 7.0%
macro level (policy)	(review) criterion	If a patient's HbA1c was > 7.0%, was appropriate action undertaken?

[2] Guideline HbA1c value originates from:
- UKPDS study : diabetes 2 patients, aged 25-65 years
- DCCT study : diabetes 1 patients, aged 13-40 years

3.4.3 Values and specifications

Marshall et al.[3] stated that the use of indicator sets developed in another country allows using equivalent measures in both countries with the possibility to carry out international comparisons. However, the direct transfer of indicators (and consequently the potential quality standards and (review) criteria) between countries with different health systems, clinical practices and cultures is not always possible. It requires an intermediate step of adaptation/modification (see also chapters 2 and 3).

In this project, the list of indicators was therefore completed with the target values (~ outcome indicators) and further specifications (~ process indicators) found within the Belgian guidelines in order to get the highest relevance for the Belgian situation (see the table below). By translating the potential indicators (and their target values or specifications) into standards and (review) criteria, the table might be translated towards the meso- and macro level as well.

However, it must be acknowledged that even these Belgian target values have severe limitations. They rely on European guidelines based either on the UKPDS study (population of 25-65 year-old diabetic 2 patients) and/or on the Diabetes Control and Complication Trial (population of diabetic 1 patients aged 13-40 years). The target values of HBA1c proposed by the Belgian (and international) guidelines are therefore not supported by solid evidence for the growing population of elderly diabetic 2 patients.

[3] M N Marshall, P G Shekelle, E A McGlynn, S Campbell, R H Brook and M O Roland. Can health care quality indicators be transferred between countries? Qual. Saf. Health Care 2003;12;8-12

Aspect	#	Topics	P / O	Guide line	Target values / Specifications
I	1	Patients should have a target HbA1c concentration	O	Be-WvvH-VDV	target HbA1c < 7.0% [4]
				Be-SSMG	target HbA1c < 7.0% - acceptable if 7-8.5%
	2	Patients should have a regular measurement of their HbA1c concentration	P	Not specifically mentioned within Belgian guidelines	
	3	Patients should receive lifestyle advice	P	Be-WvvH-VDV	lifestyle advice ~ balanced nutrition/diet, physical exercise… (linked together in the management plan)
				Be-SSMG	dietary advice, ongoing education, regular physical exercise, smoking cessation, weight control
	4	Patients should receive diabetes education on an ongoing basis	P	Be-WvvH-VDV	structured and purposive education by well trained educators to increase self-management of patients while they're trying to achieve their own goals (patient empowerment)
				Be-SSMG	ongoing education
	5	Efforts to avoid severe hypoglycaemia should be made	P	Be-WvvH-VDV	Efforts to avoid severe hypoglycaemia should be made (management + education patient)
	6	Patients should have (at least) annual disease review	P	Be-WvvH-VDV	3-monthly to yearly control (control topics ~ diabetes pass)
				Be-SSMG	3-monthly consultation with GP: history, follow-up, clinical exam, additional exam, continued education
					annual disease review, including evalution of risk factors and complications
	7	Patients on insulin therapy should receive education on blood glucose monitoring and self-management	P	Be-WvvH-VDV	self-monitoring of blood glucose: intensively at start up and regularly during therapy
	8	Patients should receive regular lifestyle control / assessment	P	Not specifically mentioned within Belgian guidelines	
	9	Insulin therapy should be considered in certain circumstances	P	Be-WvvH-VDV	very high fasting hyperglycaemia (> 300mg/dl) that doesn't respond to lifestyle management, child wish/pregnancy, contraindications for OAD

[4] Guideline HbA1c values originate from:
- UKPDS study : diabetes 2 patients, aged 25-65 years
- DCCT study : diabetes 1 patients, aged 13-40 years

Aspect	#	Topics	P / O	Guide line	Target values / Specifications
2	1	Patients should have a regular diabetic foot exam (interval depending on foot risk/problem)	P	Be-WvvH-VDV	3 monthly to yearly systematic and pro-active screening for feet at risk by inspection, palpation and monofilament examination
	2	Patients should have an eye risk (factor) classification	O	Be-WvvH-VDV	non-proliferative retinopathy (mild, moderate, severe), proliferative retinopathy, maculopathy
3	1	Patients with (at least) microalbuminuria should receive appropriate medical treatment	P	Be-WvvH-VDV	hypertensive and microbalbuminuria: ACE-I (alternative: angiotensin-II antagonists)
				Be-SSMG	microalbuminuria: ACE-I therapy
	2	Patients who don't reach their target HbA1c under non-pharmacological treatment, should receive OAD mono-therapy	P	Be-WvvH-VDV	metformin: first treatment option in overweight patients
					metformin: first treatment option unless contraindicated
					good alternatives for metformin: sulphonylurea, glinides
				Be-SSMG	start mono OAD therapy if fasting glucose concentration > 126mg/dl or postprandial glycaemia > 162mg/dl or glyHg >= 7% after 2-4 months of lifestyle interventions
					metformin: first treatment option in overweight patients (BMI > 25)
					short acting sulphonamide ~ less often hypoglycaemia than other sulphonamides
	3	Patients who don't reach their target HbA1c under optimal OAD combination therapy, should receive (combined OAD and) insulin treatment	P	Be-WvvH-VDV	if combined therapy with 2 OAD doesn't work, don't add a third OAD but start up insulin therapy (+/- OAD)
				Be-SSMG	combined OAD and insulin treatment > insulin mono therapy
	4	Patients with diabetic retinopathy should receive appropriate treatment (depending on eye risk - problem: conservative treatment, laser coagulation, vitrectomy, cataract extraction)	P	Not specifically mentioned within Belgian guidelines	
	5	Patients should receive foot care education	P	Be-WvvH-VDV	on ongoing basis with content of care and review interval depending on foot risk
				Be-SSMG	appropriate foot care education

Aspect	#	Topics	P / O	Guide line	Target values / Specifications
	6	Patients with diabetic foot / Charcot foot should receive appropriate treatment (pressure release, revascularisation, antibiotics, resection of necrotic tissue, amputation, „,)	P	Be-WvvH-VDV	foot risk class 2b (and higher): timely referral to a diabetes foot clinic for thorough evaluation
					active foot problems (eg ulcus, infection): consider as serious problems with therefore urgent referral
					severe orthopaedic malformations and/or ulcus: refer to a multidisciplinary foot team
				Be-SSMG	appropriate treatment
	7	Patients who don't reach their target HbA1c under optimal OAD mono-treatment, should receive OAD combination therapy	P	Be-WvvH-VDV	in case of combination therapy: combine OAD with different working mechanism
				Be-SSMG	Patients who don't reach their target HbA1c under optimal OAD mono-treatment, should receive OAD combination therapy
					in case of combination therapy: combine OAD with different working mechanism (combining 2 drugs of the same class does not provide any additional benefit)
4	1	Patients should have a target blood pressure	O	Be-WvvH-VDV	target BP <130/80 mmHg, in case of nephropathy < 125/75 mmHg
				Be-SSMG	target BP <140/85mmHg
	2	Patients should receive smoke cessation counselling	P	Be-WvvH-VDV	smoking cessation counselling
				Be-SSMG	smoking cessation counselling
	3	Patients with hypertension should receive appropriate antihypertensive treatment	P	Be-WvvH-VDV	Lifestyle management of raised BP should be given a good trial before beginning lipid lowering drugs: dietary management with moderateness in salt and alcohol intake, weight reduction, physical exercise, smoke cessation
					if target BP not reached under lifestyle management: pharmacological therapy -> ACE-I (recommended first choice in case of microalbuminuria, alternative: angiotensin-II receptor antagonist), diuretics, b-blockers, Ca-antagonists in mono- or combination therapy

Aspect	#	Topics	P / O	Guide line	Target values / Specifications
				Be-SSMG	BP control is more important than the drug used to reach the target values (ACE-I or b-blocker)
					combination therapy will often be needed to reach target BP values
					if microalbuminuria is present, first BP treatment option = ACE-I
	4	Patients should have a regular screening for cardiovascular risk factors and disease (+/- risk classification)	P	Not specifically mentioned within Belgian guidelines	
	5	patients with certain cardiovascular risk should receive appropriate (medical) treatment	P	Be-WvvH-VDV	all patients should be protected against CVD: smoke cessation, blood pressure control, statine therapy - especially if microalbuminuria is detected, when in doubt: cardiovascular risk assessment might help
	6	Patients with CVD should receive appropriate treatment	P	Be-WvvH-VDV	secondary prevention of CVD: aspirin 75-100mg/day recommended (unless contraindicated)
				Be-SSMG	ischemic heart disease and hyperchol: statine therapy
	7	Patients should receive intensive insulin treatment following an acute MI	P	Not specifically mentioned within Belgian guidelines	
	8	Long term treatment should be considered after an AMI (such as beta-blocking agents, ACE-I, lipid lowering drugs, and anticoagulation therapy)	P	Not specifically mentioned within Belgian guidelines	
	9	Patients with cardiovascular disease should be on lipid lowering therapy	P	Be-WvvH-VDV	hyper-LDL-C: statins recommended (target value probably < 70 mg/dl instead of < 100mg/dl)
	10	Patients' smoking status should be monitored	P	Not specifically mentioned within Belgian guidelines	
5	1	Health care professionals should be aware of potential effects of life events on stress and self-care behaviour	P	Be-WvvH-VDV	awareness and/or treatment for psycho-social problems, including sexual problems

Legend

Aspect	Five major diabetes aspects identified by the project working group i.e. : control of glycemia ; early detection of glycaemic complications (hypoglycaemia, hyperglycaemia, retinopathy, nephropathy, feet problems); treatment of glycaemic complications; cardiovascular disease (macrovascular: AMI, stroke...);quality of life
#	Number of potential quality indicators assigned to each aspect
Potential indicator	Main description of the potential quality indicator
P / O	Process or Outcome quality indicator
Guideline	Origin of the (Belgian) guideline: WvvH-VDV: Wetenschappelijke Vereniging van Vlaamse Huisartsen – Vlaamse Diabetes Vereniging SSMG: Société Scientifique de Médecine Générale
Target values	Target value as found within the respective (Belgian) guideline (assigned to potential quality outcome indicator)
Specifications	Specifications of the potential quality process indicator as found within the respective (Belgian) guideline

3.5 PHASE 5: DISCUSSION OF THE RESULTS

With relation to type 2 diabetes mellitus patients (=P), which indicators have been described in existing guidelines, published since 1993 (=I/C), to evaluate the quality of care (process and outcome) (O)?

There is no "universal" definition of an "indicator" within the international literature. To avoid misunderstandings and misconceptions concerning the meaning of and behind the word, one clear definition was adopted and applied throughout the study. Furthermore one clear definition offers the possibility for future comparisons -within or between studies- in a more standardised way.

Two major searches were performed in order to answer the research question. First, guidelines on diabetes care were searched within the national and international literature; secondly, the selected guidelines were searched for potential quality indicators of diabetes care. Both searches produced questions that were answered (whenever possible) within the study period.

3.5.1 Search for and assessment of guidelines

While searching for guidelines, it soon became clear that they derived from different sources: (local) authorities, scientific societies, patient organisations... Although all evidence-based, they sometimes did reflect on different views or highlighted different topics within diabetes care.

This variety and the lack of uniformity amongst them (structure, levels of evidence...) made it often difficult to assess (and/or evaluate or compare) them on their scientific quality. As such, the investigators not only selected those guidelines presenting levels of evidence but also those guidelines with a profound methodology and a clear presentation of the data (elements of the AGREE instrument), enabling them to assess their relevance in answering (part of) the proposed research question.

3.5.2 Search for and assessment of potential quality indicators.

The investigators searched for evidence-based indicators and this has important implications.

"Evidence-based indicators" implies that the indicators themselves have a level of evidence assigned to them (within the guideline texts). Although all guidelines were based on scientific evidence, only within a few of them levels of evidence were specifically assigned to potential indicators. The investigators nevertheless first reported on all potential indicators found within all selected guidelines, regardless of the presence of evidence levels.

Secondly, searching for evidence-based indicators also limited the search to the level of current available scientific evidence. This implies that further work might be required to test and understand the scientific properties of these indicators in order to maximise their use in quality improvement and their application in performance management. This implies the need for regular literature updates.

Furthermore the evidence-based approach delivered rigorous and scientifically acceptable indicators, but one has to keep in mind that what is regarded as good quality care for instance in general practice does not always (and sometimes never will) have experimental evidence to support it. Furthermore the applicability of evidence derived

from scientific trials on selected populations to individual patients might be questioned. The latter may be (partly) overcome by including expert opinion as this facilitates quality improvement because a broader range of aspects of care can be assessed and/or improved than if restricted to scientific evidence alone.

As the investigators followed a disease-focused approach, it should also be accounted for that other important aspects of care were not addressed in this document (such as access to care, inter-personal care, the relationship between primary care and other (health) services, patient experience of care, the organisation and delivery of services and their cost effectiveness, needs (and demands) of individual patients and those of the practice or local community as a whole, the difference between professional led quality improvement and managerially led quality assessment). As such this otherwise complex issue (for example qualitative aspects) might be over-simplified. Therefore this document can not be considered as a stand-alone document and must be read in conjunction with chapters 2 and 3.

All potential quality indicators were inventoried. Far more potential process then outcome indicators were listed. As this might (partly) be due to the way the potential indicators were formulated (semantics), and as to meet this, it was tried to formulate them –whenever possible and/or applicable- as a process as well as an outcome indicator.

Because no evidence-based tool was available (found) for a strictly evidence-based approach to narrow down the list of 64 potential indicators towards a list with only the most evidence-based indicators, the investigators opted for a personal evidence-driven approach. This approach offered easy manageable tools to reduce an otherwise long list of potential indicators, by reviewing all indicators in the same and at least evidence-driven way. Especially introducing the ratio [(QI-LoE=1 / QI-LoE) ≥ 50%] was a helpful tool for reduction. Of course other approaches might be possible as well.

The investigators did not rank the remaining indicators for importance, as no clear-cut evidence-based tool was found to assist with this matter. Nevertheless two exercises were performed to try to reconcile evidence-based (or –driven) data and the not evidence-based ("appreciation-based") importance guidelines (for which their makers gave an importance for example by mentioning them frequently or further specifying these potential indicators within their texts). The two proposed rankings are not validated and remain questionable. However they do reflect the presently available evidence and important guidelines for specific topics within diabetes care. At the same time the attempt for ranking shows how carefully these data should be handled and reviewed upon.

Again it has to be stated that reducing the list of evidence-based potential indicators does not imply to forget about potential indicators that (at present) are not or never will be supported by scientific evidence.

At the micro level the remaining 29 potential indicators were regarded in view of 5 major aspects within diabetes and diabetes care. Each indicator was assigned to the most appropriate one of the 5 aspects by the two main investigators. Although this implied (not validated) simplification of a complex issue, it also allowed the creation and use of "mini lists" of potential indicators. Such mini lists may make it more feasible or manageable for the individual health care professional to address the specific quality of care required for the individual patient with a specific diabetes care problem. This "distribution" resulted in 9 potential indicators relating to control of glycaemia, 2 potential indicators relating to early detection of "glycaemic" complications (hypoglycaemia, hyperglycaemia, retinopathy, nephropathy, feet problems), 7 potential indicators relating to the treatment of glycaemic complications, 10 potential indicators relating to cardiovascular disease (macrovascular: AMI, stroke...) and one potential indicator specifically relating to quality of life.

The adopted definition of "indicator" can not be applied at the meso and macro level, hence the introduction of "standard" and "(review) criterion" of diabetes care. This allows the indicators to be "translated" (operationalised) onto another level of care and might help to end discussions like "which indicators are important at which level and with which impact?"

While some indicators might be very important at the micro level, their translation (into standards or criteria) might not be so important at the meso and/or macro level and vice versa. Although this "translation" does not fit within the scope of this work (evidence-based indicators) it might be very important towards policy recommendations, if surrounded by the appropriate and essential preconditions (see chapters 2 and 3), as those recommendations are often made for use on the meso and/or macro level.

In a last step an attempt was made to assign the appropriate target values to the potential outcome indicators and the appropriate further specifications to the potential process indicators at the micro level. This was a difficult task, as the international guidelines suggest different target values and indicator specifications with sometimes different (or even lack of) levels of evidence. The target values and indicator specifications of the Belgian guidelines were therefore assigned to the 29 potential indicators. This was done in light of the findings from Marshall et al.[5], stating that direct transfer of indicators (and consequently the potential quality standards and (review) criteria) between countries is not always possible without an intermediate step of adaptation/modification, requiring additional information such as essential preconditions that might allow indicators, and especially standards and (review) criteria, to be implemented within a certain health care setting (at micro, meso or macro level for that matter).

As such the 29 potential indicators values and specifications have the highest relevance for the Belgian Health care system. However their applicability to the whole population of diabetic 2 patients is restricted by the limited number of studies on which the diabetes guidelines are based and by the fact that the age at inclusion in these studies was equal to maximum 65 years. The strong point of these studies, however, is their long term follow-up, thus allowing extrapolating conclusions in the elderly. Moreover, empty spaces in the resulting table of quality indicators reflect missing or insufficient level-1 rated evidence for the adult population. A proposition to fill these empty spaces is the use of the (level-1 rated) target values and indicator specifications from the other guidelines mentioning the 29 potential indicators (if available). However this can not be done without at least considering/consulting the chapters 2 and 3: these will probably assist with the possibly necessary adaptation/modification of these target values / specifications towards the Belgian Healthcare system (e.g. by addressing necessary preconditions at a Belgian level to allow the indicators as such to be implemented within the present Belgian healthcare system).

Furthermore one should keep in mind that sometimes it might even be more important to address the fact that action should be taken if there is an indication of poor care, rather than to speculate on the most appropriate target value/ specification of the proposed indicator itself (for example if differences in indicator specification from different guidelines exist).

Again the same exercise, with more or less the same remarks and proposed suggestions as above, may be made at the meso and macro level, after translation of the indicators into appropriate standards and (review) criteria.

[5] M N Marshall, P G Shekelle, E A McGlynn, S Campbell, R H Brook and M O Roland. Can health care quality indicators be transferred between countries? Qual. Saf. Health Care 2003;12;8-12

4 QUALITY INDICATORS - CONCLUSIONS

Guidelines from Belgium and 8 scope countries (Canada, Denmark, Estonia, France, Germany, Spain, The Netherlands, and the UK) were searched for potential process and outcome indicators on diabetes care. This resulted in a list of 29 at least 50% level-1 evidence-based potential indicators.

At the micro (patient) level these indicators were "redistributed" so that they covered 5 important fields within diabetes care:

- control of glycaemia: 9 potential indicators;
- early detection of glycaemic complications (hypoglycaemia, hyperglycaemia, retinopathy, nephropathy, feet problems): 2 potential indicators;
- treatment of glycaemic complications: 7 potential indicators;
- cardiovascular disease (macrovascular: AMI, stroke, ...): 10 potential indicators;
- quality of life: 1 potential indicator.

At the same micro level, specific target values and indicator specifications derived – whenever present- from the 2 Belgian guidelines, were assigned to these 29 potential indicators.

At the meso and the macro level "standards" and "(review) criteria" of diabetes care were introduced in an attempt to operationalise the indicators at these levels.

As such the resulting lists of indicators, standards and criteria (each with their own appropriate and essential preconditions) would not only reflect on quality of diabetes care, but also on the actions / preconditions necessary to provide quality of diabetes care at the micro (patient), as well as the meso (practice/population) and the macro (policy) level.

Chapter 2: Care Models for type 2 diabetes mellitus patients: a literature review

5 METHODOLOGY OF THE SYSTEMATIC LITERATURE REVIEW

The second part of the study contains the description and the results of a literature search concerning diabetes care models in Europe, US, New Zealand and Australia as published since 1993.

5.1 LIMITS TO THE ANALYSIS OF LITERATURE

The following limits for the literature analysis were defined as follows:

- Literature published since 1993: this year coincides with the publication of the DCCT, the year where important changes in the diabetes care were introduced.
- Limited to the literature relevant for Western countries. The literature and its conclusions have to be relevant for the Belgian Healthcare System.
- Literature primarily from indexed journals: literature from primary care and peer-reviewed journals were analysed. Books and (international/national) reports were also considered.

Note: a specific analysis of literature on the *cost-effectiveness* of the different care models was not included.

5.2 PHASES OF THE LITERATURE REVIEW

The literature review was built up in five phases:

- In the **first phase** the research question according to the 'PICO' principle was defined.
- In a **second phase** the search strategy was presented and searches were linked with the different parts of the PICO research question.
- In a **third phase** the different methodological terms (Mesh & Emtree) were combined and the results visualised. Full text copies of all potentially relevant studies, determined by reviewing the abstract, were obtained. For each part, the studies were reviewed by two independent reviewers.
- In **the fourth phase** the relevant articles were analysed.
- In the **fifth phase** the results of the literature analysis were described and discussed.

Systematic Reviews, Meta-analyses, Randomised Controlled Trials (RCT), Cohort Studies, Control Clinical Trials (CCT), Case Series, Case Reports, Editorials got the first priority.

The papers were searched in journals, books, reports and selected theses.

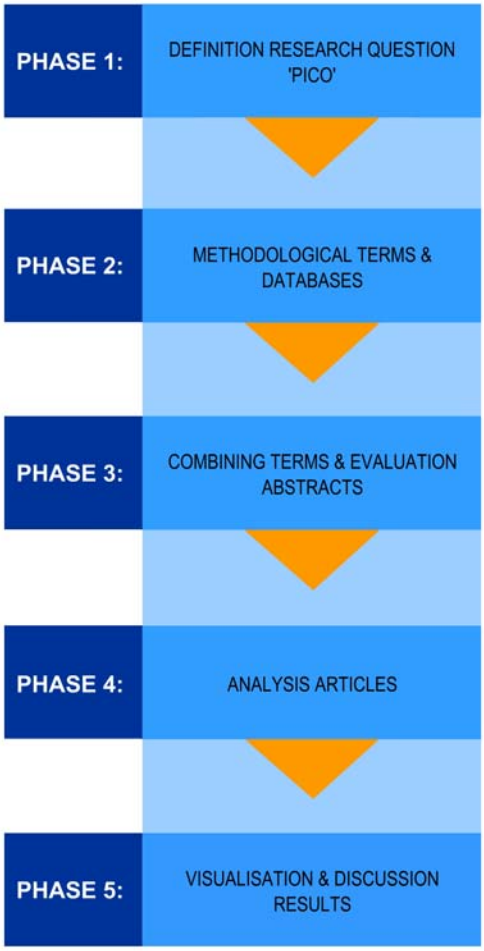
- DIMENSION diabetes care:
  - Reviewed (index)journals
  - Non-reviewed journals
  - Books
  - National reports
  - International reports

- Thesis

Other literature not related to diabetes care models *(dimension general)* was searched and analysed to the extent it was useful for the later literature analysis. It concerned a complementary literature analysis.

- DIMENSION general:
  - Indexed journals
  - Non-indexed journals
  - Books
  - National reports
  - International reports
  - Theses

PHASES LITERATURE REVIEW



6 THE LITERATURE ANALYSIS

6.1 DEFINITION OF THE RESEARCH QUESTION ACCORDING TO THE PICO PRINCIPLE

Research question:

What are the effects of the different care models (= I/C) on health and non-health related outcomes (= O) within type 2 diabetes mellitus patients (=P)?

This research question was built up according to 'PICO' principle:

P Participant/population

I Intervention

C Comparison

O Outcome

6.2 SEARCH STRATEGY

The Mesh and Emtree methodological terms were combined with the different parts of the research question (PICO). The mesh terms were used in Medline as well as in Cochrane. Identical methodological terms for mesh terms were looked-up for the search in Embase (Emtree terms).

P (Participant/population): Type 2 diabetes mellitus patients

Both patients with type 2 diabetes mellitus and health care professionals (including physicians, nurses, pharmacists…) belonged to the participants (P). The same methodological terms were used in the different care models.

The severity of the pathology was considered and made operational as:

- the use of food/diet descriptions, oral anti-diabetic medication and insulin (on daily frequency);
- the presence of diabetes related complications;
- the presence of morbidity.

Methodological terms (Mesh/Emtree terms):

- **Medline/Cochrane:** ***Diabetes mellitus***: heterogeneous group of disorders characterised by HYPERGLYCAEMIA and GLUCOSE INTOLERANCE. **Embase:** ***Diabetes mellitus***
- **Medline/Cochrane:** ***Diabetes mellitus type 2***: a subclass of DIABETES MELLITUS that is not INSULIN-responsive or dependent (NIDDM). It is characterised initially by INSULIN RESISTANCE and HYPERINSULINEMIA; and eventually by GLUCOSE INTOLERANCE; HYPERGLYCAEMIA; and overt diabetes. Type II diabetes mellitus is no

longer considered exclusively as an adult disease. Patients seldom develop KETOSIS but often exhibit OBESITY. **Embase:** ***Diabetes mellitus non insulin dependent***

- **Medline/Cochrane:** ***Patient care team:*** care of patients by a multidisciplinary team usually organised under the leadership of a physician; each member of the team has specific responsibilities and the whole team contributes to the care of the patient.

I (Intervention): Structure and process characteristics

Every intervention was classified according to structure and process characteristics for every care model presented. Every characteristic has two sub dimensions, including;

- the presence of structure and process characteristics,
- the frequency of the structure and process characteristics.

Methodological terms (Mesh/Emtree terms):

- **Medline/Cochrane:** ***Patient care planning:*** usually a written medical and nursing care program designed for a particular patient. **Embase:** ***Patient care***
- **Medline/Cochrane:** ***Patient care management:*** generating, planning, organising, and administering medical and nursing care and services for patients. **Embase:** ***Patient care***
- **Medline/Cochrane:** ***Continuity of patient care:*** Health care provided on a continuing basis from the initial contact, following the patient through all phases of medical care. **Embase:** ***Continuity of care***
- **Medline/Cochrane:** ***Patient- centred care:*** design of patient care wherein institutional resources and personnel are organised around patients rather than around specialised departments. **Embase: -**
- **Medline/Cochrane:** ***Primary health care:*** care which provides integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. (JAMA 1995;273(3):192). **Embase:** ***Primary health care***
- **Medline/Cochrane:** ***Self care:*** performance of activities or tasks traditionally performed by professional health care providers. The concept includes care of oneself or one's family and friends. **Embase: -**
- **Medline/Cochrane:** ***Long- term care:*** care over an extended period, usually for a chronic condition or disability, requiring periodic, intermittent, or continuous care. **Embase:** ***Long term care***
- **Medline/Cochrane:** ***Family practice:*** a medical specialty concerned with the provision of continuing, comprehensive primary health care for the entire family. **Embase:** ***General practice***
- **Medline/Cochrane:** ***Ambulatory care:*** health care services provided to patients on an ambulatory basis, rather than by admission to a hospital or other health care facility. The services may be a part of a hospital, augmenting its inpatient services, or may be provided at a free-standing facility. **Embase:** ***Ambulatory care***
- **Medline/Cochrane:** ***Ambulatory care facilities:*** those facilities which administer health services to individuals who do not require hospitalisation or institutionalisation. **Embase:** ***Ambulatory care***
- **Medline/Cochrane:** ***Hospitals:*** institutions with an organised medical staff which provide medical care to patients. **Embase:** ***Hospital care***

- **Medline/Cochrane:** ***Delivery of health care, integrated:*** a health care system which combines physicians, hospitals, and other medical services with a health plan to provide the complete spectrum of medical care for its customers. In a fully integrated system, the three key elements - physicians, hospital, and health plan membership - are in balance in terms of matching medical resources with the needs of purchasers and patients. (Coddington et al., Integrated Health Care: Reorganising the Physician, Hospital and Health Plan Relationship, 1994, p7). **Embase:** ***Health care delivery***
- **Medline/Cochrane:** ***Organisation:*** administration and functional structures for the purpose of collectively systematising activities for a particular goal. **Embase:** ***Health care organisation, managed care organisation***
- **Medline/Cochrane:** ***Models, organisational:*** theoretical representations and constructs that describe or explain the structure and hierarchy of relationships and interactions within or between formal organisational entities or informal social groups.
- **Medline/Cochrane:** ***Comprehensive health care:*** providing for the full range of personal health services for diagnosis, treatment, follow-up and rehabilitation of patients. **Embase:** ***Health care***
- **Medline/Cochrane:** ***Managed care programme:*** health insurance plans intended to reduce unnecessary health care costs through a variety of mechanisms, including: economic incentives for physicians and patients to select less costly forms of care; programs for reviewing the medical necessity of specific services; increased beneficiary cost sharing; controls on inpatient admissions and lengths of stay; the establishment of cost-sharing incentives for outpatient surgery; selective contracting with health care providers; and the intensive management of high-cost health care cases. The programs may be provided in a variety of settings, such as health maintenance organisations and preferred provider organisations. **Embase:** ***Health care organisation, managed care organisation***
- **Medline/Cochrane:** ***Disease management:*** a broad approach to appropriate coordination of the entire disease treatment process that often involves shifting away from more expensive inpatient and acute care to areas such as preventive medicine, patient counselling and education, and outpatient care. This concept includes implications of appropriate versus inappropriate therapy on the overall cost and clinical outcome of a particular disease. (From Hosp Pharm 1995 Jul;30(7):596). **Embase:** ***Disease management***
- **Medline/Cochrane:** ***Chronic disease:*** diseases which have one or more of the following characteristics: they are permanent, leave residual disability, are caused by no reversible pathological alteration, require special training of the patient for rehabilitation, or may be expected to require a long period of supervision, observation, or care. **Embase: -**
- **Medline/Cochrane:** ***Case management:*** a traditional term for all the activities which a physician or other health care professional normally performs to insure the coordination of the medical services required by a patient. It also, when used in connection with managed care, covers all the activities of evaluating the patient, planning treatment, referral, and follow-up so that care is continuous and comprehensive and payment for the care is obtained. (From Slee & Slee, Health Care Terms, 2nd ed). **Embase:** ***Patient care***
- **Medline/Cochrane:** ***Community health centres:*** facilities which administer the delivery of health care services to people living in a community or neighbourhood. **Embase: -**

- **Medline/Cochrane:** ***Community health planning:*** planning that has the goals of improving health, improving accessibility to health services, and promoting efficiency in the provision of services and resources on a comprehensive basis for a whole community. (From Facts on File Dictionary of Health Care Management, 1988, p299). **Embase: -**

O (Outcome): Health outcome measures

Health outcome measures are objectively measured health professional performance/process outcomes (measurements of blood pressure, blood glucose, HbA1c, cholesterol,..), patients outcomes (glycaemic control, hospital admission, mortality, …) in a clinical setting and self report measures (quality of life, well-being, patient satisfaction) with known validity and reliability.

Methodological terms (Mesh/Emtree terms):

- **Medline/Cochrane:** ***Quality indicator, health care:*** norms, criteria, standards, and other direct qualitative and quantitative measures used in determining the quality of health care. **Embase: -**
- **Medline/Cochrane:** ***Treatment outcome:*** evaluation undertaken to assess the results or consequences of management and procedures used in combating disease in order to determine the efficacy, effectiveness, safety, practicability, etc., of these interventions in individual cases or series. **Embase: -**
- **Medline/Cochrane:** ***Patient satisfaction:*** the degree to which the individual regards the health care service or product or the manner in which it is delivered by the provider as useful, effective, or beneficial.
- **Medline/Cochrane:** ***Health service research:*** the integration of epidemiologic, sociological, economic, and other analytic sciences in the study of health services. Health services research is usually concerned with relationships between need, demand, supply, use, and outcome of health services. The aim of the research is evaluation, particularly in terms of structure, process, output, and outcome. (From Last, Dictionary of Epidemiology, 2d ed). **Embase:** ***Health care organisation***

The following databases were searched:

Pubmed

Includes Medline, PreMedline and smaller data bases. Medline exists since 1966 and includes 4500 journals with 11 million articles. 65% of the RCT's are found with Medline. It is recommended to use limits and the 'waterfall' principle. http://www.pubmed.be/

EMBASE

Embase is the European dependant of Medline. It exists since 1988 and includes 3500 journals.

Cochrane Online

The Cochrane library is specialised in up-to-date information on the effects of interventions in health care. The Cochrane contains different databases on 'Evidence – Based – Medicine' e.g. The Cochrane Database of Systematic Reviews (Cochrane Reviews) and the Database of Abstracts of Reviews of Effects (DARE). http://www.cochrane.org/

CINAHL en PRE CINALH

CINAHL® is a specialised database: the 'Cumulative Index to Nursing and Allied Health Literature' and contains literature on nursing and health care starting from 1982. To be consulted from: http://bib.kuleuven.be/mgas/index.htm and https://www.cinahl.com/library/library.htm

Libis Online

Direct access through http://opac.libis.be

6.3 RESULTS OF THE SEARCH AND ANALYSIS OF THE ARTICLES

The different methodological terms (Mesh & Emtree) were combined. Full text copies of all potentially relevant studies, determined by reviewing the abstract, were obtained. For each part, studies were assessed for inclusion independently by two reviewers. Any discrepancies between reviewers were resolved by discussion. Below is a description of the results from several databases (Pubmed, Embase and Cochrane)

- Pubmed

Results: 1063 articles

Hold back articles: 331 articles

- EMBASE

Results: 515 articles

Hold back articles: 142 articles

- Cochrane Online

Results: 187 articles

Hold back articles: 85 articles

- CINAHL en PRE CINALH

Results: 130 articles

- Libis Online

Results: 9 books diabetes mellitus

The investigators made a systematic review of organisation models for diabetic care with a special focus on organisational quality criteria and the actually used quality indicators for organisational efficiency. The investigators expected that one of the final recommendations would relate to the care-context which had proven the highest efficiency in relation to the severity of type 2 diabetes mellitus and to the impact on the health status of the patient. This review was therefore based on articles retrieved in international peer reviewed journals.

Fifty-four (54) articles were selected because of the quality of their research design and their relevance for the project. The total number of studies consisted of forty-two (42) randomised controlled trials, nine (9) controlled before and after studies, one (1) non equivalent control group design, one (1) pre/post quasi experimental design and one (1) non experimental descriptive study. Out of these fifty-four articles, eleven (11) articles studied care models for hospital care and forty-three (43) articles studied care models for primary care, outpatient and community settings. Two studies were not included because only the concept was available at this stage (Shea et al., 2002 and Katon, 2003). One study only dealt with a population of type 1 diabetes mellitus children (Marrero, 1995) and had insufficient relevance. Only one study on the effectiveness of a foot clinic

for type 2 diabetes mellitus patients was found and considered too specific (Rith-Najaran, 1998). One article studied the influence of patient literacy on the effectiveness of a primary care based diabetes disease management program, which was considered out of scope (Rothmann, 2005). The references of in total 59 articles are described in the appendix part 2.1.

A. Classification of diabetes care models

In this systematic review the typology of the care models is determined by the caregiver considered as the key responsible person for (medical) decision making over the continuum of the care process. Care models in hospital, primary care, outpatient and community settings were analysed. As a preliminary result, fourteen care models were derived from the literature from 1993 until 2005. In a second phase these 14 care models were clustered into 6 care models.

Initial 14 care models	Clustering into 6 care models
1. The general practitioner model in primary care (independently working)	THE GENERAL PRACTITIONER MODEL IN PRIMARY CARE
2. General practitioner (working in own practice) + caregivers	THE GENERAL PRACTITIONER-LED SHARED CARE MODEL IN PRIMARY CARE
3. (Family) Physician (working in primary care facility/outpatient clinic) + caregivers	THE NURSE EDUCATOR-LED SHARED CARE MODEL IN PRIMARY CARE
4. Chronic care clinics in primary care	
5. Nurse educator/diabetes care coordinator/nurse case manager (working in primary care facility/HMO/Medical care)	THE SPECIALIST-LED MODEL IN PRIMARY CARE
6. Endocrinologist (working in hospital outpatient clinic)	THE HOSPITAL BASED SHARED CARE MODEL
7. Diabetologist (working in primary care clinic)	
8. Hospital based diabetes team (physician, educator, dietician/disease management program	
9. Hospital nurse educators/specialist nurses (working in general medical/regional medical/primary care clinic)	
10. Hospital nurse practitioners/nurse case managers (working in diabetes clinic/centre, university hospital)	
11. Diabetes specialist nursing service (University hospital)	THE PHARMACIST-LED MODEL
12. Medical, cardiac, internal units (Academic) medical centre	
13. Pharmacists working in primary care	
14. Foot-clinic	

B. The conceptual basis of the chronic care model and its crucial constituents

In the published literature a large variety of different elements in the care provision are tested against the qualitative outcome of the intervention. In internationally high valuated systematic reviews, as the one made in 2001 by Renders[6] and in 2002 by Bodenheimer[7], the conceptual model for chronic care developed by Wagner (2001)[8] was used to classify, aggregate and group the different chronic care interventions. In our review we defined 19 chronic care interventions, linked to the four dimensions of the chronic care model of Wagner (2001). The basic constituents of this chronic care model are:

6.3.1 Decision support

Decision support refers to all actions towards medical professionals in order to promote the use of evidence-based clinical practice guidelines. These provide standards for optimal chronic care and should be integrated into daily practice through reminders. Guidelines can be reinforced by physician 'champions' leading educational sessions.

Decision support for healthcare professionals (doctors, nurses,..)

- Distribution of educational materials (guidelines) to doctors:
- Educational meetings:
- Local consensus processes:
- Audit.

6.3.2 Self-management

Self-management support involves collaboratively helping patients and their families to acquire the skills and the confidence to manage their chronic illness, providing self-management tools (e.g., blood pressure cuffs, glucometers, diets, referrals to community resources…) and routinely assessing problems and accomplishments.

Self-management

- Distribution of educational materials to patients:
- Patient education:
- Surveillance support:
- Reminders:
- Behavioural contracts.

[6] Renders CM, Valk GD, Griffin, S, et al. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. Oxford, England: Cochrane library, Update software; 2001; issue 2.
[7] Bodenheimer T, Wagner E, Grumbach, k. Improving primary care for patients with chronic illness. JAMA, October 2002; Vol. 288,NO 14.
[8] Wagner EH, Austin BT, Davis C, Hindmarsh M. Schaefer J, Bonomi A. Improving chronic illness care: translating evidence into action. Health Affairs (Millwood), 2001; 20:64-78.

6.3.3 Delivery system design

The structure of medical practice must be altered in a way that practice teams are created defining the role of each caregiver involved. Delivery system design refers to all organisational changes executed to enhance the quality of care.

System delivery design

- Arrangements for follow-up:
- Educational outreach:
- Skill mix changes/revision of professional roles:
- Team meetings/ case discussion (between distant health providers):
- Support to doctors on organisational changes in practice:
- Implementation of a diabetes protocol/case management.

6.3.4 Clinical information systems

The use of clinical information systems has three important roles. They are reminder systems to help care teams to comply with practice guidelines. They are feed-back to physicians, showing how they are performing on chronic illness measures. Finally, they are registries for planning individual patient care and conducting population-based care.

Clinical information systems

- Changes in medical record systems:
- Electronic reminders:
- Electronic feed-back:
- Electronic patient register.

6.3.5 Health care organisation

The structure, goals and values of a provider organisation and its relationships with purchasers, insurers and other providers is defined as 'health care organisation'.

6.3.6 Community resources and policies

Community resources and policies refer to all linkages between provider organisation and community-based resources as e.g. hospitals, self-help groups, senior centres and exercise programs.

Bodenheimer et al. (2002) and Renders et al (2001) have extensively studied and reviewed if the implementation of (parts of) the chronic care model do(es) improve the quality of care. Although almost no study included the complete chronic care model within a rigorous research design, many of its elements have been included in interventions assessed by adequate study designs. Only four out of the six components of the chronic care model were addressed in the reviews of both Bodenheimer & Renders. For this project also, the crucial fifth and sixth components 'health care organisation and 'community resources' were almost never considered in the reviewed studies. The four components applied in the systematic reviews of Bodenheimer & Renders were therefore used here to classify the interventions described for the different care models.

It is important to note that the outcomes of the interventions described for the different hospital and primary care related care models only provided a partial answer to what is quality of care for type 2 diabetes mellitus patients.

C. An operational definition of quality of care

A final decision was the framework to be used to define the concept of quality and the related quality indicators. Campbell et al. (2000) have described a model that provides a good conceptual framework to define quality of care from a broad perspective, building further on the quality of care concepts of Donabedian (see the figure below). Campbell and al. consider two dimensions of quality of care i.e., 'accessibility' *(do patients get the care they need?)* and effectiveness *(is the care effective?)*. These dimensions are viewed from a structure, outcome and process perspectives[9]. Quality of care can not only be defined as the effectiveness of care (the extent to which the care delivers its intended outcome or results in a desired process, in response to need). The articles in this document presented in relation to the different care models, only provided an insight to the effectiveness of care. The conclusion is that limited or no articles with adequate study designs were found on other dimensions of quality of care such as access, affordability and availability of care. "Affordability" is a key component of access that refers to the monetary costs of access: no systematic review was found which demonstrated that the implementation of chronic care models saved euros/dollars. The dimension "availability" is the extent to which the health care system provides facilities and services which meet the needs of individuals.

Fig 1: QUALITY OF CARE MODEL BY CAMPBELL ET AL. 2000. (Adapted version, KUL, 2005).

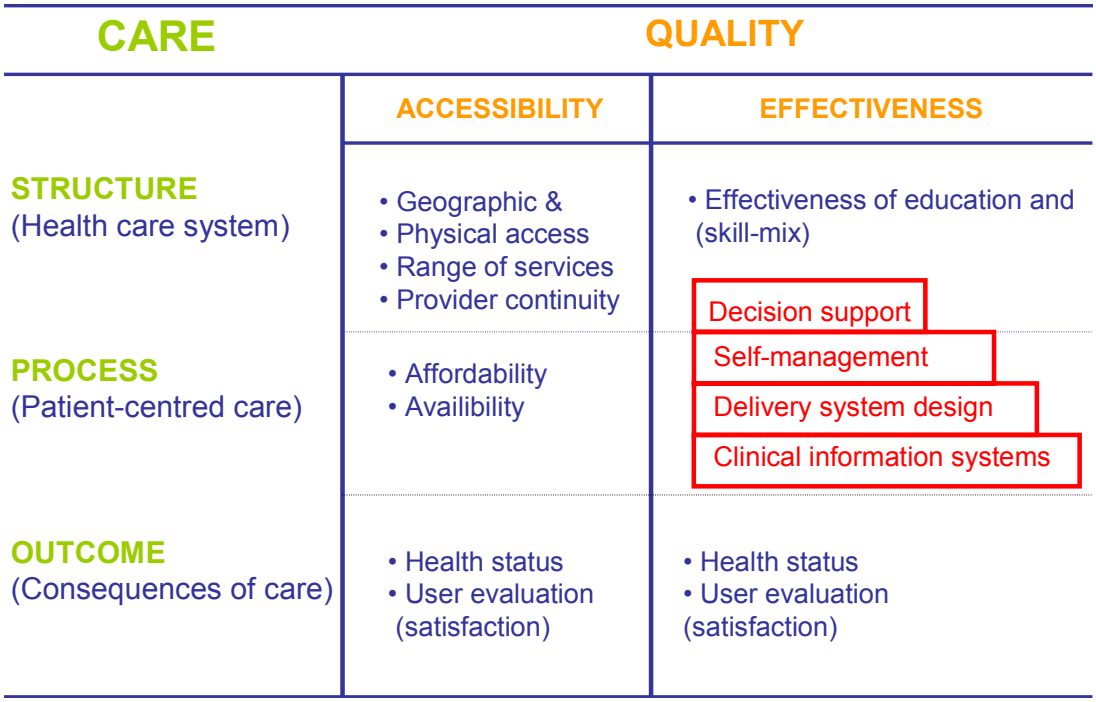
CARE	QUALITY	
	ACCESSIBILITY	EFFECTIVENESS
STRUCTURE (Health care system)	• Geographic & • Physical access • Range of services • Provider continuity	• Effectiveness of education and (skill-mix)
PROCESS (Patient-centred care)	• Affordability • Availibility	• Effectiveness of clinical care • Effectiveness if inter-personal Care • Effectiveness of co-ordination
OUTCOME (Consequences of care)	• Health status • User evaluation (satisfaction)	• Health status • User evaluation (satisfaction)

In a second figure the components of the chronic care model of Wagner (2001) are integrated with the quality of care model of Campbell. Through this integration it becomes clear that current literature on care models for patients with type 2 DM only provides an insight with regard to the effectiveness of care, and not with regard to

[9] The model of Campbell was slightly changed by positioning the dimensions accessibility and effectiveness in a vertical and not in a horizontal way, to improve the visual presentation of the model.

other dimensions of quality of care that should be considered as well. The literature does not provide good evidence that relates the type of care organisation to crucial elements such as the accessibility of care, affordability, as well as patient satisfaction with the care model. This in itself is an important result of our systematic review.

Fig 2: COMPONENTS OF THE CHRONIC CARE MODEL OF WAGNER (2001) INTEGRATED WITH THE QUALITY OF CARE MODEL BY CAMPBELL ET AL. 2000. (KUL, 2005).



D. The evaluation matrices

The appendix (part 2.2) details the constituents of diabetes care as presented in the six (6) care models that were finally selected. Initially 14 care models were defined, based on the primary responsible caregiver. In a second phase these 14 care models were clustered into the final 6 care models. One type of model was not included i.e., the model of the foot clinic (Rith-Najarian, 1998).

The final six ***diabetes care models*** are the following ones:

- THE GENERAL PRACTITIONER MODEL IN PRIMARY CARE
- THE GENERAL PRACTITIONER-LED SHARED CARE MODEL IN PRIMARY CARE
- THE NURSE EDUCATOR-LED SHARED CARE MODEL IN PRIMARY CARE
- THE SPECIALIST-LED MODEL IN PRIMARY CARE
- THE HOSPITAL BASED SHARED CARE MODEL
- THE PHARMACIST-LED MODEL

A. THE GENERAL PRACTITIONER MODEL IN PRIMARY CARE

This model refers to the general practitioner independently working in his/her own practice. For this model 9 studies were selected with the following levels of evidence:

- 6 studies (level Ib, evidence from at least on randomised controlled trial);
- 3 studies (level IIa, evidence from at least one controlled study without randomisation).

The interventions studied in this model were:

Decision support

- Distribution of educational materials (guidelines) to doctors: Naji et al., 1994 (4); Pieber et al., 1995 (8); Feder et al., 1995 (5).
- Educational meetings: Naji et al., 1994 (4); Mazze et al., 1994 (3); Pieber et al., 1995 (8); Olivarius et al., 2001 (31); Smith et al., 2002 (35).
- Local consensus processes: Naji et al., 1994 (4); Mazze et al., 1994 (3).
- Audit : Ward et al., 1996 (13).
- Feed-back (written): ----

Self-management

- Distribution of educational materials to patients: Naji et al., 1994 (4); Ward et al., 1996 (13).
- Patient education: Pieber et al., 1995 (8); Smith et al., 2002 (35).
- Surveillance support: Olivarius et al., 2001 (31).
- Reminders: Tai et al., 1999 (28).
- Behavioral contracts: ---

System delivery design

- Arrangements for follow-up: Naji et al., 1994 (4); Olivarius et al., 2001 (31); Smith et al., 2002 (35).
- Educational outreach (home visits, follow-up calls): Ward et al., 1996 (13).
- Skill mix changes/revision of professional roles: ---
- Team meetings/ Case discussion (between distant health providers): ---
- Support to doctors on organisational changes in practice: ---
- Implementation of a diabetes protocol/case management: ---

Clinical information systems

- Changes in medical record systems: Naji et al., 1994 (4); Branger et al., 1999 (24); Tai et al., 1999 (28).
- Electronic reminders: Naji et al., 1994 (4); Mazze et al., 1994 (3).
- Electronic feed-back: Ward et al., 1996 (13).
- Electronic referral system: Smith et al., 2002 (35).
- Electronic communication interface between primary and secondary care: Smith et al., 2002 (35).

B. THE GENERAL PRACTITIONER-LED SHARED CARE MODEL IN PRIMARY CARE

The general practitioner shared care model in primary care refers to general practitioners working together with a team of other caregivers. Caregivers included in the different multidisciplinary teams under study were the nurse specialist, the dietician, the pharmacist, the optometrist, the endocrinologist/diabetologist, the internist podiatrist, the behaviourist, psychologist and trained facilitator.

The general practitioner could either work in his/her own practice or in a primary care facility such as an outpatient clinic or a chronic care clinic. For this model 19 studies were found with the following levels of evidence:

- 14 studies (level Ib, evidence from at least on randomised controlled trial).
- 5 studies (level IIa, evidence from at least one controlled study without randomisation).

The interventions studied in this model were:

Decision support for healthcare professionals (doctors, nurses,..)

- Distribution of educational materials (guidelines) to doctors: Lobach et al., 1997 (16); Taplin et al., 1998 (21); Benjamin et al., 1999 (23); Halbert et al., 1999 (25); Renders et al., 2003 (40).
- Educational meetings: O'Connor et al., 1996 (12); Kinmonth et al., 1998 (17); Pill et al., 1998 (19); Woodcock et al., 1998 (22); Benjamin et al., 1999 (23); Renders et al., 2003 (40).
- Local consensus processes: O'Connor et al., 1996 (12); Lobach et al., 1997 (16); Taplin et al., 1998 (21); Benjamin et al., 1999 (23).
- Audit: O'Connor et al., 1996 (12); Lobach et al., 1997 (16); Taplin et al., 1998 (21).
- Feed-back (written):

Self-management

- Distribution of educational materials to patients: Litzelman et al., 1993 (2); Kinmonth et al., 1998 (17); Pill et al., 1998 (19); Halbert et al., 1999 (25).
- Patient education: Litzelman et al., 1993 (2); O'Connor et al., 1996 (12); De Sonaville et al., 1997 (14); Pill et al., 1998 (19); Woodcock et al., 1998 (22); Ovhed et al., 2000 (30); Renders et al., 2003 (40); Sadur et al., 1999 (26); Wagner et al., 2001 (34); Middleton et al., 2003 (39);Taylor et al., 2005 (47).
- Surveillance support: Long et al., 2005 (45); Young, 2005 (48).
- Reminders: Litzelman et al., 1993 (2).
- Behavioral contracts: Litzelman et al., 1993 (2).

System delivery design

- Arrangements for follow-up : De Sonaville et al., 1997 (14); Woodcock et al., 1998 (22); Halbert et al., 1999 (25); Ovhed et al., 2000 (30); Wagner et al., 2001 (34); Renders et al., 2003 (40); Long et al., 2005 (45); Young, 2005 (48).
- Educational outreach (home visits, follow-up calls): O'Connor et al., 1996 (12); De Sonaville et al., 1997 (14); Pill et al., 1998 (19); Taylor et al., 2005 (47).
- Skill mix changes/revision of professional roles: O'Connor et al., 1996 (12).
- Team meetings/ Case discussion (between distant health providers): De Sonaville et al., 1997 (14); Taplin et al., 1998 (21).
- Support to doctors on organisational changes in practice: Renders et al., 2003 (40).
- Implementation of a diabetes protocol/case management: Sadur et al., 1999 (26); Middleton et al., 2003 (39).

Clinical information systems

- Changes in medical record systems:Taplin et al., 1998 (21).
- Electronic reminders: Lobach et al., 1997 (16); Taplin et al., 1998 (21).
- Electronic feed-back: O'Connor et al., 1996 (12); Lobach et al., 1997 (16); Taplin et al., 1998 (21); Benjamin et al., 1999 (23); Reiber et al., 2004 (55).
- Electronic patient register: De Sonaville et al., 1997 (14).

C. THE NURSE EDUCATOR-LED SHARED CARE MODEL IN PRIMARY CARE

This model refers to nurse educators (also called diabetes care coordinator or nurse case manager) that are responsible for the main aspects of the diabetes care process. The nurses are working in primary care facilities under the supervision of general practitioners or specialists. For this model 7 studies were found:

- 5 studies (level Ib, evidence from at least on randomised controlled trial).
- 2 studies (level IIa, evidence from at least one controlled study without randomisation).

The interventions studied in this model were:

Decision support for healthcare professionals (doctors, nurses,..)

- Distribution of educational materials (guidelines) to doctors/nurses: Legoretta et al., 1996 (11); Aubert et al., 1998 (16); Peters et al., 1998 (18); Krein et al., 2004 (43).
- Educational meetings: Legoretta et al., 1996 (11).
- Local consensus processes: ---
- Audit: Peters et al., 1998 (18).
- Feed-back (written): Gary et al., 2003 (36).

Self-management

- Distribution of educational materials to patients: Legoretta et al., 1996 (11).
- Patient education: Aubert et al., 1998 (16); Peters et al., 1998 (18); Gary et al., 2003 (36); Krein et al., 2004 (43).
- Surveillance support: ---
- Reminders: ---
- Behavioral contracts: ---

System delivery design

- Arrangements for follow-up: Legoretta et al., 1996 (11); Aubert et al., 1998 (16); Peters et al., 1998 (18); Piette et al., 1999 (27); Piette et al., 2001 (32); Gary et al., 2003 (36); Krein et al., 2004 (43).
- Educational outreach (home visits, follow-up calls): Aubert et al., 1998 (16); Piette et al., 2001 (32); Gary et al., 2003 (36); Krein et al., 2004 (43).
- Skill mix changes/revision of professional roles: Legoretta et al., 1996 (11); Aubert et al., 1998 (16); Peters et al., 1998 (18); Vrijhoef et al., 2001 (33).
- Team meetings/ Case discussion (between distant health providers): Piette et al., 2001 (32).
- Support to doctors on organisational changes in practice: ---
- Implementation of a diabetes protocol/case management: ---

Clinical information systems

- Changes in medical record systems: Legoretta et al., 1996 (11); Peters et al., 1998 (18).
- Electronic reminders: ---
- Electronic feed-back: Peters et al., 1998 (18).
- Electronic patient register: ---

D. THE SPECIALIST-LED MODEL IN PRIMARY CARE

This model refers to internists or diabetologists who have the prime responsibility for the diabetes care process in primary care. The internist/diabetologist is supported by diabetes educators, dieticians and optometrists. For this model 4 studies were found with a level of evidence Ib (evidence from at least on randomised controlled trial).

The interventions studied in this model were:

Decision support for healthcare professionals (doctors, nurses,..)

- Distribution of educational materials (guidelines) to doctors/nurses: Thompson et al., 1999 (29); Maislos, 2003 (38).
- Educational meetings: Williams et al., 2003 (41).
- Local consensus processes: ---
- Audit: ---
- Feed-back (written): ---

Self-management

- Distribution of educational materials to patients: Nilasena et al., 1995 (6).
- Patient education: Williams et al., 2003 (41); Maislos, 2003 (38).
- Surveillance support: ---
- Reminders: Nilasena et al., 1995 (6).
- Behavioral contracts: ---

System delivery design

- Arrangements for follow-up: Maislos, 2003 (38).
- Educational outreach (home visits, follow-up calls):Thompson et al., 1999 (29); Williams et al., 2003 (41); Maislos, 2003 (38).
- Skill mix changes/revision of professional roles: ---
- Team meetings/ Case discussion (between distant health providers):---
- Support to doctors on organisational changes in practice: --
- Implementation of a diabetes protocol/case management: ---

Clinical information systems

- Changes in medical record systems: Nilasena et al., 1995 (6).
- Electronic reminders: ---
- Electronic feed-back: ---
- Electronic patient register: ---

E. THE HOSPITAL BASED SHARED CARE MODEL

This model refers to a hospital-based multidisciplinary team that has the responsibility for the diabetes care process. The teams described in literature consisted of a physician, nurse educator and a dietician or was only composed of hospital nurse educators (nurse case managers) or was based within a medical, cardiac or internal unit. For this model eleven studies were selected with the following level of evidence:

- 10 studies (level Ib, evidence from at least on randomised controlled trial)
- 1 study (level IIb, evidence from at least one other type of quasi-experimental design)

The interventions studied in this model were:

Decision support for healthcare professionals (doctors, nurses,..)

- Distribution of educational materials (guidelines) to doctors: Roman et al., 2001 (51).
- Educational meetings: Hurwitz et al., 1993 (1).
- Local consensus processes: ---
- Audit: ---
- Feed-back (written): Maljanian et al., 2005 (58); Greisinger et al., 2004 (42).

Self-management

- Distribution of educational materials to patients: Greisinger et al., 2004 (42).
- Patient education: Weinberger et al., 1995 (9); Gaede et al., 1999 (49); Davies et al., 2001 (50); Meigs et al., 2003 (53); New et al., 2003 (54); Greisinger et al., 2004 (42); Trento 2004 (56); Maljanian et al., 2005 (58); Rachmani et al., 2005 (59).
- Surveillance support: ---
- Reminders: ---
- Behavioral contracts: ---

System delivery design

- Arrangements for follow-up: Hurwitz et al., 1993 (1); Maljanian et al., 2005 (58); Weinberger et al., 1995 (9); New et al., 2003 (54).
- Educational outreach (home visits/follow-up calls: Weinberger et al., 1995 (9); Meigs et al., 2003 (53); Greisinger et al., 2004 (42); Kam Yet wong, 2005 (57); Maljanian et al., 2005 (58).
- Skill mix changes/revision of professional roles: New et al., 2003 (54).
- Team meetings/ Case discussion (between distant health providers): Gaede et al., 1999 (49).
- Support to doctors on organisational changes in practice: ---
- Implementation of a diabetes protocol/case management: ---

Clinical information systems

- Changes in medical record systems: Hurwitz et al., 1993 (1); Roman et al., 2001 (51); Meigs et al., 2003 (53).
- Electronic reminders: ---

- Electronic feed-back: ---
- Electronic patient register: Hurwitz et al., 1993 (1).

F. THE PHARMACIST-LED MODEL

The pharmacist-led model refers to the pharmacist being responsible for the main parts of the diabetes care process. For this model 3 studies with a level of evidence Ib (Evidence from at least on randomised controlled trial).

The interventions studied in this model were:

Decision support for healthcare professionals (doctors, nurses,..)

- Distribution of educational materials (guidelines) to doctors: ---
- Educational meetings: ---
- Local consensus processes: ---
- Audit: ---

Self-management

- Distribution of educational materials to patients: ---
- Patient education: Jaber, 1996 (10); Choe, 2005 (44); Rothman, 2005 (46).
- Surveillance support: ---
- Reminders: ---
- Behavioral contracts: ---

System delivery design

- Arrangements for follow-up: ---
- Educational outreach (home visits/follow-up by phone): Choe, 2005 (44); Rothman, 2005 (46).
- Skill mix changes/revision of professional roles: Jaber, 1996 (10).
- Team meetings/ Case discussion (between distant health providers): ---
- Support to doctors on organisational changes in practice: ---
- Implementation of a diabetes protocol/case management: ---

Clinical information systems

- Changes in medical record systems: ---
- Electronic reminders: ---
- Electronic feed-back: ---
- Electronic patient register: Rothman, 2005 (46)

6.4 MAIN CONCLUSIONS AND DISCUSSION OF THE RESULTS FOR THE ORGANISATION OF DIABETES CARE

6.4.1 GENERAL CONCLUSIONS

- Almost no field studies were found that mutually compared the effectiveness of hospital and primary care diabetes care models.
- Effectiveness is related to the type and intensity of the chronic care interventions independent from the different diabetes care models.
- Single intervention diabetes care programs are less effective than multifaceted intervention programs but no single intervention is more effective than other interventions.
- Multidisciplinary care as part of multifaceted diabetes intervention program is effective at the patient and at the process level.
- No evidence was found for the accessibility part of quality and limited evidence for the cost effectiveness part of quality, in contrast with the evidence for the effectiveness part of quality.

6.4.2 DISCUSSION

Quality is described as effectiveness

It is important to note that the outcomes of the interventions as described for the different hospital and primary care related care models only provide us with a partial answer to what is quality of care for type 2 diabetes mellitus patients. Quality of care in all studies reviewed is defined as the effectiveness of care. No article with an adequate study design was found on other dimensions of quality of care as defined by Campbell et al. (2000) such as access, affordability and availability of care. Affordability is a key component of access that refers to the monetary costs of access.

This literature search did not identify any systematic review which demonstrated that the implementation of chronic care models saves euros/dollars.

Random comparison within single care models

When the effectiveness of the different care models is compared at the patient and/or process level, no model can claim to provide better care than other models. Few studies have explicitly compared care models in hospital and primary care settings for patient and process outcomes (e.g. Hurwitz, 1993; Naji, 1994; Gaede 1999). Both care models in hospitals and primary care settings provide positive outcomes at the patient and process levels. Naji (1994) provided evidence that a model of integrated care for diabetes was at least as effective as conventional hospital clinic care. Gaede (1999) on the other hand provided evidence on the effectiveness of an intensive multifactorial intervention in a hospital setting resulting in better care than the care provided by general practitioners.

No single intervention of the chronic care model of Wagner (2001) emerged as essential (or superfluous) for effectiveness.

Because of the limited number of studies, it is difficult to determine with confidence whether studies using a greater number of chronic care interventions or specific combinations of interventions are more likely to be effective. Studies with interventions

featuring 4 chronic care model interventions were found to improve patient outcome measures. The majority of studies using fewer interventions were also found to be effective, but less frequent. The interventions most frequently used were self-management support, educational materials and meetings for physicians (decision support), use of case managers, multidisciplinary teams and scheduling of planned diabetes follow-up visits (delivery system design), reminder systems and feedback on physician performance (clinical information systems).

Educational materials (guidelines) & postgraduate education are effective on process outcomes. Interventions that are part of 'decision support' for doctors and other healthcare professionals are:

- Distribution of educational materials (guidelines) to doctors:
- Educational meetings (postgraduate education):
- Local consensus processes:
- Audit/peer review.

The distribution of educational materials (guidelines) to doctors and educational meetings (postgraduate education) are effective on process outcomes in combination with other interventions like local consensus processes, audit, reminders, feed-back, peer review or combinations of these interventions. The improvements were noted in all studies that did not demonstrate a good standard of care at baseline. The effect of decision support on patient outcomes is less clear as in most studies these outcomes were not assessed. The studies that did report patient outcomes found mainly improvements on these outcomes.

Patient-oriented interventions (self-management = support for patients) are effective on both patient and process outcomes. Interventions that are part of 'self-management' (support for patients) are:

- Distribution of educational materials to patients:
- Patient education:
- Surveillance support:
- Reminders:
- Behavioral contracts:

The addition of a patient oriented intervention such as the distribution of educational materials to patients, patient education, surveillance support, reminders and behavioural contracts generally led to improvements of patient outcomes next to improvements in process outcomes. It must be noted however that patient education is defined in many ways, from individualised diabetic dietary advice over a full range of services.

Intensive arrangements for follow-up (delivery system design) are effective on process outcomes. Interventions that are part of 'delivery system design' are:

- Arrangements for follow-up:
- Educational outreach:
- Skill mix changes/revision of professional roles:
- Team meetings/ Case discussion (between distant health providers):
- Support to doctors on organisational changes in practice:
- Implementation of a diabetes protocol.

Intensive arrangements for follow-up improve the process of care in terms of scheduled visits and rates of examinations, although there is variation in the type and intensity of the methods used. Patient tracking is operationalised by central computerised tracking systems or by nurses who regularly contact patients (educational outreach). Telephone calls for rescheduling visits failures combined with patient education are more effective

than sending multiple reminders to patients, which only affected process outcomes in the short term in comparison to a single reminder. The effectiveness of intensive follow-up on patient outcomes remains unclear.

The revision of professional roles is effective on patient outcomes. The studies in which nurse educators (partly) substituted physicians, generally demonstrated a positive impact on patient outcomes (glycaemic control), especially if the intervention was part of a more complex intervention strategy. The effectiveness of the implementation of revision of professional roles as a *single intervention* remains unclear. The revision of professional roles in combination with a patient-oriented part was associated with a small beneficial effect on glycaemic control. The results of these studies have to be interpreted with caution because of their limited methodological quality.

Information and communication systems (ICT) are effective on process outcomes. The interventions that are part of 'clinical information systems' are:

- Changes in medical record systems:
- Electronic reminders:
- Electronic feed-back:
- Electronic patient register.

Changes in the medical record systems improve process outcomes. The results suggest that computerised reminder systems improve compliance with recommended care more by facilitating the documentation of clinical findings and the ordering of recommended procedures than by providing the clinician with patient-specific information about guideline compliance status. The impact of clinical information systems on patient outcomes remains unclear.

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Chapter 3: Organisation of diabetes care in 9 Western countries

This third chapter describes the organisation of diabetes care in 9 Western countries. While chapter two analysed the organisation at micro level (the organisation of individual practices or departments), this section will focus on the organisation at macro level (national). Complementary to the first chapter (quality indicators) this one describes specifically the practical organisation of quality monitoring systems. Health promotion and primary prevention of diabetes were not part of the study. The lack of information to analyse health care systems at macro level in terms of efficiency and effectiveness has as a consequence that - contrary to the two first parts - this section will be mainly descriptive.

7 METHODOLOGY OF THE ANALYSIS

7.1 TIME LIMITS FOR THE LITERATURE ANALYSIS

As for the previous parts, the literature published since 1993 was analysed, with a focus on the most recent information.

7.2 PHASES OF THE DATA SEARCH

The data search was performed in six phases:

- Definition of the research question;
- Development of a checklist of the items that should be described for each country;
- Literature review for each country;
- Experts' interviews in each country;
- Comparison of the organisation of diabetes care between different countries;
- Conclusions : organisation of diabetes care in 9 countries.

8 LITERATURE REVIEW AND INTERVIEWS

8.1 THE RESEARCH QUESTION

The organisation of diabetes care is described for 9 Western countries: Belgium, Canada, Denmark, Estonia, France, Germany, the Netherlands, Spain and the UK. This chapter answers the following questions:

- How is diabetes care organised in each country – and what are the recent changes in this organisation?
- What are the strengths and weaknesses of the organisation of diabetes care in each country?
- Where available: what is the quality and cost of diabetes care in each country?

8.2 METHODOLOGY

8.2.1 Development of a checklist

In a first phase the items to be described for each country were listed. The following sources helped to identify the relevant items:

- The chronic care model by Wagner (1998) already mentioned in chapter 2,
- The Cochrane literature reviews on the organisation of diabetes care,
- A stakeholders' analysis of diabetes care in Belgium (Bastiaens 2005),
- The template of the European Observatory on Health Systems and Policies (2004),
- The definition of care by Donabedian (Donabedian, 1980).

The Chronic Care Model (Wagner 1998)

The chronic care model by Wagner was used in the second chapter of this study. This model was developed in the USA as a generic model to describe the chronic disease management. Rather than focusing on the behaviour of the individual patient and physician, it describes how a health care model can lead to an "informed, activated patient" and a "prepared, proactive practice team" creating "functional and clinical outcomes". The chronic care model identifies six critical components of chronic disease management already mentioned in chapter 2:

- The health system should create a culture, organisation and mechanisms that promote safe, high quality care by providing leadership, setting goals, giving incentives, handling errors and quality problems in an open and systematic way, and developing agreements that facilitate co-ordination.
- Community resources should be mobilised to meet patients' needs. Patients should be encouraged to participate in effective community programmes (for example exercise classes for the elderly). The health system should create partnerships with community organisations (e.g. patients' organisations) to fill the gaps in the services needed.
- The health system should acknowledge the patients' central role in managing their illness and enhance self-management.

- The health system should provide decision support to ensure that clinical practice is consistent with scientific evidence and patient preference. This can be achieved by providing evidence-based guidelines, sharing these guidelines with patients, organising effective provider education and integrating specialist expertise and primary care.
- The delivery system design should ensure effective and efficient clinical care and self-management support. Important elements are clearly defined roles for all team members, regular follow-up by the team, use of case management services for complex patients and attention for the cultural background of the patient.
- Clinical information systems should facilitate efficient and effective care by providing reminders for patients and providers, identifying subpopulations for proactive care, facilitating individual patient planning, sharing information with patients and other health workers and monitoring performance.

Cochrane literature reviews

The literature search in chapter 2 also included articles from the Cochrane Library. The following section summarises the conclusions of four Cochrane *reviews* on the organisation of diabetes care. These papers were selected for their potential relevance in relation with the organisation of care at the macro level.

- Systems for routine surveillance for people with diabetes (Griffin 2000).

The purpose of the literature review by Griffin et al. was to compare the cost-effectiveness of diabetes treatment in primary and secondary care. They included 5 randomised trials of which only one study had a follow-up period of more than two years. In all studies physicians received education. Well supported primary care can reach a standard as good as the one in hospital outpatient clinics. However, in studies that did not use well-developed support systems for the general practitioner, the results were worse in primary care. The analysis supports the use of call/recall systems in general practice. The cost of the treatment for the patients was lower in general practice, while the results on the overall cost-effectiveness in the primary and secondary care were unclear. For many other outcomes the study samples were too small to detect any difference.

- Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings (Renders 2002).

Renders et al. evaluated the effect of various organisational, professional and financial interventions on diabetes care in both primary and secondary care services. Studies with only patient-oriented interventions were excluded. Studies evaluating the effectiveness of financial interventions were not found. The review included 41 studies, with a maximum duration of three years. Due to the great variability in study design a meta-analysis was not possible. All studies included health workers' education. Combined interventions aimed at both health personnel and the care organisation improved intermediate outcomes as blood pressure, blood glucose, HbA1c, weight and cholesterol. But they did not yield any significant effect on the patient's outcomes as the frequency of complications, hospital admissions and mortality. Therefore the investigators concluded they could not determine which interventions were most cost-effective. It appears that – in combination with education for health personnel – the following interventions had a positive effect on clinical practice: audit, feed-back, local consensus meetings, call/recall systems and supervision. The review also indicates that patient-oriented interventions can have a positive effect when combined with the above interventions and when a nurse is included in the management.

- Specialist nurses in diabetes mellitus (Loveman 2003).

The review by Loveman et al. examined the effect of diabetes specialist nurses or nurse case managers – as an isolated intervention - on diabetes care. The review included six trials, of which two only with adolescents. The follow-up period was 6 to 18 months. The studies differed too much for a meta-analysis. Over a 12 months follow-up period the review did not find any significant effects on glycaemia control. One study found a significant effect in a subgroup of patients with an HbA1c above 8%. The quality of the trials was generally low. The investigators concluded that no conclusions could be drawn from the available data.

- Group-based training for self-management strategies in people with type 2 diabetes mellitus (Deakin 2004).

Deakin et al. evaluated the effect of group-based training programmes in self-management for adult type 2 diabetes patients. The review included 11 studies. Clinical important improvements were observed for HbA1c, fasting blood glucose levels and diabetes knowledge at four to six months' and 12 months' follow-up. If additional group education was provided on annual basis, this effect lasted for two to four years.

Stakeholders' analysis of diabetes care in Belgium (Bastiaens 2005)

In 2004 the Antwerp, Leuven and Ghent universities interviewed in Flanders 18 key persons in the field of diabetes care. The main conclusions of these interviews were:

- Diabetes care is quite accessible, though some aspects are expensive for patients who do not fit in the diabetes convention (dietetic and podiatric services, use of test strips).
- The fee-for-service payment of health professionals results in a rather demand-driven than a protocol-driven medical practice. Other payment systems rewarding e.g. screening, health education or communication between health workers, should be initiated.
- The policy makers do not have a long-term vision on diabetes care. The diabetes convention (reimbursement for education and self-monitoring material for patients with minimum two daily insulin injections in a specialist setting) is a project with a long-term vision but is not fully satisfactory. Too many patients with two daily injections of insulin (the so-called group 3 patients) are treated in secondary care. This group exceed the treatment capacity of secondary care and create a heavy financial burden.
- The health system should pay more attention to prevention of and screening for diabetes, by organising public health campaigns and giving organisational or financial support to GP's and nurses.
- More group 3 patients should be treated in primary care, but there is currently too much variation in quality of care in the first line of care. The following propositions were made to enhance the quality of care:
    - Primary care diabetes teams – with the GP as central caregiver – should be developed,
    - General practices should be better structured: evolution from solo to group practices, further development of the patient listing, strengthening of the information technology systems so that electronic medical records can be used for communication and quality measurement.
    - The role of nurses and dieticians should be strengthened with specific diabetes trainings,
    - Diabetes educators should be available in primary care.

- The recent initiative to support primary care with diabetes reference nurses is well accepted, although the communication between nurses and GP's can be improved.
- There is an urgent need for more communication and coordination between health care workers. Competition between the health workers and lack of mutual respect contribute to the problem. Local agreements on shared care could improve the interaction between health professionals but there are currently no financial incentives to develop these protocols.
- Patients should be more involved in diabetes management. The diabetes passport tries to address this issue but the passport represents extra work for the physician.

The template of the European Observatory on Health Systems and Policies (Allin 2004)

The European Observatory on Health Systems and Policies is a partnership between the WHO, several European governments and academic institutions, the European Investment Bank and the World Bank. It supports evidence-based health policy-making through the analysis of health care systems in Europe. Its Health System Profiles are country-based reports that provide a detailed description of a health system, the reforms and recent policy initiatives. In order to facilitate the comparison between countries, the profiles are based on a template, which provides guidelines, specific questions, definitions and examples needed to compile Health System Profiles.

The definition of care by Donabedian (Donabedian 1988)

The model of Donabedian also defined the structure of the checklist to describe the organisation of diabetes care:

- Structure of care: refers to the organisational factors that define the health care system under which care is provided,
- Process of care: involves the interactions between patients and the health care system. Donabedian makes the distinction between clinical care and inter-personal care (i.e. the relationship between the patient and the caregiver).
- Outcome of care: is defined as the consequences of the interaction between the individuals and the health care system.

8.2.2 The checklist as a tool for a country-based description of diabetes care

A checklist was developed on basis of the sources mentioned above, encompassing the items deemed relevant for a comprehensive country-based description of diabetes care. The list is divided in two sections (see appendix part 3). A first section describes the overall health system: its content and structure is based on the template of the European Observatory on Health Systems and Policies. A second section specifically details the organisation of diabetes care. It includes the 6 dimensions of the chronic care model of Wagner, the results of the Cochrane literature reviews and the opinions expressed in the stakeholders' analysis. These items were structured following Donabedian's distinction in structure, process and outcome.

8.2.3 Selection of the countries

The working group of the project suggested 10 foreign countries : Canada (Québec), Denmark, Estonia, France, Germany, the Netherlands, Portugal, Slovenia, Spain and the UK. The selection of the most relevant countries used the criteria proposed by van der Zee et al. (2004):

- Financing method: two models are identified:
  - a tax–based system: health care is financed from general taxes and the state is the principal provider;
  - Contribution-based system: health care is financed through specifically earmarked contributions. The state has only a limited role as a health care provider.
- Main method of payment for physicians: fee-for-service, capitation, salary or mixed.
- Role of the GP as gatekeeper.

The following selection criteria were added:

- Patients' listing with a GP;
- Accessibility: proportion of out-of-pocket payments in the total health expenditure.

Table 1 describes Belgium and the other 10 countries according to these criteria. Eight countries were finally selected : Canada (Québec), Denmark, Estonia, France, Germany, the Netherlands, Spain and the UK. The selection was based on the relevance for the Belgian situation (the neighbouring countries France, Germany, the Netherlands and the UK) and on diversity: Estonia (a post-communist country), Denmark (Northern Europe), Spain (Mediterranean Europe) and Canada (a transatlantic health system that has affinities with the health organisation in Europe).

Table 1. Main characteristics of health care systems for 11 Western countries.

	Main financing source	Main method of payment for medical doctor	GP as gate-keeper	Patients' listing with GP	Level of out-of-pocket payments
Belgium	Contribution- and tax-based	Fee-for-service (+ limited capitation fee)	No	No	17%
Canada	Tax-based	Fee-for-service	No	No	10.6%
Denmark	Tax-based	In institution: salary; GP's/ambulant specialists: fee-for-service + capitation fee	Yes	Yes	16.5%
Estonia	Contribution-based	In institutions: salary GP's/ambulant specialists: fee-for-service + capitation fee + basic allowance	Yes	Yes	19.9%
France	Contribution- and tax-based	Fee-for-service	No: only financial incentives, since 2005	No	9.7%
Germany	Contribution-based	In institutions: salary; GP's/ambulant specialists: fee-for service	Limited function for patients enrolled in specific HC plans	No	12.2%
The Nether-lands	Contribution-based	GP's: capitation fee Specialists: fee-for-service (except universities)	Yes	Yes	5.8%
Portugal	Mostly tax-based, but important private sector	Salary (Fee-for-service in private)	Yes (Not in private)	Yes	+/- 30%
Slovenia	Contribution-based	Private: fee-for-service + capitation fee Public: salary	Yes	Yes	Unknown
Spain	Tax-based	Salary (+ additional capitation fee for GP's)	Yes	Yes	23.7%
UK	Tax-based	GP's: capitation fee + quality-based payment + fee for service Specialists: salary	Yes	Yes	2.7%

Source: 'Health care systems in transition' Canada (Philips 1996), Denmark (Vallgarda 2001), Estonia (Jesse 2004), France (Sandier 2004), Germany (Busse 2004), the Netherlands (den Exter 2004), Portugal (Bentes 2004), Slovenia (Albreht 2002), Spain (Rico 2000) and the UK (Robinson 1999). For out-of-pocket payments Spain: OECD Health Data (OECD 2005A).

8.2.4 Data collection

Literature review

First the free-text terms "diabetes" and the name of the country were used in Medline. However, most information was gathered from grey literature which was accessed through internet by looking at specific national websites (and their links) i.e., from the Ministries of Health and subsidiary institutions (NICE in the UK, ANAES in France…), from the national patients' and professionals' diabetes associations, from national and regional GP's associations, from the WHO Regional Office for Europe and the OECD website. Some experts interviewed gave additional information. Only documents and websites in English, French, German, Dutch and Spanish were considered. In a few instances we asked organisations for additional information by e-mail.

Methodology of the interview

The aim of the experts' interview was double i.e., to fill the remaining gaps in the information gathered from the literature and to get an expert opinion on the strengths and weaknesses of the organisation of diabetes care in each country.

As a result the questionnaire differed from one country to another and from one person to another, depending on his/her field of expertise. However each questionnaire ended with the three same questions:

- Which are according to you the strengths of the organisation of diabetes care in your country?
- What are today the major problems in the organisation of diabetes care in your country?
- Which changes in the organisation of diabetes care do you expect in the future?

The expert received beforehand the questionnaire and the draft made on basis of the literature review. The interviews were done by phone and took on average 30 minutes. The expert first commented the draft. All interviews were done by the same person (except for France and Canada). Given language problems in Estonia an extensive written questionnaire replaced the interview. Unfortunately, none of the respondents answered the questions on strengths, weaknesses and future changes.

A few experts preferred to write down the comments on the text. One expert gave written answers to all questions in the interview and was not interviewed by phone.

Selection of the experts

For each country the objective was to interview 4 persons i.e., one secondary care expert, two primary care experts and one public health expert (academic expert or senior manager in a health insurance institution or in the Ministry of Health).

Most experts were selected on advice of the working group of the project. Some experts were also selected on basis of the names in the national guidelines or on advice of the interviewed experts, the Ministry of Health and related institutions. The list of interviewed experts is summarised in the following table:

Country	Type of Interview	Name	Function	Contact from
Canada	Interview 1	Mr. M. Aras	Director of Communications Diabète Québec (patients' organisation)	KCE + working group
	Interview 2	Prof. Dr. M.-D. Beaulieu	Department of Family Medicine University of Montreal	KCE + working group
	Interview 4	Prof. Dr. J. F. Yale	Endocrinologist University McGill	KCE + working group
Denmark	Interview 1	Mr.Mikkel Grimmeshave	Senior advisor, National Board of Health	DACEHTA
	Interview 2	Prof. Dr. Flemming Bro	Department of Family Medicine	KCE + working group
	Interview 3	Prof. Dr. Niels Olivarius	Department of Family Medicine University of Copenhagen	Prof. Flemming Bro
	Interview 4	Prof. Dr. Knut Borch-Johnsen	Medical Director Steno Diabetes Centre	KCE + working group
Estonia	Interview 2	Prof. Dr. Ruth Kalda	Department of Family Medicine University of Tartu	KCE + working group
	Interview 3	Dr. Anneli Rätsep	Research assistant at Department of Family Medicine University of Tartu	KCE + working group
	Interview 4	Prof. Dr. Margus Lember	Department of Internal Medicine University of Tartu	KCE + working group
France	Interview 1	Mr. Michel Varroud-Vial	Association Nationale Co-ordination Réseaux diabète (ANCRED)	KCE + working group
	Interview 2	Prof. Dr. Gwénola Levasseur	Department of Family Medicine University of Rennes	KCE + working group
	Interview 3	Dr. Sylvie Aulanier	President of the diabetes network Le Havre	KCE + working group / Prof. Samuelson
	Interview 5	Dr. Anne Fagot-Campagna	Institute for Health Surveillance Diabetes Programme	KCE + working group
Germany	Interview 2	Prof. Dr. H. H. Abholz	Department of Family Medicine University of Dusseldorf	KCE + working group
	Interview 3	Dr. J. Gensichen	Department of Family Medicine University of Frankfurt	KCE + working group / Prof. F. Gerlach
	Interview 4	Prof. Dr. W. A. Scherbaum	Department of Endocrinology University of Duesseldorf	KCE + working group
Netherlands	Interview 1	Dr. C.A. Baan	Epidemiologist Centre for Prevention and Health Care Research	KCE + working group
	Interview 2	Prof. Dr. G.E.H.M Rutten	Department of Family Medicine University of Utrecht	KCE + working group

Country	Type of Interview	Name	Function	Contact from
	Interview 3	Dr. Rob Dijkstra	Research assistant at Department of Family Medicine University of Utrecht	KCE + working group
	Interview 4	Prof. Dr. R. J. Heine	Diabetologist Free University of Amsterdam	KCE + working group
	Interview 5	Prof. Dr. Klaas Reenders	Family Medicine	KCE + working group
Spain	Interview 2	Dr. F.X. Cos	General Practitioner, member of redIAPP	KCE + working group
	Interview 3	Dr. J. Gervas	GP, member CESCA team	KCE + working group
	Interview 4	Prof. Dr. J. Ampudias	Endocrinologist University of Valencia	KCE + working group
UK	Interview 1	Dr. Michael Sobanja	Chief Officer NHS Alliance	KCE + working group
	Interview 2	Dr. Eugen Hughes	Chairman Primary Care Diabetes Society	KCE + working group
	Interview 3	Prof. Hilary Hearnshaw	Psychologist University of Warwick	KCE + working group
	Interview 4	Prof. Dr. Philip Home	Diabetologist University of Newcastle	KCE + working group

Interview 1: public health expert

Interview 2: primary care expert

Interview 3: primary care expert

Interview 4: secondary care expert

Interview 5: (where available): primary care or public health expert

9 RESULTS: ORGANISATION OF DIABETES CARE IN 9 COUNTRIES

This chapter gives an overview of the organisation of diabetes care in the 9 selected countries: Belgium, Canada Denmark, Estonia, France, Germany, the Netherlands, Spain and the UK. A more detailed description of the countries and the records of the interviews are provided in appendix part 3.

9.1 BELGIUM

The Belgian health system is characterised by a split of responsibilities between the federal and the community level (European Observatory on Health Care Systems 2000).

The health care system offers a comprehensive package of care to all Belgian residents, though diabetes patients without any insulin therapy have to make considerable contributions for dietetic and podiatric services, test strips and – to a lesser extent – drugs. The system is financed mainly through social contributions.

Physicians are mainly paid by a fee-for-service system. This results in an organisation of the health system that is rather supply-driven than demand-driven, and a medical practice rather determined by the patient's perceived needs than by clinical protocols. This is also reflected in the weak patients' registration system (which only covers about 1/3 of the patients and does not oblige the patients to choose one GP only) and the absence of gatekeeping function for the GP. Two thirds (65%) of all secondary care contacts are on the patient's initiative, without any referral by a GP (Demarest 2002). A recent report of the OECD criticises the absence of gatekeeping from the point of view of cost-containment (OECD 2005b).

This context partially explains the perception in the recent stakeholders' analysis that the system lacks a long-term vision on diabetes care (Bastiaens 2005).

The main government regulation in diabetes care is the diabetes convention. The convention mainly deals with secondary care and results in most diabetes patients on insulin being treated in secondary care. Its minimum standards require a multidisciplinary secondary care team with at least one endocrinologist, a diabetes nurse and a dietician. Recently the government has set standards for diabetes foot clinics as well. Foot clinics can only be organised in larger hospitals.

One of the main concerns about the diabetes convention expressed in the stakeholders' analysis was that many diabetes patients (especially those who need 2 doses of insulin a day), who are now being treated at secondary care, should be cared in primary care with the pivotal role of the GP (Bastiaens 2005).

Unfortunately, general practice is poorly structured, with a variable quality of care. Most GPs work in solo practices without any administrative support. Enhancing group practices, favouring the patients' listing system, further developing the electronic medical record, organising specific continuing medical education and integrating the GP in a primary care diabetes team, are seen as important elements to promote the quality of primary care. The introduction of diabetes reference nurses, who give health education to the patient on the demand of the GP, was generally welcomed by the stakeholders as a positive step towards more qualitative primary care (Bastiaens 2005).

The stakeholders also saw a strong need for more communication and co-ordination between primary and secondary care and between the different health workers in primary care. The roles of the different health workers should be defined in a local protocol. The competition between physicians (linked to their fee-for-service payment), the lack of adequate financing and the variation in the quality of care in primary care are seen as obstacles to develop shared care (Bastiaens 2005). The Ministry of Health has the intention to develop care pathways, which should motivate patients to follow the recommended lines of referral. The diabetes passport, a medical record held by the

patient, is designed to facilitate communication between caregivers. At the same time it is a tool for patient empowerment.

Within the diabetes convention the quality of care is measured regularly, revealing an average outcome (Debacker 2005). The stakeholders expressed the need for a broader system of quality control and a more systematic development of quality indicators (Bastiaens 2005).

9.2 CANADA

Canada's national health insurance program is designed on a prepaid basis. Canada's publicly funded health care system is an interlocking set of ten provincial and three territorial health insurance plans. Provincial and territorial governments are responsible for the management, the organisation and the delivery of health services for their residents. Some provincial governments do not have the population or tax base that provides fair and equitable access to the medications, devices and supplies that diabetic patients need.

Quebec is the province that gives the best coverage for drugs. The Public Prescription Drug Insurance covers the residents of the province who are not covered by the provincial program or by the private health insurance generally offered through employment. Private insurance generally covers 80 % of the medication and health services against 75% by the public health insurance. In the other provinces, if a patient does not have contracted a private insurance, he would be covered by the public insurance only if being older than 65 or assisted by the social welfare.

In 1999, the Government of Canada pledged 85 million euros (115 Millions$ CAN) over five years for the development of a Canadian Diabetes Strategy (CDS). Its investment in the CDS covers three areas i.e., the development of a health promotion-disease prevention strategy for the entire population; the care, treatment and prevention of diabetes for First Nations people on reserve and in Inuit communities (Aboriginal Diabetes Initiative); the improvement of national and regional data collection about diabetes and its complications.

The Canadian Diabetes Association and Diabète Québec are the two major diabetes associations in Canada. They are both very active in various aspects of diabetes care such as prevention, information but also in the development of guidelines. The 2003 Clinical Practice Guidelines for the Prevention and Management of Diabetes (from the Canadian Diabetes Association) were drafted over a 2-year period by an expert Committee of key stakeholders across Canada. These guidelines are intended to guide clinical practice but they are not a comprehensive text on diabetes management.

The GPs have a central role in the health care system. Most of them (60%) work in group practices or in multidisciplinary teams. The GP initiates the care of diabetic patients and 85% of type 2 diabetes patients are followed up by a GP. Type 1 diabetes patients are generally followed by a specialist.

The drug insurance in Canada, especially in Québec, covers a large part of the medication and health services, in particular the diabetes medication and glucose test strips. About one hundred centres for health education exist in Québec. In the hospitals, nearly all diabetes care services are covered. Some clinics have a multidisciplinary team specialised in diabetic foot care.

However, according to the experts, there is a lack of coordination in the follow-up of the patient and a lack of resources for teaching the patients. The diabetes strategy is not enough implemented and some weaknesses in ambulatory care have been reported.

Canada does not have yet any concerted quality assurance system. Today, the National Public Health Institute is developing a national database on several aspects of the diabetes: the *National Diabetes Surveillance System (NDSS).* The system makes it possible to monitor diabetes prevalence and incidence, mortality, complication rate and health services use.

9.3 DENMARK

Denmark has a tax-based health care system characterised by a far-going decentralisation of responsibilities to the 14 counties. The counties are the central managers of the health care system, while the national level sets general standards and guidelines. As owners of most of the hospitals, the counties are also important health care providers (Vallgarda 2001). In the near future the counties will be replaced by five regions, larger entities.

At county level diabetes steering committees advise the policy makers in the county administration. They play an important role in the organisation of diabetes care (interview Denmark 1).

General practice is fairly well structured. Two thirds of the GPs work in group practices (Vallgarda 2001). About half of them employ secretary staff and sometimes a practice nurse or a laboratory technologist (interview Denmark 3). GP's get their income for about 50% from capitation fees, the other part from fees for service. Nearly all patients are registered with a GP and the GP has a gatekeeper function (Vallgarda 2001), which is seen by the experts as an important strength in the organisation of diabetes care (interviews Denmark 2, 3). However there have been little efforts at policy level to strengthen the capacities of general practice in chronic disease management.

Secondary care diabetes clinics have a well developed team of endocrinologists, nurses, dieticians and podiatrists (DACEHTA 2003). A few diabetes clinics also organise diabetes schools, offering group-based training programmes for diabetes patients (DACEHTA 2003). These schools are not directly accessible for GPs and remain a rather marginal initiative (interviews Denmark 2, 3).

The Danish Centre for Health Technology Assessment (DACEHTA) developed a Health Technology Assessment for type 2 diabetes to answer to the demand of the Ministry of Health. Following this report a national diabetes steering committee was established, which developed process indicators for the quality of diabetes care. Since 2005 secondary care physicians are obliged to report on these indicators. The plan is to measure in the future outcome indicators as well (interview Denmark 4). From 2006 onwards a national database will be established to calculate incidence and prevalence of diabetes (interviews Denmark 1, 3, 4).

Most experts noted a lack of communication between caregivers (interview Denmark 1, 2, 4). Shared care protocols exist in some places but they are often not very detailed or unsatisfactory (interviews Denmark 1, 2). The GPs seem to doubt to refer patients to diabetes clinics (interview Denmark 2, 3, 4). Several reasons were mentioned. Diabetes clinics often used to keep patients referred by the GP for routine follow-ups. This is not any longer the case with the increasing workload at the diabetes clinics but this feeling still persists among GPs (interview Denmark 2, 3). The fee-for-service payment of the GP's creates a competition with the diabetes clinics (interview Denmark 4). The experts mentioned specific payments for shared care (interview Denmark 2) and the development of Information and Communication Technologies (ICT) (interview Denmark 4) as interventions that could enhance shared care.

Most experts expect more structured diabetes care in the future (interviews Denmark 1, 3, 4). The Ministry of Health is presently working on a project about chronic disease management. It will probably propose a diabetes care organisation in three levels, according to the stage of disease with the involvement of case managers for complex patients (interview Denmark 1).

Primary care experts deplored the lack of attention to lifestyle change support (interviews Denmark 2, 3). One expressed the fear that this tendency will be strengthened in the future by the emphasis on multi-pharmacological treatment (interview Denmark 3).

9.4 ESTONIA

Since its independence in 1991, the Estonian health system has undergone a major shift from a system funded by the state budget to one funded through social health insurance contributions to the Estonian Health Insurance Fund (EHIF). The number of hospital beds has been strongly reduced. The system of polyclinics has been replaced by a primary health care system based on four pillars: the development of general practice as a specific medical specialty, GPs working as private entrepreneurs, patients' listing with a GP and a gate keeping function for the GP (Jesse 2004).

The yearly health expenditure per capita is 574 USD, which is far below the expenditure of any other country in this study. Nevertheless, the EHIF offers a comprehensive package for diabetes patients (Kaarna 2005; interviews Estonia 2, 3), which is comparable with that of the other countries in this study. However private practice, not covered by the EHIF, is fairly common. A relatively large proportion of patients (6%) are not covered by any health insurance (Jesse 2004).

Most type 2 diabetes patients are followed in general practice. General practice is well structured. The general practice team consists of one or more GP's, administrative staff and often one or more practice nurses. GP's have access to podiatric services (in private or in hospital), but hardly to dietetic services. Most general practices use electronic medical records and have diabetes registers. They can get support of a diabetes nurse who provides health education (interviews Estonia 2, 3).

Secondary care is provided in secondary care health centres or hospital outpatient clinics. In secondary care an endocrinologist or a specialist in internal medicine, a diabetes nurse, a podiatrist and a dietician are ideally available, though the situation differs across the country (interview Estonia 4).

The general organisation of the health care (with a gatekeeper role for the GP) guarantees clear lines of referral, but there are so far no formal shared care protocols for diabetes care in place (interviews Estonia 2, 3, 4).

Even if there are no official regulations on quality assurance in diabetes care so far, both general practices and hospitals seem to organise regularly audits of clinical practice, health care organisation and patient satisfaction, also in the field of diabetes care (Kaarna 2005; interviews Estonia 2, 3). In 2006 GPs will be able to join on a voluntary basis a quality-based payment system, which includes indicators for diabetes care (interviews Estonia 2, 3).

9.5 FRANCE

The health care system is regulated by the Ministry of Health and by the statutory health insurance funds. At the regional level, the Ministry has directorates of health and social affairs, most importantly the regional hospital agencies, the regional unions of the health insurance funds and the regional medical associations. The health care system is gradually becoming more decentralised to the regional level. At the same time, there has been a shift of power from the health insurance funds to the state.

Health care is financed through both social contributions and general taxes. It covers all French residents. Diabetes patients and other chronically ill patients do not pay for consultation and drugs. Material for self-control (glucose meter, glucose test strips) is also for free. There is hardly any reimbursement for podiatric and dietetic services, except in the context of care networks (see below). There is need for more reimbursement for health education, dietetic and podiatric services (interview France 1).

Physicians in ambulatory care are mainly paid on a fee-for-service basis. General practitioners are the pivotal structure in the primary care. General practice is poorly structured. Most GPs work in solo practices without any administrative support. They provide follow-up care to more than 94.5 % of the diabetic patients (Weill, 2000). Secondary care is provided in secondary care health centres or hospital outpatient clinics by an endocrinologist or by a specialist in internal medicine, a diabetes nurse, a

podiatrist and a dietician. Experts complained about the lack of coordination of diabetes care (interviews France 1, 2), about the professional isolation of some physicians and their denial for any quality control procedure (interview France 1).

One of the initiatives of the Health Ministry to improve the organisation of chronic care is the "care networks". These networks are welcomed as initiatives that enhance structured care and collaboration between health professionals (interview France 2). Only 2 % of the diabetes patients take part to such a network (Bulletin Epidémiologique Hebdomadaire 2003). A mandatory procedure of quality assurance for diabetes care will be implemented in the near future : it is expected to yield a significant quality improvement (interview France 1).

9.6 GERMANY

Germany has a contribution-based health care system, characterised by a high degree of self-regulation by the health care providers and by the sickness funds. Mixed committees of sickness funds and physicians' associations at Länder level are mostly responsible for the implementation of the national policy: they negotiate the contracts and also control their execution (Busse 2004a).

The GPs usually work in solo practices, with the support of one or two practice assistants. Since January 2005 they have a limited gatekeeper function (interview Germany 2). The use of diabetes registers, call/recall systems and specific diabetes clinics are rare in general practice. The GPs treat the majority of type 2 diabetes patients. Secondary care is provided in outpatient diabetes clinics and in the hospitals. The outpatient diabetes clinics are typically staffed by a diabetologist, a diabetes adviser and a diabetes assistant (Deutsche Diabetes-Union 2004).

The strong involvement of the German Diabetes Association (Deutsche Diabetes Gesellschaft, DDG), a physicians' organisation, is typical of a self-regulatory model (postgraduate education and quality assurance). Diabetologists, diabetes advisers and diabetes assistants are mostly DDG trained. The DDG sets standards for a DDG certificate for outpatient diabetes clinics and diabetes foot clinics. The DDG has also written clinical guidelines (Deutsche Diabetes-Union 2004).

The introduction of the disease management programme (DMP) for type 2 diabetes in 2004 thoroughly changed the provision of diabetes care, especially in primary care. By mid 2005 about 25% of all diabetes patients had entered the DMP. The DMP encompasses evidence-based treatment guidelines and a shared care protocol, defining the role of the GP and the specialist and the referral criteria. The physicians have to document their clinical practice for each patient. Sickness funds receive financial incentives when patients enter a DMP (Busse 2004b). As a result most sickness funds strongly promote the DMP. The physicians also receive an incentive but this one is small and does not compensate for the extra workload due to the DMP (interviews Germany 3, 4).

Quality monitoring is a weak point of the DMP (interview Germany 3, 4). Sickness funds are supposed to use the data from the physicians to draft individualised feed-back reports. The data are usually collected by non-medical personnel and their content is not validated (interview Germany 4). In many Länder the sickness funds do not succeed to compile meaningful individual reports on basis of these data (interview Germany 3). This strengthens the physicians' feeling that the system is a loss of time (interview Germany 3).

Before the DMP was introduced, several Länder had already experience with similar programmes, yielding good results. The expectations towards the impact of the DMP on diabetes care are high (interview Germany 2). However the first data in Nordrhein, do not show significant changes in the quality indicators, except for the participation to group-based health education (Siering 2004).

While it is still too early to draw conclusions on the effect of the DMP at a national level, the DMP clearly triggered new dynamics in chronic disease management in Germany. However, it remains doubtful whether it will finally improve the quality of

care : it does not create much extra financial input for the health care delivery system, it does not monitor well the quality of care and it does not link the quality of care to financial incentives.

A remarkable aspect of diabetes care in Germany is the widespread use of structured group-based educational programmes for diabetes patients. Outpatient diabetes clinics, sickness funds and some GP's organise these programmes. About half of all diabetes patients would have participated at least once (interview Germany 2). Within a DMP, each patient should have access to a structured health education programme (Gemeinsamer Bundesausschuss 2005).

9.7 THE NETHERLANDS

The Netherlands used to combine a mandatory contribution-based public health system and a voluntary private system for people with an annual income above 32 600 . However by 2006 this will be replaced by one contribution-based public system in which people will be able to choose between different health care packages (Ministry of Public Health, Welfare and Sports 2005). The public health system used to cover most costs for diabetes patients. Under the new system the basic package will for example no longer cover podiatric services (interview Netherlands 2).

More than half of the GP's work in group practices. They are supported by practice assistants and often also practice nurses. Practice coordinators are nurses specifically employed to support chronic disease management. They are involved in health education and clinical follow-up of diabetes patients. About half (45%) of the GPs also work with a diabetes specialist nurse (Baan 2003). Almost all GPs have a diabetes register (interview Netherlands 2). Diabetes clinics – usually run by the practice co-ordinator – and call/recall systems are common (interview Netherlands 2). In some regions GPs are also supported by diabetes labs which organise regular check-ups of the patients, send reminders to patients… About 75% of all diabetes patients are treated in primary care (Baan 2003). The well structured primary care is perceived as a major strength of the diabetes care organisation (interviews Netherlands 1, 4).

Nurses (practice nurses, practice coordinators and diabetes specialist nurses) have a positive impact on diabetes care (interviews Netherlands 1, 5). They are involved in health education and clinical follow-up. Diabetes specialist nurses usually help for starting insulin therapy. One quarter of all diabetes patients had at least once contact with a diabetes specialist nurse (Baan 2003).

Shared care protocols are common, but their geographical coverage is limited and their content can differ very much from one place to another (Baan 2003). All experts think that the shared care protocols are often not well implemented and/or evaluated (all interviews). Typically the shared care protocols have been developed in a bottom-up approach: local health professionals met and tried to structure diabetes care. A feeling of local ownership is important for the successful implementation of a shared care protocol (interview Netherlands 4). A lack of IT capacity and finances is seen as a major obstacle to promote shared care (interviews Netherlands 1, 4).

The new policy on diabetes care groups and the diagnosis-treatment chain should streamline these protocols and give them adequate financial support (Taakgroep Programma Diabeteszorg 2005). Its implementation might still take two years or more (interview Netherlands 1). The main elements of this new policy are the following ones. First specific contracts for diabetes care exist between health insurers and diabetes care groups: the diabetes care groups bring together general practitioners, diabetes nurses, dieticians and podiatrists. Secondly the health insurers will monitor the quality of care within the diabetes care group. Quality-based payments are expected to be part of the contracts (interview 5). Thirdly the information technology will allow an electronic diabetes record. Finally, a "diabeteskenniscentrum" will be established as a national diabetes knowledge centre.

In general the experts were positive about the expected policy changes (interviews Netherlands 1, 2, 3, 5). One expert expressed concerns about the capacities of health insurers for the quality monitoring and the risk of fragmentation of care (interview Netherlands 2).

9.8 SPAIN

In the health care reforms of the '80's Spain chose for a tax-based National Health System responsible for the management and the provision of health care. At the same time Spain went through a process of far-going decentralisation. Since 2002 all 17 Autonomous Communities have become the central managers and providers of health care (Rico 2000, Fundación para la Diabetes 2002).

The diabetes prevalence is estimated around 8% among women and 12.5% among men, of which about half is undiagnosed. The immigration of people from regions with a high diabetes incidence (e.g. Asia) could have an important impact on the national diabetes incidence (interview Spain 2). Several Autonomous Communities have regional diabetes registers. The experts expect systems for monitoring diabetes prevalence and incidence to become generalised in the future (interviews Spain 2, 4).

Diabetes care is often included in the health plans of the Autonomous Communities. Policy proposals concern issues as shared care, IT development, training programmes for health professionals and the establishment of regional diabetes registers. Several Autonomous Communities have a specific diabetes committee that advises policy-makers (Fundación para la Diabetes 2002).

The National Health System in each Community covers the medical and nursing care and the drug costs for diabetes patients. Glucose test strips are free in the primary health care centre but one expert felt too much strips were used, causing an important waste of resources (interview Spain 3). Dietetic and podiatric services are in principle also free, but they are not sufficiently available - only in some hospitals (interviews Spain 2, 3, 4). For podiatric services many patients go to private practice, which is not covered (interview Spain 3).

All patients are registered with a GP who has a gatekeeping function. The establishment of primary health care centres was one of the key elements of the health care reforms of the '80's. Today 85% of the GP's work within health care centres. They offer a strong basis for chronic disease management: they work within a multidisciplinary team of GPs, paediatricians and nurses. They use electronic medical records and usually keep diabetes registers. GPs have often a high workload and can not spend enough time with the patient but this can be compensated by the nurse consult (interview Spain 2).

Retinopathy screening in primary health care centres, using digital cameras, is presently being piloted. Experts expect that this screening programme will cover all primary health care centres in the future (interview Spain 2, 3, 4).

Secondary care is offered in the hospital environment and in ambulatory care centres that specifically deal with patients referred from general practice. The waiting times for an endocrinology consult can be long (interview Spain 2). The endocrinologist interviewed thought there was communication between the health workers at the different levels, e.g. through clinical meetings, resulting in some consensus on shared care (interview Spain 4). On the opposite, one interviewed GP felt the coordination of care could be improved (interview Spain 3). There are usually no formal shared care protocols (interviews Spain 2, 3).

Group-based health education is common in secondary and - to a lesser extent - also in primary care (interviews Spain 2, 3, 4).

The Study Group for Diabetes in Primary Health Care (GEDAPS) is a working group in the Catalonian branch of the Spanish Association of Family and Community Medicine. They took in 1993 an interesting initiative to measure the quality of primary care. They developed indicators for organisation, process and outcome of diabetes care as well as

an information system to facilitate data collection. This project gradually spread to all branches of the Spanish Association of Family and Community Medicine (Lafita 1998).

Today most Autonomous Communities monitor the quality of primary health care through a set of indicators called the "cartera de servicio". This "cartera de servicio" is adapted every year. It includes targets for both physicians and nurses (interviews Spain 2, 3).

9.9 THE UNITED KINGDOM

Traditionally the National Health Service (NHS) was the prototype of a tax-based, top-down organised system offering free health care. In the past 15 years, the NHS has undergone a series of reorganisations that have thoroughly changed its outlook, by - among others - the introduction of some free market aspects. However diabetes care remained almost for free, an aspect that experts saw as an important strength (interviews UK 2, 3, 4).

Diabetes care is a priority area for the NHS. The national policy was set out in the National Service Framework (NSF) for diabetes in 2001 (National Service Framework 2001). A national clinical director was appointed to overlook the implementation of the NSF for diabetes. A National Diabetes Support Team has to provide support to local diabetes networks.

The strong leadership of the NHS has been important in drawing the attention of both public and professionals to diabetes (interviews UK 1, 2, 3, and 4). However concerns were also raised about the repeated reorganisations which consume a lot of efforts within the system (interviews UK 2, 3).

The process of decentralisation in the '90's resulted in Primary Care Organisations with a relative autonomy. The Primary Care Organisations (PCO's) became the pivotal players in the organisation of diabetes care at local level. Through the local diabetes networks they bring together all stakeholders in diabetes care – both professionals and patients. They initiate shared care protocols, organise continuing medical education and provide support to the general practices by organising dietetic and podiatric services (Roberts 2005).

General practice is very well structured, characterised by patients' lists and a gate keeping function. Most practices organise diabetes clinics and have a diabetes register which is used for call/recall of patients. GPs often work in multidisciplinary teams. When not available within the practice, GPs can refer their patients for dietetic and podiatric services to the Primary Care Organisation or secondary care. Primary care health workers have many opportunities to follow specific trainings in diabetes care.

The introduction of the diabetes specialist nurses seems to be the most important change in secondary care in recent years. Diabetes specialist nurses are active in the diabetes clinics providing health education, starting insulin therapy and following up of patients. They are also more and more present in primary care, having a liaison role with the primary care practice nurses, doing home visits and organising diabetes clinics as an intermediary structure between the primary and secondary care (Winocour 2002b). Experts highly valued the impact of the diabetes specialist nurses (interview UK 1, 4).

PCO's received incentives to organise shared care protocols. These protocols have shifted the care for the type 2 diabetes patients more and more from secondary to primary care.

Outcome measurement, both at individual level (the Quality and Outcomes Framework) as at aggregated level (the repeated national and local audits) measure the quality of diabetes care. The Quality and Outcomes Framework represented a potential major increase in GP income. General practices did their best to obtain the highest possible scores, e.g. by employing extra staff, training staff… As a result the measured quality of care exceeded by far the expectations. The Quality and Outcomes Framework is not only a tool for quality measurement and payment, it also resulted in the establishment of a national register for diabetes and other chronic diseases. The

results of the Quality and Outcomes Framework have only just been published and its impact seems to be huge (interview UK 2). At the other hand, one expert also expressed some fear that the emphasis on data collection and recording could go at the expense of the patient-centeredness (interview UK 2). It is important to note that the Quality and Outcomes Framework has only been possible thanks to the availability of powerful IT systems in general practice.

The interviewees also emphasised the importance of the strong research basis for ensuring a high quality of care (interviews UK 2, 3). The National Institute for Clinical Excellence became an internationally reputed institution which has produced nation-wide accepted guidelines for both type 1 and 2 diabetes.

Experts expect diabetes care to become more multidisciplinary in the future. Health professionals will have to be more flexible e.g. nurses and pharmacists will provide more and more diabetes care (interviews UK 1, 2). One expert raised concerns about this shift of professional boundaries, as diabetes care might become more fractioned e.g. private companies offering diabetes services (interview UK 2).

The further expansion of the use of IT will create new possibilities (interviews UK 3, 4). The interviewed diabetologist foresaw the development of a national electronic patient record, where all primary and secondary care health workers would be part of one virtual diabetes team (interview UK 4).

10 CONCLUSIONS: ORGANISATION OF DIABETES CARE IN 9 COUNTRIES

The analysis of the organisation of diabetes care in various European countries shows similar trends towards:

- More evidence-based clinical practice;
- More multidisciplinary and structured care with the introduction of shared care protocols;
- Quality monitoring, both at practice level and at regional or national level;
- Development of IT facilities to achieve shared care and quality monitoring.

Differences in the organisation of diabetes care are mainly explained by:

- The extent to which the intended changes – as described above - have already been implemented;
- The characteristics of the overall health care organisation in which the changes are taking place.

Several aspects could be important preconditions to achieve the above objectives:

- At macro level:
  - An overall health care organisation that favours chronic disease management,
  - Adequate financing of chronic disease management initiatives,
  - National support for the development of IT facilities,
  - Setting diabetes on the national agenda,
  - Availability of nationally accepted and regularly updated guidelines,
  - Research into the organisation of diabetes care,
- At meso level:
  - Availability of structures that support/coordinate/supervise local diabetes care,
  - Involvement of all stakeholders in the development of shared care protocols,
- At micro level:
  - Availability of multidisciplinary teams with a pivotal role for the GP and involvement of nurses,
  - Structured health education.

10.1 EVIDENCE-BASED CLINICAL PRACTICE

In the '90's several studies thoroughly changed the care for type 2 diabetes patients. They formed a basis for a more evidence-based clinical practice. By 2005 each country has evidence-based clinical guidelines for type 2 diabetes whereas it was not the case only a few years ago. More and more guidelines are developed by multidisciplinary panels in which both primary and secondary care, physicians and other health workers are represented. Our study hardly found any information about the extent to which these guidelines are actually implemented in daily practice.

10.2 MORE MULTIDISCIPLINARY AND STRUCTURED DIABETES CARE – THE INTRODUCTION OF SHARED CARE PROTOCOLS

In all countries analysed the majority of diabetes patients are treated in primary care, with the GP as central caretaker. Secondary care mainly gets involved for the management of patients on insulin therapy or with complications.

The studies of the '90's showed that more intensive diabetes treatment leads to better outcomes. The target values for glycaemia, blood pressure and cholesterol control became much stricter. Audits in several countries showed that in daily practice many patients fail to meet these targets. In all countries experts think that the diabetes outcome might be improved by a more multidisciplinary and structured organisation of the care.

Most countries develop models of shared care for diabetes patients, often translated into shared care protocols. These protocols usually describe the clinical guidelines, the roles of the physicians (in primary and secondary care) and other health workers, and the evaluation procedure. They emphasise patient's autonomy and the importance of structured health education.

Evaluation is often a weak point of the protocol. As a result the impact of these protocols on the outcome of diabetes care is not yet clear.

Some experts expressed the fear that the emphasis on the structural aspects of care within the shared care protocols could create a care that is less patient-centered, with less attention for lifestyle change and more fragmented (with elements shifting from general practice to specific diabetes services, diabetes nurses etc.).

10.3 QUALITY MONITORING

In all countries experts expressed a need for monitoring the quality of diabetes care. Several countries are taking initiatives to monitor the quality of care both at national level (through e.g. national audits or studies on a nationwide patient sample) and at practice level.

There is a wide variation between countries in the extent to which they established systems of quality monitoring. The UK has the most advanced system. The UK national diabetes audit demonstrates that quality monitoring at national level can have an important impact on the policy making process. The UK Quality and Outcomes Framework proves that monitoring at individual level has an even bigger potential to improve quality of care. However, the results in the UK can not be automatically transferred to other countries, as they are achieved in a context of very well structured general practice, important financial incentives linked to the outcome and strong IT support.

Quality monitoring is also being introduced in Germany (within the DMP), the Netherlands (in the context of the diagnosis-treatment chain for diabetes), Estonia, Denmark and Canada. In Spain diabetes care is part of the "cartera de servicio", a set of indicators that is used for quality-based payments in primary care. In Belgium the quality of care is monitored for patients under the diabetes convention.

10.4 DEVELOPMENT OF IT FACILITIES

The experts expect much of IT developments on the quality of diabetes care. It is important for two crucial elements in the organisation of diabetes care i.e., the communication between health professionals (enhancing shared care) and the quality monitoring.

Several countries took national initiatives to make IT systems compatible and to set up a common electronic medical record. Andalucía (Spain) has already an electronic medical record that is accessible for all health professionals. Germany introduces in 2006 an electronic health card. The card will be used in the first place for storage of

administrative data but can also contain medical information when the patient chooses to use this feature.

General practice in the UK has an IT system that enables centralised data collection for quality monitoring. In Spain data for quality monitoring in primary care are also extracted directly from the electronic medical record. However, in all other countries, it might still take several years before this becomes reality.

10.5 PRECONDITIONS

The description of the changes that are planned or are taking place in diabetes care in several European countries allows identifying several aspects at macro, meso and micro level that could be important for a successful implementation of these changes.

10.5.1 Preconditions at macro level

10.5.1.1 A health care organisation that favours the chronic disease management

The overall health care organisation – and especially the organisation of primary care – has a clear impact on the organisation of diabetes care. It seems relevant to distinguish the health systems by the way they try to strike a balance between the patient's demand and the public health demand. In Belgium, Canada (Québec), France and Germany, the freedom of choice of the individual patient is traditionally large. Patients are not listed with a GP, the GPs do not have a gatekeeper role and the physicians are mainly paid on a fee-for-service basis. This creates health systems responsive to the patient's demand but poorly equipped to manage chronic diseases. They have a weakly structured general practice (with most GPs working in solo practices little personnel support). The fee-for-service payments are a barrier for shared care. The systems face difficulties to make the patient follow the recommended pathways through the health system. On the other hand, Denmark, Estonia, the Netherlands, Spain and the UK chose for an alternative organisation of health care based on patients' listing, a gatekeeper role for the GP and physicians' payment systems that are not mainly fee-for-service based. In general, the general practice teams are more often multidisciplinary, providing a wider range of competences needed for chronic disease management. Health education sessions are often provided within the general practice. Specific diabetes clinics, diabetes registers and call/recall systems are more common. The referrals between primary and secondary care are better defined. The general organisation of the health system clearly favours the chronic disease management. Since a few years, the health systems of Belgium, France and Germany move towards a more structured organisation of health care through an attempt to introduce e.g. limited capitation fees in Belgium and financial gate keeping in France and Germany.

10.5.1.2 Adequate financing of chronic disease management

There was a general agreement among experts that chronic disease management requires extra financial resources for coordination, capacity building and quality monitoring. The question remains how these financial resources should be dispensed.

One of the main objectives of the diagnosis-treatment chain for diabetes in the Netherlands is to provide adequate financing for shared care protocols. The payments will be quality-based.

The Quality and Outcomes Framework in the UK encompasses considerable quality-based payments but is not linked to a shared care protocol. It had an important impact on the quality of care in general practice.

The Disease Management Programme (DMP) in Germany also provides extra finances, but mainly for the sickness funds and much less for the physicians. The physicians have to submit a detailed report of their clinical practice to the sickness funds. The sickness funds should give individualised feed-back to the physicians but often fail to do so and this feedback does not affect the physicians' payments. While the Quality and Outcomes

Framework made general practices in the UK employ and train extra staff, the extra financial input of the DMP in general practice is far too small to have such an impact. It will be interesting to analyse the impact of the German shared care model on the quality of care.

10.5.1.3 National support for development of IT facilities

The IT systems used by the different health professionals and institutions should be compatible to ensure a fruitful communication between health workers and an optimal data collection on quality of care. This requires initiatives at national level.

10.5.1.4 Putting diabetes on the national agenda

Changes in the organisation of diabetes usually originate from local initiatives. At the other hand, it is very important for these local initiatives to reach a nationwide coverage with diabetes on the national agenda. The patients' organisations are usually very effective lobbyists – especially in alliance with health professionals. A national co-ordinator or a national steering committee play an important role in putting diabetes care on the agenda.

10.5.1.5 Availability of nationally accepted and regularly updated guidelines

Every country studied had evidence-based guidelines. Guidelines remain the cornerstone of optimal diabetes care. To ensure its nationwide acceptance, all stakeholders should be involved in the guideline development. In most countries the guidelines are regularly updated.

10.5.1.6 Research into the organisation of diabetes care

The description of the organisation of diabetes care in the different countries showed a lack of valid and reliable data on the actual situation in the field. A description of the present situation is probably the first step in the process of changing diabetes care. In the UK – and to a lesser extent in the Netherlands – there is a considerable body of literature on the organisation of diabetes care. One consequence is that these countries also have more developed diabetes care models than most other countries.

10.5.2 Preconditions at meso level

10.5.2.1 Availability of structures that support, co-ordinate and supervise local diabetes care

In several countries structures at meso level (sickness funds in Germany and the Netherlands, PCO's in the UK) create a forum where health professionals can meet. They are often the initiators of shared care protocols. They are or will be involved in quality monitoring. In the UK the PCO's also have a large autonomy to organise diabetes care: they set up diabetes registers, plan training for health professionals, support primary care (e.g. by employing a dietician, organising call/recall systems and annual check-ups, setting up screenings programmes for retinopathy).

These structures at meso level can play an important role in the implementation of health policies. Their strength is probably that they can involve all local stakeholders in the implementation process. The "Samenwerkingsinitiatieven Eerstelijnsgezondheidszorg" as they are going to be established in Flanders, might take up this role in the future, provided they are adequately financed and professionally run.

10.5.2.2 Involvement of local stakeholders in the development of shared care protocols

Shared care protocols are often initiated at local level, by groups of health professionals, health insurers - and sometimes also patients. This was the case in the Netherlands, Denmark, Germany and the UK.

The importance of local involvement does not concern only the content of the shared care protocols – as within one country they are usually very similar. The value of local involvement probably lays mostly in the fact that health professionals meet, strengthen their personal relationships and develop a mutual understanding and respect.

10.5.3 Preconditions at micro level

10.5.3.1 Availability of multidisciplinary teams with a pivotal role for the GP

The composition of the general practice team differs between countries, from solo practices with informal collaborations (e.g. with dieticians and podiatrists) to multidisciplinary teams (involving practice assistants, practice nurses and sometimes even diabetes nurses, dieticians and podiatrists). The secondary care team ideally consists of a diabetologist or endocrinologist, a (diabetes) nurse, a dietician and a podiatrist, but today this is certainly not everywhere the case. The multidisciplinarity of the team enhances the communication between caregivers and hence the comprehensiveness of the diabetes care.

10.5.3.2 Involvement of nurses in the multidisciplinary teams

Diabetes nurses become more and more essential in diabetes care, both in the primary and secondary settings. Their titles, qualifications and functions differ between countries but two categories roughly emerge:

- Nurses with no or only a limited postgraduate training in diabetes care, usually working in general practice. They provide health education and clinical follow-ups of the diabetes population. They are common in the Netherlands, the UK, Spain, Estonia and - to a lesser extent - Denmark.
- Nurses who got a more extensive postgraduate training ("diabetes specialist nurses"). They work in secondary care and sometimes also in primary care. They usually work with more complex diabetes patients (e.g. starting of insulin therapy). Their functions vary from health education only to clinical follow-ups, training of staff, liaison between primary and secondary care. They exist in Belgium, Canada, Denmark, Germany, the Netherlands, Spain and the UK.

Nurses' involvement is crucial for the provision of structured individual health education. They often play an important role in the coordination of diabetes care. They also relieve the physicians' workload, especially in primary care. The diabetes specialist nurses and the practice nurses were specifically mentioned as strengths of the system in the UK and in the Netherlands, where they also had larger responsibilities than in other countries.

10.5.3.3 Structured health education

Many experts and national policies stress the importance of health education but it is hard to find data on the extent to which health education is actually provided in daily practice. Several countries as e.g. Germany developed programmes of group-based health education but the effectiveness of these programmes is not adequately evaluated. A Cochrane review showed that group-based educational programmes had an important positive effect on outcome indicators under research circumstances.

11 CONCLUSION

This project analysed the organisation and quality of diabetes care using three complementary approaches i.e., a search for evidence-based quality indicators, a systematic literature overview on diabetes care organisation and an analysis of the European health care organisation in European countries.

The first conclusion from the literature review is that the effectiveness of diabetes care is not influenced by the context: hospital-based and general practice-based models lead to similar patient and process outcomes. The complementary information from the European study highlighted the pivotal role of the GP for the care of diabetic 2 patients in all countries. However, the type and the intensity of the interventions influence the outcome of care in the different care models studied: single intervention programs are less effective than multifaceted interventions although no single intervention has proven to be more effective than the other ones. The importance of multifaceted interventions is indeed found in the organisation of different European health systems with the introduction of shared care protocols (as in Denmark, the Netherlands, Germany and UK).

The literature review analysed the organisation of diabetes care using four components of the chronic care model i.e. self-management support, clinical information systems, delivery system redesign and decision support. These elements were proposed by Wagner et al. (1991) as major components to improve the quality management of chronic diseases. One of the major findings of the literature review is that studies with interventions featuring all chronic care model interventions improved patient outcome measures. The majority of studies using fewer interventions were also effective but to a lesser extent. No single intervention of the chronic care model emerged as essential (or superfluous) for the effectiveness of diabetes care.

Most studies showed that the process of care is positively influenced by decision support materials, self management support, delivery system redesign and clinical information systems.

Decision support materials (guidelines and postgraduate education) are effective on process outcomes in combination with other interventions as local consensus processes, audits, reminders, feedbacks, peer review or combinations of these interventions. In practice, the European study confirmed a trend toward more evidence-based clinical practice as most European countries developed evidence-based guidelines. The dissemination and the implementation of these guidelines vary according to the countries: some have organised peer review groups (e.g. Belgium, Germany) whereas continuing medical education is more frequent, sometimes linked with certification (Estonia, Germany). The National Diabetes Audit project in the UK is the only European project that analyses diabetes care on a national level.

Self-management support as patient education, surveillance support, reminders and behavioural contracts also have an impact on the process of care. The European study found that few countries have organised patient education at a meso (regional) or macro (national policy) level. However education programmes are (locally) available in most countries. One of the best illustrations of patient education initiative is found in Germany, with the widespread use of structured group-based educational programmes for diabetes patients. About half of all diabetes patients would have participated at least once to such a programme.

Delivery system redesign is the third intervention that might influence the process of care. It encompasses intensive arrangements for the follow-up and the implementation varies according to the studies e.g., scheduled visits, tracking of the patients using computerised systems, regular contact by nurses, telephone calls for rescheduling visits failures. The follow-up is facilitated by initiatives such as the implementation of diabetes registers in general practice (Estonia and UK). Call/recall systems also exist in the UK and in the Netherlands.

Clinical information systems (as computerised reminder systems) are the fourth intervention with an effect on process outcomes. European experts also expressed high

expectations about the role of IT (Information Technology) to facilitate the communication between the caregivers and to monitor the quality of diabetes care. However the analysis of the field shows that the UK is the only European system with a common IT system for all general practices.

The effect of specific interventions on patient outcomes is less clear in the literature. Two types of interventions might have a positive impact on the outcome of care, i.e., patient interventions (as described above as self-management support) and the revision of the professional role. The revision of the professional role was analysed in studies in which nurses were involved in the care of diabetes patients in collaboration with other caregivers. These studies generally demonstrated a positive impact on patient outcomes, especially if the intervention was combined with other intervention strategies. The analysis of the European systems shows indeed the growing role of diabetes nurses ("diabetes educators" in Belgium). However it is difficult to draw firm conclusions about their optimal place as their training and their function greatly vary according to the different European health care systems (for example responsibility of health education and/or of the clinical follow-up).

Quality monitoring is needed to measure how far these interventions have an effect on the process and patient outcomes. Such monitoring exists in the UK, Germany, The Netherlands and Denmark. In Belgium this monitoring only concerns the patients with a diabetes convention.

The judicious development, choice and use of indicators are important to monitor the quality of diabetes care. This study found that the definition of indicators widely differs between the authors. The group decided to adopt the definition of the indicator from the UK reference "Measuring General Practice" (from Marshall et al., 2003) : "a measurable element of practice performance for which there is evidence or consensus that it can be used to assess the quality of care provided, and hence change it". In this project a selection of the guidelines was first performed on specific quality criteria given the high number of guidelines found in the exhaustive literature search. It appeared that the indicators found in the guidelines and in the indicators sets mainly referred to the process of care, a few of them to the (intermediate) outcome of care. The most important indicators are cited in the recent Belgian guideline (WVVH, 2005): they were validated by major clinical trials using different interventions (e.g. UKPDS).

This search of evidence based quality indicators raises several issues. First, the high number of "valuable indicators" (supported by the evidence) implies to prioritise some of them. However no evidence based data allows a choice to be made. The potential indicator users (e.g., clinicians, stakeholders) need therefore to keep an open mind in order to select an optimal number of quality indicators reflecting various domains of diabetes care. A second point is that important indicators at the micro level (patient and practice) are especially valuable when they can be translated at the meso (regional) and macro (national policy) levels (e.g., indicators on diabetes complications). Finally, an effort is required to adapt continuously the targets set for the indicators' values. The basic nature of the diabetes care indicators only slightly varies between the literature sources. However major adaptations in target levels are continuously performed, reflecting the last developments found in the scientific studies (ex: HbA1c target values, frequency of microalbuminuria monitoring…).

The search strategy used (i.e. mainly medical literature) allows mainly conclusions on the effectiveness of diabetes care but no conclusion can be drawn on the accessibility and cost of the different care models.

The global trends found today in European health care systems are towards a better management of chronic diseases. The care of diabetes follows these trends with the GP as a central caregiver for diabetic 2 patients, in close collaboration with a multidisciplinary team. The European heath care systems show that several conditions are important at all levels to achieve an optimal management of diabetes patients, i.e.:

- At the macro level : an overall health care organisation that is conducive for chronic disease management (as in the UK) i.e., an adequate financing, a national support for the development of IT

facilities, a national leadership and a research into the organisation of diabetes care;

- At the meso level: the availability of structures that support/coordinate/supervise local diabetes care and the involvement of all stakeholders in the development of shared care protocols;
- At the micro level: the existence of multidisciplinary teams and structured health education.

Every condition mentioned above contributes to the optimal care of the population of diabetic 2 patients. Their practical implementation needs to be carefully studied in the context of the Belgian health care system.

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