

De kwaliteit en de organisatie van type 2 diabeteszorg

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Het Federaal Kenniscentrum voor de gezondheidszorg

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VOORWOORD

Wereldwijd blijft het aantal diabetespatiënten stijgen. En, alhoewel diabetes niks te maken heeft met een infectieziekte, wordt dit ook wel eens de 'diabetesepidemie' genoemd. Deze epidemie gaat hand in hand met de andere volgens de WHO met een alarmerende snelheid op ons af komende 'obesitasepidemie'. Het type II diabetes, waarover dit rapport handelt, is niet langer een ziekte van ouderen. Ook steeds meer jongere patiënten worden ermee geconfronteerd.

Diabetes is medisch een belangrijke oorzaak van ziekte en vroegtijdige dood en heeft een enorme financiële maatschappelijke impact. Volgens internationale schattingen zou diabetes 5-10% van de middelen voor gezondheidszorg opsouperen.

Rekening houdende met de stijging in levensexpectantie en de huidige sedentaire levensstijl en voedingsgewoonten ziet het er niet naar uit dat de toename aan diabetespatiënten op korte termijn tot stilstand zal komen. België mag terecht fier zijn op haar systeem van 'diabetesconventies', oorspronkelijk gericht op insulinedependente diabetespatiënten (type I) die voor hun levenslange opvolging en behandeling van complicaties terecht kunnen in gespecialiseerde ziekenhuiscentra. Maar geneeskunde evolueert en ook een deel van de type II patiënten wordt met insuline behandeld en dient gedurende vele jaren opgevolgd. Het klassieke conventiesysteem met ziekenhuizen zal de hogerbeschreven toestroom niet aankunnen. Beleidsmatig stelt dit een ware uitdaging aan ons gezondheidszorg. Wat is dat de meest efficiënte organisatievorm voor deze chronische ziekte, die regelmatig een samenwerking tussen verschillende disciplines vergt. En hoe kan dan de kwaliteit van diabeteszorg gegarandeerd worden, wetende dat diabetes meer is dan het controleren en opvolgen van het bloedsuikergehalte en een specifieke aanpak vergt van andere cardiovasculaire risicofactoren en complicaties.

Een dergelijke onderzoeksvraag over de grootschalige organisatie van hoogkwalitatieve zorgen vergde ook een relatief grootschalige onderzoeksanpak gaande van een doorgedreven systematische literatuurstudie, het beschrijven van bestaande initiatieven en een internationale vergelijkende studie van hoe diabeteszorg in andere landen georganiseerd is en welke lessen daaruit kunnen getrokken worden. Het KCE kijkt fier terug op de eveneens vrij grootschalige en multidisciplinaire samenwerking tussen vier universitaire teams en de Vlaamse diabetesvereniging die tot een bijzonder concreet en wetenschappelijk onderbouwd rapport heeft geleid. Onze dank ook aan de vele terreinexperten die input gaven en ervoor zorgden dat de aanbevelingen realistisch zijn gebleven. Eén leidraad komt uit dit onderzoek sterk naar boven: toekomstige veranderingen in de organisatie van diabeteszorg waartoe dit rapport meerdere opties biedt dienen te kaderen in een globaal langetermijnplan met duidelijke patiëntgerichte en meetbare doelstellingen.

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INLEIDING

Wereldwijd ziet men een toenemende prevalentie van diabetes, voornamelijk van type 2 diabetes, dat momenteel 85% van alle diabetesgevallen uitmaakt. Patiënten met type 1 diabetes produceren (bijna) geen insuline, terwijl patiënten met type 2 diabetes wel insuline produceren, maar het organisme deze insuline niet meer correct kan gebruiken. De prevalentie van type 2 diabetes stijgt met de leeftijd. Er kunnen verscheidene redenen worden geïdentificeerd voor deze dramatische toename, bijv. een vergrijzing van de bevolking, een toenemende prevalentie van obesitas en een sedentaire levensstijl in de Westerse landen. Deze toenemende prevalentie van type 2 diabetes zet de organisatie van de Belgische gezondheidszorg onder zware druk. Volgens de huidige schattingen lijdt 4 tot 5 % van de Belgische bevolking aan diabetes en men verwacht een aanzienlijke stijging in de nabije toekomst. Diabetes is de voornaamste oorzaak van blindheid en van terminaal nierfalen bij volwassenen, en de aandoening veroorzaakt meer dan een verdubbeling van de cardiovasculaire mortaliteit. Dit brengt niet enkel menselijk lijden met zich mee, maar heeft ook een grote financiële impact op de uitgaven voor de gezondheidszorg. Er is een dringende nood aan een plan met strategieën voor de preventie, de vroege diagnose en een adequate behandeling van diabetes.

Een grote uitdaging in de behandeling van type 2 diabetes is de multifactoriële aanpak die vereist is om complicaties van diabetes te voorkómen: glycemieregeling, cardiovasculaire preventie en in het bijzonder aandacht voor levensstijlinterventies die de lichaamsbeweging doen toenemen en gewichtscontrole beogen.

Deze studie is erop gericht om aanbevelingen te formuleren voor de kwaliteit en de organisatie van de diabeteszorg in België. De klemtoon van deze studie ligt op type 2 diabetes, gelet op de toenemende sociale impact hiervan. Bij de behandeling van type 2 diabetes zijn veel spelers betrokken en de organisatie van de zorg is een uitdaging. Dit project werd gerealiseerd door een multidisciplinair consortium van endocrinologen-diabetologen en huisartsen van vier universiteiten in samenwerking met de Vlaamse Diabetes Vereniging (VDV). Drie vragen werden bestudeerd:

1. Welke zijn de kwaliteitsindicatoren van diabeteszorg, beschreven in de referentieliteratuur en in internationale richtlijnen?
2. Wat zijn de effecten van verschillende zorgmodellen op de uitkomst van gezondheidsgebonden en niet-gezondheidsgebonden zorgen?
3. Hoe wordt diabeteszorg in 9 Westerse landen georganiseerd (sterke en zwakke punten van de systemen)?

De zorgniveaus werden gedefinieerd op het micro-, meso- en macroniveau. Het microniveau van zorg is het niveau waar de individuele interactie tussen de patiënt en zijn/haar zorgverstrekker plaatsgrijpt (= patiëntenniveau). Het mesoniveau van de zorg is het niveau waar verschillende regionale gezondheidszorgorganisaties of interdisciplinaire platforms samenwerken (= niveau van de medische praktijk en/of regionaal niveau). Het macroniveau van de zorg is het niveau waar beleidsmakers, verzekeringsinstellingen, professionele organisaties, leerkrachten en onderzoekers elkaar ontmoeten (beleidsniveau).

I

DEELPROJECT 1: KWALITEITSINDICATOREN (PROCES EN UITKOMST) VOOR DE ZORG VOOR TYPE 2 DIABETESPATIËNTEN

Een grondig onderzoek naar op evidentie gestoelde kwaliteitsindicatoren voor de zorg voor type 2 diabetespatiënten werd uitgevoerd door hoofdzakelijk gebruik te maken van de Belgische richtlijnen en de richtlijnen van de 8 bestudeerde landen (Canada, Denemarken, Estland, Frankrijk, Duitsland, Spanje, Nederland en het Verenigd Koninkrijk).

De literatuuranalyse werd was opgebouwd uit opeenvolgende fasen. In een eerste fase werd de onderzoeksvraag gedefinieerd in overeenstemming met het 'PICO' principe. In de tweede fase produceerde de onderzoeksstrategie een integrale lijst van bestaande richtlijnen. Vervolgens werden de richtlijnen beoordeeld op hun wetenschappelijke kwaliteit en hun relevantie. Ten slotte werden de potentiële kwaliteitsindicatoren die men in de richtlijnen vond, beoordeeld en geanalyseerd. De potentiële kwaliteitsindicatoren voor het proces en de uitkomst werden opgelijst en specifieke doelwaarden of indicatorspecificaties werden toegekend.

Uiteindelijk werden vierenzestig (64) potentiële kwaliteitsindicatoren geïdentificeerd in 104 richtlijnen (gekozen op basis van hun wetenschappelijke kwaliteit en hun relevantie voor het beantwoorden van de onderzoeksvraag). Een definitieve lijst met 29 proces- en uitkomstindicatoren werd verkregen nadat men enkel de indicatoren uitsluitend op evidentie gebaseerd waren, weerhield. Deze potentiële indicatoren werden gerangschikt volgens vijf belangrijke aspecten van de ziekte en de verbonden zorg: glycemiecontrole, vroegtijdige opsporing van glycemische complicaties (hypoglycemie, hyperglycemie, retinopathie, nefropathie, voetproblemen), behandeling van glycemische complicaties, cardiovasculaire aandoeningen (macrovasculair: AMI, CVA, ...) en levenskwaliteit.

Op het microniveau werden aan de 29 potentiële indicatoren doelwaarden (voor de uitkomstindicatoren) en verdere indicatorspecificaties (voor de procesindicatoren) toegekend. Dit project concentreerde zich enkel op indicatoren, maar dezelfde procedure zou in de toekomst kunnen uitgevoerd worden om kwaliteitsstandaarden (mesoniveau) en evaluatiecriteria (macroniveau) te definiëren.

De literatuur leidde tot de conclusie dat de rechtstreekse transfer van indicatoren tussen landen met verschillende gezondheidssystemen, klinische praktijken en culturen, niet mogelijk is zonder aanpassingen. Deze correctie vereist bijkomende informatie zoals de essentiële precondities die het mogelijk zouden kunnen maken dat de indicatoren, maar ook de standaarden en (evaluatie)criteria, binnen een bepaald gezondheidzorgsysteem geïmplementeerd worden. In dit project worden de specifieke doelwaarden en de indicatorspecificaties afgeleid (indien ze voorkomen) uit de Belgische richtlijnen voor type 2 diabetes. Het resultaat is dat de 29 potentiële indicatoren de op evidentie gestoelde waarden en specificaties weerspiegelen met de hoogste relevantie voor de Belgische gezondheidszorg

De lijst met indicatoren, standaarden en (evaluatie)criteria (elk met hun eigen corresponderende en essentiële precondities) weerspiegelt niet alleen de kwaliteit van zorg, maar ook de acties of precondities die nodig zijn om een hoge kwaliteit van diabeteszorg op micro- (patiënt), meso- (praktijk/regionaal) en macro- (beleid) niveau te bieden.

Een aantal suggesties met betrekking tot de ontwikkeling en het gebruik van kwaliteitsindicatoren vloeien uit dit project voort, bijv:

- Om de lijst met potentiële proces- en uitkomstindicatoren voortdurend te evalueren, te valideren en prioriteiten toe te kennen;
- Om regelmatig op evidentie gestoelde aanpassingen te voorzien;
- Om doelwaarden en specificaties van bepaalde kwaliteitsindicatoren uit te werken waarvan men nu nog te weinig gegevens heeft. Dit kan gedaan worden door gebruik te maken van evidentie uit andere richtlijnen (indien vermeld) of door noodzakelijke precondities aan te pakken en te creëren om dit mogelijk te maken (cf. de analyse van de organisatie van diabeteszorg in de literatuur en in het buitenland);
- Om de noodzakelijke precondities te creëren om de potentiële indicatoren te kunnen vertalen naar standaarden en (evaluatie)criteria;
- Om de gevolgde methode voor het microniveau (patiënt) te herhalen voor het meso- en macroniveau om lijsten met standaarden en evaluatiecriteria te genereren met specifieke doelwaarden en specificaties.

2 DEELPROJECT 2: ZORGMODELLEN VOOR TYPE 2 DIABETES MELLITUS PATIËNTEN

Het objectief van het tweede deel van het project was om de effecten van verschillende zorgmodellen op al dan niet gezondheidsgebondenuitkomst van de zorgen bij type 2 diabetes mellitus patiënten te analyseren.

Via het systematische literatuuronderzoek werden negenenvijftig (59) studies opgespoord, waarvan twaalf (12) studies werden gerangschikt als zorgmodellen in het ziekenhuis en zevenenveertig (47) studies als zorgmodellen voor eerstelijnszorg, ambulante patiënten en voor de algemene bevolking ('community setting'). Vierenvijftig (54) artikels werden uiteindelijk geselecteerd, wat resulteerde in twaalf (12) zorgmodellen voor het ziekenhuismilieu en tweeënveertig (42) zorgmodellen voor de eerstelijnszorg, het ziekenhuismilieu en de 'community settings'.

2.1 IDENTIFICATIE VAN ZES ZORGMODELLEN VOOR DIABETES

In de onderzochte literatuur werd de typologie van de zorgmodellen bepaald door die zorgverlener die werd beschouwd als de hoofdverantwoordelijke voor het nemen van (medische) beslissingen over het hele zorgproces. Zorgmodellen voor het ziekenhuismilieu, de eerstelijnszorg, de ambulante patiënt en de gemeenschapscentra werden geanalyseerd. In de praktijk werden echter bijna geen studies gevonden die de doeltreffendheid van zorgmodellen voor diabetes in ziekenhuismilieu en in de eerstelijnsgezondheidszorg met elkaar vergeleken.

Men identificeerde de volgende zes zorgmodellen:

- Het zorgmodel met de huisarts in de eerstelijnszorg ("The general practitioner model in primary care")
- Het gedeelde zorgmodel met een leidende rol voor de huisarts in de eerste lijn ("The general practitioner-led shared care model in primary care")
- Het gedeelde zorgmodel met de leidende rol voor de verpleegkundige-educator in de eerste lijn ("The nurse educator-led shared care model in primary care")
- Het zorgmodel met een leidende rol voor de specialist in de eerstelijnszorg ("The specialist-led model in primary care")
- Het gedeelde zorgmodel in het ziekenhuismilieu ("The hospital based shared care model")
- Het zorgmodel met een leidende rol voor de apotheker. ("The pharmacist-led model")

2.2 CONCEPTUELE BASIS VOOR DE CLASSIFICATIE VAN DE CHRONISCHE ZORGMODELLEN

De onderzochte literatuur beschreef een grote waaier aan verschillende elementen in de zorgvoorziening die werden getoetst aan de kwalitatieve uitkomst van de interventies (proces- of patiëntenuitkomsten). De huidige studie gebruikte het conceptuele model ontwikkeld door Wagner (2001) om de verschillende chronische zorginterventies te classificeren, te verzamelen en te groeperen. De vier basisprincipes van dit model zijn: ondersteuning van de beslissing (hulpmiddelen voor medisch professionelen), zelfzorgondersteuning voor de patiënten en families, de ontwikkeling van een zorgverstrekkingssysteem (organisatie van de zorg) en klinische informatiesystemen. In dit werk werden 19 zorginterventies geïdentificeerd die verband hielden met deze vier dimensies.

2.3 EEN OPERATIONELE DEFINITIE VAN DE KWALITEIT VAN DE ZORG: KWALITEIT GEDEFINIEERD ALS DOELTREFFENDHEID

Het literatuuronderzoek leverde slechts een gedeeltelijk antwoord op de vraag naar het effect van verschillende zorgmodellen in het ziekenhuismilieu en de eerstelijnszorg op de kwaliteit van de zorg voor type 2 diabetes mellitus patiënten. Inderdaad, alle onderzochte studies definieerden de kwaliteit van de zorg als de doeltreffendheid van de zorg. Nochtans is doeltreffendheid niet het enige element binnen de kwaliteit van de zorg. In dit literatuuroverzicht werd geen enkel artikel aangetroffen met een bruikbare opzet voor andere dimensies van de zorgkwaliteit zoals Campbell et al. (2000) definieerden, bijv. toegankelijkheid, beschikbaarheid en betaalbaarheid (een essentieel onderdeel van de toegankelijkheid). In deze literatuurstudie werd ook geen enkele kosten-baten analyse van de implementatie van de verschillende chronische zorgmodellen voor diabetes geïdentificeerd.

2.4 KRITISCHE FACTOREN VAN DOELTREFFENDE ZORGMODELLEN VOOR DIABETES

Eén van de meest belangrijke vaststellingen van deze studie is dat geen enkel model werd gevonden dat een betere zorg bood dan andere modellen wat de doeltreffendheid op het patiënten- en/of procesniveau betreft. De doeltreffendheid van de verschillende zorgmodellen was afhankelijk van de aard en de intensiteit van de interventies, onafhankelijk van hun andere intrinsieke kenmerken. Nochtans waren zorgprogramma's voor diabetes met slechts één interventie minder doeltreffend dan interventieprogramma's opgebouwd uit meerdere facetten, zelfs als geen enkele interventie doeltreffender bleek te zijn dan een andere. Multidisciplinaire zorg als onderdeel van interventieprogramma's met meerdere facetten was doeltreffend op het patiënten- en procesniveau. Zoals hierboven vermeld, werd geen evidentie voor de toegankelijkheid van de verschillende zorgmodellen aangetroffen en werden slechts beperkte gegevens over de kosten-effectiviteitsanalyse gevonden.

2.5 GEEN ENKELE INTERVENTIE BLEEK ESSENTIEEL VOOR DE DOELTREFFENDHEID

Het beperkte aantal studies maakt het moeilijk om te bepalen of studies die een groter aantal interventies voor de chronische zorg of specifieke combinaties van interventies gebruiken, een grotere slaagkans bieden dan studies die minder interventies gebruiken. Nochtans werd vastgesteld dat studies met interventies waarin de vier soorten interventies van het chronische zorgmodel aan bod kwamen, de uitkomst voor de patiënten verbeterden. Het merendeel van de studies die minder interventies gebruikten, bleek soms ook doeltreffend te zijn.

Beslissingsondersteuning voor artsen (bijv. educatief materiaal en postgraduaatsopleiding) was doeltreffend op procesniveau. Het verdelen van educatief materiaal (richtlijnen) onder artsen en educatieve bijeenkomsten (postgraduaatsopleiding) waren doeltreffend op procesniveau (zoals de frequentie van het testen op HbA1c) in combinatie met andere interventies zoals lokale consensusinitiatieven, audits, herinneringen, feedbacks, peer review, of de combinatie hiervan. Deze verbeteringen werden opgetekend in alle studies met een lage zorgstandaard bij de aanvang van de studie. Het effect op patiëntenuitkomsten (bijv. het niveau van HbA1c) was minder duidelijk omdat deze uitkomsten in de meeste studies niet werden gemeten. Nochtans werden in de studies die patiëntenuitkomsten vermeldden, voornamelijk verbeteringen vastgesteld.

Zelfbehandelingsondersteuning ('self-empowerment') voor de patiënten en hun familie bleek doeltreffend op de patiënten- en procesresultaten. Het toevoegen van een patiëntgerichte interventie zoals het verdelen van educatief materiaal, patiënteneducatie, ondersteuning voor het toezicht, herinneringen en gedragscontracten leidden gewoonlijk tot verbeteringen van de patiëntenuitkomsten, naast de verbeteringen van de procesuitkomsten. Er moet worden opgemerkt dat patiënteneducatie op vele manieren werd gedefinieerd, gaande van geïndividualiseerd voedingsadvies voor de diabetici tot een brede waaier aan diensten.

Intensieve afspraken voor follow-up en het herzien van de rol van de professionelen waren twee veel voorkomende interventies in het opzetten van een zorgverstrekkingssysteem. Intensieve schema's voor opvolging waren doeltreffend voor de procesuitkomsten. Zij verbeterden het zorgproces in termen van geplande raadplegingen en de frequentie van onderzoeken, hoewel het soort en de intensiteit van de gebruikte methoden varieerden. Het volgen van patiënten werd uitgevoerd door centrale gecomputeriseerde monitoringssystemen of door verpleegsters die de patiënten regelmatig contacteerden (educatieve initiatieven). Telefonische oproepen om opnieuw een afspraak te maken voor gemiste raadplegingen in combinatie met patiënteneducatie waren doeltreffender dan herinneringen te sturen naar de patiënten. Veelvuldige herinneringen beïnvloedden in vergelijking met een eenmalige herinnering enkel op korte termijn de proces resultaten. De doeltreffendheid van de intensieve opvolging op de patiëntenuitkomsten blijft onduidelijk.

De doeltreffendheid van het herzien van de rol van de artsen als enkele interventie blijft onduidelijk. Het herzien van de artsenrol in combinatie met een patiëntgericht onderdeel was geassocieerd met een klein voordeel voor de glycemieregeling. De resultaten van deze studies moet men met de nodige omzichtigheid interpreteren omwille van hun beperkte methodologische kwaliteit. Nochtans toonden studies waarin de verpleegsters gedeeltelijk de artsen vervingen, over het algemeen een positieve impact op de patiëntenuitkomsten (glycemiecontrole), vooral als de interventie deel uitmaakte van een meer complexe interventiestrategie.

Ten slotte was de invoering van klinische informatiesystemen, en in het bijzonder de wijzigingen in het medische dossiersysteem, doeltreffend voor de procesuitkomsten. De resultaten suggereren dat geautomatiseerde herinneringssystemen de trouw aan de aanbevolen zorg eerder verbeteren door de documentatie van klinische bevindingen en het aanvragen van aanbevolen procedures te vergemakkelijken dan door de arts patiëntenspecifieke informatie te bieden over het beantwoorden aan de richtlijn. De impact van klinische informatiesystemen op de resultaten betreffende de patiëntenuitkomsten blijft onduidelijk.

3 DEELPROJECT 3: ORGANISATIE VAN DIABETESZORG IN 9 WESTERSE LANDEN

De studie van de organisatie van diabeteszorg in België en in 8 andere landen had drie doelen, namelijk de analyse van de organisatie van diabeteszorg in elk land (met de huidige trends), de identificatie van de sterke en de zwakke punten van organisatievormen en, indien voorhanden, het bepalen van de kwaliteit en de kosten van diabeteszorg in elk land.

De landen werden geselecteerd op basis van hun relevantie voor de Belgische situatie (de buurlanden Frankrijk, Duitsland, Nederland en het Verenigd Koninkrijk) en hun geografische representativiteit (Estland, postcommunistisch land; Denemarken, Noord-Europa; Spanje, Middellands-Zeegebied; Canada, Amerikaans land met een zorgsysteem dat vergelijkbaar is met de Europese zorgsystemen).

Eerst werd de geïndexeerde en nietgeïndexeerde literatuur. De verzamelde informatie werd voorgelegd aan vier deskundigen in elk land, d.w.z. twee deskundigen in de eerstelijnszorg, één deskundige in de tweedelijnszorg en één volksgezondheidsexpert. Zij bekrachtigden de bevindingen, vulden de onvolledigheden in de informatie aan en gaven hun mening over de sterke en de zwakke punten van de diabeteszorg in hun land.

3.1 EVOLUTIE NAAR MEER OP EVIDENTIE GEBASEERDE, GEÏNTEGREERDE EN POLYVALENTE DIABETESZORG

In alle landen bestudeerde landen, worden de meeste type 2 diabetespatiënten opgevolgd in de eerstelijnszorg, met de huisarts als centrale zorgverlener. Tweedelijnszorgverleners zijn hoofdzakelijk betrokken bij het behandelen van patiënten op insuline of met complicaties. Alle landen tonen dezelfde trend naar meer op evidentie gebaseerde, geïntegreerde en polyvalente diabeteszorg. Op heden heeft elk land zijn eigen op evidentie gebouwde klinische richtlijnen ontwikkeld voor type 2 diabetes. De richtlijnen worden in toenemende mate geschreven door multidisciplinaire panels (artsen en andere zorgverstrekkers uit de eerste- en tweedelijnszorgniveaus).

Deze trend blijkt ook uit het verschijnen van meer multidisciplinaire en gestructureerde zorg met het invoeren van gedeelde zorgprotocollen ("shared care protocols"). Deze protocollen bevatten de inhoud van de richtlijnen en definiëren de rol van de professionelen. Ze benadrukken de onafhankelijkheid van de patiënt en het belang van gestructureerde gezondheidseducatie. Jammer genoeg is de impact van deze protocollen op de uitkomst van diabeteszorg nog niet duidelijk.

Op evidentie gebaseerde en polyvalente zorg omvat ook de ontwikkeling van kwaliteitsmonitoring systemen. Alle landen ontwikkelen systemen voor de kwaliteitsmonitoring op het praktijkniveau of op het regionaal/ nationaal niveau, maar er is een grote variatie in de implementatiegraad. Het Verenigd Koninkrijk bezit het meest geavanceerde systeem en zijn nationale diabetes audit toont aan dat kwaliteitsmonitoring op nationaal niveau een grote impact kan hebben op het beleidvormingsproces. Bovendien toont het "Quality and Outcomes Framework" dat monitoren op het patiënteniveau een groot potentieel heeft om de kwaliteit van de zorg te verbeteren. Het vereist een context van heel goed gestructureerde multidisciplinaire eerstelijnssteams, een sterke ondersteuning door informatietechnologieën (IT) samen met financiële stimulansen. In Duitsland worden de ziekenfondsen verondersteld om feedback te geven aan de artsen over de kwaliteit van hun diabetesbehandeling. Nochtans zorgt de operationalisatie van deze kwaliteitsrapporten voor heel wat praktische problemen, zoals de geldigheid van de gegevens of de capaciteit van bepaalde ziekenfondsen om deze taak te vervullen.

Ten slotte moet de ontwikkeling van meer op evidentie gebaseerde en uitgebreide zorg ondersteund worden door IT. IT vergemakkelijkt de communicatie tussen de professionelen en laat kwaliteitsmonitoring toe. Verscheidene landen ontwikkelen een algemeen elektronisch medisch dossier (bijvoorbeeld in Andalusië of de elektronische gezondheidskaart in Duitsland). In het Verenigd Koninkrijk maakt de huisartsenpraktijk

gebruik van een IT systeem dat de gecentraliseerde gegevensverzameling mogelijk maakt voor kwaliteitsmonitoring.

3.2 GEÏDENTIFICEERDE PRECONDITIES VOOR EEN EVOLUTIE NAAR MEER OP EVIDENTIE GEBASEERDE, GEÏNTEGREERDE EN POLYVALENTE DIABETESZORG: ANALYSE VAN DE GESELECTEERDE LANDEN

Twee elementen zouden de verschillen in organisatie van diabeteszorg kunnen verklaren: de mate waarin de bedoelde veranderingen al werden aangebracht en de kenmerken van de globale organisatie van de gezondheidszorg. Verscheidene precondities op macro-, meso- en microniveau blijken belangrijk te zijn voor een geslaagde implementatie van deze veranderingen.

3.2.1 Precondities op macroniveau

3.2.1.1 *Een zorgorganisatie die de behandeling van chronische ziekten steunt*

De organisatie van eerstelijnsgezondheidszorg heeft een duidelijke impact op de organisatie van diabeteszorg. Het lijkt nuttig om de zorgsystemen te onderscheiden volgens de manier waarop zij een evenwicht proberen te bereiken tussen de vraag van de patiënt en de noden voor de volksgezondheid. In België, Canada, Frankrijk en Duitsland was de keuzevrijheid van de individuele patiënt traditioneel van het allergrootste belang. Denemarken, Estland, Nederland, Spanje en het Verenigd Koninkrijk ontwikkelden een alternatieve organisatie van de gezondheidszorg gebaseerd op patiëntenlijsten, een huisarts met een bewakingsrol en globale vergoedingssystemen voor artsen. In deze landen zijn de huisartsengroepen vaker multidisciplinair waardoor ze een ruimer aanbod van bekwaamheden bieden die nodig zijn voor de behandeling van chronische ziekten. Gezondheidseducatieve sessies, diabetesklinieken, diabetesregisters en oproep/herhalingsoproepsystemen komen vaak voor. België, Frankrijk en Duitsland gaan lichtjes in dezelfde richting via de introductie van financiële stimulansen die de rol van de huisarts versterken, en gedeeltelijke forfaitaire vergoedingen (België).

3.2.1.2 *Een adequate financiering van de behandeling van chronische ziekten*

De zorg coördineren, ervoor te zorgen dat de huisartsen over de capaciteit beschikken om de klinische praktijk te verbeteren, en het evalueren van de zorgkwaliteit, vereist mankracht en financiële ondersteuning. In Nederland voorziet de diagnose-behandelingcombinatie (DBC) voor diabetes financiering voor gedeelde zorgprotocols: de vergoedingen zijn gekoppeld aan de zorgkwaliteit. Het "Quality en Outcomes Framework" in het Verenigd Koninkrijk houdt ook vergoedingen in die gebaseerd zijn op kwaliteit, maar niet verbonden zijn aan een gedeeld zorgprotocol.

Het Disease Management Programme (DMP) in Duitsland behelst op evidentie gebaseerde richtlijnen en gedeelde zorgprotocols. Dit programma voorziet extra financiële middelen die eerder bestemd zijn voor de ziekenfondsen dan voor de artsen. Via een gedetailleerde documentatie van de klinische praktijk verplicht het de artsen om het protocol te volgen, maar de feedback over hun praktijk heeft geen invloed op hun bezoldiging. Het zal interessant zijn om de impact van dit Duitse gedeelde zorgmodel op de kwaliteit van de zorg te analyseren.

3.2.1.3 *Nationale ondersteuning voor de ontwikkeling van IT faciliteiten*

De IT systemen die verschillende professionelen en instellingen gebruiken, zouden compatibel moeten zijn om een vruchtbare communicatie tussen de gezondheidswerkers en een optimale verzameling van zorgkwaliteitsgegevens te verzekeren. Dit vereist initiatieven op nationaal niveau.

3.2.1.4 Diabetes op de nationale agenda plaatsen

Wijzigingen in de organisatie van diabeteszorg vloeien vaak voort uit lokale initiatieven. Het is heel belangrijk dat deze initiatieven zich uitbreiden tot het nationaal niveau. De patiëntenorganisaties hebben gewoonlijk een significante impact op het diabetesbeleid – vooral in samenwerkingsverband met artsorganisaties. Een nationale coördinator of een nationale commissie kan ook een belangrijke rol spelen door diabeteszorg op de agenda te houden.

3.2.1.5 Beschikbaarheid van nationaal aanvaarde en regelmatig bijgewerkte richtlijnen

Nationaal bijgewerkte richtlijnen blijven de hoeksteen van een optimale diabeteszorg. Alle stakeholders zouden betrokken moeten zijn bij het ontwikkelen van richtlijnen om hun succesvolle uitvoering te garanderen.

3.2.1.6 Onderzoek naar de organisatie van diabeteszorg

Momenteel is er een gebrek aan gevalideerde en betrouwbare gegevens over de organisatie van diabeteszorg in de praktijk, behalve voor het Verenigd Koninkrijk (en in mindere mate voor Nederland). Deze twee landen hebben ook meer ontwikkelde zorgmodellen voor diabetes dan de meeste anderelanden.

3.2.2 Preconditie op mesoniveau

3.2.2.1 Beschikbaarheid van structuren die locale diabeteszorg ondersteunen, coördineren en superviseren

In verscheidene landen zijn structuren op mesoniveau belangrijk voor de horizontale integratie van behandelingsprogramma's voor chronische ziekten op lokaal niveau. Voorbeelden zijnde ziekenfondsen in Duitsland en Nederland en de organisaties voor eerstelijnsgezondheidszorg (Primary Care Organisations - PCO's) in het Verenigd Koninkrijk. Zij creëren vaak een forum waar professionals gedeelde zorgmodellen kunnen opstarten en de kwaliteit van de zorg kunnen monitoren. In het Verenigd Koninkrijk hebben de PCO's zelfs een grotere autonomie bij het organiseren van de diabeteszorg: zij stellen diabetesregisters op, plannen opleidingen voor professionals, geven ondersteuning aan de eerste lijn (bijv. door een diëtist aan te werven, door oproep/herhalingsoproepsystemen en jaarlijkse controles te organiseren, door programma's voor het screenen van retinopathie op te zetten).

Deze structuren op mesoniveau kunnen een belangrijke rol spelen bij het uitvoeren van een gezondheidsbeleid. Hun sterk punt is de betrokkenheid van alle lokale "stakeholders" bij het uitvoeringsproces. De toekomstige "Samenwerkingsinitiatieven Eerstelijnsgezondheidszorg" in Vlaanderen zou deze rol op zich kunnen nemen, op voorwaarde dat zij voldoende gefinancierd en professioneel gerund worden.

3.2.3 Precondities op microniveau

3.2.3.1 *Beschikbaarheid van multidisciplinaire teams met een centrale rol voor de huisarts*

De samenstelling van de huisartsenpraktijk verschilt tussen en binnen de landen, van solopraktijken met informele samenwerkingen (bijv. met diëtisten en pedicures) tot multidisciplinaire teams met praktijkassistenten, praktijkverpleegsters en soms zelfs diabetesverpleegkundigen, diëtisten en pedicures. Het tweedelijns zorgteam bestaat idealiter uit een diabetoloog of een endocrinoloog, een (diabetes)verpleegkundige, een diëtist en een pedicure. Het multidisciplinaire karakter van de groep bevordert de communicatie tussen zorgverleners en de polyvalentie van de diabeteszorg.

3.2.3.2 *Betrokkenheid van verpleegkundigen in de multidisciplinaire teams*

Verpleegkundigen worden steeds meer betrokken in zowel de eerste- als de tweedelijns zorgteams. Hun titels, kwalificaties en functies verschillen van het ene land tot het andere, maar twee hoofdcategorieën komen naar voor. Bepaalde verpleegkundigen met enkel een beperkte postgraduaatsopleiding in diabeteszorg zijn gewoonlijk in de huisartsenpraktijk tewerkgesteld. Zij bieden gezondheidseducatie en voeren klinische follow-ups uit (in Nederland, Verenigd Koninkrijk, Spanje, Estland en – in mindere mate – Denemarken). Andere verpleegkundigen hebben een meer uitgebreide postgraduaatsopleiding gekregen (“verpleegkundigen gespecialiseerd in diabetes”). Zij werken gewoonlijk in de tweedelijnszorg, maar zijn soms betrokken bij de eerstelijnszorg. Hun functies wisselen sterk, gaande van enkel gezondheidseducatie tot klinische follow-ups, opleiding van het personeel, liaison tussen eerste- en tweedelijnszorg (in België, Canada, Denemarken, Duitsland, Nederland, Spanje en het Verenigd Koninkrijk).

De betrokkenheid van verpleegkundigen is cruciaal voor het aanbieden van gestructureerde individuele gezondheidseducatie. Zij kunnen de het werk van de arts verlichten, vooral in eerstelijnszorg. De gespecialiseerde diabetesverpleegkundigen en de praktijkverpleegkundigen werden specifiek vermeld als een sterk punt van het systeem in het Verenigd Koninkrijk en in Nederland, waar zij meer verantwoordelijkheden hebben dan in de andere landen.

3.2.3.3 *Gestructureerde gezondheidseducatie*

Veel deskundigen en nationale beleidslijnen benadrukken het belang van gezondheidseducatie, maar het is moeilijk om gegevens te vinden over de mate waarin gezondheidseducatie werkelijk in de dagelijkse praktijk voorzien wordt. Verscheidene landen zoals Duitsland, ontwikkelden programma's voor groepseducatie, maar de doeltreffendheid van deze programma's is nog niet voldoende onderzocht.

4 CONCLUSIES

Dit verslag beantwoordt aan de dringende nood aan reflectie over de chronische behandeling van de groeiende populatie van type 2 diabetespatiënten met toenemende gezondheidszorgbehoeften en -uitgaven. De uitbreidende diabetesepidemie zal de beleidsmakers inzake gezondheid aanzetten om duidelijke gezondheidsobjectieven te definiëren om deze chronische aandoening met al zijn gevolgen op de meest rendabele manier aan te pakken.

In dit project werd de organisatie en de kwaliteit van diabeteszorg geanalyseerd door gebruik te maken van drie complementaire benaderingen, namelijk het zoeken naar op evidentie gebaseerde indicatoren, het maken van een systematisch literatuuroverzicht over de organisatie van diabeteszorg en een analyse van de organisatie van de gezondheidszorg in Europese landen.

De oordeelkundige ontwikkeling, keuze en gebruik van kwaliteitsindicatoren zijn belangrijk om de kwaliteit van diabeteszorg te monitoren. Uit deze studie bleek dat de definitie van indicatoren sterk verschilt tussen de auteurs. De definitie van een indicator was overgenomen van de referentie "Measuring General Practice" van M. Marshall et al. (Verenigd Koninkrijk): "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" (een meetbaar element van de praktijkprestatie waarvoor evidentie of consensus bestaat dat men het kan gebruiken om de kwaliteit van de geleverde zorg te meten en zodoende te veranderen). In dit project werd eerst een selectie van richtlijnen doorgevoerd volgens specifieke kwaliteitscriteria omwille van het hoge aantal richtlijnen die via het grondige literatuuronderzoek werden gevonden. Het bleek dat de indicatoren die men in de richtlijnen en in de indicatorenreeksen vond, hoofdzakelijk verwezen naar het zorgproces en slechts enkele van hen naar de (intermediaire) uitkomst van de zorg. De belangrijkste indicatoren worden in de recente Belgische richtlijn geciteerd (WVH, 2005): ze werden gevalideerd door grote klinische studies die verschillende interventies gebruikten (bijv. UKPDS).

Het zoeken naar op evidentie gestoelde kwaliteitsindicatoren stelt verschillende problemen. Ten eerste impliceert het hoge aantal "waardevolle indicatoren" (ondersteund door evidentie) dat men prioriteit geeft aan enkele van deze indicatoren. Nochtans zijn er geen op evidentie gebaseerde gegevens die toelaten dat men een keuze maakt. De potentiële indicatorgebruikers (bijv. klinici, "stakeholders") moeten er daarom voor openstaan om een optimaal aantal kwaliteitsindicatoren te selecteren die verschillende domeinen van de diabeteszorg dekken. Een tweede punt is dat belangrijke indicatoren op microniveau (patiënt) vooral waardevol zijn als ze kunnen vertaald worden naar het mesoniveau (patiëntenpopulatie/regionaal) en het macroniveau (nationaal beleid) (bijv. indicatoren voor diabetescomplicaties). Ten slotte is er een inspanning vereist om de doelen die men voor de indicatorwaarden vooropstelt, voortdurend aan te passen volgens de laatste ontwikkelingen die men in wetenschappelijke studies heeft gevonden (bijv.: doelwaarden voor HbA_{1c}, frequentie van controle op microalbuminurie, ...).

De eerste conclusie uit het literatuuronderzoek van de zorgorganisatie is dat de doeltreffendheid van diabeteszorg niet beïnvloed wordt door de context: modellen gebaseerd op de ziekenhuissetting en op de huisartsenpraktijk leiden tot vergelijkbare patiënten- en procesuitkomsten. De aanvullende informatie uit de Europese studie benadrukte de centrale rol van de huisarts voor de behandeling van type 2 diabetici in alle landen. De tweede conclusie uit het literatuuronderzoek is dat enkelvoudige interventieprogramma's minder doeltreffend zijn dan interventies met meerdere facetten, hoewel geen enkele interventie doeltreffender bleek te zijn dan de andere. Het belang van interventies met meerdere facetten ziet men inderdaad in de organisatie van verschillende Europese zorgsystemen met de introductie van gedeelde zorgprotocols (zoals in Denemarken, Nederland, Duitsland en het Verenigd Koninkrijk).

Het literatuuronderzoek omvatte ook een analyse van de organisatie van diabeteszorg aan de hand van vier elementen van het chronische zorgmodel, meer bepaald: ondersteuning van zelfmanagement, klinische informatiesystemen, het hertekenen van

het zorgverstrekkingssysteem en ondersteuning van beslissingen. De studies met interventies waarin die alle soorten interventies van het chronische zorgmodel aan bod kwamen, verbeterden de patiëntenuitkomsten terwijl de studies met minder interventies ook doeltreffend bleken, maar in mindere mate. Geen enkele interventie van het chronische zorgmodel bleek essentieel (of overbodig) te zijn voor de doeltreffendheid van diabeteszorg.

De meeste studies toonden aan dat het zorgproces positief beïnvloed wordt door de vier bovenvermelde componenten.

- Materialen ter ondersteuning van de beslissing (richtlijnen en postgraduaatsopleiding) zijn doeltreffend voor de procesuitkomsten in combinatie met andere interventies zoals lokale consensusinitiatieven, audits, herinneringen, feedbacks, peer review, of combinaties van deze interventies. In de praktijk bevestigde de Europese studie een evolutie naar meer op evidentie gebaseerde klinische praktijk, gezien de meeste Europese landen op evidentie gebaseerde richtlijnen ontwikkelden. De verspreiding en de uitvoering van deze richtlijnen wisselen naargelang het land. Sommige landen hebben georganiseerde peer review groepen (bijv. België, Duitsland) terwijl het voortzetten van medische bijscholing vaker voorkomt, soms verbonden met certificatie (Estland, Duitsland). Het “National Diabetes Audit” project in het Verenigd Koninkrijk is het enige Europese project waarin de kwaliteit van diabeteszorg op nationaal niveau wordt geanalyseerd.
- Ondersteuning voor zelfmanagement (d.w.z., patiënteneducatie, ondersteuning voor het toezicht, herinneringen en gedragscontracten) heeft ook een impact op het zorgproces. De Europese studie gaf aan dat slechts weinig landen patiëntenopvoeding op meso- (regionaal) of macro (nationaal beleid) niveau hebben georganiseerd. Toch zijn opvoedingsprogramma’s in de meeste landen (locaal) voorhanden.
- Het hertekenen van het systeem van zorgverstrekking, is de derde interventie die het zorgproces zou kunnen beïnvloeden. Het behelst intensieve regelingen voor de follow-up en de uitvoering ervan en varieert in functie van de studies, bijv. geplande raadplegingen, het volgen van patiënten door gebruik te maken van geautomatiseerde systemen, regelmatig contact via verpleegkundigen, telefoonoproepen om gemiste afspraken opnieuw te plannen. De follow-up wordt vergemakkelijkt door initiatieven zoals de implementatie van diabetesregisters in de huisartsenpraktijk (Estland en Verenigd Koninkrijk). Oproep/herhalingsoproepsystemen bestaan ook in het Verenigd Koninkrijk en Nederland.
- De ontwikkeling van klinische informatiesystemen (zoals geautomatiseerde herinneringssystemen) is de vierde interventie met een effect op de procesuitkomsten. Europese deskundigen drukten ook hoge verwachtingen uit over de rol van IT (Informatietechnologieën) om de communicatie tussen de zorgverleners te vergemakkelijken en om de kwaliteit van diabeteszorg te controleren. Niettemin toont de analyse van de praktijk dat het Verenigd Koninkrijk het enige Europese land is met een gemeenschappelijk IT systeem voor alle huisartsenpraktijken.

Het effect van de vier bovenvermelde componenten op de patiëntenuitkomsten is minder duidelijk in de literatuur. Twee soorten interventies zouden een positieve impact kunnen hebben op de zorguitkomst, namelijk patiënteninterventies (hierboven beschreven als “zelfmanagement ondersteuning”) en het herzien van de professionele rollen. Vooral de betrokkenheid van de verpleegkundigen bij de zorg voor diabetespatiënten, in samenwerking met andere zorgverleners, heeft vaak een positieve impact op de patiëntenuitkomsten, voornamelijk in combinatie met andere interventiestrategieën. De analyse van de Europese systemen toont inderdaad de toenemende rol van diabetesverpleegkundigen (“diabeteseducatoren” in België). Het is

echter moeilijk om zware conclusies te trekken omtrent hun optimale plaats gezien hun opleiding en hun functie sterk varieert volgens de verschillende Europese gezondheidszorgsystemen.

Kwaliteitsmonitoring is vereist om te meten in welke mate deze interventies een effect hebben op de proces- en patiëntenuitkomsten. Dergelijke monitoring bestaat in het Verenigd Koninkrijk, Duitsland, Nederland en Denemarken. In België is deze monitoring enkel van toepassing op patiënten in een diabetesconventie. De gebruikte zoekstrategie (d.w.z. hoofdzakelijk medische literatuur) laat toe om voornamelijk besluiten te trekken over de doeltreffendheid van diabeteszorg, maar men kan geen enkele conclusie trekken over de toegankelijkheid en de kosten van verschillende zorgmodellen.

De Europese gezondheidszorgsystemen richten zich momenteel op een verbetering van de zorg van chronische ziektes in het algemeen en van type 2 diabetes in het bijzonder. Indien in de literatuur vergelijkbare klinische resultaten terug te vinden zijn voor zorg in het ziekenhuis en voor eerstelijnszorg, dan kiezen de Europese landen voor dit laatste: de huisarts wordt gezien als de belangrijkste coördinator van de zorg, in nauwe samenwerking met een multidisciplinair team. De Europese gezondheidszorgsystemen tonen dat op alle niveaus een aantal voorwaarden belangrijk zijn om te komen tot een optimale behandeling van diabetespatiënten, namelijk:

- Op macroniveau: een globale organisatie van de gezondheidszorg die de behandeling van chronische ziekten bevordert (zoals in het Verenigd Koninkrijk), nl. voldoende financiering, een nationale ondersteuning voor het ontwikkelen van IT faciliteiten, een nationale leiding en een onderzoek naar de organisatie van diabeteszorg;
- Op mesoniveau: de beschikbaarheid van structuren die lokale diabeteszorg ondersteunen/coördineren/superviseren en de betrokkenheid van alle “stakeholders” in de ontwikkeling van gedeelde zorgprotocols;
- Op microniveau: het bestaan van multidisciplinaire teams en gestructureerde gezondheidseducatie.
- Elke bovengenoemde voorwaarde draagt bij tot de optimale zorg voor de populatie van type 2 diabetici. Hun praktische implementatie moet zorgvuldig bestudeerd worden in de context van het Belgische gezondheidszorgsysteem.

5 AANBEVELINGEN

Op basis van dit wetenschappelijke project formuleert het KCE de volgende aanbevelingen voor de kwaliteit en de organisatie van de zorg voor type 2 diabetici in België.

- Het KCE beveelt een nieuwe organisatie van de zorg aan voor de toenemende populatie type 2 diabetici. De traditionele symptoomgerichte behandeling van type 2 diabetici moet verschuiven naar een globale proactieve, patiëntgerichte en geïntegreerde zorg met inbegrip van patiënteneducatie, de meer systematische opvolging en de secundaire/tertiere preventie van complicaties.
- In het bijzonder ‘empowerment’ van de patiënt en de steun van zijn familie vormen de hoeksteen om objectieve verbeteringen in de patiëntenuitkomsten te bereiken. Dit impliceert dat de patiënt zich houdt aan bepaalde procescriteria voor behandelingstrouw, zoals de frequentie van de raadplegingen, wijziging van de levensstijl en registratie van het globaal medische dossier (GMD/DMG). Gesynchroniseerde interventies om de patiënt te ondersteunen zijn vereist om de waarschijnlijkheid van significante resultaten te verhogen (bijv. intensieve opvolging, herinneringen, patiënteneducatie, groepseducatie, ...). Deze initiatieven zouden kunnen profiteren van bestaande structuren zoals de Belgische diabetesverenigingen.
- Een tweede wijziging in het behandelen van de patiënt is de zorg die door één arts werd geleverd omzetten naar een gecombineerde actie van een multidisciplinair team, dat ingebed is in de eerstelijns gezondheidszorg. Deze teams zouden voordeel moeten halen uit de netwerken die al bestaan zoals de ‘circles’ (cercle/kring), lokale discussieplatforms (LOKs/Glems) of diabetesnetwerken om een vermeerdering van de structuren te vermijden.
- Het KCE stelt voor dat de huisarts van de patiënt een centrale rol zou moeten spelen in de zorgcoördinatie voor type 2 diabetes en geassocieerde comorbiditeiten. Deze positie heeft tot gevolg dat de universiteitsopleiding en de voortdurende bijscholing van de huisartsen de essentiële bekwaamheden in verband met de opvolging van diabeteszorg, zouden moeten bevatten. De taakherverdeling binnen het multidisciplinaire team zal andere zorgverleners (bijvoorbeeld diabetesverpleegkundigen, apothekers, diëtisten) toelaten om via hun deskundigheid bij te dragen tot deze complexe opvolging. In het bijzonder is de rol van diabeteseducator cruciaal in deze context van polyvalente zorg die veel aspecten beslaat, van levensstijladvies tot technieken voor insulinetherapie. Op korte termijn moet het beroep van diabeteseducator officieel gedefinieerd en erkend te worden in de Belgische wetgeving. De beschrijving van het profiel, opleiding, functie en erkenning moet rekening houden met de huidige, al bestaande initiatieven in de praktijk. Het zou ook rekening moeten houden met al bestaand personeel zowel in de ambulante als in de residentiële zorg. Verpleegkundigen en diëtisten in verzorgingstehuizen en dergelijke, waar de prevalentie van type 2 diabetici verder zal toenemen, zou men moeten aanmoedigen in de richting van educatie en opleiding in diabeteszorg.
- Er zou een duidelijke rol voor de diabetes-specialisten (endocrinologen-diabetologen) moeten worden gedefinieerd. Hun rol zou bij voorkeur moeten liggen in het coachen en opleiden van alle leden van het multidisciplinaire team dat betrokken is bij de zorg voor de type 2 diabetespatiënt. Men zou duidelijke richtlijnen moeten overeenkomen voor het doorverwijzen van de individuele patiënt naar

een specialist. In het bijzonder zouden zowel de huisarts als de specialist complexe patiënten en patiënten die de therapeutische doelen van de indicatoren niet bereiken, moeten behandelen.

- Het KCE pleit voor de ontwikkeling van gedeelde zorgprotocols binnen het multidisciplinaire team, bijv. de definitie van de professionele rollen, de communicatiestrategie en de inhoud van de klinische zorg gebaseerd op de meest recente evidentie, bevatten. In België werden onlangs richtlijnen van hoge kwaliteit ontwikkeld voor de type 2 diabeteszorg in de huisartsenpraktijk. Er zijn inspanningen nodig, in een kader van duidelijke objectieven en doelen, om hun effectieve uitvoering door de huisartsen te garanderen en om hun toepassing uit te breiden naar andere zorgverleners.
- Het KCE beveelt de ontwikkeling van polyvalente klinische informatiesystemen aan voor de globale behandeling van type 2 diabetespatiënten. Informatie- en communicatienetwerken moeten gebruikt worden voor een optimale opvolging van de patiënten, en om de beschikbaarheid van op bewijs gebaseerde informatie en een effectieve communicatie tussen de zorgverleners in het multidisciplinaire team en erbuiten te garanderen. De toegankelijkheid van het klinische deel van het elektronisch medisch dossier voor alle betrokken zorgverleners is een cruciaal punt voor de geïntegreerde patiëntenzorg.
- Het KCE adviseert om systemen voor kwaliteitsmonitoring op te zetten om de uitkomsten van de zorg te meten, aan de hand van geschikte indicatoren, standaarden en evaluatiecriteria. Deze kwaliteitsmonitoring moet zich zowel op het eerste – als tweedelijns zorgniveau toespitsen. Het zou moeten steunen op de ervaring van de bestaande gegevensverzamelingsystemen (d.w.z. gegevensverzameling via het Initiatief voor Kwaliteitsbevordering en Epidemiologie bij Diabetes en via het Intermutualistisch Agentschap). Dit onderzoeksproject levert een reeks op evidentie gebaseerde kwaliteitsindicatoren die men moet gebruiken voor een kwaliteitscontrolesysteem. De definitie van doelen en specificaties op nationaal niveau vraagt verdere discussie en het engagement van alle betrokken “stakeholders” (bijv., zorgverleners en actoren op het vlak van volksgezondheid). Dit kwaliteitsmonitoringsysteem is essentieel om het effect van de meervoudige interventies te meten die in de context van dit project werden aanbevolen. Het zal helpen om klinische of geografische gebieden te identificeren waar een verbetering nodig is en om eropvolgende initiatieven te monitoren.
- Toekomstige hervormingen zouden rekening moeten houden met gedeelde zorg in de eerste lijn en de centrale rol van de huisarts bij type 2 diabetes. Binnen de huidige diabetesconventie is er een duidelijke stimulans om type 2 diabetici met insulinetherapie door te sturen naar een behandeling van de specialist in ziekenhuizen, om bijv. de terugbetaling te krijgen voor glucose teststrips. Met de geschatte toename van het aantal diabetici tot epidemische proporties, zullen deze diensten overspoeld en teveel gebruikt worden, terwijl hun grootste aandacht zou moeten blijven uitgaan naar type 1 diabetici, naar tweedelijnszorg en behandeling van complicaties van diabetes, en naar type 2 diabetici die een ingewikkeld insulineregime nodig hebben. Type 2 diabetici zonder ernstige complicaties en die geen complex insulineschema nodig hebben, zouden toegang moeten hebben tot de nodige ondersteuning (educatie, materiaal) binnen de eerstelijnszorg, op voorwaarde dat dit soort gedeelde zorg aan bepaalde organisatie- en kwaliteitscriteria beantwoordt.

Al deze initiatieven vereisen een consequent nationaal beleid om de interventies te ondersteunen en te coördineren. Er zijn momenteel vele interessante initiatieven om de diabeteszorg te verbeteren. Deze verspreide projecten zouden moeten vervangen worden door nationale initiatieven waarvan men voor de invulling inspiratie zou moeten putten uit de lopende locale/regionale projecten. Een centraal communicatieplatform en de bestaande diabetesorganisaties zouden in harmonie moeten samenwerken om een effectieve uitvoering van de interventies op regionaal en lokaal niveau en op patiënteniveau te verzekeren. Bij de financiële ondersteuning zou rekening moeten gehouden worden met minimale vereisten voor de zorgorganisatie en de zorguitkomsten. Op korte termijn is ondersteuning nodig om teams samen te stellen wiens activiteiten verschillen van het traditionele “fee-for-service” systeem (vergoeding per prestatie) waarbij men betaalt voor de geleverde diensten (d.w.z., groepseducatie, informatietechnologieën, levensstijladvies door een diabeteseducator). De definitie van het takenpakket is een eerste voorwaarde voor deze financiering. Men zou het later verder kunnen koppelen aan impulsen verbonden aan specifieke uitkomsten die gemeten worden door het monitoringsysteem.

Deze conclusies en aanbevelingen komen overeen met deze van de Europese Unie (Diabetes, the policy puzzle: towards benchmarking in the EU 25). Hun aanbevelingen geformuleerd voor het nationaal niveau omvatten de nood aan nationale beleidsmaatregelen, systemen voor gegevensverzameling, meetbare doelen en evaluatiesystemen, een integrale benadering voor het management van diabeteszorg en investering in specifieke educatie voor alle zorgverleners.

De KCE aanbevelingen voor het management van diabeteszorg kan men toepassen op het management van andere chronische aandoeningen, ofwel geïsoleerd of als comorbiditeit van diabetes. De rol van de huisarts als coördinator in de context van een multidisciplinair team in samenwerking met specialisten, de “patient empowerment”, de klinische informatiesystemen en een kwaliteitsmonitoring zullen de uitgebreide, geïntegreerde zorg voor patiënten met complexe chronische aandoeningen doen ontstaan.

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

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

I 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 I.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' principle¹.

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.

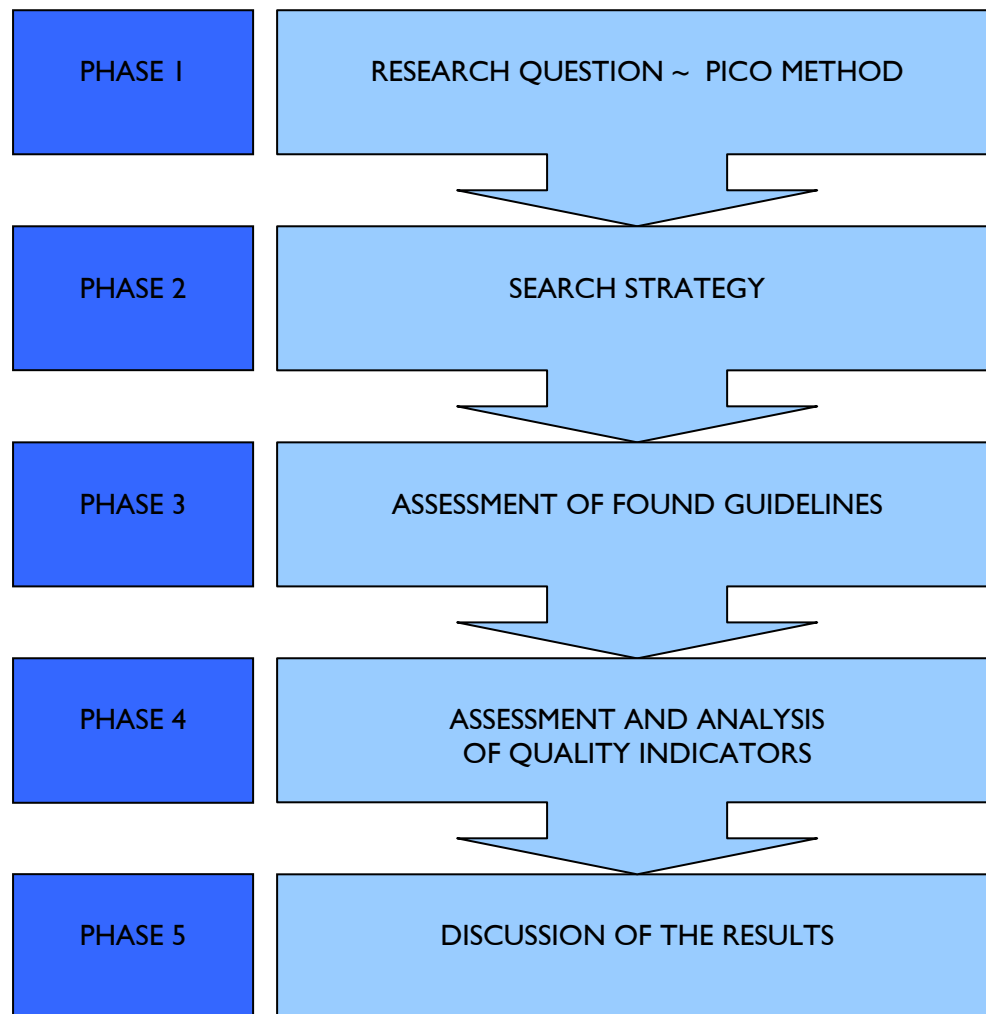
Third phase: assessment and evaluation of the resulting guidelines on their scientific quality and their relevance for answering the proposed research question (by two independently scoring researchers/reviewers), including documenting reasons for not including guidelines.

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).

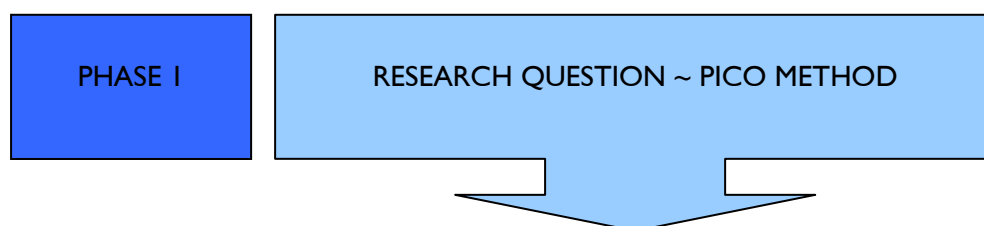
Fifth phase: description and discussion of the results.

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 I: RESEARCH QUESTION ACCORDING TO THE 'PICO' PRINCIPLE



The research question is constructed according to the PICO principle.

P Participant/population

I Intervention

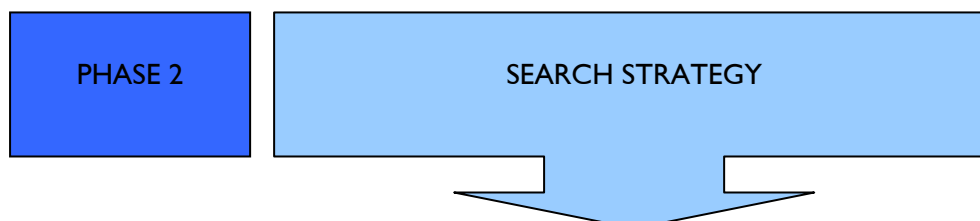
C Comparaison

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.

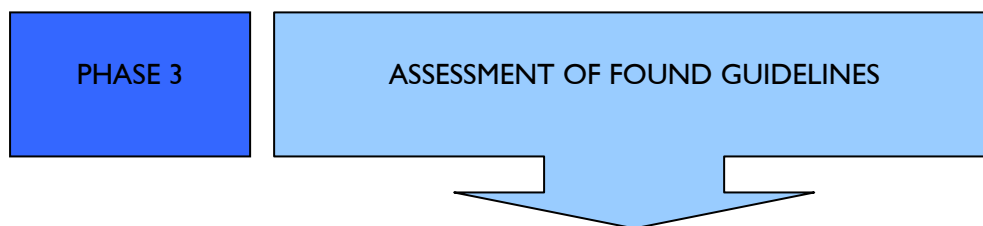
The inventory of indicators was furthermore compared with already available lists of quality indicators on diabetes care, to check whether any major indicator of care had been missed. The list was also made by the GPs, diabetologists and KCE researchers from the working group. After internal consultation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

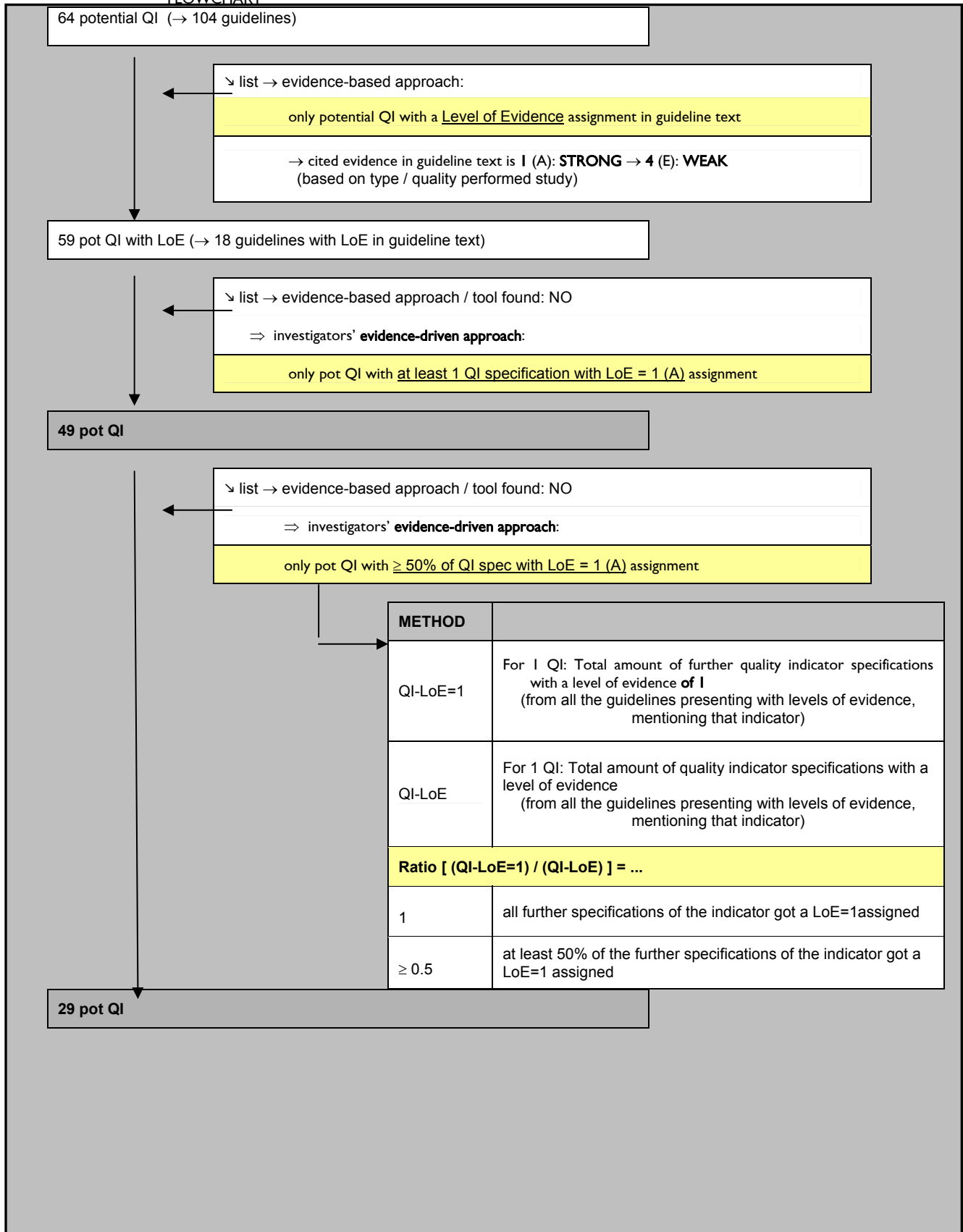
The appendix part 1.4 also specifies for each potential quality indicator (1) in how many of the guidelines it was mentioned, and (2) how many further specifications (= further detailed explanations of the indicator) were given (if given). The last two columns of this table present these data when only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



Resulting 29 potential quality indicators.

#	Potential Quality Indicators	P / O	[QI-LoE=I / 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 $[(QI-LoE=I / QI-LoE) \geq 50\%]$. 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 I.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
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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
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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-WvH-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-WvH-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-WvH-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-WvH-VDV	Efforts to avoid severe hypoglycaemia should be made (management + education patient)
	6	Patients should have (at least) annual disease review	P	Be-WvH-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 evaluation of risk factors and complications
	7	Patients on insulin therapy should receive education on blood glucose monitoring and self-management	P	Be-WvH-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-WvH-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-WvH-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-WvH-VDV	non-proliferative retinopathy (mild, moderate, severe), proliferative retinopathy, maculopathy
3	1	Patients with (at least) microalbuminuria should receive appropriate medical treatment	P	Be-WvH-VDV	hypertensive and microalbuminuria: 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-WvH-VDV	metformin: first treatment option in overweight patients
					metformin: first treatment option unless contraindicated
					good alternatives for metformin: sulphonylurea, glinides
	2	Patients who don't reach their target HbA1c under non-pharmacological treatment, should receive OAD mono-therapy	P	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-WvH-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-WvH-VDV	on ongoing basis with content of care and review interval depending on foot risk
				Be-SSMG	appropriate foot care education

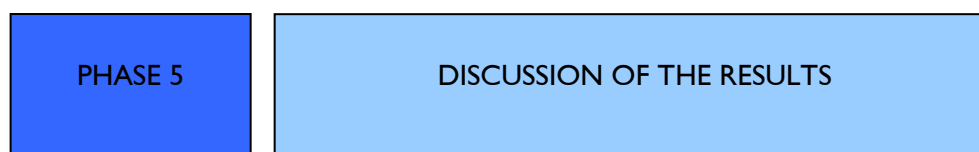
Aspect	#	Topics	P / O	Guide line	Target values / Specifications
	6	Patients with diabetic foot / Charcot foot should receive appropriate treatment (pressure release, revascularisation, antibiotics, resection of necrotic tissue, amputation, „„)	P	Be-Wvvh-VDV	foot risk class 2b (and higher): timely referral to a diabetes foot clinic for thorough evaluation
					active foot problems (eg ulcer, infection): consider as serious problems with therefore urgent referral
					severe orthopaedic malformations and/or ulcer: refer to a multidisciplinary foot team
	7	Patients who don't reach their target HbA1c under optimal OAD mono-treatment, should receive OAD combination therapy	P	Be-SSMG	appropriate treatment
				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
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	
5	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	
	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: WvH-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 than 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 $[(QI-LoE=I / QI-LoE) \geq 50\%]$ 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-I rated evidence for the adult population. A proposition to fill these empty spaces is the use of the (level-I 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-I 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.

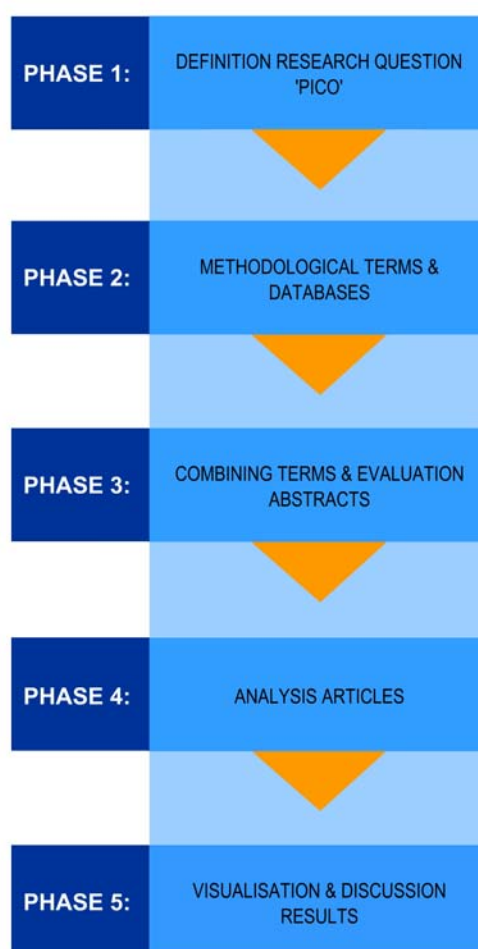
- DIMENSION diabetes care:
 - Reviewed (index)journals
 - Non-reviewed journals
 - Books
 - National reports
 - International reports

- 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

PHASE 1:

DEFINITION RESEARCH QUESTION 'PICO'

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

PHASE 2:

METHODOLOGICAL TERMS & DATABASES

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

PHASE 3:

COMBINING TERMS & EVALUATION ABSTRACTS

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

PHASE 4:

ANALYSIS ARTICLES

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	
3. (Family) Physician (working in primary care facility/outpatient clinic) + caregivers	THE GENERAL PRACTITIONER-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 NURSE EDUCATOR-LED SHARED CARE MODEL IN PRIMARY CARE
6. Endocrinologist (working in hospital outpatient clinic)	
7. Diabetologist (working in primary care clinic)	THE SPECIALIST-LED MODEL IN PRIMARY CARE
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)	THE HOSPITAL BASED SHARED CARE MODEL
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 Renders⁶ and in 2002 by Bodenheimer⁷, 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 perspectives⁹. 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 • Availability	• 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).

CARE	QUALITY	
	ACCESSIBILITY	EFFECTIVENESS
STRUCTURE (Health care system)	• Geographic & • Physical access • Range of services • Provider continuity	• Effectiveness of education and (skill-mix) Decision support
PROCESS (Patient-centred care)	• Affordability • Availability	Self-management Delivery system design Clinical information systems
OUTCOME (Consequences of care)	• Health status • User evaluation (satisfaction)	• Health status • User evaluation (satisfaction)

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 one 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 Sonville et al., 1997 (14); Pill et al., 1998 (19); Woodcock et al., 1998 (22); Ovied 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); Ovied 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 one 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

PHASE 5:

VISUALISATION & DISCUSSION RESULTS

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.

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 I 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 Netherlands	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 (Albrecht 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 (ANCRE)	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 Dusseldorf	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 Épidémiologique 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 coordinator – 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 Catalanian 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 nationwide 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 multidisciplinary nature 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.

II 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 health 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.

12 REFERENCES

1. Albrecht T, Cesen M, Hindle D et al. (2002). Health care systems in transition: Slovenia. Copenhagen: WHO Regional Office, on behalf of the European Observatory on Health Systems and Policies. Accessed at www.euro.who.int/observatory.
2. Allin S, Busse R, Dixan A et al. (2004). Health system profiles template. WHO regional office, on behalf of the European Observatory on Health Systems and Policies, Copenhagen. Accessed at www.euro.who.int/Document/Obs/HiTcon.pdf.
3. Baan CA, Hutten JCF, Rijken PM (2003). Care protocols. A background study in the care for people with chronic diseases [in Dutch]. Bilthoven: RIVM/NIVEL, report no. 282701005/2003. Accessed at www.rivm.nl
4. Bastiaens H, Sunaert P, Borgermans L et al. (2005). Vision on the care for type 2 diabetes patients: interview of 18 stakeholders. HANU 34: 500-7.
5. Bentes M, Dias C, Sakellarides C et al (2004). Health care systems in transition: Portugal. Copenhagen: WHO Regional Office, on behalf of the European Observatory on Health Systems and Policies. Accessed at www.euro.who.int/observatory.
6. Bulletin Epidémiologique Hebdomadaire (2003). Diabetes surveillance [in French]. BEH No. 49-50/2003. Accessed at www.invs.sante.fr/beh/2003/49_50/beh_49_50_2003.pdf
7. Busse R, Riesberg A (2004a). Health care systems in transition: Germany. Copenhagen: WHO Regional Office, on behalf of the European Observatory on Health Systems and Policies. Accessed at www.euro.who.int/observatory.
8. Busse R (2004b). Disease management programs in Germany's statutory health insurance system. Health Affairs 23 (3): 56 – 67.
9. DACEHTA (2003). Type 2 diabetes: health technology assessment of screening, diagnosis, and treatment. Denmark, Ministry of Health. Accessed at www.sst.dk.
10. Deakin T, McShane CE, CADE JE et al (2004). Group based training for self-management strategies in people with type 2 diabetes mellitus. Cochrane Library 2004/4.
11. Debacker N, Nobels F, Scheen A et al (2005). Initiative for quality assurance and epidemiology in diabetes [in Dutch]. Wetenschappelijk Instituut Volksgezondheid, Brussels. IPH/EPI report No. 2005 - 2. Accessed at www.iph.fgov.be.
12. Demarest S, Van Der Heyden J, Gisle L et al. (2002). Health interview survey: Belgium 2001 [in Dutch]. Wetenschappelijk Instituut Volksgezondheid, Brussels. IPH/EPI report No. 2002 – 25. Accessed at www.iph.fgov.be.
13. Den Exter A, Hermans H, Dosljak M (2004). Health care systems in transition: the Netherlands. Copenhagen: WHO Regional Office, on behalf of the European Observatory on Health Systems and Policies. Accessed at www.euro.who.int/observatory.
14. Deutsche Diabetes-Union (2004). German health information: diabetes [in German]. See www.diabetes-union.de.
15. European Observatory on Health Care Systems (2000). Health care systems in transition: Belgium. Copenhagen, WHO Regional office, on behalf of the European Observatory on Health Systems and Policies. Accessed at www.euro.who.int/observatory.
16. Fundación para la Diabetes (2002). Transfer of responsibilities in health care: how to make yourself heard by the politicians? [in Spanish] Accessed at www.fundaciondiabetes.org on 12 November 2005.
17. Gemeinsamer Bundesausschuss (2002). Criteria for the development of structured treatment programmes for type 2 diabetes patients [in German]. See www.g-ba.de.
18. Griffin S, Kinmonth AL (2000). Systems of routine surveillance for people with diabetes mellitus. Cochrane Library 2000/4.

19. Jesse M, Habicht J, Aaviksoo A et al. (2004). Health systems in transition: Estonia. Copenhagen: WHO Regional Office for Europe, on behalf of the European Observatory on Health Systems and Policies.
20. Jönsson B (2002). Revealing the cost of type 2 diabetes in Europe. *Diabetologia* 45; S5-12.
21. Kaarna M, Kalda R, Karu K et al (2005). Quality assurance of health services in Estonia. Tallinn, Ministry of Social Affairs.
22. Loveman E, Royle P, Waugh N (2003). Specialist nurses in diabetes mellitus. *Cochrane Library* 2003/2.
23. Ministry of Public Health, Welfare and Sports (2005). Are you sickness fund or privately insured? A new health insurance for everybody as from 1 January 2006 [in Dutch]. See www.denieuwzorgverzekering.nl.
24. National Service Framework (2001). National service framework for diabetes. London, Department of Health. Accessed at www.dh.gov.uk.
25. OECD (2005a). OECD health data. Accessed at www.oecd.org.
26. OECD (2005b). Economic survey – Belgium 2005. Accessed at www.oecd.org.
27. Palomo L (2002). Research and the recent evolution of primary health care [in Spanish]. *Gac Sanit* 16: 182 – 7.
28. Philips K, Swan W (1996). Health care systems in transition: Canada. Pan-American Health Association. Accessed at www.paho.org.
29. Renders CM, Valk GD, Griffin S et al. (2002). Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. *Cochrane Library* 2002/4.
30. Rico A, Sabes R (2000). Health care systems in transition: Spain. Copenhagen: WHO Regional Office, on behalf of the European Observatory on Health Systems and Policies. Accessed at www.euro.who.int/observatory.
31. Roberts S (2005). Improving diabetes services: the NSF two years on. London, Department of Health. Accessed at www.dh.gov.uk.
32. Robinson R, Dixon A (1999). Health care systems in transition: United Kingdom. Copenhagen: WHO Regional Office, on behalf of the European Observatory on Health Systems and Policies. Accessed at www.euro.who.int/observatory.
33. Sandier S, Paris V, Polton D (2004). Health care systems in transition: France. Copenhagen: WHO Regional Office, on behalf of the European Observatory on Health Systems and Policies. Accessed at www.euro.who.int/observatory.
34. Siering U et Naundorf F (2004). Quality monitoring report 2004: Disease Management Programme Nordrhein [in German]. Duesseldorf, Nordrheinische Gemeinsame Einrichtung Disease Management Programme GbR.
35. Taakgroep Programma Diabeteszorg (2005). Better diabetes care [in Dutch]. See www.minvws.nl.
36. Vallgarda S, Krasnik A, Vrangbaek K (2001). Health care systems in transition: Denmark. Copenhagen: WHO Regional Office, on behalf of the European Observatory on Health Systems and Policies. Accessed at www.euro.who.int/observatory.
37. van der Zee J, Kroneman M, Boerma W (2004). The Dutch GP in a European perspective [in Dutch]. *Huisarts & Wetenschap* 47: 266-273.
38. Wagner EH (1998). Chronic disease management: what will it take to improve chronic care for chronic illness? *Effect Clinical Practice* 1: 2-4. See also: www.improvingchroniccare.org.
39. Winocour PH, Ford M and Ainsworth A (2002b). Association of British Clinical Diabetologists: survey of specialist diabetes care services in the UK, 2000. 2. Workforce issues, roles and responsibilities of diabetes specialist nurses. *Diabetes Med* 19 (suppl. 4): 27–31.

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22. HTA Positronen Emissie Tomografie in België. D/2005/10.273/29.
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