Kwaliteitsindicatoren in oncologie: voorwaarden voor het opzetten van een kwaliteitssysteem

KCE reports 152A

Federaal Kenniscentrum voor de Gezondheidszorg
Centre fédéral d'expertise des soins de santé
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Kwaliteitsindicatoren in oncologie: voorwaarden voor het opzetten van een kwaliteitssysteem

KCE rapporten 152A

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VOORWOORD

De behandeling van kanker is in de loop van de voorbije jaren een heel stuk doeltreffender geworden. Maar toch blijft het een gevreesde diagnose. Niet verwonderlijk dat de bevolking hoge verwachtingen heeft wat betreft de kwaliteit van de behandeling. Kwaliteitsvolle kankerzorg leveren is echter een complexe opdracht die in verschillende stappen verloopt en waarbij in elk van de stappen verschillende actoren betrokken zijn. Nog ambitieuzer, en dit is wat het Belgische kankerplan beoogt, is deze kwaliteitsvolle zorg gaan inbedden in een overkoepelend kwaliteitssysteem.

Aan het KCE werd gevraagd om bij te dragen tot enkele bouwstenen van een dergelijk kwaliteitssysteem in de oncologie. Fundamenteel kent het streven naar meer zorgkwaliteit steeds de volgende vier fasen (1) Identificeren wat er moet gedaan worden, (2) dit dan ook doen, (3) weten of de facto het resultaat beantwoordt aan wat moest gebeuren en (4) zo nodig bijsturen.

Het KCE heeft intussen al een aantal richtlijnen ontwikkeld die duidelijk passen in de eerste stap. Stap twee is en blijft het werk van de clinici. Voor het meten in stap drie werden voor een aantal kankers reeds indicatoren ontwikkeld.

Voortbouwend op deze eerste drie stappen onderzoekt het huidige rapport hoe te komen tot de vierde stap, namelijk een meetbare verbetering van de zorg voor de patiënt. Het geeft een aantal richtingen en aandachtspunten voor een dergelijk kwaliteitssysteem, onder meer op basis van ervaringen in het buitenland. Deze laatste stap, de concrete constructie van een werkzaam en duurzaam kwaliteitssysteem in België, zal echter alleen volgen uit een proces waar alle betrokken actoren actief aan meewerken. De bouwstenen zijn voorhanden; het komt erop aan nu aan de slag te gaan.

Jean Pierre CLOSON
Adjunct Algemeen Directeur

Raf MERTENS
Algemeen Directeur

Samenvatting en toelichtingen

INLEIDING

Als voorbereiding voor het opzetten van een kwaliteitssysteem voor oncologie in België vroeg de Minister van Sociale Zaken en Volksgezondheid aan het KCE om de methodologische benadering van het PROCARE-project (rectale kanker) te herhalen voor een frequente kanker, namelijk borstkanker, en voor een zeldzame kanker, namelijk teelbalkanker. In een eerste fase werden de nationale richtlijnen voor beide kankertypes bijgewerkt en gepubliceerd (KCE rapporten 142 en 143). In een tweede fase werd voor beide kankertypes een set van kwaliteitsindicatoren ontwikkeld. Deze kwaliteitsindicatoren ondergingen een pilootstudie die gepubliceerd werd in januari 2011 (KCE rapporten 149 en 150).

Het doel van het huidige rapport is om aanbevelingen te formuleren voor het opzetten van een kwaliteitssysteem voor oncologie. De ervaringen uit de 3 pilootstudies (rectum-, borst- en teelbalkanker) en de internationale ervaringen dienen als input voor deze aanbevelingen. De volgende vragen worden beantwoord: is een kwaliteitssysteem nodig in België? Zo ja, wie moet betrokken worden en wat is de gewenste structuur?

Aspecten van preventie en opsporing blijven buiten het bestek van deze studie.

SPELERS IN DE ONCOLOGISCHE ZORGKWALITEIT IN BELGIË

Naast de ziekenhuizen en zorgverleners, die voor de oncologische zorg instaan, zijn er een aantal organisaties en instanties die een belangrijke rol spelen bij de bewaking van de oncologische zorgkwaliteit. De rol van de *Stichting Kankerregister* omvat vooral kankerregistratie, gegevensanalyse (voor kwaliteitsindicatoren in samenwerking met het KCE) en rapportering. Tot nog toe waren de activiteiten van het *College voor Oncologie* voornamelijk gericht op de ontwikkeling van klinische praktijkrichtlijnen, die in de meeste gevallen ontwikkeld werden met de methodologische ondersteuning van het KCE. Een nieuwe speler is het *Kankercentrum*, dat ondermeer de uitrol van het Nationale Kankerplan coördineert.

Andere belangrijke spelers, hoewel niet specifiek gericht op oncologie, zijn de *FOD Volksgezondheid*, die de minimale normen voor erkenning (bvb. borstklinieken) bepaalt, en de *regio's en gewesten*, die de correcte toepassing van deze normen controleren. Het *RIZIV* speelt een specifieke rol in de promotie van de integratie van de gezondheidsdiensten en de multidisciplinariteit, bijvoorbeeld via de financiering van het Nationale Kankerplan. Het Nationale Kankerplan heeft als doel de samenwerking te bevorderen tussen alle beleidsniveaus en de multidisciplinariteit en coördinatie tussen de zorgverleners te verbeteren.

CONCLUSIES VAN DE DRIE PILOOTPROJECTEN

SELECTIEPROCES VAN INDICATOREN

Kwaliteitsindicatoren werden gezocht in de geïndexeerde literatuur en internationale richtlijnen of werden afgeleid van de Belgische richtlijnen. De selectieprocedure resulteerde in een set van 40 indicatoren voor rectale kanker, 32 voor borstkanker en 12 voor teelbalkanker.

De meeste geselecteerde indicatoren waren proces- en uitkomstindicatoren. Het aantal patiënten dat door een ziekenhuis wordt behandeld, werd eveneens geëvalueerd als een structuurindicator in de teelbal- en borstkankerprojecten. De geselecteerde indicatoren hadden meestal betrekking op de kwaliteitsdimensies 'doeltreffendheid', 'continuïteit' en 'veiligheid'. Geen enkele indicator had betrekking op 'patiëntgerichtheid', 'tijdigheid' of 'billijkheid'. De kwaliteitsindicatoren hadden betrekking op alle fasen in de aanpak van kanker, gaande van diagnose en stadiëring tot follow-up en palliatieve zorg. Indicatoren in verband met screening werden niet geïncludeerd in de pilootprojecten.

RESULTATEN VAN DE PILOOTSTUDIES

Om de kwaliteitsindicatoren te berekenen werden vier databanken gebruikt en gekoppeld: het Belgische Kankerregister (BKR), facturatiegegevens van het Intermutualistisch Agentschap (IMA), ziekenhuisgegevens van de Minimale Klinische Gegevens (MKG) en, specifiek voor rectale kanker, de prospectieve PROCARE databank. De koppeling tussen BKR en IMA was succesvol (≥ 98% van de individuele data). Dit was niet het geval voor de koppeling tussen BKR en MKG (65%-75% van de individuele data) omwille van technische problemen.

Beschrijvende analyses omvatten percentages voor binaire indicatoren, gemiddelden voor indicatoren met betrekking tot tellingen, en totale en relatieve overlevingsfunctie voor time-to-event indicatoren. Om de variabiliteit tussen centra weer te geven, werden funnel plots gebruikt.

De beschikbaarheid van een prospectieve klinische databank bleek een groot voordeel voor de meetbaarheid van de indicatoren voor rectale kanker: 33 van de 40 indicatoren bleken meetbaar voor rectale kanker. Voor borst- en teelbalkanker bleken slechts 14 (van de 32) en 8 (van de 12) indicatoren meetbaar respectievelijk.

De voornaamste redenen voor problemen met de meetbaarheid van indicatoren waren:

- ontbrekende (niet gefactureerde) procedurecodes in de IMA-data (bijv. orchidectomie);
- niet-specifieke nomenclatuurcodes (bijv. CT, NMR, biopsie);
- hiaten in de registratie van de BKR data (bijv. recidief).

Door gebruik te maken van uitgebreide databanken, zoals IMA en BKR, bleek de toegevoegde waarde van de MKG-gegevens te beperkt om deze databank voor toekomstige gelijkaardige projecten in aanmerking te nemen. Het ontbreken van recente nationale gegevens over overlijdensoorzaken bemoeilijkte de berekening van de ziekte-specifieke overleving.

De 3 pilootstudies resulteerden steeds in een lijst van voorgestelde acties om de geïncludeerde indicatoren (meer) meetbaar te maken. Sommige van deze suggesties waren generisch (d.w.z. toepasselijk op andere kankertypes) en data-gerelateerd, Voorbeelden zijn:

- aanpassingen aan nomenclatuurcodes;
- juist gebruik van de huidige editie van de TNM-classificatie;
- volledige registratie van cStadium en pStadium;
- uitbreiding van de huidige lijst variabelen met verplichte registratie in het kankerregister (bijv. recidief, rekrutering in klinische studies, aantal positieve lymfeklieren, resectiemarges, stralingsdosis en -veld).

Andere suggesties hadden betrekking op de interpretatie van de resultaten, bijv. correctie voor risico en streefwaarden.

ERVARINGEN IN ANDERE LANDEN

Voorbeelden van buitenlandse projecten over kwaliteitsmeting in het domein van oncologie uit 5 landen (VS, Canada, Schotland, Nederland en Frankrijk) werden geëvalueerd. De belangrijkste voorwaarden voor een oncologisch kwaliteitssysteem zijn (1) de ontwikkeling van kwaliteitsindicatoren en (2) de beschikbaarheid van kwaliteitsvolle databanken en nationale registers die de ganse populatie beslaan. De meeste geëvalueerde landen richten hun kwaliteitsmonitoring op enkele veel voorkomende kankers. Deze projecten zijn meestal verticaal van aard, d.w.z. per kankertype. Het doel van de meeste kwaliteitssystemen is kwaliteitsverbetering. Het Franse systeem gebruikt zijn kwaliteitsinformatie ook voor benchmarking en accreditatie, terwijl het Nederlandse systeem ze gebruikt voor peer review en accreditatie. De Nederlandse en Canadese systemen (Ontario) lijken de meest integratieve systemen, en omvatten de ontwikkeling van richtlijnen, met daarop aansluitend de ontwikkeling van indicatoren, het verzamelen en analyseren van gegevens, en gerichte acties.

Verschillende strategieën worden gehanteerd om de kwaliteit te verbeteren, gaande van kwaliteitsinitiatieven uitgaande van de beroepsgroepen tot de introductie van betalingssystemen op basis van performantie/kwaliteit (incentives en/of sancties). Systematische en transparante feedbackrapporten worden aan een specifiek publiek bezorgd (clinici, patiënten, administraties, verzekeraars, beleidsmakers en andere belanghebbenden) om betere kwaliteit aan te moedigen. Herkenbare governance-structuren, geloofwaardige instituten voor kankerbeleid en kwaliteitsopvolgingen, het gebruik van organisationele standaarden in de ziekenhuizen blijken essentiële factoren te zijn voor kwaliteitsverbetering. Belangrijke hefbomen voor het beleid zijn medische professionals erkend voor hun expertise in de oncologie, goed geïnformeerde patiënten, publieke vertegenwoordigers die de sociale waarden bewaken, en beleidsmakers. De organisatie en coördinatie van diensten (minimale volume vereisten, flexibel en bekwaam personeel) worden beschouwd als hoekstenen voor goede klinische praktijk en het bereiken van optimale resultaten in de oncologie.

Er werden geen gegevens teruggevonden over de uiteindelijke impact van deze kwaliteitssystemen op patiëntuitkomsten.

EEN KWALITEITSSYSTEEM VOOR ONCOLOGIE IN BELGIË

Is het nodig?

Op nationaal niveau toonden de 3 pilootstudies aan dat er zeker ruimte voor verbetering is voor minstens sommige aspecten van de zorg voor patiënten met deze kankertypes. Bovendien werd voor de meeste kwaliteitsindicatoren aangetoond dat er een grote zorgvariabiliteit is, hoewel het voorlopige en niet voor risicofactoren gecorrigeerde gegevens betreft. Dit is op zich al een belangrijke reden om een kwaliteitssysteem voor oncologie op te zetten. Er moeten echter nog enkele belangrijke vragen worden beantwoord over de doelstellingen en de scope van een dergelijk kwaliteitssysteem.

Wat moet het doel van dit kwaliteitssysteem zijn?

In de meeste hierboven besproken landen wordt kwaliteitsmeting gebruikt voor verbetering en monitoring van de kwaliteit over verloop van tijd. Andere mogelijke doelstellingen zijn peer review, nationale/internationale benchmarking, openbare verantwoording, research, accreditatie, enz. Een breed gebruik van kwaliteitsinformatie wordt geïllustreerd door het Nederlandse kwaliteitssysteem waar de informatie wordt gebruikt voor kwaliteitsverbetering, peer review en accreditatie.

De beleidsmakers moeten duidelijke keuzes maken en een hiërarchie van doelstellingen vooropstellen. De uiteindelijke doelstelling moet een gezondheidssysteem van hoge kwaliteit zijn dat bijdraagt tot de gezondheid van de Belgische bevolking, en in het bijzonder van kankerpatiënten.

Is kwaliteitsmonitoring nodig voor alle kankertypes?

Alle patiënten hebben recht op de beste zorgkwaliteit. De pilootstudie voor teelbalkanker bracht op zijn minst een aanzienlijke variabiliteit in de zorgkwaliteit voor patiënten met deze kanker aan het licht en beklemtoonde daarmee het belang van kwaliteitsmeting en de erop volgende acties voor kwaliteitsverbetering, zelfs voor een dergelijke zeldzame kanker. Zeldzame kankers hebben uiteraard een beperkte impact op de volksgezondheid. Frequente kankers, zoals borstkanker, hebben een veel grotere impact, en moeten en zullen daardoor waarschijnlijk ook voorrang krijgen. Dit is het geval in de meeste landen die worden besproken in het hoofdstuk over internationale ervaringen, waar de focus typisch ligt op 4-5 frequente kankertypes, en bijna nooit op alle kankertypes. De aanpak van kwaliteitsmonitoring van zeldzame kankers zal waarschijnlijk verschillen van die voor meer voorkomende kankers.

In plaats van een verticale benadering, d.w.z. per kankertype zoals in de 3 pilootstudies, zijn meer transversale benaderingen ook mogelijk, waardoor een evaluatie van bepaalde, generieke onderdelen van de kankerzorg mogelijk wordt, onafhankelijk van het type kanker. Van de bestudeerde buitenlandse projecten zijn er slechts enkele transversaal, bijv. het radiotherapie project in Frankrijk.

Is het valide en betrouwbaar?

Pilootstudies zijn een cruciale fase in de ontwikkeling van een set kwaliteitsindicatoren. Het selectieproces resulteert in een lijst van klinisch relevante en valide indicatoren, waarvan de meetbaarheid en interpreteerbaarheid moet worden getest met de beschikbare gegevens, zodat de indicatoren verder verfijnd kunnen worden.

Mogelijke uitkomsten van een pilootstudie zijn ofwel dat een indicator meetbaar en interpreteerbaar is zonder verdere aanpassing, ofwel niet meetbaar is zoals aanvankelijk gedefinieerd. In het laatste geval kan de indicator uit de set geëxcludeerd worden, opnieuw geformuleerd worden, vervangen worden door een andere benaderende indicator of meetbaar worden gemaakt door aanpassing of registratie van de nodige gegevens.

INTERPRETATIE EN VOORSTELLING VAN DE INDICATORRESULTATEN

De 3 pilootstudies concentreerden zich vooral op beschrijvende analyses, op het produceren van nationale resultaten en tijdsevoluties, en op het rapporteren van de variabiliteit tussen de centra. In de pilootstudie over rectale kanker werd ook een aanzet gedaan om composite scores te berekenen.

Gezien dit niet de doelstelling was van de 3 pilootstudies werd er geen risicocorrectie uitgevoerd, buiten een stratificatie op basis van kankerstadium voor sommige indicatoren. Op dit moment evalueert een lopend KCE-project, dat rectumkanker (PROCARE) als case study gebruikt, een statistische methodologie om benchmarking van centra uit te voeren op basis van composite kwaliteitsindicatoren en rekening houdend met de case-mix. De resultaten van deze zullen beschikbaar zijn in juni 2011.

Voor de voorstelling van de variabiliteit tussen centra gebruikte het rectale kankerproject een verschillende benadering dan de 2 andere projecten. In het eerste project werden histogrammen gebruikt, terwijl in de borst- en teelbalkankerprojecten funnel plots werden gegenereerd. Omdat ze gemakkelijker kunnen worden geïnterpreteerd, worden funnel plots aanbevolen voor toekomstige feedback projecten.

Belangrijk is dat de uiteindelijke presentatie en bespreking van de resultaten in sterke mate afhankelijk zijn van de doelstellingen van het kwaliteitssysteem.

IMPLEMENTATIE VAN EEN KWALITEITSSYSTEEM

Om een volledig operationeel en allesomvattend kwaliteitssysteem te hebben, zijn de volgende elementen belangrijk:

- de know-how om klinische praktijkrichtlijnen en gerelateerde kwaliteitsindicatoren te ontwikkelen;
- een doeltreffende en haalbare gegevensverzameling;
- een correcte gegevensanalyse en –interpretatie;
- de mogelijkheid om feedback te geven aan de eindgebruikers;
- de mogelijkheid om gerichte en corrigerende acties te starten.

Deze elementen zijn potentieel aanwezig in België maar niet noodzakelijk bij één enkele speler, noch geïntegreerd in een werkzaam en duurzaam systeem.

Op dit moment worden reeds klinische praktijkrichtlijnen en kwaliteitsindicatoren ontwikkeld door het KCE, in samenwerking met respectievelijk het College voor Oncologie en de Stichting Kankerregister.

Bovendien beschikt de Stichting Kankerregister over een nationale databank met een hoge dekkingsgraad van alle kankergevallen, inclusief de incidentiedatum en tumorkenmerken, en gekoppeld aan de vitale status voor de meeste gevallen. Sinds 2010 zijn deze gegevens ook gekoppeld aan een beperkte set van facturatiegegevens uit de IMA-databank. In de 3 onderzoeksprojecten werden deze elementen met succes in praktijk gebracht. Het MOC en de financiering van datamanagers zijn nuttige elementen voor een doelmatige kankerregistratie ter hoogte van de ziekenhuizen.

Daarnaast is feedback een essentieel onderdeel bij de verbetering van de zorgkwaliteit. Multidisciplinaire teams moeten regelmatig feedback hierover krijgen. Streefwaarden (in plaats van gemiddelde of mediaan) dienen te worden gedefinieerd in samenwerking met deskundigen en de resultaten dienen te worden besproken. Het College voor Oncologie, dat samengesteld is uit peers, zou hierin een rol kunnen spelen. Webapplicaties moeten gebruikt worden om feedback naar de ziekenhuizen te zenden. Voor rectale kanker werd dit alles reeds gerealiseerd door de Stichting Kankerregister in samenwerking met de stuurgroep van PROCARE. Toch zijn zorgkwaliteitsprojecten met individuele feedback nog vrij zeldzaam in België en, hoewel de eerste resultaten bemoedigend zijn, moeten deze projecten nog verder worden uitgewerkt. Men kan zich hierbij ook inspireren van gelijkaardige projecten buiten de oncologie.

Naast feedback zijn gerichte en corrigerende acties een ander essentieel element in de cyclus voor kwaliteitsverbetering. Deze acties kunnen het initiatief zijn van de zorgverleners zelf, als antwoord op de geleverde feedback, maar kunnen ook opgelegd worden door de beleidsmakers. Deze rol wordt al vervuld door de federale en gefedereerde instellingen (bvb. via inspectie en erkenning). Bovendien kan het College voor Oncologie, zoals trouwens voorzien in de wet, visitaties organiseren om de redenen voor de onderprestaties van bepaalde outliers te analyseren. Zo ook kan een analyse van goed presterende centra helpen begrijpen welke processen tot betere resultaten leiden, en wat de omstandigheden zijn die leiden tot het toepassen van deze processen.

Een belangrijke bijdrage van het Kankercentrum aan een oncologisch kwaliteitssysteem zou kunnen zijn om dit systeem te laten aansluiten bij het gezondheidsbeleid en om de respectievelijke taken van de verschillende, hierboven vermelde betrokkenen te coördineren. Het Kankercentrum kan een bijkomende rol spelen door mee de coherentie te bewaken van de verschillende initiatieven vanuit ziekenhuizen of onderzoekscentra (inclusief universiteiten) en complementariteiten en synergieën te faciliteren binnen het globale kader van het kwaliteitssysteem in de oncologie, dat daarnaast ook aandacht moet hebben voor preventie en opsporing.

AANBEVELINGEN[a]

- **Om een kwaliteitssysteem voor oncologie op te starten in België moeten de doelstellingen van dit systeem zeer helder worden gedefinieerd door de beleidsmakers in samenspraak met de belangrijkste betrokkenen.**
- **Het kwaliteitssysteem moet integratief zijn, d.w.z. het moet de volgende elementen omvatten:**
  - **ontwikkeling en implementatie van evidence-based praktijkrichtlijnen,**
  - **de ontwikkeling van bijhorende kwaliteitsindicatoren,**
  - **de evaluatie van de implementatie van de richtlijnen aan de hand van de kwaliteitsindicatoren,**
  - **het geven van feedback aan de zorgverleners en centra, en**
  - **de implementatie van gerichte acties.**
- **Het kwaliteitssysteem moet generische kwaliteitsindicatoren, die relevant zijn voor alle kankertypes, bijv. overleving, recidief en multidisciplinaire bespreking, combineren met meer specifieke sets van kwaliteitsindicatoren voor de meest frequente kankertypes. Hierbij moeten de meest prioritaire indicatoren worden geselecteerd in samenspraak met de belangrijkste betrokkenen. Naast deze verticale aanpak moeten ook transversale evaluaties worden opgenomen in het systeem. Alle kwaliteitsdimensies moeten in het kwaliteitssysteem aan bod komen, zo ook patiëntgerichtheid, tijdigheid en billijkheid.**
- **De gegevensverzameling om kwaliteitsindicatoren te meten moet maximaal gebruik maken van de combinatie van reeds beschikbare gegevensstromen, met name de gegevens van de Stichting Kankerregister, het Intermutualistisch Agentschap, de Minimale Klinische Gegevens en de mortaliteitsgegevens.**
- **Het aantal kwaliteitsindicatoren dat uiteindelijk geselecteerd wordt om individuele feedback te geven moet tot het strikte minimum beperkt worden om het systeem duurzaam te houden en om op een relevante manier correctieve acties te kunnen ondernemen.**
- **Er moet toegezien worden op het effectieve gebruik van de feedbackgegevens om waar nodig correctieve acties te ondernemen. Deze integratie van een kwaliteitssysteem in de dagelijkse praktijk moet gestimuleerd worden door aangepaste incentieven of zo nodig sancties.**
- **Een volgende stap moet de uitwerking zijn van het concrete scenario voor de uitbouw van een effectief en duurzaam kwaliteitssysteem, in samenspraak met alle betrokken partijen, en waarbij de rol van elke partij duidelijk moet worden bepaald en geïmplementeerd, rekening houdend met de competenties en de wettelijke basis van elke betrokkene.**

[a] De beleidsaanbevelingen vallen onder de volledige en exclusieve verantwoordelijkheid van het KCE.

Scientific summary

Table of contents

LIST OF ABBREVIATIONS

ACS	American College of Surgeons
APR-DRG	All Patient Refined Diagnosis Related Groups
ASCO	American Society of Clinical Oncology
BCR	Belgian Cancer Registry
BS/MB	Belgisch Staatsblad / Moniteur Belge
CCC	Comprehensive Cancer Centre
CCO	Cancer Care Ontario
CE-CT	Contrast-enhanced Computed Tomography
CNK	Code National(e) Kode
CPAC	Canadian Partnership Against Cancer
CPG	Clinical practice guideline
CQCO	Cancer Quality Council of Ontario
CSBS	Clinical Standards Board for Scotland
CSQI	Cancer System Quality Index
FNCLCC	Fédération Nationale des Centres de Lutte contre le Cancer
FOD/SPF	Federale Overheidsdienst / Service Public Fédéral
HAS	Haute Autorité de Santé
HER2	Human epidermal growth factor receptor 2
ICD	International classification of diseases
IMA/AIM	Intermutualistisch Agentschap/ L'Agence Intermutualiste
INCa	Institut National du Cancer
IOM	Institute of Medicine
KCE	Belgian Healthcare Knowledge Centre
MCD-HBD	Minimal Clinical Data - Hospital Billing Data
MDC	Major Diagnostic Category
MDT	Multidisciplinary team meeting
MeSH	Medical Subject Heading
MOC/CMO	Multidisciplinary oncology consultation
MRI	Magnetic Resonance Imaging
NCCN	National Comprehensive Cancer Network
NCI	National Cancer Institute
NICCQ	National Initiative on Cancer Care Quality
NISS	Social security number
NQF	National Quality Forum
PROCARE	PROject on CAncer of the Rectum
QIS	Quality Improvement Scotland
QOPI	Quality Oncology Practice Initiative
RCT	Randomized controlled trial

RIZIV/INAMI	Rijksinstituut voor Ziekte- en Invaliditeitsverzekering / Institut National d'Assurance Maladie-Invalidité
TCT	Technische cel / Cellule technique
TTP	Trusted third party
US	United States
VLK	Vlaamse Liga tegen Kanker

1 INTRODUCTION

In 2004, the Belgian Section for Colorectal Surgery, a section of the Royal Belgian Society for Surgery, launched the PROCARE project (PROject on CAncer of the REctum) as a multidisciplinary, profession-driven and decentralized project (www.belgiancancerregistry.be). The main objective of this multidisciplinary project is to reduce diagnostic and therapeutic variability and to improve outcome in patients with rectal cancer by means of:

- standardization through guidelines (which were issued in 2007 [1]);
- implementation of these guidelines (workshops, meetings, training);
- quality assurance through registration and feedback.

In 2005, a multidisciplinary dataset was elaborated for registration in a rectal cancer specific database at the Belgian Cancer Registry (BCR). Registration started in October 2005. In order to allow individual feedback and national/international benchmarking, a quality indicator system was set up in 2008 [2]. At present, three rounds of feedback were already given to the participating centres.

The PROCARE project drew the attention of the Minister of Health. In the National Cancer Plan 2008-2010 (http://www.laurette-onkelinx.be/articles_docs/32_initiatieven_N.pdf, accessed on November 16th 2010), initiative 9 aimed at the instauration of a 'personalised care program' for all new cancer patients. The development of these care programs, together with the follow-up of the quality of care, are the responsibilities of the College of Oncology. To allow an efficient realisation of this task, a structure is needed that allows a rapid development and update of clinical practice guidelines, the translation of these guidelines into concrete care programs, and the definition and implementation of quality criteria to follow up the quality of care. At present, the College of Oncology and the KCE already collaborate for the development of clinical practice guidelines [3-5]. However, for the subsequent evaluation of the quality of care, collaborations are fragmented and need to be structured if the set-up of a quality system is envisaged.

As a preparation to set up a quality system for oncology in Belgium, the Minister of Social Affairs and Public Health asked the KCE to apply the methodological approach from the PROCARE project to a frequent cancer, i.e. breast cancer, and a rare cancer, i.e. testicular cancer. In a first phase, the national guidelines for both cancer types were updated and published earlier [6, 7]. In a second phase, a quality indicator set was developed for both cancer types. These quality indicator sets underwent a feasibility test that was published in January 2011 [8, 9].

The present report provides a summary of the main findings of the three exercises (rectal, breast and testicular cancer) and the lessons learned. Above this, an overview is given of the main structures and stakeholders in the domain of oncology in Belgium. Also, international experiences with quality measurement in the field of oncology are discussed.

The objective of the present report is to formulate recommendations to set up a quality system for oncology. The experiences with the 3 pilot studies and the foreign experiences will serve as input for these recommendations. The following questions will be answered: is a quality system necessary in Belgium? If yes, who should be involved and what should be the structure of it? To provide input for these recommendations, an expert meeting was organized on June 23rd 2010, involving most stakeholders discussed below. No separate chapter will be written on this expert meeting, but the discussion points raised during the meeting will be appropriately inserted in the discussion chapter of this report.

2 ONCOLOGY IN BELGIUM

2.1 EPIDEMIOLOGY

According to the most recent data of the BCR (Liesbet Van Eycken, personal communication), almost 60 000 new cancer cases were diagnosed in 2008 (non-melanoma skin cancer excluded). The most important cancer types in absolute numbers for the entire population were breast cancer (9 697 new female cases in 2008), prostate cancer (8 810 new cases), colorectal cancer (8 175 new cases) and lung cancer (7 182 new cases). In men, the most frequent cancer is prostate cancer (Table 1), while in women breast cancer is the most frequent cancer (Table 2).

Table 1. Top 5 of cancer types with highest incidence in Belgium (absolute numbers), 2004 – 2008, men.

		2004	2005	2006	2007	2008
C61	Prostate cancer	9 735	9 709	9 254	8 976	8 810
C34	Lung cancer	5 514	5 392	5 279	5 493	5 406
C18-20	Colorectal cancer	4 124	4 166	4 231	4 251	4 486
C00-C14, C30-C32	Head and neck cancer	2 530	2 419	2 270	1 975	1 935
C67	Bladder cancer	1 666	1 631	1 595	1 682	1 685

Table 2. Top 5 of cancer types with highest incidence in Belgium (absolute numbers), 2004 – 2008, women.

		2004	2005	2006	2007	2008
C50	Breast cancer	9 445	9 431	9 489	9 722	9 697
C18-20	Colorectal cancer	3 522	3 471	3 559	3 645	3 689
C53-56	Gynaecological cancer	3 044	3 006	2 867	3 032	2 974
C34	Lung cancer	1 553	1 585	1 677	1 878	1 776
C43	Malignant melanoma of skin	891	967	958	981	1 147

Survival data are not yet systematically analysed in Belgium, but the first data will be available for all cancer types by mid 2011. In 2008, the Belgian Cancer Registry published a report on the cancer incidence in Belgium for the years 2004-2005 [10]. Some mortality data were included in this report. Belgian cancer mortality data for 2004 showed that lung cancer is by far the most important cause of death by cancer in males (4 828 cases). In females, breast cancer is the leading cause of death by cancer (2 286 cases). Colorectal cancer is the second most important cause of death by cancer in both sexes (1 453 cases for males, 1 388 cases for females). Prostate cancer is the third most common cause of death by cancer in males (1 377 cases). Lung (24%), breast (9%), colorectal (11%) and prostate cancer (5%) are responsible for half (49%) of all deaths by cancer in Belgium.

Survival data for rectal, breast and testicular cancer were calculated as part of the three pilot projects discussed in chapter 3. For rectal cancer, relative 5-year survival was found to be 58% for all stages [2]. For cStage I a relative 5-year survival of 70% was found versus 11% for cStage IV. For breast cancer, relative 5-year survival was 93% for pStage I versus 26% for cStage IV [8]. For testicular cancer, relative 5-year survival was 97% for pStage I versus 76% for pStage III [9].

2.2 MAIN STRUCTURES AND STAKEHOLDERS

2.2.1 Belgian Cancer Registry

2.2.1.1 History

Before 1983, cancer registration in Belgium was exclusively based on information provided by the sickness funds and requested from the treating physician. Registration was done on a voluntary basis. Since 1983, the National Cancer Registry was established and managed by the Belgian Work against Cancer. The founding of the National Cancer Registry was the first step towards a coordinated cancer registration system in Belgium. The National Cancer Registry received and managed data obtained from the seven Belgian Health Insurance Companies. However, an evaluation of the registry data revealed a significant under-registration.

At the end of the eighties various cancer registration initiatives were launched in Flanders next to the National Cancer Registry. However, these separate registration systems did also not provide a complete picture of the cancer burden in Flanders. Between 1994 and 2005, the Flemish government supported the development of a cancer registration network in Flanders. The coordination of this network was assigned to the Flemish League against Cancer.

In 2003, the reimbursement of the multidisciplinary oncology consultation (MOC/CMO) and the oncological care programs were introduced. Both a mandatory participation in the cancer registration and the use of a standard registration form in the hospitals were introduced.

On June 28th 2005, the Belgian Cancer Registry Foundation was launched to ensure the continuity of the cancer registration in Belgium. This new structure brought together the MCO/CMO registration via the health insurers, the various independent initiatives of Flanders, Wallonia and Brussels and is mainly based on the former Flemish Cancer Registry Network. Article 39 of the Health Law of December 13th 2006 details the organisation of the cancer registration in Belgium.

2.2.1.2 Objectives

According to the Health Law of December 13th 2006 (BS/MB December 22nd 2006), the Belgian Cancer Registry Foundation has the following goals:

1. Reporting of the incidence, prevalence and survival of patients with different types of cancer;
2. Performing case-control and cohort studies on the causes of cancer;
3. Analysis of the geographical spread of the different types of cancer, the incidence, trends and their consequences, to allow an evaluation of possible causes and a comparison of risk factors;
4. Reporting to international organisations, including the World Health Organization.

The Foundation collects and registers the following data:

1. Identification number of the Social Security of the patient;
2. Clinical data, collected as part of the mandatory cancer registration;
3. Data of the services of pathology and clinical biology/haematology;
4. Data of survival and their geographical location;
5. Instauration of a cytohistology registry for early diagnosis and prevention

The Foundation is, among other things, charged with the conversion of the clinical information to internationally accepted classifications, the linkage of these data based on the identification number of the Social Security, the codification of the identification number of the Social Security, the analysis of not-encoded person data, and the quality control of the collected data. Furthermore, the Foundation should provide reports and results (aggregated data) to the Minister of Public Health, the Minister of Social Security and the College of Oncology.

2.2.2 College of Oncology

The College of Oncology is an official Belgian multidisciplinary council representing the medical specialties involved in cancer care. The College was established by the Law on Oncology Healthcare Programs (article 38 of the Law of March 21st 2003; BS/MB April 25th 2003), and its members are appointed by ministerial decree. The tasks of the College are detailed in article 8 of the Law of February 15th 1999 (BS/MB March 25th 1999) and article 38 of the Law on Oncology Healthcare Programs (Table 3).

Table 3. Tasks of College of Oncology.

Royal Decree February 15th 1999, article 8
To define in consensus quality indicators and criteria for good clinical practice; these criteria relate to infrastructure, manpower, medical practice and its outcomes;
To develop a computerized registration model and type of report, taking into account the guidelines of the coordinating working group;
To perform visitations and controls of registered data;
To write an annual national report with relevant data regarding medical-technical services, services, functions or care programs; these reports should be handed to the coordinating working group;
To answer questions of a service or healthcare provider regarding the evaluation process;
To write a report on the use of resources;
To give feedback to hospitals and physicians of medical-technical services, services, functions or care programs, concerning the quality indicators and criteria and the use of resources.
Royal Decree March 21st 2003, article 38
To support the hospitals in the development and update of the multidisciplinary oncology handbook that contains guidelines for the diagnosis, treatment and follow-up of neoplastic disorders, e.g. by proposing a model of a multidisciplinary oncology handbook;
To develop a model for cancer registration;
To organise audits of hospitals through visitation by members or delegated experts of the College, and to write reports on these audits;
To compare nationally the used handbooks, and to organise thematic consensus meetings depending on the priorities;
To actualise the norms for the use of antitumoral medications according to current scientific standards;
To formulate recommendations on the competence criteria that specialists should meet to be part of the medical team of an oncology care program, and on the need to establish specific professional competences for specialists involved in the oncological care;
To formulate recommendations on the specialised care programs and their minimal activity level.

Until now, the activities of the College were mainly focused on the development of clinical practice guidelines. Most of these guidelines were developed with the methodological support of the KCE [3-7]. For some guidelines, e.g. on non-small-cell lung cancer and malignant melanoma, the College constituted a guideline development group and managed the guideline development on its own. These guidelines were consensus-based.

Furthermore, in collaboration with the KCE, the College developed a general framework for a multidisciplinary oncology handbook [11].

2.2.3 Cancer Centre

2.2.3.1 History

In March 2008, the Minister of Health, Laurette Onkelinx, launched the first National Cancer Plan 2008-2010 (http://www.health.belgium.be/eportal/Myhealth/Risksanddiseases/Healthrisks/Cancer/NationalCancerPlan/13660507?ie2Term=kankerplan&ie2section=83, accessed on January 3rd 2011). This multi-year plan consisted of 32 initiatives encompassing 3 major domains: prevention and detection (6 initiatives); care, treatment and support (20 initiatives); and, research, innovative technologies and evaluation (6 initiatives). The major objectives were:

- to decrease the cancer incidence in Belgium;
- to decrease the cancer morbidity in Belgium;
- to decrease the cancer mortality in Belgium;
- to improve the quality of life of the patients and their relatives, with special attention for palliative and psychosocial care in Belgium;
- the creation of a Cancer Centre in Belgium.

The demand for the creation of a Cancer Centre originates from the concerns about the increasing incidence and prevalence of certain cancer types and from the fragmentation of the professionals active in the battle against cancer. Importantly, at the time of the writing of this report, the mission and tasks of the Cancer Centre discussed below were not yet implemented.

2.2.3.2 Mission

The Cancer Centre aims to optimize the use of the existing expertise, knowledge and financial resources. It also aims to support the existing partners active in the battle against cancer to pursue a policy based on scientific evidence and/or conscious choices where relevant. The objective is a better coordination of all partners through multilateral consultation and/or process facilitation, an optimal use of existing resources, and the development of new recommendations about the actions of the present and future National Cancer Plan.

2.2.3.3 Tasks

Impact analyses

In consultation with all actors, impact analyses and future projections will be made. This will help to evaluate the societal consequences of the different policy variants, to elaborate a long-term vision and strategy, and to gather the necessary information for a political debate and decision-making.

Multilateral consultation and process facilitation

All actors, which are listed by the Cancer Centre, will be involved in multilateral consultations. These consultations will result in a platform and shared strategy for an optimal battle against cancer. The Cancer Centre also facilitates the information transfer to and from the European level. It actively participates in initiatives relevant for the battle against cancer in Belgium.

Knowledge management

The Cancer Centre aims to help to translate scientific evidence into clear, feasible and directly implementable policy recommendations. This will be done in consultation with all actors and on demand of all policy levels.

2.2.4 Belgian Healthcare Knowledge Centre

The KCE is a federal semi-governmental institution founded on December 24th 2002 and operational since 2003. Its mission is to produce studies and reports to advise policymakers when deciding on health care and health insurance. The KCE is active in three major research fields:

- Analysis of clinical practices and development of recommendations of good practice (Good Clinical Practice)
- Assessment of health technologies and drugs (Health Technology Assessment)
- Healthcare financing and organisation (Health Services Research)

In the domain of oncology, the KCE already produced several reports, mainly in the domain of Good Clinical Practice and Health Technology Assessment (Table 4). Of the 147 reports published between 2004 and 2010, 24 (16%) were directly related to oncology [2-9, 12-29].

Table 4. Number of oncological KCE projects.

	2004	2005	2006	2007	2008	2009	2010	Total
GCP	-	1	1	2	2	2	3	11
HTA	-	2	4	3	1	1	-	11
HSR	-	-	-	-	1	1	-	2
Total N projects	**7**	**17**	**26**	**23**	**28**	**19**	**27**	**147**

For the oncological guidelines, KCE collaborates with the College of Oncology. The College of Oncology assembles a group of clinical experts with a president, who define the scope and research questions in agreement with the KCE. The KCE is then responsible for the literature search, quality appraisal, evidence tables and evidence report, which are done in collaboration with the clinical experts. The evidence tables and evidence report form the basis for the formulation of the recommendations by the clinical experts. Finally, the College of Oncology contacts all relevant professional associations to discuss the final recommendations during a stakeholders meeting.

For the quality indicator projects, the KCE also has a close collaboration with the Belgian Cancer Registry. The results of this collaboration so far are discussed in chapter 3. Furthermore, the KCE is involved in international collaborations, of which some are specifically in the domain of oncology, e.g. CoCanCPG (www.cocancpg.eu/). At this moment, the KCE collaborates with the Dutch Comprehensive Cancer Centre (CCC) on the guideline Cervical Cancer. These collaborations aim at reducing the duplication of effort and have the advantage of mutual peer-review between the collaborating organisations.

2.2.5 RIZIV/INAMI

The RIZIV/INAMI is a federal institution that organizes, manages and supervises the correct application of the compulsory insurance in Belgium. The RIZIV/INAMI is supervised by the Minister of Social Affairs. Its role in the domain of oncology is therefore considerable, just as in other health care domains. As an example, the RIZIV/INAMI recently revised the nomenclature concerning the multidisciplinary oncology consultation (see below). Furthermore, the RIZIV/INAMI plays a specific role in promoting the integration of health services and multidisciplinarity, for instance with the financing of the National Cancer plan.

Collaboration with the RIZIV/INAMI in terms of quality of care is important, since adaptations of the nomenclature can facilitate research in this domain, e.g. by creating more specific nomenclature codes (see chapter 3).

2.2.6 FOD/SPF Health, Food Chain Safety and Environment

The Federal Public Service (NL: Federale Overheidsdienst, FOD; FR: Service Public Fédéral, SPF) Health, Food Chain Safety and Environment defines the minimal norms for recognition, e.g. for breast clinics. Furthermore, it has a specific cell that is responsible for the execution of parts of the National Cancer Plan (http://www.health.belgium.be/eportal/Myhealth/Risksanddiseases/Healthrisks/Cancer/NationalCancerPlan/index.htm?fodnlang=nl, accessed on February 2nd 2011). Some examples are the financing of data managers, psychologists and oncological nurses for recognized care programs for oncology, the financing of units for cell therapy with haematopoietic stem cells and umbilical blood, and the financing of tumour banks.

2.2.7 Intermutualistic Agency

The Intermutualistic Agency (IMA/AIM) is a non-profit institution with all Belgian sickness funds as its members. The sickness funds have individual patient data on patient characteristics, reimbursed services and pharmaceuticals delivered by pharmacists, at the detailed level of the service or the prescription. Patients are identified with the social security number, which makes the linkage with other databases possible.

Besides its role as data provider, IMA produces reports on health utilization. Examples in the field of oncology are the reports on breast and cervical cancer screening (http://www.nic-ima.be/nl/projects/, accessed on February 28th 2010).

2.2.8 Other

In Belgium, the *regional governments* are responsible for preventive health care and health promotion. This includes the screening programmes for breast, cervical and colorectal cancer. Besides that, they are also responsible for the recognition of hospitals and services (e.g. care programs for oncology, radiotherapy services, etc.) through a control of the correct application of the norms as defined by the FOD/SPF.

The *Foundation against Cancer* (NL: Stichting tegen Kanker; FR: Fondation contre le Cancer) is a national non-profit organisation supporting scientific oncological research, providing social services and providing health information and promotion (www.kanker.be, accessed on February 2nd 2011). Financial support of the Foundation is mainly through private donations. However, the Foundation is also partially supported by official and governmental organisations.

As the Foundation against Cancer, the *Flemish League against Cancer* (NL: Vlaamse Liga tegen Kanker, VLK) is a non-profit organisation supporting scientific oncological research (www.tegenkanker.be, accessed on February 2nd 2011). It also offers psychosocial support to cancer patients and their relatives and launches public information and prevention campaigns. The VLK is also the organiser of the campaign 'Kom op tegen kanker'.

2.3 FACILITIES AND HUMAN RESOURCES

In Belgium, 82 specialized care programs for oncology were recognized in 83 services[a] (in 71 hospitals) in November 2010 (source: FOD/SPF Health, Food Chain Safety and Environment). All other 88 services had a recognized care program for oncological basic care. The norms to be recognized as a specialized care program for oncology or a care program for oncological basic care are described in the Royal Decree of March 21st 2003 (BS/MB April 25th 2003). Of the services with a recognized care program for oncology, 49 also had a recognized specialised oncological care program for breast cancer. The norms to be recognized as a specialised oncological care program for breast cancer are described in the Royal Decree of April 26th 2007 (BS/MB July 20th 2007). The main differences with a care program for oncological basic care are the multidisciplinary character (availability of at least 1 FTE specialist with expertise in oncology, at least 1 radiotherapist, oncological surgeons, at least 1 clinical haematologist, etc.), the availability of a multidisciplinary commission for oncology, and the availability of a specific infrastructure.

[a] Two services share one care program.

With the recognition of the specialty 'medical oncology' as described in the Ministerial Decree of May 29th 2006 (BS/MB June 14th 2006), the medical oncologist was placed at the centre of the oncological care. Nevertheless, many organ specialists, such as gastroenterologists, pneumologists and gynaecologists, have specific competences in the oncological sub-domain of their specialty and are responsible for the care of a substantial number of cancer patients. However, these specialists do not have a specific RIZIV/INAMI number reflecting their oncological activity and are therefore not traceable in this context. The same is true for surgeons specialised in the surgical care of cancer patients. Other healthcare workers involved in the care of cancer patients are radiotherapists and clinical haematologists, having the majority of their working time spent on oncological care. Radiologists, nuclear specialists and pathologists are also often specialised in oncology, but as for organ specialists and surgeons, they are not traceable in this context. Finally, many paramedical healthcare workers are involved in the care for cancer patients. In 2009, a Ministerial Decree was published describing the criteria for the recognition of nurses specialised in oncology (BS/MB February 18th 2009). For other healthcare workers, no such criteria exist.

Data on the number of medical oncologists are only available for 2008, when 107 medical oncologists were recognized. Furthermore, 23 fellows in medical oncology were counted for 2008. Importantly, as stated above, the number of medical oncologists does not reflect the actual activity level in the domain of medical oncology.

Figure 1 shows the evolution of the number of recognized radiotherapists and radiotherapy fellows between 2005 and 2008. While the number of radiotherapists gradually increased from 189 in 2005 to 211 in 2008, the number of radiotherapy fellows decreased to 46 in 2008 after a stable number of around 55 between 2005 and 2007. Twenty-five hospitals have a recognized radiotherapy service, all-but-one localised in a service with a specialised care program for oncology (source: FOD/SPF Health, Food Chain Safety and Environment).

Figure 1. Number of recognized radiotherapists and radiotherapy fellows, 2005-2008 (source: FOD/SPF Health, Food Chain Safety and Environment).

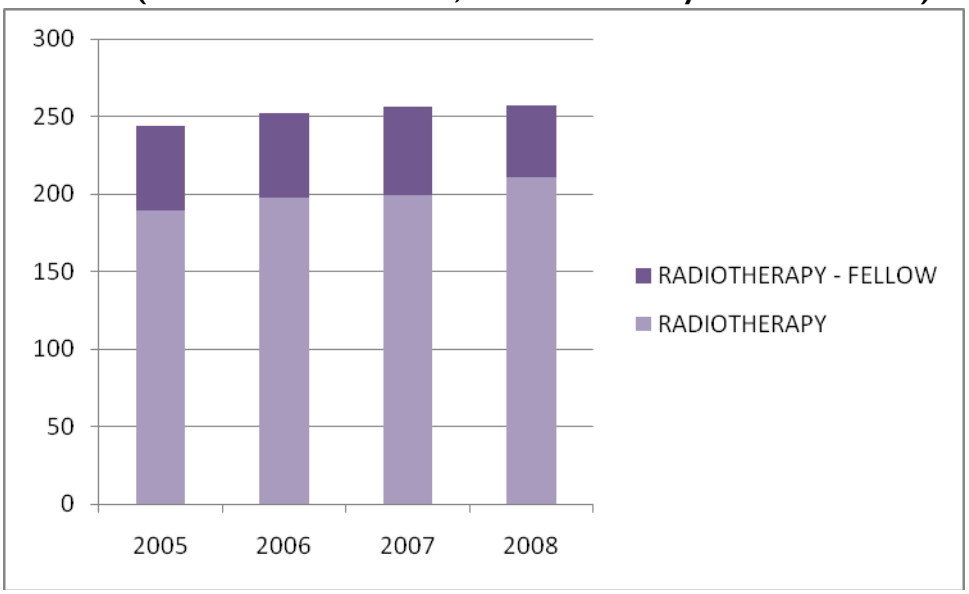
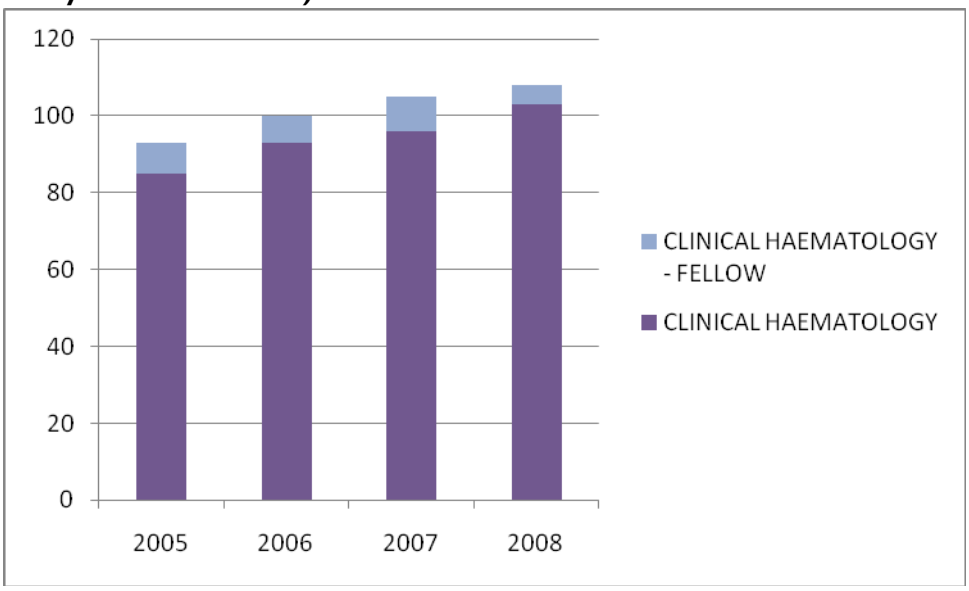


Figure 2 shows the evolution of the number of recognized clinical haematologists and clinical haematology fellows between 2005 and 2008. The number of recognized clinical haematologists gradually increased from 85 in 2005 to 103 in 2008. The number of clinical haematology fellows decreased to 5 in 2008 after a stable number of around 8 between 2005 and 2007.

Figure 2. Number of recognized clinical haematologists and clinical haematology fellows, 2005-2008 (source: FOD/SPF Health, Food Chain Safety and Environment).



Finally, in May 2010, 202 nurses were recognised as oncological nurse (Sven D'Haese, personal communication).

2.4 HEALTHCARE UTILISATION

2.4.1 Hospitalisations

On the website of the Technical Cell (https://tct.fgov.be/webetct/etct-web/anonymous?lang=nl, accessed on January 26th 2010), information can be found on the number of hospitalisations per Major Diagnostic Category (MDC) and All Patient Refined Diagnosis Related Groups (APR-DRG). Above this, the website provides financial information per MDC and APR-DRG. Since this information only relates to costs reimbursed by the sickness funds and to classical stays, without taking into account 'day care', it clearly underestimates the total number of hospitalisations.

About 20 APR-DRGs specifically relate to cancer care (see appendix). Some of these are generic (e.g. APR-DRG 692 Radiotherapy, APR-DRG 693 Chemotherapy), other APR-DRGs relate to the surgical intervention (e.g. APR-DRG 362 Mastectomy), still other APR-DRGs relate to the cancer type itself (e.g. APR-DRG 136 Respiratory malignancy). However, apart from the cancer-specific APR-DRGs, other APR-DRGs exist with an important fraction involving cancer care. The fraction involving cancer care was calculated previously for some APR-DRGs for the year 2005 [30]. Taking into account these fractions, estimations can be made about the proportion of hospital stays related to cancer care and the respective costs. Importantly, these calculations are an underestimation of the reality, since not all APR-DRGs with a fraction involving cancer care are represented.

The total number of hospitalisations increased from 1 532 567 in 2003 to 1 593 118 in 2007. The estimated proportion of stays related to cancer care slightly decreased from 8.15% in 2003 (N = 124 837) to 8.04% in 2007 (N = 128 012), although in absolute terms there was a clear increase. The total hospitalisation costs increased from € 5 771 million in 2003 to € 6 6650 in 2007. The estimated proportion of hospitalisation costs related to cancer care remained quite stable between 2003 (€ 495 million, 8.58%) and 2007 (€ 569 million, 8.56%).

2.4.2 Consultations related to cancer care

In March 2010, 6 new specific nomenclature codes were created for consultations with a medical oncologist (102270 and 102292), a clinical haematologist (102314 and 102336) and a paediatrician haemato-oncologist (102351 and 102373). Data to evaluate their utilisation are currently lacking.

Consultations with organ specialists lack specificity to distinguish cancer-related from other consultations.

2.4.3 Multidisciplinary oncology consultation

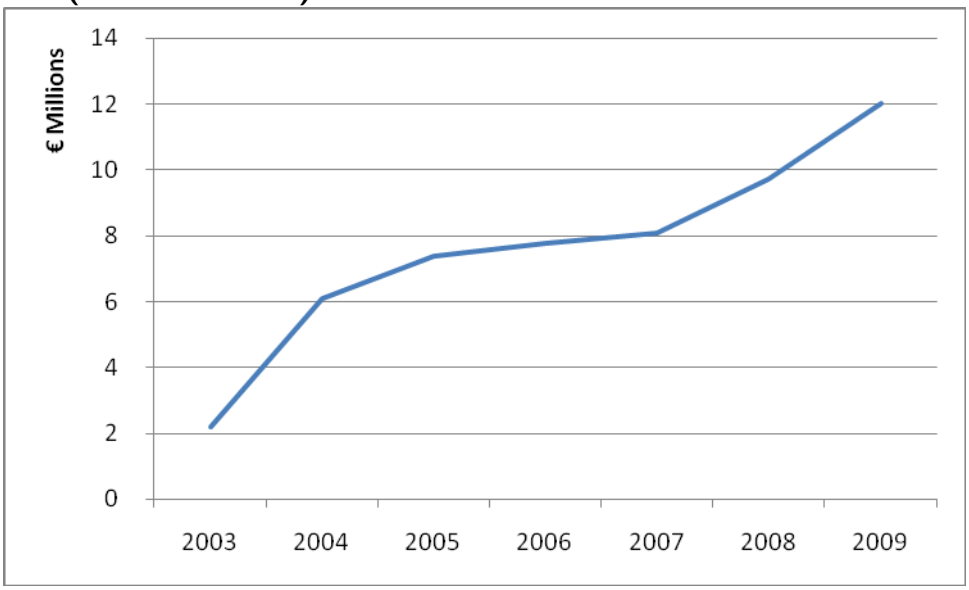
In 2002, the health authorities created the multidisciplinary oncology consultation, as it was recognized that there was a need to organize and to reimburse the existing multidisciplinary approach. The purpose of the multidisciplinary oncology consultation is to discuss the overall care of an individual within a planned meeting and to develop a strategic plan of diagnosis, treatment and follow-up. Until November 2010, 3 different nomenclature numbers were available: one for the first consultation attested by the coordinating physician (350372 – 350383), one for the participation of each individual physician of the hospital staff (350394 – 350405), and one for the participation of physicians not being part of the hospital staff (350416 – 350420). Since November 2011, several additional nomenclature codes were created, e.g. one for the consultation of the general practitioner to explain the outcomes of the multidisciplinary oncology consultation (350232), one for the consultation of the treating specialist to explain the outcomes of the multidisciplinary oncology consultation (350254 – 350265), one for a follow-up consultation (350276 – 350280), and one for a second opinion in another hospital (350291 – 350302). The minimal number of participating physicians is four, all from different specialties. At least one of these physicians should be specialised in surgical oncology or recognized in medical oncology, radiotherapy-oncology, clinical haematology or paediatric haemato-oncology.

Since the introduction of the multidisciplinary oncology consultation in February 2003, its use is growing rapidly. Between 2004 and 2009, the number of multidisciplinary oncology consultations (350372 – 350383) almost doubled to 81 352 (Table 5), corresponding to a budget of about 12 million euros (Figure 3).

Table 5. Number of Multidisciplinary Oncology Consultations, 2003 – 2009 (source: EconoDat).

Administrative codes	2003	2004	2005	2006	2007	2008	2009
350372	13 040	34 849	42 963	45 394	45 604	54 242	66 431
350383	3 335	8 318	11 338	11 121	11 719	13 630	14 921
350394	34 218	106 850	121 605	126 870	130 164	153 517	191 403
350405	10 792	27 716	32 617	31 209	33 654	39 149	43 211
350416	2 881	7 671	8 340	8 837	9 955	9 905	11 752
350420	838	2 284	2 478	2 306	2 564	2 603	2 807

Figure 3. Budget related to Multidisciplinary Oncology Consultation, 2003-2009 (source: EconoDat).



2.4.4 Antineoplastic drugs

On the website of the RIZIV/INAMI, annual data on the utilisation and costs of drugs are published (http://www.riziv.be/drug/nl/statistics-scientific-information/pharmanet/pharmaceutical-tables/index.htm, accessed on January 26th 2010). Antineoplastic drugs are part of ATC class L (Antineoplastic and immunomodulating agents). Between 2000 and 2008, the total costs (third party payer and patient) of ambulatory drug prescriptions rose from € 2 102 million to € 3 207 million. For ATC class L01 (Antineoplastic agents), the total ambulatory costs clearly increased between 2000 (€ 4.9 million; 0.23% of total costs) and 2008 (€ 31 million; 0.97%). The total inpatient costs for ATC class L01 almost quadrupled between 2001 (€ 60 million) and 2008 (€ 263 million) (Marc De Falleur, personal communication).

Key points

- **In absolute terms, the incidence of cancer is increasing. The most frequent cancer types are breast cancer, prostate cancer, colorectal cancer and lung cancer.**
- **Important stakeholders in the domain of oncology are the Belgian Cancer Registry, the College of Oncology, and the Cancer Centre, each of them playing a particular role. The role of the Belgian Cancer Registry is the most visible at this moment, involving cancer registration, data analysis (for quality indicators in collaboration with the KCE) and reporting. Until now, the activities of the College of Oncology were mainly focused on the development of clinical practice guidelines, which were developed with the methodological support of the KCE in most cases. The actual role of the Cancer Centre is still unclear.**
- **Norms for specialized care programs for oncology, care programs for oncological basic care and specialized oncological care programs for breast cancer are determined by law.**
- **The actual oncological activity level in Belgium is difficult to determine, since the medical care for cancer patients is not exclusively provided by medical oncologists.**
- **Since its introduction, the number of multidisciplinary oncology consultations rapidly increased, corresponding to a budget of about 12 million euros in 2009.**

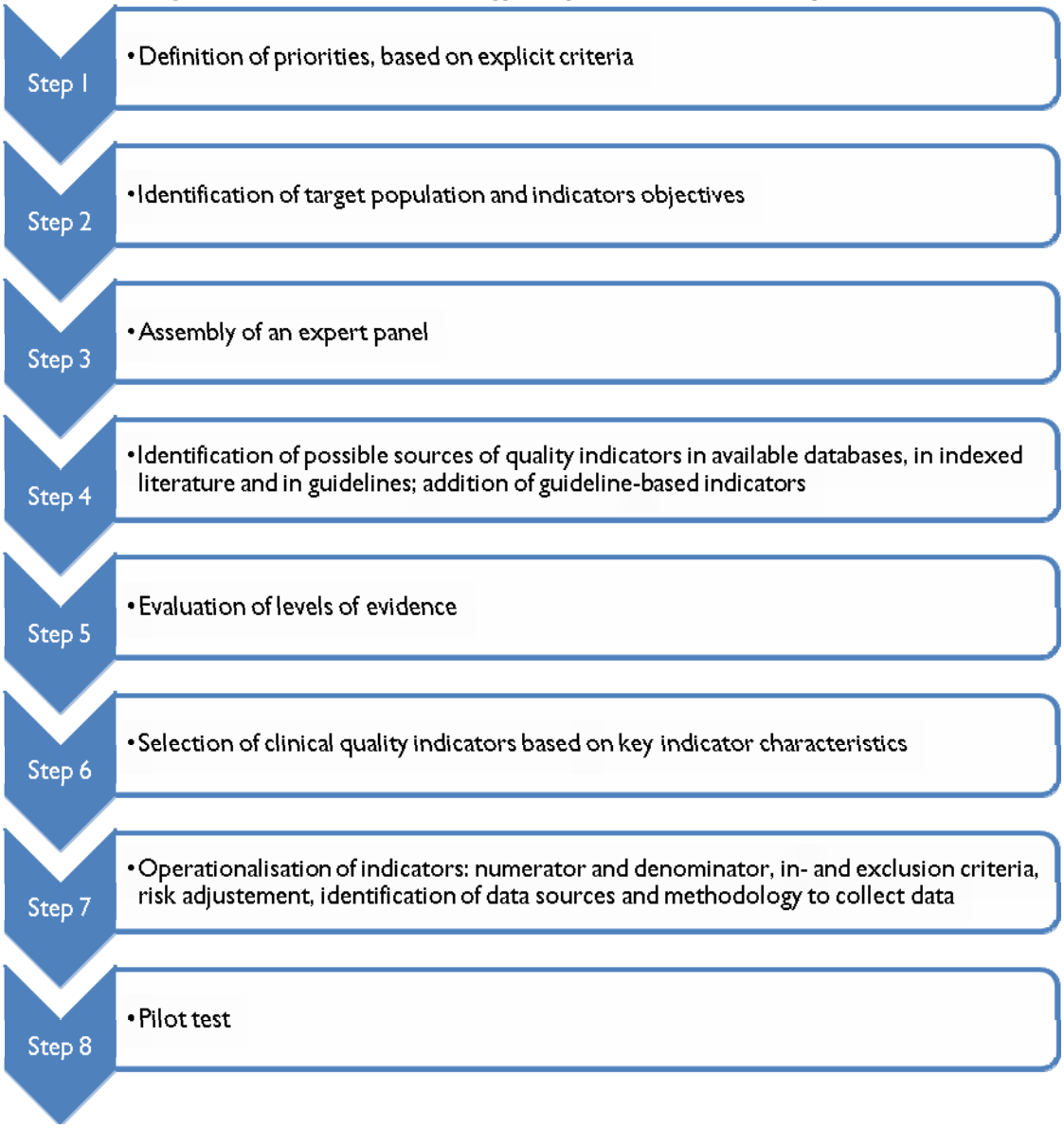
3 THREE PILOT PROJECTS: RECTAL, BREAST AND TESTICULAR CANCER

3.1 INTRODUCTION

The variability in outcome of treatment of cancers such as rectal and breast cancer is well known [31-36]. In its report 'Ensuring Quality Cancer Care' the Institute of Medicine (IOM) recommended that the quality of care be monitored and measured using a core set of quality indicators [37].

The purpose of the three KCE pilot studies was to develop and assess clinical quality indicators for cancer patients treated in Belgian hospitals. The same general approach was used for the three projects (Figure 4).

Figure 4. General methodology adopted for the feasibility studies [38].



3.2 INDICATOR SELECTION PROCESS

3.2.1 Indicator sources

3.2.1.1 Systematic literature search

For the 3 projects, both OVID Medline and the grey literature were searched to identify published and validated quality indicators [2, 8, 9]. The Medline database was searched using a combination of Medical Subject Heading (MeSH) terms related to quality of care and cancer-specific MeSH terms. For breast and testicular cancer, an additional Medline search for pattern of care studies was done. For rectal and breast cancer, the Cochrane Library was also searched. The references lists of all included papers were examined to identify additional papers not identified by our literature search. The search was always done by 2 independent researchers. The exact search strategies can be found in each individual report [2, 8, 9].

The following sources were considered to identify grey literature:

- National Quality Measures Clearinghouse: http://qualitymeasures.ahrq.gov/
- Agency for Healthcare Research and Quality: http://www.ahrq.gov/
- Joint Commission: http://www.jointcommission.org/
- Clinical Indicators Support Team: http://www.indicators.scot.nhs.uk/
- National Health Service: http://www.nhs.uk/

3.2.1.2 Addition of guideline-based quality indicators

The list of quality indicators resulting from the literature search was complemented by quality indicators derived from the Belgian guidelines. To this end, most individual recommendations were translated in at least one quality indicator.

3.2.2 Evidence base

In most cases, indicators were based on evidence found in the scientific literature. In each of the 3 projects, the strength of the scientific evidence supporting the indicator was rated using the GRADE system [39]. The highest level of evidence is obtained from RCTs without important limitations or overwhelming evidence from observational studies ('A' level of evidence). 'B'- evidence is obtained from RCTs suffering from important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies. Finally, 'C' level is attributed to observational studies or case series. Table 6 gives some examples from the 3 projects.

Table 6. Examples of levels of evidence (LoE) for quality indicators [2, 8, 9].

LoE	Rectal cancer	Breast cancer	Testicular cancer
A	Proportion of cStage II-III patients that received a short course of neoadjuvant pelvic radiotherapy	Proportion of sentinel lymph node biopsy in cN0 women without contraindications	-
B	Proportion of R0 resections	Proportion of women in whom human epidermal growth factor receptor 2 status was assessed before any systemic treatment	Proportion of patients with stage I non-seminoma treated with active surveillance
C	Number of lymph nodes examined	Proportion of women who received axillary ultrasonography with fine needle aspiration cytology of the axillary lymph nodes before any treatment	Proportion of patients with testicular cancer undergoing tumour marker assessment before any treatment

3.2.3 Selection of indicators

For breast and testicular cancer [8, 9], the long list of indicators, resulting from the literature search and addition of guideline-based indicators, was subjected to a formal assessment based on 4 criteria:

- Reliability: the extent to which the measure provides stable results across various populations and circumstances;
- Relevance: the extent to which important health conditions accounting for a major share of the burden of disease, the cost of care, or policymakers' priorities are reflected;
- Interpretability: the extent to which clear conclusions are possible;
- Actionability: the extent to which action can be taken by individuals, organised groups and public and private agencies to meaningfully address this issue.

At least 5 experts independently scored each indicator on these 4 criteria using a scale from 1 (strongly disagree) to 5 (strongly agree) [8, 9]. For each indicator and per criterion, the scores were summarized in a median score, minimum score, maximum score and the percentage of '4' and '5' scores. These summary scores were used during a plenary meeting to guide the final selection of indicators. The most important criterion during this selection was relevance.

For rectal cancer, 3 'quality levels' were defined first [2]. The first level covered the indicators that are affected by all treatment phases and that were considered essential for general quality measurement. Second level indicators were also considered essential for general quality measurement, but are affected by one specific treatment phase (e.g. surgery). Finally, third level indicators were defined as those indicators that deserved attention from individual centres if possible quality problems were identified through a level 1 or 2 indicator. In the final selection, only level 1 and 2 indicators were included. Other selection criteria were: relevance, level of evidence and relation to PROCARE recommendation(s). The selection process was not formalised.

For rectal and breast cancer, more than 200 quality indicators were retrieved from the literature [2, 8], while only 1 indicator was found in the scientific literature for testicular cancer [9]. A significant number of indicators was derived from the Belgian guidelines for all 3 cancer types. The selection process lead to a final set of 12 indicators for testicular cancer, 32 for breast cancer and 40 for rectal cancer (Table 7).

The main reasons for excluding indicators were: quality indicators developed for another (cancerous or non-cancerous) pathology or quality indicators irrelevant for the project (e.g. focus on technical matters or on cancer screening).

Table 7. Synthesis of identified and selected quality indicators.

	Rectal cancer	Breast cancer	Testicular cancer
Indicators retrieved from literature	205	229	1
Indicators derived from guidelines	17	47	31
Identified indicators	**222**	**276**	**32**
Selected indicators after formal rating	40	32	12

3.2.4 Final indicator sets for rectal, breast and testicular cancer

3.2.4.1 Types of indicators

According to Donabedian, indicators can be categorized in process (what is actually done in giving and receiving care), outcome (states of health or events that follow care, and that may be affected by health care) and structure (characteristics of providers and the health care system that affect the system's ability to meet the health care needs of individual patients or a community) indicators [38]. In the three pilot studies, the large majority of selected indicators were process and outcome indicators (Table 16 in Appendix 3) [2, 8, 9]. Outcome indicators can assess hard outcomes on the one hand (e.g. survival), and intermediate outcomes on the other hand (e.g. tumour response or stage shifts, dissatisfaction or direct results of a procedure). In all reports, overall and disease-specific 5-year survival by stage were evaluated as hard outcomes, since these indicators are essential to evaluate treatment effectiveness. In breast cancer, one indicator also specifically assessed 5-year local recurrence after curative surgery by stage [8], while for rectal cancer local recurrence at 1 year was assessed [2]. For testicular cancer, 5-year disease-free survival was assessed [9]. Examples of intermediate outcome indicators are 'Proportion of women with high-grade and/or palpable and/or large DCIS of the breast who had negative margins after surgery, whatever the surgical option [local wide excision or mastectomy]' for breast cancer and 'Proportion of R0 resections' for rectal cancer.

For testicular cancer, one structure indicator was included, i.e. 'Number of annually surgically treated patients with testicular cancer per centre' [9]. For breast cancer, no indicator was retrieved from the literature or the Belgian Guidelines to assess structure of care. However, the link between volume and outcome in breast cancer has become clear in recent years. For example, a recent systematic review of the literature [40], analyzing data of 12 observational studies, reported that breast cancer women treated in high-volume centres have better survival than breast cancer women treated in low-volume centres. This higher survival rate cannot be attributed to just one particular factor, diagnosis and treatment of breast cancer being a multidisciplinary process, which involves many healthcare professionals. Consequently, beyond the evaluation of quality indicators, we also compared survival and processes of care by hospital volume for breast cancer.

3.2.4.2 Quality of care dimensions

Quality is defined as 'the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge' [38]. In a previous KCE report, 7 quality of care dimensions were defined [38]: safety, effectiveness, patient-centeredness, timeliness, efficiency, equity and continuity. The selected indicators in the 3 pilot projects most frequently addressed effectiveness and continuity. Relatively few indicators addressed safety, and these were included only for rectal cancer. No indicator addressed patient-centeredness, timeliness or equity. Some examples of indicators per quality dimension are reported in Table 8.

Some indicators not really capture quality of care. For example, in the breast cancer report, one indicator assessed the 'Proportion of women with breast cancer who participate in clinical trials' [8]. This indicator captures a dimension of healthcare system performance, i.e. 'capacity and innovation'. This dimension covers the use of new technologies, the investments dedicated to research and development or the use of integrated care pathways. In oncology, involvement in research activities puts all healthcare professionals in touch with the up-to-date scientific knowledge and practices, so they're aware of the treatments considered appropriate for study, and of the studies considered most appropriate for comparison. Patients' recruitment in clinical trials is not considered appropriate for all patients and careful patient selection is necessary, according to the balance between benefits and harms expected from the experimental treatment.

Table 8. Examples of quality of care dimensions.

	Rectal cancer	Breast cancer	Testicular cancer
Safety			
	Inpatient or 30-day mortality	-	-
	Rate of intra-operative rectal perforation	-	-
Effectiveness			
	Overall 5-year survival by stage	Overall 5-year survival by stage	Overall 5-year survival by stage
	Disease-specific 5-year survival by stage	Disease-specific 5-year survival by stage	Disease-specific 5-year survival by stage
	Proportion of patients in whom a CT of the liver and RX or CT of the thorax was performed before any treatment	Proportion of women who received axillary ultrasonography with fine needle aspiration cytology of the axillary lymph nodes before any treatment	Proportion of patients with testicular cancer undergoing tumour marker assessment before any treatment
Continuity			
	Proportion of patients discussed at a MDT meeting	Proportion of breast cancer women discussed at the MDT meeting	Proportion of patients with testicular cancer discussed at the MDT meeting
	Proportion of p-ypStage II-III patients with R0 resection that started adjuvant chemotherapy within 3 months after surgical resection	Proportion of newly diagnosed cStage I-III breast cancer women who underwent two-view mammography or breast ultrasonography within 3 months prior to surgery	

3.2.4.3 Clinical workup phases

The selected indicators span all phases of cancer care management from diagnosis and staging to follow-up and palliative care for the 3 cancer types (Table 16 in Appendix 3) [2, 8, 9]. The histopathologic examination and reports were also covered with many quality indicators for rectal and breast cancer. However, quality indicators only focused on in-hospital care. Screening procedures and outcomes as well as outpatient procedures were not assessed.

Key points

- **Quality indicators were identified from the indexed literature and international guidelines or were derived from the Belgian guidelines.**
- **The strength of scientific evidence supporting each indicator was rated using the GRADE system.**
- **Selection of quality indicators was based on 4 criteria: reliability, relevance, interpretability and actionability.**
- **The majority of selected indicators were process and outcome indicators. Volume of patients treated by hospital was evaluated in the testicular and breast cancer projects.**
- **Selected indicators mainly addressed the quality of care dimensions 'effectiveness', 'continuity', and 'safety'. No indicator addressed 'patient-centeredness', 'timeliness' or 'equity'.**
- **Quality indicators span all phases of cancer care management from diagnosis and staging to follow-up and palliative care.**

3.3 DATA AVAILABILITY, TIMELINESS, AND LINKAGE

To analyse the measurability of the selected indicators, 4 different databases were linked using a similar linkage procedure for the 3 projects [2, 8, 9]. For each project, the primary selection of cases was done in the BCR database. The BCR data were then linked to healthcare insurance claims data from the Intermutualistic Agency (IMA) and the MCD-HBD (Minimal Clinical Data- Hospital Billing Data) database. An additional selection was done using appropriate ICD-9-CM codes in the MCD-HBD database to check the exhaustiveness of the primary selection.

Specifically for the rectal cancer project, the prospective PROCARE database was also available [2].

3.3.1 Characteristics of the four databases

The content, exhaustiveness and timeliness (how much time is needed for data to be available) of these four databases and their linkage procedure are presented in Appendix 4, and summarized in Table 9.

Table 9. Synthesis of characteristics of 4 databases.

	BCR	**IMA**	**MCD**	**PROCARE**
Type of database	Cancer Registry	Claims data	Hospital Administrative Data	Clinical data
Participation	Mandatory	Mandatory	Mandatory	Voluntary
Coverage	>97%	Unsure	Unsure	30-35% (2008)
Data completeness	100% for some variables (tumour localization, incidence date, …) but 33% missing stage (2005) and 8% for NISS (2005)	No missing data, but no information on treatments not reimbursed	No missing data, but no information on ambulatory care	Large amount of missing data for follow-up and chemotherapy. Few missing data for pre-treatment, surgery, postoperative info and pathology
Timeliness	2-3 years	1-2 years	2-3 years	0-2 years
Which data are available begin 2011	Full 2008	Full 2009	Full 2008 (in theory)	Ca 90% 2009 Ca 40% 2010

3.3.2 Linkage of databases

The linkage procedure is rather complex and time-consuming. It requires an authorization of the Sectoral Committee, and the involvement of all institutional partners described above (BCR, IMA, TCT), in addition to trusted third parties (TTP) to ensure proper and consistent recoding of patients identifiers. Technical specifications of the linkage were explained in the three previous reports. As an illustration, the linkage scheme of the breast and testicular cancer projects is presented in appendix.

The differences between the primary and additional selection are highlighted below, and the results of the linkage from the three projects are reported.

3.3.2.1 Primary selection of BCR data

The first step in the linkage is a selection of appropriate records in the BCR database. This first selection is based on ICD-10 codes and on incidence dates. Then, based on the patient INSZ/NISS number, records in the IMA database (with appropriate time frame) and in the MCD database (with appropriate time frame) are selected.

Table 10. Primary selection of BCR data and linkage with IMA and MCD data (with specific time frames) for the 3 pilot projects [2, 8, 9].

	Rectal cancer	Breast cancer	Testicular cancer
ICD-10 code	C20.9 malignant neoplasm of rectum C19.9 malignant neoplasm of rectosigmoid C21.1 malignant neoplasm of canal rectal C21.8 malignant neoplasm of anorectal junction	C50 malignant neoplasm of breast	C62 malignant neoplasm of testis
Incidence date BCR	2000-2004	2001-2006	2001-2006
IMA data	2000-2004	2001-2006	2001-2006
MCD data	2001-2004	2002-2004	2002-2004

In the breast cancer project, only women recorded with ICD-10 code C50 (invasive breast tumours) were included in the analyses [8]. Women having an ICD-10 code D05 (DCIS) were not selected in the study sample.

Results of the linkage procedure are shown below. In the three projects, the linkage percentage of BCR and IMA data was very high (minimum 98%), contrary to the linkage with MCD data, which never reached 80%. In the three projects, extensive analyses were done to understand what was the cause of this low linkage rate, but none of the hypotheses formulated could be confirmed [2, 8, 9].

Table 11. Results of the linkage between BCR-IMA and between BCR-MCD.

	Rectal cancer	Breast cancer	Testicular cancer
% of BCR linked with IMA	98.9%	98.6%	97.8%
% of BCR linked with MCD	64.6%	75.4%*	71.0%*

*Based on incidence 2002- 2004 only.

3.3.2.2 Using MCD data to assess exhaustiveness of primary selection

In each of the three projects, an attempt was made for a complementary selection of patients to evaluate the completeness of the primary patient cohort [2, 8, 9]. This complementary selection was done in the MCD-HBD database of the TCT using appropriate codes of primary diagnostic. Patients with cancer identified through this complementary step but not through the primary selection were added to the final patient cohort.

Table 12. ICD9 codes used for the complementary selection in MCD.

Rectal cancer	Breast cancer	Testicular cancer
154.1 rectal cancer 154.0 rectosigmoid cancer 154.2 cancer of the anal canal	174.1 – 174.9 malignant neoplasm of the breast	186.0 and 186.9 malignant neoplasm of the testis 236.4 neoplasm with uncertain behaviour of the testis

Due to the linkage problems mentioned in the previous section, it was not possible to use this additional selection to assess exhaustiveness of BCR data.

Key points

Four databases were used and linked to calculate quality indicators:

- **The Belgian Cancer Registry (BCR)**
- **Claims data from the Intermutualistic Agency (IMA) (administrative database)**
- **Hospital Discharge Administrative data: Minimal Clinical Data linked to Hospital Billing Data (MCD-HBD)**
- **Prospective database PROCARE (specific for rectal cancer)**

Linkage between BCR and IMA was successful (rate ≥ 98%). This was not the case for the linkage BCR-MCD (around 65%-75%) due to unidentified technical problems.

Strengths of BCR data combine a very good coverage and the availability of important clinical factors (e.g. cancer stage). The main drawback is some degree of missing data, but this is improving over time.

Strengths of administrative database are the complete coverage and the absence of missing data. Drawbacks are the lack of clinical data and of information on not reimbursed treatments (for instance in the setting of clinical trials).

The linked BCR and IMA database combine the strengths of a clinical registry (clinical data and coverage) with information of treatment received, at no additional cost or data collection.

The main strength of the voluntary PROCARE database is the availability of detailed patient clinical characteristics, outcomes and processes of care. Main drawbacks are the substantial amount of missing data, the large effort for data collection and data management, and a benchmarking that can only be performed for participating centres.

3.4 OPERATIONAL LEVEL AND LIMITS ENCOUNTERED

3.4.1 Operationalisation of indicators

After the final selection of all candidate indicators, a technical fiche was developed for each indicator [2, 8, 9]. The rationale (brief statement describing supporting health-related reasons) and the evidence base (scientific soundness – clinical logic criteria associated with quality of care outcomes and interventions) were included for each indicator. The target population (patient group, inclusion and exclusion criteria, age limits, selection based on confirmed diagnostic or specific tests, incident cases) and the indicator specifications were reported in detail. For all indicators, the population for whom the indicator was measured was carefully defined ensuring that differences among patient groups did not influence comparisons of process or outcome indicators (e.g. all women diagnosed with HER2+ cStage/pStage IV breast cancer in a given year; all patients diagnosed with stage I testicular cancer in a given year, not treated with chemotherapy or radiotherapy within 6 months post-orchidectomy).

The time period before and after incident cases was carefully defined for each indicator. For example, for the indicator 'Proportion of patients with testicular cancer undergoing CE-CT or MRI for primary staging', a time limit of 1 month before incidence date and 3 months after incidence date was set to allow the identification of these imaging tests performed for primary staging reasons [9].

An algorithm was designed to envisage all analytic steps involved in the measurement of each indicator. Each step corresponded to a dichotomous question for which the answer was either 'yes' or 'no' (e.g. whether a woman with breast cancer has undergone surgical resection, whether a breast cancer woman who underwent a surgical resection benefited from a breast conserving surgery).

Once the clinical indicators were defined, relevant administrative or nomenclature codes and their respective sources were identified for each indicator. The main sources used were BCR for source population and tumour characteristics, IMA data for all diagnostic and therapeutic procedures and MCD for in-hospital procedures and ICD-9 codes. For all pharmaceutical products, CNK codes were retrieved and reported by type of treatment (chemotherapy, hormonal therapy supporting treatments such as biphosphonates).

3.4.2 The limited added value of MCD data

One of the outcomes of the feasibility reports was to evaluate the added value of MCD data to increase the measurability of the included indicators. However, for breast and testicular cancer, many technical problems led to an incomplete linkage of MCD data to the linked BCR-IMA data (see above) [8, 9]. Eventually, linked BCR-IMA-MCD data were only available for the years 2002-2004 and for a limited number of cases.

For breast cancer, 14 quality indicators from the original set of 32 indicators were found to be measurable [8]. MCD data were only helpful to measure 1 quality indicator related to the evaluation of lytic bone metastases (i.e. 'Proportion of women with metastatic breast cancer and lytic bone metastases who received biphosphonates'). For this indicator, the selection of both ICD-10 code C79.5 and ICD-9-CM code 198.5 to identify 'neoplasm of bone and bone marrow' was needed. For all other quality indicators, IMA data were sufficient.

For testicular cancer, 8 quality indicators from the original set of 12 indicators were found to be totally or partially measurable [9]. MCD data helped improving the measurability of 2 indicators involving surgical treatment (i.e. 'Proportion of patients with testicular cancer undergoing tumour marker assessment before any treatment' and 'Number of annually surgically treated patients with testicular cancer per centre'). If there would be a more appropriate nomenclature code for orchidectomy (see below), the added value of the MCD data would become questionable. The impact on other results was much less clear or absent.

For rectal cancer, 33 quality indicators from the original set of 40 indicators were found to be totally or partially measurable, using PROCARE database and/or administrative databases [2]. The contribution of the MCD-HBD database was limited, since all quality indicators that could be measured using administrative databases benefited from more specific codes in the IMA database.

3.4.3 Reasons for being not measurable

3.4.3.1 Absence of information

Recorded codes

Being an important outcome in oncology, (local or distant) recurrence or disease-free survival is often considered for inclusion in quality indicator sets. However, in Belgium, as in other countries, recurrence is not registered exhaustively. For testicular cancer, this was solved by using a proxy for recurrence, i.e. the instauration of new treatment at least 3-6 months after the first treatment [9]. However, using this definition, patients with a real recurrence within 3-6 months after the first treatment are not counted as having a recurrence. Furthermore, for other tumour types, such as breast cancer or rectal cancer, this solution would not be adequate. An indirect measurement of this indicator by investigating the number of retreatments seemed invalid for breast cancer. Indeed, a retreatment can only be determined if there is a clear interval between the first-line and the second-line treatment. Endocrine therapy may be a long-term treatment which makes a treatment-free interval difficult to determine.

Causes of death

The absence of (easily) available and annual national data on causes of death hampered the calculation of the disease-specific survival. Relative survival, a frequently used parameter in cancer epidemiology, was used as a proxy of the disease-specific survival [41]. However, in the near future, national data should be available and also be made linkable to the cancer registration data. The upcoming European regulation in this domain should enhance the capacity to have data on causes of mortality with a delay of less than a 2-year period.

Recruitment in clinical trials

No exact data are available on the number of cancerous patients who are included in a clinical trial, resulting in an underestimation of patients receiving specific treatments (chemotherapy for example), especially if they are recruited in the investigational arm of the trial.

Clinical results

Quality indicators that measure clinical results of specific interventions (e.g. resection margins after surgery, status of HER2 receptor, status of ER/PgR receptors, number of positive lymph nodes) are currently impossible to measure using administrative data. They can only become measurable using an in-depth analysis of medical records for each patient (retrospective or prospective study).

3.4.3.2 Unspecific nomenclature codes

The current nomenclature was not conceived for quality measurement but for activity tarification and reimbursement purposes. Moreover, when codes exist in the nomenclature, they are not always specific to a pathology or an organ. This is for example the case for biopsy, medical imaging (CT and MRI) and histology assessment. This prevents researchers to evaluate many diagnostic, staging and follow-up procedures for quality purposes.

Key points

- **For each quality indicator, the rationale and the evidence base were reported; an algorithm summarized all analytical steps and data sources were identified.**
- **Compared to IMA data, the added value of MCD was too limited to consider this database in future projects.**
- **Lack of information in the IMA database for medical acts (e.g. orchidectomy), unspecific nomenclature codes (e.g. CT, MRI, biopsy) or gaps in the registration in the BCR database (e.g. cancer recurrence) were the main reasons for being not measurable.**
- **Absence of national data on causes of death hampered the calculation of disease-specific survival.**

3.5 STATISTICAL ANALYSES

3.5.1 Overall descriptive statistics

Indicators defined in the previous section can be classified in the following categories:

- The large majority of process indicators are *binary indicators* (yes/no) and involve the simple definition of a numerator and a denominator. These are described with percentages (N, n, %);
- The majority of outcome indicators (involving survival) are *time–to-event data*, and require the definition of a survival time (from time of diagnosis to the event analyzed, or the end of the follow up period). Survival functions are presented using Kaplan Meier survival function for observed survival;
- One indicator, the relative survival, compares the observed survival to the expected survival of a similar cohort of persons not having the disease (same age, same sex, same birth year). This indicator is used as a proxy of the disease-specific survival, for which the cause of death is needed (and not available at present);
- A very limited number of process indicators involve the *number of times* a certain procedure was performed, either for a patient (number of tumour markers assessment for testicular cancer) or for a centre (number of patients surgically treated for testicular cancer). These indicators are described with appropriate summary statistics (mean, median, standard deviation) and graphically with box plots.

3.5.2 Face validity of overall results

Even when the available administrative data allowed the measurement of quality indicators or descriptive statistics, the results were sometimes questionable (lack of face validity). An example is the number of patients with pStage III testicular cancer exclusively treated with surgery (N=5 between 2001 and 2006), which should be zero (and in reality probably is zero). Possible explanations for this result are absence of billing, errors in the administrative databases, or inclusion of these patients in clinical trials (rendering some of the therapeutic interventions untraceable). These considerations should be taken into account when interpreting the results of all quality indicators measured with these administrative data. Nevertheless, it should be stressed that results of quality indicators are only indicative and, if aberrant, should lead to more in depth analysis.

3.5.3 Attribution of each patient to one centre

The primary objective of the quality indicator sets is to provide centres with feedback of their quality of care and areas of improvement. In the simplest case of a patient being admitted, diagnosed, treated, and followed up in the same hospital, the attribution of the patient to that centre is straightforward. In more complex, but not uncommon cases of patients asking a second opinion in another centre, patients being operated in one centre but irradiated in another, patients being medically treated in one centre but operated in another, the attribution of a patient to one centre should be carefully reflected on, and can depend on the purpose of the feedback.

In the three projects, the feedback was aimed at the "main" centre of the patient. In the PROCARE project, being initiated by surgeons, the main centre is where the patient was operated (and if no surgery was done, radiotherapy or chemotherapy was selected)[2]. In the two other projects (breast and testicular cancer), the main centre was chosen as being the centre where the patient was discussed during a MDT meeting, because the main therapeutic interventions (and decisions to transfer the patient to another centre) would be provided by that centre [8, 9]. To deal with the fact that not all patients had a MDT meeting, a specific algorithm was developed (based on the place of surgery, the place of chemotherapy and lump sums for hospitalizations).

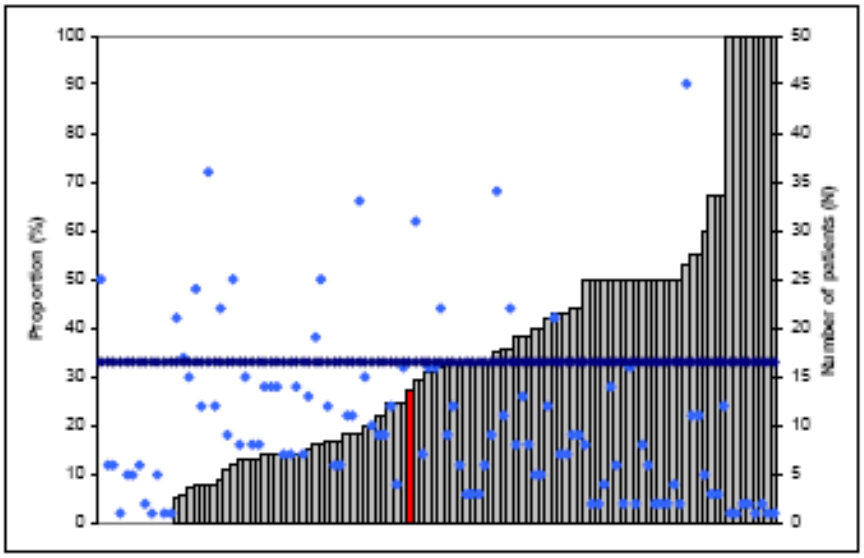
The algorithm was tested against the MCD data (which can be considered the gold standard, as they specifically contain a variable indicating where the patient was hospitalized), and the consistency was 98%. The algorithm is described in the previous reports [8, 9].

It should be noted that this approach is not suitable to evaluate the quality of care of, for example, radiotherapy centres. Some indicators related to radiotherapy (for instance in rectal cancer: Proportion of cStage II-III patients that received a short course of neoadjuvant pelvic RT) reflect the choice of the referring centre, and not the quality of the radiotherapy centre itself. For that last purpose, patients should be simply attributed to the centre where they received the treatment.

3.5.4 Variability between centres

Once all patients have been attributed to a specific centre, the question arises on how to visually present the results of an indicator for each centre. Different methodological choices were made. In the rectal cancer project (Figure 5) vertical grey bars represented the value per centre, the weighted mean (or national average) was presented as a red vertical bar, and the unweighted mean (the mean of all centres) was presented as a blue horizontal line [2]. The number of patients per centre was presented with a blue dot. This graphical presentation does not facilitate the visualization of centres performing better or worse than others, and the reader is left alone with the interpretation of the graphic.

Figure 5. Variability between centres, bar chart from rectal cancer project [2].



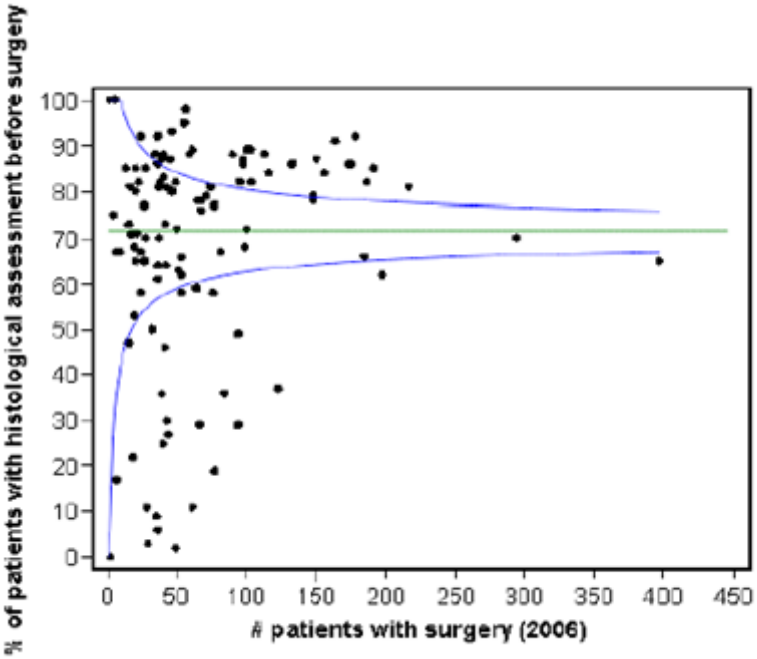
$ The weighted mean is presented with a red bar, the unweighted mean is presented with a blue horizontal line. The grey bars represent the QI value per centre, while the blue dots represent the number of patients per centre. These results are preliminary, and cannot be used to judge the quality of care.

In the breast and testicular cancer projects, the choice was made to produce funnel plots of all indicators (Figure 6) [8, 9]. In the funnel plot, the horizontal line represents the national average (the red bar in Figure 5) and funnels (or control limits) are computed around this line. The control limits are constructed so that the chance of exceeding these limits for a « in control » unit, i.e. a unit which has the same type of variability as the others, is p. Usual sets of values for p are (p=0.001, p=0.999) corresponding to 3 SD (the usual limits in the control charts framework), and (p=0.025, p=0.975) corresponding to 2 SD (the usual limits in the test of hypotheses framework). Technical details on how to compute these limits are given in the appendices of the previous reports [8, 9]. They can be based on normal approximation of binomial distribution for common cancers (such as breast cancer), and should be adapted for rare cancers (such as testicular cancer) [9].

These charts aim to differentiate between « in control » units, showing a common cause of variation, and « out of control » units, exhibiting a special cause of variability, which needs then to be further investigated. They show the outcome measure plotted against a measure of its precision, so that control limits form a funnel around the target outcome.

Funnel plots have many advantages. The axes are readily interpretable, so that additional information can be added by hand on the graphic if desired (for instance, if one knows the data – size and outcome- from a specific centre and wish to add them to the graphic). The attention is naturally drawn to important points that lie outside the funnels. Furthermore, there is no spurious ranking of institutions, and there is a clear allowance of additional variability in institutions with small volume. However, being outside the funnel does not necessarily mean being "better" or "worse" than the national average, but can be explained by differences in case mix or in billing practices. Nevertheless, this tool allows an easy identification of centres deserving further scrutiny.

Figure 6. Variability between centres, funnel plots from breast cancer project [8].



3.5.5 Missing data

Missing data can occur at several levels: at the patient level, at the level of a prognostic variable (for instance stage) or at the level of a result (the outcome or the process).

Examples of missing data at the patient level are: patients not registered in the BCR database (see section on coverage above), patients without a NISS number in the BCR database and therefore not linkable to the IMA database, or patients for which linkage cannot be performed. These patients are de facto excluded from all quality indicator results.

An example of missing data at the level of prognostic variables is the cancer stage. For some indicators, the stage is essential to calculate the indicator (e.g. 'Proportion of newly diagnosed cStage I-III breast cancer patients who underwent two-view mammography or breast sonography within 3 months prior surgery'). In these cases, patients with missing data are excluded from the results of the affected indicators. Other indicators are defined for the entire population (e.g. 'Proportion of breast cancer women discussed at the MDT meeting'). In this case, all patients (including those with missing prognostic data) will be included in the analyses. In the three projects, a high rate of unknown cStages and pStages was reported [2, 8, 9].

For example in 2006, 45% of cStages and about 20% of pStages remained unreported. However, in the same year, a MDT consultation, where cStage and pStage are essential to discuss the therapeutic options, was billed for 80.3% of breast cancer women. A possible solution to obtain this essential information would be to link the reimbursement of the MDT meeting to a properly completed MDT form (including cancer stage).

The last category of missing data occurs at the level of the result (outcome). In theory, this does not occur often when outcome and process results are retrieved from administrative database, which are by definition exhaustive. The implicit assumption is that the absence of billing of a certain process in the IMA database implies that the process was not performed. This is another approach than with a prospective database, where specific information has to be provided for each treatment (received or not received), which can lead to large amounts of missing data. As an example, in the prospective PROCARE database, a high number of missing values was identified for the radiotherapy regimen [2].

3.5.6 Risk adjustment

Benchmarking (i.e. comparison of centres) intrinsically is part of quality improvement programs, and therefore, risk adjustment of results is essential, as centres can treat different patient populations, which in turn can influence the outcomes. This was not developed in any of the three projects, but is part of another specific KCE project, which will propose a statistical methodology to perform benchmarking of centres based on composite indicators of quality of care. The results of this project will be available in June 2011 (KCE project GCP 2010-04).

However, some issues can already be raised, and are briefly discussed below:

1. Which factors (in addition to age, sex and stage) should be taken into account in risk adjustment models?
2. Should process indicators be risk adjusted? What are the implications?
3. What are the implications of using internal (compare centres to each other) or external benchmarks (compare centres to a standard of care)?

Some factors have not been tested in the pilot projects, but could be of interest in future projects. Comorbidity of patients could be evaluated based on chronic drugs taken in ambulatory setting, with an approach such as the chronic disease score [42]. Social status of patients could also be taken into account, either because social status is often correlated with morbidity, or because patients with a different social status may have different health seeking behaviours. Stratification (presenting the results of the indicators for different subgroups) can be the first step in the choice of factors in the models [43-46].

However, adjustment of all indicators, outcome *and* process, deserves some careful thoughts, and the consequences of methodological choices need to be clearly understood (since they can affect the majority of indicators, being mainly process indicators). In theory, process indicators should not be adjusted for differences in case mix. A stratification of the target population in the definition of each indicator is required, rendering subsequent risk-adjustment unnecessary (e.g. proportion of operable cT2-cT3 women who received neoadjuvant systemic therapy) [45, 46]. For instance, 'Discussion at the MDT meeting' is a process indicator which should be achieved for all patients, no matter their age, and is defined as such. If the general practice is to perform less systematically a MDT discussion for older patients, then a decision should be made whether to adjust this indicator for patient age or not. In this case, without risk adjustment, centres with an elderly population would score lower than other centres. With risk adjustment, they would score the same as other centres having a younger population. The question is whether having different processes for different groups of patients is accepted (or tolerated) as good clinical practice or not. If the answer is yes, then results should be risk adjusted. If the answer is no, then they should not. Another option is to refine the denominator of the indicator. A common solution to this problem cannot be given for all process quality indicators in general.

The reflection has to be done per indicator. In any case, presenting results of indicators stratified according to patient characteristics is good practice. The question to adjust process indicators for social characteristics has also been discussed in the context of paediatric quality indicators, [43] where the authors concluded that "the decision about risk adjustment depends on both the conceptual model guiding its use and the quality measure's purpose".

Finally, a choice should also be made between two types of benchmarking exercises: comparing centres to each other or comparing centres to an external standard (international or nationally accepted standard). Internal benchmarking of centres does not permit to evaluate quality of care, as for instance, a centre performing twice as good as all other centres could still be below the recommended standard of care.

3.5.7 Towards a composite score of quality of care

In each pilot project, indicators were classified per domain of care: general indicators, diagnosis and staging, neoadjuvant treatment, surgery, adjuvant treatment, follow up and histopathology.

Ideally, especially when the number of indicators per domain gets large, it would make more sense to calculate composite quality indicators instead of individual indicators, e.g. to assess the global quality of surgery in a centre or the global quality of adjuvant treatment given. A first attempt was made in the rectal cancer project [2], where two methods were used: first, the calculation of the average of each indicator, and second, the mean of the rank of each centre for each individual indicator. However, this exercise was not done per domain of care.

Development of composite indicators has already been tested for adult cardiac surgery in United States. Different methodologies (composite score, all-or-none measure) have been proposed and evaluated [47].

3.5.8 Volume of centre as a quality indicator

The volume of patients surgically treated per centre has been selected as a quality indicator for testicular cancer, based on the importance of surgery for this type of cancer and its low incidence[9]. In breast cancer, volume was not selected as indicator, while there is evidence that patients treated in high-volume centres have better survival than patients treated in low-volume centres[40]. This relationship has also been demonstrated on Belgian data (for incidence years 2004, 2005 and 2006) [8].

The majority of volume-outcome studies usually only show differences in outcomes (survival), which makes it difficult to explain to which differences in processes this better survival can be attributed. In the breast cancer report, processes of care were stratified by centre size [8]. Results showed that many processes of care were less often performed in small-volume centres. The use of a quality indicator set which encompasses many processes of care can thus be very useful for volume-outcome studies.

Key points

- **Once quality indicators are defined, descriptive analyses are fairly simple and include percentages for binary indicators, means for indicators involving counts, and observed survival function and relative survival function for time-to-event indicators.**
- **Funnel plots can be used to present variability between centres. National average is used as the reference, and centres are compared to the national average, taking into account their size (more variability is allowed for small centres). Being outside the funnel does not necessarily mean being "better" or "worse" than the national average, but can be explained by differences in case mix or billing practices. This tool allows an easy identification of centres deserving further scrutiny.**
- **Questions on factors to take into account for risk adjustment, adjustment of process indicators and determination of a composite score will be dealt with in a new KCE project, whose results will be available by June 2011.**
- **For some indicators, information on stage is essential to define the indicator. As a result, patients with missing stage are excluded from the results, diminishing the value of the feedback. Good reporting of stage is thus an essential component of the quality indicator set.**
- **The volume of patients treated per centre was selected as a structure quality indicator in the testicular cancer set. For breast cancer, volume was not selected as an indicator, but results based on the Belgian cohort show a relationship between high volume and better survival and high volume and more recommended processes of care.**

3.6 FEEDBACK IMPLEMENTATION: THE EXAMPLE OF PROCARE

In recent years, there is an increasing attention and participation of clinicians in prospective registration projects, quality of care studies and the setup of a national cancer plan. This clearly demonstrates a growing interest in their own and global results on quality of cancer care. An essential component of cancer control efforts is the creation of a comprehensive information database which enables measurement of process and outcome indicators.

Feedback of these results to the individual clinician, multidisciplinary team and/or hospital management seems to be experienced by the majority as an incentive and a kind of compensation for the labour intensive registration work.

3.6.1 Contents of the PROCARE feedback

In order to allow individual feedback and national/international benchmarking, a quality indicator system was set up for PROCARE in 2008. Since then, three individual feedback rounds were organised by the PROCARE steering group in collaboration with the Belgian Cancer Registry. Special about this project is the availability of in depth and prospectively registered data.

Some prerequisites, discussed within the PROCARE steering group, were taken into account when providing feedback on a paper basis (manual, tables and graphs) to the hospitals (an example of feedback for one indicator is presented in appendix):

- Feedback is provided to centres that included more than 10 rectal cancer patients in the study;
- Feedback is provided without comments and/or interpretations of the experts of the PROCARE board;
- Only the Belgian Cancer Registry has access to the name of the hospital and the clinicians;

- General results and hospital based results are anonymously presented and published at the PROCARE website;
- A manual with a glossary, definition of indicators and the methodology used are sent together with the results in order to facilitate the interpretation;
- Every member of the multidisciplinary rectal cancer team in the hospital should receive the results;
- The results should be interpreted with caution in view of the (very) small numbers for some centres, the amount of missing data and the absence of risk adjustment;
- Every centre can ask for supplementary information to the Cancer Registry.

3.6.2 Positive reactions on PROCARE feedback

Rather few reactions about the feedback itself reached the Cancer Registry and/or the PROCARE steering group. It was assumed and concluded from several communications that the feedback was appreciated and that the results were discussed in the hospitals at the multidisciplinary team meetings. After the first feedback that was sent to 65 multidisciplinary teams, another 16 hospitals joined the registration project. The Radiotherapy and Radiology scientific societies introduced new initiatives in their specific domains for feedback and improving quality of rectal cancer diagnosis and care. Another important effect was the gradually decreasing number of missing data per patient after the first feedback. All these facts were considered as positive reactions on the introduction of feedback to the clinicians.

3.6.3 Perceived advantages and disadvantages

Results of quality indicators measured from prospective registered data by physicians themselves (e.g. PROCARE) seem to be well accepted and found reliable. Only hospitals interested in feedback of their own results and willing to deliver important administrative efforts for registration, are participating in the study. Indeed, limited participation of the hospitals/clinicians and missing data are the pitfalls of this methodology. Prospective registration on a voluntary base induces important selection bias and possibly reduces the ability to obtain a national picture regarding quality of care in oncology. Moreover, large prospective registrations add a substantial workload for clinicians, resulting in a possible disengagement of some participants in the future. Finally, there is also a clear need for risk-adjustment in order to interpret the data and results correctly.

However, it is a challenge to make use of today's available administrative databases in order to avoid overlapping registration efforts. Joined forces of clinicians, researchers, epidemiologists and cancer registration experts offer a source of expertise in the techniques of sampling, abstracting, data management, analysis and interpretation of results. Together, they can overcome as much as possible the problems related to the specific methodologies.

Until today, no feedback based on administrative database linked to cancer registry has been implemented. For the previous reports on breast cancer and testicular cancer, the Cancer Registry received several questions of the hospitals about their own results. The results for each hospital should be made available individually and after each indicator measurement. This enables the hospitals and physicians to become familiar with the information. It also motivates centres to participate in future quality assessment projects. The Cancer Registry is well placed to measure the indicators on a regularly basis and to provide feedback.

Key points

- **Feedback of results to clinicians is experienced as an incentive and a compensation for the intensive registration work.**
- **Some prerequisites are needed before sending such feedback: sufficient number of patients involved, respect of clinicians anonymity, description of indicators and methodology used, risk-adjustment to interpret results, feedback to all healthcare professionals of the multidisciplinary team, and opportunity to obtain additional information.**
- **Positive effects are observed after feedback (e.g. decrease in missing data, new professional-driven initiatives).**
- **Prospective registration data on a voluntary base (such as PROCARE) induces selection bias and possibly reduces the validity of data and study results.**
- **The Belgian Cancer Registry has the legitimacy and the competencies to conduct regular studies on quality indicators and to organize feedbacks to hospitals.**

4 INTERNATIONAL EXPERIENCES WITH QUALITY MEASUREMENT IN ONCOLOGY

4.1 INTRODUCTION

Since the experience with clinical quality measurement, its implementation and use is rather limited in Belgium [38], it is important to evaluate the experience in other countries in order to feed the conclusions and recommendations of the present report.

4.2 METHODOLOGY

A non-systematic literature search was conducted focusing on countries or regions having established a quality system specifically in the domain of oncology. Local initiatives, international initiatives and publications of individual research groups were not considered, as were quality systems not focusing on oncology.

OVID Medline was searched on June 2nd 2010 (see appendix for search strategy). Above this, a Google search for grey literature was done with the search terms used for the Medline search. Finally, international experts were contacted through CoCanCPG network (www.cocancpg.eu).

4.3 OVERVIEW OF SELECTED INTERNATIONAL EXPERIENCES WITH QUALITY MEASUREMENT IN ONCOLOGY[b]

4.3.1 United States

4.3.1.1 American Society of Clinical Oncology (ASCO)

National Initiative on Cancer Care Quality

In 2000, the ASCO Task Force on Quality of Cancer Care was established in response to the April 1999 Institute of Medicine report, Ensuring Quality Cancer Care (http://www.asco.org/ASCOv2/Practice+%26+Guidelines, accessed on June 8th 2010), suggesting that many cancer patients were not receiving the care known to be effective for their disease. ASCO contracted with health services researchers at Harvard University and RAND to conduct a study, called the *National Initiative on Cancer Care Quality* (NICCQ), to examine the feasibility of a national quality monitoring system for cancer care. This retrospective cohort study of incident breast and colorectal cancer patients included detailed medical record reviews and patient self-report survey follow-up four years after diagnosis. Explicit quality of care indicators were developed for eight components of care (testing, pathology, documentation of key clinical factors, referral, timing, receipt of treatment, technical quality of treatment, respect for patient preferences). Using the American College of Surgeons (ACS) National Cancer Database as the sampling frame, the research team sampled patients newly diagnosed with breast cancer or colorectal cancer in 1998 from more than 60 ACS-approved hospital registries from five cities with large and diverse cancer populations. Patient surveys and comprehensive medical records abstractions were completed for 1 765 patients. NICCQ results indicated that the overall quality of care for patients with breast and colorectal cancer was higher than previously reported. On average, patients with breast cancer received 86% of generally recommended care, based on 36 quality care indicators. Patients with colorectal cancer received 78% of generally recommended care, based on 25 quality care indicators [48].

[b] An overview of the studied countries is provided in Table 13 after the key points.

Quality Oncology Practice Initiative

In 2002, parallel to the NICCQ study, ASCO also implemented the *Quality Oncology Practice Initiative* (QOPI®), an oncologist-led, practice-based voluntary quality improvement program. QOPI became available to all ASCO member medical oncologists and their practices in 2006. Creating an electronic registry for a selected set of quality indicators (some derived from the NICCQ list), these oncologists submitted data via a secure Web-base portal and received results, allowing them to compare their own practices with others. While NICCQ addressed the call for widespread, standardized quality monitoring, QOPI addressed the need to engage professionals directly in improvement. Results from 7 pilot practices confirmed the findings of the NICCQ [49]. A recent report of the QOPI program demonstrated quality improvement on certain indicators (e.g. documented patient consent, documented plan for chemotherapy, etc.) between two early measurement rounds in 71 practices [50].

ASCO/NCCN Quality Measures

The ASCO/NCCN Quality Measures were built upon the quality indicators developed for the ASCO's NICCQ project and recommendations of the NCCN Breast Cancer, Colon Cancer, and Rectal Cancer Guidelines (http://www.asco.org/ASCOv2/Practice+%26+Guidelines, accessed on June 8th 2010). Content and methodology panels were convened in a series of meetings to select a small number of indicators for breast and colorectal cancer based on clinical impact, scientific acceptability, usefulness, potential for improvement, reliability and feasibility. Seven indicators (three for breast cancer, two for rectal cancer, one for colon cancer, and one for colorectal cancer) were selected and specified.

Using separate processes and methodologies, the Commission on Cancer (CoC) of the ACS developed a similar set of indicators for breast and colorectal cancer and submitted them to the National Quality Forum (NQF) for endorsement as part of the NQF Cancer Project. Facilitated by the NQF, the ACS, ASCO and NCCN agreed to synchronize their developed indicators to ensure that a unified set was put forth to the public. The ASCO/NCCN indicators also served as an indicator source for the QOPI project.

4.3.1.2 National Cancer Institute (NCI)

NCI has made improving the quality of cancer care a major priority. An important element of this priority area is identifying, developing, applying, and evaluating quality of care indicators. The centrepiece of the effort to identify a core set of quality indicators, and recommendations for further indicators development, is the Cancer Quality of Care Measures Project (http://outcomes.cancer.gov/areas/qoc/canqual/). Such indicators can be used for a range of purposes, such as monitoring the quality of cancer care in defined populations, evaluating the performance of health plans and providers, and guiding quality improvement activities. The project's overall aim is to strengthen the scientific basis for public and private sector decision-making in the areas of cancer care delivery, purchasing and insurance coverage, regulation and standards setting, and the conduct of future research on improving cancer care delivery.

In this project, NCI is collaborating with other Federal agencies, a number of private sector organizations and the NQF to identify evidence-based quality indicators for diagnosing and treating major types of cancer (breast cancer, colorectal cancer and prostate cancer), as well as "cross-cutting" indicators that apply to multiple cancer sites (e.g. indicators for screening or palliative care). The project launched Phase I in 2002 and completed Phase II in the fall of 2007. The final report from the project is currently under review and NCI is working with Agency for Healthcare Research and Quality (AHRQ) and the NQF on a series of follow-up activities.

Up till now, the NCI published a series of 5 Cancer Trends Progress Reports (http://progressreport.cancer.gov/, accessed on June 8th 2010). These reports describe the US' progress against cancer through research and related efforts, and help review their past efforts and plan future ones in the field of oncology. A wide range of indicators are selected for these reports, covering several cancer types and services.

The reports are based on the most recent data from the NCI, the Centres for Disease Control and Prevention, other federal agencies, professional groups and cancer researchers.

4.3.2 Canada

4.3.2.1 Canadian Partnership Against Cancer

The Canadian Partnership Against Cancer (CPAC) is an independent organization funded by the federal government to accelerate action on cancer control for all Canadians (http://www.partnershipagainstcancer.ca/, accessed on June 7th 2010). One of its priorities is quality and standardisation of care processes. The Partnership facilitates collaborative, pan-Canadian initiatives to enable quality across the cancer control system. Partnership-led, collaborative projects include:

- Developing quality assurance for diagnostic Immunohistochemistry;
- System performance indicators;
- Working with partners to develop standards, for example, for chemotherapy delivery;
- Endoscopy quality.

A dedicated Advisory Group for Quality Initiatives and System Performance for Cancer Control in Canada, comprising volunteer experts, including patients and survivors and family members, has a mandate to provide advice on the efforts to advance the system performance and quality initiatives coordinated by the Partnership. The goal of this Advisory Group is to provide input on the policy direction for the System Performance and Quality Initiative portfolio and to provide advice on the development, validation, implementation and evaluation of a targeted Action Plan to build on initial efforts in system performance and reporting, and in the development of a systematic program of quality initiatives that will enhance the cancer control health system for Canada.

4.3.2.2 Cancer Quality Council of Ontario

The Cancer Quality Council of Ontario (CQCO) is an advisory group established in 2002 to guide Cancer Care Ontario (CCO) and the Canadian Ministry of Health and Long-Term Care in their efforts to improve the quality of cancer care in the province of Ontario [51]. The Council also monitors and publicly reports on the performance of the cancer system.

The Council works with CCO's Board of Directors to identify and assess gaps in cancer system performance and quality and advises on planning and strategic priorities. Initiatives include:

- The Cancer System Quality Index (CSQI), a web-based report, that tracks Ontario's progress towards better outcomes in cancer care and highlights where cancer service providers can increase the quality and performance of care;
- An annual Signature Event that brings together stakeholders and decision makers to address a quality gap to better understand quality issues;
- The Quality and Innovation Awards, sponsored by the CQCO, CCO and the Canadian Cancer Society – Ontario Division, which recognize significant contributions to quality or innovation in the delivery of cancer care;
- Special studies that examine selected aspects of quality of cancer care in Ontario.

The CSQI is a nation-wide monitoring system including several evidence-based quality indicators (29 indicators in 2010) covering the quality dimensions safety, effectiveness, accessibility, responsiveness, efficiency, equity and integration (http://csqi.cancercare.on.ca/cms/one_aspx?portalId=63405&pageId=63412, accessed on June 7th 2010). Data on these 29 indicators are directly employed in routine performance management and planning cycles in the cancer system. This index is the central public reporting and management planning tool with a high level of engagement from clinical and administrative leaders through quarterly review of performance against regionally specified targets and annual public release of performance. Administrative and clinical leaders increasingly feel accountable for performance.

4.3.3 Scotland

In 2001, the Clinical Standards Board for Scotland (CSBS), now NHS Quality Improvement Scotland (NHS QIS), set out clinical standards for breast, colorectal, gynaecological (ovarian) and lung cancer (http://www.nhshealthquality.org/nhsqis/4118 html, accessed on June 7th 2010). NHS QIS has recently updated these standards to produce a suite of national standards for cancer services. These comprise revisions of four tumour specific clinical standards applicable to bowel, breast, lung and ovarian cancer services. In addition, standards for core cancer services, which draw together common elements of service provision covered by the clinical standards, and which apply to all cancer services in NHS Scotland have been developed. This suite of standards aims to seek out and implement innovative, robust and supportive ways of delivering care.

Despite the development of these standards, no real quality system exists in Scotland or in the UK to monitor the quality of care in oncology specifically.

4.3.4 The Netherlands

In the Netherlands, until December 2010, there were eight Comprehensive Cancer Centres across the country, with a central office called Association of Comprehensive Cancer Centres (http://www.ikcnet.nl/index_php, accessed on June 7th 2010). This central office was responsible for national activities, while the eight Comprehensive Cancer Centres were responsible for the local activities. Since the beginning of 2011, all but one Comprehensive Cancer Centre merged into one national Comprehensive Cancer Centre (CCC). This national centre is responsible for:

- Maintenance of a quality system for the Dutch oncology care, consisting of audits of oncology care in hospitals (i.e. visitation, making use of frameworks, electronic self-assessment questionnaires). Visitation exists for more than 10 years;
- National guideline development for oncology (including revisions of existing guidelines and indicator development to assess their implementation);
- Cancer registry (data collection, national performance indicator development, epidemiological data analysis, evaluation of implementation of guidelines, benchmark of oncology care within hospitals, audits of specific parts of oncology care). The data collection is of high quality and is the preferred data source for researchers. Its standard data collection is slowly expanding to capture 5 years recurrences and modern chemotherapy too;
- Maintenance of a network of national and local multidisciplinary tumour groups. These tumour groups play a role in: the implementation of guidelines, deciding when guideline revision is needed, setting up quality improvement projects, setting up audits for specific parts of oncology care. The tumour groups are unique due to their multidisciplinary character;
- Support of oncological health care providers in hospitals (improvement projects, multidisciplinary meetings, videoconferencing);

- Support of palliative care (help desk for professionals, data collection system) and of rehabilitation (e.g. 'Herstel na Kanker', a coaching program with physical training, information and psychological support);
- Collaboration with researchers and economists (e.g. Health Technology Assessment projects).

The results of this system are being used by the Dutch Health Care Inspectorate (Nl: Inspectie voor de Gezondheidszorg, IGZ) and insurers for corrective actions. For example, only recently, a Dutch insurer decided to stop the collaboration with 6 hospitals on breast cancer care because of underperformance.

4.3.5 France

In France, two organisations have an important role in the quality assurance of the oncology care. The National Institute for Cancer (INCa) was created in 2004 in the framework of the national cancer plan to coordinate all actions in the domain of oncology, to avoid costly duplication of effort, and to establish effective quality control mechanisms (http://www.e-cancer.fr/, accessed on February 2nd 2011). Its missions are as follows:

- To observe and assess the system in place to fight cancer;
- To define benchmarks for good practices and care in the field of oncology and the criteria for certifying institutions and professionals in the field of oncology;
- To inform professionals and the public;
- To participate in the implementation and validation of continuing education for doctors and paramedical personnel;
- To implement, finance and coordinate research projects in collaboration with the relevant public research organisations and charitable associations;
- To develop and monitor public/private actions in the areas of prevention, epidemiology, screening, research, education, care and evaluation;
- To participate in developing European and worldwide actions;
- To prepare expert reports in oncology and cancer issues at the request of the relevant ministries.

The Institute is a public expertise agency (produces or co-produces regulatory documents) whose means of actions are the implementation of partnerships with and through the existing public and/or private structures of Care, Public Health and Research, and calls for proposals.

The governance of the National Cancer Institute is based on a board of directors, which defines the overall strategy, and is made of public, private and associative stakeholders in the fight against cancer. An independent international scientific advisory board ensures the cohesion of scientific and medical policies. A committee of patients and a committee of health professionals are consulted on a regular basis, they advise on all actions of the Institute and actively participate to working groups on specific issues (http://www.g-i-n.net/newsletter/engine/archives-of-engine/engine-october-2009-1/news-from-members-ans-inca#inca; accessed on January 20th 2011).

The INCa is comparable to the extramural program of the US National Cancer Institute. The organization has a small intramural program, but 90% of its budget is dedicated to supporting the external programs of the existing French cancer research centres and hospitals. Before the creation of INCa, most actions in this domain were coordinated by the National Federation of French Cancer Centres (FNCLCC), a federation of 20 cancer centres. Before the reorganisation by the national cancer plan, the FNCLCC produced several high-quality CPGs. Furthermore, FNCLCC coordinated several initiatives related to the quality of care, most of them being *ad hoc* projects without continuation. In the DOMES project, the 20 cancer centres provide data on costs, medical activities (including epidemiology), human resources etc., to a central electronic database (http://www.fnclcc.fr/fr/publications/rapports/index php, accessed on June 15th 2010). These data are used for benchmarking and performance improvement.

In another project, 13 indicators on radiotherapy were compared across the 20 cancer centres using medical charts from 2007 (http://www.fnclcc.fr/fr/publications/presse/, accessed on June 15th 2010). Based on this evaluation, action points were identified and corrective actions were initiated. A second measurement will take place by the end of 2010.

Also before the creation of INCa, the Haute Autorité de Santé (HAS) developed guidelines and HTA reports in the domain of oncology (www.has-sante.fr, accessed on February 2nd 2011). Now, as part of the National Cancer Plan 2009-2013, the HAS collaborates with INCa to develop guidance documents and patient guides for all cancer types.

4.4 LESSONS LEARNED FROM THE INTERNATIONAL COMPARISON

All countries for which quality initiatives in oncology were reported in this chapter demonstrated an increasing interest in improving their cancer system performance. All of them recognized that the main elements preceding the improvement of their oncology system were 1) the development of quality indicators and 2) the availability of high-quality databases. In each country, the development of quality indicators is done in parallel with the elaboration of clinical guidelines. All five countries have set up programs to develop evidence-based clinical guidelines.

The key to obtain adequate national data on cancer incidence, survival and mortality by cancer type is to set up a cancer registry that covers the whole country and the whole population [52]. Some countries are working with regional cancer registries covering a specific part of the population. For example in France, data for adults are limited to some geographical zones with a coverage inferior to 20% of the whole population. Different approaches are adopted by countries, with a mixture of methods, implying mandatory or voluntary registration of cancer cases. Most of them have the possibility to record data on initial cancer diagnosis, clinical and pathological stages without the consent of patients, aiming to conduct research and population surveillance. The use of electronic medical records is also considered as a key element to easily record medical and pathological information as to transfer all data to the national cancer registry [52]. They allow data collection as well as data synthesis.

Feedback reports need to be provided to a targeted public (clinicians, patients, administrators, purchasers, policymakers and other stakeholders) to encourage higher quality [52]. Examples of feedbacks are found in Ontario, such as the analysis of quality indicators in the Cancer System Quality Index. They are designed to provide useful information to patients and the public, and to act as an accountability mechanism for clinicians, administrators and policymakers. In Canada, where the Beveridge-based financial system limits the access to specific procedures, the growing interest in waiting times required intensive use of public reports on quality and performance in order to set targets and reducing waiting times in oncology. However, the impact of these reports was only moderate since not all provinces publish these reports with equal transparency. In the US, efforts to measure and document quality of care in oncology in participating centres did not result in the production of systematic reports.

Important policy levers were also identified. To continuously pursue the objective of a high-quality system in oncology, a vision and a highly coordinated direction are required [52]. Some countries, such as France and Canada, have developed national and regional cancer plans. Identifiable regional and national leader structures, credible institutions for cancer control and use of organizational standards, accreditation and regulation rules are recognized as essential factors for quality improvement. Regarding the implementation of indicators, identification of high-level medical professionals at local, regional and national levels has been essential to obtain the membership of the medical community [52]. These professionals are high-level practitioners working in teaching institutions rather than leaders in public health institutions. The implication of patients is also recognized as an important lever [52]. This is the reason why France, the US and Canada have invested in the development of Web portals dedicated to patients.

These portals allow patients to self-manage their care by obtaining evidence-based information about their diagnosis, treatment plans, possible side effects and complications, appointments, contacts with healthcare teams and waiting times. Social values accepted by the public are also gaining interest and are more and more taken into account in adopting new technologies or costly therapies [52]. In the US, public representation is expressed through lobbying from private institutions dedicated to cancer such as the ACS or Komen Foundation, that lead public campaigns on cancer prevention and screening. The engagement of policymakers is particularly important to introduce contextual changes to obtain higher quality level in healthcare. Often, the implication of policymakers is motivated by great crises linked to high costs or poor quality underlined by international/European studies (e.g. Eurocare comparing mortality rates across participating countries).

Different initiatives are adopted to improve quality of care, from professional-driven quality measurement initiatives to introduction of payment systems linked to performance/quality [52]. ASCO promotes the QOPI initiative, a practice-based system of quality self-assessment. QOPI enabled rapid and objective measurement of practice quality that allowed comparisons among practices and over time, and also provided a tool for practice self-examination that could promote excellence in cancer care. The QOPI process has been adopted by the American Board of Internal Medicine and other subspecialty boards as a qualifying improvement project for the Maintenance of Certification programs of individual physicians. Changing financial incentives to support high-quality cancer care has also led to substantial quality improvement. The interest for concepts such as pay-for-performance or quality based-purchase has stimulated most countries to introduce financial incentives applying to prevention, screening, maintaining a healthy population, and disease treatment. These also apply to recording cancer stages, pathological reports and multidisciplinary evaluations. In the US, a lot of payers have introduced a link between the conformity of physicians prescriptions to evidence-based guidelines and reimbursement of cancer drugs (e.g. limitation of prescription of Trastuzumab for positive HER2 breast cancer women). However, much remains uncertain about this initiative, including the ultimate magnitude of the incentive payments, the extent of participation (in this voluntary program), the quality of the reported data, the quality of care, and the likelihood that the incentives will succeed in obtaining improvement.

Finally, the organisation and coordination of services are more and more considered as cornerstones to adopt best clinical practices and obtain optimal results in oncology [52]. The experiences of the US, Canada, The Netherlands and France stressed the importance of identifying minimum activity thresholds and criteria of quality of care in oncology. The aim is to concentrate oncological services in a limited number of centres treating a high volume of patients, ensuring the presence of adequate infrastructures, high experience and effective services. For example, France has set minimum activity thresholds per centre associated with mandatory criteria (e.g. a minimum of 600 patients treated per centre per year in radiotherapy, a minimum of 50 to 80 patients per centre per year in chemotherapy). Similarly, Ontario is currently developing minimal requirements for thoracic surgery and access to systemic treatments. In The Netherlands, The Central Health Insurer (CZ) refuses to support surgery at low-volume hospitals from 2011 on [53]. CZ used a 2006 European Union guideline stating that 150 new patients per year are needed to maintain optimal quality to rank the hospitals. Moreover, human resources to deliver high quality of care are required, with adequate staffing levels and adequate skills. With the increasing burden of cancer in all countries, policymakers tend to envisage replacing doctors by nurses in specific activities such as screening in breast and colorectal cancer. Canada and the Netherlands tend to sustain the development of the nurses' role in specific activities or sectors such as endoscopy for colorectal screening or radiotherapy, in order to increase the capacity of the country to face the increasing number of potential patients.

Key points

- **The main prerequisites of an oncological quality system were the development of quality indicators and the availability of high-quality databases and national registries covering the whole population.**
- **Most evaluated countries focus their quality monitoring on a few frequent cancers. These projects are mainly vertical, i.e. by cancer type.**
- **The aim of most quality systems is quality improvement. The Dutch system also uses its quality information for peer review and accreditation.**
- **The Dutch system seems to be the most integrative, encompassing guideline development, subsequent indicator development, data collection and analysis, feedback, and targeted actions.**
- **Systematic and transparent feedback reports need to be provided to a targeted public (clinicians, patients, administrators, purchasers, policymakers and other stakeholders) to encourage higher quality.**
- **Identifiable leader structures, credible institutions for cancer control and use of organizational standards, accreditation and regulation rules are essential factors for quality improvement.**
- **Important policy levers include high-level medical professionals recognized for their expertise in oncology, well-informed patients, public representatives who are guardian of social values, and policy-makers.**
- **Different strategies are adopted from professional-driven quality measurement initiatives to introduction of payment systems linked to performance/quality (incentives vs. sanctions).**
- **The organisation and coordination of services (minimal volume requirements, flexible and skilled health care personnel) are considered as cornerstones to adopt best clinical practices and obtain optimal results in oncology.**
- **No data were found on the impact of these quality systems on patient outcomes.**

Table 13. Overview of countries/regions with experience in quality measurement in the domain of oncology.

Country	Organisation	System level	Cancers	Goals	Data sources
US	ASCO (NICCQ)	National (5 cities)	Breast Colorectal	Quality monitoring	Medical charts Patient surveys
US	ASCO (QOPI)	National (ASCO member physicians)	Breast Colorectal Non-Hodgkin's lymphoma (+ a core set of indicators, end-of-life indicators and indicators on symptom management)	Quality improvement	Secure electronic database
US	ASCO/NCCN	National	Breast Colorectal	Quality monitoring	National Cancer Database
US	NCI	National	Breast Colorectal Prostate (+ cross-cutting indicators)	Quality improvement	Unclear
Canada	CPAC	National	All	Quality improvement	Unclear
Canada (Ontario)	CCO	Regional	All	Quality monitoring Quality improvement	Cancer registry Administrative data Health surveys
Scotland	NHS QIS	Regional	Breast Colorectal Ovarian Lung	Quality improvement	None
The Netherlands	ACCC	National	All	Quality improvement Peer review Accreditation	Cancer registry
France	FNCLCC (DOMES)	National	All	Quality improvement Accreditation	Secure electronic database

5 DISCUSSION

5.1 A QUALITY SYSTEM FOR ONCOLOGY IN BELGIUM: IS IT NECESSARY?

On a national level, the 3 pilot studies clearly showed room for improvement for at least some aspects of the care for patients with these cancer types. Furthermore, although data were preliminary and unadjusted, there are indications of variability of care for the majority of evaluated quality indicators. This is already an important reason to set up a quality system for oncology. However, some important questions need to be answered on the scope of such a quality system.

What should be the objective of this quality system?

During the expert meeting, it was stressed that this question is the first to be answered when setting up a quality system. In most countries discussed above, quality measurement is used for quality improvement and monitoring over time. Other possible objectives are peer review, international benchmarking, public accountability, research, accreditation, etc. An example of a broad use of quality information is the Dutch quality system, where the information is used for quality improvement, peer review and accreditation.

A clear choice should be made by the policy makers, and a hierarchy of objectives should be provided. For some objectives, such as public accountability and accreditation, a culture shift will be necessary in Belgium. As already discussed in a previous KCE report [54], the ultimate goal should be a high-quality health system that contributes to the health of the Belgian population, and cancer patients in particular. The audience is potentially very broad, including the federal and regional governments and Ministers of health and/or social security, the healthcare organisations, the individual care providers and the Belgian population.

Importantly, implementation of a quality indicator set only has sense when it is embedded in a quality improvement cycle. When abnormal or unexpected results are found, indicators are indicative of a potential problem and deserve a closer look. If real problems are encountered, they should lead to (quality improvement) actions and, subsequently, a re-evaluation after a certain time period. Although actionability was one of the selection criteria for the quality indicators in the 3 pilot projects, it is clear that some indicators are more actionable than others.

Is quality monitoring necessary for all cancer types?

The feasibility study about the development and measurement of a quality indicator set for testicular cancer at least suggested a considerable variability in the quality of care for patients with this cancer, underpinning the importance of quality measurement and subsequent quality improvement actions, even for such a rare cancer. Of course, rare cancers have limited impact on public health. Other cancer types, such as breast cancer, have a much higher impact and probably should and will receive priority. This is the case in most countries discussed in the chapter on international experiences, where typically is focused on 4-5 frequent cancer types, and almost never on all cancer types. Nevertheless, also patients with a rare cancer deserve care of the best quality. However, the approach for quality monitoring of rare cancers will probably differ from more frequent cancers.

Since the survival data show that the prognosis of most patients with testicular cancer is already good with little room for improvement, it may be more useful to focus on results suggesting overtreatment (e.g. low number of patients treated with active surveillance) and on patients who died during the follow-up period. An in-depth analysis of the medical files of a limited number of (e.g. deceased) patients may be a more efficient alternative to the measurement of an entire quality indicator set.

For rare cancers with a worse prognosis and consequently a higher number of deceased patients, e.g. gallbladder cancer or male breast cancer, another approach or focus may be more appropriate and is to be evaluated ad hoc.

Instead of a vertical approach, i.e. by cancer type as done for the 3 pilot studies, more transversal approaches are also possible, allowing an evaluation of a specific part of cancer care management, whatever the type of cancer.. From the international experiences, it is clear that most projects are vertical, and only few projects are transversal, e.g. the radiotherapy assessment project in France.

Should a quality system for oncology be embedded in other existing quality systems?

In other countries, a quality system for oncology is rarely embedded in a broader quality system. Several countries integrate cancer indicators into a broader system of quality and/or performance measurement that is not focused on oncology alone. A good example is the Danish National Indicator Project (NIP), which includes quality indicators on 8 diseases, amongst which lung cancer (http://www.nip.dk/about+the+danish+national+indicator+project, accessed on June 14th 2010). Other examples are Sweden (http://www.socialstyrelsen.se/Lists/Artikelkatalog/Attachments/8365/2009-126-144_2009126144_rev3.pdf, accessed on June 14th 2010), the UK (http://www.cqc.org.uk/, accessed on June 14th 2010) and France (the IPAQSS indicators, http://www.has-sante.fr/portail/jcms/c_493937/ipaqss-indicateurs-pour-l-amelioration-de-la-qualite-et-de-la-securite-des-soins, accessed on June 15th 2010). International organisations, such as the OECD, also include cancer indicators in indicators sets with a much broader scope than oncology alone. An example is the Health Care Quality Indicators project (http://www.oecd.org/document/34/0,3343,en_2649_33929_37088930_1_1_1_37407,00.html, accessed on June 14th 2010). However, the aim of this project is of course international comparison and benchmarking, rather than quality improvement on a national level.

The experience with quality monitoring in Belgium is mainly limited to fragmented quality initiatives [38]. Only recently, it was decided to systematically monitor the performance of the Belgian health system [54]. In this monitoring system, some indicators related to oncology are included, but these only provide a limited picture of the quality of the oncological care in Belgium. Therefore, linking a quality system for oncology to existing Belgian quality initiatives seems to be difficult. Nevertheless, for consistency reasons, the conceptual framework developed for the performance measurement of the Belgian health system will probably need to be used as a basis for a quality system for oncology. This framework highlights the interaction between health(care) system performance and quality on the one hand and medical and non-medical determinants of health on the other hand. Health promotion and preventive care are essential elements in this framework. Where the 3 pilot projects focused on curative care and to a lesser extent on palliative care, the use of the conceptual framework mentioned above has the advantage of potentially broadening the scope to preventive actions, such as population screening.

Setting up a quality system for oncology will be a huge work, even when the (initial) scope is limited to the more frequent cancer types, such as breast, prostate, lung and colorectal cancer. As raised during the expert meeting, an efficient approach could be to first create a generic core set of common and straightforward indicators that are important for all cancer types, for example including overall and relative 5-year survival, volume, recurrence rates and multidisciplinary discussion. In a second phase, more specific indicator sets for individual cancer types could then be developed in addition.

5.2 OPERATIONALISATION OF A QUALITY SYSTEM

5.2.1 Construction of a quality indicator set

The main objective of the feasibility studies was to develop three specific sets of clinical quality indicators applicable to all practitioners and hospital centres involved in the care for patients with these three cancer types. All included quality indicators were either evidence-based and derived from the scientific literature or based on the national guidelines. Indicators based on level A evidence of course have the highest content validity, but when evidence is lacking, e.g. for testicular cancer and other rare cancers, selecting indicators with a lower level of evidence is acceptable.

Indicators were assessed on their validity and reliability. The selected indicators related to clearly identifiable events for healthcare providers and allow useful comparisons. These characteristics are considered key characteristics for good quality indicators [55]. In the pilot projects, the selection of relevant indicators was furthermore guided by their potential for action.

The selection process was formal in the breast and testicular cancer projects. The involved experts were selected from the multidisciplinary team that developed the clinical practice guidelines. It is possible that another constitution of the panel would have led to a slightly different quality indicator set. However, the same methodology was used by EUSOMA, that recently published a list of 17 quality indicators for breast cancer care [56]. There is a striking overlap between the selected quality indicators in the EUSOMA paper and in the KCE report on breast cancer [8], confirming the external validity of the indicators selected by our expert panel.

In the decision to include process and outcome indicators, the advantages and drawbacks of these indicator types were taken into account [38]. The major advantage of process indicators is that they directly relate to what providers are doing. They are highly sensitive to differences in the quality of clinical care. Process indicators are straightforward to interpret and generally do not require complicated statistics. Proportions and rates are often used to express measures of process (e.g. Proportion of patients with testicular cancer undergoing tumour marker assessment before any treatment; Rate of acute grade 4 radio[chemo]therapy-related complications). However, process indicators also have drawbacks. They require a strict definition of the eligible patient population and need to be updated according to advances in diagnosis and treatment. For example, an update of the TNM classification would have an impact on the definition of many indicators. In addition, new evidence-based diagnostic or therapeutic interventions will require the inclusion of new process indicators, highlighting the importance of updating quality indicator sets at regular time intervals.

Another drawback is that the feasibility of process indicators may be overestimated. When one wants to study a process in detail, data collection may be extensive and time consuming (for example for surgical processes). Sometimes, in-depth audit of medical/pathological records is needed (e.g. 'Proportion of breast cancer women who underwent an axillary lymph node dissection [ALND] after positive SNLB > 2 mm'). Above all, process indicators are only a part of the explanatory variables that determine the patient outcomes. The main disadvantage of process indicators is the lack of evidence linking some processes (e.g. use of a diagnostic procedure) to improved outcomes (e.g. longer survival).

In contrast to process indicators, outcome indicators are often generic and can be compared across several conditions and processes (e.g. 5-year overall survival, 5-year disease-free survival by stage). They reflect a global overview of all aspects of the healthcare process and not only the measurable ones. However, this is their major drawback as well, as risk-adjustment is needed to filter the influence of confounding factors, such as the natural history of the disease or patient's characteristics. Moreover, outcome indicators do not precisely reflect the quality of clinical care as they depend on many other influencing variables. Intermediate outcomes are often useful, because they are more prevalent than final outcome events.

However, the main disadvantage of some intermediate measures is the lack of data that link intermediate events to mortality outcomes [57]. Ideally, process indicators and the outcomes they can affect are evaluated in tandem. However, data to support such process-outcome measurement pairs are not typically available [58].

Indicators assessing structure are also desirable to obtain a more global picture of determinants and outcomes of quality of care. Accessibility to specific technology (e.g. MRI scan, radiotherapy system,…), frequency of national guidelines revision, proportion of specialists assigned to specific units (including physicians, physiotherapists, nurses, psychologists, etc.), having a sentinel node protocol and a standardized synoptic pathology reporting system are examples of structure indicators that are useful to include in a set of quality indicators for cancer management. Yet, the mere presence of these structural elements does not guarantee improvements in quality [59]. Moreover, a specific structure indicator linking volume to outcomes is also desirable to more profoundly analyse results obtained in low-volume centres compared to high-volume centres per cancer, after adequate case-mix adjustment [34, 40, 60].

Most selected indicators in the 3 pilot studies focused on effectiveness, and to a lesser extent on continuity and safety. Ideally, all quality of care dimensions should be covered by at least one indicator. An often forgotten dimension is patient-centeredness. However, the cancer patient is at the centre of the oncological care, and therefore probably has a good idea about the quality of care. This can be captured by for example patient surveys or quality of life measurement.

5.2.2 Available databases

In the three pilot projects, 4 databases were available to test the feasibility of the quality indicators: the Belgian Cancer Registry, the IMA database and the MCD-HBD database for all three projects, and the prospective PROCARE database for the rectal cancer project. Several lessons can be taken from the three exercises.

First, linkage with MCD data was a failure in the three projects. A number of hypotheses (problems with the creation of the patient ID in the MCD database, patients receiving different ID's over consecutive years in the MCD database, only hospitalized patients appearing in the MCD data) were formulated, but no plausible explanation was found. For that reason, the linkage with MCD data will not be tempted again in future projects.

Second, timeliness of data is an important aspect, because the older the data are, the more useless feedback becomes. There are important delays in time between the incidence or treatment date, and the moment data become available for analysis. As a prospective database, the PROCARE database probably has the shortest time lag. For the other databases, a delay of 2 or even 3 years is usual. In addition, the necessary time for linkage and analysis needs to be taken into account. Faster reporting of data to the BCR and automatisation of the linkage with IMA data and of the data analysis would probably reduce this time lag to 2 years.

Third, a choice must be made between a feedback based on an exhaustive database but with a limited number of variables and a feedback based on a very detailed prospective but voluntary database. In the BCR database, an example of a national and (almost) exhaustive database, availability of clinical data is limited to the minimum needed to report meaningful quality information (e.g. tumour stage). This database can (and will) be complemented with IMA data, containing exhaustive information on diagnostic tests and treatments in theory, but lacking specific details, e.g. short or long duration of chemotherapy or radiotherapy received. In a prospective database, such as the PROCARE database, detailed clinical data are available, but only for the set of centres (or even for a set of surgeons within these centres) participating to the project. These data provide very limited information on the quality of care at a national level, since information on the quality of care in centres not participating to the project is absent. The choice between these two approaches needs to take into account the number of measurable indicators (larger in prospective voluntary database) and the conclusions that can be drawn from the feedback (e.g. benchmarking against the national results).

If quality improvement for volunteering centres and hospitals is the purpose of a quality indicator system, the approach of a prospective database is acceptable (with the caveat that this approach requires intensive data collection). If, from the public authority perspective, the purpose is to ensure that the quality of care meets the highest standards for all citizens in *all* hospitals, then the approach based on national registry data linked to administrative data is the most obvious solution.

The three pilot projects have shown that the latter approach is feasible. However, in some cases, for centres with a recognized specialized care program compulsory registration could be implemented to prospectively collect data on specific topics within a limited time frame.

Working with prospectively collected data clearly has some important advantages. As stated above, the availability of clinical data is of major importance for the evaluation of the quality of care. This is probably the most important reason for the difference in measurability of quality indicators between both types of databases. Although the collection of the PROCARE data started about 1.5 years before the start of the feasibility study (i.e. without having a clear idea about which quality indicators to measure), already 75% of the selected rectal cancer indicators was measurable using these data. Based on the pilot study, recommendations were provided to render the prospective data even more specific. Another advantage of prospectively collected data is the quality control of the data collection. Data managers can contact the responsible clinicians in case of missing data or inconsistencies. At the same time, this is a major disadvantage of prospective databases. Data collection, data cleaning and chasing missing data is expensive and time-consuming. The PROCARE data collection was done manually (on paper) until 2010. Since then, a system is in place where data are transmitted electronically, although many centres keep registering manually. Even when using electronic support, for the involved clinicians, prospective data collection remains a burden. A possible threat for the PROCARE database is the selective inclusion of 'good' patients. Coupling with the administrative database to check the completeness of inclusion can quantify this selection bias and is currently under study.

The advantage of administrative data clearly is their efficiency. Since these data are already collected for other reasons (e.g. epidemiology, financing, accreditation, etc.), the extra workload for clinicians is negligible. Above this, in contrast to the PROCARE database, the administrative database (which is population-based) includes all Belgian patients with the cancer under study. However, administrative data can lack specificity and detail, depending on the cancer under study. The selected quality indicators in the 3 pilot studies were often not measurable using administrative data, because of the absence of specific administrative codes or clinical data. Although the MCD database offers the advantage to link procedures to diagnoses (in contrast to the IMA database), the linkage of the 3 different administrative databases did not have much impact on the measurability of the quality indicators.

Importantly, since these administrative data are collected for (often financing) reasons other than quality and are therefore associated with risks of up- or under-coding, their use for the measurement of the quality of care is at least questionable.

5.2.3 The need for pilot testing

Pilot testing is a crucial step in the development of a quality indicator set. Where the selection process results in a list of clinically relevant and valid indicators, their measurability and interpretability needs to be tested on the available data in order to allow a further fine-tuning of the indicators.

Possible outcomes of a pilot test are that an indicator is either measurable and interpretable without further adaptation or not measurable as originally defined. In the latter case, the indicator can be excluded from the indicator set, be reformulated, be replaced by a proxy indicator or be rendered measurable by an adaptation of the necessary data. In the 3 pilot studies, the most important reasons for not being measurable were the absence of administrative or nomenclature codes or the absence of the procedure's or test's results in the administrative databases.

It is well known that the current nomenclature and hospital data are not always suitable for quality measurement, simply because they were not created for this cause. Nevertheless, it is also clear that the nomenclature is not always adapted to the current state-of-the-art medicine.

The formulation of some quality indicators, such as 'the proportion of cN0 women who underwent a sentinel lymph node biopsy in the absence of contraindications', results in the inability to measure this quality indicator. Clinical parameters such as contraindications of a diagnostic procedure are never reported in administrative databases and can only be found in the medical file. At a national level, it is of course impossible to consult all medical records to obtain this information. Similarly, analyzing the content of medical files to assess the chemotherapy regimen (drug[s] prescribed, dose, and duration) is impossible due to the large number of patients involved in frequent cancer types. However, a random sample of medical files could be selected (for example 30 in each centre) to be audited in depth at regular intervals. Similar surveys are conducted in France by the National Federation of French Cancer Centres (FNCLCC) and the Institut National du Cancer (INCa), leading to identification of action points and initiation of corrective measures.

An example of an indicator that was not measurable and that was replaced by a proxy indicator is the disease-specific 5-year survival. In the 3 pilot studies, the relative survival was calculated as a proxy indicator. Relative survival is widely used as quality indicator for many cancer types.

The 3 pilot studies always resulted in a list of suggested actions to render the included indicators more measurable [2, 8, 9]. Some of these suggestions were generic (i.e. applicable to other cancer types) and data-related, e.g. adaptations to nomenclature codes, correct use of the 7th edition of the TNM classification, complete registration of cStage and pStage, extension of the current list of variables with mandatory registration at the cancer registry (e.g. recurrence, recruitment in clinical trials, number of positive lymph nodes, resection margins, radiation dose and field), etc. Other suggestions were related to the interpretation of the results, e.g. risk-adjustment and cut-off values (see next chapter).

5.3 INTERPRETATION AND PRESENTATION OF INDICATOR RESULTS

5.3.1 Establishing standards

Setting quality standards *a priori* is essential to interpret the results that are obtained and to consider the need for further evaluation or interventions if a desired attribute of care falls below the standard or an undesired attribute of care rises above this level [44]. However, this exercise was not done for the three pilot projects to avoid a quality judgement by the reader based on preliminary data. Nevertheless, for breast cancer, and to a lesser extent for testicular cancer and rectal cancer, standards were identified in the literature *a posteriori* for the results interpretation of some indicators. In some cases, standards were derived from the academic literature. For example, the standard for the appropriate use of fine-needle aspiration cytology or needle histology was set at ≥ 70% [61] or ≥ 90% [62] according to different authors. In addition to the scientific literature, the clinical experience of the research team members was also helpful to derive relevant and realistic standards for the Belgian healthcare system. Quality standards were applied whenever possible to assess the acceptability of a particular process or outcome rate. For some indicators, for which the evidence links a process to better outcomes, the desired score of the indicator is expected to be 100% (e.g. 100% of breast cancer women should undergo an ER and PgR assessment before any systemic treatment). However, a high rate of some procedures might not always be deemed appropriate. For example, high rates of systemic chemotherapy in node-negative frail elderly patients are not desirable. Similarly, a target of 100% for all cStage I-III women undergoing a breast mammography or ultrasonography within 3 months prior to surgery could be inappropriate. In this specific group, it can be expected that a subgroup of women (~ 10%) having tumours too large to be operated will undergo neoadjuvant treatment, resulting in a longer delay than 3 months between diagnostic

procedures and surgery. Finally, European guidelines have suggested that breast conserving surgery should be achievable in 70% to 80% of all cases [63]. However, patients who can be treated with breast conserving surgery, but wishing to undergo a mastectomy, should be treated according to their wish.

After adequate information, up to 20% of patients may choose for mastectomy [63]. Modified radical mastectomy is also advised in patients who have insufficient remission of the primary tumour after neoadjuvant chemotherapy [63].

The main lesson is that standards of acceptable performance or outcomes should be specified prior to the final measurement of the quality indicators in order to facilitate the objective interpretation of the results and the feedback sent to practitioners and hospitals.

5.3.2 Types of analyses and presentation of results

The 3 pilot studies focused on descriptive analyses of the study databases, on the calculation of national results, and on the variability between centres [2, 8, 9]. In the rectal cancer pilot study an attempt was also made to calculate composite scores. For the correct interpretation of the centre variability, each patient had to be attributed to one centre. The criteria to attribute a patient to one centre (based on the centre where the MDT, surgery, chemotherapy or radiotherapy took place) should be carefully chosen, and should depend on the purpose of the feedback. Indeed, comparing the quality of radiotherapy centres is different from comparing the quality of centres referring patients to these radiotherapy centres. In the breast and testicular cancer projects, an algorithm using IMA data was developed for centre attribution, and was shown to be reliable.

Since it was not the goal of the 3 pilot studies, risk-adjustment was not performed, apart from a risk-stratification by stage for some indicators. A currently ongoing KCE project, using rectal cancer (PROCARE) as a case study, is evaluating statistical methods to perform benchmarking of centres based on composite quality indicators and taking the case-mix into account. Socio-economic factors and lifestyle are not considered, although they are important for the correct interpretation of some quality indicators. The results of the study will be available in June 2011.

For the presentation of the variability between centres, the rectal cancer project used a different approach than the 2 other projects. In the former project, a histogram was used, while in the breast and testicular cancer project funnel plots were used. Funnel plots are simple graphics, showing variability between centres and taking into account inherent variability due to sample size. More variability is allowed for small-volume centres. Owed to their easy interpretation, funnel plots are recommended for future projects.

Importantly, the final presentation of the results highly depends on the finality of the quality system.

5.4 IMPLEMENTATION OF A QUALITY SYSTEM

In order to have a fully operational and integrative quality system, such as in the Netherlands for example, key elements are the know-how to develop clinical practice guidelines and related quality indicators, a highly effective data collection, correct data analysis and interpretation, the decision power to provide feedback to the end users, and the ability to initiate targeted and corrective actions. These elements are potentially present in Belgium, but not necessarily harboured in one stakeholder, and not yet integrated in an effective and durable system.

Clinical practice guidelines and quality indicators are already developed by the KCE, in collaboration with the College of Oncology and the Belgian Cancer Registry respectively. Furthermore, the Belgian Cancer Registry has a nationwide database of all cancer cases with a high coverage, including incidence date and tumour characteristics, and linked to the vital status for most cases. Since 2010, these data are also linked to a limited set of claims data from the IMA database.

In the 3 pilot projects, these elements were already put into practice with success. The MDT meeting and the financing of datamanagers are useful elements for an effective data registration at the hospital level.

Furthermore, feedback is an essential component for the improvement of quality of care. Multidisciplinary teams should receive feedback on a continuous and regularly basis. Targets (instead of using the median or the mean) should be defined in collaboration with experts and results should be discussed. This could be an important task of the College of Oncology, being constituted by peers. The today's information technology (e.g. Web applications) should be used in order to send feedback to the hospitals.

For rectal cancer, all this was already realized by the Belgian Cancer Registry in collaboration with the PROCARE steering group. However, quality of care projects with individual feedback are rather new in Belgium, and although the first results are encouraging, these projects need to be elaborated further.

Besides feedback, targeted and corrective actions are another essential element of the quality improvement cycle. These actions can be taken at the initiative of the providers themselves as a reaction to the provided feedback, but can also be imposed by the policy makers. This role is already played by the federal and federated entities (e.g. through inspection and recognition). In addition, as legally foreseen, the College of Oncology could organise visitations and audits of outlying centres to analyze the reasons for their over- or under-performance. Analysis of well-performing centres can help to understand which processes lead to better results, and which were the conditions to adopt these processes (structure indicators).

Finally, the Cancer Centre could play an additional role by guarding the coherence between the different initiatives of the hospitals and research centres (including universities) and by facilitating complementarities and synergisms within the global framework of the quality system.

5.5 CONCLUSIONS

The three pilot projects highlighted the conditions for setting up a quality system for oncology in Belgium. The necessary elements and know-how seem to be present in Belgium, but need to be structured to allow the operationalisation of such a system.

6 APPENDICES

6.1 APPENDIX 1: MEDLINE SEARCH TERMS FOR INTERNATIONAL EXPERIENCES

1	cancer mp or Neoplasms/
2	Medical Oncology/ or Radiation Oncology/
3	"Quality of Health Care"/
4	1 or 2
5	4 and 3
6	Quality Indicators, Health Care/ or Quality Control/ or Quality Assurance, Health Care/
7	"Process Assessment (Health Care)"/ or "Outcome Assessment (Health Care)"/ or Peer Review, Health Care/ or "Outcome and Process Assessment (Health Care)"/
8	Medical Audit/ or Clinical Audit/ or Nursing Audit/
9	"Peer Review"/
10	8 or 6 or 7 or 9
11	10 and 5

6.2 APPENDIX 2: APR-DRGS RELATED TO CANCER CARE AND/OR WITH AN IMPORTANT FRACTION INVOLVING CANCER CARE

Table 14. Cancer-specific APR-DRGs.

APR-DRG	Label APR-DRG
041	Nervous system malignancy
110	Ear, nose, mouth, throat and cranial/facial malignancies
136	Respiratory malignancy
240	Digestive malignancy
281	Malignancy of hepatobiliary system and pancreas
343	Musculoskeletal malignancy and pathologic fracture
362	Mastectomy
382	Malignant breast disorders
442	Kidney & urinary tract procedures for malignancy
461	Kidney & urinary tract malignancy
500	Malignancy, male reproductive system
511	Uterine & adnexa procedures for ovarian & adnexal malignancy
512	Uterine & adnexa procedures for non-ovarian & non-adnexal malignancy
530	Female reproductive system malignancy
680	Major o.r. procedures for lymphatic/hematopoietic/other neoplasms
681	Other o.r. procedures for lymphatic/hematopoietic/other neoplasms
690	Acute leukemia
691	Lymphoma, myeloma and non-acute leukemia
692	Radiotherapy
693	Chemotherapy

Table 15. APR-DRGs with important fraction involving cancer care (source: KCE report 121S).

APR-DRG-SOI	Label	Fraction cancer 2005
021-3	Craniotomy except for trauma	31,21%
021-3	Craniotomy except for trauma	31,42%
026-1	Other nervous system & related procedures	39,91%
094-2	Procedures on the mouth	26,34%
121-1	Other respiratory & chest procedures	47,97%
121-2	Other respiratory & chest procedures	55,04%
121-3	Other respiratory & chest procedures	45,72%
121-4	Other respiratory & chest procedures	38,20%
220-3	Major stomach, esophageal & duodenal procedures	50,46%
220-4	Major stomach, esophageal & duodenal procedures	44,66%
221-1	Major small & large bowel procedures	27,76%
221-2	Major small & large bowel procedures	51,53%
221-3	Major small & large bowel procedures	58,81%
221-4	Major small & large bowel procedures	43,23%
229-2	Other digestive system & abdominal procedures	42,79%
229-3	Other digestive system & abdominal procedures	32,51%
260-2	Major pancreas, liver & shunt procedures	66,92%
260-3	Major pancreas, liver & shunt procedures	62,68%
260-4	Major pancreas, liver & shunt procedures	67,86%
309-2	Hip & femur procedures for non-trauma except joint replacement	29,68%
361-1	Skin graft for skin & subcutaneous tissue diagnoses	40,04%
361-2	Skin graft for skin & subcutaneous tissue diagnoses	51,08%
364-2	Other skin, subcutaneous tissue & related procedures	35,94%
424-3	Other endocrine disorders	26,16%
446-1	Urethral & transurethral procedures	42,48%
446-2	Urethral & transurethral procedures	41,90%
446-3	Urethral & transurethral procedures	51,10%
480-1	Major male pelvic procedures	66,50%
482-3	Transurethral prostatectomy	25,19%
484-1	Other male reproductive system & related procedures	55,52%
510-1	Pelvic evisceration, radical hysterectomy & other radical gynaecological procedures	49,73%
510-2	Pelvic evisceration, radical hysterectomy & other radical gynaecological procedures	73,45%
515-2	Procedures on vagina, cervix and vulva	39,68%
517-1	Dilation & curettage for non-obstetric diagnoses	25,70%
517-2	Dilation & curettage for non-obstetric diagnoses	32,75%
518-1	Other female reproductive system & related procedures	44,04%
694-2	Lymphatic & other malignancies & neoplasms of uncertain behavior	66,30%
694-3	Lymphatic & other malignancies & neoplasms of uncertain behavior	62,57%

6.3 APPENDIX 3: FINAL SET OF INDICATOR FOR RECTAL, BREAST AND TESTICULAR CANCER

Table 16. Final sets of quality indicators for rectal, breast and testicular cancer.

Rectal cancer	Breast cancer	Testicular cancer
General Quality indicators: outcomes		
Overall 5-year survival by stage	Overall 5-year survival by stage	Overall 5-year survival by stage
Disease-specific 5-year survival by stage	Disease-specific 5-year survival by stage	Disease-specific 5-year survival by stage
Proportion of patients with local recurrence	Disease-free 5-year survival by stage	Disease-free 5-year survival by stage
	5-year local recurrence after curative surgery, by stage	
General Quality indicators: processes		
Proportion of patients discussed at a MDT meeting	Proportion of breast cancer women discussed at the MDT meeting	Proportion of patients with testicular cancer discussed at the MDT meeting
	Proportion of women with breast cancer who participate in clinical trials	Proportion of patients with relapsing testicular cancer after curative treatment that are included in a clinical trial
Diagnosis and staging		
Proportion of patients with a documented distance from the anal verge	Proportion of women with class 3, 4 or 5 abnormal mammograms having an assessment with a specialist within 2 months of mammography	Proportion of patients with testicular cancer undergoing tumour marker assessment before any treatment
Proportion of patients in whom a CT of the liver and RX or CT of the thorax was performed before any treatment	Proportion of women with class 3, 4 or 5 abnormal mammograms who have at least one of the following procedures within 2 months after communication of the screening result: mammography, ultrasound, fine-needle aspiration, or percutaneous biopsy	Proportion of patients with testicular cancer undergoing contrast-enhanced Computed Tomography (CE-CT) or Magnetic Resonance Imaging (MRI) for primary staging
Proportion of patients in whom a CEA was performed before any treatment	Proportion of newly diagnosed cstage I-III breast cancer women who underwent two-view mammography or breast sonography within 3 months prior to surgery	
Proportion of patients undergoing elective surgery that had preoperative complete large bowel-imaging	Proportion of women who received axillary ultrasonography with fine needle aspiration cytology of the axillary lymph nodes before any treatment	
Proportion of patients in whom a TRUS and pelvic CT and/or pelvic MRI was performed before any treatment	Proportion of women in whom human epidermal growth factor receptor 2 status was assessed before any systemic treatment	
Proportion of patients with cStage II-III that have a reported	Proportion of women in whom a ER and PgR status	

Rectal cancer	Breast cancer	Testicular cancer
cCRM	assessment were performed before any systemic treatment	
Time between first histopathologic diagnosis and first treatment	Proportion of breast cancer women with cytological and/or histological assessment before surgery	
Neoadjuvant treatment		
Proportion of cStage II-III patients that received a short course of neoadjuvant pelvic RT	Proportion of operable cT2-T3 women who received neoadjuvant systemic therapy	
Proportion of cStage II-III patients that received a long course of neoadjuvant pelvic RT		
Proportion of cStage II-III patients that received neoadjuvant chemoradiation with a regimen containing 5-FU		
Proportion of cStage II-III patients treated with neoadjuvant 5-FU based chemoradiation, that received a continuous infusion of 5-FU		
Proportion of cStage II-III patients treated with a long course of preoperative pelvic RT or chemoradiation, that completed this neoadjuvant treatment within the planned timing		
Proportion of cStage II-III patients treated with a long course of preoperative pelvic RT or chemoradiation, that was operated 6 to 8 weeks after completion of the (chemo)radiation		
Rate of acute grade 4 radio(chemo)therapy-related complications		
Surgery		
Proportion of R0 resections	Proportion of breast cancer women who underwent an axillary lymph node dissection (ALND) after positive SNLB > 2 mm	Number of annually surgically treated patients with testicular cancer per centre
Proportion of APR and Hartmann's procedures	Proportion of women with high-grade and/or palpable and/or large DCIS of the breast who had negative margins after surgery, whatever the surgical option (local wide excision or mastectomy)	
Proportion of patients with stoma 1 year after sphincter-sparing surgery	Proportion of cStage I and II women who undergo breast-conserving surgery (BCS) / mastectomy	

Rectal cancer	Breast cancer	Testicular cancer
Rate of patients with major leakage of the anastomosis after sphincter-sparing surgery	Proportion of women with breast cancer recurrence after breast conserving surgery who are treated by a mastectomy	
Inpatient or 30-day mortality		
Rate of intra-operative rectal perforation		
(Adjuvant) treatment		
Proportion of p-ypStage III patients with R0 resection that received adjuvant chemotherapy	Proportion of women with a breast cancer who are receiving intravenous chemotherapy for whom the planned chemotherapy regimen (which includes, at a minimum: drug[s] prescribed, dose, and duration) is documented prior to the initiation, and at each administration of the treatment regimen	Radiation dose and field in patients with testicular cancer treated with radiotherapy by stage
Proportion of pStage II-III patients with R0 resection that received adjuvant radiotherapy or chemoradiotherapy	Proportion of women receiving adjuvant systemic therapy after breast surgery for invasive breast cancer	Proportion of patients with stage I non-seminoma treated with active surveillance
Proportion of p-ypStage II-III patients with R0 resection that started adjuvant chemotherapy within 3 months after surgical resection	Proportion of women with hormone receptor positive invasive breast cancer or ductal carcinoma in situ (DCIS) who received adjuvant endocrine treatment (Tamoxifen/AI)	Proportion of patients receiving CE-CT or MRI for residual disease assessment at the end of systemic treatment
Proportion of p-ypStage II-III patients with R0 resection treated with adjuvant chemo(radio)therapy, that received 5-FU based chemotherapy	Proportion of women with HER2 positive, node positive or high-risk node negative breast cancer (tumour size > 1 cm), having a left ventricular ejection fraction of ≥50-55% who received chemotherapy and Trastuzumab	Degree and duration of active surveillance in patients with stage I non-seminoma or seminoma
Rate of acute grade 4 radio- or chemotherapy-related complications	Proportion of women treated by Trastuzumab in whom cardiac function is monitored every 3 months	
	Proportion of women who received radiotherapy after breast conserving surgery	
	Proportion of women who underwent a mastectomy and having ≥ 4 positive nodes who received radiotherapy on axilla following ALND	
	Proportion of women with HER2 positive metastatic breast cancer who received Trastuzumab with/without non-anthracycline based chemotherapy or endocrine therapy as first-line treatment	
	Proportion of metastatic breast cancer women who receive systemic therapy as 1st and/or 2nd line treatment	
	Proportion of women with metastatic breast cancer and	

Rectal cancer	Breast cancer	Testicular cancer
	lytic bone metastases who received biphosphonates	
Palliative care		
Rate of cStage IV patients receiving chemotherapy		
Rate of acute grade 4 chemotherapy-related complications in stage IV patients		
Follow-up		
Rate of curatively treated patients that received a total colonoscopy within 1 year after resection	Proportion of women who benefit from an annual mammography after a history of breast cancer	
Rate of patients undergoing regular follow-up (according to the PROCARE recommendations)		
Late grade 4 complications of radiotherapy or chemoradiation		
Histopathologic examination		
Use of the pathology report sheet	Proportion of breast cancer resection pathology reports that include the tumour size (macro-and microscopically invasive and DCIS), the histologic type of the primary tumour, the pT category (primary tumour), the pN category (regional lymph nodes including numbers), the lymphovascular invasion (LVI) and the histologic grade.	
Quality of TME assessed according to Quirke and mentioned in the pathology report	Proportion of women with invasive breast cancer undergoing ALND and having 10 or more lymph nodes removed	
Distal tumour-free margin mentioned in the pathology report		
Number of lymph nodes examined		
(y)pCRM mentioned in mm in the pathology report		
Tumour regression grade mentioned in the pathology report (after neoadjuvant treatment)		

6.4 APPENDIX 4: DATABASES USED AND LINKAGE PROCEDURE

6.4.1 The Belgian Cancer Registry

The Belgian Cancer Registry (BCR) has a database containing the following information:

- incidence date (date of first diagnosis, date of first microscopic confirmation of malignancy)
- basis for the diagnosis (histopathologic confirmation, diagnosis based on technical procedures, diagnosis based on tumour markers, diagnosis based on clinical examination only, autopsy)
- primary localisation and histology of the tumour (ICD-O-3, reported in ICD-10 code)
- laterality (for paired organs)
- differentiation grade
- staging (TNM classification)
- WHO score at time of diagnosis (a performance score)
- treatment (date of first treatment received and planned treatment)
- the date of patient death (through an access to the national register hosted by the Banque Carrefour)

For each cancerous patient, these data are registered in a continuous longitudinal way [10]. Patients are identified based on their unique social security number, which makes it possible to link these data to other administrative databases using the same patient identifier.

An important issue for the use of the Cancer Registry database is completeness. In its 2008 incidence report, the BCR defines completeness as "the extent to which all incident cancers in the Belgian population are included in the BCR". For the Flemish Region a complete coverage (>95%) was obtained for the incidence year 2000, while the other regions were only considered as nearly complete since incidence year 2004.

Another indicator of data quality is the proportion of records with missing values for certain variables. In the 2005 dataset, 100% completeness was obtained for tumour localisation, histology, malignant behaviour, incidence date, sex and age of the patient. However, the INSZ/NISS was not available for all patients (92% in 2005). Basis of diagnosis (the method used to define the diagnosis: histology, cytology, radiography, clinical exam) reached 99.7% completeness. Primary tumour localisation was well specified in 99.9% and histology in 96.2% of the cases. Data on the WHO performance score (a score on the physical status of the patient, from 0 "Asymptomatic (Fully active, able to carry on all predisease activities without restriction)" to 4 "Bedbound (Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair)") and treatment of the tumour were missing in respectively 45% and 43% of cases, which makes these variables unreliable. Information on laterality is often not complete either; 19% of cases related to pair organs lack information on laterality. [10]

The clinical stage (cStage) is based on the available information obtained before resection surgery i.e. by physical examination, radiologic examination and endoscopy. Pathologic stage (pStage) adds additional information gained by histopathologic examination of the tumour. The BCR merges both stages for reporting reasons into the Combined Stage (CombStage). During this merge, the pathologic stage prevails over the clinical stage, except when the clinical TNM is stage IV. Globally, 33.5% of records of stageable tumours miss information on the stage (CombStage)[10], with large differences between tumours (40% for prostate cancer, 35% for lung, 19% for colon and 16% for breast cancer).

There is a two-three year lag between the incidence date and the availability in the BCR data. This means that, at the beginning of 2011, the full year 2008 was available.

6.4.2 The IMA database (administrative claims data)

Sickness funds have individual patient data on patient characteristics, reimbursed services and pharmaceuticals delivered by pharmacists, at the detailed level of the service or the prescription. This information can be found in three databases:

1. "Pharmanet" is the database specific to pharmaceutical products delivered in community pharmacies (not in hospital);
2. The database "Health Care" contains all other reimbursed acts and pharmaceutical products;
3. The "Population" database contains information on the demographic and socioeconomic profile of each of the sickness funds members.

These data are collected and made available by the IMA (Intermutualistic Agency). IMA is a non-profit institution with all Belgian sickness funds as its members.

Patients are identified with the INSS/NISS number, which makes the linkage with other databases possible.

There is a one to two years lag between the date of the act or delivery of pharmaceutical product and the availability in the database. This means that, at the beginning of 2011, the year of 2009 was almost fully available.

6.4.3 The MCD – HBD (administrative hospital discharge data)

The registration of the Minimal Clinical Data (MCD) is mandatory for every hospital in Belgium since 1991. This means that for each hospitalized patient, information such as birth date, sex, postal code of domicile and other information such as length of hospital stay, hospital ward and bed type occupation, has to be recorded, along with ICD-9-CM encoding of relevant diagnoses as well as diagnostic and therapeutic procedures performed. After stripping of direct patient-identifying information, records have to be sent biannually to the Federal Ministry of Health (MoH). Here, all department registrations are concatenated with assignment of the principal diagnosis of the whole stay, determinant for the APR-DRG-grouper software.

Patient are identified with the INSS/NISS number, or, in the absence of such number, the patient's subscription number to his sickness fund.

Since 1997, the MCD records are afterwards linked to the Hospital Billing Data (HBD), yearly transmitted by the national health insurance companies to the National Institute for Health and Disability Insurance (NIHDI) and assembling the remuneration costs of each hospital stay. The linkage process takes about 2 years to completion and full validation, and is performed by the Technical Cell (TCT) of NIHDI and MoH. Linkage percentages increased over the years and exceed nowadays 95% overall (based on all stays with financial data).

6.4.4 The prospective voluntary-based PROCARE database

The PROCARE registration form was constructed in consensus by a multidisciplinary group based on the data entry for the Dutch TME trial and on data from the literature considered to be relevant for quality assessment and assurance. The data entry form contains detailed patient clinical characteristics and is based on the evidence as presented in the PROCARE guidelines [1]. Some of the data are redundant with other databases (BCR or IMA), but most are very specific.

Participating centres prospectively submit their data on a voluntary basis to the Belgian Cancer Registry. Previously, all submissions were on paper forms and were manually entered into the database. Since August 2010, an online application exists which allows a direct electronic transfer of the data in the database.

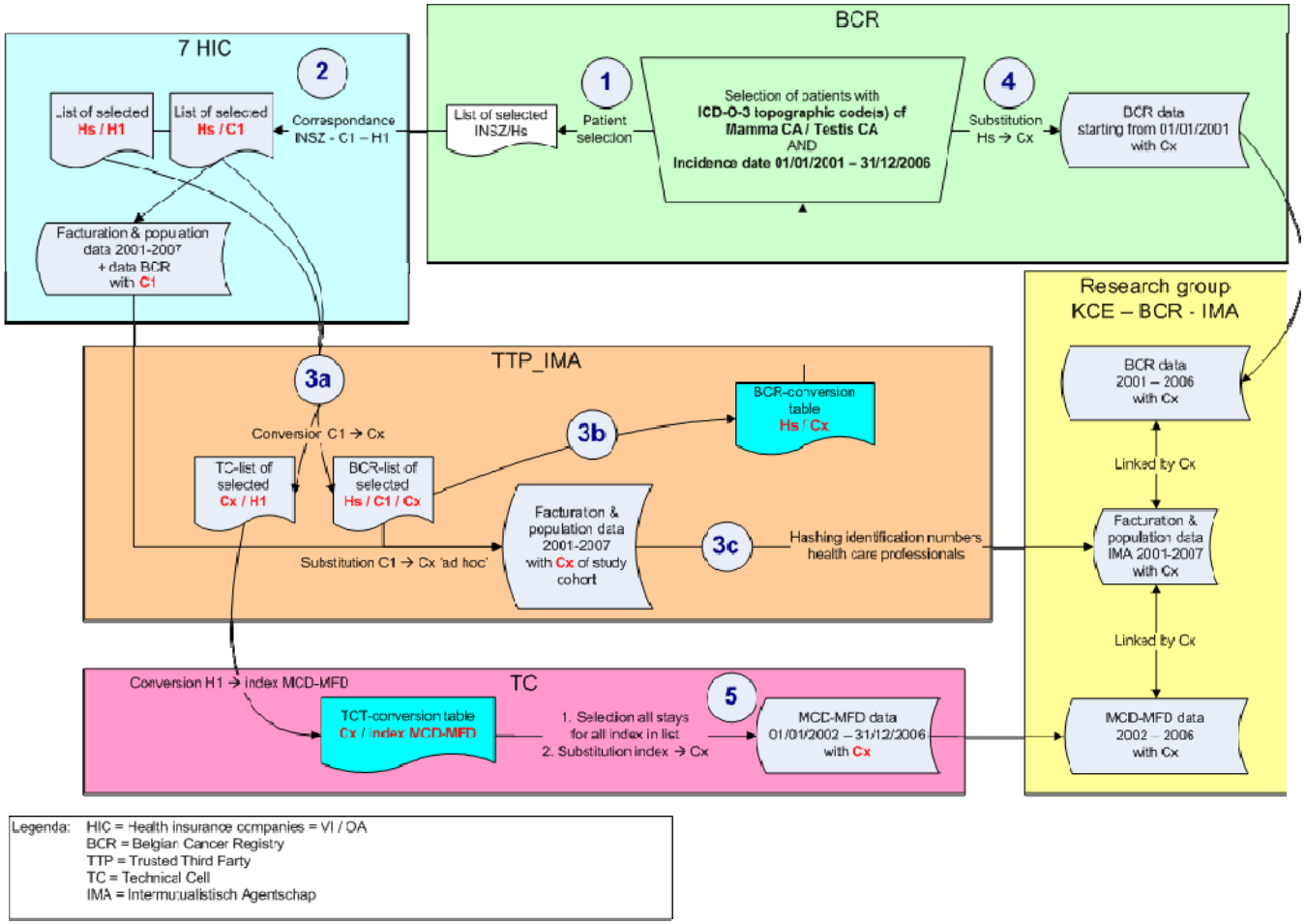
However, registration on paper is also still possible if preferred by the participants. When the submission is done on paper forms, the data are put into the database by the BCR data-manager. The data are regularly checked for quality and completeness and data requests are sent to the centres if necessary.

Active input into the database was started in January 2006. Currently (February 2010), data are available from more than 3700 rectal cancer patients. 84 centres (with 170 surgeons) are participating at present.

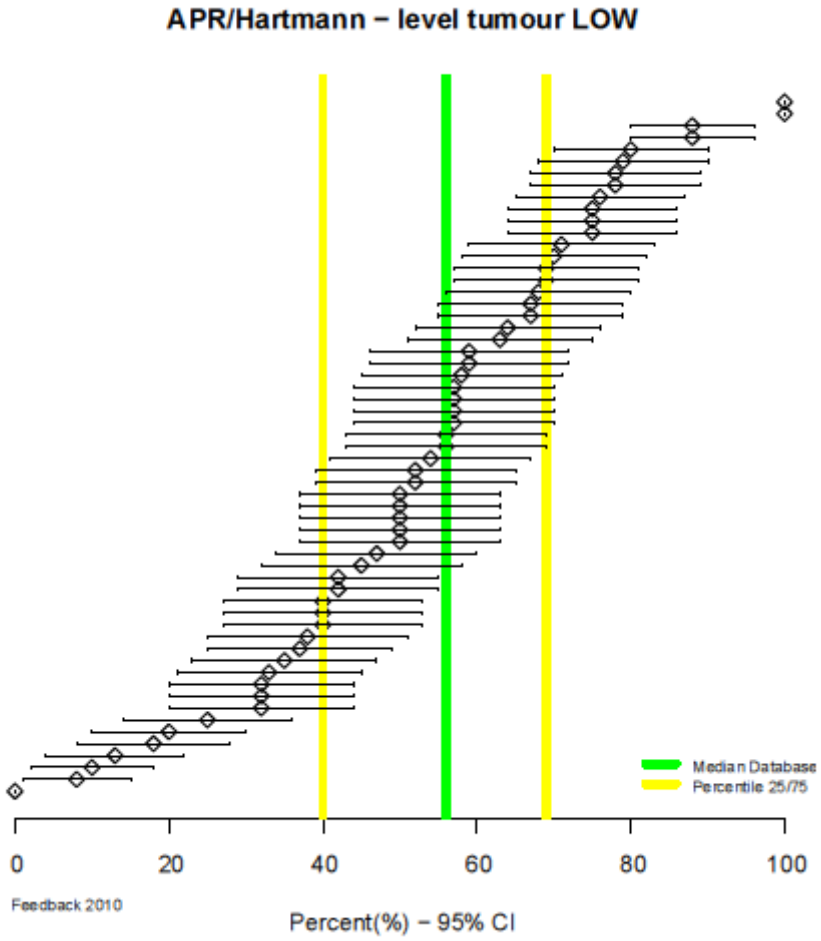
For the study on rectal cancer, inclusion was stopped on December 4th 2007. At that time, 1071 patients with rectal cancer were included, involving 56 centres and 98 surgeons.

6.4.5 Technical scheme for linkage of databases

Figure 7. Primary selection of breast and testicular cancer population.



6.5 APPENDIX 5: PROCARE FEEBACK: EXAMPLE FOR ONE QUALITY INDICATOR



6.6 APPENDIX 6: SUGGESTIONS TO INCREASE MEASURABILITY OF QUALITY INDICATORS

Table 17. Suggested actions to increase measurability of breast cancer quality indicators.

Quality indicator		Action
General indicators: outcomes		
BC1	Overall 5-year survival rate by stage	-
BC2	Disease-specific 5-year survival by stage	Collect national data on causes of mortality
BC3	Disease-free 5-year survival rate by stage	Oblige registration of recurrence?
BC4	5-year local recurrence rate after curative surgery, by stage	Oblige registration of recurrence?
General indicators: process		
BC5	Proportion of breast cancer women discussed at the multidisciplinary team meeting	-
BC6	Proportion of women with breast cancer who participate in clinical trials	Include information in MDT form
Diagnosis and staging		
BC7	Proportion of women with class 3, 4 or 5 abnormal mammograms having an assessment with a specialist within 2 months of mammography	Regular surveys on a random sample of patients medical files to know the result of the mammogram
BC8	Proportion of women with class 3, 4 or 5 abnormal mammograms who have at least one of the following procedures within 2 months after communication of the screening result: mammography, ultrasound, fine-needle aspiration, or percutaneous biopsy	Regular surveys on a random sample of patients medical files to know the result of the mammogram
BC9	Proportion of newly diagnosed cstage I-III breast cancer patients who underwent two-view mammography or breast sonography within 3 months prior to surgery	-
BC10	Proportion of patients who received axillary ultrasonography with fine needle aspiration cytology of the axillary lymph nodes before any treatment	Create specific nomenclature codes for axillary ultrasonography with fine needle aspiration cytology of the axillary lymph nodes reflecting the current state-of-the-art (with unambiguous specification of the anatomic location : axilla)
BC11	Proportion of patients in whom human epidermal growth factor receptor 2 status was assessed before any systemic treatment	-
BC12	Proportion of patients in whom a ER and PgR status assessment were performed before any systemic treatment	-
BC13	Proportion of breast cancer women with cytological and/or histological assessment before surgery	-
BC14	Proportion of sentinel lymph nodes biopsy in cN0 patients without contraindications	Include information in MDT form / Regular surveys on a random sample of patients medical files
Neo-adjuvant treatment		
BC15	Proportion of operable cT2-T3 women who received neoadjuvant systemic therapy	-
Surgery		
BC16	Proportion of breast cancer women who underwent an ALND after positive SNLB > 2 mm	Include information in MDT form / Regular surveys on a random sample of patients medical files
BC17	Proportion of women with high-grade and/or palpable and/or large DCIS of the breast who had negative margins after surgery, whatever the surgical option (local wide	Include DCIS in data selection and record resection margins in the pathology report

Quality indicator		Action
	excision or mastectomy)	
BC18	Proportion of cStage I and II women who undergo breast-conserving surgery / mastectomy	-
BC19	Proportion of women with breast cancer recurrence after breast conserving surgery who are treated by a mastectomy	Oblige registration of recurrence?
Adjuvant treatment		
BC20	Proportion of women with a breast cancer who are receiving intravenous chemotherapy for whom the planned chemotherapy regimen (which includes, at a minimum: drug[s] prescribed, dose, and duration) is documented prior to the initiation, and at each administration of the treatment regimen	Regular surveys on a random sample of patients medical files
BC21	Proportion of women receiving adjuvant systemic therapy after breast surgery for invasive breast cancer	-
BC22	Proportion of women with hormone receptor positive invasive breast cancer or DCIS who received adjuvant endocrine treatment (Tamoxifen/AI)	Include information in MDT form / Enlarge the data selection to include DCIS
BC23	Proportion of women with HER2 positive, node positive or high-risk node negative breast cancer (tumour size > 1 cm), having a left ventricular ejection fraction of > or= 50-55% who received chemotherapy and Trastuzumab	Regular surveys on a random sample of patients medical files
BC24	Proportion of women treated by Trastuzumab in whom cardiac function is monitored every 3 months	-
BC25	Proportion of women who received radiotherapy after breast conserving surgery	-
BC26	Proportion of women who underwent a mastectomy and having ≥ 4 positive nodes who received radiotherapy on axilla following ALND	Include information in MDT form / Regular surveys on a random sample of patients medical files andpathology reports
BC27	Proportion of women with HER2 positive metastatic breast cancer who received Trastuzumab with/without non-anthracycline based chemotherapy or endocrine therapy as first-line treatment	Include information on HER2 status in MDT form
BC28	Proportion of metastatic breast cancer women who receive systemic therapy as 1st and/or 2nd line treatment	-
BC29	Proportion of women with metastatic breast cancer and lytic bone metastases who received biphosphonates	-
Follow-up		
BC30	Proportion of women who benefit from an annual mammography after a history of breast cancer	-
Histopathology		
BC31	Proportion of breast cancer resection pathology reports that include the tumour size (macro-and microscopically invasive and DCIS), the histologic type of the primary tumour, the pT category (primary tumour), the pN category (regional lymph nodes including numbers), the LVI and the histologic grade.	Oblige to record all these informations, use of a standard pathology report form Regular surveys on a random sample of pathology reports
BC32	Proportion of women with invasive breast cancer undergoing ALND and having 10 or more lymph nodes removed	Oblige to record all these informations Regular surveys on a random sample of pathology reports

Table 18. Suggested actions to increase measurability of testicular cancer quality indicators.

Quality indicator	Action
Diagnosis and staging	
TC1: Proportion of patients with testicular cancer undergoing tumour marker assessment before any treatment	-
TC2: Proportion of patients with testicular cancer undergoing CE-CT or MRI for primary staging	Create nomenclature codes for CT and MRI with unambiguous specification of the anatomic location, e.g. separate codes for CT thorax, CT abdomen and CT pelvis (same applies to MRI)
TC3: Proportion of patients with testicular cancer discussed at the MDT meeting	-
Treatment	
TC4: Number of annually surgically treated patients with testicular cancer per centre	Create specific nomenclature codes for orchidectomy reflecting the current state-of-the-art (e.g. separate codes for (1) radical orchidectomy for testicular cancer and for (2) retroperitoneal lymph node dissection for testicular cancer, instead of the existing nomenclature code for orchidectomy)
TC5: Radiation dose and field in patients with testicular cancer treated with radiotherapy by stage	Include information in MDT form
TC6: Proportion of patients with stage I non-seminoma treated with active surveillance	Oblige registration of recurrence? If using the proxy definition of the present report, use 3 months instead of 6 months as time delay between surgery and new treatment
TC7: Proportion of patients receiving CE-CT or MRI for residual disease assessment at the end of systemic treatment	Create nomenclature codes for CT and MRI with unambiguous specification of the anatomic location (see above)
TC8: Degree and duration of active surveillance in patients with stage I non-seminoma or seminoma	Create nomenclature codes for CT and MRI with unambiguous specification of the anatomic location (see above)
TC9: Proportion of patients with relapsing testicular cancer after curative treatment that are included in a clinical trial	Include information in MDT form
Generic indicators	
TC10: Overall 5-year survival by stage	Collect data on risk groups to allow presentation of survival by risk group
TC11: Disease-specific 5-year survival by stage	Collect national data on causes of mortality
TC12: Disease-free 5-year survival by stage	Oblige registration of recurrence?

Table 19. Suggested actions to increase measurability of rectal cancer quality indicators.

Quality indicator	Action
Generic quality indicators	
QI1111: Overall 5-year survival by stage	• Continue follow-up (at least 5 years) • Take into account postoperative mortality (through link with administrative database)
QI1112: Disease-specific 5-year survival by stage	• Use relative 5-year survival as proxy • Continue follow-up (at least 5 years)
QI1113: Proportion of patients with local recurrence	• Continue follow-up (at least 5 years) • Remove default '0' value in PROCARE database • Use real R0 proportion (taking into account pathology results and absence of intraoperative rectal perforation) • Reduce number of missing data (type of resection, (y)pStage) • Risk-adjustment: e.g. tumour level, stage
QI1114: Proportion of patients discussed at a multidisciplinary team meeting	• Link PROCARE database to administrative databases • Reconsider relevance of this indicator
Diagnostic and staging	
QI 1211: Proportion of patients with a documented distance from the anal verge	• Data cleaning necessary
QI1 212: Proportion of patients in whom a CT of the liver and RX or CT of the thorax was performed before any treatment	• Adapt PROCARE variable in data entry set to render QI measurable
QI 1213: Proportion of patients in whom a CEA was performed before any treatment	• Consider measuring the QI for all patients
QI 1214: Proportion of patients undergoing elective surgery that had preoperative complete large bowel-imaging	• Adapt PROCARE data entry set • Consider measuring the QI for all patients
QI 1215: Proportion of patients in whom a TRUS and pelvic CT and/or pelvic MRI was performed before any treatment	• Risk-adjustment: tumour level, tumour stenosis • Consider measuring the QI for all patients
QI 1216: Proportion of patients with cStage II-III that have a reported cCRM	• Reduce number of missing data (cStage)
QI 1217: Time between first histopathologic diagnosis and first treatment	• Reduce number of missing data (date of biopsy) • Consider redefining the QI (time between first consultation and first treatment)
Neoadjuvant treatment	
QI 1221: Proportion of cStage II-III patients that received a short course of neoadjuvant pelvic RT	• Reduce number of missing data (cStage, radiotherapy regimen) • Add PROCARE variable asking for prescribed radiotherapy regimen • Risk-adjustment: e.g. tumour level, age, comorbidities • Consider measuring the QI for all cStage II-III patients
QI 1222: Proportion of cStage II-III patients that received a long course of neoadjuvant pelvic RT	• Reduce number of missing data (cStage, radiotherapy regimen) • Add PROCARE variable asking for prescribed radiotherapy regimen • Risk-adjustment: e.g. tumour level, age, comorbidities • Consider measuring the QI for all cStage II-III patients
QI 1223: Proportion of cStage II-III patients that	• Reduce number of missing data (cStage,

Quality indicator	Action
received neoadjuvant chemoradiation with a regimen containing 5-FU	chemotherapy regimen) • Consider measuring the QI for all cStage II-III patients
QI 1224: Proportion of cStage II-III patients treated with neoadjuvant 5-FU based chemoradiation, that received a continuous infusion of 5-FU	• Add PROCARE variable to render QI measurable • Consider measuring the QI for all cStage II-III patients
QI 1225: Proportion of cStage II-III patients treated with a long course of preoperative pelvic RT or chemoradiation, that completed this neoadjuvant treatment within the planned timing	• Remove default '0' value in PROCARE database • Reduce number of missing data (cStage, radiotherapy regimen) • Consider measuring the QI for all cStage II-III patients
QI 1226: Proportion of cStage II-III patients treated with a long course of preoperative pelvic RT or chemoradiation, that was operated 6 to 8 weeks after completion of the (chemo)radiation	• Reduce number of missing data (cStage, radiotherapy regimen)
QI 1227: Rate of acute grade 4 radio(chemo)therapy-related complications	• Add PROCARE variable to render QI measurable
Surgery	
QI 1231: Proportion of R0 resections	• Reduce number of missing data (cStage) • Use real R0 proportion (taking into account pathology results and absence of intraoperative rectal perforation) • Risk-adjustment: stage, cCRM
QI1232a: Proportion of APR and Hartmann's procedures	• Risk-adjustment: e.g. tumour level
QI 1232b: Proportion of patients with stoma 1 year after sphincter-sparing surgery	• Adapt PROCARE variable to render QI measurable for the PROCARE database • Risk-adjustment: tumour level, comorbidities, stage
QI 1233: Rate of patients with major leakage of the anastomosis after sphincter sparing surgery	• Reduce number of missing data (type of surgery)
QI 1234: Inpatient or 30-day mortality	• Risk-adjustment: age, stage, comorbidities (expected/observed ratio)
QI 1235: Rate of intra-operative rectal perforation	• Remove default '0' value in PROCARE database • Risk-adjustment: tumour level (including dorsal – ventral), stage
Adjuvant treatment	
QI 1241: Proportion of p-ypStage III patients with R0 resection that received adjuvant chemotherapy	• Reduce number of missing data (adjuvant treatment, (y)pStage) • Adapt PROCARE data entry form on adjuvant treatment • Use real R0 proportion (taking into account pathology results and absence of intraoperative rectal perforation) • Risk-adjustment: age, comorbidities, postoperative morbidity
QI 1242: Proportion of pStage II-III patients with R0 resection that received adjuvant radiotherapy or chemoradiotherapy	• Reduce number of missing data (adjuvant treatment) • Adapt PROCARE data entry form on adjuvant treatment • Use real R0 proportion (taking into account pathology results and absence of intraoperative rectal perforation) • Risk-adjustment: age, comorbidities, postoperative morbidity

Quality indicator	Action
QI 1243: Proportion of p-ypStage II-III patients with R0 resection that started adjuvant chemotherapy within 3 months after surgical resection	• Reduce number of missing data (adjuvant treatment, (y)pStage) • Adapt PROCARE data entry form on adjuvant treatment • Use real R0 proportion (taking into account pathology results and absence of intraoperative rectal perforation) • Risk-adjustment: age, comorbidities, postoperative morbidity
QI 1244: Proportion of p-ypStage II-III patients with R0 resection treated with adjuvant chemo(radio)therapy, that received 5-FU based chemotherapy	• Reduce number of missing data (adjuvant treatment, (y)pStage) • Adapt PROCARE data entry form on adjuvant treatment • Use real R0 proportion (taking into account pathology results and absence of intraoperative rectal perforation)
QI 1245: Rate of acute grade 4 radio- or chemotherapy-related complications	• Reduce number of missing data (adjuvant treatment, (y)pStage) • Remove default '0' value in PROCARE database • Adapt PROCARE data entry form on adjuvant treatment
Palliative care	
QI 1251: Rate of cStage IV patients receiving chemotherapy	• Reduce number of missing data (cStage) • Risk-adjustment: age, comorbidities • Use 'corrected cStage' taking into account peroperative findings of metasta
QI 1252: Rate of acute grade 4 chemotherapy-related complications in stage IV patients	• Reduce number of missing data (cStage) • Remove default '0' value in PROCARE database
Follow-up	
QI 1261: Rate of curatively treated patients that received a total colonoscopy within 1 year after resection	• Add PROCARE variable to render QI measurable
QI 1262: Rate of patients undergoing regular follow-up (according to the PROCARE recommendations)	• Add PROCARE variable to render QI measurable
QI 1263: Late grade 4 complications of radiotherapy or chemoradiation	• Longer follow-up necessary • Remove default '0' value in PROCARE database
Histopathologic examination	
QI 1271: Use of the pathology report sheet	• Add PROCARE variable to render QI measurable
QI 1272: Quality of TME assessed according to Quirke and mentioned in the pathology report	• Risk-adjustment: tumour level, stage
QI 1273: Distal tumour-free margin mentioned in the pathology report	• Risk-adjustment: tumour level
QI 1274: Number of lymph nodes examined	• Risk-adjustment: neoadjuvant treatment, (y)pN
QI 1275: (y)pCRM mentioned in mm in the pathology report	• Reduce missing data (pathology data)
QI 1276: Tumour regression grade mentioned in the pathology report (after neoadjuvant treatment)	• Reduce missing data (neoadjuvant treatment) • Risk-adjustment: neoadjuvant treatment

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Wettelijk depot : D/2011/10.273/01

KCE reports

1. Effectiviteit en kosten-effectiviteit van behandelingen voor rookstop. D/2004/10.273/1.
2. Studie naar de mogelijke kosten van een eventuele wijziging van de rechtsregels inzake medische aansprakelijkheid (fase 1). D/2004/10.273/2.
3. Antibioticagebruik in ziekenhuizen bij acute pyelonefritis. D/2004/10.273/5.
4. Leukoreductie. Een mogelijke maatregel in het kader van een nationaal beleid voor bloedtransfusieveiligheid. D/2004/10.273/7.
5. Het preoperatief onderzoek. D/2004/10.273/9.
6. Nationale richtlijn prenatale zorg. Een basis voor een klinisch pad voor de opvolging van zwangerschappen. D/2004/10.273/13.
7. Validatie van het rapport van de Onderzoekscommissie over de onderfinanciering van de ziekenhuizen. D/2004/10.273/11.
8. Financieringssystemen van ziekenhuisgeneesmiddelen: een beschrijvende studie van een aantal Europese landen en Canada. D/2004/10.273/15.
9. Feedback: onderzoek naar de impact en barrières bij implementatie – Onderzoeksrapport: deel 1. D/2005/10.273/01.
10. De kost van tandprothesen. D/2005/10.273/03.
11. Borstkankerscreening. D/2005/10.273/05.
12. Studie naar een alternatieve financiering van bloed en labiele bloedderivaten in de ziekenhuizen. D/2005/10.273/07.
13. Endovasculaire behandeling van Carotisstenose. D/2005/10.273/09.
14. Variaties in de ziekenhuispraktijk bij acuut myocardinfarct in België. D/2005/10.273/11.
15. Evolutie van de uitgaven voor gezondheidszorg. D/2005/10.273/13.
16. Studie naar de mogelijke kosten van een eventuele wijziging van de rechtsregels inzake medische aansprakelijkheid. Fase II : ontwikkeling van een actuarieel model en eerste schattingen. D/2005/10.273/15.
17. Evaluatie van de referentiebedragen. D/2005/10.273/17.
18. Prospectief bepalen van de honoraria van ziekenhuisartsen op basis van klinische paden en guidelines: makkelijker gezegd dan gedaan.. D/2005/10.273/19.
19. Evaluatie van forfaitaire persoonlijk bijdrage op het gebruik van spoedgevallendienst. D/2005/10.273/21.
20. HTA Moleculaire Diagnostiek in België. D/2005/10.273/23, D/2005/10.273/25.
21. HTA Stomamateriaal in België. D/2005/10.273/27.
22. HTA Positronen Emissie Tomografie in België. D/2005/10.273/29.
23. HTA De electieve endovasculaire behandeling van het abdominale aorta aneurysma (AAA). D/2005/10.273/32.
24. Het gebruik van natriuretische peptides in de diagnostische aanpak van patiënten met vermoeden van hartfalen. D/2005/10.273/34.
25. Capsule endoscopie. D/2006/10.273/01.
26. Medico–legale aspecten van klinische praktijkrichtlijnen. D2006/10.273/05.
27. De kwaliteit en de organisatie van type 2 diabeteszorg. D2006/10.273/07.
28. Voorlopige richtlijnen voor farmaco-economisch onderzoek in België. D2006/10.273/10.
29. Nationale Richtlijnen College voor Oncologie: A. algemeen kader oncologisch kwaliteitshandboek B. wetenschappelijke basis voor klinische paden voor diagnose en behandeling colorectale kanker en testiskanker. D2006/10.273/12.
30. Inventaris van databanken gezondheidszorg. D2006/10.273/14.
31. Health Technology Assessment prostate-specific-antigen (PSA) voor prostaatkankerscreening. D2006/10.273/17.
32. Feedback : onderzoek naar de impact en barrières bij implementatie – Onderzoeksrapport : deel II. D/2006/10.273/19.
33. Effecten en kosten van de vaccinatie van Belgische kinderen met geconjugeerd pneumokokkenvaccin. D/2006/10.273/21.
34. Trastuzumab bij vroegtijdige stadia van borstkanker. D/2006/10.273/23.
35. Studie naar de mogelijke kosten van een eventuele wijziging van de rechtsregels inzake medische aansprakelijkheid (fase III)- precisering van de kostenraming. D/2006/10.273/26.
36. Farmacologische en chirurgische behandeling van obesitas. Residentiële zorg voor ernstig obese kinderen in België. D/2006/10.273/28.

37. HTA Magnetische Resonantie Beeldvorming. D/2006/10.273/32.
38. Baarmoederhalskankerscreening en testen op Human Papillomavirus (HPV). D/2006/10.273/35
39. Rapid assessment van nieuwe wervelzuil technologieën : totale discusprothese en vertebro/ballon kyfoplastie. D/2006/10.273/38.
40. Functioneel bilan van de patiënt als mogelijke basis voor nomenclatuur van kinesitherapie in België? D/2006/10.273/40.
41. Klinische kwaliteitsindicatoren. D/2006/10.273/43.
42. Studie naar praktijkverschillen bij electieve chirurgische ingrepen in België. D/2006/10.273/45.
43. Herziening bestaande praktijkrichtlijnen. D/2006/10.273/48.
44. Een procedure voor de beoordeling van nieuwe medische hulpmiddelen. D/2006/10.273/50.
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