Prospectief bepalen van de honoraria van ziekenhuisartsen op basis van klinische paden en guidelines: makkelijker gezegd dan gedaan

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Disclaimer: This report includes a survey on clinical pathways and a review of the literature for a limited number of surgical interventions. The results from the evidence search cannot be extrapolated to other types of surgery. The conclusions of the evidence appraisal cannot be used directly as a practice guideline or clinical pathway without further local considered judgement and should therefore be treated with caution.

Voorwoord

Meerdere Westerse landen worstelen momenteel met de uitdaging om zorg van goede kwaliteit te verzoenen met een verantwoord kostenplaatje. Ingrijpende hervormingen van de financieringssystemen vinden dan ook plaats in tal van landen, zoals recent nog geillustreerd in het KCE-rapport over de financiering van geneesmiddelen in de ziekenhuizen.

Ziekenhuizen in België kennen een zogenaamde duale financiering: enerzijds de ziekenhuisfinanciering ('verpleegprijs'), die progressief meer en meer gebaseerd wordt op het pathologieprofiel van het ziekenhuis, en anderzijds (een deel van) de honoraria van de ziekenhuisartsen. In de chirurgie zijn er de afgelopen jaren enkele voorbeelden gepubliceerd die een vanuit medisch standpunt overklaarbare variaties in vooral het gebruik van allerlei diagnostische testen in klinische biologie, beeldvorming en cardiologie aantoonden. Denk maar aan de appendectomie-studie in het verleden en recent nog de variaties in het gebruik van preoperatieve onderzoeken.

De oplossing om die variaties aan te pakken lijkt dan ook eenvoudig: een standaard prijs voor een standaard ingreep. Maar hoe wordt die prijs dan bepaald? Op basis van het historische gemiddelde? De mediaan? Of, hetgeen het onderwerp was van deze studie, op basis van een kostencalculatie voor een medisch verantwoord zorgtraject zoals gedefinieerd door klinische paden en evidence-based richtlijnen? Het antwoord op deze laatste vraag bleek voorwaar geen sinecure.

Klinische paden bieden in theorie interessante mogelijkheden om de organisatie van de zorgen te standaardiseren en de middelen verantwoord aan te wenden maar er blijven nog vele vragen onbeantwoord over de te volgen ontwikkelingsmethodologie en over hun effecten. Voor de enquête in dit project naar het voorkomen van klinische paden in Belgische ziekenhuizen werkte het KCE, om duplicatie te voorkomen, samen met de onderzoeksgroep die momenteel een BOS-project uitvoert voor de FOD Volksgezondheid hierover.

Tot onze grote verbazing stelden we vast dat een soortgelijke gedetailleerde oefeningen waarbij op basis van klinische paden en evidence de kosten worden geschat voor een chirurgische ingreep nauwelijks werden teruggevonden in andere landen. Vanuit de internationale wetenschappelijke gemeenschap blijkt er duidelijke interesse naar de ervaring uit onze oefeningen.

Dit KCE-rapport bevat geen expliciete beleidsaanbevelingen, vermits dit onderzoek werd uitgevoerd ter ondersteuning van het advies dat de Multipartite-overlegstructuur voorbereidt.

Een speciaal woord van dank gaat naar de vele ziekenhuizen die bereidwillig en in alle transparantie informatie over hun gebruik van klinische paden verschaften.

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Executive summary

In een ziekenhuisfinancieringssysteem per ziekte, zoals op basis van de APR-DRG classificatie, worden de terugbetalingsbedragen per ziekte klassiek berekend op basis van de historische kosten (m.a.w. op basis van het gemiddelde van de effectief terugbetaalde kosten voor die ziekte, met diverse bijstellingen). In België wordt momenteel over een periode van enkele jaren een dergelijk APR-DRG gebaseerd systeem voor de ziekenhuisfinanciering progressief ingevoerd. De honoraria van de ziekenhuisartsen zijn in deze ziekenhuisfinanciering, in tegenstelling tot een aantal andere Westerse landen*, niet inbegrepen. Doel van deze studie is de mogelijkheid te bestuderen om deze terugbetalingsbedragen van de artsen niet te bepalen in functie van wat 'is gedaan' maar in functie van wat 'had moeten gedaan worden', zoals bepaald door 'evidence-based medicine'.

Instrumenten zoals klinische paden worden in bepaalde ziekenhuizen gebruikt om de opname van homogene patiëntgroepen te standaardiseren, teneinde de hospitalisatieduur te verkorten en de zorgkwaliteit te verbeteren. Idealiter zouden deze klinische paden de meest recente verworvenheden van evidence-based medicine moeten integreren. In het eerste deel van dit rapport wordt het concept klinisch pad verduidelijkt want deze term wordt gebruikt om zeer uiteenlopende realiteiten te definiëren. Een inventaris van de verschillende in België gebruikte klinische paden, en een analyse van hun voornaamste kenmerken is met medewerking van vele ziekenhuizen opgesteld.

Bepaling van een EB klinisch pad en de theoretische kosten voor 5 verschillende chirurgische ingrepen

Wij hebben voor 5 chirurgische ingrepen de haalbaarheid getest om precies een ziekenhuisopname te definiëren vanuit 'evidence-based' klinische paden en er de kosten van de artsenhonoraria uit te berekenen. Wij hebben geprobeerd zulke ervaringen ook in andere landen te identificeren, en de verschillende problemen die dat kan stellen te systematiseren.

Als 'test' ingrepen hebben we de meest frequente in België genomen, en zodanig dat ze verschillende situaties vertegenwoordigen : electieve chirurgie in het dagziekenhuis (amygdalectomie) of met verblijf (knieprothese, carotisendarterectomie) ; urgentie (appendicectomie), en een ingreep die soms electief en soms urgent is : laparoscopische cholecystectomie. De kosten voor de artsenhonoraria werden ingedeeld in drie groepen : klinische biologie, beeldvorming en een derde groep met overwegend prestaties inwendige geneeskunde en revalidatie. De in de analyse besloten kosten (gedefinieerd door een nomenclatuurcode) vertegenwoordigen slechts een fractie van de reële kosten van de chirurgische ingreep en omvatten niet de kosten m.b.t. de hospitalisatieduur (verblijf en verpleging). Deze methode werd gekozen om een vergelijking mogelijk te maken met de in België beschikbare gegevens (kostenstructuur van de medische honoraria voor de overeenkomstige APR-DRG – referentiebedragen of, voor de carotischirurgie, de ziekenfondsgegevens).

Bij electieve chirurgie gebeurden de diagnostische onderzoeken om de indicatie te stellen in principe ambulant, wat betekent dat ze niet in de ziekenhuiskosten moeten worden opgenomen. Wat de amygdalectomie betreft is de kostenberekening dus heel eenvoudig, namelijk gewoon de kosten van de ingreep zelf ; bovendien is de beslissing om te opereren genomen op basis van klinische elementen. Hier kunnen aanbevelingen van goede praktijk geen invloed hebben op de kosten van de operatie zelf. Het hoge aantal amygdalectomieën die in België zijn uitgevoerd roept nochtans vragen op, want het nut van amygdalectomie is maar in zeer weinig indicaties bewezen.

Voor de knieprothesen is de kostenberekening ook vrij eenvoudig. Toch schuilt een belangrijke determinant van de kost van deze ingreep in de benodigde revalidatieduur tijdens het ziekenhuisverblijf wat op zijn beurt een weerslag heeft op de verblijfduur ; helaas zijn er geen beschikbare gegevens om de optimale duur per dag en de modaliteiten van de ziekenhuisrevalidatie te identificeren. Wel is het zo dat de klinische paden die in bepaalde

* Swartenbroekx N, Van de Voorde C, Crott R, Ramaekers D. Financieringssystemen van ziekenhuisgeneesmiddelen: een beschrijvende studie van een aantal Europese landen en Canada. Brussel: Federaal Kenniscentrum voor de Gezondheidszorg (KCE); 2004. KCE reports 8

ziekenhuizen in België worden gebruikt, het systematisch gebruik van bepaalde pre- en postoperatieve onderzoeken 'standaardiseren', met name de imaging, die nochtans niet nodig zijn.

Voor de appendicectomie ligt de kostenberekening moeilijker. De indicatie van bepaalde diagnostische tests (in het ziekenhuis uitgevoerd) varieert volgens de klinische presentatie en het klinisch vermoeden van appendicitis (typisch versus atypisch). Hier hebben wij hypotheses moeten maken over de verschillende vereiste proporties (gebaseerd op in de literatuur gepubliceerde proporties) voor berekening van een 'redelijke gemiddelde kost'.

De kostenraming van laparoscopische cholecystectomie bleek nog het moeilijkste te zijn, want een zelfde interventiebeslissing kan in werkelijkheid voortvloeien uit diverse diagnostische paden met verschillende kosten (bijvoorbeeld, urgentie- of electieve chirurgie, diagnostische tests in het ziekenhuis of ambulant, lithiase van de galwegen of niet, …). Het algoritme diagnose/behandeling is complex en omvat meerdere 'beslissingsknopen'. De berekening van een 'redelijke gemiddelde kost) voor een laparoscopische cholecystectomie hangt nog meer dan de vorige voorbeelden af van hypotheses en de onzekerheidsmarge over de berekende kost is nog groter.

De zaak wordt nog ingewikkelder voor carotisendarterectomie. Sommige dure praktijken zoals preoperatieve evaluatie van het hartrisico, of het verblijf op intensieve zorgen, zijn slechts voor een klein deel van de patiënten gerechtvaardigd. Bij gebrek aan precieze gegevens hebben wij deze proporties zo goed mogelijk ingeschat om te kunnen berekenen wat wij een 'redelijke gemiddelde kost' hebben genoemd en dus een onzekerheidsmarge impliceert. In dit bepaalde geval is het verschil tussen deze 'redelijke gemiddelde kost' (theoretisch) en de overeenkomstige (reële) kost zo groot dat de methodologische zwakheden die de vergelijkbaarheid van deze kosten kunnen beperken, niet volstaan om ze te verklaren. Anderzijds lijkt het aantal carotisendarterectomieën die in België zijn uitgevoerd zeer hoog te liggen, temeer daar de beschikbare wetenschappelijke gegevens het voordeel van deze ingreep voor de meeste asymptomatische personen in twijfel trekken.

Totaal van de kosten uitgezonderd chirurgie en anesthesie van het redelijk klinisch pad voor de vijf oefeningen. Refentiekosten voor 2001 voor ernstgraad 1 (S1).

	Totale knie arthroplastie[a]	Appendectomie[b]	Cholecystectomie	Tonsillectomie	Carotis arterie endarterectomie[c]
Redelijk klinisch pad	339.11 €	63.22 €	149.12 €	0.00 €	133.21 €
2001 referentie S1 mediaan	265.70 €	104.58 €	82.46 €	37.20 €	134.27 €
2001 referentie S1 gemiddelde	378.83 €	124.10 €	170.76 €	75.29 €	265.05 €

[a] 12 dagen postoperatieve rehabilitatie

[b] typische en atypische gevallen

[c] preoperatieve en in ziekenhuis interventies

Voor de eerste vier oefeningen, bleek dat de theoretische kost met enige al dan niet verklaarbare marge relatief dicht kwam bij de reeële referentiekost van patiënten met severity-of-illness 1 van de APR-DRG.Toch werden er bij verdere detailanalyse meerdere discrepanties vastgesteld waarvan de meest bemerkenswaardige vaststellingen zich voordeden voor het overmatig gebruik of voor electieve ingrepen mogelijks herhalen van preoperatieve onderzoeken en de variabiliteit in het aanrekenen van revalidatie. Onze analyses tonen dat de kost voor carotis enderteractomie gemiddeld quasi verdubbelt, voornamelijk voor beeldvorming en voor cardiologische onderzoeken. Ook prestaties voor intensieve zorgen en anatomopathologisch onderzoek van de plaque worden in onverklaarbare aantallen teruggevonden.

Algemene conclusies

Het uitvoeren van dit onderzoek, de ontwikkelde methodologie en haar resultaten laat toe om een aantal sterke punten (sterktes) en een aantal beperkingen (zwaktes) te beschrijven, samengevat in volgende tabel.

Sterktes	Zwaktes
• Uit de enquête bij de Belgische ziekenhuizen blijkt dat al velen klinische paden implementeren om het zorgproces efficiënt te organiseren en voor een goede zorgkwaliteit • Het is haalbaar om vanuit klinische paden en klinische evidence de theoretische kost van een welbepaalde chirurgische ingreep te berekenen voor een standaard patient zonder complicaties of belangrijke co-morbiditeit. De complexiteit van de berekeningen voor meer heterogene patiëntengroepen en complexe beslissingsbomen werd aangetoond. • De methodologie laat toe om discrepanties met de reële medische praktijk en in de facturatiecultuur in detail te analyseren en te beargumenteren. • In de discussie over onverklaarbare variaties in kosten zijn er nog andere dimensies dan louter de kostprijs van een standaardingreep die aandacht verdienen zoals het volume en de therapeutische keuze (appropriateness) tot de ingreep. • Voor bepaalde praktijken waarvan initieel werd beweerd dat er geen klinische studies voorhanden waren, worden door middel van de EB methodologie innovatieve vondsten gedaan voor of zelfs tegen de praktijk in een klinisch pad.	• Er zijn belangrijke semantische onduidelijkheden rond klinische paden: Het kan gaan over verpleegpaden tot geïntegreerde multidisciplinaire paden met alle details. Ongeveer de helft van de dokumenten voldoet aan de minimum karakteristieken van een klinisch pad. • Er is geen éénduidige relatie tussen de relatief homogene en klinisch herkenbare patiëntengroep van een klinisch pad of van onze oefeningen enerzijds en het aktuele APR-DRG classificatiesysteem dat slaat op een (meestal grotere of heterogene) groep van diagnoses of aandoeningen anderzijds. • Het is onmogelijk om alle mogelijke factoren (co-morbiteit, complicaties) die kunnen leiden tot een hoger level of severity-of-illness in een DRG mee in rekening te brengen. • Het ganse proces gaande van klinisch pad, verwerken van de evidence tot berekenen van de theoretische kosten is vaak complex en vergt veel tijd. • De externe validiteit in de Belgische context van een aantal assumpties gebaseerd op de literatuur kon niet worden nagegaan en stellen sommige berekeningen bloot aan kritiek. • In overeenstemming met de opdracht werden uitsluitend de artsenhonoraria en niet de ziekenhuisfinanciering in de berekeningen opgenomen.

Globaal genomen is deze oefening van kostenberekening (voor schijnbaar 'eenvoudige' problemen) moeilijker en tijdrovender gebleken dan voorzien. Onze schatting van bepaalde 'redelijke gemiddelde kosten' is weinig robuust gebleken – m.a.w. onderhevig aan grote schommelingen, door het gebrek aan precisie van de vele onderliggende hypothesen. Wegens tijdgebrek hebben wij de hypothesen niet aan gevoeligheidsstudies kunnen onderwerpen. Om deze en nog andere redenen – namelijk het feit dat de kosten van de APR-DRG ziekenhuisverblijfkosten zijn en dus ook de co-morbiditeitskosten omvatten – kunnen de vergelijkingen tussen theoretisch berekende kosten en reële kosten (zelfs als men zich beperkt tot ernstgraad één) slechts bij grove discrepantie worden geïnterpreteerd, zoals in het geval van de carotisendarterectomie.

Over het algemeen stuit elke poging om de opnamekosten van diverse ziekten in ziekenhuismilieu op normatieve basis ('wat had moeten gebeuren') te definiëren, op de inherente complexiteit van het klinisch beslissingsproces : een groot aantal 'eenheidsprijzen' zou moeten worden berekend (voor elke bijzondere combinatie symptoom/diagnose/behandeling). Er zou een aanzienlijke investering vereist zijn om de berekening van de eenheidsprijzen te systematiseren en regelmatig bij te werken. Anderzijds zijn er niet voldoende wetenschappelijke gegevens om alle klinische beslissingen te staven.

- Dat zou een aangepast subsysteem van classificatie vergen (want de APR-DRG classificatie is niet geschikt omdat ze te vaag is), de ontwikkeling van een aangepaste methodologie voor de kostenberekening (om rekening te houden met gerechtvaardigde afwijkingen van de 'standaard' opname), en regelmatige bijwerking.
- De hospitalisatie voor een ziekte sluit meestal aan op de ambulante opname. Klinische logica (ziekte-episode) en economische logica (verschillende financieringssystemen voor hospitalisatie en ambulante opname in België) overlappen elkaar niet. Vandaar de noodzaak om het deel van de ziekte-episode waarvoor de patiënt is gehospitaliseerd nauwkeuriger te definiëren (wat echter niet altijd mogelijk is).

Gezien deze moeilijke implementering kan men zich vragen stellen over de globale impact op de zorgkwaliteit en de ziekenhuiskosten van dergelijk systeem van ziekenhuisfinanciering. Er zou slechts een beperkt aantal ziekten in aanmerking komen (en uitsluitend voor de laagste en dus minst dure niveaus van geassocieerde co-morbiditeit). Er zal geen rekening worden gehouden met het probleem van pertinentie van indicaties voor bepaalde chirurgische ingrepen (was de operatie echt nodig en nuttig).

De in deze studie beschreven moeilijkheden verklaren ongetwijfeld mede de magere resultaten van ons onderzoek over internationale experimenten. Een ziekenhuis in Zwitserland heeft de opname van haar patiënten gebaseerd op locaal ontwikkelde klinische paden en wordt op die basis gefinancierd. De kosten van de verschillende 'klinische paden' worden echter retrospectief berekend (dat vermijdt dat men alle mogelijke klinische situaties moet anticiperen en hun kosten moet ramen). Andere Zwitserse ziekenhuizen hebben dit experiment niet overgenomen en internationaal is het ook weinig bekend. Landen uit Oost-Europa (Bulgarije, Slovenië) experimenteren ook met deze financieringsmethode van ziekenhuizen, maar er zijn nog geen gedetailleerde evaluaties beschikbaar.

Samengevat vertegenwoordigen de klinische paden een poging om de zorgkwaliteit te verbeteren wat op zich al aanmoediging verdient. Vanuit het standpunt van de overheid lenen zij zich echter niet – want dat is hun doel niet – tot het definiëren van een normatieve kost per ziekte.

Momenteel lopen er vele interessante experimenten, bijvoorbeeld 'payment for performance' in de Verenigde Staten, waarbij de ziekenhuizen afhankelijk van hun resultaten financieel worden beloond of bestraft voor een reeks indicatoren die rekening houden met verschillende aspecten van de kwaliteit. Immers de echte vraag – veel breder dan de mogelijkheid om een normatieve kost per ziekte te berekenen – is te weten hoe men kwaliteit (een multidimensioneel concept – inclusief het begrip gepaste indicatie) moet koppelen aan ziekenhuisfinanciering.

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Abbreviations

ACAS	Asymptomatic Carotid Atherosclerosis Study
ACTS	Asyptomatic Carotid Surgery Trial
AF	Alkaline phophatase
ALT	Alanine Amino Transferase, a liver enzyme
APRDRG	All Patients Refined Diagnosis Related Groups
ASA	American Society of Anesthesiologists
AST	Aspartate Amino Transferase, a liver enzyme
ATE	Adenotonsillectomy
BDI	Bile duct injury
Beta-hCG	beta-human chorionic gonadotropin
CBD	Common bile duct
CBDL	Common bile duct lithiasis
CCE	Cholecystectomy
CDI	Color doppler imaging
CDR	Clinical decision rule
CHD	coronary heart disease
CI	Confidence Interval
COPD	chronic obstructive pulmonary disease
CPM	continuous passive motion
CRP	C-reactive protein
CT	Computed Tomography
DBC	Diagnosis-Behandeling Combinatie
D-code	Diagnostic code
DSA	Digital Subtraction Angiography
EBG	Evidence based guidelines
ECG	Electrocardiogram
ECST	European Carotid Surgery Trial
EEG	electroencephalogram
ERCP	Endoscopic Retrograde Cholangio-Pancreatography
ES	Endoscopic sphincterotomy
EUS	Endoscopic ultrasonography
FBC	full blood count
Ftna	full text not available
Hb	hemoglobin
Hct	hematocrit
ICD-9-CM	International Classification of Diseases, version 9, clinical modification
INR	international normalized ratio
IOC	Intra-operative cholangiography
IOUS	Intra-operative ultrasonography
IV	Intravenous
KCE	Federal Health Care Knowledge Centre
LA	laparoscopic appendectomy
LC	Laparoscopic cholecystectomy
LCDDE	Laparoscopic common bile duct exploration
LOS	length-of-stay
LR	likelihood-ratio
MA	meta-analysis
MRCP	Magnetic Resonance Cholangio-Pancreaticography
MRI	magnetic resonance iimaging
MRSA	Methicillin Resistant Staphylococcus Aure
Na	not appropriate
NASCET	North American Symptomatic Carotid Endarterectomy Trial
NSAIDs	non-steroidal anti-inflammatory drugs
OA	open appendectomy
OC	Open cholecystectomy
OCBDE	Open common bile duct exploration
OR-code	Code for operating room procedure
OSA	Obstructive Sleep Apnea Syndrome
PBO	perifeer bloed onderzoek' (full blood count)
PO	Peroral
PPS	Prospective Payement System
PW	Pathway
QA	quality appraisal
QOL	Quality of life
RCT	randomized controlled trial
RCT	Randomized Clinical Trial
RX	Radiography
SE	GallStone extraction

SOI	Severity of illness
SR	systematic review
TE	Tonsillectomy
TENS	Transcutaneous Electric Nerve Stimulation
UAO	Upper Airway Obstruction
UCE	Urea, creatinine, electrolytes
UK	United Kingdom
UOS	Upper Oeophageal Sphincter
URI's	Upper Respiratory Infections
US	Ultrasonography
WBC	white blood cell count
GT	Gamma Glutamyl Transferase, a liver enzyme

1. AN INTRODUCTION TO CLINICAL PATHWAYS

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Clinical pathways are being implemented in many healthcare systems, primarily to improve the efficiency of hospital care while maintaining or improving quality. The aim of this study is to clarify the definition of clinical pathways, to evaluate the results of clinical pathways and reported advantages and disadvantages of working with clinical pathways.

1.1. ORIGIN AND DEFINITION OF CLINICAL PATHWAYS

1.1.1. Origin of clinical pathways

Clinical pathways origin from the critical pathway methodology used for planning of industrial processes such as the "Critical Path Method (CPM)" or "Program Evaluation and Review Technique (PERT)". The first utilization of these techniques in healthcare was found in the seventies. The first more systematic use was found in the New England Medical Center in Boston (USA) in 1985 as a response to the introduction of Diagnosis Related Groups (DRGs) in 1983. DRGs are part of a patient classification system that provides a means of relating the type of patients a hospital treats (i.e., its casemix) to the costs incurred by the hospital[1]. A reference length-of-stay (LOS) and a budget are assigned to each DRG. Clinical pathways, as a method for monitoring processes and processing time, were introduced for reducing LOS and managing costs while maintaining quality of care [2]. In the UK, clinical pathways are primarily seen as tools to implement clinical governance, to streamline the care given, to improve the quality of clinical care and to ensure that clinical care is based on the latest evidence and research[3]. Clinical pathways are nowadays worldwide in use in most healthcare systems.

1.1.2. What's in a name?

Internationally, several alternative terms are used for clinical pathways. De Luc et al. [4] found 17 different names describing the concept 'clinical pathways'. The most frequent used terms were 'clinical pathway', 'critical pathway', 'integrated care pathway' and 'care map'. Other terms used were care pathways, anticipated recovery pathway, and collaborative care plan.

In the Medical Subject Headings (MeSH) database the term "critical pathway" is used and is defined as: "Schedules of medical and nursing procedures, including diagnostic tests, medications, and consultations designed to effect an efficient, coordinated program of treatment"[5] .

In this study the term "clinical pathway" was used, as this term is the most frequently used in Belgium and the international literature. On the other hand, the term "integrated care pathways" is the most common in the UK.

1.1.3. Defining clinical pathways

There is no agreed definition of a clinical pathway. De Bleser et al [6] identified 86 different definitions of the concept 'clinical pathway' in a Medline search between 2000 and 2003. For the present study, a similar methodology was followed. The study was extended from 2000 to 2005, but limited to reviews of clinical pathways only. The following search strategy was used: ["clinical pathway" or "critical pathway" or "integrated care pathway" and "systematic review"]. The search resulted in 124 articles. In 16 studies, a definition about the concept 'clinical pathway' was given (Table 1).

Most of the authors refer to earlier definitions. The agreement on the use of common definitions is rather low. The definition of a clinical pathway varies from a document or an overview, which is rather descriptive, to plans, programs and tools, which are more prescriptive. There is

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agreement that clinical pathways are multidisciplinary and outline the optimal sequence and timing of interventions. Goals are focused on achieving optimal efficiency and improving quality of care. In some definitions, the usability of clinical pathways is limited to "typical uncomplicated patients" or common diseases.

Table 1: Definitions of clinical pathways (Medline search on reviews of clinical pathways 2000-2005) N=16

Author	Definition
Banasiak et al., 2004[7]	Clinical pathways are a systematic approach to guide health care professionals in managing a specific clinical problem (Cabana et al., 1999). They are usually developed for inpatient diagnoses requiring multi-disciplinary inputs and for which care is relatively predictable (Glauber, 2001[8])
Brown, 2004[90]	A critical pathway is a specific disease management strategy that defines essential steps of a complex care process (Ellrodt, 1997[9])
Campbell et al., 1998)[46]	Integrated care pathways are structured multidisciplinary care plans which detail essential steps in the care of patients with a specific clinical problem. They have been proposed as a way of encouraging the translation of national guidelines into local protocols and their subsequent application to clinical practice. They are also a means of improving systematic collection and abstraction of clinical data for audit and of promoting change in practice.
Cannon et al., 2002[82]	Critical pathways are tools that detail processes of care and potential inefficiencies in care. (Every, 2000[81])
Cannon, 2003[47]	Critical pathways are standardized protocols for disease management that aim to optimize and streamline patient care (Cannon, 1999[10])
Ellrodt, 1997[9]	Clinical pathways are tools to coordinate the progress of a 'typical uncomplicated' patient across multiple disciplines and settings over time. (Deignan, 1995[11])
Fleischmann, 2002[12]	Critical pathways are management plans that display goals for patients and provide the sequence and timing of actions necessary to achieve these goals with optimal efficiency. (Every, 2000[81]; Pearson, 1995[13])
Harkleroad et al., 2000[14]	Integrated care pathways are plans of care that outline the optimal sequencing and timing of interventions for patients with a particular diagnosis, procedure of symptom (Ignatavicius & Hausman, 1995[15])
Jones, 2001[16]	A care pathway is defined as a single care document which outlines the problems, interventions and outcomes for a diagnosis-related group.
Jones, 2003[17]	Clinical pathways attempt to incorporate practice parameters into the care of the patients within a defined population. They also attempt to make a relationship between expected outcomes for the patient and a specific time frame within which those actions should occur (Cohen & Cesta, 1997[18])
Kercsmar et al., 2002[19]	Clinical pathways are operational versions of practice guidelines aimed at the hospital management of common disease states.
Kim et al., 2003[85]	Clinical pathways are specified guidelines or outlines for care that describe patient treatment goals and define a sequence and timing of interventions to meet these goals efficiently. (Pearson, 2001[31]) Pathways coordinate the activities of the physicians, nurses, and other staff involved in providing care for patients with a particular diagnosis or procedure. (Macario, 1998[20])
Kwan et al., 2004[82]	A care pathway can be defined as a plan of care that aims to promote organized and efficient multidisciplinary patient care that is based on the best available evidence and guidelines, for a specific condition. It is often implemented with some form of education (Pearson, 1995[13]) and usually forms all or part of the patient record. It documents the care given and can facilitate the evaluation of outcomes for continuous quality improvement (Overill, 1998[21]). A care pathway focuses on the practical delivery of multidisciplinary care in the form of daily written care plans with prompts to highlight important interventions. It is intended to assist healthcare professionals to achieve pre-specified patient goals efficiently while improving quality of care (Hydo, 1995[22]; Lanska, 1998[23]).
Pearson et al., 1995[13]	Critical pathways are multidisciplinary guidelines that display a timeline of clinical goals that patients should attain during hospitalization along with the optimal sequence and timing of interventions by hospital staff to attain those goals. (Zander, 1991[24])
Renholm et al., 2002[85]	Critical pathway is a treatment regimen including time-dependent functions used to standardize the care process throughout a treatment course. Critical pathways are best practice tools for organization and integrating different levels of healthcare delivered by providers from a number of disciplines. CPs involve

	the identification and documentation of the standardized, interdisciplinary processes that must occur for a particular type of patient to move along a continuum towards a desired outcome in a defined period of time. The critical pathway provides an overview of the entire process of care without wasted time and resources. It includes combinations of the following: physician and nurse assessments and interventions, laboratory and diagnostic tests, treatments, consultations, activity level, education of the patient and family, discharge planning, and desired outcomes.
Thomas et al., 2001[25]	Clinical pathways are more detailed programs (than guidelines) that determine not only the care to be given but also the sequence and responsibility; the most common are highly specific with clearly defined "who does what to whom, when" attributes.

1.1.4. How does a clinical pathway work?

A pathway amalgamates all the anticipated elements of care and treatment for a particular condition or disease. It consists of the actual clinical data and often has the form of a grid, indicating a time-scale horizontally and a list of interventions vertically (figure 1).

The clinical pathway as a document is probably not its crucial factor. More crucial is that the entire process of care is discussed, is made explicit and is shared by the interdisciplinary team. Because the process is made explicit, best practices can be discussed, timing and procedures can be planned and scheduled in a better way, desirable outcomes can be set and monitored, capacity and resources can be provided etc. Bandolier [26] concludes in an overview article on clinical pathways that "in industry, clinical pathways would be called something else. A mix, perhaps, of good practice and quality control, plus a large helping of ongoing quality improvement. After all, care pathways involve not one action, but many, often in a complex package of care. In these complex packages, it is the combining of individual interventions in a management framework suited to local needs and abilities that is the critical factor."

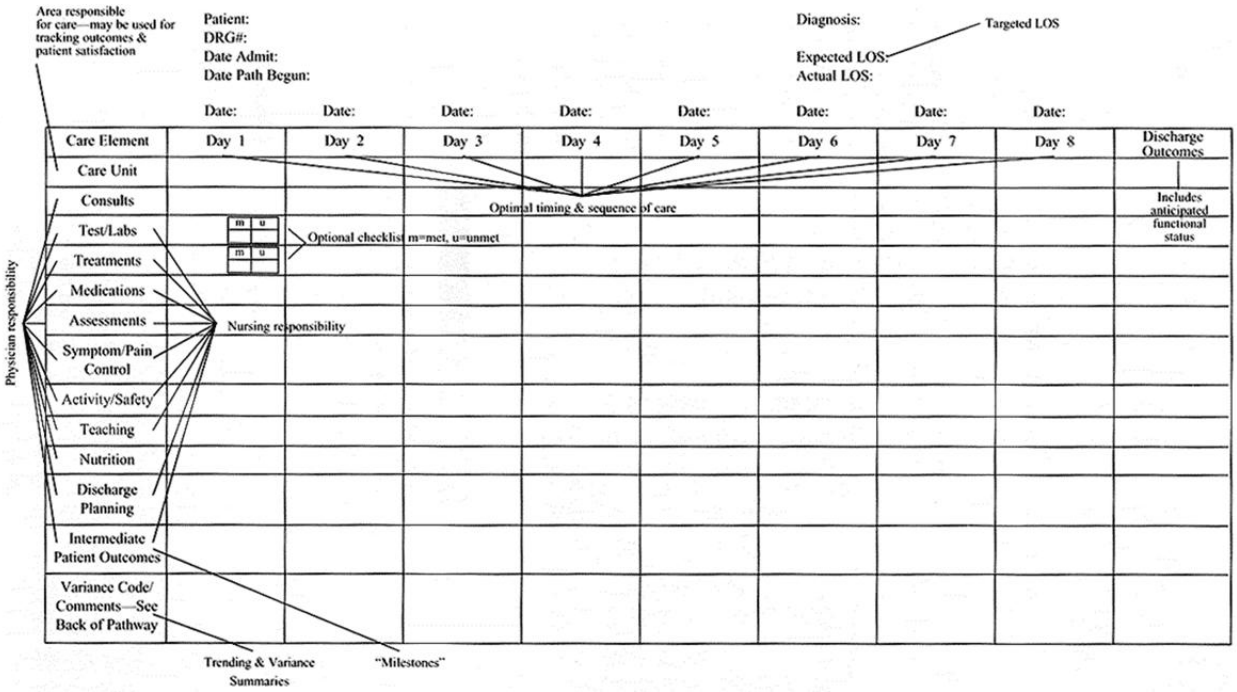


Figure 1: Example of a clinical pathway template (source: Belgian-Dutch Clinical Pathway Network, 2005[27])

1.2. CLINICAL PATHWAYS AND PRACTICE GUIDELINES

According to the Institute of Medicine, clinical guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" [28]. This broad definition is applicable to clinical pathways as well, and some researchers even use both terms as synonyms [29 30 31 32]

Bandolier[26] defines guidelines as statements to ensure that the right patient gets the right treatment. Guidelines are mainly focusing on clinical appropriateness. There is however more to deliver good care than that. It requires good organization to guarantee that the right treatment is given to the right patient at the right time and in the right way. Clinical pathways can contribute by focusing on organizational appropriateness.

A literature search in comparing clinical pathways and guidelines was done in March 2005. In the first place systematic reviews were sought. The following search strategy was used: ["practice guidelines" and "critical pathways"] and ["development" or "quality" or "implementation"]. The searched databases were: the Cochrane Library, Medline, Cinahl and the British Nursing Index. No methodology filters were used in order to conduct a sensitive literature search. We also hand searched the Journal of Integrated Care Pathways.

Both guideline and pathway developers usually follow a stringent framework when developing a clinical guideline [33] or a clinical pathway [34] respectively. Importantly, clinical guidelines and clinical pathways developed within a structured, coordinated programme tend to be of higher quality [35] [36].

Clinical guidelines usually are developed by government agencies[37] [38] [39], institutions[40] [41] or expert panels[42] [43]. One of the main reasons is that guideline development, dissemination and implementation is expensive and time-consuming [44]. However, examples of locally developed guidelines exist [45]. Nevertheless, clinical practice guidelines developed by government-supported organizations tend to be of higher quality [35].

On the other hand, clinical pathways usually are local initiatives and can be used as a means of developing and implementing local protocols of care based on clinical guidelines[46] [39] [47] or to promote the adherence to clinical guidelines [48]. It is mainly done by allocating the right resources to the right patient at the right time. This local characteristic makes clinical pathways less transportable through different hospitals than clinical practice guidelines.

Many studies reported on the poor quality of clinical guidelines[49] [50] [51] [52] . However, since the introduction of several appraisal instruments[53] the methodological quality of clinical guidelines has improved[50] [51] [52] [53] [54], though other reports proof otherwise [49]. A major problem with these appraisal instruments is the lack of content analysis [53], and the danger of appraising a guideline as high-quality despite its poor content.

Unlike clinical practice guidelines, validated appraisal instruments for clinical pathways do not exist, nor do studies comparing the content of clinical pathways. One study reported on the development of an appraisal instrument [55] yet to be further validated. Various authors claim their clinical pathway to be evidence-based[56] [57] [58], but the process of the systematic literature search is rarely described in detail.

Once developed, a guideline has to be disseminated and implemented using appropriate strategies[44]. However, costs and benefits of these dissemination and implementation strategies have to be outweighed[44]. Many controlled trials showed the disappointing effects of various implementation strategies for clinical practice guidelines[44] [59] [60] .

In contrast, because of the local development and the ownership of the development team, implementation of clinical pathways is more successful. However, specific studies concerning this issue were not found. An example of successful implementation of clinical pathways is the Children's hospital in San Diego who received the JCAHO Codman award for Quality in December 2002 for their work on implementing clinical pathways[61]. The Children's hospital was honoured for developing and implementing over 60 clinical pathways. They reported a compliance rate of physicians to the pathways of more than 90 percent (www.chsd.org).

Table 2: Literature Review on development, quality and implementation of clinical guidelines (N=15)

Study	Y	Population/Subject	Intervention	Conclusion	Comments	Study Type
Guidelines						
A. Development						
Burgers et al.[62]	2003	18 guideline development programs	Questionnaire with 32 items based on framework for description of clinical guideline programs	1. Principles of evidence-based medicine have largely affected the methodology of guideline development; 2. Consensus on the essential features of guideline programs is growing; 3. Recent new programs are benefiting from the more advanced methodology created by experienced, longstanding programs; 4. Differences exist with respect to ownership and emphasis on dissemination and implementation; 5. International collaboration should be encouraged; 6. Patient involvement could be improved.	Only programs from countries involved in the AGREE project, with a maximum of 2 programs per country	SR
B. Quality						
Vlayen J et al.[53]	2005	24 appraisal instruments of guidelines	Content analysis and comparison	1. None score the evidence-base of the clinical content of the guidelines; 2. Cluzeau instrument is the most complete appraisal instrument and validated; 3. As a simplified and validated version of the Cluzeau instrument, the AGREE instrument has the potential to serve as a basis for the development of an appraisal instrument for clinical pathways.	Medline, Cinahl and Embase search; personal communication with experts in the field	SR
Hasenfeld R et al.[49]	2003	52 AHCPR guidelines, updates of AHCPR guidelines, or guidelines that referenced or were adapted from AHCPR guidelines	Assessment with Shaneyfelt instrument by 2 independent reviewers	1. 50% of the criteria were present in every AHCPR guideline; 2. The AHCPR guidelines scored 80% or more on 24 of the 30 criteria compared with 14 for the "updates" and 11 for those that referenced/adapted the AHCPR guidelines; 3. All of the 17 AHCPR guidelines had both multidisciplinary development panels and systematic reviews of the literature compared with five from the other two categories; 4. Overall worsening quality in time.		SR
Shaneyfelt TM et	1999	279 guidelines	Assessment with	1. Low adherence to established methodological standards	Medline search	SR

Table 2: Literature Review on development, quality and implementation of clinical guidelines (N=15)

Study	Y	Population/Subject	Intervention	Conclusion	Comments	Study Type
al.[50]			guideline appraisal instrument containing 25 items	2. Improvement over time	Validation study of appraisal instrument	
Harpole LH et al.[51]	2003	51 guidelines for lung cancer	Assessment with AGREE instrument by 5 independent reviewers	1. Of the 51 guidelines evaluated, 27 (53%) were evidence-based. 2. Of the 880 clinical recommendations abstracted from the guidelines, only 253 (29%) were evidence-based. 3. As a group, the guidelines performed well in the scope and purpose domain, with only six guidelines (12%) scoring < 50%. For the remaining domains, however, the guidelines did not perform as well, as follows: for stakeholder involvement, 41 guidelines (80%) scored < 50%; for rigor of development, 29 guidelines (57%) scored < 50%; for clarity and presentation, 17 guidelines (33%) scored < 50%; for applicability, 46 guidelines (90%) scored < 50%; and for editorial independence, 47 guidelines (92%) scored < 50%. After considering the domain scores, the reviewers recommended only 19 of the guidelines (37%).	Thorough search	SR
Van Tulder MW et al.[52]	2004	17 guidelines for the management of acute low back pain	Assessment with the AGREE instrument by 3 independent reviewers	1. Overall disappointing quality; 2. Domains least often addressed were: applicability and editorial independence; 3. Seldom addressed items were: potential organizational barriers and cost implications, review criteria for monitoring or audit purposes, potential conflicts of interest; 4. Low scores on the rigor of development domain.	Medline and internet search; personal communication with experts in the field	SR
Worrall et al.[45]	1997	13 trials about effect of guidelines in primary care; 10 RCT's		There is very little evidence that the use of CPGs improves patient outcomes in primary medical care, but most studies published to date have used older guidelines and methods, which may have been insensitive to small changes in outcomes. Research is needed to determine whether the newer, evidence-based CPGs have an effect on patient outcomes		SR

Table 2: Literature Review on development, quality and implementation of clinical guidelines (N=15)

Study	Y	Population/Subject	Intervention	Conclusion	Comments	Study Type
Bahtsevani et al.[63]	2004	8 studies about effect of guidelines; 1 controlled clinical trial		Tendency toward support for the idea that outcomes improve for patients, personnel, or organizations if clinical practice in health care is evidence-based, that is, if evidence-based clinical practice guidelines are used, although these findings could be specific to the settings and context of the studies reported in this systematic review	Heterogeneous studies	SR
Du Pen SL et al.[64]	1999	81 cancer patients	Guideline (algorithm) vs. standard care	Less pain Better adherence to chemotherapy Prescriber adherence to guideline was correlated with patient outcome		RCT
Tinelli C et al.[65]	2003	123 patients with COPD	YES-GL vs NO-GL	No change in clinical evolution of COPD patients	Only abstract viewed	RCT
Katz DA et al.[66]	2004	2163 adult smokers	Guideline vs no guideline	Higher abstinence during intervention period for guideline-treated smokers	Only abstract viewed	RCT
Bousquet J et al.[67]	2003	465 patients with seasonal allergic rhinitis	Guideline vs no guideline	Significant improvement compared to patients treated with not-standardized therapy		RCT
C. Implementation						
Grimshaw JM et al.[44]	2004	235 studies about the effectiveness and costs of different guideline development, dissemination and implementation strategies		1. Lack of evidence to support decisions about which guideline dissemination and implementation strategies are likely to be efficient under different circumstances; 2. Decision makers need to consider the potential clinical areas for clinical effectiveness activities, the likely benefits and costs required to introduce guidelines and the likely benefits and costs as a result of any changes in provider behaviour; 3. Further research is required.		SR

Table 2: Literature Review on development, quality and implementation of clinical guidelines (N=15)

Study	Y	Population/Subject	Intervention	Conclusion	Comments	Study Type
Baker R et al.[59]	2003	81 general practices 3 implementation strategies	Dissemination of full guidelines, reduced guidelines in the form of prioritized review criteria, and review criteria supplemented by feedback	The dissemination of guidelines in the format of prioritized review criteria does not increase adherence to recommendations in comparison with the traditional guideline format, and the further provision of feedback has minimal additional effect		RCT
Davis J et al.[60]	2004	68 general practices 3 implementation strategies	Postal dissemination of a nationally developed clinical guideline; postal dissemination of the guideline supported by interactive, accredited workshops, and dedicated, structured protocol documents; intermediate intervention plus a nurse specialist who supported and educated practices in the establishment of epilepsy review clinics.	None of the intervention groups showed any change in the primary or secondary outcome measures or process-of-care measures.		RCT

Table 3: Literature review on development, quality and implementation of clinical pathways (N=9)

Clinical pathways						
A. Development						
Harkleroad A et al[12]	2000	9 approaches to critical pathway development			Only abstract viewed Focus on occupational therapists	SR
B. Quality						
Whittle CL et al.[55]	2004	Integrated Care Pathway appraisal tool	Validation study 68 appraisers	Crohnbach's alpha ranging from 0.77 to 0.96		
Kwan J et al.[83]	2005	3 RCTs, 12 nonRTs on stroke		Both positive and negative effects	Heterogeneous studies	SR
Kim J et al.[86]	2003	1 RCT, 10 historical controls (TKR and THR)		Shorter hospital stay and lower costs Comparable clinical outcomes	Heterogeneous studies	SR
Banasiak NC et al.[7]	2004	5 studies (1 RCT)		Reduced hospitalization costs Little reported improvement in clinical outcomes	Heterogeneous studies	SR
Feagan et al.[57]	2001	1743 patients with community-acquired pneumonia, treated in 19 hospitals	Conventional management vs. clinical pathway	No significant differences in clinical outcomes Lower number of bed days/ patient managed Fewer admissions of low-risk patients Cost savings in intervention group		RCT
Kim MH[68]	2002	18 patients with atrial fibrillation	Traditional approach of hospital admission vs. an accelerated emergency department-based strategy with low-molecular-weight	Shorter length of stay at potentially lower cost in intervention group	Small population	RCT

			heparin and early cardioversion to sinus rhythm			
Delaney CP et al.[69]	2003	64 patients undergoing laparotomy	Pathway of controlled rehabilitation vs. standard postoperative care	Pathway patients had a shorter hospital stay, with no adverse effect on patient satisfaction, pain scores, or complication rates. Patients younger than 70 years of age derived the optimal benefit, and increased surgeon experience improved outcome		RCT
Johnson et al.[70]	2000	110 patients with asthma	Conventional ward vs. ward using clinical pathway	Shorter length of stay and less nebulised beta-agonist therapy in intervention group		RCT

1.3. EFFECTS OF CLINICAL PATHWAYS

To evaluate the effect of clinical pathways, a literature search was performed by searching the Medline (2000-2004), the Cochrane Library, Cinahl, the British Nursing Index for reviews on the use and effects of clinical pathways. We used "Critical Pathways" [MeSH] AND "evaluation" as search terms. We also conducted a hand search of the Journal of Integrated Care Pathways (2001-2005). Finally, the references of the selected reviews were searched. Eleven review publications, which are frequently cited in the literature, were selected.

1.3.1. Description of the methods for evaluating the effect of a clinical pathway:

The effect of clinical pathways can be evaluated by measuring quality indicators or outcomes, by analysing variances, or by interviewing professionals and patients on their perception on pathway effectiveness.

Quality indicators and outcomes can be grouped according to their focus on clinical quality, patient satisfaction, team effectiveness, efficiency or cost. Examples of tools grouping quality indicators and outcomes are the Leuven Clinical Pathway Compass [71], Balanced Scorecard® [72], the Clinical Value Compass [73] and DataMap® [74].

In a scientific context, measuring quality indicators or outcomes for the evaluation of clinical pathways requires an appropriate design. An experimental design which is the golden standard of clinical research is not frequently used in the evaluation of clinical pathways. It is partly due by the complexity to evaluate the organizational impact of clinical pathways. Patients can easily be randomized in pathway and non-pathway groups. It is much more difficult to randomize the multidisciplinary staff in dealing with these patient groups. Some studies are solving this issue by randomizing between hospitals or departments. This procedure doesn't exclude however all confounding variables that are embedded in the differences between hospitals or departments.

More often, a quasi-experimental design is used, carrying risks for selection bias and history and Hawthorne effects. The risk of selection bias by using a historical control group is well discussed by Trowbridge et al. [75]. The risk for a history effect is illustrated by Holmboe et al. [76], who analysed the reduction of LOS in 32 Connecticut hospitals. Comparing pre- and posttest, a significant reduction in LOS was found in the hospitals that were using clinical pathways. The reduction in LOS was however not significant greater in pathways hospitals compared with non-pathway hospitals, because of a general trend towards a reduction of LOS in all hospitals. In some studies, the internal validity of the design is increased by using control groups, time series designs or cross-over designs.

Variance analysis is a second method to evaluate clinical pathways. Any deviation from the pathway is documented as a `variance'. The term `variance' in the pathway context should not be confused with its statistical meaning. In the pathway context, variance analysis is the in-built system for recording unexpected events which occur during patient care. These data can be used to review, update and improve clinical and organizational practices. By monitoring and reviewing the variances, the pathway becomes a dynamic tool. A consensus exists in the literature on four types of variances: 1) variances due to patient needs, 2) variances due to the health care worker's decision, 3) variances due to the system or the organization and 4) variances due to the community [77].

A third method to evaluate clinical pathways is interviewing professionals and patients on their perception on pathway effectiveness. Various methods can be used, such as interviews, focus groups, surveys, etc. [78] [79].

1.3.2. Overview of the results of evaluation studies of clinical pathways:

Several studies reported on the positive effects of clinical pathways on clinical outcome. In a narrative review by Vanherck et al. [84] 65,5% of the included studies reported a positive effect, while 32% reported no effect and 2,4% a negative effect. Bandolier [26] reported on improved clinical outcomes for hip and knee replacements, fractured neck of femur, inpatient asthma management, community acquired pneumonia, heart failure, community acquired lower

respiratory track infections, bronchiolitis, and caesarean section. Hindle & Yazbeck [80] described positive effects on quality of care and patient outcomes for geriatric patients with depression, patients undergoing regional anaesthesia for outpatient orthopaedic surgery, pain management, neonatal intensive care, peri-operative settings, amputation, elective infrarenal aortic reconstructions, urology patients, inpatient asthma care and hip and knee arthroplasty.

In contrast, Bryson & Browning [79] found very little evidence of improved outcomes. Every et al. [81] reported no change in clinical outcome or readmission rate. Only one of the six publications in this review reported a decreased rate of nosocomial infections[81]. Also, Cannon et al. [82] found no trials that reported improved clinical outcomes for patients with acute coronary syndromes. Finally, Kwan & Sandercock [83] found that the use of stroke care pathways may be associated with positive (lower complication rate) and negative effects (quality of life).

Besides the effects on clinical outcome, clinical pathways are effective in reducing the costs of care. In the review by Vanherck et al.[84] 82,5% of the studies reported a positive effect on reducing costs, while 13,5% described no effect and 4% a negative effect [84]. Hindle and Yazbeck [80] reported a decrease of costs for the following conditions: acute appendicitis, aortic aneurysm surgery, treatment of alcohol withdrawal syndrome, prostatectomy, colostomies and ileostomies, outpatient tonsillectomy and adenoidectomy, acute chest pain and low-risk myocardial ischemia, peri-operative care for knee replacement surgery, total colectomy and ileal pouch/anal anastomosis, severe traumatic brain injury, gastric bypass or laparoscopic adjustable gastric banding, total hip replacement, major thoracic procedures, renal transplantation, acute exacerbations of bronchial asthma, coronary artery bypass surgery, major vascular procedures, pneumonia and decubitus ulcers. In a scientific statement for The American Hearth Association by Every et al. [81] a decreased LOS and cost were described. A review on acute coronary syndrome pathways [82] found a reduction in LOS in the emergency department and the intensive care unit, but also a reduction of the entire LOS. Bandolier described positive effects on LOS and costs for different patient groups without compromise in patient outcomes [26]. Renholm et al.[85] reported positive effects on LOS for short stay surgery, while Kim et al. [86] described lower costs and LOS for total knee and hip arthroplasty.

Dy et al. [87] evaluated 48 clinical pathways at the surgery department of the Johns Hopkins Hospital, covering 40% of the admissions. They found that clinical pathways were effective in reducing postoperative LOS for only 27% of the surgical procedures [87]. In 2005, Dy et al. published a follow-up study to identify patient characteristics on the one hand and hospital care and clinical pathway characteristics on the other hand associated with pathway effectiveness in reducing LOS [88]. Clinical pathways associated with a reduced LOS had at least one of the following characteristics: 1) no pre-existing trend toward lower LOS for the procedure (71 percent), and/or 2) no previous clinical pathway implemented in its surgical service (71 percent). In addition, clinical pathways that were effective in reducing LOS tended to be for procedures with a lower severity of illness, as indicated by fewer intensive care days and lower mortality [88].

Clinical pathways also have positive effects on patient satisfaction. In the review by Vanherck et. al., 62,2% of the studies reported a positive effect on patient satisfaction, while 29,7% reported no change and 8,1% a negative effect [84]. Bandolier reported an increased patient satisfaction concerning pain control after caesarean section [26]. Renholm et al. [85] reported an improvement in patient satisfaction and patient education for clinical pathways in ambulatory surgery. Bryson and Browning [79] found a higher satisfaction, less anxiety and better understanding in patients cared for using clinical pathways. On the other hand, Kwan and Sandercock [83] reported a significantly lower patient satisfaction in stroke patients.

Van Herck et al. [84] also reported on positive effects on teamwork after the implementation of the clinical pathway (83,3% of the studies). Hindle and Yazbeck [80] reported a positive effect on stress and frustration, improved communication and improved briefing between nurses during the change of shifts. Also, an improvement in staff education, the introduction of new staff, and collective multidisciplinary learning was reported [80]. Bryson and Browning [79] found that clinical pathways were good educational tools for new staff, mainly for nurses and allied health professionals. However, a strong disagreement was found between staff members about the fact that clinical pathways improved communication [79].

Finally, a positive effect on the process outcomes after the introduction of a clinical pathway in 86% of the included studies is reported. No effect or negative effects were found in 7% of the studies respectively [84]. Cannon et al. [82] reported an improvement in the appropriate use of the

recommended medications, a decrease in unnecessary tests and improved timing of procedures in acute coronary syndrome patients. Bandolier [26] reported a reduction of the prescription of laboratory tests with 70% without an impairment of patient care. A more standardized use of antibiotics and of laboratory testing was reported by Trowbridge et.al. [75]. Bryson & Browning [79] reported an improved documentation in patient records and a reduction in the time spent on documentation. On the other hand, a number of health care workers in this study mentioned a reduction in the continuity of daily recording and in the detail of the record of nursing care. In the same study strong evidence was found for a decrease in duplication of documentation, leading to time benefits [79]. Renholm et al. [85] reported an improvement in continuity of care and in continuity of information in their systematic review on 53 clinical pathways.

As discussed in a previous review [84], the methodologies used to assess the effects of clinical pathways are often criticised, given the research designs and sample sizes. Several potential sources of bias are present. Only a few large multicentre studies with an appropriate design are available.

Table 3: Literature review on the effect of clinical pathways (N=11)

Author / Affiliation	Y	Population/Aim	Method (N_E= Number of patients in pathwaygroup)	Conclusion	Comments	Study Type
Bandolier[26]	2003	15 selected pathways	7 RCTs (6 within organization, 1 among 19 hospitals) 3 pre- post-test (1 historical control, 1 time series design) 5 unclear designs (N_E = 1119)	- positive clinical effects for multiple patient groups - increase patient satisfaction over pain control in caesarean section - risk for cookbook medicine by healthcare workers - reduction in laboratory test - standardised use of antibiotics - positive effect on length of stay - positive effect on cost	A selection of pathways to show effect No systematic review	R
Bryson & Browning (Scottish Clinical Resource and Audit Group (CRAG))[90]	1999	133 clinical pathways in 2 hospitals	20 pathways were selected and assessed by document analysis, staff and patient questionnaires. Pre- post evaluation (80 cases / pathway) (N_E = 800)	- very little evidence of positive effect on outcome - high patient satisfaction - less patient anxiety - improved understanding - strong disagreement of staff members that pathways improved communication - good educational tools for new staff mainly for nurses and allied health professionals - improved documentation - reduction in time to documentation - some teams: reduction in continuity and detail in the nursing record and more paper work - improved continuity - some pathways showed reduction in length of stay, some no change - reduced inappropriate variation from the optimum length of stay	Evaluation based on indicators & guidelines (SIGN, etc.)	CS
Cannon (National Heart Attack Alert Program)[82]	2002	Diagnostic & treatment pathways for management of patients with acute coronary syndromes	Systematic review in Medline, textbooks, articles Number of pathways evaluated is unclear	- no trial identified with improvement of clinical outcome - increased participation in clinical research - improvement in use of recommended medication and timing of interventions - decrease in unnecessary tests and procedures - providing guidance on timing of cardiac procedures - decreased hospital length of stay in the emergency		SR

Author / Affiliation	Y	Population/Aim	Method (N_E= Number of patients in pathwaygroup)	Conclusion	Comments	Study Type
				department, intensive care unit and hospital stay		
Darer et al[89]	2002	Survey on use of clinical pathways in hospitals	Survey to hospital administrators in 41 hospitals (13 academic medical centres, 13 community teaching hospitals, and 15 community hospitals.	- most hospitals evaluate at least 1 clinical outcome - 10% of academic and community teaching hospitals did not evaluate pathways on clinical outcome - in hospital mortality most commonly used - patient satisfaction only measured in minority of hospitals - one or more economic outcomes were measured in 100% of academic hospitals, 92% of community teaching hospitals and in 67% of community hospitals - 85% of all hospitals measured length of stay - 74% measured total hospital cost		Survey
Every et al (American Hearth Association)[81]	2000	6 clinical pathways & 8 clinical protocols in cardiology	Clinical pathways: 2 RCTs, 2 pre-post design, 2 designs unclear (N_E = 481) Clinical protocols:4 RCT, 1 pre-post design; 3 observational	- no change in clinical outcome or readmission rate - decreased rate of nosocomial infections in one of six publications - decreased length of stay - decreased cost		SR
Hindle & Yazbeck (European Health Property Network)[93]	2004	Report on the use of clinical pathways	EU-survey to key-respondents (17 out of 25 EU-countries; N=50)	- positive effects for multiple patient groups - positive effect on frustration and stress - improved communication and handover between nurses at change of shifts - improvement in staff education, introduction of new staff and multidisciplinary learning - decrease in repetition of tests and interventions - improvement in execution of necessary interventions - increase in patients on the most appropriate hospital ward - possible positive effect on legal risk - decrease in length of stay for multiple patient groups - decrease in cost for multiple patient groups		Survey

Author / Affiliation	Y	Population/Aim	Method (N_E= Number of patients in pathwaygroup)	Conclusion	Comments	Study Type
Kim et al.[86]	2003	11 pathways on hip and knee arthroplasty	7 historical controls 3 historical & concurrent controls 1 RCT (N_E = 2301)	- positive, negative and no effect on complication rate - improvement and no change in functional outcome - positive effect on length of stay - positive effect on cost		SR
Kwan & Sandercock [83] (Cochrane Review)	2004	15 pathways for stroke rehabilitation	3 RCT (N=340) and 12 non-experimental studies (N=4081)	- positive effect on some complications, no change in others - negative effect on quality of life - improvement in readmission rate - decrease in patient satisfaction - more early neuroimaging - no difference in quality of documentation - no difference in hospital length of stay - no difference in hospital cost		SR
Renholm et al. [85]	2002	53 pathways projects for ambulatory care	Designs are not reported Report on method of evaluation (patient chart reviews (N=31); structured questionnaires (N=12); combinations (N=6)	- improvement in quality of care and complications in some studies - increase in patient satisfaction and patient education - improvement in continuity of care and continuity of information - positive effect on length of stay for short stay surgery		SR
Trowbridge & Weingarten [75] (Agency for Healthcare Research and Quality)	2001	Evaluation of clinical pathways for patient safety (8 clinical pathways)	4 RCTs other: pre-post, historical control	- positive effect on complication rate - no change for other indicators - more standardised use of antibiotics and laboratory tests - positive and negative effects on length of stay and		SR
Van Herck et al. [84]	2002	200 publications on pathways	No selection on the design 4,5% RCTs, 45% pre-post studies, 17,5% observational studies, 4,5% SRs, 10%	- Effect on clinical outcome: evaluated in 65.5% of publications: 65.5% positive effects; 32% no change; 2.4% negative effects - Effect on service/ patient satisfaction: evaluated in 18.5% of publications: 62.2% positive effects; 29.7% no change; 8.1% negative effects		SR

Author / Affiliation	Y	Population/Aim	Method (N_E= Number of patients in pathwaygroup)	Conclusion	Comments	Study Type
			perceptions & opinions Sample size varying from 100 to more than 1000 subjects; 26% sample size is unclear; 7% multicentre	- Effect on team effectiveness / job satisfaction: evaluated in 24% of publications: 83.3% positive effects; 6.3% no change; 10.4% negative effects - Effect on process (efficiency): evaluated in 50.5% of publications: 86% positive effects; 7% no change; 7% negative effects - Effect on financial outcome (cost, length of stay): evaluated in 63% of publications: 82.5% positive effects; 13.5% no change; 4% negative effects		

1.4. USE OF CLINICAL PATHWAYS FOR FUNDING?

The goal of clinical pathways is to provide appropriate and effective health care and to reduce variation in practice [28 46]. It is considered as an effective means of reducing health care costs [90 91 92].

The two most commonly used methods base payment rates on the estimated actual average cost in a recent period or negotiation in the marketplace. Often a combination of these two methods is used. A third method - becoming increasingly common - is that of basing the payment rate on the estimated cost of providing care in a cost-effective way (which might be larger or smaller than the average cost in a recent period) [93]. This estimate of cost is known in most industries as the 'standard cost'. In the context of health care, the standard cost simply is what ought to be incurred by a well-managed clinical team, allowing for all the realities including insufficient resources to deliver best-practice care. A clinical pathway obviously is a good basis for calculating the standard cost, because it has been deliberately designed to represent a good quality care in the circumstances of continual scarcity of resources. Crucial is that the cost of normal cases (which are following the pathway) is complemented with the cost of the variances such as an extra day of stay, another radiology procedure, or an additional consultation. It takes into account variations according to patient needs, choices and expectations, appropriate changes in treatment, unavoidable risks and complications, etc. It is evident that these standard costs need to be validated.

As was shown earlier, there is literature on how clinical pathways can help to reduce costs and to maintain or improve the quality of care. Clinical pathways can also be used as a protection against funding decisions from health insurers such as arbitrarily reducing the prospectively determined price of the accepted LOS of a given DRG [94].

The literature on how clinical pathways are contributing to funding or contracting is however very limited or non-existing. This is possibly due to the fact that contracting information between purchasers and providers is not frequently reported in the public domain or in the scientific literature.

1.5. CONCLUSIONS

Clinical pathways are defined as problem-specific management plans which delineate key steps along an optimal timeline to achieve a set of described intermediate and ultimate patient goals as guidance for a multidisciplinary team. Whatever term is used (such as care paths, integrated clinical pathways, care maps, and anticipated recovery pathways), all try to increase efficiency by better organizing the care delivery process. As a result of early reports of critical pathway success, many institution and hospital administrators eagerly implemented pathways.

Although there are indications that clinical pathways have a positive effect on clinical outcome, patient satisfaction, efficiency, team effectiveness, job satisfaction and reduction of cost and LOS, the evidence is not unambiguous. There is a lack of well-designed studies analyzing the extent to which clinical pathways change clinical behaviour and patient outcomes. The vast majority of the studies describes the implementation of a pathway for a specific mostly surgical procedure and uses historical controls and poor designs. An important limitation is that the "pathway treatment" is not always described in detail so that differences between the experimental and control group are not easy to interpret. The development of validated, standardized clinical indicators is needed to enable the evaluation of the effects of clinical pathways in a more systematic way.

Clinical pathways do not always lead to an improvement of patient care. Although clinical pathways are intended to increase the quality of the multidisciplinary teamwork and the quality of care, a vast amount of pathway projects are only evaluated on economic parameters, such as LOS. This is mainly due to the specific aim of introducing some clinical pathways. If the main goal is to reduce the LOS without compromising quality of care, one cannot expect the clinical outcomes or the patient safety to improve significantly.

Despite the uncertainties about their development, implementation and evaluation, we noticed that clinical pathway programs are disseminated rapidly in hospitals throughout the world. This

reflects the need to improve the organizational effectiveness in order to meet the high pressure of budget constraints, patient expectations and professional standards.

As many health care systems worldwide are moving to output-based payment systems (e.g. DRGs), high pressure exists to use clinical pathways not only as an organizational answer on external requirements and expectations, but also as a tool for setting and negotiating contracts between purchasers and providers. Since few studies are available in the public domain or in the scientific literature, an in-depth analysis of case-studies is recommended.

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2. THE USE OF CLINICAL PATHWAYS IN BELGIUM

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2.1. INTRODUCTION

Clinical pathways are becoming more and more imbedded in the daily practice of health care. However, few studies evaluated the attitude of health care workers towards clinical pathways. A Scottish study reported on a three year project which resulted in successful development, implementation and evaluation of over hundred integrated care pathways (ICPs) in an urban teaching hospital and a district general hospital in Glasgow[1]. Through staff and patient questionnaires clear benefits of working with ICPs were demonstrated and only few disadvantages were identified. Based on their results, the authors praised ICPs as a clinical management tool with great potential. A European survey in 17 countries showed that clinical pathways are important and valuable tools, but that European countries differ in terms of progress[2]. The authors also concluded that many health professionals have only vague ideas about clinical pathways. An American cross-sectional survey of 41 hospitals showed wide variations in the use of clinical pathways between academic and community hospitals [6]. Eighty-three percent of the surveyed hospitals used at least one clinical pathway, with a higher median number of clinical pathways for academic than for community hospitals. The most commonly used clinical pathways in this survey were for community-acquired pneumonia, total hip or knee replacement and stroke or transient ischemic attack.

Little is known about the use of clinical pathways in Belgian hospitals. However, some initiatives are taken to stimulate the use of clinical pathways. In the Dutch speaking region of Belgium, the Centre of Health Services and Nursing Research of the Catholic University Leuven launched the Belgian Dutch Clinical Pathway Network in 2000 to support hospitals in developing, implementing and evaluating clinical pathways[3]. Thirty-eight Flemish acute hospitals, next to five homecare organizations and three rehabilitation centers, are actually member of this network. In 2004, the initiative was extended to the French speaking region in collaboration with the Université Catholic de Louvain (Brussels) and the Christian Insurers fund. The Belgian government also supports the use of clinical pathways by launching calls for proposals on the development of clinical pathways in the context of BIOMED. In response to a first call of proposals on surgical procedures in 2002, six projects were started. After a second call for clinical pathways on dementia care in 2003, another four projects were started. A last call was launched on clinical pathways for obesity and related conditions in 2005. Six additional projects were started.

From various contacts, we hear that some hospitals are developing clinical pathways on their own and other hospitals are not using clinical pathways at all. This study aims to identify the actual and potential use of clinical pathways in the Belgian hospitals. In this chapter, only the results of the acute hospitals will be discussed.

2.2. METHODOLOGY

2.2.1. Design and sample

A survey was used to identify the actual and potential use of clinical pathways in Belgian hospitals. The survey was sent to 129 acute Belgian hospitals, of which 69 are predominantly Dutch speaking and 60 are predominantly French speaking. Thirty-one Flemish hospitals are member of the Belgian-Dutch Clinical Pathway Network (CPN). The questionnaire was addressed to the hospital executives in October 2004, with one subsequent reminder in December 2004 to nonresponders.

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Sixty-six hospitals responded to the survey, five hospitals refused to participate, and fifty-eight hospitals didn't respond at all (table 4). The reasons given for not participating were: no current use of clinical pathways (n = 2), no experience (n = 2) or other priorities (n = 1). The response was significantly lower in the French speaking sample (table 4). Of the Network hospitals three didn't respond.

Table 4: Response to the survey for acute hospitals.

	Hospitals addressed	Participating hospitals	Hospitals that refused to participate	Hospitals that didn't answer	Chi-square
Total	129 (100%)	66 (51%)	5 (4%)	58 (45%)	
Dutch speaking	69 (53%)	43 (62%)	1 (1%)	25 (36%)	p = 0.015
French speaking	60 (47%)	23 (38%)	4 (7%)	33 (55%)	
CPN	34 (26%)	31 (91%)	-	3 (9%)	

2.2.2. Methods and structure of the survey

The survey was first prepared in Dutch and translated afterwards into French. Because of the fact that there is no agreed definition of clinical pathways, the definition used in the Medical Subject Headings database was provided: 'Schedules of medical and nursing procedures, including diagnostic tests, medications, and consultations designed to effect an efficient, coordinated program of treatment'[4]. This is a broad definition allowing for a greater sensitivity in describing clinical pathways.

To get an idea about the size of the hospital, an estimation of the number of inpatients, one-day patients and patients in ambulatory rehabilitation was asked. An estimation of the actual percentage of patients admitted within the context of clinical pathways and the percentage of patients that theoretically can be cared for with a clinical pathway were asked.

In case the hospital did not use clinical pathways, the intention of using clinical pathways in the future was asked. Hospitals that were already using clinical pathways were given additional questions: how they got in contact with clinical pathways, what term they were using internally, the number of transmural clinical pathways in use, the number of health care workers involved in the clinical pathways, the coordination of clinical pathways, the integration of clinical pathways in patient records, the use of performance indicators, the advantages and disadvantages of working with clinical pathways. The hospital executive was also asked to grade the strategic importance of clinical pathways in his hospital on a scale of 0 (not important) to 10 (very important). Finally, a list of all clinical pathways in use was asked and categorized according to the Major Diagnostic Categories (MDC) classification.

2.2.3. Reliability analysis

To distinguish clinical pathways from other methods, such as protocols and guidelines, the Federal Health Care Knowledge Centre was able complementary to the survey to retrieve a number of documents stated to be clinical pathways from the participating acute hospitals. The Federal Health Care Knowledge Centre distributed for this purpose a letter to all hospitals in Februari 2005 via the official hospital organizations by which the inventory of the first survey could be validated and by which a number of documents stated to be clinical pathways could be retrieved from the participating acute hospitals. Three reviewers examined the documents on the presence of three key characteristics of clinical pathways: a time line, multidisciplinary work, detailed overview of interventions (who-what-when).

2.2.4. Statistical analysis

All data were registered and analyzed using the statistical software SPSS 10.5. Results are predominantly given as frequencies, means and standard deviations were calculated for continuous variables. The Chi-Square Test was used to test for differences between groups for categorical data. Kruskal-Wallis Test, Mann-Whitney U Test and t-test were used to test for differences between groups for ordinal/continuous data. $P < 0.05$ was considered significant.

2.3. RESULTS

2.3.1. Use of clinical pathways

Overall, 73% of the Belgian acute hospitals use clinical pathways. Clinical pathways are more frequently written in Dutch than in French (84% vs. 52%, $p = 0.006$).

Hospitals using clinical pathways have relatively more one-day admissions than hospitals not using clinical pathways (table 5). Hospitals using clinical pathways tend to be larger. There is no significant difference based on the number of beds (table 6), but there is a significant difference on the yearly number of inpatients. 85% of the hospitals that are using clinical pathways admit more than 10000 patients per year compared with 44% of the hospitals that are not using clinical pathways ($p < 0.001$).

Table 5: Number of patients on a yearly basis in acute hospitals.

	Inpatient care	Day care	Ambulatory rehabilitation	Chi-square
Total	1042741 (56%)	779479 (42%)	33402 (2%)	
Dutch	670662 (53%)	555323 (44%)	31828 (3%)	p < 0.001
French	372079 (62%)	224156 (37%)	1574 (1%)	
CPs	860906 (56%)	651376 (42%)	27537 (2%)	p < 0.001
No CPs	181835 (58%)	128103 (41%)	5865 (1%)	

Table 6: Size of acute hospitals according to number of beds (mean ± SD)[5].

	beds	
Total	490 ± 346 (n=66)	t-test
Dutch	481 ± 389 (n=43)	p = 0.73
French	508 ± 254 (n=23)	
CPs	523 ± 377 (n=48)	p = 0.12
No CPs	401 ± 231 (n=18)	

The number of clinical pathways used per hospital varies importantly, ranging from 0 to 32 (table 7). Larger hospitals (≥ 10000 hospitalizations/year) use significantly more clinical pathways than smaller hospitals (5,9 ± 8,0 vs. 2,1 ± 3,8, $p = 0.018$).

Table 7. Number of clinical pathways per hospital (mean ± SD (range)).

Total (n=48)	6,5 ± 7,8 (1 – 32)	t-test
Dutch (n=36)	6,7 ± 7,6 (1 – 30)	p = 0.81
French (n=12)	6,0 ± 9,0 (1 – 32)	
CPN (n=35)	6,7 ± 8,1 (0 – 30)	

Almost 80% of the hospitals that use clinical pathways estimate the actual amount of patients cared for in a clinical pathway 10% or less; only 2% estimate it higher than 30% (table 8). On the other hand, 55% of the hospitals estimate that more than 40% of all patients theoretically can be included in a clinical pathway (table 9).

Dutch speaking hospitals estimate the amount of patients theoretically benefiting from clinical pathways higher than French speaking hospitals. The same is true for hospitals using clinical pathways vs. those not using clinical pathways (table 9).

Table 8: Estimated percentage of patients actually cared for using CPs (only for the acute hospitals using CPs).

	0-5%	6-10%	11-15%	16-20%	21-25%	26-30%	> 30%	Mann-Whitney U-test
Total (n=47)	53%	26%	11%	4%	2%	2%	2%	
Dutch (n=43)	63%	23%	9%	2%	2%	-	-	p = 0.34
French (n=20)	70%	10%	5%	5%	-	5%	5%	
CPN (n=31)	61%	26%	10%	-	3%	-	-	

Table 9: Estimated percentage of patients that theoretically can be cared for by using CPs (acute hospitals).

	0%	1-20%	21-40%	41-60%	61-80%	81-100%	Mann-Whitney U-test
Total (n=59)	3%	19%	24%	39%	14%	2%	
Dutch (n=41)	-	17%	20%	49%	15%	-	p = 0.043
French (n=18)	11%	22%	33%	17%	11%	6%	
CPN (n=29)	-	14%	17%	59%	10%	-	
CPs (n=45)	-	20%	20%	47%	11%	2%	p = 0.038
No CPs (n=14)	14%	14%	36%	14%	21%	-	

2.3.2. Use of clinical pathways according to the MDC classification

Three hundred and ten clinical pathways are reported by the hospitals to be actually in use. Of the 310 identified clinical pathways, the largest part was developed in MDC 8 (20.0%), followed by MDC 14 (10.0%), MDC 5 (10.0%), and MDC 1 (9.0%) (table 10). Nineteen hospitals (40%) use a clinical pathway concerning normal delivery and stroke (table 11). Other clinical pathways frequently used are: total hip arthroplasty (33%), total knee arthroplasty (33%) and breast carcinoma (21%).

For the surgical pathways in particular, the number of clinical pathways per MDC and APR-DRG is provided in detail in table 12. Most frequently, surgical clinical pathways are developed within MDC 8 (36%). 22% of the surgical clinical pathways are developed for APR-DRG 302. Total hip and total knee arthroplasty are the most frequently developed surgical clinical pathways (10% of the surgical clinical pathways).

Table 10: Number of CPs per MDC category (% of total).

MDC 1: Nervous system	28 (9.0%)
MDC 2: Eye	5 (1.6%)
MDC 3: Ear, nose, mouth and throat	11 (3.5%)
MDC 4: Respiratory system	10 (3.2%)
MDC 5: Circulatory system	31 (10.0%)
MDC 6: Digestive system	20 (6.5%)
MDC 7: Hepatobiliary system and pancreas	6 (1.9%)
MDC 8: Musculoskeletal system and connective tissue	62 (20.0%)
MDC 9: Skin, subcutaneous tissue and breast	11 (3.5%)
MDC 10: Endocrine, nutritional and metabolic diseases and disorders	19 (6.1%)
MDC 11: Kidney and urinary tract	6 (1.9%)
MDC 12: Male reproductive system	14 (4.5%)
MDC 13: Female reproductive system	12 (3.9%)
MDC 14: Pregnancy, childbirth and puerperium	31 (10.0%)
MDC 15: Newborns and other neonates	12 (3.9%)
MDC 16: Blood and blood forming organs and immunological disorders	1 (0.3%)
MDC 17: Neoplastic disorders	6 (1.9%)
MDC 18: Infectious and parasitic disorders	1 (0.3%)
MDC 19: Mental diseases and disorders	9 (2.9%)
MDC 20: Alcohol/drug use and alcohol/drug induced organic mental disorders	5 (1.6%)
MDC 21: Injuries, poisoning and other toxic effects of drugs	0 (0.0%)
MDC 22: Burns	0 (0.0%)
MDC 23: Factors influencing health status and other contacts with health services	1 (0.3%)
MDC 24: HIV	1 (0.3%)
MDC 25: Multiple traumata	0 (0.0%)
Rest category	8 (2.6%)

Table 11: Top 10 of conditions organised by CPs.

Normal delivery	40%
Stroke	40%
Total hip prosthesis	33%
Total knee prosthesis	33%
Breast carcinoma	21%
Caesarean section	19%
Transurethral prostatectomy	19%
Diabetes	17%
Herniated disk	17%

Inguinal hernia	15%

Table 12. Number of surgical clinical pathways per MDC and APR-DRG.

Surgical clinical pathway	Number	APR-DRG	% of total
MDC 1: Nervous system	**1**		**0,64**
Implantation of DCS (anesthesia)	1	23	0,64
MDC 2: Eye	**4**		**2,56**
Cataract surgery	4	71	2,56
MDC 3: Ear, nose, mouth and throat	**11**		**7,05**
MFC + SRPE	3	91	1,92
FESS	1	93	0,64
VPPP	1	95	0,64
Amygdalectomy	3	97	1,92
Septal surgery (nose)	1	98	0,64
Extraction of wisdom teeth	2	98	1,28
MDC 4: Respiratory system	**3**		**1,92**
Pneumectomy	2	120	1,28
Thoracothomy	1	120	0,64
MDC 5: Circulatory system	**14**		**8,97**
Cardiac valve surgery	1	162/163	0,64
CABG	5	164/165/166	3,21
Pacemaker	2	171	1,28
Carotid surgery	1	173	0,64
Femoral bypass surgery	2	173	1,28
Varicose vein surgery	3	179	1,92
MDC 6: Digestive system	**11**		**7,05**
Colostomy	1	221	0,64
Resection of the sigmoid	1	221	0,64
Hemicolectomy	1	221	0,64
Laparascopy	1	223	0,64
Inguinal hernia	7	228	4,49
MDC 7: Hepatobiliary system and pancreas	**5**		**3,21**
Cholecystectomy	5	262/263	3,21
MDC 8: Musculoskeletal system and connective tissue	**56**		**35,90**
Total hip prosthesis	16	302	10,26
Total knee prosthesis	16	302	10,26
Shoulder prosthesis	2	302	1,28
Joint prosthesis	1	302	0,64
Cervical fusion	1	302	0,64

Surgical clinical pathway	Number	APR-DRG	% of total
Hip fracture	1	308	0,64
Herniated disk	8	310	5,13
Cervical prothesis	1	310	0,64
Lumbar prothesis	1	310	0,64
Lumbar laminectomy	2	310	1,28
Thoracal laminectomy	1	310	0,64
ALIF	1	310	0,64
ACIF	1	310	0,64
PLIF	1	310	0,64
Arthroscopy	2	313	1,28
Hallux valgus correction	1	314	0,64

Surgical clinical pathway	Number	APR-DRG	% of total
MDC 9: Skin, subcutaneous tissue and breast	**11**		**7,05**
Breast carcinoma	10	362	6,41
Stitching using local anesthesia	1	364	0,64
MDC 10: Endocrine, nutritional and metabolic diseases and disorders	**6**		**3,85**
Bariatric surgery	6	403	3,85
MDC 11: Kidney and urinary tract	**1**		**0,64**
Transurethral bladder resection	1	441	0,64
MDC 12: Male reproductive system	**14**		**8,97**
Radical prostatectomy	5	480	3,21
Transurethral prostate resection	9	482	5,77
MDC 13: Female reproductive system	**10**		**6,41**
Vaginal hysterectomy	4	510	2,56
Abdominal hysterectomy	4	510	2,56
Hysterectomy	2	510	1,28
MDC 14: Pregnancy, childbirth and puerperium	**9**		**5,77**
Caesarean section	9	540	5,77

2.3.3. Embedding of clinical pathways in the organisation

Strategic importance for the organisation

Overall, hospitals that work with clinical pathways grade their strategic importance 7,3 on a numeric scale from 0 to 10. The strategic importance is graded slightly higher in French speaking hospitals (7,9 vs. 7,0) though the differences never reach statistical significance.

Multidisciplinary team involvement

Nurses and medical specialists are the most frequently involved in clinical pathways (table 13). In more than half of the clinical pathways physiotherapists and social workers are involved. In less extent, occupational and speech therapists, psychologists and dieticians are reported to be involved in clinical pathways.

General practitioners and home nurses are involved in only 10% and 4% of the clinical pathways respectively. However, 24% of the clinical pathways are claimed to be transmural.

Table 13. Percentage of health care workers involved in CPs in acute hospitals (% ± SD)*.

Hospital nurses	90 ± 25
Specialists	86 ± 29
Physiotherapists	64 ± 39
Social workers	52 ± 40
Occupational therapists	17 ± 25
Logopedic therapists	5 ± 10
General practitioners	10 ± 28
Home nurses	4 ± 17

*37 hospitals answered this question.

Coordination of the development of clinical pathways

79% of the hospitals have a trained nurse or physician that coordinates the development of all of the clinical pathways. In 6% and 12% of the hospitals respectively the responsible physician or nurse is involved in the coordination. The medical director is involved in 17% of the hospitals. 27% of the hospitals uses a development group (with or without a trained nurse or physician).

Use of evidence-based guidelines and quality indicators

35% of the hospitals claim their clinical pathways to be supported by evidence-based guidelines. 58% of the hospitals use quality indicators to evaluate the effectiveness of the clinical pathways.

Integration of clinical pathways in the patient records

The majority of the hospitals (69%) uses a supplementary document for their clinical pathways. In only 36% of the hospitals the patient record is replaced by the clinical pathway document. In 17% of the hospitals the clinical pathways are supported by IT resources.

2.3.4. Advantages and disadvantages of working with clinical pathways

Forty-four of the forty-five hospitals working with clinical pathways answered this question (table 14). All of them mentioned advantages, 33% also mentioned disadvantages.

The majority of the hospitals sees positive effects on the organisation of health care and team working. Only a minority sees financial advantages of working with clinical pathways.

Of the hospitals mentioning disadvantages, the majority sees clinical pathways as time consuming. Financial disadvantage is also mentioned often.

Table 14: Advantages and disadvantages of working with CPs in acute hospitals.

	Advantage (n=44)	Disadvantage (n=15)
Organisational	86%	13%
Teamwork	84%	20%
Clinical	75%	20%
Patient satisfaction	66%	7%
Hospital stay	66%	20%
Time	48%	33%
Financial	25%	33%

2.3.5. Future use of clinical pathways

The majority of the hospitals that do not use clinical pathways at present assume that at least part of their patients can be cared for by using a clinical pathway (table 7). 72% of these hospitals is planning to develop clinical pathways in the near future. The main reason for not developing clinical pathways is lack of knowledge (75%). Twenty percent claims to have a patient population not suitable to be cared for using clinical pathways.

2.3.6. Content and reliability analysis

A total of fifty-one documents stated to be clinical pathways were retrieved (table 15) by the KCE-survey. A document was considered as a clinical pathway when the three key-characteristics were present. The three reviewers agreed on 29 documents (57%) to be "real" clinical pathways.

Table 15: Scoring of documents on key-characteristics of clinical pathways.

Features	Number (% of total)
Time line	50 (98%)
Interdisciplinary involvement	32 (63%)
Detail overview of interventions	37 (73%)
3 key-characteristics present	29 (57%)

2.4. DISCUSSION

This is the first nationwide survey on the use of clinical pathways in Belgium. Important differences are shown between the Dutch and French speaking hospitals, the language preference defined by the language used in the pathways documents. First, the interest in this survey was higher in the Dutch speaking hospitals. Furthermore, more Dutch speaking hospitals use clinical pathways, with 84% of the Dutch speaking hospitals using at least one clinical pathway. This number is very much the same as that mentioned in the survey of Darer et al. [6]. However, the number of clinical pathways used per hospital was lower in our survey. Above this, the impact of clinical pathways is rather low at present, with probably less than 10% of the patients being treated using a clinical pathway. These numbers are in line with those found in the European survey by Hindle et al.[2]. Another difference between Dutch and French speaking hospitals is the potential use of clinical pathways, which is estimated higher in the Dutch speaking sample. The fact that the experience with clinical pathways is much more recent in the French speaking Belgian sample (as in France) can explain these differences[2].

Larger hospitals are more likely to use clinical pathways than small hospitals, as was also one of the findings of Darer et al. [6]. This can be explained by the fact that large hospitals have larger

numbers of patients with a specific condition and find it more worthy to develop clinical pathways for these patients. Larger hospitals probably also have more resources to develop clinical pathways.

The estimated percentage of patients eligible for clinical pathways also lies in the same range as in the study of Hindle et al.[2] and Darer et al. [6], with the majority of the hospitals estimating it between 41 and 60%.

Half of the top ten conditions organised with clinical pathways in our survey were also mentioned in the top ten of conditions in the survey of Darer et al. [6]. However, while six of our top ten conditions were pure surgical conditions, Darer et al. listed four pure medical conditions in their top ten[6].

About 60% of the Belgian acute hospitals use quality indicators to monitor the effects of their clinical pathways. This is somewhat lower than mentioned by Darer et al. [6]. In our survey, no specification was asked about which quality indicators were used.

The benefits most often mentioned were organisational benefits and improved team working. Team working was also one of the benefits mentioned by Hindle et al.[2]. Financial benefits were only mentioned by one in four hospitals, and one in three even experienced financial disadvantages. These figures are in line with those found in a survey by Riley et al.[7].

Key messages:

- **Clinical pathways have a higher penetration in predominantly Dutch speaking acute hospitals and larger acute hospitals.**
- **The impact of clinical pathways at present is below 10% in most of the hospitals, but there is a large potential for growth up to 40-60% of the patients. A multitude of pathways already exists for a large number of frequent interventions in surgery, obstetrics-gynaecology and to a lesser extent internal medicine and neurology.**
- **Currently, less than 2/3 of the pathways fulfil the three key characteristics of clinical pathways: a time line, multidisciplinary work, and a detailed overview of key elements.**

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3. PILOT ASSESSMENTS OF PATHWAYS AND TRANSLATION INTO FINANCING

In this chapter the content and the evidence base of a number of clinical pathways or local care programs with related guidelines and protocols will be critically appraised for five surgical interventions. For every pilot exercise, the costs related to the billing codes ('nomenclature') will then be calculated and compared to the average amount used in the most recent feedback on 'referentiebedragen', in the MKG/MFG-RCM/RFM data available from the Technische Cel, or in sickness fund data.

The following five interventions were selected:

1. Tonsillectomy (day care)

2. Total knee arthroplasty

3. Carotid endarterectomy

4. Appendectomy (emergency)

5. Laparoscopic cholecystectomy

The selection of these pilots was based on the following criteria:

- sufficiently high frequency of admission for the intervention or disease,
- presence of national pathways for this subject,
- availability of supporting evidence,
- increased risk for harm or for unjustified higher cost if deviation from the pathway or guideline
- specific care setting of interest, e.g. emergency, ambulatory care
- possibility to relate the often relatively homogeneous patient group of the pathway to a topic of the 'referentiebedragen' or alike.
- input from a discussion with a working group of the Multipartite concertation structure. This input motivated the researchers to choose carotid endarterectomy instead of CABG.

Pathways or guidelines retrieved in the inventory described in the previous chapter were selected for this exercise according to the following criteria: at least one national and one international pathway; sufficient details of individual interventions available; diversity between health care systems.

Most often the appropriateness of a surgical intervention cannot be judged from guidelines or a clinical pathway. There are abundant comparative data (OECD data, surveys) and evidence from the application of appropriateness criteria on individual patient files showing that part of the interventions were not indicated. A totally different methodology however, is needed to analyse the appropriateness of an intervention. In the following sections, therefore, possible problems with the appropriateness of surgical interventions will be discussed if the literature provides substantial supportive evidence.

The analysis was deliberately limited to those interventions that find their correlate directly in the physician's nomenclature. Drugs en other medical products and materials can also lead to significant expenses (e.g., antibiotics and antihistaminics after appendectomy, thrombosis prevention after knee arthroplasty, etc.). The financing of hospital drugs was already analysed recently by the KCE in a comparative study and further policy recommendations on this topic are being prepared in a separate working group of the Multipartite structure. Another main, more methodological, reason was that often a large number of 'key interventions' can be deduced from a single CP and that the timing of this study was quite strict.

3.1. METHODOLOGY

For every selected surgical intervention three to four (at least one international and one national) clinical pathways or guidelines were retrieved. The major clinical key interventions were identified, summarized and critically appraised by searching for the available evidence. In the cost-calculation the minimal costs for a standard patient with a primary uncomplicated surgical intervention, but without major comorbidity leading to higher risk for surgery and postoperative complications, are estimated and compared to the amount spent on average for patients undergoing this type of procedure and having low APR-DRG related degree of severity-of-illness SOI (i.e. level 1 or 2) .

3.1.1. Evidence search and appraisal

The search strategy always included a systematic search in the Medline database (Clinical Queries and SumSearch), Embase, the Cochrane Library and the CRD database. For certain specific questions on diagnostics Medion was consulted. For questions in the field of rehabilitation the Pedro database was also searched. Details of the search strategies are available in appendix. An evidence table with the major key interventions was constructed and levels of evidence were applied using the system of the Oxford Centre for Evidence-based Medicine (http://www.cebm.net/levels_of_evidence.asp#levels)

Critical appraisal of the retrieved trials was done based on the checklists for clinical trials on diagnosis or on therapy from the Dutch Cochrane Centre. For the appraisal of physiotherapy and rehabilitation trials, the Pedro-scale was used. The Pedro scale considers internal validity of the trial and whether the trial contains sufficient statistical information to make it interpretable. Every trial was judged on a scale from 1 to 10, based on the first 10 items of the Cochrane checklist related to internal validity and the 10 items of the Pedro scale. For every topic at least two clinical experts in the specific field were consulted to check for possible omissions in the evidence search. The full analysis was discussed with a group of external validators.

3.1.2. Cost calculations

One objective of this exercise was to compare the costs calculated for each intervention with the average expenditure for the corresponding APR-DRG, as published on the web by the Belgian federal authorities (average cost of all given APR-DRGS registered in Belgium hospitals, with the details of cost items and categories; last data available: 2001 (www.tct.fgov.be). Cost was defined as the cost for the health insurance, derived from the nomenclature. The costs included in our calculation both for the clinical pathways and the corresponding APR-DRG were chosen to allow direct comparisons with the data published on the web. They include only those items that, in our Belgian financing system, can be billed to RIZIV/INAMI during a hospital stay (out-patient care excluded) under a specific billing code. Our costs categories are those of INAMI/RIZIV.

Costs items *included* are:

- 'Main intervention' : surgeon's fees + anesthesiologist's fee
- 'Clinical biology' : the items billed under a 'clinical biology' code, excluding the 'fixed part' (75% of the clinical biology budget for the hospital);
- 'Medical imaging';
- 'Other reimbursed activities' : all billing codes covering internal medicine and physical therapy codes.

These items make up only a fraction of the real cost of any given intervention. *Excluded* costs, for example, are:

- All direct and indirect costs accounted for in the hospital (hotel, nursing, ..);
- Honorarium for medical surveillance ;
- Pharmaceuticals, blood/plasma ;

- Clinical biology 'fixed part' and imaging 'fixed part' ;
- Disposables and implants, tracheostomy material, radioisotopes, incontinence material, human tissue ;
- Costs to the patient over the amount refunded ;
- All activities not covered by RIZIV/INAMI and paid for by the patient (non reimbursed 'over the counter' pharmaceuticals, etc..).

3.1.3. Case definitions: pathway cost, minimal cost, reasonable cost

For each clinical pathway, we identified all billable items and retrieved the corresponding cost to RIZIV/INAMI. Total cost for each clinical pathway was the sum of the costs for all items included in the pathway. The 'minimal cost' is the sum of the cost of those items identified as in theory mandatory for all patients.

Some items are justified for only a certain proportion of patients or relate to plausible interventions for which no evidence if available. This proportion was estimated based on published data and factored in to calculate an average 'reasonable' cost.

3.2. CASE STUDIES

3.2.1. Tonsillectomy

Introduction and description of the intervention

The pharynx is the crossway between the respiratory tract and the digestive tract. It integrates two vital but mutually exclusive functions: respiration and swallowing. The nasal cavity and the pharynx both constitute the upper part of the respiratory system, also referred to as the upper airways. The oral cavity and the pharynx together constitute the upper part of the digestive system. During swallowing, the airways are protected against aspiration by simultaneous laryngeal and nasopharyngeal closure.

Anatomically, the pharynx is a tubular structure connecting the posterior part of the nose and the oral cavity with the trachea and the upper oesophageal sphincter (UOS). Although the pharynx may be considered a functional and anatomical unit, it can be divided in three separate parts according to their localisation: the nasopharynx, the orophaynx and the laryngopharynx. The nasopharynx is the upper part of the pharynx and extends from the skull base and the posterior nose to the superior surface of the soft palate; the orifices of the Eustachian tubes are located on both sides in its lateral wall. The oropharynx is the middle part of the pharynx and extends from the inferior surface of the soft palate to the superior border of the epiglottis; the oropharynx is the visible part of the pharynx on clinical inspection of the mouth. The laryngopharynx consists of the larynx with the vocal folds anteriorly and the hypopharynx posteriorly. It extends from the superior border of the epiglottis to the first ring of the trachea anteriorly and to the UOS posteriorly (Fig.2).

The oropharyngeal isthmus and the lateral and upper walls of the nasopharynx are covered with a ring of lympho-epithelial tissue ("Waldeyer's ring").

The palatine tonsils ("tonsils"), which constitute the lateral parts of the ring, are located on either side of the oropharyngeal isthmus. The ring is completed superiorly by the midline pharyngeal tonsil ("adenoids"), and inferiorly by the lingual tonsil (lymphoid tissue in the posterior third of the tongue)(Fig.2).

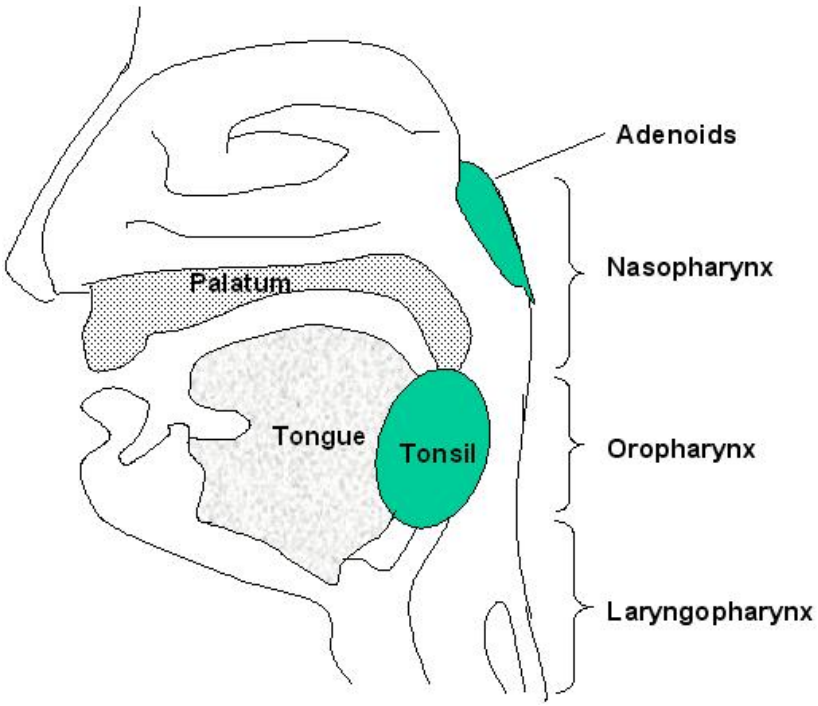


Figure 2. Schematic representation of the anatomy of the pharynx

Total removal of the tonsils or tonsillectomy (TE) and removal of the adenoids together with the tonsils or adenotonsillectomy (ATE) are both highly prevalent surgical interventions in Western societies. For instance, in England and Northern Ireland, about 40.000 TE's or ATE's are registered each year[1]. In Belgium, in 2001, 23.075 patients underwent TE or ATE.

TE or ATE is most frequently carried out in childhood and remains the most commonly performed major surgical intervention among children in many Western countries. In the US, in 1996, an estimated 287.000 children under 15 years of age underwent TE or ATE. Of these, an estimated 248.000 children (86.4%) underwent ATE and an estimated 39.000 children (13.6%) underwent TE only[2].

TE may be beneficial in patients with frequently recurring acute episodes of sore throat ("pharyngitis" or "tonsillitis"). ATE may be indicated in children with adenotonsillar hypertrophy causing significant upper airway obstruction (UAO) and obstructive sleep apnea (OSA). Other, less frequent, indications for TE include peritonsillar abscess unresponsive to medical management and drainage, and unilateral presumed neoplastic tonsil hypertrophy[3]. In general, pediatric TE represents a day-care procedure. Adults may require a more prolonged hospital stay.

The first operation on the tonsils has been attributed to Hippocrates (460-375 AD). Later, removal of the most prominent parts of the tonsils ("tonsillotomy") became a frequently performed intervention. Complete removal of the tonsils or tonsillectomy (TE) was introduced about a century ago[4]. The traditional TE-technique consists of removal of the tonsils with "cold" steel instruments with ties or packs for haemostasis. Tonsils are removed through a "guillotine" tonsil extraction technique or through dissection following an initial incision of the pharyngeal mucosa. During the past decades, several "hot" techniques have gained widespread acceptance in clinical practice and at present, electrosurgery with bipolar diathermy is a frequently used technique[5]. These techniques allow removal of the tonsils simultaneously with haemostasis. Coblation surgery, using heath generated by electromagnetic radiation, is a variation of electrosurgery but with lower tissue temperatures than diathermy (60-70 compared with 400-600).

Adenoids are removed by curettes.

The main risks of TE, some of which are potentially life-threatening, include: inhalation of blood during the intervention, obstructive apnea due to laryngeal spasm immediately after the intervention, primary or secondary postoperative haemorrhage, accidental injury to adjacent structures (palate, uvula, tongue, teeth and sensory nerve-fibers), postoperative non-haemorrhagic complications (nausea, fever and vomiting) and emotional problems.

Description of the pathways and/or guidelines

In general, patients found eligible for TE are scheduled (rather than emergency) hospital-admissions and a large majority has no significant co-morbidities.

Two different UK Integrated Care Pathways "Tonsillectomy Paediatric" have been retrieved.

A first UK pathway is used at the Royal Berkshire & Battle Hospitals NHS Trust. In this "Berkshire" pathway, the patient is admitted to the hospital on the day of the operation.

In general, preoperative testing is not indicated. However, preoperative blood testing and/or MRSA screening (with a nasal swab only) may be required in selected patient-groups. Possible blood tests include blood sugar testing in diabetic patients and testing for Sickle cell or Thalassaemia in all patients of West Indian, African, Afro-Caribbean, Mediterranean, Middle East, Asian, Cypriot, Pakistan, India, and South East Asia origin who are unaware of their Sickle cell/Thalassaemia status. MRSA screening should be performed in children at high risk for MRSA carriage i.e. in chronically ill children that have had previous hospital admissions and in all previous so-called "Buscot" babies (premature and sick newborn babies that have been admitted in the Buscot Special Care Baby Unit at the Royal Berkshire Hospital, Reading, UK). TE is performed on the hospital admission day (day 1). Discharge is planned on the same day and a paediatric TE follow up telephone call is made on the first working day following day-care admission.

A second UK pathway is used in the Ipswich Hospital NHS Trust. In general, no preoperative testing is required. As in the "Berkshire" pathway, testing for sickle cell in individuals at risk is recommended. TE is a day-care procedure.

We were also able to retrieve a single Belgian pathway on "Tonsillectomy". This pathway is used in adult patients (> 18 years old). Adult TE is performed without additional routine preoperative or postoperative testing. The patient is admitted to the hospital on the day of the operation (day 0) and discharge is planned on postoperative day 2.

Critical appraisal of content

The issue of preoperative MRSA screening in selected pediatric patients is not directly addressed in a recent Belgian guideline for control and prevention of MRSA transmission in Belgian hospitals. However, in general, this guideline states that "screening the MRSA status of patients on admission can be indicated in particular situations: for instance in case of an outbreak or when epidemiologic analysis indicates that a substantial number of MRSA cases are transferred to the hospital on a regular basis from other institutions where MRSA is (suspected to be) endemic". Whenever appropriate, screening for MRSA carriage is carried out by swabbing the two anterior nostrils and performing a selective culture in the microbiology lab. The use of the nasal swab is considered the simplest, fastest and most cost-effective technique for MRSA screening. However, even when performed properly, nasal swabs only detect 78 to 85% of the carriers. Whenever needed, the sensitivity of the test may be increased to more than 98% by combining swab-samples of the nose, throat and perineum[6]. In a recent Belgian study on MRSA carriage in nursing home residents, independent determinants of MRSA carriage included recent use of antibiotics (i.e. quinolones and nitrofuran), recent hospital admission in a surgical department, the presence of a urinary catheter and systemic disease[7]. It is not unlikely that the risk for MRSA carriage may also be elevated in Belgian children with a similar medical history as the above described "high risk" paediatric TE patients from the "Berkshire" pathway. Therefore, in this population, preoperative MRSA screening may become indicated in case of particular situations, as described above in the Belgian guideline[6].

In general, not routinely performing preoperative testing in TE patients is in line with results from clinical studies and evidence-based recommendations in guidelines[3 8] and in a recent Belgian report on preoperative testing[9].

More specifically, since haemorrhage is the most common serious complication of TE, some non-randomized clinical studies have addressed the issue of preoperative blood screening for the detection of a blood coagulation disorder and anaemia. The accuracy (sensitivity, specificity and predictive values) of routine preoperative testing in detecting a blood coagulation disorder is considered insufficient in the absence of a suggestive clinical history or a hereditary predisposition[10-13]. Given the low prevalence of anaemia, routine preoperative haemoglobin testing is not useful[14].

Translation into financing

There are no specific nomenclature-based costs related to testing or additional interventions in the pre-, peri- and postoperative patient management of TE- and ATE-patients.

However, current medical practice does generate costs refunded by health insurance.

About 48% of 23.075 patients who underwent TE or ATE in 2001 had a hospital stay instead of day-care. Costs generated during hospital stays for adenoidectomy, TE and ATE in 2001 are presented in Table 16.

Table 16. Reference values per hospital stay for adenoidectomy and/or tonsillectomy

	Clinical biology	Imaging	Other reimbursed activities	Surgery + anesthesiology	Total (without surgery)
Berkshire	0.00 €	0.00 €	0.00 €	204.74 €	0.00 €
Ipswich	0.00 €	0.00 €	0.00 €	204.74 €	0.00 €
Belgium	0.00 €	0.00 €	0.00 €	204.74 €	0.00 €
minimal	0.00 €	0.00 €	0.00 €	204.74 €	0.00 €
reasonable	0.00 €	0.00 €	0.00 €	204.74 €	0.00 €
2001 S1 median	0.00 €	12.54 €	16.26 €	205.75 €	28.80 €
2001 S1 mean	2.71 €	28.95 €	29.74 €	221.40 €	61.40 €
2001 S2 median	0.00 €	12.54 €	16.26 €	205.75 €	28.80 €
2001 S2 mean	11.13 €	66.96 €	64.77 €	227.48 €	142.86 €

For severity of illness 1, the generated costs are moderate and consist, besides surgery and anaesthesiology, mostly of RX thorax (1151 times performed, 40% of imaging cost in 2000), CT of the neck (63 times performed, 20% of imaging cost in 2000), ECG (1195 times performed, 35% of other reimbursed costs in 2000), IV perfusion in children under 7 years of age (581 times performed, 17% of other reimbursed costs in 2000), and tracheoscopy (107 times performed, 5.5% of other reimbursed costs in 2000). However, given the relative small number of these activities (11.5% receives imaging, 15% receives other reimbursed activities) and the inclusion of all hospital stays in APR-DRG 097 (adenoidectomy, TE and ATE), the non-surgical costs may potentially reflect medical justifiable interventions.

Discussion

Large variations in surgical rates

The high rates of TE in Western societies have been subject to serious concerns for more than half a century. A historical experiment on this topic, published initially in 1934 and again in 1945, has become a "classic" ever since[15 16]. A survey of 1.000 eleven-year-old children attending New York City public schools found that tonsils had already been removed in 61% of them. The remaining 39% children were evaluated by a group of physicians who considered 45% of them appropriate candidates for TE. Those rejected were subsequently evaluated by another group of physicians who recommended TE in 46% of them. Finally, after evaluation of the remaining children by a third group of physicians, a similar percentage was recommended surgery, leaving only 65 children who had not been advised a TE. At that point, the study was halted for a lack of physicians[15 16].

This study represents a classic example of uncertainty in the minds of doctors on how to approach a presumed particular medical problem[17]. According to Illich, these remarkable findings reflect a prejudice towards interpreting disease and illustrate medical decision making based on the principle of preferably diagnosing a disease rather than possibly missing one and diagnosing health[18 19].

Although TE rates have declined ever since, surgical rates in some countries, including Belgium, are still high and wide variations in TE-rates across countries persist. This may reflect ongoing uncertainty on indications for surgery, and by consequence on the appropriateness of the intervention. For instance, in 1998, TE surgical rates in children, aged 0-14 years, varied from 19 per 10.000 children in Canada to 118 per 10.000 children in Northern Ireland. Corresponding rates in the US and UK were 50 per 10.000 in the US and 65 per 10.000 in the UK. Surgical rates

in Belgium and the Netherlands were high: 101 per 10.000 and 115 per 10.000 respectively[20]. It was concluded from these findings that these considerable varying rates between countries were most probably related to continuing cultural differences in attitudes towards the indications for TE.

The absence of or non-compliance with (inter)nationally accepted guidelines on indications for this common procedure may also play an important role[20 21] . Even within countries, TE-rates have been reported to vary considerably. In some countries, TE-rates appeared to be related to socio-economic status. In Italy and Scotland, the highest surgical rates were reported in children living in the most deprived regions[3 22]. These differences could be related to a greater prevalence of recurrent sore throat, an increased risk of undergoing inappropriate surgery, or both, among more deprived children. In Switzerland, children of physicians have been reported to have a lower lifetime risk of undergoing TE than the general population[23].

Illustrated in the particular case of TE, large variations in surgical rates have also been demonstrated in certain other commonly performed surgical procedures among populations which by all appear quite similar in their need for and access to healthcare services. Large variations apparently occur to a great extent because of differences among physicians in their evaluation of individuals with a particular presumed or real medical problem (diagnosis) or in their belief in the value of the procedures for meeting patient needs (therapy)[21]. This "professional uncertainty hypothesis" is germane to controversies concerning the nature and extent of supplier influence on the demand for medical services[17 24]. Dramatic practice variations for common surgical procedures in particular or common physician practice in general may therefore indicate inappropriate use of care and appear largely affected by "physician practice styles" or "specialty ideology"[25 26]. Therefore, actions to reduce uncertainty and encourage consistency of good medical practice are needed[17 26 27].

Wennberg et al. demonstrated the effectiveness of feedback of population-based data and review on changes in TE practice and reported an average decline of 46% in TE-rates between 1969 and 1973 among 13 Vermont Hospital Service Areas. Physicians in the area with initially the highest TE-rate reviewed the indications for TE and adopted a second opinion procedure for reviewing candidates for surgery. It was concluded from this experience that feedback of population-based data on incidence of physicians' practices may be a valuable tool for the peer review process[27].

Indications

Recurrent sore throat is the most common reason for TE. In guidelines on the management of recurrent sore throat, TE is recommended in patients who meet all of the following criteria: sore throats are due to tonsillitis; five or more documented episodes of sore throat per year; symptoms for at least a year; the episodes of sore throat are disabling and prevent normal functioning. In addition, a six-month period of watchful waiting is recommended prior to TE to establish firmly the pattern of symptoms and allow the patient to consider fully the implications of surgery[3 28-30].

ATE is the most commonly performed intervention in the treatment of OSA in children[31] and guidelines recommend ATE in carefully selected patients[3 32]. Results from clinical studies underscore the expected beneficial effects of ATE in children with pronounced adenotonsillar enlargement causing significant UAO or OSA[33 34]. A potential basis for a clinical diagnosis of UAO may consist of 1) a history of loud snoring noted by the primary caregiver, with audiotape when reliability is questioned together with 2) tonsillar size of +3 or greater (filling 50% of the oropharynx)[34]. A potential basis for a clinical diagnosis of OSA may consist of 1) witnessed apnea together with 2) tonsillar size of +3 or greater[34]. However, the authors of a Cochrane Review on the efficacy of ATE in the treatment of OSA in children were unable to formulate recommendations due to the absence of RCT-data. The reviewers commented that debate on the polysomnographic criteria required to diagnose significant OSA in children is continuing and that the natural history of the condition has not been fully delineated[31].

Although one may consider frequent tonsil infections an adequate indication for TE[35] and adenotonsillar hypertrophy causing significant UAO or OSA an adequate indication for ATE in children[32-34], evidence for a substantial benefit of surgery in children with milder symptoms is lacking.

A Cochrane review on the effectiveness of TE in the treatment for chronic/recurrent acute tonsillitis revealed no trials in adults[36]. Two trials from Pittsburgh[35 37] assessed TE in children and

did not provide definitive evidence of the efficacy of TE[36]. Paradise et al. replied that TE is without doubt efficacious in reducing the occurrence of pharyngeal infections in the two years following surgery in children with severe forms of recurrent tonsillitis[36]. A review in Clinical Evidence reported that the only evidence, although limited, of the effectiveness of TE for children is restricted to those with severe forms of recurrent acute tonsillitis[38].

Results from two recent randomized controlled trials (RCT's) of TE or ATE, performed in children on less stringent indications, clearly question the appropriateness of the intervention. Paradise et al. concluded from a RCT enrolling 328 children that in those with moderate severity of throat infections (4 to 6 episodes of throat infections during the preceding year), the modest benefit conferred by TE or ATE did not justify the inherent risks, morbidity, and cost of the operations[2]. In a multi-center RCT from the Netherlands, 300 children aged two to eight years with mild symptoms of throat infections or adenotonsillar hypertrophy were randomized to ATE or watchful waiting. Inclusion criteria were aged 2 to 8 years with one or more of three indications for TE: at least 3 (but less than 7) episodes of throat infection the preceding year, recurrent upper respiratory infections (URI's), or obstructive problems. Children with OSA, Down's syndrome, craniofacial malformations and immunodeficiency were excluded, as were children whose parents either refused or insisted on tonsillectomy. During a median follow-up of 22 months, there were no clinically relevant differences between groups in health-related quality of life, fever rates, throat inflammation rates and upper respiratory inflammation rates. The authors conclude that ATE has no major clinical benefits over watchful waiting in children with recurrent URI's, mild symptoms of throat infections and mild obstructive symptoms related to adenotonsillar hypertrophy[39]. In a recent review, the same authors evaluated the pooled results from six RCT's and results from seven non-randomised controlled studies on the efficacy of TE or ATE in children younger than 18. They concluded that the frequency of sore throat episodes and URI's reduces with time whether TE or ATE had been performed or not. TE or ATE gives an additional, but small, reduction of sore throat episodes, days of sore throat associated school absence, and URI's compared to watchful waiting[40].

In the UK, it has been estimated that no more than 50% of TE's are justified and that only 25% of TE's for recurrent sore throat meet evidence-based criteria[41]. A recent survey on current indications for pediatric ATE in the Netherlands revealed that 35% of children underwent ATE for generally accepted indications such as frequent throat infections (seven or more a year) or OSA, and the remainder for less frequent throat infections, mild adenotonsillar hypertrophy, or indications such as upper respiratory tract infections, tonsillar crypt debris and non-specific symptoms such as listlessness and poor appetite [42].

Surgical techniques

To some extent, the use of "hot" surgical techniques may provide an ability to better control intraoperative bleeding but evidence that these techniques are superior to "cold" dissection is lacking[43] [44]. Coblation therapy may reduce postoperative pain[45]. Pain may be greater after monopolar dissection[43].

From the 2004 Interim Report of a National Prospective Tonsillectomy Audit in England and Northern Ireland, it appeared that bipolar diathermy was used for both dissection and haemostasis or for haemostasis alone in more than 70% of cases. Only 11% of tonsillectomies were performed with the classical technique of cold steel instruments and ties and/or packs for haemostasis. A coblation technique was used in 6% of cases[1].

Possible harms

Postoperative haemorrhage is the most common serious complication of TE and may cause considerable morbidity and additional costs i.e. hospital readmission, blood transfusion and/or re-intervention under general anaesthesia to control bleeding.

Primary postoperative bleeding occurs in the first 24 hours after surgery and may become particularly dangerous i.e. when bleeding is not recognised due to excessive sedation or when operative attempts to stop bleeding necessitate general anaesthesia in a patient with a depleted blood volume and a full stomach. Secondary postoperative haemorrhage occurs later, most frequently within seven to ten days following surgery.

The risks associated with blood loss are much greater in young children than in older children or adults because their total blood volume is much less.

Death due to postoperative haemorrhage is estimated to occur in about one per 15.000 TE's[46].

Postoperative haemorrhage rates have been reported from large patient series and varied from 1.9% to 3.4% [47]. A Cochrane review of RCT's comparing dissection versus diathermy for TE concluded that the two studies meeting inclusion criteria were of insufficient size to show significant differences in postoperative haemorrhage rates between TE techniques[43]. A recent prospective observational study found secondary haemorrhages in 6.2% of 743 patients who had a TE with cold steel dissection and bipolar diathermy and in 2.3% of 844 patients who had a coblation TE[48].

According to preliminary findings from the above mentioned Audit, 0.5% of the patients had a primary haemorrhage (< 24 hours after surgery) and 2.9% had a secondary haemorrhage (>24 hours after surgery). About two thirds of the haemorrhages should be considered particularly severe as they led to hospital readmission for surgical re-intervention and/or blood transfusion. It appeared that postoperative haemorrhage rates were related to surgical techniques with less favourable findings for diathermy and coblation than those reported elsewhere. The overall haemorrhage rate was 3.1 times (95% CI 1.9-5.0) higher with bipolar diathermy TE than with cold steel TE without any use of diathermy ($p<0.001$). The corresponding relative risk for coblation TE was 3.4 (1.9-6.2; $p<0.001$). When cold steel was used for dissection and diathermy only for haemostasis the relative risk was 2.2 (1.3-3.7; $p=0.002$). It was concluded that the use of techniques such as diathermy and coblation increased postoperative haemorrhage and that these techniques should therefore be used with appropriate caution and only after proper training[47 49].

Delayed discharge and hospital readmission due to non-haemorrhagic complications (pain, fever and/or vomiting) occurred in about 1% and 0.7% of the patients respectively[1].

Key Messages

- **No routine preoperative or postoperative testing i.e. imaging by X-ray or CAT-scan is needed in tonsillectomy patients.**
- **Tonsillectomy surgical rates are high in Belgium and large variations in tonsillectomy rates across countries persist. This may reflect ongoing uncertainty on indications for surgery, and by consequence on the appropriateness of the intervention.**
- **It is estimated that only 50% or less of the tonsillectomies are performed for generally accepted indications. Therefore, actions to reduce uncertainty and encourage consistency of good medical practice are needed.**

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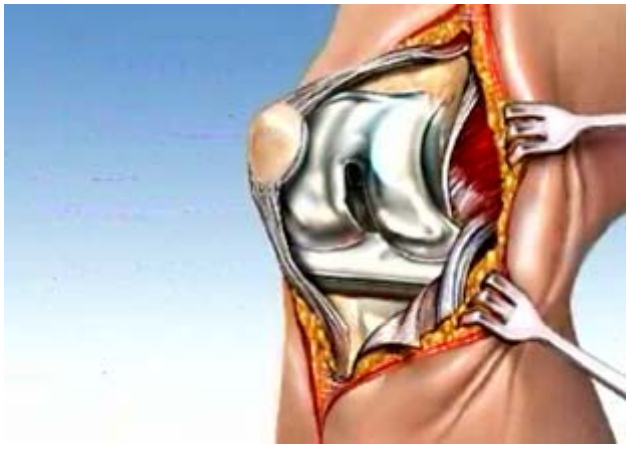
3.2.2. Total knee arthroplasty

Introduction and description of the surgical intervention

The most common indication for elective total knee arthroplasty is osteo-arthritis, a degenerative disease of the joints. Osteoarthritis is a common and important cause of pain and disability, especially in older adults. Knee disease is about twice as prevalent as hip disease in people aged over 60 years (about 10% versus 5%).

Treatment in general should consist of adequate short term pain relief by simple oral analgesics such as paracetamol or (topical or oral) non-steroidal anti-inflammatory drugs (NSAIDs)[1]. RCTs found no good evidence that simple analgesics, such as paracetamol, are significantly different from NSAIDs in pain relief, even though concerns related to trial quality and commercial bias exist. In addition, questions about the efficacy of paracetamol in osteoarthritis were raised recently.[2] [3] Paracetamol is however often recommended as a first line treatment for safety reasons.[4] Given the concerns about the gastro-intestinal side-effects of the classical NSAIDs and the cardiovascular side-effects of certain oral coxibs, guidelines on treatment are under revision currently. Irrespective of these recent concerns, only limited use of NSAIDs can be recommended and long term use for knee osteoarthritis is debatable[5]. Intra-articular injections may offer short term benefit[6]. Exercise, weight loss, physiotherapy, physical aids and education can often be beneficial.[7] So far there is no convincing evidence from placebo-controlled RCTs that glucosamine or chondroitin (or their combination) improves symptoms or disease progression[8].

Overall, only a minority of people with degenerative disease of the hip or knee joint require surgery, i.e., when other strategies fail. Systematic reviews of observational studies have found that knee arthroplasty is effective in relieving pain and improving function.1 There is a rapid and substantial improvement in the patient's pain, functional status, and overall health-related quality of life in about 90 percent of patients; about 85 percent of patients are satisfied with the results of surgery.[9] Possible harms include immediate postoperative mortality which, on average, is relatively low[10] [11] , and complications such as deep vein thrombosis (up to 5%), infection and loosening necessitating revision, the major long term risk.



The number of total knee arthroplasties will probably continue to increase, since the principal risk factors advanced age and obesity will increase as well in the next decades. In Belgium, 10 195 knee replacements were performed in 2001. These patients have an average age of 69 years and the majority of them are women (75%).

Description of the pathways and/or guidelines

Total knee replacement and hip replacement are typical interventions for which clinical pathways were developed in several countries. In Belgium, as shown in the survey in chapter 2, these two types of elective surgical interventions rank highest in number of Belgian pathways found. A systematic review[12] on their effectiveness showed that patients treated using pathways experienced shorter hospital stays and lower costs, with comparable clinical outcomes. The

studies included in this systematic review however, have substantial methodological limitations. Numerous guidelines exist for individual interventions in the care of these patients. Especially pharmaceutical therapy to prevent postoperative complications such as deep vein thrombo-embolism received attention the last years.

For the current exercise two clinical pathways used in Belgium and two clinical pathways used in other countries, one from Australia and one from the UK, were analysed (see also chapter 2 for the inventory). The Australian pathway is used in St. Vincent in Sydney. The UK pathway is used in the Rotherham General Hospital. The Belgian pathways are not publicly available and were retrieved in accordance with and with permission of the orthopaedic surgeons involved.

The clinical content of the different pathways is depicted schematically in figure 3. As expected, the general lines in the four CPs are similar. The day before surgery, the patient is admitted to the hospital. In the UK pathway, preoperative tests are only performed, if needed and if not already done on an ambulatory base. A radiograph of the knee is repeated if the previous radiograph is more than 6 months old. In the Belgian pathways (part of) the preoperative tests such as a radiograph of the thorax and extensive lab tests are systematically repeated. In one pathway advice of a cardiologist is incorporated. Noteworthy is that in the Belgian pathways a hip to ankle radiograph (or full-leg standing radiograph) is performed preoperatively.

During surgery and under anaesthesia a fluoroscopic assessment of the prosthetic components is often performed and/or a postoperative radiograph of the knee is usually taken in the recovery room, the patient still lying supine. In the foreign, but not the Belgian pathways a standard radiographs of the knee ('antero-posterior and lateral views') are taken on day one or day two after surgery. In the immediate postoperative period lab tests to check for bleeding (at least Hb) with or without electrolytes and urea is universal practice. In one of the Belgian pathways bloodgases are performed, presumably because this also includes an estimation of Hb. In the other pathway PBO is performed both on day 1 and day 2 after surgery. In all the pathways postoperative rehabilitation starts immediately after surgery (mostly day 1) and will continue up to the last hospital day. Between day 4 and 7 again a lab test is usually performed to check for blood loss. In Rotherham, INR is determined to guide oral anticoagulant therapy for thrombosis prevention. In the Belgian pathways an larger battery of lab tests is performed, including the tradition of a systematic relatively extensive 'weekly lab' in one hospital. In this same postoperative period the Belgian hospitals have an imaging of the knee by radiography ('face/profil') and one of them systematically repeats a hip to ankle radiograph (or full-leg standing x-rays).

During the whole postoperative in-hospital period the most dominant activity is rehabilitation, especially by physiotherapy. The first day it usually takes place in bed but as soon as possible the patient is referred to the rehabilitation ward. The use of continuous passive motion by e.g. a Kinetec device starts from day 1 or 2 onwards. The involvement of disciplines other than physiotherapy ('kinesitherapy'), e.g. occupational therapy, is not always clearly identified. Two pathways systematically use TENS for postoperative pain management.critical appraisal of the pathways content

Clinical pathway	Day -1	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
St. Vincent		RX knee perop		RX knee								
			FBC UCE					FBC				
		physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy		
Rotherham			RX knee									
	urinalysis cross-matching			Hb			INR					
			physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy		
Belgium 1	RX knee RX full leg RX thorax	RX knee perop						RX knee RX full leg				
	FBC INR urinalysis CRP UCE+		FBC UCE BGV					FBC INR urinalysis CRP UCE+				
			physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy
Belgium 2	RX knee RX full leg	RX knee perop				RX knee						
	cross-matching		FBC UCE+	FBC							FBC UCE+	
			physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy
Minimal		RX knee perop										
			physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy		
Reasonable		RX knee perop						RX knee				
				Hb								
			physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	physiotherapy	Physiotherapy

Figure 3. Scheme with the two international, two national, and minimal and resonable pathways. (Yellow depicts medical imaging; red depicts clinical biology; green depicts other reimbursed activities; FBC = full blood count; INR = prothrombin test ; CRP = C-reactive protein test; UCE+ = Ureum creatine electrocytes extended; Hb = hemoglobin test).

The key interventions and the results of our literature search are summarized in the following evidence table.

Topic	Key intervention	Reference	Type	n	Quality appraisal	Result	Level of evidence
Pre-operative tests	Repeating preoperative tests (RX thorax, lab tests,..) day -1	KCE report	EBG	/	N/A	Not indicated routinely	2a against routine use
	None-invasive cardiology testing day -1	KCE report	EBG	/	N/A	Not indicated routinely	2a against routine use
Imaging	RX full-leg day -1	McGrory, 2002	RCT	94	5/10	No influence on surrogate endpoints	3b against routine use
		Bathis, 2004	Observational	160	4/10		
	RX knee postop, before discharge	Glaser, 2000	Observational	750	6/10		2b against routine use
		Moskal, 1998	Observational	514	N/A		
	RX full leg before discharge	none					5, extrapolated evidence against
Laboratory tests	Hb-control postop in routine	none					5
	Other (UCE, INR, 'weekly lab')	none					5
Rehabilitation	Early and intensive in-hospital physiotherapy	Munin, 1998	RCT	86	6/10	Reduced LOS and better short term functioning; no difference at 4 mths.	2b
	Bed exercises	Jesudason, 2002	RCT	42	6/10	THP: no effect	N/A
	continuous passive motion	Beaupre, 2001	RCT	120	8/10	Small benefit on active knee flexion and LOS, not on passive knee flexion or passive or active knee extension	1a
		Milne, 2003	Cochrane SR		N/A		

	Brosseau, 2004	SR		N/A		
TENS	Breit, 2004	RCT	69	5/10	No benefit	2b against
	Walker, 1991	RCT	48	4/10		
Cold therapy	Levy, 1993	RCT	80	5/10	Conflicting evidence	(5)
	Albrecht, 1997	RCT	312	5/10		
	Healy, 1994	RCT	76	2/10		
	Scarcella, 1995	RCT	24	4/10		
	Ivey, 1994	RCT	90	4/10		

SR: systematic review (including meta-analysis)
EBG: validated evidence-based guidelines
RCT: randomized controlled trial
N/A: not available or not applicable
TENS: Transcutaneous Electric Nerve Stimulation
LOS: length-of-stay

In-hospital preoperative tests

Elective total knee arthroplasty is most often performed as a planned procedure to treat a chronic condition such as osteoarthritis of the knee. Consequently, preoperative risk stratification and possible preoperative therapeutic adjustments are done in the weeks before the planned hospital admission on an ambulatory base. The decision concerning the preoperative tests to be performed should be based on previous risk stratification as described in numerous guidelines and summarized recently in a report of the KCE.[13] Repeating certain preoperative tests the day before surgery is justifiable if previous results are not available, ideally a rare event, or if a previously abnormal test or a change in preoperative treatment (e.g. oral anticoagulation for atrial fibrillation was stopped) urges an additional control before surgery. In all other circumstances, preoperative tests should not be repeated routinely at the day of admission, unless there are specific clinical signs. Without a clinical indication to do so, it is very unlikely that abnormal test results that could not be detected during the ambulatory preoperative visit will occur. And even in that event, time is very limited for those abnormalities to lead to therapeutic consequences. A possible organisational consequence in that case is that surgery has to be postponed. Also, the choice of certain preoperative systematic test can be questioned. Coagulation tests on the day of admission, e.g., INR, are only indicated in those patients that stopped oral anticoagulants in the week before surgery. The number of that kind of patients is low. Additional non-invasive cardiology testing such as echocardiography is of limited or no value for preoperative risk stratification.13

Medical imaging

In contrast to the practice in Australia and the UK pathway, a radiograph of the of the knee is systematically repeated the day of admission in the Belgian pathways. This is surprising since it is to be expected that the large majority of these patients already had one or several radiographies of the knee in the preoperative diagnostic work-up that lead to the decision for the surgical intervention at the orthopaedic surgeon's office.

A fluoroscopy during surgery and/or a standard radiograph of the knee in the recovery room (in bed) and in the days after surgery is used to confirm the good positioning of the prosthetic components. As for hip prosthesis, a radiograph performed on the day of surgery in the recovery room is most likely unsuitable as baseline reference for longitudinal follow-up evaluation[14]. It seems more logical to perform a radiograph of the knee a few days later. Two studies however, question the value of the routine postoperative radiograph of the knee after uncomplicated primary knee arthroplasty. In a combined retrospective and prospective study on 750 patients, the postoperative in-hospital radiographs did not alter the postoperative management in any

patient and did not appear to benefit the patient. In the patients who had the first postoperative radiograph performed at 6 weeks, there were no instances in which radiographs taken before discharge were needed to aid in further management or legal defense.[15] In a second, observational study, radiographs were delayed until the first postoperative office visit for more than 600 patients. No patient at a mean follow-up of 4.3 years experienced any complication that was considered to be attributable to not obtaining early postoperative radiographs.[16] Another smaller observational study on 98 patients showed similar results.[17]

Hip to ankle radiographs (or full-leg standing x-rays) are performed based on the assumption that restoration of neutral alignment of the leg is a factor affecting the long-term results of total knee arthroplasty.[18] One randomized study however, showed that there was no difference in the postoperative mechanical axis between a group with and a group without preoperative full-leg standing radiographs.[19]

Several studies, including one Belgian study, have focused on the emerging technology of computer-assisted knee arthroplasty. Those studies compared the results of full-leg standing radiographs with a fluoroscopy-based computer navigation system. [20],[21],[22] Using surrogate endpoints related to the performance of the computer and those studies were unable to show benefits in the long-term outcome and functional improvement of the patient.

The added value of the preoperative full-leg standing radiograph in the long term outcome of the patient is thus not supported by solid evidence from the literature. Moreover, there is evidence against its possible value in the alignment of the leg from one study.

Systematically repeating the full-leg standing radiograph which is done in one of the Belgian pathways one week after surgery can be defended as kind of indirect quality control of alignment. However, more important quality indicators are related to the immediate functional improvement of the patient and pain relief and the long-term outcome including revision rate. No evidence is available showing any short term therapeutic consequence, or any functional benefit for the patient when performing an in-hospital postoperative full-leg standing radiograph.

Laboratory tests

Postoperative anaemia induced by orthopaedic surgery is a frequent finding. It is unclear whether laboratory tests for anaemia (Hb, Hct) should be performed routinely. It is very unlikely that the routine use of other tests such as UCE, INR or the 'weekly lab' we found in one Belgian pathway is indicated for patients without specific co-morbidity (e.g., renal insufficiency, hemophilia,…).

Rehabilitation

Rehabilitation *in se* is a necessary activity for every patient after major joint surgery such as a knee arthroplasty. It is much less clear which techniques, how soon after surgery and with what intensity rehabilitation should be performed. A relatively small RCT (71 patients with hip or knee replacement) compared the beginning of inpatient rehabilitation on postoperative day 3 versus day 7. Early rehabilitation resulted in shorter length of stay and more rapid attainment of short-term functional milestones. There were no differences in functional outcome at 4-month follow-up.[23] Assessments of the patients was not blinded. Another more recent good quality RCT randomly assigning subjects to either 12 supervised rehabilitation sessions between months 2 and 4 after knee arthroplasty, or to standard care, showed a modest effect on the primary outcome, i.e., walking (25 m more on the 6-minute walk test). [24]

Further trials on the role of the intensity of physiotherapy are clearly needed. Whether bed exercises on day one after knee arthroplasty are useful is unknown. For primary hip arthroplasty bed exercises did not result in any short term functional benefit in a single blind RCT on 42 patients.[25] In the studies available on in-hospital rehabilitation after knee arthroplasty, the duration of the active exercise therapy is 30 minutes39 to one hour or more23 per day. Other physiotherapy related interventions, if useful (see further), such as TENS or ice application are usually not included in this time. Questions remain on the extent of integrated self care exercises by the patient and group sessions.

Two RCTs showed that Transcutaneous Electric Nerve Stimulation (TENS) has no utility as analgesic therapy after knee arthroplasty.[26] [27] Different reviews exist on the utility of TENS in postoperative pain management. Several reviews present negative conclusions on TENS effectiveness.[28] [29] [30] These reviews dichotomised trial results. One meta-analysis concluded that

TENS provides benefit above placebo. [31] No trials on arthroplasty were included however. A general conclusion is that the study design is of paramount importance in studies on TENS in acute postoperative pain since non-randomized studies tend to overestimate treatment effects.[28]

Evidence for treatment effectiveness of cold therapy by ice application, cold pads or cold compression dressings is conflicting. Some studies show a modest effect27 [32 33 34] especially on postoperative blood loss, while other RCTs did not find a significant benefit on analgesia or outcome.[35 36 37 38]

The evidence on a *continuous passive motion* (CPM) device even years after the widespread introduction of this device, remains limited, especially for characteristics such as total duration and intensity of treatment. The first RCT on CPM for knee arthroplasty, a high-quality trial, concluded that when postoperative rehabilitation regimens that focus on early mobilization of the patient are used, adjunct range-of-motion therapies such as CPM that are added to daily standard exercises sessions offer no additional advantages in knee range-of-motion or in Osteoarthritis Index or quality of life scores up to six months after intervention.[39] A recent meta-analysis and Cochrane review from the same authors concluded that continuous passive motion in combination with physiotherapy may offer small beneficial results for patients following total knee arthroplasty.40,41

Other courses of action

Two systematic reviews conclude that there is little evidence that pre-operative education or physiotherapy should be supported for all patients. [4243]

The need for routine outpatient physiotherapy in all patients has been questioned. Following primary total knee arthroplasty in a preselected group of patients one RCT found that inpatient physiotherapy followed by a well-structured home exercise regime can dispense the need for further outpatient physiotherapy.[44] In Canada a clinic-based versus a home-based rehabilitation program showed similar outcomes up to one year after primary total knee arthroplasty surgery, leaving unanswered the question as to which type of patients are likely to have an added benefit of rehabilitation in a rehabilitation centre.

Translation into financing

The costs of the four pathways used in this exercise were calculated by using the corresponding billing codes. Based on the critical appraisal of the key interventions as described above likewise the theoretical minimal costs for a strictly evidence-based scenario and the reasonable costs taken into account defendable interventions where evidence is limited or absent were calculated.

Two different scenarios were calculated based on postoperative length of the hospital stay (see table 18). The second scenario was chosen to illustrate the direct impact of LOS on especially the use of resources for rehabilitation services. In the first scenario the postoperative stay is fixed at 12 days, in accordance with the average LOS of 14 days (including the day of admission and the day of surgery) for patients with severity 1 in 2001. In Belgium, different reimbursement possibilities for knee arthroplasty postoperative rehabilitation services are put into place. One possibility is the use of the billing code for hospital physiotherapy (so-called 'M22' in the nomenclature) with a theoretical time of 30 minutes monodisciplinary therapy spend on the individual patient by the physiotherapist. Another possibility is the use of the billing codes of the physicians specialised in rehabilitation: the 'K15' can be compared with the M22 and corresponds to a time of 30 minutes therapy. On the condition that a authorisation of the sickness fund is received, another code ('K30') can be billed corresponding to 60 minutes pluridisciplinary daily rehabilitation by several techniques. In some hospitals, still another code ('K60'), corresponding to 120 minutes multidisciplinary daily rehabilitation by several techniques is used. The different billing codes can be mixed for the same patient during the same hospital stay. For an estimation of the daily time spent for active mobilisation in the postoperative rehabilitation both the time used in clinical trials and in the pathways as described above was used. There are however, no controlled studies that compare the short-term effects on LOS and outcome measures of 30 versus 60 or more minutes average daily rehabilitation. In the two scenarios arbitrarily a daily equivalent of 60 minutes rehabilitation (K30) was used. Since it is unlikely that the average patient will support one hour of active mobilisation during the first two postoperative days, an half hour equivalent was used. Every patient will spent at least one or two weekends in the hospital in the postoperative period. It is not expected that rehabilitation services as determined

in the description of the billing codes (multidisciplinary, several techniques) will be fully available in the weekend. A reduction of rehabilitation activities in the weekend possibly has only a small, if any, effect on the LOS for knee arthroplasty, according to one non-randomized clinical trial[45], and reflects current practice in the majority of hospitals. In the following description, the calculated costs will be compared with the reference costs of SOI 1 patients. In the tables both SOI 1 and 2 are presented. The cost of patients with SOI 1 is constantly lower than the costs of patients with SOI 2 as expected.

Table 18. Two scenarios for calculating the costs of the clinical paths (for nomenclature see appendix 3.1).

Scenario	Postoperative length of stay (days)	Nomenclature for rehabilitation
Scenario 1	12	9 * K30 (558821) plus 3 * K15 (558806)
Scenario 2	Varies by clinical pathway	X * K30 (558821) plus 3 * K15 (558806)

The costs of all clinical pathways and of the calculated theoretical minimal and reasonable costs for *clinical biology* are lower than the reference costs (table 19). In general, the amount spent for clinical biology is relatively low in all the pathways. The calculated cost for the Belgian pathways is still in contrast with the foreign pathways and the theoretical reasonable costs. This is explained by repeated preoperative tests and more elaborate postoperative laboratory controls performed in routine. (complete with frequency table results).

Table 19: Average costs of a hospital stay for the clinical pathways in function of cost group for scenario 1 (postoperative length of stay for all clinical pathways = 12 days [nomenclature = K30 for 9 days and K15 for 3 days). Refence costs of 2001 for severity 1 (S1) and 2 (S2).

Clinical path	Clinical biology	Imaging	Other reimbursed activities	Surgery + anesthesiology	Total (without surgery)
rotherham	0.79 €	16.72 €	302.79 €	1 040.48 €	320.30 €
vincent	8.02 €	35.53 €	302.79 €	1 040.48 €	346.34 €
B1	18.71 €	137.94 €	302.79 €	1 040.48 €	459.44 €
B2	10.98 €	148.77 €	352.77 €	1 040.48 €	512.52 €
minimal	0.00 €	0.00 €	302.79 €	1 040.48 €	302.79 €
reasonable	0.79 €	35.53 €	302.79 €	1 040.48 €	339.11 €
2001 reference S1 mean	34.94 €	79.59 €	264.30 €	1 062.31 €	378.83 €
2001 reference S1 median	29.07 €	62.72 €	173.91 €	1 048.94 €	265.70 €
2001 reference S2 mean	46.23 €	104.16 €	321.04 €	1 087.52 €	471.43 €
2001 reference S2 median	38.73 €	75.63 €	192.94 €	1 048.94 €	307.30 €

Note: reference values extracted from the database publicly available from the Technical Cell of the Belgian Federal Public Health Services.

In the category *medical imaging* the cost of both Belgian pathways clearly exceeds the costs of the other pathways and the calculated reasonable cost, but also the reference cost for knee arthroplasty. This can be explained by the routine use of RX full leg in both Belgian pathways,

while in the majority of Belgian hospitals just the classical RX knee is used for imaging. The calculated costs for the Rotherham and St. Vincent pathway as well as the calculated theoretical reasonable cost are to a small extent lower than the reference value. A detailed analysis of real Belgian costs (SOI 1) in this category shows that antero-posterior/lateral X-ray of the knee accounts for 34% of the costs, RX full leg for 23%, thorax for 7% and echocardiography and vascular duplex both for about 5%.

For the third category ('other activities') the most contributing cost factor is the billing for rehabilitation activities. In Belgian hospitals, an enormous variability in the billing practices for this activity is present for knee arthroplasty, ranging from the systematic use of M22 (nomenclature of physiotherapists) to the systematic use of K60 in all patients (see KCE report on reference prices). Noteworthy is that the mean and median daily cost for postoperative rehabilitation is 23.35 € and 12.76 € respectively in Belgian hospitals. In this simulation 2 scenario's were used, as described above. Calculations based on the assumptions in the first scenario approximate the mean reference cost but are higher than the median reference cost. The simulation based on scenario two (table 20) illustrates the high dependence of the costs in this category on the length-of-stay of the patients. On average, the LOS in lower in the (Belgian) hospitals that use the clinical pathway, which account for the differences with hospitals with the average or even longer LOS. A detailed analysis of real Belgian costs (SOI 1) in this category shows that K60 (pluridisciplinary rehabilitation 120 min) accounts for 34% of the costs, K30 (pluridisciplinary rehabilitation 60 min) for 23%, in hospital monodisciplinary physiotherapy by M-nomenclature for 23%, K15 for 8%, pulmonary functional tests for 3% and ECG for 2%.

In general, the calculated total costs for the foreign pathways and the theoretical reasonable cost relatively approximate the reference costs for patients with SOI level 1. For both Belgian pathways, the calculated costs would be closely in line with the other pathways if the cost for imaging did not exceed the reference values and the calculated reasonable cost.

Table 20: Average costs of other reimbursed activities for a hospital stay for the clinical pathways: scenario 2 (length of stay is variable per clinical pathway; nomenclature = K15 for 2 days, K30 for the remaining number of days). Reference costs of 2001 for severity 1 (S1) and 2 (S2).

Clinical path	Other reimbursed activities (12d)	Length of postoperative stay	Other reimbursed activities	Total (without surgery)
rotherham	302.79 €	8	201.86 €	219.37 €
vincent	302.79 €	9	230.76 €	274.31 €
B1	302.79 €	10	259.66 €	416.31 €
B2	352.77 €	10	309.64 €	469.39 €
minimal	302.79 €	8	201.86 €	201.86 €
reasonable	302.79 €	10	259.66 €	295.98 €
2001 reference S1 mean	264.30 €	12	264.30 €	378.83 €
2001 reference S1 median	173.91 €	12	173.91 €	265.70 €
2001 reference S2 mean	321.04 €	14	321.04 €	471.43 €
2001 reference S2 median	192.94 €	14	192.94 €	307.30 €

Note: reference values extracted from the database publicly available from the Technical Cell of the Belgian Federal Public Health Services.

Discussion

In this brief exercise we found that for a standard patient undergoing a standard non-complicated surgical intervention such as primary knee arthroplasty for degenerative osteoarthritis several clinical pathways are available, both internationally and in Belgium. We also demonstrated that it is possible to calculate the minimal and reasonable theoretical costs for this frequent orthopaedic procedure.

A first major finding was the discrepancy between the use of diagnostic tests in medical imaging and clinical biology in the different pathways: For both imaging and clinical biology but also cardiology tests, the Belgian pathways used much more tests than the international ones.

In a next step, all the key interventions were submitted to a systematic literature search for evidence-based guidelines, systematic reviews and primary trials, followed by critical appraisal and summary in an evidence table. The fact that in the Belgian pathways some preoperative tests (ECG, radiograph of thorax, lab tests) were repeated was no surprise. Previous and recent national studies already showed that part of the Belgian hospitals have a tradition in the routine overuse of preoperative tests.

For most key interventions, evidence could be found in the medical literature. For some interventions the evidence was absent: and this most obvious for laboratory tests. While hemoglobine-control can be considered as a reasonable test to check for postoperative anaemia, the routine use of a battery of tests in a 'weekly lab' is highly questionable. The value of this practice has never been assessed (and probably never will be) and is a local tradition. The costs of these common lab tests is low in general.

The systematic imaging of the full leg preoperatively and again postoperatively in both Belgian pathways was in contrast with not only the international pathways and the evidence, but also with the average practice in the majority of other Belgian hospitals where imaging is limited to standard radiographs of the knee only. Available trials show that obtaining one series of routine postoperative joint radiographs either just before discharge or at the moment of the first postoperative visit will significantly reduce costs without compromising patient care. In contrast to total hip arthroplasty, the practice of obtaining routine, immediate postoperative knee radiographs in the absence of a specific clinical indication does not provide any additional clinical information, is not cost-effective, and does not appear to benefit patient care. The costs of routine and repeated imaging with full leg radiographies is substantial. This cost also in part accounts for the difference in costs between the two Belgian pathways and the reasonable cost we calculated.

The Belgian pathways for knee arthroplasty that were used in this exercise are more expensive for imaging and biology. Clinical pathways in general tend to reduce the length of stay. This reduction can in theory outweigh the increased use of certain billing codes. However, there is no evidence that the overuse of imaging or lab tests leads to a more efficient organisation of the care process and a reduction of LOS. In most studies a reduction in length of stay is most often associated with no significant change in patient outcomes.[46] However, very short lengths of stay can be associated with increased intensity of care following discharge of patients, inducing possible cost shifting: the cost incurred by transferring patients to rehabilitation hospitals may be greater than had the patients remained in the acute care hospital for an additional 1 or 2 days and been sent directly home.

A second major finding of this exercise is the dependence of the costs of certain interventions from the length of stay: the costs for rehabilitation is directly related to the postoperative length of stay. The highest costs, next to the billing costs directly related to the surgical procedure and anaesthesia, come from the billing of rehabilitation. There are insufficient data to support specific perioperative rehabilitation strategies. Early mobilization is considered as the gold standard and its effect on short-term outcome is supported by evidence23 [47] [48]. However, the components and the daily minimal duration of the rehabilitation activities in the hospital are unknown. Progressive active exercise therapy is probably most paramount, but there are no clinical trials that determine the content of the best exercise program. The value of other strategies such as continuous passive motion, frequently used in daily clinical practice, or electrotherapy is very limited. Moreover, there is even evidence against their use. Some trials showed that the addition of continuous passive motion improved the postoperative range of motion of the knee, whereas other studies have demonstrated no difference. The rigor of the study designs has been questioned[49]. All the studies concluded that CPM did not affect the long-term knee range of

motion. Recent systematic reviews therefore concluded that there may be some short term but not long term benefits. Specific trials for postoperative TENS after arthroplasty were not able to show a beneficial effect on the use of analgetics.

This brief exercise has several potential limitations. As the time frame for this study was limited, it was impossible to perform a full systematic review including the grey literature for all the key interventions described in the pathways. Nevertheless, most controlled trials are published in indexed peer-reviewed journals. Although a number of clinical experts were consulted, it cannot be excluded that certains key interventions were forgotten in the evidence search.

In addition to the pure financial billing costs, other facets of cost need to be considered too, e.g., cost related to subjective patient comfort, patient transport, nurse and technologist time, and radiation exposures for medical impagin, among others. Although the choice of interventions withheld for the calculation of the minimal versus reasonable costs was based on the evidence table whenever the information was available, this approach prompted for some arbitrary decisions such as the use of a daily 60 minute equivalent for the rehabilitation billing code. This equivalent takes into account an average daily time of twice 30 minutes for active mobilisation by a physiotherapist and possible ergotherapy and does not include CPM or TENS. Surprisingly, no randomised clinical studies on the optimal duration and components of immediate postoperative rehabilitation are available. In the specific Belgian context with a difference in reimbursement depending on the time spend (30, 60 or 120 minutes) and a enormous variability in billing practices, a randomised trial comparing short- and long-term outcome measures after arthroplasty depending on the time spent to immediate postoperative rehabilitation is to be recommended for the research agenda of university hospitals, physiotherapists and rehabilitation centres.

Key Messages

- **For total knee arthroplasty, it is feasible to calculate the theoretical costs based on critically appraised pathways and assumptions on billing practice for rehabilitation services. This cost approximates the historical reference cost for the lowest level of severity.**
- **The use of medical imaging and to a lesser extent of clinical biology was much higher in the Belgian pathways in comparison with the international pathways. Repeating preoperative tests on the day of admission and the systematic imaging of the full leg both pre- and postoperatively is in contrast with current practice guidelines and available evidence.**
- **Rehabilitation is the major cost driver and is highly dependent on the postoperative length-of-stay of the patient. The optimal daily duration and components of immediate postoperative rehabilitation are unknown. The benefits of the routine use of continuous passive motion are limited. TENS is ineffective.**

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3.2.3. Carotid endarterectomy

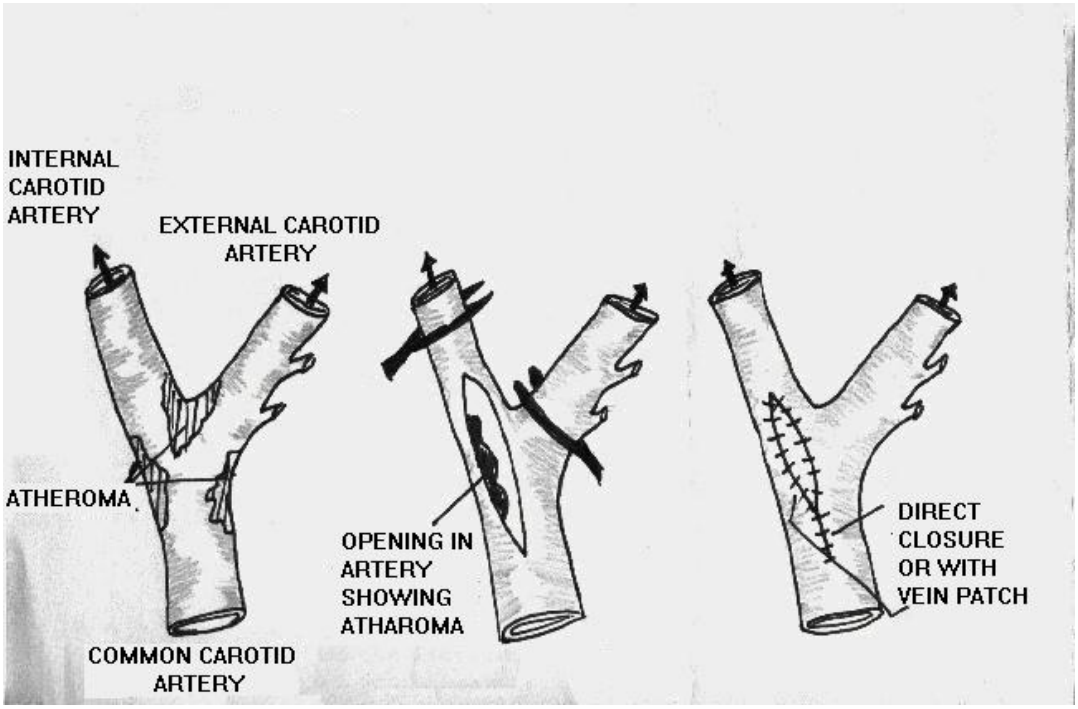
Introduction

Carotid endarterectomy (CEA) is a surgical procedure which involves removing an abnormal thickened and stenotic part of the proximal part of the internal carotid artery (ICA), which carries arterial blood to the brain. Such stenosis can give rise to major or minor strokes or transient ischemic attacks (TIA) through complete occlusion of the stenosis or more often by giving rise to embolism originating on the thrombogenic surface of the atheromatous arterial lining of the arterial wall.

The aim of the procedure is to reduce the risk of a new or recurrent ischemic stroke in these patients. This risk depends largely on the fact of whether a patient had or had no recent (i.e. < 6 months) symptoms related to the carotid stenosis. In asymptomatic patients a carotid narrowing may be an incidental finding, often by non-invasive testing following the detection of a cervical bruit during routine physical examination. In both symptomatic and asymptomatic patients in which severe ICA stenosis has been documented, carotid endarterectomy can prevent stroke but this benefit has to be balanced against the risk of stroke as a consequence of surgery, the risk of other complications of surgery and the cost of surgery, as well as the risk and cost of investigations to select suitable patients.

CEA can be performed both under general and loco-regional anaesthesia. The carotid bifurcation in the neck is exposed[1], then gently mobilised and slings are placed around the internal, external and common carotid arteries. After applying clamps to the three arteries, if possible away from any atheromatous plaque, the bifurcation is opened through a vertical incision, the entire stenotic lesion cored out, the distal intimal margin secured, the arteriotomy closed and the clamps released to restore blood flow to the brain (figure 1[2]). Sometimes, a shunt is installed to bypass blood flow over the clamped vessels, in order to prevent cerebral ischaemia during the operation.

Carotid artery stenting (CAS) is an alternative and less invasive technique for treating carotid artery stenosis, introduced in recent years. A comprehensive study of the scientific literature on the indications for CAS has been performed in our centre[3]. Figure 4 presents the evolution of the estimated number of CEAs and CAS in Belgium between 1997 and 2001.



From Repatriation General Hospital Daw Park - SouthAustralia Vascular Surgical Services

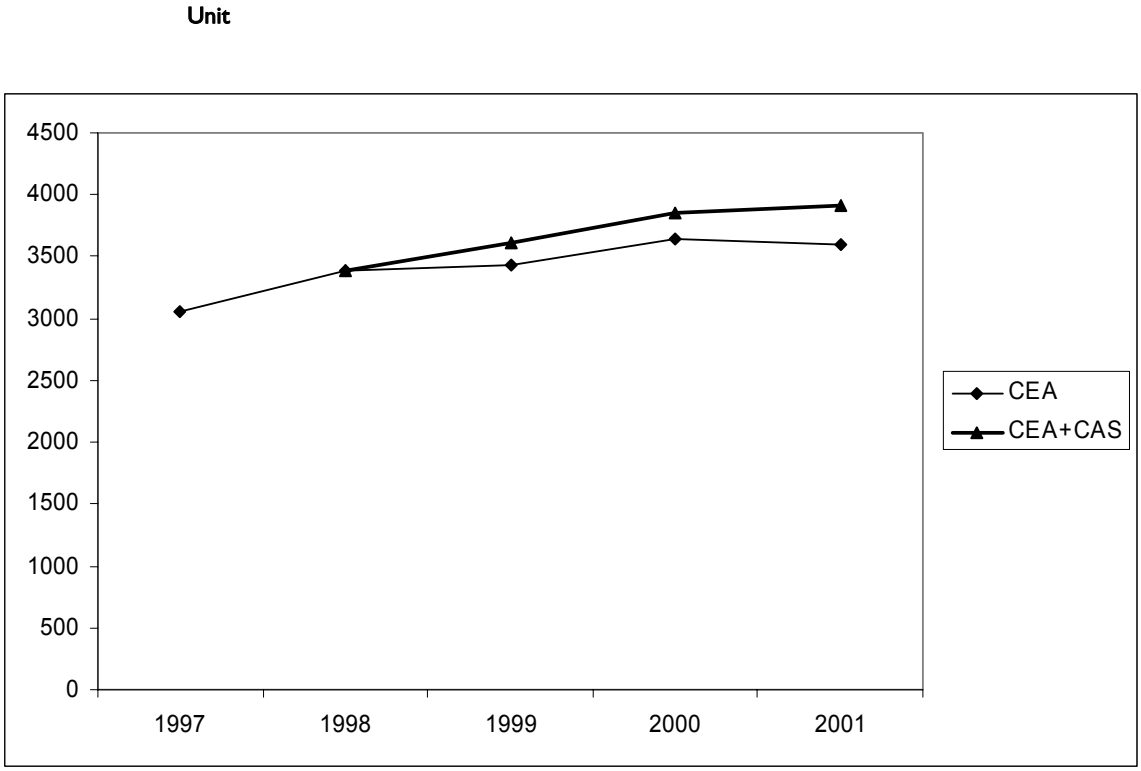


Figure 4: Estimated number of CEA and CAS between 1997 and 2001 in Belgium.

Description of the pathways and/or guidelines

Clinical pathway	Day -1	Day 0
Sewickley	DUS	peroperative EEG (monitoring) post anesthesia care unit monitoring
Carolina	DUS stress thallium scintigraphy digital subtraction angiography FBC UCE glucose ECG	
Pennsylvania	DUS digital subtraction angiography	post anesthesia care unit monitoring
Belgium	DUS digital subtraction angiography FBC glucose	
Minimal	DUS magnetic resonance imaging (10%) ECG	anesthesia local or general post anesthesia care unit monitoring (6%)
Reasonable	Chest X-ray DUS and in some patients digital subtraction angiography and/or magnetic resonance imaging (20%) FBC UCE glucose ECG	anesthesia local or general post anesthesia care unit monitoring (30%)

We performed a limited literature survey to retrieve Clinical Pathways (CP) that are in use at different domestic and international institutions[4 5 6 7 8 9]. None of these CP's considered an entire pathway including the whole of preoperative assessment of patients through postoperative care. Most describe a specific part of the pathway and have been introduced for different reasons: to try to limit hospital length of stay, to guide the use of imaging techniques (arteriography vs duplex or magnetic resonance), the need to screen for coronary heart disease (CHD) or to electively admit patients postoperatively to intermediate or intensive care units. Some CP's stress the importance of the use of general vs local anesthesia. For the current study we selected three international CP's of which sufficient data were available from our literature survey (Sewickley Valley Hospital-Pennsylvania, Univ of South-Carolina, Univ of Pennsylvania).

One Belgian pathways sent to us, consisted of nursing care pathways rather then clinical pathways. A second one stressed nursing activities in particular as well but did however give some information on imaging and timing of events.

The typical course of a CP is depicted in the table and consists of three discrete episodes:

1. In the pre-operative phase the operative indication is assessed and complementary testing is performed if needed. This can mostly be done on an ambulatory basis. In some hospitals, patients are admitted the day preceding the operation to perform the angiography.

2. Mostly, the patient is admitted to hospital the same day as the operation. Decisions have to be made on the type of anaesthesia and whether or not to follow-up patients in the ICU postoperatively.

3. In most of the CP's retreived, the authors intended to discharge the patient on the first postoperative day.

Preoperative assessment

The CP starts at the surgeon's office where information is given to the patient and his relatives and where the preoperative exams are planned. The surgeon evaluates the operative risk of his patient by history taking and physical examination and decides which additional tests are needed to elaborate the surgical risk.

Laboratory tests

Sewickley Valley Hospital and University of Pennsylvania School of Medicine do not mention explicitly which lab tests should be ordered. In the CP of the Medical University of South Carolina a very limited set of routine tests is defined: Hct, glucose, potassium and creatinine. By implementing a CP and hence trying to limit preoperative laboratory examinations, these authors saw a reduction in laboratory charges of 77%. In the single available Belgian pathway, lab tests are done on the preoperative day and are repeated on day 1.

Cardiac risk evaluation

Both Pennslylvania based CP's do not specifically mention cardiac preoperative examinations. The Medical University of South Carolina protocol specifically targeted selective cardiac stress testing in which it succeeded: due to the CP, cardiac testing charges were reduced by 73%. In the outpatient part of the CP, ECG is not specifically asked, but a cardiology consult is ordered "if indicated". Before introducing the CP, it was routine practice to do noninvasive dobutamine stress testing with thallium scintigraphy in all patients. Still a high proportion (80%) of their patients underwent thallium stress testing, sometimes followed by catheterisation later on.

Imaging

In Sewickley, prior to May 1992, arteriography was performed routinely but from 1993 on, it was changed to duplex ultrasound (DUS) and a CT head-scan. Selective angiography from than on was used only for patients with questionable scans or symptoms. In 1994, the CT head scan also was ordered selectively in those patients with strokes or questionable symptoms. In their follow-up study, published in 1998, DUS was used in 93% of patients vs 7% angiography.

In the Medical University of South Carolina, imaging was limited to DUS in the following cases: in symptomatic patients with clear duplex evidence of at least a 70% stenosis and in asymptomatic patients with at least a 80% stenosis. Nevertheless angiography still was done in 91% of their patients, whereas before introduction of a CP, it was routinely done in all patients before CEA.

At the University of Pennsylvania School of Medicine, a major component of the pathway emphasized the decreased reliance on invasive contrast angiography and a significant decrease in the percentage of patients receiving arteriograms from 96.9 to 43.7 was noted.

In the Belgian pathway patients are admitted on "day–2" for pre–procedural assessment and on "day-1", angiography is done, presumably in all patients.

Day 0

Admission

In both Pennsylvania based CP's most patients are admitted the day the operation has been scheduled ("same day admission"). The Medical University of South Carolina intended to perform angiography and stress testing as much as possible on an outpatient basis, yet only 51% of their patients were admitted on the same day as surgery.

Anesthesia

Some CP's stress the importance of the use of local anesthesia while other leave it to the anestesiologist to decide which type of anesthesia to use. In Sewickley, 87% of the CEA's were performed with regional block anesthesia. At the Medical University of South Carolina no attempt was made to standardize the type of anesthesia. At the University of Pennsylvania School of Medicine all CEA's were performed employing general anesthesia.

Early postoperative care

Because most complications following CEA occur during the early postoperative period, patients have to be followed a certain number of hours (3-6) in the PACU (post anesthesia intensive care unit). Depending on their status, they can be transferred from the PACU directly to the surgical floor or otherwise to a monitored floor or if necessary to the ICU. In Sewickley, the patient is monitored in the PACU for a minimum of three hours. If his or her blood pressure is maintained below 180 mm Hg without additional medication and cardiac and neurologic status both are normal, the patient is transferred to a medical surgical floor. Only 10% of their patients required transfer to the ICU.

Su et al from the University of Pennsylvania School of Medicine, stress the importance to admit the patient to the hospital early in the day to allow for early start and completion of surgery. Patients were evaluated 6 hours postoperatively and if cardiovascular and neurological status were stable, they were transferred from the intensive care unit to a step-down unit.

At the Medical University of South Carolina, ICU utilization was avoided when possible, and it was attempted to reduce postanesthesia recovery unit use to 6 hours postoperatively, followed by transfer to the regular nursing unit if the patient was stable. Detailed figures in ICU are not given.

At the University of Pennsylvania School of Medicine patients were evaluated 6 hours postoperatively and, if stable, were transferred to a step-down unit.

Day 1

At Sewickley Hospital, discharge is tentatively scheduled for the morning after the operation if strict criteria are met. 84% of patients were in the hospital for only 1 day and average length of stay (LOS) was 1.27 days. After implementing the CP, the Medical University of South Carolina achieved lowering the average LOS from 5.7 to 2.2 days. At the University of Pennsylvania School of Medicine, the implementation of a CP significantly decreased LOS from 6.0 to 3.3 days.

Critical appraisal of the pathways content

In critically appraising the need for routine investigations and procedures in CEA patients, we had to decide which grade of invasiveness carotid surgery was to be considered. In the ACC/AHA Guideline Update on Perioperative Cardiovascular Evaluation for Noncardiac Surgery (Eagle) different types of noncardiac surgery are classified in three risk categories in which CEA is designated as "intermediate" risk, together with major head and neck surgery, intraperitoneal and intrathoracic surgery, orthopaedic surgery or prostate surgery. The NICE guidelines on the other hand not specifically mention CEA but for example endoscopic resection of the prostate is categorized as a grade 3 (major) operation whereas radical neck dissection is considered as grade 4. In applicating the NICE guidelines we considered CEA as being a grade 3 (major) operation.

Apart from the surgical procedure as such, i.e. CEA being an intermediate-to-major severity procedure, one should take into account the physical status of the patient. An often used classification are the ASA-grades as proposed by the American Society of Anesthesiologists[10]. It

ranks patients depending on their health status from ASA 1 (patients considered to be normal and healthy) to 6 (clinicaly dead patients being maintained alive for harvesting of organs). ASA 2 patients have mild to moderate systemic disease and ASA 3 patients have severe systemic disease that limits activity but is not incapacitating.

The key interventions and the results of our literature search are summarized in table 21.

Table 21 Key interventions and the results of the literature search.

TOPIC	KEY INTERVENTION	REF	TYPE	n	QUAL-ITY APPRAI-SAL	RESULT	LEVEL OF EVIDENCE
PREOPE-RATIVE TESTS	Lab testing	NICE	EBG		-	routinely indicated	2a
	Chest X-ray	NICE	EBG		-	uncertain	5
	Resting ECG	NICE	EBG		-	routinely indicated	2a
	Cardiac risk evaluation	Circulation. 2003.	EBG		-	not routinely indicated	2a
IMAGING	Duplex ultrasound (DUS), digital subtraction angiography (DSA), magnetic resonance imaging (MRI)	Nederkoorn. 2003.	SR	63 patient series	-	MRI had a significantly better discriminatory power than DUS in diagnosing 70% to 99% stenosis. No significant difference was found in detecting occlusion (cf table) for which both techniques were very accurate	1a
	DUS associated with MRI at some stage	Norris, 2004	EXPERT OPINION		-	In an ultrasound laboratory where accuracy and reliability are established and regularly reviewed, DUS can be reliably used for determining carotid stenosis if the results are clear and indisputable.	5
ANESTHE-SIA	BRAIN MONITORING	SIGN	EBG		-	no firm recommendations can be given	4
POSTOPE-RATIVE ANESTHE-SIA CARE UNIT (PACU)		SIGN	EBG		-	indicated and able to prevent admission to ICU	4
POSTOPE-RATIVE ICU		McConnell DB,, 1996	Retro-spective study		5/10	ICU needed in 37% of patients	2b
		McGrath JC, 1996	Retro-spective study		6/10	ICU needed in 22% of patients	2b

Laboratory tests

The NICE extensively reviewed the literature on the use of preoperative tests[11] and we published ourselves a report on the subject[12]. Concerning preoperative haemoglobin, haematocrit, full blood count (FBC), biochemistry and hemostasis tests, there is no direct evidence that carrying out these tests on a routine basis would or would not improve health outcomes for patients.

In ASA 1 patients, the NICE-guideline recommends FBC in patients older then 40 years and renal function in patients older then 60 years. Haemostasis tests are not indicated. In ASA 2 and 3 patients, the NICE-guideline recommends FBC and renal function in all patients. Haemostasis tests are mostly not considered appropriate except for some categories of patients where the panellists as a group remained uncertain.

In all patients, a consensus could not be obtained on the usefulness of random glucose measuring, blood gases and urine analysis.

Chest X-ray

There is no direct evidence either that carrying out preoperative chest x-rays improves outcomes for patients or that it does not. The NICE panel concluded that chest X-ray is not indicated in ASA 1 patients < 60 years old, but remained uncertain for all others and hence a straightforward advice could not be given. In ASA 2 adults with comorbidity from respiratory disease in which there has been a change in patient's symptoms a chest X-ray might be considered.

Resting ECG

NICE-Panellists agreed that everyone over the age of 60 years should have a routine ECG, regardless of comorbidity. However, not all abnormalities present an increased operative risk to the patient and not always indicate that there should be a change in clinical management, unless there were a corresponding clinical finding.

Lung function testing

These tests should only be carried out for specific groups of patients at the discretion of the consultant surgeon or anesthesist, e.g. patients with chronic bronchitis or CHD. Apart from ASA 2 patients with COPD, CEA patients should not undergo lungfunction testing.

Cardiac risk evaluation

Carotid artery disease is a manifestation of widespread atheromatosis in a certain patient. This is illustrated by the fact that on average, even an asymptomatic carotid stenosis is associated with a 7% risk of myocardial infarction yearly[13]. This means that whatever therapeutic action is taken in patients with carotid artery atheromatosis, a more general strategy to look for and correct cardiovascular risk factors should accompany treatment of the carotid artery disease.

There is no consensus with regard to the most optimal or necessary preoperative assessment of cardiac and medical risks before CEA. Associated medical risks including CHD may affect indications for CEA, especially in asymptomatic patients and those with less severe carotid stenosis for whom surgery may be less beneficial. In patients with symptomatic carotid artery stenosis, more advanced medical risk factors are associated with higher surgical risk and with greater absolute and relative reduction in stroke and death after CE[14]. There is no specific evidence to support altering perioperative management protocols in the setting of silent or clinically overt CHD. Most authors have advocated judicious anesthetic and medical measures in the perioperative period in patients with known, treated, or asymptomatic CHD. Others have advocated aggressive treatment of CHD before, with, or closely staged after CE. No level I or level II evidence supports a particular strategy of management of concurrent CHD and CE.

In 2003 the American Heart Association and the American Stroke Association jointly published a scientific statement on coronary risk evaluation in patients with TIA and ischemic stroke[15] which concluded that routine testing for CHD before CEA is not recommended but that it might be prudent for subgroups at high risk on the basis of the patient's atherosclerotic risk profile. While in the late seventees, routine coronary angiography had been recommended at the Cleveland Clinic[16] to all patients undergoing CEA, in its 2002 update, the ACC/AHA states that it is almost

never appropriate to recommend coronary bypass surgery or other invasive interventions such as coronary angioplasty in an effort to reduce the risk of noncardiac surgery when they would not otherwise be indicated[17].

Medical imaging

As mentioned earlier, benefit from CEA is highly dependent on the degree of carotid stenosis and so, accurate quantification of carotid narrowing is of utmost importance in decisionmaking. Current guidelines differentiate between moderately severe (50-69%) stenosis, severe (>70%) stenosis and "near-occlusion" to guide practice and label appropriateness of the operation.

Screening is classically performed non-invasively with doppler ultrasound (DUS) but, until recently, because DUS is highly observer and performer dependent, most surgeons demanded carotid angiography (Digital Subtraction Angiography, DSA) in patients considered for endarterectomy. However, substantial risks are associated with angiography. The risk of minor stroke as a consequence of diagnostic angiography is reported to range from 1.3% to 4.5% and the risk of major stroke from 0.6% to 1.3%[18]. In the ACAST trial half of the strokes associated with surgery were attributable to the arteriogram. Hence interest grow to less invasive and less dangerous techniques to adequately visualize the carotid arteries. Both duplex technology and magnetic resonance (MRI) are progressively replacing invasive imaging and interest in CT-angiography is growing.

Particularly MRI has gained progressively more interest. In a recent systematic review, incorporating 63 patient series, all performed after 1994, Nederkoorn et al.[19] concluded that MRI has a better discriminatory power compared with DUS in diagnosing 70-99% stenosis and is a sensitive and specific test compared with DSA in the evaluation of carotid artery stenosis. For detecting occlusion, both DUS and MRI are very accurate (cf. table 22).

Table 22: Pooled Weighted Sensitivity and Specificity Calculated in a Random-Effects Model

	Pooled Sensitivity, % (95% CI)		Pooled Specificity, % (95% CI)	
	MRA	DUS	MRA	DUS
70%–99% vs <70%	95 (92–97)	86 (84–89)	90 (86–93)	87 (84–90)
<100% vs 100%	98 (94–100)	96 (94–98)	100 (99–100)	100 (99–100)

The use of DSA as a gold standard, which was done in the abovementioned studies, however has been questioned by some authors, the real gold standard for carotid bifurcation disease being the explanted atherosclerotic specimen. When the results of DUS and DSA were compared with the explanted lesion rather than with each other, DUS was actually found to be more accurate than DSA (Moore).

For the moment, there is no consensus among vascular surgeons on the strict indications of DSA before CEA. In a recent paper, published in Stroke, Norris[20] contends that in an ultrasound laboratory where accuracy and reliability are established and regularly reviewed, DUS can be reliably used for determining carotid stenosis if the results are clear and indisputable. When there is doubt, contrast enhanced MRI should be performed. According to Norris, when these guidelines are used, the need for catheter angiography becomes vanishingly small.

Anesthesia

There is a wide variation in using general or locoregional anesthesia, even within a same institution by different surgery. A systematic review of 1996 of small randomised trials comparing local and general anesthesia provided no definite evidence that either was superior[21]. General anaesthetic can be more comfortable to patient and surgeon and is usually preferred where there are technical difficulties such as a high bifurcation. Operating under local anaesthetic has the advantage that patients are able to alert the surgeon to new focal symptoms which might be due

to focal cerebral ischaemia. This might reduce the need for other types of intra-operative monitoring.

Peri-operative cerebral function monitoring

Controlling systemic blood pressure before, during and after surgery is crucial to avoid hypotension (which will make any cerebral ischaemia worse) and hypertension (which may cause cerebral oedema or even intracerebral haemorrhage). Electrocardiogram, oxygen saturation and blood pressure should be monitored in the peri-operative period, the latter ideally using an arterial line. (SIGN 1997; grade C, level IV = expert opinion).

Early warning of cerebral ischaemia may be provided by different intraoperative techniques or by monitoring the neurological state of the patient if operated under local anaesthesia. However, this may be too late for a quickly inserted shunt to ameliorate the consequences of cerebral ischemia. Otherwise, ischaemia may anyway not be reversible if it is actually due to embolism rather than low flow.

To study cerebral protection during CEA, Reuter et al[22] retrospectively reviewed 251 consecutive carotid endarterectomies from 2000 to 2003. They concluded that an intraoperative EEG based decision to shunt may not be as effective as other methods for prevention of perioperative neurologic events. Some surgeons (Lavenson in Reuter et al) conclude that none of the available methods of determining when not to use a shunt under general anesthesia are perfect. Lavenson comments that the only reliable way of determining the patient's neurologic status during cross-clamping of the carotid artery is to monitor the awake patient. He performs CEA under local anesthesia and let the patient squeeze a squeak toy in the contralateral hand during cross-clamping. If CEA has to be done under general anesthesia, some surgeons always use a shunt.

The SIGN 1997 guideline states that no firm recommendations can be given concerning the optimal method of peri-operative monitoring.

Postoperative monitoring

According to the SIGN guidelines, patients should be monitored in a high dependency unit in the immediate postoperative period (post anesthesia care unit, PACU) to allow careful monitoring of blood pressure and neurological condition.

Later postoperative monitoring in an ICU has long been considered as a standard of care after CEA but the need for routine ICU care after uncomplicated CEA has come under close scrutiny in the managed care era. Because most hemodynamic and neurologic instability occurs in the first few hours after CEA, a 3- to 4-hour observation period in a recovery area could be sufficient to discharge most patients to floor care.

McConnell et al[23] retrospectively reviewed the records of 126 patients that underwent CEA. They defined risk factors which would identify patients requiring active intensive unit care and found that preoperative assessment did not aid in predicting the need for ICU care. Selection of patients could be accurately determined by a short period of recovery room observation. They defined requirement for "active" ICU (AIC) as the need for infusion of vasocative, bronchodilator or antiarrhythmic medication beyond the recovery room. In addition treatment for coronary ischemia or myocardial infarction, need for active diuresis or requirement for mechanical ventilation were indications for AIC. There were 132 CEA's in 126 patients in whom 37% required AIC. They concluded that the best predictor for ICU care is the status of the patient in the recovery room.

In a similar study, McGrath et al retrospectivaly evaluated valid indications for ICU admission in 305 patients following CEA[24]. Only 18% of them had an absolute indication for ICU admission (mechanical ventilation, invasive monitoring, intravenous vasoactive drug use). A history of remote MI, arrhythmia or cerebrovascular accident did not support the need for ICU care. The authors recommend that, except for presence of an absolute indication for ICU, only patients with perioperative hemodynamic instability or acute neurological changes be admitted to the ICU. In their series, this would be the case in 22% of all cases.

In a more recent study, Jordan et al, by introducing a strict PACU algorithm in their post-CEA patients[25] could minimize ICU bed utilization to 6.4%. After an implementation period the

average LOS of patients in the PACU stabilized around 180 minutes. Only those patients who were hemodynamically unstable were transferred to the ICU.

Translation into financing

Deciding to perform a CEA is largely based on medical imaging. As the decision to operate a particular patient should normally be taken prior to hospital admission, all imaging should have been done before. Table 24 describes the costs associated with the hospital stay, imaging costs (and other preoperatives) not taken into account. In table 23 we added these costs to the hospital stay costs by way of comparison to the previous calculations.

Table 23. Average costs of a hospital stay for the clinical pathways in function of cost group for scenario 1 (preoperative and hospital stay costs). Refence costs of 2001 for severity 1 (S1) and 2 (S2).

Clinical path	Clinical biology	Imaging	Other reimbursed activities	Total previous columns	Surgery + anesthesio-logy	Intensive care monitoring	Anatom-ical patho-logy
carolina	3.29 €	307.66 €	40.34 €	351.29 €	1 014.93 €	0.00 €	0.00 €
pennsylvania	0.00 €	134.13 €	0.00 €	134.13 €	1 014.93 €	0.00 €	0.00 €
sewickley	0.00 €	58.90 €	62.62 €	121.52 €	1 014.93 €	113.92 €	0.00 €
belgium	1.11 €	134.13 €	0.00 €	135.24 €	1 014.93 €	0.00 €	0.00 €
minimal	3.29 €	73.53 €	16.26 €	93.08 €	1 014.93 €	6.84 €	0.00 €
reasonable	3.29 €	113.66 €	16.26 €	133.21 €	1 014.93 €	34.18 €	0.00 €
2001 reference S1 median	24.76 €	59.58 €	49.93 €	134.27 €	1 023.38 €	216.88 €	50.35 €
2001 reference S1 mean	30.57 €	120.09 €	114.39 €	265.05 €	1 049.32 €	174.98 €	70.94 €
2002 reference S2 median	41.75 €	87.78 €	110.41 €	239.94 €	1 023.38 €	216.88 €	50.35 €
2002 reference S2 mean	48.58 €	188.48 €	190.16 €	427.22 €	1 070.88 €	181.70 €	68.92 €

Table 24. Average costs of a hospital stay for the clinical pathways in function of cost group for scenario 2 (only hospital stay costs).

Clinical path	Clinical biology	Imaging	Other reimbursed activities	Total previous columns	Surgery + anesthesiology	Intensive care monitoring	Anatomical pathology
carolina	3.29 €	248.76 €	40.34 €	292.39 €	1 014.93 €	0.00 €	0.00 €
pennsylvania	0.00 €	75.23 €	0.00 €	75.23 €	1 014.93 €	0.00 €	0.00 €
sewickley	0.00 €	0.00 €	62.62 €	62.62 €	1 014.93 €	113.92 €	0.00 €
belgium	1.11 €	134.13 €	0.00 €	135.24 €	1 014.93 €	0.00 €	0.00 €
minimal	0.00 €	0.00 €	0.00 €	0.00 €	1 014.93 €	6.84 €	0.00 €
reasonable	0.00 €	0.00 €	0.00 €	0.00 €	1 014.93 €	34.18 €	0.00 €

For medical activities not explicitly mentioned in a certain pathway, a cost of 0.00 euro was introduced in the table. Hence, comparing different CP's should be done cautiously but nevertheless important discrepancies are clear when one compares Belgian references to the CP's studied. We did not have access to the 2001 all-Belgian-data that were used to calculate the "reference cost" but instead we could retrieve the resource use for CEA in 2001 of one single insurance company, representing 28% of the Belgian population and 1056 CEA's. These data should be representative for de whole Belgian CEA-population.

A 7 to 12 times higher cost for "other reimbursed activities" was incurred in the reference cost, compared to the "reasonable cost" calculated by us. We found out that these extra costs were generated by an important spending on preoperative cardiac risk assessment. Electrocardiography was performed on average 3.5 times per peri-operative period and echocardiography in 74% of the cases.

Following international accepted guidelines, we calculated peri-operative laboratory costs to be ten times lower then actual claims. This difference can be attributed to the repeating of several lab-tests. Electrolytes as an example were up to 8 times in a single patient, while these should be done for most patients only once. Blood gases and certain hemostasis tests were asked on average 4 to 5 times while these tests are not routinely recommended in international guidelines.

Spending on imaging matched reference costs except for the "Carolina CP" in which the imaging section also included cardiac stress thallium scintigraphy. In our Belgian sample constituting 28% of the population, DUS and DSA was done in virtually 100% of patients. Chest X-ray was asked on average twice and a brain CT-scan in 40% of patients. In 2001, only 5% of patients underwent MRI imaging.

From the additional data we did receive, another stunning finding was that in Belgium, in 24% of CEA cases, a pathological examination of the operative specimen was ordered, which to our knowledge can be justified in scientific research projects but not in clinical practice.

Last but not least, ICU costs explained an important part of the difference between reference costs and our calculations. In most countries it has long been common practice to routinely admit all patients to the ICU following CEA but since the early nineties efforts are done to define low-risk groups of patients that do not require an ICU-stay. Three quarters of patients stayed two days in the intensive care whereas we found that it is only reasonable for 30% of patients being admitted to the ICU for one day.

Discussion

Carotid surgery is only effective in selected patients and if performed with a low rate of complications. There are many tens of thousands of people with carotid stenosis in Belgium but relatively few of these would benefit from surgery. It is essential that safe surgery is offered to patients who have the most to gain (those at highest risk of ischemic stroke, i.e. symptomatic patients with recent onset of symptoms and severe narrowing of the ICA) and who are most likely to survive to enjoy that gain for a number of years.

In selecting patients for CEA, a different strategy is taken into account depending on whether the patient has or has no symptoms which can be related to the index carotid artery stenosis. Major studies on the indications of CEA in asymptomatic patients are the Asymptomatic Carotid Atherosclerosis Study (ACAS)[26] and the Medical Research Council Asyptomatic Carotid Surgery Trial (ACTS)[27]. In its October 2004 update[28], the Cochrane Database of Systematic Reviews concluded that in asymptomatic patients, the risk of stroke in those with "severe" narrowing is not very high. This risk can be reduced by surgery but the surgery itself can sometimes cause a stroke or death. It was found that about 50 people would have to be operated on to prevent one of them having a stroke.

Landmark studies of CEA in symptomatic patients are The North American Symptomatic Carotid Endarterectomy Trial (NASCET)[29] and the MRC European Carotid Surgery Trial (ECST)[30]. Patients who have had a TIA or ischemic stroke during the last six months and are found to have severe stenosis of the proximal internal carotid artery on the side appropriate to the symptoms should be considered for CEA in order to reduce their future risk of stroke. For symptomatic patients, the number needed to treat to benefit within two years is between 3 and 19, depending on age and the degree of stenosis[31].

Symptomatic patients are those with a stroke, TIA or retinal infarction, related to the ipsilateral hemisphere. The clinical diagnosis of stroke is reasonably reliable but diagnosis of TIAs is more difficult and depends on the interpretation of the patients symptoms. There are no symptoms or signs which reliably indicate whether a patient has a severe carotid stenosis. Cervical bruits may be present with quite mild internal carotid disease and are often absent in very severe stenoses. Carotid artery screening always is done by DUS. Depending on the surgeon or the institution, invasive DSA is added before surgery although during the last decade, more and more surgeons rely solely on the results of DUS, sometimes supplemented by MRI in difficult cases.

The risk of stroke and death resulting from CEA is highly dependent on the clinical indication. Bond et al[32] stress that categorization of patients as symptomatic or asymptomatic is an oversimplification and is of limited use in predicting operative risk. There are clinically important differences in risk between different symptomatic indications and patients with only ocular ischemic events are closer in risk to patients with asymptomatic stenosis (in their meta-analysis 2.8 % in both subgroups). In symptomatic patients, the absolute risk of stroke and death from CEA was 5.1 %. In relation to the timing of surgery, the operative risk of CEA in the acute phase of ongoing cerebral ischemia was considered by them as being too high to be justified in routine clinical practice, but surgery in the subacute phase in patients with a stable neurological syndrome is not associated with a higher operative risk than later surgery.

In the nineties, CEA worldwide became the most frequently performed non-cardiac vascular procedure. An estimated 89.000 CEA's were performed in the US in 1993, of which 71% involved patients > 65 years of age (McGrath). The accompanying increasing financial burden lead to a search for a more cost-effective resource use and the implementation of CP's in certain institutions. Different points of interest were stressed by different authors: optimal carotid imaging strategies, preoperative cardiac risk assessment, anesthetic techniques, peroperative brainmonitoring, need for postoperative cardiac monitoring, total length of stay, etc

In order to reduce LOS several strategies can be combined. Patients can be admitted the same day as surgery, they can be discharged early postoperatively and one can also try to reduce the length of stay in an intensive care unit. Preoperative assessment and risk profiling seem to be unreliable to depend on to predict the need of an ICU stay. Several studies have shown that the decision to transfer the patient to an ICU can best be made during the first hours postoperatively, while residing in the PACU. Probably, less than 30% of patients will need intensive care after the first 3 hours postoperatively.

In the CP's we studied, historically determined LOS significantly decreased in all hospitals by introducing the CP: at Sewickley's, average LOS was 1.27 days, at the Medical University of South-Carolina, after 1 year, average LOS was reduced from 5.7 to 2.2 days and at the University of Pennsylvania School of Medicine, it was reduced from 6.0 to 3.3 days. The majority of patients can be discharged the first postoperative day. In a recent study, Sheehan et al reports on a series of 207 CEA patients of which 59 (32%) were discharged to home the same evening[33].

When one compares Belgian references to the CP's studied, impressive discrepancies emerge (table A) resulting in an enormous gap between reasonable and factual practice. Especially imaging techniques, cardiac risk assessment and postoperative monitoring were much more executed than appropriate according to international guidelines. Moreover in an unexplainable amount of patients pathologic examination of the operative specimen was asked for.

People undergoing CEA represent a high risk group of patients in which tolerance for perioperative problems is very low, especially because it concerns a prophylactic operation which by definition is done to prevent (and not to treat) stroke. This explains why so much investment in time and money has previously been done, both by patients and by physicians, hoping that doing as much as possible examinations would result in a better outcome. With the advent of managed care and evidence based medicine, use of resources became more critically assessed and eventually lead to the conclusion that more was not necessarily better. In our country, much work is yet to be done, to close the enormous gap we found between reasonable and factual spending in CEA.

Key messages

- For CEA, it is feasible to calculate the theoretical costs based on critically appraised pathways but there is a clear discordance with daily practice.
- This leads to a major discrepance in cost calculations: in real life (sickness fund data) a much larger proportion of patients than expected underwent imaging techniques, preoperative cardiac risk assessment and postoperative intensive care monitoring. Similar and unexplained findings were witnessed for pathological examination of the operative specimen which was ordered in nearly a quarter of cases.
- Duplex ultrasound of the carotid arteries is a reliable technique for selecting patients for CEA, on condition that the accuracy and reliability of the ultrasound laboratory are established and regularly reviewed.
- The high rates of CEA performed in Belgium at least question the appropriateness of the operation in a number of cases. Implementation of guidelines for patient selection and clinical pathways for the surgical stay are mandatory.

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3.2.4. Appendectomy

Introduction

Appendectomy remains one of the most common surgical procedures in Belgium. In 2001, 15.041 cases were reported, or about 1.5/1000[1]. It has been established that a steady decline can be observed, at least between 1986 and 1996[2]. In the United States, an incidence of 290 000 cases has been reported in 1999, which means a rate of 1/1000[44]. There is also a tendency towards decline [2]. 1/4 to 1/3 of the patients operated on in Western countries are children [69]; peak-incidences are the second and third decade of life.

Accurate diagnosis of acute appendicitis continues to pose a great challenge to clinicians, because the initial presentation of the disease is often obscure and closely mimicked by other common diseases. Moreover, unusual presentations can occur when the the patient is young or elderly, and when the patient is a female of childbearing age or is pregnant[53]. Between one third and one half of the patients presenting to the emergency department in which the diagnosis of appendicitis is considered, have atypical clinical findings (in this text referred to as "**Atypical**" or "**Equivocal**" patients, whereas patients who present with obvious, classical signs and symptoms of appendicitis will be referred to as "**Typical**" or "**Unequivocal**" patients)[3 4 47 37]. Others report as many as 60 to 80% of atypical cases[69]. As a result, many patients with suspected appendicitis but uncertain diagnosis, are admitted to the hospital for a period of inpatient observation ("Wait and Watch", mean time from admission to discharge or surgery 15 hours) [5]. As time evolves, diagnosis often becomes more clear; and on the other hand it is well-known that a beginning appendicitis can resolve spontaneously as well. However, the delayed diagnosis of appendicitis may also lead to a gangrenous or perforated appendix, the incidence of which varies from 11 to 35% in the literature [6 44] Perforation itself is a frequent cause of complications like major abscess, peritonitis, sepsis, or bowel obstruction[52], with resulting increases in morbidity and eventually mortality [69]. In perforated appendicitis, literature reports an average postoperative complication rate of 20 to 33 %, compared with 2 to 13% in patients with unperforated appendicitis[6 7 8].

Another finding is that in 8 to 33% of patients who undergo appendectomy a normal appendix is removed, with a slightly higher incidence in open than in laparoscopic procedures [91]. It has to be noted that in case of appendectomy for acute abdominal pain, it is generally accepted to remove the appendix (when no other medical reason for the complaints can be found) even if macroscopically normal since microscopic abnormalities can be present[10]. Of course, in taking the decision to go to surgery, one has to balance the risks of unnecessary appendectomy to an intervention in cases of perforation[28]. On the other hand, once thought to be relatively harmless, appendectomies that show a normal appendix on pathological examination (often referred to as negative appendectomies) result in considerable clinical and economic cost[11].

A perfect diagnostic test for appendicitis does not exist[11]. Although clinical examination remains the cornerstone of the diagnosis attention has turned towards laboratory assessment, scoring systems as well as radiologic imaging, in an attempt to improve accuracy. The evidence for their specific role in the diagnostic process will be addressed below.

Concerning the classical surgical procedure, on the one hand of an open appendectomy can be performed, in which the appendix is resected through an incision of several cm in the right lower quadrant of the abdomen. On the other hand, since the introduction of laparoscopy, video technology and endoscopic instruments became available which make endoscopic surgery possible. After a small incision (approximating the diameter of the cannula for the laparoscope) is made, cannula and laparoscope can be inserted. This is followed by insufflation of the abdomen with carbon dioxide, to keep the viscera away from the abdominal wall. Then two other small incisions are made, allowing the technical instruments to be introduced. After appendectomy, incisions are carefully sutured. (Figure 5)



Figure 5A

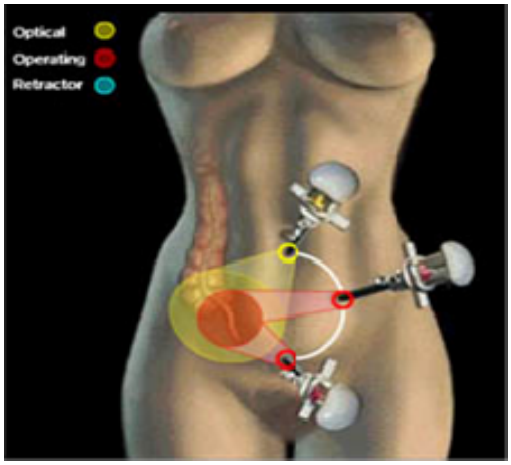


Figure 5B

Although there is little variation among surgeons in the management of early appendicitis, clinical practice differs greatly in the management of gangrenous or perforated appendix. The role of intraoperative cultures, the use of a wound drain or the use of delayed primary wound closure will be shortly addressed below.

There is also a wide disparity in the choice of antimicrobial therapy, the duration of antimicrobial therapy, or the use of antibiotics in the irrigation fluid during surgery. These points however are not the topic of this review. Less literature is available concerning other management points of post- appendectomy complications (e.g. when to repeat imaging studies…), and this topic will also not be included in this short review. Last but not least, the length of hospital stay is another issue causing much debate, but this point also does not belong to the main subject of this paper.

Description of the Pathways and/or Guidelines

The clinical content of the 3 most important pathways found in international peer-reviewed articles (for search strategy: see Appendix) is presented in figure 6[12 13 11]. Only those pathways including medical interference rather than practical patient care (e.g. NeLH guideline appendectomy) were included. On the other hand pathways concentrating selectively on patients with complications after appendectomy were omitted since evidence-based medical literature concerning this topic usually deals with rational use of antibiotics which is not subject of this topic.

To be mentioned is that no international clinical pathways for adults could be found, apart from protocols regarding the use of imaging techniques. The lack of pathways including adult patients is confirmed by Paulson[71]. The issue of choice between different imaging techniques will be addressed in the critical appraisal of the presented pathways (see below). Another remark is that all centers that developed and introduced the presented pathways are tertiary reference (university) hospitals.

Apart from the international pathways, 2 Belgian pathways were retrieved (see Chapter 2, Methodology). One of them contained rather practical patient care ("Care Pathway ") and was omitted; the other pathway (see also Figure 2) is included in figure 6.

Also included in figure 6 are the theoretical evidence-based "minimal" and "reasonable" pathway; for explanation see further (see Critical appraisal of pathway content).

Figure 6 : Acute Appendectomy: 3 international clinical pathways, 1 national clinical pathway. Theoretical evidence-based minimal and reasonable pathway (for information: see " 3.Critical appraisal of pathway content")

Clinical pathway		Day 0	Day 1	Day 2
Cincinnati	atypical (children)	Echography (50%) CT (50%) RX abdomen (20%)		
		FBC + formula urinalysis pregancy test		
			incentive spirometry	incentive spirometry
	typical			
			incentive spirometry	incentive spirometry
Boston	atypical (children)	Echography (25%) CT (75%)		
		WBC + formula urinalysis pregnancy test		
	typical			
		pregnancy test		
Texas	atypical (children)	Echography (30%) CT (20%)		
		WBC + formula, urinalysis (repeat all)		
	typical			
Belgium	atypical (children + adults)	Alvarado-score (clinical)		
		Echography (100%) CT (75%)		
		amylase, OT/PT, LDH, bilirubine, creatinine, alk. fosfatase, CRP, γGT, glucose, Hb, FBC+ formula, pregnancy test, urinalysis (repeat WBC+formula)		
	typical	Alvarado-score (clinical)		
		WBC + formula		

Minimal	atypical (children + adults)	Echography (children only) CT (adults only) CRP, WBC + formula, urinalysis (repeat all)		
	typical	CRP, WBC + formula, urinalysis		
Reasonable	atypical (children + adults)	Echography +/- CT (children only) (Echo +/-) CT (adults) amylase, bilirubine, creatinine, OT/PT, CRP, γGT, glucose, WBC + formula, pregnancy test, urinalysis (repeat WBC+formula, CRP, urinalysis)		
	typical	CRP, WBC + formula, urinalysis		

FBC: full blood cell count
WBC: white blood cell count
OT/PT: aspartate aminotransferase/alanine aminotransferase
UCE+: ureum, creatinine, potassium extended
γGT: gamma-glutamyltransferase
Hb: hemoglobine

It also has to be mentioned that in all pathways additional specifications were made concerning indications for imaging studies. In the *Cincinnati* pathway, in atypical cases ultrasonography (US) should be used if the patient is female, thin, of preschool age or if the clinical symptoms are rather focal. On the other hand, CT-scan is meant for males, for obese patients or patients with signs of guarding, or if plain abdominal X-ray is difficult to interprete due to gaseous bowels. For cost calculation, it was estimated that 50% of the patients in this pathway need an US, 50% a CT-scan. In the pathway of *Boston*, in the case of an atypical patient, US is to be used in girls of reproductive age (>11 years) and in thin patients (estimated on 25% of all the patients), whereas CT-scan is used in all others (estimated on 75%) . In the *Texas* study, the decision whether or not to perform imaging and which imaging was taken by the surgeon; in the presented data about 30% of patients received US and 20% CT-scan. In the *Belgian* pathway, US is used in all atypical presentations, and a senoir staff member decides on the usefulness of an additional CT-scan. For purposes of cost calculations, it was assumed that about 75% of all atypical patients in this pathway received an additional CT-scan.

Critical Appraisal of the Pathways Content

The key interventions and the results of our literature search are summarized in Table 25.

Table 15 : Summary of critical appraisal of pathways content "Acute Appendectomy" (Q.A.*: Quality Appraisal Dutch Cochrane Centre; Levels of Evidence: Oxford-Centre for Evidence Based Medicine;MA: meta-analysis; SR: systematic review; Na.: not appropriate; ftna: full text not available; Levels of Evidence: Oxford-Centre for Evidence Based Medicine)

Topic	Key Intervention	Reference	Type of Study	n	Q. A.*	Result	Level of Evidence
Preoperative Evaluation: Scoring Systems	Alvarado score (MantrelsScore)	Saidi HS 2003[22]	Prospective	189 patients	ftna	(Modified) Alvarado score as a diagnostic test: much debate (Modified) Alvarado score to stratify for imaging indications : debate	2B
		Pruekprasert 2004[18]	Prospective	231 patients	ftna		
		Chan 2001[21]	Retrospect	148 patients	ftna		
		Al-Hashemy 2004[19]	Prospective	125 patients	ftna		
		Denizbasi 2003[20]	Prospective	358 patients	8/9		
		Chan 2003[27]	Prospective	175 patients	3/9		
		Saidi RF 2000	Prospective	128 patients	4/9		
		Owen 1992[23]	Prospective	215 patients	ftna		
		Bhattacharjee 2002[24]	Prospective	110 patients	4/9		
		Malik 1998[25]	Retrospect	106 patients	3/9		
		Kalan 1994[26]	Prospective	49 patients	ftna		
		Douglas 2000[28]	RCT	302 patients	5/10		
		Stephens 1999[29]	Retrospect	94 patients	ftna		
		Macklin 1997[15]	Prospective	118 patients	Ftna		
Preoperative Tests if clinical high suspicion or equivocal: Lab tests	WBC, formula	Kwok 2004[52]	SR	5 studies	Na.	Children:Sensitivity high if 10 000-15 000/mm3-low specificity/no pooled estimate	2A
		Andersson 2004[31]	MA	24 studies (5833 pat)	Na.	Adults, children: Inflammatory parameters strongly discriminative only if combined (WBC, formula, CRP), esp. perforated appendicitis	1A
		Cardall 2004[30]	Case Series	293 pat	Na.	Adults, children:Medium sensitivity, low specificity	1C
	CRP	Andersson 2004[31]	MA	24 studies (5833 pat)	Na.	Adults, children: Inflammatory parameters strongly discriminative only if combined (WBC, formula, CRP), esp. perforated appendicitis	1A
		Hallan 1997[32]	MA	22studies 3436pat	Na.	Medium diagnostic accuracy, slightly inferior to WBC	Ftna
		Kwok 2004[52]	SR	3 studies 124 patients	Na.	Children:Moderate to low sensitivity and specificity	2A
	Urinalysis	Puskar 1995[34]	Cohort	66 patients	Na.	Abnormal urinalysis in 48% of patients with appendicitis	4

Topic	Key Intervention	Reference	Type of Study	n	Q. A.*	Result	Level of Evidence
	Beta-hCG	No evidence					5
Preoperative Tests if clinical high suspicion: Imaging	Ultrasonography (US)abdomen & CT scan abdomen	Teo 2000[70]	Case Series	126 patients	Na.	Children:Imaging does not significantly affect decision in case of clinically high/low suspicion of appendicitis.	4
	-/+rectal or IV contrast	Lessin 1999[37]	Case series	215 patients	Na.	Children:No US warranted in clinically high suspicion of appendicitis because false positive rate of surgery without US is only 6% .	4
Preoperative Tests if clinical equivocal: Imaging	Ultrasonography (US)abdomen & CT scan abdomen	Terasawa 2004[40]	MA	1516:US 1172:CT 280:both	Na.	In adults and adolescents CT superior to US in diagnosing appendicitis; CT recommended in all cases of uncertain diagnosis of appendicitis	1A(minus)
	-/+rectal or IV contrast	Kwok 2004[52]	SR	4studies: US 4studies: CT 3studies:both	Na.	Children: CT high accuracy but not always applicable; evidence still conflicting but first US followed by CT most common practice	2B
Surgical Procedure	Laparoscopy vs. open appendectomy	Sauerland 2004[54]	MA	54 studies	Na.	Laparoscopy preferrable if available; in-hospital more expensive but out-hospital less expensive	1A
	Intra-operative culture	Bilik 1998[62]	Retrospect	499 patients	3/9	Intra-operative culture doesn't influence antibiotic choice and can be abandoned	4
		Kokoska 1999[59]	Retrospect	308 patients	6/9		4
		Gladman 2004[61]	Retrospect	721 patients	1/9		4
	Primary/Delayed wound closure for complicated appendicitis	Rucinski 2000[60]	MA	2532 patients	Na.	Primary wound closure preferrably; delayed closure no better results but higher costs	1A
	Drain	Petrowsky 2004[58]	MA	7 RCT's	Na.	Systematic drains in all cases of appendectomy don't reduce complications; but in specific complications drainage might be indicated	2B
Postoperative Management	Incentive spirometry, respiratory physiotherapy	Pasquina 2003Error! Bookmark not defined.	SR	18 studies, 1457 patients	Na.	Usefulness of respiratory physiotherapy after cardiac surgery remains unproven	2B

Topic	Key Intervention	Reference	Type of Study	n	Q. A.*	Result	Level of Evidence
		Gosselink 2000[67]	RCT	67 patients	6/10	No difference between outcome for postoperative respiratory physiotherapy with/without incentive spirometry in thoracic surgery	2B
		Thomas 1994[9]	MA	14 studies	Na.	Respiratory physiotherapy (e.g. incentive spirometry) less postoperative complicaties compared to no physiotherapy in upper abdominal surgery.	fnta

Diagnosis: Diagnostic Score

The Alvarado or Mantrels score is a 10 point scoring system, initially developed from a large cohort of mainly adults, and based on clinical signs and symptoms as well as a differential leucocyte count. In his original paper, Alvarado recommended an operation for all patients with a score of 7 or more and observation for patients with scores of 5 or 6[14]. Since then, a modified Alvarado score has been developed also[15 16 17 24].

Subsequent retrospective as well as prospective studies have suggested that the Alvarado score or its modified version alone are inadequate as a diagnostic test[18 19 20 21 22], but this remains a point of debate since positive results are reported as well, especially in men, and at both edges of the score (low or high)[23 24 25 26].

Moreover, the score has also been advocated as a means of selecting patients who should undergo imaging or could be discharged (risk stratification)[27 28 29]. However, also in this issue no clear statements could be made yet. Some emphasize that no better results are obtained, others do find a more accurate outcome or a reduction in cost by early discharge.

Alternative scores, incuding pediatric scores, have been proposed as well; their value also remains to be proven.

Diagnosis: Laboratory Tests

Some advocate lab tests as part of the initial diagnostic process, others find it only useful in case of diagnostic uncertainty.

White blood cell count and white blood cell formula (**WBC + formula**) as well as **CRP** are often ordered in patients with suspected appendicitis.

Overall, a single WBC appears neither sensitive nor specific, even when neutrophil count is considered as well[30]. CRP-level is even slightly inferior to WBC[31 32]. The WBC and CRP are not specific for appendicitis, as leukocytosis is found in patients with other infectious diseases.

However, there is evidence[33] that the inflammatory parameters are strongly discriminative if they are combined, especially in case of perforated appendicitis. When the values of all inflammatory variables (WBC, formula, CRP level) are normal, appendicitis is unlikely (LR- <0.10). Conversely, appendicitis is very likely when the values of 2 or more inflammatory variables are increased (LR+>10 or more). The evidence is even higher in perforated appendicitis. Thus, since the clinical diagnosis of acute appendicitis remains difficult, it seems reasonable to advocate the use of combined inflammatory parameters in the initial evaluation of every patient. Also, these data might support the practice of repeating labs in cases of uncertainty about the diagnosis.

Approximately 10% of patients with abdominal pain who are seen in the emergency department have urinary tract disease[71] An **urinalysis** may confirm or rule out urologic causes of abdominal pain. Although the inflammatory process of acute appendicitis may cause pyuria, hematuria or bacteriuria in as many as 48 % of patients, but if clearly abnormal (e.g. high erythrocyte or

leucocyte counts) a urinary tract disorder is suggested[34] . There are insufficient data to determine sensitivity and specificity of an urinalysis in the diagnosis of appendicitis.

Some authors and one of the selected clinical pathways (Boston) advise for all women of reproductive age who present with acute abdominal pain, to measure the **urine or serum** beta-**human chorionic gonadotropin (**beta-**hCG) level** to rule out uterine or ectopic pregnancy[71] . However, little data can be found to prove the value of this statement. On the other hand it is well-known that the diagnosis in female patients is more difficult, and it has been noted in a retrospective multi-centre study that females had a 2.3 fold risk of false-positive surgery.[35]. In case of diagnostic uncertainty in women of reproductive age it seems reasonable to measure the urine beta-human chorionic gonadotropin (beta-hCG) level to rule out uterine or ectopic pregnancy.

Last (but not least), no literature was found which addressed the need of **preoperative lab assessment** in view of anesthetic risks in case of acute appendicitis. For this topic, we refer to the publication "Het preoperatief onderzoek", KCE reports vol.5A, Federaal Kenniscentrum voor de Gezondheidszorg / Centre Fédéral d'Expertise des Soins de Santé, België, 2004.

Diagnosis: Imaging

If the clinician has the feeling from the patient's history and physical examination, together with inflammatory blood parameters (WBC+formula and CRP), that there is no doubt about the diagnosis of acute appendicitis, there is a general agreement on prompt surgical referral and operation without further testing. The expected diagnostic accuracy in these circumstances approaches 95% and is probably not improved by imaging. The same is true for cases with a very low clinical likelihood of appendicitis[70]. (Paulson 2003, , Lessin 1999).

If the diagnosis of appendicitis cannot be readily made nor excluded based on history, physical examination and inflammatory parameters, imaging procedures are generally believed to contribute to the diagnostic process.

Plain radiography is not specific and can even be misleading in this situation since in fewer than 5 percent of patients an opaque fecalith may be apparent. Plain abdominal films generally are not recommended, unless other conditions (e.g. perforation, intestinal obstruction, ureteral calculus…) are suspected[361].

The principal advantages of **ultrasonography (US)** are its noninvasiveness, lower cost, lack of ionizing radiation, and ability to precisely delineate gynecologic disease. Criteria for diagnosis of acute appendicitis by US are well established and reliable, graded-compression is generally accepted as being the preferable technique. Nevertheless, due to failure to visualize the appendix the study is inconclusive in up to 10% of the cases. This is attributed to superimposed air or feces, or an atypical appendiceal location (e.g. retrocecal). Also, diagnostic accuracy is highly dependent on operator skill and subject-dependent as well e.g. obesity, abdominal rigidity or pain, an uncooperative child.... The sensitivity of US ranges from 72 to 88% and a specificity of 73 to 86% for adults; and 71 to 92% respectively 96 to 98% for children. However, these numbers of sensitivity ans specificity can be substantially higher if the US is performed by a very experienced echographist. Thus, in children the diagnostic accuracy of US surpasses the accuracy in adults. Three additional prospective studies point towards the diagnostic support of US in children with equivocal appendicitis[37] [38]. US in case of equivocal diagnosis in children also seems to be cost-effective[39]. There are only limited data about newer techniques including color Doppler and hydrocolonic ultrasonography.

The principal advantages of **CT scan** are its operator independency with resultant higher diagnostic accuracy, enhanced delineation of disease extent in perforated appendicitis, and readily identification of alternative diagnoses. The disadvantages of CT compared with ultrasonography include higher cost, potential need for sedation, invasive nature of contrast medium, and potential risks of contrast and ionizing radiation.The sensitivity of CT ranges from 90 to 96% and a specificity of 92 to 97% for adults; and 94 to 97% respectively 87 to 99% for children [40].

Sensitivity and specificity values for CT in the individual studies enrolled in the meta-analysis of Terasawa et al. were similar despite the diversity in the prevalence of appendicitis versus other diagnoses (appendicitis suspected or equivocal), use of contrast material, and diagnostic criteria for positive appendicitis. The most common protocol was helical scanning with enteric (rectal) contrast material, limited to the periappendiceal area. Thus, CT scan appears to have a higher

diagnostic accuracy than US, especially in adults. Debate is still going on about the usefulness of contrast material (oral, IV, rectal…) to perform CT, but probably rectal contrast gives the best results. Again, it has to be emphasized that US performed by a very experienced echographist can give excellent values for sensitivity and specificity, approximating the values for CT scan.

Does the high accuracy of CT scan in diagnosing acute appendicitis lead to improved patient outcomes? Concern has been raised about the increased time interval between admission and surgery in case of additional examinations. However, no increase in perforated appendicitis (in several studies even a decrease) could be noted [69]. The effect of the use of CT-scan in uncertain diagnosis of appendicitis, on the incidence of negative laparotomy/-scopy is not totally clear yet. However, many studies seem to point towards a decrease of negative appendectomy, as well in adults [41] [42], mixed populations, as in children[43] [69]. On the other hand, some studies point towards an equal level of negative appendectomies despite the use of CT scan as an diagnostic aid[44] [45]. (in children[46]). A very large population-based retrospective study (63.707 patients) didn't show a decrease in unnecessary appendectomy between 1987 and 1998, despite the introduction of CT, US and diagnostic laparoscopy altogether.

The cost of CT still remains considerably less than that of removing a normal appendix or hospital observation (which is currently an average of 1.6 days to rule out appendicitis in the USA) [71] [11]. Numbers of 16 to 1, or 22 to 1, for cost of negative appendectomy to cost of CTscan in the USA are found. For this reason, 2 authors even claim the systematic use of CT in female nonpregnant patients with clinical high suspicion of appendicitis, in order to reduce the high rate of negative appendectomy in this group and thus also the costs[47] (, Naoum 2002)[48].

As seen before, the use of CTscan did often but not always result in a decreased negative appendectomy[49] [50] [51]. In the meta-analysis of Terasawa et al. it was mentioned that limitations in study design and reporting might have led to overestimation of the diagnostic accuracy of the imaging tests. Differential reference standard bias was encountered in almost all included studies. This means that a pathologic reference standard (i.e. the biopsy) was used for patients with positive US/CT, whereas for patients with a negative US/CT the clinical follow-up (often ill-defined) was used as the reference standard. Also, the interpreters of the US respectively CT usually were not blinded from other clinical information and/or results of laboratory tests. These two biases might have led to an overstimation of the diagnostic value of the evaluated imaging techniques.

Concerning Magnetic Resonance Imaging, there are still insufficient data to establish sensitivity and specificity for diagnosing appendicitis [52]. The results of a few studies indicate that MRI is helpful in diagnosing acute appendicitis in certain patient populations (e.g. pregnant women with equivocal US)[53].

Diagnostic laparoscopy and Surgical Treatment

Diagnostic laparoscopy has been advocated to clarify the diagnosis in equivocal cases (after classical diagnostic work-up) and has been shown to reduce the rate of unnecessary appendectomy since it makes it possible to visualize other pathologies as well. It is most effective for female patients, since a gynecologic cause of pain is identified in approximately 10 to 20 percent of such patients[54]. However, diagnostic laparoscopy still is an invasive procedure with approximately a 5 percent rate of complications, mostly due to general anesthesia[71].

Concerning **surgical treatment**, in a Cochrane meta-analysis of 54 randomised clinical trials by Sauerland et al. updated in 2004[54], following results were found. In adults, wound infections are less likely after laparoscopic surgery (LA) than after conventional, open appendectomy (OA). The incidence of intraabdominal abcesses is possibly increased in LA (Sauerland's results on intra-abdominal abcesses have been criticized in later publications). The duration of surgery is longer for LA (especially during learning curve), but postoperative pain on day one is less and hospital stay is reduced. Return to normal activity, work and sport occurred earlier after LA than after OA. In the meta-analysis of Sauerland[54] the costs outside hospital were reduced while the operation costs of LA were significantly higher. In the same meta-analysis, five studies on children were included, the results didn't seem to be much different when compared to adults. Previous meta-analyses including less studies and presenting less data on quality of included papers and/or on data extraction usually could already present the same results as Sauerland et al. concerning longer duration of LA in combination with less postoperative pain, fewer wound infections and earlier return to normal activities after LA; whereas those meta-analyses were inconclusive or

not significant for length of hospital stay and incidence of intra-abdominal abcesses. In a retrospective study [55] LA also seemed feasable and safe for appendicitis with signs of perforation, peritonitis and abces with less complications and a shorter hospital stay; however a 39% conversion rate was noted (open appendectomy following LA because LA insufficient). When compared to other authors, a 39% conversion rate seems high. Numbers of 12 to 20% are found several times in the literature (REF) and probably are more close to the daily surgical experience[56 57].

In conclusion, in those clinical settings where surgical expertise is available and affordable, diagnostic laparoscopy and LA seem to have various advantages over OA. Laparoscopy and LA is generally recommended in patients with suspected appendicitis unless laparoscopy itself is contraindicated or not feasable. Especially young female or obese patients seem to benefit from LA. (Note that in Belgium the reimbursement for OA and LA is the same).

Postoperative Management

One meta-analysis [58]concludes that systematic **drains** for any stage of appendicitis do not reduce complications after appendectomy. However, in specific indications it can be appropriate to use a drain [59].

Another meta-analysis[60] supports the use of primary and not **delayed wound closure** for complicated (gangrenous or perforated) appendicitis. Delayed wound closure generally has no advantages but does increase costs.

Several retrospective reports on the necessity of a systematic **intra-operative culture** in all cases of appendectomy emphasize that this practice can be abandoned since it does not influence the initial choice of antibiotics [61 59 62].

The use of incentive spirometry hourly (5 to 10 breaths per session) while awake for the first 48 to 72 hours post extubation is recommended in the Cincinnatti group based on the statement that respiratory complications including atelectasis, pneumonia and respiratory failure are frequent causes of postoperative morbidity and mortality following major abdominal surgery. The rate of postoperative respiratory complications in case of appendicitis in the literature varies but seems to be only a fraction of the total complication rate, except for very young children or persons over 50 as well as persons with other co-morbidities[63 64 65 66]. The efficacity of postoperative respiratory physiotherapy, like (among others) incentive spirometry, is not known in case of appendectomy. However, the efficacy of prophylactic respiratory physiotherapy after cardiac surgery was summarized in a systematic review and the usefulness remained unproved[9]. Incentive spirometry compared with other breathing exercises does not enhance recovery after thoracic surgery[67]. On the other hand, Thomas[9] claims that respiratory physiotherapy (e.g. incentive spirometry) yields less postoperative complications compared to no physiotherapy in upper abdominal surgery. However, the methodology of his meta-analysis is critised by others[9].

Little evidence is present on the necessity of or indications for postoperative use of laboratory tests and/or imaging in case of complications after surgery.

Critical Appraisal of the Pathways Content: Conclusion

In conclusion, it is clear that each element of clinical and laboratory examinations taken alone is of weak discriminatory and predictive capacity in the diagnostic process of acute appendicitis. Contrary to common opinion, the combination of simple and easily performed laboratory tests of the inflammatory response (WBC, neutrophil count, CRP) appears to have good predictive value, especially in advanced appendicitis. Since the clinical diagnosis of acute appendicitis remains difficult, it seems reasonable to advocate the use of combined inflammatory parameters in the initial evaluation of every patient. Urinalysis may help in discriminating with urinary tract pathology, but there are insufficient data to determine sensitivity and specificity in the diagnosis of appendicitis. Because it is simple to perform and if clearly abnormal can help to avoid an unnecessary appendectomy, it can be done in every patient with suspected appendicitis.

The value of systematic urine beta-hCG to exclude (ectopic) pregnancy remains to be documented by further studies.

If the diagnosis of acute appendicitis is possible but not sure, the presented evidence might also support the practice of repeating inflammatory parameters after some hours. Repeat urinalysis is reasonable as well. It seems logical to perform additional tests like liver tests, renal function,

urine beta-hCG…, depending on the presumed diagnostic possibilities. Although lists of differential diagnostic possibilities are readily available in the literature, no clear recommendations about additional laboratory examinations were found. Concerning imaging, for adults with equivocal appendicitis consensus is moving toward the use of CT scan (if not contra-indicated like in case of pregnancy, as complementation (but not replacement) of clinical assessment and judgement. Although still some debate is going on in the literature, especially the meta-analysis of Terasawa et al.[40] in adults as well as adolescents gives support to this statement. US also remains a useful diagnostic test in case of uncertain diagnosis (especially in pregnant women) but with only moderate accuracy. However, if in adults the US is performed by a radiologist with high experience in appendicitis, sensitivity and specificity can be much better, approximating the values for CT scan. In this case, the systematic use of US, completed by CT scan only if the result is unclear or if the appendix could not be visualised, can be supported. Apart from the demonstrated advantages of CT, the use of either CT or US should also be based on body physics or cooperativeness of the patient.

In children, the diagnostic accuracy of US is better than in adults. Moreover US is generally better tolerated, although the need for sedation for CT in reality seems to be very limited[68]. Most authors still prefer to start with US, and if equivocal, to proceed towards CT[69 70]. For the role of clinical scoring systems like the Alvarado-score to perform risk-stratification ("who needs imaging, who not") evidence is still insufficient.

If the results of the imaging are indeterminate, watchful waiting and repeated clinical examination is advised[71]. Nowadays, many patients prefer to go home and to come back the next day on the outpatients clinic for reevaluation and repeat blood tests. No clear evidence is available about which imaging modalities to repeat.

Diagnostic laparoscopy can be considered as well, especially in females.

Concerning the surgical procedure, LA seems to have various advantages over OA, and should certainly be preferred if experience is available. Evidence so far does not support the systematic use of intra-operative cultures and drains or delayed wound closure in case of complicated appendicitis. There are many questions about the usefulness of systematic postoperative incentive spirometry after appendectomy.

Translation into financing

The cost of the 3 international and the Belgian pathways described above were calculated by using the corresponding billing codes.

Secondly, based on the critical appraisal of the key interventions, the theoretical "minimal" costs for a strictly evidence-based scenario and the "reasonable" costs taking into account defendable interventions where evidence is limited or absent were calculated.

For the pathways as well as for "minimal" and "reasonable" costs, two different scenario's were calculated: one based on the scenario where after the doctor's clinical examination of the patient, there is no doubt about the diagnosis of acute appendicitis ("Typical" or clinically unequivocal); the other scenario where the patient presents with clinical signs and symptoms that might point towards acute appendicitis but other diagnoses are still possible as well, so further evaluation and/or exploration is necessary ("Atypical" or clinically equivocal). In atypical cases, as pointed out above, evidence is different for children compared to adults, the latter group being rather evaluated by means of CT-scan, the first group often by means of ultrasonography. Hence, to calculate the "minimal" and "reasonable" cost for atypical cases based on evidence in the literature it was taken into account that 3/4 of the total appendectomy group consists of adults and 1/4 of children (see introduction). Also, we assumed the following: even in the hospitals where US is performed by a very experienced radiologist and where all "atypical" adults first have US before- if still necessary- CT scan, the cost of single US (without CT-scan) for some "atypical" adults combined with both US and CTscan in the others, will not exceed the cost of the other hospitals where it is advised to proceed to CT scan (without US) for all "atypical" adults. Note that all the international pathways are outlined for children; the Belgian pathway however has been set up for both children and adults. Finally, to merge the Typical and the Atypical scenario into one final cost for each included pathway and for "minimal" and "reasonable" cost, it was considerd fair, based on data in the literature (see introduction), that on average about 50% of cases are typical and 50% atypical.

Table 26. Average costs of a hospital stay for the clinical pathways in function of cost- group for typical (clinical diagnosis of appendicitis is obvious) patients.

Clinical path	Clinical biology	Imaging	Other reimbursed activities	Surgery + anesthesiology	Total (without surgery)
boston	0.53 €	0.00 €	0.00 €	266.49 €	0.53 €
cincinnati	0.00 €	0.00 €	12.72 €	266.49 €	12.72 €
texas	1.25 €	0.00 €	0.00 €	266.49 €	1.25 €
belgium	0.79 €	0.00 €	0.00 €	266.49 €	0.79 €
minimal	2.08 €	0.00 €	0.00 €	266.49 €	2.08 €
reasonable	2.08 €	0.00 €	0.00 €	266.49 €	2.08 €

Table 27. Average costs of a hospital stay for the clinical pathways in function of cost- group for atypical (clinical diagnosis of appendicitis is possible but not sure) patients (25% children and 75% adults; international pathways: children only).

Clinical path	Clinical biology	Imaging	Other reimbursed activities	Surgery + anesthesiology	Total (without surgery)
boston	1.78 €	87.17 €	0.00 €	266.49 €	88.95 €
cincinnati	2.30 €	68.59 €	12.72 €	266.49 €	83.61 €
texas	2.50 €	28.53 €	0.00 €	266.49 €	31.03 €
belgium	8.84 €	104.16 €	0.00 €	266.49 €	113.00 €
minimal	4.16 €	87.17 €	0.00 €	266.49 €	91.33 €
reasonable	10.01 €	114.34 €	0.00 €	266.49 €	124.35 €

Table 28. Average costs of a hospital stay for the clinical pathways in function of cost-group for typical (50%) and atypical patients (50%). Refence costs of 2001 for severity 1 (S1) and 2 (S2).

Clinical path	Clinical biology	Imaging	Other reimbursed activities	Surgery + anesthesiology	Total (without surgery)
boston	1.16 €	43.59 €	0.00 €	266.49 €	44.74 €
cincinnati	0.89 €	34.30 €	12.72 €	266.49 €	47.91 €
texas	1.88 €	14.27 €	0.00 €	266.49 €	16.14 €
belgium	4.84 €	52.08 €	0.00 €	266.49 €	56.90 €
minimal	3.12 €	43.59 €	0.00 €	266.49 €	46.71 €
reasonable	6.05 €	57.17 €	0.00 €	266.49 €	63.22 €
Reference value S1 median	12.52 €	58.46 €	33.6 €	270.4 €	104.58 €
Reference value S1 mean	14 €	67.38 €	42.72 €	274.27 €	124.10 €
Reference value S2 median	18.71 €	68.92 €	65.16 €	270.4 €	152.79 €
Reference value S2 mean	25.94 €	101.54 €	79.14 €	283.6 €	206.62 €

In the following description, the calculated costs will be compared with the Reference cost of SOI 1 patients. In the tables both SOI 1 and 2 are presented. The cost of patients with SOI 1 is constantly lower than the costs of patients with SOI 2, as expected. As already explained in chapter 3, the possibility that patients (typical or atypical) develop complications after surgery has not been taken into account when calculating the cost for international and Belgian pathways nor for the theoretical minimal or reasonble cost. For this reason, when making a comparison between the calculated costs and the Reference costs for Belgium in 2000-2001 especially the Reference costs of SOI 1 patients were used.

For *clinical biology,* the costs of all clinical pathways and of the calculated theoretical minimal and reasonable costs are lower than the reference costs for SOI 1 (table 26, 27, and 28). In general, the amount spent for clinical biology is low in all the pathways. The calculated cost for the Belgian pathway is still higher than the foreign pathways but within the theoretical reasonable costs. The Reference cost however, exceeds this value. This is explained by the frequency tables for clinical biology for appendectomy in Belgium (2001), which show that "chemistry" and "coagulation" are used in more than 50% of cases in the Belgian hospitals, whereas, as shown above, it is assumed to be reasonable to consider 50% of the cases as Typical. Even when taken into account that all Atypical patients need some lab tests and that some of the Typical patients might need preoperative biochemistry (see "Het preoperatief onderzoek"[72]), it is difficult to understand that in 80% respectively 61% of all SOI 1 hospitalizations costs were made for "chemistry" respectively "coagulation".

In the category *medical imaging,* the median Reference cost SOI 1 approximates the reasonable theoretical cost. For the *other reimbursed activities*, the Reference value SOI 1 clearly exceeds the cost of 3 out of four pathways (included the Belgian pathway) which amounts zero. Only one pathway ("Cincinnati") systematically includes this type of costs, due to the included postoperative respiratory rehabilitation for which little evidence is available. The cost for the the

"other reimbursed activities" for the Belgian Reference value for Severity I however, also included different physiotherapy prestations in 11% of hospitalisations (if assumed that 70% of all hospitalisations belong to category SOI I). Moreover, electrocardiography counted for 45% of this cost group (performed in 20% of hospitalisations) whereas indications in routine pre-operative screening in this low severity group are limited (see KCE Reports vol. 5A, Federaal Kenniscentrum voor de Gezondheidszorg/ Centre Fédéral d'Expertise des Soins de Santé, België, 2004). (Note that the cost for anatomopathological examination is not included in the pathways, nor in the theoretical minimal or reasonable cost nor in the Reference values.)

In general, the total theoretical reasonable cost and the total cost for the Belgian pathway correspond fairly well; whereas the total reference costs (median and mean) for patients with SOI level I for the year 2000 in Belgium are higher. The latter is due to higher costs for clinical biology and even more to the use of "other reïmbursed activities" for which little evidence exists.

Discussion

The abundant use of *clinical biology* in Belgium, and more specificially pre-operatively, is not unique for appendectomy. It has been described before, and for further detail we refer to "Het preoperatief onderzoek", KCE reports vol. 5A, 2004.

The fact that in the category *medical imaging,* the median Reference cost SOI I approximates the reasonable theoretical cost, does not exclude a large difference between individual Belgian hospitals or Belgian regions in use of medical imaging for suspected appendicitis, as has been shown by Bossens M. et al., in 2001[73]. The SOI I only reflects the budget spent for this severity degree in 2001 for the Belgian hospitals all together.

The category *other reimbursed activities* shows the largest difference between pathways, theoretical reasonable cost and the Belgian Reference values. Although definite conclusions about necessity for certain prestations can only be drawn if additional details about co-morbidity and/or complications are known (which was beyond the scope of this paper), we draw attention especially to electrocardiography (also a frequently found unnecessary technical prestation in other surgical interventions, since it often is included as a routine preoperative examination) as well as physiotherapy (peak-incidences for appendectomy are the second and third decade of life).

The pitfalls in the exercise for "Appendectomy" are generally speaking the same as the pitfalls for the other studied interventions. The time for this study was limited, and some literature, more difficult to find, about key interventions in the pathways might have been missed. The choice of interventions withheld for the calculation of the minimal versus reasonable costs was based, where possible, on the evidence table but when calculating the cost we were prompted for some arbitrary decisions such as the percentage of patients undergoing US versus CT-scan. The costs of complications are not included, although complications are not rare and can augment expenses a lot.

Key messages

- **The content of the Belgian pathway for adult patients was to a large extent in accordance with our critical appraisal based on evidence.**
- **For children, evidence on best imaging modalities in case of unclear diagnosis is still insufficient. Whether the difference in costs related to the paediatric pathways is justified or not cannot be judged.**
- **The theoretical, evidence based minimal costs are lower but the theoretical reasonable costs are relatively close to the reference cost for SOI I patients. Discrepancies were present especially for routine pre-operative tests, like laboratory tests (chemistry: in 80% of hospitalisations, coagulation: in 61%), and in the category 'other': electrocardiography (in 20%). Moreover, physiotherapy was performed in 11% of SOI I hospitalisations.**

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3.2.5. Laparoscopic cholecystectomy

Introduction

Since the early nineties both absolute numbers of cholecystectomies as well as the rate of laparoscopic cholecystectomy (LC) rapidly increased in Belgian hospitals (figure 7).

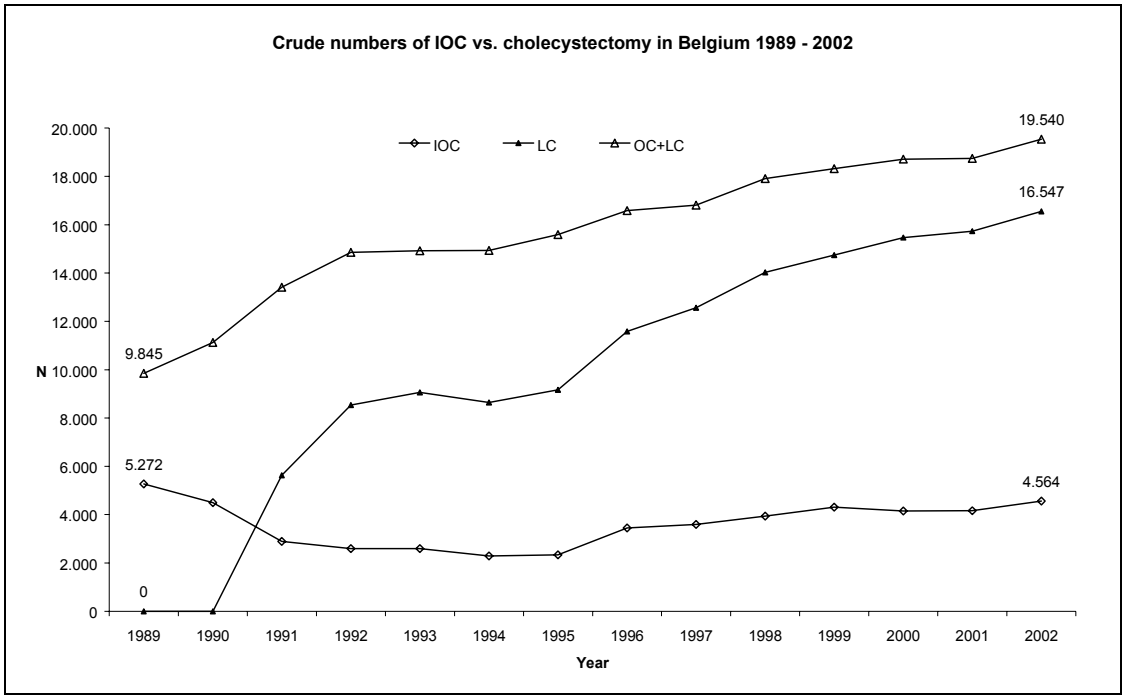


Figure 7. crude numbers of cholecystectomy and IOC in Belgian hospitals 1989 – 2002 (source: RIZIV/INAMI – Sectie Profielen/Section Profils – aggregated billing code data)

In 2002 the LC-rate for Belgium was 85% whereas the total number of cholecystectomies nearly doubled from 9.845 in 1989 up to 19.540 in 2002[1]. The same observations were made world-wide[2-4]. Parallel with this evolution we observed a substantial increase in the Belgian rates of therapeutic endoscopic retrograde cholangiopancreatography (ERCP) combined with falling choledochotomy counts. Diagnostic ERCP initially followed that evolution but came to a plateau in the mid 90's. In 2002, the total amount was lower than that of 1989. The rate of *pre-cholecystectomy ERCP* in Belgium was 14,5%[1] including diagnostic as well as therapeutic procedures. As for the rate of *intra-operative cholangiography*, it clearly dropped from roughly 54% for all cholecystectomies in 1989 to far less then half that percentage - about 23% - in 2002.

With few exceptions, the majority of patients with asymptomatic gallstones need not be treated[5 6]. Once a patient with gallstones becomes symptomatic, elective cholecystectomy is indicated. Acute cholecystitis is the primary indication for urgent cholecystectomy: it should be treated surgically within 72 hours after the onset of the symptoms[7]. Patients with acute biliary pancreatitis[8 9], symptomatic choledocholithiasis (common bile duct stones), and cholangitis require in-hospital investigations[10] and treatment within the next 24 hours.

Cholecystectomy may be performed by laparoscopic techniques or by laparotomy. The advantages of the laparoscopic approach are less pain, shorter hospital stay, faster return to normal activity, and less abdominal scarring[11]. A laparoscopic approach is feasible in most patients. Conversion to an open procedure may be required because of the presence of adhesions, difficulty in delineating the anatomy, or a suspected complication. The incidence of conversion to an open procedure is about 5%, but can be much higher depending on the patient population[12]. Conversion is more often necessary in elderly patients and those with prior upper abdominal operations, a thickened gallbladder wall (peri-cholecystitis 'plastron'), or acute cholecystitis.

The risks of cholecystectomy are low in patients undergoing elective cholecystectomy and include: injury to the bile ducts (BDI), retained stones in the bile ducts, spilled stones in the abdominal cavity or injury to surrounding organs. The incidence of major biliary ductal injury ranges from 0.25% to 0.74%, and of minor injury from 0.28% to 1.7%[13-16]. The mortality rate in a good-risk patient undergoing elective operation is not higher than 0.1%[13 15].

Common bile duct lithiasis (CBDL) is found in 5–15%[17-19] of patients with symptomatic gallstones with an incidence of unsuspected stones of up to 5 % when routine cholangiography is performed[11]. Coexistent gallbladder and common duct stones are correlated with increasing age and CBDL can remain more or less asymptomatic for a long period of time, but eventually CBDL will lead to bile duct and/or pancreatic duct obstruction with major morbidity and mortality. Hence detection and treatment of CBDL is important. Spontaneous passage of common bile duct stones occurs in a little over one-quarter of patients[20]. Expectant management of asymptomatic CBDL is reasonable in the short term but sooner or later common duct stones will have to be removed either endoscopically or surgically. Scoring systems can help in predicting choledocholithiasis[18 21-24].

Nowadays a some key questions concerning diagnostic and surgical management of gallstone disease remain unsettled: past decades matters of debate are summarized in Table 29.

Table 29: Past decades matters of debate concerning cholecystectomy

Topic	Choices	Status questionis 2005
Asymptomatic lithiasis	Wait-and-see vs. pre-emptive surgery	Wait-and-see > pre-emptive surgery (for highly selected indications)
Cholecystectomy	LC vs. OC	LC > OC
	Conversion LC → OC	5% (elective) - 10% (emergency) ?
	Hospital or outpatient ?	Selected outpatient procedures
	Subhepatic drainage ?	Not routinely
	Nasogastric tube ?	Not routinely
Acute cholecystitis	Early vs. delayed surgery ?	Early (if within 72 h.) > delayed
Prevention BDI	IOC vs. IOUS	IOC > IOUS ?
	Routine vs. selective	Routine > selective ?
Diagnosis of CBDL	Preop: ERCP / MRCP / EUS	MRCP > EUS > ERCP ?
	Intraop: IOC / IOUS	IOUS > IOC ?
Clearance of CBDL	2-stage : preop ERCP + ES + SE 2-stage : postop ERCP + ES + SE 1-stage : intraoperative IOC + LCBDE (or OCDDE)	Intraop (1-stage) > Postop > Preop LCBDE > OCBDE

LC = laparoscopic cholecystectomy; OC = open cholecystectomy; IOC = intraoperative cholangiography;
IOUS = intraoperative ultrasonography; EUS = endoscopic ultrasonography;
ES = endoscopic sphincterotomy; SE = stone extraction)

The majority of good-risk patients undergoing elective laparoscopic cholecystectomy can usually be discharged the same day[25-28] or after a 1 to 4 days[4 13 16]. High-risk patients and those undergoing emergency operations may require longer hospital stays. When open cholecystectomy is performed, patients are usually discharged after one week in-hospital stay. Hospitalization may be prolonged in patients requiring placement of abdominal drains, exploration of the bile duct, or those with complicated biliary tract disease. Nearly 95% of patients experience relief of biliary pain following cholecystectomy[11 29]. The remaining 5% may have a cause of pain other than gallstones. Abdominal pain after cholecystectomy may be caused

by residual or recurring stones in the biliary tract, biliary strictures, iatrogenic biliary leaking, papillary stenosis or dysfunctional sphincter of Oddi. Patients with dyspepsia or diarrhoea before surgery may find that these symptoms persist after operation. After BDI and repair, there are long-term detrimental effects of BDI on health-related QOL[30].

Description of guidelines and pathways

Clinical pathways

For this study two clinical pathways used in Belgium and two clinical pathways used in the UK were analysed (Table 30).

Table 30 : International pathways (UK)

Hospital	BUPA Hospitals Trust	Airedale Hospitals Trust
Subject	Hospitals Care Pathway for Laparoscopic Cholecystectomy	Care Pathway for Laparoscopic Cholecystectomy
Reference	UK - NHS - BUPA General Hospitals	UK - NHS - Airedale Hospitals
Type (Crit PW / Care PW)	Care PW	Care PW
Range (Hosp. / One day)	H	H
Pre-hospitalisation	No	Only pre-anaesthesia
Post-hospitalisation	No	No
Brief description	Multi-disciplinary patient care record to document laparoscopic cholecystectomy carried out.	Multi-disciplinary patient care record to document laparoscopic cholecystectomy carried out.
Informal (I), consensus (C), evidence based (E)	C	C
Crit. Appr. KCE	Both do not refer to recommended presurgical diagnostic and therapeutic procedures; they are more 'patient care path' then 'clinical pathway'	

The Belgian pathways are not publicly available and were retrieved in accordance with and with permission of the hospitals and their gastroenterologic surgeons involved (Table 31).

Table 31: Belgian pathways

Hospital	Hospital 1	Hospital 2
Subject	Cholecystolithiasis: klinisch zorgpad	Galblaas laparoscopisch
Type (Crit PW / Care PW)	Crit PW	Care PW
Reference	Belgian hospital (anonymous)	Belgian hospital (anonymous)
Range (Hosp. / One day)	Hospital & one day	Hospital
Pre-hospitalisation	Yes	No

Post-hospitalisation	Yes	No
Brief description	Well documented & complete clinical pathway, with diagnostic algorithm for pre-surgical assessment of CBDL	Mono-disciplinary patient care record to document laparoscopic cholecystectomy carried out
Informal (I), consensus (C), evidence based (E)	E	I
Reference to evidence sources? (+ or -)	Yes	No
Quality appraisal / external validation	Not mentioned	Not mentioned
Quality appraisal KCE	Well documented & complete clinical pathway, with diagnostic algorithm for pre-surgical assessment of CBDL	No reference to recommended presurgical diagnostic and therapeutic procedures; more 'patient care path' then 'clinical pathway'

Guidelines

Cholecystectomy related guidelines were electronically searched (Table 32) and only 4 guidelines - suitable or not - were found :

1. Gallstones and Laparoscopic Cholecystectomy. NIH Consens Statement 1992 Sep 14-16;10(3):1-26[11]

   Covers the whole field of diagnosis and treatment of cholecysto- and choledocholithiasis. Each NIH consensus statement is the product of an independent, non-Federal panel of experts and is based on the panel's assessment of medical knowledge available at the time the statement was written. Therefore, a consensus statement provides a "snapshot in time" of the state of knowledge of the conference topic.

2. Treatment of gallstone and gallbladder disease. Society of Surgery of the Alimentary Tract[31] Guidelines; USA 1996 - revised 2003 Feb 01

   Patient care guidelines written for the primary care physicians to guide them to the appropriate utilization of surgical procedures and based on critical review of the literature and expert opinion. Both of the latter sources of information result in a consensus that was recorded in the form of these guidelines.

3. NIH state-of-the-science statement on endoscopic retrograde cholangiopancreatography (ERCP) for diagnosis and therapy. NIH Consens State Sci Statements. 2002 Jan 14–16; 19(1):1-23[19].

   Very elaborated guideline based on systematic review with evidence tables and assessed by expert consensus.

4. Recommandations de Pratique Clinique. La cholécystectomie. S.N.F.G.E., France; 1995-2001[32]

   Non-evidence referenced recommendations under the form of 4 Q&A's concerning indications of LC and OC, benefits and possible harms of laparoscopic cholecystectomy and finally systematic or selective application of IOC (not conclusive).

Table 32: Searching for cholecystectomy related guidelines

National Guidelines Clearinghouse	http://www.guideline.gov/
Agency for Healthcare Research and Quality (AHRQ) - Clinical Practice Guidelines Online	http://www.ahrq.gov/
Agence nationale d'accréditation et d'évaluation en santé (ANAES)	http://www.anaes.fr/anaes/anaesparametrage.nsf/
Société Nationale Française de Gastroenterologie (S.N.F.G.E)	http://www.snfge.org/index.asp
EBM Guidelines	http://www.ebm-guidelines.com/ (pay-site)
National Institute for Clinical Excellence (NICE)	http://www.nice.org.uk
Scottish Intercollegiate Guidelines Network (SIGN)	http://www.sign.ac.uk/search.asp
Canadian Medical Association (CMA) clinical practice guidelines	http://www.cma.ca/
New Zealand Guidelines Group	http://www.nzgg.org.nz/
Centraal BegeleidingsOrgaan (CBO)	http://www.cbo.nl/product/richtlijnen/

Critical appraisal of the pathways content

In-hospital preoperative tests

For *elective cholecystectomy* preoperative risk stratification and possible preoperative therapeutic adjustments are commonly done in the weeks before the planned surgical admission and this on an ambulatory base or preceding short hospitalization (if ERCP was done for concomitant CBDL). The tests that can be useful to perform as preoperative tests should be based on previous risk stratification as described in numerous guidelines and summarized recently in a report of the KCE[33]. To repeat certain preoperative tests the day before surgery is justifiable if previous results are not available, which should be rarely the case, or if a previously abnormal test or a change in preoperative treatment (e.g. oral anticoagulation for atrial fibrillation was stopped) urges an additional control before surgery. Also, the choice of certain preoperative systematic tests can be questioned. Coagulation tests on the day of admission e.g. (INR) are only indicated in those patients that stopped oral anticoagulants in the week before surgery. The number of that kind of patients is low (Table 33).

Table 33: Belgian data for APRDRG 263 - year 2000[1]

Condition	N	Total LC	%
PO antico	70	14.300	0,49%
Acute cholecystitis / cholangitis	3.910	14.300	27,34%
Acute pancreatitis	714	14.035*	5,09%
	* excl. cancers		

Additional systematic non-invasive cardiology testing such as ECG and/or echocardiography is of limited or no value for preoperative risk stratification.

Key diagnostic & perioperative interventions

Possible key interventions are, in addition to skilful anamnesis and clinical examination :

- blood tests with red & white blood cell count, serum electrolytes, urea, creatininiaemia, blood sugar, CRP, alkaline phosphates, ALT‡‡ (formerly SGPT), AST (formerly SGOT), γGT , bilirubinaemia, amylase;
- upper abdominal ultrasonography (US;
- peroral cholecystography and IV cholangiography;
- ERCP;
- Intraoperative cholangiography (IOC);
- MRCP;
- Endoscopic ultrasonography (EUS) & intraoperative ultrasonography (IOUS).

Key interventions and the results of our search for evidence are summarized in a comprehensive evidence table: Table 34.

‡‡ http://www.angelfire.com/mt/medicalinks/medabrev.html

Table 34 : Evidence table

Topic	Key intervention	Reference	Type	N	Quality appraisal	Result	Level of evidence
Preop. tests	Repeating preop. tests (RX thorax, lab tests,..) day -1	Mambourg F, 2004[33]	EBG			Not indicated routinely	
	Non-invasive cardiology testing day -1	Mambourg F, 2004[33]	EBG			Not indicated routinely	
Liver & pancreas blood tests	Alkaline phosphates, ALT (SGPT), GT Bilirubinaemia Amylase, lipase	Katz D, 2004[21]	CDR tested within one clinical centre	427 patients		Dilated CBD in association with abnormal liver function tests most useful predictor of CBD stones on ERCP	1b
		Wang CH, 2001[34]	Explicatory cohort study	458 patients		Alkaline phosphatase and GT significant independent factors	2b
Imaging	Ultrasonography	Shea JA, 1994[35]	Meta-analysis	30 articles	Only Medline & English	Best sensitivity & specificity with US for cholelithiasis	2a
	Peroral cholecystography	Shea JA, 1994[35]	Meta-analysis	30 articles	Only Medline & English	US better than PO cholecystography	2a
	IV cholangiography	Rothlin M, 1997[36]	Prospectively controlled study	85 patients	Small N	IVC is of little help in the diagnosis of anatomical variations of the biliary tree and should be omitted from the preoperative diagnostic work-up of LC	2b
	ERCP	NIH , 2002[19]	EBG			ERCP not required if low probability CBDL (<5%)	
	MRCP	Flamm CR, 2002[37]	SR	10 studies, 834 patients		MRCP diagnostic ERCP Sensitivity & specificity > 90%	2a

		Kaltenthaler E, 2004[38].	SR	28 studies		Some evidence that MRCP is an accurate investigation compared with diagnostic ERCP, although the values for malignancy compared with choledocholithiasis were somewhat lower. Estimated clinical and economic impacts of diagnostic MRCP versus diagnostic ERCP are very favourable	2a
	EUS	Flamm CR, 2002[37]	SR	9 studies, 601 patients	Small studies	EUS diagnostic ERCP Sensitivity & specificity > 90%	2a
	IOC	Flum DR, 2003[39]	Retrospective nationwide cohort analysis	1.570.361 patients	CBDI rates based on Medicare data registry	Routine use of IOC may decrease the rate of CBDI injury	2b
		Ludwig K, 2002[40]	Treatment outcome meta-analysis	103 major BDI	Only detection CBDI addressed	Routine IOC better	2c
		Nies C, 1997[41]	RCT	275 patients	Only detection CBDL addressed	Routine IOC not justified for detection of CBDL	2b
	IOUS	Birth M, 1998[42]	RCT	518	Good	IOUS performed by experienced surgeons is a good and effective method to assess the CBD	1b
CBDL clearance	LECBD vs. postop ERCP	Rhodes M, 1998[43]	RCT	80	Good but 'morbidity' not well defined	Equivalent success rates and patient morbidity for the two management options but a significantly shorter hospital stay with the single-stage laparoscopic treatment	1b
	Preop ERCP (2-stage) vs. LECBD (1-stage)	Cuschieri A, 1999[44]	Multicenter RCT	269 patients	Good		1b
Suction & drainage	Nasogastric tube	Nelson R, 2005[45]	SR	28 studies, 4.194		Routine nasogastric tube not justified	1a

				patients			
	Subhepatic drainage	Budd, DC, 1982[46]	RCT	300		Surgical drainage after every uncomplicated cholecystectomy unnecessary	2b

Laboratory tests

There is little to say about appropriateness of blood testing in case of *acute biliary disease* : red & white blood cell count, serum electrolytes, urea, creatininiaemia, blood sugar, CRP, liver enzymes alkaline phosphates, ALT (formerly SGPT), AST (formerly SGOT) GT, bilirubinaemia, amylasae− mia & lipasaemia are justified in the light of elaborating the severeness and extension of acute disease as well as the differential diagnosis with acute pancreatitis.

For *elective cholecystectomy* increased serum concentrations of ALT (formal SGPT), alkaline phosphatase and bilirubin, associated with an attack of pain are indicative but not pathognomonic of common bile duct stones[47 48]. However, they play a contributive role in useful predictive scoring systems (vide infra).

Medical imaging

- Upper abdominal ultrasonography is undoubtly the keystone for the diagnosis of both uncomplicated and complicated cholelithiasis. It is cheap, quick, and harmless. Estimates of diagnostic test sensitivity and specificity in suspected biliary tract disease[35] showed that ultrasound had the best sensitivity (97%; 95% - 99%) and specificity (95%; 88% - 100%) for evaluating patients with suspected gallstones. Ultrasound findings of a thickened gallbladder wall and fluid around the gallbladder suggest the presence of acute cholecystitis[49 50]. Sensitivity and specificity of ultrasound for evaluating patients with suspected acute cholecystitis are somewhat lower: 94% (92% - 96%) and 78% (61% - 96%). Addition of Doppler imaging (CDI) demonstrates hyperaemic changes in thickened gallbladder walls and can be an important adjunct in the diagnosis of acute cholecystitis[49 50]. As for detection of common bile duct stones[35] sensitivity was 87,5% and specificity and overall accuracy were greater than 95%.
- Peroral cholecystography[35] and IV cholangiography[36] have little, not to say no additive value in the investigation of gallstone disease.
- Whether intraoperative cholangiography (IOC) should be routinely performed - or at least attempted - during laparoscopic cholecystectomy is still a matter of strong debate among hepatobiliary surgeons, with advocates[39 51-59], objectors[41 60-62] and others who advise a more balanced approach depending for instance on hospital injury rates and in the learning phase of young surgeons[63-66]. However, some major publications suggest that broader use of IOC may decrease the rate of common bile duct injury[39 52 67].
- Radionuclide scanning is not a useful test for the diagnosis of gallstones. Diagnosis of acute cholecystitis with radionuclide scanning should be reserved for instances in which uncertainty persists after conventional diagnostic imaging[35 47].

Diagnostic endoscopy with imaging

- ERCP (endoscopic retrograde cholangiopancreatography) may be used both for the diagnosis and extraction of common bile duct stones and traditionally is considered as the 'gold standard' test for diagnosis of common bile duct stones. Nevertheless, the test can produce both false-negative and false-positive results[8 19 43 68-70]. In the absence of optimal predictors of CBD stones, a large number of preoperative ERCP are negative for stones. The literature quotes figures for negative preoperative ERCP as between 40% and 70%[47 71]. Furthermore, endoscopic sphincterotomy is associated with recurrent stone formation (up to 16%) with associated cholangitis. The main complication[8 72-75] of endoscopic retrograde cholangiopancreatography (ERCP) is acute pancreatitis. Pancreatitis occurs in about 5 to 7% of patients undergoing ERCP, whether for diagnosis or therapy. Other complications include haemorrhage, perforation, cholangitis, cholecystitis and cardiopulmonary complications (see also discussion on endoscopic sphincterotomy further on).
- Non-invasive MRCP, magnetic resonance cholangio-pancreaticography[18 76-78], has proven to be an accurate imaging technique for the detection of CBDL before laparoscopic cholecystectomy. Most of the evidence on MRCP allows only

conclusions as to whether MRCP and ERCP are concordant, rather than which test is superior. Most studies show fairly good concordance, with sensitivities and specificities both higher than 90 percent. Evidence limited to one study may indicate that ERCP is slightly better than MRCP. Patients with jaundice, cholangitis or severe acute gallstone pancreatitis require early therapeutic ERCP, but those with other established risk factors may undergo MRCP leading to a significant reduction in preoperative ERCP and its potential complications.

- Endoscopic ultrasonography (EUS) and intraoperative ultrasonography (IOUS)[21 23 79-81] have proven to be valuable alternatives to diagnostic ERCP/MRCP and IOC respectively. Although most of the studies are small, within the limits of the evidence available, it appears that EUS is similar to ERCP in the detection of common bile duct stones. Both techniques are rapid, sensitive, provide immediate results, and do not involve the use of ionizing radiation, but require additional technical skills and capital investment for endoscopists and surgeons.

Diagnostic value of individual risk factors or predictive models for assessing the likelihood of having a common bile duct stone

The single risk factors commonly examined in studies included age, clinical jaundice or elevated bilirubin, liver function tests, and ultrasound findings of a dilated common bile duct. Studies varied in the definitions and cut-off thresholds for the various tests, in particular concerning the CBD diameter. Although all of them have significant associations with the presence of stones, none of them have outstanding ROC characteristics. The presence of any of these factors certainly increases the probability of the presence of a common bile duct stone, possibly high enough to change clinical decision-making[22 24 82-88]. However, changing the cut-off value to increase the positive predictive value (by increasing the specificity) usually results in poor sensitivity.

Multivariable modeling of risk factors[18 22 23 89 90] for prediction of common duct stones shows promise as a method of triage for determining appropriate treatments, given that they appear to have superior discriminatory power. These prediction models have yet to be integrated into clinical decision models to determine optimal cut-offs to prevent unnecessary preoperative ERCP. Table 34 gives us different pre-cholecystectomy ERCP rates, ranging from 10% to 39% (rounded to 40%).

Table 34 : ERCP rates prior to cholecystectomy	
Katz - 2004 - Endoscopoy - 41 ERCP on 427 patients[21]	10%
Lillemoe - 1992 - Ann Surg - 44 ERCP on 400 patients[91]	11%
Kruis - 1997 - Endoscopy - 19 ERCP on 139 patients[92]	14%
Kum - 1996 - Eur J Surg - 46 ERCP on 303 patients[93]	15%
Bergamaschi - 1999 - Am J S - 155 ERCP on 990 patients[84]	16%
Sarli - 1999 - Gastrointest Endosc - 231 ERCP on 1.305 patients[94]	18%
Pietra - 2000 - Eur J S - 225 ERCP on 1.155 patients[95]	19%
Alponat - 1997 - Surg Endoscopic 180 ERCP on 878 LC-patients[82]	21%
Topal – 2003 – Br J S – 81 ERCP on 366 patients[18]	22%
Coppola - 1996 - Surg Endosc - 97 ERCP on 407 patients[96]	24%
Menezes - 2000 - Br J S - 55 predicted ERCP on 190 patients[22]	29%
Trondsen – 1998 – Arch Surg – 72 ERCP on 192 patients[89]	38%
Houdart - 1995 - Am J S - 108 predicted ERCP on 279 patients[48]	39%

ERCP or surgery for common bile duct stone clearance

Endoscopic sphincterotomy is still widely accepted as a valid treatment for patients with symptomatic common bile duct stones. Stone extraction is successful in up to 97% of patients, be it with a procedure-related morbidity of 5-10% (pancreatitis, bleeding, perforation, stent-related complications,…) and a mortality rate up to 2%[70 75 97-101]. The rate of post-Endoscopic Sphincterotomy (ES) haemorrhage, about 0.2 to 5%, is more often related to anticoagulation (within 3 days after endoscopic sphincterotomy), coagulopathy, and acute cholangitis. 30-day mortality is about 1% to 3%[18 102 103]. Routine preoperative ERCP identifies accompanying CBD stones but carries risks of complications and may delay definitive care[104 105]. Selective postoperative ERCP, performed only if a CBD stone is seen on intraoperative cholangiography (IOC), avoids unnecessary ERCP but risks unsuccessful stone extraction[43]. In selected patients at prohibitive operative risk, ERCP with stone clearance alone may be definitive therapy[104].

Surgical removal of CBDL can be performed using open or laparoscopic techniques. Open common bile duct exploration (OCBDE) is a safe and effective treatment, especially in the acutely ill. Laparoscopic common bile duct exploration (LCBDE)[58 70 106-108] and ERCP with stone extraction are comparable in achieving stone clearance and in safety[19]. Postoperative ERCP appears to be associated with greater health care resource use, increased length of stay, and higher cost[19]. Accordingly, laparoscopic common bile duct exploration is more efficient and is preferable when appropriate equipment and surgical expertise in this technique is available. Otherwise, postoperative ERCP is indicated for patients with retained stones.

However, since success and complications of laparoscopic cholecystectomy with laparoscopic common bile duct exploration may be operator dependent, findings may not be generalisable across clinical settings. The availability of expertise in this technique is rather limited in Belgian hospitals at present. Therefore, decisions regarding individual patients will depend on local expertise.

Methods

Based on our evidence search we were able to set up a diagnostic-therapeutic flow chart for cholecystectomy patients (Figure 8).

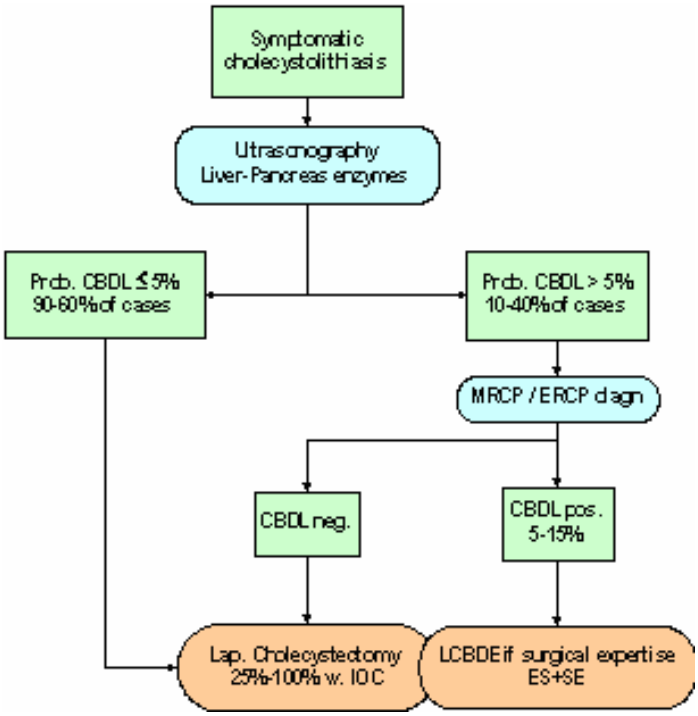


Figure 8 : Diagnostic-therapeutic pathway for financing LC (CBDL = common bile duct lithiasis; LCBDE = laparoscopic common bile duct exploration; ES = endoscopic sphincterotomy; SE = stone extraction)

Pre-cholecystectomy ERCP rates, ranging from 10 to 40% (Table 35), were used as a proxy for 'acceptable' preoperative diagnostic ERCP or MRCP billing frequencies, whereas the incidence of CBDL in cholecystectomy patients, ranging from 5 to 15%, served as a basis for frequency of therapeutic ERCP (ES+SE) billing. Another decision involved the range of 'acceptable' IOC billing frequency: should it be routine or selective; and in the latter case, how selective? We settled for a minimal incidence of 25% and a reasonable incidence of 100%, considering that routine IOC cannot be labelled as exaggerated[40 52].

There is however one major shortcoming in our diagram: the recommendable alternative of LCBDE, emerging from solid recent literature, was not accounted for in this exercise, since it would imply for instance the fractional uptake of yet another (higher) surgical billing code with corresponding anaesthesiological fee. On the other hand LCBDE definitely would allow a reduction of therapeutic ERCP rates. The American Society For Gastrointestinal Endoscopy issued in 2001 an annotated algorithm for the evaluation of choledocholithiasis covering the whole decision making spectrum[109], which turns out to be very ramified and by this almost impossible to incorporate in full into proportionate calculations.

This said, integration of former 3 ranges resulted in 2 major calculation scenarios: a theoretical 'minimal' scenario, combining the lowest ranges of our flow chart, and a theoretical 'reasonable' scenario for the highest ranges. For each scenario the corresponding frequencies were translated into equivalent fractions of related RIZIV/INAMI billing codes and subsequently totalized.

Table 8 summarizes all interventions incorporated in this exercise; when applicable billing proportions are given between brackets.

Table 35 : Overview of included interventions (applicable billing proportions between brackets)

Clinical pathway	Scenario	Preop: Day -30 to -1	Surgery: Day 0	Postop: Day 1 to 4
UK1/UK2/B1	elective LC wo CBDL			
B2	proportional calculation	Echography, NMR (44%), diagnostic ERCP (22%), therapeutic ERCP (12%)	IOC (25%),	
		ALT, amylase, bilirubine, CRP, AF, γGT, lipase		
		Fibroduodenoscopy for diagnostic ERCP (22%) and for therapeutic ERCP (12%)		
	CBDL+	Echography, therapeutic ERCP	IOC (25%)	
		ALT, amylase, bilirubine, CRP, AF, γGT, lipase		
		Fibroduodenoscopy for therapeutic ERCP		
	elective LC wo CBDL		IOC (25%)	
minimal	proportional calculation	Echography, diagnostic ERCP (5%), therapeutic ERCP (5%)	IOC (25%),	
		ALT, amylase, bilirubine, CRP, AF, γGT, lipase		
		Fibroduodenoscopy for diagnostic ERCP (5%) and for therapeutic ERCP (5%)		
	CBDL+	Echography, therapeutic ERCP	IOC (25%)	
		ALT, amylase, bilirubine, CRP, AF, γGT, lipase		
		Fibroduodenoscopy for therapeutic ERCP		
	elective LC wo CBDL		IOC (25%)	

reasonable	proportional calculation	Echography, diagnostic ERCP (25%), therapeutic ERCP (15%)	IOC	
		ALT, amylase, bilirubine, CRP, AF, γGT, lipase		
		Fibroduodenoscopy for diagnostic ERCP (25%) and for therapeutic ERCP (15%)		
	CBDL+	Echography, therapeutic ERCP	IOC	
		ALT, amylase, bilirubine, CRP, AF, γGT, lipase		
		Fibroduodenoscopy for therapeutic ERCP		
	elective LC wo CBDL		IOC	

elective LC wo CBDL = "simplest case"; CBDL+ = "complex case"; ALT: alanine aminotransferase; AF: alkaline phosphatases; γGT: gamma-glutamyltransferase

= imaging = clinical biology = internal medicine

There is another way to look at the problem of clinical variability: instead of integrating it into proportionally composed 'minimal' and 'reasonable' allowances, one can make separate calculations for:

1. the 'simplest' case, i.e. an entirely planned LC with a full diagnostic work out being completed beforehand and revealing no CBDL; the 'minimal' option in this case would allow 25% IOC, the 'reasonable' 100% IOC;

2. and, on the other side, the complex case with symptomatic CBDL necessitating a preoperative therapeutic ERCP with sphincterotomy and stone extraction, followed by LC; here too the 'minimal' option would allow 25% IOC, the 'reasonable' 100% IOC.

Indeed, a detailed analysis of actual Belgian costs in APRDRG 263 (year 2000) and severity of illness 1 (SOI 1) showed that in almost 26% of the stays no clinical biology tests whatsoever were performed, undoubtly suggesting a foregoing preoperative work out. On the other hand nearly 26% of the actual costs for internal medicine were due to fibroduodenoscopy for ERCP, either with or without endoscopic sphincterotomy.

Results

Since one Belgian (B1) and both UK (UK1 & UK2) pathways merely are care pathways, not taking into account the necessary preoperative diagnostic work out and the CBDL-related decision nodes, their translation resulted in a very minimal outcome: the non-variant cost of surgery and anaesthesia for a simple laparoscopic cholecystectomy.

The second Belgian pathway (B2) on the other hand proved suitable for a more extensive calculation and comparison with our theoretical 'minimal' and 'reasonable' scenarios. Nevertheless, we should bear in mind that the 36 and 37 summarize the different calculation results. Fees and related costs were divided into 4 groups: clinical biology, medical imaging, internal medicine and surgery-anaesthesia (see introduction part of this chapter).

Table 36 : Calculated costs per hospital stay for the clinical pathways in function of cost group versus reference costs for year 2001, severity 1 (S1) and 2 (S2).

Clinical path	Clinical biology	Imaging	Internal medicine	Surgery + anaesthesia	Total (wo surgery-anaesthesia)
Care Pathways UK1 / UK2 / B1 (diagnostic work out and CBDL not accounted for)	0,00 €	0,00 €	0,00 €	474,45 €	0,00 €
Clinical Pathway B2 (diagnostic work out and CBDL accounted for)	4,54 €	120,39 €	56,88 €	485,72 €	181,81 €
Minimal	4,54 €	36,17 €	18,40 €	485,72 €	59,11 €
Reasonable	4,54 €	76,66 €	67,92 €	519,51 €	149,12 €
2001 reference S1 median	12,29 €	37,11 €	33,06 €	479,60 €	82,46 €
2001 reference S1 mean	17,15 €	66,99 €	86,62 €	491,51 €	170,76 €
2001 reference S2 median	24,58 €	73,07 €	124,14 €	479,60 €	221,79 €
2001 reference S2 mean	34,26 €	117,97 €	160,38 €	513,41 €	312,61 €

In Table 36, for clinical biology all 4 studied pathways as well as both theoretical 'minimal' and 'reasonable' scenario's show lower calculated allowances than the reference costs in APRDRG 263 (Laparoscopic cholecystectomy), for SOI 1 as well as SOI 2. There are several possible explanations for this discrepancy such as:

1. firstly, the fact that APRDRG 263 assembles by definition all stays having a ICD-9-CM procedure code 51.23 for laparoscopic cholecystectomy in combination with a principal diagnostic code 57.4x – 57.5x (Cholelithiasis and 'Other disorders of the gallbladder' respectively), whether or not the intervention was preceded by a diagnostic work out in the same global stay (as with unforeseen admissions for 'biliary crisis') and irrespective eventual secondary medical problems dealt with. In other words: purely elective surgical stays, with diagnostic work out previously done in outpatient clinic, are mixed with combined diagnostic and surgical stays;

2. secondly, there is, even in severity class 1, co-morbidity potentially bringing along for instance specific blood controls (e.g. non-complicated diabetes; Thrombotest/INR monitoring for patients under long-term oral anticoagulants, etc…);

3. moreover, reference costs reflect overall medical expenditures in Belgian hospital stays with frequently repeated preoperative tests and more elaborate postoperative laboratory controls performed in routine: for APRDRG 263, SOI 1, year 2000, more than 66% of the stays had full blood count testing and more than 51% coagulation-haemostasis testing.

In the categories medical imaging and internal medicine the 3 care pathways UK1, UK2 and B1, as expected, show zero expenditure for the reasons exposed earlier. This put aside, a rather eye-catching observation is that both theoretical 'minimal' and 'reasonable' allowances remarkably enclose, not to say almost fit the median and mean reference costs of severity class 1 respectively. With all due reservations, some of which were listed in previous paragraph, we could prudently assume that the middle group of stays in APRDRG 263, severity class 1, does not fundamentally deviate from standard medical practice recommendations with respect to medical imaging and internal medicine procedures. There is however one major caveat against this

assumption: the highly divergent ranges for precholecystectomy ERCP and IOC frequencies in our calculation algorithm. Furthermore, our detailed analysis of actual Belgian costs in APRDRG 263 (year 2000), SOI 1 showed that more than 14% of the costs for medical imaging were due to CT-scan, more than 13% to RX thorax, more than 6% to duplex echocardiography preoperatively and more than 5% to IV cholangiography.

Table 37 : Calculated costs per hospital stay for the clinical cases 'simplest' and 'complex'

Clinical case	Clinical biology	Imaging	Internal medicine	Surgery + anaesthesia	Total (wo surgery-anaesthesia)
Cholecystectomy without CBDL **(simplest)**					
Minimal	0,00 €	5,23 €	0,00 €	485,72 €	5,23 €
Reasonable	0,00 €	20,90 €	0,00 €	519,51 €	20,90 €
Cholecystectomy with proved CBDL and ERCP+ES+SE **(complex)**					
Minimal	4,54 €	111,48 €	240,84 €	485,72 €	356,86 €
Reasonable	4,54 €	127,15 €	240,84 €	519,51 €	372,53 €

The figures in Table 37 clearly illustrate the impact of inherent clinical variability by revealing a considerable span between the theoretical cost estimations for the most 'simple case' and those for a complex one (71x higher cost). To put it otherwise: our 'minimal' and 'reasonable' cost estimations are very sensitive to assumptions on 'acceptable' ranges.

Finally, some comments about the calculation results for the second Belgian clinical pathway B2 in Table 36. First of all we have to underline that it was the only comprehensive and therefore truly clinical pathway. Moreover it included an additional 'decision node' concerning the use of MRCP for the preoperative assessment of risk factors for common bile duct stones (CBDL probability). This turns out to be the main reason why the calculated expenditure for the category medical imaging exceeds our 'reasonable' allowance, by this challenging the very grounds for the latter.

Discussion

In this pilot study we managed to calculate the theoretical 'minimal' and 'reasonable' costs for a common clinical entity such as symptomatic cholelithiasis with well-established diagnostic and therapeutic strategies leading to laparoscopic cholecystectomy. However, we cannot overemphasize the impracticability of incorporating all modern diagnostic as well as therapeutic subtleties into proportionate calculations, by this crippling the outcome as well as the justification of the latter.

Several clinical pathways exist, both internationally and in Belgium, for this frequently performed surgical intervention. A first major finding was a striking *semantic dichotomy* with:

1. on the one hand so called '*care pathways*': merely checklists for safely 'routing' the patient through a straightforward surgical stay, but not containing any decisional nodes ('if-then-else' branches);

2. on the other hand we studied one truly *clinical (critical) pathway* with a decisional algorithm dealing with preoperative CBDL probability (pathway B2) and a scope beyond the sheer surgical stay.

A second major finding of this exercise is the dependence of the calculations on *decision nodes* prompting for various estimations, such as the admitted ranges for precholecystectomy ERCP, frequency range for CBDL and frequency range of IOC, leading to fractional additions of various remunerations. Although based on best estimates from the medical literature and from clinical expert input, the resulting ranges turned out to be rather wide, resulting in a 'reasonable' allowance being 2,1 times the 'minimal'.

Things get even worse if we consider the implications of case variability, inevitable from a clinical-epidemiological point of view and plainly illustrated in Table 37. If we add to that the whole spectrum of essentially unpredictable co-morbidity, not accounted for in this exercise of 'prospective payment' based on guidelines and EBM, it is unclear whether the levels of severity of illness of the APRDRG sufficiently take into account this large spectrum.

There is yet another (methodological) caveat to be put against this concept of pin-point prospective payment based on APRDRG-classification of hospital stays. Surgical APRDRG classification relies on complex grouping algorithms (processed by specific 3M™ Grouper software) by which all hospital stays having a ICD-9-CM operating room procedure code (OR-code) belonging to a common main clinical-therapeutical category, in combination with a related principal diagnostic code (D-code) belonging to the same clinical-therapeutical category, retrospectively are classified in a so-called 'All Patient Diagnosis Related Group', considered homogeneous with regard to consumption of hospital resources. Whether or not the intervention was preceded by a diagnostic work out in the same global stay has no influence whatsoever on this grouping process and the same applies to possible secondary diagnoses (co-morbidity) dealt with, albeit that some of the latter contribute to a certain extend to the secondary refinement in severity classes. Anyhow, we should always bear in mind that 1) neither OR-procedure nor principal diagnosis have to be identical in all stays of a given APRDRG and 2) the grouping unit is the *hospital stay* as a whole. In contrast to this, clinical pathways in their ideal form deal with *episodes of care* as a whole, which is something quite different: the scope of the specific care is wider than that of the merely surgical hospital stay and can include foregoing work in an outpatient setting or previous hospital stay as well as eventual aftercare.

Key messages

- **Calculation of the theoretical costs for laparoscopic CCE is feasible, but highly complex to due several decision nodes related to the heterogeneity of gallstone disease manifestations that prompt for assumptions based on the literature.**
- **These theoretical costs approximate the real life reference costs for SOI 1. However, discrepancies are noted especially for clinical biology (repetitive blood tests) and medical imaging (inclusion of MRCP, IOC frequency).**
- **APRDRG classification does not sufficiently take into account important differentiation factors such as planned versus non-planned gallstone admissions and dealing with concomitant bile duct lithiasis.**

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4. THE USE OF CLINICAL PATHWAYS AND GUIDELINES IN THE DETERMINATION OF PROSPECTIVE FINANCING

4.1. GENERAL CONSIDERATIONS

Several options exist to link quality of care and financing in hospital. The use of clinical pathways and guidelines in the determination of prospective fixed hospital fees is only one among several possibilities, and an analysis of its strengths and weaknesses would therefore be more useful if combined and compared with an analysis of other possible methods.

Within a prospective payment system (PPS), prices calculated for a given unit of care classically have their basis in historical costs or charges (other methods could in theory be used), and therefore are based on what physicians do, not what they "ought" to do. Calculating these prices based on what physicians 'ought to do' seems at first glance a tempting idea. The price for an intervention is one issue. However, other factors that highly influence the total budget spent for the treatment of a certain disease or indication are the volume or the national number of interventions and the therapeutic choice that is made. These factors are more related to the appropriateness of an intervention. We review here several issues that arise when considering the implementation of such a system.

4.2. WHICH CLASSIFICATION SYSTEM? APR-DRGS AND CLINICAL PATHWAYS

Most PPS rely on widely recognised classification systems such as APR-DRGs, or a similar concept. The unit of care (and therefore of payment) defined by an APR DRG is the hospital stay. APR DRG systems are based on international classifications of diseases (ICD-9 or 10), which are grouped into a manageable number of units (+/- 350). Homogeneity of cost more than clinical logic drives the grouping of diagnosis or procedures into one particular APR-DRG, and this does not necessarily require a precise identification of the pathology. Per APR-DRG, costs vary depending on the severity-of-illness (SOI) level. This level is determined by the co-morbidity of the patient, by complications or by additional interventions during the same stay.

Clinical pathways cannot be applied to 'a group of pathologies'. If they are to be used to define and calculate prices, another classification system is needed. Nevertheless the degree of clinical precision varies between APR-DRGs, and could be sufficient for some well defined surgical procedures like those used as examples in this work. However, already in this brief exercise, not all procedures can be linked directly to one specific APR-DRG. Total knee arthroplasty e.g. is part of a larger APR-DRG (302) that includes other procedures such as total hip arthroplasty. The APR-DRG not always takes into account whether surgery has been performed electively or more as an emergency (e.g. urgent versus elective cholecystectomy). Whether a clinical pathway can be matched to a particular DRG and whether additional filters need to be introduced to obtain a more clinically homogeneous patient group therefore requires a specific analysis of each pathway for each DRG.

4.3. WHICH CLASSIFICATION SYSTEM FOR A PPS ? CLINICAL PATHWAYS AND DECISION ALGORITHMS

Clinical pathways and guidelines meet primarily a clinical logic, they are designed to help clinicians in systematising their practice. They vary in their scope. Some apply to symptoms ('management of acute abdominal pain'); some to diagnosis ('management of gallstones'), and some to a particular procedure (total knee replacement). Clinical guidelines and pathways that have been compiled for this report make for a rather heterogeneous list because they do not all apply to the same dimension.

It is relatively easy to systematise good practice for elective procedures with a more straightforward treatment process, such as total knee replacement, and translate it into one unit price, as we have done. But guidelines such as those for the 'management of gallstones' are algorithms where decisions have to be made at various points (in the decision analysis jargon called decision nodes) , and cover a wide range of sub-diagnosis and therapeutic approaches

requiring very different resources. The number of possible diagnosis/treatment combinations (and costs) within one pathway, or guidelines, can be very high (consider myocardial infarction).

This complexity is inherent to the clinical decision-making process. An illustration of this complexity can be found in the registration system recently introduced in the Netherlands, where each episode of care is described (a posteriori) by a code combining codes for symptoms, diagnosis, and treatment. In the pilot phase, more than 14.000 different combinations were observed; 1544 of them (11%) causing 80% of hospital costs[1]. (This system integrates in and out-patient care). It would be a rather long process to try documenting evidence and calculating costs even if only for these episodes presently making up 80% of hospital costs. The cost of developing such a system would be prohibitive. (For about 30 surgical operations, 'evidence-based' costs have been calculated for standard patients by health insurance companies in the Netherlands, see later).

Attempts to systematize good practice into a coherent classification systems in use in hospitals have taken place in the US in the '80 ,('patient management categories, PMC) but were abandoned in favour of the more simple and robust DRG's system.

4.4. AVAILABILITY OF EVIDENCE-BASED GUIDELINES OR CLINICAL PATHWAYS

In an 'evidence-based medicine' world, probabilities should be attributed to each decision node within a clinical decision algorithm, but the available information is frequently far from sufficient (and probably will never be) to 'feed' all possible decision nodes for all possible symptoms and diagnosis. However there is still a good deal of evidence available particularly for the most common procedures and diagnosis (these being also the most studied). Our search retrieved clinical pathways or guidelines - though not all validated - for almost all of the 30 most important surgical interventions in Belgium (ranked by their total cost to the social insurance).

Therefore, if guidelines-based costing is to be implemented for only a part of surgical interventions, even if the majority of most frequent interventions can be covered, it will necessarily need to co-exist within a PPS with units of care priced using the 'historical costs method'. Such a mixed system is likely to increase administrative complexity. A more perverse effect is the risk of cost shifting, sometimes referred to as 'up coding': assigning an intervention or diagnosis the code of another, more expensive one. This is a possible drawback in all prospective payment systems[2], but scope for cheating might be larger when a different method of pricing is used for a subset of pathologies within a PPS as cost control would be much stricter for these pathologies than for the others. It is not clear if the method used to finance this subset of pathologies (guidelines-based, or based on a historical cost reference) would have any influence on the occurrence of upcoding. It could be the case if guideline-based pricing is perceived to be insufficient and/or recommended guidelines conflict with local practices and traditions or if they have negative financial consequences for the physician or the hospital and are not complied with.

Guidelines-based pricing could either be done for all interventions or diagnosis where evidence permits, and where adequate a-priori costing can be calculated; or could be limited to selected interventions like the more common surgical procedures. The former would imply not only researching all existing evidence (and costs) for all possible diagnosis and interventions, but also regularly updating it. The cost of maintaining such a system would be considerable.

Therefore the options are:

1. either a *complete* switch towards a diagnosis/procedure -based classification system. Such a 'paradigm shift' would probably not be justified if its *only* rationale was changing the way a limited number of interventions are paid to the provider.

2. or a separate, ad-hoc sub-system for a subset of limited, simple diagnosis/procedures to be financed based on best practices guidelines, which would co-exist with the APR-DRG system. The development of a classification tailored to the specific purposes of this parallel system (and based on information already collected in routine, like ICD-9-CM) might be manageable if only a limited number of interventions are concerned.

4.5. VALIDITY OF GUIDELINES AND PATHWAYS

A PPS using guidelines and clinical pathways to calculate the reimbursement price for a given intervention, needs to rely on tools supported by the strongest evidence. An underestimation of the resources needed because guidelines used were not sufficiently validated, would be unacceptable. For instance a debate arose in the US when a study in a large sample of children hospitalised for selected conditions, found that actual length of stay was generally in excess of the published, widely used guidelines3. These guidelines in some contexts (like health maintenance organisations) were also used to estimate resource consumption. This raised concerns about their potential effects on both patients and the hospitals caring for them. The study questioned the methods used to develop and validate guidelines, as neither their internal nor external validity (that is, validity in a different context) appeared to have been up to standard.

This means that clinical pathways and guidelines need to be systematically reviewed for their evidence-based content used. In addition what is considered best practice changes over time, and regular updating will be necessary in this continually evolving field.

4.6. MINIMAL COST AND VARIANCES

Costs derived from good-practice guidelines or pathways incorporate the cost of all necessary items: they represent a 'minimal' cost, for a 'standard' patient. By definition, a lower cost would indicate inadequate care, and for 'non-standard' patients costs can only be higher.

A clinical pathway suggests what to do, but is not an edict. Each clinician must always use his or her own best judgement about care for individual patients. Departures from the recommended method of care ('variances') will be justified and necessary in some cases, such as when therapies are adjusted in response to an unexpected change in the patient's condition. Therefore only a certain proportion of patients actually are 'standard' patients.

The basic idea in a PPS is that adequacy of payment is possible if measured over an aggregate of services (all cholecystectomies for example), but not if measured at the level of a particular unit, or individual patient (one cholecystectomy). It is not possible to consider all exceptions – and not necessary so far as the unit cost of a clinical pathway is properly uplifted to make provision for 'necessary' variances. Of crucial importance is of course how to calculate this uplift.

There is very little experience to build upon in this field, so the costing methodology might require new conceptual developments. Some of the questions arising are 1) what is the expected proportion of justified variances for each pathway, and how will it vary between hospitals? 2) How to define and estimate the average cost of a variance? Should co-morbidity be included, or should it be considered as a different episode in the same patient? Etc…

4.7. APPROPRIATENESS OF THE INTERVENTION

Clinical pathways or guidelines applying to symptoms, or diagnosis, incorporate an algorithm defining 'best practice' for each decision node. They help decide whether, for instance, a given intervention is the right treatment option for the patient, given its diagnosis and other clinical data.

Clinical pathways applied to simple surgical procedures are relatively easy to define and to calculate their cost – as we have done - because they simply describe best practice on how a given intervention should be performed. They give no clue on whether the intervention was justified in the first place. They do not incorporate an important dimension of quality of care, namely appropriateness.

An appropriate procedure is one in which "the expected health benefit […] exceeds the expected negative consequences […] by a sufficiently wide margin that the procedure is worth doing, exclusive of cost" [4]. Wide variations among geographic areas in the rates of use for a given procedure (called in the jargon 'small area practice variations') raise the suspicion of different appropriateness levels for this intervention - although this interpretation calls for caution as both under-use and overuse of procedures might be occurring simultaneously in the same area[5]. The

interventions described earlier in this report show a wide variation between countries, but also in the United States, per county, hospital, and even providers.

Table 38. Crude rates of selected surgical procedures in some OECD countries, per 100,000 general population, 2001

Procedure	Tonsillectomy	Appendectomy	Cholecystectomy (all)	Knee replacement
ICD-9-CM	*28.2-28.3*	*47.0x*	*51.2x*	*81.54-81.55*
Australia	169,9	136,8	237,1	112,4
Austria		208,4		139,3
Belgium	***224,0***	***139,0***	***170,0***	***99,0***
Canada	141,3	106,5	245,3	95,8
Denmark	203,9	102,5	119,5	58,9
Finland	173,5	151,9	153	110,9
France	146,5	217,3	182,8	85,1
Italy	105,1	113	174,6	47,2
Netherlands		94,7	111,6	57,3
New Zealand	117,1	136,6	97,4	64,2
United Kingdom	112,3	70,7	88,4	74,7
United States		107,3		124,3

Source: OECD health data 2004, 1st edition except Belgium (so: RIZIV/INAMI/KCE)

(NB: most interventions are more prevalent in particular age and sex groups; crude rates are therefore highly influenced by the underlying population structure and should be compared with caution. Age and sex adjusted rates are unfortunately not easily available).

Methods have been developed, and are being increasingly used, in order to determine and identify which care is overused and which is underused, like the RAND/UCLA Appropriateness Method [5]. This method combines the best available scientific evidence with the collective judgement of experts to yield a statement regarding the appropriateness of performing a procedure at the level of patient-specific symptoms, medical history and test results. From a compilation of studies using this method, it appeared that one-third or more of all procedures performed in the United States were of questionable benefit[6].

To measure under-use, the RAND/UCLA method was expanded to measure the necessity of clinical procedures. Appropriateness criteria have been developed using the RAND method for a range of interventions. The method however does not have sufficient reproducibility to justify its use as a gold standard of appropriateness[7]. It could therefore be useful to compare appropriateness levels between populations, but under no circumstances should the care of individual patients be guided solely by the results of the appropriateness method without additional clinical information. There seems to be no documented attempts to link measures of appropriateness to the financing of a given interventions within a PPS (personal communication James Kahan, RAND corporation Europe).

Clearly the issue for many interventions (for instance, appendectomy or tonsillectomy) is not so much how they are performed, but whether they should have been performed in the first place. If clinical pathways are used only to calculate the cost of certain interventions – because this is so much easier to do than costing complex algorithm incorporating clinical decision-nodes, their impact on cost and quality of care is bound to be rather limited.

4.8. 'INTERVENTION PACKAGE': OVERLAP WITH OUT-PATIENT CARE

Clinical pathways for surgical procedures incorporate the complementary exams that need to be performed before the operation, so these pre-op exams should logically be included in the costing if they have to be performed in-hospital such as for an urgent surgical procedure or if they can be considered that they are a specific requirement for a certain surgical procedure (and not the general preoperative risk stratification) and always need to be done on the day of admission. Excessive use of some pre-op exams has been documented in Belgium, like ECG before appendectomy or full leg X-ray before TKA, and there is definitely room for improved clinical practice in that respect[8].

The point here is that these pre-op exams are sometimes done (or could easily be done) in an out-patient setting, whereby falling under a different financing system. Post-operative care can also extend after discharge has taken place. If limited to the in-patient setting, the unit of care defined (and priced) by a clinical pathway will not be comparable across hospitals, something which is of course is not acceptable.

4.9. ACCEPTABILITY

Such a direct equation between 'evidence-based' practice and financing is a drastic way of trying to improve clinical practice. On the one hand evidence-based medicine is only slowly penetrating practice; on the other hand this system is likely to be perceived as rigid and authoritarian. Combining such unpopular changes with the already difficult changes in hospital financing is likely to meet strong resistance.

4.10. INTERNATIONAL EXPERIENCES IN USING CLINICAL PATHWAYS AND GUIDELINES TO CALCULATE COSTS WITHIN A PROSPECTIVE PAYMENT SYSTEM

4.10.1. Methods

Several websites were searched. These included the official website for the Department of Health or Ministry of Health in the UK, the Netherlands, and France; in the US: Centers for Medicare & Medicaid Services (CMS), the Agency for Health Care Research and Quality (AHRQ), various large health maintenance organisations, insurance and consulting companies; some international organisations like Patient Classification system International. In addition a standard message was sent to persons identified through various channels, like the GIN network, or relevant websites. An exhaustive list of the websites searched, and persons contacted, is given in annex.

4.10.2. Results

Clinical pathways/ guidelines to calculate costs in a PPS

Such a system does not appear to be used on a large scale in any Western European or North American country, but a few experiences limited in scale merit a brief description.

The "mipp" method

The "model of integrated patient pathways", or "mipp" method was developed and implemented in Aarau hospital, in Switzerland. It started in 1998 as a local initiative and is still ongoing today. The published information on this experience is scarce, mainly in German, and refers to its first years [9-12]. The most useful information was obtained by way of personal communications.

"Mipps" are presented as 'a tool for quality improvement and cost management in health care'[10]. The aim of the "mipp" method was to develop an exhaustive classification system, based on clinical pathways, as an alternative to the APR-DRGs. Clinical pathways were all developed locally, involving multidisciplinary teams, and integrating local practices as well as some published

guidelines. Developing clinical pathways proved a highly time-consuming exercise: for the first 50 'mipps', 3 years were necessary. Now 150 mipps are in use in Aarau hospital (Personal communication: Dr Hans-Peter Muller, former head, Mipp project, Arau hospital).

MIPPS are used, on the one hand, to guide and routinely monitor clinical practice; on the other hand, they define a package of care for financing by the sickness funds. It is important to note that the prices of MIPPS are still established on an historical basis. They cover most of the hospital acute activity; 20 other non-mipp groups cover the rest of the hospital activity. To our knowledge, Mipps are not used in any other hospital in Switzerland.

A rough comparison of costs, made on a one-to-one basis between the available mipps and the corresponding AP-DRGs, when possible, showed no sensible differences. Costs for a given product varied only slightly (by 5-10%) between Aarau (mipp) and other hospitals using classical AP-DRG costing methods.

The local experience is that costs of 'clinical variances' have little influence on the mean costs of any given pathway.

The local team in Arau appears convinced of the usefulness of their system. At the level of federal Swiss authorities however, the experience has been considered to be too difficult to implement, and too expensive to be scaled up (Personal communication; Jean-Claude Rey, Executive Secretary, APDRG Switzerland) : the existing 'mipp' system presently in use appears limited in scope, and is likely to remain so.

Consulting/Insurance companies in the US

One of the persons contacted described experiences of 'guidelines-based' pricing, used on a limited scale and for a well-focused objective, for instance pricing the entire continuum of care needed for common workers injuries (work done for insurance companies; Personal communication: Richard Minnifie, actuarian working with Milliman and Robertson, a consulting company specialised in health care financing.)· Unfortunately we retrieved no written document or hard data on the subject.

Other interesting experiences on linking quality of care and financing

United States : The 'pay-for-performance' initiative13

In the U.S., payers (and in particular Medicare) have relatively little influence at the point of care. More recently, the focus of private payers and policymakers has been on "pay for performance"--typically meaning higher payment for providers who demonstrate better outcomes (fewer hospitalizations, higher screening rates) or who have better processes in place (electronic medical records, order entry systems for pharmaceuticals). The notion is not bottom up (how to price evidence-based care), but top down (how to encourage better care at any given price) (Personal communication; Murray Ross, director, Health Policy Analysis and Research, Kaiser Permanente Institute for Health Policty. Former director of Medicare payment Advisory Commission - MedPac).

The Hospital Quality Initiative focuses on an initial set of 10 quality measures by linking reporting of those measures to the payments the hospitals receive for each discharge. Hospitals that submit the required data receive the full payment update to their Medicare DRG payments.

A pilot project involving almost 300 hospitals (Premier Hospital Quality Incentive Demonstration) aims at improving the quality of inpatient care for Medicare beneficiaries by giving financial incentives for high quality. Under this demonstration, CMS (Centers for Medicare and Medicaid Services) is collecting data on 34 quality measures relating to five clinical conditions. Hospital specific performance will be publicly reported on CMS's web site. Hospitals scoring in the top 10% for a given set of quality measures will receive a 2% bonus payment on top of the standard DRG payment for the relevant discharges. Those scoring in the next highest 10% will receive a 1% bonus. In the third year of the demonstration, those hospitals that do not meet a predetermined threshold score on quality measures will be subject to reductions in payment.

The Netherlands: 'alles aan de markt'

- In the Netherlands, the DBC classification system (see earlier) aims at providing a clear identification of 'care products' whose price could be negotiated between health insurers and health providers. The background is a trend towards an ever-increasing competition within the health care system ("alles aan de markt"). In that context, the association of health insurers in the Netherlands has published a 'Diagnosis – Behandeling – Combinaties (DBC) purchasing guide' (DBC Inkoopgids[14]) which provides reference prices for some of the most frequent diagnosis-treatment combinations (like hip or knee replacement…). Resources needed are estimated based on evidence-based guidelines or pathways. Time spent by medical specialists (surgeon, anesthesist, radiologist…) has been quantified (to the minute!) and translated into costs. There is no mention of the problem of 'variances' .

- link between quality of care and financing : the system is not yet implemented, but it is foreseen to publish, for each hospital, regularly updated indicators measuring quality for as many DBCs as possible. The avowed objective is to enable insurers and consumers to do better informed choices. In effect, the link between quality of care, and financing, is therefore entrusted to market laws.

- such indicators are at present being developed for 10 pilot DBCs at CBO (Centraal Bureau Onderzoek).

The UK

- In the UK, Health Resource Groups (HRGs) are the UK equivalent of the DRGs. A standard tariff is calculated for each HRG based on historic costs and various adjustments for inflation, some provider factors like geographical situation, etc (translating into a 'general uplift)[15].

Link between quality of care and financing

For some HRG, additional adjustments to costs have been made following NICE guidance[16]. For instance, a NICE appraisal recommended to use Drug Eluting Stents (DES) for Percutaneous Transluminal Coronary Angioplasty, (PCTA) for arteries with either narrow, or long lesions. It was estimated that half of all stented arteries in the UK could benefit from a DES, costing an additional 700 pounds each. These data were used to adjust HRG E15 (PTCA) for the likely level of activity and cost. A NICE guidance for myocardial perfusion scintigraphy was published in 2003. Needs estimates (number of exams, number of cameras, investment needed) were included in the appraisal. This procedure is covered by 4 different HRGs. The distribution of the additional costs between these HRGs was made in accordance with relative activity; costs were spread over several years.

Technology appraisals where a cost saving is anticipated, and/or which cannot be attributed to specific HRGs , are reflected in the overall uplift reflecting the inflation uplift[16].

Spain

- The Basque country is trying to implement a system presenting similarities to the 'pay-for performance' described in the US. A list of criteria and objectives is used to evaluate the quality of some surgical intervention (Personal communication. Rosa Rico Iturrioz, Basque Office for Health Technology Assessment). Points are attributed when targets are reached, and the overall percentage is translated into more or less resources for the hospital. For instance median length of stay for total hip replacement should be <= 11 days, >= 26% of patients should not get a blood transfusion, etc.

Australia

An article published in 1998[17] discuss the (then) recent obligation in Australia for all private hospitals and clinics to supply standardised data on all patients to a central bureau. The authors of the article believe that it will 'provide the foundation for nationally developed clinical pathways and utilisation reviews which could modify clinical practice, improve standards and reduce health costs', but whether this ever happened has not been documented.

4.11. SUMMARY – MAIN POINTS

Defining costs in a PPS based on best practice guidelines, or clinical pathways, faces the following problems:

- Given the complexity inherent to clinical decision making, a very large number of 'unit prices' (for each particular combinations of symptoms, diagnosis, and treatment) would need to be calculated; in addition there is not enough evidence to support all clinical decisions, and probably never will be. Development costs, and maintenance costs, of such a system should be taken into account.
- A more realistic option would be to limit this costing method to a few, well defined and frequent surgical procedures. Problems arising in this case are:
    - Increase in administrative complexity due to the co-existence within the hospital financing system of two different methods of pricing, and (maybe) increased risk of upcoding.
    - The need to develop the costing methodology to adjust the minimal cost of an intervention for necessary deviations from the standard of care (e.g. for complications); and cost of dealing with co-morbidity.
    - Possible overlap of the intervention package that is priced (pre and post op exams and care) with out-patient care, falling under a different financing system
    - Limited overall impact on quality of care and costs, as the problem for various interventions is not only how the intervention package is done, but also why it has been done in the first place (appropriateness).

One hospital in Switzerland uses clinical pathways instead of APR-DRGs to define packages of care for financing by the sickness funds, within a prospective payment system. However prices are still defined on the basis of historical costs. The system was found by higher authorities to be too complicated and expensive to be scaled up. No detailed and objective written evaluation is available.

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5. GENERAL DISCUSSION AND CONCLUSIONS

5.1. LESSONS LEARNED FROM THE THEORETICAL COSTING EXERCISE

To test the feasibility of using clinical pathways and guidelines to calculate the costs for units of care in a prospective payment system, we have tried here to estimate the cost of 5 frequent surgical interventions, as defined by clinical pathways and by clinical evidence from systematic reviews and clinical trials.

5.2. STRENGTHS AND WEAKNESSES LEARNED FROM THE PROCESS

Several **strengths** of our research coming from the survey (chapter 2) and the exercises (chapter 3) on five surgical interventions we performed are worth mentioning.

1. About two-thirth of Belgian acute hospitals responded to the survey on their *use of clinical pathways*, either via the KCE-survey that was directed to the hospital associations or via the BOS-research project survey where the hospitals were addressed directly. Of the hospitals that responded, the majority had already implemented several pathways (on average 7 different pathways with a maximum of 32 pathways). We can conclude that it is reassuring that a large number of hospitals is already developing and implementing clinical pathways for quality improvement purposes or as a management tool.

2. It was *feasible* to identify the key interventions corresponding to an 'ideal' evidence-based clinical pathway, to find the corresponding billing codes and thus to calculate the theoretical cost for a standard patient for a well defined surgical intervention. The theoretical cost approximated with some reserve the historical reference cost for 4 of the 5 exercises (all except carotid endarterectomy). The calculation was most easy for day care surgery such as tonsillectomy and for straightforward elective surgery such as total knee replacement. For an emergency such as appendectomy and especially cholecystectomy performed on a heterogeneous patient population and highly depend on skills and choices of the surgeon, the calculations turned out to be increasingly complex since several decision nodes and assumptions on patient characteristics had to be taken into account.

3. Our analysis was able to identify several *discrepancies in real medical practice and billing culture* in detail. This was most illustrative for the overuse of pre-operative tests in general, for the use of several unexplainable tests in vascular surgery and for the billing of physiotherapy. It is possible to verify whether the systematic use of a certain billing code is still to be considered as good and acceptable medical practice or whether there is a high likelihood for overuse or for 'creative' billing. The methodology we developed is therefore also suited for quality assurance and for evaluation and audit purposes on the level of health insurance bodies, sickness funds and the Ministry of public health.

4. So far, the Belgian discussion on unwarranted variations in health insurance expenditure for frequent surgical interventions has focussed on the simple principle of unit or reference pricing. However, another dimension that is at least as important from a patient point of view is whether the surgery had to be performed at all. In this project we show for e.g. tonsillectomy and carotid endarterectomy that based on the conclusions from the clinical evidence and the large number of these interventions performed in Belgium, the *appropriateness* of part of them should be questioned. For policy makers this is a far more complex issue to tackle. Opinion leaders in scientific/professional associations and universities have a major role to play in peer review and in guideline development as instruments to improve appropriateness and by this quality of care.

5. Our review of the evidence and appraisal of the pathways lead to some 'innovative' findings. For several issues (systematic full leg radiography pre- and postop, continous passive motion, arteriography, echography appendix,…) it was though that no evidence existed even by foremost experts, while our detailed review was able to find clear evidence from clinical trials that challenged current opinions and practices. Our synthetic review and summary of the clinical evidence should be interpreted with caution. They can be used as a first step toward guideline development, but the steps of considered judgement and validation that are mandatory in state-of-the-art guideline development methodology were no part of the mission and were not

encountered in this short project. The 'new' findings from the literature can certainly give rise to an interesting further debate in the scientific community.

Our analysis was also able to demonstrate several **weaknesses** related to either methodological problems or conditions that need to be fulfilled in order to introduce another financing system:

1. There are still problems with the *semantics* of clinical pathways, giving rise to a spectrum going from pure nursing files to integrated multidisciplinary pathways with all key interventions in full detail. A detailed analysis of the pathways we received shows that there is room for improvement of the quality and the content of several of these pathways: Our appraisal shows that only half of them fulfil some obvious criteria; In the exercises we were able to illustrate that a systematic literature search for strong evidence does not seem to get high priority in pathway development methodology. In the near future the quality of the pathways is probably bound to improve, as was seen about a decade ago for the development of clinical practice guidelines. If needede, the pathways we examined can easily be adapted towards a more evidence-based content. However, this can have financial repercussions for both the hospital and its physicians.

2. We showed that it is cumbersome to use the current APR-DRG *classification system* without any modification or the introduction of additional conditions to introduce a prospective payment system for surgical interventions. There is clearly no one-on-one fit between a clinically recognisable patient population undergoing a well defined surgical technique (like in a clinical pathway) and a DRG-based classification system containing 'groups of pathologies'. In several of our exercises we were prompted to use decision algorithms and assumptions resulting in a high number of possible diagnosis/treatment combinations (and related costs) that have no immediate match in the current classification system.

3. Although our calculations mostly approximated the real reference costs of patients with the lowest severity-of-illness, it is methodologically impossible to take into account all possible factors of *co-morbidity and complications* that can increase the level of severity-of-illness. This is related to the enormous complexity and often long lists of possible co-morbidities leading to higher severity levels in de DRG-grouper, severity being determined by higher expected costs and not necessarily by a clinically higher risk. The majority of patients in a DRG has severity one or two. The substantially higher cost of SOI 2 versus 1 can be simulated or validated based on clinical evidence for an individual patient but never for a large group of patients where numerous secondary diagnoses can be involved.

4. Although the cost calculations based on clinical evidence proved to be feasible purely from a methodological point of view, the whole process was highly *complex* for part of the exercises and quite *time-consuming*. If the same exercise is to be made for the 50-100 most frequent surgical interventions, including their updating every few years, the consequences for timing and human resources should be taken into account.

5. Our mission inherently included a very strict timing and for every exercise only a limited number external experts could be consulted. One of the implications is that there was no real life testing of the *external validity* and acceptability of the findings. Not all hospitals use clinical pathways and even if they do, their content can differ widely. Ideally, prospective payment is based on pathways and guidelines that are validated nationally to assure a broad implementation and adequate changes in clinical behaviour in all hospitals. Sudden changes in financing systems can otherwise lead to evasive reactions yielding more costs in other sectors or for the patient. Because of the many assumptions involved, our cost estimations are insufficiently robust. In addition, all the assumptions made render these estimations vulnerable to endless discussions.

6. Our calculations only included some *physicians' hospital fees* in accordance with the mission. These fees however, are only (a small) part of the financing of a hospital and of the care process. It is unclear what the consequences, if any, will be of a financial incentive placed on a limited part of the hospital financing. Certainly, risks for up-coding and cost-shifting possibilities that neutralise the financial incentive to reduce unwarranted cost variations should be assessed. This project defined costs from a health insurance point of view. Other possible approaches however exist, especially for utilisation review from a hospital perspective. Clinical pathways indeed can be used to assess the proces costing of a surgical procedure. This is particularly useful in financing systems were fixed reimbursements for surgical procedures exist. In such a system with other financial incentives, the costs of every specialty can be determined by the cost per unit of time required.

5.3. METHODOLOGICAL PITFALLS OF THEORETICAL COST CALCULATIONS

Although originally thought to be simple, the exercise proved rather complex and time-consuming. It was needed to search the literature and databases for clinical pathways, then systematically assess the evidence-base of their various key interventions in order to decide which interventions and to what extent should be included in the costing.

Some clinical pathways do not include decision nodes (total knee prosthesis, tonsillectomy) and are easier to cost, while others are in fact algorithms, and each branch of the algorithm needs to be calculated separately (examples: appendectomy: 'typical ' patient vs non-typical); or cholecystectomy (elective vs non-elective, probability common bile duct lithiasis CBDL<= 5% vs CBDL >5% etc…). Assumptions based on best estimates from the literature and from expert input had to be made to assign probabilities to the decision nodes.

Another difficulty relates to the exact definition of the costs included in the overall cost of the intervention. A surgical intervention is a treatment decision resulting from a diagnostic process. For elective surgery (4 out of 5 of our 'test cases', and the majority of surgical interventions in Belgium), the diagnostic process usually takes place before the intervention, in an out-patient setting (for some interventions, post-discharge care can also be considered as pertaining to the intervention package). Costing only the care given during the hospital stay misses part of the cost of the preoperative and postoperative care episode. To make our data more comparable with the costs of APR-DRGs, we did not include in the costing diagnostic tests that could, or should have taken place in ambulatory practice, although we tried to assess separately the cost of the diagnostic process for a procedure like carotid artery endarteriectomy, where the diagnostic process is quite costly in relation to the intervention itself.

Whereas comparing theoretical costs between different clinical pathways is straightforward, comparing the theoretical cost of a pathway with the real distribution of costs of the corresponding APR-DRGs is not. First of all, the total cost of an APR-DRG is the cost of *an hospital stay*, and includes the cost of any treated co-morbidity, and complications. By limiting our comparison to the cost of the APR-DRGs, severity 1, we can reduce, but not entirely remove, this bias. As explained above, assumptions were needed to define the 'minimal cost' (what is estimated to be needed for all or a well defined part of the patients in general), but even more to define a 'reasonable' cost (what can be considered as acceptable in absence of solid evidence). Assumptions have cost implications: consider e.g. the possible impact of changing the assumptions made on the prevalence of common bile duct lithiasis on the cost estimation of laparoscopic cholecystectomy. The more assumptions involved in a cost estimation, the less robust is the estimation. Our time was limited, and we could not produce costs for the range of all possible different assumptions. Secondly, the subtleties of our billing system complicate matters further. E.g the same needs for physiotherapy can be met by different types of nomenclature use for postoperative rehabilitation (enormous variability in billing practice of the K and the M nomenclature) and result in different costs.

Given all these limitations, only *very wide* differences between our calculated '*reasonable* cost' and the real costs of the APR-DRG can be considered as meaningful. This was the case for only one (CEA) of the 5 interventions. It can here be concluded that the average cost of CEA in Belgium is higher than can be logically be explained and our analysis of current billing practices based on sickness fund data illustrated the details on possible overuse. Our cost data do less easily permit to document underuse, because our cost estimations include some diagnostic exams that can or preferably should be done in ambulatory care.

5.4. CLINICAL PATHWAYS, QUALITY OF CARE, AND HOSPITAL FINANCING

We have gone in chapter 4 in detail through several issues arising when considering financing units of care based on clinical pathways, guidelines or the like. The most realistic option would be to limit this costing method to well defined and frequent surgical procedures, as we have tried to do here. Our exercise illustrates the strengths and weaknesses of the process of translating the complexities of clinical decision making for seemingly simple interventions into costs. Although it is in theory possible to develop a financing system based on ideal evidence-based clinical pathways, it is unclear what the impact on quality of care and cost would be. Only a limited number of interventions could be targeted (the most frequent ones) and only for severity-of-

illness level 1 of the corresponding APR-DRG. An alternative would be to estimate the cost of a clinical pathway based on historical costs, as was done in one hospital in Switzerland. It would produce more robust cost data as not all possible deviations from standard care would have to be anticipated, and their price estimated. This would require the hospitals implementing clinical pathways for one or a few interventions, and later document the costs of doing so.

The important problem of (lack of) appropriateness of surgery is not addressed by the use of clinical pathways or guidelines. Clinical pathways and guidelines represent a worthy attempt at improving quality of clinical care, which deserves to be encouraged, but the link between appropriate care and hospital financing is difficult to establish. This is most probably the reason why our search of international experiences on this topic returned so little, in a context where the increasing cost of health care has prompted a vast body of research on cost-containment and quality of care. Moreover, *quality* is a multidimensional concept, and clinical pathways address only one of its many dimensions, especially the organisational dimension.

Summary - Key points

- We tested the feasibility of costing surgical interventions in 5 tests cases presented in this rapport. The exercise, although theoretically feasible, proved complex and time consuming. Some costs estimations involve many assumptions and cannot be considered as sufficiently robust without further testing and external validation. And although the calculated cost approximated the real reference historical cost, this theoretical cost is not directly comparable with the mean/median historical cost of the corresponding APR-DRG for various reasons as we showed, and only wide differences can usefully be interpreted.
- Clinical decision making is often a complex process; there is not enough evidence to support all clinical decisions and there never will be. Costing *all* these decisions according to what doctors 'should' do rather than on what they do for *all* interventions is therefore basically impossible. Prospective costing for many surgical interventions could in theory still be done, giving it the time and care needed. A more realistic option would then be to limit this method of calculating prices to a few, well defined and frequent surgical procedures for illustrative purposes. If a wider range of surgical interventions is to be covered, costing based on historical data seems a more feasible option. The methodology we developed can certainly be used for joint quality improvement and audit purposes.
- A prospective payment system based on pathways or guidelines cannot be fit into the APR-DRG classification system (because the unit of care priced by an APR-DRG is the hospital stay, not the intervention), and therefore requires the development of an ad-hoc, specific classification system for the chosen procedures. Other difficulties arise when considering implementing pathway- or guideline-based pricing: increase in administrative complexity (due to the co-existence of different classification systems, and methods of pricing) ; overlap with in- and out-patient care; increased risk of up-coding.
- The overall impact on quality of care and costs is likely to be limited: only part of all surgical interventions and a fortiori of all hospital activity will be priced this way, costs are possibly shifted to other sectors or to the patient and the problem for various interventions is not only how the intervention package is done, but also why it has been done in the first place (appropriateness).

APPENDIX 1 CLINICAL PATHWAYS NOMENCLATURE DETAILS FOR TOTAL KNEE ARTHROPLASTY

Scenario[a]	billing code	description	price	cost group	b1	b2	minimal	reasonable	rotherham	vincent
	127024	Doseren van hemoglobine door elektrofotometrische methode	0.26 €	clinical biology	3	2	0	1	1	2
	127061	Tellen van de leucocyten	0.26 €	clinical biology	3	3	0	0	0	2
	540525	Bepalen van de pH van het bloed en van de partiële CO2- en O2-drukken,inclusief eventueel de berekeningen van de andere parameters van het zuur-base evenwicht	1.65 €	clinical biology	3	2	0	0	0	2
	540945	Doseren van kalium	0.53 €	clinical biology	3	2	0	0	0	1
	125086	Doseren van ureum	0.33 €	clinical biology	3	2	0	0	0	1
	127046	Tellen van de erythrocyten en/of hematocriet	0.26 €	clinical biology	3	3	0	0	0	2
	540341	Doseren van creatinine	0.46 €	clinical biology	3	2	0	0	0	1
	126523	Microscopisch onderzoek van urinesediment met of zonder eenvoudige kleuring	0.46 €	clinical biology	3	1	0	0	0	1
	127120	Tellen van de thrombocyten	0.26 €	clinical biology	3	3	0	0	0	2
	540260	Doseren van chloriden	0.40 €	clinical biology	3	2	0	0	0	1
	541365	Doseren van natrium	0.46 €	clinical biology	3	2	0	0	0	1
	541063	Doseren van CRP met een immunologische methode	0.83 €	clinical biology	2	0	0	0	0	0
	554584	Thromboplastinetijd (prothrombinetijd)	0.53 €	clinical biology	2	0	0	1	1	0
	466244	Radiografie van de knie met visualisatie van knie en	16.72 €	imaging	2	2	0	1	1	1

Scenario[a]	billing code	description	price	cost group	b1	b2	minimal	reasonable	rotherham	vincent
		patellagewricht, minimum twee clichés								
	455302	Vergelijkende mensuratie door scanometrie of teleradiografie van beide onderste ledematen in hun geheel	37.62 €	imaging	2	1	0	0	0	0
	469125	Radioscopie met beeldversterker en televisie in gesloten keten in de operatiekamer in de loop van een heelkundige of orthopedische bewerking	18.81 €	imaging	1	1	0	1	0	1
	463702	Radiografie van de thorax en de inhoud ervan, één cliché	10.45 €	imaging	1	0	0	0	0	0
	469825	Volledig transthoracaal echografisch bilan van het hart, waarbij bidimensionele beelden bekomen worden in minstens drie verschillende snedevlakken, en kleuren-Doppler signalen en in spectraal mode ter hoogte van minstens drie klepopeningen. De opname en archivering van het onderzoek op magneetband of digitale drager is vereist, evenals een gedetailleerd protocol	58.90 €	imaging	0	1	0	0	0	0
	290286	Femorotibiale arthroplastiek met gelede prothese	665.57 €	main intervention	1	1	1	1	1	1
	200104	Anesthesie verricht tijdens een verstrekking: Gerangschikt in een categorie gelijk aan of lager dan K 390 of N 650 of 1 750 en hoger dan K 300 of N 500 of 1 600	374.91 €	main intervention	1	1	1	1	1	1
12d	558821	Pluridisciplinaire revalidatie met een behandelingsduur van 60 min. per zitting en tijdens dewelke bij elke zitting ten minste twee disciplines waaronder ergotherapie of kinesitherapie aan de behandeling deelnemen en minstens twee van de volgende technieken worden toegepast : revalidatie door beweging, psychomotore therapie, elektrostimulatie bij motorische uitval of antalgische elektrotherapie, mechanotherapie, oefeningen met externe prothesen en/of orthesen en/of complexe technische hulpmiddelen, hydrotherapie in zwembad (K30)	28.90 €	other reimbursed activities	9	9	9	9	9	9

Scenario[a]	billing code	description	price	cost group	b1	b2	minimal	reasonable	rotherham	vincent
variable					8	8	6	8	6	7
12d	558806	Revalidatie die behalve oefentherapie tenminste één van de hierna vermelde technieken omvat per zitting (psychomotore therapie, elektrostimulatie bij motorische uitval of antalgische elektrotherapie, ergotherapie, oefeningen met prothesen en/of orthesen en/of complexe technische hulpmiddelen, hydrotherapie in zwembad, tractietherapie). de eerste 18 zittingen (K15)	14.23 €	other reimbursed activities	3	3	3	3	3	3
variable					2	2	2	2	2	2
	475823	Inspannings- of hypoxieproef, met continue monitoring van minstens één afleiding vóór elke belastingsverandering, op het einde van de proef en gedurende minstens drie minuten na het beëindigen van de proef, meerdere elektrocardiografische registraties op verschillende afleidingen en bloeddrukmetingen, met uittreksel en gestandaardiseerd protocol	33.72 €	other reimbursed activities	0	1	0	0	0	0
	475086	Elektrocardiografische onderzoekingen, met protocol, ten minste 12 verschillende derivaties	16.26 €	other reimbursed activities	0	1	0	0	0	0

[a] Empty = in both scenarios; 12d = 12 days postoperative length of stay for all clinical pathways; variabel = postoperative length of stay depends on clinical pathway

APPENDIX 2 CLINICAL PATHWAYS NOMENCLATURE DETAILS FOR CAROTID ENDARTERECTOMY

scenario	billing code	description	price	cost group	sewickley		carolina		minimal		reasonable		pennsylvania		belgium	
					included	percent included	included	percent included	included	percent included	included	percent included	included	percent included	included	percent included
hosp	540260	Doseren van chloriden	0.40 €	clinical biology			1	100%								
preop + hosp							1	100%	1	100%	1	100%				
hosp	540341	Doseren van creatinine	0.46 €	clinical biology			1	100%								
preop + hosp							1	100%	1	100%	1	100%				
hosp	125064	Doseren van glucose	0.33 €	clinical biology			1	100%							1	100.00%
preop + hosp							1	100%	1	100%	1	100%			1	100.00%
hosp	540945	Doseren van kalium	0.53 €	clinical biology			1	100%								
preop + hosp							1	100%	1	100%	1	100%				
hosp	541365	Doseren van natrium	0.46 €	clinical biology			1	100%								
preop + hosp							1	100%	1	100%	1	100%				
hosp	125086	Doseren van ureum	0.33 €	clinical biology			1	100%								
preop + hosp							1	100%	1	100%	1	100%				
hosp	127046	Tellen van de erythrocyten en/of hematocriet	0.26 €	clinical biology			1	100%							1	100.00%
preop + hosp							1	100%	1	100%	1	100%			1	100.00%
hosp	127061	Tellen van de leucocyten	0.26 €	clinical biology			1	100%							1	100.00%
preop + hosp							1	100%	1	100%	1	100%			1	100.00%
hosp	127120	Tellen van de thrombocyten	0.26 €	clinical biology			1	100%							1	100.00%
preop + hosp							1	100%	1	100%	1	100%			1	100.00%
hosp	460320	Bilateraal kleurenduplexonderzoek van de arteria carotis	58.90 €	imaging											1	100.00%
preop + hosp					1	100%	1	100%	1	100%	1	100%	1	100%	1	100.00%

scenario	billing code	description	price	cost group	sewickley		carolina		minimal		reasonable		pennsylvania		belgium	
					included	percent included	included	percent included	included	percent included	included	percent included	included	percent included	included	percent included
hosp	459421	NMR-onderzoek van de hals of van de thorax of van het abdomen of van het bekken, minstens drie sequenties, met of zonder contrast, met registratie op optische of elektromagnetische drager	146.31 €	imaging												
preop + hosp									1	10%	1	20%				
hosp	453246	Radiografie van de aorta thoracalis en/of abdominalis en van de vertakkingen ervan, minimum drie clichés (mag niet worden gecumuleerd met verstrekking nr. 453294 - 453305, dezelfde dag verricht)	75.23 €	imaging			1	100%					1	100%	1	100.00%
preop + hosp							1	100%			1	20%	1	100%	1	100.00%
hosp	463702	Radiografie van de thorax en de inhoud ervan, één cliché	10.45 €	imaging												
preop + hosp											1	100%				
hosp	442400	Tomografisch onderzoek tijdens een scintigrafie, met verwerking op computer die ten minste twee niet-parallelle reconstructievlakken omvat, met protocol en iconografische documenten	173.53 €	imaging			1	100%								
preop + hosp							1	100%								
hosp	200104	Anesthesie verricht tijdens een verstrekking: Gerangschikt in een categorie gelijk aan of lager dan K 390 of N 650 of 1 750 en hoger dan K 300 of N 500 of 1 600	374.91 €	main intervention	1	100%	1	100%	1	100%	1	100%	1	100%	1	100.00%
preop + hosp					1	100%	1	100%	1	100%	1	100%	1	100%	1	100.00%
hosp	235082	Revascularisatie van de arteria carotis of vertebralis door endarteriëctomie, endoaneurysmorrhafie, pontage of resectie met enten of anastomose	640.02 €	main intervention	1	100%	1	100%	1	100%	1	100%	1	100%	1	100.00%
preop + hosp					1	100%	1	100%	1	100%	1	100%	1	100%	1	100.00%

scenario	billing code	description	price	cost group	sewickley		carolina		minimal		reasonable		pennsylvania		belgium	
					included	percent included	included	percent included	included	percent included	included	percent included	included	percent included	included	percent included
hosp	214023	Continu toezicht op de hartfunctie (met of zonder toezicht op andere vitale waarden) met een waaktoestel dat, benevens het elektrocardiogram, op zijn minst bestendig een van de volgende parameters volgt : de arteriële druk door middel van een intra-arteriële catheter, de intracavitaire of pulmonale druk door middel van een intracardiale catheter, de intracraniële druk door middel van een intracraniële catheter (buiten de narcoses, de heelkundige en verloskundige bewerkingen en buiten de functionele harttests), inclusief de eventuele registraties : De eerste dag	113.92 €	other	1	100%			1	6%	1	30%				
preop + hosp					1	100%			1	6%	1	30%				
hosp	475086	Elektrocardiografische onderzoekingen, met protocol, ten minste 12 verschillende derivaties	16.26 €	other reimbursed activities			1	100%								
preop + hosp							1	100%	1	100%	1	100%				
hosp	477142	Elektro-encefalografisch onderzoek, met verslag, ten minste 6 gelijktijdige elektro-encefalografische derivaties	62.62 €	other reimbursed activities	1	100%										
preop + hosp					1	100%										
hosp	475543	Farmacodynamische proef bij cardiale scintigrafische of echografische stress-test, gevolgd door electrocardiografische controles, met protocol	24.08 €	other reimbursed activities			1	100%								
preop + hosp							1	100%								

APPENDIX 3 CLINICAL PATHWAYS NOMENCLATURE DETAILS FOR APPENDECTOMY

Scenario	billing code	description	price	cost group	belgium		minimal		reasonable		boston		cincinnati		texas	
					included	percent included	included	percent included	included	percent included	included	percent included	included	percent included	included	percent included
atypical adults	541623	Doseren van amylasen	0.83 €	clinical biology	1	100.00%			1	100.00%						
atypical children					1	100.00%			1	100.00%						
typical																
atypical adults	125145	Doseren van aspartaat aminotransferasen en alanine aminotransferasen	0.99 €	clinical biology	1	100.00%			1	100.00%						
atypical children					1	100.00%			1	100.00%						
typical																
atypical adults	120046	Doseren van bilirubine	0.46 €	clinical biology	1	100.00%			1	100.00%						
atypical children					1	100.00%			1	100.00%						
typical																
atypical adults	540260	Doseren van chloriden	0.40 €	clinical biology					1	100.00%						
atypical children									1	100.00%						
typical																
atypical adults	540341	Doseren van creatinine	0.46 €	clinical biology	1	100.00%			1	100.00%						
atypical children					1	100.00%			1	100.00%						
typical																
atypical adults	541063	Doseren van CRP met een immunologische methode	0.83 €	clinical biology	1	100.00%	2	100.00%	2	100.00%						
atypical children					1	100.00%	2	100.00%	2	100.00%						
typical							1	100.00%	1	100.00%						

Scenario	billing code	description	price	cost group	belgium		minimal		reasonable		boston		cincinnati		texas	
					included	percent included	included	percent included	included	percent included	included	percent included	included	percent included	included	percent included
atypical adults	541925	Doseren van de alkalische fosfatasen	0.53 €	clinical biology	1	100.00%										
atypical children					1	100.00%										
typical																
atypical adults	541903	Doseren van de gammaglutamyltransferasen	0.53 €	clinical biology	1	100.00%			1	100.00%						
atypical children					1	100.00%			1	100.00%						
typical																
atypical adults	125064	Doseren van glucose	0.33 €	clinical biology	1	100.00%			1	100.00%						
atypical children					1	100.00%			1	100.00%						
typical																
atypical adults	127024	Doseren van hemoglobine door elektrofotometrische methode	0.26 €	clinical biology	1	100.00%										
atypical children					1	100.00%										
typical																
atypical adults	540945	Doseren van kalium	0.53 €	clinical biology					1	100.00%						
atypical children									1	100.00%						
typical																
atypical adults	541785	Doseren van melkzuurdehydrogenasen	0.53 €	clinical biology	1	100.00%										
atypical children					1	100.00%										
typical																
atypical adults	541365	Doseren van natrium	0.46 €	clinical biology					1	100.00%						
atypical children									1	100.00%						
typical																

Scenario	billing code	description	price	cost group	belgium		minimal		reasonable		boston		cincinnati		texas	
					included	percent included	included	percent included	included	percent included	included	percent included	included	percent included	included	percent included
atypical adults	125086	Doseren van ureum	0.33 €	clinical biology					1	100.00%						
atypical children									1	100.00%						
typical																
atypical adults	123082	Leucocytenformule vastgesteld met microscoop op minimum 100 cellen	0.53 €	clinical biology	2	100.00%	2	100.00%	2	100.00%						
atypical children					2	100.00%	2	100.00%	2	100.00%	1	100.00%	1	100.00%	2	100.00%
typical					1	100.00%	1	100.00%	1	100.00%					1	100.00%
atypical adults	126523	Microscopisch onderzoek van urinesediment met of zonder eenvoudige kleuring	0.46 €	clinical biology	1	100.00%	2	100.00%	2	100.00%						
atypical children					1	100.00%	2	100.00%	2	100.00%	1	100.00%	1	100.00%	2	100.00%
typical							1	100.00%	1	100.00%					1	100.00%
atypical adults	125926	Opzoeken van humane choriogonadotrofines (h.C.G.) met plaatjestechniek	0.53 €	clinical biology	1	100.00%			1	100.00%						
atypical children					1	100.00%			1	100.00%	1	100.00%	1	100.00%		
typical											1	100.00%				
atypical adults	127046	Tellen van de erythrocyten en/of hematocriet	0.26 €	clinical biology	1	100.00%										
atypical children					1	100.00%							1	100.00%		
typical																
atypical adults	127061	Tellen van de leucocyten	0.26 €	clinical biology	2	100.00%	2	100.00%	2	100.00%						
atypical children					2	100.00%	2	100.00%	2	100.00%	1	100.00%	1	100.00%	2	100.00%
typical					1	100.00%	1	100.00%	1	100.00%					1	100.00%
atypical adults	127120	Tellen van de thrombocyten	0.26 €	clinical biology	1	100.00%										

Scenario	billing code	description	price	cost group	belgium		minimal		reasonable		boston		cincinnati		texas	
					included	percent included	included	percent included	included	percent included	included	percent included	included	percent included	included	percent included
atypical children					1	100.00%							1	100.00%		
typical																
atypical adults	460165	Bidimensionele echografie met geschreven protocol en iconografische drager die ontstaat na digitale beeldverwerking van de gegevens ongeacht het aantal echogrammen van het abdomen: Lever en/of galblaas en/of galwegen	22.65 €	imaging	1	100.00%										
atypical children					1	100.00%	1	100.00%	1	100.00%	1	25.00%	1	50.00%	1	30.00%
typical																
atypical adults	458824	Computergestuurde tomografie van de hals (weke delen) of van de thorax of van het abdomen, met en/of zonder contrastmiddel, met registreren en clichés, minimum 15 coupes, voor het hele onderzoek	108.68 €	imaging	1	75.00%	1	100.00%	1	100.00%						
atypical children					1	75.00%			1	100.00%	1	75.00%	1	50.00%	1	20.00%
typical																
atypical adults	461521	Radiografie van het abdomen en/of van de blaasstreek voor rechtstreeks onderzoek zonder manipulatie noch contrastmiddelen, ongeacht het aantal clichés	14.63 €	imaging												
atypical children													1	20.00%		
typical																
atypical adults	200266	Anesthesie verricht tijdens een verstrekking: Gerangschikt in categorie K 120 of N 200	77.25 €	main intervention	1	100.00%	1	100.00%	1	100.00%						
atypical children					1	100.00%	1	100.00%	1	100.00%	1	100.00%	1	100.00%	1	100.00%
typical					1	100.00%	1	100.00%	1	100.00%	1	100.00%	1	100.00%	1	100.00%
atypical adults	243364	Appendectomie in het koude of het acute stadium, met of zonder perforatie	189.24 €	main intervention	1	100.00%	1	100.00%	1	100.00%						
atypical					1	100.00%	1	100.00%	1	100.00%	1	100.00%	1	100.00%	1	100.00%

Scenario	billing code	description	price	cost group	belgium		minimal		reasonable		boston		cincinnati		texas	
					included	percent included	included	percent included	included	percent included	included	percent included	included	percent included	included	percent included
children																
typical					1	100.00%	1	100.00%	1	100.00%	1	100.00%	1	100.00%	1	100.00%
atypical adults	515200	Individuele kinesitherapiezitting waarbij de persoonlijke betrokkenheid van de kinesitherapeut per rechthebbende niet gekoppeld is aan het begrip duur	6.36 €	other reimbursed activities												
atypical children													2	100.00%		
typical													2	100.00%		

APPENDIX 4 CLINICAL PATHWAYS NOMENCLATURE DETAILS FOR LAPAROSCOPIC CHOLECYSTECTOMY

scenario	billing code	description	price	cost group	minimal		reasonable		b2		uk	
					included	percent included	included	percent included	included	percent included	included	percent included
all	120120	Doseren van alanine aminotransferasen	0.53 €	clinical biology	1	100%	1	100%	1	100%		
CBDL					1	100%	1	100%	1	100%		
no CBDL												
all	541623	Doseren van amylasen	0.83 €	clinical biology	1	100%	1	100%	1	100%		
CBDL					1	100%	1	100%	1	100%		
no CBDL												
all	120046	Doseren van bilirubine	0.46 €	clinical biology	1	100%	1	100%	1	100%		
CBDL					1	100%	1	100%	1	100%		
no CBDL												
all	541063	Doseren van CRP met een immunologische methode	0.83 €	clinical biology	1	100%	1	100%	1	100%		
CBDL					1	100%	1	100%	1	100%		
no CBDL												
all	541925	Doseren van de alkalische fosfatasen	0.53 €	clinical biology	1	100%	1	100%	1	100%		
CBDL					1	100%	1	100%	1	100%		
no CBDL												
all	541903	Doseren van de gammaglutamyltransferasen	0.53 €	clinical biology	1	100%	1	100%	1	100%		
CBDL					1	100%	1	100%	1	100%		

scenario	billing code	description	price	cost group	minimal		reasonable		b2		uk	
					included	percent included	included	percent included	included	percent included	included	percent included
no CBDL												
all	541844	Doseren van lipasen	0.83 €	clinical biology	1	100%	1	100%	1	100%		
CBDL					1	100%	1	100%	1	100%		
no CBDL												
all	460165	Bidimensionele echografie met geschreven protocol en iconografische drager die ontstaat na digitale beeldverwerking van de gegevens ongeacht het aantal echogrammen van het abdomen: Lever en/of galblaas en/of galwegen	22.65 €	imaging	1	100%	1	100%	1	100%		
CBDL					1	100%	1	100%	1	100%		
no CBDL												
all	451824	Cholangiowirsungografie door fibroduodenoscopie en catheterisme van de pancreas- en galwegen (minimum tien clichés)	82.29 €	imaging	1	5%	1	25%	1	22%		
CBDL												
no CBDL												
all	451905	Cholangiowirsungografie door fibroduodenoscopie en catheterisme van de pancreas- en galwegen met papillectomie (minimum 10 clichés) mag niet worden gecumuleerd met verstrekking nr 451813 - 451824 dezelfde dag verricht	83.60 €	imaging	1	5%	1	15%	1	12%		

scenario	billing code	description	price	cost group	minimal		reasonable		b2		uk	
					included	percent included	included	percent included	included	percent included	included	percent included
CBDL					1	100%	1	100%	1	100%		
no CBDL												
all	459421	NMR-onderzoek van de hals of van de thorax of van het abdomen of van het bekken, minstens drie sequenties, met of zonder contrast, met registratie op optische of elektromagnetische drager	146.31 €	imaging					1	44%		
CBDL												
no CBDL												
all	451780	Peroperatieve cholecysto en/of cholangiografie tijdens een heelkundige bewerking, verricht in een operatiekamer onder algemene anesthesie	20.90 €	imaging	1	25%	1	100%	1	25%		
CBDL					1	25%	1	100%	1	25%		
no CBDL					1	25%	1	100%	1	25%		
all	200200	Anesthesie verricht tijdens een verstrekking: Gerangschikt in een categorie gelijk aan of lager dan K 240 of N 400 of 1 450 en hoger dan K 180 of N 300 of 1 350	159.05 €	main intervention	1	100%	1	100%	1	100%	1	100.00%
CBDL					1	100%	1	100%	1	100%	1	100%
no CBDL					1	100%	1	100%	1	100%	1	100%
all	242480	Cholecystectomie met peroperatoire cholangiografie	360.46 €	main intervention	1	25%	1	100%	1	25%		
CBDL					1	25%	1	100%	1	25%		

scenario	billing code	description	price	cost group	minimal		reasonable		b2		uk	
					included	percent included	included	percent included	included	percent included	included	percent included
no CBDL					1	25%	1	100%	1	25%		
all	244786	Laparoscopische cholecystectomie	315.40 €	main intervention	1	75%			1	75%	1	100.00%
CBDL					1	75%			1	75%	1	100%
no CBDL					1	75%			1	75%	1	100%
all	473745	Fibroduodenoscopie (2e en 3de duodenum) met manipulatie met het oog op een cholangiowirsungrafie	127.16 €	other reimbursed activities	1	5%	1	25%	1	22%		
CBDL												
no CBDL												
all	473701	Fibroduodenoscopie met papillotomie	240.84 €	other reimbursed activities	1	5%	1	15%	1	12%		
CBDL					1	100%	1	100%	1	100%		
no CBDL												

APPENDIX 5 : METHODS AND RESULTS OF THE SEARCH STRATEGY FOR CHAPTER 4.

Search strategy

Search websites judged particularly relevant

Trying to identify key informants

1) Standard message

Here at the Belgian Federal Health Care Knowledge Centrum, we are investigating methods for pricing DRGs (or a similar concept) for some common surgical operations. In particular, we are trying to identify experiences where pricing is based not on historical cost data, but rather on inputs defined from evidence-based guidelines, or clinical pathways; or a combination of these methods (historical+evidence-based). Do you know anything about such experiences - or/and could you direct me to somebody who could help me?

2) Standard message sent to persons identified through various channels

- relevant websites. For instance, many addresses found on the **Patient Classification System International (PCSE) website** http://www.pcse.org/

PCSE organizes every year what seems to be the main international conference on DRGs and classifications systems. Researchers presenting (even remotely relevant) abstracts at the PCSE conference in Washington (2002) were contacted. Contacts made in most European countries, US, Canada, Australia, Japan

- GIN members (guidelines international network)
- persons referred by other contacts, personal contacts in Spain, UK, Austria

Search databases

1) Pubmed

Search #28 and #30 Limits: only items with abstracts, English 06:04:22 134
#31

#30 Search "Diagnosis-Related Groups"[MeSH] Limits: only items with abstracts, English 05:55:27 3723

#28 Search "Costs and Cost Analysis/methods"[MeSH] Limits: only items with abstracts, 05:54:27 2138
English

None of the 134 articles retrieved relevant

2) National Guidelines Clearinghouse

search: on 'financing' / costing / pricing in the clinical guidelines database. No hits

Results : websites searched and contacts made, by country

United Kingdom

Department of Health (DH) website:

DH > home Policy and guidance > Organisation policy > Finance and planning **Payment by results**

DH> home Publications and statistics > Publications > **Publications policy and guidance**

Implementing payment by results: Technical guidance 2005-06 http://www.dh.gov.uk/assetRoot/04/09/79/94/04097994.pdf

Payment by results: A step by step guide to the calculation of the tariff 2005-06 http://www.dh.gov.uk/assetRoot/04/09/79/97/04097997.pdf

National Centre for Clinical Excellence (NICE)

Mail exchanges with Françoise Cluzeau,PhD ; Jennifer Field (Project Accountant).

For some HRG, adjustments to costs have been made following NICE guidance. We have retrieved the related NICE guidance documents:

Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction http://www.nice.org.uk/pdf/TA073guidance.pdf

Full guidance on the use of coronary artery stents http://www.nice.org.uk/pdf/TA71_coronaryarterystents_fullguidance.pdf

USA

Centers for Medicare & Medicaid Services (CMS) http://www.cms.hhs.gov/

Formerly Health Care Financing Administration. Federal agency within the U.S. Department of Health and Human Services. At the origin of Prospective Payment System. Mail exchanges with Stuart Guterman, Director, Office of Research, Development, and Information Services

Medicare Payment Advisory Commission. http://www.medpac.gov/

An independent federal body to advise the U.S. Congress on issues affecting the Medicare program. Mail exchanges with former director Murray Ross

Agency for Health Care Research and Quality

The lead Federal agency charged with supporting and conducting health services research. Mail exchanges with: Joanna E. Siegel, Sc.D. Director, Research Initiative in Clinical Economics (RICE) ; Mary P. Nix Center for Outcomes and Evidence

Contacts (unanswered) with various researchers whose adress found on the website. Herbert Wong HWong@ahrq.gov Irene Fraser IFraser@ahrq.gov Carolyn Clancy CClancy@ahrq.gov

Rand Corporation – Health and health care area.

Various researchers whose e-mail addresses were found on the web were contacted. http://www.rand.org/research_areas/health/ Mail exchange with James Kahan, senior research leader, Senior Research Leader, RAND Europe.

Kaiser Permanente

Large Health Maintenance Organisation – Known for its focus on quality of care. Apart from the HMO itself, it has several satellite organisation for instance. We searched

Center for Health research http://www.kpchr.org/public/default.asp
Center for Care management http://www.kpcmi.org/
Institute for Health Policy

Mail exchanges with Murray Ross, director, Health Policy Analysis and Research, Kaiser Permanente Institute for Health Policy

Mayo Clinic

https://www.mayoclinic.com/ (contacts attempt, unanswered)

Institute of Medicine of the National Academy

http://www.iom.edu/

Washington State Department of Labor and Industries

http://www.lni.wa.gov/

Workers protection and health coverage (interesting site – various guidelines).

Mail exchange with Roy Plaeger-Brockway, Manager for Health Services Analysis

Private insurance/consulting companies

No information retrieved from the following sites /contacts made

- **Logical Medical Review** akrager@logicalmedicalreview.com
- Medical Director Solutions, LLC www.myMedicalDirector.com
- Physicians' Review Network (PRN) www.prniro.com
- Healthcare Management, Inc. www.allmedmd.com Access Health Group, McKesson HBOC www.access-health.com

Information retrieved

- Sonata Group Mail exchange with Richard Minifie, Principal (?), former experience with costing health packages when working with Milliman & Robertson
- Milliman & Robertson, a large, well respected consulting company specialised in health care. In particular, developing and publishing such tools as evidence-based clinical care guidelines and health cost guidelines used by insurers to estimate expected health insurance claim http://www.milliman.com/tools_products/default.aspx?view=health
  Mail exchange and telephone call with John Meerschaert, actuary.

3M

Marc Berlinguet, M.D.International Medical Director, 3M Health Information Systems. Mail exchange, + visit to KCE

Harvard School of Public Health

Dr Hsiao Department of Health Policy and Management (unanswered)

Other interesting contacts made :

Mail exchange with Alain Enthoven, Professor of Public and Private Management, Stanford Graduate School of Business, (special interest in health systems)

FRANCE

Mail exchanges with :

Dr Sun Hae Lee Robin, chef de service evaluation des actes professionnels , ANAES (now HAS-santé)
Philippe Burnel, directeur de l'accréditation, HAS-santé

THE NETHERLANDS

DBC onderhoud http://www.dbconderhoud.nl/

Rianne Welvaarts, Ministry of Health, Welfare and Sports Joost Zuurbier : independent consultant, worked on developing DBC costing methodology Jako Burgers, CBO Sandra Vanderbruggen, in charge of DBC , Maastricht hospital

Brigitte Essers, researcher at Maastricht Hospital, worked on correspondences between DBC/DRGs

SWITZERLAND

Dr *Peter Indra* (through) GIN network (affiliation ?)

Mipp project: http://www.mipp.ch/u_documents/Schlussbericht%20als%20PDF(1).PDF (in German)

Mail exchange with Dr.med. *Peter H. Lessing* Oberarzt der Medizinischen Klinik Projektleiter »mipp. > Kantonsspital Aarau AG . Mail exchanges + phone conversation with Dr med Hans-Peter Muller, former director (now retired); Dr Thomas Holler and Christopher Riimts, physicians in practice, Aarau hospital.

Jean-Claude Rey, executive secretary, APR-DRG Switzerland (mail exchanges+ phone conversation).

SPAIN

Rosa Rico Iturrioz - Basque Office for Health Technology Assessment (through GIN network) mail exchange
Dr Jose-Maria Quintana , Research unit, Gildakao teaching hospital (?) , Basque country mail exchange

ONTARIO

Mail exchange with Christina Hoy, Team Leader, Ontario Case Costing Initiative (OCCI), MoH.(GIN)

AUSTRALIA

Mail exchange with Terry Jackson, Senior Research Fellow , School of Public Health , LaTrobe University Bundoora 3086 AUSTRALIA (through PSCE)

JAPAN

Mail exchange with Kiyohide Fushimi, Associate Professor, Department of Health Care Informatics, Tokyo Medical and Dental University Graduate School ((through PSCE)

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Wettelijk depot : D/2005/10.273/19

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. Validatie van het rapport van de Onderzoekscommissie over de onderfinanciering van de ziekenhuizen. D/2004/10.273/11.
7. Nationale richtlijn prenatale zorg. Een basis voor een klinisch pad voor de opvolging van zwangerschappen. D/2004/10.273/13.
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.

Inlichtingen

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