Videoregistratie van endoscopische chirurgische interventies: rapid assessment

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Federaal Kenniscentrum voor de Gezondheidszorg
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VOORWOORD

Chirurgen voeren reeds verschillende decennia endoscopieën uit voor diagnostische en therapeutische doeleinden.

Het beeldmateriaal dat tijdens die interventies wordt geproduceerd is nuttig op het moment zelf om de handelingen van de chirurg te sturen. Deze beelden kunnen evenwel ook opgenomen worden en later gebruikt worden voor verschillende doeleinden. Er zijn beroepsbeoefenaars die hierin een gelegenheid zien om de kwaliteit van de interventies te verbeteren, om een bijkomende ondersteuning te geven bij opleiding van artsen of nog, een manier om zich te wapenen tegen juridische vervolgingen of om zich te verdedigen in rechtzaken.

De vraag is of men deze gelegenheid moet benutten en of men nu systematisch beelden die genomen zijn tijdens endoscopische interventies moet registreren. Het KCE werd gevraagd om hierop een licht te werpen.

Het onderwerp is zeker interessant maar ook vrij complex omdat het zowel medische, als technologische, juridische en economische vragen opwerpt. In het kader van een multidisciplinaire aanpak, heeft het KCE ervoor gekozen al deze aspecten te onderzoeken en heeft hiervoor samengewerkt met het consultancybureau HICT, vooral voor wat betreft de meer technologische aspecten.

We hopen met deze studie een denkkader te kunnen bieden en een antwoord te geven op de vragen die chirurgen die endoscopie uitvoeren, het ziekenhuismanagement en de overheden verantwoordelijk voor het gezondheidszorgbeleid zich stellen met betrekking tot de ontwikkeling van het registreren van beelden, van de kost en van het gebruik ervan.

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Samenvatting

INLEIDING

Momenteel is het mogelijk om videobeelden van chirurgische interventies te bekijken en op te nemen. Deze technologische evolutie werpt verschillende vragen op betreffende het gebruik ervan, vooral inzake een potentiële verbetering van de kwaliteit van zorg, voor (voortgezette) opleiding van chirurgen maar ook voor een potentieel gebruik van de videobeelden inzake medische aansprakelijkheid.

Deze studie spitst zich omwille van verschillende redenen toe op chirurgische interventies via endoscopie. Ten eerste maakt men bij deze interventies vaak gebruik van beeldvorming. Bovendien zijn er een aantal Belgische chirurgen die reeds ervaring hebben met videoregistratie in dit specifieke domein. Ten slotte stelt deze discipline talrijke aspecten met betrekking tot de kwaliteit van zorg in vraag zoals bekwaamheid, het naleven van regels betreffende hygiëne, kwaliteit van beeldmateriaal en de opname, de kwaliteit van de interventie op zich en de verwachte resultaten.

DOELSTELLINGEN

De voornaamste doelstelling van deze studie is een aantal punten onder de aandacht te brengen die in beschouwing dienen te worden genomen door de beleidsmakers indien zij zouden beslissen om een systeem van videoregistratie van endoscopische chirurgische interventies te implementeren.

Dit rapport formuleert een antwoord op de volgende vragen:

- Is videoregistratie efficiënt en effectief voor het kwaliteitsbeleid van endoscopische chirurgische interventies ?
- Is videoregistratie een nuttig instrument inzake opleiding ?
- Is videoregistratie nuttig voor wat betreft een gerechtelijk-geneeskundige verdediging?

Om hierop een antwoord te formuleren hebben we de technische context bekeken tot begin 2008, de Belgische juridische context, de juridische context van een aantal andere landen en de aspecten kwaliteit en wenselijkheid van het implementeren van deze technologie bij abdominale chirurgen en bij gynaecologen, die de grootste groep uitmaken. De mogelijke kost van deze technologie is geschat voor verschillende implementatiemogelijkheden op basis van vier vooraf gedefinieerde scenario's.

OVERZICHT VAN DE TECHNOLOGIE BETREFFENDE VIDEOREGISTRATIE

De publicaties en websites van de drie belangrijkste organisaties zijnde IHE (Integrating the Healthcare Enterprise), HL7 (Health Level 7) en DICOM (Digital Imaging and Communication in Medicine) werden bestudeerd.

Een niet exhaustieve lijst van producenten werd opgesteld aan de hand van de bezochte websites en hun gepubliceerde documentatie werd bekeken. Ten slotte zijn twee vooraanstaande wetenschappelijke experten uit het domein geconsulteerd om de mogelijke toekomstige ontwikkelingen en technologische toepassingen toe te lichten.

Uit de studie kan worden afgeleid dat de technologie die nodig is voor de videoregistratie van chirurgische endoscopische interventies moet beantwoorden aan functionele vereisten die toelaten om de beelden opnieuw te bekijken, te analyseren, te stockeren, te verspreiden naar verschillende plaatsen en te certifiëren en beveiligen. Bovendien dient het registratiesysteem te worden geïntegreerd in de infrastructuur van het ziekenhuis hetgeen reeds is mogelijk gemaakt door de standaarden IHE, HL7 en DICOM.

Er werden momenteel geen producten gevonden op de markt die tegemoet komen aan het geheel van de technische vereisten. De automatische beeldanalyse bestaat nog niet.

DE BIJDRAGE VAN VIDEOREGISTRATIE AAN KWALITEITSCONTROLE

Teneinde videoregistratie in een bredere context van het beleid en de kwaliteitsverbetering in het operatiekwartier te plaatsen, is de medische wetenschappelijke literatuur gepubliceerd tussen januari 2003 en januari 2008 in de bibliografische databases Medline en Embase doorzocht. Deze zoektocht is aangevuld met informatie van websites van officiële nationale verenigingen betreffende endoscopie.

Uit de literatuur is gebleken dat er weinig publicaties en evidence beschikbaar zijn en dit terwijl endoscopie één van de domeinen is waar videoregistratie het meest wordt gebruikt.

Videoregistratie biedt aldus geen specifieke meerwaarde aan de kwaliteitsverbetering, hoewel het instrument nuttig is voor de beoordeling van de competenties en de bekwaamheid van de arts. De belangrijkste elementen voor de zorgkwaliteit blijven de procedures voor de opname van de patiënt, de controle van de infrastructuur zoals de operatiezaal, de kwaliteitscontrole van de procedures en het bestaan van een kwalitatief hoogstaande basisopleiding. Met het oog op kwaliteitsverbetering van de endoscopie van chirurgische ingrepen, hebben wetenschappelijke organisaties handboeken met klinische praktijkrichtlijnen gepubliceerd.

Het gebruik van videoregistratie voor opleidingsdoeleinden is vermeld in de literatuur maar de impact ervan in termen van vorming is slechts beperkt gedocumenteerd.

JURIDISCHE CONTEXT

DE BELGISCHE CONTEXT

Ten eerste werd de juridische literatuur en de rechtspraak betreffende de patiëntenrechten, de bescherming van de privacy van de patiënt en/of de arts, het medisch beroepsgeheim en de reglementering betreffende de ziekenhuizen en de zorg opgezocht in de databank Jura. Bijkomende relevante artikels en boeken werden eveneens in overweging genomen.

Aangezien er geen specifieke wetgeving bestaat betreffende de videoregistratie van endoscopische chirurgische interventies, werd het zoekproces opgevolgd door een groep van externe juridische experten.

Het juridische kader betreffende videoregistratie bestrijkt hoofdzakelijk drie domeinen: de wetgeving betreffende de bescherming van de persoonlijke levenssfeer ten opzichte van de verwerking van de persoonsgegevens (Wet van 8 december 1992 die een implementatie is van de Europese Richtlijn 95/46/EG en het uitvoeringbesluit van 13 december 2001 bij deze wet) van de patiënt maar ook van de gezondheidszorgbeoefenaar, het beroepsgeheim betreffende de medische gegevens (art. 458 Strafwetboek) en de patiëntenrechten.

Afhankelijk van het doel waarvoor de endoscopische beelden worden geregistreerd, dienen verschillende voorwaarden te worden vervuld die hun grondslag vinden in voornoemde wetgeving. De voornaamste worden hieronder weergegeven.

Rechten van de betrokken persoon

Niet enkel de patiënt maar ook de beroepsbeoefenaar kunnen worden beschouwd als betrokken persoon aangezien het beeldmateriaal aan hun persoon kan worden verbonden.

A. Recht of geïnformeerde toestemming

- De patiënt

Vooraleer endoscopische procedures worden opgenomen is de toestemming van de patiënt vereist en dient er te worden geïnformeerd waarvoor de geregistreerde beelden zullen worden gebruikt.

Indien de beelden in eerste instantie rechtmatig werden opgenomen in het kader van de therapeutische relatie, voor kwaliteitsmanagement of voor opleidingsdoeleinden is voor het eventuele latere gebruik voor de rechtbank geen bijkomende toestemming van de patiënt of van de chirurg nodig.

- De beroepsbeoefenaar

Indien het ziekenhuismanagement beslist de beelden systematisch te registeren, dient de beroepsbeoefenaar hierin toe te stemmen en zou dit in het algemene reglement, die de juridische relatie tussen het ziekenhuis en de arts regelt, moeten beschreven zijn.

Indien evenwel de systematische videoregistratie wettelijk is opgelegd, is de toestemming van de beroepsbeoefenaar niet vereist.

B. Recht op informatie

De betrokken persoon heeft het recht op informatie betreffende de naam en het adres van de persoon of de entiteit die het doel en de middelen van de verwerking van de persoonsgegevens bepaalt (verantwoordelijke voor de verwerking), zijnde de directie van het ziekenhuis, de chirurgen of de overheid, afhankelijk van het doel. De betrokken persoon heeft ook recht op informatie over de doelstellingen van de verwerking, van de wettelijke rechtvaardiging voor de verwerking van het beeldmateriaal en van de bestemmeling die de beelden zal krijgen.

C. Rechten m.b.t. het medisch dossier

De patiënt heeft recht op toegang tot het medisch dossier en op een kopie ervan. Hij heeft bovendien het recht om de gegevens in het dossier te corrigeren

Plichten van de verantwoordelijke voor de verwerking

De verantwoordelijke voor de verwerking van de gegevens dient de categorieën van personen die toegang hebben tot het beeldmateriaal en hun hoedanigheid ten opzichte van de verwerking mee te delen. Desgevallend moet hij een lijst van deze personen ter beschikking houden van de Commissie voor de Bescherming van de Persoonlijke levenssfeer. Hij moet ook melding maken van de wettelijke basis die de verwerking van het beeldmateriaal rechtvaardigt. Hij dient er ten slotte voor te zorgen dat zijn personeel het vertrouwelijke karakter van de gegevens in acht nemen. .

Verwerking van de gegevens onder de verantwoordelijkheid van een gezondheidszorgbeoefenaar

De endoscopische beelden kunnen in principe enkel worden verwerkt onder de verantwoordelijkheid van een gezondheidszorgbeoefenaar. Hierop zijn een aantal uitzonderingen waaronder de belangrijkste in casu: de schriftelijke toestemming van de betrokkene.

Gebruik van gecodeerde gegevens

Voor het verdere gebruik van het beeldmateriaal voor wetenschappelijk onderzoek in het kader van kwaliteitsverbetering dienen de gegevens te worden gecodeerd voordat ze ter beschikking worden gesteld voor onderzoek.

In het geval verscheidene ziekenhuizen het beeldmateriaal meedelen aan dezelfde derde met het oog op latere verwerking ervan voor wetenschappelijk onderzoek (bijvoorbeeld aan de overheid) dienen de geregistreerde gegevens te worden gecodeerd door een intermediaire trusted third party en dit voor de overdracht van de ziekenhuisgegevens.

Betreffende het gebruik van gecodeerde beelden, zijn er tevens bijkomende verplichtingen geformuleerd voor de verantwoordelijke voor de verwerking en de coderende instantie in het Koninklijk besluit ter uitvoering van de wet tot bescherming van de persoonlijke levensfeer ten opzichte van de verwerking van persoonsgegevens.

Aangifte aan de Commissie voor de bescherming van de persoonlijke levenssfeer

Videoregistratie van endoscopische interventies vereist een voorafgaandelijke aangifte door de verantwoordelijke voor de verwerking of zijn vertegenwoordiger aan de Commissie voor de bescherming van de persoonlijke levenssfeer per geheel van verwerkingen. In het geval van verwerking van gecodeerde beelden dient de verantwoordelijke voor de verwerking en/of de coderende instantie bijkomende informatie aan te geven en kan de Commissie binnen bepaalde termijnen aanbevelingen formuleren.

DE INTERNATIONALE CONTEXT

We hebben bestudeerd op welke manier aspecten betreffende kwaliteitsverbetering in de klinische zin en de implementatie van de bescherming van persoonsgegevens wordt geregeld in vier Europese landen: Duitsland, Nederland, Frankrijk en het Verenigd Koninkrijk.

Kwaliteitsverbetering en endoscopie

De verschillende Europese landen hebben, elk op hun manier, een algemene, collectieve strategie betreffende kwaliteitsverbetering, die betrekking heeft op verscheidene onderwerpen, waaronder ook endoscopie (dit kan worden verklaard door het technisch karakter en het risico verbonden aan deze techniek).

Bescherming van persoonsgegevens

Wat ook de beoogde doelstelling is, de bescherming van persoonsgegevens beantwoordt in heel de EU aan gemeenschappelijke principes, gedefinieerd door de Europese Richtlijn 95/46/EG (zelfs als de praktische uitwerking tot de bevoegdheid van het nationale niveau behoort).

Het gebruik van gegevens voor onderzoeksdoeleinden beantwoordt aan striktere regels dan deze geformuleerd in de Richtlijn (specifiek autorisatiemechanisme) en is het onderwerp van specifieke methodologieën in verschillende landen, opdat een hoog niveau van veiligheid kan worden gegarandeerd voor het geheel van betrokkenen (bv. UK).

ALGEMENE KOSTENRAMING

Op basis van vier hypothetische scenario's van verschillende intensiteit en gradaties van implementatie van videoregistratie van endoscopische chirurgische ingrepen, en op basis van de beschikbare prijzen, is een raming gemaakt van de kosten verbonden aan het gebruik van deze technologie. .Momenteel bestaat er geen kant en klare oplossing op de markt en zijn de prijzen van de verschillende componenten niet toegankelijk.

Een ad hoc registratie (op initiatief van de arts of van de patiënt) (scenario 1) zou tussen € 150 et € 350 kosten voor de aankoop van het registratiemateriaal (DVD of Blu-ray) waarbij men dan nog de kost voor de disks moet rekenen.

Voor een ad hoc registratie voor opleidingsdoeleinden (scenario 2), moeten de kosten voor de aankoop van indexatie- en encrypteringsoftware en de kosten verbonden aan de analyse door een expert worden toegevoegd.

In het kader van beperkte prospectieve registratie, zoals bijvoorbeeld voor onderzoeksdoeleinden in een beperkt aantal ziekenhuizen (scenario 3), stijgen de kosten significant. De investering verbonden aan het systeem dat de integratie in de zorginfrastructuur mogelijk maakt moet in rekening worden gebracht, maar hangt af van het bestaande systeem in het ziekenhuis. De kosten voor het opslaan van de gegevens zijn ongeveer € 4 per video. Hierbij moeten nog de kosten voor het herbekijken en de analyse door een expert worden toegevoegd ten belope van € 83 à € 104.

Ten slotte, in het geval van een systematische registratie op nationaal niveau (scenario 4), bestaan de bijkomende kosten ten opzichte van een beperkte registratie uit de kosten van integratie, de kosten van een communicatieplatform, ongeveer € 500 000 (per jaar) voor het opslaan en ongeveer € 12 800 000 voor het herbekijken en de analyse door een expert. Deze kosten zijn gebaseerd op het aantal interventies uitgevoerd in 2006 (RIZIV). Kosten voor een intermediaire trusted third party (TTP) moeten desgevallend ook in rekening worden gebracht.

VERKENNEND KWALITATIEF ONDERZOEK

Een verkennend kwalitatief onderzoek via semi-gestructureerde individuele interviews werd uitgevoerd om de mening betreffende de aanvaardbaarheid van een institutioneel besliste implementatie, de mogelijke bezwaren en hefbomen van een dergelijke technologie in het operatiekwartier te kennen van de chirurgen die endoscopieën uitvoeren.

Een groep van 11 Nederlandstalige en Franstalige abdominale chirurgen en gynaecologen werd samengesteld en liet toe om saturatie van de resultaten te bereiken (dit betekent dat geen nieuwe informatie werd bijgebracht door een bijkomend interview). Hun antwoorden werden geanalyseerd op een beschrijvende manier.

De resultaten tonen aan dat videoregistratie nuttig wordt geacht zowel voor opleiding als voor de kwaliteit in de therapeutische relatie met de patiënt en als bewijsmiddel voor de rechtbank. In de twee laatste gevallen, kan er zich een averechts effect voordoen. Nadelen zoals de tijd besteed aan de inwerkingstelling en de analyse van de beelden, het risico op technische problemen en de kosten die daardoor worden veroorzaakt maar ook het risico op inbreuken op de therapeutische vrijheid van de arts. Volgens de ondervraagde artsen, behoort het beheer van de kwaliteit van de praktijkinterventies voornamelijk toe aan de verantwoordelijkheid van de beroepsorganisaties.

Ten slotte kan worden gesteld dat de juridische implicaties van videoregistratie niet gekend blijken.

BEPERKINGEN VAN DE STUDIE

De resultaten van deze studie moeten met enige voorzichtigheid worden bekeken. Het gaat immers om een verkenning relatief vroeg in de ontwikkeling van de technologie. Hoewel technologische oplossingen beschikbaar zijn, zijn ze nog niet op een operationele manier geïntegreerd en zijn ze momenteel nog nergens in gebruik. We hebben ons enkel op fragmentarische informatie en hypotheses kunnen baseren. Bovendien verliep het verkrijgen van informatie van de industrie niet bijzonder vlot. Ten slotte zijn de resultaten van het kwalitatieve gedeelte gebaseerd op de opinies van enkele beroepsbeoefenaren uit twee specialiteiten en in geen geval van het geheel van beroepsbeoefenaars die endoscopische interventies uitvoeren en registreren. Deze opinies zijn dus louter indicatief.

CONCLUSIES

Videoregistratie biedt geen duidelijke meerwaarde voor de opvolging en de kwaliteitsverbetering van chirurgische interventies via endoscopie. Bovendien is de technologie nog niet voldoende rijp voor een collectief gebruik van beeldmateriaal.

Te meer de technologie wordt overwogen op grote schaal, des te groter zijn de technologische en juridische beperkingen en de implementatiekosten.

Het is gebleken dat dit instrument nuttig kan zijn bij het doceren maar deze vaststelling is niet gesteund op wetenschappelijke evidence. Het blijkt bovendien dat het bestaande aanbod van registraties voor opleidingsdoeleinden reeds volstaat. De meerwaarde voor (voortgezette) opleiding van artsen is niet aangetoond.

Het gebruik van dit materiaal voor de gerechtelijk-geneeskundige verdediging is mogelijk onder bepaalde voorwaarden.

In elk geval leidt het idee aan een systematische en verplichte videoregistratie nu al bij sommige beroepsbeoefenaars tot enige reserve.

Men kan concluderen, wat betreft de drie potentiële aanwendingen van videoregistratie zoals bestudeerd in de context van chirurgische endoscopische interventies, dat het instrument een bescheiden toepassing kent .

AANBEVELINGEN

In de huidige stand van de technologie en de actuele kennis, beveelt het KCE het systematisch gebruik van videoregistratie van chirurgische endoscopische interventies niet aan.

Desalniettemin wenst het KCE toch de volgende aanbevelingen te formuleren, aangezien de technologie reeds door sommigen wordt gebruikt :

- Wanneer videoregistratie wordt gebruikt op individueel niveau door een chirurg, moet deze zich bewust zijn van de juridische implicaties van het registreren van dergelijke beelden. Volgende aspecten moeten systematisch worden onderzocht:
    - De patiëntenrechten, in het bijzonder de toestemming van de patiënt en het recht op toegang tot het medisch dossier;
    - De bescherming van de persoonlijke levenssfeer ten opzichte van de verwerking van persoonsgegevens van de patiënt
- Indien een systematische videoregistratie van interventies wordt ingevoerd door een verzorgingsinstelling, dienen niet enkel voorgaande punten te worden gerespecteerd maar dienen ook de volgende elementen in beschouwing te worden genomen:
    - De bescherming van de persoonlijke levenssfeer ten opzichte van de verwerking van persoonsgegevens van de patiënt, maar ook van andere betrokken personen (artsen, verpleegkundigen, enz.);
    - Er dient te worden gezorgd dat de artsen betrokken worden bij het proces. De nodige vermeldingen dienen te worden opgenomen in de algemene reglementering, die de juridische relatie tussen het ziekenhuisbeheer en de arts regelt;
    - Er dient een algemeen toepassingskader te worden gedefinieerd betreffende de registratie van de gegevens en het gebruik ervan:
        - De doelstelling(en) van de verwerking van de gegevens;
        - De procedures die de bevoegdheden bepalen;
        - Het proces van de verwerking.
    - Men dient erop toe te zien dat het registratiesysteem goed wordt geïntegreerd in de informaticainfrastructuur van het ziekenhuis.

Scientific summary

Table of contents

LIST OF ABBREVIATIONS

ACG	American college of Gastroenterology
AUGIS	Association of Upper Gastrointestinal Surgeons
AVI	Audio Video Interleave
BFDI	Bundesbeauftragte für des Datenschutz und die informationsfreiheit
BIG	Wet op beroepen in de individuele gezondheidszorg (Netherlands)
CBP	College for protection of personal data (Belgium)
CEMR	Computerized endoscopic medical record
CMS	Centres for medicare and medicaid services
CNIL	Commission nationale de l'informatique et des libertés (France)
COTS	Commercial of the shelf
DECT	Digital Enhanced Cordless Telecommunications
DICOM	Digital imaging and communication in medicine
DV	Digital video
EHR	Electronic health record
EMIS	Endoscopic multimedia information systems
ESGE	European society of gastrointestinal endoscopy
EUS	Endoscopic ultrasonography
GOALS	Global Operative Assessment of Laparascopic skills
GRS	Global Rating Scale
HAS	National authority for health (France)
HIS	Hospital Information System
HKZ	Foundation for harmonization of quality policy in the care sector
HL7	Health Level 7
HTA	Health Technology Assessment
ICO	Information commissioner office
ICSAD	Imperial college surgical assessment device
IDE	Integrated Development Environment
IHE	Integrating the healthcare enterprise
IQWIG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
JAG	Joint Advisory Group
LPPD	Law on the protection of privacy concerning the processing of personal data (Belgium)
LPR	Law on patient's rights (Belgium)
MPEG	Moving Picture Experts Group
MST	Minimal standard technology
NAS	Network attached storage
NEED	Networked European Endoscopy database
NHS	National Health Service (UK)
NIAZ	National institute for accreditation of hospitals (Netherlands)

NICTIZ	National ict institution for the care (Netherlands)
NIHDI	The National Institute for Health and Disability Insurance /Rijkinstituut voor ziekte- en invaliditeitsverzekering/ institut National Assurance maladie & invalidité (Belgium)
NVEC	Dutch association of obstetrics and gynaecology
NVVH	Dutch surgery association
OMED	World organization of digestive endoscopy
OSATS	Objective structured assessment of technical skills
OT	Operation theatre
PACS	Picture Archiving and Communication Systems
RAID	Redundant Array of Independent Disks
RATE	Remote analysis of team environments
RD	Royal Decree (Belgium)
REC	Research ethics committee
ROVIMAS	Robotic video and motion analysis software
SAN	Storage area network
SCSI	Small Computer System Interface
SCT	Script concordance test
TTP	Third trusted party
WBP	Wet bescherming persoonsgegevens (Netherlands)
WGBO	Wet op de Geneeskundige Behandelingsovereenkomst (Netherlands)
WMO	Wet maatschappelijke ondersteuning (Netherlands)

1 INTRODUCTION

In the context of increasing use of innovative technologies, the question of accuracy of these techniques has become more and more crucial. In order to address this issue, an accurate assessment of these techniques has become essential for all stakeholders.

Quality improvement of health care has also become a key subject in the political debate, both for health care providers and public decision-makers. However, quality improvement is an objective that can be reached thanks to a wide range of techniques or practices: innovative technologies, but also exchange of best clinical practices, updating of academic and/or continuous training, improvement of teamwork and optimized workflows, better coordination between health care stakeholders and institutions etc.

In the same time, more and more patients have taken legal actions against health care providers, and we have to assume that this is a major trend in Belgium as in in all western countries.

The use of such innovative techniques as video registration has been identified by many stakeholders as a powerful lever to improve quality of care, quality of training, but also to help health care providers cope with medical liability issues.

Given this context, the main goal of this report is to perform a quick assessment, with a view to analysing the accuracy of video registration against specific objectives, and to producing recommendations accordingly. As explained further in this report, we focused on endoscopic techniques. Our pragmatic approach is based on real word practices and also resorts to qualitative analysis on specific points.

Recent technology makes the recording of optical images easier: small digital camera's and DVD technology are now wide-spread and affordable. Surgical intervention using endoscopy (eg. Laparoscopy) is now also affordable and widespread. Using a digital camera to view the surgery automatically makes it possible to record these images, either moving or still pictures. There have been attempts and trials using analogue and digital video recording in operating theatres.

1.1 SCOPE

1.1.1 Original scope of the research

The original scope of this research originally entailed the whole field of surgery ie:

- In the field of medical specialities: virtually all surgical specialities (cardiac surgery, gastroenterology, gynaecological surgery, neurological surgery, ENT surgery, etc..).
- In terms of patient pathways: screening exams and procedures, diagnostic exams and procedures, and surgical interventions.
- In terms of space field: surgical intervention as such, limited to the optical viewing instruments or including open view recording, but also recording the actions in the operating theatre in order to analyze the quality of teamwork (communication between the members of the team, coordination, leadership skills etc…).

Apart from workload and time constraints for the research team, this option would not have been relevant, as not all surgeons are in a position to use video registration with the same frequency, at least in today's practice. Moreover, the objective of our study is to issue pragmatic recommendations on implementation of such video registration devices in today's hospitals considering today's actual practice, acceptability issues, and contribution to quality improvement policy (if any). We also need to address barriers and limitations existing within work habits and professional culture of surgeons.

Hence, it is of paramount importance to give the priority to the most relevant issues and not to address too many subjects at once, especially when video registration is not routinely practiced.

Therefore, we agreed empiric criteria in order to identify relevant and applicable topics to focus on, considering today's healthcare suppliers' practice in Belgium:

- Routine (or at least frequent), or low entry barrier to use of video recording;
- Existing experience of video registration among Belgian specialist surgeons;
- Possible impact in terms of liability issues;
- Importance of video recording in quality management and quality improvement.

1.1.2 Selection of one specific subject: endoscopic surgery

In the light of these criteria, we eventually selected the subject of endoscopic surgery, for the following reasons:

- Endoscopy is a field in which capture of video pictures has already been experimented in many Belgian hospitals. Moreover, the presence of an optical viewing system makes recording very easy.
- Surgery is a field in which liability issues are frequently identified and reported. Such problems also exist for screening or diagnosis, but are occurring less frequently, and more difficult to study as the status of the patient at the time of screening / diagnosis may be evolving.
- Endoscopic surgery presents unique quality management topics: technical skills in using the endoscopic tools, hygiene standards, quality of pictures and viewing, quality of intervention, outcome of procedure etc.

As explained further in this report, the number of endoscopies performed in Belgium is quite important: in 2006, as almost 127 770 endoscopic procedures were billed to the INAMI/RIZIV, 43% of them being related to abdominal surgery. 20% to orthopaedic techniques. Endoscopic techniques are also mentioned in the field of Gynaecolgy, Gastro-enterology, and Urology.

Regarding the feasibility we explored the following subjects:

- Technical context as of early 2008;
- Legal context as of June 2008 in Belgium;
- The possible relationship to quality management in endoscopic surgery;
- An explorative interviewing of surgeons and gynaecologists, in order to sound for potential barriers for a video registration set-up.

We defined the limits as follows:

- Country of study: Belgium;
- Medical area: use of endoscopy for surgical intervention (as opposed to diagnostic endoscopy);
- Recording by video technology of the endoscopic image, probably digital recording on DVD or CDROM media or server;
- A record would entail the whole or part of the intervention;
- Moving pictures as opposed to still images (photographs).

1.2 OBJECTIVES

1.2.1 Exploratory dimension of the research

The objective of our survey is to bring a contribution to the decision-making process of public stakeholders and health-care managers, in the field of health technology. Hence, the key issue for us is not to perform an in-depth analysis of all video registration techniques as such, but to put this technical subject into the wider context of the organization of healthcare, and to analyze the possible contribution of this technique to quality improvement, training, etc…

Technical aspects of video registration will be analyzed, but with a view to providing decision-making tools, and helpful points of reference to the stakeholders.

1.2.2 Research questions

The main goal of this research is to identify all the problems and issues that must be identified and addressed by decision-makers, when considering the implementation of a video registration system.

This KCE project is an exploratory Health Technology Assessment (HTA) of endoscopic video registration of surgical interventions. An assessment is made of the feasibility and usefulness of endoscopic video registration.

The research question is: "Can video registration (recording) of endoscopic surgery contribute to quality management of endoscopic surgical procedures?"

We have defined sub-questions:

- Is using video registration effective and efficient to monitor the quality of the procedure performed?
- Is video registration useful for training purposes?
- Is video registration useful regarding medico-legal issues?

1.3 KEY SUBJECTS ADDRESSED BY THE REPORT

Recent technology makes the recording of optical images easier: small digital camera's and DVD technology are now wide-spread and affordable.

Surgical intervention using endoscopy (e.g. laparoscopy) is now also affordable and widespread. Using a digital camera to view the surgery automatically makes it possible to record these images, either moving or still pictures.

There have been attempts and trials using analogue and digital video recording in operating theatres.

In this exploratory study we want to find out whether video recording of endoscopic surgery is feasible, affordable and whether it could help in managing the quality of surgery by endoscopy.

Regarding the feasibility we explored the following subjects:

- Technical context as of early 2008
- Legal context as of June 2008 in Belgium
- The possible relationship to quality management in endoscopic surgery;
- An explorative interviewing of surgeons and gynaecologists in order to sound for potential barriers for such a technological set-up.

Following chapter 1 (introduction) and chapter 2 (methodology) we will review the existing technical means of recording moving digital recorded and stored video images in chapter 3 ; however we will also associate that with the purpose of quality assurance, in which the legal and procedural requirements (e.g. analysis of the images) are opposed to the technical means existing today. We only looked at technology available to be put in to production today as opposed to research programs.

In chapter 4 we present a literature study of Quality management systems as they exist today in operating theatres. The conclusions of this chapter have to assess the chapter on technology towards our initial research question on feasibility in training and quality improvement to nowadays practices.

In chapter 5 we inventory and review the European standards on privacy protection and the Belgian legal context for registering video recordings of endoscopic surgery. This chapter is closed by an exploration in a limited number of countries where we expected some of such legislations to be available. As explained further, these countries have been selected on pragmatic and agreed criteria, in such a way that it could bring an interesting contribution to Belgium. However we found no country with specific legal context for recording of video film of surgical endoscopy, as such.

We tried to look at the general legal context in these countries, to identify which rules were applicable to our subject.

In chapter 6 we did a first consolidation of the findings, resulting in four possible scenarios, each of them being a combination of usefulness, legal and technical constraints.

Chapter 7 is a limited exercise in estimation of costs of the different scenarios, in order to be able to put potential benefits in perspective of costs.

Chapter 8 is a qualitative study on video registration amongst Belgian surgeons to assess their opinion on the subject.

In Chapter 9 discuss the different findings, scenario's and cost benefit equations of potential setups of using video recording in endoscopic surgery.

In Chapter 10 we present our conclusions.

2 METHODOLOGY

We will present her the different methodologies used for each part of the present study.

2.1 TECHNOLOGY

First, we looked at commonly accepted standards: IHE (Integrating the Healthcare Enterprise), HL7 (Health Level 7) and DICOM (Digital Imaging and Communication in Medicine). The publications of the maintenance organizations are the key drivers for manufacturers of medical equipment including hardware and software. A search was performed on the publications of these organizations with keywords movie, film and video.

Then we looked at the technology required at the hospital, versus the centralised systems and feeding networks.

Therefore, a shortlist of manufacturers (see appendix to Methodology) was drawn up by combining the manufacturers published on the websites of the international standardization organizations as being the manufacturers that take part in drawing up the standards and the results of a query on the Google search engine with combinations of the keywords medical, video, image, DICOM, IHE, endoscope and camera.

Based on published product sheets of manufacturers a list of possible uses of video registration will be consolidated.

All useful scientific publications found until February 2008 have been involved. For current information and future expectations, an interview at TU Delft with Prof J Dankelman and an interview at Noldus with Ir W.J. ten Hove had taken place. This last information is not evidence based, but gives some clues to present actions and plans in the near future.

2.2 LEGAL CONTEXT OF VIDEO REGISTRATION

2.2.1 Literature

The legal part of the study deals with the question whether and how the above mentioned purposes of endoscopic video registration can be fitted in into the Belgian legal context. Legal issues such as patient's rights, privacy protection of the physician and/or the patient, professional secrecy, hospital and care institution regulations were studied.

The available literature and jurisprudence on these items was scanned in the database Jura. Complementary articles and books were taken into account when relevant for the study.

For the international context of video registration - i.e. Germany, the Netherlands, France and the United Kingdom - relevant websites, literature and portals were searched to address the topics on quality, education and liability for each specific country.

2.2.2 External expertise

Since it appeared (throughout the research) that relevant and specific legislation is not directly related to the video registration topic, an external expert panel was assigned to assist the research team in completing the juridical chapter.

Legal experts were asked to give their opinion on the legal framework in a first phase. Their suggestions to be more precise and complete were integrated into the report.

A second panel session was called to critically review the pre-final report where the implications of legal matters on technology and practical processes were studied and discussed.

Description of certain part of legal aspects of certain foreign countries[a] was submitted to local experts for checking and validation.

2.3 VIDEO REGISTRATION AND QUALITY CONTROL: WHICH CONTRIBUTION?

Given the objectives of the report mentioned above, one specific research question has been identified:
"Is using video registration effective and efficient to monitor the quality of the procedure performed? "

Therefore, the prerequisite is to know whether such quality improvement systems do exist, and then whether video registration is already in use in this context. For all the reasons explained above, we finally will focus on endoscopic interventions.

2.3.1 Research questions

The research questions we will try to answer in this section are:

1. Are there currently any quality management systems in operating theatres and more specifically for surgical interventions?
2. Is video recording in the operating theatre currently used for quality control for surgical endoscopic interventions?

2.3.2 Literature review

The literature review complies with the search procedure in use at the Belgium Health Care Knowledge Centre. A consistent search strategy was built up to find answers to both research questions. We performed a literature search in MEDLINE and EMBASE, seeking publications from January 2003 to January 2008. Since technology evolves rapidly, we only included literature of the last 5 years. The search was based on Emtree key words and Mesh terms. More details about those search strategies can be found in appendix to this part. Patent search has not been undertaken.

The following Emtree key words were used, to answer the first research question: 'operating theatre', 'surgical technique', 'surgery', 'quality control', 'practice guidelines', 'peer review', 'hospital information system', 'medical record', 'register', 'medical documentation', *'adverse event* free word*, 'surgical error'.

The following Mesh terms were used, to answer the first research question: 'operating theatres', 'surgery', 'surgical Procedures, operative', video-Assisted surgery', 'quality control', 'peer review', 'peer review, health care', 'practice guideline', 'hospital information systems', 'medical records', 'medical records systems', 'computerized, registries', 'operating theatre information systems', 'medical errors'.

A specific and focused search was performed with regard to the research question:

"Is video registration in the operating theatre currently used for quality control for surgical interventions?"

The following Emtree key words were used: 'endoscopy, surgery' and 'video recording', 'operating theatre', 'surgery' and 'surgery technique'.

The following Mesh terms were used: 'endoscopy', 'capsule endoscopy', 'video recording', 'video-assisted surgery', 'videotape recording' ,'operating theatres', 'surgery', 'surgical procedures, operative', 'video-assisted surgery'.

2.3.3 Selection of the articles

Two researchers independently selected the articles title and the abstract. The search was limited to articles written in English, French or Dutch.

The following selection criteria, based on title and abstract, were used:

[a] France and UK

- Inclusion of articles related to:
  - Control/audit of surgical intervention;
  - Safe patient care practices with focus on the technical quality of surgery;
  - Guidelines; but not related to any pathology;
  - Techniques, such as image control;
  - Reporting adverse event;
  - Hospital Information system;
  - Training programs, but not with the topic of simulation or education.
- Exclusion of articles related to:
  - Teamwork;
  - Control environment;
  - Ergonomics;
  - Medication;
  - Detection wrong patient, RFID;
  - Decision systems;
  - Telemedicine.

2.3.4 Additional search

To obtain a complete overview of quality systems in the operating theatre, as the literature did not provide sufficient specific information on endoscopic surgery, we conducted a search to obtain more information sourcing from the official national organizations for endoscopy.

A matrix with an overview of the type of the articles, the study design, the year of publication, and country of the included articles is included in appendix to the methodology chapter.

2.4 QUALITATIVE EXPLORATIVE ANALYSIS

In order to have a clear view on the opinions of surgeons about video registration of endoscopic interventions, we opted for a qualitative approach with face-to-face interviews with surgeons.

Historically used by social sciences, this scientific method allows to improve our understanding of medicine[1] and to get explorative data of an still unknown subject.

This type of research could help policy makers and planners to get descriptive information and to understand the context in which policies will be implemented[2]

In HTA studies[2], as in larger health care context[3], qualitative research methods are also more and more used to collect, analyse and interpret data that are not easily reduced to numbers.

Compared to quantitative methods, qualitative approach tries to answer questions such as "what is X ?" instead of "how many X are there?"[3]. In addition it studies people in their natural environment rather than in artificial or experimental settings[3].

In that purpose, "qualitative researchers use conversation, in the form of interviews, to collect data about people's views and experiences"[b]. These could be done individually or in focus groups[3].

To answer our question on acceptability, facilitating factors and barriers to implementation of video registration in surgical endoscopy, as well as for practical reasons, we opt for individual face to face interviews.

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b Pope, 2006 p 8[3].

2.4.1 Sample

The purpose of this explorative part of the study was to collect data on opinion of surgeons. This study being the first one ever conducted on the usefulness of video recording of these procedures, it was decided to limit the number of different medical specialties to those performing endoscopic interventions frequently. Based on figures from the Belgian National Institute for Health and Disability Insurance (NIHDI) we concluded that most of the endoscopic procedures or approaches are performed by gynaecologists and abdominal surgeons. Therefore, only these types of surgeons were included in the study.

As usually in qualitative research, the final number of interviews to carry was not determined beforehand. So, in order to have a homogeneous and relevant sample, i.e. that allow us to have a broad overview of the opinion that can exist among the surgeons, whether these opinions are the most representative or not, we based our purposive sample on the following criteria:

- The mother tongue (Dutch and French-speaking surgeons)
- Place of work: in a university or in a general hospital
- The medical specialities (abdominal surgery or gynaecologist)

Interviews were carried out until saturation of the data, i.e. when additional interviews had no substantial added value (new information, new vision).

In a first stage, a selection of 11 surgeons was made, namely 6 gynaecologists and 5 abdominal surgeons according to our criteria. As the saturation level was obtained after those interviews, no additional selection was done.

2.4.2 Interview guideline

A standard semi-structured questionnaire was developed in Dutch and translated into French. This guideline was build with open-ended questions. The list of questions included 5 main parts:

1. An introductory part: questions to have some background information about the surgeon,
2. The current use of video registration during endoscopic interventions,
3. The use of video registration during endoscopic interventions in the future, following 4 scenarios (see appendix),
4. The consequence for patients when using endoscopic interventions,
5. The opinion on the role of the government in imposing and controlling quality in an operating theatre.

The detailed interview guideline is presented in the appendix.

2.4.3 Execution of interviews

A semi-structured face-to-face interview of 1 hour was scheduled. The participating surgeons received a presentation letter beforehand. Before the interview only a small introduction was given. By giving only a little amount of information, it was intended to avoid manipulation of thoughts and opinions of the interviewees.

2.4.4 Interview processing

The interviews were registered and written out. The full text has been sent to the interviewees for validation. Afterwards, each interview was summarized in key points. All remarkable citations of interviewees were also indicated. Finally, an overview of all key points is given per topic.

3 TECHNICAL VIEW OF VIDEO REGISTRATION

As discussed in the introduction we will explore the feasibility of recording the video images (moving pictures) of views available at endoscopy through the endoscope's optical system.

We will not dwell on the feasibility of taking still pictures, as this very often already routine. The images are analogue or digital, and in a default set-up tend not to capture patient identity information. These images are considered as anonymous

3.1 FUNCTIONAL REQUIREMENTS OF ENDOSCOPIC VIDEO REGISTRATION

The possible functional requirements of an endoscopic video registration system are, amongst others:

3.1.1 Replay and analysis

- Allowing the surgeon or another authorized party to review a specific procedure later on. The video record is archived appropriately and should be unambiguously retrievable.
- Allowing the surgeon or another authorized party to extract fragments of video or still images for documentation, expertise reports or any other legitimate use.
- Allow the surgeon or other authorized parties to make notes on the video to underline important facts. (add comments and or metadata (flags)
- Allow the surgeon to integrate other biomedical data like time, vital signs, patient identity and markers[4].

3.1.2 Storage

- The objective consists in storing all video fragments in a relational database to add associated data. This facilitates queries of video by patient, surgeon, time & date, metadata, etc. This also allows to associate data from third party devices in the operating theatre, with the relevant video sequence. including metadata in order to be able perform database queries, data analysis and reporting;
- When metadata is linked to the video stream, the video stream becomes pseudo-anonymous. As a consequence, a link needs to be established from the patient's medical record to the video fragment and its associated data. The link may be physical or logical, but this requirement arises from the fact that non-anonymous data is considered to be an element of the medical record. This in turn means that the information needs to be safely stored for 30 years after the last patient contact[c]. This implies the use of a mechanism to prevent unauthorised access. Using encrypted storage, an algorithm is used to render the data unreadable using a key. Persons who require access to the information in the encrypted file need to provide the key to turn the data into a readable format again. This task should be managed by a so-called Trusted Third Party;
- Provide on-line storage capacity: From any workstation on the network, video fragments can be searched for and replayed. The storage can be located anywhere on the network, providing the added flexibility of using storage technologies eventually already in place (IDE, SCSI, RAID, NAS, SAN, etc.) and to distribute storage throughout the network, maximizing fault tolerance;

c Art. 1 §3 Royal Decree 3 May 1999 concerning the general minimum conditions for the medical file, as referred to in art. 15 of the Hospital Law coordinated on 7 August 1987, Law Gazette 30 July 1999

- Provide media archive storage: For performance and capacity purposes, database maintenance of the on-line storage is required. Using a rule-engine, video fragments are moved from on-line storage to a media archive. Schedules to control when archiving should take place. The rule engine should be flexible, covering all potential scheduling needs. Rules are e.g. characterized by a recurrence pattern (daily, weekly, monthly, yearly or specific dates) or driven by characteristics or flags which can be set on video fragments;
- The solution should ensure continuous service availability with failover mechanisms and protection against accidental data loss. Users can obtain the highest level of archive availability by using a combination of the described technology;
- Video down sampling can be used to decrease the volume of stored video files. The amount of data reduction achieved with this technique will depend on the requirements on the video quality for quality control purposes (see chapter 4).

3.1.3 Routing

A digital video matrix can be used to distribute to video signal in real-time to different devices, e.g. display in the training room next to the operating theatre, display in front of the surgeon, storage, etc. A digital video matrix is a software module which replaces traditional hard wired video switches.

3.1.4 Fingerprinting

In case video fragments are intended to be used for liability or any other legal purposes (see chapter 5), the value of the evidence will largely depend on the authenticity and the maintained validity over time (integrity of the record). For this purpose, "fingerprinting" technology needs to protect the integrity of stored video. Each video file stored on the server is fingerprinted electronically. In essence, this technology analyzes and uniquely identifies each video frame while also linking each frame to the previous one through a complex algorithm. This prevents malicious persons from deleting, modifying or adding a video frame to an archived video. For instance, if a single pixel is changed, the fingerprint will no longer match, and the system will notify the user that the video has been tampered with.

3.1.5 Data & information security

- Unauthorised access to patient data and video files is an important security threat. A powerful identity and access management utility needs to restrict access to the system resources by means of segmenting the data and assigning roles and responsibilities to the users of the system.
- The audit trail stores all actions on each record in the database. The identity of any user who opens a record, reads or modifies data in the record will be stored in the audit trail of the corresponding record.
- In order to prevent data of being intercepted, all communication over the data network (LAN and/or WAN) needs to be encrypted.

3.2 THE INTEGRATION OF VIDEO IN THE HOSPITAL INFRASTRUCTURE

The technical integration of video data in hospitals systems is comparable with image data integration. One needs to acquire a system, implement it and integrate it into the hospital technical architecture.

Standards exist to support integration of information in and between hospitals. Standards which are internationally used in hospitals are Health Level 7 (HL7), Digital Imaging and Communication in Medicine (DICOM) and Integrating the Healthcare Enterprise (IHE).

DICOM: At the moment 80% of all digital images of healthcare providers are based on DICOM standard. DICOM describes how medical image information has to be stored, shared and printed[5].

DICOM supports retrieving video from other file formats like DVD's, DV, AVI, MPEG4 and HDTV to DICOM MPEG2[6]. This set of standards was developed by a list of suppliers of different products used in healthcare[7].

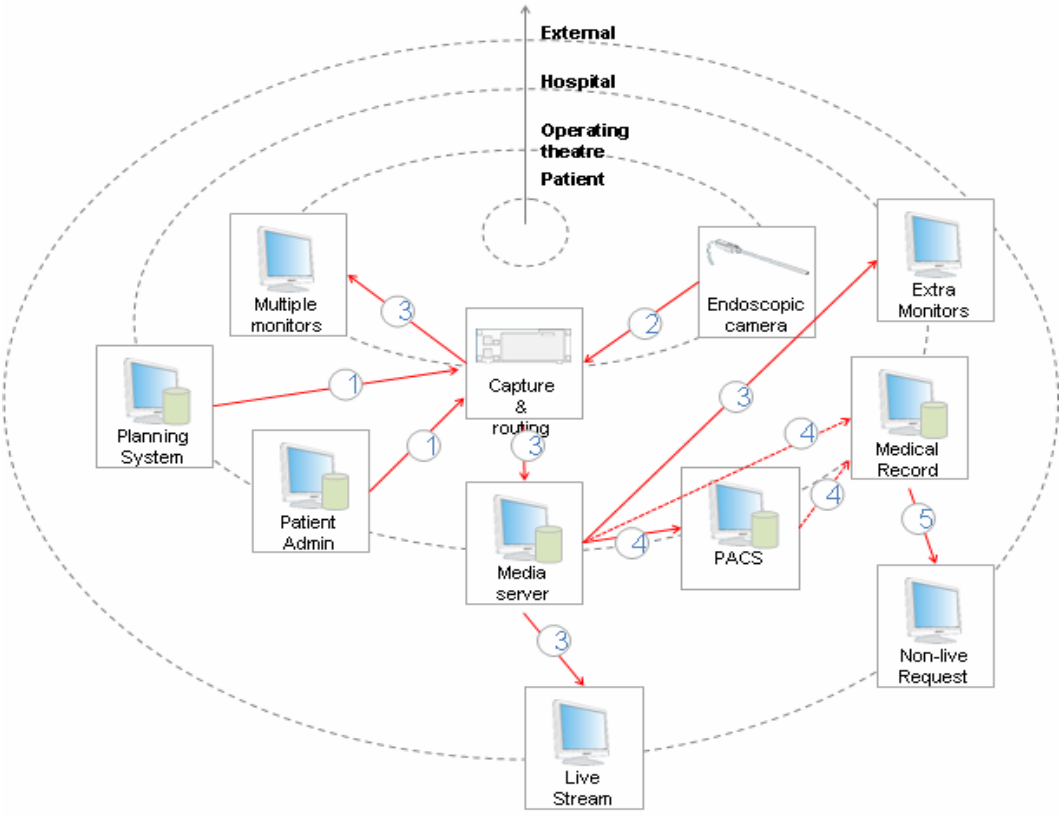
HL7 is an international standard for electronic interchange of medical, financial and administrative data between health information systems. The standard is made by the HL7 organization. HL7 supports such functions as security checks, participant identification, availability checks, exchange mechanism negotiations and data message structure[8].

IHE is an initiative taken by both healthcare professionals and industry to improve information sharing in the field of computerized systems. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical need in support of optimal patient care[9].

The Work Group 13 of DICOM is developing a standard for video since 2004. When completed, we will have a standard definition of how to integrate, share and administer video files. Current information shows that the discussion on this is still running.

The next figure shows the routes of the data and their places[10],[4],[11]: Administrative information from planning system and patient administration is sent to the capture and routing component. The goal is to add information about the patient to the video. To avoid typing mistakes the healthcare staff performing the endoscopic procedure should be provided with an automatically generated list of patients to choose from. This is similar to a PACS broker that provides the work list for an imaging modality.

Figure 1: The routes of the data and their places



1. The video signal of the endoscopic camera is captured in the capture and routing component.
2. The video signal can, from the capture and routing component, then be routed to any desired location: multiple monitors inside the operation theatre itself, extra monitors outside of the operation theatre (e.g. waiting room, observation room and classroom) or even outside of the hospital to provide a live feed of ongoing surgery.
3. Once the operation is complete, the video can optionally be edited on the media server and then saved to the PACS. When saving to the PACS a notification to the medical record might be required. If there is no PACS, the video could also be stored in the medical record immediately.
4. Further, and thus per definition non-live, requests for the video will need to be made towards the medical record.

3.3 THE MARKET TODAY (2007)

Most of the technical requirements stated here above can be filled in by ICT technology of some sort, at least on the basis of individual technologies.

However integration of systems and automation requires complete integration, security and extensive testing and maintenance. We did not find a clear market proposition today as required as COTS (Commercial Of The Shelf), nor as COTS + development.

3.4 ANALYSIS OF ENDOSCOPIC VIDEO REGISTRATION

Video records can be useful if they are analysed properly according to purposes. The video registration could be used in real-time, supplying the surgeon(s), students or staff by just looking at the video registration without editing or analyzing. But video registrations have to be systematically captured for real-time or post-procedure reviews and analyses.

Hardware and software tools have to be developed to capture, analyze, and provide user-friendly and efficient access to important content on endoscopic video registrations[12]. Human errors in the analysis and evaluation can be reduced by automated analysis. The increased technological complexity of surgery and the growing importance of quality assessment demand objective analysis of the surgical process[13].

The time-action analysis is a quantitative analysis method and proved to be a successful tool in measuring the events during endoscopic/laparoscopic surgery. The use of combined video images together with the standardised evaluation of the recordings[14]. Because the time-action analysis method is detailed, it is relatively time-consuming; the analysis of one procedure takes generally as long as the total operation time of the analysed procedure. However, the level of detail can be reduced, depending on the objectives of each study. Furthermore, software is becoming available to facilitate and quicken the data collection and evaluation (e.g. The observer®, Noldus information technology, Wageningen, the Netherlands)[13].

A view by video gives no clear systematic nor a geometric view that could be recognised by some algorithm[15] [196]. Moreover most patients have body movements, making analysis difficult, and most patients will present a pathological (i.e. abnormal) anatomy, that will not be recognised by the computerized system.

A project has been proposed to develop an Endoscopic Multimedia Information System (EMIS) which captures high quality endoscopy videos, analyzes the captured videos for important contents, and provides efficient access to these contents[12]. This is however limited to educational purposes. EndoMetric is a suite of software tools that automatically analyses the quality of colonoscopy exams and provides easy viewing of the quality measurements[16]. The researchers say the colonoscopy technology has the potential to be adapted to other medical procedures that use endoscope technology, including examinations of the bladder, lungs, stomach and joints[16].

Outside the hospitals some analysis systems are being used and available to implement in hospitals. Useful possibilities of other products are[17]:

- The possibility to integrate multiple analogue and digital data in one analysis system nearly as much as needed.
- The possibility to synchronize multiple analogue and digital data in one analysis system. The combination of different data and synchronisation between them is important for analysis.

However this will use the record as a source of synchronised multiple data (e.g. heartbeat, blood pressure, duration of endoscopy etc), but will not evaluate the images automatically).

Automated analysis of endoscopic video of moving images is a long shot and is not to be expected within the first ten years since the current analysis tools focus on verification techniques (data base statistics) rather than clinical identification (complex and specific), or on pattern recognition, but by simplifying patterns so much that it is not applicable to this field (e.g. irisscopy)

Key points on technological aspects of video recording of endoscopic surgery

- **Recording video's of endoscopic surgery is technically possible**
- **Legally compliant systems may turn out to be expensive through technical and procedural safeguarding**
- **Current analysis tools are built around pattern recognition or data system comparison whereas endoscopic images demand precise and specific recognition of moving biological forms, that apart from abnormal tissue and anatomy (disease), have a broad variance in appearance**
- **The analysis technology necessary for endoscopic video is not to be expected in the forthcoming years.**

3.5 DISCUSSION

While some technical specificities are already available, several problems remain unsolved:

3.5.1 Technology available today

We did not find a clear market proposition today as required as COTS (Commercial Of The Shelf), nor as COTS + development depending on the requirements and IT-environment as defined in specific situation. The solution will be a combination of COTS, customization, use of experimental software and significant piloting and testing. The testing and certification effort is significant, and has not been done before in this area of interest or industry. This also assumes that the required programming and validation skills can be found and mobilized.

3.5.2 Evaluation and scoring of images

Until today, applications enabling the computer based analysis of moving images of non-geometrical images do not exist. The video images do not present a pattern that can be analysed by algorithms. The images to be analysed are of the "biological" type , but are dealing with pathology and not necessarily normal anatomy: this makes the algorithmic evaluation of moving pictures even more remote.

As the video records cannot be scored or evaluated by an automated system, this would have to be done by human beings. Who is competent in science and medical practice to do that? Only a panel of peers can be. Reviewing such video records will be time consuming. This is expensive in time and skills availability. The peers would have to be paid at least as much as they would be earning in the medical profession (see further in the chapter on costs).

3.5.3 Standardisation and normalisation

The whole matter of archiving and processing video-images on a systematic base is still experimental, as a result of which the technical and metadata standards and norms are not well defined or agreed upon. As of today there is not yet an agreed standard to identify, index and store such records. The DICOM group is the most advanced in the matter but still has not published[d]

[d] http://medical.nema.org/Dicom

3.5.4 Digitisation versus automation

The ability to capture digital moving pictures, at the time of writing, does not imply that automated integration of records in the infrastructure and processes is available. Human interaction is needed to stop/start the recording, add the metadata, sign-off the record etc . I.e.it does not fit in seamlessly into the daily practice

3.5.5 Combined procedures

For simplicity's sake we assumed that each endoscopy would entail only one surgical procedure. In reality this may not be the case. How should these procedures combined in one endoscopy /anaesthesia be encoded and labelled?

Key points from technology discussion

- **Single Technological elements exist and are useable.**
- **The combined technology is not available as such, nor does it seem to have been used before.**
- **Automated evaluation of images is not possible today nor in the near future, as a consequence of which, image evaluation will need a human being.**
- **Technology is not a blocking factor for recording endoscopies.**
- **Digital technology does not ensure automated integration and processing.**

4 VIDEO REGISTRATION AND QUALITY CONTROL: WHICH CONTRIBUTION?

4.1 INTRODUCTION

In this chapter, based on a systematic literature review, the existence of quality management systems of surgical interventions in use was examined. Then, more specifically, quality control aspects specific for endoscopic surgery and the place of video registration within these quality systems was focussed on.

The literature search methodology is explained in chapter 2.

As results, the research team selected 88 abstracts based on these inclusion criteria. We selected articles addressing methods and issues relevant for the development of quality management systems for endoscopic surgical.

In the end we included 27 articles based on their full-text.

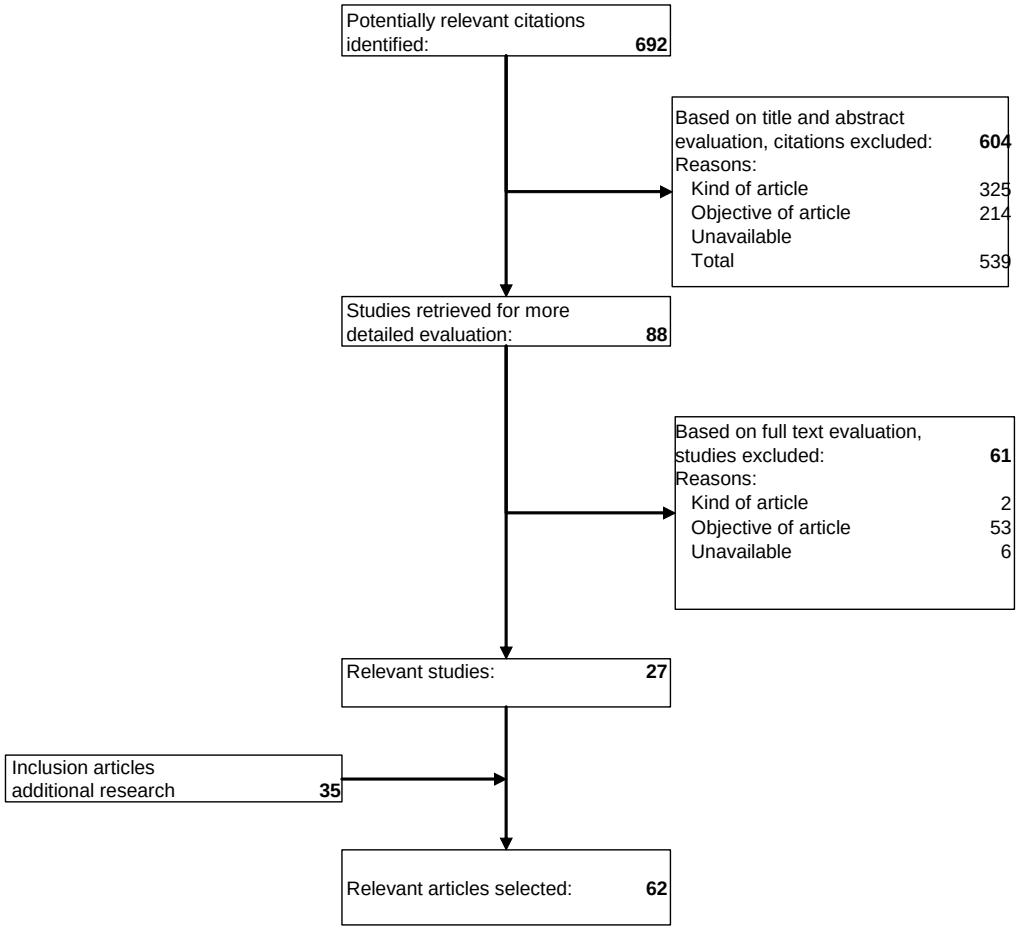
The screening of the reference lists of these articles provided another 15 articles for inclusion. The search strategy delivered 692 articles (Embase 543 articles, Medline 149 articles). An additional search resulted in 20 extra articles with recommendations and guidelines.

The flow-chart representing the process of the selection the articles used is presented in the next figure.

The first part of this section deals with quality management systems for surgery in an operating theatre. We summarized the international literature to describe the various aspects of quality management systems. If possible and relevant, we have zoomed in on endoscopy.

The second part of this section describes the role of video recording used as a quality management system to improve the quality of surgical interventions in the operating theatre. After a broader view has been given on quality and the possible role of video registration a further focus will be on endoscopic video registration.

Figure 2: Flow-chart with study selection of the articles used



4.2 QUALITY MANAGEMENT SYSTEMS IN THE OPERATING THEATRE FOR SURGICAL INTERVENTIONS

We present our results according to different aspects: quality control, practice guidelines, reporting of adverse events and the role of the hospital information systems and operation theatre information systems.

4.2.1 Quality control of surgery

4.2.1.1 In general

There are concerns regarding quality and safety issues in medical practice, some of these concerns are focused on surgical procedures. Variations in both practice and outcomes imply some opportunities for improving the quality and consistency of surgery.

In matters of quality control, measurement is essential; only when measurements of outcomes are sufficient, the right control actions can be taken. As the Deming cycle indicated one can only act after checking[18]. It is not only important to measure with the aim of reporting, but also to use this information for improvement purposes. The study of van Tiel et al. describes a quality improvement program using these plan-do-study-act (PDSA) cycles as a method to improve compliance with infection control guidelines[19]. Also in other healthcare improvement programs PDSA cycles have been widely used[18]. The study also reports that improvement of compliance is achievable but that repeated measurements are needed to ensure that compliance is retained.

Surgical outcome is focused on the role of patient's pathophysiological risk factors[20]. But, the outcome of surgery needs to be seen in a broader context. Surgical outcome is depending on the quality of care received by the patient in his journey through the hospital and on the performance of a number of health professionals, all of whom are influenced by the environment in which they work. It is a matter not just of therapy and treatment but also of correct diagnosis.

Vincent et al. suggest in their review of the literature the development of an operation profile to capture all salient features of a surgical operation. The operation profile encompasses the full range of factors implicated in the surgical outcome in the peri-operative period (Table 1). By this, he intends to achieve the following objectives:

- to expand operative assessment beyond patient factors and the technical skills of the surgeon,
- to extend assessment of surgical skills beyond 3D models to the operating theatre,
- to provide a basis for assessing interventions and to provide a deeper understanding of surgical outcomes.

Table 1. Principal features of the operation profile.

Patient factors
Principal complaint
ASA, BMI, age, and other relevant clinical information
Co-morbidities
The surgical team
Personnel
Experience of previous work together
Familiarity with procedure
Fatigue, sleep loss, stress, etc
Processes and procedures
Adequacy of notes and management plan
Consent and preparation
Anaesthetic procedures
Key operative events
Blood loss
Minor and major complications
Error compensation and recovery
Flow of information following patient
Adequacy of notes and consent
Specific intra-operative communications
Handover
Technical skills
Ratings of good general surgical practice
Ratings of operation specific steps
Identification of specific technical errors
Team performance and leadership
Leadership
Coordination between team members
Willingness to seek advice and help
Responsiveness and flexibility
Decision-making and situation awareness
Patient limitations
Operation limitations
Surgeon's limitations
Team limitations
The operative environment
Availability and adequacy of equipment
Availability of notes, records

	Noise and lighting
	Distractions
Interruptions	
	Phone calls, messages, outside theatre events, etc

Source: Vincent et. al,[20]

They suggest in their article that given the uncertainty that we do not know which factors are the most critical to the outcome, beyond patient risk factors, basic level of individual skill and the organization of care, the initial measurement instrument should be broad in its focus. Also in the review of Moorthy, it is mentioned that surgical competence is a combination of knowledge, technical skills, decision making, communication skills and leadership skills[21].

While recognizing the importance of all these aspects that have an influence on the patient's outcome, this research focuses predominantly on the technical performance, the technical skills of the surgeon. This focus is chosen as the scope of this review is on the quality of the chirurgical intervention itself.

Technical performance specifically consists of surgical knowledge, judgment, and dexterity[22].

In the literature we find evidence of various methods for the assessment of the surgical skills of the surgeon and their trainees[21-23]. The ability to measure and provide feedback of technical skills is crucial to the structured learning of surgical skills[21]. The measurement is the foundation of quality improvement[24]. These measurements can be qualitative and quantitative. While the quantitative methods are extending beyond time alone to include factors such as motion analysis, are the qualitative methods done by direct observation of the task and then scoring or by using a virtual reality based simulation[22].

Moreover, assessment method should be feasible, valid and reliable. Methods used for assessing surgical competence do not always live up to the criteria of the latter criteria, validity and reliability. Examinations and logbooks do not give an insight into the technical ability. The time taken for a procedure or the morbidity and the mortality data are too dependent on environmental and patient factors and therefore do not reflect the quality of the surgical competence. Objectivity cannot be guaranteed with direct observations without checklists or guidelines[21].

Recent developments have improved the validity of the observations as checklists and global rating scales have been developed. Good examples of objective assessment methods are OSATS (objective structured assessment of technical skills) and ICSAD (Imperial college surgical assessment device). These recent developments are discussed in 4.2.3.

These assessments are conducted in a training environment, and do not include real surgery on patients.

In the controlled study of Meterissian, a specific tool for clinical-reasoning assessment is described. This assessment focuses on problem solving, requiring a combination of knowledge and judgment, which are both a part of technical performance. The script concordance test (SCT) developed in Canada, is based on cognitive psychology script theory. This tool can be used to evaluate a candidate's approach to ill-defined problems encountered in the operating theatre[25]. They suggest in their article to compare the test with the present golden standard, the oral examination, in order to determine its place as an assessment tool.

The above-mentioned methods are primarily developed for the training environment. However, there is a necessity for a regular assessment of performance by audit in the operating theatre, as the Association for European Paediatric Cardiology highlights. They suggest comparison of the assessment results with data available internationally. No specification however is given on the assessment criteria[26].

We conclude that the literature indicates that assessment of the surgical skills is necessary; but however, no suggestion is given on the implementation of systematic assessments to review differences in medical practice.

4.2.1.2 Focus on the endoscopy

We have already described the role of assessment as a part of quality control for surgical interventions in the operating theatre. In the following part we focus on quality control aspects that are specific for endoscopic surgery.

There are several reasons for the growing demand for quality control among endoscopists, being the following[27, 28]:

- Patients require more precise information on the surgical intervention beforehand. The patients should be asked, in accordance with national legal requirements, to sign an informed consent form.
- Healthcare payers, national and private insurance, require at the very least proof that the procedure has been performed and performed in a satisfactory manner. Recording the endoscopy may provide such proof.
- The trend towards an increased number of legal actions being brought after interventional procedures may justify the collection of objective evidence on the surgeon's performance during an endoscopic procedure.
- To improve the quality of minimally invasive surgery, a better understanding of why variation occurs in the first place is necessary. Regional variation in procedures is undoubtedly multifactorial. The assessments of the risks and benefits associated with specific procedures and the extent to which patient preferences are incorporated into treatment recommendations vary between surgeons[29]. The ability to measure and provide feedback on surgeon-specific performance is a prerequisite to meaningful quality improvement in minimally invasive surgery. Appropriated performance measures to this specialty and better systems for collecting the necessary data are essential. Quality improvement requires a better understanding of specific processes of care that cause the most variation in patient outcomes. Moreover, systems are necessary to ensure that such best practices are broadly implemented.

Several well-known organizations in the field of endoscopy have developed initiatives to come to an effective measurement of quality for endoscopic procedures. Further on an overview of these organizations and their initiatives is provided.

Both, the European Society of Gastrointestinal Endoscopy (ESGE) and the American Society for Gastrointestinal Endoscopy (ASGE) have developed a standard to report endoscopic interventions.

The National Endoscopy team of the National Health Service Institute (UK) has developed an endoscopy Global Rating Scale (GRS) in order to assess clinical quality and quality of patient experience. The British Society of Gastroenterology elaborated the GRS in more detail for quality and safety indicators for endoscopy.

European Society of Gastrointestinal Endoscopy

The European Society of Gastrointestinal Endoscopy (ESGE) represents national societies of Endoscopy in Europe, the Mediterranean and North Africa. The aims and objectives of the society are among others to promote endoscopy and good endoscopic practice and to publish guidelines. The practice guidelines are described in detail in the next paragraph.

The ESGE stresses the importance of the endoscopy report[28]. This report is an integral part of the quality assurance policy in all endoscopic units. It is also a requirement in any process for hospital accreditation or certification in Europe. They mention that the production of an accurate endoscopy report, using modern technology such as a standard classification method and a computerized system, gives an added value in practice. They also suggest that image and video recordings could give an added value in day to day clinical practice.

Traceability requirements, the needs of healthcare providers, quality assurance, patients' requests, and, in some cases, fear of medical lawsuits, all together are factors that oblige the endoscopic community to develop new software for standardized endoscopy reports.

The ESGE recommends the use of an electronic report that has been developed by David Lieberman in the United States[28]. This report is accurate, allows data transmission from the hospital to the general practitioner or other medical services, and collects data for cost-effectiveness assessment of gastrointestinal endoscopic procedures. Procedural details (endoscope type, model, number, accessories), cleaning and disinfection procedures that are used, are included in this report.

The report describes, apart from the usual administrative data, the mandatory reporting aspects, namely the indication for the procedure, a description of how the examination was carried out, the results or diagnosis, and the suggested follow-up.

The different aspects that a report should include are the following[28]:

- Administrative, technical, and procedural data: patient data, practitioner, anaesthesiologist, duration of the procedure, description of the lesion, etc.
- Indications: clinical indications, medical history, therapeutic procedures (including recorded data; still pictures or video), incidents or side effects, immediate follow-up.
- Results or diagnosis: final diagnosis, location of the lesion; number and location of polyps, histological findings.
- Medical follow-up: medical treatment, surgery, long-term follow-up, e.g.3-yearly repeat colonoscopy.

The ESGE recommends that all reports should be based on the OMED (World Organization of Digestive Endoscopy) Minimal Standard Terminology (MST). This classification was introduced in Europe by ESGE and then implemented at an international level. All information based on the MST can be used for data collection, regardless of the languages used. The MST has been approved by national societies and is available in 14 languages.

The ESGE mentions that the Networked European Endoscopy database (NEED) should allow data collection and production of an endoscopy report. The database should be compatible with the software of Olympus (Endobase) and Fuji (ADAM).

Another objective of the ESGE is to make the images available for communication to the patient or to the endoscopists' colleagues (general practitioners or surgeons). The ESGE is now recommending that a minimal checklist of images (photos) should be introduced into the code of good practice[28].

In our selected articles we didn't find any evidence that the endoscopy reports are used as a standard for endoscopic procedures in Belgium.

The American society for gastrointestinal endoscopy

The American Society for Gastrointestinal Endoscopy (ASGE) promotes the standards for endoscopic training and practice, recognizes contributions to the field of endoscopy; and is one of the resources for endoscopic education. The ASGE and American College of Gastroenterology (ACG) recognize that if they do not develop evidence based quality measures themselves, an administrative or governmental agency without experience or insight into the practice of endoscopy will define the measures[30].

ASGE Guidelines recommend a procedure report as a part of a quality control system. It contains the following elements[31]:

- Date of procedure, patient identification data, endoscopists , assistant, anatomic extent of examination, limitation(s) of examination
- Documentation of relevant patient history and physical, examination, endoscopic procedure, indication, type of endoscopic instrument, medication (anaesthesia, analgesia, sedation), complications (if any), disposition
- Findings, diagnostic impression, results of therapeutic intervention (if any)
- Recommendations for subsequent care

Comparing the different reporting elements mentioned by the ESGE and ASGE, it can be concluded that the aspects are covered. An element that is not mentioned by the ESGE, but is mentioned by the ASGE is the indication of informed consent.

In America, as mentioned by the ASGE, the concept of the computerized endoscopic medical record (CEMR) for gastrointestinal procedures should provide the essential information of including patient identifier, Surgeon identifier, date of the procedure, relevant medical history, procedure type, medication, indication of the procedure, limitation of the examinations, findings, tissue acquired, adverse events, final diagnosis, results of the therapeutic interventions, complications, disposition, and notification if images were acquired[32].

It is not clear to what extend the reporting standard of ASGE is currently use in practice in the USA.

The taskforce of the American Society for Gastro Intestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG) have developed quality indicators for the four major endoscopic procedures, these are: colonoscopy, esophagogastroduodenoscopy (EGD), endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasonography (EUS), to improve patient care[33]. The aim was to create indicators that in most cases could be extracted from the endoscopy report or procedural documentation.

For each endoscopic procedure, indicators were considered for three occasions: pre procedure, intra procedure and post procedure.

- Pre procedure indicators include proper indication for the procedure, consent, antibiotic prophylaxis, etc.
- Intra procedure indicators include completeness of the examination and completion of therapeutic procedures.
- Post procedure indicators include follow-up of pathology and recognition and management of complications.

Table 2 shows the proposed quality indicators for endoscopic procedures. They mention that these points should be studied and validated as they are most useful and feasible for widespread use.

Table 2. Summary of proposed Quality Indicators for Endoscopic Procedures

Quality Indicator	Grade of Recommendation: explanation
Proper indication	1C+: Clear benefit, overwhelming evidence from observational studies
Informed Consent	3 : Unclear benefit, expert opinion only
History and Physical examination	3: Unclear benefit, expert opinion only
Risk stratification	1C: Clear benefit, observational studies
Prophylactic antibiotics	2C: Unclear benefit, observational studies
Timeliness recorded	3: Unclear benefit, expert opinion only
Sedation plan recorded	3: Unclear benefit, expert opinion only
Anticoagulants recorded	3: Unclear benefit, expert opinion only
Team pause	3: Unclear benefit, expert opinion only
Photo documentation of major abnormalities	3: Unclear benefit, expert opinion only
Patient monitoring	3: Unclear benefit, expert opinion only
Medications are documented	3: Unclear benefit, expert opinion only
Reversal agents	3: Unclear benefit, expert opinion only
Discharge criteria	3: Unclear benefit, expert opinion only
Discharge instructions	3: Unclear benefit, expert opinion only
Pathology follow up	3: Unclear benefit, expert opinion only
Procedure report	3: Unclear benefit, expert opinion only
Reporting of complications	3: Unclear benefit, expert opinion only
Patient satisfaction	3: Unclear benefit, expert opinion only
Communication with referring providers	3: Unclear benefit, expert opinion only
Plan for post procedure resumption of anti coagulants	3: Unclear benefit, expert opinion only

Source: Adapted from Guyatt G, Sinclair J, Cook D, Jaeschke R, Schunemann H, Pauker S. Moving from evidence to action: grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, eds. Users' guides to the medical literature. Chicago: AMA Press; 2002. pp. 599–608.

National Endoscopy team of the National Health Service Institute (UK)

The National Health Service (NHS) Institute for innovation and improvement supports of the United Kingdom has established a National Endoscopy team. The strategy of the National Endoscopy team is focused on supporting the achievement of high quality and safe endoscopy.

The NHS has set up a quality framework for endoscopy. This framework consists of standards and processes for measurement. The quality standard for endoscopy units is the endoscopy Global Rating Scale (GRS)e. This scale is a quality improvement and assessment tool for the gastrointestinal endoscopy. The GRS assesses two domains of patient care, namely clinical quality and quality of patient experience.

Twelve patient-centred standards were defined, as a result of meetings throughout England endoscopy staff (Table 3). The GRS measurement is a web-based self-reporting tool. The web tool allows endoscopy units to compare their ratings with local and national averages. All endoscopy units are encouraged to complete the GRS twice a year and to use the GRS to plan and monitor service improvement.

To validate self reporting, and to obtain evidence to support achievement of the measures of the GRS, there is an accreditation visit for every endoscopy unit in an acute hospital. This process is called the Joint Advisory Group (JAG) peer review accreditation. The quality assurance standards for endoscopists are measures of competence and performance. Performance is measured on how good an endoscopist is from the patient's perspective. To assess performance only outcomes that matter to the patient, are measured. These are accuracy, extent of procedure, time taken to complete, comfort, sedation and adverse outcomes.

Table 3. Twelve patient-centred standard of the Global Rating Scale (NHS)

Clinical quality	Quality of patient experience
Appropriateness	Equality
Informed consent	Timeliness
Safety	Choice
Comfort	Privacy and dignity
Quality	Aftercare
Timely results	Ability to provide feedback

This structured approach that includes a quality framework for endoscopy using a global rating scale is the first quality improvement and assessment tool for gastrointestinal endoscopy. The focus performance measurement is on the patient perspective.

British Society of Gastroenterology

The British Society of Gastroenterology is an organization focused on the promotion of gastroenterology within the United Kingdom. The organization is intimately involved in all aspects of training of British gastroenterology and to original research in the field. Research is supported indirectly through the promotion of high standards and by offering platforms for scientific presentation and publications.

Together with the national Bowel Cancer Screening Program, Association of Upper Gastrointestinal Surgeons (AUGIS) and ACP, quality and safety indicators for endoscopy are developed (Table 4). These indicators for different endoscopic procedures are included in appendix.

e Available on 20 February 2008; http://www.globalratingscale.com/Default.aspx

Table 4. General quality and safety indicators (British Society of gastroenterology)

	Quality	Safety
Structure	• Adequate numbers of video endoscopes to provide an uninterrupted service • An appropriate range of ancillary equipment for all procedures performed in the department • IT endoscopy reporting system • Supportive radiology and pathology service • Image capture	• Correctly functioning diathermy equipment • Haemostasis equipment to control unexpected bleeding, e.g. loops, clips • Properly equipped recovery area of appropriate size • Appropriate equipment for 0_2 monitoring, BP and ECG monitoring • Resuscitation equipment in procedure and recovery areas compliant with Trust (or organization) policy
Process	• Agreed antibiotic policy • Agreed anticoagulant policy • Agreed diabetic policy • Agreed sedation policy • All policies published in paper and electronic form in the department • Compliance with Trust (or organization) consent policy	• Monitoring and review of unpredicted adverse events and near misses • Adherence to BSG and DH guidelines on decontamination and traceability • Agreed radiology protection policy • Adherence to local resuscitation policy
	• All policies based on UK National Guidelines where they exist • An endoscopy user group that meets regularly	
Staffing	• Staffing levels and skill mix appropriate to the volume and type of procedures • Staff are assessed according to the Knowledge and Skills Framework (KSF) • Only staff assessed to be competent for that task are allowed to practice without supervision • Adequate managerial and clerical support staff to ensure that the unit operates with maximum efficiency • Identified medical and nurse leads • All trainees must be supervised • Trainees allowed to practice independently after formal evaluation of competence	
Auditable outcomes	• Number of procedures performed by each operator	• Unplanned admissions and operations within 8 days of procedure • 30 day mortality • Use of flumazenil • Use of naloxone • Need for ventilation • Perforation • Bleeding • Sustained drop in O2 saturation <90%[f]

The quality and safety indicators underpin the respective items of the GRS. They recognize the minimum items that should be monitored and the GRS assesses the extent to which the audit cycle has been applied to them. The intention for the layering of the GRS is to remain fixed, while the quality and safety indicators remain flexible as evidence and practice evolve. The difference between the benefits and harm of endoscopic procedures has been respectively separated into quality and safety indicators. These indicators have been separated further into broad categories:

- Relatively fixed items: structure, process and staffing;
- Dynamic indicators: auditable outcomes and quality standards

An auditable outcome refers to an outcome, which is important to monitor and review, but for which it is not possible to assign a standard (E.g. use of reversal agents for over-sedation, minimum number of procedures required to maintain competence, outcome of endoscopic therapy for bleeding varicose veins).

A quality standard is an auditable outcome for which there is an evidence base that can recommend a minimum standard (e.g. completion rates for colonoscopy or bleeding rates for sphincterotomy).

The British Society of Gastroenterology is the first organization in Europe that has developed quality and safety indicators for endoscopy.

[f] These markers apply to all endoscopic procedures performed within the department

4.2.2 Practice guidelines

The previous paragraph focused on measuring quality, this paragraph deals with steering the quality of the surgical intervention, by providing practice guidelines.

Practice guidelines are systematically developed statements to assist practitioners and patients in decisions on appropriate health care for specific clinical circumstances[34]. An additional objective of guidelines is to standardize medical care, to raise the quality of care, and to reduce severe kinds of risk.

The focus in this report is to give an overview of the possible quality systems in the operating theatre, specifically for surgical interventions. Evidence based medical practice guidelines, may play a role in the improvement of the quality of the surgical interventions. They can be seen as a part of a quality system. However, current literature does not reveal if there is adequate assurance of medical practice guidelines and if they are followed by the surgeons.

The controlled study of Ahmed et al[35] determines that various trends in peri-procedural care are observable, but standards of care are not well established.

Specifically to minimize complications associated with interventional pain management techniques, the pain management community should agree on safety guidelines for all procedures, much as those advocated by the American Society of Anaesthesiology for surgical anaesthetic care[35].

Two other recent studies show that there is a large variation of practice in both hip replacement and primary total knee replacement on actual practice and the best practices described in the British Orthopaedic Association (BOA). Differences in patient outcomes have been identified[36, 37]. These studies suggest that an introduction of a properly funded national arthroplasty register will surely help to clarify the effect of such diverse practices on patient outcome. Moreover these insights on practices can be used to determine the best practices, which in turn can be translated into guidelines.

4.2.2.1 Focus on the surgical discipline endoscopy

As stated previously, the demand for quality control in endoscopic procedures is gaining force in most European Countries, and this justifies the preparation of good practice guidelines for such procedures.

European Society for Gastrointestinal Endoscopy

The European Society for Gastrointestinal Endoscopy (ESGE) guidelines committee is consistently involved in monitoring the state-of the art procedures and techniques in various endoscopy related areas. Therefore the ESGE is publishing relevant guidelines and recommendations.

The following guidelines are approved by the committee:

- Process validation and routine testing for reprocessing endoscopes in washer-disinfectors[38]
- Quality assurance in reprocessing: Microbiological surveillance testing in endoscopy[38]
- Video capsule endoscopy[39]
- Quality Control of Endoscope Service and Repair[40]
- Cleaning and Disinfection in Europe according to the Endoscopic Societies' Guidelines[41]
- Variant Creutzfeldt-Jacob Disease and Endoscopy ESGE Recommendations for Quality Control in Gastrointestinal Endoscopy:[42]
- Image Documentation in Upper and Lower GI Endoscopy[27]
- Check List for Purchase of Washer Disinfectors for Flexible Endoscopes[43]
- Antibiotic Prophylaxis For Gastrointestinal Endoscopy[44]
- Endoscopic Ultrasonography, Part II: Retroperitoneum and Large Bowel, Training[45]

- Endoscopic Ultrasonography, Part I: Technique and Upper Gastrointestinal Tract)[46]
- Protocol for Reprocessing Endoscopy Accessories[43]
- Cleaning and Disinfection in GI Endoscopy[47]

According to the literature, it is not clear of these guidelines are followed by all European endoscopic surgeons.

British Society of Gastroenterology

The British Society of Gastroenterology has developed several guidelines specifically for endoscopic procedures in order to improve standards in medical practice.

The clinical guidelines cover the following topics: endoscopy, gastro-duodenal, inflammatory bowel disease, liver, neuro-gastroenterology and motility, oesophageal, pancreatic, pathology and small bowel nutrition.

The British Society of Gastroenterology is one of the European leaders in the development of guidelines.

American Society for Gastrointestinal Endoscopy

The American Society for Gastrointestinal endoscopy has also developed guidelines for gastrointestinal endoscopy. All guidelines are systematically developed; clinically related evaluations and recommendations are included. The guidelines intend to assist the practitioner in providing appropriate, cost effective and high quality patient care.

Several guidelines are already published on the following topics: the preparation for endoscopy, upper gastrointestinal endoscopy, lower gastrointestinal endoscopy, biliary and pancreatic endoscopy, establishment of gastrointestinal endoscopy areas and miscellaneous techniques.

4.2.3 Adverse events

As can be deducted from the high proportion of error-related deaths, the operating theatre environment is a high-risk area with high level of complexity, and high stakes. The concept of safe surgery has received significantly more attention since the publication of the Institute of Medicine report in 1999[48].

After medication errors, surgically related errors are the most frequent cause of error-related death[49]. Moreover, operating theatre errors lead to more harm than errors elsewhere in the hospital. Adverse events can be catastrophic for patients, caregivers, and healthcare institutions, therefore improving patient safety is an increasing priority for surgeons and hospitals[24].

Surgical adverse events may be due to poor communication, bad operative technique, malfunctioning or improperly used equipment, cognitive errors due to stress or inattention, all compounded by resource and organisational problems[20].

Hospitals have ongoing programs to improve medication safety. However, most hospitals currently do not focus on the second most frequent cause of error related death by improving the operating theatre safety in a structured manner. That is so even despite the available and clearly effective technologies and despite the important financial contribution of the operating theatre to the institutions.

Attention turned to developing a safer practice to ensure that patients would be free from injuries caused by errors in the difficult environment of the operating theatre. Patient safety practices in the operating theatre are based on strategies for reducing error. Different aspects such as education, self reflection, and informal discussion of adverse outcomes at morbidity and mortality rounds will inform and guide safe practice[50]. However, before being able to learn and discuss the errors and the adverse events it is vital that the errors must be admitted and well documented in medical records[51]. These medical records are legal documents that must be kept authentic and accurate. To be able to learn from the errors made and to learn what can be done to avoid these errors a root cause analysis need to be undertaken. This should be done under the leadership of trained and respected personne[51].

In this report we focus on quality systems that assess the technical performance of the surgeon. Technical operative errors can cause surgical operative morbidity and adversely affect the clinical outcome of patients. Surgical expertise underpins good and safe practice[52]. Other errors enacted by surgeons are described in Table 5.

Table 5. Distal (coal-face) errors enacted by surgeons

Distal errors enacted by surgeons
Diagnostic and management errors
Resuscitation errors
Situation awareness errors
Identification/misappropriation errors
Teamwork errors
Prophylaxis errors
Prescription/parenteral administration errors

Several concepts have been developed to report in a way that helps the personnel involved in an operation to be held publicly accountable. We discuss the role of reporting systems and the concept of the clinical report cards. Then we described the further developments in the literature with the focus on endoscopy.

4.2.3.1 Reporting systems

Reporting systems for adverse events have two important functions. With the stored information the surgeon involved can be held accountable for performance or, alternatively, the information can be used to improve safety[48]. However, to be effective the systematic recording of intra operative events in a database is necessary. In the American report "To err is Human: Building a safer health system" states that a nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm.

All health care organizations should report standardized information on a defined list of adverse events. The stored information can be used by many experts for safety analysis and quality assurance purposes[53].

Not only should the errors that have caused damage be reported, but also the near misses[49]. A healthcare "near miss" is a situation in which an error or omission, or a sequence of errors or omissions, arising during clinical care fails to cause injury to a patient (sometimes as a result of compensating action). These near misses occur more frequently than actual adverse incidents and provide a valuable opportunity for learning by quantitative analysis about the nature, frequency, and types of safety issues. The study of the near misses can indicate where flaws in systems lie.

However, the lessons that can be learned from this valuable source of information are ignored because the patient has not experienced harm[54]. The data collected of errors and near misses must be analysed. The analyses should be reported back and be used for systemic changes to reduce recognized patterns of human error. With the review of the errors and the near misses, including the root cause analysis, changes to the processes will contribute to improved patient safety in the operating theatre[49].

4.2.3.2 Concept of clinician report cards

In the USA, another initiative for the quality control is the clinician report cards to monitor complications and outcomes. Information on these cards is used for public reporting and can be applied to hold the clinicians publicly accountable[55]. There is much controversy on the topic of public reporting, including concerns with misinterpretation of results released to the public affecting the reputation of surgeons[56]. Many surgeons may oppose the public reporting of medical errors of the idea of a surgeon 'report card'.

4.2.3.3 *Risk management*

Incident reporting is only one aspect of the identification of risk. Risk management is the process where risks are recognized, interpreted and new strategies are developed to alter the risk and keeping track of the process outcomes[57]. Patient safety and risk management literature and guidelines advise the prospective monitoring of incidents considered to be near misses or mishaps[58]. Singh et al. describe risk management as a process to help in patient safety and to stimulate best practice initiatives[59]. In the US there has been a greater focus on patient safety through hospital, government and initiatives in the area of risk management. The Society of Obstetricians and Gynaecologists of Canada has created the MOREOB (Managing Obstetrical Risk Efficiently) program with expansion throughout Canada and the USA[60].

4.2.3.4 *Focus on the surgical discipline endoscopy*

With the advancement of operative laparoscopy, there has been a necessity to develop a system that ensures accountability, quality of care, patient safety and best practice[55, 59]. Cuschieri states that standardization of endoscopic surgical operations and their execution are essential for the procurement and maintenance of quality assurance in endoscopic surgical practice[52]. Essential patient safety practices in the operating theatre include the application of standard processes of care, the use of a protocol as a checklist to reduce reliance on memory, the employment of simpler processes as much as possible and the design and use of error proof devices with frequent training in the use of these devices. Cuschieri discusses in his paper the origin and generic mechanisms underlying technical operative errors during the execution of endoscopic operations (Table 6)[52].

Table 6. Origin and generic mechanisms underlying operative technical errors during endoscopy surgery

Distal errors enacted by surgeons
Cognitive errors of judgement
Procedural
Executional
Misinterpretation
Misuse of energized dissection
Missed iatrogenic injury

Quality assurance monitoring should include several parameters. Parameters that may also be included for the operative laparoscopist are: surgical outcomes, complication rates, equipment failure or injury rates[59]. Cuschieri states that it is possible to formulate and adopt a surgical error reduction system for endoscopic operations based on standardisation of operations, surgical operative proficiency, and human reliability assessment and its related clinical counterpart, observational clinical human reliability assessment[52].

4.2.4 Hospital information systems and operation information systems

When looking at surgical interventions, information technology represents an especially valuable tool for reducing errors and near misses by utilizing the information in various improvement approaches. Li and Hsu[61] refer to many publications in which the use of information systems to increase surgical safety is mentioned for domains such as operating theatre scheduling[62], computer-assisted surgery and measurement of surgical outcomes[63]. Not only will the information technology be used for above mentioned aspects, but moreover shall it will used for communication, monitoring and decision support[61]. The computerized decision support can clearly improve safety especially during prescribing, preventing the most frequent cause of error- related death being medication.

Internationally discharge data from the hospital information system is increasingly being used for outcomes research and for benchmarking hospital and provider performance. In America we can find specialised peer review organisations, the Centres for Medicare and Medicaid Services (CMS), the University Health System Consortium, and third-party payers use the Hospital Discharge Data Set (HDDS), for the analysis of clinical

outcomes[64, 65]. Furthermore public reporting of outcomes of surgical procedures is expected to increase and may be part of the centres for Medicare and Medicaid Services (CMS) 'pay for performance' initiative.

However, the information provided by the hospital information system does not allow looking in a more detailed manner to the quality of the surgical procedures. Nevertheless it can be used to assess the quality indirectly by benchmarking outcomes.

The retrospective study of Bertges et al. shows a significant difference between the number of complications recorded by a concurrent database overseen by clinicians and a retrospective administrative data base overseen by medical records analysts[66]. So it can be conclude that administrative data sets have been faulted for the accuracy of their reporting of in-hospital complications[67].

During the surgical procedure, it is imperative that all of the physiologic data, the pharmaceutical and commodities utilized, and procedural steps are well documented[68]. These data must be readily retrievable for access in the postoperative period. Given the acuity and financial costs associated with surgical procedures, it is of utmost importance that perioperative information is provided where en when it is needed during the operation. However for monitoring and improvement purposes it is vital that information of a surgical intervention is also accurately documented[68].

One of the initiatives that is worth mentioning in this review as a good example, is the anaesthesia data system that is developed in Michigan. Michigan operating theatre CARE (morCARE) is an anaesthesia data system that is physically connected to anaesthesia machines and monitors in the operating theatre and the PACS on the operating theatre network. This anaesthesia data management system obtains data from various other hospital computer systems and also sends data to those systems, including email and paging systems. It is possible to automatically track time, patient location, operating theatre status, billing, drug/pharmaceuticals, commodities and consequently overall costs[68]. This system is also able to capture quality assurance data, namely pre operative data, intra operative data and post operative date.

Although the vast majority of anaesthesia information systems primarily focus on replacing the intraoperative anaesthesia record, morCARE is focused on the entire perioperative workflow and process.

4.3 VIDEO REGISTRATION FOR QUALITY CONTROL FOR SURGICAL INTERVENTIONS IN THE OPERATING THEATRE

In this part we aim to answer the second research question "Is video registration in the operating theatre currently used for quality control for surgical interventions?"

We describe how video can be used in numerous ways to improve the quality of the surgical interventions. First we illustrate the use of video registration as a quality control system. Secondly we illustrate the use of video registration in objective methods of assessing technical skills. We also highlight the role of video with the assessment of communication. After this we look at the video registration in operating theatre workflow improvement and surveillance for patient safety. Finally we underline the possibilities of endoscopic video registration.

4.3.1.1 Video for quality control

Currently, the documentation of surgical procedures is limited by the accuracy of description. The capture of images of the video registration, as a picture, can play a role in improving the documentation of the surgical procedure. The capture of images of the surgeon interacting with the patient, the patient's anatomy, and video screens used to monitor vital signs or make diagnoses (e.g., colonoscopy images, ultrasound scans) or perform surgery (e.g. laparoscopy, telerobotic images) gives a comprehensive picture of events useful for multiple future analyses[69].

Today, it is possible to incorporate the video record of an entire surgical or medical procedure in the electronic medical record and voice-activated operative note dictation to allow in-depth review after the procedure is completed[69]. In this way the surgical procedure can be reviewed when complications have occurred.

Endress et al. state that image documentation of intra-operative result is important, because it concerns all operative disciplines[70]. By the establishment of large-coupled device cameras, digital image documentation complies with the technological requirements in all operative disciplines. However, this technology is being used non-systematically. The requirements for automated and systematic video registration are demanding.
Currently there is no explicit statutory obligation for image documentation of intra-operative results. But as operating theatre image documentation makes a huge contribution to quality assurance by hospitalisation of patient care and legal covering, more and more healthcare organisations classify operating theatre images as a necessary record.

Although the literature clearly indicates the importance of video registration in quality improvement, no clear indication can be found of the use of video registration in current practice.

4.3.1.2 Objective methods of assessing technical skills

Objective methods of assessing technical skills are fundamental to obtain a reliable view on technical performance. Without standardization and assessed methods of training and examining it is difficult to assure the patients of the proficiency of the surgeons operating on them and with this assurance of the quality of the surgical intervention[50].

The need for improvement in the assessment of surgical skills is indicated by the large number of unnecessary complications, for example during the introduction of laparoscopic surgery[50]. Assessment can help reducing the variance in technical between surgeons. In improving the assessment, objective measures are essential because deficiencies in training and performances are difficult to correct without objective feedback. Therefore the primary aim should be to integrate objective assessment of surgical skills into training programs[23].

Recently there has been an influx of tools enabling the objective assessment of qualitative and psychomotor skills acquisition in both open and laparoscopic surgery [23]. In the next paragraphs these assessment tools are discussed covering different parts aspects of the technical performance.

Objective Structured Assessment of Technical Skill (OSATS)

With global rating scales such as the Objective Structured Assessment of Technical Skill (OSATS) one can asses the procedural and qualitative aspects in an objective manner. OSATS, developed in Canada, proposes a generic evaluation of surgical performance through the use of a global rating scale. The aim of a global rating scale is to assess general surgical principles, whereas a checklist based assessment is by definition specific to the operation. The drawback is the need of having several staff surgeons to observe the performance of trainees or performing surgeons; however this can be solved by the use of retrospective video assessment.

College Surgical Assessment Device (ICSAD)

There are also analysis systems for the assessment of dexterity. The Imperial College Surgical Assessment Device (ICSAD), developed in the United Kingdom uses electromagnetic tracking of movement. Another method for dexterity assessment is the Advanced Dundee endoscopic Psychomotor Tester (ADEPT), which uses optical motion tracking. The electromagnetic tracking of movements is preferred as the optical system can suffer from disturbances in the line of sight causing loss of data. The ICSAD makes it possible to quantifiably assess surgical dexterity by comparing the performance of experienced and novice surgeons on a simple surgical task. It is possible to objectively assess dexterity based on criteria for task performance such as targeting, transfer and dissection in laparoscopic surgery, and criteria for procedural performance. However this system does not provide an insight in the quality of the operation performed or its outcome. Although ICSAD and ADEPT may be used without the use of video registration, it is advisable to use these in combination for analysis purposes, as we see below with the assessment tool ROVIMAS.

Robotic Video and Motion Analysis Software (ROVIMAS)

Robotic Video and Motion Analysis Software (ROVIMAS), developed in the UK, is a motion tracking system for the assessment of laparoscopic technical skills in the operating theatre[23]. ROVIMAS was developed using the ICSAD measurement technique for motion and uses specialised software to automatically store and to instantly analyse the data on motion dexterity. Motion and video data are captured in a time-synchronous manner. When the motion data analysis indicates an error, it is possible to easily look at the video data at that precise moment, saving time in looking up the right images.

However with the motion analysis, it is not possible to look at the qualitative and procedural aspect of the operation. Therefore the OSATS method was integrated to analyse the other technical skills using the global rating scale. The research revealed a significant correlation between the motion tracking analysis and the scores obtained form the OSAST global rating scale[23].

Remote analysis of team environments (RATE)

The Remote analysis of team environments (RATE) tool, developed in the USA, is a digital audiovisual data collection and analysis system, which automates the ability to digitally record, score, annotate, and analyze team performance. The rate tool allows prospective analysis of performance measures such as technical judgments, team performance, and communication patterns offers the opportunity to conduct prospective intra operative studies of human performances. Moreover the RATE tool allows postoperative discussion, review, and teaching[71]. In their study they suggest also that gaps in situational awareness might be an underappreciated source of operative adverse events.

Global Operative Assessment of Laparoscopic Skills (GOALS)

The Global Operative Assessment of Laparoscopic Skills (GOALS), developed in the USA, is a valid, objective assessment tool for evaluating technical surgical performance. It is used to blindly evaluate an intra-operative videotape recording of a laparoscopic procedure[72]. GOALS looks at 5 different domains, namely depth perception, bimanual dexterity, efficiency, tissue handling, and overall competence.

The GOALS tool is not only an evaluation of overall technical performance but is also intended to provide surgeons with specific feedback on their technical skills. The Table 7 gives an overview of the various assessment tools. It is remarkable that none of these advanced tools are systematically used in operating theatre practice. Especially for ROVIMAS usage beyond the training environment may be of use for the improvement of surgical quality.

Table 7. Overview of different assessment tools

Assessment tool	Dexterity	Procedural and qualitative	Team performance	Specific for training environment	County of development
Objective Structured Assessment of Technical Skill (OSATS)		X			Canada
Imperial College Surgical Assessment Device (ICSAD)	X			X	UK
Advanced Dundee endoscopic Psychomotor Tester (ADEPT),	X			X	Scotland
Robotic Video and Motion Analysis Software (ROVIMAS)	X	X		X	UK
Remote analysis of team environments (RATE)			X		USA
Global Operative Assessment of Laparoscopic Skills (GOALS)	X	X			USA

Due to the fact that the assessment can be anonymous, retrospective video watching of the performance may be a way forward. Integrated computerized dexterity analysis with video based assessment is an efficient and comprehensive method of surgical skill assessment. In the controlled study of Aggarwal et al. significant differences in dexterity have been seen between experienced and novice laparoscopic surgeons[23].

Dosis et al. mention that it is necessary for expert surgeons to analyse a video of the procedure, ensuring each surgeon is progressing in a safe and purposeful manner[73]. By using an objective assessment tool it is possible to define progression in terms of improvement of dexterity and quality, rather than on the number of procedures performed, or complications experienced.

4.3.1.3 Video for assessment of communication

Verbal communication is a preoperative aspect that indirectly influences the surgical outcome. Our focus in this research is on the technical aspects, however because literature indicates the importance of communication, it is briefly discussed.

Verbal communication in the operating theatre during surgical procedures affects team performance, and is related to the complexity of the operation process. Analysis of verbal communication is difficult. Video can play a role in the analysis of the verbal communication, and could provide insight into the teaching processes[74]. Insight into communication contents may be used to specify training needs, and may contribute to the evaluation of different training methods. The study of Grantcharov et al. surgeons receiving constructive feedback, make a significantly better improvement in their performance in the operating theatre[75]. Technical deficiencies and possible errors performed by the trainee can be discussed by receiving the feedback, supported by review of the videotape.

4.3.1.4 Video for operating theatre Workflow improvement

Process improvement is the basic method to improve safety and quality in any medical practice setting. Video can augment the ability to discover the needed process improvements. The article of Endress et al. describes how the integration of an image documentation system can play a role to analyze and modify the operating theatre workflow[70]. Image documentation is an excellent starting point for systems integration because of the advanced development stage and the need for all operative disciplines[70]. In this manner video can also play a role in patient identification, medication safety, infection control, intra operative factors, such as laser safety, monitoring of critical variables. Analysis of these recordings can identify the necessary improvements on this process.

4.3.1.5 Video for adverse events

Adverse events and near misses are difficult to capture, especially those with severe consequences on patient outcomes. Continuous use of video recordings can provide a form of surveillance and allow retrospective review of only those cases with extreme or unexpected outcomes, as demonstrated by Weinger et al[76].

Video data has many applications in the medical domain, including use for research data collection, in support of quality-improvement initiatives. Video can assist in command and control and training, along with recordation and recall of events[49].

4.3.1.6 Video for endoscopic procedures

As mentioned, video technology can be used in a number of ways as a quality system and to support improvements in patient safety in the operating theatre. Video can capture team performance, document technical skills, and be used to analyze system factors. Video as a rich medium and allows systematic and repeated examination of factors impacting on patient care, including instrument setup, patient monitors, sterile practices, operator postures, procedures, and interpersonal interactions.

The introduction of video endoscopic surgery allows video documentation of the operative procedure mainly for educational and training purposes[20].

The endoscopic image can also be a part of the medical patient record. In the article "Recommendations for Quality Control in Gastrointestinal Endoscopy: Guidelines for Image Documentation in Upper and Lower GI Endoscopy" it is proposed that eight images should be taken to illustrate the whole examination[27]. Due to the electronic video endoscopy it is possible to easily take the images during the endoscopic examination.

In our literature review no other references can be found for usage of video in the practice environment of endoscopic surgical procedures. In the training environment GOALS indicates the advantage of video registration. However the general described principles of video registration are also applicable for endoscopy.

Concluding it can be stated that the operating theatre should be a safe, efficient, learning environment for all care providers and patients. Leveraging and harnessing computing and communication technology can be a powerful approach to this objective goal. The ability to record and review events in the operating theatre can be useful for studying team behaviour, the effectiveness of various interventions, or the usability of newly acquired equipment. This will lead to insights into human performance in this high risk setting.

4.4 CONCLUSION

The literature gives an overview of the quality systems that are currently available for the measurement of quality in surgical interventions. We can conclude that currently there are no systematic quality systems available that cover the wide scope of quality factors in surgical interventions; other factors are more important to quality assurance in an operating theatre than video registration.

The quality of surgical interventions depends on such factors, as patient's health, recruitment of surgical team, processes and procedures, professional skills, quality of teamwork, leadership, decision making process, environmental environment, etc.

In our report the emphasis is mainly laid on surgical intervention and on the technical performance of the surgeon. Technical performance specifically consists of surgical knowledge, judgment, and dexterity. It must be emphasized that technical skills are only part of a surgeon's competence, and the assessment of technical skills needs to be integrated with cognitive and behavioural characteristics such as team skills and decision making in order to develop methods that assess surgical competence comprehensively.

Quality improvement needs to be based on systematic measurement and reporting of the key factors that influence the outcome of surgical interventions. The right control actions can be taken, only once measurements of outcomes are sufficient.

Demand for quality control measurement also grows due to legal requirements, required proof by healthcare providers and the need for improved understanding of outcome variation. The bases for reliable reporting are objective and practical measurement and assessment methods.

Several systematic reporting methods specifically for endoscopy have been developed. Although the European and the American society for gastrointestinal endoscopy (ESGE and ASGE) strongly recommend the use of systematic reporting, no verification in the literature can be found that currently systematic reporting is actually used in practice. The British Society of Gastroenterology has extended the global rating scale of the NHS, by adding quality and safety indicators underpinning the respective items of the GRS.

An example of a reporting method is the operation profile, which encompasses the full range of factors implicated in the surgical outcome in the peri-operative period. We have to admit the fact that peri-operative factors especially patient factors influence the surgical outcome, however in this review we focus on the technical performance.

One must bear in mind that reporting of surgical adverse events needs development. Adverse events can be catastrophic for patients, caregivers, and healthcare institutions. Moreover, after medication errors, surgically related errors are the most frequent cause of error-related death. Therefore, it is advisable to systematically report these adverse events, including the near misses.

Poor communication, bad operative technique, malfunctioning or improperly used equipment, cognitive errors due to stress or inattention, and organizational problems all can lead to adverse events. The reporting is valuable in cause analysis and in determining the prioritization in the factors that need to be addressed to reduce these adverse events.

To incite surgeons to report adverse events and near adverse events, incentives should be put in place that outweigh the possible sources of reluctance such as needed extra effort, risk of investigations and even prosecution. Improving quality is one clear benefit for all surgeons; however benefits, impacting the surgeon individually, need further investigation.

Interesting are the developments made in improving the objective assessment of surgical quality in the training environment. Objective structured assessment of technical skills (OSATS) is valuable as it can be used for assessment of procedural and qualitative aspects, using a global rating scale.

In assessing surgical dexterity, which is especially vital in endoscopic procedures, Imperial college surgical assessment device (ICSAD) is a good development. This method, based on electromagnetic motion tracking, can already be used for training purposes. However it is not clear if the sensors placed on the hands of the surgeon may have any hindering effect on the surgeon's performance.

ROVIMAS is more promising as it integrates ICSAD and OSATS together with video registration. The two methods support with each other, focusing on different aspects of quality.

However there is no indication that these developments are systematically used in practice. These assessment methods may be helpful in practice but they require further practical and financial feasibility research.

Measurements are only valuable if they lead to an improvement of the surgical practice. One means of improving quality is the development of guidelines. Evidence based practice guidelines are useful to standardize medical care, improve quality of care, reduce risk and reduce negative differences in patient outcomes.

The ASGE and the ACG had to admit the need of the development of evidence based quality guidelines by themselves, as they fear that otherwise the government, without experience or insight into the practice, will develop these.

Currently there is no register on which guidelines are applied to each individual surgical intervention. This information in combination with data on the kind of the surgical intervention and the patient outcome can be of great importance as they can be used to make recommendations on which guidelines can best be followed in different circumstances. In practice, it is however not possible to impose recommendations as legally mandatory rules, as surgeons enjoy therapeutic freedom for the treatment of their patients (even if these recommendations are acknowledged and valuable from a scientific point of view).

Key points

- **There are no mandatory systematic quality control systems currently in use. Report cards do exist and could enable follow-up of surgical acts, but they are not in use in the Belgium.**
- **However, several concepts and quality frameworks have already been defined in the field of quality: several organizations have developed initiatives to come to an effective measurement of quality for endoscopic procedures by development of standard reports (ESGE, ASGE) ; in the United Sates of America quality indicators for four major endoscopic procedures have been developed to improve patient care ; the National Health Service (UK) has set up a quality framework for endoscopy. The framework uses a global rating scale that allows comparison between local and national peer averages. A Joint Advisory Group monitors this data and audits if need arises.**
- **Video recording is seen by many as a useful record for quality assurance, but cannot be seen as an isolated method ensuring quality.**

5 LEGAL CONTEXT OF VIDEO REGISTRATION

Getting a clear view of the legal context is of key importance for our subject. us, but practical implementation of videoregistration devices also involves the use of data and raises data protection problems mainly addressed by the EU Directive (95/46-EC). Besides, it is essential to know how quality improvement policies are defined and implemented in each EU country (this latter subject being a purely national matter) but also how EU data protection principles are applied in practice (practical implementation of the EU Directive remains a national matter).

For all the reasons mentioned above, this chapter will address the three following issues:

- European standards on confidentiality and privacy in health care
- Belgian legal context
- Foreign legal context

5.1 EUROPEAN STANDARDS ON CONFIDENTIALITY AND PRIVACY IN HEALTHCARE

5.1.1 Introduction

Legal aspects undoubtedly play an important role in the issue of endoscopic video registration since the patient's as well as the Surgeon's privacy is at stake. In this chapter first the general principles of the European legislation on data protection will be elaborated since Belgian and national data protection legislation of the member states is derived from it. Moreover the role and the guidelines set out by the Data protection working party will be highlighted as they are of an utmost importance for the interpretation and implementation of the European Data protection legislation.

5.1.2 Directive 95/46 EC : common European standards

The Directive 95/46 EC aims at protecting the rights and freedoms of persons with respect to the processing of personal data by laying down guidelines determining when this processing is lawful. From a political point of view, its main objective was to strike the right balance between data protection as such and the need for information/ data sharing (which is also necessary).

It is opposable to any EU country, and has been transferred into each Member State's legislation in the late nineties. The key principle of this regulation is to ensure that patients' rights are fully respected when health data are processed. This is thus applicable to all health data, including, *inter alia*, endoscopy pictures.

The **guidelines** relate to the **quality of the data**: personal data must be processed fairly and lawfully, and collected for specified, explicit and legitimate purposes. They must also be accurate and, where necessary, kept up to date.

They also relate to the **legitimacy of data processing**: personal data may be processed only if the data subject has unambiguously given his/her consent or processing is necessary:

- for the performance of a contract to which the data subject is party or;
- for compliance with a legal obligation to which the controller is subject or;
- in order to protect the vital interests of the data subject or;
- for the performance of a task carried out in the public interest or;
- For the purposes of the **legitimate interests** pursued by the controller;
- **Special categories** of processing: it is forbidden to process personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life.

This provision comes with certain qualifications concerning, for example, cases where processing is necessary to protect the vital interests of the data subject or for the purposes of preventive medicine and medical diagnosis;

- **Information** to be given to the data subject: the controller must provide the data subject from whom data are collected with certain information relating to himself/herself (the identity of the controller, the purposes of the processing, recipients of the data etc.);
- The data subject's **right of access** to data: every data subject should have the right to obtain from the controller:
    - confirmation as to whether or not data relating to him/her are being processed and communication of the data undergoing processing;
    - rectification, erasure or blocking of data the processing of which does not comply with the provisions of this Directive in particular, either because of the incomplete or inaccurate nature of the data, and the notification of these changes to third parties to whom the data have been disclosed.
- **Exemptions and restrictions**: the scope of the principles relating to the quality of the data, information to be given to the data subject, right of access and the publicising of processing may be restricted in order to safeguard aspects such as national security, defence, public security, the prosecution of criminal offences, an important economic or financial interest of a Member State or of the European Union or the protection of the data subject;
- **The right to object to the processing** of data: the data subject should have the right to object, on legitimate grounds, to the processing of data relating to him/her. He/she should also have the right to object, on request and free of charge, to the processing of personal data that the controller anticipates being processed for the purposes of direct marketing. He/she should finally be informed before personal data are disclosed to third parties for the purposes of direct marketing, and be expressly offered the right to object to such disclosures.
- The **confidentiality and security** of processing: any person acting under the authority of the controller or of the processor, including the processor himself, who has access to personal data must not process them except on instructions from the controller. In addition, the controller must implement appropriate measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access.;
- The **notification** of processing to a supervisory authority: the controller must notify the national supervisory authority before carrying out any processing operation. Prior checks to determine specific risks to the rights and freedoms of data subjects are to be carried out by the supervisory authority following receipt of the notification. Measures are to be taken to ensure that processing operations are publicised and the supervisory authorities must keep a register of the processing operations notified.

Every person shall have the right to a **judicial remedy** for any breach of the rights guaranteed him by the national law applicable to the processing in question. In addition, any person who has suffered damage as a result of the unlawful processing of their personal data is entitled to receive compensation for the damage suffered.

Transfers of personal data (e.g.: research purposes) **from a Member State to a third country (= outside the EU)** with an adequate level of protection are authorised. However, they may not be made to a third country which does not ensure this level of protection, except in the cases of the derogations listed.

5.1.3 "Article 29" Data Protection Working party (EU)

5.1.3.1 Background

Under the article 29 of the EU Directive 95/46 EC, it was agreed to set up a specific working group called "*Article 29 Data Protection Working Party*", in order to support implementation of the Directive and to organize follow-up of its application.

5.1.3.2 Membership

This working party is composed by Presidents, Directors, or high-level members of national Data Protection agencies of each Member State. The Belgian representative is the President of the "*Commission de la Protection de la Vie Privée*".

5.1.3.3 Key tasks and objectives

This working party has been set up with a view to:

- Providing expert opinion from member state level to the EU Commission on data protection subjects
- Promoting the uniform application of the general principles of the EU directives across all the Member States
- Advising the EU Commission on any measure affecting data protection
- Making recommendations on data-protection / privacy matters

The Article 29 working party covers the whole range of data protection including health data. Health data are set high on their work programme for 2008-2009. Among the latest decisions agreed, the document called: *"**Working Document on the processing of personal data relating to health in Electronic Health Records**"* (adopted on 15 February 2007) is likely to have an impact of the management of health data. , especially related to the **Electronic Health Record** (**EHR**). This document, although not being a regulatory one, is of key importance for future recommendations or reflections on that matter. It also reflects the point of view of all members of the working party, including the Belgian representative (who is the President of the Commission de la Protection de la Vie Privée).

It must be outlined that the EHR as such raises specific problems, in comparison with paper records:

- It enables concentration of health data and thus highly sensitive data in one single data base.
- Technically speaking, multiple access points to the EHR can be easily provided to several health professionals, but also to people who are not always health professionals (e.g. IT technicians or administrator).
- It enables easy transfer and/or dissemination of health data between a potentially large number of professionals (especially considering the use of portable media). This does have positive aspects (improving coordination and thus quality of care) but also negative aspects (increased risk in terms of secrecy and security).

Some basic principles have been reminded by the working paper: **limitation principle** (ie only accurate information have to be selected for storage), **data quality** (data must be updated and handled with care), **accurate retention period** (ie no longer than actually useful).

Given the specific risks brought about by EHR, the Working Party put the following reflections or propositions forward:

- **Reliable identificatio**n of patients and health professionals is of crucial importance in the context of EHR. Specific measures must be taken on that point.
- **Patient consent**: opt-in and opt-out options (or even a complete withdrawal option) should be considered.
- **Secrecy**: data must be processed by health professionals or people who are subject to an equivalent obligation of secrecy.

- **Organisation of EHR systems**: a thorough and comprehensive reflection must be conducted to make a choice between three kinds of EHR models :
  - *Decentralized EHR system*, which implies a reliable search path.
  - *Centralized EHR system*, which is more reliable but more risky in terms of data protection (high concentration of health data in one single data base)
  - *Storage under control of the data subject:* this latter option is attractive from a human point of view, but it is considered as not really satisfying in terms of data accuracy and quality.
- **Data Modules**: given the potentially huge amount of data stored in EHR the working party's proposal is to set out a clear **hierarchy of data** and information. Indeed, all health data are not of the same importance, both from a clinical and privacy point of view (eg HIV status, mental health). Within the framework of HER, different data modules should be set out with specific access **requirements for each of them**.

All the principles set out or reminded by the Working Party are not legally binding, but they are of great importance for long-term implementation of EU Data Protection legislation. Therefore, these key issues should come under intense scrutiny and regular contacts should be taken with the Commission de la Protection de la Vie Privée.

Key Points

- **EU Directive 95/46 CE: corner stone of data protection legislation.**
- **Data transfer and sharing with non EU countries must be considered with care (eg: research or patient exchange).**
- **Integration of other people than health professionals into data processing requires the same level of secrecy.**
- **Belgian authorities should keep a close eye on the activities of the Article 29 working party and keep in touch with the Belgian representative (ie President of the "Commission de la Protection de la Vie Privée").**

5.2 ENDOSCOPIC VIDEO REGISTRATION: BELGIAN LEGAL CONTEXT

5.2.1 Introduction

The registration of the endoscopic surgery could be very interesting for various reasons. First of all the video recordings can optimize the quality of care in the hospital, for instance they can be useful in discussions between peers in the local quality groups. Secondly they can be used for the care of the patient, for example as a tool to discuss the further treatment of a patient in a multidisciplinary team. A third possible purpose for the endoscopic video registration is as educational tool or the use of the data for scientific research. Finally it can also be used as evidence in medical liability cases.

The legal part of the study deals with the question whether and how these purposes of endoscopic video registration can be fitted in into the Belgian legal context. Three principal legislations are being taken into account. Since all endoscopic video data is personal, even medical data, the data protection legislation must be observed. Medical data is also protected by the professional secrecy, stipulated in article 458 Penal Code. Finally patient's rights have to be protected in a hospital environment.

Some other more general legislations (e.g. contract law, civil law) could also be applicable but these are not taken into the scope of this project.

In a first chapter, the applicability of the above mentioned laws, on the issue of video registration will be studied and the main general principles of the three sets of applicable rules will be elaborated. The second chapter will explore these laws from the point of view of the different purposes for video registration.

5.2.2 Legal framework for endoscopic video registration: general principles

5.2.2.1 Data protection laws

Law of December 8th 1992 on the safeguard of privacy concerning the processing of personal data[77] and Royal Decree of February 13th 2001 that executes the law of December 8th 1992 on the safeguard of privacy concerning the processing of personal data.[78]

5.2.2.2 Introduction

These last decades a lot of new technologies and automatic information processing tools were introduced, also in the health care.

Consequently, a lot of data, and in particular personal data are processed in a hospital environment. This evolution raises questions on how to protect the privacy of the patients. The right to a private life is a fundamental right protected not only in the Belgian Constitutional law[g] but also in the European Convention on Human Rights[h].

National and international legislative initiatives were taken in order to protect the private life in this new technology world.

In 1992 Belgium enacted the "Law on the protection of privacy concerning the processing of personal data", hereafter named LPPD[77]. The European Parliament promulgated in 1995 Directive 95/46/EC with the intention to harmonize national initiatives.[80] In 1998 the Belgian legislator implemented the Directive into the LPPD.

5.2.2.3 Scope

The LPPD is ratione materiae applicable "for each totally or partly automated processing of personal data as well for each non-automated processing of personal data which are stored in a file or are destined to be stored in such a file" (Art. 3, § 1 LPPD).

In order to determine if the endoscopic video registration falls within the scope of the LPPD, at least three questions need to be answered[81]: is the endoscopic video data personal data (1), is the personal data being processed (2) and is the processing automated (3)? If these questions get a positive answer, the LPPD is applicable.

Personal data

Personal data is defined in the LPPD as "each information regarding an identified or identifiable natural person". The notion 'data' is not defined in the law, but it is very broad[82]. The 'Article 29 data protection working party' states that the concept of personal data includes information available in whatever form[83]. It includes information kept on paper, as well as, information stored in a computer memory by means of binary code, or a videotape, for instance.

It is everything that can be observed or stated[81]. Not only texts like medical reports, but also photographs, video images (consideration 14 of Directive 95/46/EG)[84], etc qualify as personal data[85-88].

Personal data also needs to be "identified or identifiable". This is the case if the person can be identified, directly or indirectly, by means of identification number of by one or more specific elements characteristic of one's physical, physiological, psychological, economical, cultural or social identity .(Art. 1 § 1 LPPD)

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g Art. 22 Constitutional law[79]: "Ieder heeft recht op eerbiediging van zijn privé-leven en zijn gezinsleven, behoudens in de gevallen en onder de voorwaarden door de wet bepaald. De wet, het decreet of de in artikel 134 bedoelde regel waarborgen de bescherming van dat recht.",

h Art. 8 European Convention for the Protection of Human Rights and Fundamental Freedoms: "Article 8 . Right to respect for private and family life 1 Everyone has the right to respect for his private and family life, his home and his correspondence., 2 There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others." http://www.echr.coe.int/NR/rdonlyres/D5CC24A7-DC13-4318-B457-5C9014916D7A/0/EnglishAnglais.pdf.

Data regarding a person is personal data in the sense of LPPD as long as somebody is capable to retrieve the identity of the person in question, taken into account that only means within reasonable limits can be used[88, 89] .[i]

If the data is protected by a code, so only the one that holds the code key, is able to link the data to a person, this 'enencoded' data is also defined as personal data. Enencoded data falls within the scope of the LPPD because identification using reasonable means is still possible[88, 92] (Art. 1 §3 Royal Decree of February 13th 2001 that executes the law of December 8th 1992 on the safeguard of privacy concerning the processing of personal data, hereafter RD LPPD).[78] When data is anonymous, i.e. if identification of the person that is object of the data is no longer possible using means within reasonable limits, the LPPD not applicable (Art. 1, 5° RD LPPD) [81, 89].

It should be noted that endoscopic video data are or can easily be linked to the surgeon that has performed the endoscopy. This information can also be considered as personal data of the surgeon (cfr. Infra).

Special categories of personal data: personal data concerning health

The LPPD determines not only general restrictions and requirements, but institutes also a stricter protection regime for special categories of data, namely sensitive data, data concerning health and legal data[j][81]. If the personal data can be classified in one of these categories, these stricter regulations have to be observed on top of the other rules stated in the LPPD[81].

The LPPD defines medical data as "personal data regarding health." (Art. 7, § 1 LPPD). This definition refers to all personal data related to the past, present or future physical, or psychological health condition of the involved data subject[81, 93]. The notion "concerning" in the law, implies that the personal data must be related directly to the health of the data subject. If processing personal data only gives an indirect idea about the medical condition as a side effect[k][81], then this data is not considered as medical data and therefore only the general rules apply and not the specific rules applicable on the special categories of personal data[81]. The European Court of Justice has decided that data concerning health must be given a wide interpretation so as to include information concerning all aspects, both physical and mental, of the health of an individual[94].

As a rule, processing data that can be categorized in one of these three groups is prohibited (Art. 6, § 1, Art. 7, § 1, Art. 8, § 1 LPPD). But the LPPD describes well-defined cases in which this general prohibition does not apply (Art. 6, § 2, Art. 7, § 2, Art. 8, § 2 LPPD). If one of these exceptions on the prohibition is applicable, the processing of the data also satisfies the condition of a legitimate purpose required by article 5 LPPD[81]. Below these cases will be discussed from the point of view of the different purposes of the video registration of the endoscopic surgery.

Since the endoscopic video registration data reveal direct information concerning the patient's health, it is a special category of personal data, namely medical data. Consequently not only the general regulations of the LPPD must be observed, but also the specific rules stated in the LPPD and Royal Decree executing this law.

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[i] Consideration 26 of Directive 95/46/EG[90] and Exploratory Memorandum on the bill to conversion of Directive 95/46/EG of October 24th 1995 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data, *Parl. St.* Kamer 1997-1998, nr. 1566/1, 12[91] (hereafter named Exploratory Memorandum LPPD).

[j] These special categories are described in art. 6, 7, 8 LPPD. The terms 'sensitive and legal data' are not used in the LPPD but are commonly used in literature to refer to the data referred to in article 6 and 8 LPPD.

[k] For example: a picture of a person taken for reasons that have nothing to do with health (conditions), can nevertheless reveal a physical disability and thus reveal indirect information concerning health.

Automated processing

The notion "processing" is defined in the LPPD as "each operating or each totality of operatings regarding personal data, whether accomplished by means of automated procedures or not, like collecting, recording, grouping, saving, correcting, changing, requesting, consulting, using, providing by means of redirecting, dispersing or in each possible other way providing, assembling, combining, as well for protecting, erasing or destroying of personal data" (Art. 1, § 2 LPPD). Out of this very broad definition, one can conclude that any manipulation of personal data can be seen as processing this data[92, 95].

Endoscopic video data will be collected, recorded, stored, consulted, archived transmitted, etc. In case of video recording, data are processed in the sense of the LPPD.

The handling of the data is automated if automated means are used[81]. The registration of the endoscopic surgery, is an automated process. Also the archiving and consultation is automated.[l]

Key points

- **The collecting, recording, storing, consulting, archiving and transmitting of non anonymised endoscopic video data falls within the scope of the LPPD**
- **Moreover endoscopic video data are medical data, so the stricter regulations applicable on special categories of personal data are applicable (cfr. 5.2.2.7.)**

5.2.2.4 Lawfulness of processing personal data

The LPPD determines a set of rules that can be labelled as principles related to data quality (Art. 4 LPPD)[81]. Those rules comprise the basic principles concerning the protection of the private life.

The first principle can be described as data must be processed fairly and lawfully (Art. 4, § 1, 1°, LPPD). Fairly implies transparency of the processing[81]. The data subject must be acquainted of the fact that his personal data will be processed and with what purposes and this at the latest[m] when the data are gathered. He must be informed by 'the person/entity responsible for processing'.[n] The requirement 'lawfully' draws the attention to the fact that the processing has to comply with all other regulations stated in the LPPD[81].

If the data subject is sufficiently informed by the data controller and if all requirements stated in the LPPD are fulfilled, the processing of the endoscopic video registration is allowed.

Secondly the personal data must be collected for legitimate purposes. This rule requires first of all specific, explicitly described purposes for the processing, then legitimate purposes and finally the prohibition as a rule of further purposes[81] of processing data beyond the original, expressively described and legitimate purposes (Art. 4, § 1, 2° LPPD) [81]. To assess if these requirements are satisfied, all relevant factors are taken into account, for example the reasonable expectations of the data subject and all applicable laws and standards (Art. 4, § 1, 2° LPPD). The description 'the personal data is collected for all useful purposes' and the processing without a specific purpose or only an implicit purpose do not satisfy these requirements[81].

Subsequent processing for historical, statistical or scientific purposes, that are not compatible with the original purpose of processing is allowed if the specific provisions of chapter two of the Royal Decree are respected.

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[l] See also technical part of the study.

[m] This requirement results from article 9 LPPD stating that the information concerning the processing should be given to the data subject at the latest when the data are collected from the data subject or from somebody else.

[n] Art. 9, § 1-2, LPPD determines which information should be provided in case of information obtained from the data subject or from another source.

When processing endoscopic video registered data, the patient undergoing the endoscopic procedure has to be informed about all possible purposes of this registration. Important are the expectations of the patient. If the patient knows his data will be processed for quality purposes, he will expect that it can be used for different projects involving quality.

A third rule is the principle of proportionality; the processed data must be adequate, relevant and not excessive, taken the purposes of the processing into account (Art. 4, § 1, 3° LPPD).

Endoscopic video registration can be considered as a proportional measure to pursue the four purposes defined above.

The LPPD requires also accurate and up-to-date data to process (Art. 4, § 1, 4° LPPD). This continuous quality assurance and duty to take all necessary steps to ensure that inaccurate or incomplete data will be erased or rectified, is a perpetual obligation for the 'person responsible for the processing'.

Endoscopic recorded video data is in itself static data. So once the surgery is recorded, the data will be up-to-date and accurate provided that it is stored and archived properly. In case this video data will be linked to other patient data, the data controller has to make sure the right data is related to the right patient.

Finally the LPPD prohibits keeping identified or identifiable longer than is necessary for the purposes for which it was collected (Art. 4, § 1, 5° LPPD) [81]. Again, there is an exception for the further use for historical, statistical or scientific purposes on condition that the regulations of the Royal Decree are observed.

Key point

- **Data must be processed fairly and lawfully, must be collected for legitimate purposes and must be adequate, relevant and not excessive, taken the purposes of the processing into account**

5.2.2.5 Roles and responsibilities in the LPPD

In the previous chapter we have taken the position that the LPPD is applicable on endoscopic video data if the data is not completely anonymous. The question dealt with in the next section is who is responsible for the endoscopic video registration data. The LPPD defines on one hand the data controller and on the other the processor.

Data controller

The 'controller' is the person(s) or entity who determines the purposes and the means of the processing of the personal data (Art. 1, § 4 LPPD). These conditions are cumulative[81].

As mentioned before, endoscopic video registration can serve different goals. Depending on these goals, the data controller can differ. Moreover it is also possible that a different choice is made per hospital.

From the point of view of quality improvement, there are different possibilities. In a following chapter there will be argued that the hospital manager, the medical board, the head physician and the departmental head physician each play a role and have a responsibility in the quality assurance in a hospital. Hence, in theory all these entities can be the controller because the initiative and thus also the determination of the purposes and means can be done by either of these people. If the endoscopic video registration data is going to be used for educational purposes, namely for the training of future surgeons, it makes sense to give the responsibility to the individual surgeon using the data. It can also be argued that the hospital management is responsible in university hospitals since those surgeons are employees. The third possible purpose of the endoscopic video registration is to collect evidence for medical liability cases. In this case a possible choice could be the hospital management.

One could argue that the hospital manager as data controller is the most logical choice since this entity has the general and the final responsibility for the hospital activities not only for the functioning and the finances but also for the organisation of the hospital (Art. 11 Law of August 7th 1987[96] on hospitals, hereafter named Hospital Law)[93, 95, 97]. Then he is the one to determine the purposes and the means of the registration of the endoscopic surgery.

The data controller has an elaborated responsibility since he must ensure that all obligations and all stipulations stated in the LPPD are respected (Art. 4, § 2; Art. 9 § 1-2, Art. 10 § 1 Art. 15 bis LPPD) [81, 88, 92, 97]. He is liable if the data subject suffers any damage by infringement of stipulations imposed by the LPPD unless he proves that he cannot be held responsible for the suffered damage (Art. 15 bis LPPD). The LPPD assigns a set of rights to the data subject. Each of these rights corresponds with an obligation of the controller [81].

The data controller has also quite some obligations with regard to security and confidentiality. These set of rules require technical, organizational and administrative measures and are elaborated in the LPPD (Art. 16 LPPD).

The Royal Decree stipulates additional responsibilities for the data controller in case medical data is processed (Art. 25 RD LPPD).

Databases, comprising an intellectual creation by an author by the choice or the organization of the elements of the database are protected by copyright[o]. The author of the database is the employer, or in case of video registered data the hospital (manager) and not the employees who created the database, except if stipulated otherwise[p]. Moreover the law concerning the transposition of the European Directive on the legal protection of databases formulates the rights of producers of databanks and regulates the use of databanks for third parties.[q]

Processor

The 'processor' is a person or an entity which processes the personal data, for the benefit of the 'controller', the people under direct responsibility excluded (Art. 1, § 5 LPPD).This definition implies that an employee, processing data, working within the organisation is no processor in the sense of the LPPD. If an IT company or a provider of endoscopic recording material would process data, those entities are processors.

The relation between the controller and the processor is described in the LPPD (Art. 16 LPPD).

5.2.2.6 Rights of the data subject

The LPPD assigns a set of rights to the data subject. As already discussed before, the processing has to be fairly which implies transparency. This means first of all that the data subject has the right to be informed on the name and the address of the controller, the purpose(s) of the processing, the recipient(s) of the data, the fact that the patient has the right to access and to correct the data (Art. 9 §1).[r] There are exceptions[s] on the obligation to provide information. However they seem not to be applicable to video registration.

Moreover the patient has, at his request, the right to be informed on the existence of processed data, the logics of the processing, the existence of the right to appeal and the right to access (Art. 10, § 1 LPPD).

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o Art. 20bis Law of 30 June 1994 concerning copyright and neighbouring rights[98]

p Art. 20ter Law of 30 June 1994 concerning copyright and neighbouring rights[98]

q Law of 31 August 1998 concerning the transposition of the European Directive of 11 March 1996 on the legal protection of databases[99]

r For the enumeration of the information that should be provided to the data subject, please see art. 9, § 1 LPPD.

s Namely if the notification appears impossible or requires a disproportional effort in case of processing for the historical, statistical or scientific research purposes or for the purpose of public health or in case the registration of the provision of the personal data is done with a view to the satisfaction of a provision imposed by or under a law, decree or ordinance. (Art. 9 LPPD.)

For medical personal data, like the endoscopic video registration data, a specific right of access applies (cfr. Infra for the modalities of the right to access) (Art 10, § 2 LPPD).

Next to the regulations described in the LPPD, the Patients' rights act also institutes a right to access, applicable if the medical data is part of the medical file (Art. 9, § 2 Law of August 22nd 2002 concerning the rights of the patients, hereafter named LPR)[100]. As will be discussed further on, non anonymised endoscopic video registration data must be considered as part of the medical file.

A third set of rights are described in article 12 of the LPPD. There is the right to have inaccurate personal data rectified, the right to erase certain data or to prohibit the use of the data and the right to object to the processing (Art. 12, § 1 LPPD). The procedure (Art. 12 LPPD and Art. 32-33 RD LPPD) that has to be followed is also specified in this law.

An important remark must be made on the concept of data subject: even if patients are always data subjects, one must bear in mind that any person, especially a health professional, can become a data subject as well. Indeed, registered video images relate not only to the patient's state of health, but also to the surgeon's own work. Therefore, these data become the surgeon's data, and the surgeon becomes a data subject.

Hence, all the rights described above, especially access to data, are apt to be applied to surgeons participating in video registration of endoscopic data. Hospital managers and health care authorities must be fully aware of this constraint. Health professionals must be fully aware of these rights as well. Information by the hospital management on that point should be recommended (cfr. Infra)

Key points

- **The 'controller' is the person(s) or entity who determines the purposes and the means of the processing of the personal data. Depending on the purpose of video registration this can be the surgeon, the hospital manager, the medical board, the head physician or the departmental head physician.**
- **The 'processor' is a person or an entity which processes the personal data, for the benefit of the 'controller', the people under direct responsibility excluded. IT companies or data providers are processors, except if they are employees of the controller.**
- **The LPPD specifies a set of rights for the data subject such as the right to be informed on the name and the address of the controller, the purpose(s) of the processing, the recipient(s) of the data, the right to access and to correct the data. The patient as well as the surgeon who performed the endoscopy can be considered as data subjects, since they can be linked to the recorded data. The person concerned has to right to informed consent to the processing of his/her personal data.**

5.2.2.7 Processing medical data

If the personal data can be classified as a special category of data, namely the sensitive, medical or legal data, stricter regulations must be observed. Since endoscopic video data is medical data, we will discuss only those rules applicable to personal data concerning health care.

Prohibition of processing as a rule

As a rule, processing medical data is prohibited (Art. 7, § 1 LPPD). But the LPPD describes well-defined exceptions (Art. 7, § 2 -5). Below we will discuss these exceptions, from the point of view of the four purposes.

Processing under responsibility of health care professional

Medical data can only be processed under the responsibility of a health care professional (Art. 7, § 4, LPPD). The notion of health care professional is not described in the law, but the King has the authority to determine which categories of persons can be considered as health care practitioners.t So far the King has not promulgated a Royal Decree on this subject. There is however diversity of opinion if the notion health care professional should be interpreted broadly.

According to some it encloses all persons who provide care professionally and thus it covers more than just practitioners in medicine[81].

The rule, that the medical data can only be processed under the responsibility of a health care professional, is not absolute, since exceptions are possible, namely in case of written consent of the data subject or when it is necessary for the prevention of a real danger or for the suppression of a specific criminal offence (Art. 7, § 4, LPPD) [81].

Legally, it is possible that technicians or other non health care practitioners process medical endoscopic data without the supervision of a health care professional if the data subject gave his written consent. The sectoral Committee of Social Security and Health Care (= department of the 'Privacy Commission') however states that personal data in general and as much as possible should be processed under the supervision of a physician.[101]

The health care practitioner, his appointees and authorized representatives are bound by secrecy (Art. 7, § 4, section 3 LPPD). Instead of referring to existing professional secrecy rules, the legislator has chosen to create an independent obligation to secrecy[81]. The violation is punished by criminal sanctions[u81]. This professional secrecy, as stated in the LPPD, does not detract from other obligations to secrecy stipulated in the Criminal Code or in deontological documents. Only the most severe punishment pronounced by the jurisdiction for the violation of the professional secrecy stated by Art. 458 of the criminal code and by the LPPD for the violation of Art. 6, 7 or 8 will be enforced. The enforcement of the most severe punishment however is an application of the notion "ideal course": when the intent of different offences is the same, the most severe punishment will be then enforced (Art. 65 Criminal Code). It has to be stressed that the judge has his own assessment and can choose between a penalties range.

Health care data must be collected from the data subject

The LPPD stipulates that medical data must be collected from the data subject (Art. 7, § 5, LPPD). It can only be obtained from other sources in case the data subject is not capable to provide the health care data or if this is required for the purposes of the processing. This rule has the intention to prevent that medical data would be collected from various sources, for instance from other health care providers without any control by the data subject. [91] Endoscopic video data is primarily always collected from the patient.

Specific right to access

As stated before, the LPPD stipulates a specific right of access the him/her concerning processed medical data (Art. 10, § 2, LPPD). When these medical data are part of a patient file, the Patients' Rights act is also applicable. If the medical data are no part of the patient file, the provisions of the LPPD described below are applicable if all conditions are fulfilled (Art 10 §2 LPPD). [84].

The right to access specified in the LPPD can be direct and thus exercised by the data subject himself or can take place with the help of a health care provider (Art. 10, § 2, LPPD). A deviation of this direct right is only possible upon the request of the data subject or the data controller. In that case the access must be exercised with intervention of a health care professional (Art. 10, § 2, LPPD) [81].

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[t] Ibid.

[u] The obligation of professional secrecy is mentioned in art. 6 §2, in fine, art. 7 § 4 in fine, art. 8, §3 LPPD. Art. 39, 3° LPPD provides sanctions for the violation of the art. 6, 7 and 8

If the data are part of the medical file, the patients' rights act stipulates that there's a direct right to access[v] (Art. 9 § 2 LPR). If both legislations are applicable, the disposition of the patients' rights act has to be applied since the LPPD explicitly refers to the application of the patients' rights act. Hence, even if the controller requests the intervention of a health care professional, the patient will have a direct access to the patient file.

The communication of the information can be postponed in a number of conditions. First of all if there's no danger for the private life of the data subject and secondly if data cannot be used to take measures or decisions with regard to the data subject (Art. 10, § 2, LPPD). Thirdly the data needs to be processed for purposes of medical scientific research.[w]

The communication of the data must also seriously interfere with the research and the communication can only be postponed at the latest until the end of the research.[x] Written consent of the data subject is required stating that he agrees to the postponement of communication for medical scientific purposes.[y]

Additional obligations for the data controller in case of processing medical data

The data controller has to indicate the categories of persons which have access to the medical data, in this case to the endoscopic recordings (Art. 25, 1° RD LPPD). This list of categories needs to be at the disposal of the Privacy commission (Art. 25, 2° RD LPPD). He has to make sure that all categories are bound by legal or at least contractual confidentiality (Art. 25, 3° RD LPPD). It's conceivable that IT and technical staff can also be bound by professional secrecy as they are necessary collaborators in the process. Even if they are not bound by professional secrecy however they are submitted to the legal duty to discretion if they work as employees (art 17 3°, a), Law of July 3rd 1978 concerning labour contracts[102]). Disclosure of patient data can also be considered as a violation of the general standard of care (Art. 1382 Civil Code) applying to every citizen. Moreover contractual confidentiality clauses can be stipulated. The data controller must also inform the patient of the cases in which the processing is allowed (Art. 25, 4° RD LPPD). This information must also be mentioned in the prior notification to the Privacy Commission (cfr. Infra).

Key points

- **Medical data can only be processed under the responsibility of a health care professional, except in case of written consent of the data subject or when it is necessary for the prevention of a real danger or for the suppression of a specific criminal offence.**
- **Medical data must be collected from the data subject, except in case the data subject is not capable to provide the health care data or if this is required for the purposes of the processing.**
- **The patients' rights act specifies a direct right to access to the patient file whereas the LPPD provides an exception to the right to direct access him/her concerning processed medical data in case the controller requests the intervention of a health care professional. In case both legislations are applicable, the disposition of the patients' rights act prevails.**
- **If medical data are processed the data controller has to indicate the persons having access to the medical data and he has to guarantee that the data are treated confidentially by his personnel. Moreover he has to inform the patient on the legal ground justifying the processing of the medical data.**

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[v] more details on the modalities of the right to access specified by the LPR cfr. infra

[w] Ibid.

[x] Ibid.

[y] Ibid.

5.2.2.8 *Prior notification to the privacy commission*

The data controller has to notify the Privacy Commission in case of automated processing of personal data and he has to do this before the processing (Art. 17, § 1 LPPD). The content of this compulsory notification is enumerated in the LPPD (Art. 17, § 3 LPPD). As mentioned before, there is an additional content related rule to follow for processing data of a special category, the so-called sensitive data (Art. 25, 4° RD LPPD). In the notification the legal ground(s) justifying the processing of this sensitive data which is in principle prohibited is described. If the processing of the same data, serves more than one purpose, all purposes will have to be mentioned in the notification. Related to this it is also possible to make the necessary arrangements in the privacy policy document in the hospital.

If one wants to register the endoscopic surgery on video, notification stating the legal grounds of processing this medical data is required. The person responsible for the processing of this data, is obliged to notify every individual purpose of the endoscopic video registration.

Next to the notification to the Privacy Commission legislation[z] (which however did not yet enter into force) stipulates that an authorization of the Sectoral Committee of Social Security and Health[aa] (which is part of the Privacy Commission) for the transfer of medical data (as defined in the LPPD) is needed. The law however formulates some exceptions. Applied to videoregistration this implies that if images are transferred in the scope of research for quality improvement, the data controller has to launch a procedure in order to obtain authorization for transfer. If images are exchanged in the therapeutic relationship with the patient by health care professionals bound by professional secrecy, this authorization is not needed. The demand for authorization has to specify amongst others the objectives of the use of the images, a justification, the modalities of use and storage, privacy and safety guarantees.

Key point

- **Endoscopic video registration requires a notification to the privacy commission. The purposes for processing have to be specified.**

5.2.2.9 *International data exchange*

The LPPD regulates also the transfer of personal data to countries outside the European Union. The transfer to third countries can only take place if this country ensures an adequate level of protection (Art. 21, § 1 LPPD). This prohibition of transfer to countries without sufficient guarantees to protect the personal data is no absolute rule, since the LPPD enumerate instances in which the transfer is allowed to countries without an adequate level of protection (Art. 22 LPPD).

If one has endoscopic video registration data at his or her disposal, the use of this data outside the hospital doors, even outside the country or the European Union is a small step. However the right to a private life has to be protected maybe even more if a patient is treated at a distance. These last years telemedicine[104] is coming on. In this situation the need for transparency is even more important than in a classical treatment relation[105]. The surgeons having (electronically) data collected at a distance at their disposal can very easily use this data for purposes not related to the treatment of the patient, like for instance for education or scientific research[105]. As will be discussed later the patient needs to be informed of this further use.

5.2.2.10 *Additional regulations for the secondary processing of personal data for historical, statistical and scientific purposes*

The concept of secondary processing is not defined as such in the legislation. However its meaning can be derived from Art. 4 § 1, 2° of the LPPD and to Art. 6.1. B. of the Directive 95/46/EC.

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z Art. 70 Law of 1 March 2007 on diverse provisions[103]

aa http://www.privacycommission.be/nl/sectoral_committees/social_security/

The note to the King linked to the RD LPPD[106] states that the concept refers to the situation where the data controller in the scope of his normal and legitimate activities wishes to re-use the data himself or to transfer the data in the scope of historical, statistical of scientific research.

Secondary processing of personal data with another purpose than the initial purpose can only be legally performed in the following conditions:

- Secondary processing of which the purpose(s) is/are compatible with the purpose of the primary processing. The regulations applicable to the primary processing will be applicable.
- Secondary processing of which the purpose(s) is/are not compatible with the purpose of the primary processing. In this case the secondary processing is only allowed for statistical or scientific purposes complying with the stipulations of chapter II of the RD LPPD.

A compatible purpose is a purpose that falls within the expectations of the data subject or that can be considered as compatible based on legal grounds.

The specific stipulations of Chapter II RD LPPD specify a cascade principle: as far as possible anonymous data have to be processed. In that case the LPPD is not applicable since anonymous data can not be linked to a person and consequently do not risk violation of privacy. If personal data can not be anonymised, encoded data have to be processed. Encoded data is protected by a code, so that only the one holding the code key is able to retrieve the identity of the data subject[81].If the data can not be encoded, non-encoded data can be used. Since in case of videoregistration of endoscopic surgery solely the use of anonymous or encoded data are at stake, the dispositions on the treatment of non-encoded data will not be studied in the report.

Justification for the use of the respective (encoded or not encoded) data has to be provided in the notification to the Privacy Commission. Chapter II provides a specific procedure for the notification to the Privacy Commission for the encoding and the secondary treatment of encoded data (cfr. infra). For the use of encoded data, additional obligations are elaborated in the RD LPPD related to the researcher, the data supplier and the encoding need to be observed (Artt. 7-17 RD LPPD). The encoding needs to take place before the processing and is done by the data controller or by an intermediary association (Third Trusted Party-TTP) (Art. 8 RD LPPD). If different controllers transfer the data to a same third party for secondary processing, the encoding needs to be done by a third trusted party (Art. 10 RD LPPD). If video recording will be legally imposed, different hospitals will have to transfer the data to the government. Consequently, a TTP will have to encode the data before the transfer.

If the encoded data is medical data, the data subject has to be informed on the identity of the data controller, the categories of treated data, the source of the data, a precise description of the historical, statistical or scientific purposes, the addressees of the data, the right to access of his personal data and the right to correct them, the right to oppose (Art. 14 RD LPPD). If informing the data subject would be impossible, a disproportionate effort or in case the intermediary association is an official body the previous information requirements do not have to be accomplished. (Art. 15 RD LPPD). In that case however the notification to the Privacy commission has to be completed with the following information: the precise description of the historical, statistical or scientific purposes of treatment, the reasons justifying the treatment of medical personal data, the reason why the information mentioned in Art. 14 RD LPPD could not be notified to the data subject, the categories of persons whose medical data will be treated, the persons or categories of persons that are allowed to consult the data, the source of the data. The Privacy commission will send a recommendation 45 days after the receipt of the notification. If not, the notification is estimated to be accepted. The term of 45 days can be prolonged once for another term of 45 days (Art. 16 RD LPPD).

5.2.2.11 Patient's rights: Patients' rights act August 22nd 2002

Before 2002, the legal protection of patients in Belgium was quite fragmented and incomplete[107-112]. But in 2002 the different rights of the patients have been centralized and formalized in the patients' rights act. First we will discuss the scope and more particularly the applicability of the law on endoscopic video registration. Then we will discuss the dispositions of the patients' rights act that are most relevant for video registration of endoscopy.

5.2.2.12 Scope

The first question is if the patients' rights act will have to be taken into consideration if one wants to record the endoscopic surgery. The law is applicable on "(contractual and extra-contractual) private law and public law determined legal relations concerning healthcare provided by a professional to a patient" (Art. 3, § 1 LPR) [84, 109, 113].

In order to investigate the applicability of the Law on patients Rights on endoscopic video registration, a good understanding of the terminology is essential. 'Health care professionals' are the people enumerated in the Royal Decree number 78 (Royal Decree 78 of 10 November 1967 concerning the practice of health care professions, hereafter named RD nr. 78)[114] and the non-conventional practitioners as mentioned in the Law of 29 April 1999 related to the exercise of non-conventional medical practices[115]. The notion 'patient' refers to the person who receives health care, on his request or not on his request (Art. 2, 1° LPR). It is obvious that the most important health care professionals involved in the endoscopic surgery and thus also in the registration of this procedure are surgeons and nurses. Both these groups of professionals fall within the scope of Royal Decree nr. 78. The patients' rights act is applicable to the relation between the patient and the surgeon as well as between the patient and the hospital as far as medical, nursing and other health care aspects are concerned (Art. 17novies, first section Hospital Act). Other aspects such as food, hosting, administration etc. fall out of the scope of the patients' rights act.

The question open for discussion is whether the registration of the endoscopic surgery falls under the notion 'health care' as defined in the LPR. This expression is described in the LPR as 'all services provided by a health care professional with the intention to stimulate, assess[bb], maintain, recover and improve the health condition of the patient' (Art. 2, 2° LPR).

Obviously, the purpose of the service does not necessarily have to be therapeutic. One of the purposes can be to assess the health condition of a patient. Video registration is often used to assess the patient's health condition, e.g to qualify the surgical intervention or diagnosis, to provide information for upcoming surgical procedures to patients, to enable second opinions by external experts independent of their location or time. Consequently a recording made to assess the health condition of the patient is "health care" as defined in the LPR. Moreover the concept of "services" is not defined in the LPR and has to be interpreted broadly. There is no specification on the used method. Even if a distinction can be made between the means (video registration) and the results (obtained medical data), they are linked. Consequently the LPR applies to video registration if it is used to assess the health condition of the patient, for a therapeutic purpose or for any other purpose mentioned in Art. 2,2° LPR. Even if the final use of the taped data is different from the care or the assessment of the health of the individual patient, endoscopic interventions are always videotaped in the medical relationship between the surgeon and the patient in which the primary purpose is the care for the patient. Consequently one can argue that the patients' rights act applies even in case the final use or the secondary purpose is not a therapeutic purpose or a purpose mentioned in Art. 2,2° LPR (e.g. a scientific purpose, quality management,..).

Several rights are enumerated in the patients rights act, namely the rights of: Information (Art. 7), free and informed consent (Art. 8), direct access to the patient file and the right to have a copy of it (Art. 9), protection of private life (Art. 10), mediation (Art. 11) and representation (Art. 12 to 15).

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bb This has to be understood as in the usual language

The central liability of the hospital could also be applicable in the conditions of Art. 17novies of the hospital law, coordinated on the 7th of august 1987. In the following listing of patients' rights only those that are of major interest for videoregistration of endoscopies will be elaborated.

5.2.2.13 The right to be informed (Art. 7)

The Patients' rights act regulates the right to information about the health status (e.g. the diagnosis). The right to be informed about the health status has to be distinguished from the right to informed consent. Whereas the right to informed consent is linked to a decision, the right to information about the health status is not. The patient has the right to be informed by the health care provider about all information concerning him/her that is required to understand his health status and the probable evolution. The information has to be communicated in a clear language. In principle information is given orally but the patient can request that the information will be confirmed in writing.

Information can be withheld to the patient on his own initiative (right not to know), except if this causes obviously serious damage to the health condition of the patient or third persons and on condition that the physician consulted an other health care professional and the confidant, if there's one (Art. 7 § 3). The request of the patient has to be noted in the patient file.

Information can also be withheld on the physician's initiative (therapeutic exception) if the communication would cause obviously serious damage to the health condition of the patient and on condition that the physician consulted an other health care professional. The physician has to add a written motivation to the patient file and if need be informs the patient's confidant (Art. 7 § 4).

As medical information on the health status can be derived from the endoscopic registered images, the patient has the right to this information.

5.2.2.14 The right to informed consent (Art. 8)

The right to informed consent can be derived from the right to physical integrity and to self-determination. The right to receive information prior to consent concerns every medical intervention. According to the content of the information a non exhaustive list is enumerated by the law: The patient has to be informed about the nature, the purpose, the urgency, the frequency, the follow – up care of the intervention, the relevant contra indications, the risks and the side effects of the intervention, alternatives and the financial information. In the scope of video registration, the patient should first of all be informed on the fact that the endoscopy will be taped and the modalities and purpose(s) of taping.

The explanatory memorandum of the law states that consent has to be given explicitly, except when the physician, after having sufficiently informed the patient, can reasonably deduce from the behaviour of the patient that he/she consents.[116] Explicit consent implies that consent can be given orally as well as written. The intention of the legislator was to promote oral consent in order to prevent the increasing use of consent forms, because of the risk of standardisation and uniformisation.

Patients as well as physicians however have the right to ask for a written consent form that will be added to the medical file. If the patient refuses to give a written consent, while the physician thinks that a written consent is necessary, the refusal can be noted in the patient's medical file. It has to be stressed that the signature of the patient can only be regarded as valid if the patient has inspected or could reasonably inspect the information. Extremely technical or unclear forms do not meet this condition. Moreover information has to be given in advance and timely.

5.2.2.15 The right to access to the patient file

The LPR stipulates the right to an accurate and carefully stored patient file from the health care professional and the right to add documents to the file (Art. 9, § 1 LPR). Above that the patient has a direct right[108, 117] (Art. 9, § 2, § 3 LPR) to access to the file and to a copy of the entire or a part of the file (Art. 10, § 2 LPR). The reason of existence of these rights is principally the protection of the patient's privacy. It enables the patient to verify the data in the patient file and thus protect his private life.

The right to access can on no account be considered as a surrogate for the default in the right to information (as expressed in Art. 7 and 8 LPR).

The modalities of the right to access are also defined (Art. 9, § 2 LPR). Access has to be permitted at the latest within 15 days following the request. Personal notes made by the health care professional and data related to third parties are excluded from access.

Only if he decides it, the patient can be assisted by a reliable person who may or not be a health care professional. The request to be assisted has to be written and the identity of the reliable person is has to be added to the patient file. If this person is a health care professional, this person is also allowed to consult the personal notes of the practitioner. The patient can also decide that the reliable person can consult his patient file, without his/her presence.

Exceptionally a physician may withhold information on the health status of the patient, if there are clear indications that providing this information would cause obviously serious harm to the health situation of the patient. He can do this after having consulted a colleague – physician. This is called the therapeutic exception (Art. 7 § 4, 1st section). If a therapeutic exception was noted in the patient file, the patient can only have indirect access to his patient file via the physician that he or she has designated (Art. 9 § 2, section 4). This physician has also access to the personal notes.

After the patient's death the spouse, the legally cohabiting partner, the partner and the relatives till the second degree, have an indirect right via a physician designated by the requestor as far as the request was sufficiently motivated and specified and the patient didn't have explicitly opposed to it during life. This health care professional has also access to the personal notes of the practitioner.

The patient has the right to obtain a (direct or indirect in case of therapeutic exception) copy of his patient file. The physician can refuse to give a copy if he has clear indications that the patient was put pressure on to provide a copy of the patient file to a third party**.** In the scope of the protection of private life of the patient, the concerned physician can refuse the request of the mandatary[cc] or the representative[dd] to access or copy of the patient file (Art. 15 § 1). In that case the right to access or a copy is exercised by a health care professional that is designated by the mandatary or representative. The physician having refused access or a copy of the patient file has to add a written motivation to the patient file (Art.15 § 3)

The maximum price per page may not exceed 0,10 € and 5€ per image (Royal Decree of 2 February 2007 determining the maximum amount per copy that can be required from the patient in the scope of the right to obtain a copy of the patient file[118]). If one or more pages or images are copied to a digital carrier, the maximum amount is 10 €. Per request the total amount may not exceed 25 €.

The standards on how to store and archive the patient file safely, are also determined in the LPPD[119]. The right to access stipulated in the LPR is a particular case of the right to take note of the personal data being processed elaborated in the LPPD [84, 116]. This implies that the LPR is applicable if medical data is processed by a health care professional and is part of the patient file. The LPPD also applies to medical data that is no part of the patient file[119].

The LPR does not exactly define the content of the patient file. Next to the LPR and the LPPD however the notion of patient file is defined in other legislation. The Royal Decree of 3 May 1999 determining the minimum content of the medical file[120] defines it as the file kept by the health care professional regardless of its carrier comprising all data concerning the patient's identity, the personal and familial precedents, the actual history of the disease, data of previous consultations and hospitalisations, the results of clinical, radiological, biological, functional en histopathological examinations, the advices of the consulted physicians, the provision and definitive diagnosis, the treatment, in case of an operation the operative protocol and the anaesthesia protocol, the evolution of the disease, the report of and eventual autopsy and a copy of the discharge report[119].

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cc The mandatary is a person priorly designated by an incompetent person in order to exercise the patients' rights if and as long as the patient is incompetent to exercise his/her rights (art. 14 § 1).

dd A representative is a person assisting minor patients, incompetent patients with a specific status or incompentent persons that did not priorly designate a mandatary (see 5.2.2.17)

It's clear that the medical result of an endoscopy is part of the patient file. The question however is if the registered endoscopic video data can be considered as part of the patient file. As the result of the endoscopy is derived from the carrier (the image), it is desirable that the carrier is also included in the patient file (cf. RX images[ee]). Moreover the purposes of the endoscopic video registration can be achieved best if the video data are incorporated in the patient file. In order to get a full picture of the patient's medical condition other medical information in order to interpret the video recordings thoroughly is needed. This is the best way to use the video data, not only for therapeutic purposes obviously, but also as quality improvement tool, as educational tool, as data for scientific research and also as evidence in medical liability cases.

The hospital law stipulates that the medical activity in a hospital must be qualitatively tested, both internally and externally, therefore a medical file must be kept in the hospital, among other things (Art. 15 Hospital Law)[96].

According to the Royal Decree determining the minimum content of the medical file (art 1 § 3[120]) and the Code of medical conduct (Art.46[ff]), a medical file should be kept for at least 30 years in the hospital. It is possible to store the medical files outside the hospital if there are enough guarantees concerning security and accessibility[121]. If the hospital has a subcontractor responsible for the archiving of the medical files, article 16 of LPPD has to be observed. According to several legal texts, the head physician is responsible for the medical file[121]. A medical file can be electronically (Art. 1, § 3 RD minimum conditions medical file[120])[122]. Since 2006, there is also a Flemish Decree concerning the healthcare information systems[123] (hereafter named, Flemish Decree on HIS).

In this legislation a definition is given of the individual health care record (Art. 2, 8° Flemish Decree on HIS). Data transfers in the operational information system are only allowed with consent of the patient (Art. 19 Flemish Decree on HIS).

5.2.2.16 Right to protection of private life (Art. 10)

The patient has the right to protection of his private life for every intervention by a physician, particularly with regard to the medical information. No interference is admitted with regard to the exercise this right, except if it was provided by law and if it is needed for the protection of public health. The professional secrecy is closely linked to this right. In the scope of video registration, the registering of endoscopies without the consent of the patient is also a breach of the right to protection of the private life [124].

5.2.2.17 Mediation (Art. 11)

The patient has the right to complain about the exercise of the rights stipulated in the patients' rights act to the competent ombudsperson. According to the hospital law (Art. 70quater) hospitals are obliged to have a ombudsservice. The tasks of the ombudsperson are the prevention of questions and complaints by stimulating the communication between the patient and the physician. Moreover the ombudsperson has the task to mediate in case of complaints, to inform the patient about the possibilities to find a solution for the complaint, to provide information on the organisation, the functioning of the procedure of the ombudsservice and the formulation of recommendations preventing the repetition of shortcomings leading to complaints. The ombudsperson does not take sides in the dispute. Not only the patient or the mandatary or the representative of the patient but also the cohabiting spouse, the legally or the actually cohabiting partner, a parent, an adult child can complain.

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ee Art. 42 of the deontological code states that the physician can communicate objective data such as RX images or results of medical examinations, at request of the patient or if the physician considers that it can be useful. http://195.234.184.64/frame-totaal.htm. In the scope of the LPR however, the patient has the right to information (and thus to the results based on RX images). Moreover the patient has the right to access and to a copy of the medical file.

ff http://195.234.184.64/web-Ned/deonton.htm#Art.%2038

5.2.2.18 Representation (Art.12- 15)

Minors (Art. 12)

If a patient is a child younger than 18, the patients' rights are exercised by the parents having the parental authority or by the tutor. However, the minor can independently exercise his/her rights if he/she is mature enough to make a reasonable appraisal of his/her interest. Unfortunately there's no definition in the law of the concept „mature enough to make a reasonable appraisal of his/her interests" Consequently the physician will have to judge from case to case if a minor patient can consent independently to an intervention. There are no criteria specified in the LPR. Consequently, the physician has to envisage all elements which he estimates relevant to appreciate the ability of the minor to exercise his patient's rights. Factors that can be considered are e.g. the chronological age, the risks linked to the intervention, necessity and benefit of the proposed treatment and cognitive capacity for understanding treatment information. If the minor is not estimated to be able to exercise his patient's rights, he must be in any case associated with the exercise of these rights.

Patients with a specific status: Extended minority and adults that are declared incompetent (Art. 13)

If a patient is incompetent to act legally and he/she is protected by a system as the "declaration of incompetence" or the "extended minority", his/her rights will be exercised by the parents having the parental authority or a tutor. An adult who's in a constant state of insanity has to be declared incompetent, even if there are intervals of lucidity (Art. 489 Civil Code). The LPR does not specify a possibility of an independent exercise of the patients' right, as for the minor patients, not even if the patient has intervals of licidity[84]. Some institutions[125] and doctrine[126] have a different opinion and state that for each intervention, the physician has to examine the ability of the patient to give his consent for this specific intervention, and that's the case for the intervals of lucidity.

Extended minority can be applied to minors as well as to adults. A minor that is found incapable and seems to remain incapable to manage himself because of serious mental retardation can be declared as "extended minor". Serious mental retardation must be understood as a state of mental handicap, congenital or started during early childhood, and characterized by the undeveloped capacities of intellect, feelings and intention. Extended minority can also be adjudicated to adults that manifested the above mentioned characteristics in their minority (Art. 487 civil code). An extended minor is subjected to parental custody or guardianship with regard to their person. According to the patients' rights act these categories of patients have to be involved as much as possible in the exercise of their rights depending on the condition they are in. An independent exercise of their rights however cannot be granted to these patients due to the severity of the incapability.

Patients without a specific status, unable to exercise their rights

For a large group of patients the above mentioned systems of protection are not offering a solution. Think about the patients having no decisional capacity due to a disease, age, a trauma,… There's no specified criterion in the patients' rights act rendering patients incapable of informed consent to medical interventions. The physician will have to judge the patients' capacity to consent. It has to be noted however that it's of an utmost importance for the physician to consider the patient's decisional capacity very conscientiously because an invalid consent of the patient can cause the physicians liability.

The rights of this patient group are exercised by the person that has been previously designated by the patient (=the mandatary) (Art. 14 § 1), if and as long as the patient cannot exercise his of her rights. The designation needs to be recorded in a dated and personally signed document giving the mandate to the designated person. The mandate can be revoked any time by the patient or by the designated person. If the patient did not designate a mandatary or if the mandatary omits to act, the rights will be exercised by the cohabiting spouse, the legally cohabiting partner or the actually cohabiting partner.

If there's no such person or this person is not willing to exercise the patients' rights, the rights will be exercised to descending order by an adult child, a parent, an adult brother or sister of the patient. If there's no such person, the physician will protect the interest of the patient, if necessary after consultation of a multidisciplinary team (Art. 14 § 2). The physician is obliged to deviate from the representatives' decision if this decision violates the patient's interest (Art. 15 § 2). If the decision was taken by a mandatary, the health care professional can only deviate from this decision if the mandatary can not appeal to the explicit intention of the patient. Although in case of mandate or representation the patient cannot decide himself, the patient has to be as much as possible and proportional to his understanding involved in the decision-making (Art. 14 § 3).

Central liability of the hospital (Art. 17novies Hospital Law[96])

Each hospital has to comply with the patients rights (formulated in the LPR) concerning the medical, nursing and other professional aspects in the relation towards the patient. Moreover each hospital has to make sure that the self employed health care professionals working in the hospital respect the patients' rights.

Each hospital has to dispose of an ombudsservice. .that handles complaints related to the patients' rights. The patient has the right to receive information

From the hospital on the nature of the legal relations between the hospital and the health care professionals working at the hospital. The content of this information and the way of informing are specified by Royal Decree, following the advice of the National Commission Patients' Rights.

The hospital is liable for the breaches of the patients' rights committed by the health care professionals working at the hospital, except if the hospital explicitly and priorly informed the patient that it will not be liable, given the legal relationship between the health care professional and the hospital. A similar clause aiming at disclosure of liability can not detract from other legal stipulations regarding liability for acts of another.

Key point

The LPR applies to video registration of the endoscopic surgery.

Hence, the different patient rights enumerated in the law, such as the right to information, the right to informed consent, the right to direct access to the patient file and the right to have a copy of it, the right to protection of the private life, can be claimed by the patient or his/her mandatary (priorly designated by an incompetent person) or representative (person assisting a minor, incompetent person with a specific status or incompetent person that did not designate a mandatary).

The right to mediation can be exercised by the patient or his/her mandatary or representative, the cohabiting spouse, the legally or actually cohabiting partner, a parent or an adult child.

5.2.2.19 Professional secrecy

The general principle of the professional secrecy is: professionally obtained secret information cannot be disclosed, except in cases of lawful lifting of the oath of secrecy. In Belgium the medical professional secrecy is first of all established in article 458 Criminal Code (hereafter named Art. 458 C.C.). The purposes of this professional secrecy are twofold according to jurisprudence and doctrine[gg]: it serves the interest of the individual patient as well as the public interest [84, 128-130]. This first purpose means that the individual patient should be able to confide intimate information to his health care professional with a view to the best possible treatment[129, 130]. The public interest lies in the fact that all individuals must have no restraints to seek treatment in all confidence, so the medical care for everybody is guaranteed [129-131]. The rules of the medical professional secrecy are part of the Belgian public order[129, 130, 132, 133].

[gg] Some are of the opinion that the court of cassation only takes the protection of the individual patient into account.[127]

Surgeons are not only bound by professional secrecy as stated in article 458 Penal Code, they have also a deontological duty to respect the confidentiality of the medical information confided to them.[hh]

The traditional controversy between the absolute versus the functional view on the professional secrecy, has been settled meanwhile in favour of the latter[112, 129, 130, 132-136]. The absolute view implied that only the exceptions stated in the law, can release the health care practitioners from their professional secrecy, so the consent of the patient himself was not accepted as an exception[130]. The functional view interprets the professional secrecy in function of the values and interests of the patient.[ii] Here the patient becomes 'master' of his secrets[129]. The consequences of violation of the professional secrecy rules are legion: rarely criminal sanctions based on Art. 458 Criminal Code, sometimes civil action by applying Art. 1382 of the Civil Code[137] or disciplinary sanctions, unlawful evidence and possible discharge by the employer[136].

Below, we will discuss the scope of the professional secrecy, the applicability of this principle on the video registration of the endoscopic surgery. The exceptions on the duty of confidentiality will be discussed from the point of view of the different purposes of the video registration of the endoscopic surgery[jj].

5.2.2.20 Scope

The professional secrecy is applicable to "Physicians, surgeons, officers of health, pharmacists, midwifes and all other persons who on account of their status or profession have knowledge of secrets that are entrusted to them and that are made public by them exclusive of the case they are being appealed to bear testimony in law (or in front of a parliamentary investigation commission) and exclusive of the case where the law obliges them to make secrets public, are being punished" (Art. 458 Criminal Code) [138]. Important to stress that the above listed health care professionals fall only under the scope *ratione personae* of the professional confidentiality rule if they are necessary confidents[84, 130, 139]. The treating physician, the nurses and paramedics taking part in the care process are bound by this secrecy and according to some also the medical director of the hospital[84]. It's conceivable that IT and technical staff can also be bound by professional secrecy as they are necessary collaborators in the process. Even if they are not bound by the medical professional secrecy, they are not allowed to disclose patient data like that. Employees are submitted to the legal duty to discretion (art 17 3°, a), Law of July 3rd 1978 concerning labour contracts)[102]. Moreover disclosure of patient data can be a violation of the general standard of care (Art. 1382 Civil Code) applying to every citizen. Moreover, the data processor is obliged to assure that the persons processing the medical data respect the confidential character of the data by contractual clauses, or legal or statutory provisions (Art. 25, 3° RD LPPD).

The scope *ratione materiae* can be defined as 'secrets confided to a person by virtue of his profession. This implies that only information obtained by virtue of one's profession or position are covered by the professional secrecy[84]. So if a health care professional would have learned the same information but in a private setting, he would not be bounded by a pledge of secrecy[130]. The notion 'confided to' cannot be interpreted too literally[84]. Not only secrets explicitly entrusted fall within the scope, but also everything the health care practitioners have observed and every document describing or revealing the health condition of a patient[84, 130, 133, 136, 140]. The interpretation of the notion secrets is a source of difficulties[84]. Secrets can be defined as facts that because of their nature are secret or that are explicitly or tacitly entrusted to a physician.[141] According to B. Allemeersch the power to determine what qualifies as secret belongs to the magistrate and not to the patient nor to the disciplinary authorities[139]. J. Vandemoortel is of the opinion that the exact delineation of secrets protected by the professional secrecy has to be determined by the legislator, the patient and the health care professional together[142]. The question if data is secret or not can not be seen separately from the context of the specific situation of the patient and the one bounded by the secrecy[84].

[hh] Art. 55-77 code of medical conduct http://195.234.184.64/web-Ned/deonton.htm#Art.%2038. (Although not legally binding, still important)

[ii] *Ibid.*

[jj] See for an elaborated discussion of all possible exceptions: Nys 2005[84].

If the data are anonymous, it is no longer secret information covered by the professional secrecy rules.

The surgeon performing the endoscopic surgery and his medical staff, involved and related to the specific intervention fall within the scope ratione personae of the professional secrecy.

Since the endoscopic video data reveals information about the health care condition and that is generally seen as 'sensitive' data, we can conclude that the professional secrecy is applicable on this data. Another argument in favour of this point of view is the purposes of the professional secrecy, the protection of the individual patient should be broadly seen. But as discussed above it can depend on the context.

Key points

- **The general principle of the professional secrecy is: professionally obtained secret information cannot be disclosed, except in cases of lawful lifting of the oath of secrecy (Art. 458 Criminal Code).**
- **Endoscopic video registration data, identified or identifiable fall within the scope of the professional secrecy.**
- **The treating physician, the nurses and paramedics taking part in the care process are bound by this secrecy.**
- **It's conceivable that IT and technical staff can also be bound by professional secrecy as they are necessary collaborators in the process. Even if they are not bound by the medical professional secrecy, they are not allowed to disclose patient data like that. Employees are submitted to the legal duty to discretion. Moreover disclosure of patient data can be a violation of the general standard of care (Art. 1382 Civil Code) applying to every citizen. The data processor is also obliged to guarantee that his personnel treats the data confidentially.**

5.2.3 Purposes of video registration

5.2.3.1 Introduction

As mentioned before four purposes of endoscopic video registration data can be distinguished: the use of the data as quality improvement tool in the hospital, as educational tool for future physicians or as data for scientific research, as evidence in medical liability cases and as tool for the care of the patient in general (e.g. the assessment of the health status of a patient and the probable evolution of his health state, cure of complications,…) on the condition that the data is not anonymous. In this chapter we will sketch the cases in which the use of the endoscopic data is lawful taken the fact into account that both the LPPD regulations and the professional secrecy rules are applicable. The main principles of both set of rules are respectively prohibition of processing medical data and the prohibition of disclosure of professionally obtained secret information. But in both cases, exceptions on this prohibition are possible. Below we will describe the cases in which transfer of medical confidential information is allowed. Since they will vary for the different purposes, we will elaborate them from the point of view of these four objectives of video registration. The exceptions not applicable on one of these purposes will not be discussed.[kk]

While discussing the scope of the professional secrecy rules and the LPPD, it became obvious that in many cases both regulations are applicable on medical data. The interfaces between both regulations can mainly be situated in the domain of transfer of the protected data to third parties, and not as much in the obligations involving their collection and management[143]. Both legislations do not restrict one another in any way[97]. The person responsible for the professional confidentiality is not per definition the same as the responsible person in the sense of the LPPD.

[kk] See for a complete elaboration of all possible exceptions on the prohibition of processing medical data: De Bot 2001[81] and for an elaborated discussion of all possible exceptions on the professional secrecy: Nys 2005[84].

This latter is the entity defining purposes and means of the processing and is responsible for the safeguarding of the confidentiality and to provide an appropriate level of security (Art 1 §4 LPPD and art 16 LPPD). This is likely the hospital manager. From the point of view of the professional secrecy the responsible person is the treating health care provider.

5.2.3.2 Therapeutic purposes

In this section we investigate the legal framework if one wants to use the endoscopic video registered data for the care of a patient. Only if the data can be linked to the patient, it can be used for therapeutic purposes. In that case, the data is not anonymous and is part of the patient file.

5.2.3.3 Data protection legislation

If we keep the therapeutic purpose in mind, following exceptions on the prohibition of processing medical data as a rule are applicable.

Informed consent

Processing of medical data is allowed, is if the data subject has given his written consent (Art. 7, § 2, a, LPPD). This consent, as described in the LPPD, has to be informed, freely given and specific (Art. 1, § 8 LPPD). Informed consent implies that the data subject knows the purposes of the processing. He needs to know all information objectively necessary to make a decision to give permission to the processing[81].

The LPPD provides the possibility to the King to identify cases in which a free consent is more an illusion because of the specific nature of the relationship between the controller and the data subject[81]. Art. 27 R.D. LPPD has determined cases in which consent alone may not be sufficient to process medical data lawfully, namely if the controller is the employer of the data subject or if there is some position of dependency. The restrictions are no longer applicable if the processing is in favour of the data subject (Art. 27 RD LPPD)

Again if the processing is allowed solely on the grounds of the consent, the Royal Decree also stipulates additional obligations. The controller must inform the data subject of the purposes of processing and must provide a list of categories of people with access to the data (Art. 26 RD LPPD).

Necessity for the care of the patient

The processing of medical data is also allowed (without consent of the patient) if necessary for the care of the patient. The LPPD describes it as follows: "if necessary for purposes of preventive medical science or medical diagnosis, the provision of care or treatments to the party involved or a related person, or the management of the health services accomplishing in the interest of the involved person and the data are being processed under supervision of a health professional" (Art. 7, § 2, j, LLPD). This exception intends to meet the wishes of the health care providers to have easy access to medical data for their daily activities[81].

This provision can be applicable on the endoscopic registration. The video data is necessarily used for providing care. If the patient has for instance a complication, it can be necessary for the physician to examine the video of the endoscopic surgery in order to determine the most effective treatment for the complication.

However; as stated above the LPR is in general applicable to video registration for therapeutic purposes or to assess the current and probable evolution of the patient's health state. The LPR states that the patient has the right to consent informed and freely, before any intervention of the health care professional**.** In case of two conflicting laws, the doctrine states that a law governing a specific subject matter (*lex specialis*) is not overridden by a law which only governs general matters (*lex generalis*). In case, the LPR can be seen as specific to the protection of the patient and it could be considered as preponderant in the interest of the patient. Consequently the consent of the patient is required even if there was necessity for the care of the patient.

5.2.3.4 *Professional secrecy*

As a rule, professionally obtained secret information cannot be disclosed. But there are cases in which the disclosing of the secrets is lawful. The exceptions on the duty of confidentiality of importance for therapeutic purposes are described below.

Shared professional secrecy

Confidential information can be shared with other health care professionals under some conditions[97]. The fact that the addressee is also bound by professional secrecy is a necessary but is not a sufficient condition for a lawful transfer of information[143]. The sharing of the confidential information must also be necessary to continue the diagnosis, the treatment or the guidance of the patient[97, 143]. The patient has to give his explicit or tacit consent or the transfer should at least be in his best interest[143]. To qualify as lawful transfer of information between 'colleagues' all these conditions must be fulfilled.

So access to confidential information of third parties not bound by professional secrecy or health care professionals who are not part of the team treating the patient is not allowed. So all IT and technical staff that could be involved in the endoscopic video registration have no access to this data on the grounds of shared confidentiality. In order to have lawful access another exception is required, the consent of the patient for instance.

Consent of the patient

There is controversy about if the patient's consent alone is sufficient to release the health care professional from his oath of secrecy. Some decades ago, the Court of Cassation stated that the consent of the patient did not discharge the physician of his duty of professional confidentiality.[144] But more and more doctrinal defenders of the vision that consent alone is enough, appeared[84, 145]. The opinion stated in the jurisprudence is still divided, but in quite some of the judgements consent was enough[132]. The consent must be given in advance, must be free and the patient should have enough knowledge and be the sole party concerned[84]. The code of medical conduct expresses the opinion that consent alone does not discharge the physician of this oath of secrecy.[II]

Key points

- **If the purpose of the video registration is therapeutic:**
- **From the point of view of data protection law: The processing of this medical data, although as a rule prohibited, is justified in case of written consent.**
- **From the point of view of professional secrecy: Transfer of professionally obtained confidential secrets is justifiable with consent or when data are shared with colleagues (also bound by professional secrecy) of the medical team treating the patient (=shared confidentiality). In this latter case data sharing has to be necessary for the care of the patient**

5.2.3.5 *Use of endoscopic video data as quality improvement tool*

Quality of care in hospitals: applicable legislation

Quality of care in hospitals is a hot topic. These last decades the legislator took a lot of initiatives to improve the quality of care in a hospital environment. Below we will describe in short the obligations and responsibilities in regard to quality of care in a hospital.

The hospital law states that the medical activity in a hospital must be qualitatively tested, both internally and externally. The head physician is responsible for taking the necessary initiatives to involve the physicians into this test and into initiatives to preserve or even elevate the quality of the medical activity (Art. 16 Hospital Law[96]). A Royal Decree has elaborated the quality of care of the medical activity[146].

[II] Art. 64 code of medical conduct http://195.234.184.64/web-Ned/deonton.htm#Art.%2038.

Important to stress that these internal and external testing of the quality is only related to the care programmes and not to the individual physicians[84]. The regulations stated above are obliged conditions for the recognition of the hospital (Art. 70 Hospital Law)[96]. Another Royal Decree determines the regulations and the term that have to be respected by the hospital management to give information concerning the financial condition and the organization and management of the quality[147]. Not only data concerning the surveillance of the quality is provided, but also information about the organization and the general management of the quality, the quality of service towards the patients and towards the general practitioner[145].

Not only the head physician, but also the medical board sees to it that the physicians lend their assistance to improve the quality of the medicine practiced in the hospital and to stimulate scientific medical activities (Art. 124 Hospital Law). The tasks of the medical board and the head physician must be exercised complimentary and therefore there is shared responsibility[145].

A Royal Decree executing the Hospital Law stipulates that the head physician must have possibilities to elevate the quality of care (Art. 3 Royal Decree of 15 December 1987, executing the articles 13-17 of the law on hospitals of 7 August 1987,. hereafter named RD Hospital Law[148]). He also needs to take initiatives to improve the quality of the medicine and must evaluate this on a permanent basis (Art. 5 RD Hospital Law).

The departmental head physician also must have possibilities to elevate the quality of care of his department (Art. 13 RD Hospital Law).

Another important law concerning quality is the Decree of the Flemish Community concerning quality of health and welfare provisions (Decree of 17 October 2003, of the Flemish Community concerning quality of health and welfare provisions, hereafter named Quality Decree[149]) Every care institution must provide 'well-considered' care, without distinction between age, sex, race, sexual inclination, mental condition or ideological, philosophical or religious beliefs (Art. 3, § 1 Quality Decree). The well-considered care must fulfil the requirements of efficiency, efficacy, continuity, social acceptable and user friendly (Art. 3, § 2 Quality Decree). Among other things, respect for the private life is important when providing care.[mm] Both users and care institutions have a responsibility towards the quality of care, undiminished the responsibility of the government (Art. 3, § 3 Quality Decree). This quality policy should be elaborated in a quality manual and quality plan.

At first the health-and disablement insurance laws did show a lot of interest in the quality of care, but this is changed by introducing the system of accreditation of the physicians and the legislation concerning the recognition of some departments for instance the laboratory of clinical biology[145]. The law on accreditation is introduced in 1995 and aims to improve the quality of care, the quality and efficiency of the relations between physicians and the permanent education as quality improving tool (Art. 36 bis Law of 14 July 1994 concerning the compulsory health insurance[150]). One of the conditions physicians have to fulfil to receive accreditation is cooperate to initiatives, taken by peers, to assess the quality. In 1996 the local quality groups were introduced. One of their assignments is to reach a consensus about medical strategies[145].

The Code of medical conduct also stipulates some articles concerning the quality of care.[nn]

We can conclude that quite some persons and entities are involved in the safeguarding of the quality of care in a hospital, namely the head physician, the medical board and the departmental head physician. Those entities can be involved in the strategy on how to use the video recordings of the endoscopic surgery as quality improvement tool, since they are responsible for quality of care in the hospital. The endoscopic video data is also an interesting tool to use for peer review or to discuss in the local quality groups.

[mm] Ibid.

[nn] Art. 34-37 Code of medical conduct, http://195.234.184.64/web-Ned/deonton.htm#Art.%2034.

How can these quality measures be imposed to (independent) physicians?

The question raises how these quality improving measures can be imposed on the (independent) physicians. The key issue is to know whether registration of surgery is organised on a purely local and voluntary basis or on the basis of mandatory legislation.

A. Video registration on a purely local and voluntary basis

As mentioned above, in case, not only the patient is a data subject but also the surgeon having performed the endoscopy. The registered pictures can be linked to the surgeon and thus generates personal data that can serve for instance for the evaluation of the registration. In case the LPPD is consequently also applicable to the surgeon. In order to process the personal data, consent of the surgeon is needed (Art. 5 a) LPPD). In practice, in every hospital the legal relation between the hospital and the physicians is described in the 'general arrangement' (Art. 130, § 1 Hospital Law). The medical board, representing the physicians, gives advice concerning the content of the general arrangement (Art. 125 Hospital Law). It is important to stress that the general arrangement cannot threaten the professional autonomy regarding the diagnosing and the medical treatment in any way (Art. 11 RD nr. 78 and Art. 130, § 1 Hospital Law.)

Stipulations without respect for the professional autonomy will be disregarded (Art. 12 RD nr. 78). It is also important to stress that the privacy of the physician in this regard is of vital interest too as the possibility of a third part controller and the notion of data subject is applicable.

Therefore, if the hospital management wants to register all endoscopic surgeries for purposes of quality improvement in the hospital, and thus to organize routine video registration, it would be best to organize this in the general agreement. One of the provisions of the general agreement could be the obligation of the physicians to cooperate to initiatives, taken by the hospital, to improve the quality of care, like for instance the use of the endoscopic video registration data. In this perspective it is important to stress that possible discrimination towards endoscopic surgeons can be excluded if well defined categories in physicians for who this rule applies are determined in the general agreement. We can recommend also to describe the other purposes of the video registration in the general agreement. This agreement must respect the non-discrimination principle between physicians.

If video registration is organised on a purely local and voluntary basis in the scope of quality improvement of the hospital, it should be remarked that this can be seen as an experiment as defined in the law of May 7, 2004 concerning experiments on the human person. Indeed, the term "experiment" in the law is defined very largely as every trial, study or research on humans aiming at the development of knowledge related to the execution of the health care professions as determined in the RD nr. 78. The law sets some specific conditions. Written consent of the patient is needed (Art. 6). Specific liability insurance covering liability of every person collaborating to the experiment needs to be contracted by promotor (Art. 29). In case of video registration, the risk for damage in the scope of the experiment is limited to a possible privacy breach**.** Moreover the promotor needs to submit the study for advice to a Commission for medical ethics (Art. 11).

B. Mandatory video registration

In case video registration was legally imposed, consent of the surgeon is not required since the legal ground (Art. 5 c) LPPD) justifies the treatment of his personal data.

Admissibility rules to be considered if use of endoscopic video data for quality improvement

The question asked here is whether the medical information, captured by means of the endoscopic video registration can be used as quality improvement tool knowing this information is covered by the professional secrecy rules and LPPD.

Data protection legislation

Here we will describe the cases in which the use of endoscopic video registration as quality improvement instrument is lawful.

Informed consent

Again the written; informed, freely given and specific consent of the patient justifies the processing of the data (Art. 7 §2 a) LPPD). In case of mandatory video registration however it is discussable if informed consent of the patient is needed. Indeed, Art. 7 § 2 e) LPPD states that treatment is justified (without consent of the patient) if it was imposed for important reasons by a law, a decree or an ordinance. The question should be raised however if in case the patients' rights act applies as a "lex specialis" that prevails the "lex generalis" (the LPPD). If the patients' rights act applies, informed consent of the patient is required. The purpose of the video registration is in this case not the assessment of the individual patients' health or any other purpose specified in Art. 2, 2° LPR but quality management in general.

On the other hand, interventions are always videotaped in the medical relationship between the surgeon and the patient in which the primary purpose is the care for the patient. One could thus state that the primary purpose of the data collection is the care for the patient, whereas the secondary purpose is a scientific purpose, namely quality management. Since the patient's Rights act is specific to the protection of the patient and it could be considered as preponderant in the interest of the patient, its application and the requirement of informed consent is indicated.

Necessity for scientific purposes

The second possible applicable exception defined in the LPPD includes the necessity of processing for scientific purposes (Art. 7, § 2; k, LPPD). If endoscopic recording is to be used as quality tool, scientific research will be a necessary means. If data is collected for a certain original purpose and one wants to use this data afterwards (secondary processing) for the 'scientific purposes' that are *compatible* with the primary purposes, the regulations applicable on the primary processing (= regulations of the LPPD) will apply[92]. In case of secondary processing of personal data for historical, statistical and scientific purposes *not compatible* with the original purpose(s) of the collection, specific more stringent regulations defined in chapter two of the Royal Decree apply[81, 92].

If the endoscopic data were initially collected for another purpose than for quality improvement, one has to assess the compatibility with the original purpose. A compatible purpose is a purpose that falls within the expectations of the data subject or that can be considered as compatible based on legal grounds.

As stated before, one could argue that endoscopic interventions are always videotaped in the medical relationship between the surgeon and the patient and that the primary purpose is the care or the assessment of the health state of the patient. If the government makes video recording of all endoscopic procedures mandatory for the purpose of quality management, secondary processing of endoscopic data for the use as quality tool could be foreseen by the patient based on legal grounds and is thus compatible with the primary purpose. Consequently the specific regulations in the RD LPPD are in principle not applicable. However in an advice of the privacy commission on the concept of secondary processing of personal data for historical, statistical and scientific purposes and its consequences[151], it states that even though the specific regulations of the RD LPPD are not applicable if there is compatibility with the original purpose, it can be desirable to process anonymous or encoded data instead of unencoded data. The legal basis for this statement is the principle of proportionality. The processed data must be adequate, relevant and not excessive, taken the purposes of the processing into account. Given the fact that the assumed purpose of quality management does not imply a direct (medical) individual benefit, a maximum guarantee of privacy of the individual patient should be aimed at. Consequently enencoded data should be used.

For the use of enencoded data, additional obligations are elaborated in the RD LPPD (cfr. supra 5.2.2.10)

A law concerning the creation and the organisation of an eHealth platform has entered into force (Law of 21 August 2008 concerning the creation and the organisation of an eHealth platform[152]). The eHealth-platform is an electronically secured data exchange platform where all health care actors can exchange information with respect for privacy.

Health care providers, health care institutions, mutualities, Ministry of healthcare, Safety of the foodchain and environment, NIHDI, governmental services of the regions and patients will be able to connect to the network. It's important to stress that the platform will not centrally store health care data. In that scope video data could be exchanged between hospitals and the government via the eHealth platform.

One of the purposes of eHealth is to improve the quality of care and patient safety by exchanging relevant information about the patient and the provided care in a well organized way. Another opportunity of eHealth is that it will simplify the administration for patients; health care providers and health care institutions (Art. 4). For instance, it will be possible to make legal, electronic prescriptions with minimal administrative burden and with the guarantee of free choice of the health care provider by the patient. eHealth also aims at supporting health policy by providing information from research and analysis.

The missions of the eHealth platform as an organization are very diverse (Art. 5).

- The elaboration of a vision and a strategy for effective, efficient and safe electronic service and information – sharing in health care, respecting the protection of private life and in close collaboration with the different public and private actors in health care.
- Determining relevant ICT related functional and technical norms, standards, specifications and basic architecture
- Verifying if software packages for the management of electronic patient files comply with the ICT related functional and technical norms , standard and specifications and the registration of these software packages
- Conceiving, managing en creating a platform of collaboration for the secured exchange of data with the associated basic services
- Arranging a division of tasks with regard to the collection, validation, storage and the supply of the data that are exchanged in the platform of collaboration and of the quality standards applying to the data, and the verification of the respect of these quality norms
- Promoting and coordinating the execution of programs and projects that realize the vision and the strategy of the collaboration platform en/or the connected basis services.
- Managing and coordinating the ICT related aspects of data exchange in the scope if electronic patient files and electronic medical prescriptions
- Acting as independent trusted third party (TTP) for the coding and anonimising of personal data with regard to health for specific, in the law enumerated institutions for the support of scientific research and policy.
- Being the driving force of the necessary changes for the execution of the vision and the strategy
- Organizing the collaboration with other governmental services that are in charge of electronic services

In the scope of video registration the Ehealth platform may offer interesting opportunities such as time stamping, serving as TTP, providing security and encryption, authentication of users etc (see scenario 3 & 4 infra)[oo]. However it must be clear that Ehealth will not provide any application to collect and store video records.

[oo] Some critics can be vented on the Ehealth platform:
- Although the Belgian Ehealth infrastructure is meant to be supporting facilitating electronic exchanges about health and patients between parties, it will still be a governmental agency or body. Suspicion can arise when the main user of that service would turn out to be the government. Will the separation of powers normally expected of a TTP still be present?
- Within Europe and Belgium there is no or little data nomenclature, data normalisation (standards). Without these it will be almost impossible to organise this data collection and transfer. Ehealth would have been an ideal platform to streamline the whole data standardisation process.

Professional secrecy

As a rule, professionally obtained secret information cannot be disclosed. The informed consent[PP], given in advance is also here a lawful exception.

Key points

- **If the purpose of the video registration is used as quality improvement tool:**
- **From the point of view of data protection law: The processing of this medical data, although as a rule prohibited, is justified in case of written consent.**
- **A second possible justification is the necessity for scientific purposes. If legal regulations impose systematic video registration for the use in quality management data have to be enencoded by a third trusted party before the data are transferred to the government. Informed consent of the patient is needed. Consent of the surgeons is not required.**
- **From the point of view of professional secrecy: transfer of professionally obtained confidential secrets is justifiable with consent.**

5.2.3.6 Training purposes: Admissibility rules to be considered if use of endoscopic video data

Data protection legislation

The written consent is the only possibility if one wishes to process medical data lawfully for training purposes.

Professional secrecy

If the treating surgeon himself wants to use the endoscopic video registration data for training purposes or he wants to give this data to another (health care) teacher for these purposes, this transfer is a breach of the duty to confidentiality as a rule. The conditions necessary for a lawful shared confidentiality are not fulfilled here. It is not only required that the addressee of the confidential information is also bound by professional secrecy, above that, the transfer must be indispensable for an optimal continuation of the patient care. Shared confidentiality is in case of the educational purpose no lawful exception on the duty of confidentiality.

Key points

- **Use of data as educational tool:**
- **From the point of view of data protection law: The processing of this medical data, although as a rule prohibited, is only justified in case of written consent.**
- **From the point of view of professional secrecy: Transfer of professionally obtained confidential secrets is justifiable with consent.**

5.2.3.7 Evidence in medical liability cases

Basic principle: freedom of evidence

The concept of evidence is not defined as such by Law (no list of items of evidence). Parties involved in legal actions are allowed to use any kind of evidence material, irrespective of the media. This principle is called "freedom of evidence".

Freedom of evidence remains a corner stone of this jurisprudence. This remains true both for Civil or Criminal proceedings.

Given that the value of evidence is not defined by law, it is up to the judge to assess the value.

[PP] See above for the elaborated explanation about the consent in the context of the professional secrecy.

Admissibility rules

The admissibility rules are based on lawful collection of data. If data are collected with respect of the legal conditions, they can be used as evidence in civil and criminal cases.

The general requirements on data processing of the LPPD: as specified before, "Lawfulness of processing personal data" have to be respected. Since the LPPD provides no specific stipulation on the processing of medical data for the use of defence in court, written informed consent of the patient must be obtained before taping. If the endoscopy was primarily recorded for general care for the patient, quality management or training purposes, consent of the patient is not needed for the ulterior use by a physician in court. A physician can lawfully breach professional secrecy and thus use medical confidential material for defence in court[84].

The patient himself can freely use the images in court. As mentioned above, it is important to note that in case of endoscopic video registration the patient as well as the physician can be considered as a data subject. Videotaping links the intervention of the physician to the physician's identity. This information is general personal data (>< medical personal data) that could be used by hospital managers in liability cases. Hospital managers can use the video material in court as far as the physician was informed (e.g. in the general agreement) and consented that his work will be taped.

The law of May 15th 2007 concerning the compensation of damage resulting form health care (Law of May 15th 2007 concerning the compensation of damage resulting form health care[153]) and the law of May 15th 2007 concerning the regulation of disputes in the scope of the former law (Law of May 15th 2007 concerning the regulation of disputes in the scope the law of May 15th 2007 concerning the compensation of damage resulting form health care[154]) reforms the actual regime of civil liability entirely[111]. Instead of a liability system based on proof of a fault, the new legislation introduces a no – fault compensation system. These two above mentioned laws however have not yet entered into force. The foreseen date for being into force is the 1st of January 2009.

In the mean time however, the council of Ministers decided on the 23rd of October 2008 to give a new orientation to the "no-fault" legislation and to adapt the Belgian system to the French system in which patients can go to the civil courts as well as to a solidarity Fund. An official bill however has not been drawn up yet.

In the scope of this study the question rises if the new legislation makes any difference with regard to the use of registered endoscopic images in liability cases. In the new system the proof of fault has been abandoned. However, the proof of a causal link between the act/element that caused the damage (or the absence of an act) and the damage still has to be proven. This implies that medical expertises - usually with regard to discussions on the causal link between the act/element that caused the damage - will continue to exist and that registered endoscopic images still can serve as evidence. Although in the new system – as today formulated in the law of May 15th 2007 - the patient can not go to the civil court any more in order to claim compensation, disputes will be handled by the Fund for compensation of medical accidents and the insurers (of the health care professionals)[qq].

Key points

- **If video data were lawfully collected, they can be used as evidence in court by the patient and the physician. The value of these images is to be assessed by the judge.**
- **The new no fault legislation does not render the use of video images in court redundant.**

qq For an overview of the specific procedure see art. 17 and following Law of May 15th 2007 concerning the compensation of damage resulting form health care

5.2.3.8 Use of pictures for commercial purposes

Both for research and/or education-training purposes, pictures can be part of commercial material (e.g. training material) or used as an illustration in commercial publications. In both cases this kind of material or publication can be sold as commercial goods , according to the rules of commercial law.

In this latter case, consent of the patient must be collected on the basis of protection of private life, as it is utterly different from a patient – physician relationship.

5.3 ENDOSCOPIC VIDEO REGISTRATION: FOREIGN LEGAL CONTEXT

It remains essential to analyze the foreign legal context for the following reasons:

- Considering the historical background of each health care system, but also the subsidiarity principle, practical implementation of EU principles on data protection was left to the Member States' initiative and remains strongly connected with national existing institutions. Therefore, even if all the principles of the EU Directive are applicable Europe-wide, practical implementation of this directive requires a further analysis, on a national basis.
- Quality improvement policy remains a purely national subject, and some learnings from neighbouring countries could be very useful for Belgium. As far as endoscopic techniques are concerned, one must bear in mind that this subject is one of the key subjects addressed by west European countries in the field of quality improvement strategy. Indeed, most of these countries resorted to specific quality standards or guidelines and laid emphasis on quality of endoscopy, as it is considered as an "at-risk technique". Hence, endoscopy is an interesting subject in terms of quality improvement.

For all these reasons, it remains important to analyze each country's policy to have a more practical view on these complex issues. The following paragraphs will thus embrace several dimensions of this issue:

- **Clinical dimension of quality improvement**: as underlined above, practical organization of health care systems remains a purely national matter, which is not addressed by EU institutions. Therefore, definition and implementation of quality improvement policy vary across EU countries, especially on the following points:
  - Involvement of political stakeholders in the decision-making process
  - Definition of the quality standards (who does what ?)
  - Implementation of quality control and evaluation of health care providers
  - Access to evaluation-related information (for patients and citizens)
- **Practical implementation of data protection**: as explained above in the report, practical implementation of the EU Directive was organized on a national level, as each Member State is also reliant on its own legal and historical traditions. This is true, *inter allia*, for :
  - The organization of **data protection agencies** about which further details will be provided in this part of the report.
  - The **use of data in the field of research:** as a practical matter, this use requires a specific approval process; nevertheless, each approval process has been defined and implemented nationally, as explained below.
  - **Practical aspects of data exchange policy** between health care providers.

5.3.1 Selection of the most relevant foreign countries

Among all EU countries, a handful of countries has been selected for the following reasons:

In all these west European countries, organization and delivery of health care has reached similar quality standards as in Belgium, and therefore the frequency of the use of innovative techniques (such as endoscopic techniques and registration procedures) is similar to the Belgian one.

Practical organization of the health care system and involvement of health care providers into delivery of care is close to the Belgian situation in three of these countries: Germany, France, Netherlands.

Historically, these countries have been at the forefront of contemporary reflections on data protection (see below: France, Germany, UK).

In some of these countries, especially UK and Germany, the implementation of quality improvement processes have been the cornerstone of the recent health care policy, mainly due to strict cost/effectiveness constraints.

In all these countries, endoscopy is considered by health care establishments as one of the key issues in terms of quality of care (both for the staff and for the managers), especially considering its surgical environment. Over the last years, all surgical techniques, *inter allia* endoscopy, have drawn attention of decision-makers for various reasons, as explained below.

5.3.2 Quality improvement strategy across Europe

In the vast majority of the European countries, **endoscopy** is considered by health care establishments as one of the **key issues** in terms of quality of care (both for the staff and for the managers), especially considering **its surgical environment**. Over the last years, all surgical techniques, *inter allia* endoscopy, have drawn attention of decision-makers for the following reasons:

- **Patient security** is a sensitive subject, from a political point of view: in terms of health care supply and funding policy, meeting security standards is a prerequisite to keep a hospital open.
- **Quality improvement policy** is one of the main tools to grade hospitals and it is put forward by all stakeholders: hospital managers, health authorities and funding authorities, but also the media. In most European countries, basic information on quality policy of hospitals is considered as public domain information. In some European countries, an unofficial "ranking" of hospitals is published in the press. The latter is not legally opposable, but can be used as a decision-making tool by many patients, which cannot be ignored by decision-makers.
- **Surgery and surgical techniques (incl. endoscopy) are generally considered as "risky" and sensitive subjects**, and thus require specific attention of the decision-makers. Great emphasis has thus been laid on quality improvement over the last years (even if decision-making processes may differ across European countries).

For all the reasons mentioned above, endoscopic video registration can not be considered separately and must be put back in a much wider context of quality improvement policy, as it is designed by each European country.

5.3.3 Political definition of priorities on the national level

In most of the European countries, quality improvement priorities have been defined on the national level, both for financial reasons (control of medical expenditure and appropriate use of public funds) and political reasons (getting a wide range of stakeholders involved into the quality improvement strategy).

The role of each institution is largely connected with historical traditions of each country, and transferability of these principles has to be considered with care.

- ***In the UK***, quality improvement strategy is defined by the **Parliament**, in close connection with NHS authorities. Given the **use of public funding** in the UK (strict public budgetary framework), there is no discrepancy between quality improvement as such and other objectives of the NHS. In short, the main objectives of the quality improvement are :
  - Improvement of cost/benefit ratio of public funding
  - Reduction of waiting times
  - Improvement of quality as such but also "patient experience"
- ***In France***, quality improvement strategy is defined by the Law. The key objective is to **improve quality**, rather from a **public health point of view**. In short, the main objectives of the quality improvement are :
  - Definition of obligations of physicians and hospitals.
  - Definition of "at-risk specialities" (especially those using **endoscopy**) that must meet specific quality requirements, especially to be **insured**.
- ***In Germany***, quality improvement strategy is defined by a specific parliament's committee called "**Joint Health Federal Committee**" that is composed of representatives of doctors, hospital managers, and health care insurance funds. For historical and political reasons, doctors' representatives are very much committed in this process. The main task of the Committee is to organize monitoring of quality indicators and quality improvement on the national level. It is also to commission the IQWIG (German KCE) on specific quality improvement subjects.
- ***In the Netherlands***, several laws are stipulated to guarantee the quality in care institutions[rr].
  - Law on quality in care institutions. This law intends to improve quality in care institutions by increasing transparency between hospitals and by stipulating some quality requirements that has to be fleshed out by each care institution. All institutions have to elaborate a clear quality policy, have to identify and measure systematically quality indicators and have to publish a yearly report on quality efforts. The inspection on health care is responsible to enforce this law.
  - Law on individual care professions (BIG). This law intends to guarantee quality by individual care providers. The law consists of title protection, obliged registration of some care professions in a central register and acts that only can be provided by registered professionals.
  - Law on health care agreement (WGBO). This law regulates the agreement between physician and patient.
  - The 'National Institute for accreditation of hospitals' (NIAZ)[ss] and the 'Foundation for harmonization of quality policy in the care sector' (HKZ) [tt] are two external organisations, which elaborated quality standards. Hospitals and other care institutions can obtain a certification if their policy complies with those standards.

5.3.3.1 Which connection between quality standards and funding?

As a matter of principle, a clear connection should exist between quality improvement and funding policies. In reality, connections exist between funding channels and quality data, but they have to be considered in each country's context.

In the UK, there is a clear and direct connection between funding and quality requirement. Routine controls are undertaken to check that each hospital's department does meet quality requirements.

In France and in Germany, connection exists, even if more indirect. Key findings of inspections are sent to the Regional level (Länder's health authorities in Germany,

rr www.wetten.nl
ss www.niaz.nl
tt www.hkz.nl

Regional Hospitalisation Agency in France) and can be used as decision-making tools to undertake funding arbitration, concerning health care establishments.

In the Netherlands, there is a direct connection, because each year healthcare providers have to negotiate with there local health insurers. If the quality of their service is not acceptable, the health insurers can contract another hospital or hospitals for that same service.

5.3.3.2 Patient Information on health care establishments (concerning quality achievements)

Key information on health care establishments are accessible to patients in each country.

In France, Certification reports on health care establishments are accessible to the patients (Public domain information / website of the Haute Authorité de Santé, including possible "reservations" of this report [155].

In the UK, comprehensive and comparative information and data are accessible to patients. The Health Care Commission [156] also known as the "*Healthcare Watchdog*" provides with a wide range of information, and enables patients to make compare quality standards between the health care establishments.

In Germany patients have access to the percentage of documented items on quality reports (which is a good indication on quality achievements). Nevertheless, precise information on quality standards, as described by the national report framework, remain anonymous data.

In the Netherlands, some initiatives make the data on heath care establishments accessible to all patients (e.g. websites[uu]). The public standardized parameters of each individual hospital are defined by the 'National association of hospitals' (NVZ), the Inspection of health care, the order of medial specialists and the Federation of university centres.

5.3.4 Scientific definition of quality standards

In order to get all stakeholders involved into the quality improvement strategy, it is crucial to define **irrefutable quality standards**. In all the European countries we focused on, quality standards have been defined on organisation. The key objective is to make sure that delivery of care is designed in line with quality standards. Guidelines were also defined on medical acts as such.

In the UK, specific standards are defined for each kind of pathology or each kind of care. As far as endoscopy is concerned, specific standards have been defined and specific rating rules have been set out by the "**National Endoscopy Team",** called "**Global Rating Scale**" (see appendix). Thanks to this methodology, quality data can be monitored in a very precise way (bottom-up collection), in order to improve "Patient experience".

Data collection is organised accordingly. Individual training standards have also been set out for physicians, but these standards are also used by GRS as a reference.

In France, three kinds of quality standards have been set out by the National Authority for Health **HAS**:

- **Certification** of health care establishments is performed by the HAS with a view to controlling each hospital against key organisational requirements.
- **Evaluation of Professional Practices (EPP)** is a more demanding process, which focuses on physicians' practices.
- **Accreditation** of physicians is very demanding and requires compliance with top level quality standards, set out for "at-risk specialities" (legal definition), especially those using endoscopy.
- The **HAS** has also published guidelines on a large number of subjects (*incl. endoscopy*).

uu www.kiesbeter.nl en www.ziekenhuistransparant.nl

Training standards are mainly defined by universities.

In Germany, **quality reports** have defined quality standards on a very wide range of subjects, but collection of data quality remains anonymous.

Apart from the quality report process, 4 types of guidelines have been set out (either by the National Authority for Health **- IQWIG -** or by scientific societies: Richtlininien, Standards, Leitlinien, Empfehlungen und Stellungnahmen. Of the four types, only Richtlininen (clinical subjects) and standards (generally technical subjects) are legally opposable.

Training standards are defined by the **National Order of Doctors**, and specific quality improvement training programmes have been set out by the Order in Germany. Historically, the National Order of Doctors has always been very much committed in **quality-related issues**.

In the Netherlands, standards and guidelines for endoscopic surgeries are mainly provided by the Dutch surgery association (NVvH) and the Dutch association of obstetrics and gynaecology and the Dutch association of endoscopic surgery (NVEC).

Key Points

- **Combining collective approach and individual obligations is a key factor for the smooth running of quality improvement processes**
- **Definition of standards requires a strong commitment of scientific and/or ordinal institutions**
- **Matching quality objectives and data collection of is of great importance**
- **Basic information on quality achievements of each establishment is accessible to patients**

5.3.5 Data protection

5.3.5.1 Definition of "data" and "patient file": key principles

Endoscopic video registration is a sensitive subject in terms of data protection, as pictures are apt to be stored and used by several stakeholders (not only the surgeon in charge of the patient), and to be shared very easily, considering today's techniques (CD-Rom, DVDs, Memory sticks etc..). Endoscopic pictures can also be used for different purposes (treatment, but also training or research purposes) Therefore endoscopic pictures are not to be considered as "pictures" only but also as "data". Indeed, in most of the European countries, a very broad and general definition of "data" is applicable. As a matter of principle, any kind of "pictures" including endoscopic pictures is considered as "data" irrespective of the media.

Endoscopic pictures are also, by definition, related to the patient's health. They deliver key information for further treatment strategy and are as important as other pieces of the patient file (minutes, X-Rays, blood tests, etc..). Hence, endoscopic pictures must be put back in the context of "patient file". Indeed, definition of "patient file" is very general. None of the countries we focused on excluded pictures from the content of the "patient file" (either in a paper form or an electronic form).

Key Point

- **In all these EU countries endoscopy pictures are not excluded from the definition of "personal data" and video pictures are actually treated as part of the patient file. Therefore, we can work on the assumption that endoscopic pictures (as other clinical pictures) are "personal data".**

5.3.5.2 Key principles of data protection

Europe wide, **legislation on data protection is largely derived from the EU Directive 95/46 EC (see above)**, without noticeable differences. Given that the EU Directives set out minimum requirements, some countries may be a bit more protective than others, but as a whole, **the key principles of the EU legislation, described below are applicable to all Member States, especially those we focused on (France, Germany, UK, Netherlands)**, i.e.:

- Quality of data
- Legitimacy of data collection
- Information to data subject
- Right to access and to object
- Confidentiality and security
- Key role of the supervisory authority (Data Protection Agencies)
- Exchange of data outside the EU possible if similar protection is provided

The role of Data protection agencies has been outlined in the Directive, but the status and the practical organisation of these agencies has been left to the Member States' discretion. Hence, structure of the Data Protection Agencies may vary across Europe:

In the UK, the "*Information Commissioner Office*" (ICO) [157] is entitled to:

- Enforce data protection legislation and provide a general enquiry and inspection service
- Resolve complaints from citizens who deem that Data Protection legislation has been breached
- Maintain the public register of Data Controllers
- Prosecute institutions or individuals who commit offences under the Data Protection legislation (legal sanctions)
- Organise and promote exchange of best practices in the field of Data Protection
- Enforce legislation on "Freedom of information" i.e. access to public information.

Local branches of the ICO have been set up in Wales, Ulster and Scotland.

The German Data Protection agency, called "*Der Bundesbeauftragte für Datenschutz und Informationsfreiheit*" (BFDI) [158] is quite comparable, in terms of jurisdiction and missions (Data Protection and "Freedom of Information") but Regional Agencies also exist on the Länder level, due to the federal structure of Germany.

The French Data Protection Agency (*Commission Nationale de l'Informatique et des Libertés* – CNIL) focuses on Data Protection only. For historical reasons « Freedom of Information » i.e. access to public information and documents is not within the remit of the CNIL.

It must be outlined that the CNIL is entitled to adapt Data Protection legislation (by defining "simplified requirements or requests") or to issue special dispensations on very specific subjects (if required).

In the Netherlands, there are several institutions and laws installed by the government for looking after the privacy of citizens in general. Some of them are specific for how to handle patient data in healthcare settings. All of them are based on or in line with the European Directive 95/46 EC.

- Law on protection of personal data (WBP). This law is the national implementation of the European Directive 95/46.
- Law on health care agreement (WGBO) is complementary with the law on protection of personal data but is specific for health care data [159]. Some key points are:

- The care provider has to protect the privacy of the patient in each situation
- The physician is obliged to have an individual medical file and the patient has access to his medical file
- Only the persons who are directly related to the treatment have access to the patient file. There are some exceptions: patient consent, obligations for the physician stipulated in a law or information for medical research (within stringent conditions).[vv]

There are two important institutions in the Netherlands: the 'college for protection of personal data' (CBP)[ww] and the 'National ICT institution for the care' (NICTIZ). The CPB is responsible to supervise all laws concerning personal data. The NICTIZ designs national standards regarding ICT in the healthcare.

Professional secrecy is stipulated in the WGBO. Processing personal data, as described in the WBP, is forbidden in those cases in which professional secrecy is necessary.

In the Netherlands there are no special laws, acts or behavioural codes specific for making and storage endoscopic images.

5.3.5.3 Use of data for research purposes

In the 4 EU countries we focused on, the use of health data for research purposes must abide by specific rules and go through a specific authorization process, generally to check ethical standards, but also for security reasons:

UK: Specific approval process

1. Any research project involving identifiable data has to be approved by an NHS Research Ethical Committee (REC) that scrutinises the main ethical implications of the Research project.

2: Informed consent of patient:

Informed consent of the patient is the general principle. Information must be delivered to the patient: identity of the "data controller", purpose of data collection, which data are to be collected, specific disclosures that will be made. Consent requirement are often burdensome as many RECs demand a "*consent to consent*" i.e. a further formal consent from the patient to pass their details on to research teams.

3. "Section 60" support

Section 60 of the Health and Social Care Act 2001[160] allows health authorities to permit the use of patients' medical information **without their consent, in some very specific cases**: "*essential medical purposes that are in the interest of patients, or in the interest of public health, and for which obtaining consent is impracticable*". This provision has been used mainly for **cancer registries** and **communicable diseases.**

France: Specific approval process

1. Specific Consultation Committee,

A specific Consultation committee has been appointed by the Ministry of Research: it has to verify the need to resort to personal data, the key points of the methodology with regard to the main legal requirements, and accuracy of these data with regard to the objectives of the objective of the research project.

2. Referral to the Data Protection Authority

Once the committee has given its approval, the request is referred to the National Data Protection Authority ("CNIL" in French).

3. Specific coding process.

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vv See further.

ww www.cbpweb.nl

Transmission of personal identifiable data by health professionals is allowed but requires a coding process. However, coding is not required within the framework of cooperative studies or considering the needs of the research project (if duly justified both from a scientific and technical point of view).

Nevertheless, presentation of the findings must not enable identification of patients.

Direct identification of patients is clearly forbidden.

Germany

1. Specific approval process: National Ethics Committee (National Order of Doctors)

A specific approval process is required under the control of the National Ethics Committee , which is set by the National Order of Doctors The National Ethics Committee [161] has issued an official position paper in 1999 [162], to reinforce ethical requirements, concerning the use of health data in the field of research. Stakeholders involved in research projects must address the following issues:

- Conducting a risk / benefits assessment: risk assessment (and correcting measures), reliability of findings, cost transparency, etc…

- Application of EU legal requirements (Directive 95/46 EC) especially concerning data exchange with non-EU countries (allowed if this country provides patients with a similar level of data protection)

- Striking the right balance between patient's rights (patient agreement requests) and the needs of research (easy and quick data processing)

2. Patient's consent

The key principle is obviously the patient consent but, exceptions to this principle are tolerated in specific cases (mainly: physical impossibility to obtain patient's consent, recruitment of a very large number of patients from whom consent cannot be obtained). However, these exceptions are tolerated provided research does serve a public interest.

3. Other key points:

Research stakeholders must be aware of the distinction between "core personal data" and "other personal data" and process data accordingly. Moreover, professional secrecy for "secondary use" of data must be in any case guaranteed, and more generally, patient health data are supposed to enjoy the same level of security and secrecy in a research context as in a traditional clinical context.

Eventually, at the end of the research process, data must be rendered anonymous, as soon as the research has reached its objective.

The Netherlands

1. The professional secrecy stipulated in the WGBO is applicable[163] for scientific medical research. Personal health data cannot be used for research without patient consent. There are three exceptions in which patient consent is not necessary:

- Patient is not able to give consent but there are some guarantees that the protection of the privacy will be protected within reasonable standards.

- It is not possible to ask for consent due to the character and the scope of the study but the form of the data is adapted so that it is impossible to link the data to individual persons.

Those exceptions are only applicable whenever research work serves a common interest, and actually requires these data. Besides, it is applicable provided the patient did not explicitly raise an objection for this use.

2. There exists also a special behavioural code for medical research ('Gedragscode voor Gezondheidsonderzoek "Goed Gedrag" '), which consists of concrete rules based on the WGBO (for data that can be linked to individual persons) but also of rules for anonymous data.

3. Medical scientific research with human law (WMO) [xx] is intended for all medical researches in which human are subject to actions or human have to follow rules of conduct. One of the stipulations of this law is that the study protocol has to be approved by a medical-ethical commission.

Collecting and investigating own patient data by a physician and his or her colleagues or within an institution with colleagues is allowed if the purpose is to improve medical knowledge.

If healthcare workers want to show identifiable personal data and patient records to a third party, they have to obey the European rules. (Directive 95/46 EC)

As a conclusion on this subject, it must be outlined that these rules must be set out with great care, basically **to strike the right balance between the patient's rights** (data protection) **and the needs of the researchers**. Imposing too many constraints could be penalizing for research. Within the NHS for instance this legislation has drawn fire from some researchers, who considered it as too rigid and somewhat burdensome.

5.3.5.4 Data exchange policy

Within each country, specific rules or recommendations have been issued to improve security of data exchange. In France and in Germany, a large number of guidelines or recommendations have been set out on that matter to embrace legal issues and technical issues simultaneously.

However, the most interesting reflection is to us the **British one**. Should endoscopic pictures be used for training or research purposes, or shared in a national integrated network, the key issue for Belgium would be to manage the sharing of a large volume of data and a large amount of pictures. For historical reasons, UK's National Health Service owns the largest integrated health data base in the world. Therefore, one of the main concerns of NHS authorities is to set up reliable and strict rules to manage these data exchange, nationwide.

France: guidelines mainly focused on the electronic patient file

In France, a large number of guidelines and recommendations has been issued on health data exchange, especially regarding the electronic patient file[164]. Over the last years, the CNIL (Data Protection Agency) has played a major role on that matter. Nevertheless, these rules or reflections mainly focus on access to individual patient files or individual security problems. Similar reflections are ongoing for future health cards, called "SESAM-VITALE 2", as they will host medical data.

Germany: guidelines focused on the electronic health card

Over the last years some rules have been defined mainly to implement the electronic health-card, and more precisely the patient file entered onto this card [165]. Very precise requirements have been set out within the framework of a "security-concept". However, this concept remains a traditional approach on access to data and security of data, from an individual point of view: access, identity control, authentification, etc. Apart from electronic health cards, other technical requirements in the field of data are coding and encryption. As a whole, the German guidelines are quite precise, from a technical point of view, but mainly focus on access to individual data (rather than exchange of large amount of data). Moreover, they do not embrace the whole scope of data exchange issues.

United Kingdom: specific NHS "Good Practice Guidelines for the transfer of batched person identifiable data by means of portable electronic media"

Over the last years, the use of portable data (CD-ROMs, DVDs, but also memory sticks) became more and more popular in British hospitals, where a considerable amount of data has to be handled. This phenomenon has raised concerns in terms of data protection and security. Therefore, the main objective of the NHS is to ensure safe data exchange, for security reasons (safeguard of data) and legal reasons (data protection issues).

xx Wet medisch-wetenschappelijk onderzoek met mensen.

As mentioned above, exchange protocols, coding systems or technical requirements exist in all western countries. However, the **NHS's reflection goes much further** than technical issues and addresses all problems related to data transfer. The **guidelines issued by the NHS** [166] have thus focused on the whole process of data transfer i.e. the 5 following steps:

1. **Appropriate training of staff** and access to clear policies and guidelines
2. **Authorisation** procedures for extraction of batched data
3. **Encryption** of data and management of removable media
4. **Secured courier arrangements**
5. **Actual deletion of data** from the portable media used to transfer

The rationale behind this guideline is that only duly trained people must be in the position to perform health data exchange. Data exchange itself must be performed in absolutely secured conditions from the beginning to the end of the process. This reflection could be applied to other data exchange hypotheses.

5.3.5.5 Retention constraints

In all EU countries (like in most of the western countries), storage of data – especially patient files- must be organised and structured in such a way that it can meet the civil liability requirements (should a legal action be brought against health care institutions or hospitals). Therefore, there is a very strict connection between storage policies and legal and judicial requirements. However, there is presently no harmonization of civil law on the European level (at least on that point).

Therefore, there are no uniform rules across Europe on that point. In some countries (France) a fixed period of time has been set up, whereas in others (UK) minimum and maximum periods have been agreed.

Key points

- **General data protection principles are very similar across Europe: principles of EU Directive 95/46 EC.**
- **Specific authorization process is required in all countries for the use of data for research purposes; however right balance between data protection and the needs of researchers must be struck.**
- **Specific methodologies for data exchange (esp. large amount of data) have been set out in some countries. Transferability of the British reflection to Belgium could be considered, as it meets the security needs of a national network, whenever a large amount of data and pictures is exchanged.**

5.3.6 Medical liability

Some rules may vary across Europe, depending on each judicial tradition. However, the key principles underpinning production and reception of evidence are quite similar:

- Production of evidence abides by similar principles:
  - General principle of freedom of evidence for each party
  - Use of pictures is allowed, provided pictures were legally collected.
- Reception of evidence by the Courts
- There are many rules on production of evidence but fewer written rules to address the problem of reliability of evidence as such. Besides, no specific rules concerning the use of pictures as such (same rules as the other media).
- Sovereignty of the courts remains the general principle. This means that it is up to the courts to appraise the reliability of evidence brought by both parties, but courts generally work on the assumption that electronic devices are reliable and that documents produced by these devices are reliable as well (until opposite evidence is brought by one of the parties) .
- In some countries, public records are received without further proof.

As an illustration of the principles mentioned above, two countries can be mentioned:

5.3.6.1 UK Civil Evidence Act 1995 [167]

General rule (Art. 9)

"*A document which is shown to form part of the records of a business or public authority may be received in evidence in civil proceedings without further proof".*

"A document shall be taken to form part of the records of a business or public authority if there is produced to the court a certificate to that effect signed by an officer of the business or authority to which the records belong".

In the article mentioned above "records" means records in whatever form, which may include videos or pictures. The concept of "public authority" includes any government department, without restriction. The NHS is thus considered as a public authority. There is no specific distinction between videos and still images or other evidence material.

5.3.6.2 France

In the French Civil Code, two articles have set out the key principles on reliability of evidence : Art 1316-1 [168] and 1316-2 [169].

The first one sets out that electronic documents can be received in the same conditions as traditional written documents, provided:

- the person who produced it is clearly identified
- the document is stored and kept in such a way that its integrity is guaranteed

The second one sets out that it is the role of the Court to sort evidence conflicts, whenever neither the law nor the parties did not set relevant principles on that subject.

6 SCENARIOS ON TECHNOLOGY MODALITIES

6.1 INTRODUCTION

Technology as such, and based on a limited volume of endoscopies, imposes only few constraints, but depending on possible process scenarios and their legal implications technology becomes intricate. In that scope four scenarios in tune with the explorative study's base questions have been defined. The scenarios representing a form of escalation in scale of use and consequently in complexity of legal and technical matters, allow the assessment of feasibility and venture into basic cost projections. Moreover the scenarios will serve as a basis to discuss the matter with stakeholders (cf. qualitative analysis further).

6.2 HOW DID THE SCENARIOS EMERGE?

Early in the research it appeared that technology in principle is unlimited, as long as budgets are limitless. However, very soon, the legal implications on technological requirements, and requirements of system validation sky-rocketed (see further).

In parallel, first discussions with experts in the field quickly showed that we needed to focus their attention through presenting concrete scenario's of set-ups, for the simple reason that whereas many people have had several experiences with video recording of surgery, almost always the objectives and settings were so different that experiences and cost estimates could not be compared.

Starting from our 3 sub-research questions, e.g. quality, training and liability of video registration, we have thus built 4 scenarios in order to discuss the added value of video registration

6.3 FOUR SCENARIOS

An overview of the characteristics of each scenario and technical requirements is presented in a matrix in the appendix to this chapter. All legal and technical principles surrounding the scenario's were described in previous chapters.

6.3.1 Scenario 1: ad hoc recording

Surgeons make recordings of surgical endoscopies without any obligation, nor a specific regulatory framework, except for existing laws. They do this on their own initiative, may or may not have conferred with the patient beforehand. It is either done out of scientific curiosity or for documenting an (un)expected finding. It could be done on the spur of the moment. Another possibility is that they want to document new materials, technology or procedure. In the simplest form the patient identity is not kept on the record, and thus the record is truly anonymous (or should be).

This scenario implies that:

- In legal terms a patient's informed consent is mandatory beforehand;
- If the record is truly anonymous it is not considered to be an element of the patient record;
- The surgeon records what he wants at any chosen time and is able to edit the record;

Scenario 1 is a default situation present today.

6.3.2 Scenario 2: ad hoc recording for training or teaching purposes

Out of different grounds (technical test, new scientific document, document for seminars, congresses or teaching, expected bio-anatomical rarity,…) the surgeon plans and knows in advance that he will record the procedure.

In practice only the "interesting bits" are recorded or kept for long term storage. For identification purposes, discussion, or scientific evaluation the record will not be anonymous, because of the vested interest to be able to know contextual information (anamnesis, concomitant diseases, patient demographic information etc). The patient identifier may be encoded but in legal terms this is regarded as equal to being NOT anonymous. Even if the patient number or id is deleted, contextual information may lead to the identification of the patient, so such records are not considered to be anonymous.

This scenario implies that (see chapters before):

- Written Informed consent is mandatory. ;
- All non-anonymous information is legally an element of the patient file;
- The record has to be kept safe for 30 years after the last patient contact. (Safekeeping, confidentiality, 30 years after last contact...);
- Safekeeping is assumed to mean that unwarranted access is impossible, and that the record can be consulted for the required lapse of time;
- In terms of patient rights legislation the patient is entitled to access and ask for a copy of the patient file;
- In this scenario it is unclear whether these aforementioned implications require special proof and technologies, beyond the safekeeping as a "good family father", as opposed to proof-of-authenticity, time-stamping and proof of integrity of the record;
- In case the record is part of a clinical trial of a new device, a specific informed consent, authorisation by an ethics review committee, an liability insurance and a written contract between study sponsor and hospital and physician is required (see further details scenario 3).

Scenario 2 is also already being in use, although we found that after early experimentation with the new medium (analogue or digital recording), surgeons have become somewhat disillusioned with the capabilities offered by the video recording technology.

6.3.3 Scenario 3: prospective limited recording

One or more centres participate to a prospective study that includes video recording of the surgery. The recording is systematic for a given indication, and or patient category and or disease. This may be a scientific project, a clinical trial, or a prospective sampling organised by the regulators.

This scenario implies the same legal and technical issues as those applicable to scenario 2. In addition:

- Codification of patient information becomes important, although in case of these studies, it may be acceptable that patient data can be stripped irreversibly, or else a Trusted Third Party will be needed (Art. 7 RD LPPD).
- Infrastructure demands are increased because permanent availability of the validated environment is needed;
- In operational terms, the burden increases because the surgeon cannot choose his moment/schedule or patient and whether to record or not, or at least his degrees of freedom in planning, scheduling or work may be reduced;
- There will be a need for centralised archiving. Initially though or with few projects or low volume projects this can be handled by shipping DVD's;
- A multicentre registry is needed in order to uniquely identify each record. Ideally this unique ID is allocated and recorded at video recording: unless a wide-area network provides this information, somebody will have to enter or capture that ID.

Scenario 3 may be initiated by the regulators or authorities, by hospital management, professional bodies or academic centres. If scenario 3 is performed within the context of medical research, the law concerning experiments on the human person is applicable.

Indeed, the term "experiment" in the law is defined very largely as every trial , study or research on humans aiming at the development of knowledge related to the execution of the health care professions as determined in the RD nr. 78. The law sets some specific conditions. Specific liability insurance covering liability of every person collaborating to the experiment needs to be contracted by promotor (Art.29). In case of video registration, the risk for damage in the scope of the experiment is limited to a possible privacy breach**.** Moreover the promotor needs to submit the study for advice to a Commission for medical ethics. Since the study will be take place at different location, one leading Commission for medical ethics will give the advice (Art. 11 §3). In legal terms the promotor of the prospective campaign will also have notify the treatment to the privacy commission to collect and use the data. The purpose of the data collection needs to be clearly defined in advance. Any posthoc "new" purpose for the data needs to be authorised. This however might be limited because in the original submission the organising body cannot collect more data than deemed relevant to the declared purpose. This is sensible in terms of privacy protection, but limits the usefulness of the data collection for academic research.

6.3.4 Scenario 4: systematic national recording

By regulation systematic video recording of all endoscopic procedures is mandatory. All technical and legal requirements for scenario 3 apply. In addition:

- All locations in the hospital/practice/campus where endoscopies can be done need to be able to monitor and record endoscopic procedures;
- All records need unique indexing, identification within the organisation where they originate. They also should be uniquely labelled on a national level;
- Date, time, surgeon identifier, some patient demographics and institution identifier need to be captured as record metadata;
- Metadata need to be encrypted so that unauthorised consultation of the metadata is impossible;
- Sampling can be according to any of the metadata;
- A trusted third party will have to code the data from hospitals before sending them to the public authorities and to manage access/retrieval of the records
- The record retrieval could be warranted in case of:
    - Liability litigation (and used either as proof to charge or discharge);
    - Quality sampling by the regulators or professional bodies;
    - Forensic evaluation (single case or samples).
- Indexing, integrity and access need to be protected, secured, tracked and disaster safe;
- Permanent proof of this protection and integrity needs to be available. This requirement relates to the patient rights legislation and regulations on the safekeeping of medical files;
- Such records could be used in court. Nevertheless the infrastructure would not need to meet requirements applicable to the validity of elements used in court other than the requirements applicable to the safekeeping of medical records;

In scenario 4 the legal impact on technology is profound, and compliance of systems to these requirements (time stamping, security, and audit trails) are significant. Proof of compliance through validation, active monitoring and repeated validation will also increase the cost. A nationwide systematic recording scheme, or any variant that includes the use of encoded patient information, needs to involve the services of a TTP since data from different hospitals are transferred to the government (art 10 RD LPPD). At the moment of writing, there are no "public" TTP's available, though some organisations or academic institutions have played this role in the past on a per-project basis.

At the start of this study, the exact status of Ehealth (at that time known as BeHealth) was unclear, in the meantime some advances have been made in terms of infrastructure and legal context for such a scheme.

Ehealth may become a technological and process enabler for scenario 3 and 4: time stamping, TTP, security and encryption, authentication of users etc . However it must be clear that Ehealth will not provide any application to collect and store video records.

6.4 HOW DO THE SCENARIOS RELATE TO THE RESEARCH QUESTIONS?

The implication of each scenario for each research question is described in this section regarding quality, training and liability. It is summarized in the Table 8.

6.4.1 Use of video registration to improve quality:

From scenario 1 to 4, the intensity in the search for quality improvement and the scale of use are increasing.
In scenario 1, when recording ad hoc, there is no primary intention to improve or monitor quality.
The training aspect of the scenario 2 could have an indirect impact on quality but there is no specific aim to improve general quality system. In scenario 3, there is a clear goal to reach better quality overall. However, the scale of use is still limited since only predefined samples are used for a specific purpose. This could lead to new scientific findings resulting in improved quality of care .
Finally, scenario 4 represent the largest scale of use: the primary purpose is to improve quality and therefore video registration has to be systematically done for every intervention.

6.4.2 Use of video registration for training and education purposes:

In the first scenario, an ad hoc recording could allow the surgeon to review the interventions he decided to register, by himself or with peers. The video registration could thus be here considered as a 'self-learning' tool.
Scenario 2 is totally dedicated and build to answer to the question of the use of such technology for training and educational purposes. Use can be very different, e.g. presentation, peer review, documentation, etc.
As in scenario 1, in the scenarios 3 and 4, there is no direct concern for training purposes. Nevertheless, the systematic recording of all interventions (scenario 4) could provide material that could be useful for training, while the images are not primarily recorded for this purpose.

6.4.3 Use of video registration for liability

None of the 4 scenarios aimed to study liability in particular. Nevertheless, since images are collected and saved and are part of the medical file, they could be potentially used as evidence before courts. The use of images in the scenarios 1 to 3 is less likely than in scenario 4. In this last, all interventions will be taped and thus will be systematically available for the use as proof in court.

Table 8: Link between the 4 theoretical scenarios and the research purposes

	Quality	Training/education	Liability
Scenario 1: ad hoc recording		X	X
Scenario 2: ad hoc recording for training purpose	X	X	X
Scenario 3: prospective limited recording	X		X
Scenario 4: systematic global recording	X	X	X

7 GENERAL COST ESTIMATES

Due to the fact that only a small portion of the necessary technology described in chapter 6 (scenarios on technology modalities) is available as commercial products, it is, at this point in time, impossible to make a solid budget estimate for the entire scope of the intended project.

Attempts were made to contact several businesses and researchers (supposedly) active in this field. Though we did manage to get contact, both academic and industrial labs were reluctant to share information on technical information or cost estimates. Most contact persons admitted that the automated image analysis was still many years off. It is therefore the intention of this chapter to outline the different cost components associated with the technology and to provide cost estimates where possible. All figures mentioned in this report are rough estimates, based on market figures. All amounts in this chapter do not include VAT of 21%.

7.1 COST COMPONENTS

Costs of implementation and correct use of… are determined by the cost of technology and operating cost. The technology component relates to the initial investment. The operating cost relates to the effort of recording and safely indexing, storing and safekeeping, but also to the cost of evaluating the records.

7.1.1 Investment costs

The investment covers the acquisition of hardware/software, the project cost to get the solution operational, including engineering work, installation, testing & validation and training.

7.1.2 Operating costs

Personnel costs

Video registration of endoscopic images can have a considerable impact on the workflow and workload.

- First of all, there is extra preparation work before the intervention. Following the principles of DICOM, a patient has to be identified in the system before starting the video record to ensure that the relevant metadata are added to the right electronic file and that the file 'properties'' has all information needed to identify patient, operator and time information.
- Furthermore, there is also extra workload during the operation. During the operation the surgeon notably has to use more technical functions to get a good and sharp view on his work, the operating field and the place markers.
- After the operation, time is needed to complete and process the record. Exporting the film record to a printer, CD/DVD burner, email or PACS may require more or less work, depending on whether the record is analogue or digital.
- Efforts are required to operate the system according to the workflow definition in order to guarantee the data is correctly tagged and stored. E.g. someone has to confirm correct indexation of the record, complete associated data, order the video registration in the system etc.
- Extra cleaning and disinfecting work and costs are needed when the system is located in the operating theatre[170]. However, using digital technology and the data network in situ, all infrastructures necessary for the storage and applications for video registration can be outside the operating theatre.
- Since automated image evaluation is not possible in the foreseeable future, competent, authorised and rare experts will be needed to spend time reviewing the records.

Operating theatre time

With regard to the use of the operating theatre, there is a risk that the recording requirements cause pauses and delays in the surgical procedure. This may increase the time at the operating theatre.

Logical security

Logical security of all devices and data bases is also to be taken into account. Physical security, especially security of physical hosting and redundant environment (data bunker) is a perennial cost as well;

Maintenance

As for any informatics device or system, there is an important maintenance cost to be taken into account. The annual maintenance costs due to the system suppliers are typically in the range of 15% of the initial investment on an annual basis;

Hosting, broadband and upgrades

Annual costs for hosting, broadband, and upgrades are also to be considered.

7.2 IMPACT OF THE SCENARIOS ON THE COSTS

In this section we did not comment on the costs of devices which we assume are already present in the hospitals (e.g. endoscopic cameras).

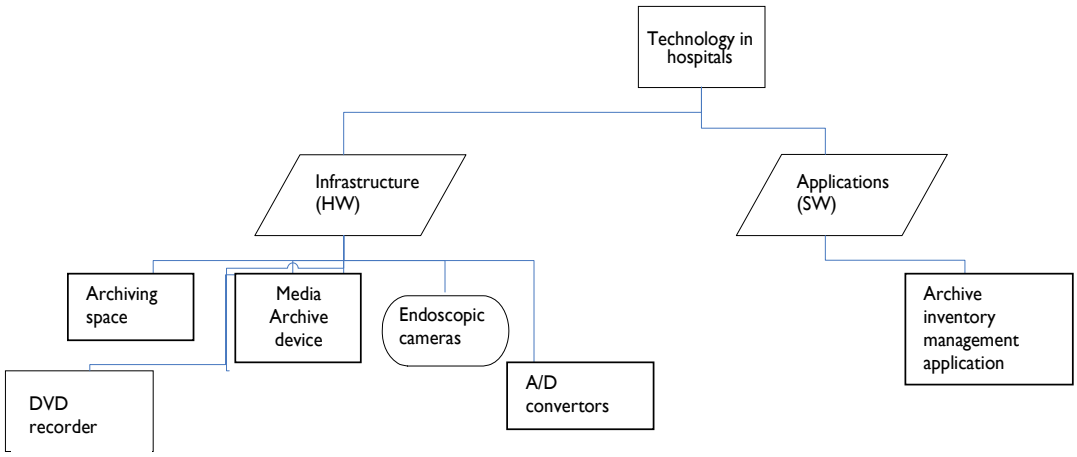
However, included are the systems and applications necessary in every hospital in order to manage the recorded video files, the central archive & management system, required for the governmental body assigned with this task, and finally the communication platform.

7.2.1 'Ad hoc recording' scenario

In the 'ad hoc recording' scenario the cost of technology is limited:

- Most endoscopic materials in use in western hospitals nowadays have the possibility to tap into a digital recorder, usually a DVD recorder (approx. € 150) or a blue-ray recorder (approx € 350);
- Additional cost is the cost of DVD's (approx. € 1,25 /DVD) or blue-ray discs of 50GB (approx € 24/disc). However the records are anonymous, and not necessarily indexed, this makes later retrieval difficult;
- Including a library and indexing facility (inventory management) is possible but increases the cost significantly.
  We did not differentiate between cost of software purchase and cost of developing software oneself. Obtaining comparable functions and quality is not expected to be cheaper by doing it with in-house resources.

Figure 3: Ad hoc recording scheme



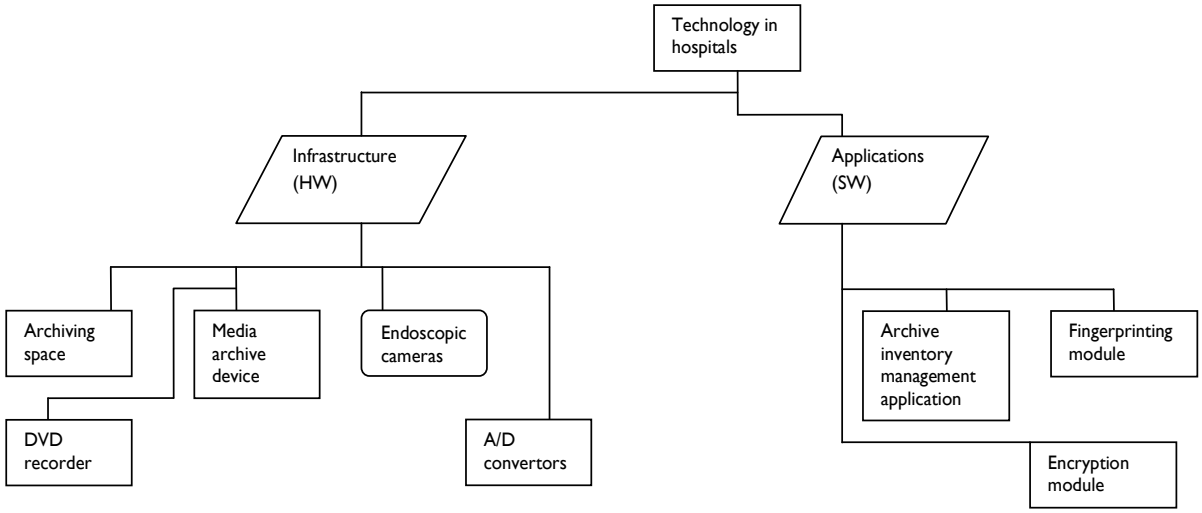
- Budget for the physical space itself is not estimated as it depends a lot on the hospital infrastructure.
- This scenario does not require on-line storage solutions

This scenario requires minor investments for infrastructure at the hospital-side. No infrastructure is necessary at a central governmental level.

7.2.2 Ad hoc recording for training purposes' scenario

In the 'ad hoc recording for training purposes' scenario, basic costs are related:

Figure 4: Ad hoc recording for training purposes scheme



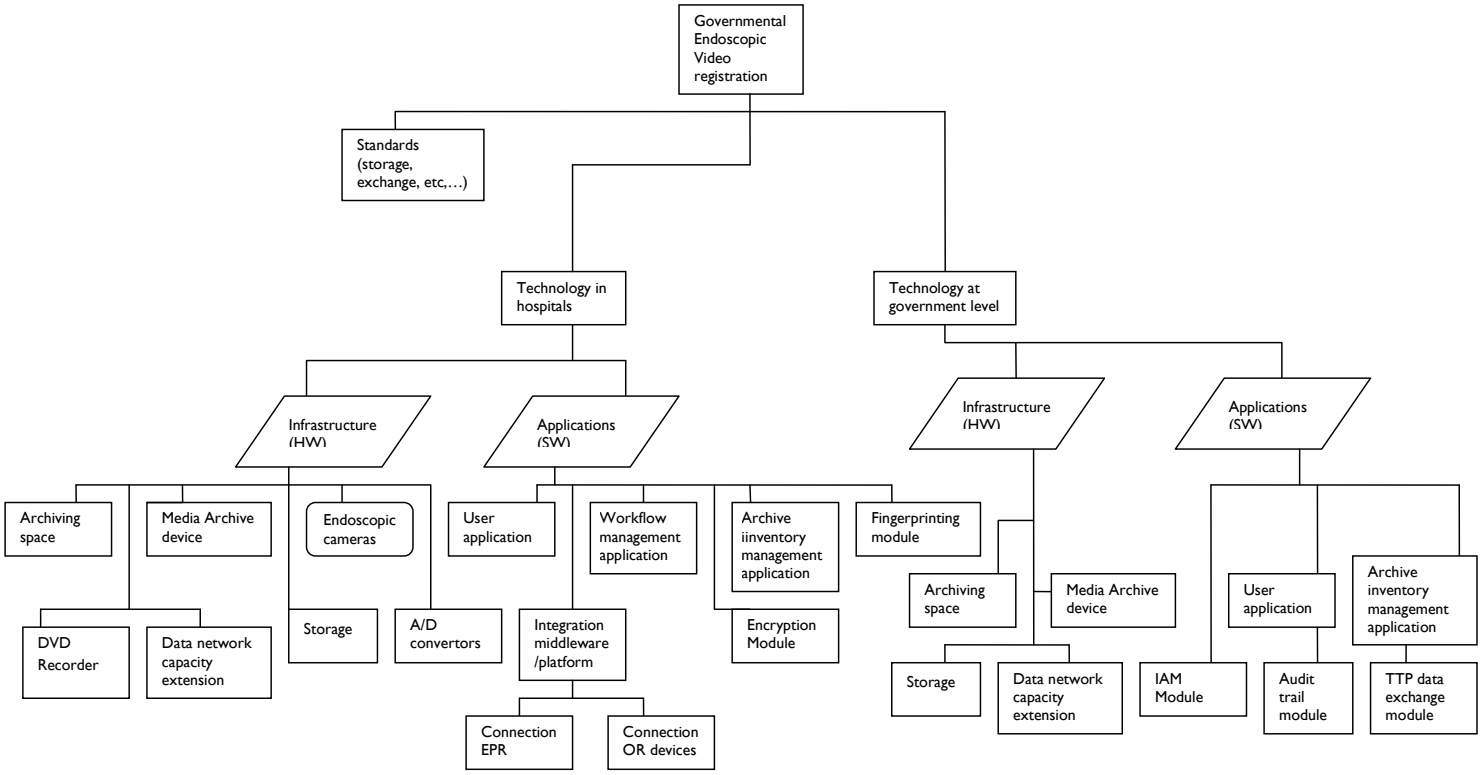
- to acquire a DVD writer,
- to acquire a writing/indexing software (inventory management);
- if the purpose is communication at seminars, congresses or in courses, the record will need editing. This increases cost as either technology and/or specific skills are required;
- as we assumed that in this scenario the records were pseudo-anonymous, the juridical consequences have an important impact on technology: techniques as encryption and fingerprinting will be required. Cost for such functionality is not available at this point in time as commercial products used in this context have not been identified.

7.2.3 'Prospective limited recording' scenario

In the 'prospective limited recording' scenario, costs start at the level of scenario two.

The permanent availability of the recording facilities, possibly in more than one endoscopy room, ups the requirements on technology and validation.

Figure 5: Prospective limited recording scheme



- As the recording is not an ad hoc initiative anymore but a regular activity in the operating theatre, it needs to be well embedded in the operating procedures in order not to disturb or endanger the quality of the surgery. For this purpose, supporting workflow and user applications will be required. Cost for such application is not available at this point in time as such commercial products have not been identified. Cost estimates for development require an in depth analysis of the required functionalities for such applications;
- As a consequence of the systematic character of recording in this scenario it is unlikely to manually link each recording into the patient's medical record. In order to automate this process an integration platform or middleware has to be set up between the recording platform and the system hosting the medical record.
  The costs of implementation depend on the actual systems in the hospital. A broker with integration inclusive is about €5.000,00 to € 25.000,00 depending on the hardware and time needed for integration. A DICOM module with fitting to specific modality costs about € 19.000,00 to € 21.500,00. Per modality which needs to be matched with the broker a budget of approx. € 2.000,00 is necessary[171];
- Cost estimates for integration of other devices in the operating theatre providing meta-data (e.g. heartbeat monitor) would require an identification of the useful data sources and a feasibility study of the integration;

- Storage solutions come in different forms and technologies, and different sources: a quick survey of internet prices brings us to prices per Gigabytes (GB) ranging from € 0,4 to € 1,4 up to € 14 per GB[yy]. Looking at fast performance, high stability and managed storage we assume that the high end technology will be needed, putting € 10 /GB cost being a reasonable assumption.
- Knowing that an edited and compressed file SD (standard definition) would be approximately 400MB big, on-line storage infrastructure cost per video equals € 4 /video.
- With the advent of HD (High Definition) video data volumes of 112 MB up to 300 MB per minute of video are estimated (DICOM Suppl 137: MPEG2 MP@HL Transer Syntax, DICOM Standards committee, WG13 Visibible Light). This would result in a cost of € 0,3 /minute of video;
- Considering the amount of data generated for the digital video stream, an important capacity increase of the data network will be required in order to transport these video files across the backbone. It will also require the implementation of multi-service capabilities on the backbone in order to prevent congestion of the different services. Cost estimates for the network infrastructure changes largely depend on the infrastructure in place, its capacity, capabilities and architecture. This needs to be studied on a per hospital basis;
- The functional requirements of the application required at a central governmental level in order to perform data analysis have to be identified and will drive the cost of the application to be developed for this purpose.
- Ensuring correct and useful recording will increase the human cost; time of staff handling the recording, but also delays on the whole team as people have to wait for the recording to be synchronised. In theory this should not be an issue, however practise seems to indicate that harvesting useful recordings needs attention to be paid to how the recording is done, often leading to requests to the surgical team for waiting or delays during the procedure;
- The evaluation of the records is an essential element of the set-up. We have not come across any reliable and industrialised way to have automated image review. Image recognition works by geometrical pattern recognition. This is so far not useable for analysing biological forms. Further these forms are moving, and most likely will present a deviant anatomy or aspect. This means that only a capable surgeon (peer) can do the evaluations; i.e. an expert needs to be available and spend his time reviewing and scoring the recordings. This is expected to be expensive: most competent experts have a flourishing practise, spending several days reviewing video records should entail compensation commensurate with the earnings of clinical practise. Add to that that experience shows that most of the recording (80%) is not useful for the evaluation: preparation time, procedure initiation, reconnaissance, ending and closing etc
  Assuming a daily wage of € 2.000 to € 2.500 for an expert reviewer[zz], and assuming that one person can process about 3 video recordings (average duration of 45 minutes) per hour using a professional studio, the evaluation cost per video would vary from € 83 to € 104 per video.

7.2.4 'Systematic global recording' scenario

In the 'systematic global recording' scenario, all costs that apply to scenario three, are also applicable. Nevertheless, other costs have to be added:

- The infrastructure has to be expanded to all locations where endoscopies can be performed.

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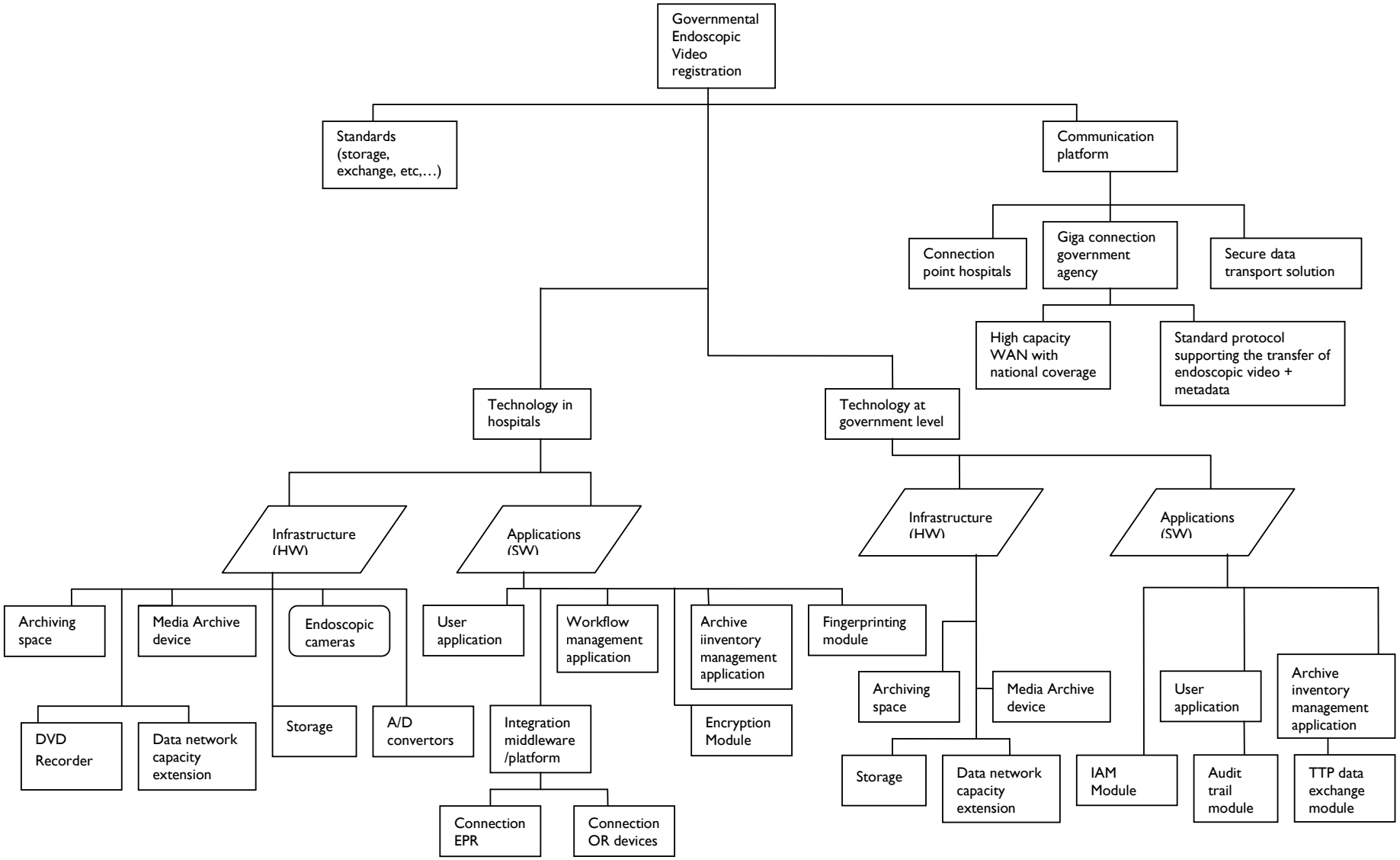
yy date of consultation: 29/09/2008

zz General physician, at least 15 years of experience

Figure 6: Systematic global recording scheme



This scenario requires a high capacity communication platform enabling near real time distribution of records to the governmental agency. Considering that all recordings will be done at HD video bitrates in the near future, such on-line communication platform would have to provide a bandwidth between 5 and 13 Gbit/s on an application layer, overhead of transport layers excluded, to take in 127.770 interventions on a yearly basis. This is in a WAN environment, with today's technology an absolute challenge, beside the large cost it would require to establish such WAN.

Table 9: Number of endoscopies billed to the INAMI/RIZIV in 2006 per specialty

Speciality	Number of endoscopies*
Abdominal surgery	55.075
Orthopaedic	25.469
Gynaecology and obstetrics	17.971
Gastro-enterology	13.594
Urology	12.428
Thorax surgery	2.727
Oto-rhino-laryngology	333
Vascular surgery	173
TOTAL	**127.770**

* Doc N Art35bis 2006

If we project artificially the storage cost to all the endoscopies realized in 2006 (RIZIV/INAMI), this will correspond to a systematic recording system. Knowing that an edited and compressed file would be approximately 400MB big, for 127.770 interventions, we need a storage capacity of 51 108 000 MB[aaa].

Assuming a cost of € 10 /GB for managed storage, the acquisition cost on a yearly basis for storage capacity equals € 511 080,00.

Assuming an average cost of € 100 per expert review, the total yearly cost due to experts for reviewing all endoscopy videos reaches € 12 777 000,00.

The requirements for security, audit trail, authentication linking with informed consents etc are a significant cost as of writing. Once the Belgian Government Ehealth platform will be operational this could be reduced as we expect authentication and monitoring of record-consultations, as well as audit trails would be offered by such a platform. It is unclear at the moment of writing whether this infrastructure would also provide enough bandwidth, storage or logical and physical secure storage. The Ehealth platform as a Belgian organisation has declared to become a TTP which might help reducing costs, though it is not known whether the TTP services would be free of charge or not.

7.3 DISCUSSION

Our ultimate hypothesis represents the extreme form of implementation (scenario 4), which however causes a number of legal and technical issues. Our findings show that there is today nowhere a tested and proven system that fulfils these legal and technical ? needs. Technically, it would be feasible to start developing such a system, or even to use COTS applications. However, the costs for the development and its use would be considerable. The benefits are to be found in an improvement of the quality of procedures, but quantifying financial returns is difficult.

Key points

- **The ad hoc recording scenario costs € 150 - € 350 to acquire a recording system and disks.**
- **For the ad hoc recording for training purpose scenario, costs for indexing and encryption software need to be added.**
- **To record prospectively (limited) interventions, costs are seriously increasing but will depend on the infrastructure already present in the hospital. Storage will cost +/- € 0.3 per video and € 83- € 104 to analyse it.**
- **The systematic recording of endoscopic interventions will cost the same as the limited (ad hoc) recording. In addition, infrastructure costs, communication platform costs and +/- € 500 000 for storage and +/- € 12 800 000 for reviewing have to be added (based on 2006 figures). Extra costs for a Third Trusted Party may be added.**

8 QUALITATIVE EXPLORATORY ANALYSIS

8.1 INTRODUCTION

In the previous chapters, the feasibility of the video registration in terms of legal and technical aspects has been analyzed. Also, the added value of video for quality control during surgical interventions per endoscopy is described based on a literature review. In this chapter, we want to crosscheck those findings with the opinions of the most relevant stakeholders in this area, namely the surgeons. Based on their daily routine in the operating theatre, what do they think about the added value and the feasibility of video registration of surgical interventions per endoscopy?
In this qualitative approach the feasibility of the use of video registration is also being addressed based on the four elaborated scenarios. These scenarios are explained above and can be found in addendum. To wrap up the chapter we will formulate a discussion and conclusion.

The specific research questions we will address in this chapter are the following:

1. What is the current experience of surgeons with video registration of endoscopic interventions?
2. What is the opinion of surgeons towards video registration of endoscopic interventions in the future? What are the pros and cons in terms of advantages/disadvantages, facilitating / hindering factors?

As we used a qualitative exploratory approach (see methodology part), we are looking for the content of opinion of the interviewees, not for the occurrence of the responses. If an answer or an idea appears once, reported by a single interviewee, it is as much useful for us that if this idea appears three times. If we want to assess how strong the opinion of the surgeons is in this matter, we need to complete the study with a quantitative approach.

All the findings are reported below. They solely reflect the thoughts of the surgeons interviewed. The aim was not to judge the opinions or to rectify legally incorrect statements.

8.2 FINDINGS

Answers reported into our document must be considered as the point of view of the physicians interviewed by us only.

Further conclusions cannot be drawn for all physicians and surgeons.

In the first part of the descriptive results, a general overview of the sample population of surgeons will be worked out with an overview of experience, hospital profile and background of the surgeons selected in the sample.

In the second section we will explore the current use of video registration among the surgeons.

The third section goes thoroughly into the surgeons' conception on future use of video registration. The opinion of the surgeons is asked in general and on the four scenarios, as described above.

In a fourth and a fifth paragraph, the surgeons' view on the position of the patient and government is addressed.

In each chapter the findings are organised in accordance with the research questions on training, quality and legal aspects.

8.2.1 Sample

Our sample of 11 surgeons is described in the next table.

Table 10: Description of the sample

ID	Specialty	Region	Type of hospital	Experience in surgery (years)	Experience in endoscopy (years)	Number of interventions per year	Number of endoscopic interventions per year	Supervise trainees	Teaching activities	Association's membership
1	Abdominal surgeon	Flanders	General hospital	16	16	800	± 640	yes	No	National + international
2	Abdominal surgeon	Flanders	General hospital	9	9	800	± 200	yes	No	National + international
3	Abdominal surgeon	Flanders	University hospital	30	9	550	± 150	Yes	Yes	National + international
4	Abdominal surgeon	Flanders	General hospital	11	11	800	± 500	No	No	National
5	Abdominal surgeon	Wallonia	University hospital	33	18	350	± 250	Yes	Yes	National + international
6	Gynaecologist	Flanders	General hospital	25	25	250	± 125	Yes	No	National + international
7	Gynaecologist	Flanders	General hospital	28	28	750	± 60	Yes	Yes	National + international
8	Gynaecologist	Flanders	General hospital	26	26	150	± 361	Yes	No	National
9	Gynaecologist	Brussels	General hospital	28	28	200	_	No	No	National + international
10	Gynaecologist	Brussels	University hospital	10	10	300	260	Yes	Yes	National
11	Gynaecologist	Brussels	University hospital	26	20	350	150	Yes	Yes	National + international

This purposive and pragmatic sample, as well as its size allows us to reach a justifiable saturation, enough for an explorative approach. Answers have although to be interpreted with caution and are not generalizable to the overall population of surgeons. It consists of opinions of some of them while we can assume that by the way we have constructed our sample, the majority of opinions have been raised. These could be used by policy makers to have an idea of the content of some of the reticences they could meet if they want to implement such technology. It remains although impossible by such a method to weigh the responses and to add frequencies. We are looking for the sense, not the numbers.

As a whole, eleven gynaecologists and abdominal surgeons were interviewed. They are all well-experienced surgeons, both for the abdominal and gynaecological group, with the slight nuance that gynaecological surgeons have more experience towards endoscopic surgery than the abdominal surgeons in our sample.

As it comes to the experience in the domain of number of surgical interventions over a year all have more than one hundred surgical operations in total.

Apart from experience matters other factors need to be taken into account. Especially educational purposes can influence the use of video registration. Of the eleven surgeons in the sample, seven teach at least at a level at nurse schools or higher.

The surgeons linked to university centres have an academic responsibility. Only four stated they never held classes.

Besides the teaching aspect, only four surgeons explicitly confirm their collaborative or steering role in research and publication studies. Four surgeons point out firmly that they have never taken an active role in research tasks. Three surgeons say to participate when asked to. A third aspect of educational purposes for surgeons is managing trainees. Of eleven, eight state they presently manage trainees. Only three say they currently and in the past do not assist trainees. One of these three works together with colleagues where trainees are active.

The vast majority is at least member of one Belgian or regional association. Seven out of the eleven surgeons in the sample are member of an international (European mostly) association in endoscopy or surgery practice in their specialisation filed. Four out of eleven have a very pronounced membership in a specific domain such as oncology, hepatobiliary surgery, sedioscopy or colorectal surgery. These are indicators of how active these members are in their domain. This is likely to influence their knowledge of the latest techniques.

8.2.2 Current use of video registration

8.2.2.1 Preliminary remark

This section takes stock of the situation against the main subjects we addressed in the report: quality, education/training and legal aspects. Advantages and disadvantages mentioned by the interviewed surgeons are also reported here: as advantages are mixed with the goals of video registration they are not presented separately and appear here and there in the text. Others consequences not directly related to one of the 3 purposes are presented in a separated section.

Likewise, training and education are often considered as a quality process. That is why there are no clear-cut responses between these two purposes. While quality improvement depends on training, responses related to education or training of the surgeons we have mentioned them in the 'training/education' section.

8.2.2.2 Current use of video registration in general

At present, there is a wide variety in use and experience with endoscopic video registration. University hospitals seem to have started some decades ago ("video registration was fashionable 15 years ago") while regional hospitals have substantially less experience. Moreover there is also a difference in the specific use of the video images. University hospitals use the endoscopic video images particularly for education purposes (presentation for students or during international congresses) while other hospitals use video registration rather for clinical purposes (discussion with colleagues and documentation of the medical file).
Some surgeons indicate that videotaping surgical interventions is a waste of time and money. One statement has been done that taping surgical interventions is no longer necessary since all surgery procedures already are taped. There's one case where a surgeon explains that taping on VHS-tapes is still possible in his hospital. Next to the obtained answer towards video registration, three respondents spontaneously indicate the possibility to take shots with photos instead of video.

There is not a single surgeon that indicates that today systematic video registration is done or the option to it. However, some of them mentioned the use of photos instead of video. Three surgeons routinely use photos to document the patient file. Others use photos for *ad hoc* documentation of some specific cases or procedures. Only one surgeon says it is not possible to take photos during surgery activities due to incompatibility of the current hospital systems with electronic images.

Asked for other possible users of video registration between the hospital walls the abdominal and gynaecological surgeons say they know that neurosurgery, urology, cardio surgery, orthopaedics and pneumology are interested in video registration. For orthopaedics, specifically some surgeons say that they use photos during the surgery to document better the status of the patient.

Only one surgeon acknowledges that none of his colleagues in the hospital uses video registration as it is not available.

Requests to document a scene or specific case from foreign colleagues or from physicians when they are patients are an incentive to tape surgery activities with video, at least sequences of the surgery.

8.2.2.3 Current use of video registration for quality

It appears in the interviews that, today, the video registration permit a wide variety in use.

The video registrations could be consulted in case of complications or when a new intervention is necessary. Almost half of the surgeons report that they decide to tape the scene specifically for complicated cases or interventions or at an expected risk of complications. Another advantage is the possibility to share the video images with colleagues inside and outside the hospital (in case of referral to a more specialized centre or physician).

Video registration brings also the advantage that taping surgical activities can lead to comparison in terms of the state of the medical problem at the origin, the intervention done and finally, the result of it.

This application is made in addition to other means used today to reach surgical quality standards in hospital in general:

- by reviewing of problem cases with colleagues
- by tracking of complications
- by retakes retrospectively
- by reporting yearly on performance
- by reporting incidents
- by documenting different parameters regarding interventions (time a patient is in operating theatre, entry time…)

Next to this, the safety of the installations and surgery environment is mentioned. The presence of a technical team that takes care of the available technical knowledge, a user guide for nurses, sterilization guidelines and review of the operational and sanitary status of equipments is considered to be important for the implementation of quality insurance.

The interaction with colleagues is also an important instrument in quality insurance. Half of the surgeons of the sample confirm this. Sub specialisations in units, in such a way that more interventions of the same kind can be executed by the same surgeon are mentioned as an interesting solution. An informal agreement on this is said to be an effective quality instrument. Only one surgeon admits that nor are peer review, nor ideas on total quality management in an operation theatre present in his hospital.

One could think that guidelines or procedures are widely spread but only a minority of the respondents say they attribute and are fully aware of these guidelines.

Complaint management by general practitioners or patients is once mentioned as a quality evaluation instrument.

One surgeon told he takes photos, not videos, to show that the correct procedure has been followed.

8.2.2.4 Current use of video registration for training or education

Keeping up with scientific knowledge and updating his own skills through continuous training is said to be essential to focus on the right techniques and procedures. Therefore, scientific reports towards comparison between endoscopic surgery with classic surgery can deliver an added value. In this educational environment courses, manuals and DVD's with the use of images can help the surgeon ensure the quality of his interventions. Two surgeons told that they use photos instead of videos for training or education activities.

Next to documentation and specific cases some surgeons say that they use video clips for congresses or seminars and for training and education purposes.

8.2.2.5 Legal aspects of current use of video registration: liability

A minority of the surgeons, from the sample, report that in some cases they use video registration for medico-legal issues as a preventive rule. For example in bariatric surgery in the domain of abdominal surgery, some juridical cases already popped up so the surgeon keeps the record to be able to document the case. Two surgeons say they use photos instead of video in case of sterilisations (gynaecologists) to avoid possible medico-legal problems afterwards.

Indeed, surgeons mention that video registration as it is currently used provides access to the right documentation, via video, to prove that no mistake has been committed. Thanks to this, they explain that good surgeons have nothing to fear, on the contrary. One surgeon also suggests that this video documentation is also a request from the courts to have more extended evidence in medical liability

Without questioning it directly, some surgeons directly indicate possible risks regarding medical liability issues and informed consent for privacy reasons whenever the intervention is recorded. In this optic, one surgeon always asks for patient's consent before the surgery starts when he plans to tape the intervention. Another one underlines the necessity of working by informed consent consistently. Another respondent says a patient has no right to see or receive a copy of the video.

Next to the potential use for liability, video registration of interventions raised questions on privacy: For example, in case of use for a congress or seminar, a patient recognises someone or recognises himself. Nevertheless, for the technology as it is currently used, one surgeon explains that it is neither a disadvantage nor a problem of privacy if the images are consulted by other colleagues.

8.2.2.6 Perceived general disadvantages and restraints in the current use of use of video registration

Next to disadvantages directly related to the quality, the training or the liability goals of video registration of endoscopy, several general disadvantages already appear today in the current use of this technology.

The first negative aspect of video registration seems to be the **enormous amounts of information** that are generated. Three surgeons underline this and the concern of the time needed to analyze and edit all tapes. The editing of the tape is a clear item since they bring forward that not the whole tape is useful (or has added) value within the process of screening an intervention.

A couple of surgeons say that it is, in their opinion, **time consuming to prepare** the set-up of the video setting and to test it. This time element is also valid during surgery where a risk of interruptions appears.

As far as technology itself is concerned, **possible compatibility problems** with other existing systems in the hospital environment are mentioned, certainly with the current problems around electronic medical files. On top of that, one surgeon thinks video images are useless when not electronic since the quality of the images would be too poor.

As already spontaneously mentioned in the current use of video registration by some surgeons two participants of the interviews say that the **ability or authority to view video or images is unclear** so that medical liability issues could appear. In that perspective the negative idea of individual evaluation of surgeons by fellow-colleagues is a fear among surgeons, as reported by one of them.

Also**, budget reasons** are put forward by two surgeons for not implementing video registration systems. This could have a link with the expensive and extensive storage capacity that has been indicated by two surgeons.

Key points

In the surgeons' view:

- **Video registration seems to be more used in university hospital, particularly for educational purposes.**
- **Interviewed surgeons use (also) photos to document a patient file**
- **While video registration is useful in case of complications of an intervention and could be shared with colleagues, today, surgeons perceive few added value of this technology for the quality improvement.**
- **Video registration has a clear added value for training or educational purposes by the possibility to improve skills by learning and evaluating and seeing new techniques.**
- **Video registration is used today as a preventive tool, as proof utilizable in case of medico-legal procedures.**
- **Today, not every surgeon is aware of privacy / inform consent issues for the patient whenever he/she will video registration an intervention.**
- **Video registration causes several disadavantages, i.e. amount of information, time consuming, technical problems, costs.**

8.2.3 Use of video registration in the future

8.2.3.1 Preliminary remark

The surgeons are being asked to what extent, and in which way video registration can be useful in the future. After that, we suggested them four scenarios of potential use of technology in the future (see chapter seven and eight).

In this section we will first report the opinion of the interviewed surgeons, both in terms of advantages and disadvantages, of video registration against the three objectives we focus on in this report. Responses come therefore from the general questioning on future use of the technology as well as from the four proposed scenarios. To summarize our findings, we have collected responses within the text following our three themes while responses were made by the interviewees, scenario by scenario. In order to stick to the original structure of the responses, they will appear in this form in the different tables illustrating our purpose.

Finally we will present the surgeons' view on our four scenarios.

8.2.3.2 Future use of video registration for quality

The majority of the respondents underlined that documentation of some cases or parts of an intervention with videos can be useful, with different purposes:

A first one is **extra documentation for the medical patient file**. Indeed, a well documented patient file with video fragments is very useful for the surgeon. Video registration of fragments at stated intervals of a surgical intervention could complement or even replace the current surgical report. Nevertheless, some respondents say that much depends in this situation on the storage capacity of the available systems and connectivity with medical file and other operational systems throughout the hospital and departments.

A second argument is **documentation of representative or specific interventions and complications** so that they can be used in similar cases or in discussions with colleagues both internally and externally in congresses or seminars. This is considered as an advantage by the surgeons, as reported in the responses related to the third scenario.

More precise **information in case of re-interventions and complications** is also rewarded as an asset when video is used to cover the surgical interventions.

A final idea about possible future use of video registration is the possible follow-up of a specific pathology for the same patient.

In general, the use of video registration could present numerous advantages for the surgeon, as it has already been mentioned: **improvement of knowledge, evaluation of skills or of particular interventions, image sharing with colleagues, documentation and comparison of techniques** seems to be the headlines. It could be used for **quality control** and also in consequence **should stimulate quality improvement**. Consequently bad surgeons would be eliminated, which is indirectly a recognition for good surgeons.

The fact that assistants are able to follow the intervention outside the operating theatre is preserving both the **serenity and the sterility in the operating theatre**. In a second time, they will be better prepared and therefore will be more efficient.

If the video registration is used in a quality system, it could lead to **risk avoidance**. In other words, surgeons who do not fell themselves able to do some intervention should renounce to perform it. Only good surgeons would dare to do the intervention and this will result in a better general quality of care, certainly in the 'systematic' scenario. However, in some cases, it could have for consequence that some patients would not receive the care they need.

As quality could benefit from such technology, this will have a direct impact on the patients. That is probably why surgeons mention almost the same advantages for themselves than for patients in terms of quality: the quality control made thanks to the video registration should lead to quality of care for the patient.

For the patient, the fact that images are recorded enables transmission to another surgeon, even in an other hospital. This could be **useful to ask for another advice**.

More specifically, patients could **compare results of surgeons**.

One surgeon sees hard evidence in video as a proof for the quality of his work and in this perspective one sees video registration also as an incentive to work in such a way that **quality is ensured for the patient**. However, this surgeon thinks evaluation of surgeons is a bridge too far.

Finally the video images could be used **to inform the patient about the intervention**. Nevertheless the latter has to be treated warily because it is not always recommended to show the videos to patients in all circumstances. Some physicians are concerned about the consequences if a patient sees the registrations (e.g. tumour, metastasis, bleedings…). Consequently the added value for such patients should be limited.

For the hospital, next to the direct advantages for the surgeons themselves and for the patients, the video registration of the interventions could allow managers to **control the quality and compare competences of surgeons**. It could also help him **to recruit skilled surgeons**. A positive consequence could be that the risk on medical proceedings lowers, which is good for the hospital image.

On the other hand, disadvantages or risks related to the use of technology for quality purposes are reported by surgeons, particularly in the 'prospective' scenario:

Indeed, if bad experiences for any hospital are documented and made known, its image could be negatively influenced. That could involve that complicated interventions would be therefore avoided. This decision could come from the surgeon him/herself or from the managers of the hospital.

Irritation or inconvenience through stress, comparison with colleagues, is also important to the surgeons.

The scenario on systematic recording could set a precedent in doing all operations by endoscopy to prove quality, even if a better or more suitable technique would be preferable. Moreover, scenarios three and four seem to be too aggressive for today's standards whereas video registration in scenarios one and two seem worthwhile but not the best way in quality improvement.

Two suggestions towards extra scenarios are made by the surgeon group. The first one is using the video registrations in discussions through video analysis among colleagues.

The second one is merely putting the video registrations in the patient medical file as documentation. Both suggested scenarios connect to the two first presented scenarios in the report and express the focus of the surgeons on rather informal approaches in the field of video registration.

8.2.3.3 Future use of video registration for education and/or training purposes

Another key element in the interviews is the added value of videos in the field of educative purposes in a wide range of subjects: guidance of trainees, permanent self-training, documentation for congresses and seminars. However, a remark is made that open view of surgical activity is also useful for training purposes: it allows viewing what is happening outside the body and, for example metadata about the patient, how instruments and incisions are made (such as the moment when the trocars are put in). With endoscopy video registration only, several information that could be interesting for educational purpose are therefore lacking.

For the second scenario, the educative added value is acknowledged, certainly given the idea that most interviewed surgeons work with assistants/trainees so that it is easier to guide and follow up the assistants. Nevertheless, surgeons fear for technical problems arises because the surgeons wish to register specific things useful for the training, which could complicate the intervention.

The prospective scenario shows a peer evaluation effect and input for scientific research or newly presented techniques.

8.2.3.4 Legal aspects of future use of video registration: liability

A much discussed topic of video registration is the medico legal aspect. Registering interventions involves both advantages and disadvantages both for the physician and patient. The video registration can be used by the physician to prove innocence in case of complications. So could the hospital. But on the contrary, the fear exists that video images can always be used against physicians, as if the recording is systematic, surgeons could not hide their mistakes anymore.

Looking repeatedly images reveals more than what a physician can see in real time during the intervention ("It is comparable with a disputable situation in a football match: TV viewers see a lot of replays but the referee cannot). Especially the gynaecologists fear a rise in medico-legal claims comparable to medico legal problems with registrations of medical Ultrasound of foetus. A physician stated that it will end in a situation in which each surgeon is "paranoid" due to a fear of medico legal consequences. Nevertheless, another physician was also wondering if the video registrations will be necessary if the no fault liability principles will be implemented in the future.

From the patient's point of view, video registration is perceived by surgeons as a useful mean to prove medical mistakes in case of legal actions. But there is a substantial risk of misuse by lawyers too. The registrations can lead to many unnecessary legal actions. Patients will get involved in long, difficult and complex cases in which the chance on a positive result for the patient is limited ("video registration is a weapon is the hands of patients").

Also, some surgeons stress the fact that the privacy for the patient should be considered.

8.2.3.5 Other future utilizations and consequences of the future use of video registration

First of all we have to notice that one surgeon thinks that documentation with videos for the patient is useless.

The others see several other future positive utilisations of video registration:

- The utilisation for the image and marketing aspect for the hospital are put central (mainly for scenario two). The use of such an innovation would attract patients, as being perceived as a guarantee for quality, making more efficient interventions. Patients should also be recruited on advice of young surgeons who have been trained in the hospital. It could even go further in recruitment strategy as the hospital who joins prospective programmes becomes more attractive as the hospital in that case is not afraid to show results and quality (scenario three).
- The idea has been raised that systematic prospective video registration (as presented in the fourth scenario) could also be used for the evaluation of medical staff members by the hospital.
- Because the assistant will follow the intervention outside the operating theatre, this will reduce the cost for sterile clothes.

Nevertheless, several disadvantages or concerns about video registration in the future are also mentioned:

- As for the current use of this technology, a disadvantage centrally put forward is the time required to evaluate and assess procedures as interventions might take a long time.
- The surgeons express their concern that the relation between patient and surgeon could be threatened as the focus could change towards images and analysis of this instead of trust in therapeutic skills.
- The misuse of images in combination with bad quality of images is evoked.

If the video registration is not made ad hoc (scenario 3 and 4):

- There is a risk of change in the behaviour of the surgeon because of his fear of control
- The image of the hospital could be negatively influenced
- Surgeons express their concern towards misinterpretations
- Surgeons express their concern towards limitations of their therapeutic freedom and professional secrecy, which could lead to exclusion from professional insurance.
- The health insurance could misuse the information to exclude certain patients from health insurance.
- There is a risk of tendency towards recruiting more expensive surgeons
- Atmosphere could change around interventions.

Several technical or practical aspects are also pointed out:

- The need for strong computers that could manage sufficient storage capacity
- The risk of technical failure
- The maintenance of the systems
- The high investment costs
- Additional workload to guarantee no deletion (copies, administrative tasks)
- The presence of extra staff in the operating theatre to operate registration system
- All the problems related to implementation (but surgeons have not detail them here)

The problems and restraints linked to the implementation of the video registration were asked specifically to the surgeons and will be detailed in the next section.

Table 10: Advantages perceived by the surgeons, for the stakeholders (surgeon, patient, hospital) in terms of quality, training, liability or other for the 4 proposed scenarios

	Ad hoc recording	Ad hoc recording for training purpose	Prospective limited recording	Systematic global recording
Advantages for surgeon				
Quality	• Consultation with colleague • Possibility to evaluate intervention/skills • Possibility to control quality • Use in case of medical complications • Clear documentation of intervention • Comparison of different techniques (taking into account post operation results) • Use in case of second intervention for one patient • Use in case of similar interventions • Assistants can follow outside the operating theatre: more serenity in operating theatre	• Consultation with colleague • Possibility to evaluate intervention/technique • Quality control • Interventions done by assistants more efficient (better preparation)	• Consultation with colleague • Possibility to evaluate intervention/technique • Acknowledgement of competences • Elimination of bad surgeons (recognition of the good surgeons)	• Use in case of medical complications • Acknowledgement of competences • No operation report needed anymore
Training	• Better education	• Better education: show and explain mistakes of assistant • Better training for surgeons (live interventions during conferences)	• Better education • Comparison with better experienced surgeons	
	• Proof in case of medico-legal proceedings			• Proof in case of medico-legal problems • Compensation
Liability	• Show and discuss own techniques/skills with firms (of instruments)	• Time (not always present at interventions done by assistants)	• Less interventions (no delicate interventions anymore)	

	Ad hoc recording	Ad hoc recording for training purpose	Prospective limited recording	Systematic global recording
Advantages for patient				
Quality	• Documentation of intervention • Quality of care • Assistants can follow outside the operating theatre: increased sterility in operating theatre • Use in case of consultation with other surgeon or in other hospital	• Quality of care • Use in case of consultation with other surgeon or in other hospital • Higher quality and efficiency of interventions done by assistants(better preparation)	• Quality of care • Use in case of consultation with other surgeon or in other hospital • Comparison results of different surgeons • Only good surgeons	• Quality of care • Only good surgeons
Training		• Better trained surgeons in future		
Liability	• Proof in case of medico-legal problems	• Proof in case of medico-legal problems		• Proof in case of medico-legal problems
Advantages for hospital				
Quality	• Complete, well documented medical file • Stimulate quality improvement		• Control, compare competences and recruit good surgeons	• Evaluation of medical staff
Training	-	-	-	-
Liability	• Proof in case of medico-legal problems • Less medico-legal proceedings (as consequence of recruitment of better skilled surgeons)			

	Ad hoc recording	Ad hoc recording for training purpose	Prospective limited recording	Systematic global recording
Others		• Assistants can follow outside the operating theatre: less costs for sterile cloths • Assistants who experienced good education will refer patient to that hospital in future • Image hospital: good centre for education • Image hospital: hospital known for quality, innovation… • Image hospital: in showing images during (inter)national conferences	• Image hospital: good surgeons • Image hospital: good surgeons - good quality of care - good for recruitment of new surgeons • Image hospital: less complications, more efficient interventions	• Image hospital: good surgeons • Image hospital: good surgeons - good quality of care - good for recruitment of new surgeons

Table 11 : Disadvantages perceived by the surgeons, for the stakeholders (surgeon, patient, hospital) in terms of quality, training, liability or other for the 4 proposed scenarios

	Ad hoc recording	Ad hoc recording for training purpose	Prospective limited recording	Systematic global recording
Disadvantages for surgeon				
Quality		• Duration of intervention	• Chance on prohibition on certain interventions • Control and comparison of skills with colleagues • Inconvenience for surgeon • Irritation of surgeon • Stress • Tendency to do all operations by endoscopy	• Chance on prohibition on certain interventions • Evaluation of intervention: who and how? • Relevant information outside endoscopic image is not available
Training	-	-	-	-
Liability	• Risk of misuse of images by lawyers			• Proof in case of legal proceedings • Impossible to hide mistake
Others	• Time to look the video registration afterwards • Duration of intervention	• Time to look the video registration afterwards • Sometimes bad quality images	• Time to participate in study • Time to look the video registration afterwards • Chance on exclusion from professional insurance	• Limited therapeutical freedom • Misinterpretation of banal problems • Threat to professional secrecy

	Ad hoc recording	Ad hoc recording for training purpose	Prospective limited recording	Systematic global recording
Disadvantages for patient				
Quality	• Fear of surgeon: no delicate interventions any more	• Duration of intervention	• Fear of surgeon: no delicate interventions any more • Change in surgeon behaviour • Stress of surgeon	• Stress of surgeon • Suspicious relation between patient and surgeon • Duration of intervention
Training	-	-	-	-
Liability	• Long legal proceedings • Privacy of patient	• Privacy of patient		• Long legal proceedings • Privacy of patient
Others		• Duration of intervention in case of technical problems	• Duration of intervention in case of technical problems	• Duration of intervention in case of technical problems • Misuse by health insurance: exclusion from health insurance

	Ad hoc recording	Ad hoc recording for training purpose	Prospective limited recording	Systematic global recording
Disadvantages for hospital				
Quality	• Fear of surgeon: no delicate interventions any more • Extra staff in operating theatre (to operate registration system)→ change in the atmosphere	• Duration of intervention	• Fear of surgeon: no delicate interventions any more	• No more surgeons would dare to do endoscopic intervention
Training	-	-	-	-
Liability	• Proof in case of medico-legal problems			
Others	• Time of medical staff • Strong computers • Storage • Risk of technical failure/problems • Maintenance of registration system • Investment costs • Extra staff in operating theatre (to operate registration system)→ more costs • All kind of problems related to implementation	• Time of medical staff • Investment costs	• Time of medical staff • Investment costs • Image hospital: in case of negative evaluation	• Time of medical staff • Storage capacity • Investment costs • All kind of problems related to implementation • Image hospital: in case of negative evaluation • Additional workload to guaranty no deletion (make copies, administrative tasks…) • High wage for surgeons • Suspicious atmosphere

8.2.3.6 Restraints/problems for implementation of video registration in the future

As already mentioned, implementing video registration will lead to disadvantages for the hospital.

The time needed to review images and sequences is mostly considered to be burdensome and inefficient. During interventions, the setting of taping the activities could cause a delay in the surgical procedure as the images have to be perfect for possible future use.

Infrastructure, time, cost, rising technical and logistic problems and maintenance seem to be major obstacles, already, especially when some surgeons want to have some ad hoc video registration of interventions for their own use.
With a scale of use increasing, the spreading and storing of images becomes more important and the investment costs play a greater role. In the last scenario where registration is prospective and systematic, the large administrative burden to safeguard the images and the storage capacity are important.

As for possible restraints in this field, technical elements are important as the investment costs are considered to be high. This means storage capacity, compatibility with other applications.

Generally, the resort to comply with the informed consent is seen as an important obstacle as this is time consuming by explaining the purposes to the patient.

Other possible restraints are the more extensive information and data management that the surgeon has to make for the patient, loss of time, editing images and the procedure on how to evaluate an interventional procedure (who, what, how).

A negative factor as seen by a surgeon is that this kind of systems outdate rapidly so they are barely useful as a systematic instrument.

Table 12: Problems/restraints linked to the implementation of video registration in the future according 4 scenarios

	Ad hoc recording	Ad hoc recording for training purpose	Prospective limited recording	Systematic global recording
Technical	• Compatibility and integration within other applications • Purchase and implementation of video registration system (once-only) • Storage	• Compatibility and integration within other applications	• Infrastructure: registration facilities in all operating theatres • Investment costs • Resistance of surgeons • Storage • Compatibility and integration within other applications	• Infrastructure: registration facilities in all operating theatres • Storage • Technical problems • Compatibility and integration within other applications
Legal	• Asking for 'informed consent' is time-consuming • Asking patient consent (explanation about new procedure)	• Asking for 'informed consent' is time-consuming • Asking patient consent (explanation about new procedure)	• Legal constraints (general)	• Legal constraints (general) • Asking patient consent (explanation about new procedure)
Other	• Investment costs • Lost of time for medical staff	• Edit images is time-consuming • Fear for misuse • Investment costs • Lost of time for medical staff	• Selection of registrations for evaluation • Volume of registrations to control	• Evaluation of intervention: who, what and how? • Investment costs • Resistance of surgeons • Threat to professional secrecy

8.2.3.7 Facilitating factors to implement video registration in the future

In terms of potential facilitating factors for video registration in the informal first scenario both legal and technical arguments are expressed. An easy system to register and more technical innovations combined with support of legal experts in this field would be facilitating factors. Also guarantees in the domain of compensations, professional secrecy and protection on accessibility would be useful to facilitate the introduction of video registration. In scenario two an explicit demand of trainees is seen as an incentive to use video registration.

Only in scenario four a totally new idea is expressed: support from government is seen as an important facilitator.

Table 13: Facilitating factors to implementation of video registration in the future according to 4 scenarios

Ad hoc recording	Ad hoc recording for training purpose	Prospective limited recording	Systematic global recording
• Support of legal experts • Technical support • Registration system easy to use • Compensation • Other applications in hospitals compatible with registration system • Enough guarantees that video registration is part of professional secrecy • Protection on accessibility of images • Limited costs for surgeon and hospital • Garantuee of no misuse • Technical innovations	• Support of legal experts • • Explicit demand of assistants • Compensation • Patient consent asked by other person than surgeon • Central database for storage • Technical innovations	• Compensation • Technical support • Other applications in hospitals compatible with registration system • Compensation	• Compensation • Governmental support for implemenation • Other applications in hospitals compatible with registration system

8.2.3.8 Appreciation of feasibility of the theoretical scenarios proposed

During the interviews, four scenarios (as described above and in addendum) were thus introduced to gauge for the feasibility of possible video registration set-ups. The objective of this input is to structure the ideas and opinions in these built up scenarios, from informal towards systematic video registration in four steps. To test them, we have asked the respondent what they think about the feasibility of these scenarios because we could consider them as hypotheses and might recommend one or more of them to authorities.

All but one respondent confirm that the first two scenarios namely informal, colleague consultations of video and registration for education and training are feasible. Apparently, there is no discussion in the sample around this theme.

When it comes to the prospective or sampling campaigns and moreover the integral, systematic video control more doubts arise. There is likely to be a split opinion around selective prospective campaigns as long as they are voluntary. Almost half of the surgeons do not want to consider such a kind of video registration. For systematic video follow-up, all but one surgeon think this is a bad idea. The reasons for this are numerous. Guarantees of protection of the images, legal aspects, other as important parameters to cover, costs, editing and time problems are put forward. Important to note is also that fear and resistance are strongly stressed. Quality improvement is only seen in the prospective scenario as a topic without confirming the added value of the instrument but in the systematic approach broader arguments are expressed as costs, legal aspects and resistance.

Key points

In the surgeons' view:

- **In the future, video registration could serve quality since it could be part of the medical file, document specific interventions or complications and only qualified surgeons would perform risky interventions. It also limits the staff in the operating theatre and it could be used for quality control.**
- **Video registration could be useful to inform patients on the intervention**
- **Video registration will be very useful for training purposes but is not sufficient because information is still lacking**
- **Video registration could be used in medico-legal procedures but with some disadvantages as well for the patients as for the surgeon. Moreover it rises privacy issues.**
- **Video registration could serve marketing for the hospitals**
- **It will present also disadvantages, i.e. technical, time consuming, costs, implication on the relationship between the surgeon and his/her patient, consequences on therapeutic freedom and issues about health or professional insurance.**
- **Implementation of video registration in the future could be balanced by the costs and the technical requirement such as storage and compatibility with other applications.**
- **A more clear view on the legal aspects would facilitate implementation of video registration (for guarantee professional secrecy, privacy, accessibility). The support from the government could also facilitate implementation.**

8.2.4 Impact of video registration on the patient: access to images

Next to the benefits in quality if the video registration is used and the potential use of image in court, the video registration of the intervention by endoscopy raised the general question for the patients in terms of his/her access to images.

Most comments of surgeons on the possible consequences in providing patients with images are that the patient will need clarification that goes along with these images. The patient is most of the times not capable of interpreting the video. This can lead to misinterpretations and have negative consequences such as worried patients that start medical shopping. Besides, individual explanation to each patient about video images is clearly time-consuming.

Next to that, the technical compatibility of the video provided by the hospital with the domicile TV set could lead to problems since different technologies are applied. Providing the patient with a copy is therefore both time consuming and costly for the patient.

Providing the patient with the images can never lead to decent quality control since the patient is not in the position to analyze them. In this situation, there are no direct consequences for the surgeon.

The idea is stated that there is an increased pressure on the surgeon but the right on information for the patient is considered as fundamental. On the contrary, one surgeon denies this right and believes he can refuse to deliver images or even make the video.

The fact that the patient's access to the videos could lead to a rise in legal claims is also a subject that has been identified by the surgeons. On the other hand, they state that video evidence will help them win legal claims against the patient. This situation can have a big impact on the confidence between surgeon and patient in general. Video registration in this discussion is a negative factor.

Key points

In the surgeons' view:

- **Next to technical problems, access to image for patients will raise issues on explanation of the images and confidence between the surgeon and his/her patient.**
- **There is an uncertainty in matters of legal consequences in case a copy of the video registration is given to the patient.**

8.2.5 Potential perceived role of the government

The government could play a role in implementing video registration since cost and standards are important. Therefore, the surgeons were asked to give their opinion on the link between government and quality procedures in an operating theatre and more specifically on video registration.

8.2.5.1 Government and quality procedures in operating theatre

It is a major task for the government to set quality standards, by such means as quality indicators and frames, more than direct guidelines that are too strict and do not safeguard therapeutic freedom anymore. The surgeons acknowledge that external control can be useful and that more initiatives have to be taken to discuss quality but that the government as such is not qualified to do this. The best way of organising some sort of control is through the own surgeon professional associations.

The respondent group also states that the budgetary issue to realize these standards and quality frames are important obstacles.

Very few examples of detailed quality improvement instruments in an operating theatre have been described. Only mandatory continuous education programs set out by the government are suggested. The interviewed surgeons clearly state that the current accreditation procedure is an empty box since it is only formal and not challenging.

The feeling among the surgeons exists that the government's role should be to help surgeons implement quality improvement policy, instead of controlling. This controlling aspect is considered to be a threat for the surgeon community.

The responsibility for quality insurance has to remain a professional association duty as the impact of these groups is bigger and better appreciated.

8.2.5.2 Government and implementation of video

The opinion has been formulated that quality control thanks to video could be positive since this would help surgeons focus on delivering quality.

The majority of the opinions however go into better options to invest governmental money towards training and tertiary centres that can provide training material and evidence based reports. The budget for video registration would be too big in relation with the return on investment on quality. An exact example of added value in obliging the implementation is that video documentation could prevent expensive biopsies ? in endometriosis cases to prove that the correct procedure has been followed.

A quality control of endoscopic intervention by the government is not relevant according to physicians.

- Some physicians are wondering why endoscopic surgeons should be controlled while open surgery is more delicate ("If systematic video registration of endoscopic interventions would be implemented, all physicians leave. Why endoscopy and not other interventions?"). Moreover a lot of other professions also have a high social responsibility ("why not putting a video recorder in each bakery to control if the baker is using only high quality products in his bread?").

- The endoscopic intervention is only a small part of a whole process. Other factors are at least as important. For example, other parameters and pre- and post-intervention activities can be crucial. The video registration of endoscopic interventions can nor register the insertion of the carter which is a crucial point in the intervention. A lot of the complications are originated at this early stage..
- What is an optimal intervention? The outcome of the whole process is more important than the technical precision of an intervention and physicians set great store by therapeutic freedom. Even physicians have discussions about the most efficient interventions and correct technical acts ("How can the government judge about quality if even experienced surgeons on international congresses disagree about technical aspects of interventions?).
- Video registration is not a good controlling tool because there are too many possibilities to avoid this control: how to guarantee that all interventions are registered? How to guarantee that critical intervals of interventions are registered? How to guarantee that the physician is doing the intervention by himself?

Most surgeons are not only convinced that governmental control is irrelevant, they are even concerned about the negative impact of systematic video registration. There is a large variability in arguments:

- Almost all physicians are convinced that video registration will have a negative effect on the quality of the intervention because of the fear of possible consequences ("Big brother is watching you"). Besides the fear and additional caution will inhibit the operation and will extend the intervention time which is negative for the patient ("A surgeon has already stress for very complex interventions, video registration would be an additional stress factor").
- Some physicians will choose to do each intervention by open surgery to avoid the control. Conversely, other physicians will perform only endoscopic interventions to prove themselves even when this is medically not the correct method.
- Some risky interventions will not be carried out anymore because of the high risk on problems which would be registered.

Key points

- **In the surgeons' view:**
- **The government is responsible in setting a frame of quality standards and indicators but the professional associations have the duty to assure quality in practice.**
- **Video registration is considered not to render the best cost benefit relation in instruments improving quality.**

8.3 DISCUSSION

8.3.1.1 Interview conducting and limits:

Before discussing briefly the findings from the interviews of the surgeons regarding the feasibility of video registration as a quality improvement tool, it is of key importance to stress that the frame of the interviews is a qualitative approach in an exploratory context. This means that the input of the surgeons is not evaluated in a pure numeric approach but that the content of the ideas expressed was taken into account and are indicative.

We interviewed 11 surgeons and we rapidly reached "saturation of the data", were no new information emerge. In their study on the number of interviews needed, Guest et al concluded that saturation occurred within the first twelve interviews of their dataset, although basic elements were already present in the six first ones[172]. In consequence this small number of interviews, while it could have been larger, could be considered as accurate for our explorative purpose.

The saturation was rapidly reached probably because the technology we study here is not very much implemented in the daily practice of the surgeons.

Also probably due to this scarce use of video registration but also to the more extended use of endoscopy, several responses of the surgeons do not concern specifically the 'video registration' aspect. Advantages of visualisation of the intervention on a screen are well described while it is not the specific purpose of our study. Nevertheless, we have anyway reported the responses because they could be used in the general reflection on the future utilisation of this technology.

Question is: do we need to record and save the images? This has been difficult to isolate in the interviews.

There are also two general remarks that are important to make. In case the respondents do not see advantages in a proposed scenario, this does not mean that they do not see advantages at all since their opinion can be quite biased by the other suggested scenarios. Besides, in scenarios three and four some respondents do not express disadvantages since they already expressed an unrealisable opinion on video registration as such. We can conclude that the theme of video registration is on the one hand not seen by surgeons as a driver for quality improvement and that on the other hand the opinion on video registration is rather passive.

The opinion about the added value of future endoscopic video registration in the operating theatre is clearly linked with the current use and level of experience. University hospitals see mainly a role of video in the future for education purposes. They are cautiously optimistic about the added value and are aware of the disadvantages based on their experience. One could conclude that the hype in this type of hospitals is already over. Conversely, most physicians of other hospitals are more enthusiastic but they see the advantages of video registration specifically for the documentation of the medical file or for clinical reasons through discussions with peers.

8.3.1.2 Video registration and quality

As a general comment coming from the interview round of gynaecological and abdominal surgeons, one can say that video registration is not the first topic that crosses their mind when talking of quality improvement of surgical interventions. The lack of knowledge on technical implications and the unclear direct added value besides of more fundamental documentation does not support the four different propositions as scenarios. Only the informal, collegial discussion is clearly and largely supported but video registration is only a minor step in this.

We noticed a lot of doubt on the questions "how do you manage quality in your operating theatre" and "how do you manage quality specifically during endoscopic interventions". The answers were short and varied a lot: a regular check of the operating equipment, the preparation of the room by the physician, a registration of complications, registration of duration of intervention etc.

This probably proves the vagueness of the term 'quality of care' and especially 'quality management in the operating theatre': what is quality in health care and how to improve? Consequently the physicians also have different views on the role of video registration of endoscopic surgery to improve quality of care. On the one hand, some physicians see a direct link because video registration implies a better training of the future surgeons. Others are convinced that video registration will improve the attentiveness of surgeons during operations. Another argument is that bad surgeons will disappear automatically.

On the other hand almost all physicians were opposed to a systematic quality control by the government based on video registration: One can say that all surgeons are concerned about quality improvement, but they have different views on its implementation. Quality insurance and control are also not considered to be the responsibility of higher authorities, but the tasks of professional associations of surgeons.

8.3.1.3 Video registration and training

The most renowned aspect on training in the video registration domain is the possibility to conference with peers and to decide on best options in specific expertise domains. Next to that specifically more visual material that is been provided for students is also stressed. Surgeons have nevertheless mentioned the fact that recording images for training purposes present a lot of disadvantages. This process is time-consuming. The time is also an issue in reviewing images with assistants. Indeed we know from the external expert panel that an efficient reviewing of images takes a lot of time. It is also insufficient to use the video only for training purpose.

8.3.1.4 Legal aspects of video registration

It is noticeable that only a few physicians think spontaneously of the legal implications of video registration. Some of them are even convinced that a patient consent is not necessary, what is wrong. It seems that physicians are not familiar with such legal aspects as privacy law, law on patient rights, etc.

Those thinking about the necessity of a patient consent have also a total different view on the concrete implementation, varying from a small written notice on other standard patient forms to an oral explanation by the physician to each patient. The latter is mentioned as very time-consuming. Besides, if the video registration is used for specific purposes, there is a substantial risk on a refusal of the patient. Indeed, one example could be that in case of a new surgical procedure (see scenario one): some patients will prefer an existing procedure instead of a new one to limit risks.

8.3.1.5 Other aspects

Time is also reported as a key issue. The concern about time efficiency is probably more important in general hospitals where most surgeons are independent and where the physicians' revenue is linked with the number of treated patients.

It is surprising that links between video registration and professional insurance for physicians have hardly been ever mentioned during the interviews. It seems that they are not concerned about a possible impact of the registrations on their insurance contribution while this could be affected because of its potential use for liability purposes.

Regarding the related investment costs, some respondents consider that the costs are an important constraint for the implementation of video registration in each operating theatre, others do not. The varying views could be probably linked with the different financial structures of hospitals: in some hospitals physicians have to carry out such investment costs by themselves while in other hospitals this is part of the general management.

8.4 CONCLUSION

The added value of the video registration in the view of surgeons, based on current utilization or on the future use of it is not clear. There are more inconveniences than possible advantages that can be found whatever the purpose is: quality improvement, training or liability. Wrong ideas about legal issues are present on the mind of some surgeons. Acceptability of an imposed video registration is unlikely.

9 GENERAL CONCLUSIONS

Originally, the purpose of this study was to answer the following questions:

"Can video registration of endoscopic surgery contribute to quality improvement in the field of surgical procedures, based on the available technology?"

There are three sub-questions:

- Is using video registration effective and efficient to monitor the quality of the procedure performed?
- Is video registration useful for training purposes?
- What role can video registration play in matters relating to professional liability?

We looked at technology, legal context for Belgium, and included a quick overview of surrounding countries, and interviewed a sample of surgeons doing endoscopies. We also did a literature search on quality management systems in endoscopy.

In this section we will formulate answers to these questions, and add some contextual comments and observation

9.1 CAN VIDEO REGISTRATION OF ENDOSCOPIC SURGERY CONTRIBUTE TO QUALITY MONITORING AND IMPROVEMENT IN THE FIELD OF SURGICAL PROCEDURES?

Looking at technology, scientific literature, legal issues, cost, and acceptability of surgeons, we conclude that the use of video registration of endoscopic procedures is not an optimal quality improvement tool. We will discuss the systematic recording scenario that supposedly would intend to have the quality improvement aspects.

9.1.1 Limitations in available technology

Today, the technology required for video registration of surgical interventions does exist but, given that systematic registration requires security, extensive testing and maintenance and storage, an integrated system is needed. A commercial-of-the-shelves product for this kind of use does not exist today. The solution will consist of a combination of COTS, customization, use of experimental software and significant piloting and testing.

Secondly, the technology to analyse the videos is missing: today, we have no useful technology to score and assess moving images of non-standardised flexible anatomy. Only pattern recognition is possible.

Finally, secured and automated metadata registration and coding is very important, but cannot be made absolutely reliable nor tamper-proof. Today, in the crossover between reality, clinical operations, technology and semantics, we cannot ensure that all mandatory metadata will always be collected and not tampered nor adulterated.

9.1.2 Limitations in effectiveness of video registration

Using endoscopy video records for quality evaluation, limits the evaluation to images of a surgical procedure:

According to scientific literature, video registration of surgical interventions, and in particular endoscopies, is not the priority. It could help assess skills and dexterity but several other issues related to the patient, the operation theatre, the procedure, the training, etc. have to be monitored or assessed. Endoscopic surgery is an action that is the consequence of a multidisciplinary and multifactorial path leading up to it. Video recording of the endoscopy does not take that into account.

Moreover, other quality tools such as clinical practice guidelines, systematic reporting, already exist and are recommended by scientific societies.

None of the existing systems however have proven their effectiveness in an evidence-based way.

Scientific societies also stated that the use of images could be useful in the communication between the surgeon and the patient and for training purposes. Nevertheless, no example of such use has been found in the literature and in Belgian practice. Moreover, there is no evidence of the effectiveness of video registration as such, nor of the added value of it, compared to the existing quality improvement systems.

There are several risks of ineffectiveness of using video record for quality evaluation that were pointed out by our external expert panel:

- The procedure could be well executed, but this procedure could not be the best one for that patient. Moreover, it is possible that there is no link to diagnosis or to therapeutic options;
- a well performed procedure does not ensure a good outcome, The link between the procedure and the desired outcome is not guaranteed;
- On the other hand, there might be a wrong focus: procedure might be suboptimal for anatomical or physiological reasons, yet the outcome is satisfactory.
- There are schools of thought in medicine, regarding choice of procedure and manner in which one procedure is carried out. On top of that every surgeon may have his own ways of handling the materials, but without any effect on the outcome. So how can we assess the video in an objective and reproducible manner?

9.1.3 Need for a framework and defined procedures:

A robust and sensible quality management system is part of a consistent framework, with clear rules and principles. Video recording should have its clear motivation as to what aspect of quality it helps and how that works. In this early moment, this is not the case:

- Lack of framework: Today there is no defined quality system approach describing objective, privileges and duties of such a system: who is entitled to see the records, who is entitled to see the records metadata, who is qualified to express an opinion on the quality of work as recorded on video? Would there be an accreditation? What role would CME (continuous medical education) credits play?
- Definition of the record:
    - What constitutes the start and end of a record? From the moment of switching on the light in the endoscope, or from the moment the endoscope is introduced in the body? And the reverse for endpoint definition. How do you want to avoid the possibility that two endoscopies are done in the same anaesthesia, but only one is recorded?
    - Experience has shown that such records have significant amounts of "slack period": up to 80% of the recording is not useful for any purpose
    - It will be hard to limit endoscopy recording to therapeutic endoscopy, as a number of "exploratory/diagnostic" endoscopies, become therapeutic as the surgeon decides to intervene during the endoscopy. If there is a regulatory push towards recording intervention endoscopy, surgeons already declare today that they might code more diagnostic procedures.
- How to score the records? Using video records to monitor quality of work on endoscopic surgery implies that one can evaluate and score the images in a repeatable and consistent way. This is far from reality in practice.

- Significance of the video record: What, in terms of quality improvement philosophy is the exact positioning of the video record? What aspect of quality is being monitored? Diagnosis? Care? Competence? Nursing quality? What is it we are looking for? The video looks only at a very limited aspect of the process that would lead to good cure and care for the patient.
- Human failure: human assessment fails to some degree because, with the best of intentions, the assessor cannot be consistent.
- Capacity problems:
  - Who is qualified?
  - Does the qualified person have time to spend doing this?
  - Who pays for that precious time?
  - The most qualified individuals will be peers of the group being quality assured, this will cause a conflict of interest, and if the latter is to be avoided by calling in surgeons from farther field, then the difference in culture and school of thought will increase.

In Belgium, medicine is a regulated private market. Patients enjoy a large freedom of choice as they can choose their physician or surgeon. Likewise, surgeons enjoy a large freedom for diagnostic approach and therapeutic intervention. This freedom is not absolute, as it is expected from them to adhere to "best practices" and guidelines as set forth by scientific committees. This enforcement is ensured by the medical council and scientific societies. From a technical point of view, practitioners and hospitals are requested to register their work with codes, either through direct reporting or through detailed normalised bills.

9.1.4 Legal matters

If legal regulations impose systematic video registration for the use in quality management, data have to be encoded by a third trusted party (TTP), who holds the key. This TTP can query the storage system to retrieve the records needed for quality assurance. Being compliant with this increases the administrative and audit trail burden.

A encoded record is considered to be an element of the medical record to which the patient has the right to access and to a copy.

Video recording will be linked with the person of the surgeon executing the procedure, and possibly used for the evaluation of his performance; he has certain rights as to privacy and professional protection. Use of videotaped images by the hospital managers for quality monitoring should be mentioned in the general agreement. The patient as well as the surgeon should give their consent, although in case of mandatory video registering, the surgeons' consent is not legally required. Again safeguarding these legal aspects increases the administrative burden. Unadulterated proof of legal compliance must be available as well. A legally compliant process and architecture needs to be robust, protected, and secure and have a reliable audit trail. This will cause a major cost increase. (see "financial impact")

9.1.5 Cost and patient and societal profit in terms of quality improvement

Based on our theoretical analysis, we can draw the conclusion that, implementing a routine video registration system, would involve significant investments. The technology needed for best ergonomics, best acceptance, best performance and legal compliance is theoretically available, but is not known to exist or be proven. It is however foreseeable that cost will be exponential.

At the same time, there is no clear evidence for a solid and reliable return in terms of quality improvement. Therefore, one should then ensure that such budgets might not be used more effectively.

Trouble is whether the return on investment is acceptable, because the return does not increase commensurately: the more return you want, the more money you need to spend, but also the bigger the complexity and risks. Investing more money does not improve the cost/benefit ratio.

It is important to address the possible advantages and disadvantages for patient and society over cost. Low cost easy technology may improve knowledge and quality at an individual level, but systematising this approach would cause an exponential increase in cost, mainly due to legal compliance and validation of the complete process. Building it up to a region of nation level also increases the cost. Volumes of records and absolute numbers of transactions mean that a massive capacity in storage and indexing is needed: in 2006, according to the RIZIV/INAMI approx 127770 endoscopies were performed (billed) in Belgium (see "financial impact").

For all the reasons mentioned above, it is clear that setting up a national and systematic video registration system is not accurate in terms of cost/benefit balance.

9.1.6 Acceptability among surgeons

Today, video registration is fragmentarily used in addition to other means to reach quality at the individual patient level. Nevertheless, it is not the primary quality tool mentioned. Surgeons are opposed to systematic, mandatory video registration because they think that quality insurance and control has to remain the task of professional associations.

Moreover, according to the interviewed surgeons, video registration for quality purposes might induce unwanted behaviours, especially if no clear connection is established between video registration as such, "labelling" procedures of surgical operations and assessment of individual clinical practices. For instance, individual acceptability problems or individual avoidance behaviours might appear among surgeons (or at least among some of them). However, opinions reported are those of a small number of surgeons, and it is difficult to draw further conclusions so far.

In order to avoid such problems, one must always bear in mind that transparency policy and definition of a clear framework are of key importance.

9.2 IS VIDEO REGISTRATION USEFUL FOR TRAINING PURPOSES?

The video registration can be used for training purposes next to the other available tools but the importance tends to be overstated.

9.2.1 Technology aspects:

Today, the technology needed to use video registration for training purpose does exist. It is simple and not very costly.

9.2.2 Effectiveness

From a purely technical point of view, video registration is reliable and efficient as a training material. However, one must bear in mind that a reliable supply already exists worldwide: a large number of private firms are in the position to provide hospitals, universities or physicians with a wide range of education / training material and tools (pictures, films, etc…) on a very large number of subjects. Therefore, the key issue is to check that video registration does bring an added value, compared to the existing products.

9.2.3 Legal aspects

If the treating surgeon himself wants to use the endoscopic video registration data for educational purposes or he wants to give this data to another (health care) teacher for these purposes, consent of the patient is required.

9.2.4 Costs

Should video registration be organised routinely in all hospitals for education or training purposes, costs would mainly consist of human resources costs (i.e. work time to review video pictures).

Should video registration be used as an ad hoc training tool, costs would be very limited as it would involve no storage or data base costs.

Besides, a large supply of training material already exists at a low cost, which can also contribute to improve quality of care.

9.2.5 Acceptability

Most surgeons we interviewed, had to admit that they to used recordings in order to review cases with peers either as a second opinion on the medical matter or as a review of technical performance.

Regarding the training of surgeon trainees, video registration could be seen as a useful training tool at least at first glance. However, after action review, has been considered as impractical and extremely time-consuming by most senior surgeons, (spending generally as much time reviewing the surgery as performing it). They indicate that no remuneration was associated with this time spent. They all emphasised the need and greater value of active coaching during the procedure, and real time teaching of the trainee. In practice, the presence of the senior surgeon is almost always required, in order to ensure the smooth running of the training session. The added value of having a record was not seen to be great.

Regarding teaching purposes, video registration is seen as an accurate tool. However this is no longer a pressing need, as most professors seem by now to have a wide range of useful records at their disposal. Experience has shown that recording many hours of film is one thing, editing in order to have good teaching images requires further efforts. Hence, instead of undertaking routine registration, planning video recording of specific surgical procedures in advance (performed if possible by a professional cameraman) would probably be more accurate.

9.3 IS VIDEO REGISTRATION USEFUL FOR PROFESSIONAL LIABILITY MATTERS?

9.3.1 Technology aspects:

Today, the technology needed to use video registration for liability purpose does exist. It is simple and not very costly. To be legally compliant, several additional technological requirements are needed: images have to be linked to a patient ID and surgeon ID, they have to be protected against falsification and certified, etc. this extra complications make the setup much ore expensive. Who will pay for that, and to whom will the investment benefit?

9.3.2 Effectiveness

Video pictures captured by video recording can be used before courts, without specific difficulties or restraints, provided pictures are legally collected. However, it is most probably inefficient to set up a video registration system for liability reasons only. Indeed, only a relatively small number of patients take legal actions against hospitals. Besides, the vast majority of patients are “ordinary cases” for whom video pictures do not bring complementary information (compared to other items of the patient file).

9.3.3 Legal aspects

If the video images were lawfully obtained, they can be used as proof in court by the patient as well as by the surgeon. If there are serious doubts however about the authenticity of the images, the judge can order further investigation.

Since the images are part of the medical file the patient has a right to access and to a copy. The surgeon has access to the medical file in the scope of the therapeutic relation with the patient, or in case of defence in court.

When video images are used in court, sufficiently able, willing and qualified peers without a conflict of interest (competition between surgeons) should be available for interpretation of the images in the judicial expertise. Hopefully the number of such cases remains limited, and thus peers would probably be available for assessment

Anecdotal reports from surgeons suggest that experience so far has been in favour of the surgeon, by discharging his liability; the video does usually not support the claim of the patient against the surgeon.

9.3.4 Costs

In case of prospective ad hoc recording, neither significant extra cost nor investment is due. In case of systematic recording (initiated by surgeons, or the hospital, the volume of archiving will be a cost driver (as well as the duration: 30 years after last contact), as well as the need to validate and secure the technical architecture

9.3.5 Acceptability

In terms of medical liability, some surgeons considered that the use of pictures might be a double-edged tool. Nevertheless, the vast majority of them is firmly convinced, that in most of the cases, their liability will not be concerned.

Should video registration be performed ad hoc for specific liability purpose, it would mean that one of both parties has asked for this registration. This might raise confidence issues in the surgeon-patient relation. However, should systematic registration be performed with samples (hospital, patient) and not applied to all patients nationwide, there might be an inequity between patients considering access to evidence (in case of legal action). This remark could also be applied to surgeons.

Recording images raises ethical issues, even if the information is encrypted:

As we have seen in the interviews, if the patient has access to the images, he will need further support to understand them. Indeed, he might not be able to understand what he sees what could lead to some anxiety, at least for some patients.

10 APPENDICES

APPENDIX TO CHAPTER 2

List of manufacturers

Bio-Imaging Technologies

Boston Scientific

Carestream Health

Carl Zeiss Meditec

Conmed

DaPict

DatCard Systems

DCS Medical

DeJarnette Research Systems

Digital Vitamin

Dynamic Imaging

Esaturnus

ETIAM

FujiFilm Medical Systems U.S.A.

GE Healthcare

GFA U.S. Healthcare

Hologic

IBM Life Sciences

Karl Storz

KODAK

Konica Minolta Medical Corporation

MatrixView

McKesson Medical Imaging Company

MEDIS

Merge Healthcare

Olympus

Philips Medical Systems

RadPharm

Sectra Imtec AB

Siemens Medical Solutions USA, Inc.

Sony healthcare

Stryker Imaging

3DHISTECH

Toshiba America Medical Systems

Wisap

LITERATURE SEARCH

The following table shows the keywords and search strategy for first research question: "Are there currently any quality systems in the operating theatre specifically for surgical interventions?" in the databases Embase and Medline.

Search Strategy	
Keywords	In the database Embase, the following Emtree key words were used : • 'operating room', • 'surgical technique', 'surgery', • 'quality control', • 'practice guideline', • 'peer review', • *'adverse event* free word*, 'surgical error' • 'hospital information system', 'medical record', 'register', 'medical documentation' In the database Medline, the following Mesh terms were used: • 'operating rooms' • 'Surgery'; 'Surgical Procedures, Operative'; Video-Assisted Surgery' • 'Quality Control' • 'Peer Review', 'Peer Review, Health Care' • 'Practice Guideline', 'Practice guidelines as topic' • 'Medical Errors' • 'Hospital Information Systems', 'medical Records', 'Medical Records Systems, Computerized', 'Registries', 'Operating Room Information Systems'

Date	**Search strategy elaboration: 28/01/2008**
Database	Embase
Search Strategy	('quality control'/exp AND [embase]/lim AND [2003-2008]/py) AND (('operating room'/exp AND [embase]/lim AND [2003-2008]/py) AND (('surgical technique'/exp AND [embase]/lim AND [2003-2008]/py) OR ('surgery'/exp/mj AND [embase]/lim AND [2003-2008]/py))) 28 Jan 2008 (**90**) ('practice guideline'/exp AND [embase]/lim AND [2003-2008]/py) AND (('operating room'/exp AND [embase]/lim AND [2003-2008]/py) AND (('surgical technique'/exp AND [embase]/lim AND [2003-2008]/py) OR ('surgery'/exp/mj AND [embase]/lim AND [2003-2008]/py))) 28 Jan 2008 (**109**) ('peer review'/exp AND [embase]/lim AND [2003-2008]/py) AND (('operating room'/exp AND [embase]/lim AND [2003-2008]/py) AND (('surgical technique'/exp AND [embase]/lim AND [2003-2008]/py) OR ('surgery'/exp/mj AND [embase]/lim AND [2003-2008]/py))) 28 Jan 2008 (**1**) (('adverse event*' AND [embase]/lim AND [2003-2008]/py) OR ('surgical error'/exp AND [embase]/lim AND [2003-2008]/py)) AND (('operating room'/exp AND [embase]/lim AND [2003-2008]/py) AND (('surgical technique'/exp AND [embase]/lim AND [2003-2008]/py) OR ('surgery'/exp/mj AND [embase]/lim AND [2003-2008]/py))) 28 Jan 2008 (**20**) (('hospital information system'/exp AND [embase]/lim AND [2003-2008]/py) OR ('register'/exp AND [embase]/lim AND [2003-2008]/py) OR ('medical record'/exp AND [embase]/lim AND [2003-2008]/py) OR ('medical documentation'/exp AND [embase]/lim AND [2003-2008]/py)) AND (('operating room'/exp AND [embase]/lim AND [2003-2008]/py) AND (('surgical technique'/exp AND [embase]/lim AND [2003-2008]/py) OR ('surgery'/exp/mj AND [embase]/lim AND [2003-2008]/py))) 28 Jan 2008 (**95**)

Date	Search strategy elaboration: 01/02/2008
Database	Medline
Search strategy	"operating rooms"[MeSH Terms] AND ("Surgery"[Mesh] OR "Surgical Procedures, Operative"[Mesh] OR "Video-Assisted Surgery"[Mesh]) AND "Quality Control"[Mesh] AND ("2003/02/03"[PDAT] : "2008/02/01"[PDAT]) (**1**)
	"operating rooms"[MeSH Terms] AND ("Surgery"[Mesh] OR "Surgical Procedures, Operative"[Mesh] OR "Video-Assisted Surgery"[Mesh]) AND ("Peer Review"[Mesh] OR "Peer Review, Health Care"[Mesh]) AND ("2003/02/03"[PDat] : "2008/02/01"[PDat]) (**0**)
	"operating rooms"[MeSH Terms] AND ("Surgery"[Mesh] OR "Surgical Procedures, Operative"[Mesh] OR "Video-Assisted Surgery"[Mesh]) AND ("Practice Guideline "[Publication Type] OR "Practice Guidelines as Topic"[Mesh]) AND ("2003/02/03"[PDAT] : "2008/02/01"[PDAT]) (**11**)
	"operating rooms"[MeSH Terms] AND ("Surgery"[Mesh] OR "Surgical Procedures, Operative"[Mesh] OR "Video-Assisted Surgery"[Mesh]) AND "Medical Errors"[Mesh] AND ("2003/02/03"[PDAT] : "2008/02/01"[PDAT]) (**38**)
	operating rooms"[MeSH Terms] AND ("Surgery"[Mesh] OR "Surgical Procedures, Operative"[Mesh] OR "Video-Assisted Surgery"[Mesh]) AND ("Hospital Information Systems"[Mesh] OR "Medical Records"[Mesh] OR "Medical Records Systems, Computerized"[Mesh] OR "Registries"[Mesh] OR "Operating Room Information Systems"[Mesh]) AND ("2003/02/03"[PDAT] : "2008/02/01"[PDAT]) (**27**)

The following table shows the keywords and the search strategy for the second research question: "Is video registration in the operating theatre currently used for quality control for surgical interventions?".

Keywords	Emtree words: • 'endoscopy surgery' and 'video recording' • 'operation room' • 'surgery' and 'surgery technique' The following Mesh terms were used: • 'Endoscopy', 'Capsule Endoscopy', 'Video Recording', 'Video-Assisted Surgery' 'Videotape Recording' • Operating Rooms • 'Surgery', 'Surgical Procedures, Operative', 'Video-Assisted Surgery'

Date	Search strategy elaboration: 28/01/2008
Database	Embase
Search Strategy	(('**operating room**'/exp AND [embase]/lim AND [2003-2008]/py) AND (('**surgical technique**'/exp AND [embase]/lim AND [2003-2008]/py) OR ('**surgery**'/exp/mj AND [embase]/lim AND [2003-2008]/py))) AND (('**videorecording**'/exp AND [embase]/lim AND [2003-2008]/py) OR ('**endoscopic surgery**'/exp AND [embase]/lim AND [2003-2008]/py)) 28 Jan 2008 (**228**)

Date	Search strategy elaboration: 01/02/2008
Database	Medline
	"operating rooms"[MeSH Terms] AND ("Surgery"[Mesh] OR "Surgical Procedures, Operative"[Mesh] OR "Video-Assisted Surgery"[Mesh]) AND ("Video Recording"[Mesh] OR "Video-Assisted Surgery"[Mesh] OR "Videotape Recording"[Mesh] OR "Endoscopy"[Mesh] OR "Capsule Endoscopy"[Mesh]) AND ("2003/02/03"[PDAT] : "2008/02/01"[PDAT]) (**73**)

APPENDICES TO CHAPTER 4

MATRIX WITH OVERVIEW OF LITERATURE

Authors	Title	Year	Country	Type of article	Study design	Subject	N	Type of surgical discipline
Aggarwal R;Grantcharov T;Moorthy K;Milland T;Papasavas P;Dosis A;Bello F;Darzi A;	An evaluation of the feasibility, validity, and reliability of laparoscopic skills assessment in the operating room	2007	UK	Scientific article	Controlled study	Assessment tool (software)	19	Laparoscopic cholecystectomy
Ahmed SU;Tonidandel W;Trella J;Martin NM;Chang Y;	Peri-procedural protocols for interventional pain management techniques: A survey of US pain centers	2005	USA	Scientific article	Controlled study	Survey pain management	105	Protocols in pain centers
American Society for gastrointestinal Endoscopy;	Quality Improvement of Gastrointestinal Endoscopy	1999	USA	Guideline	N.A.			
Axon ATR;Bellenhoff U;Bramble MG;Ghosh S;Kruse A;McDonnell G.E.;Neumann C;Rey J-F. SK;	Variant Creutzfeldt-Jakob Disease (vCJD) and Gastrointestinal endoscopy	2001	Europe	Guideline	N.A.			Endoscopy
Bann S;Khan MS;Datta VK;Darzi AW;	Technical Performance: Relation between Surgical Dexterity and Technical Knowledge	2004	UK	Scientific article	Controlled study	Development of an instrument for assessment	30	Surgical trainees
Bellenhoff U;Neumann C;Rey JF;Biering H;Blum R;Schmidt V;ESGE Guideline committee;	ESGE-ESGENA guideline for quality assurance in reprocessing:Microbiological surveillance testing in endoscopy	2007	Europe	Guideline	N.A.			Endoscopy
Bellenhoff U;Neumann CS;Biering H;Blum R;Schmidt V;Rey J;ESGE Guideline committee;	ESGE/ESGENA guideline for process validation and routine testing for reprocessing endoscopes in washer-disinfectors	2007	Europe	Guideline	N.A.			Endoscopy
Bertges D;Shackford S;Cloud A;Stiles J;Stanley A;Steinthorsson G;Ricci M;Ratliff J;Zubis R;	Toward optimal recording of surgical complications: concurrent tracking compared to the discharge data set	2007	USA	Scientific article	Retrospective study	Comparison with hospital discharge data set and SATS	798	N.A.
Best W;Khuri S;Phelan M;Hur K;Henderson W;Demakis J;Daley J;	Identifying patient preoperative risk factors and postoperative adverse events in administrative databases: results from the Department of Veterans Affairs National Surgical Quality Improvement Program.	2007	USA	Scientific article	Prospective study	Preoperative risk factors	123	N.A.
Birkmeyer;	Evidence-Based Surgery: Improving the Quality of Minimally Invasive Surgery	2004	USA	Descriptive article	Discussion	Quality in surgery	N.A.	Minimally invasive surgery

Authors	Title	Year	Country	Type of article	Study design	Subject	N	Type of surgical discipline
Bjorkman D;Popp J;	Measuring the quality of Endoscopy	2006	USA	Descriptive article	Critical review with limited literature references	Endoscopy	N.A.	N.A.
Blom E;Verdaasdonk E;Stassen L;Stassen H;Wieringa P;Dankelman J;	Analysis of verbal communication during teaching in the operating room and the potentials for surgical training	2007	Netherlands	Scientific article	Controlled study	Skill and communication during surgery	8	Laparoscopic cholecystectomy
Bohnen J;Lingard L;	Error and surgery: can we do better?	2003	Canada	Descriptive article	Critical review with limited literature references	Safety in OR	N.A.	N.A.
Brzezinska-Rajszys G;Carminati M;Qureshi SA;	The ideal configuration of the modern theatre for paediatric cardiac catheterisation: Recommendations of the Association for European Paediatric Cardiology	2003	UK	Recommendations	N.A.	European Pediatric Cardiology	N.A.	Pediatric cardiologists
Caletti G;Deviere J;Fockens P;Lees WR;Mortensen B;Odegaard S;R÷sh T;Souquet JC;Vilmann P;	Endoscopic Ultrasonography, Part I: Technique and Upper Gastrointestinal Tract	2008	Europe	Recommendations	N.A.			Endoscopy
Caletti G;Deviere J;Fockens P;Lees WR;Mortensen B;Odegaard S;R÷sh T;Souquet JC;Vilmann P;	Endoscopic Ultrasonography, Part II: Retroperitoneum and Large Bowel, Training	1996	Europe	Recommendations	N.A.			Endoscopy
Centers for Medicare and Medicaid Services.;	Hospital Quality Initiative (HQI)	2006	USA	Internet communication	N.A.			
Chang L;Hogle NJ;Moore BB;Graham MJ;Sinanan MN;Bailey R;Fowler DL;	Reliable assessment of laparoscopic performance in the operating room using videotape analysis	2007	USA	Scientific article	Controlled study	Laparoscopic general surgeons (reviewers)	10	Laparoscopic cholecystectomy
Clavien P;Nahrwold D;Soper N;Bass B;	Surgeon competency? Teaching old dogs new tricks	2005	Swiss	Scientific article	Critical review with limited literature references	Competence	N.A.	N.A.
Cuschieri A.	Reducing errors in the operating room: Surgical proficiency and quality assurance of execution	2005	Italy	Descriptive article	Review with limited literature	Errors	N.A.	N.A.

Authors	Title	Year	Country	Type of article	Study design	Subject	N	Type of surgical discipline
					references			
Dagi TF;Berguer R;Moore S;Reines HD;	Preventable Errors in the Operating Room-Part 2: Retained Foreign Objects, Sharps Injuries, and Wrong Site Surgery	2007	USA	Scientific article	Systematic review	Errors	N.A.	N.A.
Dain S;	Management of high-risk peri-operative systems	2006	Canada	Descriptive article	Review with limited literature references	Risk management	N.A.	N.A.
Dopp A;	Smooth flow. Technology helps midwest healthcare network avoid OR scheduling conflicts	2003	USA	Descriptive article	Case report	OR scheduling conflicts - Scheduling	N.A.	N.A.
Dosis A;Aggarwal R;Bello F;Moorthy K;Munz Y;Gillies D;Darzi A;	Synchronized video and motion analysis for the assessment of procedures in the operating theater	2005	UK	Scientific article	Controlled study - development of software	Development of software	10	Laparoscopic cholecystectomy
Dugas M;Scheichenzuber J;Hornung H;	An intranet-based system for quality assurance in surgery	1999	Germany	Scientific article	Controlled study - development of software	N.A.	N.A.	laparoscopic cholecystectomies
Endress A;Brucker S;Wallwiener D;Aydeniz B;Kurek R;Zubke W;	Systems integration in the operating room: The challenge of the decade	2006	Germany	Descriptive article	Critical review with limited literature references	System integration	N.A.	N.A.
ESGE Guideline committee;	Check List for Purchase of Washer Disinfectors for Flexible Endoscopes	2000	Europe	Recommendations	N.A.			Endoscopy
ESGE Guideline committee;	Protocol for Reprocessing Endoscopy Accessories	2000	Europe	Protocol	N.A.			Endoscopy
Faigel D;Pike I;Baron T;Chak A;Cohen J;Deal S;Hoffman B;Jacobson B;Mergener K;Petersen B;Petrini J;Rex D;Safdi M;SGE/ACG Taskforce on quality in Endoscopy;	Quality Indicators for Gastrointestinal Endoscopic Procedures: An Introduction.	2006	USA	Guideline	N.A.	N.A.	N.A.	N.A.

Authors	Title	Year	Country	Type of article	Study design	Subject	N	Type of surgical discipline
Grantcharov TP;Schulze S;Kristiansen VB;	The impact of objective assessment and constructive feedback on improvement of laparoscopic performance in the operating room	2007	Denmark	Scientific article	Controlled study	Objective assessment and feedback	16	Surgical trainees
Guerlain S;Adams R;Turrentine F;Shin T;Guo H;Collins S;Calland J;	Assessing team perfomance in the operating room: development and use of a 'black-box' Recorder and other tools for intraoperative environment	2005	USA	Scientific article	Controlled study - development of software	Development of an instrument for assessment	10	Laparoscopic cholecystectomy
Kohn L;Corrigan J;Donaldson M;	To Err Is Human: building a safer health system. Institute of Medicine, Committee on quality of Healthcare in America.	1999	USA	Book	N.A.	N.A.	N.A.	N.A.
Kruse A;Rey J;	Guidelines on Cleaning and Disinfection in GI Endoscopy	2000	Europe	Guideline	N.A.			Endoscopy
Li YC;Hsu MH;	Using information technology to improve surgical safety	2005	Taiwan	Descriptive article	Descriptive letter	Surgical safety	N.A.	NA.
Luce V;Auroy Y;Ausset S;Luci P;Velay H;Benhamou D;	Intraoperative arterial hypotension recorded by an anaesthesia information management system	2004	France	Scientific article	Retrospective study	anesthesia information management system	2691	Arterial hypotension
Makary MA;Sexton JB;Freischlag JA;Millman EA;Pryor D;Holzmueller C;Pronovost PJ;	Patient safety in surgery	2006	USA	Scientific article	Prospective study	Surgical safety	N.A.	N.A.
Malik MHA;Chougle A;Pradan N;Gambhir A;Porter ML;	Primary total knee replacement: a comparison of a nationally agreed guide to best practice and current surgical technique as determined by the North West Regional Arthroplasty Register	2005	UK	Scientific article	Controlled study	Comparison registration	86	Orthopaedic surgeons
Malik MHA;Gambhir AK;Bale L;Pradhan N;Porter ML;	Primary total hip replacement: A comparison of a nationally agreed guide to best practice and current surgical technique as determined by the North West Regional Arthroplasty Register	2004	UK	Scientific article	Controlled study	Comparison registrations	86	Orthopaedic surgeons
Mandal K;Adams W;Fraser S;	"Near misses" in a cataract theatre: how do we improve understanding and documentation?	2005	UK	Scientific article	Prospective study	documentation of near miss events	500	Cataract
Marasco S;Ibrahim J;Oakley J;	Public Disclosure of surgeon-specific report cards: current status of the debate	2005	Australia	Scientific article	Systematic review	Clinical report cards	N.A.	N.A.
Meterissian S;Zabolotny B;Gagnon R;Charlin B;	Is the script concordance test a valid instrument for assessment of intra-operative decision-making skills?	2007	Canada	Scientific article	Controlled study	Development of an instrument for assessment	36	N.A.

Authors	Title	Year	Country	Type of article	Study design	Subject	N	Type of surgical discipline
Moorthy K;Munz Y;Sarker S;Darzi A;	Objective assessment of technical skills in surgery	2003	UK	Scientific article	Systematic review	Objective assessment	N.A.	N.A.
Rey J;	The Endoscopy report and quality assurance	2007	Europe	Recommendations	N.A.			
Rey J;Budzynska A;Axon A;Kruse A;Nowak A;	Antibiotic Prophylaxis For Gastroinenstinal Endoscopy	1998	Europe	Guideline	N.A.			Endoscopy
Rey J;Kruse A;	Cleaning and Disinfection in Europe according to the Endoscopic Societies' Guidelines	2003	Europe	Guideline	N.A.			Endoscopy
Rey J;Ladas S;Alhassini A;Kuznetsof K;ESGE Guideline committee;	Video capsule endoscopy: Update to guidelines	2006	Europe	Guideline	N.A.			Endoscopy
Rey J;Lambert R;ESGE Quality Assurance Committee;	ESGE Recommendations for quality control in gastrointestinal endoscopy: Guidelines for image documentation in upper and lower GI Endoscopy	2001	Europe	Guideline	N.A.	N.A.	N.A.	N.A.
Rey J;Spencer KB;Jurkowski P;Albercht HW;	ESGE Guidelines for quality control in servicing and repairing endoscopes	2004	Europe	Guideline	N.A.			Endoscopy
Royal college of obstetricians and gynaecologists;	Improving patient safety: Risk management for maternity and gynaecology, Clinical Governance advice	2005	UK	Guideline	N.A.			
Schimpff SC;	Improving operating room and perioperative safety: Background and specific recommendations	2007	USA	Recommendations	N.A.	Safety in OR	N.A.	N.A
Singh SS;Condous G;Lam A;	Primer on risk management for the gynecological laparoscopist	2007	Australia	Scientific article	Systematic review	Gynecological laparoscopist		Gynecological laparoscopy
Society of Obstetricians and Gynaecologists of Canada.	MOREOB Program	2008	CANADA	Internet communication	N.A.			
Speroff T;O'Conner GT;	Study designs for PDSA quality improvement research	2004	USA	Scientific article	Critical review with limited literature references	PDSA	NA.	NA.
Stephen C;Schimpff M;	Improving Operating Room and Perioperative Safety: Background and Specific Recommendations	2007	USA	Recommendations	N.A.			

Authors	Title	Year	Country	Type of article	Study design	Subject	N	Type of surgical discipline
Tremper KK;O'Reilly M;Kazanjian P;Van Der Spek A;Kheterpal S;	A perioperative information system: Design and implementation	2004	USA	Scientific article	Controlled study - development of software	Peri-operative information system anaesthesia	N.A.	N.A.
University Health System Consortium;	University Health System Consortium.	2008	USA	Internet communication	N.A.			
van Tiel FH;Elenbaas TWO;Voskuilen BMAM;Herczeg J;Verheggen FW;Mochtar B;Stobberingh EE;	Plan-do-study-act cycles as an instrument for improvement of compliance with infection control measures in care of patients after cardiothoracic surgery	2006	Netherlands	Scientific article	Controlled study	infection control	715	Cardiothoracic surgery
Vincent C;Moorthy K;Sarker S;Chang A;Darzi A;	Systems approaches to surgical quality and safety	2004	UK	Descriptive article	Critical review with limited literature references	Safety in OR	N.A.	N.A.
Vinck I;Paulus D;Van Braband H;Rademaekers D;	Medico-legale aspecten van klinische praktijkrichtlijnen. Brussel: Federaal Kenniscentrum voor de Gezondheidszorg (KCE) Reports vol. 26A. Ref. D/2006/10.273/05.	2006	Belgium	Report	N.A.	Medical-legal aspect of guidelines	N.A.	N.A
Weinger M;Gonzales D;Slagle J;Syeed M;	Video capture of clinical care to enhance patient safety	2004	USA	Scientific article	Controlled study - development of software	System integration	270 clinical cases	N.A.

QUALITY AND SAFETY INDICATORS FOR ENDOSCOPY

Diagnostic upper GI endoscopy		
	Quality	**Safety**
Auditable outcomes	• Success of intubation • Completeness of procedure	
Quality standards	• Repeat endoscopy for gastric ulcers within 12 weeks. (100%). Gastric ulcer defined by break in gastric mucosa >5mm in diameter and beyond submucosa. *If repeat endoscopy not indicated (because of age+/- co-morbidity) this should be recorded in the patient file.*	

Colonoscopy/flexible sigmoidoscopy		
	Quality	**Safety**
Auditable outcome	• Sedation and analgesic doses • Comfort levels	
Quality standards	• 86% unadjusted completion rate rising by 1% on the 1st April each year until 90%. 86% is the standard for 2007/8 (this standard applies to colonoscopy) • Adenoma detection rate >10% for colonoscopy and flexible sigmoidoscopy • Polyp recovery >90% • Tattooing of suspected malignant polyps (100%) • Tattooing of tumours if small, or if position not clear (100%) • Good quality bowel prep > 90% • Diagnostic colo-rectal biopsies for persistent diarrhoea (100%)	• Colonoscopy perforation rates <1:1000 • Post polypectomy bleeding requiring transfusion <1:100 (for >1cm polyps) • Post polypectomy perforation rate <1:500 • Flexible sigmoidoscopy perforation rate < 1:5000

NOTE: there has been much debate about the use of polyp detection as a quality standard with differing, strongly-held views. Concerns have been raised about the influence of age and case mix and the difficulty with current IT systems in capturing adenoma, as opposed, to polyp detection rates. The standard of >10% adenoma detection rate has been left in but it is appreciated that current IT systems might make it difficult to monitor this standard. Local audit processes are encouraged to take this into account when reviewing performance. However, there is a consistent view that if IT systems were able to capture the important quality endpoint (significant adenoma as defined in the ACP/BSG guidelines), and if standards could take into account case mix and age, then we should eventually have a standard for detection of significant adenoma.

THUS: the service is given due warning that in 2-3 years (2009-10) there will be a standard of significant adenoma detection, adjusted for case mix, that will supercede previous polyp detection rate standards. This will give the service sufficient time to set in place IT systems that can capture this information automatically.

Therapeutic Upper GI Endoscopy (non GI bleeding)		
	Quality	**Safety**
Structure	• Adequate provision of equipment for the dilatation of upper GI strictures (TTS & OTW balloons, bougies) • Units offering palliation of oesophageal cancer should have access to multimodal therapy (laser, SEMS, APC, brachytherapy)	• Access to radiographic screening must be available to assist dilatation whenever there is difficulty passing a guidewire/balloon catheter through a stricture for the purpose of dilatation
Process	• Agreed guidelines on dilatation of oesophageal stricture • The decision to deploy an oesophageal stent should be taken by the upper GI cancer multidisciplinary team, or after discussion with a named consultant of that team. • Patients with suspected achalasia should undergo contrast radiography (and normally manometry) to confirm the diagnosis before treatment	• Agreed guidelines on monitoring of patients following all dilatation and stent placing procedures
Staffing	• Oesophageal dilatation and SEMS insertion should be undertaken by (or under direct supervision of) experienced endoscopists who perform sufficient numbers to maintain their skills	• Access to appropriate surgical opinion and management should be readily available to endoscopy units performing oesophageal dilatation in case perforation should occur
Auditable outcomes	• Satisfactory positioning of SEMS at the end of the procedure • Re-intervention (dilatation, laser/APC, re-stenting) rate in SEMS • Dysphagia assessed using a standard scoring system in > 90% to provide an objective measure of the efficacy of therapeutic intervention	• 30-day mortality for SEMS
Quality standards		• Perforation rates following dilatation of: - Benign stricture <1:100 - Malignant stricture <1.20 - Achalasia <1:20 - Gastric outlet obstruction <1:20

Therapeutic Upper GI Endoscopy (GI bleeding)		
	Quality	**Safety**
Structure	• Availability of equipment to treat ulcer-related bleeding (adrenaline 1/10000 injection, thermal haemostatic device [heater probe, bipolar coagulation], endoscopic clips) • Availability of equipment to treat variceal bleeding (banding ligation device, sclerosant [eg ethanolamine] or tissue adhesive [eg cyanoacrylate glue] injection, balloon tamponade • Availability of equipment to treat mucosal bleeding (laser or APC) • Facilities to provide emergency endoscopy out of hours	• Availability of facilities to perform endoscopy with anaesthetist and GA support
Process	• Documented agreed guidelines on preferred management approaches to ulcer-related and variceal bleeding • Contemporaneous written report in notes of all in-patients including recommendations on further management	• Documented agreed guidelines on the monitoring and resuscitation of patients before and after all emergency procedures for GI bleeding • Locally agreed policies on the involvement of anaesthetists in patients with GI bleeding
Staffing	• Endoscopy for GI bleeding should only be undertaken by (or under direct supervision of) experienced endoscopists who perform sufficient numbers to maintain their skills	• Access to a surgical opinion should be readily available to endoscopy units performing emergency endoscopy for upper GI bleeding For each case, a minimum of 3 endoscopy assistants with appropriate competences.
Auditable outcomes	• Rates of primary haemostasis (exact definition to be determined locally – eg failure defined by transfusion, +/- need for repeat endoscopy, +/- surgery)	
Auditable outcomes (affected by factors other than the procedure and thus beyond the remit of GRS)	• Operation rates • Timeliness indicators (ie time from admission to first endoscopy) • Blood transfusion requirements • Appropriate use of medication – PPIs for ulcers, pressins for varices • Length of stay	• 30-day mortality in relation to the Rockall or equivalent risk assessment scoring system • Pneumonia • Spontaneous bacterial peritonitis in patients with variceal bleeding

ERCP		
	Quality	**Safety**
Structure	• An Endoscopy Unit caseload of at least 150 procedures per year • Sufficient accessories to perform all standard therapeutic manoeuvres at the time of the procedure	• Haemostasis equipment to control unexpected bleeding • Availability of emergency lithotriptor
Process	• Pre-ERCP assessment of all patients by appropriately trained staff • Indications for ERCP and place of ERCP in the management pathway to be agreed locally • Evidence of consultant involvement in every decision to perform (c/f request) ERCP • Contemporaneous report in notes of all patients	• Formal record of adverse incidents e.g. significant complications and mortality • Compliance with local radiological protection guidelines • Prophylactic antibiotics given according to local guidelines
Staffing	• An agreed minimum workload (procedure type/volume) per endoscopist • A minimum of 2 ERCP-trained endoscopists within a centre or local network, to enable continuous service provision	• For each case, a minimum of 3 endoscopy assistants with appropriate competences
Quality standards	• >90% of ERCPs intended as therapeutic • Completion of the intended therapeutic procedure (eg decompression of dilated and/or obstructed biliary system) at initial ERCP in at least 80% of cases • Following failed initial ERCP, decompression of obstructed biliary systems within 5 working days in a stable patient, or within 24hr in an unstable patient (e.g. severe cholangitis)	• Sphincterotomy bleeding requiring transfusion < 2% • Perforation rate <2% • Clinically symptomatic pancreatitis < 5% • Procedure related mortality <1% • Continued appropriate antibiotic treatment when obstruction unrelieved by ERCP in 100% of cases
Auditable outcomes	• Number of procedures performed by each operator • Success in cannulating desired duct and in performance of intended therapeutic procedure	• Frequency of post-procedure clinical pancreatitis • Please refer back to "General quality and safety indicators"

EUS		
	Quality	**Safety**
Structure	• Image storage facilities – video and paper print or digital imaging/PACS	
Process	• Integration of findings into appropriate multidisciplinary team meetings • Agreed protocols for: - indications - antibiotic use - FNA / biopsy • Other interventional EUS: - oesophageal dilatation for staging EUS	
Staffing	• Experienced cytopathologist or cytology technician essential	• Staff familiar with use of FNA/core biopsy needles and slide/smear preparation
Auditable outcome	• Minimum agreed procedure volume/centre/endoscopist: - oesophagogastric cancer - staging - pancreaticobiliary imaging - EUS fine needle aspiration	
Quality standards	• Completion rates for diagnostic imaging should approach >90% • Completion rates for FNA/biopsy should approach: - >90% mediastinal /other lymph nodes - >75% pancreatic /other masses • Diagnostically adequate FNA specimens should approach: - >75% (pancreas); - >90% other lesions • Staging accuracy for cancers consistent with major published figures	• Complication rates <1%. This includes oesophageal perforation, acute pancreatitis post FNA, infection, bleeding.

PEG		
	Quality	**Safety**
Structure	• Appropriate equipment for placing a PEG	•
Process	• Agreed guidelines on indications for PEG • Multidisciplinary team involvement in all decisions • Agreed policy on consent for individuals unable to give consent • Post procedure guidelines for managing the PEG	• Agreed guidelines on antibiotic prophylaxis
Staffing	• Two operators with the appropriate competences to complete the procedure, at least one of which is an competent upper GI endoscopist • Involvement of dietetic team (or equivalent) following placement	
Auditable outcome	• Satisfactory placement of PEG (satisfactory determined at the end of the procedure)	• Infection requiring antibiotics • Peritonitis • Bleeding
Quality standards		

QA standards specific to colonoscopy in the National Bowel Cancer Screening Programme (Investigation after positive guaiac FOBt: Age 60 – 69)		
Objective	**Measure**	**Standard**
1. Investigate individuals with positive FOB test results	• Acceptance rate of colonoscopy after positive FOBt	• ≥ 85% undergo colonoscopy
2. Entire colon examined	• Completion rate with photographic evidence of ileo-caecal valve/appendix orifice	• 90% unadjusted completion
3. Identification of adenoma/cancer present in the sample	• Adenoma detection rate	• 6 per 1000 people screened • 35 per 100 colonoscopies
	• Cancer detection rate	• 2 per 1000 screened • 11 per 100 colonoscopies
4. Availability of polyps for pathological examination	• Polyp recovery	• >90% polyps excised
5. Planning of surgery	• Identification of tumour position in correct segment of colon	• >95% cancers
	• Tattooing of suspected malignant polyps	• 100%
6. Minimising harms to the population	• Minimum number of screening colonoscopies undertaken per year by each screening colonoscopist	• >150 (with full audit data of all standards listed)
	• Perforation rate	• <1:1000 colonoscopies
	• Post polypectomy bleeding requiring transfusion	• <1:100 colonoscopies
	• Post polypectomy perforation rate	• <1:500 colonoscopies
	• Rate of serious colonoscopic complications requiring unplanned admission	• ≤3 per 1000 colonoscopies

APPENDICES TO CHAPTER 6

CHARACTERISTICS OF THE FOUR SCENARIOS

dimension	Voluntary quality improvement Scenario 1	For scientific or training purposes Scenario 2	Prospective quality study Scenario 3	Integral permanent quality control Scenario 4
frequency	ad hoc	Looks at unknown surgery	Studies, campaigns, prospective	Always
Intra/extra muros	Intra only	Sometimes extra	extra	Extra (with archiving facility)
Element of EPD	Does not need to be if anonymous	Does not need to be if anonymous	must	must
immediate debriefing after procedure	sometimes	sometimes	sometimes	sometimes
Use of open field video-recording	little	yes	sometimes	Not in scope
archiving	?	after editing	At least 30 years after last patient contact because element of patient record	At least 30 years after last patient contact because element of patient record
Proven and safeguarded Integrity of the video "record"	Not critical	Not critical	Preferred or critical	Critical
Coding of patient identity (ie not anonymous)	Sometimes	Sometimes	Mandatory	Mandatory
Compression	Not needed	Very useful	Critical, preferable loss-less	Critical , preferable loss-less
Sealing of record (notary seal, time stamping, fingerprinting, …	Not needed	Not needed	Critical	Critical
Automatic filtering: removing non-value add images	useful	Not needed but useful	Useful or critical	? needs attention when context and rules are defined
Surgeon's consent	voluntary	Not needed	Voluntary enrolment by surgeon	Critical
Patient's consent	needed	Not needed but preferred if the record is anonymous, otherwise mandatory	Critical	Critical
System security	useful	Not needed if anonymous	Mandatory if not anonymous	Critical
Real-time input on image	useful	useful	Critical	Critical
Image quality	++	preferred +++	+++	+++ !!
LAN & local buffer archive	Critical	Not needed	Useful	Critical
Video-recording disturbs the procedure (delays, better views etc)	acceptable	acceptable	acceptable	Not acceptable
Maximal system continuity and availability needed	Not critical	Not critical	Critical in at least one theatre	Critical in all locations and rooms where endoscopies can be performed
SW to analyse and score images	Useful	Too expensive?	Too expensive	Critical enabler

SCENARIO 4: SPECIFICITIES

Dimension	Value
Entity definition	Automatic loading of pat id from hospital administration system and surgeon id must always be present and tamperproof Definition of recording start and end should be system driven
Extra muros: all campuses and all hospitals/clinics	Significant broadband needed, high transfer speed, Queuing needed , high read and write speed, handshaking protocols, buffering in order that technology would not slow down clinical work
Element of the patient record	If the record is not anonymous (eg encoded identity) then it is, by law, and element of the EPR. The safekeeping and archiving of the patient record is the responsibility of the head physician and the hospital management. This will induce significant cost for the institutions.
Immediate post-op debriefing	Not critical
Open field surgery	Not in scope
Endoscopic optical image	Compatibility with existing optical hardware is critical. Loading of metadata will be critical for ease of use (patient id , Surgeons id, type of surgery etc)
Archiving	Archiving is still expensive, and needs to be for 30 years after last patient contact, readability after 30 or more years need to be ensured. Difficulty in registering last patient contact and linking that to the original video record. Archiving at the hospital unavoidable in todays legal context
Integrity of the "video"record (data file)	Requires specific software and keys to archive securely: fingerprinting, time-stamping, encryption and active monitoring of attempts to break-in Physical protection also needed: back up, second or third copy at different location etc , impossibility of unauthorised copying or downloading Time-stamping : need to synchronise clocks so that all records (central and local) have same time data)
Encoded identity	Requires the use of the services of a TTP for managing the true access to the records
Interface with other systems (analogue or digital endoscopy, anaesthesia)	Anaesthesiology, patient administration system (Patient id, surgeon id, type of surgery,), electronic or analogue patient medical record
Data compression	Critical element, loss-less
consent by the surgeon	Critical
Patient consent	Critical
System protection	Active monitoring is critical
Real-time input superposed on image/record	No erasing or modifications possible, how to interface with myriad of applications and systems on the market?
Continuity of service, continuous availability of recording and archiving,	100% availability is not possible; how to deal with breakdowns in availability? Alternative process in case of breakdown must be tamper-proof too

APPENDICES TO CHAPTER 8

QUESTIONNAIRES

The questionnaire was carried out both in French and Dutch. Both versions can be found in addendum.

Dutch version:

5 min	1. Inleiding bij het interview <u>Voorstelling KCE – HICT - interviewers</u> Interviewers:… HICT:… KCE:… <u>Omschrijven doel van het project</u> Het doel van het project is het uitwerken van een analyse van het mogelijk gebruik van videoregistratie bij endoscopische chirurgie. Binnen het project zijn er 3 belangrijke luiken: een analyse van de technische mogelijkheden, een analyse van de juridische gevolgen en een analyse van dit soort procedures in het kader van kwaliteitssystemen in het operatiekwartier. Een belangrijk element hierbij is de bevraging van chirurgen om na te gaan hoe de artsen vanuit hun praktijkervaring staan tegenover deze technologie en haar toepassingen. <u>Omschrijven doel en verloop van het gesprek</u> Doel van het gesprek Zicht op het gebruik van videoregistratie bij endoscopische chirurgische ingrepen in het OK nu en de situering binnen andere kwaliteitssystemen. Zicht op het gebruik in het OK in de toekomst (voor- en nadelen, remmende factoren en aspecten die de invoering vergemakkelen). Verloop van het gesprek Het gesprek zal maximaal één uur duren. Feedback zal achteraf ter validatie toegestuurd worden. Alle interviews worden samen verwerkt en enkel het eindrapport is publiek. Uw naam wordt enkel vermeld op een lijst van deelnemende artsen in addendum van het eindrapport. Gesprek wordt opgenomen maar dit dient enkel om de latere verwerking van het interview te vergemakkelijken

5 min	2. Inleidende vragen *Doel: situering arts en ziekenhuis* **Vragen** Hoeveel jaren medisch ervaring hebt u? Hoeveel jaren ervaring hebt u met endoscopische chirurgie? In hoeveel ziekenhuizen werkt u? *Indien meer dan 1*: doet u aan endoscopische chirurgie in alle ziekenhuizen? Hoeveel operaties doet u gemiddeld per jaar (totaal aantal)? Hoeveel endoscopische ingrepen (therapeutisch, niet diagnostisch) doet u gemiddeld per jaar? Bent u geaccrediteerd? Geeft u, naast uw job als arts, ook nog les? Doet u, naast uw job als arts, aan wetenschappelijk onderzoek? *Indien ja:* Als onderzoeker of als deelnemer aan wetenschappelijk onderzoek uitgevoerd door derden? Ben u verantwoordelijk voor het begeleiden van geneesheren-specialisten in opleiding? Van welke associaties bent u lid? *Indien lid*: welke is je rol hierbinnen?

15 min	3. Gebruik van videoregistratie in het OK nu? *Doel: een zicht krijgen of er gebruik gemaakt wordt van videoregistratie in het OK nu en in welke mate en voor welk doel.* **Vragen** Wat is uw huidige ervaring met videoregistratie bij endoscopische operaties? *Enkel video opnames van endoscopische operaties, vertrekkende van het bestaande beeld die er is tijdens de operatie (geen open veld)* → Indien ervaring: Voor welk type ingrepen gebruikt u het? Hoe vaak gebruikt u het? Voor welk(e) doel(en) gebruikt u het? *(kwaliteit, opleiding, aansprakelijkheid?)* Op welke manier wordt het ingezet? *- Bewegende videobeelden of enkel foto's?* *- Welke apparatuur/technologie voor opname en opslag van de beelden?* *- Maken de beelden deel uit van patiëntendossier?* *- Zijn de beelden anoniem?* *- Wordt er toestemming gevraagd aan de patiënt?* Volgens u, wat zijn de eventuele nadelen van het gebruik of videoregistratie? *(nadelen voor de arts, voor de patiënt, het ziekenhuis (infrastructuur), andere…?)* Bij uw weten, wie van uw collega's (in termen van type specialisten) in het ziekenhuis waar u werkt, maakt er (ook) gebruik van videoregistratie bij endoscopische chirurgie? Hoeveel collega's? Voor welk type ingrepen gebruik ze het? Hoe vaak gebruiken ze dit? Voor welke doelstelling(en) gebruiken ze het? *(kwaliteit, opleiding, aansprakelijkheid?)* *Enkel indien de geïnterviewde arts nog geen videoregistratie gebruikt, vraag stellen waarom videoregistratie nog niet gebruikt wordt. Toepasselijke vraag kiezen in functie van voorgaande info.* *Zowel geïnterviewde arts als collega's gebruik nog geen videoregistratie:* Zowel u als u andere collega's, maken nog geen gebruik van videoregistratie bij endoscopische chirurgie. Waarom gebruikt u niet of nog niet? Ofwel: *Geïnterviewde arts gebruikt geen videoregistratie, maar enkele van zijn collega's wel.* Sommige van uw collega's gebruiken videoregistratie bij endoscopische chirurgie. Waarom gebruikt u het niet of nog niet? *Enkel indien de geïnterviewde arts videoregistratie gebruikt, en zijn collega's niet:* U maakt gebruik van videoregistratie, maar uw collega's nog niet. Waarom gebruiken ze het nog niet, volgens u? Hoe doet u aan kwaliteitsmanagement (in verband met technische vaardigheden en verloop) in het OK (algemeen)? Hoe doet u aan kwaliteitsmanagement (in verband met technische vaardigheden en verloop) in het OK specifiek bij endoscopische chirurgie? *(Indien er reeds gebruik gemaakt wordt van videoregistratie)* In hoeverre maakt de videoregistratie deel uit van dit kwaliteitsysteem?

20 min	4. Gebruik van videoregistratie in het OK in de toekomst? *Doel: inzicht krijgen tot op welk niveau en voor welke finaliteit de geneesheer videoregistratie bij endoscopische chirurgie haalbaar inschat binnen het OK voor de toekomst (op MLT en LT).* **Vragen** Welke (andere) toepassingen van videoregistratie bij endoscopische chirurgie kunnen nuttig gebruikt worden in het OK in de toekomst, denkt u persoonlijk vanuit uw praktijkervaring als arts? *(haalbaar om het te gebruiken? En zo ja, voor welke doeleinden?)* We zullen u een aantal scenario's schetsen over het gebruik van videoregistratie bij endoscopische chirurgie in het OK in de toekomst. Bij elk van de scenario's zouden we graag uw mening weten over de mogelijke voor- en nadelen, de meerwaarde en de remmende en de bevorderende factoren. **Scenario 1**: De chirurg beslist ad hoc om de beelden van een aantal van de endoscopische chirurgisch ingrepen op te slaan wanneer hij gebruik maakt van een nieuwe technologie of procedure. Op basis van de beelden kan hij achteraf de procedure herbekijken en evalueren. De beelden worden enkel bekeken door de betrokken arts en worden slechts tijdelijk bijgehouden. De beelden zijn niet anoniem en er wordt op voorhand schriftelijke toestemming gevraagd aan de patiënt. Is dit scenario realistisch in de praktijk? *Indien nee, waarom niet?* Welke meerwaarde zou videoregistratie kunnen hebben in dit scenario? Welke zijn de mogelijke voordelen van het gebruik van videoregistratie in dit scenario voor u, als arts? Welke zijn de mogelijke voordelen van het gebruik van videoregistratie in dit scenario voor de patiënt? Welke zijn de mogelijke voordelen van het gebruik van videoregistratie in dit scenario voor het ziekenhuis? Welke zijn de mogelijke nadelen van het gebruik van videoregistratie in dit scenario voor u, als arts? Welke zijn de mogelijke nadelen van het gebruik van videoregistratie in dit scenario voor de patiënt? Welke zijn de mogelijke nadelen van het gebruik van videoregistratie in dit scenario voor het ziekenhuis? Als dit scenario morgen geïmplementeerd zou worden, welke zijn de mogelijke hindernissen of problemen? *(problemen qua materieel, infrastructuur, procedure, opslag, kosten…)* Als dit scenario morgen geïmplementeerd zou worden, welke factoren zouden de invoering stimuleren of vergemakkelijken? **Scenario 2**: De chirurg beslist om ad hoc beelden van een aantal van de endoscopische chirurgische ingrepen op te slaan voor de opleiding van chirurgen in opleiding. Enerzijds gebruikt hij de beelden om deze te kunnen tonen aan geneesheren-specialisten in opleiding. Anderzijds neemt hij de beelden op van een chirurgische ingreep uitgevoerd door een geneesheer-specialist omdat deze onmiddellijk na de operatie te kunnen herbekijken en te bespreken met de stagiair in kwestie. Er wordt wel op voorhand schriftelijke toestemming gevraagd aan de patiënt. *Algemeen* Is dit scenario realistisch in de praktijk? *Indien nee, waarom niet?* Welke meerwaarde zou videoregistratie kunnen hebben in dit scenario? Welke zijn de mogelijke voordelen van het gebruik van videoregistratie specifiek in dit scenario voor u, als arts? Welke zijn de mogelijke voordelen van het gebruik van videoregistratie specifiek in dit scenario voor de patiënt?

	Welke zijn de mogelijke voordelen van het gebruik van videoregistratie specifiek in dit scenario voor het ziekenhuis? Welke zijn de mogelijke nadelen van het gebruik van videoregistratie specifiek in dit scenario voor u, als arts? Welke zijn de mogelijke nadelen van het gebruik van videoregistratie specifiek in dit scenario voor de patiënt? Welke zijn de mogelijke nadelen van het gebruik van videoregistratie specifiek in dit scenario voor het ziekenhuis? Als dit scenario morgen geïmplementeerd zou worden, welke zijn de mogelijke hindernissen of problemen? *(problemen qua materieel, infrastructuur, procedure, opslag, kosten…)* Als dit scenario morgen geïmplementeerd zou worden, welke factoren zouden de invoering stimuleren of vergemakkelijken? **Scenario 3**: Een tijdelijke campagne opgelegd door een derde partij of overheid legt vast dat de beelden van een bepaald type ingrepen gedurende een bepaalde periode opgenomen en bijgehouden moet worden, voor een prospectieve kwaliteitsstudie. De beelden kunnen achteraf gecontroleerd of geëvalueerd worden. De beelden worden gecodeerd. De beelden maken juridisch deel uit van het patiëntendossier. Er wordt wel op voorhand schriftelijke toestemming gevraagd aan de patiënt. *Algemeen* Is dit scenario realistisch in de praktijk? *Indien nee, waarom niet?* Welke meerwaarde zou videoregistratie kunnen hebben in dit scenario? Welke zijn de mogelijke voordelen van het gebruik van videoregistratie specifiek in dit scenario voor u, als arts? Welke zijn de mogelijke voordelen van het gebruik van videoregistratie specifiek in dit scenario voor de patiënt? Welke zijn de mogelijke voordelen van het gebruik van videoregistratie specifiek in dit scenario voor het ziekenhuis? Welke zijn de mogelijke nadelen van het gebruik van videoregistratie specifiek in dit scenario voor u, als arts? Welke zijn de mogelijke nadelen van het gebruik van videoregistratie specifiek in dit scenario voor de patiënt? Welke zijn de mogelijke nadelen van het gebruik van videoregistratie specifiek in dit scenario voor het ziekenhuis? Als dit scenario morgen geïmplementeerd zou worden, welke zijn de mogelijke hindernissen of problemen? *(problemen qua materieel, infrastructuur, procedure, opslag, kosten…)* Als dit scenario morgen geïmplementeerd zou worden, welke factoren zouden de invoering stimuleren of vergemakkelijken? **Scenario 4**: De chirurgen zijn verplicht om alle endoscopische chirurgische ingrepen systematisch op te nemen en te archiveren. De beelden kunnen gebruikt worden door het ziekenhuismanagement of een overheid om de kwaliteit te controleren. De beelden kunnen ook gebruikt worden bij gerechtelijke aansprakelijkheidsprocedures door beide partijen. Deze toepassing wordt opgenomen in het algemeen akkoord tussen artsen en ziekenhuizen. De beelden maken deel uit van het patiëntendossier. Er wordt op voorhand schriftelijke toestemming gevraagd aan de patiënt. *Algemeen* Is dit scenario realistisch in de praktijk? *Indien nee, waarom niet?* Welke meerwaarde zou videoregistratie kunnen hebben in dit scenario? Welke zijn de mogelijke voordelen van het gebruik van videoregistratie specfiek in dit scenario voor u, als arts? Welke zijn de mogelijke voordelen van het gebruik van videoregistratie specifiek in dit scenario voor de patiënt?

	Welke zijn de mogelijke voordelen van het gebruik van videoregistratie specifiek in dit scenario voor het ziekenhuis? Welke zijn de mogelijke nadelen van het gebruik van videoregistratie specifiek in dit scenario voor u, als arts? Welke zijn de mogelijke nadelen van het gebruik van videoregistratie specifiek in dit scenario voor de patiënt? Welke zijn de mogelijke nadelen van het gebruik van videoregistratie specifiek in dit scenario voor het ziekenhuis? Als dit scenario morgen geïmplementeerd zou worden, welke factoren zouden de invoering stimuleren of vergemakkelijken? Als dit scenario morgen geïmplementeerd zou worden, welke zijn de mogelijke hindernissen of problemen? *(problemen qua materieel, infrastructuur, procedure, opslag, kosten…)* *Indien niet aanbod gekomen in de vorige vraag:* Welke zijn de hindernissen op vlak van ICT, medico-legale aspecten, financiële aspecten, evaluatie van beelden, publicatie van resultaten enz…

5 min	5. Gevolgen van videoregistratie voor de patiënt? *Doel: inzicht krijgen in de gevolgen van videoregistratie voor de patiënt* **Vragen** Stel dat videoregistratie gebruikt wordt bij chirurgische ingrepen en de patiënt heeft toegang tot de beelden: Wat zijn er dan volgens u mogelijke aandachtspunten? Welke mogelijke gevolgen zijn er voor de patiënt volgens u? *(voordelen/nadelen?)* Welke mogelijke gevolgen heeft dit voor de arts volgens u? *(voordelen/nadelen?)*
5 min	6. Rol van de overheid *Doel:Inzicht krijgen in de mening van de artsen over de rol van de overheid in het opstellen van algemene regels rond kwaliteitsprocedures in het OK in het algemeen en specifiek het gebruik van videoregistratie in het OK.* **Vragen** Wat is uw mening over de rol van de overheid inzake het voorschrijven van kwaliteitsprocedures in het OK in het algemeen? Wat is uw mening over de rol van de overheid inzake het opleggen van videoregistratie van endoscopische chirurgische ingrepen?
	7. Open-veld opnames *(enkel indien er voldoende tijd is!)* Wordt er door u of uw collega's soms gebruik gemaakt van "open-veld-opnames" in het OK? → Indien ja: Wie gebruikt het? *(welk type specialisten, hoeveel collega's…)* Voor welk type ingrepen gebruik ze het? Hoe vaak gebruiken ze dit? Voor welke doelstelling(en) gebruiken ze het? *(kwaliteit, opleiding, aansprakelijkheid?)*
5 min	8. Slot *Doel: Nog ruimte laten voor bijkomende vragen of opmerkingen indien de artsen dit wensen.* **Vragen** Welke vragen, bedenkingen of aanvullingen hebt u nog over het gebruik van videoregistratie bij endoscopische chirurgie? *Bedanking + uitleg over de vervolgstappen (verslag wordt per mail doorgestuurd ter verificatie)*

French version:

5 min	1. Introduction lors de l'interview <u>Présentation KCE – HICT - interviewers</u> Interviewers:… HICT:… KCE:… <u>Description du but du projet</u> Le but du projet est l'élaboration d'une analyse de l'utilisation possible de l'enregistrement vidéo lors de la chirurgie par endoscopie. Il y a 3 volets importants dans le projet: une analyse des possibilités techniques, une analyse des conséquences juridiques et une analyse de l'utilisation de ce type de procédure dans le cadre des systèmes de qualité dans le quartier opératoire. Un élément important est le questionnement des chirurgiens pour savoir comment les médecins se positionne par rapport à cette technologie et à ses applications, de part leur expérience de la pratique vanuit hun praktijkervaring staan tegenover deze technologie en haar toepassingen.(de leur expérience pratique face à cette technologie et à ses applications) <u>description du but et le déroulement de l'entretien</u> But de l'entretien Aperçu sur l'utilisation de l'enregistrement vidéo lors des interventions chirurgicales dans le quartier opératoire et leur place dans les autres systèmes de qualité. Aperçu sur l'utilisation future dans le quartier opératoire (avantages et inconvénients, facteurs entravants et aspects qui facilitent l'instauration). Déroulement de l'entretien La conversation durera maximum 1h00. un feedback sera envoyé à postériori pour validation. Tous les entretiens sont traités ensemble. Seul le rapport final sera publié. Votre nom sera mentionné uniquement sur la liste des médecins ayant participé aux entretiens dans l'addendum du rapport final. L'entretien est enregistré mais sert uniquement à faciliter le traitement ultérieur de l'interview
5 min	2. Questions préparatoires *But: localisation médecin et hôpital* **Questions** Combien d'années d'expérience avez-vous en médecine? Combien d'années d'expérience avez-vous en chirurgie par endoscopie? Dans combien d'hôpitaux travaillez-vous? *Si plus d'un*: pratiquez-vous la chirurgie par endoscopie dans tous les hôpitaux? Combien d'opérations pratiquez-vous en moyenne par an (nombre total)? Combien d'interventions par endoscopie (thérapeutique, non diagnostique) pratiquez-vous en moyenne par an? Etes-vous accrédité? Donnez-vous encore des cours en plus de votre pratqie médicale? Faites-vous des recherches scientifiques en plus de votre pratqie médicale? *Si oui:* en tant que chercheur ou en tant que participant à une recherche scientifique exécutée par des tiers? Etes-vous responsable pour l'accompagnement des médecins-spécialistes en formation? De quelles associations êtes-vous membre? *Si membre:quel est votre rôle?*
15 min	3. Utilisation <u>actuelle</u> de l'enregistrement vidéo dans le quartier opératoire? *<u>But</u>: avoir un aperçu quant à l'utilisation actuelle de l'enregistrement vidéo dans le quartier opératoire, dans quelle mesure et dans quel but.* **Questions** Quelle est votre expérience actuelle avec l'enregistrement vidéo lors d'opérations par endoscopie?

	Uniquement enregistrement vidéo des opérations par endoscopie partant de l'image existante pendant l'opération (pas de champ-ouvert) → si expérience: Pour quels types d'interventions l'utilisez-vous? A quelle fréquence l'utilisez-vous? Dans quel(s) but(s) l'utilisez-vous? *(qualité, formation,responsabilité?)* De quelle manière l'utilisez-vous? *- Images vidéo 'mobiles' ou uniquement les photos?* *- Quel appareillage/technologie pour l'enregistrement et le stockage des images?* *- Les images font-elles partie du dossier du patient?* *- Les images sont-elles anonymes?* *- Demandez-vous l'autorisation au patient?* Selon vous, quels sont les inconvénients éventuels quant à l'utilisation de l'enregistrement vidéo? *(inconvénients pour le médecin, pour le patient, l'hôpital (infrastucture), autres, …?)* A votre connaissance, qui <u>parmi vos collègues</u> (en terme du type de spécialistes) dans l'hôpital où vous travaillez, utilise (également) l'enregistrement vidéo lors de chirurgie par endoscopie? Combien de collègues? Pour quels types d'interventions l'utilisent-ils? A quelle fréquence l'utilisent-ils? Dans quel(s) but(s) l'utilisent-ils? *(qualité, formation, responsabilité?)* *Uniquement si le médecin interviewé n'utilise pas encore l'enregistrement vidéo, poser la question de savoir pourquoi l'enregistrement vidéo n'est pas encore utilisé.* *Choisissez la question appropriée en fonction de l'information précédente.* *<u>Aussi bien le médecin interviewé que les collègues n'utilisent pas encore l'enregstrement vidéo:</u>* Aussi bien vous que vos collègues ne faites pas usage de l'enregistrement vidéo lors de chirurgie par endoscopie. Pourquoi cette technologie n'est-elle pas ou pas encore utilisée? <u>Ou bien:</u> *<u>Le médecin interviewé n'utilise pas l'enregistrement vidéo mais bien certains de ses collègues.</u>* Certains de vos collègues utilisent l'enregistrement vidéo lors de chirurgie par endoscopie. Pourquoi ne l'utilisez-vous pas ou pas encore? *Uniquement si le médecin interviewé utilise l'enregitrement vidéo et pas ses collègues:* Vous utilisez l'enregistrement vidéo, mais pas encore vos collègues Pourquoi ne l'utilisent-ils pas ou pas encore, selon vous? Comment faites gérez-vous la qualité (en rapport avec l'habileté technique et le déroulement) dans le quartier opératoire (en général)? Comment gérez-vous la qualité (en rapport avec les l'habilleté technique et le déroulement) dans le quartier opératoire lors de <u>la chirurgie par endoscopie</u>? *(Si l'enregistrement vidéo est déjà utilisé) Dans quelle mesure l'enregistrement vidéo fait partie de ce système de qualité?*
20 min	4. Utilisation <u>dans le futur</u> de l'enregistrement vidéo dans le quartier opératoire? *<u>But :</u> avoir un aperçu de : dans quelle mesure et pour quelle finalité l'enregistrement des traitements chirurgicaux par endoscopie est faisable dans le quartier opératoire à l'avenir (à moyen et logn terme)* **Questions** quelles (autres) applications de l'enregistrement vidéo lors de chirurgie par endoscopie peuvent être utiles dans le quartier opératoire à l'avenir. Qu'en pensez-vous personnellement en tant que médecin de par votre pratique? *(faisable de l'utiliser ? et si oui pour quelles finalités?)*

	Nous allons vous décrire un nombre de scénarios sur l'utilisation de l'enregistrement vidéo lors de chirurgie par endoscopie dans le quartier opératoire dans le futur. Pour chaque scénario, nous aimerions connaître votre avis sur les avantages et inconvénients possibles, la plus-value et les facteurs favorisants et entravants leur implémentation. **Scenario 1**: Le chirurgien décide au cas par cas de stocker des images de certaines interventions chirurgicales par endoscopie lorsqu'il utilise une nouvelle technologie ou procédure. Sur base des images, il peut, à postériori, reconsidérer et évaluer la procédure. Les images sont examinées uniquement par le médecin concerné et ne sont conservées que temporairement. Les images ne sont pas anonymes et une autorisation écrite est demandée au préalable au patient. Ce scenario est-il réaliste dans la pratique? Si non, pourquoi? Quelle plus-value pourrait avoir l'enregistrement vidéo dans ce scénario? Quels sont, selon vous, en tant que médecin, les avantages possibles de l'utilisation de l'enregistrement vidéo dans ce scénario? Quels sont les avantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour le patient? Quels sont les avantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour l'hôpital? Quels sont, selon vous, en tant que médecin, les désavantages possibles de l'utilisation de l'enregistrement vidéo dans ce scénario? Quels sont les désavantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour le patient? Quels sont les désavantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour l'hôpital? Si ce scénario était réalisé demain,quels seraient les problèmes ou obstacles possibles? *(problèmes quant au matériel, infrastructure, procedure, stockage, coûts,…)* Si ce scénario était réalisé demain, quels facteurs stimuleraient ou faciliteraient l'instauration? **Scenario 2**: : Le chirurgien décide au ca spar cas de stocker des images de certaines interventions chirurgicales par endoscopie pour la formation de chirurgiens en formation. D'une part, il utilise les images pour les montrer aux médecins-spécialistes en formation. D'autre part, il enregistre les images d'une intervention chirurgicale effectuée par un médecin-spécialiste afin de pouvoir, immédiatement après l'opération, les réexaminer et en débattre avec le stagiaire en question. Une autorisation écrite est demandée au préalable au patient. *En général* Ce scenario est-il réaliste dans la pratique? Si non, pourquoi? Quelle plus-value pourrait avoir l'enregistrement vidéo dans ce scénario? Quels sont, selon vous, en tant que médecin, les avantages possibles de l'utilisation de l'enregistrement vidéo dans ce scénario? Quels sont les avantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour le patient? Quels sont les avantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour l'hôpital? Quels sont, selon vous, en tant que médecin, les désavantages possibles de l'utilisation de l'enregistrement vidéo dans ce scénario? Quels sont les désavantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour le patient? Quels sont les désavantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour l'hôpital? Si ce scénario était réalisé demain,quels seraient les problèmes ou obstacles possibles?

	(problèmes quant au matériel, infrastructure, procedure, stockage, coûts,…) Si ce scénario était réalisé demain, quels facteurs stimuleraient ou faciliteraient l'instauration? **Scenario 3**: Une campagne temporaire imposée par un tiers ou par le gouvernement impose que les images de certains types d'interventions doivent être prises et tenues à jour durant une période limitée, pour une étude de qualité prospective. Les images peuvent, à postériori, être contrôlées et évaluées. Les images sont codées. Les images font juridiquement partie du dossier du patient. Une autorisation écrite est demandée au préalable au patient. *En général* Ce scenario est-il réaliste dans la pratique? Si non, pourquoi? Quelle plus-value pourrait avoir l'enregistrement vidéo dans ce scénario? Quels sont, selon vous, en tant que médecin, les avantages possibles de l'utilisation de l'enregistrement vidéo dans ce scénario? Quels sont les avantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour le patient? Quels sont les avantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour l'hôpital? Quels sont, selon vous, en tant que médecin, les désavantages possibles de l'utilisation de l'enregistrement vidéo dans ce scénario? Quels sont les désavantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour le patient? Quels sont les désavantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour l'hôpital? Si ce scénario était réalisé demain,quels seraient les problèmes ou obstacles possibles? *(problèmes quant au matériel, infrastructure, procedure, stockage, coûts,…)* Si ce scénario était réalisé demain, quels facteurs stimuleraient ou faciliteraient l'instauration? **Scenario 4**: Les chirurgiens sont obligés de filmer systématiquement toutes les interventions chirurgicales par endoscopie et de les archiver. Les images peuvent être utilisées par le management de l'hôpital ou les autorités afin de contrôler la qualité. Les images peuvent aussi être utilisées par les deux parties lors de procédure judiciaire en responsabilité. Cette application est reprise dans l'accord général entre les médecins et les hôpitaux. Les images font partie du dossier du patient. . Une autorisation écrite est demandée au préalable au patient. *en général* Ce scenario est-il réaliste dans la pratique? Si non, pourquoi? Quelle plus-value pourrait avoir l'enregistrement vidéo dans ce scénario? Quels sont, selon vous, en tant que médecin, les avantages possibles de l'utilisation de l'enregistrement vidéo dans ce scénario? Quels sont les avantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour le patient? Quels sont les avantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour l'hôpital? Quels sont, selon vous, en tant que médecin, les désavantages possibles de l'utilisation de l'enregistrement vidéo dans ce scénario? Quels sont les désavantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour le patient? Quels sont les désavantages possibles de l'utilisation de l'enregistrement vidéo dans ce scenario pour l'hôpital? Si ce scénario était réalisé demain,quels seraient les problèmes ou obstacles possibles?

	(problèmes quant au matériel, infrastructure, procedure, stockage, coûts,…) Si ce scénario était réalisé demain, quels facteurs stimuleraient ou faciliteraient l'instauration? *Si pas apparu dans la question précédente:* Quels sont les obstacles sur le plan de ICT, aspects medico-légaux aspects financiers, évaluation des images, publication des résultats, etc…
5 min	5. Résultats de l'enregistrement vidéo pour le patient? *But: avoir un aperçu des conséquences de l'enregistrement vidéo pour le patient* **Questions** Supposons que l'enregistrement vidéo soit utilisé lors d'interventions chirurgicales et que le patient ait accès aux images: Quels seraient selon vous les points d'attention possibles? Quelles sont selon vous les conséquences possibles pour le patient? *(avantages/inconvénients?)* Quelles sont selon vous les conséquences possibles pour le médecin? *(avantages/inconvénients?)*
5 min	6. Rôle du gouvernement *<u>But</u>:avoir un aperçu de l'avis des médecins sur le rôle du gouvernement dans la rédaction des règles générales autour des procédures de qualité dans le quartier opératoire en générale et spécifiquement l'utilisation de l'enregistrement vidéo dans le quartier opératoire.* **Questions** Quel est votre avis sur le rôle du gouvernement en matière de prescription des procédures de qualité dans le quartier opératoire en général? Quel est votre avis sur le rôle du gouvernement en matière de l'obligation d'enregistrement vidéo d'interventions chirurgicales par endoscopie?
	7. enregistrement à champ-ouvert *(uniquement si le temps est suffisant!)* Avez-vous, vous ou vos collègues, parfois utilisé des enregistrement à champ-ouvert en quartier opératoire? → Si oui : Qui l'utilise? *(quel type de spécialistes, combien de collègues,…)* Pour quel type d'intervention l'utilisent-il ? a quelle fréquence l'utilisent-ils? Dans quel but l'utilisent-ils? *(qualité, formation, responsabilité?)*
5 min	8. Bilan *<u>But</u>:si les médecins le souhaitent, espace disponible pour les questions ou remarques complémentairesNog ruimte laten voor bijkomende vragen of opmerkingen indien de artsen dit wensen.* **Questions** Quels questions, réflexions ou compléments souhaitez-vous encore formuler sur l'utilisation de l'enregistrement vidoé lors de chirurgie par endoscopie? *Remerciement + explications sur les étapes à suivre (la synthèse sera envoyée par mail pour vérification)*

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Wettelijk depot : D/2008/10.273/97

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.
20. HTA Moleculaire Diagnostiek in België. D/2005/10.273/23, D/2005/10.273/25.
21. HTA Stomamateriaal in België. D/2005/10.273/27.
22. HTA Positronen Emissie Tomografie in België. D/2005/10.273/29.
23. HTA De electieve endovasculaire behandeling van het abdominale aorta aneurysma (AAA). D/2005/10.273/32.
24. Het gebruik van natriuretische peptides in de diagnostische aanpak van patiënten met vermoeden van hartfalen. D/2005/10.273/34.
25. Capsule endoscopie. D/2006/10.273/01.
26. Medico–legale aspecten van klinische praktijkrichtlijnen. D2006/10.273/05.
27. De kwaliteit en de organisatie van type 2 diabeteszorg. D2006/10.273/07.
28. Voorlopige richtlijnen voor farmaco-economisch onderzoek in België. D2006/10.273/10.
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30. Inventaris van databanken gezondheidszorg. D2006/10.273/14.
31. Health Technology Assessment prostate-specific-antigen (PSA) voor prostaatkankerscreening. D2006/10.273/17.
32. Feedback : onderzoek naar de impact en barrières bij implementatie – Onderzoeksrapport : deel II. D/2006/10.273/19.
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34. Trastuzumab bij vroegtijdige stadia van borstkanker. D/2006/10.273/23.
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44. Een procedure voor de beoordeling van nieuwe medische hulpmiddelen. D/2006/10.273/50.
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48. Chronische lage rugpijn. D/2006/10.273/63.
49. Antivirale middelen bij seizoensgriep en grieppandemie. Literatuurstudie en ontwikkeling van praktijkrichtlijnen. D/2006/10.273/65.
50. Eigen betalingen in de Belgische gezondheidszorg. De impact van supplementen. D/2006/10.273/68.
51. Chronische zorgbehoeften bij personen met een niet- aangeboren hersenletsel (NAH) tussen 18 en 65 jaar. D/2007/10.273/01.
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53. Financiering van verpleegkundige zorg in ziekenhuizen. D/2007/10 273/06
54. Kosten-effectiviteitsanalyse van rotavirus vaccinatie van zuigelingen in België
55. Evidence-based inhoud van geschreven informatie vanuit de farmaceutische industrie aan huisartsen. D/2007/10.273/12.
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60. Longfunctie testen bij volwassenen. D/2007/10.273/27.
61. Vacuümgeassisteerde Wondbehandeling: een Rapid Assessment. D/2007/10.273/30
62. Intensiteitsgemoduleerde Radiotherapie (IMRT). D/2007/10.273/32.
63. Wetenschappelijke ondersteuning van het College voor Oncologie: een nationale praktijkrichtlijn voor de aanpak van borstkanker. D/2007/10.273/35.
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66. Health Technology Assessment: Drug-Eluting Stents in België. D/2007/10.273/47
67. Hadrontherapie. D/2007/10.273/50.
68. Vergoeding van schade als gevolg van gezondheidszorg – Fase IV : Verdeelsleutel tussen het Fonds en de verzekeraars. D/2007/10.273/52.
69. Kwaliteit van rectale kankerzorg – Fase 1: een praktijkrichtlijn voor rectale kanker D/2007/10.273/54.
70. Vergelijkende studie van ziekenhuisaccrediterings-programma's in Europa D/2008/10.273/57.
71. Aanbevelingen voor het gebruik van vijf oftalmologische testen in de klinische praktijk .D/2008/10.273/04
72. Het aanbod van artsen in België. Huidige toestand en toekomstige uitdagingen. D/2008/10.273/07
73. Financiering van het zorgprogramma voor de geriatrische patiënt in algemene ziekenhuizen: definitie en evaluatie van een geriatrische patiënt, definitie van de interne liaisongeriatrie en evaluatie van de middelen voor een goede financiering. D/2008/10.273/11
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78. Richtlijnen voor farmaco-economische evaluaties in België. D/2008/10.273/23.
79. Terugbetaling van radioisotopen in België. D/2008/10.273/26
80. Evaluatie van de effecten van de maximumfactuur op de consumptie en financiële toegankelijkheid van gezondheidszorg. D/2008/10.273/35.
81. Kwaliteit van rectale kankerzorg – phase 2: ontwikkeling en test van een set van kwaliteitsindicatoren. D/2008/10.273/38
82. 64-Slice computertomografie van de kransslagaders bij patiënten met vermoeden van coronaire hartziekte. D/2008/10.273/40
83. Internationale vergelijking van terugbetalingsregels en juridische aspecten van plastische heelkunde. D/200810.273/43
84. Langverblijvende psychiatrische patiënten in T-bedden. D/2008/10.273/46
85. Vergelijking van twee financieringssystemen voor de eerstelijnszorg in België. D/2008/10.273/49.
86. Functiedifferentiatie in de verpleegkundige zorg: mogelijkheden en beperkingen. D/2008/10.273/52.
87. Het gebruik van kinesitherapie en van fysische geneeskunde en revalidatie in België. D/2008/10.273/54.
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90. Huisartsgeneeskunde: aantrekkingskracht en beroepstrouw bevorderen. D/2008/10.273/63
91. Hoorapparaten in België: health technology assessment. D/2008/10.273/67
92. Nosocomiale infecties in België, deel 1: nationale prevalentiestudie. D/2008/10.273/70.
93. Detectie van adverse events in administratieve databanken. D/2008/10.273/73.
94. Intensieve maternele verzorging (Maternal Intensive Care) in België. D/2008/10.273/77
95. Percutane hartklep implantatie bij congenitale en degeneratieve klepletsels: A rapid Health Technology Assessment. D/2008/10.273/79
96. Het opstellen van een medische index voor private ziekteverzekerings-overeenkomsten. D/2008/10.273/82
97. NOK/PSY revalidatiecentra: doelgroepen, wetenschappelijke evidentie en zorgorganisatie. D/2009/10.273/84
98. Evaluatie van universele en doelgroep hepatitis A vaccinatie opties in België. D/2008/10.273/88
99. Financiering van het geriatrisch dagziekenhuis. D/2008/10.273/90
100. Drempelwaarden voor kosteneffectiviteit in de gezondheidszorg. D/2008/10.273/94
101. Videoregistratie van endoscopische chirurgische interventies: rapid assessment. D/200/10.273/97