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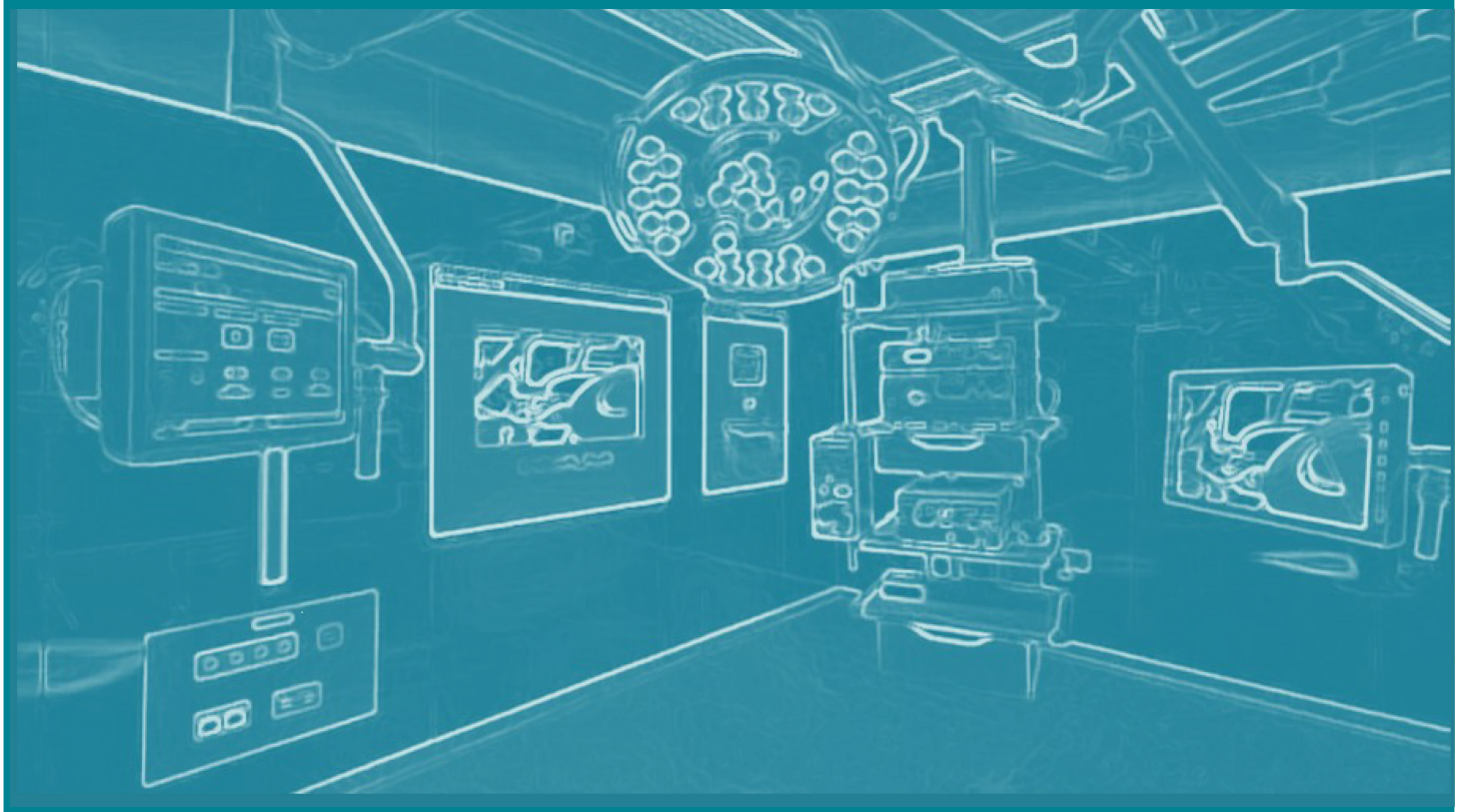
Central Denmark Region

Integrated Operating Rooms - A Health Technology Assessment



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Integrated Operating Rooms – A Health Technology Assessment

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PREFACE

This Health Technology Assessment (HTA) concerns integrated operating rooms.

The project is based on the fact that in recent years an increase has been observed in the use of the technology 'integrated operating rooms'. Integrated operating rooms can be described as a collection of systems and technologies that are functionally linked to one unit, which allows the surgical staff to control equipment in the operating room from a single control unit (touchpad). The technology has already been introduced in around 77 operating rooms in Denmark, and since the cost of establishing the technology is considerable, this may well result in a significant increase in the total costs within this area.

Consequently, the Health Directors in the Danish Regions have initiated a Health Technology Assesment (HTA) to look into whether or not it is relevant to continue to introduce the technology and if so how this should be done. The assessment includes examination of effects and risks related to use of integrated operating rooms, as well as organizational and economic consequences of implementation and use of the technologies.

The HTA-report is conducted by an interdisciplinary project group comprising relevant academic, research and methodological knowledge. DEFACTUM, Central Denmark Region, was responsible for project management during conduction of the HTA report and a reference group was established for the HTA project.

The report is intended for regional decision-makers and can be used in local and national decision-making processes.

DEFACTUM would like to thank the members of the project group for their efforts in the conduction of the report and the reference group for their contributions and comments. Finally, DEFACTUM would like to thank professional and methodological reviewers as well as peer-reviewers for advice and comments.

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LIST OF ABBREVIATIONS AND DEFINITIONS

A/V	Audio/Video
AUH	Aarhus University Hospital
CI	Confidence Interval
COR	Conventional Operating Room
DARE	The Database of Abstracts of Reviews of Effects
ECO	Costs and economic evaluation
EFF	Clinical effectiveness
EUnetHTA	European Network for Health Technology Assessment
GRADE	Grading of Recommendations, Assessments, Development and Evaluation
HTA	Health Technology Assessment
ICD	International Classification of Diseases
IOR	Integrated Operating Room
MeSH	Medical Subject Headings
MIS	Minimally Invasive Surgery
OR	Operating Room
ORG	Organisational
PICO	Patient-Intervention-Comparison-Outcome
RCT	Randomised Controlled Trial
REA	Relative Effectiveness Assessment
ROBIS	Risk of Bias in Systematic Reviews
SAF	Safety
SIGN	Scottish Intercollegiate Guidelines Network
SR	Systematic Review
TEC	Technology characteristics

RESUMÉ

Denne medicinske teknologivurdering (MTV) omhandler integrerede operationsstuer. MTV'en blev igangsat af Sundhedsdirektørkredsen i Danske Regioner med henblik på at vurdere kliniske effektforhold samt organisatoriske og økonomiske konsekvenser ved at anvende integrerede operationsstuer. En integreret operationsstue er en samling af systemer og teknologier, som funktionelt er knyttet sammen til én enhed, hvilket giver operationspersonalet mulighed for at styre alt integreret udstyr (f.eks. perifert udstyr, kirurgisk udstyr og video-routing) på operationsstuen fra en enkelt trykfølsom skærm (touchpad). Teknologien muliggør, at det kirurgiske personale kan få kontrol over alt relevant udstyr fra det sterile felt gennem en enkelt berøringsflade (touchpad), hvilket potentielt kan være med til at reducere uhensigtsmæssige arbejdsgange og spare tid. I rapporten sammenlignes integrerede operationsstuer med konventionelt indrettede operationsstuer. De integrerede stuer anvendes typisk ved endoskopiske og laparoskopiske procedurer, dvs. minimalt invasiv kirurgi, men kan anvendes på alle operationsstuer til alle typer operationer og patientgrupper. DEFACTUM, Region Midtjylland har udarbejdet MTV'en i samarbejde med en tværfagligt sammensat projektgruppe samt Indkøb & Medicoteknik, Region Midtjylland.

Definition af integrerede operationsstuer i denne MTV:

- Er en samling af systemer og teknologier, som funktionelt er knyttet sammen til én enhed.
- Enheden giver mulighed for at styre integreret udstyr (f.eks. perifert udstyr, kirurgisk udstyr og video-routing) fra en enkelt betjeningsenhed (touchpad.)
- Integrerede operationsstuer er ikke defineret ud fra, hvilket udstyr, der kan integreres på stuen, og omfatter således ikke en evaluering/vurdering af det udstyr, som er integreret, men ser alene på værdien ved at have udstyret integreret i en enkelt betjeningsenhed (touchpad).

Metodisk tilgang

MTV'en omfatter beskrivelse og tekniske karakteristika af teknologien (TEC), klinisk effektivitet (EFF), risici (SAF), organisation (ORG) samt omkostninger og økonomisk evaluering (ECO) med afsæt i EUnetHTA's Core Model. Der blev inden for alle domæner gennemført systematisk litteratursøgning. Søgningen blev begrænset i forhold til sprog (dansk, engelsk, norsk, svensk og tysk sprog) og med en tidsafgrænsning på 10 år (januar 2009 til januar 2019). For at opnå høj følsomhed i søgningen blev der søgt bredt på teknologien, hvilket medførte et resultat på 6.159 referencer til gennemgang og udvælgelse. Gennemførelsen af udvælgelsesprocessen blev foretaget på baggrund af udvælgelseskriterier beskrevet i formålet (se 'Scope', sektion 1) for denne rapport. Derudover blev der indsamlet empiriske data via producenter, via interviews med 20 kliniske informanter (med repræsentation fra alle danske regioner) samt via en kortlægning over implementerede integrerede operationsstuer på danske hospitaler. Empiriske data til en økonomisk analyse blev indsamlet i to afdelinger på et dansk hospital.

Nedenfor præsenteres rapportens hovedresultater, struktureret efter domænerne med afsæt i EUnetHTA's Core Model.

- **Beskrivelse og tekniske karakteristika af teknologien (TEC):** Integrerede operationsstuer er en gruppe af systemer, som funktionelt er koblet sammen til én enkelt trykfølsom skærm (touchpad) med det formål at understøtte at operationen udføres hensigtsmæssigt. Integrerede operationsstuer anvendes primært til minimal invasiv kirurgi. Touchpaden er placeret i det sterile felt, hvilket giver det sterile operationspersonale mulighed for at administrere det integrerede udstyr. I praksis kan touchpaden også placeres i det ikke-sterile felt. At det integrerede udstyr kan styres fra én touchpad står i modsætning til konventionelle operationsstuer, hvor styringen sker fra separate kontrolpaneler placeret forskellige steder på operationsstuen. I Danmark er der identificeret integrerede operationsstuer på 24 hospitaler fra producenterne Karl Storz, Olympus og Stryker. Både litteraturen om samt producenter af integrerede operationsstuer peger på, at stuerne kan reducere operationstiden og muliggøre et mere effektivt og optimeret arbejdsflow til gavn for patienter og kirurgisk personale, når der sammenlignes med konventionelle operationsstuer.

- **Klinisk effektivitet (EFF):** På baggrund af en omfattende systematisk litteratursøgning blev der fundet et begrænset antal studier, som sammenligner integrerede og konventionelle operationsstuer. Der blev inkluderet to studier, hvori kliniske effektforhold blev vurderet. Studierne inkluderede patienter, som gennemgik laparoskopisk fjernelse af livmoderen eller kirurgiske øre-/næse-/halsindgreb. Der blev ikke fundet statistisk eller klinisk signifikante effekter ved brug af integrerede operationsstuer sammenlignet med konventionelle operationsstuer, om end en tendens pegede mod tidsbesparelse ved anvendelse af integrerede operationsstuer. Disse fund hviler på et meget begrænset evidensgrundlag.

- **Risici (SAF):** Der blev ikke fundet statistisk signifikante forskelle i forekomsten af komplikationer eller signifikante forskelle i flow (målt ved antal forstyrrelser i forbindelse med operative indgreb) ved brug af integrerede operationsstuer sammenlignet med konventionelle operationsstuer. Resultater fra to survey-studier indikerede formodede potentielle fordele i relation til operationel risiko ved anvendelse af integrerede operationsstuer.

- **Organisation (ORG):** Organisationsanalysen viste, at integrerede operationsstuer ikke er en teknologi med store konsekvenser for den eksisterende organisering og arbejdsprocesserne på operationsstuen. Anvendelse af teknologien medfører mindre ændringer i arbejdsdelingen mellem den sterile og ikke-sterile operationssygeplejerske under operation samt mindre ændringer i operationssygeplejerskernes arbejdsopgaver under forberedelse til og afslutning af operation. Anvendelse af integrerede operationsstuer har heller ikke væsentlige konsekvenser for samarbejdet og kommunikationen blandt operationspersonalet på operationsstuen. Generelt oplevedes integrerede stuer lette at anvende og ikke forbundet med en læringskurve. Dog forudsætter korrekt betjening af touchpaden og udnyttelse af den integrerede operationsstues mulige potentialer en vis introduktion og oplæring af operationspersonalet. Oplæring bør omfatte introduktion til og oplæring i betjening af touchpaden, introduktion til de integrerede funktionaliteter og udstyr, samt introduktion til og oplæring i håndtering af fejlfinding. Organisationsanalysen viste, at den nuværende oplæring af det kirurgiske personale er administreret lokalt på hospitalsafdelingerne og generelt organiseret som sidemandsoplæring.

  Operationspersonalet udtrykte overvejende tilfredshed med de integrerede operationsstuer og oplevede ikke, at anvendelsen af stuerne var forbundet med betydelige organisatoriske gevinster eller udfordringer. Organisationsanalysen identificerede særligt tre mindre udfordringer og gevinster associeret med brugen af integrerede operationsstuer med formodet potentiale i relation til fremtidig anvendelse og udbredelse af teknologien. *For det første* kan integrerede operationsstuer medføre en oplevet forbedring af arbejdsflowet under operationen, forudsat at touchpaden betjenes i det sterile felt eller fleksibelt mellem det sterile og ikke-sterile felt. Desuden blev det indikeret, at forbedringer i arbejdsflowet især synes realiseret i forbindelse med langvarige og komplekse operationer. *For det andet* viste organisationsanalysen en variation i anvendelsen af integrerede operationsstuer med betydning for mulighederne for at realisere eventuelle potentialer i stuerne vedrørende forbedret arbejdsflow. Dette indbefattede dels variation, hvad angik i hvor høj grad touchpaden anvendtes til at betjene det integrerede udstyr og funktionaliteter, dels variation i, hvorvidt touchpaden blev betjent i det sterile eller ikke-sterile felt. I forhold til at tilvejebringe de bedste betingelser for at kunne realisere eventuelle potentialer af integrerede operationsstuer viste organisationsanalysen et formodet potentiale i at sikre en klar forståelse for teknologiens positive effekter og i at styrke den eksisterende oplæring af operationspersonalet. *For det tredje* kan integrerede operationsstuer for den ikke-sterile sygeplejerske lede til oplevede positive gevinster for arbejdsmiljø og ergonomi. Der blev ikke fremhævet ergonomiske gevinster eller udfordringer for det øvrige operationspersonale.

- **Økonomi (ECO):** På baggrund af en systematisk litteratursøgning var det ikke muligt at identificere studier, som havde undersøgt omkostninger eller omkostningseffektivitet af integrerede operationsstuer. Det var heller ikke muligt at identificere klinisk relevante, kvantificer- og målbare effekter af integrerede operationsstuer, og den økonomisk analyse blev derfor designet som en omkostningsminimeringsanalyse af integrerede vs. konventionelle operationsstuer baseret på et evalueringsstudie i Region Midtjylland. En analyse af

tidsregistreringer fandt ingen statistisk signifikante forskelle i proceduretiden mellem den konventionelle og den integrerede operationsstue, hvilket medførte eksklusion af personaleomkostninger fra den inkrementelle omkostningsanalyse. Omkostningsanalysen viste inkrementelle omkostninger for en integreret operationsstue sammenlignet med den konventionelle, der varierede fra 695.000 DKK svarende til en årlig meromkostning på 92.925 DKK for den mest enkle løsning til 1.125.000 DKK svarende til en årlig meromkostning på 149.359 DKK for en mere omfattende løsning. De budgetmæssige konsekvenser, ved fuld implementering af integrerede operationsstuer på et hospital (baseret på 60 stuer), varierede fra samlede investeringsomkostninger på 41.700.000 DKK til 67.000.000 DKK svarende til årlige meromkostninger på mellem 5.575.500 DKK og 8.951.540 DKK afhængig af den valgte integrationsløsning. De nationale budgetmæssige konsekvenser varierede mellem samlede investeringsomkostninger på 535.150.000 DKK til 866.250.000 DKK svarerende til årlige meromkostninger på 68.757.150 til 112.211.300 DKK igen afhængig af niveauet af den integrerede løsning.

Diskussion

Funktionaliteterne, som er tilkoblet touchpaden på en integreret operationsstue, varierede i litteraturen såvel som i praksis, og yderligere hardware og software er ofte nødvendigt for at understøtte integrationen og den touchpad, som funktionaliteterne kontrolleres fra. Omfanget af funktionaliteter tilknyttet den integrerede operationsstue var i denne MTV defineret til som minimum at inkludere 1) kontrol af perifert udstyr, 2) kontrol af kirurgisk udstyr samt 3) video-routing.

Det kan ikke på nuværende tidspunkt dokumenteres, hvorvidt integrerede operationsstuer medfører relevante effekter i forhold til tid og flow. Vedrørende effektforhold blev kun to studier inkluderet, og det var ikke muligt at gennemføre metaanalyse grundet studiernes heterogenitet. Evidensgrundlaget for effektestimaterne var meget lavt - særligt grundet risiko for bias i studierne samt studiedesigns af ringe kvalitet. På grundlag af disse fund var det ikke muligt at drage nogen endelige konklusioner. Det kan dertil bemærkes, at analysen var baseret på surrogat-effektmål, som kun repræsenterer en mulig association til patientrelevante udfald; dog rapporterede enkelte studier på komplikationsrater. Da touchpaden kun er en lille del af et større organisatorisk setup, kan det være svært at vise forskelle mellem alternativer, da mange andre faktorer kan påvirke resultaterne. Samlet set var mængden af litteratur om integrerede operationsstuer ekstremt begrænset og af metodisk dårlig kvalitet, hvor studiernes design og måleparametre medførte restriktioner for den interne validitet. I studierne er det særligt information om interventionen og sammenligningsgrundlag, der mangler.

Organisationsanalysen var begrænset ved, at såvel litteraturgennemgang som interviewstudie var fortrinsvis deskriptivt. Organisationsanalysen gav således indblik i de organisatoriske forandringer anvendelsen af integrerede operationsstuer medfører, men kun i begrænset omfang vurderedes de positive og negative konsekvenser og effekter ved disse forandringer. De konsekvensbetragtninger, som indgår i denne analyse, fremkom af interviewstudiet og er således baseret på interviewpersonernes subjektive oplevelser af og forestillinger om anvendelsen af integrerede operationsstuer frem for mere objektive effektmål. Tilvejebringelse af mere systematisk viden omkring organisatoriske forandringers positive og negative konsekvenser forudsætter studier med en tættere kobling af de identificerede organisatoriske forandringer og relevante effektindikatorer, f.eks. operationstid, patientsikkerhed og kvalitet i behandling. I forhold til interviewstudiet var det desuden en begrænsning, at ikke alle hospitalsafdelinger, som anvender integrerede operationsstuer, blev inddraget i studiet. Det betød, at organisationsanalysen ikke nødvendigvis giver et fuldstændigt billede af anvendelsen af integrerede operationsstuer samt de forbundne gevinster og udfordringer. Dog blev analysen baseret på et relativt stort sample med interviewpersoner repræsenterende forskellige specialer, afdelinger og professioner, og datamætning blev drøftet løbende undervejs i dataindsamling og analyse. I forhold til litteraturgennemgangen bør den geografiske kontekst af de inkluderede studier overvejes i relation til overførbarhed og generaliserbarhed af resultaterne i forhold til en dansk kontekst. Dette bør foregå da sundhedsvæsenets organisering og processer varierer mellem nationale kontekster og således også potentielt i

forhold til anvendelsen af integrerede operationsstuer. De fleste af resultaterne af litteraturgennemgangen blev dog genfundet i interviewundersøgelsen, hvilket underbygger validiteten af disse resultater.

Den økonomiske analyse var begrænset af, at der ikke i litteratursøgningen blevet identificeret relevante studier. Teknologiomkostningerne blev således baseret på indkøbsdata fra Region Midtjylland, og grundet forskel i regionale prisaftaler med producenter kan de estimerede teknologiomkostninger og scenarier variere marginalt på tværs af regioner. De præsenterede omkostninger estimerer imidlertid et troværdigt omkostningsniveau, som beslutningstagere kan forvente i tilfælde af en udrulning af teknologien. Resultater omkring proceduretid blev ligeledes kun udtrukket fra en enkelt region, hvilket eventuelt kan påvirke generaliserbarheden af resultaterne, da mulige tidsbesparelser er tæt relateret til operationsprocedurer, som muligvis varierer imellem hospitaler og regioner. Det relativt store tidsdatasæt var dog en styrke for validiteten af det empiriske økonomiske studie, og lokale forskelle i procedurer vurderes til at være af mindre betydning for det samlede resultat.

Selv om denne MTV ikke finder signifikante effekter af teknologien, er det ikke utænkeligt, at der kan findes potentielle effekter eller værdi af integrerede operationsstuer over tid. Positive effekter kunne måske findes i tid og sikkerhed i akutte situationer, når man skifter fra laparoskopisk til åben operation (ikke målt på grund af lav frekvens). Udvidet brug af undervisnings- og samarbejdsmuligheder som følge af muligheden for video streaming kunne potentielt sikre effektiv og kontinuerlig uddannelse af læger og kirurger og dermed forbedre kvaliteten af behandlingen. Oplevede forbedringer i arbejdsflow og ergonomi (jf. organisationsanalysen), kunne eventuelt få indflydelse på arbejdsmiljøet og jobtilfredsheden, og det kunne med tiden muligvis påvirke omkostningerne positivt i form af nedsat sygefravær.

Hvis integrerede operationsstuer implementeres, er det vigtigt at sikre løbende monitorering af brugen i relation til forskning og opfølgning. Når der anvendes ny teknologi, skal udbredelsen af teknologien være velfunderet og baseret på konsekvent og pålidelig beslutningstagning på baggrund af eksplicitte kriterier og udbredelsesbehov.

Konklusion

Integrerede operationsstuer er en nyere teknologi, som skal understøtte kontrollen over kirurgiske og ikke-kirurgiske funktionaliteter på operationsstuen ved brug af en touchpad. Integrerede operationsstuer er implementeret på 24 hospitaler i Danmark med kun små forskelle i væsentlige karakteristika og tilsigtet brug på tværs af producenter.

Tilgængelige resultater viste ingen klinisk eller statistisk signifikante forskelle i forekomsten af komplikationer, forstyrrelser i det kirurgiske flow under operation eller i operationstiden, når integrerede operationsstuer sammenlignedes med konventionelle operationsstuer. Evidensgrundlaget for disse effektmål var meget lav.

Organisationsanalysen viste, at implementering og anvendelse af integrerede operationsstuer ikke har store konsekvenser for den eksisterende organisering og arbejdsprocesserne på operationsstuen samt for kommunikationen og samarbejdet blandt det kirurgiske personale. Integrerede operationsstuer oplevedes generelt lette at anvende, men en vis introduktion og oplæring af operationspersonalet blev vurderet vigtigt for at sikre korrekt og optimeret brug af den integrerede operationsstue. Organisationsanalysen viste, at integrerede operationsstuer kan medføre en oplevet forbedring af arbejdsflowet under operationen, forudsat at touchpaden betjenes i det sterile felt eller fleksibelt mellem det sterile og ikke-sterile felt. Desuden fandtes i analysen et muligt potentiale i at sikre en klar forståelse for teknologiens positive effekter og i at styrke den eksisterende oplæring af operationspersonalet med henblik på at tilvejebringe de bedste betingelser for at udnytte den integrerede operationsstues eventuelle potentialer. Endelig viste organisationsanalysen, at integrerede operationsstuer opleves at kunne indvirke positivt på arbejdsmiljø og ergonomi for den ikke-sterile sygeplejerske.

Der fandtes ingen statistisk signifikante forskelle i operationstid mellem integrerede og konventionelle operationsstuer. Omkostningsanalysen viste inkrementelle omkostninger for en integreret operationsstue sammenlignet med den konventionelle, der varierede fra 695.000 DKK svarende til en årlig meromkostning på 92.925 DKK for den mest enkle løsning til 1.125.000 DKK svarende til en årlig meromkostning på 149.359 DKK for en mere omfattende løsning. De budgetmæssige konsekvenser ved fuld implementering af integrerede operationsstuer på et hospital (baseret på 60 stuer) varierede fra samlede investeringsomkostninger på 41.700.000 DKK til 67.000.000 DKK svarende til årlige meromkostninger på mellem 5.575.500 DKK og 8.951.540 DKK, afhængigt af den valgte integrationsløsning. De nationale budgetmæssige konsekvenser varierede mellem samlede investeringsomkostninger på 535.150.000 DKK til 866.250.000 DKK svarerende til årlige meromkostninger på 68.757.150 til 112.211.300 DKK, igen afhængigt af niveauet af den integrerede løsning.

SUMMARY

Scope

In this Health Technology Assessment (HTA) integrated operating rooms (IOR) are examined and compared to conventional operating rooms (COR), with the purpose of establishing a basis for decision-making prior to prioritization of any major investments in establishing IORs as an alternative to CORs. The HTA has been produced at the request of the Health Directors in the five Danish Regions. The scope can be found at 'Scope' (section 1).

Introduction

As many factors relate to surgical outcome, operative environment are also considered responsible for the outcome together with more traditional criteria such as patient characteristics and surgeon skills (1). Surgery is often compromised by surgical flow disturbances owing to technology- and equipment-related failures, and especially in minimally invasive surgery (MIS), patient safety relies on smooth procedures, depending on proper functioning of the equipment and the working environment (1). Basically, the technology 'Integrated operating rooms' (IOR) relates to how the surgical staff can gain control of all relevant equipment from the sterile field through a single touchpad, thereby potentially reduce inappropriate workflows and save time. Another complementary single touchpad could be placed outside the sterile field.

Definition of integrated operating rooms in this HTA:

- Is a group of systems and technologies that are functionally linked to one unit
- Integrated operating rooms allow the surgical staff to control all the integrated equipment/ functionalities (peripheral equipment, surgical equipment and audio/video signal routing) from a single device (touchpad)
- Integrated operating rooms are not defined by the specific equipment/functionalities integrated in the OR, and thus does not include an evaluation of the integrated equipment, but only looks at the value of having the equipment integrated in a single control unit (touchpad)

Description of technology and comparators

The IOR is a group of systems/technologies that are functionally linked to one unit. IOR is developed over a number of years to support appropriate surgery. The IOR is used primarily for MIS which is endoscopic and laparoscopic interventions. The IOR allows the surgical staff to control all IOR equipment/functionalities such as environment (light, climate, etc.), medical devices and video distribution from a touchpad. A computerised video matrix controlled by this touchpad distributes images to boom-mounted monitors thus allowing the best viewing angle to each operator (2). The touchpad is usually placed in the sterile field allowing the sterile surgical staff to interact and control the system. In practice, the touchpad can also be placed in the non-sterile field. In a COR, functionalities are often the same as in an IOR, but are arranged around the room. Machines and equipment such as lights, curtains, room climate control, audio/video (A/V) equipment, table(s), doors and surgical apparatus are controlled by their own control panel from the non-sterile field. This requires persistent presence of non-sterile nurse to assist the sterile dressed personnel. In Denmark there have been identified implemented IORs at 24 hospitals from the manufactures Karl Storz, Olympus and Stryker. According to these manufactures and the literature, the claimed benefit of IOR is to reduce operating time and enable a more efficient and optimised workflow for the benefit of the patient and the surgical staff compared with a COR.

Methods

A systematic literature search was performed for all domains of this assessment. The search was structured via the Patient-Intervention-Comparison-Outcome (PICO) structure. Only search terms in relation to intervention was used in order to uncover all relevant material – thereby not limiting the search by patient, compara-

tor and outcome search terms. Also this initial search was limited by language (Danish, English, Norwegian, Swedish and German language) and a time limit of 10 years (January 2009 to January 2019) to achieve high sensitivity (and low precision) in the initial search. Conducting the selection process the search met the inclusion and exclusion criteria described in the Scope of this assessment. For the technical characteristics (TEC), and safety (SAF) domains, information was identified through the systematic literature search, clinical and technical experts, manufacturer submission files, and internet searches on the topic. For all domains literature selection and data extraction were performed independently by two researchers.

The quality of the included cohort studies were assessed using the Scottish Intercollegiate Guidelines Network (SIGN) methodology checklists for cohort and case-control studies. No randomised controlled trials (RCT) and systematic reviews (SR) were included. The quality of the body of evidence was assessed using Grading of Recommendations, Assessment, Development and Evaluations (GRADE). Quality assessment was performed independently by two researchers.

Mapping of IOR activities was conducted and empirical data was collected in two departments in a Danish hospital. 20 informants (employees at hospitals from all Danish regions) participated in interviews mainly supporting the organisational analysis.

Results

Available evidence

Two studies met the inclusion criteria for the clinical effectiveness (EFF) domain, four studies for the SAF domain, six studies for the organisation (ORG) domain and no studies met the inclusion criteria for the costs and economic evaluation (ECO) domain.

Clinical effectiveness

Comparative studies examining IOR were very limited. Two studies were included for clinical effectiveness outcomes (1,3). The studies included patients undergoing laparoscopic hysterectomy or ear, nose and throat surgery. No statistically significant effects were shown using IOR although a tendency towards time savings was shown.

Safety

No significant differences in the incidence of complications were found, no differences in flow disturbances were shown. Findings from two surveys (2,4) indicated potential benefits in relation to surgical risk using IOR.

Organisational

Despite minor change in division of labour among the sterile and non-sterile nurse and smaller changes in work tasks during preparation and surgery for surgical nurses, IORs are not a technology associated with great implications for the existing organisation and work processes, nor for the co-operation and communication of activities among the surgical personnel. Although IORs are generally experienced easy to use and not experienced to be associated with a learning curve, proper introduction to and training of the surgical personnel using IORs is important in order to ensure correct and optimised use of the IOR. Currently training of surgical personnel is managed locally in the hospital departments and generally organised as peer-to-peer training.

The organisational analysis identified three small size challenges and opportunities associated with use of IOR with assumed potential in relation to any future use and spreading of IORs. First, IORs lead to experienced improvements of the workflow during surgery, presupposed that the touchpad is administered in the sterile field or flexibly between the sterile and non-sterile field. Second, variation in use of IORs exists as a consequence of habits among the surgical personnel and insufficient competencies in use of IORs. Thus, in order to unfold assumed potential of the IOR there seems to be a potential in ensuring clear incentives and understanding of the effects of the technology among the surgical personnel, and in strengthening the current training requirements and processes in place for surgical personnel using IORs. Third, IORs have an experienced positive impact on working environment and ergonomics for the non-sterile nurses.

Costs and economic evaluation

No existing studies explored the costs or cost-effectiveness of the IOR. Therefore, the economic analyses were primarily based on an empirical study performed in the Central Denmark Region. The EFF and SAF domain as well as the empirical study did not identify any clinically relevant and measurable effects. Therefore, the economic analysis was designed as a cost minimisation analysis.
The analysis of time registrations found no statistically significant differences in procedure time between IOR and COR leading to exclusion of staff cost from the incremental cost analysis.
The cost analysis revealed incremental costs of an IOR varying from investment costs of 695,000 DKK corresponding to an equivalent annual additional cost of 92.925 DKK for the most simple solution to investment costs of 1,125,000 DKK corresponding to an equivalent annual additional cost of 149.359 DKK for a more comprehensive solution compared to the COR.
The budget impact of the integrated solutions for one hospital (based on 60 ORs) varied from total investments of 41,700,000 DKK to 67,000,000 DKK corresponding to an equivalent annual additional cost of 5,575,500 DKK to 8,961,540 DKK compared to the COR depending on chosen solution. The national budget impact varied between total investments of 535,150,000 to 866,250,000 DKK corresponding to an equivalent annual additional cost of 68,757,150 to 112,211,300 DKK compared to COR depending on the chosen integrated solution.

Discussion

The functionalities contained in the IOR vary both in the literature and in practice and additional hardware and software are often needed to support the integration with user control of all functionalities from the touchpad which can vary. The minimum of functionalities in an IOR was in this assessment defined to include: control of peripheral equipment, control of surgical equipment and audio/video (A/V) routing. Only a narrative summary on outcomes from two studies was provided in this assessment, as meta-analysis was not possible due to study heterogeneity. The evidence level for the outcome estimates was very low, mainly due to the risk of bias and poor study design, which weakened the robustness of our findings. On the basis of our findings it was not possible to draw any final conclusion. Moreover, the outcomes presented are proxy outcomes, and as such only represent a possible association to patient relevant outcomes, though some studies reported on complication rates. Since the touchpad is only a small part of a larger organisational setup it can be difficult to show differences between alternatives as many other factors may affect the results. Overall the literature in the field of IOR is extremely limited and of methodically poor quality, where the design and measurement parameters of the studies impose restrictions on the internal validity of the studies. In the studies, in particular, detailed information on interventions and comparators are lacking.

The organisational analysis was limited by its mainly descriptive literature review and interview study. Perspectives on consequences of implementation and use of integrated operating rooms included in the organisational analysis were based on qualitative interviews with surgical personnel using IORs and thus subjective experiences and perceptions rather than objective quality and performance measurements. As such,

there is a need for future research that systematically integrate analysis of organisational aspects with more objective quality and performance indicators, e.g. surgical time, patient safety and quality in treatment, to substantiate conclusions on optimised use of IORs. Also, the geographical context of the included studies should be taken into consideration in relation to the transferability and generalisability of the results of these studies to a Danish context. However, most of the results of the literature review are rediscovered in the interview study, which underscores the validity of these results. Finally, all hospital departments using IORs were not included in the interview study. Thus, the organisational analysis did not provide a complete picture of the use of IORs in Denmark. However, the interview study was based on a relatively large and diverse sample and data saturation was regularly discussed during data collection.

The economic analysis was limited by the fact that no relevant studies were identified in the literature search. Thus, the economic analysis was based on an evaluation study in Central Denmark Region. The technology costs were based on purchase data from the Central Denmark Region and due to differences in regional price agreements with manufacturers, the estimated technology costs and scenarios may vary marginally across regions. However, the presented cost analysis estimates a credible cost level that decision makers may expect in the event of technology rollout. Procedural time results were also based on data extracted from a single region, possibly affecting the generalisability of results, as possible time savings are closely related to surgical procedures that may vary between hospitals and regions. However, the relatively large time dataset was a strength for the validity of the empirical economic study and local differences in procedures are expected to be of minor importance to the overall result.
Even though not detected in this assessment, effects or value of the IOR may be found over time. Positive effects might be found on time and safety when switching from laparoscopic to open surgery in acute situations (not measured due to low frequency). Extended use of teaching and collaborating possibilities due to video streaming might ensure efficient and continuous education of medical students and surgeons and thereby possibly improve quality of treatment. Experienced improvements in workflow and ergonomics (see ORG) might influence the working environment and job satisfaction, and this might over time influence positively on costs in terms of reduced sick-leave.

If IOR is implemented in the operating room, it is important to ensure continuous monitoring of the use of IOR in relation to research and follow-up. Basically, when using new technology the dissemination of the technology has to be well-founded and based on consistent and dependable decision-making considering explicit criteria and need for dissemination.

Conclusion

Integrated operating room (IOR) is a recent technology to control surgical and non-surgical functionalities in the operating room (OR) by the use of a touchpad-interface. IORs are implemented in 24 hospitals in Denmark, with only small differences in principal characteristic/intended use between the manufactures.

Available results showed no significant effects concerning flow disturbances during surgery, or differences in operation time or complication rates using IOR when compared to COR. The evidence level for these outcome estimates was very low.

The organisational analysis showed that implementation and use of IORs do not have great implications for the existing organisation and work processes, nor for the co-operation and communication among the surgical personnel. IORs were generally experienced to be easy to use, but proper introduction to and training of the surgical personnel was found important in order to ensure correct and optimised use of the IOR. The organisational analysis found that IORs lead to experienced improvements of the workflow during surgery, presupposed that the touchpad is administered in the sterile field or flexibly between the sterile and non-sterile field. In order to unfold the full potential of the IOR, there was identified a potential in ensuring a clear understanding of the positive effect of the technology, and in strengthening the current training requirements

and processes in place for surgical personnel using IORs. Finally, IORs had an experienced positive impact on the working environment and ergonomics for the non-sterile nurses.

The cost analysis revealed incremental costs of an IOR varying from investment costs of 695,000 corresponding to an equivalent annual additional cost of 92.925 DKK for the most simple solution to investment costs of 1,125,000 DKK corresponding to an equivalent annual additional cost of 149.359 DKK for a more comprehensive solution compared to the COR. The budget impact of the integrated solutions for one hospital (based on 60 ORs) varied from total investments of 41,700,000 DKK to 67,000,000 DKK corresponding to an equivalent annual additional cost of 5,575,500 DKK to 8,961,540 DKK compared to the COR depending on chosen solution. The national budget impact varied between total investments of 535,150,000 to 866,250,000 DKK corresponding to an equivalent annual additional cost of 68,757,150 to 112,211,300 DKK compared to COR depending on the chosen integrated solution.

1. SCOPE

In this HTA, integrated operating rooms (IOR) are examined and compared to conventional operating rooms (COR). IORs are typically used for endoscopic and laparoscopic procedures, i.e. minimally invasive surgery (MIS). It is deemed highly relevant to discover the preconditions for and consequences of introducing IOR using a HTA approach. The purpose of the project is to establish a basis for decision-making prior to prioritisation of any major investments in establishing IORs as an alternative to CORs.

Description	Project scope
Population	• Integrated operating rooms are used for all types of patient groups and indications. In this project, no specific population is chosen in relation to the use of the technology integrated operating rooms.
Intervention	• The intervention under assessment is "integrated operating rooms" (integrated operating rooms include a wide range of technologies alone or in combination to support communication, documentation and streamlining of operating procedures)
Comparison	• Comparators of interest are conventional operating rooms not utilising smart technology.
Outcomes	• Operation time (in relation to minimising risk of infection, ischemia and blood loss)
Study design	• For the domains clinical effectiveness (EFF), safety (SAF) as well as costs and economic evaluation (ECO) the following study types will be eligible for inclusion: o High quality systematic reviews or meta-analyses of randomised controlled trials (RCTs) or controlled trials published within the last five years and RCTs or controlled trials published within the last ten years. o If the subject under assessment does not allow the possibility to conduct an RCT or other controlled trials (e.g. the comparator is "no treatment"), evidence of lower quality will be included in the assessment (e.g. case studies and non-systematic reviews). o Studies that compare different types of integrated operating rooms will be excluded. • For the description and technical characteristics of technology (TEC) and the organisational (ORG) domains information will primarily be obtained from clinical experts using the technology, and from literature (i.e. descriptive publications) and grey literature as well as anecdotal information from general web-searches.

2. METHODS AND EVIDENCE INCLUDED

2.1 Source of assessment elements

The selection of assessment elements was based on the HTA Core Model 4® for Rapid Relative Effectiveness (REA) (version 4.2). The assessment elements were translated into research questions that would be addressed in this assessment regarding technical characteristics (TEC), clinical effectiveness (EFF) and safety (SAF). Research questions for the organisational aspects (ORG) and economic (ECO) domain were based on assessment elements from the EUnetHTA HTA Core Model. Additionally, assessment elements from other HTA Core Model® Applications (for medical and surgical interventions, diagnostic technologies, or screening) were screened and included/merged with the existing questions if deemed relevant. The research questions are formulated on the basis of the generic domain issues from the domains.

2.2 Search

A comprehensive systematic literature search was performed for all domains in the report. The search was performed to meet inclusion and exclusion criteria described in the Scope (see section 1) of this assessment, and also addressed the organisational as well as the costs and economic evaluation domain. The search was structured via the Patient-Intervention-Comparison-Outcome (PICO) structure. Only search terms in relation to intervention was used in order to uncover all relevant material – thereby not limiting the search by patient, comparator and outcome search terms. Also this initial search was limited by language (Danish, English, Norwegian, Swedish and German language) and a time limit of 10 years (January 2009 to January 2019) to achieve high sensitivity (and low precision) in the initial search.

The search resulted in 6,159 hits. The search strategy can be obtained from the study authors.

The following databases were used in the search of studies and guidelines:

- The Cochrane Library (including The Cochrane Database of Systematic Reviews (CDSR), The Database of Reviews of Effects (DARE), The Cochrane Central Register of Controlled Trials, and The Cochrane Methodology Register)
- EMBASE
- PubMed
- Cinahl
- JSTOR
- Web of Science
- CRD-INAHTA database
- G-I-N
- NICE
- SBU
- Manual search (in reference lists of relevant studies)

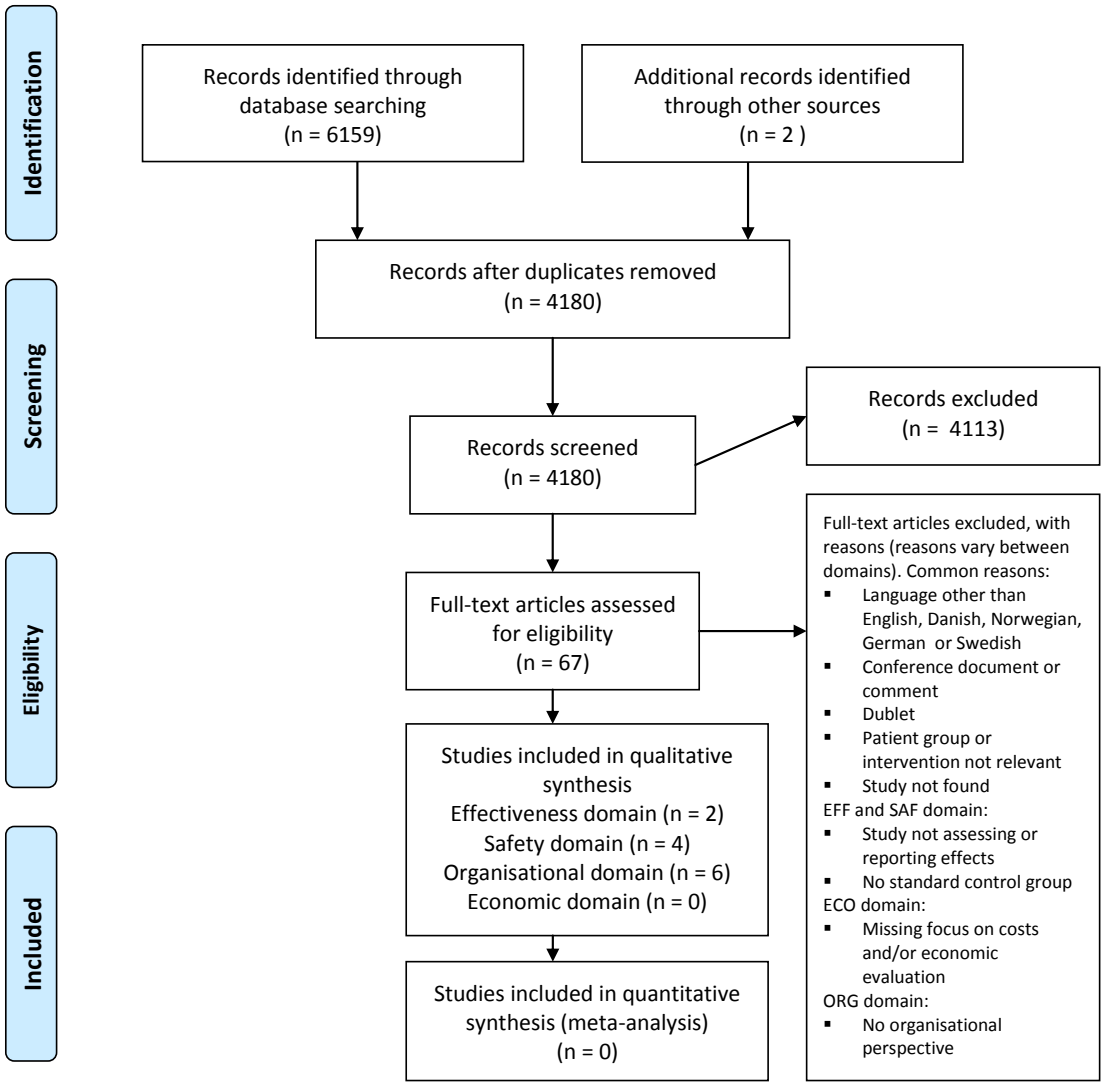
Furthermore, clinical trial databases were searched to identify on-going studies on integrated operating rooms (ORs):

- ClinicalTrials.gov

Beside the systematic literature search, information was sought through clinical and technical experts, internet searches on the topic and manufacturers' submission files[1]. Relevant manufacturers offering integrated operating room (IOR) solutions to Danish hospitals were identified through a comprehensive process that included contact to a wide range of manufacturers, hospitals, clinicians, medical technology personnel and through internet searches and the project group. Manufacturers were subsequently contacted and asked to submit information about their product via the submission file.

After removal of duplicates, literature selection was performed independently by two researchers from DEFACTUM using the inclusion and exclusion criteria and according to the research question and PICO scheme. Disagreements were resolved by consensus. The PRISMA flow diagram (Figure 1) display the phases of literature selection.

Figure 1: Flow chart of systematic literature search[2]



[1] Reduced file of EUnetHTA's submission file for manufacturers (short version)

[2] http://www.prisma-statement.org/

2.3 Study selection

The search generated 6,159 records, which reduced to 4,180 after removal of duplicates. These studies were then screened by title and abstract to identify potentially relevant studies, resulting in a parent pool of 67 studies after an overall initial exclusion and selection applying to all domains. From this pool studies for the single domains were selected.

Literature selection for the EFF and SAF domains was performed by full text review by two project participants, resulting in inclusion of respectively two and four studies. For the ORG domain, literature selection was also performed by full text review by two project participants, resulting in inclusion of six studies. Literature selection for the ECO domain was performed by full text screening by two project participant, resulting in inclusion of no studies.

2.4 Data extraction and analyses

Data extraction tables for the domains are shown in Appendix 1.

For each outcome, an evidence profile is generated using the GRADEpro software[3]. Results are presented narratively.

2.5 Quality rating

The quality of included reviews will be assessed using the Risk of Bias in Systematic Reviews (ROBIS) tool[4]. RCT studies will be assessed using the Cochrane risk-of-bias tool. Risk of bias in cohort and case-control studies is assessed using Scottish Intercollegiate Guidelines Network (SIGN) methodology checklists[5]. Cross-sectional studies will be assessed using the Strobe Checklist[6]. The quality of the body of evidence will be assessed using Grading of Recommendations, Assessment, Development and Evaluation (GRADE). Quality assessment is performed independently by two DEFACTUM researchers. Any disagreement will be resolved by consensus. For the TEC domain, no quality assessment is applied, but multiple sources were used to validate potentially biased sources. Descriptive analyses of different information sources were applied.

Further methodological descriptions of primary data collection for the domains ‘organisation’ and ‘costs and economic evaluation’ can be found in these sections.

[3] https://gradepro.org/

[4] https://www.bristol.ac.uk/population-health-sciences/projects/robis/

[5] https://www.sign.ac.uk/checklists-and-notes.html

[6] https://www.strobe-statement.org/fileadmin/Strobe/uploads/checklists/STROBE_checklist_v4_cross-sectional.pdf

3. DESCRIPTION AND TECHNICAL CHARACTERISTICS OF TECHNOLOGY (TEC)

3.1 Research questions

Element ID	Research question
[B0001]	What are integrated operating rooms and what are the comparators?
[B0002]	What is the claimed benefit of the IORs in relation to conventional operating rooms?
[B0004]	Who administers the IORs and the conventional operating rooms, and in what context and level of care are they provided?
[B0008]	What kind of special premises are needed to use the IORs and the conventional operating rooms?
[B0009]	What equipment and supplies are needed to use the IORs?

3.2 Results

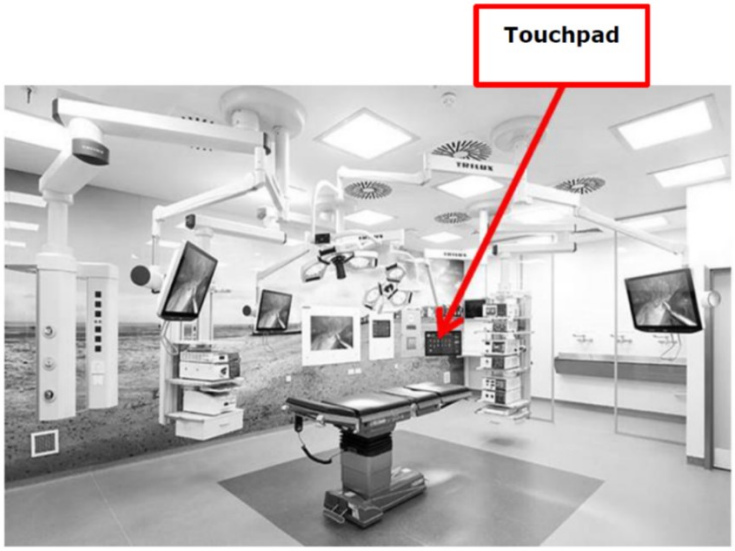
The research questions for this assessment refer to two types of technologies; respectively the integrated operating room (IOR) and the conventional operating room (COR) as comparator. The IOR is also referred to as "digital OR" or "interventional suite" in the literature, and it is a group of systems/technologies developed over a number of years to support appropriate surgeries. The IOR is used primarily for minimally invasive surgery (MIS) which is endoscopic and laparoscopic interventions. In the following, we describe features and benefits of these technologies and the comparator, special premises, equipment and supplies needed to use these technologies.

Features of the technology and the comparator

[B0001]	What are integrated operating rooms (IORs), and what are the comparators?

An IOR is a collection of systems and technologies that are functionally linked to one unit. This unit allows the surgical staff to control all IOR equipment/functionalities such as environment (light, climate, etc.), medical devices, and video distribution from a touchpad (Figure 2). A computerised video matrix controlled by this touchpad distributes images to boom-mounted monitors thus allowing the best viewing angle to each operator (2). An operating room (IOR as well as COR) is typically divided into two different zones; the sterile and the non-sterile field. The sterile field is created by a field of sterile cover around the patient's surgical site, and on the stand that will hold sterile instruments and other items needed during surgery. According to the literature, the touchpad in the IOR will typically be placed in the sterile field allowing the sterile surgical staff to interact and control the system. In practice, another touchpad can also be placed in the non-sterile field. The surgical staff is organised hierarchically where the senior surgeon instructs the assistant surgeon and sterile nurse. The non-sterile field around the area of the sterile field is the work zone of the anaesthesiologist and the non-sterile nurse (5).

Figure 2: **An integrated operating room (IOR)**



In a COR functionalities are often the same as in an IOR, but machines and equipment such as lights, curtains, room climate control, audio/video (A/V) equipment, table, doors and surgical apparatus are controlled by their own control panel from the non-sterile field (Figure 3). This requires persistent presence of the non-sterile nurse to assist the sterile dressed personnel.

Figure 3: A conventional operating room (COR)

In practice, the difference between an IOR and a COR can be more than only the touchpad, as the integration is often implemented as part of a larger modernisation of the operating room (OR), where the equipment/functionalities are being boom-mounted etc. In a non-modernised COR machines and equipment are arranged around the room and are pulled in or pushed back as needed. When the functionalities are moved this way with intermittent use, cables and cords from the equipment can accidentally lie in the way for the surgical staff, the anaesthesiologist and the non-sterile nurse. Moreover, the more narrow space in a COR can cause contamination of the sterile field especially by the non-sterile nurse, compromised ergonomics and overall work environment (5).

Manufactures of integrated operating rooms

We have identified Karl Storz, Olympus, and Stryker as the leading medical device manufactures of products and services for IORs to Danish hospitals. Table 1 shows characteristics and implementation status.

Karl Storz

Karl Storz is a global manufacturer and distributor of medical devices. In the late 1990s, Karl Storz developed the IOR called OR1™. The system has three key components; 1) device/OR control via touchpad, 2) data documentation and 3) data transmission through digital routing and streaming A/V. All fixed equipment or mobile equipment in the OR can be connected to the system. The connection is digital and made via the ceiling-mounted equipment in the OR connected to a server either outside or inside the OR. The system can have interface with the hospital information system and can get access data from the electronic patient record. In addition, the partial third part integration with devices from other manufactures can be included[7].

Olympus

Olympus is a global medical technology manufacturer. Olympus offers IOR solutions such as EndoAlpha. The equipment in the OR is usually connected via cobber or fibre cabling to a touchpad located in the ORand digital routing within the OR is possible. Live and stored videos can be streamed throughout the hospital's video network[8].The system can get access to data from the electronic patient record. Moreover, partial integration of other suppliers is possible[9].

Stryker

Stryker is global medical technology manufacturer. Their IOR solution iSuite has connected OR voice control. It is based on digital cabling and video over IP. Inside the OR, the custom cables are connected to the local networks. The set-up can be an analogue connection, or only fibre. The OR is connected to the hospital's network for live connections and data management. The system can also connect with hospital information systems such as electronic patient record. Moreover, the partial third part integration with devices from other manufactures can be included[10].

[7] https://www.karlstorz.com/cm/en/karl-storz-or1.htm

[8] https://www.olympuseuropa.com/medical/rmt/media/en/Content/Content-MSD/Documents/Brochures/Surgical-Systems-Integration_Brochure_EN_18600.pdf

[9] https://www.olympuseuropa.com/medical/en/Products-and-Solutions/Products/Product/Operating-Room-Integration.html

[10] https://www.stryker.com/us/en/ communications/products/isuite-powered-by-connected-or-operating-system.html

Table 1: Manufactures of integrated operating rooms (IORs) and their implementation status in Danish hospitals

Manufacturer	Product name	Implementation status	Principal characteristics/Intended use
Karl Storz	OR1™	Implemented in several hospitals	Device/OR control via touch panel Routing and streaming A/V Interface with hospital information systems Documentation archive Third part integration with devices from other manufactures
Olympus	EndoAlpha	Implemented in several hospitals	Device/OR control via touch panel Routing and streaming A/V Interface with hospital information systems Documentation archive Partial integration of other suppliers is possible
Stryker	I.Suite	Implemented in few hospitals	Device/OR control via touch panel Routing and streaming A/V Interface with hospital information systems Voice command/ control Partial third part integration with devices from other manufactures

Implemented integrated operating rooms in Denmark

Relevant manufactures of IORs on the Danish market have been identified as a part of the assessment of the technology. Karl Storz, Olympus, and Stryker have been contacted for identification of IORs in Denmark. According to these manufactures, IORs are implemented in 24 hospitals in Denmark with variation across regions. These IORs are mainly dedicated for MIS within the specialties of gynaecology, urology and paediatrics as well as thoracic and cardiovascular surgery and gastrointestinal surgery. The implemented IORs have different functionalities contained, including control of peripheral equipment, control of surgical equipment, video routing, documentation and video streaming. Common to all implemented IORs in Danish hospitals is the integration of peripheral equipment, surgical equipment and video routing while the integration of especially video streaming varies (Appendix 2). Additionally, more IORs are under implementation.

Claimed benefits of integrated operating rooms

[B0002]	What is the claimed benefit of the IORs in relation to conventional operating rooms?

According to manufactures and the literature, the IOR is claimed to reduce operating time and enable a more efficient and optimised workflow for the benefit of the patient and the surgical staff when compared with a COR. However, the benefits of the IOR will vary according to the particular circumstances of a facility's implementation (6). In the COR, every medical device typically works as a stand-alone device with its own control unit and is incapable of communicating with other devices or technologies. The surgical staff has to handle a high number of foot switches, and the surgeon cannot reach the control units of the devices where parameters have to be changed (7). In the IOR, the touchpad in the sterile field results in fewer interruptions during surgery, faster equipment setup and time release for the non-sterile nurse, so instead of setting the equipment individually the nurse can concentrate on other tasks (8,9). There is less need to have as much

equipment in the IOR because it is standardised throughout the OR with easy electronic access and display monitors. The surgical staff can focus on many of their tasks more efficiently without the need for moving equipment around which protects them from hazards of wires, hoses and carts (10). The IOR use of information can support the surgeon during diagnosis, education and treatment. In addition, a potential benefit from the use of the IOR compared with a COR is that it may provide some convenience within the OR for the surgical staff which may play a role in attracting or retaining competent operating room personnel (6).

Administration of the integrated operating room and the comparator

[B0004]	Who administers the IORs and the conventional operating rooms, and in what context and level of care are they provided?

Typically, the surgical staff in the sterile field administers the touchpad connected to the IOR while non-sterile staff operates the COR on guidance from the senior surgeon. The surgical intervention and the use of IORs are performed in community and private hospitals as well as in university hospitals. The technology is offered through the surgical intervention to all patients groups, outpatients and inpatients.

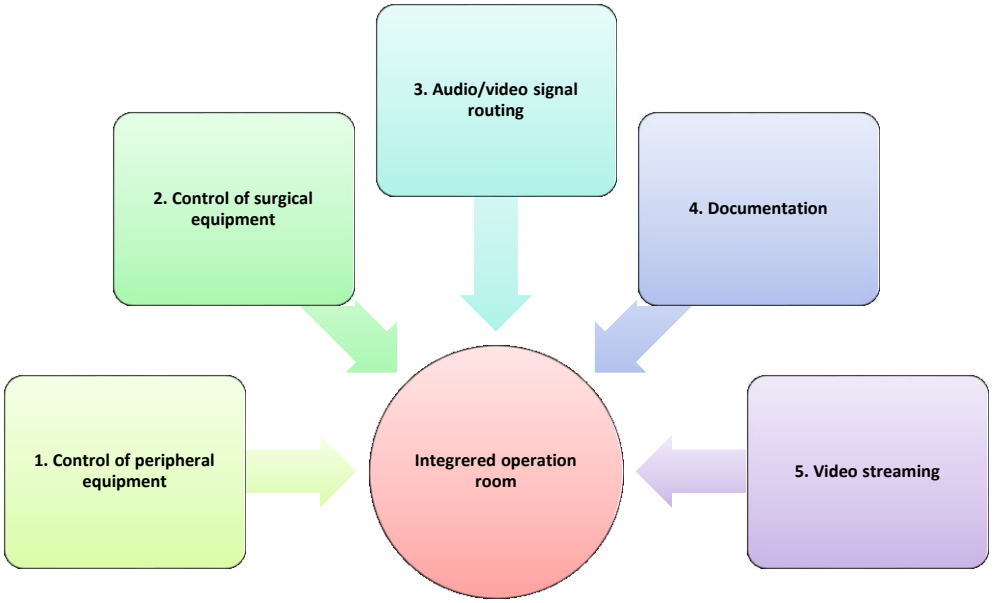
Special premises of the integrated operating room

[B0008]	What kind of special premises are needed to use the IORs and the conventional operating rooms?
[B0009]	What equipment and supplies are needed to use the IORs?

An IOR can be built around the same frames and functionalities as a COR. Most modern CORs make use of boom and wall mounted video displays especially when MIS is performed. However, hardware and software are needed to support the integration with user control of all functionalities from a touchpad in the OR such as in-room video sources and complex A/V routing equipment cabling and connections (6).

The number of functionalities contained in the IOR is variable in different contexts, but in this assessment, we define the minimum to include 1) control of peripheral equipment, 2) control of surgical equipment and 3) A/V routing (Figure 4).

Figure 4: Functionalities in the integrated operating room (IOR). As a minimum we define the IOR in this report to include 1) control of peripheral equipment, 2) control of surgical equipment and 3) A/V routing.



1. Control of peripheral equipment

This functionality enables that equipment such as surgical and room lights, room climate control (heating, venting, and air conditioning), table, curtains and endoscopic equipment can be set from a touchpad in the sterile field. This means that the surgeon or the sterile nurse can adjust the equipment during surgery as needed. For comparison, each element in a COR will need to be separately adjusted by either the sterile or non-sterile nurse.

2. Control of surgical equipment

The control of the surgical equipment entails the surgeon or sterile nurse to continuously adjust all the surgical equipment from the touchpad, and not as in a COR room in which they must set the equipment individually.

3. A/V signal routing

A/V signal routing is designed to electronically forward signals from multiple input sources such as cameras and computers to one or more display devices in the OR. This means that e.g. images/video from the surgical equipment is sent to the installed monitors in the OR so that everyone can follow the surgery. In a COR, video is sent via wired solutions and thus exclusively to the wired monitors. The functionality also implies the possibility that patient's record may be displayed on the surgeon's monitor as needed, so that the surgeon does not have to leave the sterile field to be orientated in the record during surgery as in a COR.

4. Documentation

The documentation functionality allows all surgeries to be recorded and stored on a server, so they can be downloaded for documentation, teaching or conferences.

5. Video streaming

Video streaming allows the signal to be transmitted out of the OR and is also controlled via the touchpad. This means that the surgery can be transmitted live for off-site teaching in auditorium, conference room, or the surgeon can get in contact with a colleague who is not in OR.

4. CLINICAL EFFECTIVENESS (EFF)

4.1 Research questions

Element ID	Research question
D0001	What is the expected beneficial effect of integrated operating rooms on mortality?
D0005	How does use of integrated operating rooms affect symptoms and findings (severity, frequency) of the patients undergoing surgery?
D0006	How does integrated operating rooms affect progression (or recurrence) of the disease or health condition?

Numerous medical device manufacturers offer integrated operating room (IOR) systems as an integration solution for the operating room, and the development within the area is extensive with a vast development within the various devices and communication between devices. Thus this section can only present a snap-shot of the expected beneficial effects of using IOR. It is assumed that the complexity of human-machine interaction can be compensated using the interface in the IOR and consequently facilitate the work of the surgeon and the surgical staff (5) resulting in greater efficiency in the operating room (OR).

4.2 Results

Comparative studies examining IOR are very limited. Two studies were included for clinical effectiveness outcomes (1,3). These studies included patients undergoing laparoscopic hysterectomy or ear, nose and throat surgery. In the study by Blikkendal et al. the laparoscopic hysterectomy procedure was chosen partly because it required a wide array of endoscopic instruments and equipment testing the IOR interface within many areas (1). Details of the studies are provided in Appendix 1. Also, patient outcomes were surrogate outcomes such as procedure time and disturbances. No studies were found examining patient specific outcomes. Results are presented according to the research questions. The quality of the included cohort study by Blikkendal et al. were moderate and the quality of the study by Strauss et al. were low.

Blinding and confounding issues was the criteria described most unevenly. Reporting of the blinding status of study participants, personnel, and assessors was in general incomplete, making the risk of bias unclear. All in all, 159 patients in the intervention and 248 in the standard group were included. Study details are presented in Appendix 1.

Table 2 presents the risk of bias of the cohort studies.

Table 2: SIGN checklist

Item	Question	Blikkendal et al.	Strauss et al.
1.1	The study addresses an appropriate and clearly focused question.	Yes	Yes
1.2	The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	Yes	Yes
1.3	The study indicates how many of the people asked to take part did so in each of the groups being studied.	Does not apply	Does not apply
1.4	The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.	Does not apply	Does not apply
1.5	What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed?	0 %	0 %
1.6	Comparison is made between full participants and those lost to follow up, by exposure status.	Does not apply	Does not apply
1.7	The outcomes are clearly defined.	Yes	Yes
1.8	The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable.	No	No
1.9	Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	No	Yes
1.10	The method of assessment of exposure is reliable.	Yes	Yes
1.11	Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable.	No	No
1.12	Exposure level or prognostic factor is assessed more than once.	Does not apply	Does not apply
1.13	The main potential confounders are identified and taken into account in the design and analysis.	Can't say	No
1.14	Have confidence intervals been provided?	Yes	No

Mortality

[D0001]	What is the expected beneficial effect of the technology on mortality?

There were no studies reporting on mortality.

Morbidity

[D0005]	How does use of integrated operating rooms (IOR) affect symptoms and findings (severity, frequency) of the patients undergoing surgery?

Surgical flow disturbances is considered a surrogate outcome with the potential to impact on patient symptoms and safety due to prolonged surgery and interruptions that might influence on the quality of the surgical

intervention. Structural changes and changes in work tasks in an OR often include implementation of new hardware (and software). Although, the technology is considered an organisational change, and it is challenging to isolate the effect of individual parts of the technology - the user interface and associated functions. Thus the results are reported with some reservations, since conditions other than user interface can have an impact on procedural time and disturbances during surgery.

In a prospective study by Blikkendal et al. all standard laparoscopic equipment in the conventional operating room (COR) was placed on a cart with one flat-screen high-definition monitor on top of the cart and one monitor on a swivel arm (20 procedures)(1). Electrosurgical equipment was placed on a separate cart. Standard laparoscopic and electrosurgical equipment was in the IOR placed on a ceiling mounted boom arm (20 procedures). Three monitors (of which one was a touch screen) were attached to separate ceiling-mounted boom arms.

In a retrospective study by Strauss et al. data from a total of 228 interventions were available describing the current standard surgical procedures (3). In comparison, a total of 139 standard procedures in an IOR (9 different surgeons) were analysed. In the new OR the surgical cockpit was designed so that in all possible configurations of an ear-nose-throat surgery display of surgical areas, presentation of information and ergonomics was as optimal as possible for all surgeons. For this purpose, two HD screens were arranged in an optimised visual axis for the surgeon.

Procedure time

In two different clinical settings procedure time was measured and found reduced. Blikkendal et al. found that in the IOR, repositioning of monitors was a frequent and time-consuming source of disturbance resulting in non-significant differences in procedure time (Table 3). In the IOR-group the procedure time was 11 minutes shorter than in the standard group, although not significant. In the retrospective study by Strauss et al. the slot time, preoperative time and documentation time were all shorter than in the standard group. Statistical significance was not reported. No attempt was made to pool these data because of the heterogeneity between the studies - both in patient group and study design. See the costs and economic evaluation (ECO) domain (section 7) for further information on procedure time.

Table 3: Results from primary studies

Author	Results: surgical time	Results: flow disturbances
Blikkendal et al.	COR vs. IOR: Procedure time: Mean 161 minutes ± 27 (SD) vs. 150 minutes ± 34 (SD).	A total of 1651 surgical flow disturbances were observed (mean ± SD per procedure 40.8 ± 19.4 vs. 41.8 ± 15.9, NS). The mean number of surgical flow disturbances per procedure with regard to equipment was 6.3 ± 3.7 versus 8.5 ± 4.0, NS
Strauss et al.	COR vs. IOR: Reduction in slot* time: 8.2 minutes, from 73.8 min to 65.6 min (−11%) Reduction in preoperative time: average 8 minutes (31%) per case Reduction in documentation time: average 6 minutes (67%) per case.	The interaction steps of the surgeon with the system were reduced by 70% (from 17 to 5 steps).

COR = conventional operating room
IOR = integrated operating room
* total patient time (preparation and surgery time)

Regarding surgical flow disturbances the results from Blikkendal et al. demonstrated no differences statistically or clinically between the groups, and the authors conclude that the presence of equipment-related surgical flow disturbances remains multifactorial. They also conclude that reductions in disturbances during minimal invasive surgery (MIS) in an IOR could not be shown, to some extent because of the already established effects of using MIS resulting in potentially increased safety, shortened operating time and fever conversions.

Strauss et al. show that procedural steps are reduced with 70%. The surgeon's interaction with the system was reduced from an average of 17 to 5. The IOR used the integrated navigation device much more frequently than during conventional surgery. The authors however emphasise that in their study no information on the interaction steps in the COR was presented. Hence it can be assumed that some of the surgeon tasks were transferred to other surgery team members.

All in all no significant effects were shown using IOR although a tendency towards time savings was shown.

Progression of disease

[D0006]	How does the technology affect progression (or recurrence) of the disease or health condition?

There were no studies that reported on progression of the disease.

Table 4: GRADE evidence profile

Quality assessment							Number of participants		Effect		Quality
Outcome (number of studies)	**Study design**	**Risk of bias**	**Inconsistency**	**Indirect evidence**	**Imprecision**	**Publication bias**	**IOR**	**COR**	**Relative (95 % CI)**	**Absolute**	
Flow disturbances (1)	Observational study	Serious	None	Serious	Serious	Not detected	20	20	-	40.8 ± 19.4 vs. 41.8 ± 15.9 (NS)	⊕OOO VERY LOW
Procedure time (2)	Observational study	Serious	Serious	Serious	Serious	Not detected	159	228	-	8-11 min. (NS)	⊕OOO VERY LOW

5. SAFETY (SAF)

5.1 Research questions

Element ID	Research question
C0008	How safe is the use of integrated operating rooms (IOR) in relation to conventional operating rooms?
C0002	Are the harms related to dosage or frequency of applying the technology?
C0004	How does the frequency or severity of harms change over time or in different settings?
C0007	Are the technology and comparator(s) associated with user-dependent harms?
B0010	What kind of data/records and/or registry is needed to monitor the use of IOR?

Safety issues can be divided in technical errors and use errors. The majority of use errors are errors resulting from a lack of suitability in using a medical device. They usually arise from interaction problems between users and the system. (5) Kasparick et al. state that equipment-related incidents and surgical errors constitute a significant proportion, and that IORs have been identified as a promising concept to meet these challenges (11). Important safety issues related to IOR and interconnected systems are that the right devices are affected by the remote-controlled interface, and to make sure that the right devices exchange data.

5.1 Results

Given that the technology does not interact directly with the patient, no studies assess direct impact of using the interface and patient hazards, although many studies reflect on safety issues related to the use of the technology. This section focus on safety issues using the touchpad from the sterile field. With background in the three outlined areas regarding control of peripheral equipment, control of surgical equipment and audio/video signal routing, possible safety issues are presented, though some areas are not considered in this context, e.g. the physical conditions of the equipment and its impact on surgery flow. Also conditions that are considered similar for both systems are not assessed.

Included studies

This domain included the two studies from the clinical effectiveness (EFF) domain (section 4) as well as two additional studies reporting safety concerns using IOR and statements from interviews (see the organisational (ORG) domain at section 6). Safety issues not identified or discussed in these studies may exist since understanding and inclusion/evaluation of risks vary. Also operability and characteristics of the described operating room (OR) systems vary which complicates transferability of results. This section merely summarises possible safety issues. Here, focus relates exclusively to the use of the touchpad (interface).

Patient safety

The use of IOR relates to safety issues in the way that the technology is developed to maintain surgical flow and reduce untimely intrusion thereby potentially decrease errors.

[C0008]	How safe is the technology in relation to (the) comparator(s)?

No significant differences in the incidence of complications were observed (3), but the surgeons reported an improved allocation of information. The authors assume this could be due to the synchronisation of medical technology systems including the DICOM viewer and navigation system.

Table 5: Results from primary studies

	Safety issues	
	Integrated operating room (IOR) vs. conventional operating room (COR)	
Study	**Results**	**Findings (surveys)**
Strauss et al. (Observational study)	No significant differences in the incidence of complications, but surgeons reported an improved allocation of information in the OR.	
Blikkendal et al. (Observational study)	No difference in flow disturbances.	
Nocco et al. (Survey)		Surgeons indicate a risk reduction related to surgery. Surgeons and surgical nurses reply that many functionalities available in an IOR could help reduce clinical risk for patients.
Rockstroh et al. (Survey)		Automated distribution of patient identification from a centralised control console and the forwarding of alarms are mentioned as important steps toward improved patient safety Operator confidence in an expectation of increased patient safety and improved quality of care is limited. Interaction with devices is often described as difficult and is based on team communication, and therefore, a sterile interaction with the key operational parameters directly at the situs was considered useful by the surgeons

Blikkendal et al. point out that implementation of new technology, devices or instruments could potentially be hazardous because you have to be aware that devices are not always intuitive or straightforward in use (1). Therefore, in an IOR, the use of devices, for example monitor positioning, has to be carefully planned and prepared preoperatively. However, Blikkendal et al. reported no differences in flow disturbances. Findings from two surveys (2,4) indicate potential benefits in relation to surgical risk using IOR. These findings are merely suggestive of a possible improvement in patient safety.

Interviews with surgeons and nurses conducted in the organisational analysis (see ORG domain at section 6), yielded corresponding findings related to IOR and safety (Table 6).

Table 6: Results from interviews

Safety issues
Integrated operating room (IOR) vs. conventional operating room (COR). Statements from interviews.
• Surgeons mention that at in an IOR, the equipment is set in advance with which settings are supposed to be right prior to surgery. This applies, for example, to insufflation that can be adjusted according to weight. Hence, there is greater certainty that surgeons use the right values in relation to the specific patient. • Actions by the surgeon without disruptive intermediaries (nurse or other) can increase safety • Specific scenarios can be added to the device and as it can be controlled from one device enhances security. • Decentralised control is supposed to result in a greater margin of error. • Overview is much better with IOR, so it is easier to identify possible errors. One surgeon describes it the following way: 'places where one can make mistakes are gathered in one place.' • Some surgeons do not believe or cannot immediately see that safety should be improved with IOR • One surgeon mention that using IOR, nurses tasks are more defined/delimited, which may increase patient safety - it may be that a nurse who is doing a job does not have to set light or other parameters at the same time. • However, control via the touchpad is also mentioned as an interference in the nurses focus in the operating field

Findings from studies and interviews suggest improved allocation of information, improved patient identification, and overall that adjustments are made easier. Also direct interaction with touchpad was mentioned as being useful, and some find that general overview is improved. Yet some surgeons cannot conceive any improvements in safety and indicate that interaction with the touchpad might interfere with the surgery.

[C0002]	Are the harms related to dosage or frequency of applying the technology?

No studies reported on any dosage or frequency-dependent issues in relation to IOR, whether it would be better or worse with increased use of the technology.

[C0004]	How does the frequency or severity of harms change over time or in different settings?

No studies reported on direct measures of harm. Looking at flow disturbances as a proxy for potential harm no differences between the groups was found. Also here is no evidence that harms increase or decrease in different organisational settings.

[C0007]	Are the technology and comparator(s) associated with user-dependent harms?

Although not described in the literature, malfunction of a device, touchpad or any interaction with IOR or standard systems, due to incorrect use may have consequences for surgical procedures (see the ORG domain at section 6). The issue of learning curves and interpretation/user errors are not described in the literature. Some areas remain unexamined, e.g. in relation to pre-setting of equipment in IOR in relation to manually setting of equipment, and how will the use of IOR respond to different professional operator groups.

[C0010]	What kind of data/records and/or registry is needed to monitor the use of the technology and the comparator?

To compare IOR with COR, registries should collect device-related data reflecting flow disturbances (e.g. on a seven-point ordinal scale including number, duration and effect of the surgical flow disturbances, e.g. mal-functioning or intraoperative repositioning) as described by Blikkendal et al. (1). More importantly procedure time divided into pre-, peri- and post procedure time should be collected under different clinical settings - different procedures involving long and short term surgeries.

6. ORGANISATIONAL ASPECTS (ORG)

6.1 Research questions

Element ID	Research question
G0001	How do integrated operating rooms affect the current work processes?
A001	How much are integrated operating rooms utilised and what affects the utilisation?
A0012	What kind of variations in use are there across wards, hospitals and regions?
G0004	How do integrated operating rooms affect co-operation and communication of activities among staff in the operating room (surgeons, nurses and anaesthesia)
G0003	What kind of process ensures proper education and training of staff (surgeons, nurses and anaesthesia) in relation to use of integrated operating rooms?
B0013	What kinds of skills and training characteristics and information are needed for the staff using this technology?
G0008	Which organisational challenges and opportunities are attached to use of integrated operating rooms?
Added question	Which organisational perspectives can be pointed out in relation to future use and spreading of integrated operating rooms?

The aim of the analysis of organisational aspects is to describe the organisational preconditions and consequences of using integrated operating rooms (IORs). This includes description of how IORs affect current work processes and co-operation and communication among staff in the operating room (OR) as well as description of education and training requirements for using the technology. Moreover, the analysis seeks to identify the organisational challenges and possibilities of using IORs, and organisational perspectives on future use and spreading of the technology. The analysis takes as its point of departure the research question outlined above.

Below the methodological approach of the chapter is outlined. Subsequently, the results of the organisational analysis are presented through answer of the research questions. The presentation of results is structured in three parts. In *Part One* the impact of IORs on the current organisation is explored. This includes how IORs affect the current work processes (G0001, A0012) and how IORs affect co-operation and communication among the surgical staff (G0004). In *Part Two* the educational preconditions for use of IORs are described, including description of the education and training requirements (B0013) and the education and training processes in place for the surgical staff (G0003). Finally, *Part Three* presents the organisational challenges and possibilities associated with use of IORs (G0008, A001) and organisational perspectives on future use and spreading of IORs (added question). Conclusions of the total organisational analysis as well as discussion of the methodological approach are presented in the Discussion (section 8) and the Conclusion (section 9).

6.2 Methods

The organisational analysis combines a systematic literature review (see 'Methods and evidence included' at section 2 for description) and a qualitative interview study. The combination of the two methodological approaches ensures a more thorough and valid analysis. Where the literature study helps to provide an over-

view of international experiences with use of IORs, the qualitative interviews provide knowledge on how use of IORs is organised in a Danish context as well as on the organisational challenges and opportunities associated with use of IOR. Furthermore, the systematic literature review contributes to identify essential organisational aspects to be further investigated in the interview study.

Qualitative interview study

The qualitative interview study is designed with a comparative case design in which we have included informants representing different specialties, hospitals and regions. Thus, the comparative design enables to identify variations in use of IORs.

We have included informants from one to two hospital departments in each of the five regions; in total 10 departments in seven hospitals. We have sought to include departments from both large and smaller hospitals, and we have sought to include departments representing different specialties using IOR. Medical technology advisers in the five regions have assisted the selection of hospital departments.

Selection of informants and conduction of interviews

Informants were recruited and interviewed in February to April 2019. We performed interviews with surgeons, surgical nurses and anaesthesia nurses as they represent different perspectives on the use of IOR, and thus together provide a more thorough perspective on the research questions. Besides professional background the inclusion criterion was experience with working in an IOR.

In the recruitment of informants we were assisted by the regional medical technology advisers. The adviser made the initial contact to the selected hospital departments in order to get consent of participation in the interview study, and to invite the department to select and provide contact information on relevant informants for interview. When receiving the contact information we contacted the informants to provide further information about the health technology assessment (HTA), the organisational analysis and the interview. If the informant still wanted to participate in an interview, a time was scheduled. In total, 24 informants was recruited and all initially agreed to participate in an interview. However, four interviews ended up being cancelled due to unforeseen circumstances in the hospital departments. Thus, 20 informants participated in an interview, including nine surgeons, eight surgical nurses and three anaesthesia nurses. The interview informants varied with respect to their level of experience with working in IORs however, most had a considerable level of experience. Table 7 provides an overview of the informants and conducted interviews. Appendix 3 provides a more nuanced overview of both asked and participating informants.

Table 7: Overview of conducted interviews

Informants	Number
Surgeons	9
Surgical nurses	8
Anaesthesia nurses	3
In total	20

The interviews were conducted as telephone interviews (n = 9) or performed face-to-face as part of explorative site visit at hospital departments using IORs (n = 11) (see the costs and economic evaluation (ECO) domain at section 7, for further information on the site visits). The interviews were guided by semi-structured interview guides with open-ended questions (12). The interview guides were informed by the research ques-

tions, the site visits and the literature study and developed in close co-operation with the project group. The interview guides are presented in Appendix 4. The interviews lasted approximately 30 min, and all were digitally recorded and transcribed verbatim. The interviews were analysed using a thematic approach (13).

6.3 Results

Results of the systematic literature study

The result of the systematic literature search and the selection process, including the in- and exclusion criteria guiding the process, is described in 'Methods and evidence included' (section 2) and presented in the flowchart (Figure 1).

Characteristics of included studies

Six studies were included in the systematic literature review (Figure 1). The six studies are presented in Appendix 1 with regards to aim, study design and methodological approach, main results and quality assessment. The studies are published between 2009 and 2017 in USA (10), The Netherlands (1), Belgium (14), Italy (2), Germany (4) and United Kingdom (15). Study designs include cross sectional questionnaire survey studies (2,4,15), a prospective cohort study (1), a review article (14) and a case study of local experiences (10). The results of the studies primarily focus on the anticipated and/or experienced usefulness and added value of IORs from the perspective of the users (surgeons, nurses, consultants etc.), and on education and training requirements and processes in relation to the use of IOR. The implications of IOR on existing work processes are only sparsely addressed. Common for the included studies are that the experiences and perspectives presented remain overall and primarily based on subjective experiences and anticipations rather than objective quality and performance measurements.

In the presentation of the literature, focus will be on the experiences that are considered most relevant in a Danish context, as organisation of and processes within health care systems to varying degrees differ across national contexts, and thus potentially also in relation to implementation and use of IOR. As such, the geographical contest of the included studies may impact the transferability and generalisability of the results in a Danish context.

Part One: Impact of IORs on the current organisation

The impact of IOR on current work processes

G0001	How do integrated operating rooms affect the current work processes?
A0012	What kind of variations in use are there across wards, hospitals and regions?

On an overall level the organisational analysis shows that IORs only to a limited extend affect the work processes in the OR and of the surgical staff when compared to conventional operating rooms (COR).

Impact on work processes of surgical nurses

Most profoundly IORs affect the work processes of the surgical nurses. This relates to the fact that across hospitals and regions in most surgical wards the surgical nurses are responsible for administering the touchpad and thus the integrated equipment and functionalities. The interview study shows that most IORs have a

touchpad placed in both the sterile and non-sterile field allowing both the sterile and non-sterile surgical nurse to administer the technology. As a consequence variation exists with respect to whom of the nurses that administer the touchpad depending on habits and preferences among the nurses (see further under 'Proper training as prerequisite for utilisation of the potential in IOR'). Most commonly however, the touchpad is administered by the sterile nurse.

The interview study shows that when the touchpad is administered by the sterile nurse, use of IORs leads to a change in division of labour between the sterile and non-sterile nurse, compared to CORs. Administration of the touchpad by the sterile nurse allows the sterile nurse to control all integrated OR equipment and functionalities, which in CORs are controlled by the non-sterile nurse. First of all this change provides the sterile nurse with greater autonomy, and makes her less dependent on the non-sterile nurse in the administration of the OR equipment and functionalities during surgery. Following this provides the non-sterile nurse with extra time resources and fewer disruptions in handling other tasks during surgery (e.g. documentation, preparation of surgical equipment and preparation of material for pathologists). The interviewed sterile nurses do not report the change in division of labour to lead to disruptions or less time to handling their tasks during surgery.

In situations where the touchpad is administered by the non-sterile nurse no changes in the existing work processes and division of labour are reported.

Besides changes in division of labour, the interview study shows that compared to CORs the use of IORs cause small changes in the work tasks of the surgical nurses (both sterile and non-sterile) during preparation for and completion of surgery. First, the use of IORs brings smaller additional tasks during preparation and completion. These include switching on/of the integration system and sterile covering and un-covering of the touchpad in the sterile field. Interviews with surgical nurses however indicate that these additional tasks are not associated with significant extra time use. This contrasts to findings of the literature study in which the study by Rockstroh et al. state that IORs will lead to increased preparation time due to additional tasks in the setup of the hardware components (4). The scale of the extra preparation time however is not specified or measured in the study.

Second, most IORs in use in Denmark entail the possibility of scene selections, meaning pre-installation of equipment and functionalities in relation to the specific surgical procedures performed in the OR. This implies that instead of manually adjusting all equipment and functionalities for the surgical procedure as in CORs, the IOR allows the nurses to automatically adjust all equipment at once by few clicks on the touchpad. This is experienced to ease the preparation for surgery.

Impact on work processes of surgeons

The interview study shows that generally IORs do not affect the work processes and work tasks of the surgeon and assistant surgeon as the administration of the touchpad is handled by the surgical nurses. The interview study identifies very few cases where the touchpad is administered by the surgeon (or partly by the surgeon). In these cases the surgeon becomes responsible for controlling and adjusting the IOR equipment and functionalities during surgery. This is evaluated positively by surgeons working within this division of labour as it is experienced to improve their working conditions by providing greater degrees of freedom during surgery and less dependency on the surgical nurses in responding on adjustment requests.

Impact on work processes of anaesthesia personnel

Finally, IORs do not affect the work processes of the anaesthesia personnel neither through preparation or completion of surgery or during surgery. The interviewed anaesthesia nurses mention minor improvements in their working conditions in IORs when compared to CORs. This stems from better opportunities for overview during surgery, e.g. of the progress of the surgical act and changes in patient values. However, these im-

provements mainly stem from better equipment in the IOR such as more and better adjustable monitors rather than the integration of equipment it self.

The impact of IOR on co-operation and communication

G0004	How do integrated operating rooms affect co-operation and communication of activities among staff in the operating room (surgeons, nurses and anaesthesia)?

When compared to CORs, IORs do not significantly affect the co-operation among staff in the OR. The interview study shows that all professional groups experience the inter-disciplinary co-operation in the IOR to be highly similar to co-operation within the CORs. Few sterile nurses mention experiences of becoming a more integrated part of the surgical act when administering the touchpad because their administration of the touchpad presupposes closer communication and causes greater dependency between them and the surgeon. This is echoed by the literature study that identifies better team work between surgeons and sterile nurses as an experienced advantage of IORs (15).

The interview study shows a generally sparse impact of IORs on communication of activities among staff during surgery. Thus, the form and content of the communication during surgery is experienced to be highly similar between IORs and CORs regardless of whom that administers the touchpad. Few surgical nurses mention that when the touchpad is administered by the sterile nurse the communication of activities tends to become more concentrated within the sterile field, which is perceived to result in faster communication and action (see section 'Improvement of work flow during surgery').

Part Two: Educational preconditions for use of IORs

Education and training requirements

B0013	What kinds of skills and training characteristics and information are needed for the staff using this technology?

The interview study shows that surgical staff generally experience IORs easy to use and not associated with extensive training requirements. Furthermore, neither surgeons, surgical nurses nor anaesthesia personnel experience use of IOR to be associated with a learning curve. However, both the literature study and the interview study point to the importance of providing proper introduction to and training of the clinical personnel using IORs in order to ensure correct use of the IOR and to unfold the full potential of the integrated technology (1,2,4,10) (see further section 'Proper training as prerequisite for utilisation of the potential in IOR').

Recommended training requirements for the clinical personnel are not specified into details neither in the literature nor the interviews, but are on an overall level stated to comprise introduction to and training in administration of the touchpad and introduction to the different functionalities and equipment integrated in the system. Furthermore, clinical personnel should receive introduction to and training in how to solve technical problems emerging from the touchpad and the IOR in general.

The interview study emphasises an importance in ensuring introduction to and training in use of IORs among all clinical personnel working in IORs. However, as the main administers of the touchpad and integration system, interviews point to a particular importance in ensuring proper introduction and training in use of IORs among surgical nurses. Similarly, in the literature study it is stressed that as IORs affect the nurses' role in preparation of and during surgery by increasing the amount and complexity of technological support that

must be provided. Consequently, there is an importance in ensuring training processes that support nurses feel well equipped for handling this increased complexity (10).

For anaesthesia personnel there are no information or training requirements as they are not affected by the integration nor involved in the administration of the touchpad.

Education and training processes

G0003	What kind of process ensures proper education and training of staff (surgeons, nurses and anaesthesia) in relation to use of integrated operating rooms?

Currently there are no national or regional guidelines regarding education and training for use of IORs in Denmark. Education and training is thus administered at the local level in the hospital departments using IORs. The interview study shows that across hospitals and hospital departments, education and training of staff is characterised by a low level of formalisation. However, there are great similarities in education and training processes across hospitals and departments.

Below education and training processes of surgical nurses, surgeons and anaesthesia personnel respectively are described. The descriptions are mainly based on the interview study as the literature study besides brief and overall recommendations do not specify how education and training should be organised.

Education and training of surgical nurses

Across hospital departments it is sought to spread competencies in use of IORs among all surgical nurses employed in the department. As such, all nurses should receive introduction to and training in use of the IOR.

The interview study shows that in connection with implementation of the IOR, manufactures across hospital departments have offered introduction and training sessions (approx. one week duration) for surgical nurses involved in use of the IOR, including both theoretical and practical training in use of the touchpad, setting and adjusting integrated equipment and functionalities and problem solving. Introduction and training of nurses employed after the implementation of the IOR is generally organised as peer-to-peer training managed by an experienced nurse or a super user (see below). To supplement the initial training of nurses (and other surgical personnel) and to support maintenance of competencies the interview study show that in some hospital departments super users together with the manufacture have developed written user guides with instructions for using the touchpad.

Across most hospital departments surgical nurses have assigned one to four nurses to be super users of IORs. Super users have received extended introduction and training by the manufacture and have as their responsibility management of training of staff, solving of problems related to the IOR and communication with the manufacture, e.g. in relation to updates in the integration system, solving of technical problems and development of scene selections. Super users are generally positively evaluated by staff.

Education and training of nurses are generally perceived unproblematic by the interviewed nurses. However, in all hospital departments included in the interview study there appear to be variation in the level of competencies among surgical nurses caused by differences in experience with working in the IOR, sufficiency in received introduction and training, technical flair and personal interest in the technology. Particularly, it appears challenging to ensure proper training of and thus competencies among nurses that only work in the IOR occasionally. For further information on challenges with training and competencies among nurses, see the section 'Proper training as prerequisite for utilisation of the potential in IOR.

Education and training of surgeons

As for surgical nurses there is no centralisation of competencies for surgeons in use of the IOR. Rather, all surgeons perform surgery within the IOR if the IOR is used for types of surgery relevant to the surgeon.

The interview study shows that introduction to and training in use of IORs for surgeons is generally sparse. Most commonly introduction and training takes form as peer-to-peer training managed by an experienced surgeon or as learning by doing handled by the individual surgeon. In few hospital departments surgeons have received short introduction and training sessions by manufactures in connection with implementation of the IOR (similar to sessions for nurses).

Only in few hospital departments surgeons have assigned a surgeon to be super user. Where this is the case responsibility of the super user is similar to super users among nurses and super users are positively evaluated.

The low level of introduction and training is generally not perceived problematic among surgeons. IORs are generally experienced intuitively easy to use and by many surgeons as a technology administered by surgical nurses. However, nurses point to the importance of surgeons receiving a minimum of introduction to the touchpad and the integrated equipment as well as training in problem solving to be able to assist nurses in management of the IOR when needed. This is echoed by the literature study in which one study emphasises the importance of training sessions to the complete surgical team in order to ensure familiarity with the integrated operating setting in the whole surgical team (1).

Education and training of anaesthesia personnel

The interview study shows that as IORs do not affect the work processes of the anaesthesia personnel and as the anaesthesia personnel is not involved in the administration of the touchpad there are no introduction and training processes in place for anaesthesia personnel.

Part Three: Organisational challenges and possibilities and perspectives on future use of IORs

G0008	Which organisational challenges and opportunities are attached to use of integrated operating rooms?
A001	How much are integrated operating rooms utilised and what affects the utilisation?
Added question	Which organisational perspectives can be pointed out in relation to future use and spreading of integrated operating rooms?

This section describes organisational challenges and opportunities associated with use of IORs. Moreover, it presents perspectives on future use and spreading of IORs in order to accommodate existing organisational challenges and ensure an optimised future use and spreading of IORs. The section is based on organisational challenges and opportunities identified by the interviewed surgeons, surgical nurses and anaesthesia nurses and on the international experiences with use of IORs identified in the systematic literature review.

Both the literature review and the interview study show an overall satisfaction with and preference for working in IORs by the surgical personnel and identify only few experienced challenges and negative consequences related to current use of IORs.

The clinical personnel perceive the IOR as a technology that does not require major changes in the organisation or workflow in the OR. The IOR is considered a practical technological solution but without major im-

pact on daily work. Thus, IORs are generally not experienced to lead to major improvements or associated with major advantages, but both within the literature and by the interviewed clinical personnel IORs are experienced to cause different small size organisational improvements. The same counts for the experienced challenges and negative consequences.

The section do not provide a complete exposition of all small size challenges and opportunities identified in the organisational analysis but focus on presentation of those challenges and opportunities where there seem to be the greatest potential in relation to future use and spreading of IORs. This includes the topics 'Improvement of work flow during surgery', 'Proper training as prerequisite for utilisation of the potential in IOR' and 'Improved ergonomics and working conditions'.

Improvement of workflow during surgery

The interview study reveals that across hospital departments and professional groups the main organisational advantage of IORs is experienced to be improvements of the workflow during surgery. Both surgeons and surgical nurses generally experience IORs to facilitate more smooth and efficient working procedures in terms of faster response on requests for adjustments of surgical equipment and functionalities and fewer disruptions during surgery. Few interviewed surgeons and nurses report no experience of improved workflow compared to conventional ORs.

The positive impact of IORs on workflow is generally rediscovered in the literature review where several studies emphasise how IORs by clinical personnel is experienced to contribute to improvement and streamlining of the work processes during both preparation for surgery and the surgical act (2,4,14,15). However, the experience of fewer disruptions during surgery identified in the interview study is challenged by one of the included studies in the literature review who finds that IORs do not reduce the number of surgical flow disturbances or the effect of these disturbances on the sterile team members when compared to CORs (1) (see clinical effectiveness (EFF) domain at section 4 for further details).

The interview study shows that the improvement of the workflow relates to the fact that in IORs the sterile personnel is less dependent on the non-sterile nurse in adjustment of equipment and functionalities as this can be managed by use of the touchpad in the sterile field. Thus, compared CORs, IORs lead to fewer disruptions and less waiting time for the sterile personnel caused by situations where the non-sterile nurse is not able to control and adjust the equipment and functionalities as requested because she is engaged in other tasks in the OR or shortly out of the OR.

It should be highlighted that from the interview study it appears that realisation of improvements in workflow presupposes administration of the touchpad in the sterile field or flexible administration of the touchpad, meaning that the sterile personnel administers the touchpad when the non-sterile nurse is occupied or not present in the OR. Furthermore, the interview study indicates that improvements of workflow are particularly experienced in connection with surgical procedures of a certain length and complexity as the need for adjustments in surgical equipment and functionalities are greater in such procedures compared to shorter and less complex procedures. In relation to future use of the IOR this makes some surgeons and nurses stress that IORs have the greatest potential in relation to complex and lengthy surgical procedures.

The organisational analysis do not provide basis for conclusions on whether the experienced improved workflow during surgery results in shorter surgical time. However, no surgeons or nurses interviewed perceive the surgical time to be particularly shortened. Some anticipate the surgical time to be shortened by few minutes at most while others do not think that the improvements in workflow translate into time savings. The effect of IORs on surgical time is further explored in the ECO domain (at section 7) based on statistical analysis of preparation, completion and surgical time data.

Proper training as prerequisite for utilisation of the potential in IOR

Across hospital departments the interview study reveals a variation in use of the IOR. This includes both variation in to which degree the surgical personnel make use of the touchpad to control and adjust the surgical equipment and functionalities at all, and variation in whether the touchpad is administered in the sterile field or in the non-sterile field.

On one hand both types of variation in use appear to relate to habits and culture about division of labour and work processes among the surgical personnel, particularly among the surgical nurses. Thus, the interview study points to a need for change of culture and habits to promote use of the touchpad in the sterile field and in general. Generally, change of habits is a difficult task and requires clear incentives and understanding of the positive effect of the technology.

On the other hand the interview study shows that the variation in use of the IOR stems from different levels of competencies in administration of the touchpad and varying knowledge about the integrated equipment and functionalities. This relates to a varying level of experience with working in the IOR and because of insufficient introduction to and training in use of the IOR. On this basis, the interview study emphasises the importance of proper training of the clinical personnel using the IOR and thus points to a potential in strengthening the current training requirements and processes in place for surgical personnel using IORs to promote use of the IOR. The organisational analysis do not provide basis for specifying the form and content of a strengthened education and training process and requirements. This should however by a point of attention in relation to future use of IOR.

Challenges with utilisation of the potential of IORs are recovered by the literature study. In accordance with the interview study the literature emphasises that a great degree of initial training is required to ensure correct use of the IOR and to unfold the full potential of the technology, especially among surgical nurses as the primary users of the technology (1,2,4,10). Furthermore, one study underscores the importance of not only ensuring initial training but also determining how to continuously maintain competency in working within the integrated settings (10). However, as is the case with the interview study, the literature study does not provide specific recommendations on how to best organise training of clinical personnel.

Improved ergonomics and working conditions

From interviews with surgical nurses it appears that IORs lead to better working environment and better ergonomics for the non-sterile nurse when compared to conventional ORs. This relates to the fact that IOR makes it possible to set and adjust integrated equipment and functionalities in the OR from the touchpad in stead of from equipment specific monitors and panels placed around the OR. Nurses emphasise that this change contributes to removal of inexpedient working postures, reduction of risk of falling over cables and leads to less steps for the non-sterile nurse.

For the sterile nurse no improvements in working conditions and ergonomics are identified. Similarly surgeons generally do not experience any changes in ergonomics and working conditions. Few surgeons speculate that in situations where surgeons administer the touchpad this can cause inconvenient working postures in terms of inexpedient rotations of the body depending on the placement of the touchpad. Also few surgeons mention that IORs lead to a greater utilisation of the possibilities in the surgical equipment (e.g. the possibility for change of pictures on monitors) as the touchpad eases use of these possibilities. For these surgeons this advantage is perceived to positively affect their working conditions.

Improved ergonomics and working conditions of the surgical personnel following from IORs are sparsely addressed in the literature study. In few studies the IOR is stated to contribute to a reduction of the stress level among the surgical personnel during surgery because of the ease in control and adjustment of surgical equipment provided by the touchpad (2,15).

7. COSTS AND ECONOMIC EVALUATION (ECO)

7.1 Research questions

ID	Research question
E0001	What types of resources are used when using integrated operating rooms and conventional operating rooms (resource use identification)?
E0002	What amounts of resources are used when using integrated operating rooms and conventional operating rooms (resource use measurement)?
E0009	What were the measured and/or estimated costs of integrated operating rooms and conventional operating rooms (resource use valuation)?
G0007	What are the likely budget impacts of implementing integrated operating rooms?

The overall objective of the health economic domain was to compare costs and effects of the integrated operating room (IOR) compared to the conventional operating (COR) room and thus evaluate the relative cost-effectiveness of the technology.

Systematic literature review

We performed a systematic literature review (see 'Methods and evidence included' at section 2 for description). The results are presented in the flow diagram (Figure 1 at section 2). As shown, no studies assessing costs or cost-effectiveness of the IOR were found.

Empirical study

To complement the systematic literature review an empirical assessment of the two alternative operating rooms (ORs) were designed. The objective was to evaluate the costs and costs-effectiveness of the IOR compared to the COR.

7.2 Methods

Recruitment of hospital units

An appropriate hospital setting for evaluating the IOR was identified based on an assessment of surgical tasks and availability/implementation of an IOR. Moreover, the departments had to have both an IOR and COR and they had to perform comparable surgery at both ORs. The departments were identified within the Central Denmark Region at Aarhus University Hospital (AUH). They were contacted and accepted to participate in the study.

The participating departments were:

1. *Hjerte-, Lunge- og Karkirurgi at Aarhus University Hospital*

   Hjerte-, Lunge og Karkirurgi is a department within the surgical specialty of heart, lung and vascular surgery. The department is highly specialised and performs surgical treatment and care of adults with diseases of the heart, lungs, oesophagus, thorax and blood vessels as well as related tumours. In 2018 the department performed a total of 1,267 surgeries. The department is organised in a heart surgical section, lung surgical section and vascular surgical section. Only the lung surgical section was participating in this present study.

2. *Mave- og Tarmkirurgi at Aarhus University Hospital*

   Mave- og Tarmkirurgi is a department within the surgical specialty of gastrointestinal surgery. The department is highly specialised and serves as the regional surgical centre for the upper surgical gastroenterology. The upper surgical gastroenterology includes two primary subject areas; the hepatopanreaticobiliary area and the oesophagus/ventricle area. In 2018 the department performed a total of 2,627 surgeries.

Department characteristics are shown in Table 8 further below.

All participating departments at AUH were recently renewed as part of the hospital building and modernisation. Therefore, the COR (baseline) was equipped according to the described design guide for the standard operating room[11]. The ORs were built ensuring sufficient space provided for the equipment to be used and in order to keep the floor clear of loose cables etc. The ORs were also built with equipment boom-mounted with the possibility to be positioned ergonomically in relation to the user.

Costing

This cost analysis applied a hospital perspective and a short-term incremental costing approach based on the assumption that only the costs related to differences in procedures following implementation of the IOR would vary. Costs common to both IOR and the COR were not recorded, e.g. overhead costs including hospital administration, cleaning and rent and the costs of surgical equipment and medicines.

Identification

E0001	What types of resources are used when using integrated operating rooms and conventional operating rooms (resource use identification)?

Field studies were conducted to identify activities/resources that varied with differences in the OR set-up. Furthermore, unstructured interviews were performed during the observational visits to ensure that observed activities were properly understood and described.

Through initial observational visits, the following differences in existing activities and working processes were identified:

1. Difference in preparation procedures of the OR and surgical equipment
2. Differences in procedures for the sterile nurse during surgery
3. Differences in procedures for the non-sterile nurse during surgery
4. Differences in procedures in cases of acute reshuffle of the surgery from laparoscopic to open

[11] *DESIGNGUIDE FOR HOSPITALSBYGGERI I REGION MIDTJYLLAND, Standard Operationsstue, 2014*

Working procedures related to COR and IOR respectively are described in Figure 5 and Figure 6. Identified differences in procedures are written in blue. Of the identified differences, acute reshuffle of the surgery from laparoscopic to open (number 3) was considered a rare event (~1 per month), and thus costs and resource use related to this procedure were excluded from the costs analysis.

The combination of the pre-setting possibilities of equipment, differences in procedures for both the sterile and the non-sterile nurse that leads to a difference division of tasks during surgery might affect the time spend during the surgical procedure. Therefore, staff time was identified as a resource category that might be affected when implementing an IOR.

Figure 5: Surgical procedures in the conventional operating room (COR)

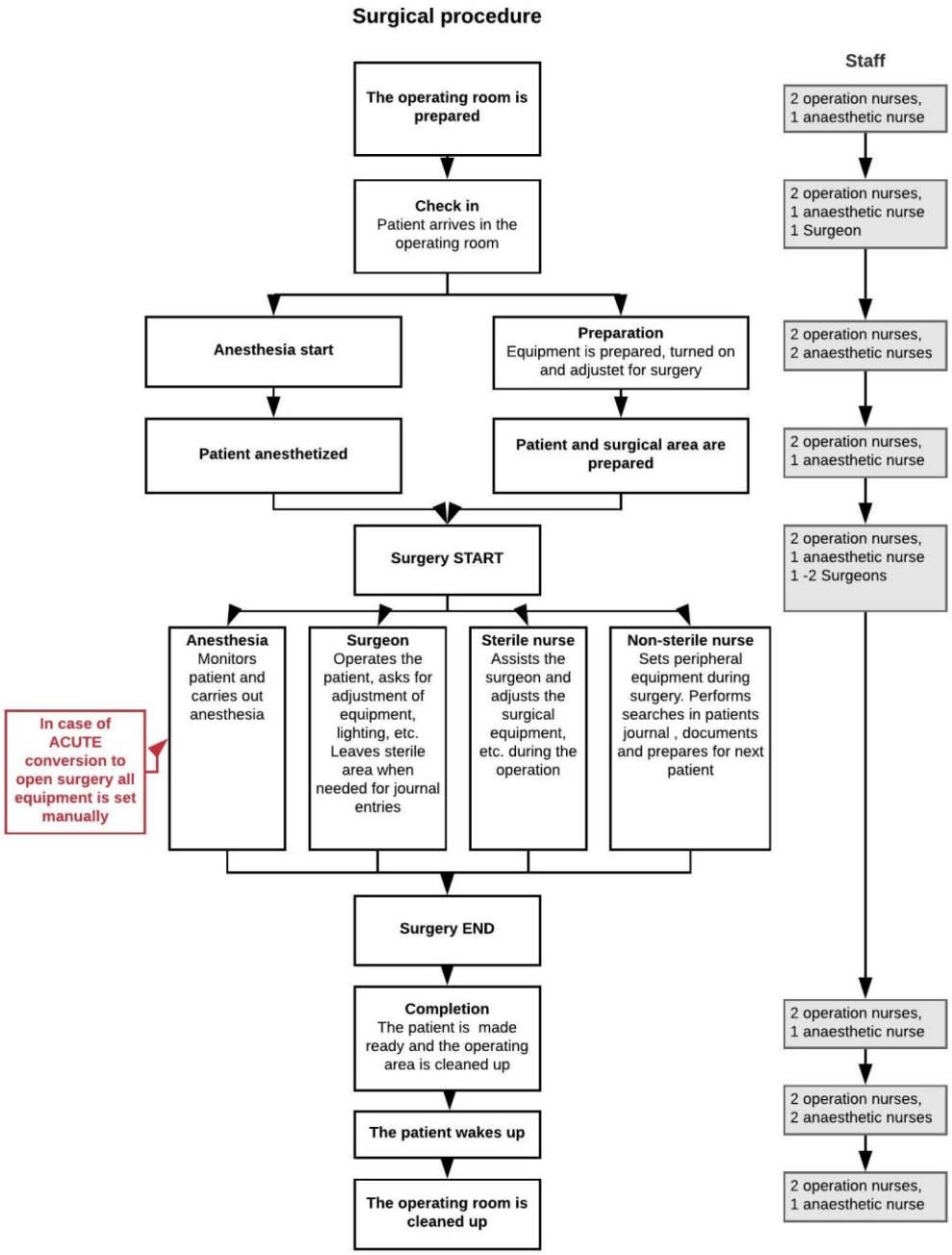
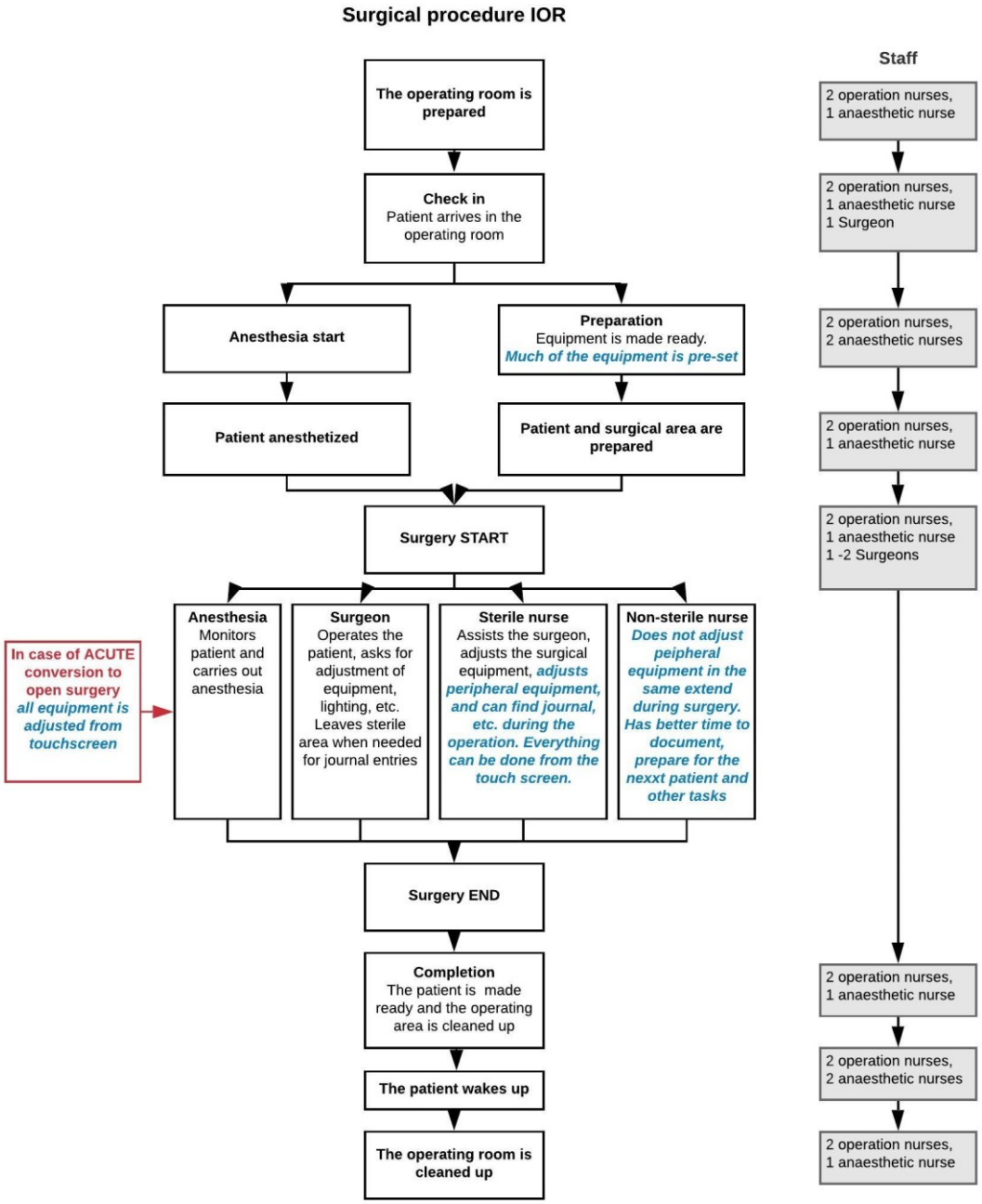


Figure 6: Surgical procedures in the integrated operating room (IOR)



Staff cost

E0002	What amounts of resources are used when using integrated operating rooms and conventional operating rooms (resource use measurement)?

Staff time was identified as a resource category that might be affected when implementing an IOR. To measure staff time spend during surgery at IOR and COR, data was extracted from the clinical booking system at AUH. Following data points are registered by clinicians during every surgery: 1) patient entering the OR, 2) first incision, 3) last suture and 4) patient leaves the OR.

Due to differences in time of implementation of the IOR in the participating departments, data was extracted for different time periods. For Mave- og Tarmkirurgi data was extracted for 6 months from 1st October 2018 to 31th March 2019. For Hjerte-, Lunge- og Karkirurgi data was extracted for 32 months from 1st October 2016 to 31th March 2019. Both extraction periods were organised to be at least four months after installation with regard to ensuring full implementation and minimise start-up difficulties and learning curve effects.

Clinical experts assisted in identifying types of surgeries assumed to be comparable and performed at both IOR and COR. All included types of surgeries were laparoscopic procedures. Table 8 presents the two participating departments and the identified and included types of surgery.

Table 8: Participating departments and included types of surgeries

Department name	Hjerte-, Lunge og Karkirurgi	Mave- og Tarmkirurgi
Full time employees	94	152
Annual number of surgeries[a]	1,267	2,627
Selected surgical unit	OP-ØST	OP-SYD 1
Total number of OR's in the surgical unit[b]	5	3
Total number of IOR's in the surgical unit	1	1
Specialty of selected types of surgery	Lung surgery	Gastrointestinal surgery
Selected types of surgery	Lobectomy	Lap. Colecystectomy
	Esophageal resection	Lap. Appendectomy
	Pectus excavatum	
	Lung resection	
	Pectus carinatum	
Data extraction period	01.10.16 - 31.03.19	01.10.18 - 31.03.19
	32 months	6 months

All costs are stated in DKK
OR = operating rooms
a = Activity data is extracted for 2018
b = Including integrated operating rooms (IOR)

Wages for the clinical staff were extracted from the administrative systems and average hourly salary was calculated for each staff-group.

Technology costs

Technology costs were estimated based on procurement data for the past 3 years at AUH. The costs included were the purchase of various equipment and installation costs. The technology costs were presented by functionality according to Figure 4 (see 'Description and technical characteristics of technology' (TEC) domain at section 3). Investments were inflated to 2018 DKK prices using the common consumer price index.

Moreover, to present not only the investment costs, but also the depreciation of the equipment, the costs were converted to an equivalent annual cost based on the equipment's estimated technical lifetime and at an interest rate of 2%. Technical lifetime was defined as the time until re-investment is necessary. This in contrast to technological lifetime, which is time until the equipment is outdated. Technological lifetime is typically much shorter than technical lifetime. Technical lifetime was obtained from the Swedish data base MTPreg, which is based on the international database The Global Medical Device Nomenclature (GMDN) and used by the medico-technical department.

Based on initial visits in the clinical departments and unstructured interviews with manufactures it became clear that implementation of the integrated operating room was handled by the manufacturers and was included in the technology costs. Therefore, Implementation costs were disregarded in the cost analysis. Education and training was generally perceived unproblematic by the clinical staff (see 'Education and training requirements' at section 6), and costs of continuous training of staff was considered of small economic impact and thus disregarded from the analysis as well.

Service and support costs (running costs)

Data concerning different support solutions and their costs were obtained from manufacturers. As an alternative to the service and support options delivered by manufacturers we included an estimate of a service/support solution delivered by the regional medico department and medico-technical staff. The annual time spend on the integrated operating room by medico-technical staff was estimated by medico-technical experts based on actual time consumption in AUH. The medico-technical staff time was multiplied by the average hourly wage cost obtained from StatBank Denmark and the national statistics about labour, income and wealth.

Effectiveness

No significant differences were found in either effects or safety between the COR and IOR (see the clinical effectiveness (EFF) domain at section 4 and the safety (SAF) domain at section 5). Additionally, as a part of the empirical study, observational visits and unstructured interviews were conducted in the participating departments in order to identify possible clinical significant changes in effect or safety as a result of implementation of the IOR. It became clear that such changes were hard to identify, thus supporting the results of the literature review in EFF domain and SAF domain (see section 4 and 5). Therefore, measurements of effectiveness were excluded and the economic analysis was framed as a cost minimisation analysis, which is used in case of small or no effect and in which only the costs will be analysed and compared.

Cost minimisation analysis

Staff time was analysed for preparation (a), surgery (b) and completion time (c) separately as well as total procedure time (d). These were calculated as follows: a = time between patient entering the OR and first incision, b = time between first incision and last suture, c = time between last suture and patient leaving the operating room, d = time between patient entering OR and leaving OR.

In case of missing data for all the three data points (a, b, c) observations were deleted. All other observations were included. Outliers were investigated and if considered registration errors these observations were left out of the analysis.

Independent t-test was used to estimate the statistical difference in mean time between the two alternatives (COR vs. IOR). Distributional tests were performed to be sure that data was normally distributed. Missing data were excluded from the statistical analyses.

As different surgeons presumably influence the time of the procedure, we applied a linear regression model adjusting for the influence of the surgeon to test the robustness of the staff time results.

Analyses of staff time were performed using STATA 15. The original data sets were maintained and analyses made by the use of DO-files. A statistical significance level of 0.05 was used.

The mean time (if statistically different between IOR and COR) was multiplied with the average salary for each staff-group to estimate the staff cost per surgical procedure. The staff cost per procedure was multiplied by the total number of procedures and to calculate the annual incremental staff cost, the staff cost of the IOR was subtracted the staff cost of COR.

To estimate the incremental annual cost of the IOR, the incremental staff cost was added the equivalent annual technology cost as well as the service/support costs.

Budget impact

In Denmark decisions are made locally in each hospital by the hospital management regarding whether or not to fund IORs. A simple budget impact analysis was performed to exemplify the direct investment needed to implement the technology. To provide a useful estimate of the total budget required to fund the implementation of IORs in a specific context, the incremental "unit" cost of the IOR must be multiplied by the number of ORs at the hospital. We calculated the hospital budget impact exemplified by AUH where the total number of ORs was 60. Moreover, we calculated the national budget impact based on a total number of ORs of 770. The total number of ORs was estimated by calculating number of ORs in two Danish regions and this number was up scaled under the assumption that there is an equal number of ORs per citizen throughout the country.

7.4 Results

Staff cost

During the study period at total of 1,192 surgeries of the selected types were performed in the OR's. However, as not all surgeries had complete time registrations 9 surgeries were excluded prior to analysis.

The results of the analyses are shown in Table 9. We found no statistically significant differences in preparation time, operating time, termination time or procedure time between IOR and COR. Regression analyses adjusting for potential influence of the surgeon did not change these results.

As no statistically significant difference in mean time were detected in either of the operating processes, it was not relevant to calculate the incremental staff costs, and thus this was excluded from the cost analysis.

Table 9: Mean time and time differences between integrated operating room (IOR) and conventional operating room (COR)

		Preparation time (minutes)[a]							Surgical time (minutes)[b]						
		Integrated OR			Conventional OR			*p* value[e]	Integrated OR			Conventional OR			*p* value[e]
Surgical specialty	**Type of surgery**	*N*	Mean (95 % CI)		*N*	Mean (95 % CI)			*N*	Mean (95 % CI)		*N*	Mean (95 % CI)		
Gastrointestinal surgery	Appendectomy	40	37	(34.59;40.16)	43	40	(35.19;43.93)	0.41	39	47	(41.41;53.31)	41	58	(47.35;68.94)	0.09
Gastrointestinal surgery	Colecystectomy	33	51	(46.30;54,91)	22	55	(48.68;61,23)	0.23	33	95	(77.43;112.75)	23	92	(74.87;108.78)	0.79
Heart, lung and vascular surgery	Lobectomy	239	72	(69.66;75,23)	120	77	(73.12;80.08)	0.08	242	142	(135.03;148.00)	122	147	(127.86;166.82)	0.49
Heart, lung and vascular surgery	Esophageal resection	145	105	(100.01;109.30)	37	98	(90.63;105.47)	0.19	151	305	(288.92;320,88)	37	290	(253.38;327,21)	0.43
Heart, lung and vascular surgery	Pectus excavatum	79	46	(41.34;50.15)	102	47	(43.68;50.58)	0.62	79	42	(36.15;48.28)	100	41	(35.12;46.32)	0.72
Heart, lung and vascular surgery	Lung resection	128	68	(64.05;71.34)	141	69	(65.57;72.55)	0.59	130	63	(57.00;68.28)	140	59	(53.44;63.79)	0.30
Heart, lung and vascular surgery	Pectus carinatum	7	55	(40.10;69.05)	11	55	(36.10;74.63)	0.95	7	188	(140.24;235.18)	11	165	(110.47;219.35)	0.52

		Completion time (minutes)[c]							Procedure time (minutes)[d]						
		Integrated OR			Conventional OR			*p* value[e]	Integrated OR			Conventional OR			*p* value[e]
Surgical specialty	**Type of surgery**	*N*	Mean (95 % CI)		*N*	Mean (95 % CI)			*N*	Mean (95 % CI)		*N*	Mean (95 % CI)		
Gastrointestinal surgery	Appendectomy	35	18	(14.63;21.48)	39	19	(15.71; 22.59)	0.65	38	101	(93.37;108.79)	38	111	(101.05;120.95)	0.11
Gastrointestinal surgery	Cholecystectomy	32	24	(18.11;29.45)	18	18	(15.06;20.83)	0.14	30	168	(147.24;189.69)	21	170	(152.18;188.01)	0.91
Heart, lung and vascular surgery	Lobectomy	202	23	(20.76;24.36)	102	25	(22.85;27.45)	0.09	219	233	(226.53;239.43)	112	239	(228.76;249.78)	0.29
Heart, lung and vascular surgery	Esophageal resection	113	31	(26.63;35.53)	29	30	(24.65;35.56)	0.83	122	435	(417.41;452.50)	30	399	(363.85;433.95)	0.07
Heart, lung and vascular surgery	Pectus excavatum	61	20	(17.34;22.96)	78	19	(16.64;21.31)	0.52	66	104	(94.05;113.04)	84	101	(93.59;108.46)	0.67
Heart, lung and vascular surgery	Lung resection	107	23	(20.58;24.73)	124	23	(20.88;25.49)	0.74	114	148	(140.07;155.05)	130	147	(140.49;153.91)	0.94
Heart, lung and vascular surgery	Pectus carinatum	4	22	(5.49;39.01)	9	25	(15.33;34.67)	0.71	5	236	(190.24;280.96)	9	230	(183.41;276.37)	0.85

OR = operating room
a = Time between patient entering OR and first incision
b = Time between first incision and last suture
c = Time between last suture and patient leaving OR
d = Time between patient entering OR and leaving OR
e = Independent t-test
* = Significant (none)

Technology costs

E0009	What were the measured and/or estimated costs of integrated operating rooms and conventional operating rooms (resource use valuation)?

As staff costs were not relevant to include in the cost minimisation analysis due to insignificant differences between alternatives, technology costs were the only remaining identified cost category. Therefore, technology costs represent the cost difference between alternatives and thus the results of the incremental analysis.

Table 10 presents the estimated incremental costs of the technology and required equipment as well as the incremental annual costs based on the technical lifetime of the different equipment. The costs are presented separately for all functionalities of the full IOR (see TEC domain at section 3, Figure 4).

Table 10: Incremental costs and equivalent annual costs of the technology (DKK)

	Technology cost	Technical lifetime[a]	Eqival. annual cost[b]
Control of peripheral equipment			
(Single remote control is a prerequisite for central control)			
Ergonomic room lighting (ergonomic - patented)	150,000	10	16,699
Surgical lightning	140,000	10	15,586
Box to enable central control	25,000	10	2,783
Total control of peripheral equipment	**315,000**		**35,068**
Control of the surgical equipment			
Box for management of equipment incl. touchpad[c]	**120,000**	8	**16,381**
Video routing	**110,000**	8	15,016
Required equipment:			
Monitor mount (for 3 screens/monitors)	150,000		
Screens/monitors (1-4 per room, in average 3)		15	11,674
27" 4K	30,000	5	6,365
32" 4K	130,000	5	27,580
31" 3D / 4K	120,000	5	25,459
Lowest total video routing (incl. required equipment)[d]	**350,000**		**45,784**
Highest total video routing (incl. required equipment)[e]	**650,000**		**109,431**
Documentation module	**105,000**	8	**14,333**
Video streaming/conference	115,000	8	15,699
Required equipment:			
Room camera	10,000	5	2,122
Speaker	8,000	5	1,697
Microphone	2,000	5	424
Total video streaming	**135,000**		**19,942**
Installation of the integrated operating room	**100,000**	8	**13,651**
Other recommended equipment (not a prerequisite)			
Big screen 55 " 3D / 4K	150,000	5	31,823
Monitor mount for surgical equipment	200,000	15	15,565
Monitor mount for anaesthetic equipment	75,000	15	5,837
Support solutions (optional)[f]			
Service from manufacturers:			
Most simple support agreement			15,000
Most comprehensive support agreement / full coverage			185,000
Service from regional medico department:			
Service and support by regional medico-technical staff			**4,200**

All prices are stated in DKK
a = Stated in years
b = The equivalent annual costs were calculated using an interest rate of 2 % and the estimated technical lifetime of equipment
c = This is the box that enables central management of the other sub-systems as well
d = Estimated lowest costs of video routing are based on the purchase of three of the cheapest screens
e = Estimated highest costs are based on the purchase of the three most costly screens
f = Support solutions are presented as estimated annual running cost per integrated operating room

As shown in Table 10, the incremental costs of the different functionalities varied between 105,000 DKK and 650,000 DKK. The estimated lowest costs of video routing were based on the purchase of three of the cheapest screens/monitors while the estimated highest costs were based on the purchase of the three most costly screens/monitors. The estimated costs of control of peripheral equipment included surgical lightning and ergonomic room lightning as these were the most commonly integrated peripheral equipment in the Danish setting. Other peripheral equipment such as curtains and patient's bed could be added to the solution as well however at an additional cost. Other recommended equipment is presented but not considered a prerequisite for installation of the IOR and thus not included in the estimates; however, it might be relevant to install a big screen/monitor when installing video streaming. The big screen/monitor was not a part of the estimated costs of video screening.

Table 11 presents examples of three different integrated solutions, the functionalities and the incremental and equivalent annual costs. In the integrated solution 1, only control of surgical lightning was included as peripheral equipment, in the other two solutions ergonomic room lightning was included as well. The installation of a full IOR was estimated to 100,000 DKK, but due to more simple solutions in solution 1 and solution 2, only a smaller percentage of the installation costs were included. The annual service/support costs operated by the regional medico-technical staff were added the equivalent annual costs. The examples showed that the minimal integrated solution (solution 1) had an incremental cost of 695,000 DKK corresponding to an equivalent annual additional cost of 92,925 DKK compared to the COR. The incremental costs of the full integrated solution (solution 3) were 1,125,000 DKK with an equivalent annual additional cost of 149,359 DKK compared to the COR.

Table 11: Technology costs and equivalent annual costs of integrated solution examples (DKK)

Integrated solution	Technology cost	Equivalent annual cost[a]
Integrated solution 1		
Control of surgical lightning (peripheral equipment)	165,000	18,369
Control of surgical equipment	120,000	16,381
Video routing (incl. required equipment)[b]	350,000	45,784
Installation of the integrated operating room (60%)	60,000	8,191
Service/support by regional medico-technical staff	-	4,200
Total	**695,000**	**92,925**
Integrated solution 2		
Control of peripheral equipment[b]	315,000	35,068
Control of surgical equipment	120,000	16,381
Video routing (incl. required equipment)[c]	350,000	45,784
Documentation module	105,000	14,333
Installation of the integrated operating room (80%)	80,000	10,921
Service/support by regional medico-technical staff	-	4,200
Total	**970,000**	**126,687**
Integrated solution 3		
Control of peripheral equipment[b]	315,000	35,068
Control of surgical equipment	120,000	16,381
Video routing (incl. required equipment)[c]	350,000	45,784
Documentation module	105,000	14,333
Video streaming/conference	135,000	19,942
Installation of the integrated operating room (100%)	100,000	13,651
Service/support by regional medico-technical staff	-	4,200
Total	**1,125,000**	**149,359**

All prices are stated in DKK
a = The equivalent annual costs were calculated using an interest rate of 2 % and the estimated technical annuity of equipment (5-15 years)
b = Based on Total Control of peripheral equipment (incl. ergonomic room lighting, surgical lighting and box to enable central control)
c = Based on Lowest total Video Routing (incl. required equipment)

Budget impact

G0007	What are the likely budget impacts of implementing integrated operating rooms?

The budget impact of implementing IORs is highly dependent on the local setting and the specific number of ORs. Table 12 shows the hospital and national budget impact, where calculations of hospital investments were based on a total number of 60 ORs at AUH while national investments were based on 770 ORs.

Table 12: Budget impact (DKK)

Integrated solution	Unit cost IOR	Equiv. annual costs	Budget impact one hospital (AUH)		National budget impact (DK)	
			Total investment[a]	Equiv. annual costs[a]	Total investment[b]	Equiv. annual costs[b]
Integrated solution 1	695,000	92,925	41,700,000	5,575,500	535,150,000	68,757,150
Integrated solution 2	970,000	126,687	58,200,000	7,601,220	746,900,000	94,753,890
Integrated solution 3	1,125,000	149,359	67,500,000	8,961,540	866,250,000	112,211,330

All prices are stated in DKK
IOR = Integrated operating room
AUH = Aarhus University Hospital
DK = Denmark
a = In AUH the calculation is based on a total of 60 operating rooms
b = The national calculation is based on a total of 770 operating rooms

As shown in Table 12, the budget impact of implementing the integrated solutions for one hospital (60 ORs) varied between total investments of 41,700,000 DKK for the integrated solution 1 to total investments of 67,000,000 DKK for the integrated solution 3. The national budget impact varied between total investments of 535,150,000 to 866,250,000 DKK corresponding to an equivalent annual additional cost of 68,757,150 to 112,211,300 DKK compared to CORs depending on the chosen solution.

8. DISCUSSION

The present Health Technology Assessment (HTA) examines integrated operating rooms (IOR). The HTA has been initiated by the regional manager from the five Danish regions in order to assess clinical effects as well as organisational and economic consequences of using IOR. The scope is integrated operating rooms (IOR), and comparators of interest are conventional operating rooms (COR). Integrated operating rooms are used for all types of patient groups and indications. In this project, no specific population is chosen in relation to the use of the technology integrated operating rooms.

8.1 Description of technology and comparators

An integrated operating room (IOR) is a collection of systems and technologies that are functionally linked to a touchpad, which allows the surgical staff to control all IOR functionalities from one unit. In a conventional operating room (COR), the functionalities are arranged around the room and controlled separately by their own control panels from the non-sterile field. In the literature, the touchpad is placed in the sterile field. There are several claimed benefits to this position of the touchpad: fewer interruptions during the surgery, faster equipment setup and time release for the non-sterile nurse. However, in practice the touchpad is also sometimes placed in the non-sterile field in the IOR.

The functionalities contained in the IOR vary both in the literature and in practice. However, we defined the minimum of functionalities in an IOR to include: control of peripheral equipment, control of surgical equipment and audio/video (A/V) routing. We found that IOR can be built around the same frames and functionalities as a COR. However, additional hardware and software are often needed to support the integration with user control of all functionalities from the touchpad which can vary.

The report and the analysis do not include assessment of the different single technologies that typically accompanies the integration, e.g. new scanning equipment, top-mounted equipment and monitors.

We identified three leading medical device manufactures of products and services for IORs to Danish hospitals; Karl Storz, Olympus and Stryker which are implemented in 24 hospitals in Denmark with more to come. We identified only small differences in principal characteristic/intended use between the manufactures such as use of documentation archive and integration of voice command. Karl Storz was the manufacture with most implemented IORs (OR1^{TM}) in Danish hospitals. Common to all implemented IORs in Danish hospitals was the integration of peripheral equipment, surgical equipment and video routing while the integration of especially video streaming varied.

8.2 Clinical effectiveness

Two studies were included for assessment of clinical effectiveness outcomes (1,3). The studies included patients undergoing laparoscopic hysterectomy or ear, nose and throat surgery. This assessment provided only a narrative summary on outcomes as meta-analysis was not possible due to study heterogeneity. The evidence level for the outcome estimates was very low, mainly due to the risk of bias and poor study design, which weakens the robustness of our findings, and on the basis of this section it is not possible to draw any final conclusions. Available results show no significant effects in regard to flow disturbances during surgery with only minor differences between the alternatives. Also only minor, non-significant differences in operation time were shown using IOR when compared to COR although a tendency towards time savings was shown. No outcomes represent any patient-specific endpoints such as morbidity or quality of life. The outcomes presented

are proxy outcomes, and as such only represent a possible association to patient relevant outcomes for example risk of infection. No results on other outcomes were reported in the included studies.

Overall the literature in the field of IOR is extremely limited and of methodically poor quality, where the design and measurement parameters of the studies impose restrictions on the internal validity of the studies. In the studies, in particular, detailed information on interventions and comparators are lacking. At the moment nothing speaks against the use of IOR, but at the same time no significant benefits have been demonstrated in the use of the touchpad. For this reason, it may be difficult to determine a rational level of use of IOR within surgery compared to COR. This circumstance requires a need to assess the most appropriate use and dissemination of IOR in the future.

8.3 Safety

Although no direct interaction between the technology and the patients occur some studies assess the direct impact of using the interface and patient hazards on short-term outcomes demonstrated through complication rates (3), but find no differences between the alternatives. Some studies reflect on safety issues in relation to the use of IOR and interconnected systems, and point out important issues e.g. that the right devices are affected by the remote-controlled interface, and to make sure that the right devices exchange data. Another study (1) points out that implementation of a new technology potentially can be unsafe because of possible absence of an intuitive and straightforward use of the technology. However, Blikkendal et al. reported no differences in flow disturbances. Findings from two surveys where interviews were conducted with surgical staff indicate potential benefits in relation to surgical risk using IOR. As could be expected no difference between alternatives was shown, since the touchpad is only a small part of a larger organisational setup and many other factors may affect the results, which makes it difficult to evaluate the technology separated from other technical solutions in the operating room (OR).

8.4 Organisational aspects

Implementation and use of IORs do not have great implications for the existing organisation and work processes. The organisational analysis identifies a change in division of labour between the sterile and non-sterile surgical nurse during surgery when the touchpad is administered (at least partly) in the sterile field, and smaller changes in work tasks of the surgical nurses in preparation for and completion of surgery. Generally IORs do not affect the work processes of the surgeon or the anaesthesia personnel. IORs do not significantly affect the co-operation and communication of activities among the clinical personnel in the OR.

The clinical personnel generally experience IORs easy to use and not associated with a learning curve. However, proper introduction to and training of the surgical personnel using IORs is important in order to ensure correct and optimised use of the IOR. Training of surgical personnel is managed locally in the hospital departments and generally organised as peer-to-peer training.

IORs are generally considered a practical technological solution by the clinical personnel but without major impact on daily work. The organisational analysis identifies three small size challenges and opportunities associated with use of IORs with assumed potential in relation to future use and spreading of IORs:

1. IOR lead to experienced improvements of the workflow during surgery caused by faster response on requests for adjustments of surgical equipment and functionalities and fewer disruptions. However, realisation of the improvements in workflow appears to presuppose administration of the touchpad in the sterile field or flexibly between the sterile and non-sterile field. Moreover, the organisational analysis in-

dicates that experienced improvements in workflow are particularly achieved in lengthy and complex surgical procedures.

2. Variation exists in the use of the IOR, both in terms of variation in the degree to which the touchpad is used to control and adjust the surgical equipment and functionalities integrated at all, and in whether the touchpad is administered in the sterile field or in the non-sterile field. Both types of variation appear to relate to habits among the surgical personnel and to insufficient competencies in use of IORs. Thus, to unfold the full assumed potential of the IOR there seem to be a potential in ensuring a clear understanding of the positive effect of the technology, and in strengthening the current training requirements and processes in place for surgical personnel using IORs.

3. IORs have an experienced positive impact on the working environment and ergonomics of the non-sterile nurses in terms of fewer inexpedient working postures, reduction of risk of falling and less steps. IOR do not significantly affect the working environment and ergonomics of sterile nurses, surgeons and anaesthesia personnel.

The conclusions of the organisational analysis contribute to our knowledge about the organisational aspects of use of IORs in Danish hospitals. The consequences of specific ways of organising use are more sparsely addressed. The comparative design of the analysis provides insight into the variation and complexity that characterise use of IORs in a Danish context.

Some methodological challenges should be taken into account. First, both the literature review and the interview study are mainly descriptive. They provide insight into how use of IORs can be organised, but only to a limited extend are the consequences of the organisation assessed. Perspectives on consequences included in the organisational analysis are based on qualitative interviews with surgical personnel using IORs and thus on subjective experiences and perceptions rather than objective quality and performance measurements. As such, there is a need for future research that systematically integrate analysis of organisational aspects with more objective quality and performance indicators, e.g. surgical time, patient safety and quality in treatment, to substantiate conclusions on optimised use of IORs. Second, the geographical context of the included studies should be taken into consideration in relation to the transferability and generalisability of the results of these studies to a Danish context. This, due to the fact that organisation of and processes within health care systems differ across national contexts and thus potentially also in relation to use of IORs. However, most of the results of the literature review are rediscovered in the interview study, which underscores the validity of these results. Third, all hospital departments using IORs have not been included in the interview study. Thus, the organisational analysis does not provide a complete picture of the use of IORs and associated challenges and opportunities in Denmark. However, the interview study is based on a relatively large sample with representatives from both different regions, hospitals, specialties and professional background, all with experience with working in an IOR, and data saturation was regularly discussed during data collection.

Despite these outlined challenges the organisational analysis forms a substantial contribution to a systematic description of the organisational aspects associated with use of IORs in a Danish context. Furthermore, the organisational analysis provides a first step towards establishing relevant knowledge about challenges and opportunities associated with use of IORs to support an optimised future use and spreading of IORs.

8.5 Costs and economic evaluation

The relatively large dataset of time registration was a strength of the empirical study. However, the number of surgeries within each operation type varied with very few observations in some types and thus larger CI-intervals and larger statistical uncertainty.

Time data was extracted from only one region, which limits the generalisability of the results as possible time savings are closely related to operating procedures that may vary among settings.

The costs of the technology were based on procurement data from the Central Denmark Region. Due to different price agreements that the different regions negotiate with manufacturers, the estimated costs of the technology and the scenarios may vary among regions. However, the presented costs show the level of costs that decision makers may expect.

The quality of the data was closely related to the quality of the registrations, and the registrations might be subject to bias as data was recorded manually by the non-sterile nurse in the OR. However, this potential bias was expected to be randomly distributed and thus of limited importance.

In the case that the IOR is experienced as better or safer among staff (see the organisational (ORG) domain at section 6) systematic differences between the ORs might occur if complicated procedures are systematically allocated to the IOR. This would result in selection bias and might lead to underestimation of time differences between the ORs as complicated procedures expectedly are more time consuming than simple procedures.

We adjusted the analyses of operation time for influence of the surgeon, which did not change results. Other factors such as patient age, sex and comorbidities might have influenced results as well however due to lack of data it was not possible to include these variables into the regression analysis.

The time data for the empirical study was based on data from AUH, where the COR was modernised and newly equipped. This comply to the guidelines in economic evaluations recommending that new technologies must be compared to best practice to ensure that the cost-effectiveness of the technology is not over estimated.

Costs of the technology were presented with all costs of functionalities and equipment separately to ensure transparency of the estimates. The costs of functionalities included required equipment such as screens, microphone etc. In the case that this equipment is already available and possible to integrate into the solution, this will lower the estimated total costs.

Previous studies by Blikkendal et al. and Strauss et al. showed no significant effects but a tendency towards time saving (see the clinical effectiveness (EFF) domain at section 4). The empirical study supports the findings of no significant time differences but found no tendency towards time savings. Even though not detected in this assessment, effects or value of the IOR may be found over time. Positive effects might be found on time and safety when switching from laparoscopic to open surgery in acute situations (not measured due to low frequency). Extended use of teaching and collaborating possibilities due to video streaming might ensure efficient and continuous education of medical students and surgeons and thereby possibly improve quality of treatment. Experienced improvements in work-flow and ergonomics (see 'Impact of IORs on the current organisation' at section 6) might influence the working environment and job satisfaction, and this might over time influence costs positively in the form of reduced sick-leave.

Further improvements in IOR technical solutions might possibly change current results, since development within the area is extensive. If IOR is implemented in the operating room, it is important to ensure continuous monitoring of the use of IOR in relation to research and follow-up. Basically, when using new technology the dissemination of the technology has to be well-founded and based on consistent and dependable decision-making considering explicit criteria and need for dissemination.

9. CONCLUSION

Integrated operating room (IOR) is a recent technology to control surgical and non-surgical functionalities in the operating room (OR) by the use of a touchpad-interface. IOR can be built around the same frames and functionalities as a conventional operating room (COR). However, additional hardware and software are often needed to support the integration with user control of all functionalities from the touchpad, which may vary. IORs are implemented in 24 hospitals in Denmark, with only small differences in principal characteristic/ intended use between the manufactures.

Available results show no clinical or statistical significant effects concerning flow disturbances during surgery or differences in operation time using IOR when compared to COR. The evidence level for these outcome estimates was very low. Regarding complication rates no differences was found between the alternatives. Other findings indicate potential benefits in relation to surgical risk using IOR.

Implementation and use of IORs do not have great implications for the existing organisation and work processes, nor for the co-operation and communication among the surgical personnel. IORs are generally experienced to be easy to use, but proper introduction to and training of the surgical personnel is important in order to ensure correct and optimised use of the IOR. Currently training of surgical personnel is managed locally in the hospital departments and generally organised as peer-to-peer training.

The organisational analysis identifies three small size challenges and opportunities associated with use of IOR with assumed potential in relation to future use and spreading of IORs. First, IORs lead to experienced improvements of the workflow during surgery, presupposed that the touchpad is administered in the sterile field or flexibly between the sterile and non-sterile field. Second, variation in use of IORs exists as a consequence of habits among the surgical personnel and insufficient competencies in use of IORs. Thus, to unfold the assumed potential of the IOR there seem to be a potential in ensuring a clear understanding of the positive effect of the technology, and in strengthening the current training requirements and processes in place for surgical personnel using IORs. Third, IORs have an experienced positive impact on working environment and ergonomics for the non-sterile nurses.

No studies were found exploring the costs or cost-effectiveness of the IOR. Therefore, the economic analyses were primarily based on an empirical study performed in the Central Denmark Region. The EFF and SAF domain as well as the empirical study did not identify any clinically relevant and measurable effects. Therefore, the economic analysis was designed as a cost minimisation analysis. The analysis of time registrations found no statistically significant differences in procedure time between IOR and COR leading to exclusion of staff cost from the incremental cost analysis. The cost analysis revealed incremental costs of an IOR varying from investment costs of 695,000 DKK corresponding to an equivalent annual additional cost of 92,925 DKK for the most simple solution to investment costs of 1,125,000 DKK corresponding to an equivalent annual additional cost of 149,359 DKK for a more comprehensive solution compared to the COR.

The budget impact of the integrated solutions for one hospital (based on 60 ORs) varied from total investments of 41,700,000 DKK to 67,000,000 DKK corresponding to an equivalent annual additional cost of 5,575,500 DKK to 8,961,540 DKK compared to the COR depending on chosen solution. The national budget impact varied between total investments of 535,150,000 to 866,250,000 DKK corresponding to an equivalent annual additional cost of 68,757,150 to 112,211,300 DKK compared to COR depending on the chosen integrated solution.

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APPENDIX 1: CHARACTERISTICS OF INCLUDED STUDIES

Study (author, year, country)	Aim	Study design and methods	Results	Quality
Acevedo, 2009, United States	To provide an overview of the Naval Medical Center renovation project in which 12 ORs were converted to integrated suites that fully support minimally invasive surgery (MIS). Furthermore, to examine why MIS ORs increasingly are becoming the norm, why stakeholder collaboration during the planning phase and throughout the integration project is vital, and what perioperative nurses need to understand to function effectively in the emerging environment.	Case study based on compilation of local experiences and expert statements.	Feedback from surgeons, nurses, and surgical technologists revealed that implementation of integrated operating rooms led to need of less equipment in the OR. Consequently, integrated operating rooms protect staff members from the hazards of wires, hoses and carts. Furthermore, integrated operating rooms are experienced to enhance patient safety and increase workflow efficiency. Implementation of integration system in conventional ORs is an expensive and time consuming process that requires extensive planning, but it is worth the effort and costs.	No quality assessment performed because of study design.
Blikkendaal et al., 2015, The Netherlands	To compare a conventional OR with an integrated OR with regard to the incidence and effect of equipment related surgical flow disturbances during an advanced laparoscopic gynaecological procedure [laparoscopic hysterectomy (LH)].	Prospective cohort/registration study based on video recording of 40 LH procedures (20 in a conventional cart-based OR and 20 in an integrated OR). The video recordings were analysed by two different observers. Outcome measures were the number, duration and effect (on a seven-point ordinal scale) of the surgical flow disturbances (e.g., malfunctioning, intraoperative repositioning, setup device).	A total of 103 h and 45 min was observed. The interobserver agreement was high (kappa .85, p\.001). Procedure time was not significantly different (NS) [conventional OR vs. integrated OR, minutes ± standard deviation (SD), mean 161 ± 27 vs. 150 ± 34]. A total of 1651 surgical flow disturbances were observed (mean ± SD per procedure 40.8 ± 19.4 vs. 41.8 ± 15.9, NS). The mean number of surgical flow disturbances per procedure with regard to equipment was 6.3 ± 3.7 versus 8.5 ± 4.0, NS. No clinically relevant differences in the mean effect of these disturbances on the surgical flow between the two OR setups were observed.	Moderate quality (Quality assessment performed by use of the SIGN checklist)
Konnickx et al., 2013, Belgium/UK/Russia/ Italy/USA/France	To generate reflection on integrated operating rooms as a basis to help with clinical validation.	Review article.	The understanding of a digital operating room is highly variable. Thus rapid incorporation in hospitals, clinical validation of improved quality of surgery for integrated OR is limited. The proven and expected usefulness of image distribution inside and outside the OR, of integrating information, of image and video registration, and of intelligence, is reviewed with the perspective of quality and safety of surgery. It is expected that the digital OR will contribute to learning and teaching and to quality of surgery. Involvement of surgeons in shaping and orienting the future of integrated operating rooms is important.	No quality assessment performed because of study design.
Nocco & Torchio, 2010, Italy	To evaluate surgeons' and staff nurses' satisfaction and comments on the integrated ORs installed in a new OR block of the Varese Town and University Hospital.	Questionnaire survey study in which a multiple answer questionnaire has been handed to and answered by 17 surgeons and 9 scrub nurses from Varese Town and University Hospital after 2 years of use of integrated ORs. Questionnaires were answered with the interviewer present. Informants were select-	Surgeons and scrub nurses agree that an integrated OR can be very effective in increasing quality, risk reduction and surgery time reduction through the use of digitalised video acquisition system, boom-mounted devices and multiple displays. Scrub nurses are more confident than surgeons that medical device control can reduce	No quality assessment performed because of study design.

Study (author, year, country)	Aim	Study design and methods	Results	Quality
		ed mainly from general surgery (less from orthopaedics, urology and ENT).	confusion inside the OR, and reduce the number of setting errors. A very positive judgment are given to the system's teaching capabilities, but both surgeons and scrub nurses agree that more education and a cultural change are needed to use the system in a correct and complete way.	
Rockstroh et al., 2017, Germany	To qualitatively evaluate a subset of proposed concepts from the perspectives of various stakeholders based on an OR.NET demonstrator set up at the innovation Center Computer Assisted Surgery at the University of Leipzig.	Qualitative evaluation based on a questionnaire survey and structured qualitative interviews. The questionnaire survey was used to obtain feedback from staff responsible for medical devices and for information technology in eleven hospitals to evaluate the technical dimensions of the demonstrator set up (70 questionnaires distributed with a response rate of about 20 %). Structured interviews with surgeons, anaesthesiologists and OR staff (n = 10) were conducted to evaluate the clinical implications of the integrated operating room.	The implementation of openly integrated operating rooms will positively affect clinical and technical personnel. The greatest impact may be achieved through improvement of work processes. The feedback from clinicians indicates that there is a need for a flexible data and control integration. Moreover, initial training is required to unfold the full potential in the integrated operation rooms. The hospital operators stress the need for tools to simplify risk management in openly integrated operating rooms.	No quality assessment performed because of study design.
Stavroulis et al., 2013, United Kingdom	To determine staff perceptions of the effect of integrated operating rooms on surgical teamwork including working interactions and behaviour in the operating room.	Exploratory cross-sectional questionnaire survey based on completion of a questionnaire survey by 27 theatre staff (nine nurses, nine consultants and nine trainees) working in both Integrated and conventional laparoscopic theatre. The questionnaire included questions on general demographics and their perception regarding the theatre environment and team interaction. Visual analogue scores were used to compare the integrated and non-integrated theatres. Non-parametric statistical analysis was used.	Overall the theatre team members had a strong preference for working in an integrated theatre environment. They felt that it resulted in greater efficiency, better teamwork and reduced stress levels. Differences were highly significant ($p<0.0001$). Within group differences were also significant for the variables.	No quality assessment performed because of study design.
Strauss et al., 2010, Germany	To compare the integrated operating theatre system "Surgical Deck1-ENT" with the previous standard.	The scientific basis of this work represents a surgical workflow analysis. Over 200 completely documented operations in conventional operating theatres were available for comparison. In the period from 1st June 2009 to 31st September 2009 a total of 139 standard procedures (9 different ENT surgeons) were analysed in the newly integrated operating theatre system "Surgical Deck1-ENT".	The comparison to the conventional operating theatre system the slot time was reduced from 73.8 min to 65.6 min (−11%), the preoperative time was reduced on average by 31% (8 min) per case and the documentation time was decreased on average by 6 min (67%). The interaction steps of the surgeon with the system were reduced by 70% (from 17 to 5 steps). No significant differences in complications could be observed. In the total evaluation of all 16 questions on the ergonomics there was a significant improvement of the workplace layout.	Low quality (Quality assessment per-formed by use of the SIGN checklist)

APPENDIX 2: INTEGRATED OPERATING ROOMS IN DANISH HOSPITALS*

Region	Hospital	Department	Surgical speciality	Manufacture	Functionalities				
					Peripheral equipment	Surgical equipment	Video routing	Documentation	Video streaming
Capital Region of Denmark	Bispebjerg Hospital	Operationsafsnit K *(not in use)*	Gastrointestinal	Olympus	X	X	X	X	
		Operationsafsnit K *(not in use)*	Gastrointestinal	Olympus	X	X	X	X	
	Bornholms Hospital	Kirurgisk Afdeling	Gynaecology	Olympus	X	X	X	X	
	Gentofte Hospital	Anæstesiologisk Afdeling	Gastrointestinal	Olympus	X	X	X		
	Herlev Hospital	Afd. ADG, Operationsafdeling	Urology/Gynaecology	Olympus	X	X	X	X	X
		Afd. ADG, Operationsafdeling	Gastrointestinal	Olympus	X	X	X	X	X
	Hvidovre Hospital	Dagkirurgisk	Multiple	Olympus	X	X	X	X	X
(continued)	*(continued)*	Dagkirurgisk	Multiple	Olympus	X	X	X	X	X

Region	Hospital	Department	Surgical speciality	Manufacture	Functionalities				
					Peripheral equipment	Surgical equipment	Video routing	Documentation	Video streaming
		Dagkirurgisk	Multiple	Olympus	X	X	X	X	X
		Dagkirurgisk	Multiple	Olympus	X	X	X	X	X
		Dagkirurgisk	Multiple	Olympus	X	X	X	X	X
		Dagkirurgisk	Multiple	Olympus	X	X	X	X	X
		Endoskopi	Gastrointestinal	Olympus	X	X	X	X	X
		Endoskopi	Gastrointestinal	Olympus	X	X	X	X	X
		Gynækologisk-Obstetrisk Afdeling	Gynaecology	Karl Storz	X	X	X	X	
		Gynækologisk-Obstetrisk Afdeling	Gynaecology	Karl Storz	X	X	X	X	
(*continued*)	(*continued*)	Gastroenheden	Gastrointestinal	Karl Storz	X	X	X	X	X

Region	Hospital	Department	Surgical speciality	Manufacture	Functionalities				
					Peripheral equipment	Surgical equipment	Video routing	Documentation	Video streaming
		Gastroenheden	Gastrointestinal	Karl Storz	X	X	X	X	
		Gastroenheden	Gastrointestinal	Karl Storz	X	X	X	X	
		Gastroenheden	Gastrointestinal	Karl Storz	X	X	X	X	
		Anæstesiologisk Afdeling	Gastrointestinal	Olympus	X	X	X	X	X
		Anæstesiologisk Afdeling	Gastrointestinal	Olympus	X	X	X	X	X
	Nordsjællands Hospital, Hillerød	Anæstesiologisk Afdeling	Gastrointestinal	Olympus	X	X	X	X	
		Anæstesiologisk Afdeling	Gynaecology	Olympus	X	X	X	X	
	Rigshospitalet	Anæstesi- og Operationsklinikken, Center for Kræft og Organsygdomme	Gastrointestinal	Olympus	X	X	X	X	
(continued)	*(continued)*	Anæstesi- og Operationsklinikken, Center for Kræft og Organsygdomme	Urology	Olympus	X	X	X	X	X

Region	Hospital	Department	Surgical speciality	Manufacture	Functionalities				
					Peripheral equipment	Surgical equipment	Video routing	Documentation	Video streaming
		Anæstesi- og Operationsklinikken, Juliane Marie Centret	Gynaecology	Karl Storz	X	X	X	X	X
		Børnekirurgisk afsnit	Paediatrics	Olympus	X	X	X	X	
		Thoraxanæstesiologisk Klinik	Cardiothoracic	Olympus	X	X	X	X	
		Thoraxanæstesiologisk Klinik	Cardiothoracic	Olympus	X	X	X	X	X
Central Denmark Region	Aarhus Universi-tetshospital	Operationsafsnit for Kvinde- og Urinvejs-sygdomme	Gynaecology/urology	Karls Storz	X	X	X	X	X
		Lungekirurgisk Afsnit, Hjerte-, Lunge- og Karkirurgi	Cardiothoracic	Karl Storz	X	X	X	X	X
		Bedøvelse og Operation	Gastrointestinal	Olympus	X	X	X	X	
(*continued*)	*(continued)*	Klinik for Kikkertundersøgelser	Gastrointestin	Olympus	X	X	X	X	X
		Bedøvelse og Operation, Børn & Unge	Paediatrics and adolescents	Karl Storz	X	X	X	X	X

Region	Hospital	Department	Surgical speciality	Manufacture	Functionalities				
					Peripheral equipment	Surgical equipment	Video routing	Documentation	Video streaming
	Regionshospitalet Horsens	Operation og Opvågning	Multiple	Olympus	X	X	X	X	X
		Operation og Opvågning	Multiple	Olympus	X	X	X	X	X
		Operation og Opvågning	Multiple	Olympus	X	X	X	X	
		Operation og Opvågning	Multiple	Olympus	X	X	X	X	
North Denmark Region	Aalborg Universi-tetshospital	Operationsafsnit for Mave- og Tarmkirurgi	Gastrointestinal	Karl Storz	X	X	X	X	X
		Operationsafsnit for Mave- og Tarmkirurgi	Gastrointestinal	Karl Storz	X	X	X	X	
	(continued)	Operationsafsnit for Mave- og Tarmkirurgi	Gastrointestinal	Karl Storz	X	X	X	X	X
(continued)		Operationsafsnit Nord	Urology	Olympus	X	X	X	X	
		Operationsafsnit Nord	Gynaecology	Olympus	X	X	X	X	

Region	Hospital	Department	Surgical speciality	Manufacture	Functionalities				
					Peripheral equipment	Surgical equipment	Video routing	Documentation	Video streaming
	Regionshospital Nordjylland, Hjørring	Almen Kirurgisk Operationsafsnit (AKO)	Gastrointestinal	Olympus	X	X	X	X	
		Almen Kirurgisk Operationsafsnit (AKO)	Gastrointestinal	Olympus	X	X	X	X	
Region Zealand	Holbæk Sygehus	Kirurgisk Afdeling	Gynaecology	Olympus	X	X	X	X	
	Nykøbing F. Sygehus	Kirurgisk Afdeling	Gastrointestinal	Karl Storz	X	X	X	X	
	Næstved Sygehus	Anæstesiologisk Afdeling *(not in use)*	Multiple	Karl Storz	X	X	X	X	
(continued)	Sjællands Universi-tetshospital, Køge	Kirurgisk Afdeling	Gastrointestinal	Karl Storz	X	X	X	X	X
	(continued)	Kirurgisk Afdeling	Gastrointestinal	Karl Storz	X	X	X	X	X
		Kirurgisk Afdeling	Gastrointestinal	Karl Storz	X	X	X	X	X

Region	Hospital	Department	Surgical speciality	Manufacture	Functionalities				
					Peripheral equipment	Surgical equipment	Video routing	Documentation	Video streaming
	Sjællands Universi-tetshospital, Roskilde	Kirurgisk Afdeling	Urology	Olympus	X	X	X	X	
		Kirurgisk Afdeling	Gynaecology	Olympus	X	X	X	X	
		Kirurgisk Afdeling	Urology	Olympus	X	X	X	X	X
		Kirurgisk Afdeling	Gynaecology	Olympus	X	X	X	X	X
		Kirurgisk Afdeling	Gastrointestinal	Olympus	X	X	X	X	X
		Kirurgisk Afdeling	Gastrointestinal	Olympus	X	X	X	X	
(continued)	Slagelse Sygehus	Kirurgisk Afdeling	Gastrointestinal	Olympus	X	X	X	X	X
	(continued)	Kirurgisk Afdeling	Gastrointestinal	Olympus	X	X	X	X	X
Region of Southern	Kolding Sygehus,	Organkirurgi/Gynækologi	Gastrointestinal	Olympus	X	X	X	X	X

Region	Hospital	Department	Surgical speciality	Manufacture	Functionalities				
					Peripheral equipment	Surgical equipment	Video routing	Documentation	Video streaming
Denmark	Sygehus Lillebælt	Organkirurgi/Gynækologi	Gastrointestinal and gynaecology	Karl Storz	X	X	X	X	X
		Organkirurgi/Gynækologi	Gastrointestinal and gynaecology	Karl Storz	X	X	X	X	X
		Organkirurgi/Gynækologi	Gastrointestinal and gynaecology	Karl Storz	X	X	X	X	X
		Dagkirurgisk Afdeling	Orthopaedic	Stryker	X	X	X	X	X
	Odense Universi-tetshospital	Gynækologisk Obstetrisk Afdeling D	Gynaecology	Olympus	X	X	X	X	X
		Kirurgisk Afdeling A	Gastrointestinal	Karl Storz	X	X	X	X	X
(*continued*)	*(continued)*	Hjerte-, Lunge- og Karkirurgisk Afdeling T	Cardiothoracic and vascular	Olympus	X	X	X	X	X
		Urinvejskirurgisk Afdeling L	Urology	Karl Storz	X	X	X	X	X
	Odense Universitets-hospital, Sygehusen-	Kirurgisk Afdeling A	Gastrointestinal	Olympus	X	X	X	X	

Region	Hospital	Department	Surgical speciality	Manufacture	Functionalities				
					Peripheral equipment	Surgical equipment	Video routing	Documentation	Video streaming
	heden i Nyborg								
	Svendborg Sygehus	Kirurgisk Afdeling A	Gastrointestinal	Olympus	X	X	X	X	X
		Kirurgisk Afdeling A	Gastrointestinal	Olympus	X	X	X	X	X
	Sydvestjysk Sygehus, Esbjerg	Kirurgisk Afdeling	Gastrointestinal	Olympus	X	X	X	X	
		Kirurgisk Afdeling	Gastrointestinal	Olympus	X	X	X	X	X
	Sygehus Sønderjyl-land, Aabenraa	Afsnit for Kirurgi	Gastrointestinal	Olympus	X	X	X	X	
(*continued*)	Vejle Sygehus, Sygehus Lillebælt	Dagskirurgisk afdeling	Orthopaedic	Stryker	X	X	X	X	X
		Organ- og Plastikkirurgisk Afdeling	Urology	Olympus	X	X	X	X	X
			Urology	Olympus	X	X	X	X	X

* This table is based on information provided by Olympus, Karl Storz and Stryker. Hospital and department names are stated in Danish in order to maintain and specify the exact place of the integrated operating room. The information is based on the best available knowledge at the time of writing.

APPENDIX 3: INVITED AND PARTICIPATING INFORMANTS IN INTERVIEWS

Region	Hospital	Speciality	Surgeon	Surgical nurse	Anaesthesia nurse
North Denmark Region	Regionshospital Nordjylland, Hjørring	Gastrointestinal surgery	o	x	
Central Denmark Region	Aarhus Universitetshospital	Gastrointestinal surgery	x	x	x
		Cardiothoracic and vascular surgery	x	x	
		Gynaecological surgery	x	x	x
	Regionshospitalet Horsens	Gastrointestinal surgery	x	o	o
Region of Southern Denmark	Odense Universitetshospital	Gynaecological surgery	x	x	x
The Sealand Region	Roskilde Sygehus	Gastrointestinal surgery	x	x	
		Urological surgery	x		
	Holbæk Sygehus	Gastrointestinal surgery	o		
The Capital Region	Rigshospitalet	Paediatric surgery	x	x	
	Hvidovre Hospital	Gastrointestinal surgery	x	x	

X indicates participation in interview.

0 indicates invited for participation but no participation in interview.

Empty space indicates not invited for participation in interview

APPENDIX 4: INTERVIEW GUIDES, ORGANISATIONAL ASPECTS (ORG)

Interviewguide: Kirurger

Forandringer

Kan du prøve at beskrive, hvordan arbejdsprocesserne i forbindelse med operationer på en integreret operationsstue adskiller sig fra operationer på en konventionel operationsstue?

I hvor høj grad gør du brug af de forskellige funktionaliteter, der er omfattet af integrationen?

Firmaerne bag de integrerede operationsstuer angiver, at tiden til forberedelse og operation mindskes ved anvendelse af integrerede operationsstuer. Hvordan oplever du dette?

Firmaerne bag de integrerede operationsstuer angiver, at sikkerheden for patienterne øges ved anvendelse af integrerede operationsstuer. Hvordan oplever du dette?

Hvilke forandringer oplever du, at implementeringen af den integrerede operationsstue har medført for jeres samarbejde og kommunikation på operationsstuen?

Forudsætninger

Hvad forudsætter anvendelse af integrerede operationsstuer af jer som kirurger?

Hvordan foregår kirurgisk oplæring til at kunne anvende integrerede operationsstuer?

Hvordan ser læringskurven ud for anvendelsen af integrerede operationsstuer?

Hvordan er udbredelsen af kompetencer i at operere på den integrerede operationsstue blandt kirurger og øvrigt operationspersonale?

Konsekvenser

Hvordan vil du beskrive personalets holdning til den integrerede operationsstue?

Hvilke udfordringer/potentielle negative konsekvenser ser du ved anvendelsen af integrerede operationsstuer?

Hvilke muligheder/positive gevinster ser du ved anvendelsen af integrerede operationsstuer?

I hvilken grad oplever du, at I udnytter potentialet i den integrerede operationsstue?

Hvilke fordele/ulemper ser du i at udbrede integrerede operationsstuer?

Interviewguide: Sygeplejersker

Forandringer

Kan du prøve at beskrive, hvordan jeres arbejdsprocesser som sygeplejerske på hhv. gulv og i det sterile felt i forbindelse med operationer på en integreret operationsstue adskiller sig fra operationer på en konventionel operationsstue?

Firmaerne bag de integrerede operationsstuer angiver, at tiden til forberedelse og operation mindskes ved anvendelse af integrerede operationsstuer. Hvordan oplever du dette?

Firmaerne bag de integrerede operationsstuer angiver, at sikkerheden for patienterne øges ved anvendelse af integrerede operationsstuer. Hvordan oplever du dette?

Hvilke forandringer oplever du, at implementeringen af den integrerede operationsstue har medført for jeres samarbejde på operationsstuen?

Forudsætninger

Hvordan har I blandt sygeplejerskerne organiseret jer i forhold til den integrerede operationsstue?

Hvilke forudsætninger kræver anvendelse af den integrerede operationsstue for sygeplejersker?

Hvordan oplever du, at I udnytter potentialet i den integrerede operationsstue?

Hvordan foregår oplæring af sygeplejersker til at kunne anvende den integrerede operationsstue?

Hvilke udfordringer oplever I i forbindelse med oplæringen?

Hvordan ser læringskurven for sygeplejersker ud for anvendelsen af integrerede operationsstuer?

Konsekvenser

Blandt dine sygeplejerskekolleger, hvordan vil du beskrive holdningen til den integrerede operationsstue?

Hvilke udfordringer/potentielle negative konsekvenser ser du ved anvendelsen af integrerede operationsstuer?

Hvilke muligheder/positive gevinster ser du ved anvendelsen af integrerede operationsstuer?

Interviewguide: Anæstesi

Forandringer

Oplever du, at implementeringen af den integrerede operationsstue har medført forandringer for jeres arbejdsgange på operationsstuen som anæstesipersonale?

Oplever du, at implementeringen af den integrerede operationsstue har medført forandringer i samarbejdet på operationsstuen?

Forudsætninger

Hvordan har I i anæstesien organiseret jer i forhold til den integrerede operationsstue?

Hvilke forudsætninger kræver anvendelse af den integrerede operationsstue for jer i anæstesien?

Hvordan foregår oplæring af anæstesilæger og anæstesisygeplejersker til at kunne anvende den integrerede operationsstue?

Konsekvenser

Blandt dine kolleger i anæstesien, hvordan vil du beskrive holdningen til den integrerede operationsstue?

Hvilke udfordringer/potentielle negative konsekvenser ser du ved anvendelsen af integrerede operationsstuer?

Hvilke muligheder /positive gevinster ser du ved anvendelsen af integrerede operationsstuer?