CLINICAL WORKFLOW AND HUMAN FACTORS IN OT DESIGN: THE ROOM IS THE SYSTEM

EuHPN Workshop Copenhagen, 28.3.2023

Discolsure

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Clemens Bulitta MD, is a consultant to Avidicare AB, Lund, Sweden.

The world and the OR have evolved…

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Source: Advisory Board Company, Dräger

The world and the OR have evolved…

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The world and the OR have evolved…

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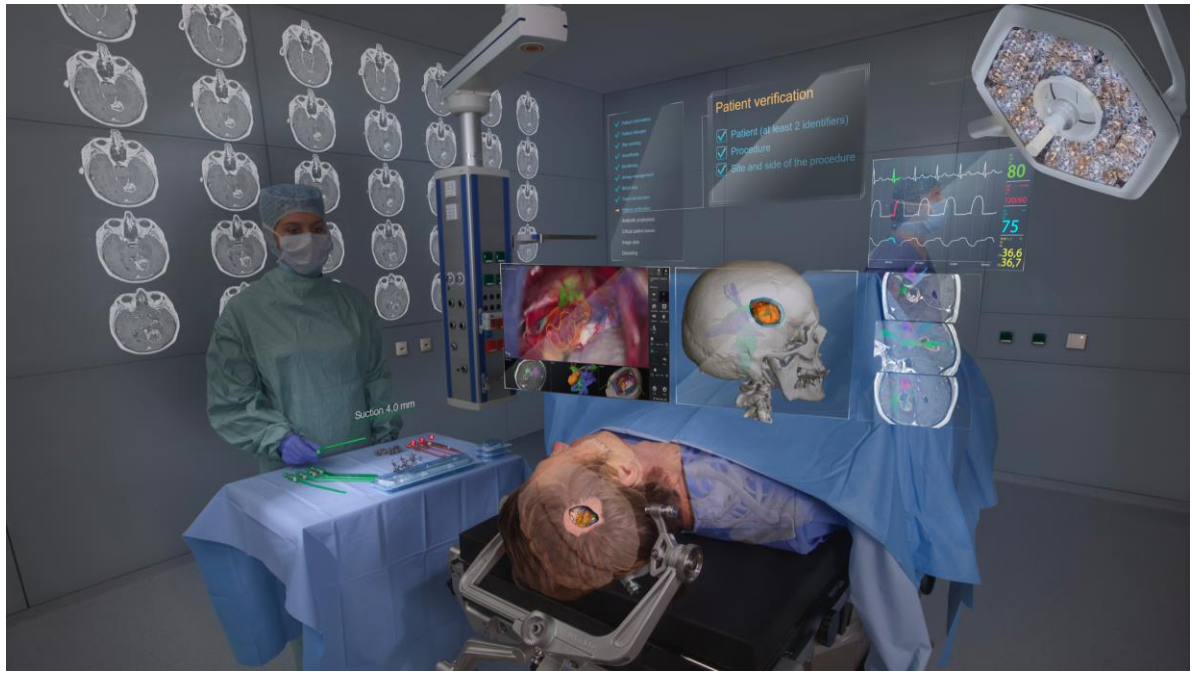
BRAINLAB



BRAINLAB

Hightech: Benefit and Danger

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THE LANCET

"Medicine used to be simple, ineffective and relatively safe; now it is complex, effective and dangerous."

Chantler C. Lancet 1999;353(9159):1178-81

What does this mean…and…how do we do it…

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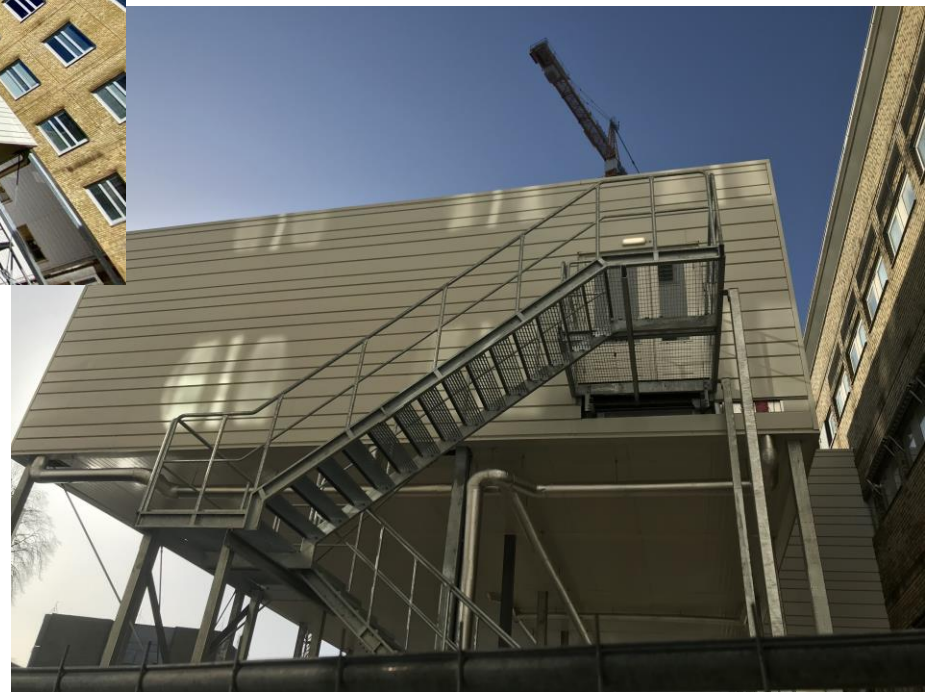

Q-bital / Vanguard in cooperation with Avidicare

Flexible OT

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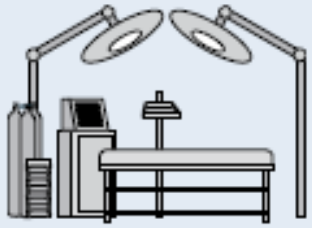
OR Design Imperatives

Imperative #1



Rightsizing the OR

Accommodating technologies without crowding out staff

Imperative #2

Installing an Adaptable Infrastructure

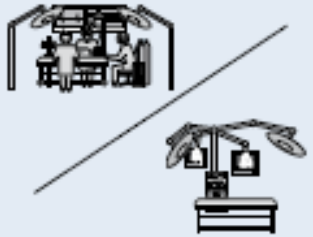
Anticipating changes in surgical offerings

Imperative #3

Anticipating Future Technology Demands

Maximizing future technology compatibility, integration

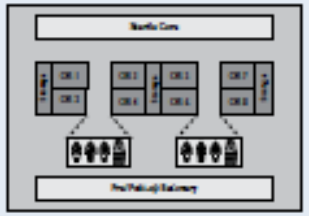
Imperative #4



Balancing General and Specialty Needs

Customizing ORs only when necessary, prudent

Imperative #5



Configuring Suites Around Service Line Strategy

Configuring spaces that align with processes, priorities

Source: Advisory Board Company

Flexible OT - Versatility

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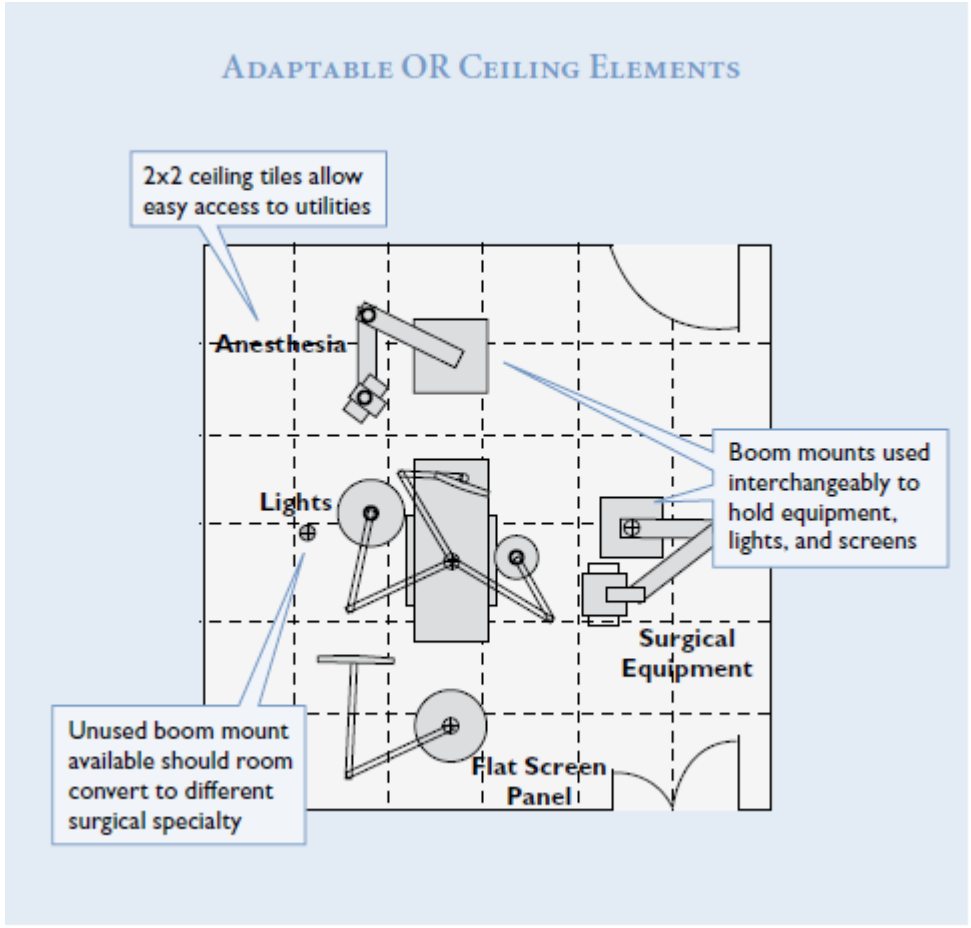
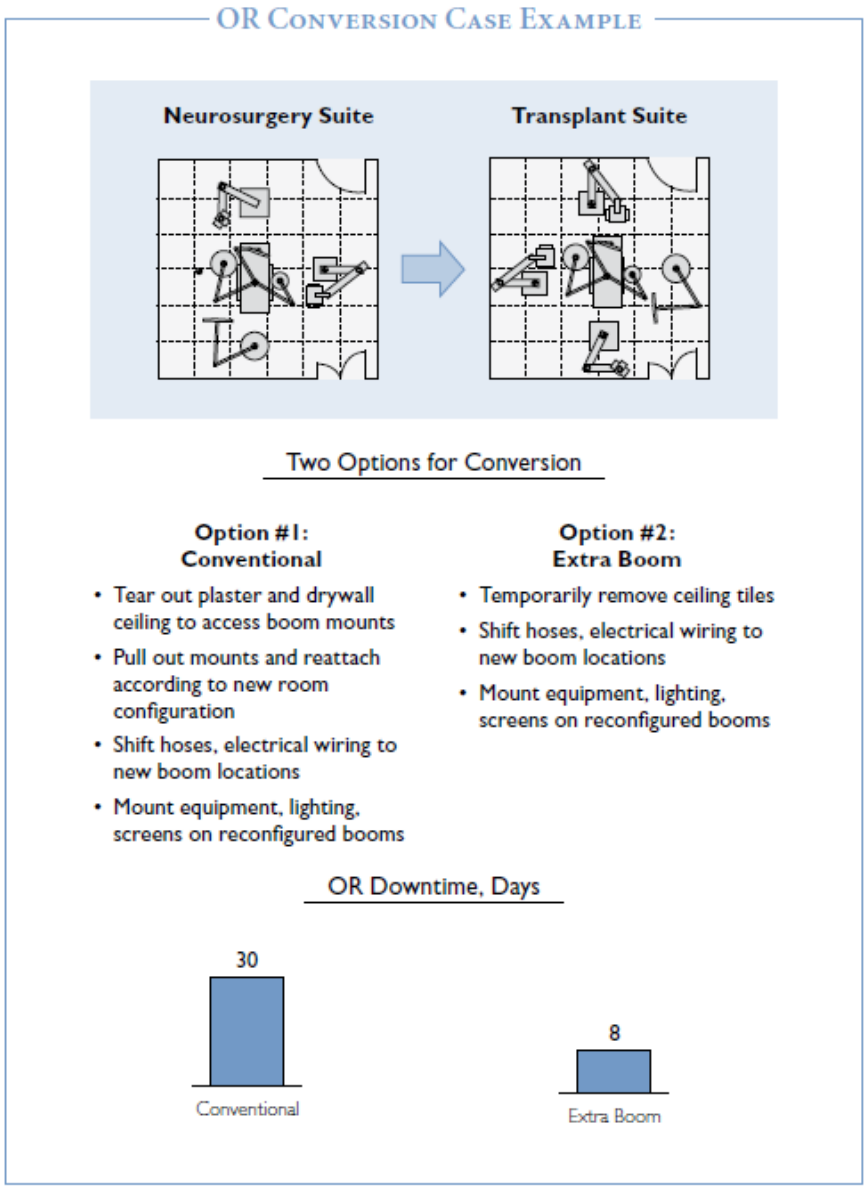
Source: Advisory Board Company





Standard Design

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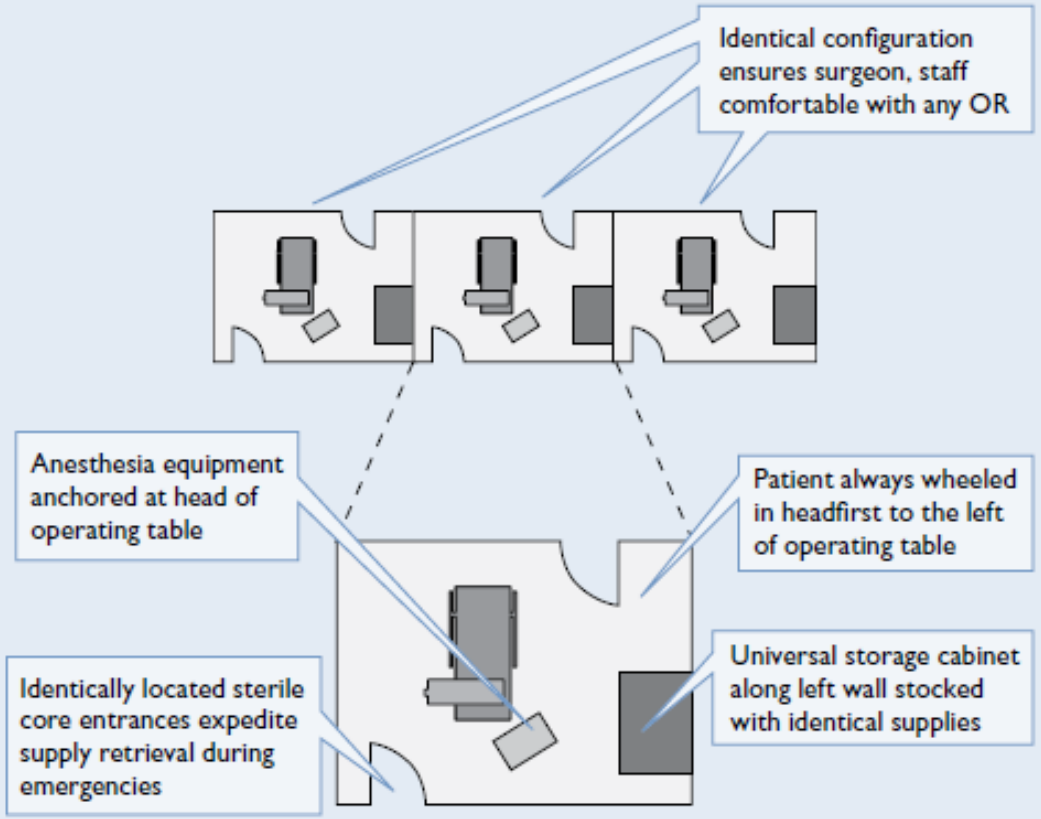
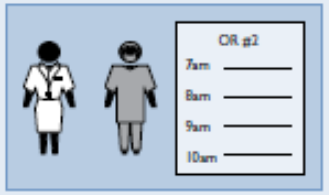
The Same-Handed OR

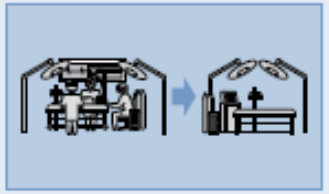


Universal Design Benefits

Reducing Mid-procedure Delays
Circulating nurses no longer squander critical time searching for supplies, equipment during operation



Improving Scheduling Flexibility
Surgeons, nurses equally familiar with each OR's layout, less inclined to demand specific ORs



Expediting Room Turnover
Fewer delays in room preparation, clean-up due to staff's inability to find outlets, materials, and equipment

Source: Advisory Board Company

Room Planning goes further than most people expect

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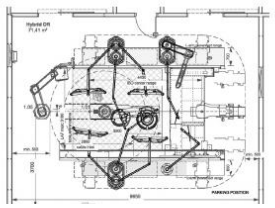
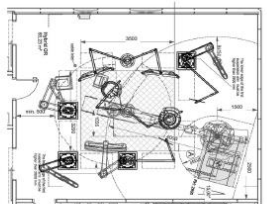
Quellen und Forschung zur Medizintechnik und Hygiene

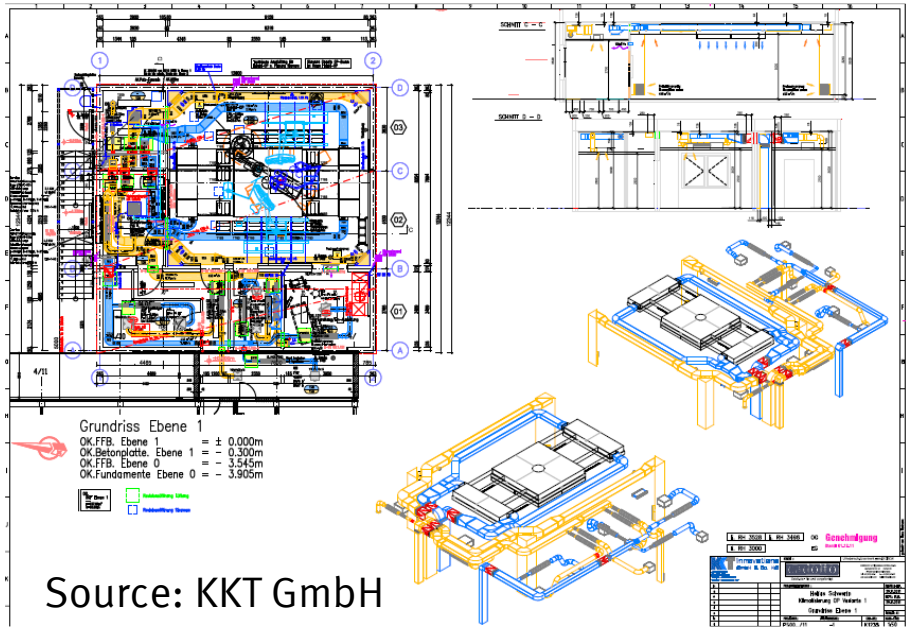
Hybrid-Operationssaal mit Angiographiesystem

- Planungshilfe -

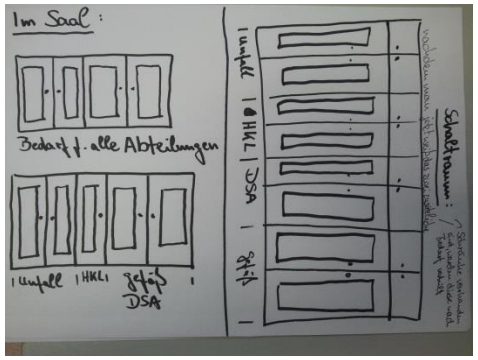




Inhalt



Source: KKT GmbH



Challenge Human-Machine Interface

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Source: Getinge


léger comme l'oiseau, et non comme la plume
040636

- > 400 Caffè / hour
- 24/7 in the high saison
- Focused, happy, service mind-set

- Caffè, caffè lungo, deca, in tazza, nel vetro
- Cappuccino, chiaro, tiepido, di soia
- Latte macchiato, macchiato doppio
- Macchiatone in tazza piccola, in tazza grande

Hightech OT Projects are Solution Business

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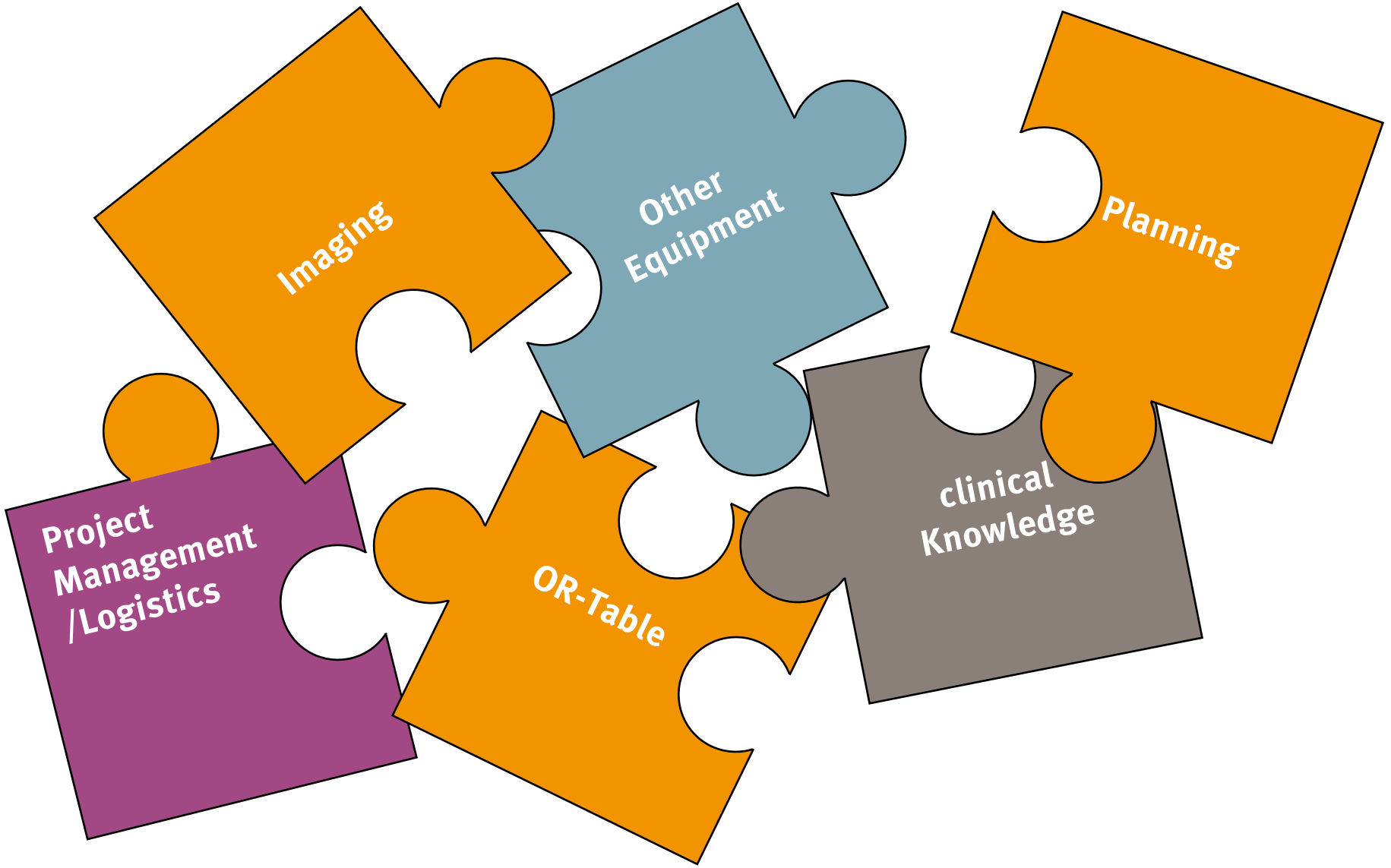

Hightech OT Projects are Solution Business

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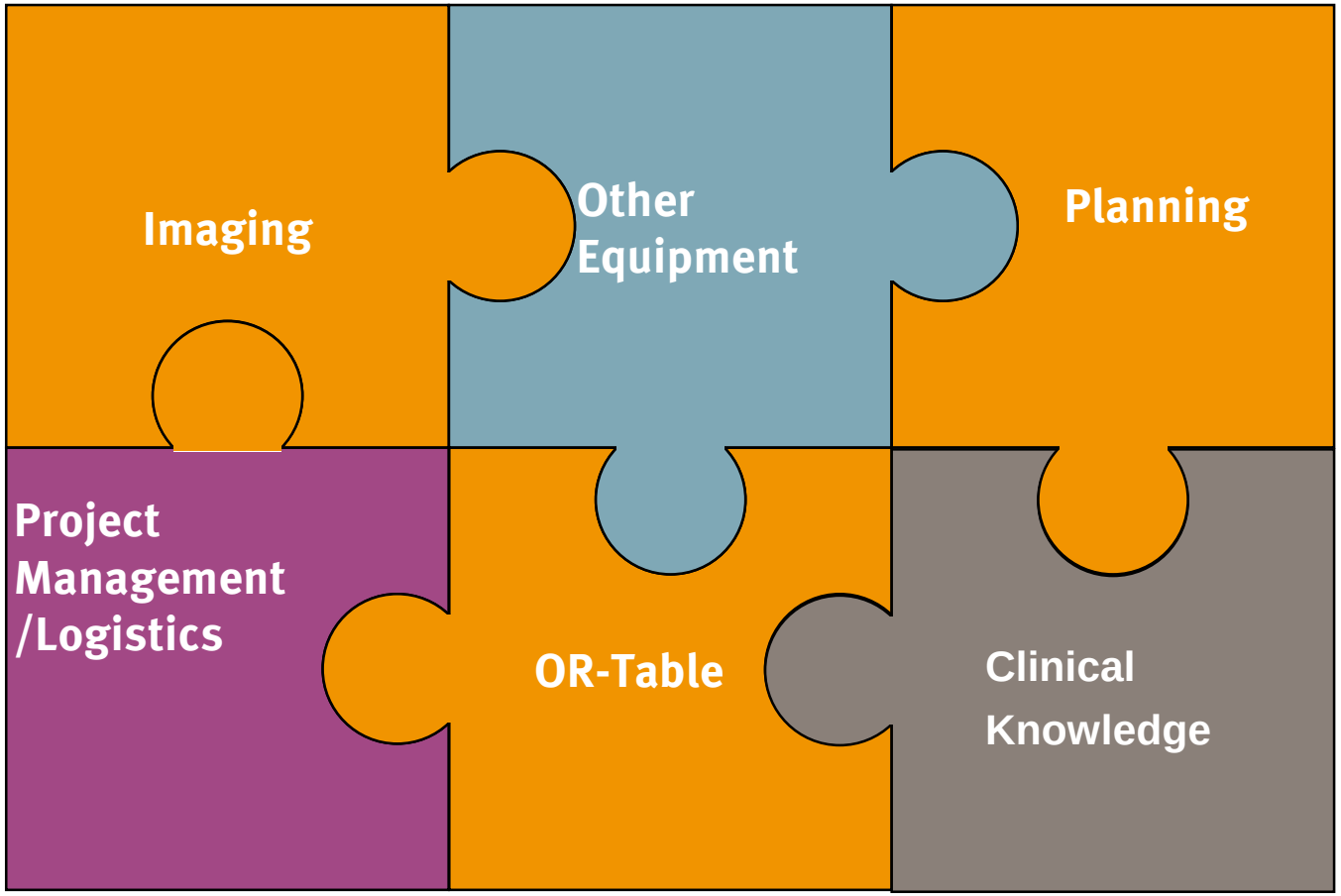

The Room is the SYSTEM!!!

Involve all stakeholders as early as possible in the project for workflow and requirement assessment

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Discuss layout/concept with all involved parties on hospital and vendor side

Involved parties may be:

- Surgeons
- Cardiologists
- Interventionalists
- Technical director
- Hygienist
- Anesthetist
- Scrub nurses
- Radiographer
- Project Managers
- Vendor representatives
- Medical Equipment Planers
- Consultants
- ….

Workflow is key !

Clinical Workflow

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know how means,

comprehension of clinical operations:

- Clinical and operational processes
- process interfaces as well as

technical interfaces and application of the various technologies

➔ Who – What – How – By what means

Human Factors

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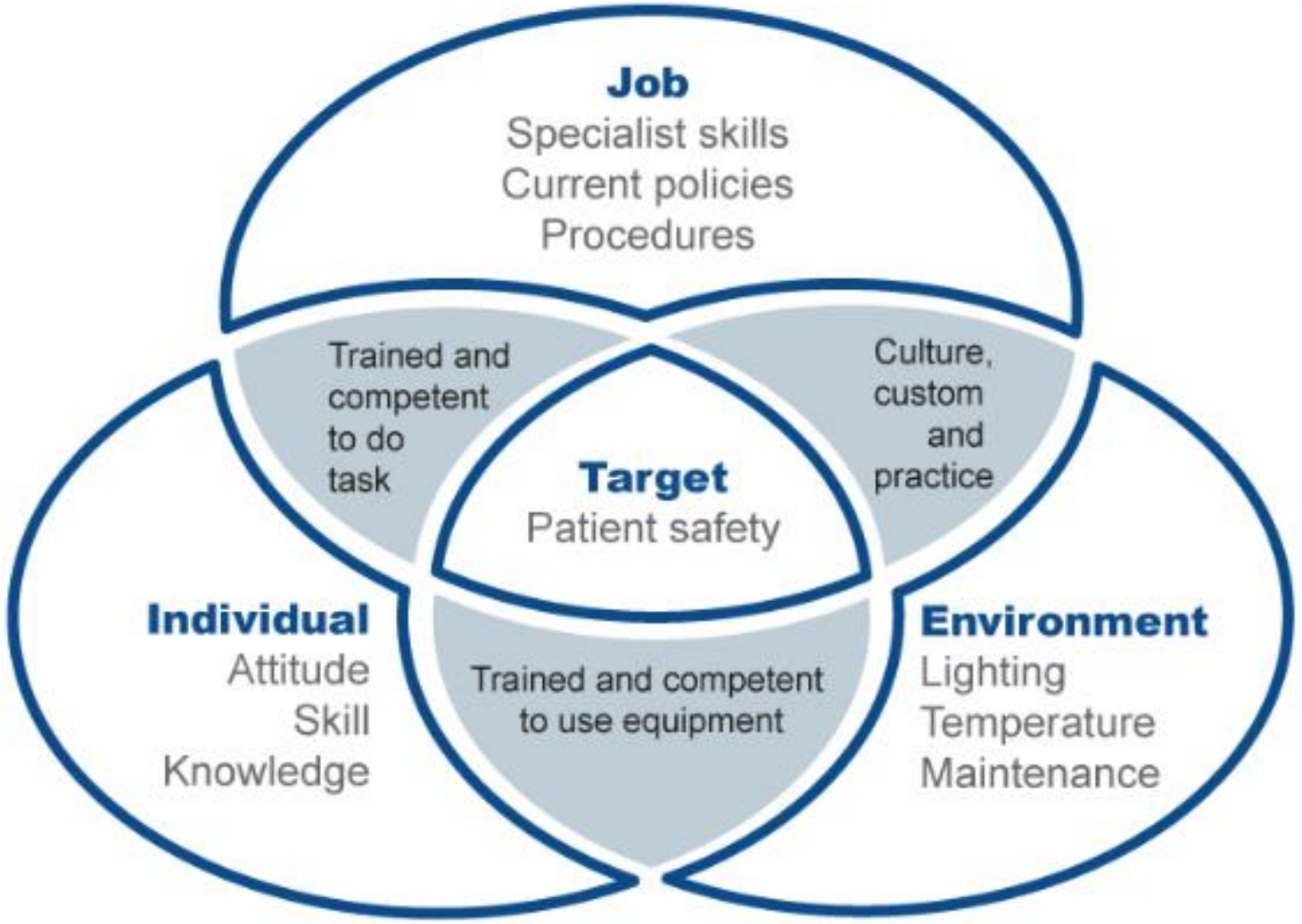
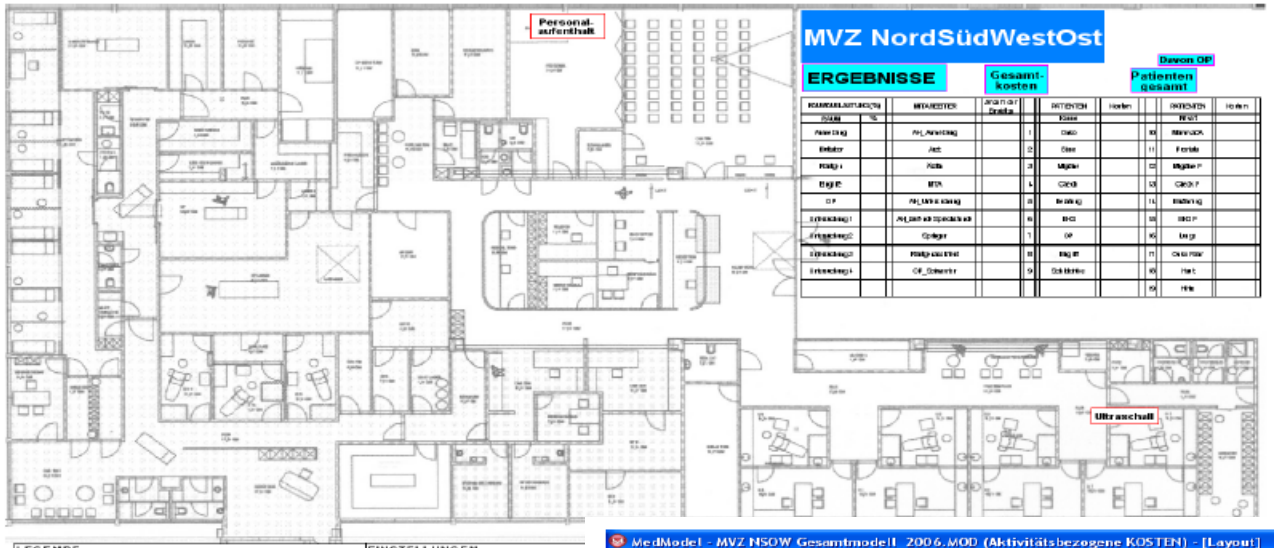
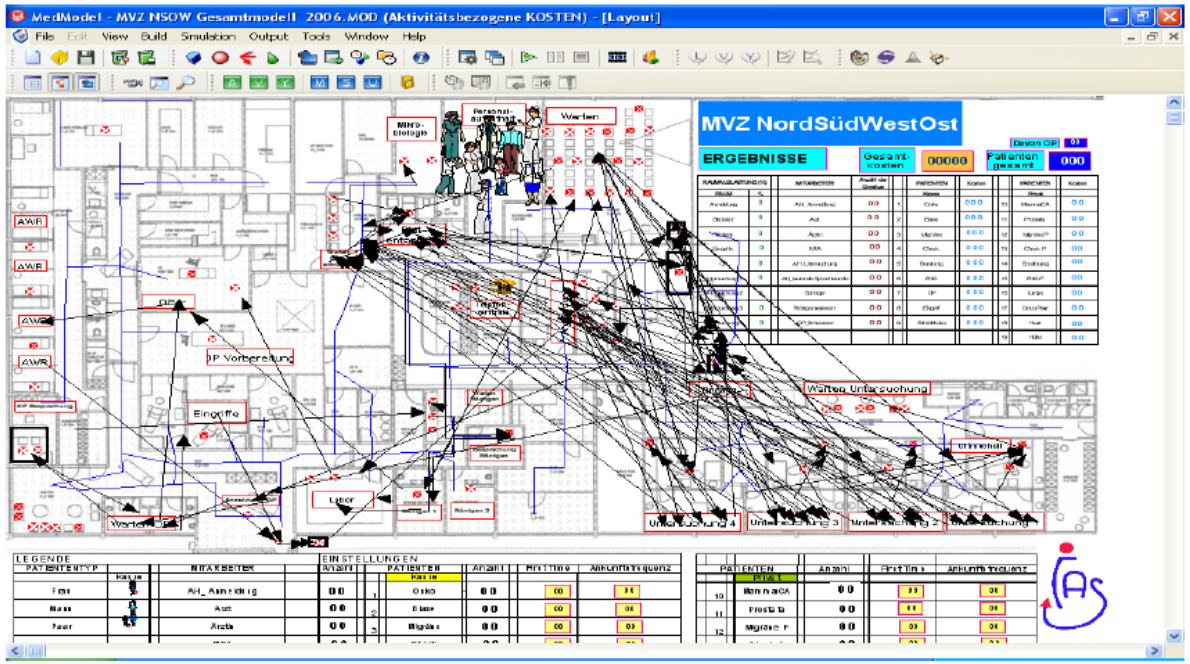


www2.rcn.org.uk





Quelle: Kühn, IAS

Mock up Session

Planning in 2D and Visualization in 3D

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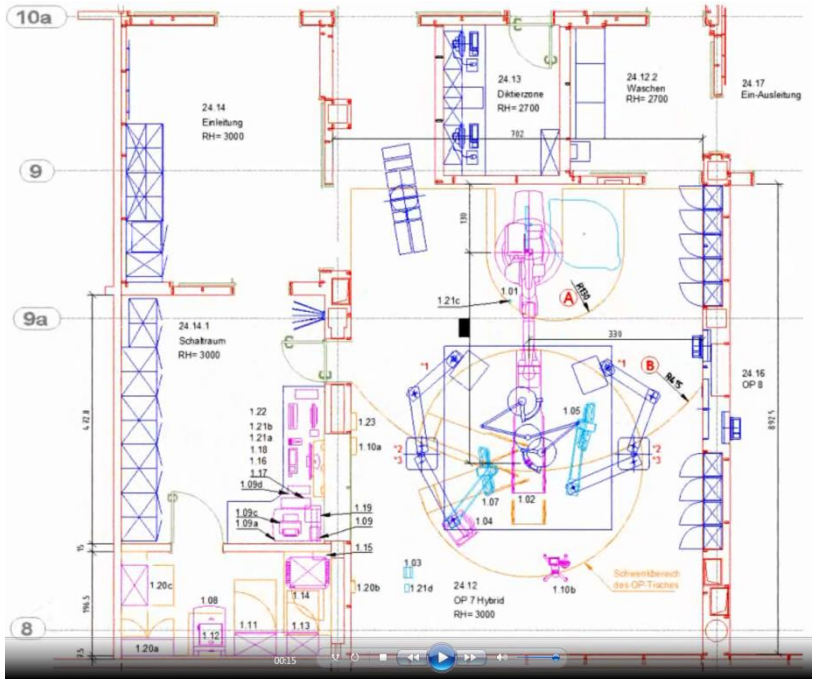

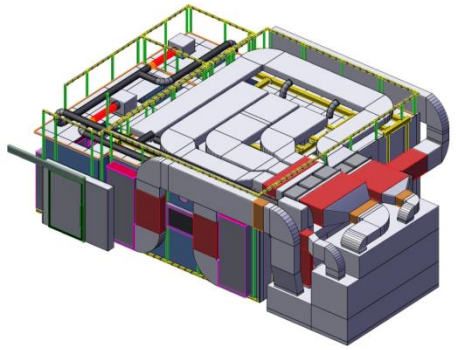

Source: Hybrid OR Project Kliniken Nordoberpfalz AG, Weiden Germany

EXAMPLE OT VENTILATION

Schematic display of the alternative ventilation systems

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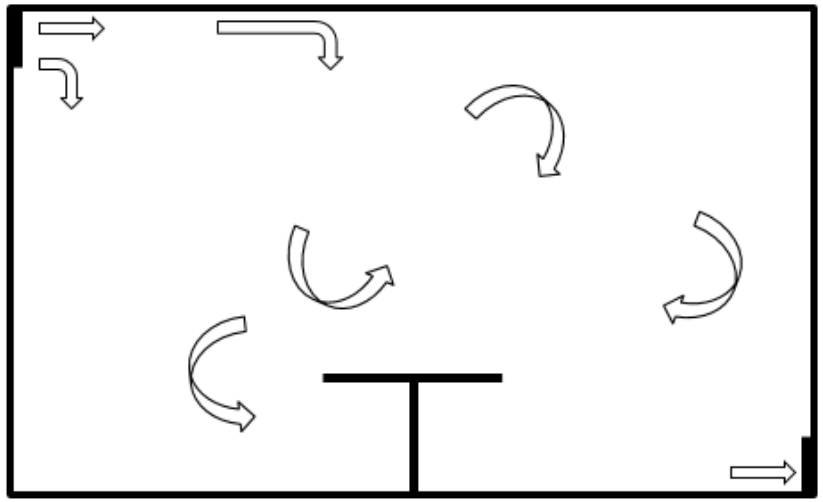
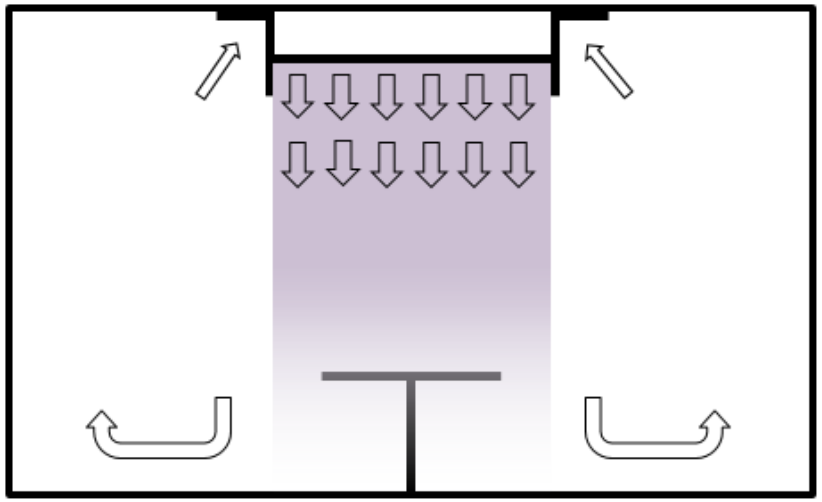


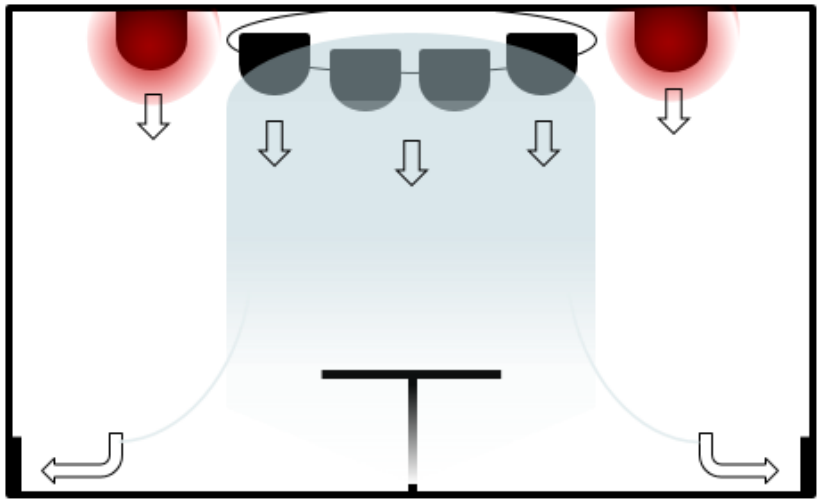
Turbulent

Mixing Ventilation - TMV



Low turbulence

Displacement Flow - TAV



Temperature controlled

Airflow - TcAF

Source: M. Alsved et al. / Journal of Hospital Infection 98 (2018) 181-190

Controversial Scientific Discussion

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Effect of laminar airflow ventilation on surgical site infections: a systematic review and meta-analysis

Peter Bischoff, N Zeynep Kubilay, Benedetta Allegranzi, Matthias Egger, Petra Gastmeier

Conclusion:

The available evidence shows no benefit for laminar airflow compared with conventional turbulent ventilation of the operating room in reducing the risk of SSIs in total hip and knee arthroplasties, and abdominal surgery. Decision makers, medical and administrative, should not regard laminar airflow as a preventive measure to reduce the risk of SSIs. Consequently, this equipment should not be installed in new operating rooms.

Lancet Infectious Diseases:
Published online February 16, 2017 http:l/dx.doi.org/10.1016/51473-3099(17)30059-2

Challenges regarding OT ventilation systems

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- **Multiple impacting factors**
- **Complex thermodynamic system**
  - Staff behavior - Human Factors
  - Changing „environment“
- **Different international standards and no uniform validation/performance assessment methodology**

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Risk factor airborne microorganisms

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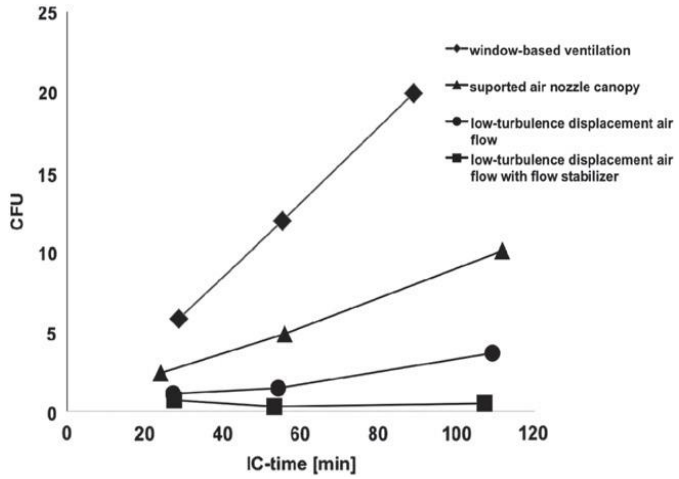
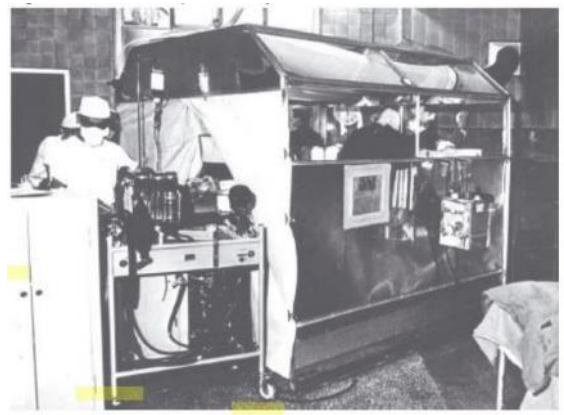
- Sir John Charnley (1959-1974):
  Reduction of surgical site infections after total hip replacement from 8,5% to 0,7% by reduction of airborne bacteria from 600 cfu/m³ to ‹1 cfu/m³
- Lidwell et al 1993 :
  Independent reduction of surgical site infections through antibiotic prophylaxis and improved air cleanliness. Ultraclean air defined at ‹10 cfu/m³



Comparison of the total germ immission with regard to increasing incision to closure time.



Source: American Journal of Infection Control xxx (2012) e1-e5, Hirsch et. al
Lidwell OM. Sir John Charnley, Surgeon (1911-82): the control of infection after total joint replacement. J Hosp Inf 1993;23:5-15

Challenge convection currents

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- Most surgical procedures have a similar “set-up". The patient on the operating table, 3-5 sterile dressed staff around the patient, 1-2 anesthesia staff at the patient's head end and 1-2 other staff elsewhere in the operating room.
- The majority of the generated cfu´s are released very close to the wound and the sterile instruments and must be transported away from there
- The effect of convection currents from staff is often neglected.

Comparison of two different OR garments

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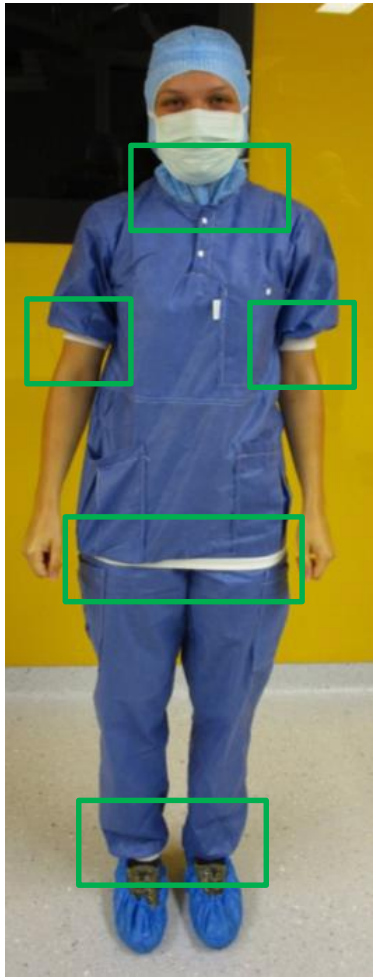

Challenges regarding OT ventilation systems

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- Multiple impacting factors
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Examples

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Examples

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Infection control in a complex environment: Example „planning“ and reality in the Hybrid OR

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Source: Maquet

Interferences with ventilation systems

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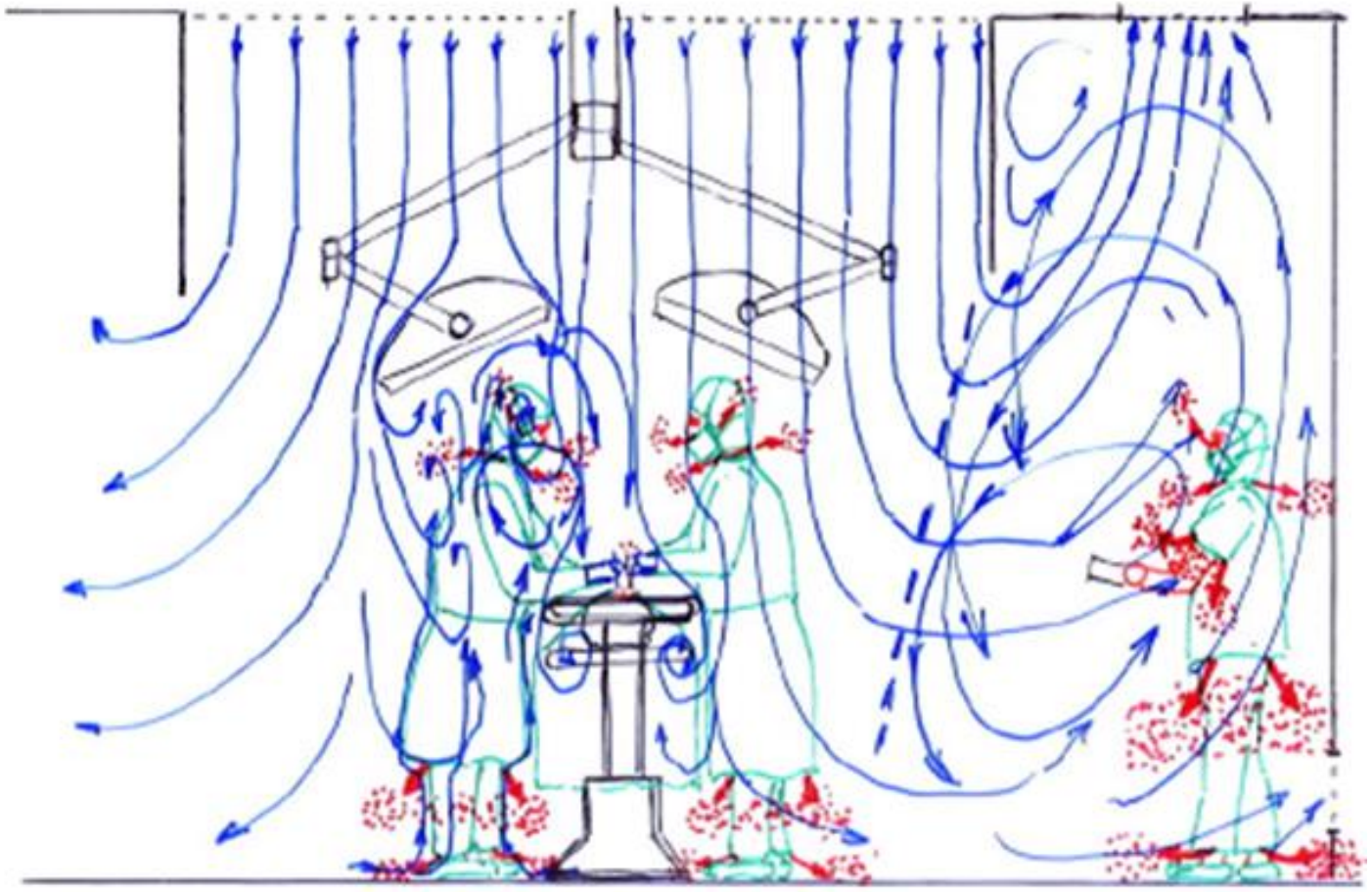

Source: P. Lüderitz, Krankenhaushygiene up2date, 3 2008

Example door opening

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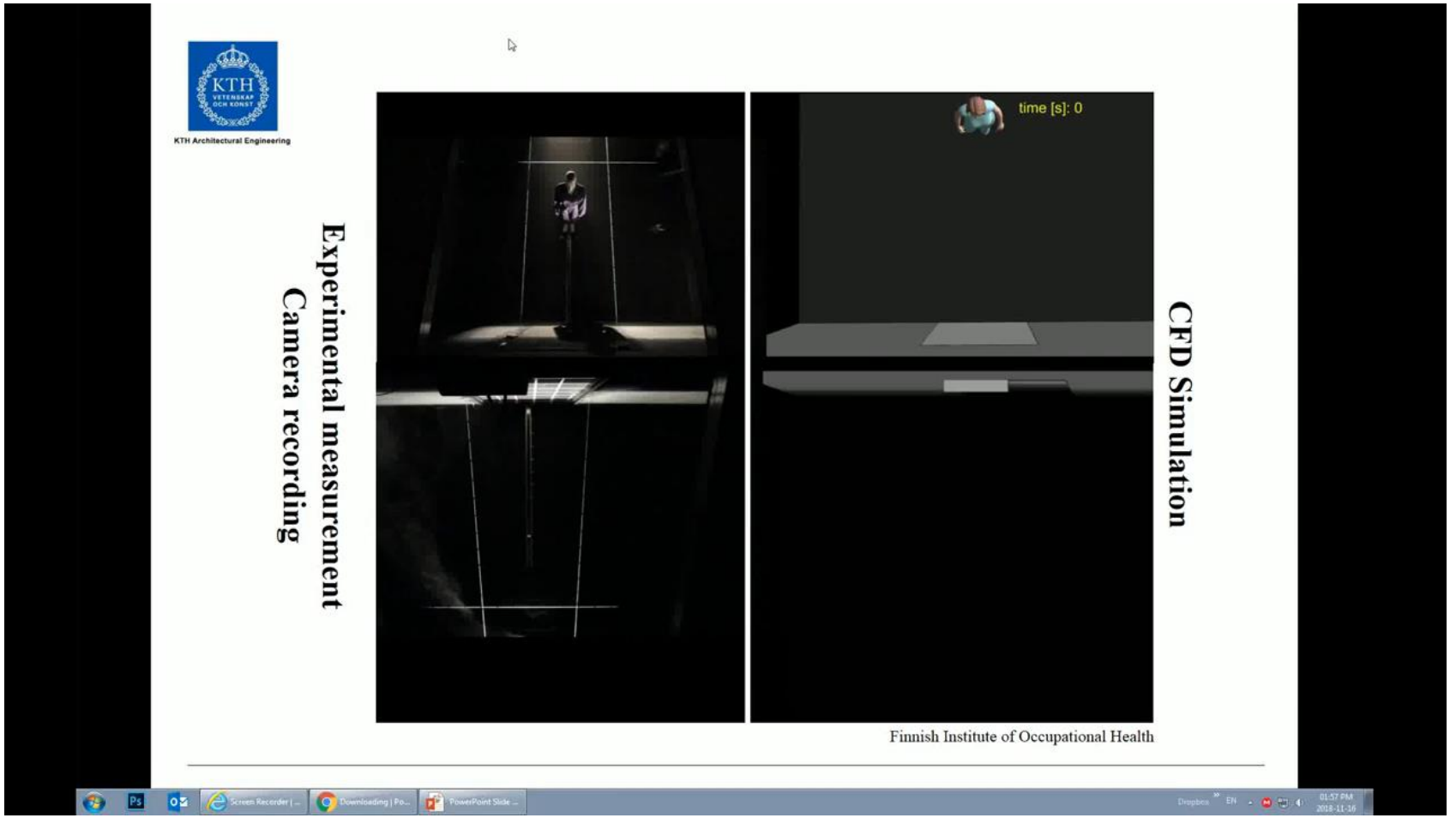

Workflow and positioning analysis are critical for infection prevention

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| Originalia

Keywords
Surgical site infections
LAF
Ia-OR
Ib-OR
Medical device contamination

Thomas Benen[1], Frank Wille[1]*, Lüder Clausdorff[2]
1 Hybeta GmbH, Münster
2 Ebendorfergrund

Influence of different ventilations systems upon the contamination of medical devices

Summary

Background: The sterility of the medical devices used in an operating rooms (OR) is one main aspect to avoid surgical site infections. This study analyzed the influence of different ventilations situations according the contamination of the medical devices.
Method: We analyzed laminar airflow ceilings (LAF) size 3.2 m x 3.2 m (Ia-OR) and turbulent ventilation systems (Ib-OR). The Ia-OR was successfully qualified with the protection degree measurement according the DIN 1946-4: 2008. The Ib-OR was qualified with a recovery test. Within the Ia-OR additional measurements were done outside of the protected area of the LAF to show the importance of this area.
Results: The results show a dependency between the contamination of the medical devices and the kind of ventilation system. The medical devices in the Ib-OR and out of the protection area are contaminated more often and with more germs than within the protection area under the LAF.
Discussion: It has to be questioned if under those ventilations systems the requirements of the medical device guideline (KRINKO/ BfArM-guideline) are fulfilled. The sterility of the medical devices until its use is one main aspect of this guideline. With this study we want to focus one until now rarely observed point of the intraurgical medical device contamination.
Hyg Med 2013; 38|4|142–146

Introduction

Some four years on from the amendment of DIN 1946-4:2008-12 on the use of heating, ventilation and air-conditioning (HVAC) systems in buildings and rooms used in the health care sector, the potential benefits of large airflow ceilings in OR rooms continue to elicit animated discussion (Table 1) [1]. This is due to the unclear study results. The findings of the studies carried out are contradictory with regard to infection prophylaxis [2–4]. Nor has light been cast on this situation by the commentary made by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) on DIN 1946-4:2008-12 [5]. While assignment of this matter to the category of 'unresolved issues' is scientifically comprehensible, the resultant conclusion, advocating discontinuation of the use of Ia-OR rooms is less understandable.

The greatest challenge when investigating the efficacy of ventilation systems derives from the fact that the impact of the ventilation system in the OR cannot be viewed in isolation. Among other influence factors is, in particular, the role of perioperative antibiotic prophylaxis, which is now a standard procedure, especially for endoprosthetic operations. However, all other risk factors mentioned in the KRINKO Recommendation for Prevention of Postoperative Surgical Site Infections play a role [6]. But many of these factors are dependent on the surgical team or patient, hence it is very difficult to assess their individual impact.

However, this situation can be greatly remedied by focusing exclusively on contamination of sterile instruments during an operation. Contaminated instruments can be the source of surgical site infections. Hence the KRINKO Recommendation for Prevention of Postoperative Surgical Site Infections cites observance of strict aseptic practices as being one of the most impor-

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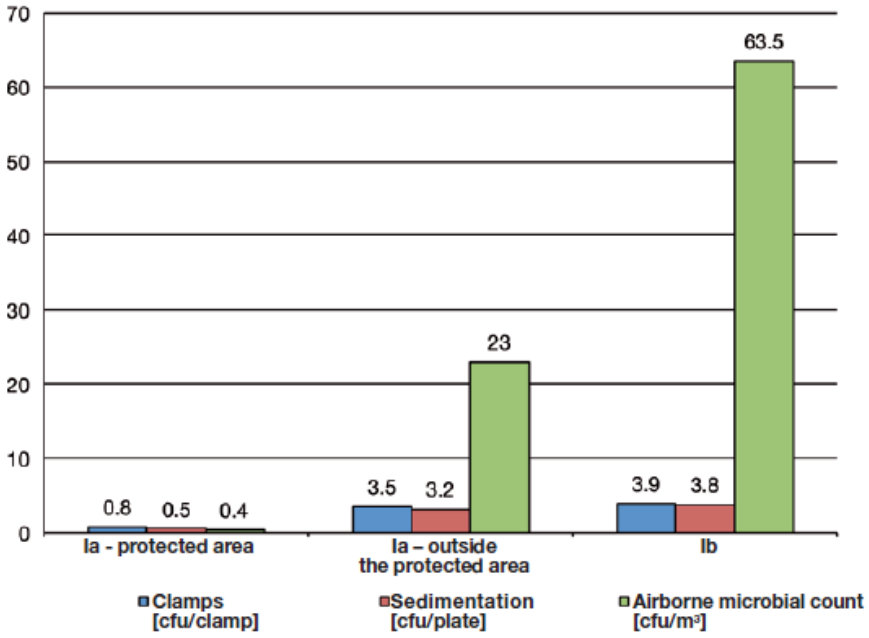

Figure 2: Comparison of airborne microbial count determination, of sedimentation plate and Crile clamp contamination levels for the various ventilation systems.

*Thomas Benen, Frank Wille, Lüder Clausdorff - Influence of different ventilations systems upon the contamination of medical devices, Hyg Med 2013; 38–4

LAF is not an adequate solution outside the immediate ultraclean zone around the OR-table

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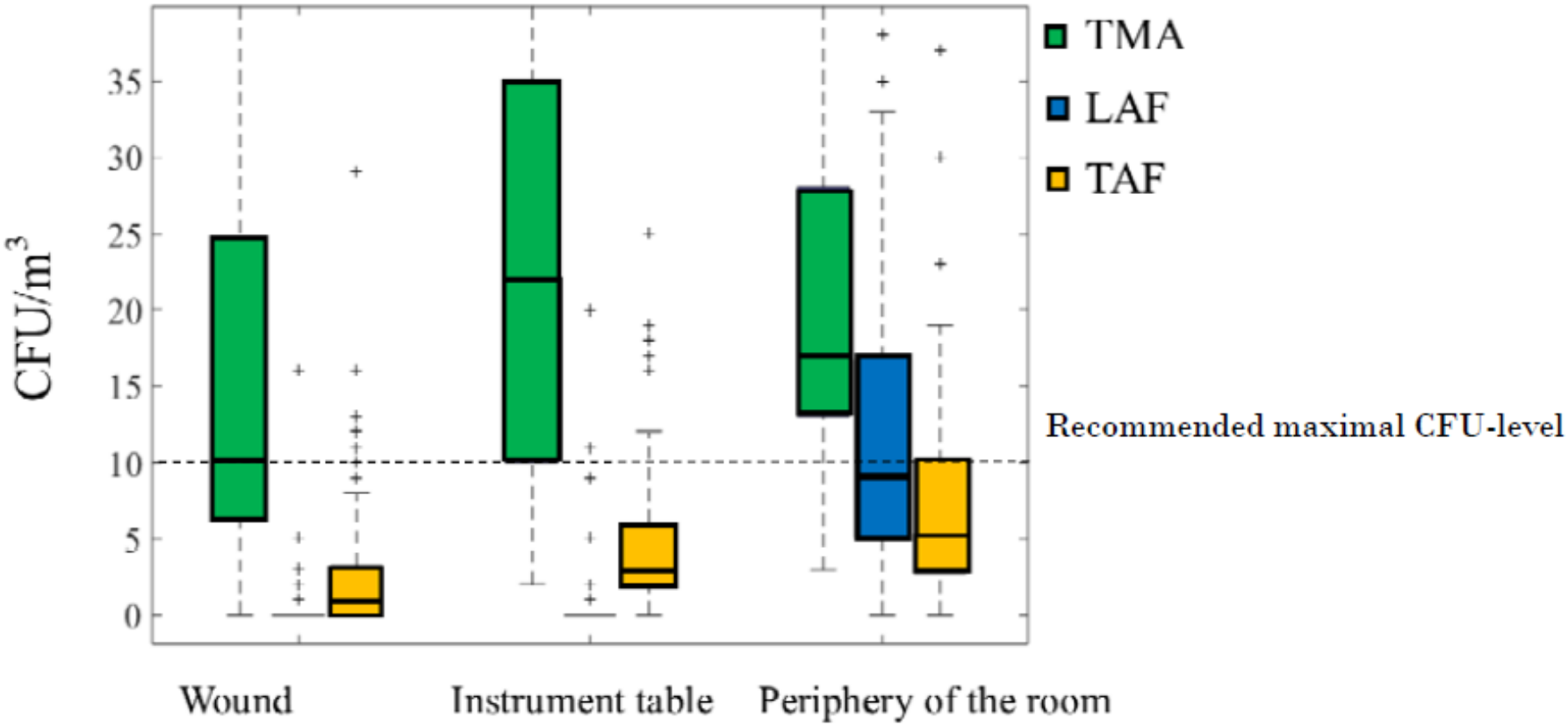

Source: M. Alsved et al. / Journal of Hospital Infection 98 (2018) 181-190

CFD Simulation of alternative ventilations systems (airflow velocities)

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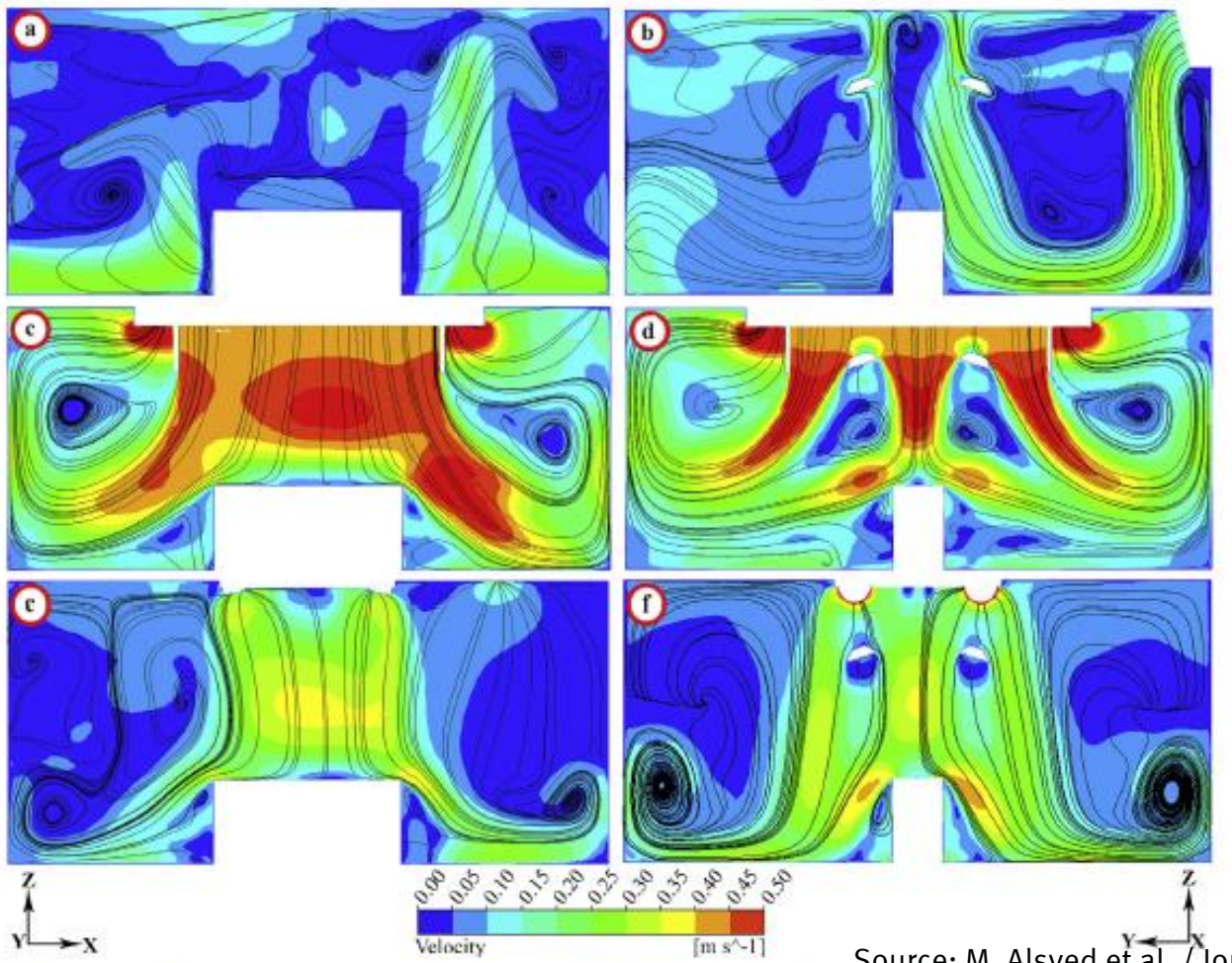

Turbulent mixing ventilation (TMV)

Low turbulence displacement flow (TAV)

Temperature controlled Airflow (TcAF)

Source: M. Alsved et al. / Journal of Hospital Infection 98 (2018) 181-190

How conventional LAF and TcAF compare

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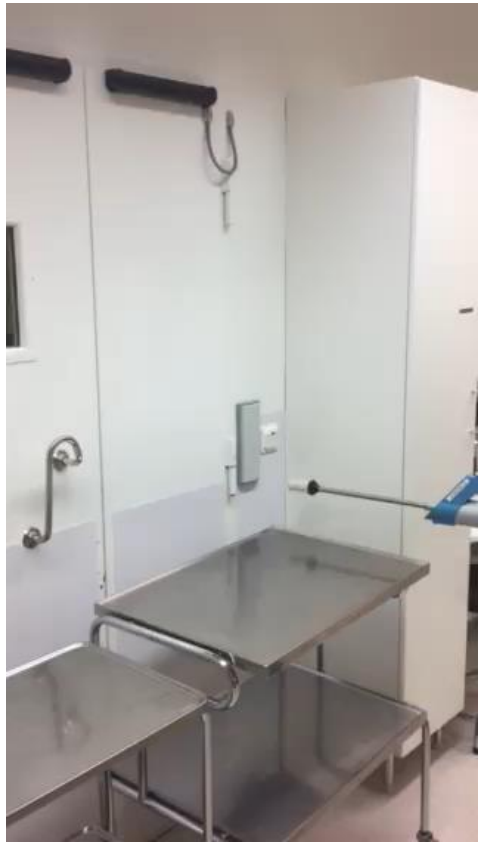

TAV is unable to protect the periphery whereas
TcAF maintains downward airflow throughout the room, including the periphery.

How conventional LAF and TcAF compare

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TAV is challenged by obstacles whereas TcAF “navigates” obstacles and maintains downward airflow.

Limitations of Conventional Laminar Air Flow (LAF)

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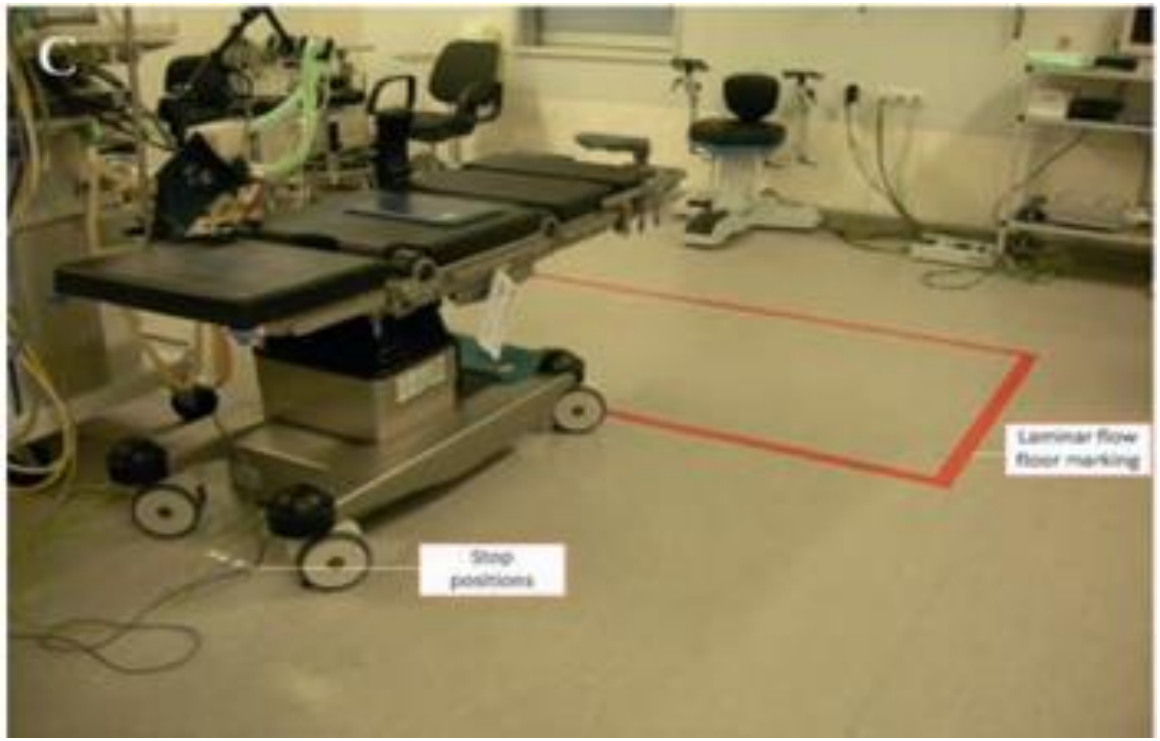
SSI guidance requires placement of surgical instruments, implants and devices within the ultraclean zone. But, how often is this requirement met?

Safety by design: Effects of operating room floor marking on the position of surgical devices to promote clean air flow compliance and minimize infection risks.

- Investigators used floor markings to evaluate frequency of positioning of surgical devices within the clean zone.
- Prior to marking, devices were in the clean zone in only 6.1% of surgeries, after marking 36-52% were in clean zone.



Basic Investigation and Assessment according to DIN 1946-4:2018-09

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A.2.3 Basic investigation

- Describing the functions and activities.
- Describing processes.
- Relevant regulations, standards, guidelines.
- Resources.
- Choice of location, structural dimensions, infrastructure.
- Future prospects (laws, standards, changes in medical treatment procedures).
- Consideration of the medical tasks and the strategic planning for future treatments and equipment requirements
- Positioning analysis

Source: DIN 1946-4:2018-08

Approach

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1. To determine the protected area, the known worst-case situation with regard to the area occupied by the respective operative specialty must be used as a setup.
2. All necessary materials, people, tables (instrument and side tables) as well as medical equipment (e.g. X-ray C-arm, surgical microscope, etc.) must be taken into account.
3. Due to the physical properties of the downflow in a LAF ventilation ceiling, an additional surcharge of approx. 15-20cm on each long side of the protected area must be added to the area of the protected area that is then determined. This is due to the physical constriction of the outflow cube due to the required temperature gradient (Δ-t between inflowing air and room background = 1 - 1.5 k).

Approach

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4. In addition to the static positioning of the OR staff, the possible paths of action (circulation) of the surgeons, nursing staff and assistants during the operation process must also be taken into account.

5. A critical point is the observation of mobile X-ray, navigation devices or surgical microscopes. As a rule, these facilities are equipped with sterile covers for use near the patient. Since these devices are not used permanently, but only temporarily, they have to be temporarily moved out of the operating room and brought back to the operating room when they are in use. Since, from experience, the sterile cover is not changed, the area outside of use must also be included in the determination of the protected area

Conclusions:

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- The positioning analysis revealed that **required protected areas of LAF systems need to be significantly larger than provided by the existing setup**. Typically, an average of at least approximately **4.00 m x 4.00 m** is required to ensure appropriate protected areas for most interventions.
- Individual **workflow and positioning analysis is critical** for planning and designing proper LAF systems. Most existing LAF installations are likely to be too small.
- The larger protected areas actually require **significantly larger rooms** in order to maintain proper thermodynamics. Furthermore, **significantly higher volumetric flow** rates are required. Finally, the **current mismatch** between actual and necessary protected areas **would be a possible explanation for the controversial data regarding the infection protective** effects of LAF systems.
- This also shows the **need to consider alternative ventilation systems like temperature controlled airflow (TcAF)** which cater to a holistic approach for creating the entire OR space as a protected area with less energy.

Challenges regarding OT ventilation systems

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- Multiple impacting factors
- Complex thermodynamic system
  - Staff behavior - Human Factors
  - Changing „environment“
- **Different international standards and no uniform validation/performance assessment methodology**

Standards for assessment of ventilation and air conditioning systems

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No uniform/consistent international standard for the assessment/validation of room ventilation systems:

NF S 90-351;2013
SIS-TS 39;2015
DIN 1946-4;2018
HTM 03-01;2007
SWKI VA105-01
VCCN RL7; 2014
AIA/ASHRAE Guidelines

Main difference of the approach:

Measurement of protection degree or protected area respectively by using artificially generated particles „at rest“

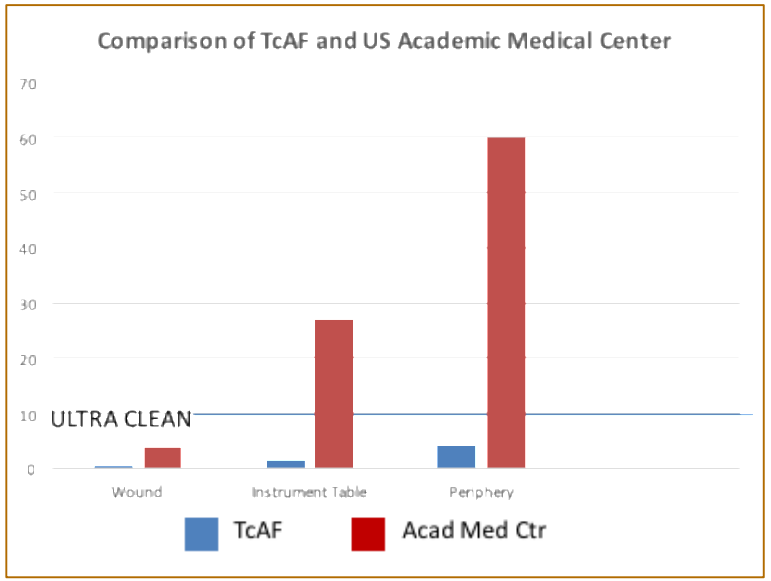
or

measurement of total microbial burden of room air during surgery „in operation“

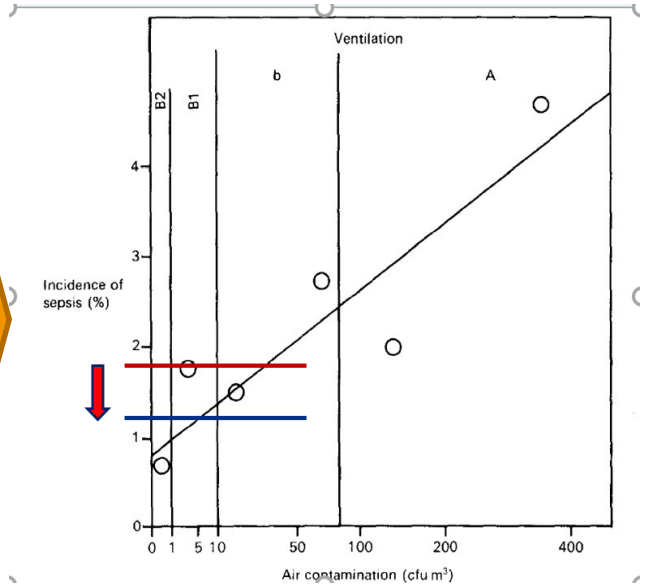
or

defined conditions regarding rate of air changes

TcAF installations vs a U.S. academic medical center
Ultraclean could achieve 40% reduction in SSI



What does 10X level of microbial contamination mean for outcomes?



- **TcAF**: 700 measurement events, live surgery, 30 procedure types, 2-11 personnel, different clothing
- **Academic Medical Center**: Live neurosurgery, multiple operating rooms

- 10 to 100 CFU/m³ SSI rate theoretically: 1.8%
- <10CFU/m³ (ultraclean) – SSI rate theoretically 1.2%
- If the U.S. institution achieved ultraclean levels, a 40% reduction in SSI may be attainable.

TcAF implementation shows significant reduction in SSI

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Clinical validation and efficacy of a temperature-controlled ventilation system (TcAF) in the OR to reduce surgical site infections.

Objective

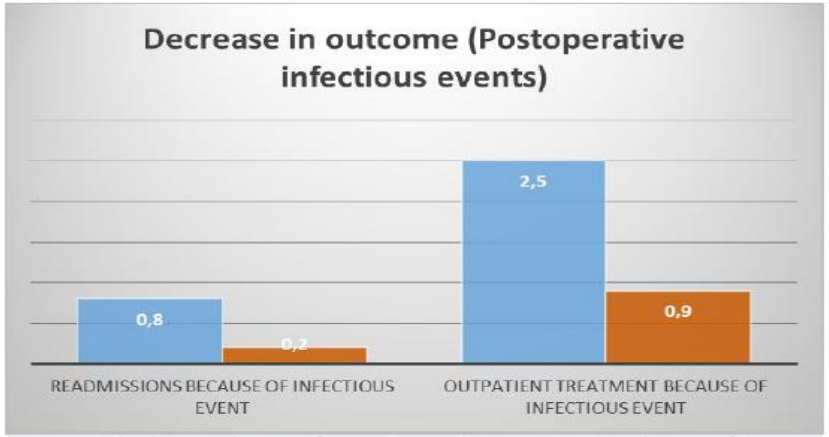
To evaluate the efficacy of TcAF system under routine conditions and assess impact on rates of prosthetic joint infection (PJI).

Methods

- Retrospective analysis of 1,000 consecutive cases of primary total joint arthroplasty before installation of the TcAF system and 1,000 consecutive cases after installation.

Results

- Overall surgical site infection rate decreased from 3.1% to 1% .
  OR - 0.3259 (95%CI, 0.16-0.65, p<0.05).



test group (n)	readmissions because of infectious event	in percent	outpatient treatment because of infectious event	in percent
1000	2	0,2	9	0,9
control group (n)	renewed hospital stay	in percent	ambulat treatment	in percent
1000	8	0,8	25	2,5

Fig. 1 – decrease in postoperative infectious events before (blue) and after (orange) installation of TcAF

Vasiuk S, et al. Clinical validation and efficacy of a temperature-controlled ventilation system (TcAF) in the OR to reduce surgical site infections. Curr Dir in Biomed Eng. 2019:5 (1):1-3.

Conclusion

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- **Ultraclean air (<10 CFU/m³) has been shown to significantly reduce SSI.**
- **Conventional ventilation,** including TAV**, is challenged** by vortices, heat convection and movement of personnel **and does not maintain ultraclean conditions** throughout the OR**.**
- **TcAF system combines advantages** of turbulent mixing ventilation and unidirectional displacement flow (protected area).
- **TcAF system leads to a significant reduction of airborne microbial load** in the **entire OR** and **reduces the risk for SSI**.
- Regarding planning qualification (DQ, IQ, OQ, PQ) **PQ is essential for the assessment of the effectiveness and efficacy of ventilation systems**

Hightech OT Projects are Solution Business

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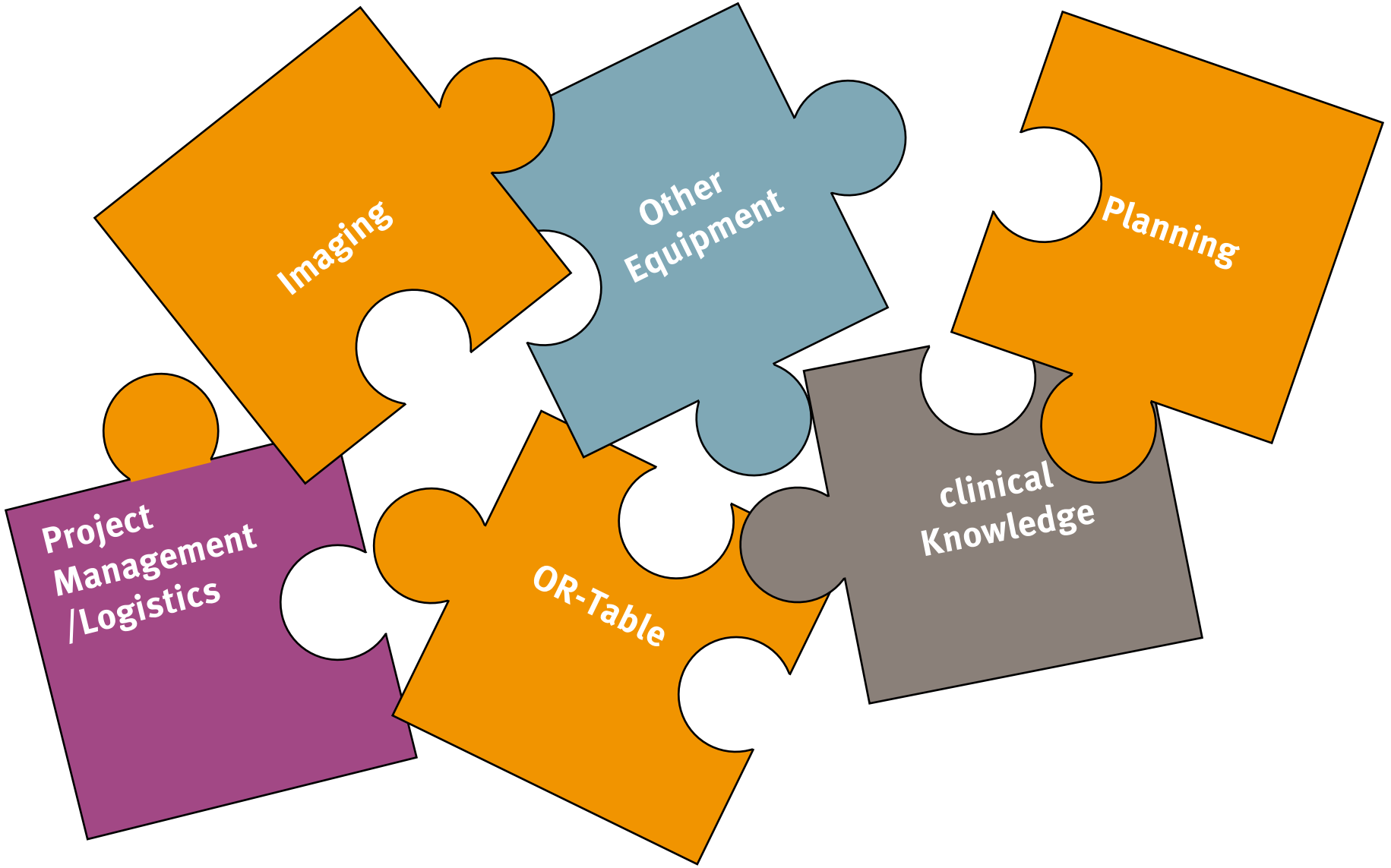

Hightech OT Projects are Solution Business

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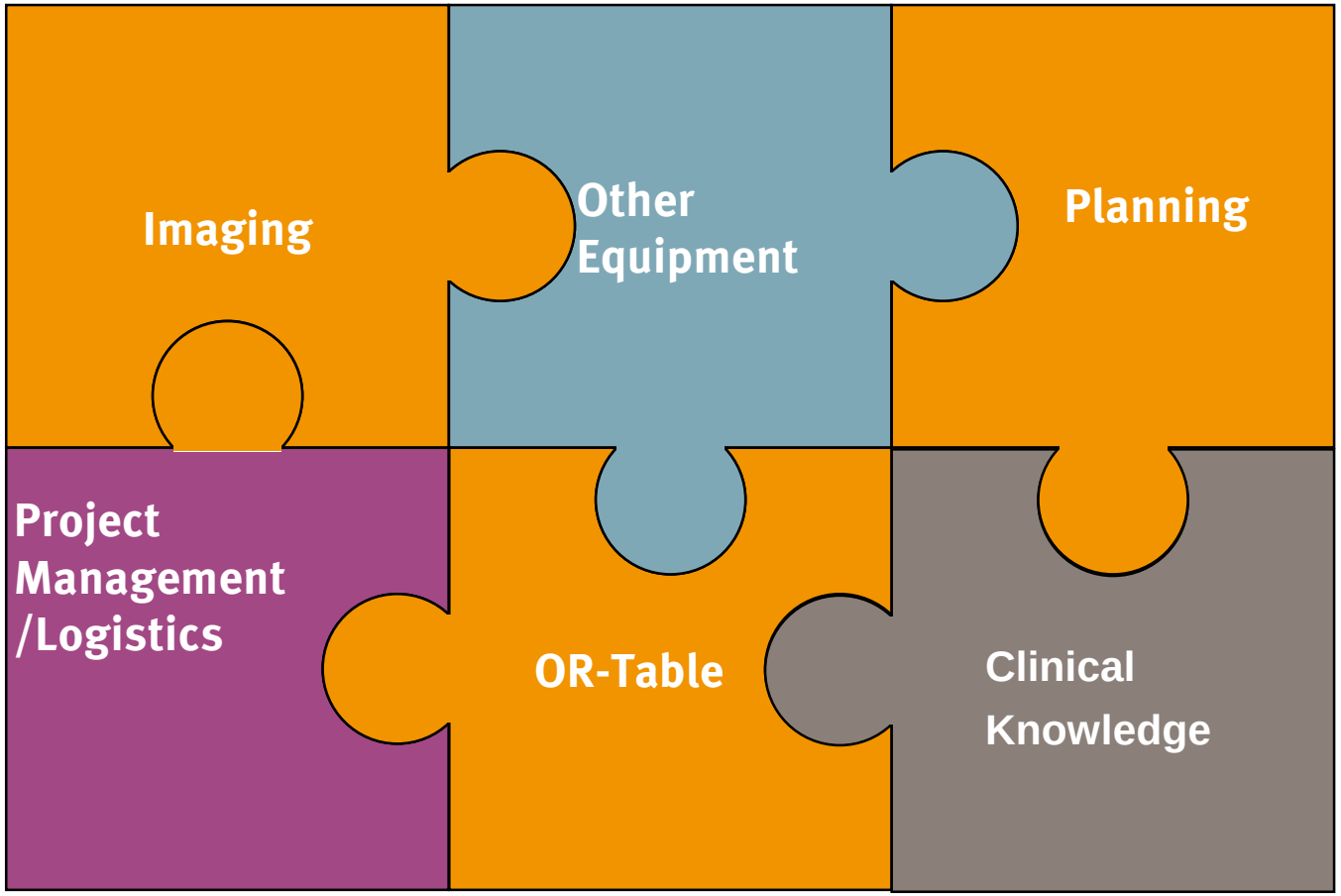

The Room is the SYSTEM!!!

THANK YOU FOR YOUR ATTENTION

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