IHE Surgery White Paper

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1. Integrated Patient Care with IHE

For many members within the IHE community, one of the motivational drives to develop IHE integration profiles is to contribute towards the goal of an integrated patient care (IPC), see figure 1.

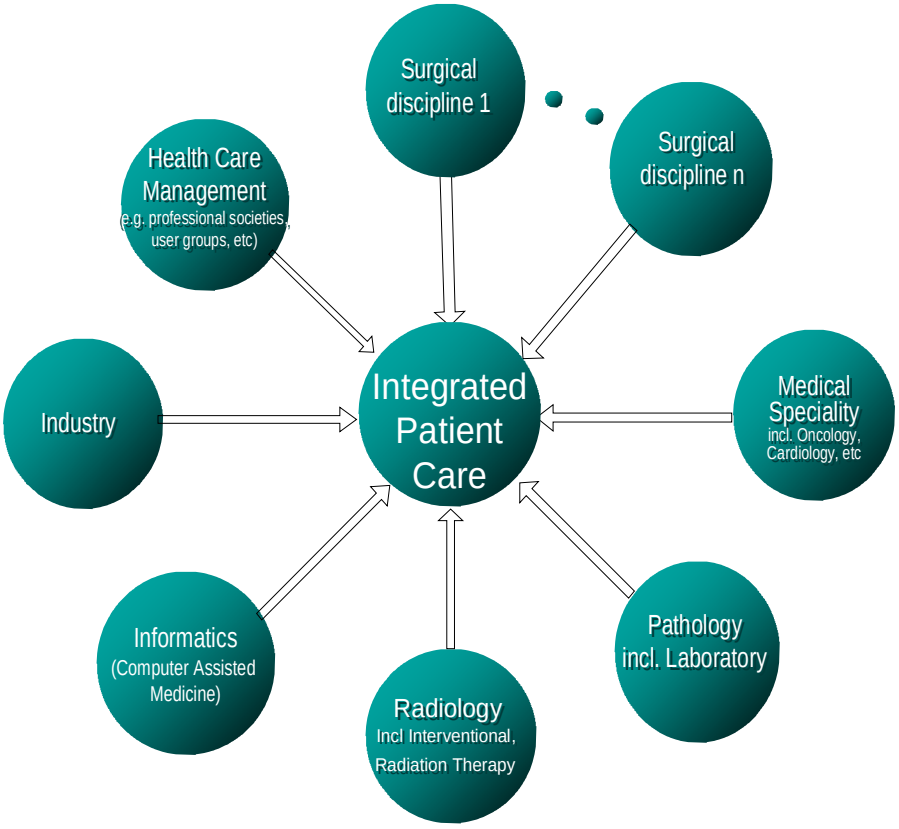

Figure 1. Integrated patient care in the context of surgery and its integration with other relevant actors

The eight components contributing towards the IPC shown in figure 1, may be seen in the context of decision making for patient specific therapeutic approaches including surgery but may not be representative for health care in general. The health care units which typically play a major role in the process of therapy decision making are specific therapy planning units (TPUs), tumour boards, interventional units, operating suites, etc. Here ideally, many information sources available about the patient (radiology, pathology, oncology, surgery etc.) should be considered before subsequent steps in the diagnostic or therapeutic workflow are being taken.

In a real clinical setting this means, that a combination of quantitative and qualitative information about the patient has to be mentally integrated by the physician to create

an abstract representation (model) of the patient which must be as close as possible to reality to serve as a basis for decision making in medical diagnosis and therapy. Based on the model created in the physician's mind and perhaps with some consultation with colleagues, a diagnosis, prognosis (prediction), treatment plan and associated workflow is deduced. This is commonly known as clinical judgment.

IPC applied in TPUs and operating rooms (OR) as well as related environments can only be achieved if some basic interoperability between all disciplines engaged in the care of a particular patient is being supported [1]. Specifically, communication methods and tools as well as appropriate procedures have to be put into place, such as

- Standards for the transmission of data
- Communication infrastructures
- Common terminology and understanding (ontologies)

In addition, behavioural agreement of all parties involved with respect to the acceptance and use of patient information structuring and displays as well as interventional workflow models, is a further essential requirement. This type of interoperability would not only benefit the interventional environments but also the hospital or health care organization at large. IHE Surgery has been created to promote the above interoperability features as part of its vision.

Brief vision statement for IHE Surgery:

> To promote patient-driven design, modeling, and architecture in the operating room and to ensure communication, knowledge management, safety, and improved outcomes through interoperability.

But how can communication infrastructures and procedures to be put into place in the health care setting relating to the OR to achieve something like an IPC with access to the right information, at the right place, in the right time, by the right people?

One way to move towards IPC is by

a) building on what has already be achieved by the IHE community with existing integration profiles and advancing their adoption while at the same time
b) developing specific new integration profiles, for example for therapy planning units, surgical units, etc.

The "building on" part is being followed by the European Union (EU) and the "developing specific new integration profiles" is a path taken by a relatively large community supporting the new IHE Surgery Domain.

2. EU Recognizes for Procurement IHE Profiles

On July 28, 2015, the European Commission announced its decision to identify 27 IHE profiles that should be referenced in public procurement documents for health IT systems throughout the European Union as part of its eHealth European Interoperability Framework (eEIF).

The Commission's announcement (2015/1302) states, "The 27 IHE profiles have the potential to increase interoperability of eHealth services and applications to the benefit of patients and medical community."

This extensive list includes profiles that define standards-based interoperability for laboratory, pharmacy, radiology and enterprise information and communication systems, as well as health information exchanges.

For industrial members of the IHE community this now means, that in the process of Requests for Proposals (RFPs), vendors are encouraged to publish IHE integration statements to document the IHE profiles supported by their products. Referencing the appropriate IHE profiles in RFPs can now greatly simplify the systems acquisition process for public hospitals, health systems, and health information organizations.

Some of the interesting IHE integration profiles (IPs) in the EU list which relate to workflow and interoperability and thereby motivate to also give attention to surgical workflows, are:

12. IHE XD-MS: Cross-Enterprise Sharing of Medical Summaries Integration Profile

21. IHE SWF: Radiology Scheduled Workflow

25. IHE LTW: Laboratory Testing Workflow

27. IHE LWA: Laboratory Analytical Workflow

It will be interesting to observe the real impact these specific workflow oriented IPs will have on the health care community in general, and for an IPC specifically.

Relating to and possibly extending this list with future potential IPs, for example, for TPUs and surgery units, a need can be identified for IPs such as:

XX. IHE SSWF Surgery Scheduled Workflow

XX .IHE XD-SMS: Cross-Enterprise Sharing of Surgical Models Summaries

XX IHE CRSI Consistent Representation of Surgical Information in the OR

This is only a small list of potential IHE IPs which have been proposed and discussed in the newly formed IHE Surgery Domain.

3. Observations from the IHE Surgery Domain Kick-off Meeting

After an extensive preparation time, the IHE Surgery Kick-off Meeting took place during CARS 2015 (Computer Assisted Radiology and Surgery) in Barcelona, Spain on June 27, 2015.

Some of the major topics and issues which were presented and discussed at this Surgery Kick-off Meeting included:

- The Digital OR infrastructure and IHE Surgery

- OR.NET - the German OR-IT integration project
- SCOT - the Japanese OR-IT integration project
- MD PnP – a USA OR-IT integration project
- Viewpoints from industry and bridging the Radiology - Surgery gap
- IHE Surgery Planning and Technical Committee Work Tasks
- Proposal for IHE Integration Profiles
- Approval and certification strategies

The meeting was attended by 94 participants from 15 countries. Therefore, a wide spectrum of viewpoints was presented by the research community and industry on the future role of IHE in the interventional domain. A compressed version of these viewpoints is considered here to represent the core of this White Paper for IHE surgery.

In particular, it was acknowledged, that it is a challenging task to put into practice in the operating room many of the new technological and system advances, associated interventional procedures and the corresponding redesign of healthcare infrastructures. Three main areas of technology development for the digital OR (DOR) have been identified:

1. Devices, including signal detection and recording, robotics, guidance systems, simulation technologies, which allow precision in the delivery of personalized operative healthcare
2. IT Infrastructure, including DICOM, IHE, EMR, Therapy Imaging and Model Management System (TIMMS) infrastructure for the storage, integration, processing and transmission of patient specific data (e.g. a type of surgical PACS including images, graphics, signals and display)
3. Functionalities, including modelling of specific interventional processes, patient specific modelling, optimization of surgical workflows, visualization, validation, etc.

The interoperability problem between these technological areas was highlighted at the kick-off meeting in a number of specific project presentations from different parts of the world, for example:

OR.NET – the German OR-IT integration lighthouse project
B. Bergh, Univ. Hospital Heidelberg (D)

ORiN for SCOT (Smart Cyber Operating Theater)
Y. Muragaki, J Okamoto, K. Masamune, K. Yoshimitsu, H. Iseki, Tokyo Women´s Medical University (J)

MD PnP: A community effort leading interoperability and accurate recording in the OR
K. Vosburgh, J, Goldman, Brigham and Women's Hospitals, Boston, MA (USA)

Integrating imaging modalities for surgery in the AMIGO Suite
T. Kapur, Brigham and Women's Hospitals, Boston, MA (USA)

The funding received for these nationally supported and mainly academically driven projects accumulates to something like 60 to 80 M€ and if anything at all, reflects the

importance given to the issue of integration and interoperability in the OR on a world wide basis.

As an example, figure 2 shows the Japanese vision of an integrated OR [2], presented as a Smart Cyber Operating Theatre (SCOT) realising information integration in the OR.

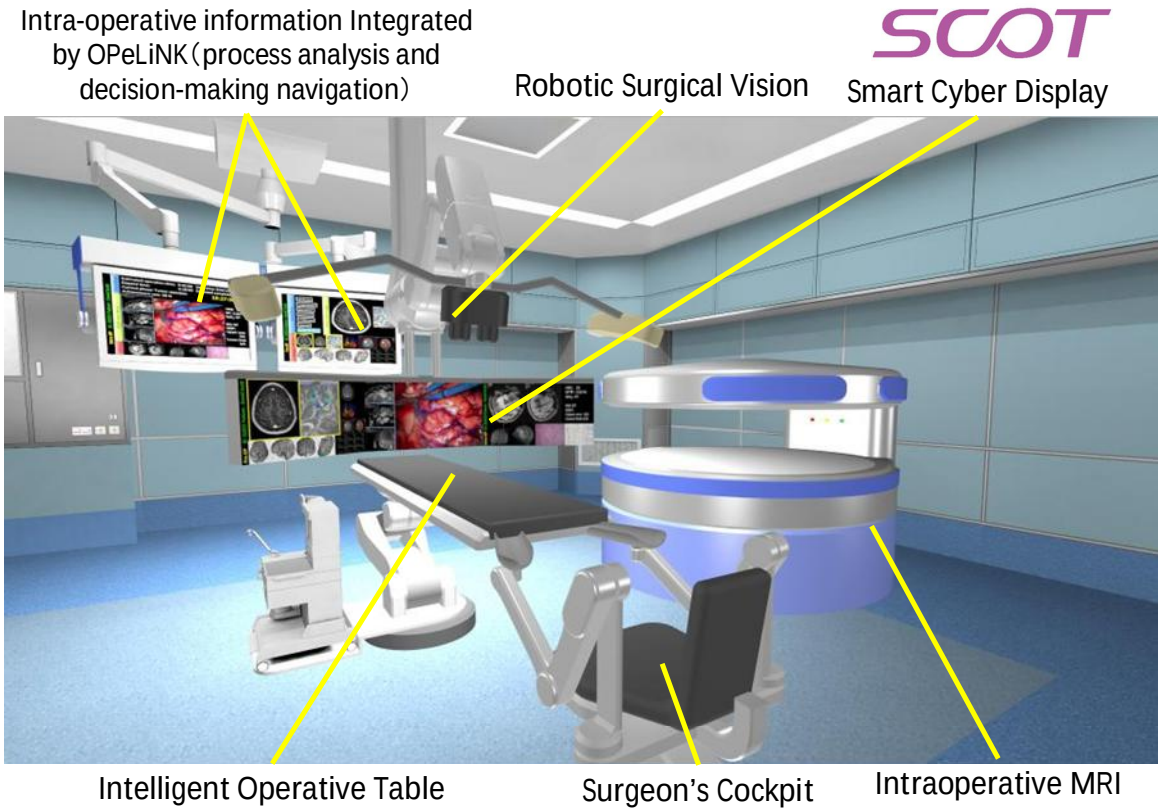

Figure 2. Smart Cyber Operating Theatre (SCOT) [2]

It is also noticeable that industry, both small and large, is developing specific viewpoints on the issue of interoperability in the OR. Examples were given in the presentations by:

> Viewpoints from industry
> *K.-M. Irion, Karl Storz GmbH & Co.KG, Tuttlingen (D)*
>
> Bridging the Radiology - Surgery Gap
> *R. Schilling, EchoPixel, Inc., Los Altos Hills, CA (USA)*
>
> IHE-FHIR-based trial implementation of a surgical interoperability platform
> *J.-U. Meyer, MT2IT GmbH & Co. KG (D)*

Some of the requirements stated in these presentations may be summarised that within the scope of OR-integration, workflow driven process and documentation as well as data availability and visualisation are critical components.

Specific user needs may be summarised as:

- Only display of relevant information

- No redundant information display
- Ergonomic layout and man-machine interaction
- Workflow driven information displays

From this an IHE integration-profile for “Consistent representation of information in the OR” was suggested, taking into account:

- Existing PCD profiles (ventilation, monitoring, clinical decision support)
- Surgical use cases
- Surgical workflow aspects
- Ergonomy, safety, efficiency
- Relevance of information

Existing and suggested IHE IPs derived from IHE use cases may well play a major role in the approval process, as outlined in a presentation by A. Janss et al.

> Approval and certification strategies
> *A. Janss, A. Mildner, J. Dell'Anna, P. Knipp, RWTH Aachen (D)*

The current approach that a single manufacturer is responsible for the development and the approval process has the disadvantage of

- proprietary systems by various manufacturers,
- small and medium-sized enterprises can not participate in this market,
- health care operators cannot choose individual medical devices from different manufacturers and combine them into an integrated OR system.

However, it is being recognised, that there are problems with an open approach also. For example, network partners may not know each other and risk analysis and process of approval may have to be done by different parties. From this observation some requirements for safe and reliable open networks and safe workflows may be derived such as:

- new methods for the accreditation process have to be developed (for the health care provider and the manufacturer)
- new methods for modular technical risk analysis
- new methods for use-oriented risk analysis
- responsibilities and liabilities of manufacturers and health care operators have to be defined newly regarding the interconnection of medical devices and systems

Specifically for the manufacturer it may involve that new interconnection and interoperability features imply the necessity for a new statement of conformity and the possibility that integrated functions may change the risk class of the medical device or system.

The statement of conformity could also include IHE IPs in their device/systems description. In this context it is interesting to note, that the FDA is responding positively to 510(k) applications which include in their device description compliance to IHE, DICOM and HL7. For an example see [3] which refers to a recent PACS approval procedure by a major manufacturer who included in its device description:

“Centricity PACS is a standards-based, customizable, and scalable solution supporting several of the Integrating the Healthcare Enterprise (IHE) profiles, Digital Imaging and Communications in Medicine (DICOM), and the Health Level Seven (HL7) protocol standards for managing digital medical images and patient data. Centricity PACS supports radiographic imaging-as in clinical radiography, cardiology, dentistry, and mammography and non-radiologic imaging, including video support”.

Also in the area of PACS components or devices it can be observed that compliance to IHE integration profiles is thought to be a significant advantage in FDA approval procedures. For example, Three Palm Software, LLC stated in their application [4]:

“The enterprise workflow of the workstation (WorkstationOneTM Breast Imaging Workstation) follows IHE integration profiles, specifically, MAMMO (Mammography Image Profile) and RWP (Reporting Workflow Profile)”.

Another example of FDA approval applications with IHE integration profiles is in the area of digital radiography software tools for Quality Assessment (QA), in particular “Standardized Dose Reporting for QA” [5]. The Alliance for Radiation Safety in Paediatric Imaging recommends the IHE Radiation Exposure Monitoring (REM) profiles and DICOM Structured Reports (SR) to be applied in this context.

It can be expected that the EU Commission decision 2015/1302 will further enhance the level of importance for IHE IPs in CE and FDA approval procedures.

Within the context of the TPU and associated units, conformity statements may in the future also include aspects relating to, for example, who are the responsible parties and what is their role in the design, building, maintenance, improvement as well as development and dissemination of standards and best practices for interoperability in the OR.

4. General observations

It should be observed, that the clinical domain of surgery/intervention is substantially different from all other existing IHE domains, as it combines and extends the scope of IHE integration profiles in a significant way from the workflow point of view. In several kickoff presentations indicated above, it was clearly stated, that workflow based integration profiles, such as workflow driven information displays for the OR should be developed. It was also recognised that the workflow issue in the OR is extremely complex as compared to the other clinical IHE domains.

In order to reflect the difference to other domains, an extension of this White Paper on IHE in Surgery is in preparation, which will summarise the concept of surgical integration profiles derived from a selected set of workflows from different surgical domains. It will also outline the future direction IHE Surgery may take reflecting the expected evolution of interventional workflows including, for example, intelligent infrastructures in the OR.

The expected changes in the patterns of therapeutic care by means of the introduction of new technologies as well as the major government and private sector

initiatives such as OR.NET, SCOT and MDPnP need to be understood by all actors in the IHE Surgery domain and can give this domain the potential to occupy a flag ship position in support of an integrated health care.

In the above mentioned and many other presentations given at the IHE Surgery Kick-off meeting, it was acknowledged, that existing IHE IPs and those envisaged by IHE Surgery may well contribute to finally realise a vendor independent integration of systems and devices in the OR, and thereby contribute to clear the way towards the goal of an integrated patient care. From these observations, an extended vision statement for IHE surgery may be derived:

Extended vision statement for IHE Surgery:

> (1) To facilitate and promote purpose-driven design, modeling, and architecture in the operating room, (2) through the application of ergonomics, engineering, and information technology, (3) achieving consolidation and coordination of components (4) and to ensure communication, modularity, efficiency, knowledge and decision management, safety, and improved outcomes for the patient through interoperability, (5) for optimal performance of the specific tasks of any given surgical specialty.

References

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