	HoliDes **Holi**stic Human Factors **Des**ign of Adaptive Cooperative Human-Machine Systems	

Health related scenario descriptions

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RECORD OF REVISION

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V1.1	15-02-2014	Internal review comments processed	Peter van der Meulen

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Abbreviations

3DRA	3D Rotational Angiography
AdCOS	Adaptive Cooperative Human-Machine System
AdHW	Adaptive Hospital Workflow
AVM	Arteriovenous Malformation
DICOM	Digital Imaging and Communications in Medicine
EHR	Electronic Health Record
HF-RTP	Human Factors Reference Technology Platform
iXR	Interventional X-ray
MRI	Magnetic Resonance Imaging
PACS	Picture Archiving and Communication System
PHR	Personal Health Record
PRP	Product Realization Process
RF	Radio Frequency
WADO	Web Access to DICOM Objects

1 Overview

The overall scenario we selected to derive the requirements from WP 6: Health, is defined from point of view of a patient, who needs to have medical examinations and treatment.

The patient goes through the following stages:

For each stage several uses cases are derived that are described in a more formal manner, following the agreed template. The use cases are the basis for the set of WP6 requirements, defined for the HF-RTP.

2 Description of the overall scenario

2.0 Introduction

Desmond Guinea and his wife, Holi, are on holidays in Spain. Desmond is a retired male, age 67 years. He is severely obese, as his weight is 120 kg and height 1.75 m (BMI: 39). They have a good time visiting art galleries and eating tapas, but unfortunately Des is suddenly not feeling well: he experiences serious headaches and has problems to speak fluently.



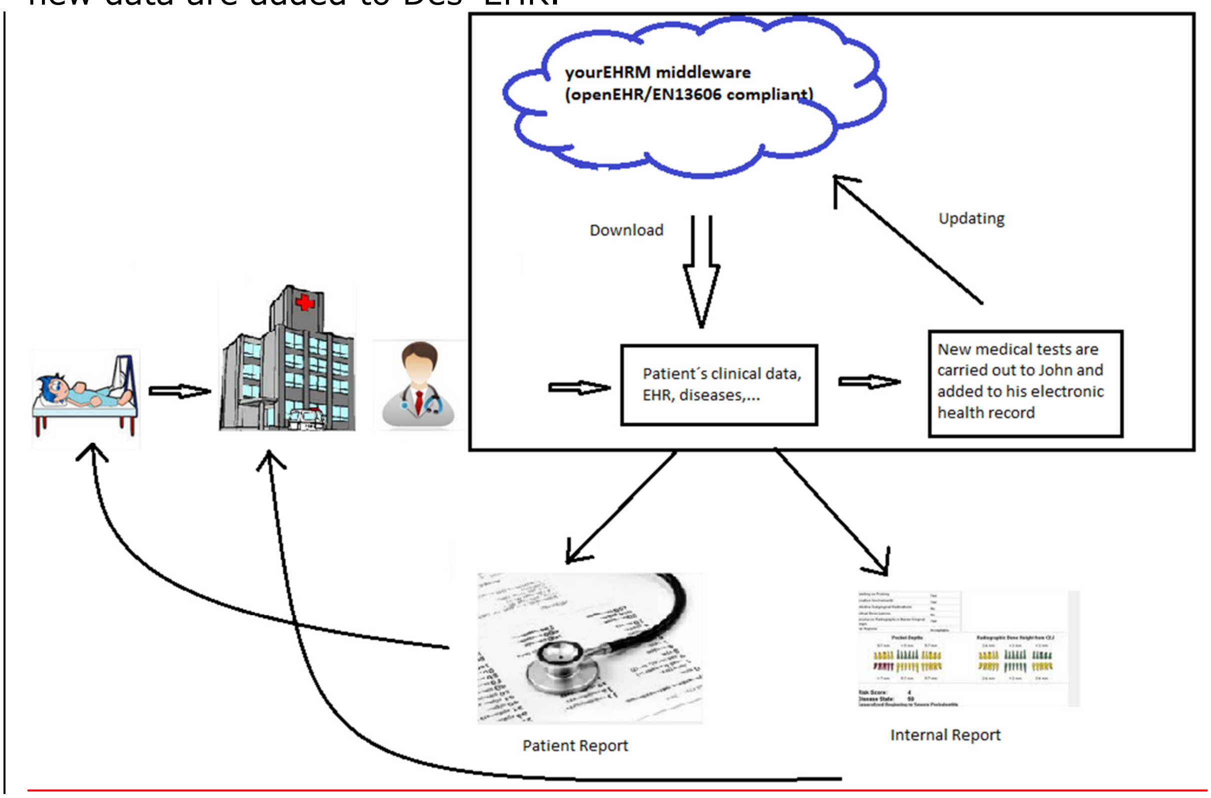
2.1 Stage 1: The Medical Consult

Holi makes a phone call to receive specialized support, and she is recommended to go as fast as possible to the nearest Hospital, which already has received the information about this upcoming patient.

Holi drives Des to the nearest hospital. Because of the previous phone call, the patient is received at the hospital by Alicia, a young nurse with good English language skills and not doing any critical task when Desmond arrives.

The selection of the proper staff is based on specific patient profile (foreign patient, English mother tongue, symptoms…). Alicia has a handheld device that notifies her for this task.
Additionally, and based on the patient information, Alicia is already with a wheel chair to avoid Desmond get more tired.

It is obviously not the hospital where he usually goes, but after giving his personal data (ID, Name, Surname, etc.) the physician, dr. Adrian Costello, accesses Desmond´s Electronic Health Record (EHR), which provides all his clinical details: diseases, habits, allergies, etc. (Note: The systems are usually not interconnected between them and have different user interfaces.). He also could retrieve earlier acquired clinical images via WADO (Web access to DICOM images). Dr. Costello examines Desmond and carries out some tests, including ECG recording, blood pressure, and blood test. All new data are added to Des' EHR.



Dr. Costello makes a diagnosis quickly and efficiently thanks to the instantly access to the EHR information, the European medical standard EN13606 enables the access from anywhere in Europe.

The doctor concludes that Desmond's head needs to be examined right away and prescribes an MRI brain examination.

The doctor's assistant makes an appointment this examination. She checks Desmond's EHR for specific needs and for MRI contraindications (e.g. implants). The appointment is saved in the system and forwarded to the Radiology department.

Use cases:

- WP6_HEA_CON_UC01_Operator_task_schedule_and_guidance
  - Goal: Clear guidance for medical staff
  - Use Case achievements:
    1. To support the decision to assign the proper operator based on user profile, operator profile, and their current availability (status/activities of staff to be monitored and processed)
    2. To support instructions (such as "take a wheelchair")

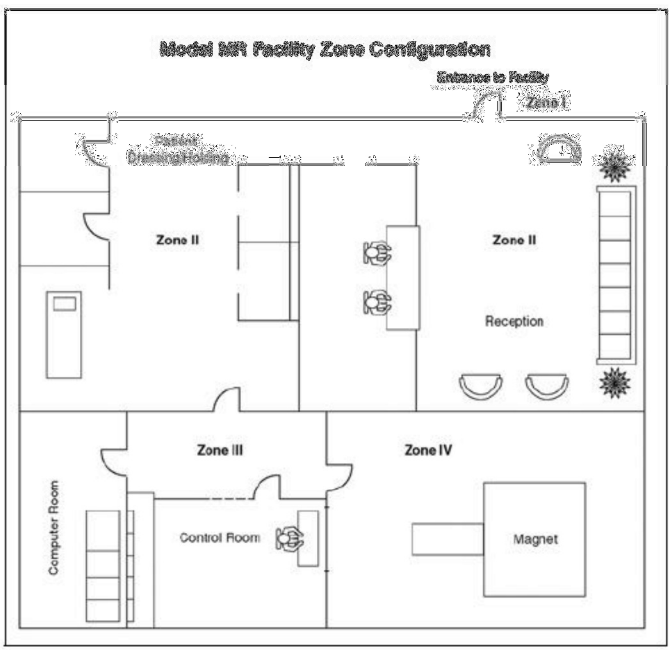
- WP6_HEA_CON_UC02_Querying_openEHR_data
  - Goal: Ability to effectively access and modify patient data in EHR
  - Use Case achievements:
    1. Accessibility of all patient data from any location

2. Easy to use and as fast as needed to facilitate medical diagnosis
3. Automatic report generation of relevant patient data

2.2 Stage 2: The MRI examination

Desmond is put in a wheel chair in order not to tire him any further as his condition is weak. Holi brings Desmond with the wheel chair to the waiting room of the Radiology department.

The radiology department is happy to have an advanced 7.0T MRI system, which amongst others enables very accurate brain imaging. However, this does require special adjustments.



To optimize the MR image quality for certain anatomical regions, a phased antenna array is used in 7T head imaging. Each array elements applies a unique temporal modulation of the transmitted radiofrequency signal.

The resulting electric fields and heating cannot be detected directly with MRI and their spatial patterns are highly patient specific due to the complex electromagnetic interaction of RF signals with the human body. The RF power absorption can only be determined by means of electromagnetic simulations employing dielectric models of the scanned subject.

For this purpose a dielectric model of the patient has to be constructed based on initial low power imaging that is based upon generic models in which a pathological area (from the to be scanned patient) in inserted. In addition to patient positioning and scanning, the operator has to approve or reject the model, before scans can be run with high RF exposure levels. Furthermore, the operator has to define a mask defining in which region the image quality should be approved.

2.2.1 Stage 2a: The MRI preparation

A novice MRI technician, Addie Costner, gets Desmond from the waiting room. She asks Holi to stay in the waiting room.
Addie has a phone where she can read the itinerary that Desmond will follow in the hospital. The device has the Adaptive Hospital Workflow (AdHW) application to provide dedicated task support, which provide guidance and tracks if Addie is performing her work correctly. She receives from the instructor the task planned for each day, chronologically organized.

She uses the AdHW that guides her to explain Desmond about the examination. She checks if Desmond is allowed to enter the MRI room (implants and other contraindications, piercings, conductive eyeliner, etc.) and asks him to undress and change to MRI compliant clothing. Given the fact that Desmond is overweight and feels sick, Addie uses her mobile handheld device to ask for help to position the patient on the tabletop, mounted on an MRI compliant trolley. They position him on his back on the tabletop and provide additional accessories to support legs and arms.

Desmond is wheeled on the trolley into MRI room. The trolley is positioned over the patient support, which in low position. The patient support is lifted to carry the tabletop and the trolley is removed.

Addie prepares Desmond for the examination:

- Places the nurse call in the hand of Desmond. She instructs Desmond to press twice the air balloon during scanning when assistance is needed (e.g. heating is experienced).
- Positions the receive coil for the head
- The eight channel transmit antenna array, needed for very accurate brain imaging, is shifted over the head receive coil
- Carefully positions the arms of Desmond, and instruct him not to move
- Provide ear plugs
- Provides the headset and adjust the volume
- Adjust the patient ventilation
- Adjust the in-bore lights
- Determines the centre of the anatomy to be scanned (the head)
- Insert Desmond into the magnet

Addie leaves the MRI examination room leaving Desmond alone in the scanner.

A camera mounted on the MRI scanner shows the operators the patient's position and allows the operators to verify that the patient has followed the instructions and to check if Desmond still is comfortable.

Use cases:

- WP6_HEA_MRI_UC01_safe_patient_transfer
  - Goal: Design and validation tooling to assess the design on safety and usability for all reasonable use cases, patient types, pathologies, and operators.
  - Use Case achievements:
    1. Reliable method to assess usability and safety of the patient transfer in all relevant conditions
    2. Potential distributed support from other operators
    3. Effectiveness of icons and markers on the trolley and tabletop to guide the operator

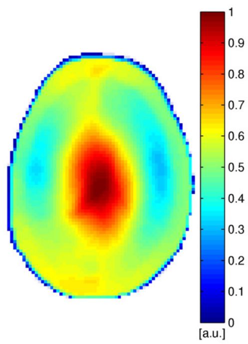
- WP6_HEA_MRI_UC02_guided_patient_positioning
  - Goal: Clear guidance for the operator to position and instruct the patient
  - Use Case achievements:
    1. Effectiveness of operator training for patient positioning
    2. Effectiveness of dedicated guidance on gantry display
    3. Applicability of cameras to assist the operator

2.2.2 Stage 2b: The brain MRI examination

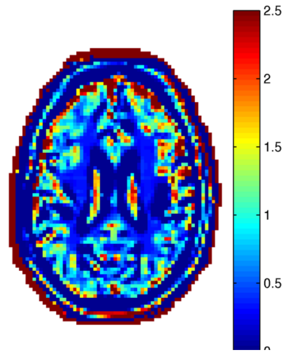
Meanwhile Addie's colleague, Maria Ries, selects the prescribed brain ExamCard.

Maria asks via the intercom, connected to the headset, if Desmond still is comfortable. If he responds positively she starts the examination. The first survey scan uses low radiofrequency power settings producing a first image of the patient. The next scan in the ExamCard is a fast complete head scan with low resolution to extract anatomical features which are used to identify the two most similar, dielectric head models from a model archive.

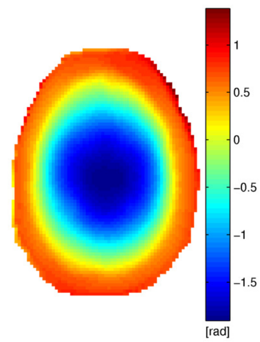
Maria starts the RF calibration scan using conservative RF power settings. The resulting images of this scan are used to map the transmit field of each separate transmit array element. This is followed by a dielectric mapping scan to identify the dielectric properties of the pathological brain region. The maximum allowed RF power is constrained based on the generic models.



B_1^+ map



Conductivity map



Phase map

Maria runs a first conventional diagnostic scan that does not require high RF power setting. Meanwhile two more individualized dielectric models of the patient are constructed by inserting the measured, dielectric map of the pathologic region into the 2 generic head models. Maria inspects the models and approves or rejects them. Models are fed to electromagnetic solvers calculating the expected RF electric field patterns per transmit element for the patient. Except for model inspection, this whole process is automated.

Maria defines on the image of the previous scan a mask around the pathological region where the excitation homogeneity should be improved by parallel transmit technology. When the region is defined, an algorithm starts automatically that calculates the RF waveforms per transmit channel. The algorithms takes the measured transmit maps, the electric field patterns and the desired excitation pattern as input parameters. The complete process takes 1 minute.

As a result, the algorithm returns the RF waveforms for each transmit element, and the RF heating parameters required according to IEC guidelines for both models (the total RF absorption of the head and the highest local RF power absorption level averaged over 10 gram of tissue and its spatial location, predicted maximum and local temperature rise, as specified by IEC 60601-2-33: particular requirements for the safety of magnetic resonance equipment, 3rd edition; Geneva: IEC, 2010)). The RF absorption parameters are visually displayed to OP in a separate pop-up window. Furthermore, the expected time course of the forward/backwards powers per transmit element are calculated.

Maria approves/rejects the expected heating for the subsequent scan that uses the optimized RF drive of the 8 channel antenna array.
The clinical scan, employing the optimized RF drives, is started. The actual, measured forwarded/backward power and total RF power absorption are constantly compared with the predicted readings and are displayed in a separate window for monitoring by Maria. The scan was successful, with optimal image quality in the target region and scan ran within limits of local SAR levels.

Potential Issues:

- An unexpected deviation between predicted and recorded forward/backward power is automatically detected. This raises the suspicion that one of the array element has failed.
- Patient pressed air balloon and complains about uncomfortable sensation of heating close to his ear.
- A large discrepancy is detected between the expected image quality and the measured image quality.
- The patient moves/tilts his head during scanning.
- The generation of the patient specific dielectric model does not work as the dielectric mapping sequence gives unreliable values.
- The patient is extremely obese resulting that in a situation that his/her anatomy is strongly deformed by the bore such that no good match to generic model can be found.
- The patient has a history with a compromised cerebral blood flow. Therefore uncertainties exists in certain brain areas how RF absorption translates in local tissue temperature rise.
- Patient with metallic implants: risks that can act as a resonant antenna leading to large heating of tissue in direct vicinity. The resonant coupling between implant and RF transmit coil are difficult to predict by modelling. Therefore some monitoring device should be in place for this patient category that detects that a strong coupling is taking place.
- In an extreme situation, it might happen due to malfunctioning of the safety monitoring, that extreme tissue heating took place at a body location, where no thermo-sensory system is present (brain tissue).

Patient will therefore not complain and tissue damage or even neurological malfunctioning might appear after some time (days or weeks). In such a scenario it should be possible to retrieve the exposure levels.

Use cases:

- WP6_HEA_MRI_UC03_safe_parallel_transmit_scanning
  - Goal: Safe and reliable parallel transmit system
  - Use Case achievements:
    1. Reliable calculation of electric properties and predicted temperature distribution, including accuracy indication
    2. Clear and reliable feedback on system calibration results and required actions from the operator

2.2.3 Stage 2c: Remote assistance

Although the clinical scan was successful Maria is in doubts whether this scan gives enough information for the radiologist, Dr. Manuel Rico, to diagnose. To be sure she shares a view of the image made with Dr. Rico, who can preview it on his tablet PC. Because he wants more detail, he walks up to a calibrated screen and swipes the image over to the calibrated screen. He can do this because of the secure connection software installed on the PACS of the hospital and the certificate on Dr. Rico's iPad that is registered with the hospital. On the screen the doctor notices an artefact that blocks the ability to diagnose. He calls Maria to discuss how a better scan can be made. Maria adjusts the scan settings and redo the scan. Dr. Rico receives the new results on his iPad and judges that these are of diagnostic quality.

2.2.4 Stage 2d: The end of the MRI examination

As the images are of diagnostic quality she asks Addie to get Desmond out of the scanner and return him to the waiting room. Addie get the trolley, goes into the examination room, shifts the trolley underneath the tabletop, warns Desmond that table is going to move, so he should keep his arms close to his body, move the tabletop out of the system, lowers the patient support, pushes Desmond on the trolley out of the examination room, lowers the trolley and helps Des to switch to the wheel chair again.

Meanwhile Maria selects all images to be archived, runs the automatic formatting program, optimized for each clinical application, and stores the images on the PACS.

2.2.5 Stage 2e: The MRI reading

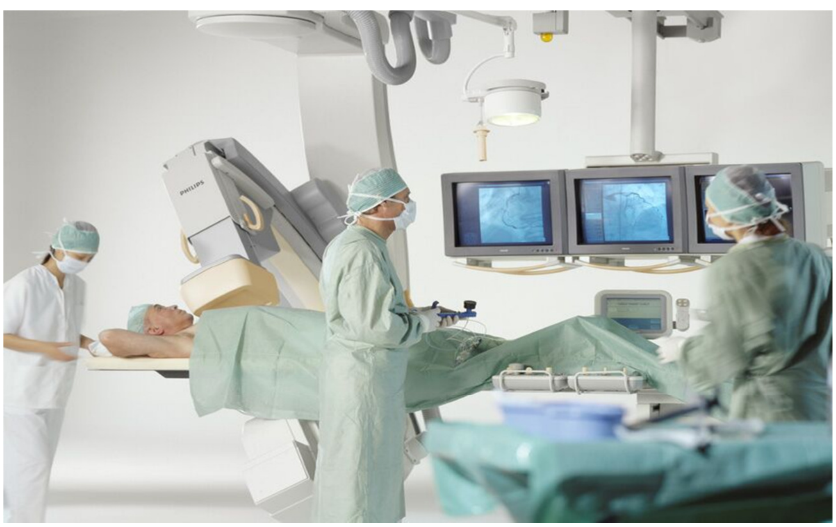
Because of the urgency of the situation the MRI images Dr. Rico quickly reviews the results in the reading room, retrieving all images from the PACS of the hospital. Dr. Manual Rico concludes that Desmond has an AVM (Arteriovenous Malformation) in the brain and needs to get an AVM embolization right away.

2.3 Stage 3: The iXR intervention

Desmond is brought the angiography department. He is asked to get dressed for the procedure in one of the change rooms. Then he is walked to the intervention room and lies down on the table.

2.3.1 iXR Procedure preparation

Nurses are already busy preparing the intervention room. Drips are being prepared. Desmond gets sedated and is intubated by the anaesthesiologist. His head is fixed in a special holder to reduce motion artefacts during the imaging. One nurse shaves Desmond's groin. This is the place where the catheters will be inserted into his vascular system. Then they put a sterile drape over Desmond.
In the Control Room, which is situated next to the intervention room behind a lead shield glass, Dr. Racardio (Interventional Neurologist) is preparing for the procedure. He looks at the previously acquired MRI via PACS and imports the MRI data into XtraVision (the interventional workstation for 3D data).
In the meantime nurses prepare sterile tools, catheters and fill the injector pump with contrast agent. When the physician is done preparing he scrubs in and enters the intervention room. He confirms XtraVision with the MRI data is displayed on one of the monitors. In the meantime Dr. Racardio's fellow has joined him at the table. She will assist Dr. Racardio during the procedure.



2.3.2 Vascular access for iXR

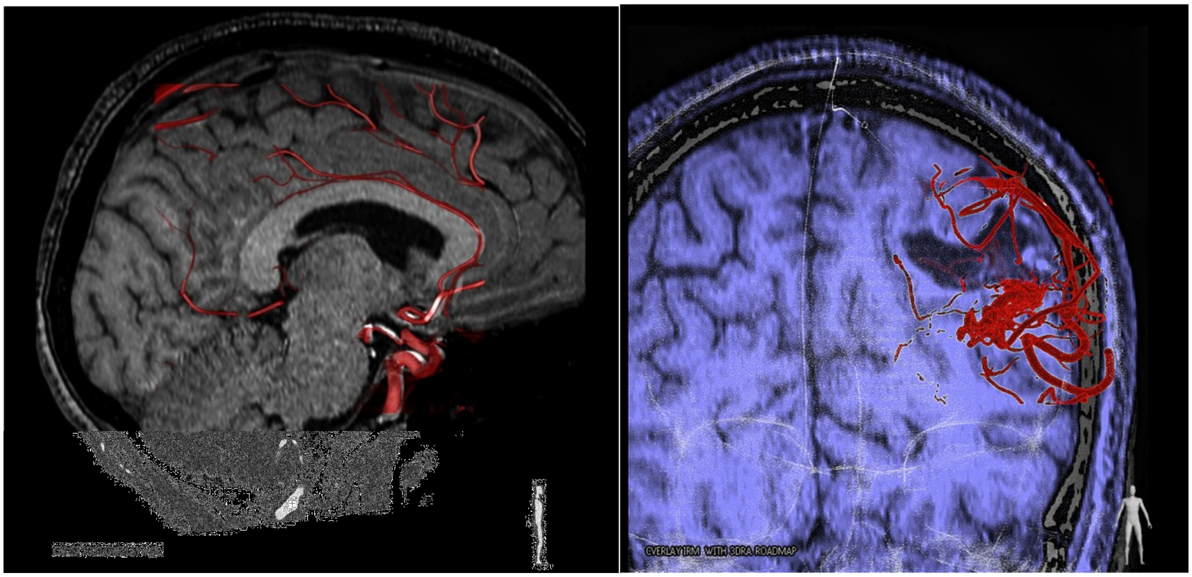
Dr. Racardio starts by creating a small incision in the groin and femoral artery to insert the guiding catheter. Because Desmond is a fairly large patient he has to use ultrasound to guide the catheter to the artery.

2.3.3 iXR Navigation

The catheter is pushed up via the aorta to the carotid area in the neck of Desmond. Once in the carotid area they navigate with help of fluoroscopy and contrast puffs to the exact position. Now they are ready to acquire the 3D Rotational Angiography (3DRA) to create a 3D vessel map of the brain which will later be used for guidance during treatment.

2.3.4 iXR: 3DRA and multi-modality matching

By using fluoroscopy and changing the table height and position Desmond’s head is put in the exact isocenter of the c-arc. This is required to capture all required anatomy during the 3D scan.
A test round is performed to check if the c-arc does not collide with the patient or cables around the table. During the test round the collision protection system (BodyGuard) stops the motion because it has detected something. After inspection by the nurse it appears to be a small drip line that triggers the alarm, but the c-arc is actually not touching it so it is no problem to continue.
After the 3D scan is made the data is reconstructed on the XtraVision workstation. One of the assisting radiology technicians in the Control room registers the MRI data with the 3DRA data. This is called multi-modality matching.



MRI slab + 3DRA data overlayed

Use case:

- WP6_HEA_iXR_UC01_3D_acquisition
    - Goal: adaptive product agent that adapts to variability of staff (e.g. number of involved people and assigned role, education/experience, physiological characteristics, culture). and helps staff to become more skilled and confident in acquiring and using 3D data.
    - Use Case achievements:
        1. Adapt to variability of user agents
        2. Help user agents perform more efficient and feel more confident

2.3.5 iXR: Micro-catheter into AVM

Now Dr. Racardio uses the multi-modality view to navigate a micro-catheter to the AVM. Because of this '3D roadmap' he has to use less x-ray and toxic contrast agent for navigating the catheter.

2.3.6 iXR: Embolization with Onyx

Once in the AVM he acquires x-ray images with contrast from different angles and copies them to the reference monitors to be used as reference.

He then starts the embolization process. This is a very precise job in which Dr. Racardio injects Onyx (a kind of glue) into the AVM to fill and close it. He uses the reference images to check where to inject and live fluoroscopy to check the result.

2.3.7 iXR: 3DRA to check final result

Once done another 3DRA is acquired to assess the quality of the treatment. Dr. Racardio can compare this new 3DRA with the previous 3DRA to see before and after treatment. He is satisfied with the result.

2.3.8 End the iXR procedure

Dr. Racardio goes to the Control Room and unscrubs. Catheters are removed by the fellow. A nurse closes the incision in the femoral artery with help of a closure device. The anaesthesiologist removes intubation. Once awake Desmond is transferred to a patient bed and moved to the recovery room. Dr. Racardio asks for Holi, who was patiently sitting in the waiting room, that the procedure went well, but that Desmond needs some time recover.

2.3.9 iXR Reporting

The radio technician in the Control Room selects images to post-process and send to PACS. Later on the day Dr. Racardio will voice dictate the images in the Radiology reading room. All information will be added to the EHR of Desmond.

2.4 Stage 4: The data analysis, report and visualization

After all information added to the EHR of Desmond, the referring physician, Dr. Adrian Costello, wants to analyse possible causes that has brought Desmond to the hospital by comparing and analysing data with other patients in order to avoid possible future illness from Desmond or any other patient.

Dr. Costello selects a group of patients with a similar disease and generates an internal report with risks factors and predictions (using, for example, rapid-miner, free software tools for developing data mining models).

Besides the predictive report for the doctor the tool would permit to generate simple reports for the patients just to provide a general overview of his/her health status.

He gives Holi the EHR code to be able to access Desmond's data, which gives a clear overview of the recent findings and images, together with the approval form signed by Desmond that his wife is allowed to view these data.

Holi and Des now can access the EHR through their Personal Health Record (PHR). They realize that they can do it from the Netherlands or from Spain due to the fact that both hospitals are semantically interoperable. They can check the medications ordered in Spain during their vacations but also the images collected there.

Use cases:

- WP6_HEA_DAT_UC01_internal_analysis_and_reporting
  - Goal: merge several patients' clinical data to locate risk factors and be able to take action.
  - Use Case achievements:
    1. Fast and reliable access of all EHR data in order to gather information from different patients
    2. Easy to use for the doctors allowing automatic generation and extract predictions
    3. Security and privacy

- WP6_HEA_DAT_UC02_patient_access_of_data
  - Goal: Allow patients and other authorized people to access medical data
  - Use Case achievements:
    3. Secure access of patient data
    4. Clear presentation of data to avoid misunderstanding and unnecessary worries

- End of Document -

PvdM, 09-02-2014

	use cases	lead	Contributors	Main Needs
1	WP6_HEA_CON_UC01_Operator_task_schedule_and_guidance	Integrasys	AnyWi, ATOS	Nurse needs to find the right staff to serve the patient
2	WP6_HEA_CON_UC02_ Querying_openEHR_data	ATOS	AnyWi	Access of all patient related data by any (authorized) physician at any location for fast and full documented medical support
3	WP6_HEA_DAT_UC01_ internal_analysis_and_reporting	ATOS	AnyWi	Access to patient data for statistical analysis of pathologies
4	WP6_HEA_DAT_UC02_ patient_access_of_data	ATOS	AnyWi	Remote access for the patient access own data
5	WP6_HEA_MRI_UC01_ safe_patient_transfer	Philips (MRI)		Safe transfer and transport of patients on and off a patient support
6	WP6_HEA_MRI_UC02_ guided_patient_positioning	Philips (MRI)	AnyWi	Safe positioning of patients for MRI exams by any operator

7	WP6_HEA_MRI_UC03_ safe_parallel_transmit_scanning	UCMU	Philips (MRI), AnyWi	Safe behaviour of the system and effective feedback
8	WP6_HEA_iXR_UC01_ 3D_acquisition	Philips (iXR)		Optimized design to reach high confidence level of users and assure high efficient in acquiring and using 3D data.

AdCoS	Baseline Currently applied tools	Links with WP2 (HF modeling T&T)
Handheld device for guidance of medical staff in various situations in the hospital, inclding connection with the OpenEHR	Currently workflow tools are being deployed at hospitals but usability is not optimal. Tools are lacking to support the models of workflow based on model and human factor.	2.2, 2.3 (Task and Resource Models : Task sharing across agents, mostly human) 2.6 (Training models to find optimal guidance)
Open Electronic Health Record system (OpenEHR)	No integral solution within hospitals and in between hopitals to share patient data and facilitate promp access	2.2, 2.3 (Task and Resource Models : Task sharing across agents, mostly human) 2.5 (Optimal interaction with AdCoS for use case)
Open Electronic Health Record system (OpenEHR)	No integral solution to analyse patient databases for statistical analysis	see above (for different use case)
Open Electronic Health Record system (OpenEHR)	Patient may get own data on paper or DVD	see above (for different use case)
Human Factors Design tooling: Tooling to analyse Human Factor properties of patient trolley concepts and to systematically validate the final design on safety and easy handling.	No tools, validation after product creation	2.5 (Modeling tools required for concept validation) 2.8 (integration of HF analysis tools and mechnical design tooling)
Dedicated guidance for the operator based on patient characteristics and type of examination via a local display + UI and with camera guidance	Only operator training; instruction poster	2.4 (operator's overt actions, experience level) 2.5 (interaction with physical equipment) 2.6 (training models)

Semi-automatic system calibration facilities of the parallel transmit system of an MRI scanner	Automatic settings for less complicated configuration; user interaction via pop-ups	2.2 (task sharing, identification of dielectric model) 2.4 (operator experience) 2.5 (optimize operator interaction)
A variable system of acting agents that consists of user agents and the product agent. Variability is in the roles of different users, order in which they perform tasks, skills they have, the way they are organized to work with 3D acquisitions and feedback provided by the product agent based on detected events.	In current practice it is a challenge to design optimal user interfaces and product behavior for the variance in user roles/skills and ways of working.	2.2, 2.3 (Task and Resource Models : Task sharing across agents, mostly human) 2.5 (Optimal interaction with AdCoS covering the variability of use cases)

other WPs

WP3 (Adaptation T&T)	**WP4** (Model based analysis)	**WP5** (Empirical analysis)
3.2 (SW framework to support all cases on AdCoS with guaranteed secirity and reliability) 3.3 (context assessment)	4.3, 4.4 (formal simulation and verification of implementation)	5.2 (metrics for human factors based analysis derived from regulations and standards) 5.3 (Models and AdCoS) development 5.4 (Models and AdCoS validation)
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see above (for different use case)	see above (for different use case)	see above (for different use case)
see above (for different use case)	see above (for different use case)	see above (for different use case)
3.3, 3.4 (Tools required for effective product validation)	4.2 (Automatic analysis of model output)	5.2 (Metrics for analysis)
3.3 (context assessment) 3.4 (re-configuration of the AdCoS) 3.5 (communicate system adaptation)	4.2 (metrics for human factors based analysis derived from regulations and standards) 4.3 (Formal imulation analysis) 4.4 (Formal verification of implementation)	5.2 (metrics for human factors based analysis derived from regulations and standards) 5.3 (Models and AdCoS) development 5.4 (Models and AdCoS validation)

3.3 (context assessment) 3.4 (which controls can be automatic and which need to be human operator controlled) 3.5 (communicate system adaptation)	4.2 (metrics for human factors based analysis derived from regulations and standards) 4.3 (Formal imulation analysis) 4.4 (Formal verification of implementation)	5.2 (Metrics for analysis of concepts and implementation)
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