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Harnessing The Power Of Interoperability Within Medical Devices

An Asia Pacific Perspective

APACMed Digital Health Committee
Interoperability Working Group

Executive Summary

Medical Device Interoperability is an important topic, as it will help to improve patient outcomes and optimize the work of nurses, physicians and others that provide patient care every day.

We outline how medical device interoperability can be leveraged in different scenarios, ranging from remote monitoring of the daily activities for cancer diagnoses to intra-hospital protection of clinical staff during their care of infectious patients. Moreover, a selection of the technical specifications and terminology standards are described which can be applied to implement the medical device interoperability scenarios.

Recommendations are outlined for the relevant medical device manufacturers and medical technology providers for medical device interoperability that will help them to implement the scenarios. In addition, recommendations for hospitals are provided that allow them to request certain standards in the RFPs they issue to leverage the benefits of medical device interoperability and maximize investment protection.

Moreover, recommended adoption of regulatory frameworks and science are provided that will allow easier market entry for products, foster innovation and improved healthcare models while still ensuring patient safety and data privacy.

This White Paper is dedicated to our colleague and friend Sandeep Shah

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Introduction

Medical Device Interoperability is an important topic that will help to improve patient outcomes and optimize the work of nurses, physicians and others that provide patient care every day.

This White Paper has been written especially with the following stakeholders in Medical Device Interoperability in mind:

- Hospitals and other types of healthcare / medical facilities
- Medical Device Manufacturers and Medical Technology Providers
- Regulatory Agencies
- Government Bodies

and therefore, addresses the different viewpoints expressed by these stakeholders regarding medical device interoperability.

In the following sections, we outline how medical device interoperability can be leveraged in different scenarios, ranging from remote monitoring of the daily activities for cancer diagnoses to intra-hospital protection of clinical staff during their care of infectious patients. The description of the scenarios is enriched by a short description of the system architectures needed to implement them. Next, we describe a selection of technical specifications and terminology standards which can be applied to implement the system architectures.

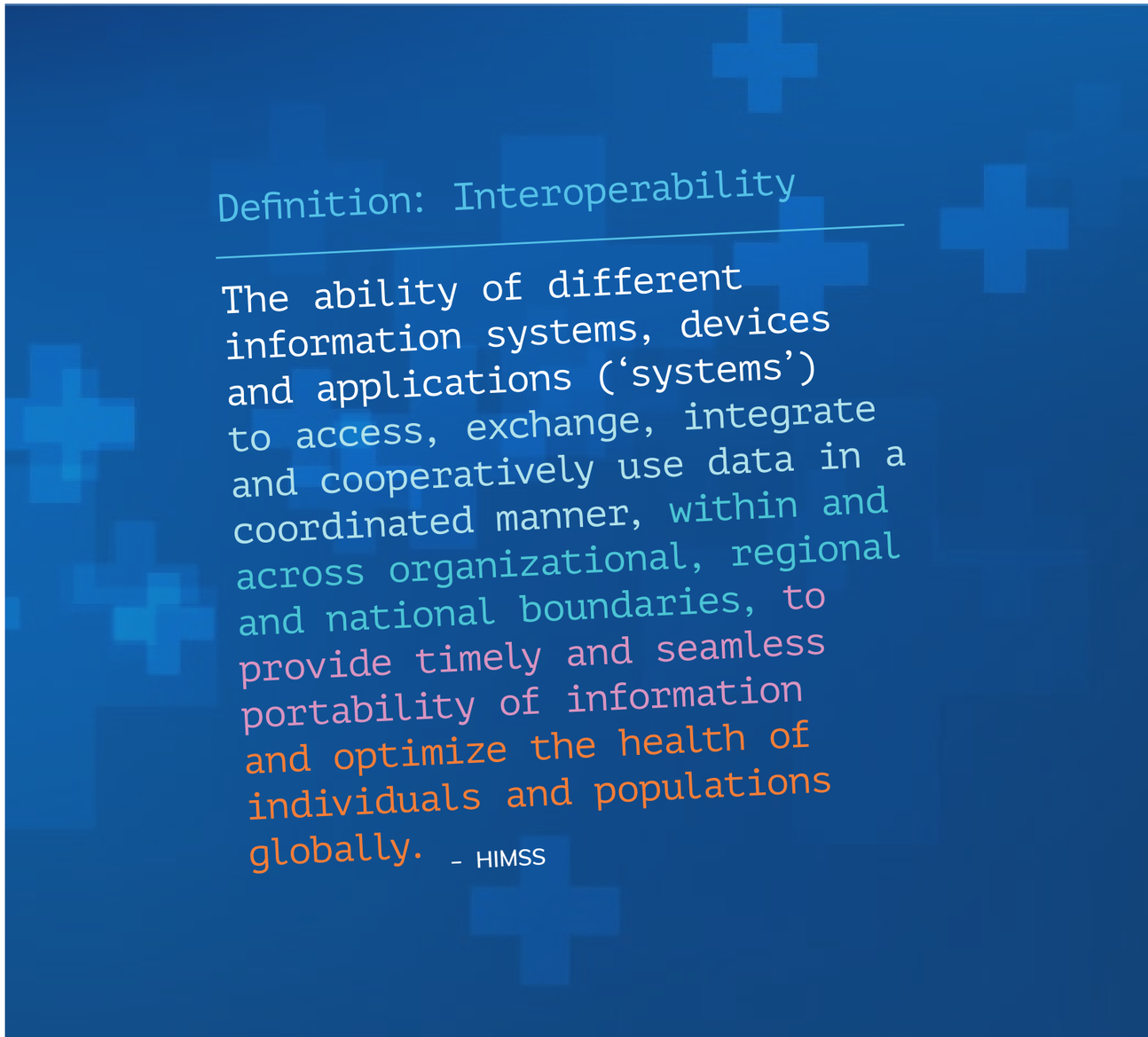
Next, the best approach for decision makers from the relevant medical device manufacturers and medical technology providers for medical device interoperability are outlined for the implementation of their parts of the scenarios. This information can also be used for hospitals to request medical technical manufacturers and medical technology providers to provide certain standards in their RFPs in order to leverage the benefits of medical device interoperability and maximize investment protection.

Moreover, we provide recommended adaptions of regulatory frameworks and science to allow products to be easier placed on the market to foster innovation while still ensuring patient safety and data privacy.

Medical Device Interoperability

As a start, the terms “interoperability“ and “medical device interoperability“ will be defined as the key concepts in this White Paper.

There is no single definition of what Medical Device Interoperability is and different organizations define it slightly differently, but for this White Paper we use the general definition of Interoperability from HIMSS [HIMSS] and apply it to systems that comprise at least one Medical Device, in-vitro diagnostic or Personal Health Device.



Medical Device Interoperability Scenarios

This section comprises different medical or health-related scenarios that demonstrate the importance and benefits of Medical Device Interoperability.

TeleHealth Loop For Chronic Disease

Fuji Sakamata is a 75 year old man who lives near Hokkaido in the north of Japan. His nearest hospital is a 40 minute drive away where he receives treatment from his endocrinologist. Mr Sakamata has had Type 2 diabetes for four years, and has recently been put on an insulin regimen. Mr Sakamata has been struggling with the complexities of diabetes management on a daily basis and requires coaching and support to manage his diet, exercise and medication considerations. On top of this all, Mr Sakamata is grievously worried about a hypoglycaemic event which may result in his hospitalization.

Mr Sakamata's endocrinologist, Professor Nakamura, has offered to do a telehealth consultation via a video call for his next appointment. During that appointment, the healthcare professional (HCP) has recommended that due to Mr Sakamata's age, relative distance to the hospital and his need for extra care and support, his diabetes should be able to be monitored remotely. He has recommended Mr Sakamata be fitted with a sensor with Wi-Fi connection, which will enable the ongoing monitoring of the data at the hospital. Professor Nakamura sends a sensor to Mr Sakatama in the mail and sets up a follow-up appointment.

In the meantime, Professor Nakamura briefs his head diabetes educator to support Mr Sakatama at the next appointment. In that next appointment, Nurse Yamamoto uses a video call to walk Mr Sakamata through the new procedure with a briefing on the sensor, downloading the app on to his phone and showing Mr Sakamata how to use the app with the sensor, and setting up a secure account for him on the phone.

After Nurse Yamamoto finishes that follow-up consultation, she looks into the cloud storage system and she can see data coming through from the sensor. Nurse Yamamoto immediately sets up the key parameters for her to be able to be alerted around Mr Sakamata's condition. Mr Sakamata's account is linked, with his permission, to his hospital record.

On his next appointment with Mr Sakamata, Professor Nakamura writes a lab request to gather a HbA1C test reading for him. He tells Mr Sakamata to take a trip to his local pharmacy who can run the test for him. Nurse Yamamoto, again with Mr Sakatama's permission, sends the diagnostic request to the relevant pharmacy. When the results come back a week later, Mr Sakamata inputs the HbA1C input into his app, which gets automatically uploaded into the cloud system,

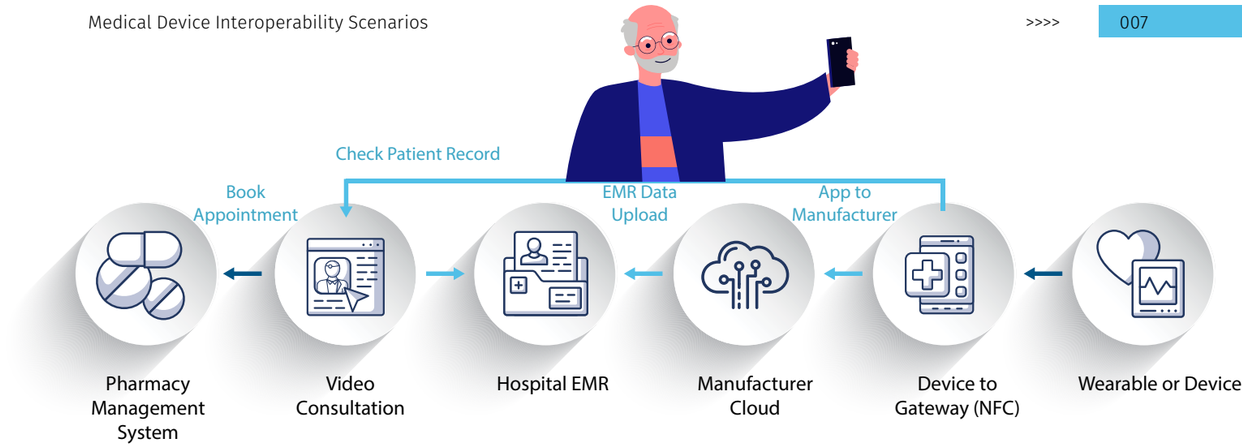


Figure 1 System Architecture For TeleHealth Loop Scenario

making it accessible to Professor Nakamura and Nurse Yamamoto.
Based on the recent HbA1c readings and the glucose readings that have been coming through for a few weeks, Professor Nakamura can see multiple regime changes that are required to be made.

Mr Sakamata has a tendency for post-prandial glucose excursions, leading to extended periods of hyperglycaemia: its clear Mr Sakatama's diet needs to be better managed. Professor Nakamura orders a remote dietician consult with Mr Sakatama on a regular basis.

Professor Nakamura observes in his discussions with Mr Sakatama long periods of low glucose in the early morning, and realises that Mr Sakatama takes long walks with only a small breakfast which results in a drop in glucose. Professor Nakamura instructs the dietician to recommend changes in his breakfast foods.

Nurse Yamamoto has alerted Professor Nakamura that there was a period of very low glucose identified occurring between 1am and 3am on a regular basis. Professor Nakamura immediately calls Mr Sakatama to adjust his night-time insulin levels to avoid this.

Professor Nakamura and Nurse Yamamoto review Mr Sakamata's record and pass his readings into the hospital electronic medical record (EMR). With this connection, they can additionally track:

- Cardiovascular risk
- Kidney function
- Changes in hbA1C over time
- Prescription medications
- Insulin treatments
- Notes from the podiatrist, renal physician, cardiologist and dietician.

After 6 months of remote management with the aid of a dynamic data feed, Mr Sakatama's glucose has been brought under control.
This change allows Mr Sakatama to access additional insurance funding so he can manage his diabetes even better over time. His recent hBA1C and glucose readings are now showing vast improvements in stability, which can result in fewer long-term complications, and improved knowledge and education on diabetes management.

Hospital administrators can now extract records of all patients with diabetes and supply their key markers anonymously to the payer bodies as proof of the value that remote monitoring offers.

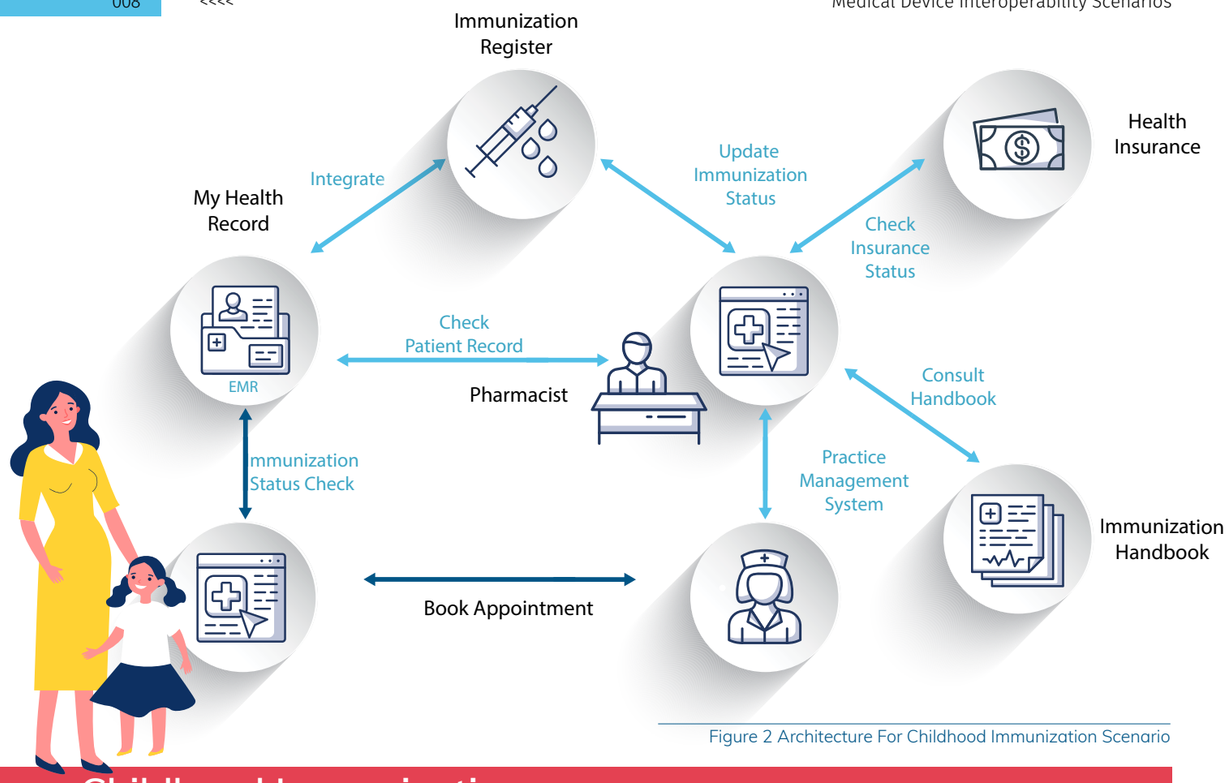


Figure 2 Architecture For Childhood Immunization Scenario

Childhood Immunization

Suzan is a working mother with three children who has recently moved to Western Australia from another state for work. Ellie is Suzan's third child who has just celebrated her 7th birthday.

Suzan has been reminded about disease prevention through vaccination. Suzan has decided to ensure all her children have been fully vaccinated, and to ensure that Ellie is able to take advantage of all vaccinations made available by her government at this time. Suzan is quite sure that all her children vaccinations are up to date but feels somewhat uncertain about Ellie because though she does remember that Ellie was vaccinated against several diseases through her school vaccination program, she cannot remember which ones.

Sadly, Suzan cannot locate the documentation she received at the time from Ellie's previous school. Suzan sits at her computer, and a quick internet search shows her that Ellie should have been vaccinated against diseases like chickenpox, diphtheria, tetanus, measles, mumps, rubella and many more before she was 4 years of age. Suzan is now feeling confused and apprehensive about the way forward.

Luckily, Suzan and Ellie can access the Australian Immunisation Register (AIR).

Suzan has web access to the AIR, which is a database maintained and made available by the Government and which can be easily accessed through the government portal my.gov.au. It forms part of every Australian citizen's electronic health record (EHR) which is known as My Health Record.

Suzan is able to access all her children's medical and immunisation records online though My Health Record. She checks Ellie's immunisation history which shows what vaccines and dosages Ellie has received and when she received them. Suzan also takes the opportunity to search the records of her other children and update her own understanding of her children's immunisation status and needs.

In some countries Suzan would have to write to request a written report, and in others this information would simply not be available to her.

Suzan sees that though her other children's immunisation records are current, Ellie has missed her MMR (measles mumps rubella) vaccination, so she decides take Ellie to the local pharmacy. Suzan books an MMR vaccination appointment for Ellie online via the pharmacy's appointment scheduling system. This triggers the pharmacist's practice management system to secure the MMR vaccine for Ellie.

Ellie and Suzan then present at the pharmacy at the designated time. There are a number of legal requirements:

- The pharmacist must obtain written consent from the person (or in this case their carer) before the vaccination and must retain this consent for seven years (in accordance with the Health Records Information and Privacy Act). Suzan digitally signs the form on the pharmacist's system.
- The pharmacist must undertake a thorough pre-vaccination assessment in accordance with the recommendations in the Australian Immunisation Handbook (AIH) which is accessed digitally. The pharmacist simply either enters the answers on the checklist, or the list is automatically updated by the diagnostic instruments used by the pharmacist to perform the examination.
- During the pre-vaccination assessment, the pharmacist must check if the person - in this case Ellie - is eligible for Government funded vaccines and advise Suzan if Ellie is eligible for this, and how Suzan can access the funded vaccines. Ellie is listed on Suzan's health insurance account, so the pharmacist is automatically reimbursed for the service digitally by the Government once Ellie has been inoculated.
- The pharmacist must not vaccinate a person with a contra-indication or precaution to vaccination as listed in the AIH. The pharmacist's system checks Ellie's EHR to ensure the vaccine is safe for her, based on her medication records.
- The pharmacist must record the vaccination and additional information like Ellie's name, address, date of birth and contact details and the brand, batch number and expiry date of the vaccine. The pharmacist system extracts the medication details, and the combined data is uploaded to Ellie's EHR. Once the vaccination has been completed, the AIR is updated with this information electronically by the pharmacist, which in turn updates Ellie's EHR.

The next time Suzan takes Ellie to be seen by a general practitioner/doctor, that practitioner can readily see Ellie's current health history, including her immunisation status.

Fast Infection Screening & On-Site Confirmation

Peter has a global business and must travel interstate and internationally. However, due to the pandemic outbreak, Peter has been trapped in Taiwan for over 4 months. He, like many other businessmen, has been waiting for a solution to travel without the risk of getting infected. And more importantly, the border control and quarantine policies of many of his destination countries need an effective way to facilitate the re-opening of business while maintaining the low risk of the disease spreading as well.

The digital “immunity passport” initiated by the World Health Organisation (WHO) could be a future solution for the situation. However, the implementation and practice of such an idea requires new technologies to be ready where they are needed – for example, a quick yet sensitive screening test to be carried out immediately before the traveler checks in for the flight or immediately after the flight lands but before immigration clearance. The results are uploaded and incorporated into the cloud database by the integrated transmission circuitry on the same semiconductor biosensor used for serological and molecular tests, which makes the test machine portable and easy to use. The immigration authority and border control agency access the encrypted data and evaluate the risk of the incoming travelers or passengers on the outbound flights.

Peter was on his way from Taiwan to England.

He arrived at the TaoYuan International Airport three hours prior to departure. Before he checked in for his flight, he went into a booth located next to the airport entrance. The booth looked no different from any telephone booth you would find on the street; however, it equipped with a small machine with a screen showing the procedures Peter must follow for the serological and molecular tests for COVID-19. It took Peter about 15 minutes to complete the test, then he went to the airline counter for check-in. With the embedded circuitry and analysis algorithm, the test machine transmitted the analysed data within 15 minutes, showing there is neither viral infection nor IgG/IgM responses in Peter’s tests. With Peter at the check-in counter, the database connected with airline ticketing and immigration systems suggested to the ground staff and immigration officers that Peter had low risk of spreading the pandemic disease; however Peter was at risk of getting infected because the tests Peter took showed he did not have enough neutralizing antibody to protect him from SARS-CoV-2 infection.

With the encrypted information showing only a binary yes or no regarding whether Peter is safe to travel or not, the ground staff issued the boarding pass for Peter since his tests came back negative of infection. The ground staff also asked Peter to sign a waiver form, showing he understood the risk he took of getting infected during the flight: this was due to the ground staff noticing the negative neutralizing antibody test showing in Peter’s test results. Peter signed the waiver form without hesitation because he had received the test results on his mobile phone on his way from the test booth to the check-in counter, and he understood his risk of getting infected but he felt safe because he trusted the procedure he just experienced. He believed the system had lowered that risk by alerting the airport and border control officials the potential asymptomatic COVID-19 patients from flying with non-infected passengers. Peter also felt financially relieved because, with the test certificate, he successfully purchased the travel insurance covering the potential costs he might incur if he did get infected during his travel.

With his boarding pass and the signed wavier form, Peter went on to the immigration station where he was notified by the Immigration Officer of his test results and he was issued a digital “immunity certificate” as a required document for his travel.

At his time of departure, Peter boarded the airplane as in the past, except this time, in addition to his passport and boarding pass, he had his immunity certificate and the wavier form with him. This was his entrance ticket for the point of entry of his destination – Heathrow Airport, London, England - where he would be welcomed.

Isolation Room

Steve was admitted to the hospital's Intensive Care Unit (ICU) after a bicycle accident, suffering from several injuries including a collapsed left lung and a brain trauma. He was admitted in an Isolation Room as he responded positive to COVID-19 tests. During his stay in the Isolation Room (IR) in the ICU, Nurse Joe needs to check regularly on Steve's hemodynamic and ventilation status. When Steve's ventilation therapy needs to be changed, Dr Terry needs to adjust the ventilator settings.

Due to the COVID-19 infection, Steve's condition is getting worse and he needs to be checked more and more frequently as time goes by.

His resistance to other infections is decreasing: both Dr Terry and Nurse Joe need to be extremely careful when entering Steve's IR to ensure they're not bringing in other infection diseases.

Dr Terry and Nurse Joe normally need to get into the IRs to check the status and to change settings of ventilators and infusion pumps for patients. In order to get into an IR, Dr Terry and Nurse Joe need to be protected from infections, so both caregivers need to carefully wash their hands and wear gloves, masks and other PPE. This can take up to 20 minutes which can cause unsafe delays in case of a critical situation.

Steve tested positive to the Tuberculosis test: further tests need to be performed as this infection might be highly contagious, presenting an added risk for the medical staff. Normally upon leaving the IR, both Dr Terry and Nurse Joe need to dispose of the PPE and wash their hands carefully before continuing their other work.

With the implementation of a new system effectively using interoperability between medical devices, it is possible to remotely control devices in a safe and secured way.

This interoperable system enables remote access to control devices: Dr Terry and Nurse Joe can check Steve's ventilation status and medication dose in the pumps from one central display mounted outside his IR and they can change the device settings, if needed, without having to enter the IR.

This means that Dr Terry and Nurse Joe will no longer need to change and put on their PPE before entering the room, losing crucial time in critical situations, nor will they be exposed to the potential infection risk.

As Steve's condition is very weak, he will be less exposed to additional infection risks as Dr Terry and Nurse Joe do not need to enter the IR to check the ventilator status or to change the device settings.

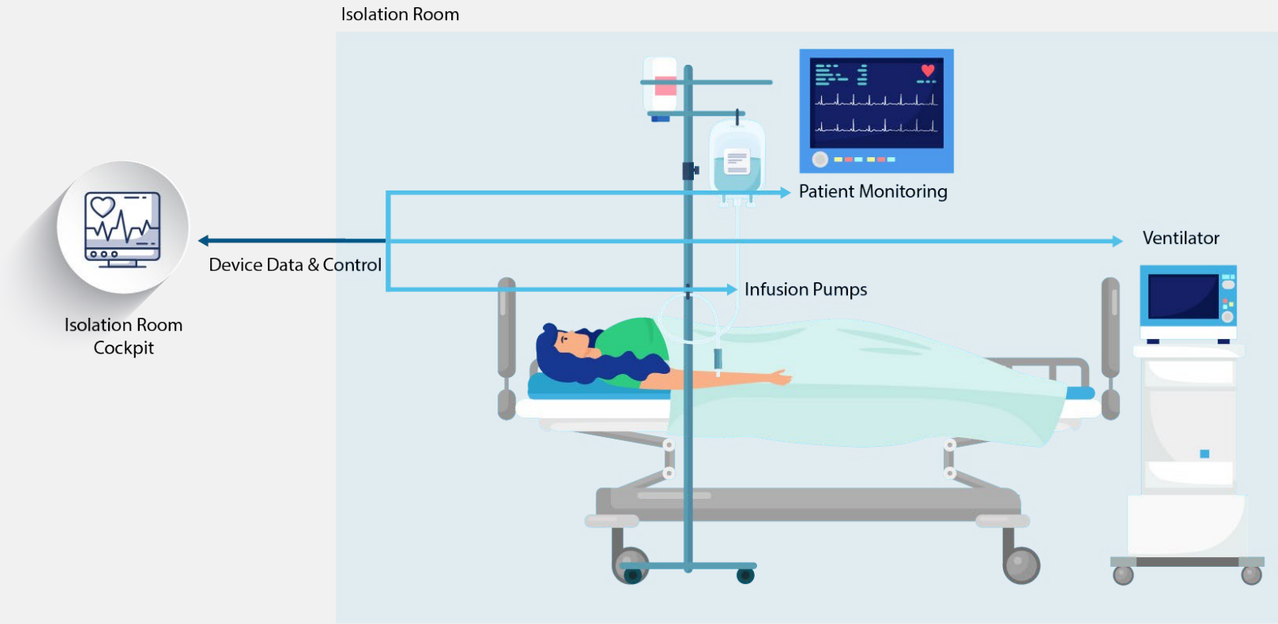


Figure 3 Architecture For Isolation Room

The fact that all the medical devices used in the IR are networked, and all are using the same communication protocol, allows the hospital to export the device data to the EMR using a Gateway and FHIR with a time synchronization between the medical devices and the Health Information System (HIS). This allows more accurate data to be provided for taking better and safer clinical decisions to improve patient outcomes.

In-Vitro Diagnostics During Tumor Treatment

Sarah likes nothing more than trekking and jogging, but this recent trek left Sarah feeling rather un-well. At first, everyone thought it was nothing more than a bad cold but after several weeks and bouts of antibiotics, she still didn't get better and she maintained a persistent cough, and so her doctor ordered a chest x-ray to see what's wrong. The x-ray showed diffused masses at the bottom of her lungs: this could mean many things i.e. a chest infection, bronchitis, pneumonia or in the worst case, cancer. To rule out cancer, Sarah's doctor ordered further tests, including a lung biopsy.

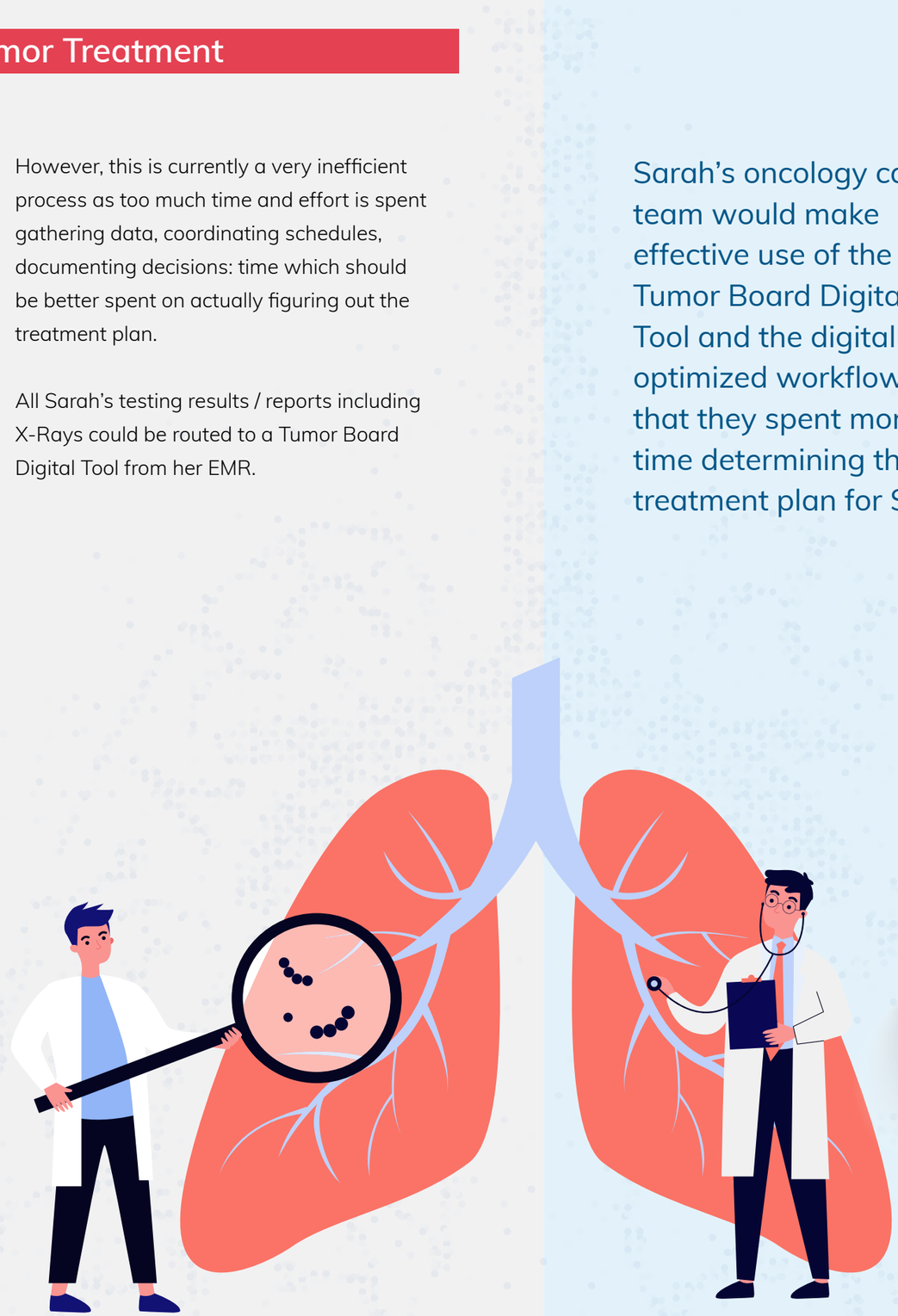
We're now in an anatomical pathology lab, where samples can arrive from everywhere across the country. The question we want answered here is whether or not Sarah has cancer, and a pathologist will be able tell after analyzing the slides under a microscope. Sadly, he did conclude that Sarah does have cancer. The next question, however, is what sort of cancer? This is important because even though we found cancer in her lung, it could have originated from another part of the body (metastasis), and this will determine how Sarah will be treated. Based on her results, the pathologist informs Sarah's oncologist that she has Stage 2 lung adenocarcinoma.

So now that we know she has lung adenocarcinoma, her case would typically be reviewed by a Tumor Board - a group of multidisciplinary specialists, ranging from surgeons, radiologists to social workers, who meet and discuss the best treatment plan for Sarah.

However, this is currently a very inefficient process as too much time and effort is spent gathering data, coordinating schedules, documenting decisions: time which should be better spent on actually figuring out the treatment plan.

All Sarah's testing results / reports including X-Rays could be routed to a Tumor Board Digital Tool from her EMR.

Sarah's oncology care team would make effective use of the Tumor Board Digital Tool and the digitally optimized workflow, so that they spent more time determining the best treatment plan for Sarah.



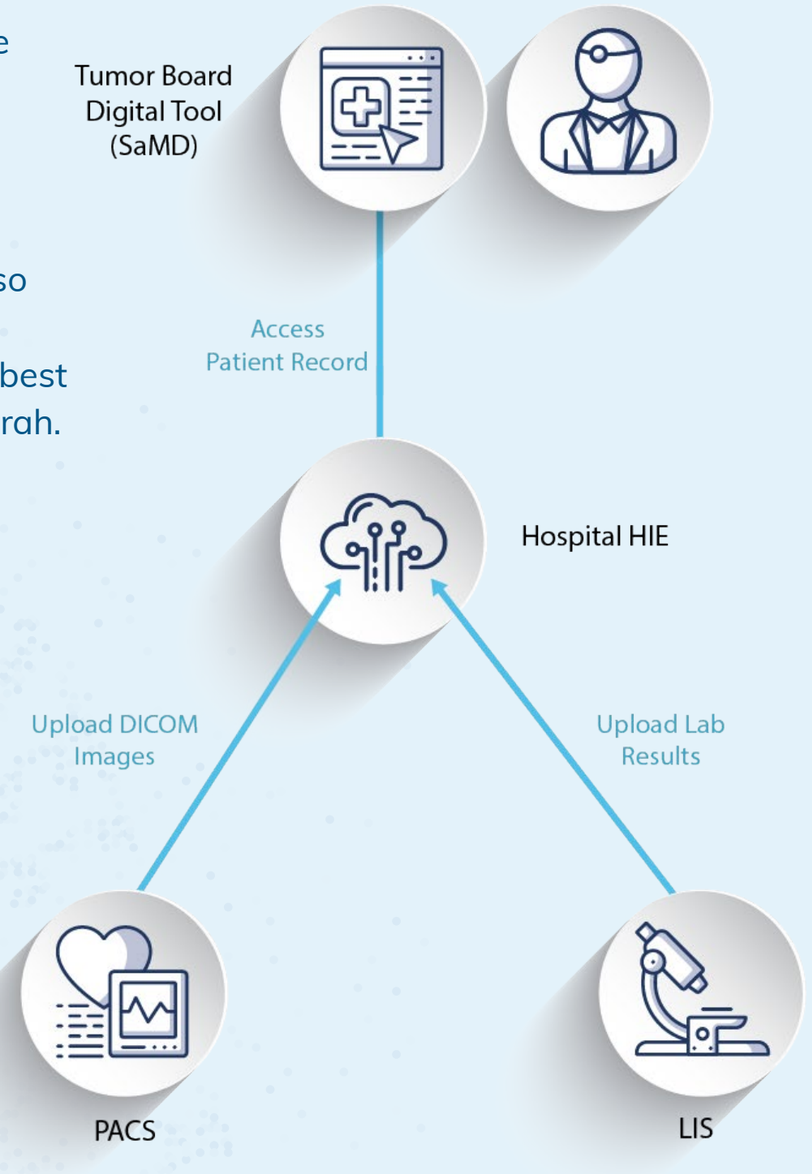


Figure 4 In-Vitro Diagnostics During Tumor Treatment

Knee Replacement Surgery

Greg is an avid golfer and enjoys nothing more than an afternoon round of golf on a frequent basis. The past few times though, he has been noticing some pain in his right knee that has begun to affect his game. Being a marathon runner in his younger days, Greg knows that his knee joints may be showing the effects of aging.

Greg makes an appointment with his primary care physician. Post examination, it is determined that to maintain the level of activity that Greg is used to and wants, he needs to have knee replacement surgery. The primary care physician is affiliated with a local hospital where surgery is scheduled. All of Greg's medical history and details are transmitted from the primary physician's chart to the hospital EMR and scheduling systems.

When Greg presents to the hospital for admission, his details are already present making for a smooth admission process. Greg is then rolled into surgery. The charge nurse pulls up Greg's details in any of the systems she uses, including the digital capture system, directly from the EMR. This integrated system is used to increase the efficiency of the surgical staff by ensuring the correct data is presented at the correct location with optimal focus on patient care.

During surgery, the surgeon and hospital staff take images and videos of the surgery to share with Greg later, and to inform his recovery plan. These captured videos and images are transferred to Greg's EMR. Greg is then given an option to download an app that will enable him to view the images and videos with his primary care physician. The physician can devise physiotherapy exercises to speed Greg's recovery and monitor his progress via the app.

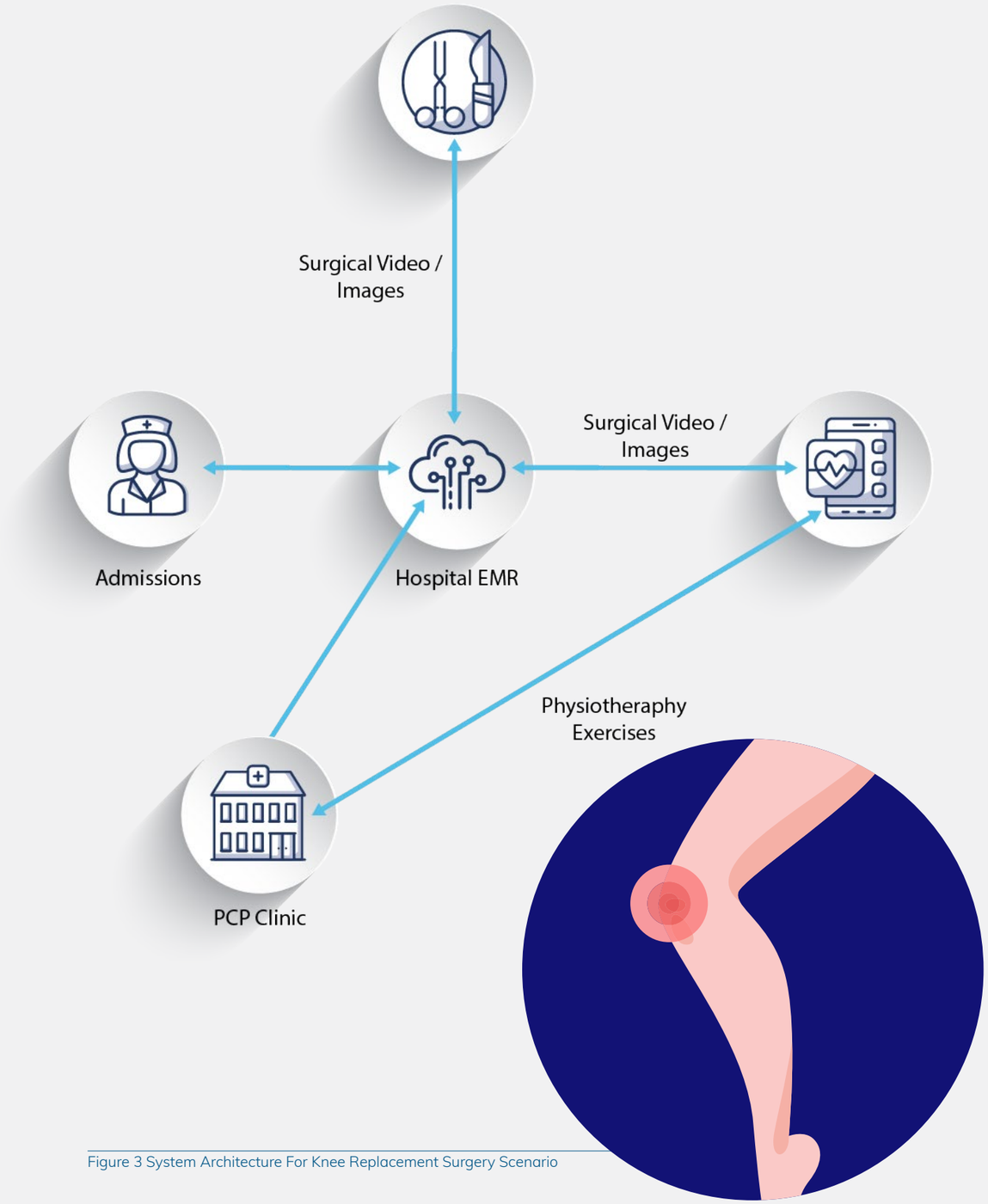


Figure 3 System Architecture For Knee Replacement Surgery Scenario

Intraoperative

After his check-in process in complete, John is driven into the Operating Room (OR) and placed on the Imaging Table. As John enters the OR, he notices that all the displays in the OR are showing some kind of a digital checklist. John is asked by the team to confirm some personal information regarding the surgery he is having today.

When the confirmation is completed, the nurse switches all the displays to a soothing beach video. Because this is the first time in the OR for John, he feels very nervous. But the combination of this digital video and audio technology makes him feel more relaxed and less anxious. John is given anesthesia and falls asleep with a monitor above his face displaying the soothing beach video.

As soon as John is asleep, Jocelyn - one of the nurses from the OR team - goes to the touch screen to switch off the beach video and to begin the surgery. During the surgery, Jocelyn can use the touch screen to trigger the integrated HIS in the room to help the surgeons capture images and record videos. She is also able to quickly switch between capturing and displaying the output of different medical devices connected to the HIS, based on the surgeon's request. If required during surgery, surgeons can easily initiate high quality real-time communication to departments such as pathology, radiology or any other service inside and outside of the healthcare facility using the HIS in the OR, thus allowing surgical teams to make better informed decision faster.

When the surgery ends, the surgeon looks over all the multimedia file captures and selects the files that they want archived to the hospital system, before giving back the system to Jocelyn, to prepare for the next surgery.

Jocelyn quickly looks at the OR schedule, which is autoloaded from the EMR, displayed on the HIS for the next surgery. She selects the preset for that specific surgery: with the click of a button the settings for the surgical lights and monitor are finalized and ready to go. With an integrated HIS that is as easy to use as her smartphone, Jocelyn is able to minimize the setup process, minimize human error from typing information herself and concentrate her attention on the patient more, leading to a better patient outcome.

Now she awaits the next patient to be wheeled in.

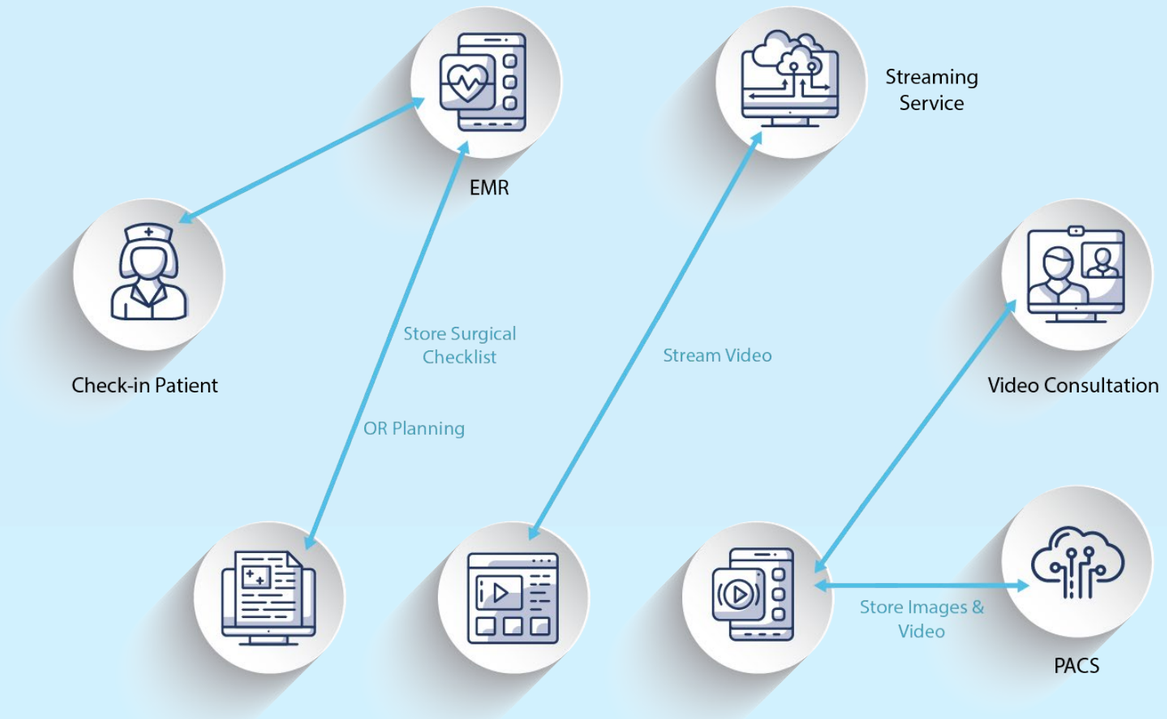


Figure 4 System Architecture For Intraoperative Use Scenario

Overview of Medical Device Interoperability Standards

The majority of health information exchanged and data interoperability itself is historically document-based. Whether faxed, emailed, or sent electronically, providers typically have to choose a set of data to transmit and then generate a message that contains only that data.

While this approach does help organizations communicate successfully, it is too limiting for meaningful care coordination, decision-making, or data analytics. Having complete information is important, but a document-based exchange doesn't allow a provider to delve into the context of the data received and therefore limits the ability to implement the clinical and health related scenarios outlined above.

For this reason, this section contains an alphabetically ordered list of standards, or profiles for standards, that are relevant for Medical Device Interoperability in the APAC region. We not only include technical specifications, but also terminology standards that are used in the Medical Device Interoperability domain to precisely communicate the semantics of the content.

DICOM

Digital Imaging and Communications in Medicine (DICOM)[DICOM] is a message standard that describes the format and exchange of medical images and imaging-relevant information. DICOM is the standard for handling, storing, printing, and transmitting medical imaging data. The standard was developed by the American College of Radiology and the National Electrical Manufacturers Association and first released in 1985.

The most common uses of the DICOM standard are in the storage and transmission of medical imaging data, enabling connection of imaging and storage devices including workstations, printers, Advanced Visualization, PACs systems and therapy planning systems from various manufacturers.

The DICOM standard includes specifications for implementing secure transport connections, digital signatures or securing only sensitive parts of DICOM objects. These extensions allow applications to exchange and archive DICOM information objects in a secure way. For example, include the extensions mechanisms for securing the transport of DICOM objects via e-mail or via TLS or HTTPS for the traditional DICOM transport resp. The DICOM web service transport.

HL7 FHIR

The HL7 specification called Fast Healthcare Interoperability Resources (FHIR, pronounced "fire") was created with the complexity of healthcare data in mind, and takes a modern, HTTP-based RESTful approach for connecting different elements of healthcare IT systems. HL7 FHIR is the latest generation standards framework created by HL7 and combines the features of HL7 v2 and other HL7 specifications with a focus on implementability. HL7 FHIR version R4, published in 2019, is the first version with normative content.

Healthcare related information elements are exposed as "resources," each having a unique identifier, just like the URL of a web page. Resources exist to represent information elements from domains like Clinical and Public Health Laboratories, Immunization Registries, Clinical Decision Support Systems, Devices, or general patient-related data as one can find in EMRs or Personal Health Records (PHRs).

As HL7 FHIR is based on technologies that are widely used in other IT architectures, it also uses state-of-the-art technologies regarding cybersecurity.

Participants in a HL7 FHIR-based system typically must be authenticated, and FHIR defines a security label infrastructure to support access control management. Exchange of data may be carried out using HTTPS (instead of HTTP), which creates a secure communication channel using TLS protocol.

The HL7 FHIR specification assumes that other security mechanisms and services exist in the IT environment like OAuth2 and are used together with the HL7 FHIR endpoints.

HL7 v2

HL7 v2 has been developed to transfer clinical and administrative data between Hospital IT software applications, and was originally created at the end of the 1980's. The current release of HL7 v2 is 2.9.

HL7 v2 is a message-oriented standard that uses a syntax based on message segments with composites (fields) that are separated by delimiters. A composite can also possess sub-composites.

In most installations, the messages are transported using MLLP (Minimal Lower Layer protocol), which is a minimalistic frame protocol and refers to lower layer transport protocols like TCP for topics like error correction.

For this reason, HL7 v2 does not specify any specific security transport layer, but secure channels like TLS connections can be utilized and are recommend in the related IHE profiles (i.e. IHE ITI ATNA).

ISO/IEEE 11073 PHD

Demographic changes (the rapidly aging population in many industrialized countries) and an increase in chronic diseases (such as diabetes and heart disease) has led many to ask how technology can be used to ease the burden on health care professionals and provide useful tools to the elderly and infirm – and in particular how technology can help people cope with their conditions within their own homes. This is leading to the development of “personal health devices” (PHDs) which allow people to monitor their own conditions within their own homes and provide the information that such devices obtain to health care professionals and other care givers.

ISO/IEEE 11073 PHD standards [IEEE-PHD] are a group of standards addresses this topic by providing a set of interoperability specifications for PHDs such as weighing scales, blood pressure monitors, blood glucose monitors and the like. The standards draw upon earlier IEEE11073 standards work but differ from this earlier work due to an emphasis on devices for personal use (rather than hospital use) and a simpler communications model.

In the words of IEEE 11073-20601-2008, that standard addresses a need for an openly defined, independent standard for converting the information profile [of PHDs] into an interoperable transmission format so the information can be exchanged to and from personal health devices and for example cell phones, personal computers, personal health appliances, and set top boxes.

The IEEE 11073 PHD standards have the concept of “agents” and “managers”. The agents are the PHDs and are generally small, inexpensive, battery-powered devices. The managers are typically computers or smartphones with greater computing resources and have the required routing capabilities to convey information from the delivering source to the named target destination. Agents and managers may operate in staggered architectures with multiple layers of agents as well as of managers.

All communications between agents and managers are preferably mobile and autonomous, as the carrying patients or nurses are mobile subject themselves. When the agents transmit their data to more capable managers, the data can be processed and displayed by the managers, and then perhaps transferred through the Intranet to people’s caregivers and to health care professionals. A transfer via Internet is technically viable, however this maybe of lower level of data security and protection / privacy.

To date, the IEEE 11073™ PHD standard family does not provide any method to ensure security of the data exchange. It assumes that data exchange is secured by other means, for example, a secure transport channel, but there is currently on-going work addressing this topic.

ISO/IEEE 11073 SDC

The ISO/IEEE 11073 service-oriented device connectivity (SDC) [IEEE-SDC] family of standards defines a communication protocol for point-of-care medical devices. The main purpose is to enable manufacturer-independent medical device-to-device interoperability, enabling interconnection between medical devices and medical information systems.

IEEE 11073 SDC is based on the paradigm of a service-oriented architecture (SOA). The IEEE 11073 SDC family of standards currently comprises three parts:

- core standards,
- Participant Key Purpose (PKIP) standards, and
- Devices Specialisation (DevSpec) standards.

The core standards consist of a transport standard, ISO/IEEE 11073-20702, called Medical Devices Communication Profile for Web Services, a Domain Information and Service Model (ISO/IEEE 11073-10207), and Architecture and Binding definition (ISO/IEEE 11073-20701).

The IEEE 11073 SDC standards utilize TLS-based security mechanisms with mutual authentication based on X.509 certificates.

The IEEE 11073 SDC standards are currently employed in applications in the operating room and ICUs.

IHE Profiles

Integrating the Healthcare Enterprise (IHE) is a non-profit organization with the objective to foster information sharing between different IT systems in the healthcare enterprise. In order to achieve that objective, IHE is organized into domains that define IHE profiles that translate the needs of purchasers into technical specifications that allow a vendor to implement or participate in the user scenarios. The IHE profiles include use cases as well as the technical specifications and are part of the IHE Technical Frameworks.

IHE Technical Frameworks have been published for:

- IHE Devices deals with the integration of personal health or medical devices into the healthcare enterprise. The use cases range from publication of information from the devices into the electronic health record system over to alarm management device point-of-care integration including device control (IHE DEV SDPi).
- IHE Patient Care Coordination that deals with uses cases that go beyond one care providers or multiple patient problems or the timely sequence of process steps during the care process.

- IHE Pathology and Laboratory Medicine takes care of use cases around sharing information captured in vitro diagnostic testing in pathology, clinical laboratories or the point of care.
- IHE Radiation Oncology is responsible for the use cases around information sharing, workflow, and patient care in radiation oncology.
- IHE IT Infrastructure addresses the requirements for the IT infrastructure to implement the use cases of other domains.

More information on the IHE Profiles as well as further IHE Profiles can be found on the IHE website [IHE].

Regional MDI Standards

It should be noted that some regional medical device interoperability standards and IHE profiles exist. Examples include the SS-MIX2 “Standardized Structure Medical Information Exchange” in Japan [SS-MIX2] and the work of the IHE regional deployment committees [IHERegional].

Terminologies

For enabling interoperability, terminologies play an integral role and therefore are widely used within the communication based on interoperability standards: the communication based on interoperability standards:

Standard	Description
ICD-10	The International Classification of Diseases, Tenth Revision (ICD-10) was developed and is maintained by the World Health Organization (WHO).
LOINC	LOINC (Logical Observation Identifiers Names and Codes) provides terms and identifiers to medical terminology related to assist in the electronic exchange and gathering of clinical results. Examples for the areas of LOINC usage are laboratory tests, clinical observations, outcomes management as well as research. [LOINC]
SNOMED	The Systematized Nomenclature of Medicine (SNOMED) is a systematic, computer-processable collection of medical terms, which cover for example anatomy, diseases, findings, procedures, microorganisms, substances in human and veterinary medicine. [SNOMED]
IEEE 11073	Within the context of the ISO/IEEE 11073 family of standards a nomenclature is provided that supports the semantic content exchanged with medical devices. The nomenclature is specialized for patient vital signs information representation and medical device informatics, with major areas including concepts for electrocardiograph (ECG), hemodynamics, respiration, blood gas, urine, fluid-related metrics, and neurology, as well as specialized units of measurement, general device events, alarms, and body sites. [IEEENom]

Recommendations for Manufacturers

It is expected that the use of standardized protocols for medical device interoperability will become mandated by governmental bodies more and more in order to support the cost effective development of data-driven clinical applications that are the backbone in the age of digital health. Examples for these initiatives are the US ONC Health IT certification program [ONC] and the German Digital Health Applications [DiGa].

If such a mandatory requirement exists already, the choice for the manufacturer is straight forward: they have to adopt the interoperability standard in order to place their product in the market, or at least get reimbursement.

If such a requirement does not exist, the manufacturer or technology provider has the choice. Nevertheless, it is recommended that manufacturers of medical or personal-health devices as well as healthcare technology providers should consider the use of interoperability standards for utilization within their products. Figure 6 above depicts a decision tree for manufacturers or technology providers that may help them to decide whether or not to implement a use scenario by contributing an interface based on interoperability standards.

APACMed strongly recommends manufacturers/providers consider one of the interoperability standards laid out in the section above.

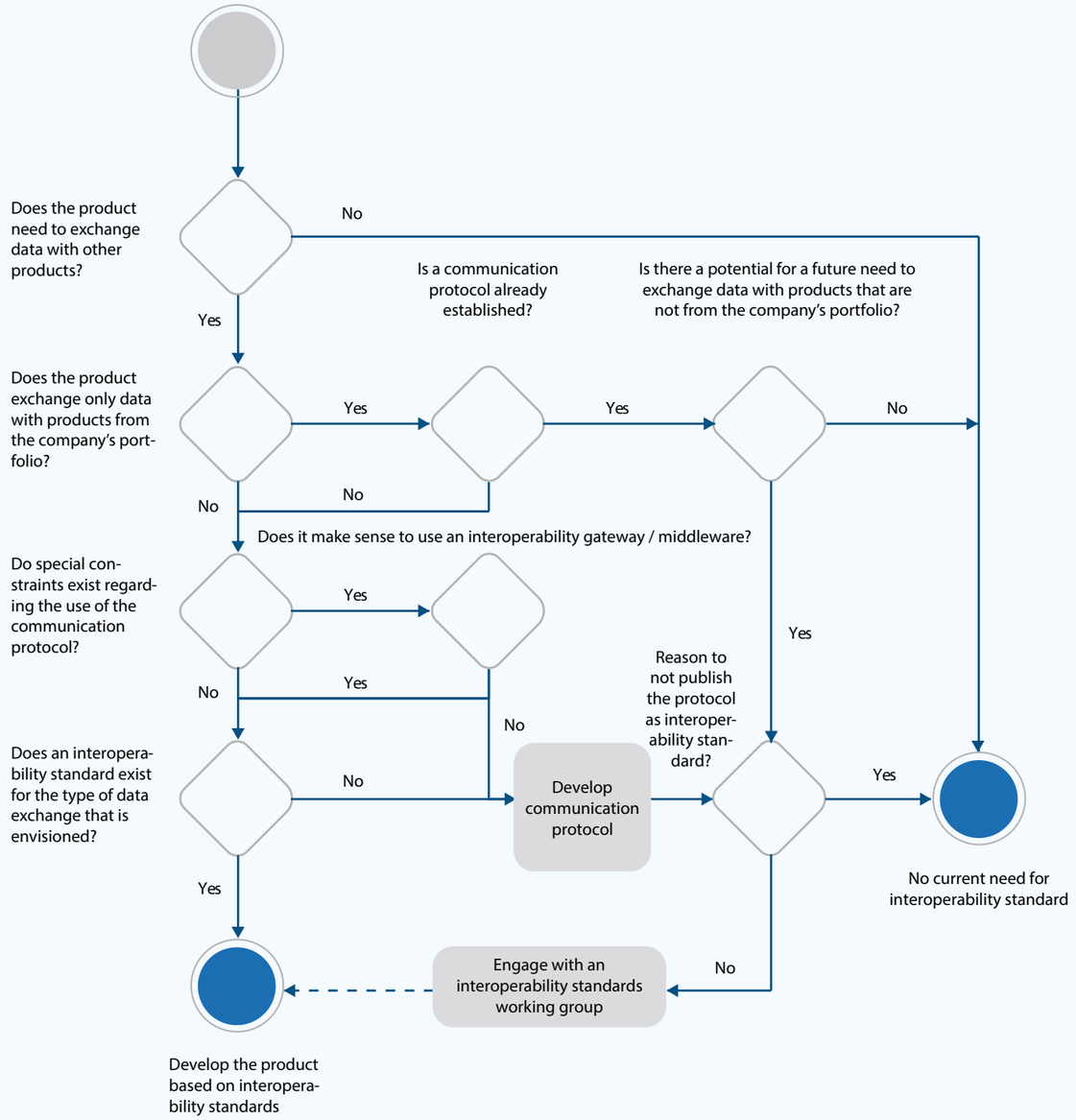


Figure 6 Recommendations For Manufacturers

Recommendations for Hospitals

Hospital management should consider implementing a medical device interoperability strategy as part of their overall hospital strategy, in order to ensure that the data is available for the transition to a digital hospital.

For Hospital Management and procurement departments, the inclusion of clauses into RFIs and RFPs to foster the development of interoperable medical device systems is recommended, in order to protect investment protection. For example, procurement language has been developed at the Medical Device Plug-and-Play Interoperability & Cybersecurity (MD PnP) Program at Massachusetts General Hospital and can be freely downloaded [MDFire].

As some of the medical device interoperability standards are not yet fully available for all products, procurement departments may also consider including a staged approach for medical device interoperability requirements in an RFI or RFP. This staged approach could include requests for information on when, on the planned or committed time horizon, certain functionality will be available in a product.

Moreover, it is recommended the hospital prefer an IHE profile over a pure technical specification if the profile addresses the envisioned medical device interoperability scenarios, as the IHE profiles clarify the exact usage of the technical specifications in certain use cases.

For IT and Clinical Engineering Management, it is recommended that the right processes and tools are in place for managing medical devices as part of the hospital IT infrastructure. Specifically, the process of performing risk management for the IT-network for medical devices should be considered. Moreover, the responsibilities between IT and clinical engineering need to be clearly defined.

The clinical staff (physician, nurses, therapists, etc.) should participate in the definition of use scenarios for medical device systems: their participation in the development of IHE profiles and other standards should be considered as they can provide valuable input as part of a cross-functional team.

Moreover, clinical staff should collaborate within their clinical associations to identify the benefits that could be attained using medical device data or due to the interactions of medical devices.

Hospital Care

Include medical device interoperability in the strategy for the digital hospital

Procurement

Include language in RFIs and RFPs that request the use of IHE profiles and international standards

IT & Clinical Engineering

Define processes to manage interoperable systems

Clinical Staff

Engage in the development of medical device interoperability standards

Recommendations for Regulatory Agencies & Governmental Bodies

Value-based care is a model of delivering healthcare in which care providers are incentivized to maximize the patient-relevant outcomes while reducing the cost of delivering healthcare [Porter]. In determining the patient-relevant outcome, it is of utmost importance to collect as much data as possible along the patient journey. In addition, the standards-based collection of data along the patient journey helps to provide a better understanding of the total costs related to a patient care path and to reduce the costs by avoiding duplicate or unnecessary medical testing & treatments. In this, interoperability is crucial.

The combined data collected from different interoperable data sources along the patient journey is not only helpful for the individual assessment of patient-related outcomes, but also underpins the general improvement of managing epidemics as it facilitates the comparison of different patients or patient populations, as well as the overall analysis of the epidemic.

Moreover, not only specific epidemics can be managed more effective and efficiently based on the combined data from different interoperable data sources, but also the general development of medical devices, medical technologies or the applications of these for different diseases. To allow this data to be used, the creation of consistent data pools for research and development that ensures the required data privacy is key.

Such a data pool fed by different interoperable data sources is also a powerful tool for regulatory agencies to assess the safety of a medical device or medical technology when it is already in the market, as it allows an automated analysis for incidents or near-incidents that could not be detected or analyzed before as the data may not be available or is hard to analyze. This is especially true when more and more interoperable medical device systems from potentially multiple manufacturers are used for achieving a clinical function during the patient care. An example for these interoperable medical device systems can be found in the “Isolation Room” scenario above.

Hence, it is recommended for governmental bodies to foster and facilitate the adoption of medical device interoperability standards, so that dataset from different data sources can be assessed in its entirety to determine the patient-relevant outcome, and to be used as real-world evidence for the safety and effectiveness of an interoperable medical device system.

Furthermore, it is recommended they adopt suitable guidance for the manufacturers similar to the FDA’s “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices” [FDAInterop] to facilitate safe and effective interoperability of medical devices in the APAC region.

Conclusion on Recommendations

Standards-based interoperability of medical devices is the key for a successful implementation of medical device interoperability scenarios for fostering innovation by combining products from different manufacturers for new healthcare-related solutions. Additionally, standards-based medical device interoperability fosters digital health in general as it eases the implementation of care models like value-based care and supports market oversight activities.

To create the basis for medical device interoperability applications and digital health, it is therefore of utmost importance that all stakeholders, from device manufacturers and hospitals as well as regulatory agencies and governmental bodies, work together to support the adoption of medical device interoperability standards throughout the APAC region.

For this reason, we - the APACMed Interoperability Working Group – see this White Paper only as the first step to support this overall objective, and we will together with other APACMed committees continue to jointly shape the future of digital health in the Asia-Pacific region.

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About APACMed

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. In 2020, APACMed established a Digital Health Committee to support its members in addressing regional challenges in digital health. For more information, visit www.apacmed.org.