Safety Analysis of Clinical Workflows: *The case of the Workflow within a Radiology Department*

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Abstract—Radiology Information Systems (RIS) and Picture Archiving and Communication systems (PACS) are used widely nowadays to help in the workflow management in radiology departments. Different architectures have been developed and several workflows are in use in different hospitals even for the same system. Effective safety analysis tools are needed to ensure the reliability of these high-risk workflows, because errors that may happen through routine workflow propagate within the workflow to result in harmful failures of the system's output.

With this prevalence of RIS/PACS in healthcare institutions, there is a growing need to analyse their safety. This paper showed how to apply a software technology called Hierarchically-Performed Hazard Origin and Propagation Studies (HiP-HOPS) to analyse the safety of RIS/PACS workflows.

The results of using HiP-HOPS comprised identification of the root causes of hazardous workflow failures that may put patient's life at risk.

We concluded that HiP-HOPS is applicable to this area of healthcare and is able to present added value through the detailed information on possible failures both their causes and effects. Therefore, it has the potential to improve the safety of RIS/PACS workflows and other clinical workflows.

Keywords—clinical workflows; safety analysis; radiology; HiP-HOPS

I. INTRODUCTION

Radiology Information Systems (RIS) and Picture Archiving and Communication Systems (PACS) technology has advanced dramatically in recent years, including the technology of acquiring, storing, retrieving, displaying, and distributing clinical images [1]. It has become a mature technology and has been commonly implemented in a number of developed countries [2]. Different systems have been designed and developed to assist different workflows in the radiology departments in several hospitals. In Jordan for example, RIS/PACS are implemented in a number of private, government, and military hospitals. To investigate the concerns that medical staff have due to the adoption of RIS/PACS systems, we conducted a number of interviews in one of the Jordanian hospitals. These were followed by another set of interviews to document the workflow in the radiology department in the same hospital, where RIS/PACS has been adopted. We found that faults and errors in the workflows might lead to harmful failures in the outputs (e.g. producing a report that has an incorrect description of the patient's situation, or leading to undesired reactions by the patient). Having the wrong report potentially results in an incorrect diagnosis and treatment, placing the patient's life at risk, while the effect of having unwanted side effects by the patient varies depending on how serious these effects are.

With this prevalence of RIS/PACS in healthcare institutions, there is a growing need to analyse their workflow safety, both ensuring the safety of the workflow design and the safety during the operational phase. In other words, securing the design of the theoretical workflow in terms of safety issues, and then making sure about following this workflow in the operational phase. Analysing and modelling the workflow plays an important role in medical information technology projects, as the implementation of these systems requires an understanding of the processes involved in them [3].

A RIS as defined by [4] is a computer system designed to support operational workflow and business analysis within a radiology department; it is a repository of patient data and reports which contributes to the electronic patient record (EPR) or electronic health record (EHR). [4] described the RIS as an imaging information system since it supports many additional specialists in areas including nuclear medicine, radiotherapy, and endoscopy.

As a RIS contributes to EHRs, then any errors in these systems propagate to affect the EHRs, which may put clinicians in a situation where they make wrong diagnosis and consequently put patients' lives at risk.

The interviews showed that one of the main concerns about adopting the RIS/PACS systems is the potential lack of reliability and thus lack of safety of these systems; this is due to the difference between the theoretical workflow and the operational workflow. Furthermore, even the theoretical workflow possibly has many problems with its safety, as where the safety issue was not addressed specifically during the workflow design. This leads to output failures of different parts of the workflow and eventually failure of the final output of the system. These failures of outputs can be defined by output deviations, where an output deviation outlines a set of Boolean expressions that shows the causes of the output failure, and the relationships between them. These causes can involve internal failures, input deviations, or both.

There is a scarcity of published literature addressing the problem of analysing clinical workflows and its safety. It is uncommon to have a formal automated safety analysis in healthcare for the management of clinical workflows such as the workflow within the radiology department. Little information is available regarding operational errors in RIS/PACS workflows (e.g. [5]). Safety of clinical workflows needs an intensive investigation and analysis, as well as clear approaches for this investigation and analysis. Lessons learned by industry in safety analysis have the potential to help healthcare organisations to avoid prospective hazards.

Research to date has not identified efficient automated approaches for workflow errors risk reduction. Many aspects of RIS/PACS design can be changed through the safety analysis of the workflow, as a flawed workflow design has the potential to decrease the efficiency and increase user errors during the operational phase of the workflow.

In the face of these limitations, this paper identifies potential significant errors in a RIS/PACS workflow by means of the following:

- Construction of a safety analysis from the results of an empirical study.
- Using the results of the empirical study to document and model both the detailed processes and the in depth tasks of one failure scenario of a RIS/PACS system's workflow.
- Collecting data regarding occurrence of the workflow errors and their prevention in the same scenario environment.
- Discussing current approaches to reduce the risk of errors in the RIS/PACS workflow.
- Proposing a new approach for the safety analysis of RIS/PACS workflow.

II. AN INTEGRATED APPROACH FOR SAFETY ANALAYSIS OF RIS/PACS WORKFLOW

Fault Tree Analysis (FTA) [6] is a common safety analysis technique through which root causes of an undesired event are identified. It is a deductive technique which determines how an undesired event (often termed the top event) can be caused by lower level failures (or events) or their combinations. Quantitative analysis of the FTA can be implemented to calculate the probability of the top event and qualitative analysis is performed to identify the necessary and sufficient combinations of events which caused the top event (termed Minimal Cut Sets (MCS)). Failure Mode and Effect Analysis (FMEA), on the other hand, is an inductive safety analysis technique that examines the effect of lower level (component) failures towards the higher-level system failures. FTA and FMEA has a wide use in exploring and analysing healthcare issues related to patient safety (e.g. [7]; [8]; [5]), and they showed their ability to analyse clinical processes. Automated FTA and FMEA would present and provide more efficiency in analysing clinical processes.

Hierarchically-Performed Hazard Origin and Propagation Studies (HiP-HOPS) which was initially proposed by [9], is a state-of-the-art technique, which has been prominently used in mechanical systems to effectively identify weak points in system design. It is a predictive safety analysis technique which enables semi-automated FTA and FMEA. In other words, it incorporates, automates, and integrates a number of classical techniques.

HiP-HOPS works in combination with a number of frequently used system modelling tools or packages (e.g. Matlab

Simulink), from which it receives block diagrams of systems being analysed and associated failure behaviour. It includes three main phases: a modelling phase, a synthesis phase, and an analysis phase where MCSs and FMEA are generated. The process starts when designers build a model of the system, then they annotate the model and its components with detailed failure information. Internal failure information can be annotated into the components as a set of expressions that are manually added to each component to describe how failures of the component output can be caused by a combination of an input failure and/or by internal malfunctions of the component itself.

HiP-HOPS can in general be applied to systems that involve data, information or material flow. However, in our case "components" may represent clinical processes, humans, tasks, or any other components of a clinical workflow architecture.

HiP-HOPS was used to analyse the safety of the workflow of a home Telemonitoring system in [10]. This paper uses HiP-HOPS to conduct safety analysis of a RIS/PACS workflow. The result of the analysis is the root causes of different failures, and their direct and indirect effects on both the workflow and the patients themselves.

III. CASE STUDY

A. System Architecture and System Workflow

The ideal architecture for a RIS has a hospital information system (HIS) which works as a master patient index, where data goes immediately to the RIS without the need for a technologist to enter any data.

In our case, the hospital combined the RIS and PACS and has them as a stand-alone departmental radiology system. They have a non-complete HIS that does not have full functionality and is not connected to the RIS. All the data needs to be entered in the RIS by the clinicians. The information to be entered includes the following: Patient name, Patient National Number, Date of Birth (DoB), Age, Address, Patient medical Information, and Order Information.

After the above information is entered into the RIS either by the clinician (as in our case) or by coming immediately from the HIS, then this information (which includes patient's medical, administrative, demographics, and billing information) is kept in the RIS, in addition to the information which is added at the RIS to identify the examination order. These may include the following: Order ID, Order Description, Scheduling, Patient Arrival Information, and Examination Room Scheduling.

This discussion considers the case where the clinician enters part of the information into the RIS, and there is some information that is entered into the RIS by another party who might be a radiologist. After that, the output of the RIS goes to the modality worklist (MWL) where the orders are scheduled to be sent to the image acquisition modality. Here at the image acquisition modality, there is no chance for human error as the data comes immediately from the RIS. However, this database, which has all the scheduling information and orders information, is open to hardware and software errors. At the image acquisition modality the patient is supposed to have the examination that is specified in the order. The output of the image acquisition modality is patient id, patient name and the image itself.

After that, these outputs are sent automatically to the PACS which archives them and then sends them to the diagnostic workstation to be seen by the radiologist. The radiologist is now able to interpret examinations from several clinical sites and/or hospitals (in the case of Teleradiology), and produce a report as an output. This report is to be passed to the clinician to make the diagnoses and give a medicine or recommend for another procedure such as an operation.

The following figure shows the workflow within the system. The information from the EHR is relayed back to the HIS component.

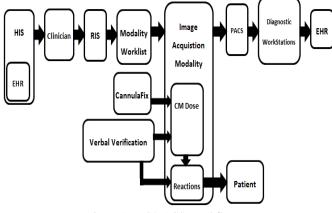


Figure 1: RIS/PACS Workflow

The EHR has the following information:

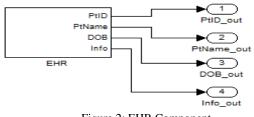


Figure 2: EHR Component

This paper considers one of the workflow scenarios; the purpose is to analyse possible failures of this scenario and to find out the root causes of these failures. This scenario is the workflow for a computerised tomography (CT) scanner. A CT scanner creates cross-sectional images of the body using X-rays; the result is a very detailed 3D view of the body interior. CT scans are used to make a cancer diagnosis or assess the effects of cancer treatment.

When the patient sees the clinician, the clinician decides if there is a need for a CT scan. Once a CT scan is recommended, the risk of exposure to radiation is considered before deciding to send the patient to the exam. This is because the accumulative amount of radiation the patient is exposed to has a potential risk for the patient, so clinicians recommend it when they think that the benefits will exceed possible risks. In order to consider the amount of radiation, in most cases the date of the last CT scan must be considered by the clinician before such a decision can be confirmed. Moreover, a pregnancy check must be done to make sure that the woman who will start the exam is not pregnant.

Commonly, patients who will receive a CT scan must follow certain preparation guidelines. These include no eating for two hours before the appointment, and drinking 500 ml of water over this time. The water is useful to hydrate the patient before having the Contrast Media (CM) for the CT scan. Another preparation guideline is to ask the patient to drink another 500 ml of water after arriving to the waiting area. It also helps to show the bladder on the scan.

Verbal verification by the radiologist is needed to check these preparations with the patient together with other preparations such as ensuring there is no metal present (e.g. wearing of a metal belt, or jewellery or having an internal device inside their bodies). Moreover, verbal verification of the patient's DoB at this point plays an important role in correcting any previous errors in the DoB, as the DoB is important in determining the amount of CM and the amount of radiation. Some patients may require a blood test before CM can be given.

An injection of the contrast is often given before or throughout the scan. CM contains iodine and appears as white areas on the scans, which help the radiologist to differentiate between certain organs or tissues and the other structures. The contrast may be ingested as a drink, or injected around the required area, or given via a cannula which is placed in the patient's arm prior to the scan. Again, verbal verification is required here to confirm any allergies and medications that the patient takes in order to judge the suitability of the injection and to minimise interactions with other medications.

The CM is modelled as a separate component:

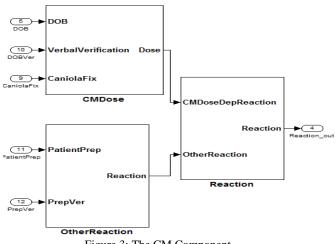


Figure 3: The CM Component

Typically, people who feel claustrophobic do not have problems with CT scan as they might have with other scans, like Magnetic resonance imaging (MRI). However, the radiographer should check this with the patient before the scan, as if the patient thinks that he is expecting to feel this way then an injection may be given before the scan to calm the patient.

After the scan is finished, the patient should be asked to wait for an hour at least after the injection to make sure the patient is in good health, and he/she did not have allergic reaction to the CM injection, because people sometimes have different reactions; in these circumstances, medical staff should be able to manage different reactions appropriately. The radiologist then should give some instructions to the patient to follow once he goes home, for example, again asking the patient to drink 500ml of water to rehydrate the body after the CM injection.

B. Errors Propagation is the cause of failures

Errors may happen at any point where there is a data entry. This paper focuses on the failures caused by DoB errors in the CT scan workflow scenario.

A CT scan is considered as a safe procedure, although there can be reactions to contrast media CM which usually cannot be predicted [11].

For example, the dose of contrast media which is given to the patients is different for adults and children. Therefore, date of birth is an important factor for specifying the amount of CM to administer. Giving the patient an overdose of CM has reactions that affect patient health and put the patient in a hazardous situation.

Faults may occur at different points in the workflow and need to be identified. Failure annotation is performed using the HiP-HOPS tool; all the components need to be annotated with possible faults. HiP-HOPS then analyses the model to give the fault trees that detects the possible failures and provide the root causes for them. In addition, it provides us with information about their effects on the output of the workflow.

C. Failure Annotation

The interview's data are analysed to document the RIS/PACS system's workflow. Then the documented information is used to model the workflow to enable the automated analysis. After that, the model is extended with failure information for several scenarios. This failure information describes how a failure in the component output is caused by a propagation of failure from the component input or the internal malfunction of the component itself. Failure is represented in the format of "FailureType-ComponentName.ComponentPort" in HiP-HOPS.

The first scenario analysis focuses on having side effects or bad reactions by the patient. As described by the system architecture, the effect on the patient is considered as an 'output' component. This failure is represented by the value failure of the patient component, and so is referred to as V-Patient.Out1.

The patient's DoB is entered into HIS together with other information. Value failure of DoB which could be caused by wrong data entry is represented as V-DoB_out, also omission of the DoB causes problems and it is classified here as output deviation of the HIS. Omission of DoB is represented here as O-DoB_out. Moreover, HIS internal malfunctions can cause the output failures of the HIS; these are represented as HWError, SWError, and DataEntryError.

Similarly, the clinician — who is included in the workflow as a separate component — can have output deviations. Clinician might make data entry errors which are represented here as IDDataEntryError or DoBDataEntryError. The output deviations are represented as V-PatientID_out and V-DoB_out. RIS internal malfunctions may include software or hardware malfunction, represented as HWError, SWError. RIS as well as potentially receiving the wrong DoB from the Clinician, represented as DoBDataEntryError. In addition to these malfunctions, RIS may suffer from failure of the preparation data, which is PrpDataEntryError. Therefore, output deviations at RIS could be the omission of DoB or having the wrong DoB or having the wrong preparation information or omission of preparation information; these are represented respectively as: O-DoB_out, V-DoB_out, V-PatientPreparationInfo, and O-PatientPreparationInfo.

ModalityWorkList is a database, which keeps orders' scheduling information and patients' information. It can have two basic events, which are software error or hardware error. These are represented as SWError and HWError respectively. Each of the ModalityWorklist inputs has its own failure but in the first scenario, some failures have been considered and the others are ignored as they are assumed to be free from failures. The failures which are to be analysed are: the failure of the value of the DoB and the failure of the preparation information output either as a value failure or omission of this value. These are represented as V-DoB_out, V-Prep_out, and O-Prep_out.

When it comes to the image acquisition modality itself, at the time of the test the radiologist should verify some information with the patient, e.g. DoB, name, and preparations for the test. The process of verbal verification is represented as a separate component which may have two basic events, both human errors; they are represented as: DoBHumanError and PrepHumanError. Failures of the output of this component are represented as: O-DOBVer and O-PrepVer.

Fixing the cannula for the contrast medium is considered as well as a separate component, and annotated with the failures that might be a human error (represented as HumanError); the output failure of this component is represented as V-Out1.

The CM dose is considered as a subcomponent of the image acquisition modality and failure of this is giving the wrong dose for the patient. This failure is represented as V-Dose, which can be caused by either wrong dose calculation or wrong measurement. Other reactions are considered as well as subcomponents of the image acquisition modality component, which may have a failure that is represented as V-Reaction, where the patient has some reactions or Side effects when he is not supposed to have them. These kinds of reactions that happen according to not following the preparation guidelines by the patient are separated from the CM dose-dependent reactions.

The output of the CMDose component and OtherReactions component goes to the Reaction component. This separate component is annotated as well with possible failures.

The Reactions component is connected to the patient who is having these reactions. The image output is connected to the PACS component that receives the images and archives them into a database.

We did not annotate both the PACS and the diagnostic workstations component with failure information for the purpose of this scenario. We assumed that they only propagate failures. A comprehensive analysis must consider failures of these components and annotate them with all possible errors to get the root causes for the other possible failures of the workflow.

There are other scenarios that may possibly cause defective results, but again, for simplicity, they are not covered in this paper. For example, when the patient gives information to the clinician, the patient might not tell the right information about his situation and the clinician might not check. Those two conditions together result in creating the wrong history for the patient. When the clinician has the wrong information, he or she will ask for the wrong exam order that in turn causes the wrong examination description. At the time of the examination, if the patient did not tell and the radiographer did not verify this, and he or she has the wrong exam description, these conditions together might give a false report for the patient, which results in an incorrect procedure or the wrong medication.

Another failure that can potentially cause patient harm but is not considered in this paper is when images are mislabelled for the wrong patient and/or the wrong study. These kinds of failures result in images that are incorrectly associated with the patient's EHR and may lead to incorrect diagnoses, medication, or procedures.

Other failures might happen because of an incorrect entry for the DoB of the patient, which occurs when the clinician enters the wrong DoB in both the HIS and the RIS. These faults together result in the wrong DoB of the patient which cause an incorrect dose of both radiation and the CM. Here the patient is under the risk of extra dose of radiation and dose dependent reactions of CM. The dose dependent reactions of CM are analysed in this paper.

D. Analysis Results

We annotated the components of the model with the corresponding failure information and then performed the root cause analysis. HiP-HOPS synthesises and analyses the system fault trees and produces the FTA and FMEA results, which shows how the value failure in an input and the component failures (or their combinations) can lead to the failure in causing unintended reactions or side effects towards the patients.

The following figure shows the FTA result. For clarity, V-Reaction is represented as Unintended Reaction in the FTA and FMEA table:

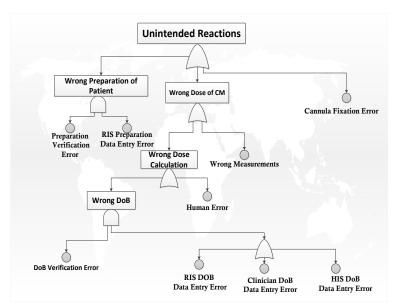


Figure 4: FTA Result

The following list shows the MCS [6] from the FTA:

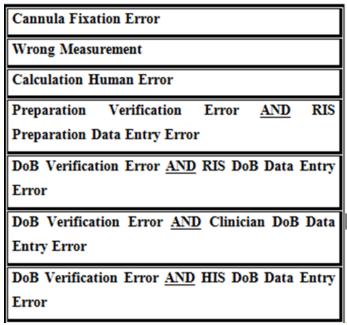


Table 1: MCS from FTA

The following table shows the resulting FMEA table of the direct and further effects:

| Component: Cannula Fixation | |
|---|----------------------|
| Failure Mode | System Effect |
| Human Error | Unintended Reactions |
| Component: Clinician | |
| Failure Mode | System Effect |
| DoB Data Entry Error | Unintended Reactions |
| Component: RIS | |
| Failure Mode | System Effect |
| DoB Data Entry Error | Unintended Reactions |
| Preparation Data Entry Error | Unintended Reactions |
| Component: Verbal Verification | |
| Failure Mode | System Effect |
| DoB Human Verification Error | Unintended Reactions |
| Preparation Human Verification Error | Unintended Reactions |
| Component: HIS | |
| Failure Mode | System Effect |
| DoB Data Entry Error | Unintended Reactions |
| Component: CM Dose | |
| Failure Mode | System Effect |
| Wrong Measurement | Unintended Reactions |
| Calculation Human Error | Unintended Reactions |
| T 11 0 EMEA T 11 | |

Table 2: FMEA Table

To summarise, the FTA and FMEA results show that the following failures may lead to the failure of the first scenario (which is in this case getting unwanted reactions by the patient):

- Human error in fixing the cannula for the CM, where the radiologist or the nurse makes an error in placing the cannula prior the scan. This mistake cause problems for the patient as the CM is injected through the scan, which might lead to both side effects of the CM or extra dose of radiation because radiologist might need to repeat the scan.
- Data entry error for the DoB by the clinician combined with an error in the verbal verification of the DoB by the radiologist at the time of the scanning. This combination of errors might lead to an extra dose of radiation and/or extra dose of CM, which may put patient's life at risk.
- Data entry error for the DoB by the radiologist combined with an error in the verbal verification of the DoB by the radiologist at the time of the scanning. Again this focuses our attention on the importance of the verification of the DoB by the radiologist at the time of the scanning.
- Data entry error for the preparation guidelines by the radiologist combined with an error in the verbal verification of the preparation guidelines by the radiologist at the time of the scanning. This means, if the patient received the wrong preparation guidelines or did not receive them at all, then at the time of the scanning, if the radiologist does not make sure about their accuracy (and whether they were followed by the patient or not), the patient will experience the reactions.
- Data entry error for the DoB in the HIS combined with an

error in the verbal verification of the DoB by the radiologist at the time of the scanning.

- Wrong measurements to calculate the dose of CM can directly cause the unwanted reactions. This might happen because of not understanding the units of measurements, or using wrong equipment to measure the dosages.
- Human error in calculating the dose can directly cause the reactions. This may happen through making mistakes in calculations that result in wrong dose.

This means that if there is any error in the data entry in HIS, clinician, and the RIS, combined with a situation where the radiologist does not verify (or verifies incorrectly) the data for DoB or preparation information, the unintended reactions towards the patient will occur. These errors can be avoided by adding extra functionality to the HIS or RIS or both of them (for example, bar coded patients help to avoid data entry errors by radiologists and clinicians). Moreover, adding extra tasks in the workflow may help to avoid the errors.

Human error in fixing the cannula for the CM also contributes directly to the unintended reactions. So, radiologists or nurses who perform this task should be informed about potential failures which it may cause and about their direct and indirect effects on the patient.

E. Validation of the Approach

Initial data on the applicability of the approach were gathered through an informal testing shown positive usability and effective results.

Our results were discussed with experts in the hospital in which the data were collected and they appreciated the ability of the approach to focus on processes and human errors, as well as how this could be employed for several applications in clinical workflows. Moreover, having the fact that our analysis results are happening in the hospital as actual failures has the potential to validate our approach. Our approach drew the map for the root causes of these failures. This is the major contribution of this work as to date there is a lack of automated tools which allow the modelling and analysis of real-world workflows. The approach provides an effective means to accomplish this goal, is able to provide a valid theoretical frame consisting of modelling the processes and sub processes and their error analysis. The study findings contribute towards a larger research effort being proposed for reducing medical errors and enhancing patient safety.

F. Conclusions and Contributions

The automated identification of these root causes allows greater understanding of the factors contributing to the undesired event which can potentially lead to a serious clinical risk. This enables the identification of weak points, which could then be effectively addressed and improved.

The simple act of undertaking a safety analysis in this way helps to improve understanding of the behavior of the workflow and its potential for failure, thus highlighting areas where additional checks or amendments to the workflow need to be introduced. The automation then additionally helps deal with the complexity and time cost issues, offering benefits over a simple manual analysis. While in this case there were only order 2 MCS, more comprehensive analyses might introduce even higher order MCS that are even more difficult to spot manually, potentially highlighting issues that are not even apparent from a manual analysis.

For example, through the simple structure in this example, the application of HiP-HOPS shows the ability to systematically assist in the identification of failures in the workflow (i.e. failure in the verbal verification or failure in the data entry of the DoB) and the identification of the failures in the system (i.e. hardware or software error in the MWL). This information can be used to guide the improvement in the design of both the system and the workflow. The system can be improved by targeting the areas where highly-reliable components and fault tolerant mechanisms can be prioritised and introduced to make the architecture more robust and fault tolerant.

Moreover, the workflow can be improved by designing the workflow in a way which takes the safety analysis into consideration and to use the results of the analysis to target areas where reliable components (in this case the components are processes and tasks) can be introduced. The workflow should have an exact determination of the processes, tasks, and the procedures which must be done by each party.

Having this detailed workflow with a detailed analysis of the failure behaviour can enable healthcare organisations to develop material to be used by medical staff in safety training workshops. These workshops should help the medical staff to build safety awareness that may be useful to avoid the expected failures in the workflow.

Using HiP-HOPS in workflow analysis in general has the potential to give effective analysis by detecting possible design flaws early before serious problems happen. This also helps to provide the medical staff the awareness they require and aids in redesigning the workflow to produce an effective and fault free workflow.

Moreover, such modelling of the workflow and the analysis results can also be used as an educational tool for training of radiologists, nurses, and clinicians. This helps the trainees in identifying errors and preventing the potential errors from leading to adverse events.

The example presented in this paper is based on one scenario, while different scenarios need to be modelled and analysed to get a comprehensive analysis of the workflow. Moreover, conducting research of this nature on only one location is limiting, and having more sites opens a wider range of failures determination.

G. Future Research

We have done this work as a part of a clinical workflow safety analysis project at University of Hull. Here in this paper we showed how to use HiP-HOPS to analyse one of the RIS/PACS workflow scenarios. This identified the need for further investigation with a comprehensive analysis for all the scenarios. Moreover, implication of probability analysis in future studies may aid in giving a complete analysis, and at this point human factors uncertainty needs to be taken into consideration (uncertainty in probabilistic analysis due to human factors). To conclude, further research is needed to enable more valuable recommendations to hospitals on how to redesign their workflows with the consideration of workflow analysis, how to use the workflow safety analysis results to redesign their workflows and to support the medical staff awareness culture. This awareness culture is expected to contribute in minimising the chances for workflow's failures.

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