

## An Evaluation of a Low Dose Rate (LDR) Brachytherapy Procedure using a "Systems Engineering & Error Analysis Methodology for Health Care" (SEABH)

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Health Care Failure Modes and Effects Analysis (HFMEA®) is an established tool for risk assessment in health care. A number of deficiencies have been identified in the method. A new method called Systems and Error Analysis Bundle for Health Care (SEABH) was developed to address these deficiencies. SEABH has been applied to a number of medical processes as part of its validation and testing. One of these, Low Dose Rate (LDR) prostate Brachytherapy is reported in this paper. The case study supported the validity of SEABH with respect to its capacity to address the weaknesses of (HFMEA®).

### INTRODUCTION

Health care technology and processes are currently advancing at a rapid pace, with, for example, dramatic changes occurring in cycles of less than 5 years in the field of surgery (Amalberti, 2009). This rate of change has a significant impact on the stakeholders, requiring up-skilling and continuous adaptation of existing practices. The introduction of advanced technology systems has been found to negatively affect the quality of treatment delivery, e.g. by changing existing work practices and communication methods, and increasing the dependence on technology in the delivery of care (Ash et al., 2007). It has also been found to result in ad hoc system configurations and a lack of continuity and integration of systems in treatment processes (Chadwick, Fallon, Kirrane, & van der Putten, 2012). Worryingly, it also has the potential to introduce new errors and error pathways into treatment processes that may not have previously existed and which can go undetected until the occurrence of an adverse event or series of incidents (Ash, Berg, & Coiera, 2004; Graber, 2004; Han et al., 2005; Patton, Gaffney, & Moeller, 2003).

The widespread adoption of advanced technology and treatment types has also been driven by the need to retro-fit 'safety' into already functioning departments and treatment processes to meet new safety standards. Frequently such technology adoption is completed with little consideration regarding its impact on the stakeholders or process. Unfortunately, the fast paced introduction and integration of new technology has not been adequately supported by the availability and use of suitable proactive analysis methods to prevent the introduction of new errors in the treatment process.

HFMEA® (Derosier, Stalhandske, Bagian, & Nudell, 2002) has become a widely used analysis tool in health care for the proactive analysis of treatment processes with several case studies reporting predominantly positive feedback (Esmail et al., 2005; Florence & Calil, 2006; Gilchrist, Franklin, & Patel, 2008; Ouellett-Piazzo, Asfaw, & Cowen, 2007).

Despite the positive findings from these case studies, a number of negative aspects of HFMEA® have been identified

that give rise to questions regarding its fundamental design and ability to facilitate and achieve its intended purpose (Chadwick & Fallon, In Press; Habraken, Van der Schaaf, Leistikow, & Reijnders-Thijssen, 2009; Wetterneck et al., 2006). These include: difficulty using the flowchart, identifying failure modes, determining corrective measures, using the hazard scoring system and the time required to complete studies. The Systems and Error Analysis Bundle for Health Care (SEABH, pronounced 'SAVE') was developed to address these issues.

### SEABH

The SEABH method includes constructs and concepts from a number of existing tools including IDEFØ (IEEE, 1998), Failure Modes and Effects Analysis (FMEA) (IEC, 2006), Cognitive Reliability and Error Analysis Method (CREAM) (Hollnagel, 1998), Health Care Failure Mode and Effect Analysis HFMEA® (Derosier et al., 2002) and the Irish HSE Risk Assessment Tool (Office of Quality and Risk, 2008). It has been designed to improve the efficiency of the analysis process, while increasing the support information available for use by health care stakeholders. The methodology includes a flowchart, see Figure 1, which guides the analysis, taxonomies of human error and related potential causes and a detailed health care specific risk assessment tool.

SEABH requires team members to analyze sub-processes or tasks using the FMEA categories presented in IEC (2006). Also, a modified version of the CREAM error taxonomy and antecedent/consequent taxonomies and of the Irish HSE Risk Assessment Tool which includes a new data/information category is used to formally complete the risk assessment (Chadwick & Fallon, In Press).

SEABH supports the identification of error related Performance Shaping Factors (PSFs) and Psychological Error Mechanisms based on the CREAM method, see Table 1 for an example. It directly links the identified potential human errors to potential causes which in turn support the determination of appropriate control measures. It also reduces the need for the risk assessment of individual process steps through the logic of the flowchart and supports continuous improvement.

The Flowchart is based on the logical principles used in the HFMEA™ method but clarified for the user:

1. If a failure mode is recoverable → ‘Stop’ the analysis and move on to the next failure mode.
2. If a control measure exists for a failure mode → ‘Stop’ the analysis and move on to the next failure mode.
3. If a failure mode is high risk or critical, is not controlled and not detectable → continue to in-depth analysis, identifying the potential causes and repeating the progression through the flowchart.

The SEABH Flowchart overcomes a number of issues identified with the HFMEA® flowchart through its design and inherent logic (Chadwick & Fallon, In Press). Primarily, it prioritizes risk detection, recovery and control measures before formal risk assessment. SEABH does not assume an implied ability to recover from errors once detected, instead it first queries the detection of a failure/error then if detection is possible it queries the ability to recover the failure/error. It reduces the need for the risk assessment of individual process steps through the logic of its flowchart, which only requires the formal risk assessment of individual processes that cannot be recovered or are already controlled; see Figure 1 a simplified version of the SEABH Flowchart used for illustrative purposes.

The SEABH method has been validated using the Validation Square, a prescriptive tool for the validation of new methods, and tested using two distinct theory-testing case studies: Low Dose Rate prostate brachytherapy using the real-time planning method and the prescription administration process in a cardiothoracic unit. The first of the two case studies is presented in this paper.

### TESTING AND VALIDATION PROCESS

SEABH has been validated using the Validation Square (Pedersen, Emblemsvåg, Bailey, Allen, & Mistree, 2000; Seepersad et al., 2006), a prescriptive tool for the validation of new methods, supported by the completion of two distinct theory-testing case studies (Chadwick, 2010). The Validation Square is a framework for guiding the process of validating an engineering design/analysis method based on a Relativist / Holistic /Social View of Scientific knowledge. The Relativistic/Holistic/Social View is suited to open ended problems such as design and analysis methods where no definitive answer exists and many possible solutions for the same problem can be identified based on objective and subjective information sources. The approach incorporates inductive reasoning where application of the theory is used to build confidence in the theory’s usefulness with respect to its stated purpose. ‘Usefulness’ in this case requires that the theory was developed to fit some purpose and its validity must prove its usefulness with respect to achieving this purpose. Usefulness has two components: Effectiveness and Efficiency

1. Effectiveness incorporates three elements;

- a. accepting the individual constructs validity
- b. accepting the constructs consistency
- c. accepting the appropriateness of the example problems that will be used to verify the performance of the method
2. Efficiency also incorporates three elements
  - a. accepting that the method is useful with respect to the initial purpose for some chosen example problems
  - b. accepting that the achieved usefulness is linked to applying the method
  - c. accepting the usefulness of the method is beyond the example problem

The validity of the developed theory (i.e. SEABH) using the Relativistic / Holistic / Social View of Knowledge requires the application of the theory using examples or case studies. Evidence to support the validation of the developed SEABH method has been provided through its application in a multiple-case study comprising two holistic cases. The first case study, Low Dose Rate (LDR) prostate brachytherapy, is briefly described here in this paper. This process has not previously been analyzed using similar methods, but it fits the appropriate application criteria and boundaries of the developed theory’s (SEABH) use. SEABH is primarily recommended for application with processes that can be modeled using a detailed process modeling method, e.g. IDEFØ. This implies that the process under analysis must have an established process flow, with a defined allocation of functions, roles and responsibilities amongst stakeholder participants. Consequently, the application of the SEABH method would not extend well to emergency situations, or situations where a predictable treatment process does not exist or it breaks down. The second of the two case studies, prescription administration process in a cardiothoracic unit, has been briefly described elsewhere.

### LDR PROSTATE BRACHYTHERAPY CANCER

Permanent prostate brachytherapy at the study site uses a low dose rate of Iodine 125 (<sup>125</sup>I) seeds implanted transperineally into the prostate. The seeds are implanted during a single anaesthetised surgical procedure typically lasting 50-90 minutes, depending on the number of seeds to be implanted. The procedure is completed by a multidisciplinary team including:

- Radiation Oncologist
- Medical Physicists
- Anaesthetists
- Nurses

A real-time continuous ultrasound and on-line 3D dosimetry is used throughout the procedure. This facilitates the implantation of seeds in a manner that ensures an isodose to the gland. The ultrasound and 3D dosimetry provide real-time feedback to the team during the procedure allowing for a greater degree of flexibility, accuracy and quality of the completed implant.

## APPLICATION OF THE METHOD

An IDEFØ model of the brachytherapy treatment process was developed following a data collection phase which included semi-structured interviews with the different stakeholder groups and direct observation of the procedure during a number of live cases. Model development involved several cycles of *collect, build, check and modify (as required)*. The completed IDEFØ model contained 26 model diagrams with over 130 individual functions, detailing up to 6 hierarchical levels of analysis. An example of the IDEFØ model is shown in Figure 2.

The focus of the analysis was on the clinical activities completed as part of the brachytherapy procedure, rather than the administrative activities (e.g. collation of patient data) or medical physics activities (e.g. isotope ordering).

In total 18 individual clinically related process steps from the IDEFØ model were analyzed using the SEABH methodology. Of the 18 process steps analyzed, two required the determination of their risk scores and the identification of potential causes following the logic of the SEABH Flowchart, i.e. they were neither recoverable nor controlled.

One of the two processes requiring the determination of their risk scores was related to the quality of the radiation oncologist's use of the seed applicator. The following task was identified as having errors that were potentially not recoverable or controlled:

1. A326732 Implant Seed – 'Too Fast' or with 'Too Much Force' resulting in damage to the prostate

The determined risk score for the identified error was related to three of the nine SEABH risk categories:

1. Injury
2. Patient Experience
3. Compliance with Standards

The error was determined to have a 'Remote' probability of occurrence and an 'Extreme' severity of occurrence. The error could result in the seeds migrating to the patient's blood supply and becoming lodged in healthy tissue. The seeds used in the brachytherapy treatment are sufficiently small to be transported by the patient's pulmonary system to other parts of the body, e.g. lungs or heart. If they are not correctly placed in the prostate, they can potentially result in severe damage in the locations where they become lodged. Subsequently the error was rated 'Critical' and 'Unacceptable' using the SEABH Risk Matrix and required the determination of the potential causes following the SEABH Flowchart.

The error identified from the SEABH error taxonomies for the 'Implant Seed' task are related to potential 'Performance Variability' errors of the radiation oncologist performing the procedure, resulting in a 'Lack of precision' in the use of the equipment or completion of the task. Using the SEABH error taxonomies the following factors were

considered to potentially cause and influence the occurrence of the 'Performance Variability':

1. Lack of training
2. Over-Enthusiasm
3. Insufficient Skills

These findings highlight the critical requirement for suitable skills training and assessment in the use of the seed applicators before stakeholders perform procedures.

It can be seen from the SEABH error types that they include information related to the Psychological Error Mechanisms (PEMs) underpinning the potential errors.

In general, the use of real-time feedback and monitoring of the brachytherapy procedure using the ultrasound and 3D dosimetry planning software, allows for extensive error recovery during the procedure, should they occur. The team based nature of the procedure ensures that the process is actively monitored by multiple team members and includes the use of multiple safety checks. These procedural measures reduce the potential for failures and errors to go unnoticed during the procedure, further facilitating error recovery.

## DISCUSSION AND CONCLUSIONS

The SEABH 'SAVE' methodology provides a structured and detailed assessment method for the analysis of certain types of health care processes, i.e. structured and defined processes. The analysis identified the criticality of training oncologists in the use of surgical type equipment, which they might not be very experienced in handling.

SEABH resulted in a better quality of description for the potential failures and errors than other analysis methods support and it directly linked the human errors to potential causes. The SEABH error taxonomies support the identification of better error descriptions, including contextual information regarding influencing PSFs and PEMs. The use of health care specific risk categories for severity and likelihood of occurrence supports analysts in the completion of risk assessment when required. However, the SEABH Flowchart logic reduces the need for the completion of risk assessment for every process step.

Unfortunately, this benefit of having greater detail in the process and error descriptions can potentially extend the analysis time, but this is counter-balanced in the method by the significantly reduced requirement for the risk assessment of each individual task being analysed.

The case study provided evidence to support the internal and external validity of the method and its usefulness as a proactive health care focused systems and error analysis method.

Overall, the results of the case study provided support for both the external and internal validity of SEABH and its usefulness as a proactive healthcare focused systems and error analysis method. The effectiveness and efficiency of the method was established and the validity of the method was successfully applied in radiation therapy.

The validity of the SEABH method will be improved with additional applications of the method and its use in other health care disciplines. Future work is required to further test the efficacy of SEABH in other health care settings and to develop a software support tool for users.

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**FIGURES AND TABLES**

Figure 1. Simplified Version of the SEABH Flowchart

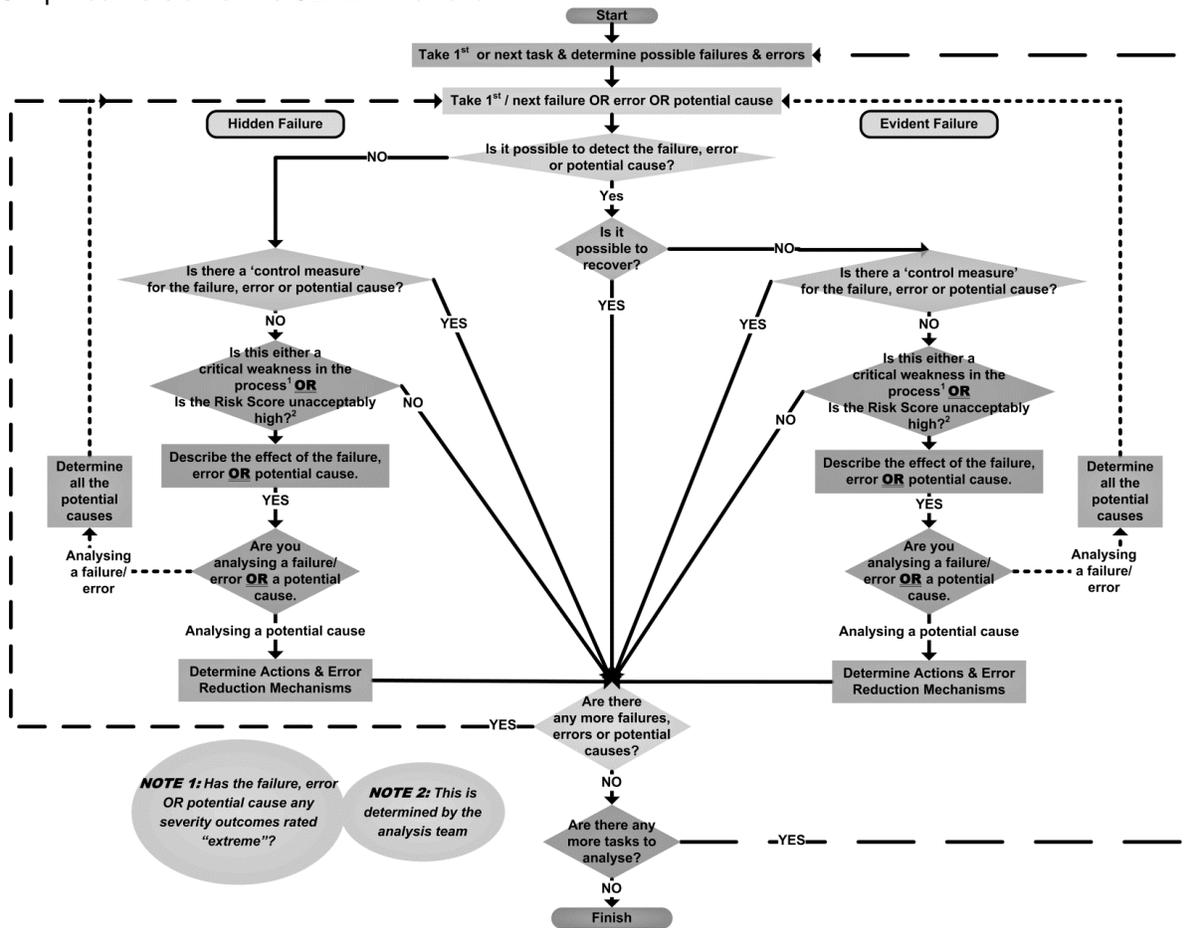


Figure 2. IDEF0 Diagram for the LDR Prostate Brachytherapy Treatment Step 'A3267 Perform Implant'

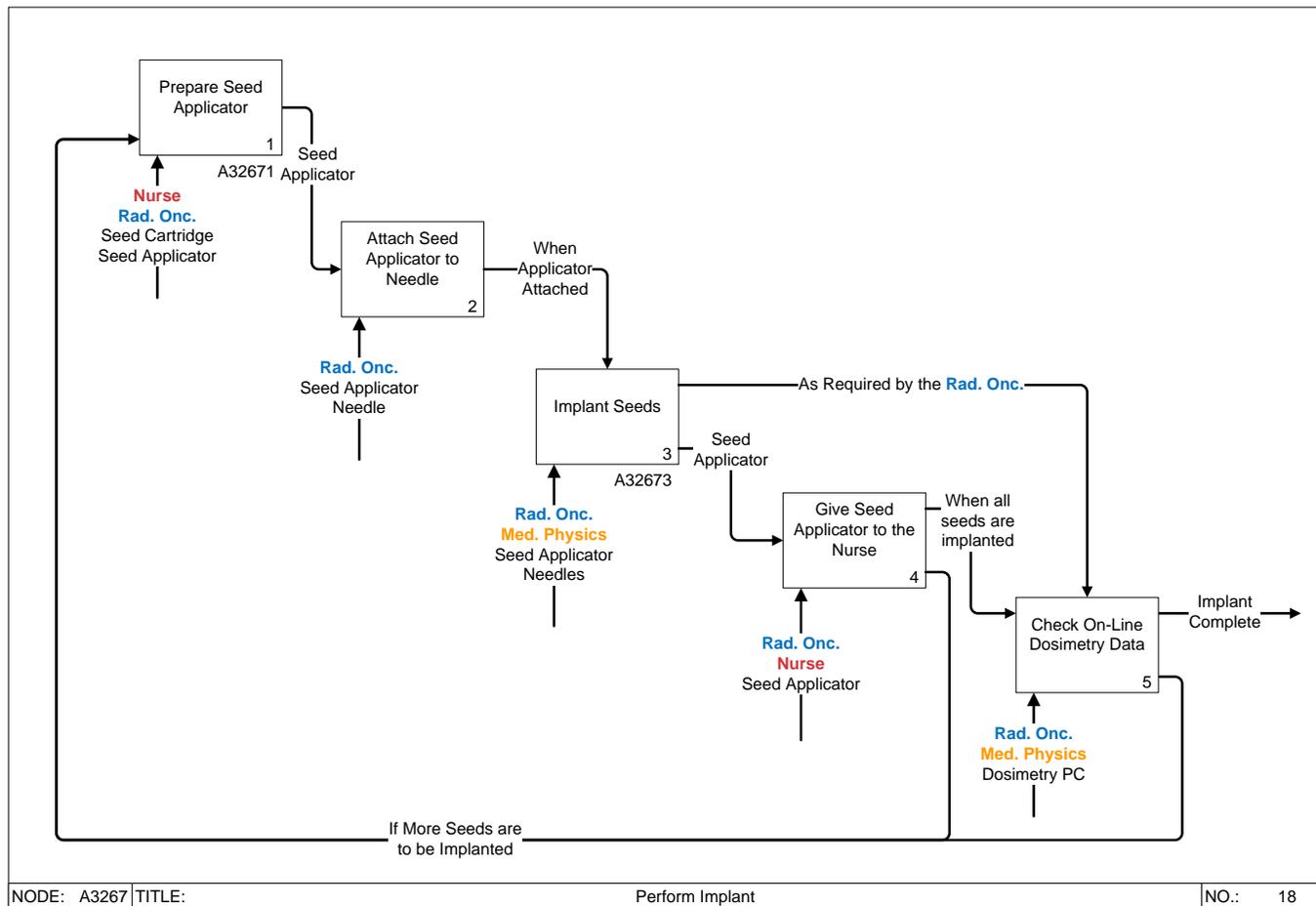


Table 1. SEABH Error Type and Causes for the Error Category 'Interpretation'

General Error Type	Specific Error Type	Definition/ Explanation	Potential Specific Error Cause	Further Potential Error Causes (Related Error Category)
Decision Error	Decision Paralysis	Inability to make a decision in a situation.	Lack of Knowledge Mode Error Shock Stimulus Overload Workload	<b>Fear</b> (Temporary Person Related Functions) <b>Cognitive Bias</b> (Permanent Person Related Functions) <b>Distraction</b> (Temporary Person Related Functions) <b>Social Pressure</b> (Organisation)