Supplementary Material

PRISMA-medical

PRISMA is based on causal-sequence models (Sklet (2004)) and is used for identifying causal risk factors which underlie performance variation. PRISMA aims to decrease the chance of corresponding adverse events occurring, by allowing effective measure to be developed (Brook, et al. (2015)). Within the medical environment, PRISMA-medical (PM), the causal tree endpoints are largely coded, using the Eindhoven Classification Model (ECM) (Williams (2001)).

When an error has occurred, a PM-analysis must be performed as soon as possible with al involved personnel contributing to the analysis. If too much time passed between the error and the PM-analysis important details may be missed. Not having all involved personnel contributing to the analysis may dilute facts via fictionalization or speculation (Williams (2001)). Making a proper PM-analysis with valuable outcomes is nonetheless dependent on the skill of the investigator and the investigator's relationship with the involved staff member. When investigators are inappropriately trained, conversations are of inadequate quality or staff does not trust to be treated fairly or that positive actions will be taken results might be incomplete or focused on the least manageable contributors (Carroll, Rudolf, & Hatakenaka (2002)).

TRIPOD-ß

TRIPOD-β is an easy and practical investigation method of accidents (Katasakiori, Sakellaropoulos, & Manatakis (2009)). This analysis method searches for failed, missing, inadequate or effective barriers associated with the accident and why these barriers were ineffective (Fu, et al. (2020)). Further definition of the latent failures in a TRIPOD-β analysis proceeds using eleven defined basic risk factors (BRF) (Sklet (2004)). TRIPOD-β is used for the analysis of single incidents. Especially in the investigation of more severe incidents TRIPOD-β seems to be well applicable (Fu, et al. (2020)). The investigation method of TRIPOD-β is based on the causal-sequence model with the barrier analysis based on the energy model (Sklet (2004)).

A TRIPOD-β analysis is conducted based on five hypotheses (Edwards (2017)):
Accidents happen because controls fail;
Underlying causes of controls failing are latent failures in management;
These latent failures are present long before accidents occur;
These failures are known by some before the accidents occur;
By identifying and taking action to remove the latent failures, the probability of accidents reduces.

Formal education is not required before using the TRIPOD-β method, but some form of specialized training is required. Introductory courses without hands-on training or experience does not suffice (Sklet (2004)).

Systematic Incident Reconstruction and Evaluation (SIRE)

SIRE is a Dutch adaptation of a method developed by the National Center for Patiënt Safety of the department of Veteran Affairs (Hooker, Etman, Westra, & Kam (2018)). A SIRE analysis focusses on thoroughly reconstructing what happened, learning from incidents and prevent repetition of incident by the same root causes (Leistikow, & Blijham (2004)). The thorough investigation of SIRE starts with

broadly collecting and chronologically organizing relevant information about the subject calamity. This data collection and organization is followed by the analysis of root causes via a method of choice, for example PRISMA-medical, Ishikawa analysis or TRIPOD-β (Leistikow, Ridder, & Vries (2009)).
SIRE is most effective for investigating more severe incidents or incidents that happen with high frequency. Because improvement measure have a higher impact in these cases, the time investment needed for SIRE achieves a higher return (Boelhouwers, Heemskerk, Kroeze, & Nap (2009)).

To be able to improve processes in which people play a part, it is important to find out which mistakes are or can be made. To gain this information it is of great importance that people can speak openly about failures or unsafe situations. The most important characteristic of SIRE is the freedom of speech, the seductive but devastating habit of seeking a culprit is scrupulously avoided (Boelhouwers, Heemskerk, Kroeze, & Nap (2009)).

Ishikawa (fishbone) diagrams

Ishikawa diagrams graphically examine factors contributing to a problem, visualizing the relationships between these contributing factors and their relative potency or importance (Kunadharaju, et al. (2011)). Ishikawa diagrams allow the analyst to immediately categorize ideas about causes of problems into themes for further data gathering or analysis (Abdulai, et al. (2020)). The contributing factors visualized in an Ishikawa diagram are typically organized using four or six generic category labels. The version using four categories describes people, tools, materials and methods (Kunadharaju, et al. (2011)). The version using six categories adds environment and management to the version using four categories (Abdulai, et al. (2020)).

The extensiveness of the data input, does not affect the need for judgment. Discussions about the diagram lead to productive conversations about assumptions and data interpretation (Davey, & Morell (2020)). On the same factor levels Ishikawa diagrams provide no insight in the relative importance of the inputs. Also the interaction among elements are not accounted for within Ishikawa diagrams (Davey, & Morell (2020)).

Video-reflexive ethnography (VRE)

VRE is increasingly used within healthcare, by professional teams in collaboration with patients and researchers. VRE can be used as a tool for inquiry, education and the improvement or development of service (Carroll (2009)). Healthcare professionals and patients are involved in the VRE process. After producing and reviewing video footage of their everyday practices a reflexive deliberation is performed. Within the reflexive deliberation meanings, significances and implications of the video footage under review are discussed (Iedema, et al. (2019)).

The potential of VRE is dependent on participants' engagement with the footage and discussion resulting from this footage. VRE outcomes are contingent on the individuals, problems, opportunities and resources that intersect with the VRE intervention in time and space (Iedema (2020)).

Healthcare Failure Mode and Effects Analysis (HFMEA)

HFMEA is a hybrid prospective analysis model combining concepts found in Failure Mode and Effects Analysis (FMEA), Hazard Analysis and Critical Control Point (HACCP) and definitions from the Root Cause Analysis (RCA) process (DeRosier, et al. (2002)). HFMEA aims to identify system vulnerabilities and develop actions and outcome measures to which management must agree. HFMEA uses

interdisciplinary team, process and subprocess flow diagramming, failure mode and failure mode cause identification, hazard scoring matrixes and a decision tree algorithm to achieve the identification of system vulnerabilities (DeRosier, et al. (2002)). While these components help in the identification process, HFMEA specific components are subject to negative participant comments (Habraken, et al. (2009)). In The Netherlands a version of HFMEA streamlined into a faster version is promoted. This abbreviation is called Scenario Analysis of Failure modes Effects and Risks (SAFER) (Rah, et al. (2016)).

The role of the facilitator in the multidisciplinary team plays a crucial role in the successful application of HFMEA. Besides being knowledgeable about the method, explain the HFMEA steps and control the analysis process, the facilitator should assist the team in applying a systems approach when identifying failure mode causes and action description. This makes careful selection or training for the facilitator role necessary (Habraken, et al. (2009)).

Bowtie

The Bowtie analysis (BTA) method is an analysis method used as a means of identifying and managing barriers (McLeod (2017)). A BTA provides a clear visualization of the relationships between causes of an incident, the range of its possible escalated outcomes, the controls preventing the incident from occurring and the measures implemented to limit the consequences (Lewis, & Smith (2010)). The major benefits of a BTA is the awareness it generates of the key controls relied on to prevent serious adverse events, the nature of these controls and their weaknesses, and what actions are necessary to ensure these controls are in place and effective (McLeod, & Bowie (2020)).

Despite the benefits BTA can be time-consuming. The usefulness and reliability of the BTA results is dependent on the input, data gathering needs to be adequately managed and of high quality to ensure reliable results. Bowtie analysts need training in - for instance - the method, necessary software and terminology (McLeod, & Bowie (2020)).

Hazard and operability study (HAZOP)

HAZOP is a structured analysis method for systematically and multidisciplinary examining systems, processes or operations (Crawley, & Tyler (2015), p.1). These systems, processes or operations may be planned or existing, but for the HAZOP detailed design information about the subject is necessary (Crawley, & Tyler (2015), p.1-2). HAZOP aims to identify and evaluate all imaginable remaining hazards not identified or designed out in earlier stages and also incorporates significant operability or quality problems as a study objective (Crawley, & Tyler (2015), p.11) (Kletz (1999), p.9). HAZOP is best applicable to novel, hazardous or complex processes. Using HAZOP for examining simple and repeating processes is equally possible, although the benefits of the method may be lowered (Crawley, & Tyler (2015), p.8).

The HAZOP method relies on using guidewords combined with process parameters. Cause-consequence pairs and their safeguards are identified by the multidisciplinary team for the deviations determined via the guidewords and process parameters (Dunjó, et al. (2010)). Crucial factors for the success, quality and completeness of a HAZOP are the accuracy of the information available to the team, the expertise and experience within the team, analysis scope, communication, overall manner in which the analysis is performed and engagement of management (McKelvey (1988)) (Crawley, & Tyler (2015), p.11-12).

Hazard Analysis and Critical Control Points (HACCP)

Since its introduction HACCP is widely used within the food industry and is now being used in the medical-device manufacturing (McDonough (2002), p.3). HACCP can be applied to any process, to systematically examine hazards and their controls (Hyman (2003)). HACCP was originally designed to guarantee that the food provided for space travelers was not contaminated microbially, chemically or physically (Baird (2001)). The application of HACCP in radiotherapy puts the patient at the center of the analysis, while accounting for specific traits of the treatment, internal organization, personnel and equipment involved in each stage of the process (Bleichner, & Legrand-Hamon (2019)).

In contrast to the failure mode and effects analysis (FMEA) used within healthcare, HACCP is almost exclusively used within the food production and service besides the recent implementation within the medical device engineering (McDonough (2002), p.11).

Enterprise Risk Management (ERM)

ERM is a recent risk management technique practiced increasingly by large corporations (Melnick (2008)). Though, there is no standard universal way to implement ERM (Rubino (2018)). Most corporations adopt the definition of ERM proposed in the 2004 ERM framework from the Committee of Sponsoring Organizations of the Treadway Commission (COSO) (Melnick (2008)). The definition of ERM in this framework is defined as: a process, affected by an entity's board of directors, management and other personnel, applied in strategy setting and across the enterprise, designed to identify potential events that may affect the entity, and manage risk to be within its risk appetite, to provide reasonable assurance regarding the achievement of entity objectives (Committee of Sponsoring Organizations (2004)). An objective commonly assigned to ERM is to maximize firm value, since ERM provides a framework for businesses to consciously optimize relationship between risk and return through the alignment of corporate strategic goals and risk appetite (Melnick (2008)).

Despite being the most complete and comprehensive, the COSO ERM framework is less lean and harder to understand and apply in comparison to other ERM frameworks (Rubino (2018)).

Functional Resconance Analysis Method (FRAM)

FRAM is a method for modelling complex socio-technical systems to be able to identify differences between the intended procedures (work as imagined, WAI) and their actual performance (work as done, WAD), highlight essential functions of the system and provide input for clinical process or procedure (re-)design (Patriarca, et al. (2020)). By focusing on functions and their characteristics FRAM aims to visualize how interdependencies between functions may result in performance variation (Clay-Williams, Hounsgaard, & Hollnagel (2015)). FRAM does not consider variability to be a failure nor does FRAM focus on finding the cause of failures, unlike most traditional analysis tools (Kaya, Ovali, & Ozturk, (2019)). Also, obtained FRAM models can be used in either a prospective or retrospective analysis (Smith (2017)).

Especially within prospective risk assessments FRAM encourages the cooperative creation of the model, fostering mutual understanding throughout the organizational levels. This encouraged cooperative creation makes FRAM to be marked as an expert-friendly method, while needing more intensive resources from frontline personnel (Patriarca, et al. (2020)).

Systems-Theoretic Process Analysis (STPA)

STPA is an analysis method that aims to identify a systems hazards, including the hazards related to software (Abdulkhaleq, Wagner, & Leveson (2015)). A STPA can be performed throughout the entire systems life cycle (Leveson (2016), p. 212-213), it is not necessary to have a completed safety process before starting the STPA. This opens up the opportunity to base the safety process on the STPA outcomes (Karatzas, & Chassiakos (2020)). The systematic process and guidance STPA provides, leads to the identification of hazardous states resulting from inadequate control or enforcement of safety standards (Abdulkhaleq, Wagner, & Leveson (2015)). STPA was developed to include newly identified causal factors not handled by older techniques. Thus, STPA was designed to include design errors, including software flaws; component interaction accidents; cognitively complex human descision-making errors; and social, organizational and management factors contributing to errors (Leveson (2016), p. 211).

Initially, performing successful STPA analyses might need involvement of a STPA process expert alongside the subject experts (Adesina, et al. (2017)). Reviewing the outputs and validating completeness of the STPA requires big time investment from the subject experts. The labour-intensiveness of STPA and the amount of time needed to perform STPA makes is more suitable high-risk processes critical for patient safety or regulatory compliance (Adesina, et al. (2017)).

References

Abdulai, M. N., Prah, J. K., Walker, E., & Afrifa, A. D. (2020). A Fishbone Analysis of the Use of Electronic Health Records (EHR) in a Primary Health Setting: The Case of University of Cape Coast Hospital. *International Journal of Applied Information Systems*, *12*(33), 27-31.

Abdulkhaleq, A., Wagner, S., & Leveson, N. (2015). A comprehensive safety engineering approach for software-intensive systems based on STPA. *Procedia Engineering, 128*, 2-11.

Adesina, A. A., Hussain, Q., Pandit, S., Rejzek, M., & Hochberg, A. M. (2017). Assessing the Value of System Theoretic Process Analysis in a Pharmacovigilance Process: An Example Using Signal Management. *Pharmaceutical Medicine*, *31*, 267-278.

American Society for Healthcare Risk Management (2006). An overview of the patient safety movement in healthcare. *Plastic Surgical Nursing, 26*(3), 166-120.

Baird, D. R., Henry, M., Liddell, K. G., Mitchell, C. M., & Sneddon, J. G. (2001). Post-operative endophthalmitis: the application of hazard analysis critical control points (HACCP) to an infection control problem. *Journal of Hospital Infection*, *49*, 14-22.

Bleichner, O., & Legrand-Hamon, C. (2019). Adaptation de la méthode HACCP à la prevention des risques en radiothérapie. *Cancer/Radiothérapie*, *23*, 520-522.

Boelhouwers, P., Heemskerk, B. Th., Kroeze, M. M., & Nap, E. W. (2009). Praktijkgids Veilig incident melden. *VMSzorg*

Brook, O. R., Kruskal, J. B., Eisenberg, R. L., & Larson, D. B. (2015). Root cause analysis: Learning from adverse safety events. *RadioGraphics, 35*(6), 1655–1667.

Carroll, J. S., Rudolph, J. W., & Hatakenaka, S.(2002). Lessons learned from non-medical industries: root cause analysis as culture change at a chemical plant. *BMJ Quality & Safety, 11*(3),266-269.

Carroll, K. (2009). Outsider, Insider, alongsider: Examing reflexivity in hospital-based video research. *International Journal of Multiple Research Approaches, 3*(3), 246-263.

Clay-Williams, R., Hounsgaard, J., & Hollnagel, E. (2015). Where rubber meets road: Using the FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines. *Implementation Sci, 125*(10).

Crawley, F., & Tyler, B. (2015). *HAZOP: Guide to best practice.* Elzevier, 3rd edition.

Davey, M. E., & Morell, J. A. (2020). Method for Using Rubric Ratings on Fishbone Diagrams to Compare Case Studies. *Journal of MultiDisciplinary Evaluation*, *16*(34), 56-64.

De Rosier, J., Stalhandske, E., Bagian, J. P., & Nudell, T. (2002). Using Health Care Failure Mode and Effect Analysis™: The VA National Center for Patient Safety's Prospective Risk Analysis System. *The Joint Commission Journal on Quality Improvement, 28*(5), 248-267

Dunjó, J., Fthenakis, V., Vílchez, J. A., Arnaldos, J. (2010). Hazards and operability (HAZOP) analysis. A literature review. *Journal of Hazardous Materials, 173*, 19-32.

Edwards, D. R. (2017). Tripod beta: Guidance on using tripod beta in the investigation and analysis of incidents, accidents and business losses. *Energy Institute.*

Everdij, M.H.C. (2004). Review of techniques to support the eatmp safety assessment methodology. *Report for EEC Safety Methods Survey project, 1.*

Fu, G., Xie, X., Jia, Q., Li, Z., Chen, P., & Ge, Y. (2020). The development history of accident causation models in the past 100 years: 24model, a more modern accident causation model. *Process Safety and Environmental Protection, 134*, 47 -82.

Habraken, M. M. P., Van der Schaaf, T. W., Leistikow, I. P., & Reijnders-Thijssen, P. M. J. (2009). Prospective risk analysis of health care processes: A systematic evaluation of the use of HFMEA™ in Dutch health care. *Ergonomics, 52*(7), 809-819.

Hooker, A. B., Etman, A., Westra, M., & Van der kam, W. J. (2019). Aggregate analysis of sentinel events as a strategic tool in safety management can contribute to the improvement of healthcare safety. *International Journal for Quality in Health Care, 31*(2), 110-116.

Hyman, W. A. (2003). The Application of HACCP in Clinical Engineering. *Journal of Clinical Engineering*, *28*(3), 158-162.

Iedema, R. (2020). Video-reflexive ethnography as potentiation technology: What about investigative quality?. *Qualitative Research in Psychology*.

Iedema, R., Carroll, K., Collier, A., Hor, S., Mesman, J., & Wyer, M. (2019). *Video-Reflexive Ethnography in Health Research and Healthcare Improvement: Theory and Application.* CRC Press.

Karatzas, S., & Chassiakos, A. (2020). System-Theoretic Process Analysis (STPA) for Hazard Analysis in Complex Systems: The Case of "Demand-Side Management in a Smart Grid". *Systems, 8*(3), 33 – 50.

Katsakiori, P., Sakellaropoulos, G., & Manatakis, E. (2009). Towards an evaluation of accident investigation methods in terms of their alignment with accident causation models. *Safety Science, 47*(7), 1007 - 1015.

Kaya, G. K., Ovali, H. F., & Ozturk, F. (2019). Using the functional resonance analysis method on the drug administration process to assess performance variability. *Safety Sience, 118,* 835-840.

Kletz, T. A. (1999). *HAZOP and HAZAN: identifying and assessing process industry hazards*. IChemE, 4th edition.

Kunadharaju, K., Smith, T. D., & DeJoy, D. M. (2011). Line-of-duty deaths among U.S. firefighters: An analysis of fatality investigations. *Accident Analysis & Prevention*, *43*(3), 1171 – 1180.

Leistikow, I. P., & Blijham, G. H. (2004). Nieuw licht op incidenten. Een methode voor risicoanalyse in de patiëntenzorg. *Medisch Contact, 59,* 1022-4.

Leistikow, I. P., Ridder, K., & Vries, B. (2009). Patiëntveiligheid: systematische incident reconstructie en evaluatie. *Elsevier gezondheidszorg.*

Leveson, N. G. (2016). *Engineering a safer world: Systems thinking applied to safety*. The MIT Press.

Lewis, S., & Smith, K. (2010). Lessons learned from real world application of the bow-tie method. *In 6th Global Congress on Process Safety (pp. 22-24).* American Institute of Chemical Engineers, San Antonio, Texas.

McDonough, J. E. (2002). *Proactive hazard analysis and health care policy*. Milbank Memorial

Fund.
McKelvey, T. C. (1988). How to improve the effectiveness of hazard & operability analysis. *IEEE Transactions on Reliability, 37*(2), 167-170
McLeod, R. W. (2017). Human factors in barrier management: Hard truths and challenges. *Process Safety and Environmental Protection, 110,* 31-42.
McLeod, R. W., & Bowie, P. (2020). Guidance on customising Bowtie Analysis for use in healthcare. *Contemporary Ergonomics and Human Factors*.
Melnick, E. L., & Everitt, B. S. (2008). *Encyclopedia of quantitative risk analysis and assessment, Vol. 1*. John Wiley & Sons, p.559-565.
Patriarca, R., Di Gravio, G., Woltjer, R., Costantino, F., Praetorius, G., Ferreira, P., & Hollnagel, E. (2020). Framing the FRAM: A literature review on the functional resonance analysis method. *Safet Science, 129*.
Pawlicki, T., Dunscombe, P., Mundt, A. J., & Scalliet, P. (Eds.). (2010). *Quality and safety in radiotherapy*. CRC Press.
PRISMA-RT (2020). *200107 Notulen.* Unpublished article.
Rah, J., Manger, R. P., Yock, A. D., Kim, G. (2016). A comparison of two prospective risk analysis methods: Traditional FMEA and a modified healthcare FMEA. *Medical Physics*, *43*(12), 6347 – 6353.
Rubino, M. (2018). A Comparison of the Main ERM Frameworks: How Limitations and Weaknesses can be Overcome Implementing IT Governance. *International Journal of Business and Management*, *13*(12), 203-214.
Sklet, S. (2004). Comparison of some selected methods for accident investigation. *Journal of Hazardous Materials, 111*(1), 29 - 37.
Smith, D., Veitch, B., Khan, F., & Taylor, R. (2017). Understanding industrial safety: Comparing Fault tree, Bayesian network, and FRAM approaches. *Journal of Loss Prevention in the Process Industries, 45*(2017), 88-101.
Williams, P. M. (2001). Techniques for root cause analysis. *Baylor University Medical Center Proceedings, 14*(2), 154–157.
Woloshynowych, M., Rogers, S., Taylor-Adams, S., & Vincent, C. (2005). *The investigation and analysis of critical incidents and adverse events in healthcare.* NCCHTA.