Developing human-centred safety indicators:

using a FRAM approach

Summary report

IOSH, the Chartered body for safety and health professionals, is committed to evidence-based practice in workplace safety and health. We maintain a Research for Public Benefit Fund to support research and inspire innovation as part of our work as a thought leader in safety and health.

All recipients of funding from our Research for Public Benefit Fund are asked to compile a comprehensive research report of their findings, which is subject to peer review.

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This work gives a summary of an independent study, which we jointly commissioned with the National Institute for Insurance against Accidents at Work (INAIL) in Italy, under the SAF€RA EU funding scheme.

What's the problem?

Investigations of past accidents, such as the gas explosion at Esso Longford in 1998 and the BP Texas City refinery explosion in 2005, have shown that organisations need effective process safety indicators. Such indicators can complement the more traditional measures of occupational safety (i.e., lost time injury frequency). Process safety indicators are based on accident causation models; in other words, on how we assume that accidents happen.

A common and currently recommended approach is to develop safety indicators based on the wellknown Swiss Cheese Model, an accident causation model in which a precise alignment of weaknesses in a system leads to an unintended event. Following this approach, safety indicators measure the effectiveness of risk control systems, both in terms of failures of risk control systems in use (i.e., lagging or retrospective) and in terms of the effectiveness of safety activities and risk control systems during inspections and audits (i.e., leading or upstream).

New ways of thinking about accident causation have been developed since the mid-2000s. This type of thinking, included in the domain of Resilience Engineering (RE), suggests that accidents in modern, complex systems can arise from everyday performance variability and from unanticipated and dysfunctional interactions, rather than simply from failures of risk control systems. The challenge, then, is to identify safety indicators efficiently based on this newer type of thinking.

So IOSH, together with National Institute for Insurance against Accidents at Work, commissioned a team of researchers based at the National Agency for Technology (ENEA)[1], Sapienza University of Rome[2] and Middlesex University[3] to explore this. The team specifically set out to:

- define an approach for the development of safety indicators based on resilience engineering thinking
- partly automate this approach to enhance its efficiency and quality
- test the feasibility of the approach in an industrial case study.

What did our researchers do?

The research team developed a conceptual framework to support the identification of potential safety indicators based on resilience engineering thinking (see Figure 1). The functional resonance analysis method (FRAM) is a system-based approach, which models complex sociotechnical systems. FRAM enables learning from accidents or undesirable safety states. It can also be used to understand how things

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go well in a system. It can help to identify gaps between “work-as-imagined” (WAI) and “work-as-done”(WAD). This is a comparison between a theoretical representation (using protocols) of work activities undertaken in ideal conditions, on the one hand, and actual work (which may include the adaptations and variability of human operators) on the other. Understanding such gaps may provide useful clues about ways to improve safety without waiting for things to go wrong.

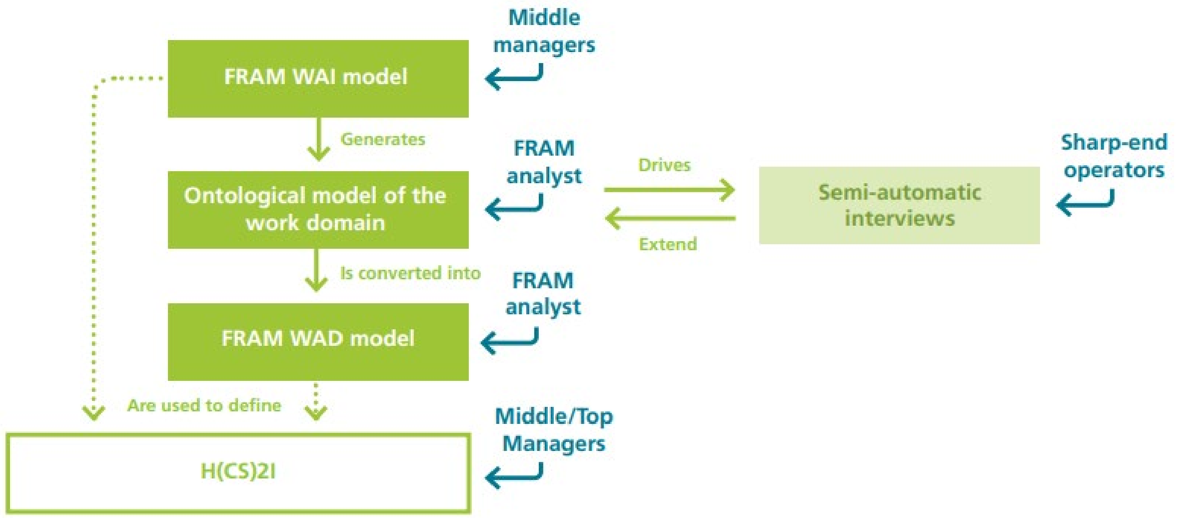

Figure 1: Conceptual framework for the development of safety indicators

The researchers enlisted the help of a multinational pharmaceutical company, whom they [the researchers] had identified as a suitable case study site for testing the feasibility of the approach. In the first phase of the case study work, the research team used FRAM to model a “fill and finish” process in a pharmaceutical manufacturing site.

The model was based was based on information obtained from managers and from process documentation. The process in question was highly automated, and it was regarded as stable and well-understood by the organisation. This was felt to be more beneficial than the use of a more safety-critical process for this initial research. It led to the work-as-imagined analysis.

In the second phase, the FRAM model resulting from the work-as-imagined analysis was used to automatically build a computerised representation (a so-called “ontology”) of the process[4]. An ontology is a formal representation of the way that things are related to one another. In this case, the ontology building process was

[4] The ontology building step is completely automated and does not require the involvement of technical Information and Communications Technology experts.

completely automated and didn't require technical expertise. Using this computerised representation, a semi-automated process was then used to elicit possible variations of work from operators (for example, changing of the precision and timing of outputs, or removal of couplings between process functions). This process led to the identification of credible variations, work-as-done. In this way, the semi-automated analysis provided a FRAM WAD model, based on the initial results of the work-asimagined analysis, that represented the work-as-done.

Finally, in the third phase, potential safety indicators were identified by looking at the functions that have the greatest impact on variability, and by comparing and contrasting the two FRAM models of work-asimagined and work-as-done. For this, our researchers employed an innovative approach based on complex network analysis and an artificial intelligence technique called semantic similarity reasoning.

Complex network analysis aims to prioritise the object of safety analysis by identifying the functions that are most likely to affect the whole process in the event of a change. Semantic similarity reasoning aims to quantitatively measure how different the two models are and determine which parts of the whole process have changed most (e.g., human, automated, or organisational functions).

Each potential safety indicator was then validated by managers and workers at the case study organisation in terms of:

- whether the safety indicator was credible and meaningful
- whether the safety indicator was feasible
- whether the safety indicator was already monitored by the organisation
- whether the organisation would consider adopting the safety indicator.

What did our researchers find out?

The FRAM analysis identified 85 interactions (couplings) among 37 functions that make up the fill and finish process: 15 were automated, 16 were done by operators, and 6 were organisational. The tasks of the operators were concerned mainly with:

- doing device challenges – these are a series of specified tests the automated equipment needs to undergo at the start of the process
- housekeeping – action that covers aspects such as availability of process resources
- removing rejects – operators need to manually remove items that have been rejected by the automation
- monitoring process – operators need to continuously monitor the state of the process and take actions as required

- setting up process – operators need to configure process parameters for different batch sizes and production speeds.

The variability in the process as described by managers (work-as-imagined) arises from the need to accommodate different product sizes and market requirements, from the quality of the materials used, and from changes in staffing levels and the availability of suitably trained operators.

The semi-automatically generated WAD model, which was validated by operators, consisted of 103 interactions among 39 functions. Additional functions and interactions were identified when mapping the work actually done by the operators; for example, in the way that alarms and alerts were monitored, prioritised and acted upon. The benefit of the chosen approach was that the WAD model produces a comprehensive list of potential variations and enables us to prioritise those that might be significant.

Potential indicators were identified automatically by (i) ranking their relative importance in terms of variability propagation, and (ii) the difference between WAI and WAD analyses. The automatic process produced scores for every function, but these were then sense-checked manually to identify the most promising and relevant potential indicators. In this way, a smaller set of potential indicators was developed, which were then assessed and critiqued by staff from the case study organisation. This is illustrated in Table 1. The indicators are arguably better understood as quality indicators rather than safety indicators in the strict sense. This is because the process itself is not safety-critical, and process issues and concerns relate more generally to quality.

Function	Potential indicators	Credible / Meaningful	Feasible	Currently monitored?	Adoption if not already monitored?
Do device challenges	% devices checked	Yes	Yes	Yes	-
	Time required	Yes	Yes	Yes. Time is recorded online.	-
	% devices checked after repair / restart	Yes	Yes	Yes	-
Housekeeping	% presence of auxiliary equipment (scissors, safety blade etc.)	Yes	Yes	The organisation currently uses the 5-S approach (see footnote 2).	-
	% presence of process equipment (leaflets etc.)	Yes	Yes	No. Unless the resource runs out completely, this would be recorded on the system as "waiting for components"	Yes
Remove rejects	Actual reject rate / estimated reject rate	Yes	Yes	Yes	-
Monitor process	Workload (number of alerts or cues / number of staff)	Yes	Yes	No. Currently, the First Line Supervisor confirms workload by visiting the line, monitoring performance, and speaking to operators.	No. The organisation is not intending to adopt this as a formal indicator. The qualitative, informal approach is perceived to work well.
	Alert accuracy (number of alerts / number of rejects)	Yes	Yes	The organisation currently records failure on piece of equipment, but doesn't break this down to accuracy of alert.	No. The organisation is happy with the current approach.
	Non-alert problem recognition (e.g., machine doesn't sound right)	Yes	Yes	No	No. The organisation doesn't intend to adopt this as a new indicator, but it would be considered as part of a continuous improvement exercise.
Set up process	Actual process changes / planned process changes	Yes	Yes	Yes	-

Table 1: Evaluation of potential indicators

All of the proposed indicators above were perceived to be both credible and feasible. Most of the indicators were already being monitored, even though not necessarily in exactly the same way as suggested. For example, regarding device challenges, these are recorded as suggested. Regarding housekeeping, the case study organisation has implemented a 5S approach[5] (lean methodology), and it records the presence of equipment, but this would not extend to the presence and availability of process materials, such as leaflets. The non-availability of process materials would be recorded in the ordering system, but only when the site runs out of stock completely. That information is not fed into quality and safety management. A different process exists for recording the absence of materials in the packaging room where they are needed. Similarly, the product rejection rates and the frequency of changes to the process parameters are recorded.

The function "monitor process" created most discussion, because the nature of indicators related to this function appears to be less formally captured by the organisation. These are human factors and ergonomics indicators related to workload, the accuracy of alerts (low accuracy of alerts can lead to delayed recognition of production problems as well as alert fatigue and frustration), and operator situation awareness. The organisation addresses these issues currently through informal discussions with staff (i.e., in team briefings and as part of

[5] 5S is a workplace organisation methodology for organising, cleaning, developing and sustaining a productive work environment (adapted from United States Environmental Protection Agency, Lean Thinking and Methods - 5S, 4 February 2022).

continuous improvement) and through supervisors' general awareness of supervisors of the state of the process and the equipment.

The feedback suggests that the organisation perceives that it would capture the issues contained in the proposed indicators largely through its existing processes. As a result, the proposed indicators would fit easily within its existing quality and safety management approach, but there might not be sufficient added value for adopting the indicators formally.

However, the feedback was very positive about the terminology and the concepts which Resilience Engineering and Safety-II bring, as this could provide a useful extension to its existing efforts for collecting feedback from operators (i.e., managers could ask about work-as-done and variability rather than just process failures).

What does the research mean?

The research demonstrated the feasibility of a partly automated process for the development of safety indicators based on resilience engineering reasoning. This process uses an ontology representing the workas-imagined to automatically create a questionnaire, which then predicts and elicits knowledge of operators on the work-as-done. All collected knowledge is then used to achieve a qualitative understanding of work-as-imagined and work-as-done differences, to measure them quantitatively and to prioritise safety analysis. Such automation is particularly needed in the case of large complex industrial processes where manual safety analysis might not be feasible.

The assumption underlying the methodology is that there is a gap between work-as-imagined and work-as-done. In addition, it assumes that safety indicators that help monitor this gap and that can provide insights into the realities of workas-done are different from traditional, risk-based safety indicators, which are concerned with the functioning of risk controls (i.e., safety barriers).

In practice, the safety indicators identified through the methodology here are not groundbreakingly novel in themselves, but are often distributed over a diverse range of quality and safety management processes as well as other organisational processes – both formal and informal.

The proposed methodology brings these together and into focus through a coherent approach, by examining potential variations in a comprehensive and structured manner. This brings value to stakeholders, but it is open to debate whether the main value comes from the safety indicators themselves or from the shift in mindset (and terminology) that a Resilience Engineering approach brings.

Food for Thought

Mindful safety management uses diversity of thinking. Organisations should reflect on the strengths and weaknesses of different approaches for the development of safety indicators and seek ways in which these can complement one another, rather than limit themselves to a singular perspective.

The practical application of newer types of thinking in safety science, including this research on the development of safety indicators, still has a much weaker evidence base than more established approaches. Organisations adopting these approaches should use appropriate monitoring and evaluation frameworks to enable them to learn from experience. Further research could provide rigorous empirical evidence about how these newer approaches can improve safety, for whom and under what circumstances.

Gathering continuous data on decision-making, perhaps through apps that are based on our approach, opens up real possibilities to capture front-line operator practice in an efficient way. Work-as-done may be a better start point for research into why people do what they do and to explore what people think is the best – or safest – way to do something without directing their thinking through Standard Operating Procedures.

Our summary report gives you all the major findings of the independent project report by the National Agency for Technology (ENEA), Sapienza University of Rome, and Middlesex University. If you want to read about the study in more depth, you can download the full reports from **projects.safera.eu/projects**.

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