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Chapter 9

Preoperative anticoagulation management in everyday clinical practice: an international comparative analysis of work-as-done using the functional resonance analysis method

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ABSTRACT

Objectives

Preoperative anticoagulation management is a complex, multidisciplinary process important to patient safety. The Functional Resonance Analysis Method (FRAM) is a novel method to study how complex processes usually go right at the frontline (labelled Safety-II), and how this relates to predefined procedures. This study aimed to assess preoperative anticoagulation management in everyday practice and explore the usability and utility of FRAM.

Methods

The study was conducted at an Australian and European Cardiothoracic Surgery department. A FRAM model of work-as-imagined was developed using (inter)national guidelines. Semi-structured interviews with 18 involved professionals were used to develop models reflecting work-as-done at both sites, which were presented to staff for validation. Workload in hours was estimated per process step.

Results

In both centers, work-as-done differed from work-as-imagined, such as in the division of tasks among disciplines (e.g. nurses/registrars rather than medical specialists), but control mechanisms had ben developed locally to ensure safe care (e.g. crosschecking with other clinicians). Centers had organized the process differently, revealing opportunities for improvement regarding patient information and clustering of clinic visits. Presenting FRAM models to staff initiated discussion on improvement of functions in the model that are vital for success. Overall workload was estimated at 47 hours per site.

Conclusions

This FRAM analysis provided insight into preoperative anticoagulation management from the perspective of frontline clinicians, revealing essential functions, interdependencies and variability, and the relation with guidelines. Future studies are warranted to study the potential of FRAM, such as for guiding improvements in complex systems.

Key words: medication safety; patient safety; continuous quality improvement; safety-II; FRAM

INTRODUCTION

Anticoagulation is a common and effective therapy for patients with an increased risk of thromboembolic events (e.g. due to atrial fibrillation or mechanical heart valves)[1,2] yet also responsible for a substantial proportion of medication-related adverse events.[3–6] Management of anticoagulation therapy is delicate and complex, especially around surgical procedures where it involves a trade-off in decision-making: continuation increases the risk of perioperative bleeding, but interruption increases the risk of thromboembolic events (e.g. stroke).[7,8] Some patients may temporarily need 'bridging therapy' (e.g. low-molecular-weight heparin) during interruption of their anticoagulation therapy. A team of healthcare professionals must coordinate anticoagulation care, including medical specialists, nurses, pharmacists, general practitioners, and in some countries, anticoagulation services.[9] Communication and coordination issues are common, increasing risks of adverse outcomes.[9–11] While guidelines have been developed to support this process,[12–16] guideline adherence is highly variable, which may expose patients to unnecessary risks of perioperative complications.[17–20]

Rather than continuing the search for guideline non-adherence and root causes of complications (labelled as the Safety-I approach[21]), a promising alternative is to increase understanding of this complex process in everyday practice, including the capacities that facilitate safe patient care. This approach, referred to as Safety-II, is linked to other positive approaches to patient safety, such as positive deviance,[22,23] appreciative inquiry[24] or learning from excellence.[25] Safety-II seeks to understand how processes usually go right at the front line, and how this relates to predefined procedures, such as protocols or process design.[26–28] Analysis of actual practice is also recognized as an important first step when striving to implement improvements.[29] A useful tool for this purpose is the Functional Resonance Analysis Method (FRAM), which has been endorsed by safety experts, such as James Reason,[30] as a promising way forward to improve safety in complex systems. FRAM has been applied in various settings, including aviation,[31] air traffic management,[32,33] railway traffic,[34] manufacturing,[35] and construction.[36] While healthcare is a classic example of a complex system, the uptake of this new approach has been limited in medical research.[37,38]

This study assessed preoperative anticoagulation management (PAM) using semi-structured interviews with front-line clinicians in an Australian and European hospital. The study aimed: (1) to obtain a deeper understanding of how PAM is conducted in everyday practice (work-as-done) and how this relates to predefined procedures (work-as-imagined); and (2) to examine the applicability of a Safety-II approach using FRAM for medication management research, as a tool to reconcile work-as-imagined and actual work-as-done.

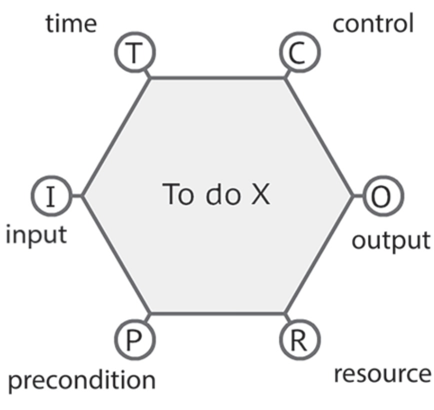
METHODS

This study was conducted at the Cardiothoracic Surgery departments of both an Australian and Dutch university hospital. These settings were selected for high incidence of complex surgeries with patients on anticoagulation therapy regimens. In this study, PAM relates to continuing, ceasing or bridging anticoagulation therapy, including vitamin K-antagonists, non-vitamin K antagonists (e.g. dabigatran, rivaroxaban) and platelet aggregation inhibitors (e.g. acetylsalicylic acid, clopidogrel), in patients planned for elective open-heart surgery.

Functional Resonance Analysis Method

FRAM can be used to describe essential activities that build up a process, visualized in models.[30] In a FRAM model, activities are represented in 'functions' depicted as hexagons with six different labels or 'aspects' (Figure 1). The models can be based on various sources of information, including guidelines, observations or interviews with the frontline. To obtain a deeper understanding of a complex process, FRAM requires a targeted, defined scope.[39] Hence, the focus of this study was limited to the preoperative phase. For detailed information on FRAM, we refer to practical instruction guides[40] and prior publications.[37–39] The study investigators attended workshops on the methodology,[41,42] and were supervised by researchers with experience in Safety-II and FRAM (R.C-W. and J.B.).

Figure 1. FRAM function with all aspects.



In 'To do X', X can represent any activity (e.g. to admit patient). The six aspects represent:
- *input*: what the function starts, acts on, or changes;
- *time*: any time constraints that might affect the function (e.g. by which it will be carried out later);
- *control*: how the function is monitored or controlled, work agreements, visions or objectives;
- *output:* the outcome or state change that emerges from the function;
- *resource*: material or people needed to carry out the function, or consumed *during* the function;
- *precondition*: a condition that must be satisfied *before* the function can be commenced.

Interviews and modeling

In accordance with previous FRAM studies,[37,39] an initial model of PAM 'as-imagined' was constructed based on the leading international guideline from the American College of Chest Physicians[43] and a Dutch national guideline.[44] The Australian Clinical Excellence Commission and Commission on Safety and Quality in Health Care both confirmed that Australia has no common guideline. This initial model provided the basis for semi-structured interviews, which were conducted between April and June 2017 with 18 healthcare professionals involved in PAM (Table 1). Interviewees were purposively selected: the director at the Australian hospital and a senior physician assistant at the Dutch hospital provided the initial point of approach for recruitment, and additional professionals were recruited through interviewees. Interviews were held individually with one interviewer in Australia (N.L.D.) and two interviewers in the Netherlands (M.S.d.V/M.J.M). Following written consent, interviews were audio-recorded and summarized immediately afterwards for the investigators. Interviews were guided by a topic list (Appendix 1) based on questions of the FRAM method, with minor adaptations made for the specific discipline interviewed.[39,40] FRAM models reflecting PAM 'as-done' were developed based on the interviews by the investigators who also conducted the interviews. An iterative modeling process was applied with preliminary models developed after each interview, and updated versions guiding the following interviews. The 'FRAM Model Visualizer' was used to construct FRAM models.[45] Interviews were conducted until data saturation was reached for the model,[46] defined as three consecutive interviews during which no new functions emerged for the model. In both hospitals, a discussion meeting was organized to present the final models to involved staff as a means of validation, and to elaborate on potential clinical implications and recommendations. To examine usability of this novel method (e.g. for quality managers), total workload in hours was estimated per step of the FRAM analysis (excluding study-related work, such as drafting the manuscript).

Analyses

FRAM models can be studied by assessing variability and interdependence of functions.[38,40] Variability can be due to human, organizational or environmental factors affecting timing or precision of functions.[38] Functions may also be interdependent (known as 'coupling') in which case a function impacts later functions ('functional upstream-downstream coupling'). This interdependence between functions may allow variability in one function to spread through the process, e.g. information omitted in one function may impact later functions that use this information. Variability and interdependence was assessed for the 'foreground functions', which are the main steps in the process depicted in hexagons, in contrast to 'background functions' depicted in grey boxes, which are considered to be more stable and have a less prominent role in analysis.

Table 1. FRAM process steps and disciplines interviewed, with estimated workload per site.

Process steps			**Time (hours)†**
Work-as-imagined model	Development of model based on international guidelines.		7
Interviewed professionals (n)* incl. preparations, processing, and iterative model development	*AUSTRALIA (10):* ● Cardiothoracic surgeon (1) ● Cardiologist (2) ● Nurse case manager (1) ● Nurse unit manager(2) ● Anesthetist (1) ● Pre-admission clinic nurses (3)*	*THE NETHERLANDS (8):* ● Cardiothoracic surgeon (1) ● Cardiologist (1) ● Cardiothoracic PA (2) ● Registrars (2) ● Anesthetist (1) ● Planning office secretary (1)	20
Work-as-done model	Development of final model based on information gathered in interviews and analysis of potential variability and interdependence.		15
Meeting with frontline (team discussion)	Department meeting gathering all involved staff to present, validate and discuss the final model (ca. 1-2 hours), with subsequent processing of feedback.		5
TOTAL			47

PA, physician assistant.

* Interviewed disciplines differ because of the different disciplines involved in the centers (Table 1). Australian interviews were conducted in two instances within a two-month time frame because of time limitations for providers. All were interviewed individually, except for the pre-admission clinic nurses who were interviewed together.

† Overall workload per site for the analysis carried out by three main investigators collaboratively.

RESULTS

The PAM 'as-imagined' model reflected guideline recommendations for task division and communications between healthcare professionals. A key role was assigned to anesthetists, who were expected to decide upon a definitive PAM strategy (i.e. to continue, cease or bridge), after a proposal by treating physicians, and to inform patients and other clinicians (Appendix 2). Interviews with healthcare professionals about PAM 'as-done' lasted between 45 and 60 minutes. Data saturation was reached for the models in both settings (Table 1). Notable differences between the models and time investments are discussed in Tables 1 and 2.

Australian model

The Australian model (Figure 2) consists of 8 main functions:

1. **To decide on surgery and PAM:** at the clinic, cardiothoracic surgeons see referred patients to inform them about the treatment as well as PAM strategy and provide them with a 'pre-admission booklet'.
2. **To discuss PAM with the patient:** subsequently, patients see the nurse case manager (CM) who schedules the surgery, further explains the PAM strategy and checks whether the surgeon noted this on the pre-admission booklet. If not, the nurse asks the surgeon or,

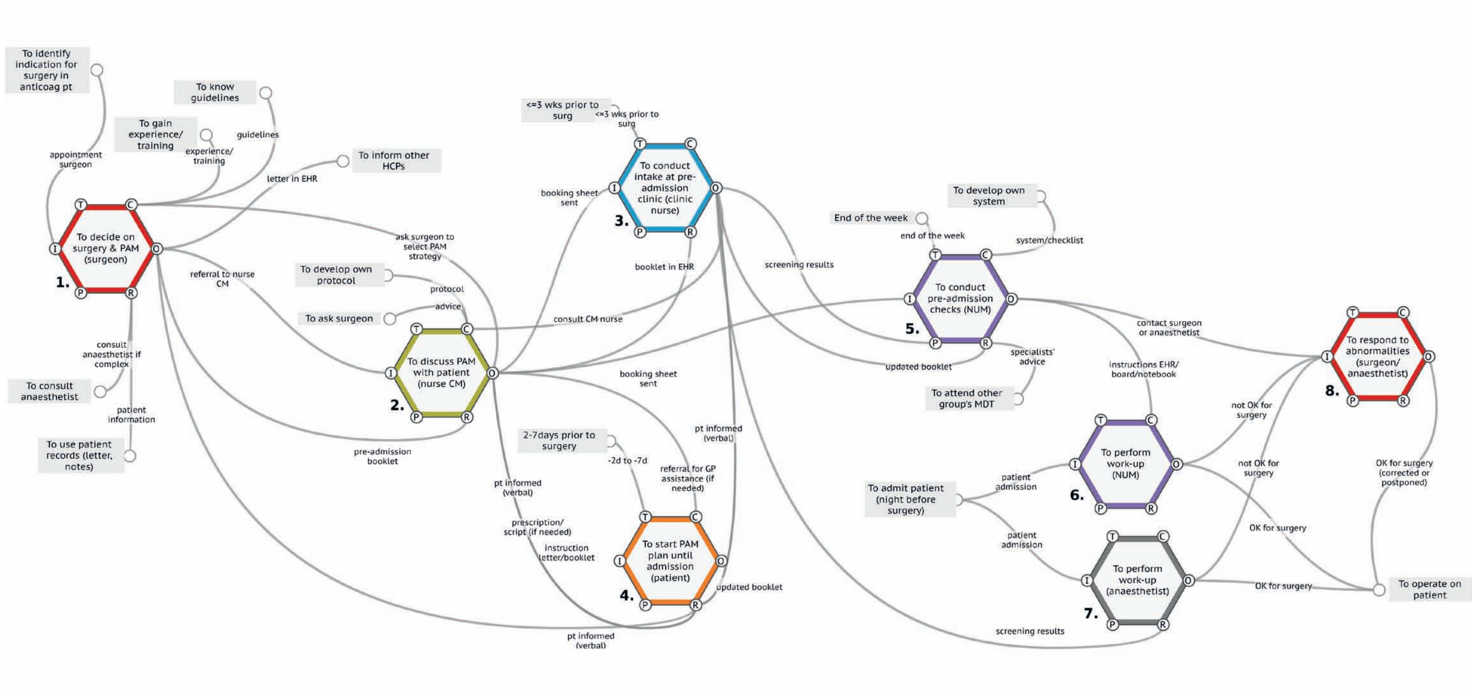
Table 2. Preoperative anticoagulation management 'as-done' in Australia vs. the Netherlands

Theme	Australia	The Netherlands
Patient visits	Two preoperative hospital visits: one with surgeon and afterwards nurse CM, and one pre-admission clinic visit.	One-day preoperative clinic visit, including pharmacy assistant, PA/registrar, cardiothoracic surgeon, and anesthetist.
Disciplines	Central role for nurses, including NUM, nurse CM, and clinic nurse. Anesthetist involved in work-up upon admission and in case of abnormalities.	Central role for PA/registrar and role for planning office secretary. Anesthetist not involved in PAM strategy or in case of abnormalities.
Multidisciplinary communication	NUM might ask questions about PAM strategy during other cardiac group's multidisciplinary meeting.	Daily heart team meeting with surgeon and cardiologist; preoperative clinic with multiple disciplines at same location.
Decision-making	Surgeons decide on PAM strategy and consider themselves solely responsible for this. However, if surgeons omit this, the nurse CM will remind them to or, if the case is straightforward, select a strategy using her personally developed protocol.	Surgeons and cardiologists consider themselves responsible to select a PAM strategy at their team meeting, but, in practice, the PA/registrar mostly selects an anticoagulation strategy according to the departmental protocol.
Resources	• Patient records, referral letters, medication list • Booking sheet (also via e-mail) • Preoperative screening results • Pre-admission booklet • Instructions by NUM • NUM's notebook, surgery board • Asking patient (upon admission)	• Patient records, referral letters, medication list (verified by pharmacy assistant) • Heart team meeting form • Preoperative letter • Secretary's patient lists • Asking the patient (clinic, admission)
Protocols	Surgeons use their knowledge of international guidelines, and nurse CM uses own protocol.	Departmental (2-page) protocol based on guidelines,* used by registrars/PAs and surgeons.
Patient instructions		
Verbal	• Surgeon, nurse CM, clinic nurses	• PA/registrar, secretary (over phone)
Written	• Prescription (if indicated) • Instruction letter; pre-admission booklet	• Prescription (if indicated)
Signalling abnormalities†		
Outpatient setting	If the clinic nurse notices that PAM strategy is unclear (e.g. mixed information), she consults nurse CM.	The anesthetist (at clinic) or secretary may notice that a missing, unclear or unusual PAM strategy, and contact the surgeon, registrar or PA.
Inpatient setting	If the NUM signals abnormalities during pre-admission checks or admission, she notifies the surgeon or, in case of low platelet levels, the anesthetist.	If the PA/registrar signals abnormalities during preparations or upon admission, a proper response will be discussed the surgeon.
Signalling channels (least to most urgent)	face-to-face (e.g. ward rounds) > e-mail > texting > phone.	Face-to-face (e.g. clinic or during afternoon handoffs) > phone.
Individual systems	• NUM developed system for pre-admission checks (notebook, surgery board, EHR notes, and mental checklist) • Nurse CM developed protocol for PAM strategy based on local experience.	• Locally developed departmental protocol for PAM based on guidelines • Secretary developed own checklist to list patient information to guide phone calls

CM, case manager. *EHR*, electronic health record. *NUM*, nurse unit manager. *PAM*, preoperative anticoagulation management. *PA*, physician assistant.

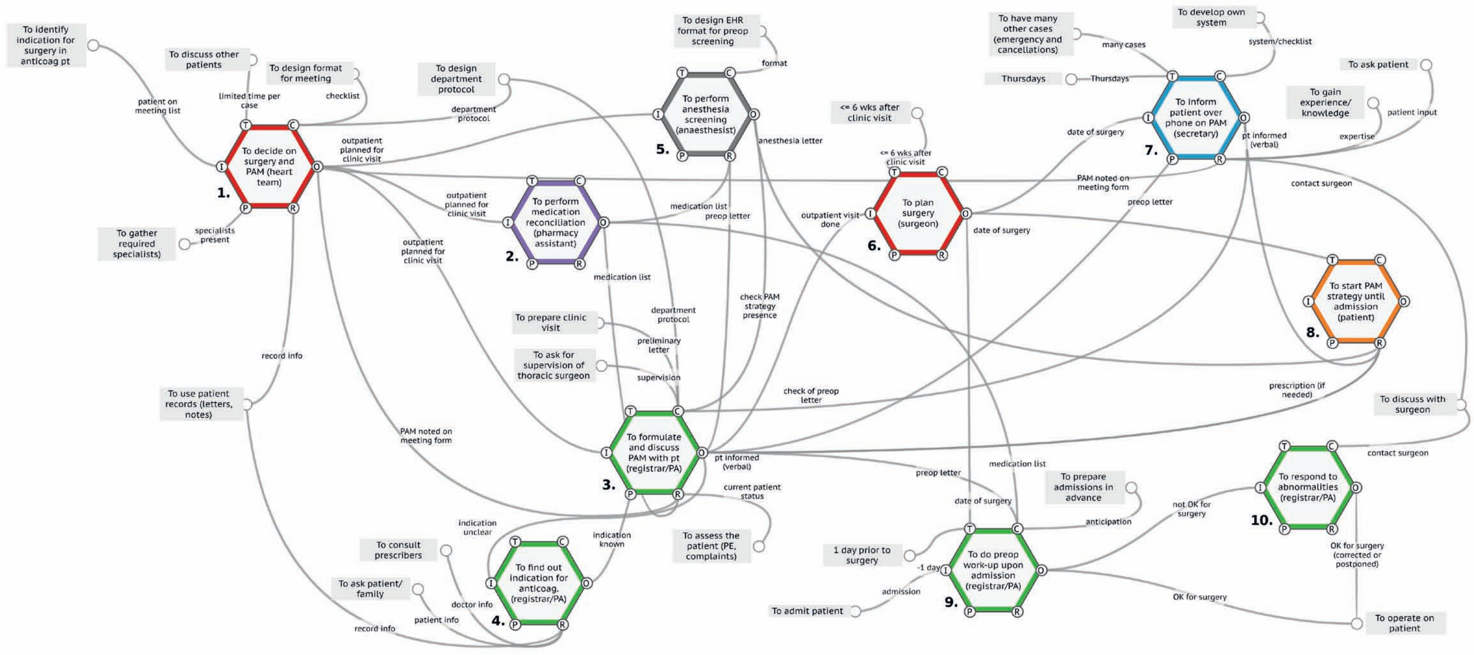
* Guidelines include ACCP 2012; ESC/EACTS 2014; ESC 2016. † Response to abnormalities is identical at both sites: a reversal agent (e.g. vitamin K) or platelets will be administered to ensure values within an appropriate range for surgery. If not effective or not possible, the surgery is postponed.

Figure 2. Work-as-done model of preoperative anticoagulation management in the Australian hospital.



Anticoag, anticoagulation therapy. *HCPs*, healthcare professionals. *MDT*, multidisciplinary team meeting. *Nurse CM*, nurse case manager. *NUM*, nurse unit manager. *PAM*, preoperative anticoagulation management. *Pt*, patient. *Surg*, surgery. *Wks*, weeks.
Involved professionals (function in model): surgeon (1/8); nurse CM (2); pre-admission clinic nurse (3); patient (4); NUM (5/6); anesthetist (7).

Figure 3. Work-as-done model of preoperative anticoagulation management in the Dutch hospital.



Anticoag, anticoagulation therapy. *PA*, physician assistant. *PAM*, preoperative anticoagulation management. *Preop*, preoperative. *Pt*, patient. *Wks*, weeks.
Involved professionals (function in model): surgeon (and cardiologist) (1/6); registrar or PA (3-4/9-10); pharmacy assistant (2); anesthetist (5); secretary (7); patient (8).

if straightforward, selects a strategy based on a self-developed protocol. The patient also receives an instruction letter, and prescriptions for bridging therapy if required. Lastly, the nurse e-mails a 'booking sheet' with patient, surgery, and PAM details to the pre-admission clinic, admission wards, anesthetists, and operating theaters.

3. **To conduct intake at pre-admission clinic:** two to three weeks prior to surgery, patients visit the hospital again for a preoperative screening with several tests. At this pre-admission clinic, a nurse checks whether the patient received and understood the PAM strategy. If unclear, the clinic nurse contacts the nurse CM *(function 2)* to provide the patient with PAM instructions.
4. **To start selected PAM strategy up until admission:** at home, patients are expected to adhere to the PAM strategy.
5. **To conduct pre-admission checks:** in preparation for the following week's surgeries, the nurse unit manager (NUM) of the admission ward retrieves the preoperative screening results from the electronic health record (EHR) and PAM strategies from booking sheets. If the NUM identifies anticoagulation-related abnormalities, the surgeon and/or anesthetist will be texted or called. The NUM notes all patient details, including PAM strategy, in a personal notebook (Figure 4) and on the 'surgery board' (i.e. white board on the ward). The NUM usually admits patients, but provides electronic instructions for colleagues if this is not the case (e.g. weekends).

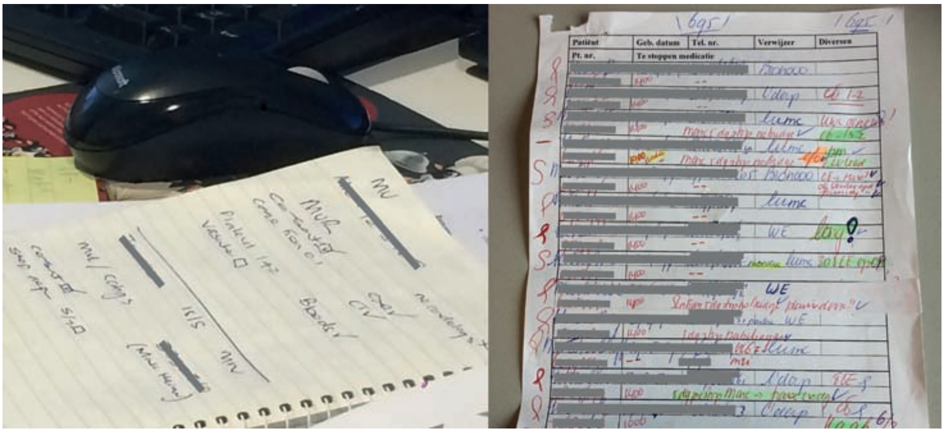


Figure 4. Photographs of naturally developed individual systems of Australian nurse unit manager (left) and Dutch planning office secretary (right)

6. **To perform work-up:** upon patient admission the night before surgery, the NUM determines whether patients adhered to the PAM strategy by asking and by assessing International Normalized Ratio (INR) and platelet levels.
7. **To conduct an anesthetic work-up:** the work-up of the anesthetist also includes a check of anticoagulation medication and INR.

8. **To respond to abnormalities:** if patients did not adhere to the PAM strategy and/or the INR is not within the appropriate range, the NUM notifies the surgeon (Table 2), who decides whether or not to administer a reversal agent (e.g. vitamin K) or postpone the surgery. If platelet levels are too low, the nurse texts or calls the anesthetist, who can decide on administering extra platelets so that surgery can proceed.

Dutch model

The Dutch model (Figure 3) is comprised of 10 main functions:

1. **To decide on surgery and PAM**: the cardiothoracic surgeon and interventional cardiologist discuss treatment options for referred patients in a daily 'heart team meeting'. They document their decisions, including a PAM strategy, in the EHR. Surgical patients are scheduled for a one-day preoperative clinic visit with various clinicians in a fixed order (functions 2-5).
2. **To perform medication reconciliation**: a pharmacy assistant ensures an up-to-date medication list in the EHR.
3. **To formulate and discuss PAM with the patient:** patients consult a registrar or physician assistant (PA) (alternating shifts), who provides them with verbal instructions on the PAM strategy and prescriptions if needed. All required preoperative actions are noted in a 'preoperative letter' in the EHR (not provided to patients). Often, no PAM strategy has been selected or documented by the 'heart team' (function 1), in which case the registrar or PA selects a strategy according to the departmental protocol and, if needed, supervision from the attending surgeon (Table 2).
4. **To find out the indication for anticoagulation therapy**: to select the appropriate PAM strategy, the registrar or PA revisits the patient's indication for anticoagulation therapy, which can be obtained from the patient, EHR or by consulting the prescribing specialist by telephone or e-mail. Patients subsequently visit the surgeon, but this consult serves to educate patients on the surgery rather than PAM.
5. **To perform pre-anesthesia screening:** the anesthetist conducts a screening and provides patients with a letter that includes a medication list with preoperative instructions. For anticoagulation therapy, however, this is no more detailed than 'stop in consultation with surgeon'.
6. **To plan surgery:** a surgeon schedules the following week's surgeries and informs the planning office. Surgeries are planned at least five days in advance, unless vacant spots have to be filled.
7. **To inform patients**: the planning office informs patients over the phone about their exact date of surgery in the upcoming week, and any required preoperative actions, such as a PAM strategy. Phone calls are guided by information in the preoperative letters (function 3), and if necessary, digital meeting forms (function 1). One of the secretaries developed

a checklist to guide this process (Figure 4). If surgeries are rescheduled, the secretary informs patients in a similar fashion.

8. **To start the selected PAM strategy:** At home, patients are expected to adhere to the PAM strategy.
9. **To perform work-up:** upon admission the day before surgery, the registrar or PA determines whether patients adhered to the PAM strategy and performs appropriate testing (e.g. INR), according to notes in the preoperative letter (function 3) and/or the medication list. Platelet levels are tested at the clinic (function 2) and only repeated if six or more weeks have passed.
10. **To respond to abnormalities:** registrars or PAs respond to abnormalities (e.g. elevated INR) after discussing with the surgeon whether or not to administer a reversal agent or to postpone surgery.

Variability and interdependence

In the Dutch setting, variability became particularly apparent for function 1, as registrars and PAs mentioned that the team meeting mostly did not produce a PAM strategy. Similarly, the Australian nurse CM often selected a PAM strategy if the surgeon omitted to note this in the pre-admission booklet. In complex cases, the nurse CM would consult the surgeon, which is similar to Dutch registrars/PAs who may ask for supervision from the surgeon.

At both sites, functions 1-3 provided outputs that served as important resources for several 'downstream' functions. These functions generated documents that served important roles later on, namely the Australian booking sheet (output of function 2; input for 3/4) and the Dutch preoperative letter (output of function 3; resource for 5; precondition for 7; control for 9) (Figures 2 and 3).

Both models also included downstream functions that controlled upstream functions. The Australian nurse CM could remind surgeons to fill out a PAM strategy (i.e. function 2 controlling 1), and the clinic nurse consulted the nurse CM if the PAM strategy was unclear (i.e. function 3 controlling 2). Both Dutch anesthetists (function 5) and secretaries (function 7) could signal a missing or incomplete preoperative letter, thereby controlling function 3.

Interdependence was particularly apparent for Dutch function 3, linked to as many as five other foreground functions (i.e. 1, 2, 4, 5 and 7) (Figure 3). Remarkably, there were two similar, partially overlapping functions (7 and 8) for work-up upon admission in Australia causing duplicate measurements of INR (Figure 2).

The functions that represented patients adhering to the PAM strategy (Australian function 5; Dutch function 8) appeared to have no formal 'input' or 'active agent' to start this function, and hence seemed to depend solely on the patient's memory and support from verbal and/or written instructions.

DISCUSSION

This study was the first to use a Safety-II approach and FRAM in the context of medication management in healthcare. This provided insight into the complex process of preoperative anticoagulation management 'as-done' and 'as-imagined' in two international contexts. This process differed substantially between the study sites, both in practical organization and disciplines involved. While, in both centers, 'work-as-done' at the front line differed from 'work-as-imagined' in generic guidelines, both had developed control mechanisms to ensure successful PAM, such as critical review of a colleague's decisions and documents, and individual systems to enhance efficiency and thoroughness.

Work-as-done differed from the process 'as-imagined' by guidelines, which assumed that physicians, specifically anesthetists, play a central role in PAM. In both centers, however, this was the responsibility of surgical staff rather than anesthesia staff, with key roles assigned to (specialized) nurses or registrars/PAs. This may have practical purposes, as these disciplines also have a central role in inpatient care. Furthermore, in contrast to the national guideline,[44] the Dutch process did not involve anticoagulation services, usually responsible for outpatient anticoagulation management in the Netherlands. Instead, the department temporarily took over this responsibility to enhance clarity for patients. These examples illustrate how studying work-as-done might help to identify potential differences between local practices and guidelines, but also the pragmatic, practical reasons behind it. Moreover, this study revealed varying perceptions on roles and responsibilities among clinicians involved in anticoagulation management, which aligns with a recent survey study.[9] For example, interviewed surgeons felt responsible for formulating and documenting the PAM strategy, but other staff reported that this was often omitted in which case they made a decision.

Opportunities for improvement

While patients received various forms of information, both centers relied on the patient's memory to adhere to the PAM strategy at home. Modern information technology may provide solutions for a more active 'input' for this function, such as automated text messages on the day the patient has to stop anticoagulation. Simple written instructions, as used in Australia, could be developed in the Dutch department to offer a useful reminder for patients at home. Learning cuts both ways, as the Australian department might consider limiting the number of information sources as this also increases the risk of conflicting information. In addition, they may consider introducing a single-day multidisciplinary clinic with involvement of a pharmacy assistant, as used in the Dutch setting, in order to limit the number of hospital visits for patients and ensure accurate medication information.

Inaccuracies in, or unavailability of, documents produced in early functions to record the PAM strategy could negatively affect later steps in the process (e.g. informing the patient). In these situations, the identified control mechanisms may prove their value, e.g. other staff may select a PAM strategy if omitted in function 1. While this illustrates clinicians' profound adaptive skills, it may also result in habituation to the fact that this information is missing, decreasing use of this resource. Therefore, there should be clear agreements on what can be expected from staff carrying out these functions. Individual staff had naturally developed some of these control mechanisms, such as a checklist or notebook. While these are likely to support thoroughness, they may also pose safety risks when key persons are absent or replaced and colleagues are unfamiliar with these methods. To illustrate, the Dutch secretary seemed to view her checklist as a 'personal aid' and did not plan on transferring this method to new staff members. Hence this potentially valuable control mechanism may be jeopardized because of its individual and not structural nature.

Practical implications and usability

FRAM appeared to be a promising tool that can be readily applied to study a multidisciplinary medication management process, and identify functions that are important for success. The workload of FRAM, collaboratively was estimated to be about 47 hours per site (Table 1), which is comparable to the workload associated with traditional methods, such as a root cause analysis (RCA).[47] In line with a previous study,[37] clinicians seemed to easily understand the relevance, background, and design of FRAM. Reflection meetings with staff were considered insightful and raised awareness of interdependencies between activities of colleagues. For example, Dutch senior staff questioned whether anesthetists could actually signal a missing or incorrect PAM strategy, but a junior registrar confirmed that he had experienced this occasionally. Staff also used the model to discuss opportunities for improvement, such as the redundancy in the Australian work-up upon admission. This way, FRAM may be used to reconcile and improve the synergy between the world of guidelines and systems design (work-as-imagined) and the world of everyday clinical practice (work-as-done). FRAM could also be used as a support tool for incident analyses because it allows studying how an event emerged in relation to work-as-done rather than only comparing such events with expectations of a process (e.g. protocols).[39] A unique feature of FRAM is that it does not need to be triggered by an incident, as it can be used proactively to gain understanding of work-as-done. This could potentially respond to recent calls for greater proactivity and a greater focus on what goes right in patient safety improvement.[48] Future studies could seek to combine more quantitative analyses with qualitative FRAM models, for example, to measure defined outputs of functions with statistical process control[49] or to quantify functions' variability so that probability simulations can be applied.[50]

Study strengths and limitations

To our knowledge, this is the first study to study a medication management process 'as-imagined' and 'as-done'. A specific strength of the method is its focus on activities that are responsible for the fact that clinical work usually goes right rather than specific situations where things go wrong. Studying work-as-done offers a way forward for patient safety, which under the traditional Safety-I domain is mainly focused on complications or incidents, which are very important — but also very specific, and often rare.[21,27] This study has international applicability as it showed that visualization of work-as-done using FRAM can be used to study and compare challenges and strengths in two international contexts. While the multicenter context is also an advantage, both sites were cardiothoracic surgery departments at teaching hospitals, which may limit generalizability to other units. More research in other settings is warranted, as PAM is also common practice for other specialties. Moreover, real practice may still differ from the models developed in this study as we did not use direct observations,[51] and the purposive sampling strategy may introduce the risk of selecting a subgroup or network of professionals, which could be prevented with random samples in future studies. In mitigation, and in accordance with qualitative research guidelines,[52] we used data saturation to increase the ability to identify the most relevant functions and interdependencies.

CONCLUSIONS

This study provided a deeper understanding of anticoagulation management in practice and in relation to guidelines. FRAM appeared to be an insightful tool, suitable for studying complex healthcare processes, such as medication management, identifying functions that are important to ensure the process functions as intended, including their interdependence and variability. In addition, this proactive approach revealed the opportunities for improvement and the presence of naturally developed individual systems, which otherwise remained undetected. Future studies are warranted to investigate PAM as well as the applicability of FRAM in other healthcare contexts.

Acknowledgement

We like to thank all healthcare professionals who were willing to reflect on the process so openly in the interviews and department meetings.

LIST OF ABBREVIATIONS

CM, case manager
EHR, electronic health record
FRAM, functional resonance analysis method
INR, international normalized ratio
NUM, nurse unit manager
PA, physician assistant
PAM, preoperative anticoagulation management

REFERENCES

1. Wysowski DK, Nourjah P, Swartz L. Bleeding Complications With Warfarin Use A Prevalent Adverse Effect Resulting in Regulatory Action. *Arch Intern Med*. 2007;167:1414-9.
2. Gomes T, Mamdani MM, Holbrook AM, et al. Rates of hemorrhage during warfarin therapy for atrial fibrillation. *CMAJ* 2013;185:E121-7.
3. Bates DW, Cullen DJ, Laird N, et al. Incidence of Adverse Drug Events and Potential Adverse Drug Events Implications for Prevention. *JAMA* 1995;274:29-34.
4. Budnitz DS, Lovegrove MC, Shehab N, et al. Emergency Hospitalizations for Adverse Drug Events in Older Americans. *N Engl J Med* 2011;365:2002-12.
5. Hakkarainen KM, Gyllensten H, Jönsson AK, et al. Prevalence, nature and potential preventability of adverse drug events - A population-based medical record study of 4970 adults. *Br J Clin Pharmacol* 2014;78:170-83.
6. Damen NL, Baines R, Wagner C, et al. Medication-related adverse events during hospitalization: a retrospective patient record review study in The Netherlands. *Pharmacoepidemiol Drug Saf* 2017;26:32-9.
7. Nielsen VG, Asmis LM. Hypercoagulability in the perioperative period. *Best Pr Res Clin Anaesthesiol* 2010;24:133-144.
8. Wysokinski WE, McBane RD. Periprocedural bridging management of anticoagulation. *Circulation* 2012;126:486-90.
9. Flaker GC, Theriot P, Binder LG, et al. Management of Periprocedural Anticoagulation: A Survey of Contemporary Practice. *J Am Coll Cardiol*. 2016;68:217-226.
10. NHS Herts Valleys Commissioning Group. Hertfordshire guidelines for oral anticoagulation of patients with non-valvular AF. UK: 2016. *UK*. 2016. Available at: http://hertsvalleysccg.nhs.uk/publications/pharmacy-and-medicines-optimisation/local-decisions/cardiovascular-system/anticoagulants/3206-af-treatment-guideline-long-december-2015/file. Accessed January 29, 2018.
11. Dutch Health Care Inspectorate. *Anticoagulant Care Chain Not Sufficiently Sound* (Dutch). The Hague, the Netherlands; 2010. Available at: http://www.sin-nl.org/pdfs/igz_rapport_keten_trombosezorg_niet_sluitend_okt._2010.pdf. Accessed January 29, 2018.
12. Kirchhof P, Benussi S, Kotecha D, et al. 2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS: the task force on myocardial revascularization of the European Society of Cardiology (ESC) developed with the special contribution of the European Heart R. *Eur Hear J* 2016;37:2893-962.
13. You J, Singer D, Howard P, et al. Antithrombotic Therapy for Atrial Fibrillation: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest* 2012;141:e531S-75S.
14. Heidbuchel H, Verhamme P, Alings M, et al. Updated European Heart Rhythm Association practical guide on the use of non-vitamin-K antagonist anticoagulants in patients with non-valvular atrial fibrillation: Executive summary. *Eur Hear J* 2017;38:2137-49.
15. Keeling D, Tait RC, Watson H, British Committee of Standards for Haematology. Peri-operative management of anticoagulation and antiplatelet therapy. *Br J Haematol*. 2016;175:602-13.
16. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Thorac Cardiovasc Surg*. 2014;148:e1-132.
17. Tompkins C, Cheng A, Dalal D, et al. Dual Antiplatelet Therapy and Heparin "Bridging" Significantly Increase the Risk of Bleeding Complications After Pacemaker or Implantable Cardioverter-Defibrillator Device Implantation. *J Am Coll Cardiol* 2010;55:2376-82.

18. Eijgenraam P, ten Cate H, ten Cate-Hoek AT. Practice of bridging anticoagulation: Guideline adherence and risk factors for bleeding. *Neth J Med* 2014;72:157-164.
19. Steinberg BA, Kim S, Thomas L, et al. Lack of concordance between empirical scores and physician assessments of stroke and bleeding risk in atrial fibrillation: Results from the outcomes registry for better informed treatment of atrial fibrillation (ORBIT-AF) registry. *Circulation* 2014;129:2005-12.
20. Damen N, Damen P, van Dijk L, et al. *Implementation of the National Standard Anticoagulation Chain (V2.0): Current State of Affairs (Dutch).* Utrecht, the Netherlands; 2015. Available at: https://www.nivel.nl/sites/default/files/bestanden/Rapport-quickscan-implementatie-LSKA.pdf?. Accessed January 29, 2018.
21. Hollnagel E. *Safety-I and Safety-II. The Past and Future of Safety Management.* Farnham, UK: Ashgate Publishing Limited, 2014.
22. Lawton R, Taylor N, Clay-Williams R, Braithwaite J. Positive deviance: a different approach to achieving patient safety. *BMJ Qual Saf* 2014;23:880-3.
23. Baxter R, Taylor N, Kellar I, Lawton R. What methods are used to apply positive deviance within healthcare organisations? A systematic review. *BMJ Qual Saf* 2016;25:190-201.
24. Scerri A, Innes A, Scerri C. Discovering what works well: Exploring quality dementia care in hospital wards using an appreciative inquiry approach. *J Clin Nurs* 2015;24:1916-25.
25. Kelly N, Blake S, Plunkett A. Learning from excellence in healthcare : a new approach to incident reporting. *Arch Dis Child* 2016;101:788-91.
26. Hollnagel E, Wears R, Braithwaite J. From Safety-I to Safety-II: A White Paper. Published simultaneously by the University of Southern Denmark, University of Florida, USA, and Macquarie University, Australia.; 2015. Available at https://resilienthealthcare.net/wp-content/uploads/2018/05/WhitePaper-Final.pdf Accessed January 29, 2018.
27. Braithwaite J, Wears RL, Hollnagel E. Resilient health care: Turning patient safety on its head. *Int J Qual Heal Care* 2015;27:418-420.
28. Hollnagel E, Braithwaite J, Wears RL. Resilient Health Care. Farnham, England: Ashgate Publishing Limited, 2015.
29. Grol R, Wensing M. Effective implementation of change in healthcare: a systematic approach. In: Grol R, Wensing M, Eccles M, Davis D, Eds. Improving Patient Care: The Implementation of Change in Health Care. Oxford, UK: John Wiley & Sons, Ltd, 2013:40-63.
30. Hollnagel E. FRAM: The Functional Resonance Analysis Method. Modelling Complex Socio-Technical Systems. Surrey, UK: Ashgate Publishing Limited, 2012.
31. Nouvel D, Travadel S, Hollnagel E. Introduction of the Concept of Functional Resonance in the Analysis of a Near-Accident in Aviation. Introduction of the Concept of Functional Resonance in the Analysis of a Near-Accident in Aviation. 33rd ESReDA Seminar: Future challenges of accident inv. In: *33rd ESReDA Seminar: Future Challenges of Accident Invesitgation*. Ispra, Italy, 2007. Available at: https://hal-mines-paristech.archives-ouvertes.fr/hal-00614258/document. Accessed January 29, 2018.
32. Woltjer R. Functional Modeling of Constraint Management in Aviation Safety and Command and Control [Doctoral thesis]. 2009. http://liu.diva-portal.org/smash/get/diva2:210824/FULLTEXT01.pdf. Accessed August 22, 2017.
33. De Carvalho PVR. The use of Functional Resonance Analysis Method (FRAM) in a mid-air collision to understand some characteristics of the air traffic management system resilience. *Reliab Eng Syst Saf* 2011;96:1482-98.
34. Belmonte F, Schön W, Heurley L, et al. Interdisciplinary safety analysis of complex socio-technological systems based on the Functional Resonance Accident Model: An application to railway traffic supervision. *Reliab Eng Syst Saf* 2011;96:237-49.

35. Amorim AG, Pereira CMNA. Improvisation at Workplace and Accident Causation - An Exploratory Study. *Procedia Manuf* 2015;3:1804-11.
36. Rosa L, Haddad A, de Carvalho P. Assessing risk in sustainable construction using the Functional Resonance Analysis Method (FRAM). *Cogn Technol Work* 2015;17:559-73.
37. Clay-Williams R, Hounsgaard J, Hollnagel E. Where the rubber meets the road: using FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines. *Implement Sci* 2015;10:125.
38. Raben DC, Bogh SB, Viskum B, at al. Learn from what goes right: A demonstration of a new systematic method for identification of leading indicators in healthcare. *Reliab Eng Syst Saf* 2018;169:187-98.
39. Hounsgaard J. Patient safety in everyday work. Learning from what goes right [MSc thesis]. University of Southern Denmark; 2016. http://functionalresonance.com/onewebmedia/Hounsgaard%20(2016).pdf. Accessed January 29, 2018.
40. Hollnagel E, Hounsgaard J. FRAM – The Functional Resonance Analysis Method – A Handbook for Practical Use of the Method. Middelfart, Denmark; 2014. Available at: http://functionalresonance.com/onewebmedia/FRAM_handbook_web-2.pdf. Accessed January 29, 2018.
41. Resilient Health Care Net Meeting. Available at: http://resilienthealthcare.net/meetings/index.html. Accessed August 23, 2017.
42. FRAMily meeting. Available at: http://functionalresonance.com/framily-meetings/index.html. Accessed January 29, 2018.
43. Douketis J, Spyropoulos A, Spencer F, et al. Perioperative Management of Antithrombotic Therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. *Chest* 2012;141:e326S-50S.
44. Dutch National Steering Committee on Chain of Antithrombotics Care. Dutch National Standard Chain of Care on Antithrombotics – Version 2.0 (Dutch). Utrecht, the Netherlands; 2014. Available at: https://www.knmp.nl/patientenzorg/samenwerking/landelijke-standaard-keten-antistolling-2-0-lska. Accessed August 22, 2017.
45. Hill R. FRAM Model Visualiser. version 0.4.1. Available at: http://functionalresonance.com/the%20fram%20model%20visualiser/index.html Accessed January 29, 2018.
46. Mason M. Sample Size and Saturation in PhD Studies Using Qualitative Interviews. *Forum Qualitative Sozialforschung / Forum: Qualitative Social Research* 2010. doi: 10.17169/fqs-11.3.1428.
47. Taitz J, Genn K, Brooks V, et al. System-wide learning from root cause analysis: a report from the New South Wales Root Cause Analysis Review Committee. *Qual Saf Health Care* 2010;19:e63.
48. Hounsgaard J. Using FRAM as a Quality Improvement Tool in Health Care. In: *The FRAMily Meeting*. Munich, Germany; 2013.
49. Patriarca R, Di Gravio G, Costantino F. A Monte Carlo evolution of the Functional Resonance Analysis Method (FRAM) to assess performance variability in complex systems. *Saf Sci*. 2017;91:49-60. doi:10.1016/j.ssci.2016.07.016.
50. Feeley D. Six Resolutions to Reboot Patient Safety. Institute for Healthcare Improvement. Available at: http://www.ihi.org/communities/blogs/_layouts/15/ihi/community/blog/ItemView.aspx?List=7d1126ec-8f63-4a3b-9926-c44ea3036813&ID=365&Web=1e880535-d855-4727-a8c1-27ee672f115d. Published 2017. Accessed September 1, 2017.
51. Catchpole K, Neyens DM, Abernathy J, et al. Framework for direct observation of performance and safety in healthcare. *BMJ Qual Saf* 2017;26:1015-21.
52. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Heal Care*. 2007;19:349-57.

Appendix 1. Topic list used during interviews to identify aspects and coupling of FRAM functions.

Aspects	Questions
Input	What starts the function? What does the function act on or change?
Output	What is the output or results of the function? Do you have to inform anyone? Do you have to collect or record/report anything? If so, where? Who needs the output? Who will use what is produced? Have you agreed with whoever uses this that it is what they need?
Precondition	What should be in place so that you can complete the function normally? What do you do if the preconditions are not available?
Resource	What resources do you need to perform the function, such as people, equipment, IT, power, buildings, etc.? What do you do if the resources are not available?
Control	Do you have any goals for the function, such as do something within a time frame (this is a control)? What is the purpose of this function? Why do we do this? Do you have formal procedures or instructions controlling the function? Do you have people, such as supervisors, controlling the function? Are there values controlling the function? Do unofficial work practices or culture control the function? Do you have priorities, such as a triage system? Are there constraints such as budget?
Time	Is there any time related to the function? Is there a certain time where you have to perform the function? What happens if you are delayed— will you still do the function or not and what is the consequence for the following functions? Time only has four options: too early, too late, on time, or not at all.

Appendix 2. FRAM model of preoperative anticoagulation management as stipulated by guidelines (i.e., work-as-imagined).