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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Objectives: Preoperative anticoagulation management (PAM) 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 (labeled Safety-II) and how this relates to predefined procedures. This study aimed to assess PAM 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. Semistructured 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 been 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 PAM 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

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 nonadherence and root causes of complications (labeled 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. The FRAM has been applied in various settings, including aviation,[31] air traffic management,[32,33] railway traffic,[34] manufacturing,[35] and construction.[36] Although 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 semistructured interviews with frontline 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.
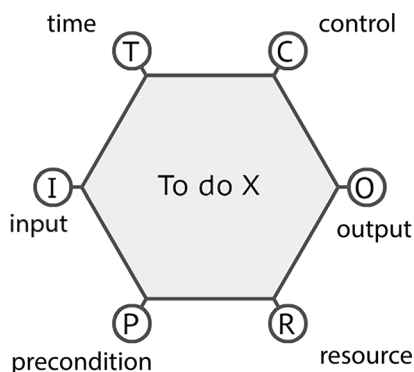
METHODS

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, nonvitamin 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

The 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 6 different labels or "aspects" (Fig. 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 previous 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.).

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 semistructured 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 (PA) at the Dutch hospital provided the initial point of approach for recruitment, and additional professionals were recruited through interviewees. Interviews were held individually with 1 interviewer in Australia (N.L.D.) and 2 interviewers in the Netherlands (M.S.d.V./M.J.M.). After written consent, interviews were audio recorded and summarized immediately afterward for the investigators. Interviews were guided by a topic list (Appendix 1, http://links.lww.com/JPS/A165) based on questions of the FRAM method, with minor adaptations made for the specific discipline interviewed.[39,40] The 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 the FRAM models.[45] Interviews were conducted until data saturation was reached for the model,[46] defined as 3 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

The 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 1 function to spread through the process, e.g., information omitted in 1 function may impact later functions that use this information. Variability and interdependence were 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.

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, http://links.lww.com/JPS/A166). 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 (Fig. 2) consists of the following 8 main functions:

FIGURE 1. The FRAM function with all aspects. Subscript: In "To do X," X can represent any activity (e.g., to admit patient). The 6 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.

TABLE 1. The FRAM Process Steps and Disciplines Interviewed, With Estimated Workload per Site

Process Steps			Time, h[†]
Work-as-imagined model	Development of model based on international guidelines.		7
Interviewed professionals (n)* including preparations, processing, and iterative model development	*Australia (10):* • Cardiothoracic surgeon (1) • Cardiologist (2) • Nurse case manager (1) • Nurse unit manager (2) • Anesthetist (1) • Preadmission 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

*Interviewed disciplines differ because of the different disciplines involved in the centers. Australian interviews were conducted in 2 instances within a 2-month timeframe because of time limitations for providers. All were interviewed individually, except for the preadmission clinic nurses who were interviewed together.

[†]Overall workload per site for the analysis carried out by 3 main investigators collaboratively.

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 "preadmission 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 preadmission booklet. If not, the nurse asks the surgeon or, 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 preadmission clinic, admission wards, anesthetists, and operating theaters.
3. **To conduct intake at preadmission clinic:** 2 to 3 weeks before surgery, patients visit the hospital again for a preoperative screening with several tests. At this preadmission 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 preadmission 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 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).
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 (Fig. 3) is composed 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 1-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 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

TABLE 2. Preoperative Anticoagulation Management "as-done" in Australia vs. the Netherlands

Theme	Australia	The Netherlands
Patient visits	2 preoperative hospital visits: 1 with surgeon and afterwards nurse CM, and 1 preadmission clinic visit.	1-day preoperative clinic visit, including pharmacy assistant, PA/registrar, cardiothoracic surgeon, and anesthetist.
Disciplines Multidisciplinary communication	Central role for nurses, including NUM, nurse CM, and clinic nurse. Anesthetist involved in work-up upon admission and in case of abnormalities. NUM might ask questions on PAM strategy during other cardiac group's multidisciplinary meeting.	Central role for PA/registrar and role for planning office secretary. Anesthetist not involved in PAM strategy or in case of abnormalities. 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 • Preadmission 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	• Surgeon, nurse CM, and clinic nurses • Prescription (if indicated) • Instruction letter; preadmission booklet	• PA/registrar, and secretary (over phone) • Prescription (if indicated)
Signaling 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 preadmission 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.
Signaling 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 preadmission 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

*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.
[†]Guidelines include ACCP 2012; ESC/EACTS 2014; ESC 2016.

e-mail. Patients subsequently visit the surgeon, but this consult serves to educate patients on the surgery rather than PAM.

5. **To perform preanesthesia 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 5 days in advance, unless vacant spots have to be filled.
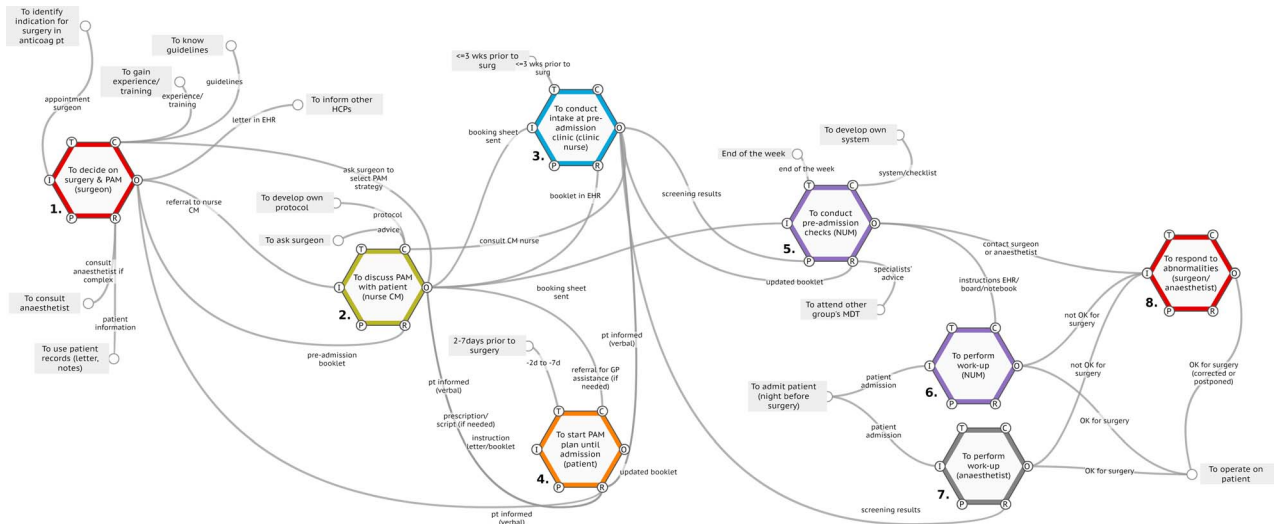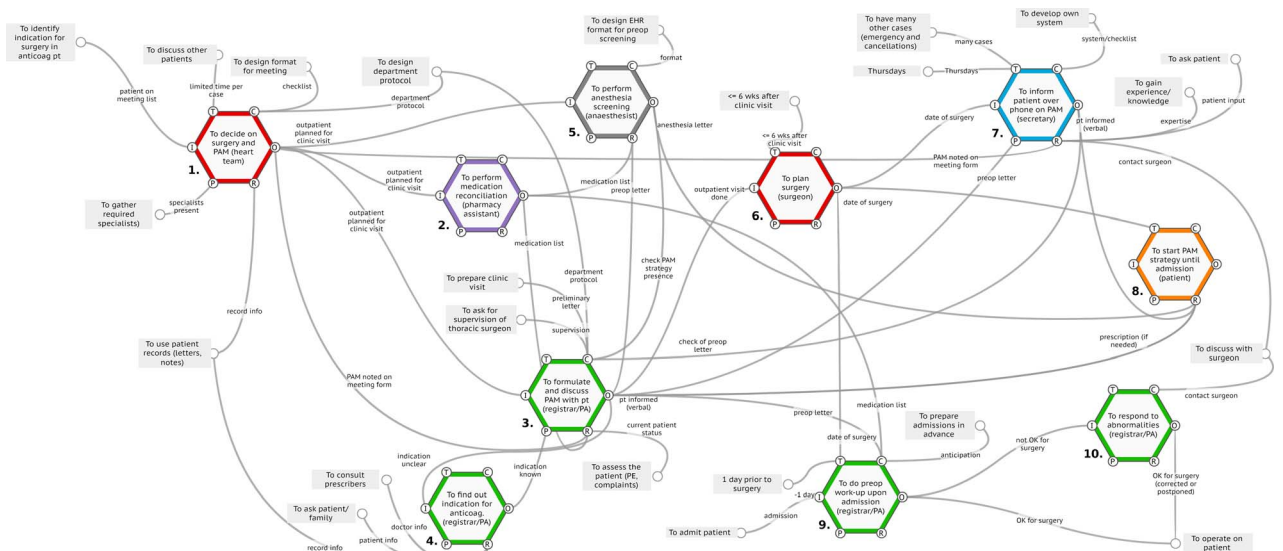
FIGURE 2. Work-as-done model of PAM in the Australian hospital. Subscript: Anticoag, anticoagulation therapy; HCPs, healthcare professionals; MDT, multidisciplinary team meeting; Nurse CM, nurse case manager. NUM, nurse unit manager. PAM, preoperative anticoagulation management; Pt, patient; Surg, surgery; Wks, weeks. Involved professionals (function in model): surgeon (1/8); nurse CM (2); preadmission clinic nurse (3); patient (4); NUM (5/6); anesthetist (7).

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 (Fig. 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 6 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 preadmission booklet. In complex cases, the nurse

FIGURE 3. Work-as-done model of PAM in the Dutch hospital. Subscript: 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).
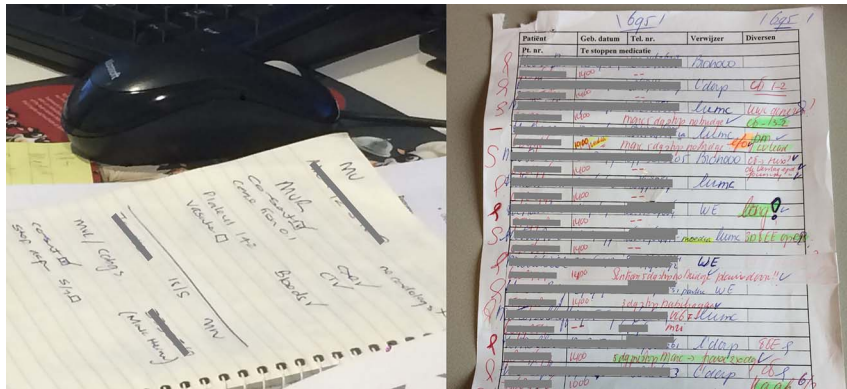
FIGURE 4. Photographs of naturally developed individual systems of Australian nurse unit manager (left) and Dutch planning office secretary (right).

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) (Figs. 2, 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 5 other foreground functions (i.e., 1, 2, 4, 5, and 7) (Fig. 3). Remarkably, there were 2 similar, partially overlapping functions (7 and 8) for work-up upon admission in Australia causing duplicate measurements of INR (Fig. 2).

The functions that represented patients adhering to the PAM strategy (Australian function 5; Dutch function 8) seemed 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 PAM "as-done" and "as-imagined" in 2 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, because 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 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

Although 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, 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. Although 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. Although 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

The FRAM seemed 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 approximately 47 hours per site (Table 1), which is comparable with the workload associated with traditional methods, such as a root cause analysis.[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). The 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, because 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 the 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 2 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, because PAM is also a common practice for other specialties. Moreover, real practice may still differ from the models developed in this study because 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. The FRAM seemed 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.

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