

## **Deviations from Double-Check Protocols in High-Risk Medication Administration: A Functional Resonance Analysis Method (FRAM) Study of Everyday Clinical Work**

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**Received:** 24 March 2023; **Revised:** 28 June 2023; **Accepted:** 01 August 2023

### **ABSTRACT**

Adherence to double-check protocols during medication administration remains limited. Despite this, most administrations of high-risk drugs proceed without adverse events. This study explored how high-risk medications are prepared and administered, identifying real-world variations and the reasoning behind departures from the prescribed standards. Ten hospital wards in the Netherlands took part. Using the Functional Resonance Analysis Method, we produced a model reflecting the national guidance and a cross-ward model representing actual work processes. To construct the cross-ward model, each ward participated in eight semi-structured interviews focusing on the preparation and delivery of high-risk drugs. Subconscious decision processes were categorized using Efficiency-Thoroughness Trade-Off principles. A total of 77 nurses were interviewed. Six discrepancies emerged between the guideline-based model and the cross-ward model. Importantly, four distinct deviations in double-check routines appeared. Time constraints played a major role. Nurses evaluated patient condition, calculation complexity, and other risk cues to decide whether to complete the double-check. Additional tacit judgements—such as reliance on personal or colleagues' competence—also shaped decisions. Time pressure is the dominant factor preventing consistent completion of the double-check. Instead, nurses rely on situational risk assessments to determine its necessity. As a result, the double-check may become routine for some drugs and omitted for others. Future work could use FRAM insights to redesign ward-specific, feasible double-check procedures that support safety in everyday practice.

**Keywords:** Patient safety, Double check, Work-As-Imagined, Work-As-Done

**How to Cite This Article:** Papadopoulos G, Karamanlis N, Kontos D. Deviations from Double-Check Protocols in High-Risk Medication Administration: A Functional Resonance Analysis Method (FRAM) Study of Everyday Clinical Work. *Interdiscip Res Med Sci Spec.* 2023;3(2):64-73. <https://doi.org/10.51847/XrvmNdj57Y>

### **Introduction**

The rising volume of medication use increases the likelihood of patient harm [1]. Parenteral therapies—such as intravenous infusions or intramuscular and subcutaneous injections—carry especially high risk because of their complexity and immediate physiological impact, which heightens the chance of irreversible outcomes [2]. Due to these factors, parenteral medications are labelled as high-risk. Prior studies have reported administration error rates of at least 48 % for such drugs [3–6]. In the Netherlands, 32 % of adverse events leading to death among hospitalized patients in 2019 were linked to medication use [7]. To reduce such incidents worldwide, standards grounded in the “five rights” of medication administration—right drug, right dose, right patient, right route, and right time—have been promoted [8]. National guidance following these principles was introduced in the Netherlands in 2009 [9].

The Dutch protocol outlines 17 required steps spanning both preparation and administration of high-risk medications [9]. During preparation, clinicians verify the medication order (e.g., dosage accuracy), complete all preparatory tasks, and ready the medication for use. During administration, required checks are performed, the double-check occurs, and the drug is administered [9]. The double-check involves an independent verification by

another trained professional, typically a nurse, who confirms the medication at the bedside before administration [10].

International studies show high compliance with most components of these protocols [11–15]. Nevertheless, adherence to the double-check has consistently remained low [11–18], suggesting that performing it reliably in daily clinical work is challenging. These studies predominantly assess guideline adherence [11–16, 18], representing a Safety-I lens in which safety is defined as “a condition with as few failures as possible” [19]. Under this view, systems are expected to operate exactly as written, and professionals are expected to act in line with procedures [19]. However, such a lens offers limited insight into the variability of real-world practice.

Limited research has explored the double-check procedure through a Safety-II lens. This viewpoint emphasizes ensuring that “as many things as possible go right,” highlighting how systems function successfully under shifting conditions and routine variation [19]. A small investigation conducted in two Dutch hospital units adopted this angle to study everyday high-risk medication administration [2]. It reported low adherence to hand hygiene requirements and frequent workarounds during the double-check. These deviations were linked to rising workloads, staffing gaps, and limited time. Staff must continually balance being efficient versus being thorough (Efficiency–Thoroughness Trade-Off; ETTO). Prioritizing efficiency involves completing tasks with minimal resources, including time and materials [20]. In the context of high-risk medication, this may ensure timely dosing for all patients, though some procedural steps may be skipped. When thoroughness is prioritized, adequate resources allow professionals to follow all recommended procedures [20], but timely administration for every patient may not be guaranteed.

Although double-check adherence is often low, the majority of high-risk administrations remain safe [21], suggesting nurses adjust their behavior to real-world demands. Yet the way nurses successfully adapt and manage varying conditions to maintain safety—despite not always complying with formal rules—has not been investigated on a larger scale. Similarly, the judgments and trade-offs guiding their choices to ensure safe medication use are not well understood. To clarify how day-to-day safety is maintained during high-risk medication administration, this study examines how nurses carry out the double-check in routine settings and what factors influence their decisions when they diverge from guidelines or standard procedures. The hypothesis is that most deviations occur during steps requiring a second nurse, and that hand hygiene may not always be completed as instructed. Furthermore, perceived time pressure and the presence of colleagues are expected to be major drivers of guideline deviation.

## Materials and Methods

### *Design and participants*

A comprehensive outline of the original multi-theme study protocol (high-risk medication, medication verification, and frail elderly) is available in the publication by Van Dijk *et al.* (2021) [22]. Early outcomes of the other safety themes have been published separately [23]. This observational work concentrates on everyday nursing routines and experiences surrounding high-risk medication administration. COVID-19-related restrictions necessitated several modifications to the data-collection process: in-person observations were not feasible, and all interviews took place online.

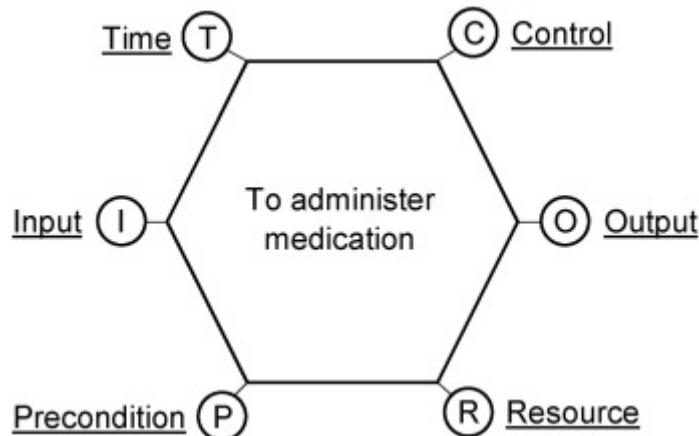
Because high-risk medication is common in several settings, three types of adult wards were eligible for inclusion: internal medicine, surgical, and intensive care units (ICUs). After each ward agreed to participate, a designated contact person—often the head nurse—coordinated with the research team regarding study goals and scheduling. This contact person informed all ward nurses and selected eight interview participants. Nurses had to be comfortable discussing preparation and administration of high-risk medication and, when possible, represent differing perspectives on guideline use. Selecting nurses with varied viewpoints enabled the team to capture a broad range of everyday practices, yielding the most complete depiction of each ward.

### *Functional resonance analysis method*

To contrast prescribed procedures with actual practice, two process models were made for each ward. A Work-As-Imagined (WAI) model was derived from hospital protocols, and a Work-As-Done (WAD) model was built using interview data. Both models followed the Functional Resonance Analysis Method (FRAM), which graphically portrays and examines healthcare workflows by identifying gaps between formal guidance (WAI) and

real-world performance (WAD) [24]. By mapping all activities, the method highlights how tasks interrelate [25, 26]. Each activity is shown as a hexagon reflecting six components (**Figure 1**) [25, 26]:

1. Input: triggers or modifies the activity.
2. Time: temporal elements influencing the activity.
3. Control: mechanisms that regulate or oversee the activity.
4. Output: what results from the activity.
5. Resource: items or supports needed to carry out the activity.
6. Precondition: requirements that must be met before the activity can occur.



**Figure 1.** Example of a FRAM hexagon and its associated elements.

#### *Efficiency–Thoroughness Trade-Off*

The ETTO concept reflects the balance between carrying out a task thoroughly versus completing it efficiently [20]. The degree to which an action leans toward thoroughness or efficiency depends on underlying considerations related to the work setting, team availability, and how important the task is perceived to be [20]. These considerations are organized into ETTO rules [20], which fall into three categories: work-related, individual, and collective rules [20]. This study concentrated on the work-related category and applied the ETTO framework to clarify the largely unconscious choices made when nurses depart from formal procedures.

#### *Data collection*

Data were gathered between June 2020 and June 2021. Wards were enrolled gradually to balance workload and accommodate unit availability. Enrollment details are presented in **Table 1**. At the start of participation, each hospital's instructions for preparing and administering high-risk medication were requested, so the researcher was familiar with local policies before interviewing began. Interview scheduling was arranged directly with each participant. Nearly all interviews occurred one-on-one to ensure every selected nurse could take part. The researcher ensured that all steps required by the national Dutch guidelines were addressed during the interviews, resulting in a full discussion of the entire administration process. Particular focus was given to the double-check and hand hygiene stages, as these have shown the lowest adherence levels in earlier Dutch research [2]. Each semi-structured interview lasted around 30 minutes. The interview guide was structured around the six FRAM features. All interviews were conducted in Dutch and, with verbal consent, audio recorded. Transcripts were produced verbatim, then summarized and returned to participants for verification.

**Table 1.** Overview of the sequence of ward enrollment.

Ward	2020						2021						
	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
A	x	x											
B		x	x										
C		x	x										
D		x	x										
E				x	x								

F	X	X				
G			X	X		
H					X	X
I					X	X
J					X	X

### Data analysis

Interview data were analyzed using MAXQDA 11. For each ward, both WAI and WAD diagrams were developed using the FRAM Model Visualizer [27]. Once data collection finished, the hospitals' internal protocols were compared with the national Dutch standards to identify differences. Because only small differences were detected, the Dutch guidelines [9] were used to construct a consolidated WAI model across wards. An overarching WAD model was then built by first identifying common elements in all ward-specific WAD models and then adding the distinctions observed between them.

To determine what reasoning patterns (ETTO rules) contributed to deviations from protocol, coding combined inductive and deductive approaches. Deductive coding drew on the six FRAM aspects (**Figure 1**) [26] and the work-related ETTO rules [20]. Inductive coding involved axial and selective coding, with new codes added and unused codes removed as needed. Two researchers (SvS, AV) independently coded transcripts from two wards, resolving discrepancies through discussion. The remaining transcripts were coded by one researcher (AV) and reviewed by another (SvS) to confirm completeness.

### Ethical approval

The Medical Ethics Committee of the VU University Medical Centre Amsterdam reviewed the project and determined it did not fall under the Dutch Medical Research Involving Human Subjects Act (WMO) (reference 2019.571). All requirements were followed, informed consent was obtained before participation, and all data are stored in secure, restricted-access systems.

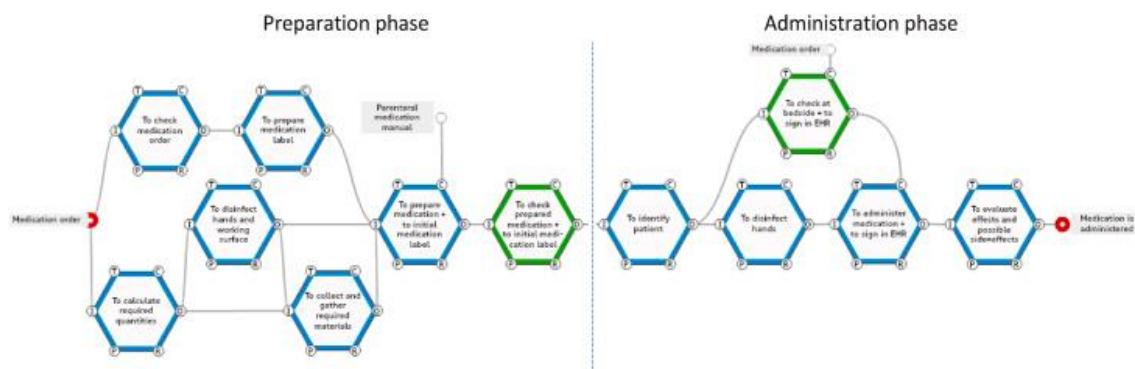
## Results and Discussion

### Study population

Altogether, ten wards from nine hospitals took part. These institutions consisted of four general hospitals, two academic centers, and three tertiary hospitals. A total of 77 nurses were interviewed: 30 from ICUs, 24 from surgical wards, and 23 from internal medicine units. Of all participants, 91% were women, and the mean professional experience was 13 years (SD = 5.9).

### Work-As-Imagined

The official guidance lists seventeen steps, nine for preparation and eight for administration [9]. To simplify the model, the steps "prepare the medication" and "sign the medication label" were combined, as were "double-check the medication (second nurse)" and "sign the label (second nurse)." This produced an overarching WAI diagram (**Figure 2**) with seven hexagons representing preparation tasks. Hexagon color indicates who performs the step: blue for the nurse preparing/administering the medication (first nurse) and green for the second nurse conducting checks.



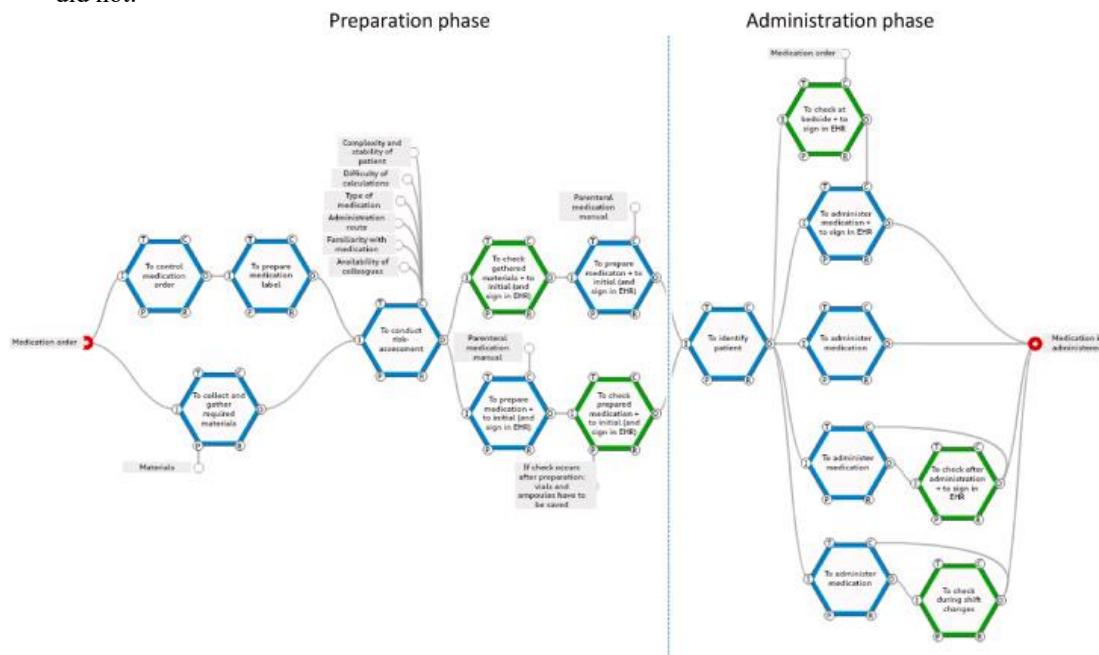
**Figure 2.** The WAI-model developed according to the Dutch standards.

The Dutch guidance differentiates between the nurse who prepares and the nurse who administers. To avoid duplication, the first three administration-phase tasks were not added to the WAI diagram, leaving only the final five tasks displayed as hexagons.

#### *Differences between guidelines and routine practice*

The overarching WAD model (**Figure 3**) is also separated into the preparation and administration phases, each containing eight hexagons. Within the preparation phase, four key discrepancies emerged when comparing the overarching WAI and WAD models:

1. The step “to calculate the required quantities” did not appear in the WAD model.
2. The action “to disinfect the working surface and hands” was absent.
3. The WAD model included an additional step, “to conduct a risk assessment.”
4. The order of “prepare the medication and sign the label” and “double-check and sign the label (second nurse)” differed. One order (preparation followed by checking) aligned with the WAI model; the other did not.



**Figure 3.** The overarching ward-level WAD model.

The chosen sequence depended on two considerations. First, if another nurse was immediately available, the check was often done before preparation in order to reduce time spent. Second, a nurse’s level of expertise influenced the choice—less experienced staff tended to request a double-check before beginning.

In the administration phase, two distinctions were noted:

1. The missing step “to disinfect hands,” and
2. variability in the second-nurse double-check.

Nurses consistently identified the double-check as the most difficult step to perform, which is reflected in the four variations depicted in the WAD model:

1. The process follows the written guidelines: a second nurse checks at the bedside during administration, often with shared verbal information to speed things up.
2. The double-check is omitted entirely, and the nurse administers independently.
3. The double-check occurs after administration; the second nurse may arrive up to 30 minutes later.
4. The check is postponed until the shift handover, when both outgoing and incoming nurses visit each patient to verify that all administrations were done correctly.

Guidelines require that the double-check be documented in the EHR during or immediately following administration of high-risk medication. Results showed that signing may occur at various points. When no later check was expected, nurses often preemptively signed the EHR during the preparation-stage double-check.

### *Risk assessment*

Before preparing or giving a medication, many nurses undertook—sometimes unconsciously—a risk assessment to decide whether a double-check was needed and how it should be done. This occurred in eight of the ten participating wards. On the two wards where it did not occur, either the double-check was not used (nor included in local policy), or the guideline separated parenteral medications into two categories: a mandatory double-check for high-risk agents and no requirement for the rest. This clearer distinction made the rules easier to follow, removing the need for an additional assessment.

Across the other wards, several factors shaped the risk assessment, and these varied both across and within wards. Generally, nurses consider three main elements. One commonly mentioned aspect was patient complexity. If a patient was receiving palliative care or managing multiple chronic conditions (and therefore numerous medications), nurses were more likely to perform a double-check.

“Sometimes a drug seems uncomplicated, but our patients are extremely ill. Their physiology behaves differently, so accuracy is essential. Even routine medications become complex with unstable patients.” — Nurse 1, Intensive Care Unit

A second consideration was the type of medication. Nurses evaluated whether the medication truly represented a high-risk category by considering the severity of possible errors or adverse consequences. Familiarity also played a role: the more often a nurse administered a particular drug, the less likely they were to ask for a second nurse. “I’m less strict with medications we use all the time. I feel the guidelines can be too rigid for certain drugs—some are straightforward, and harm is unlikely if a mistake occurs.” — Nurse 2, Internal Medicine Unit

A third factor concerned the route of administration. Changing pump rates or pump modes often prompted nurses to request a second check. Calculation difficulty was also noted. Although national guidelines [9] state that calculations only require double-checking during preparation, very complex calculations led nurses to repeat the check during administration as a form of additional verification. Finally, the availability of colleagues and overall ward busyness strongly influenced decisions: when other nurses were tied up or the ward was crowded, seeking a second nurse for the check was often not attempted.

### *Work-related ETTO rules*

In addition to the elements nurses evaluated during the risk assessment, several other underlying motives influenced their actions. These considerations often occurred automatically and were therefore not explicitly factored into the assessment. The work-related ETTO rule mentioned most frequently was “deviation due to time pressure.” In practice, this meant that when no colleague was available at the exact moment a high-risk drug needed to be given, nurses proceeded without a double-check.

“During night duty, each nurse cares for fifteen patients. When a high-risk dose must be given overnight, there is usually no one to assist. Still, the patient needs their medication right then.” — Nurse 3, Surgical unit.

The second most commonly cited rule was “deviating out of habit.” Nurses reported that they routinely skipped the double-check for certain medications, especially when past administrations had never resulted in adverse events.

“We tend to take high-risk medicines less seriously. The majority are given without a second check, and it’s become routine. It’s basically the norm now.” — Nurse 4, Surgical unit.

Other frequently referenced ETTO rules included “trust in one’s own expertise” and “trust in a colleague’s competence.” These reflect situations in which nurses felt that either their own abilities or those of their peers were adequate, making the double-check redundant. Also recurrent were the rules “the medication has already been checked” and “not important,” suggesting that nurses sometimes deemed the second check unnecessary.

“I admit I’m not always convinced of the value of the double-check. Automated system checks already reduce risk a lot, and whatever the system can’t verify is usually addressed during handover. Without seeing its additional benefit, it’s hard to stay motivated to perform the double-check.” — Nurse 5, Internal medicine unit.

This study applied the FRAM approach to explore real-world variation in the administration of high-risk medication, focusing in particular on the double-check. It also examined the decision-making processes that guide deviations from formal instructions. Several inconsistencies were identified between the guideline-based WAI model and the WAD representation of everyday practice. In the preparation phase, four main differences emerged: the WAD model did not include “to calculate the required quantities” nor “to disinfect the working surface and hands.” The step “to conduct a risk assessment” was added, and the sequencing of “preparing/signing the medication label” and “checking/signing the label (second nurse)” sometimes differed. The version in which

materials were checked before preparation did not appear in the WAI model. The omission of sanitation and the variations in checking aligned with our expectations.

The administration phase demonstrated similar findings. Two divergences appeared between the WAI and WAD models: the absence of “to disinfect hands” and the presence of four distinct approaches to the second-nurse check:

1. conducting it at the bedside during administration,
2. omitting it entirely,
3. completing it after administration, and
4. carrying it out during shift handover.

These outcomes correspond with earlier work documenting low adherence to hand hygiene and double-checking requirements [13, 14], as well as prior evidence showing variability in how double-checks are performed [2, 17, 28]. Nurses also noted that COVID-19 conditions did not simplify medication preparation or administration. Increased staffing shortages heightened time pressure, though many emphasized that time constraints already existed prior to the pandemic. Isolation measures were considered additional obstacles to performing the double-check.

Nurses’ considerations were also explored. Through FRAM, this study provides insight into how safe medication practices are still achieved despite guideline deviations and fluctuating work conditions. Various factors influenced the risk assessment. The availability of a second nurse and overall busyness fit within the broader theme of limited time/time pressure, supporting our hypothesis and prior evidence that high workload is a major contributor to low double-check adherence [2, 10, 18, 29, 30]. Given that double-checks require time [10, 14, 30, 31], nurses must decide which administrations warrant one. Criteria such as patient complexity and medication type have been identified in earlier studies [2, 10, 17]. Additional considerations—familiarity with the medication, administration route, and availability of colleagues—have previously been reported only by Schutijser *et al.* (2019) [2]. A newly identified factor in our study was “difficulty of the calculations.” Calculation-related tasks are known contributors to high-risk medication errors in hospitals [32], and earlier studies have shown that nurses may lack confidence in their calculation abilities or possess insufficient calculation knowledge [33, 34]. This highlights the essential role of the double-check as a safeguard to promote patient safety.

Additional subconscious considerations emerged and were organized using work-related ETTO rules. These reflected the prevailing mindset and shared norms on each ward concerning the double-check practice. Notably, most wards highlighted one or two dominant ETTO patterns, yet the specific rules differed between units. This indicates that local culture and team attitudes likely shape these tendencies. The most cited rule was “deviation due to time pressure.” The second was “deviating out of habit,” implying that nurses often skip the double-check once they have repeatedly administered a medication without previous problems. Other commonly reported ETTO rules included “trust in own expertise,” “trust in a colleague’s expertise,” “the medication has already been checked,” and “not important,” pointing toward a belief that the double-check adds little value or is unnecessary when they consider themselves or their coworkers sufficiently competent.

A positive aspect of this situational appraisal is the intention of nurses to safeguard patients as much as possible. However, the downside is that varying levels of experience make risk assessment decisions highly individualized and inconsistent. Repeated administration without a double-check may also cause some medications to be perceived as not needing one. Additionally, the double-check can turn into a routine task, and when done mechanically, its effectiveness diminishes, increasing the chance of errors [29, 31].

The findings demonstrate that the FRAM approach is effective for depicting a (healthcare) workflow and for clarifying how everyday practice unfolds. Nevertheless, the outcomes also raise doubts regarding the actual contribution of the double-check in routine care, as many nurses question its necessity. Existing literature does not offer strong evidence for its benefit [35], and evaluating its effectiveness remains challenging. Several studies rely on self-report or incident databases [36–38], although these sources are known to underrepresent actual events [21]. Research comparing single versus double-checks shows mixed results: some report a significant association between double-checks and fewer medication errors [38–40], while others find no meaningful difference [31, 36, 37].

When interpreting these results, it is important to recognize that the real-world execution of the double-check diverges considerably from formal guidelines. The ETTO rules illustrate that most deviations stem from habit or limited time, given that double-checking is a labor-intensive step. Nurses also weighed their own skills and those of colleagues when opting to bypass standard procedures. This aligns with the previously described risk

assessment factors, where time constraints, patient complexity, and familiarity with the medication all influence the decision. Consequently, practice often departs substantially from the recommended process, and when a double-check does occur at the bedside, it is typically not independent. Nurses tend to exchange information about the medication or its administration, creating a “primed” double-check [29, 31]. Such priming may increase the chance of oversight through confirmation bias [31, 41]. These insights raise the question of whether a fully independent double-check is achievable—or even necessary—in daily work [31]. Most high-risk medication administrations occur without problems [21], and nurses rely on their risk assessment to preserve safety. Thus, future studies should use FRAM-based insights to tailor ward-specific adjustments that fit actual workflows while upholding patient safety. Such changes might create more opportunities for meaningful double-checks.

#### *Strengths and limitations*

Several methodological considerations should be noted. First, direct observations were not possible because of COVID-19 safety restrictions. Second, interviews could not take place on the wards for the same reason. As a result, the reconstruction of preparation and administration processes depended entirely on nurses’ accounts. Some unconscious actions may not have been recalled during interviews. Nevertheless, interviewing multiple staff members per ward likely minimized missing data. Furthermore, the inclusion of several wards across different hospitals provided a broad perspective on high-risk medication procedures within Dutch hospital settings.

## Conclusion

This study demonstrated clear inconsistencies between guideline expectations (WAI) and actual work patterns (WAD) when preparing and administering high-risk medication. The double-check is performed frequently, yet time pressure often prevents its completion. Nurses carried out a risk assessment—including factors such as medication type, patient complexity, and calculation difficulty—to determine whether the double-check was warranted. Although these considerations aimed to protect patient safety, they were highly individualized. A drawback of this approach is that double-checks may be done, or omitted, out of habit, eventually making the procedure seem redundant and reducing its usefulness. These results prompt reflection on whether flawlessly performing the double-check at all times is a realistic or necessary goal in everyday practice. Therefore, upcoming research should apply FRAM insights to develop ward-specific adjustments that better align with actual workflows while keeping patient safety intact.

**Acknowledgments:** We would like to thank all participating hospitals, wards, and contact persons for their cooperation. Finally, we would like to thank the nurses who participated in this study.

**Conflict of Interest:** None

**Financial Support:** The study was funded by the Dutch Ministry of Health, Welfare and Sports.

**Ethics Statement:** This study was assessed by the Medical Ethics Committee of the VU University Medical Centre Amsterdam, and it was declared that the study was not subjected to Medical Scientific Research with humans (WMO) (number 2019.571). This study complies with all regulations and informed consent from all participants was obtained before starting the interview. The data are stored securely, accessible only to the research team.

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