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Modeling the COVID-19 vaccination process using the FRAM Method

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Abstract *Vaccination is crucial in a primary care unit and relevant for society. This study aimed to map and analyze the COVID-19 vaccination process adopting Resilience Engineering concepts to identify possible sources of failure and recommend improvements. A case study was conducted in a Primary Health Care unit, and data were collected through semi-structured interviews in a cross-sectional study. The vaccination process was analyzed and modeled using the Functional Resonance Analysis Method (FRAM), which provided a greater understanding of the procedural flow and the identification of the system's primary functions and points of variability. The results pointed out the couplings between functions that can generate high variability, which engineered improvements in the system's resilience by proposing countermeasures for the situations identified as bottlenecks.*

Key words *FRAM, Vaccination, COVID-19, Health System Resilience, Primary Health Care*

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Introduction

The pandemic caused by the novel coronavirus (SARS-CoV-2) represented a global challenge for health systems[1-3]. Although Brazil has an important public health network, the COVID-19 pandemic caused a significant growth in hospitalizations, which put pressure on the reorganization of the Unified Health System (SUS)[4,5]. Vaccination activities for COVID-19 represented an extraordinary labor in the preexisting vaccination routines in the National Immunization Program (PNI)[6].

In Brazil, the SUS relies on the National Immunization Program Information System (SI-PNI), which primarily aims to plan decision-making regarding vaccination activities[7-9]. The SI-PNI is an important technological innovation in managing immunization operations, but its use remains a challenge[7,9]. Despite its several benefits for health care services, according to Silva *et al.*[9], "some challenges are observed regarding its operationalization, completeness, and quality of the data collected (duplicity and underreporting)". Another issue is the workload imposed on health teams by the pandemic and the different challenges in properly recording information, which ranges from the lack of equipment and team training to the prioritization of patient care over records, given the higher-than-usual number of appointments[1,10-12].

Previous research has identified flaws in the vaccination process regarding the availability and quality of COVID-19 vaccination data in Brazil[1,10,12]. According to data presented in the technical note 'Vaccination Transparency'[12], 74% of the questions related to the COVID-19 vaccination process have issues such as incomplete (37%), totally lacking (30%), or inconsistent (7%) information. In this sense, it is important to know the nuances of using the SI-PNI and how it is used in the PHC units' vaccination rooms during the vaccination process.

Furthermore, Health Information Systems (SIS) often reflect the complexity of health care. Ferreira *et al.*[13] state that "health activities, in general, are often characterized as complex sociotechnical systems, with non-linear interactions between human beings and technological or organizational artifacts". Therefore, to identify and manage risks, resilience engineering is a good approach to address variability and its impacts on complex sociotechnical systems[14-16] since ensuring adequate immunization registration on the user's vaccination card and in information systems is one of the ten steps published by the Ministry of Health for PHC workers to ensure expanded vaccination coverage in the units[17].

Health systems' resilience is the ability of these systems to adapt to provide uninterrupted health services with safety and quality. This ability must be developed continuously and not only when an extraordinary event occurs, such as the COVID-19 pandemic[18,19]. In this research, the critical moment of the pandemic was used to model and analyze the vaccination process, seeking its variabilities and exposing opportunities for improvement.

Given the above, this study aims to map and analyze the main points of variability in the COVID-19 vaccination process based on resilience engineering concepts[14,19]. The case study was adopted as the research strategy. Observations were performed in a vaccination room of a PHC unit and interviews were conducted with the responsible team's members. Based on the data collected, the vaccine registration and application process was modeled using the Functional Resonance Analysis Method (FRAM), an effective tool for identifying and understanding the leading causes of failure propagation in sociotechnical systems based on coupling variabilities between functions[15,20].

The National Immunization Program Information System

The SIS is a data collection and processing tool that transforms data and information into knowledge. The collection of immunization data supports important decisions and actions for health management[21-24]. The PNI was created in 1973 and gathers information on vaccination nationwide. It is responsible for the national vaccination policy and the national operationalization plan for vaccination against COVID-19[25].

The SI-PNI was implemented in 2010 and records information on each vaccinated person individually, by age group and vaccine doses administered and calculates vaccination coverage[23].

The immunization process during COVID-19 has been monitored and followed through records made in the SI-PNI, facilitating the planning and control of the immunobiologicals distributed. The registration can be made in 'real-time' online or after vaccination, as in non-computerized vaccination rooms, without Internet connectivity, or in extramural vaccination outside the vaccination room, for example, at home[25].

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Immunization record errors are defined as typing errors and doses administered outside the current vaccination protocol or divergent immunological protocol. Thus, they are classified as immunization errors[26].

Functional Resonance Analysis Method (FRAM)

FRAM is considered an analysis method that reflects Resilience Engineering and Safety II thinking and seeks to understand how work adjusts to 'unexpected' situations and what the positive and negative consequences of such adjustments may be[27,28]. The FRAM analysis[28] aims to describe or represent how a system should function to achieve its objectives (i.e., daily work) and understand how the possible variability of functions (alone or in combination) can affect how this happens.

Although FRAM was initially applied in accident analysis, it is now used as a modeling tool in various domains, including health[29-33].

Material and methods

The study was divided into two stages: (i) mapping and analyzing the COVID-19 vaccination process and (ii) FRAM modeling.

Stage 1: Mapping and analyzing the COVID-19 vaccination process

A cross-sectional qualitative approach was employed to map the event, which involved adopting a case study as a research strategy, as it is "an empirical investigation that investigates a contemporary event within its current context, especially when the boundaries between the event and the context are not clearly defined"[34].

A PHC unit in the northern zone of Rio de Janeiro was selected by convenience to analyze the security of data recording during the vaccination process due to two main characteristics: (i) The possibility of access and availability of employees to collaborate in implementing the research and (ii) the interest of the organization's leaders in contributing to the research, after presenting the research already conducted and this research's purposes.

The analysis unit considered all professionals who directly administer vaccines and register immunization regarding COVID-19 vaccination activities in the PHC unit. The team consisted of one nurse and one nursing technician. All selected professionals expressly consented to participate in the research.

Data and field notes were collected through face-to-face and individual interviews with professionals to identify potential system variability. The interviews were semi-structured and followed the questionnaire in the link https://doi.org/10.48331/scielodata.A82INX, which consisted of sociodemographic and technical questions that addressed functional mapping and contextualization of using the SI-PNI system. Each interview lasted approximately two hours, with no need for repetitions or recording of audiovisual material.

This study was conducted in the capital of Rio de Janeiro state in November 2021, when the first dose of the COVID-19 vaccine was administered to people aged 12 and over, and the booster dose was administered to the following cases: people aged 59 and over; patients with a high immunosuppression level (12 and over); healthcare professionals and workers who took the second dose up to 31/05/21; and people aged 18 and over who took the second dose more than five months earlier[3].

Stage 2: FRAM modeling

FRAM[27] was adopted to model the vaccination process. The FRAM model aims to analyze how variability in function outputs can be combined to prevent their resonance, which can lead to undesirable results[35]. Hollnagel[27] recommends that the purpose of the analysis be defined before applying FRAM since the modeling can be related to accident investigation (looking at past events, retrospective analysis) or safety assessment (looking at future events, prospective analysis).

FRAM is based on four principles or assumptions about how things occur[27,28]. The principle of equivalence (of successes and failures): failure and success are equivalent, as they have the exact origin: the causes of adequate or inadequate functioning.

1. The principle of approximate adjustments states that people constantly adjust their activities to adapt them to their environment (considering resources, demands, opportunities, conflicts, and interruptions) so that the actions correspond to the established conditions.

2. Principle of emergent events: Variability alone is unlikely to be large enough to cause a failure or accident. However, variability in multiple functions can combine in unforeseen ways and cause disproportionate and non-linear effects.

3. Principle of functional resonance: When the cause-effect principle (causality) cannot be explained, functional resonance can describe and explain non-linear interactions and outcomes.

Once the purpose of the investigation was defined, the FRAM was applied, which consists of four stages[27,28], namely:

• The first stage identifies and describes the system's important functions and characterizes each function using six essential characteristics (called aspects) (Figure 1): Input, Output, Preconditions, Resources, Time, and Control. Together, the functions constitute an FRAM model.

• The second stage characterizes the potential variability for each function in the FRAM model and the possible actual variability in one or more model implementations.

• The third stage is identifying functional resonance, which consists of determining the possibility of functional resonance based on the dependencies/couplings between functions, given their potential and actual variability. This stage aims to determine how a function's variability can spread in the system and how it can combine with the variability of other functions.

• The fourth step consists of developing recommendations/countermeasures for monitoring and influencing variability, either by mitigating variability that may lead to undesirable results or increasing variability that may lead to desired results.

Results and discussion

Modeling the studied environment with FRAM: A Primary Health Care unit

The vaccination process includes the organization and operation of the vaccination room, conservation of immunobiologicals, and procedures for preparing and administering the vaccine. Nursing technicians are allocated to the immunization room and supervised by a Responsible Nurse (RN).

The vaccination room begins to operate when the emergency room opens. Before proceeding with vaccination, nursing technicians must sanitize their hands, check the cold room's temperature, take inventory, and record the relevant data in the Order and Occurrence Book. Afterward, the cooler boxes must be prepared to reach a temperature between 2°C and 8°C, and then the most commonly used vaccines must be transferred into them.

After preparing the room, the nursing technician must receive the patient and begin the care. The nursing technician must request documentation (CPF or National Health Card (CNS) and vaccination card or booklet), register the dose of the vaccine administered (patient's name, date of birth, and immunobiological), which must be personalized/individualized in the SI-PNI system, make the entry in the control book, and complete the vaccination certificate. The nursing technician must do all patient listening and vaccine preparation and administration. Once the process is complete, the certificate is handed over, and the patient is released.

Step 1 - Identifying essential functions

Interviews were conducted with professionals from the selected PHC unit to understand the event studied better, including one RN and one Nursing Technician. The first respondent is 28, has a technical course in nursing and a higher education degree in Nursing, and has worked in the PHC for six months but has been in the vaccination room as an RN for two months. The second respondent is 33 years old, has a technical course in Nursing and has worked in the PHC for three months, during which time he has worked in the vaccination room.

The team of professionals analyzed the setting and summarized the main activities throughout the vaccination process, from welcoming the patient to their release after the vaccine was administered. Based on the responses, we identified the main functions and characteristics of the vaccination process.

The questions asked focused on daily routines rather than specific successes and failures. Questions in the questionnaire that addressed function aspects were based on work already accepted in the related literature[20,28,36]. Questions that addressed system aspects were adopted from the work of Ferreira *et al.*[7]. The questionnaire employed is provided in the link: https://doi.org/10.48331/scielodata.A82INX.

After data collection, a general model of the vaccination process containing the potential variability of the functions was developed. The FRAM Model Visualiser (FMV), version 2.2.0, was used, as shown in Figure 2 below. The link https://doi.org/10.48331/scielodata.A82INX, provides the textual representations of the mapped functions.

Figure 2 presents the FRAM model considering the following setting: vaccination room, morning shift, vaccination of the first dose of

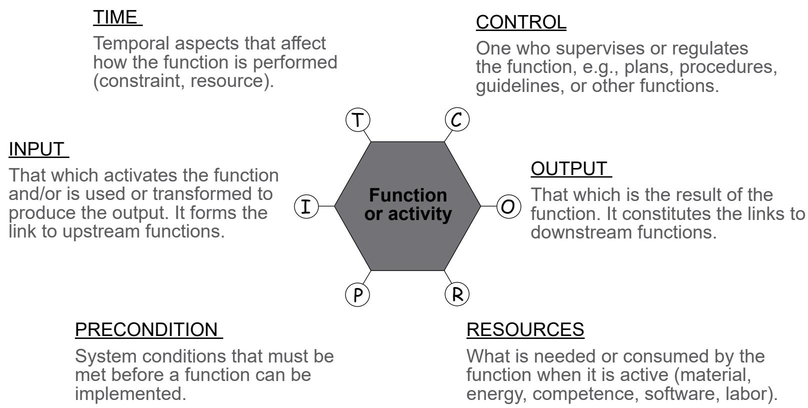

Figure 1. FRAM model function or activity aspects.

Source: Adapted from Hollnagel *et al.*[28].

the COVID-19 vaccine in the general population, adult patient without allergies/comorbidities, not pregnant, postpartum, or lactating women. This is a typical setting in the area with the highest volume of patients, per data presented in the Municipal Immunization Plan[3]. Twenty-one functions were identified in the process, all human type, of which one is performed by the RN, represented by the gray color in the model, and the others are under the responsibility of the nursing technician, represented by the white color.

In the construction of the FRAM model, the graphical representation of each function is made by a hexagon, and the tool's fundamental principle is that each input (Input, Precondition, Resource, Control, Time) – that is, the input aspects – for a function is an Output of another function[28]. Each input aspect represents the inputs of a function circled in bold and/or by all the lines that arrive at the hexagon through the aspects I (Input), P (Precondition), R (Resource), C (Control), and T (Time). The outputs are represented by the Output (O) aspect, circled in bold and/or by the lines that depart from it.

Step 2 - Identifying the variability

Hollnagel *et al.*[28] recommend describing the variability of functions' outputs in a simplified way regarding Timing and Precision. Thus, concerning Timing, an Output can occur too early, on time, too late, or not at all. In terms of Precision, an Output can be precise, acceptable, or inaccurate.

A sinusoidal wave in the model representation signaled the functions with the most significant potential variability (Figure 2). Chart 1 lists the FRAM model's functions, outputs, and potential variability.

In summary, of the 21 functions, 11 show real variability in time or precision. The 11 functions identified with variability in their Output were: <Open room>, <Check cold room's temperature>, <Enter in the Order and Occurrence Book>, <Transfer vaccines to cooler boxes>, <Prepare cooler boxes>, <Start Service>, <Request documentation>, <Consult the system>, <Register in the SI-PNI>, <Register in the vaccination book> and <Prepare Vaccine>.

Step 3 - Identifying the Functional Resonance

The FRAM basis describes the functions that comprise an activity or process. However, the relationship between the functions is not described directly but indirectly through the relationships defined by the functions' aspects. The common technical term for such relationships is coupling[28]. FRAM can show how functions are coupled and the potential sources of more significant variability, besides determining which functions may be affected in a given situation[37]. For example, in Figure 2, the functions <Regis-

ter in the SI-PNI> and <Complete receipt> are interconnected since the Output of the <Register in the SI-PNI> function serves as input to the <Complete receipt> function, so the two functions are potentially coupled. This means that the variability of the Output of <Register in the SI-PNI> can affect the performance of <Complete receipt>. Furthermore, the <Register in the SI-PNI> function uses the Output of the <Request documentation> function as a Resource, which means that the variability of the Output of <Request documentation> can affect the performance of <Register in the SI-PNI>. For example, the service registration is discontinued if the patient does not submit documentation.

The number of aspects is analyzed by following the potential couplings between the functions step by step[28]. To this end, the aspects are organized into two groups, which can be upstream or downstream, also identified as the upstream and downstream groups, respectively[20]. Based on the mapping of functions in the previous section, Chart 2 indicates the couplings between functions through the coupling numbers (NAC) of the functions. Each function's upstream and downstream aspects are added together to do this. The 'upstream' NAC group comprises the input, resource, control, precondition, and time aspects. The outputs form the 'downstream' NAC group (Chart 2).

According to Hollnagel *et al.*[28] and Volken and Rosário[20], the greater the number of upstream aspects, the more significant the function's homeostatic potential; that is, the greater the function's capacity to receive inputs with

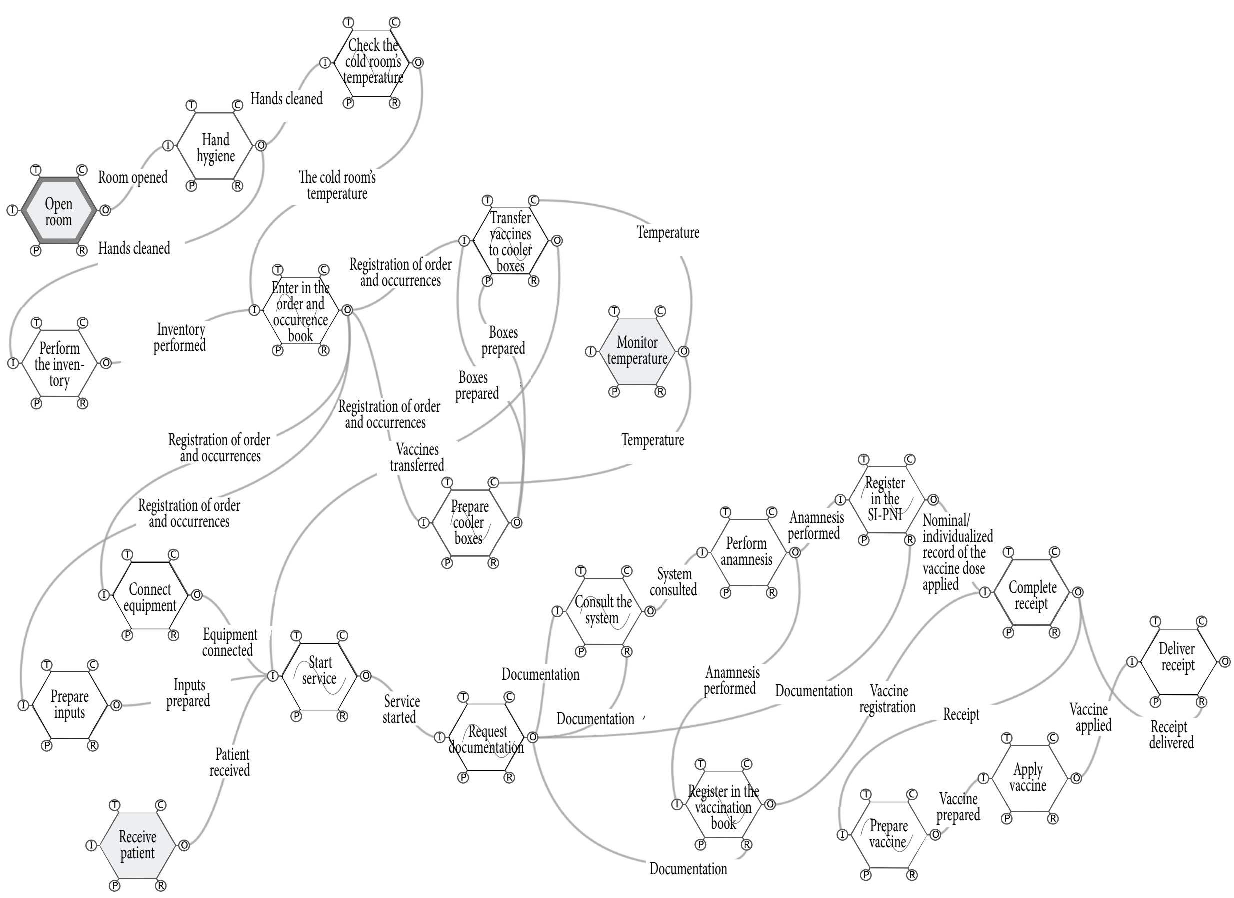

Figure 2. General model of the vaccination process, created in FMV v.2.2.0..

Source: Authors, 2024.

Chart 1. System functions.

Activity performed	Output	Potential Output Variability
Open room	Room opened	*Very late*: The vaccination room must be opened first thing in the morning. *Acceptable*
Hand hygiene	Hands cleaned	*In time* *Precise*
Check the cold room's temperature	The cold room's temperature	*In time* *Acceptable*: Conference errors may occur.
Perform the inventory	Inventory performed	*In time* *Precise*
Enter in the order and occurrence book	Registration of order and occurrences	*In time* *Acceptable*: Registration error may occur.
Prepare cooler boxes	Boxes prepared	*Very late*: Interruptions may occur while performing this activity. *Inaccurate*: There may be inaccuracy in the temperature, which should be between 2°C and 8°C.
Transfer vaccines to cooler boxes	Vaccines transferred	*In time* *Acceptable*: Errors may occur during transfer. The most commonly used vaccines must be transferred.
Monitor temperature	Temperature	*In time* *Precise*
Prepare inputs	Inputs prepared	*In time* *Precise*
Connect equipment	Equipment connected	*In time* *Precise*
Receive patient	Patient received	*In time* *Precise*
Start service	Service started	*Very late*: The person vaccinating is the same person who records the information in the system. *Acceptable*
Request documentation	Documentation	*In time* *Acceptable*: The patient may not have documentation, such as a vaccination card.
Consult the system	System consulted	*Very late*: Wait for the computer to become available or Internet connectivity. *Acceptable*
Perform anamnesis	Anamnesis performed	*In time* *Precise*
Register in the SI-PNI	Nominal/individualized record of the vaccine dose applied	*Very late*: Wait for the computer to become available or Internet connectivity. *Inaccurate*: Not every field in the record is filled in (e.g., adverse events after vaccination and losses of immunobiologicals) to speed up the process.
Register in the vaccination book	Vaccine registration	*In time* *Acceptable*: Registration error may occur.
Complete receipt	Receipt	*In time* *Precise*
Prepare vaccine	Vaccine prepared	*In time* *Acceptable*: An error may occur when preparing the immunobiological.
Apply vaccine	Vaccine applied	*In time* *Precise*
Deliver receipt	Receipt delivered	*In time* *Precise*

Source: Authors, 2024.

unexpected variability and, given its resilience capacity, prevent deviations from propagating in the process. Thus, the functions <Transfer vaccines to cooler boxes> and <Start service> have the greatest homeostatic potential, presenting the most significant sum of upstream NACs. On the other hand, the greater the number of downstream aspects a function has, the greater its potential for propagating failures. The functions <Enter in the Order and Occurrence Book> and <Request documentation> had the most significant potential for propagating failures, as they are functions with the most significant sum of downstream NACs. Notably, the functions <Enter in the Order and Occurrence Book>, <Transfer vaccines to cooler boxes>, <Start service>, and <Request documentation> are functions with the highest NAC when adding both aspects (upstream and downstream). This information shows how these functions are central to the activity. These results corroborate the findings of Volken and Rosário[20] concerning identifying homeostatic potential functions and fault propagation and allowing the implementation of applications in resilience engineering.

Chart 2. Functions and numbers of couplings (NAC).

Activity performed	Upstream NAC	Downstream NAC
Open room	4	1
Hand hygiene	2	2
Check the cold room's temperature	1	1
Perform the inventory	2	1
Enter in the order and occurrence book	3	4
Prepare cooler boxes	3	2
Transfer vaccines to cooler boxes	6	1
Monitor temperature	1	2
Prepare inputs	2	1
Connect equipment	2	1
Receive patient	1	1
Start service	5	1
Request documentation	3	4
Consult the system	3	1
Perform anamnesis	1	2
Register in the SI-PNI	4	1
Register in the vaccination book	2	1
Complete receipt	2	2
Prepare vaccine	2	1
Apply vaccine	3	1
Deliver receipt	2	1

Source: Authors, 2024.

Step 4 - Proposed countermeasures

After applying FRAM, we identified countermeasures to ensure more substantial control of the identified variability situations to monitor, mitigate, and even prevent possible adverse impacts. These countermeasures were grouped into human, technological, and organizational countermeasures:

1) Human countermeasures:

a) Increasing the number of professionals dedicated to the vaccination process. The professionals interviewed highlighted the importance of having at least two professionals in the vaccination room and that the activities be divided in such a way as to ensure that the information is recorded in the system during the service in all cases. This action aims to reduce the possibility of errors in the performance of functions such as <Open room> and <Start Service>, which are considered to be only "Too late" in accuracy.

b) Expanding the activities of the Responsible Nurse with the implementation of a routine of constant monitoring of the records made by the vaccination team and sensitizing the team about the importance of using the system. This action aims to reduce the possibility of errors in performing functions such as <Enter in the Order and Occurrence Book> and <Register in the vaccination book>, which have only an "Acceptable" accuracy.

c) Correctly fill in the fields of the SI-PNI system, especially the data on losses of immunobiologicals. This action aims to reduce the possibility of errors in the performance of functions such as <Register in the SI-PNI>, whose accuracy is considered "Too late" and "Inaccurate".

2) Technological countermeasures:

a) The SI-PNI should replace the permanent file with the control card. The replacement will allow better data management and increased monitoring of activities. It is highly recommended to eliminate parallel records and adopt a unified and integrated solution. This action aims to reduce the possibility of errors in performing functions such as <Request documentation>, whose accuracy is considered only "Acceptable".

b) Vaccination units without an Internet connection can adopt a local network registration system and synchronize their records with the central SUS server. The synchronization should not exceed 48 hours to ensure data is available nationwide. This action aims to reduce the possibility of errors in the performance of functions such as <Consult the system>, whose accuracy is considered only "Too late".

3) Organizational countermeasures:

a) Investing in a highly available technology infrastructure can mitigate the current access problems faced by the unit. The data collection instruments (computers, tablets, and cell phones) used to feed the information systems must be made available in adequate amounts to the team responsible for the vaccination process, as pointed out by the professionals during the interviews. This action aims to reduce the possibility of errors in the performance of functions such as <Consult the system>, whose accuracy is considered only "Too late", and <Register in the SI-PNI>, whose accuracy is considered "Too late" and "Inaccurate".

Creating an integrated and reliable database for the vaccination process can facilitate the detection of cases in which the system may become overloaded. Examples include identifying the need to purchase new doses of a vaccine, the side effects of vaccines on the local population, and better organization and planning of vaccination campaigns.

Despite the countermeasures presented, Walker *et al.*[38] state that investing in innovation and skills is necessary, stakeholders should agree on the direction to take, and access to inputs, financial resources, and infrastructure should be available to maintain a balanced sociotechnical system.

Complex sociotechnical systems, such as the PHC unit environment, have particularities that require a robust approach to solve their problems. FRAM models have been widely used to represent the variability that affects the functions of complex sociotechnical health systems[15,18,19].

This study's results are consistent with previous research[13,29] and indicate that applying the FRAM model in health systems can identify sources of variability that contribute to functional resonance. As a result, the FRAM model improves the understanding of the problem based on the variability analysis. This analysis and implementation of corrective actions can curb resonance and increase the system's resilience.

Conclusions

Vaccination is a crucial process in a PHC unit and extremely important to society. This study aimed to understand how FRAM can reduce registration errors in the COVID-19 vaccination room. The method was adopted to model and analyze the vaccination process to improve its resilience.

The model was applied in a real case study to analyze the security of data recording during the vaccination process. From the instantiated model, we identified potential sources of recording errors in the COVID-19 vaccination room, providing a greater understanding of the domain and identifying the system's primary functions and points of variability. A positive point of FRAM is the method's easy application, which requires a good understanding of how the work is performed without demanding more time than is acceptable or an unfeasible number of people involved.

The results indicated the coupling of functions that can generate high variability and countermeasures proposed. FRAM's application provided the study participants with a didactic view of the evaluated process, facilitating the identification of discrepancies between the work as performed and the work as imagined. We also identified that, for the national vaccination campaign against COVID-19, the dose registration applied is nominal/individualized, which is the process most crucial activity.

The research shows its relevance and originality by proposing an explanatory design for the flow of information on COVID-19 vaccination.

It could serve as a roadmap for managing similar events in the future and as a basis for improving the resilience of the vaccination process. Future research development will integrate technological and organizational aspects besides human ones so that it is applicable in other healthcare situations or environments.

Collaborations

NM Nascimento, AS Amaral Neto, AB Loureiro, and MF Silva contributed to the conception and design of the study, interpretation of the results, FRAM modeling, and writing of the manuscript. C Araújo, MPA Rubio, and AS Ribeiro critically reviewed the text, emphasizing the interview script. NM Nascimento, AS Amaral Neto, and AB Loureiro conducted the interviews. All authors are part of the HumânITas group, led by MF Silva, and read and approved the article's final version.

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