

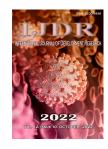
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HEURISTIC VALIDATION OF AN APP FOR THE NOTIFICATION OF DRUG-RELATED INCIDENTS IN A MOBILE EMERGENCY SERVICE

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ABSTRACT

Objective: To validate an app of the mobile health technology type for the notification of drugrelated incidents in a Mobile Emergency Care Service. **Method:** Heuristic validation study of an app devised for notifying drug incidents in a pre-hospital emergency care service. To operationalize the entire process, from elaboration to validation of the app, the *Design Thinking* methodology was used. Validation was carried out following Nielsen's 10 heuristics, in a computer science institute from Rio de Janeiro, based on the analysis by 12 evaluators, who issued individual evaluations and then, in group reports. These assessments were carried out from use cases shared during validation. The evaluators were able to use the app to send a supposed notification and rate it. **Results:** The evaluators agree that the app fulfills its role, requiring usability adjustments, which were duly carried out, following the demands set out in the report. **Conclusion:** Analysis of the application by the evaluators resulted in an improvement in the app's interface. Therefore, the infringement points presented were developed to define a possible satisfactory correction, according to the end users' reality.

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INTRODUCTION

Notification of incidents is a strategy recommended for adoption by the health services, so that they can more accurately manage the risks related to patient care and safety. The tendency is to state that this notification has emerged as one of the tools to promote quality of the health services at any level of attention and care. Currently, notifying incidents is an important guideline, both in Brazil and internationally. Increased safety can only be achieved by identifying errors and failures, sharing them and planning improvement actions (Nuñez, 2016). In Brazil, notification is an essential part of the National Patient Safety Program (*Programa Nacional de Segurança do Paciente*, PNSP), established by Ordinance No. 529/2013 of the Ministry of Health. It is also recognized as mandatory by Collegiate Management Resolution No. 36 (*Resolução de Direção Colegiada* -RDC 36), which institutes actions for patient safety (Brasil, 2013). However, individualized offices, clinical laboratories, mobile services and home care are excluded from the scope of the Resolution. Among the mobile services, the mobile prehospital care, performed outside the hospital environment in urgency/emergency situations. Although not included in the scope of RDC 36/2013, it is considered important in risk mitigation. Mobile pre-hospital emergency care (Atendimento Pré-hospitalar de Emergência, APHE) is potentially dangerous with the possibility that patients experience safety-related incidents. However, when compared to the care provided in other health settings, such as hospitals, little is known about these incidents (O'Connor, 2021). There are some factors that contribute to this potential presence of incidents and harms to the patient. The professionals see patients of all ages, with varied clinical conditions and sometimes with limited communication skills. Care is offered in adverse environments, 24 hours a day and generally far from adequate support.

This complex context poses many barriers to effective research studies. In addition, APHE has problems in identifying, notifying and disclosing incidents (Hagiwara, 2019). Therefore, the objective of this study is to validate an app of the mobile health technology type for the notification of drug-related incidents in a Mobile Emergency Care Service (SAMU 192). Data regarding the occurrence and notification of incidents in pre-hospital emergency care (APHE) are scarce, but they point to some important relationships in this environment which, in turn, justify the need for greater monitoring and risk management. In a study carried out at the Mobile Emergency Care Service (Servicio de Asistencia Móvil de Urgencia, SAMU) of Asturias/Spain, 194 notifications were made in six months. Of these, 88.1% were considered preventable and 74.7% were related to harms to the patient. The number of incidents related to health care notified in Brazil in 2016, on the NOTIVISA portal, showed a total of 1,274 notifications in Urgency/Emergency services in a universe of 53,997 notifications in various sectors (Agência Nacional de Vigilância Sanitária, 2016). This number represents a small portion over all the incidents notified. However, it can be affected by some factors, such as underreporting.

Threats to patient safety in APHE are varied, including areas such as clinical decision, communication, transportation, intubation and medication. It is estimated that drug-related incidents cause at least one death every day and harm approximately 1.3 million people annually in the United States, and that they are also responsible for an estimated cost of 42 billion dollars globally (Bennecka, 2019; World Health Organization, 2017). In pre-hospital services, especially in Brazil, it is not uncommon to use medications in ambulances, especially in advanced units. In the basic ambulances, the medication system is developed even through Telemedicine, despite the nonmandatory existence of drugs in the arsenal of this modality, by Ordinance 2048/2002 (Brasil, 2002). Based on the representation of medication errors, drug-related incidents and adverse events, it is imperative that the health services have tools designed in order to know the nature of the incidents, so as to make use of prevention strategies that result in their reduction. In addition to being harmful, drug-related adverse events are linked to the increase in health costs worldwide. It is to be noted that adverse events are a classification of incidents in which there was harm to the patient (World Health Organization, 2011). Analyzing these issues, it was decided to use the the elaboration and validation of a Mobile Health Technology, in the form of an app, for the notification of drug-related incidents, specific for health care in ambulances from the SAMU 192 service. In the context of notifications at APHE, the environment is dynamic, diversified in its demands and subjected to errors; the applicability and relevance of implementing mobile technologies in health is understood, as a possibility of obtaining information on clinical data reliably, available at any time and place, and designing therapeutic interventions.10

METHOD

Type of study: This is a heuristic validation study of an app elaborated for notifying drug-related incidents in a pre-hospital emergency care service. To operationalize the entire process, from elaboration of the app to its validation, the Design Thinking (DT) methodology was used. DT consists of three macro phases, namely: inspiration, ideation and implementation (BROWN, 2008). Heuristic validation was carried out in the implementation phase, as a tool for usability validation by experts in the field of computing, based on the premises established by Jacob and Nielsen, namely: System status visibility, Correspondence between the system and the real world, User control and freedom, Consistency and standardization, Recognition instead of memorization, Use flexibility and efficiency, Aesthetic and minimalist design, Error prevention, Support for recognition, diagnose and repair errors, Help and documentation. Heuristics are general principles of interface design, being considered golden rules in heuristic evaluation (BARRY, 2019).

In this study, the premises established by the Equator instrument for qualitative studies, COREQ¹, were followed.

Study scenario: Validation was carried out in a Computer Science Institute located in Rio de Janeiro, Brazil, during a course on Human-Computer Interface (HCI); with 12 evaluators, who were attending the referred academic discipline, all from the computing area. It was proposed that they record, access and classify the SAMU drug-related incidents, in a use case. All had low familiarity with the tool. This number of evaluators was obtained for convenience, according to their participation in the validation date. No participant refused to conduct the app validation process. The app's end users will be physicians, nurses and nursing technicians from SAMU 192/Metropolitan Region II – RJ. The validation process was conducted by 3 individuals from the research team, 1 professor from the Computer Science Institute, who was teaching that academic discipline at the time, and 2 scholarship students from the Computer Science course, who participated in elaboration of the app.

Data collection and treatment: To devise the app, mapping of the drug administration process was carried out, according to the routine of SAMU 192/Metropolitan Region II in Rio de Janeiro, workplace of the health professionals who are the end users of the app. Elaboration of the app called NotiSAMU was conducted based on the Flutter platform. It had some essential premises, such as notifier's anonymity and access to the list of all medications found in the ambulance for notification, according to the service checklist. Some data related to the patient and the occurrence in question were included in elaboration of the app: date of occurrence, type of ambulance, patient's age, care locus and comorbidity; with possibilities to prepare some future mapping for risk management. After mapping the service's drug administration process, a survey of requirements was carried out to identify and understand what the software developed is expected to solve. As functional requirements, those that determine the function of a software component and as non-functional, related to the quality of the services and software functions, those in Chart 1.

In order to specify the scenarios of possible use of the system, either by a user or by other systems, the use cases represented in charts 2, 3 and 4 were established. As for the screen layout, it was sought to develop the app in a logical sequence so that the user can notify according to the service's medication process. There are 9 screens, from Login to Notification completion. The first screen, Login, where after entering the login information, the user sees an explanatory message, in order to recognize the relationship of the notification with patient safety and be informed that they will not be identified. On the third screen, the professional's identification data are collected, with the name being optional. This screen is only part of the notifier's login process, different from the screens for the manager. On the next screen, the user finds the location for recording the patient's data, their initials being optional. On the 5th screen, the user finds the fields to characterize the occurrence. Care was taken so that the notifier and the team were not identified. On the sixth screen, the user finds the list of medications in the ambulance and has the opportunity to select the medication(s) related to the incident. On the 7^{th} screen, the user can record the incident, according to the category (notifiable circumstance, near miss, incident without damage and adverse event). After selecting the category, the options for selecting the type of incident itself are visible. The 8^{th} screen refers to the drug administration route.

It should be noted that this screen only appears if the wrong route option is selected. On the 9^{th} screen, it is possible to add extra information about the incident, and the user is invited to enter some information that they believe contributed to the incident. This filling is not mandatory. The next screens are reserved for reviewing the notification, leaving the user free to make changes as they deem necessary.

^a Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups. International Journal for Quality in Health Care; (2007) Volume 19, Number 6: pp. 349–357.

The heuristic evaluation (part of the app usability validation process) followed Nielsen's 10 heuristics. The evaluation process was developed in 5 phases, which took around 3 hours, namely:

- **Preparation:** the Human-Computer Interface (HCI) students were given a use case that brought up hypothetical situation with the *persona* of a nursing technician from the SAMU who needed to notify an incident that happened in an ambulance service. The objective of the tool and the use environment were also shared. In this same phase, a case of the leader nurse was presented, a person who would have access to the database generated by the app; in addition to presentation of the app download link for evaluation, for the entire group.
- **Brief individual assessment sessions:** After the case, the evaluators were asked to download the app for the first assessment session, which should be individual. Each evaluator used the app and evaluated it in an individualized way; the app was used to perform the notification in order to identify violations in Nielsen's 10 heuristics.
- *Consolidation of the individual assessments:* The evaluators met in 3 groups of 4 people to compare and consolidate the report of their individual evaluations.
- *Prioritization of the problems found:* A discussion is generated prioritizing which main infringements to heuristics and problems found in the group are.
- *Final concluding report:* A report is generated on the main infringements, their severity and recommendations for improvement. From the 3 consolidated reports, the research group generated a final report to perform the necessary actions in the app, considering severity of the infringements and applicability of the suggestions.

Ethical aspects: This study has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. It is to be noted that this study sought to comply with all determinations found in Resolution 466/12 of the National Health Council, that it was submitted to the Research Ethics Committee through *Plataforma Brasil*, and that it was approved under opinion number 3,785,038. The Free and Informed Consent Form was voluntarily signed by the participants, who received a copy.

RESULTS

This topic contributes the result of the app's heuristic evaluation, understood as an app of the DT implementation phase, comprising technology validation.

After the individual report, the considerations relating to the 3 reports of the 12 evaluators are presented, with the corrections made.

Heuristic 1: System status visibility

- Verification of data entered during the review is unclear.
- *Reason:* Instead of having icons that point out that the fields can be edited, it only presents a warning that the next data can be edited if clicked. Data review could be done in only one page or in up to two, at the most.
- *Correction:* Icons that represent the possibility of editing the fields presented were inserted. Although the evaluators have indicated that data review could be done in only one page or in up to two, it was decided that the number of pages would remain the same, as it is of great importance that the user sees all the information completed.

Heuristic 2: Correspondence between the system and the real world

• No critical occurrences were indicated for this heuristic.

Heuristic 3: User control and freedom

• Medications require the exact name when performing the search.

- *Reason:* When searching by medication name, it is not possible to search for parts of it (for example, typing "alo" with the intention of searching "haloperidol" indicates that no medication was found).
- *Correction:* When searching by medication name, it is now possible to search parts of it. For example, when typing "alo" with the intention to search "haloperidol", the medication is displayed in the list.

Heuristic 4: Consistency and standardization

- Lack of consistency in the app design.
- Reason: It was recommended to improve the app's visual and communicative consistency, aiming to facilitate task recognition and system usability. Also at this point, it was recommended that the mandatory fields be made explicit, with some differentiation in relation to the optional ones.
- Correction: The app design was standardized in general. The buttons to access the app are the same size and color, the items in the review section are left-aligned, and the app's primary color was changed, intending to smooth and improve the users' experience.

Heuristic 5: Recognition instead of memorization

- The checkbox works like a dropdown menu.
- Reason: It is not clear to the user how the incident category list works. It can be strange using a checkbox referring both to defining a section and to marking an incident.
- Correction: As the user selects the incidents and not the topics of their category, dropdown functionality was introduced, which are buttons that toggle visibility of the lists. This feature is more familiar to the users and will cause less strangeness.

Heuristic 6: Use flexibility and efficiency

- Lack of filter diversity.
- Reason: As an Administrator, it is difficult to filter cardrelated information, with few filters, making it harder to find specific cards.
- Correction: On the administrator page, the option to filter notifications according to incident classifications and sort them according to occurrence date or patient's age was added.

Heuristic 7: Aesthetic and minimalist design

- Indication for occurrence classifications.
- *Reason:* While it is possible to filter by rating, this information is important enough to be illustrated in the main reports feed. This would facilitate an overview of the problems in that database.
- **Correction:** The filters and the order selected by the user are indicated at the top of the page. Another modification made is that, inside the card, it is indicated which classification was assigned to it, facilitating identification.

Heuristic 8: Error prevention

- Indication of the type of occurrence by the administrator can cause confusion.
- *Reason:* The user needs to understand that, even after checking the desired option, they still need to press the button with a green check. Another issue is the presentation of the checkbox list, which can give the impression that more than one classification can be chosen.
- *Correction:* A label called "*Confirmar*" ("Confirm") was inserted in the buttons, inside the notification details, so that the administrator understands that it is not only necessary to mark the incident but also to confirm it. Another point changed was moving from from checkbox to radio button list, so that the user can choose only one option.

Chart 1. Functional andnon functionalrequirements, Rio de Janeiro, 2021

IDENTIFIER	DESCRIPTION	IDENTIFIER	DESCRIPTION
FR01.	The system must have a login screen to allow users' access.	NFR01.	Once the notification has been sent, the report must
			be available to administrators in less than 1 minute.
FR02.	The system must have optional patient and reporter data fields.	NFR02.	NotiSAMU must be available 24 hours a day.
FR03.	The system must have mandatory fields about the incident.	NFR03.	Incident reports can only be viewed by administrators.
FR04.	The system must ask yes or no questions about the incident.	NFR04.	A trained user must be able to send the notification in less than 1 minute and an untrained user must be able to send the same notification in less than 3 minutes.
FR05.	The system must allow the notifier to send information about the incident.	NFR05.	Corrective changes must be implemented in less than 3 hours.
FR06.	The system must allow the administrator to view the notification history.	NFR06.	<i>NotiSAMU</i> must promote safety regarding anonymity and incident reporting.

* FR – Functional Requirement; * NFR – Non functional requirement; Chart Font: Autors

Chart 2: Use case 1, Niterói, 2021

UC1 - Log in

Actors: User.

General view:
It allows employees who work in the SAMU from one of the registered databases to have access to the incident notification system.
Cross-reference:
Requirements: FR01.
Typical sequence of events:

The user enters their username and password for the database.
The user confirms the data entered and submits the information.
The system authenticates the data provided by the user.

4 - The system grants access to the user.

Alternative sequences:

3.1 - The system does not authenticate the data filled in by the user, going back to step 1.

* UC - Use Case FR - Functional Requirement ; Chart Font: Autors

Chart 3. Use case 2, Niterói, 2021

UC2 - Notify the incident
Actors: Notifier.
General view:
It allows users to inform administrators on incidents.
Cross-reference:
Requirements: FR01, FR02, FR03, FR04, FR05.
Pre-condition: The notifier must be logged into the system. **Typical sequence of events:**1 - The notifier fills in the optional fields.
2 - The notifier fills in the mandatory fields.
3 - The notifier fills in the field with some additional information about the incident.
4 - The system sends the notification to the administrator.
Alternative sequences:

1.1 - The notifier does not fill in the optional fields and goes to step 2.

4.1 - The notifier does not fill in the field and goes to step 5.

* UC - Use Case FR - Functional Requirement ; Chart Font: Autors

Chart 4. Use case 3, Niterói, 2021

UC3 – Analyze the data
Actors: Administrator.
General view:
The administrator views the incident history.
Cross-reference:
Requirements: FR01, FR06.
Pre-condition: The administrator must be logged into the system.
Typical sequence of events:
1 - The administrator sees all the most recent notifications.
2 - The administrator selects an incident.
3 - The administrator selects a category that best fits the incident.
4 - The system saves the category and returns to the incident screen.

- The administrator does not select any category and goes back to the incident screen.

^{*} UC - Use Case FR - Functional Requirement; Chart Font: Autors

Heuristic 9: Support for recognizing, diagnosing and repairing errors

- Mandatory uncompleted fields are not highlighted.
- *Reason:* The app has asterisks to show which fields are required. However, in windows that have more than one mandatory field, if the user clicks "*Continuar*" ("Continue"), only a notification that there is a mandatory element missing is displayed, without highlighting which field must be filled out.
- *Correction:* If the user has not filled in all the required fields and then clicks on the "Continue" button, the app will highlight which field(s) must be filled out.

Heuristic 10: Help and documentation

- Lack of a guide and documentation of what the tool does and what its purpose is.
- *Reason:* Even with context, it would be good for the app to offer more explanations on how to use the tool (tutorial) and its purpose. On each page, perhaps, there can be an explanation about its fields.
- *Correction:* The changes requested in this item are in the process of being corrected, given the priority and greater severity of the previous ones.

DISCUSSION

Mobile health has been gaining more prominence in care, as well as in health management. It is believed that the following can be listed among the benefits of the massification of Intelligent Wearable Devices (IWDs): contribution to the reduction of health expenses, prevention of unnecessary hospitalizations and expansion of the possibilities for interaction between patients and health professionals; as well as a contribution to the minimization of errors related to health care, through the implementation of preventive strategies.¹⁰ In this regard, the app developed in this study is characterized as a promising tool in the management of risks related to drug administration in the SAMU 192 scenario, as it provides fast notification, which can be performed in real time of the event, dynamic and adjusted to the end users' reality. Data from the scientific literature are still very scarce regarding risk management initiatives in APHE. In a systematic review that sought to survey methods for monitoring patient safety in the pre-hospital mobile emergency service, only 10 of the 67 methods described were related to incident notification systems. However, their characteristics or the types of incidents reported were not described (O'Connor, 2021). Another study published by the same authors included articles that addressed a variety of incidents in APHE; the most common being the so-called "any type of incident with the patient", followed by the incidents involving medications. However, of the 22 studies included in the review, only 6 used reporting tools. It is noted that many tools for reporting incidents used internationally belong to larger safety programs or information systems, and that they are not designed for use in APHE, such as in Spain with the Notification and Learning in Patient Safety (Notificación y Aprendizajeen Seguridad del Paciente, SINASP) system, in the United Kingdom with the National Reporting and Learning System (NRLS) and in Germany, Austria and Switzerland, with the Critical Incident Reporting System (CIRS).¹³⁻¹⁵ In Brazil, these notifications are forwarded to the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, ANVISA) through the NOTIVISA information system, although there is no specificity for the mobile prehospital emergency care.¹ Considering APHE to be a scenario full of singularities, which are even more present when considering the SAMU reality, the structuring of apps and other electronic tools concerning these scenarios can represent extremely relevant gains not only in risk management and patient safety but in several recurrent needs in mobile emergency assistance such as data recording, handling and retrieving; in addition to the possibility of improvements in the final assistance provided to the service users. Recently, APHE has evolved from a transport-related model to an integrated part of the health care system, where advanced care is directed towards critically-ill patients. Thus, this environment is potentially dangerous with the possibility that patients suffer an incident, including harms. However, when compared to secondary care, little is known about how patient safety is managed; thus, the imperative need for greater resources to deal with this issue becomes clear. In general, the evaluators agree that the app fulfills its role, requiring usability-related adjustments. These adjustments were duly implemented, following the demands set out in the report prepared in the heuristic evaluation. The most serious problems were found in aesthetics.

CONCLUSION

Despite being frequent, incidents related to patient safety are little notified and disclosed in APHE. With a unique setting and a potentially dangerous environment, various events can reach the assisted individual. In this universe of incidents are those related to medications. The app's analysis by the evaluators resulted in an improvement in its interface, with the objective of clarifying what each field on the screen represents and generally facilitating usability for the end users. Therefore, all the infringement points presented were developed to establish possible satisfactory corrections, maintaining applicability of the app to the users' reality. Content validation was performed at a later time by specialists in the urgency/emergency area and/or patient safety. Given the weaknesses identified in the prototype, some adjustments were made according to the assessment but, in order to ensure usability of the product, a second validation stage will be carried out with interventionist professionals, end users of the product, (physicians, nurses and nursing technicians) of the study setting.

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