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Design and evaluation of a prototype of augmented reality applied to medical devices

Paula Escalada-Hernández[a], Nelia Soto Ruiz[a,*], Leticia San Martín-Rodríguez[b]

[a] Public University of Navarre, Avda. Barañain, 31008, Pamplonan, Spain
[b] Department of Health Sciences, Public University of Navarre Avda. Barañain, s/n; 31008 Pamplona (Navarra) - Spain

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ABSTRACT

Background: According to current legislation, medical devices have to incorporate all the necessary information to eliminate or greatly minimise any problem associated with their use. However, the physical capacity of the actual device's packaging may frequently not be enough to contain all this information. To address this limitation, this study aimed to design and evaluate a prototype app for mobile devices applying augmented reality technology. The main feature of this kind of technology is combining virtual images with images from the real world.

Methods: This work, carried out in Spain, was developed in three different phases. 1) Assessment of users' needs: Through a focus group and an online questionnaire, information was obtained about the following aspects: type of medical devices likely to be included in the app, relevant information that should be included and format in which this information should be presented. 2) Development of the prototype: Considering all the functional features identified in the previous phase, the software was developed by a team of professionals specialised in AR technology and applying a user-centred model. 3) Evaluation of the software: functionality and usability were assessed by means of the think-aloud method.

Results: 1) Assessment of users' needs: a total of 11 nurses participated in the focus group and 280 healthcare professionals answered the questionnaire. Their findings showed that users consider that information about the following aspects of medical devices should be included in the app: instructions for use, indications for use, brief description of the device, special precautions and biocompatibility, image of the content with its components and meaning of icons. 2) Description of the prototype: Once the app has been launched, when the user scans the medical device with the mobile device camera, access to the home screen is activated, where three sections can be found: name of the medical device, image of the device and four icons which provide access to: a brief description of the device, a detailed description of it, the packaging iconography and a video about use of the device. 3) Evaluation of the software: the app was defined by users as "very intuitive". They highlighted, as one of its main positive aspects, the chance to obtain information about the medical device just by scanning the object. Additionally, the evaluation performed through the think-aloud method identified potential improvements in the app. These improvements were subsequently implemented to make the prototype more functional.

Conclusion: Working with potential prototype users made it possible to identify information considered relevant for these users and to delve into the format which they consider more appropriate to show this information in the prototype. Our results show that AR technology can be used as support for clinical practice.

1. Introduction

Nowadays, health technology plays an essential role in healthcare. Countless medical devices are routinely used for diagnosis, treatment, monitoring or rehabilitation of patients all over the world [1]. It is estimated that there are about 2 million different types of medical devices worldwide, classified into more than 22,000 generic device groups [2].

A medical device is defined as "any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: (1) diagnosis, prevention, monitoring, treatment or alleviation of disease, (2) diagnosis,

* Corresponding author.
E-mail address: nelia.soto@unavarra.es (N. Soto Ruiz).

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monitoring, treatment, alleviation of or compensation for an injury, (3) investigation, replacement, modification, or support of the anatomy or of a physiological process, (4) supporting or sustaining life, […]; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, […]" [3].

Even though use of medical devices is extremely beneficial for patient care, potential problems associated with their use may produce severe, negative consequences, compromising patient safety. Complications and incidents related to medical devices might be linked to the device itself or to its use, as well as clinical problems, such us allergic reactions [4–7]. It is difficult to provide real figures on the magnitude of this issue, because the proportion of medical device adverse events that are registered is estimated to be less than 0.5% [8,9]. According to the literature, problems with the use of medical devices, which may result in user-error incidents, are associated with inadequate labelling, confusing instructions, deficient packaging, design problems which make it difficult to use them, or insufficient training of healthcare professionals on how to use the devices [6,7,10].

In this sense, the International Standardisation Organisation (ISO) and the World Health Organisation (WHO) proposed regulatory frameworks for design and use of medical devices, to improve patient safety [2,11]. In the context of this study, medical device manufacturers are obliged by Spanish legislation for each device to include "the necessary information to use it completely safely and properly, considering potential users' training and knowledge, and to identify the manufacturer" [12] (*translated by the authors*). However, in this Royal Decree, legal alternatives are established where it is impossible to include all this information on each individual device. For example, as well as using standardised symbols, it is stipulated that the instructions for use do not have to be included in the individual device but presented in the packaging for multiple devices. In the same way, European legislation considers that the information required on the label shall be provided on the device itself and if this is not practicable, some or all of the information may appear on the packaging for multiple devices [13].

It seems obvious that the actual device's packaging may not be physically capable of containing all the necessary information to eliminate or greatly minimise any problems associated with the use of medical devices. In order to address this limitation, we propose applying augmented reality (AR) technology, through mobile devices such as smartphones, tablets or glasses.

1.1. Augmented Reality

The main feature of Augmented Reality (AR) technology is combining virtual images with images of the real world. In other words, AR complements, reinforces or "augments" the real world with virtual content, but does not replace it completely, as in the case of virtual reality [14]. AR applications are defined by the International Standardisation Organisation (ISO) as "a live view of a real-world environment whose elements are augmented by computer-generated content, such as sound or graphics" [15].

Nowadays, AR is highly present in different fields, such as education, business, advertising, entertainment, security, etc. In the medical area, numerous AR applications and techniques have been described in the literature over the last two decades. In their literature review, Chen and colleagues (2017) identified five main application areas in this context: treatment, rehabilitation, surgery, training of medical/surgical procedures and medical education [16].

It seems clear that applying AR technology within the healthcare field has the potential to offer infinite possibilities and advantageous solutions for many different aspects. In this particular case, AR can offer two major advantages. On the one hand, the capability to recognise images immediately through the camera on a mobile device, so that by simply focussing on any medical device in front of us, it can be recognised immediately. On the other hand, and as a consequence of this recognition, AR would also be capable of immediately projecting all the information related to the device, so that the user can browse interactively through this information, looking for the most important aspects for them at any one time. What's more, it should be emphasised that no examples have been found of employing AR technology associated with using medical devices, although there was an experiment on its use to support antibiotics prescription education [17].

The aim of this study was to design and evaluate an app prototype for mobile devices using Augmented Reality to improve the use of medical devices. The project was developed in Spain.

2. Materials and Methods

In order to meet the project goals, a project has been planned based on the "Rapid Application Development" methodology [18]. This methodology, based on the use of prototyping as a mechanism, aims to create high quality apps with fast development and delivery and low costs [19], by means of a collaborative atmosphere where users participate actively in prototyping [20]. The phases developed within this methodology are as follows:

- Definition of requirements
- Prototype design and development
- Testing: functionality and usability

2.1. Definition of requirements

A focus group and a questionnaire were developed to determine the users' needs and system requirements relating to the app to improve the use of medical devices.

Firstly, a focus group was set up with 11 nurses from a hospital in Spain, who were particularly familiar with managing and using medical devices. After welcoming the group, one of the project researchers explained the aim of the study to the participants and the details of the methodology that was going to be followed when developing the focus group. In addition, the participants were offered some basic information on AR (difference from virtual reality and operating using Image Targets and trigger image) taking the example of applications based on this technology that are commonly used by the general public (e.g. Snapchat). Subsequently, the discussion during the focus group was led by two of the researchers, who followed an interview guide including the main aspects to be explored: type of medical devices likely to be included in the app, relevant information that should be included and format in which this information should be presented (video, text, etc.). The focus group session was audio-recorded and transcribed verbatim. Content analysis, following Miles, Huberman and Saldaña's approach [21], was performed using the Atlas.ti software package. After the coding process, the identified codes were classified into 3 topic themes. Institutional authorisation was obtained to carry out this phase of the study.

Secondly, an anonymous questionnaire was produced, based on the results of this analysis to confirm information obtained from the group. The questionnaire included several socio-demographic questions and three closed questions. Before starting the questions, the participants were informed in writing about the aim of the study and the capabilities of AR were briefly explained to them regarding immediate recognition of medical devices and the option to show the necessary information on the actual mobile device. In the first question, they were asked to score (range: 1–5) the importance of different options for the type of information which should be included in the app (e.g. "Brief description of the product", "Image of the contents, with its components", "Meaning of the icons and symbols that appear on the product"). In the second question, participants were asked to select their preferred options for display format for each item in the first question, from among different options: "In text form", "in video", "as a visual guide", "as alarms or notifications". In the third question, the participant was asked

Table 1
Topics and codes from qualitative analysis.

Topics	Information that should be included in the app	Display Format	Medical devices which could benefit from the app
Codes	• Device fact sheet (extended and abbreviated format) • Instructions for use • Instructions for maintenance • Special precautions • Information for purchase orders (code, price) • Expiration date • Meaning of symbols/signs • Other information (other sizes, other alternatives)	• Video format • Text format • Image • Brief visual guide • Detailed visual guide	• Most used or least used devices • Devices which require assembly • Devices associated with equipment • Similar products with different uses • New devices • More expensive devices

for his/her opinion on the groups of medical devices that might benefit from using this App (e.g. “Biosafety products”, “expensive products”, “less frequently used products”). The answer options were based on the topics in the qualitative analysis.

The questionnaire was sent out to healthcare professionals using a web platform. Using a purposive sampling approach, members from the Spanish scientific association ANECORM (association for healthcare professionals related to material resources management) were sent an email inviting them to participate with a link to the survey and, following the snowballing method, they were asked to send out the email to their networks.

Data obtained was analysed using with descriptive statistics using SPSS v.24. The questionnaire introduction stated that answering the questionnaire was considered to be informed consent and that full confidentiality and anonymity were ensured.

2.2. Prototype design and development

In the second phase, the software or prototype was developed, considering the devices and the function features identified in the previous phase. Specifically, work on the prototype focussed on three products: a peripheral venous catheter (representing the group of devices “most used in “my” work”), a safety Huber Port-a-cat needle (representing the group of “new devices which ‘I do not know’”) and a pleural drain (representing the group of “devices about which it is necessary to provide information to patients and/or family”).

The prototype was developed by a team of highly qualified professionals from the company iAR (Industrial Augmented Reality), consisting of a computer technician specialised in AR technology, an industrial management engineer and a project engineer. In this phase, it was essential for the engineers and the healthcare professionals in the research team to work together. The software was developed by applying the human-centred model, considering the context of use (users and environment), specific user requirements (user’s goals that have to be met to ensure the success of the device), product design (different approaches to the final design) and user assessment (user-centred evaluation). Participation from the research team, as future users, led to a participatory design involving users in the design of the device [22].

Firstly, based on information obtained from the focus group and the questionnaires, the different app screens were designed using sketches made on paper. This first design was developed taking into account the quality criteria for content, appearance, navigation, structure and design [23].

Secondly, the computer technician developed the preliminary version of the software, compatible with Android system (the most widespread operating system), with a Tablet version and a modified version for mobile devices. Once the preliminary version of the app was programmed, the research team performed an initial assessment, suggesting some changes for the definitive version of the prototype.

2.3. Testing: functionality and viability

Finally, in the third phase, the software’s functionality and viability were assessed. The think-aloud method was applied to assess functionality, as also used in other AR projects [17]. This method consists of asking participants to try the software while they constantly think and verbalise out loud what they are thinking as they interact with the user interface [24].

As recommended by Andrews [25], six nurses (as potential users of the app) were selected by applying the following selection criteria: 3 with no experience in using mobile apps and 3 with experience; working in different clinical settings: hospitalisation units and outpatient clinics. Individually, they entered a room with audio and video recording equipment, and they were asked to use the app with a particular medical device and to complete a series of tasks in the app, based on a guide developed for that purpose.

Thus, the usability of the prototype was evaluated, understood as the ability of a system to make users perform the tasks in a satisfactory, safe, effective and efficient way [26]. Specifically, the aspects being assessed included: the ability to help users achieve the goal, ease of learning for users, occurrence of minor and major errors and users’ satisfaction with the system.

3. Results

Further on, the results of this study are presented following the same sequence of methodological phases as described previously.

3.1. Assessment of users’ needs

Data from the focus group qualitative analysis was organised into three topics. The codes included in each topic are described in Table 1.

The data obtained from the survey helped to weight these elements. The survey was completed by 280 healthcare professionals throughout the country (87.1% nurses, 4.7% nurse assistants, 1.1% physicians and 7.1% other types of professionals), with a mean age of 44.1 years (SD = 10.6 years). About 74.1% of them were working in hospital settings, 6.8% in primary health care, 2.9% in nursing homes and 16.2% in other healthcare settings.

The survey results identified the instructions for use as the most important piece of information which should appear in the app (mean = 4.51 points out of 5), followed by the indications for use (4.48 points), brief description of the device (4.33 points), special precautions and biocompatibility (4.17 points), image of the content with its components (4.08 points) and meaning of icons (3.78 points). On the other hand, the format preferred by users to view this information was video format (40.3%) or text format (44.7%) for the instructions for use, format in the form of brief visual guide (31.29%) for the brief description of the device, text format (38.2%) for the special precautions and biocompatibility, format in the form of visual guide or similar formats (46.3%) for the image of the content with its components and the meaning of icons.

Finally, the data from the survey revealed that the medical devices which might most benefit from the prototype identified by users included: devices most used in ‘my’ work (51.43%), new devices which ‘I do not know’ (44.68%), devices about which it is necessary to provide

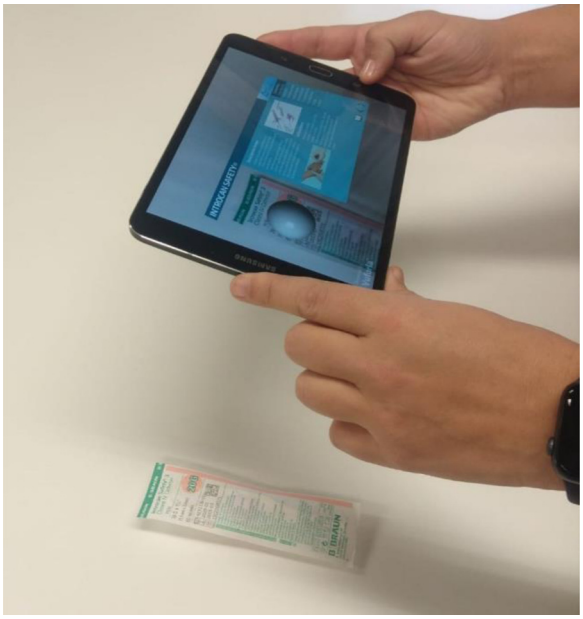

Fig. 1. The app home screen.

information to patients and/or family (44.29%), devices with special precautions (39.64%) and devices which require assembly or have many pieces (30.71%).

3.2. Description of the prototype

Information about only 6 medical devices was included in the developed prototype, by way of example. This app offers the structure to organise all the relevant information about different medical devices. Thus, data about any medical device can be easily uploaded into the app. In this way, the potential administrators of the app will be able to catalogue their chosen medical devices, offering users customised information.

The app works as explained here. As illustrated in Fig. 1, when the user scans the real object (i.e. the medical device) with the mobile device camera, a tracker point is recognised, and the augmented information can be viewed in the mobile device. At this point, the user accesses the home screen, containing three sections: name of the medical device, image of the device and four icons or shortcuts.

These four icons provide access to: a brief description of the device, a detailed description of it, the packaging iconography and a video about the use of the device. Thus, the first icon gives access to a quick user guide, which includes basic relevant information about how to use the device, plus its main features. This description is accompanied by different images of the device. Fig. 2 shows one of the screens

Fig. 2. Screen containing the brief description.

containing the brief description of the device. Tapping the second icon brings up a detailed description of the device, showing a screen with different sections of information about the device. These sections offer information concerning the complete name and description, components, conditions of use, special precautions, technical features and cleaning conditions. The user can browse this menu and access these sections. On the other hand, with the following icon the user can watch a video showing how to use the device. Additionally, the user can play the video either on a small screen or on full-screen. Lastly, by pressing the "packaging iconography" icon, the user can bring up a screen which will display the meaning of each of these icons and symbols by simply tapping each one of them.

3.3. Results of the prototype evaluation

The characteristics of the six nurses who evaluated the prototype as potential users of the app were as follows. All of them were women; the three with no experience using mobile apps were older than 50 years old and the three with experience were younger than 45 years old.

During the evaluation process, users highlighted several positive aspects of the app. The chance to obtain information about the medical device just by scanning the object, without having to type in its name, was one of the main advantages they identified. Additionally, another popular aspect was that it was easy to browse through the different sections, once the app was launched. The app was defined by users as "very intuitive". The ability to get a detailed image of the medical device was also positively scored. Lastly, it is worth mentioning that all the users who participated in the evaluation said they would like to have the app on their mobile devices.

On the other hand, the think-aloud method evaluation identified potential improvements for the app. The findings of this assessment focused on three aspects of improvement:

1) Vibration of the image: all participants in the evaluation noted that it was difficult to use due to excessive vibration of the virtual image.
2) Ability to zoom in on the texts or images: whilst browsing through the app, three participants tried to use the touch zoom function without success, as this function was not installed in the prototype.
3) Ability to keep using the app, even when not focusing the device: during the evaluation, three users expressed the need to be able to keep viewing the information, images or video of the prototype, without the device necessarily being focused by the app constantly.

After developing the improvements suggested in the evaluation, users now have an icon on the home screen which can fix the virtual image on the screen, with a dual aim. On one hand, it avoids vibration, caused by software not detecting tracker points clearly, which sometimes made it difficult to use the app. On the other hand, by fixing the virtual image, the app remains functional even when the camera is not focusing on the device. Additionally, in relation to the zoom ability, the touch zoom function was incorporated.

4. Discussion

This paper presents the design and evaluation of an app prototype that offers detailed information about different medical devices using AR. The aim was to develop an app for mobile devices to improve the use of medical devices.

In the current context where development and use of medical devices is endlessly growing, implementing measures to facilitate their safe use is essential to guarantee patient safety. Evidence shows that a significant proportion of device-related adverse events are caused by human error [10,27]. Therefore, ensuring that potential users of a certain medical device know how to use it properly could help reduce adverse events, and thus, enhance patient safety [28–30]. However, training and informing healthcare staff about the use of the wide range

of medical devices available in the different clinical settings is an extensive, resource-intensive task [28,31].

In this way, the prototype presented in this paper has the potential to overcome some of the difficulties associated with healthcare professionals using very complex or new medical devices. The possibilities offered by the app could reinforce the proficient use of medical devices, and consequently, lower potential adverse events. Thus, the prototype includes a quick user guide as well as detailed information about all aspects and features of the device. Additionally, as previously explained, users can access a video showing how to use the device. Nonetheless, the app has the potential to contain not only videos about using the device, but also informative videos about patient education, maintenance protocols or any further information that might be of interest to users.

Another aspect to consider is the use of a human-centred approach for the app design and evaluation. Applying this approach makes it possible to design a more useful prototype, enhancing usability and user satisfaction [22,32,33]. Working with potential prototype users made it possible to identify information considered relevant for these users and to delve into the format which they consider more appropriate to show this information in the app. For example, the chance to see the meaning of signs and symbols, which is offered by the app, aims to solve one of the problems mentioned by the healthcare professionals in the focus group. They expressed that, in many cases, they do not know, or they misunderstand the icons on the device.

The benefits of the human-centred design were also evident in the evaluation stage, demonstrating that each iteration provided significant improvements to the app design, as suggested by the literature [22,32]. In the project, the evaluation of the initial prototype version by six potential users made it possible to implement the necessary improvements to make the prototype satisfactorily functional.

The prototype being developed is an example of including innovative solutions in clinical practice by using AR; its potential seems huge in the healthcare context. The possibilities offered by AR technology could reduce current limitations on the ability of medical devices to provide users with all information on the composition and utilization of each device. From the device fact sheet to a 3D view of the content of the individual packaging, including an explanatory video about its use, everything can be available for professionals, by means of an app installed in a mobile device. This app could not only make it easier for users to handle devices which have appeared on the market for the first time or which already exist but have been recently included in the hospital's medical devices inventory, but also could help professionals, who are new in a certain setting, use those setting-specific items. The prototype offers the chance to share information about medical devices in any clinical setting, using the potential value of AR.

4.1. Limitations

As explained, the app offers the structure to organise all the relevant information about different medical devices. Thus, data has to be uploaded into the app by potential administrators. Although this makes it possible to customise the information according to the clinical context, it also requires significant upkeep. The information which the app offers to the user about each medical device, at least in Spain, is not stored in any database in a standardised way, as is the case of information about medicines, for example. Therefore, this is one of the main limitations of the app, as "feeding" the app with updated information requires continuous maintenance work, which is the main problem for integrating this app in the clinical setting.

4.2. Conclusions

Our results show that AR technology can be used as a source of support for clinical practice, making it easier for healthcare professionals to perform daily activities and increasing patient safety. As has been also illustrated, the simplicity and accessibility of mobile technology makes it possible to easily incorporate this type of app into the daily routine in healthcare settings.

Summary table

What was already known on the topic

- Use of medical apps is increasing among healthcare professionals.
- In the medical field, AR technology is applied in different areas, such as treatment, training and education, etc.
- A significant proportion of device-related adverse events are caused by human error.
- Ensuring that potential users of a certain medical device know how to use it properly could help reduce adverse events.

What this study added to our knowledge

- An app for mobile devices could be useful for improving the use of medical devices.
- AR technology can be used as a source of support for clinical practice, facilitating the performance of the daily activities of healthcare professionals and increasing patient safety.
- This app could not only make it easier for users to handle devices which have appeared on the market for the first time or which already exist but have been recently included in the hospital's medical devices inventory, but also could help professionals, who are new in a certain setting, use those setting-specific items.

Authors' contributions

All the authors contributed significantly to the preparation of this manuscript following the International Committee of Medical Journal Editors guidelines. Study design: NSR and LSMR. Data collection and analysis: PEH, NSR and LSMR. Preparation of the manuscript: PEH, NSR and LSMR. Editing and final revision of the manuscript: PEH, NSR and LSMR. The manuscript has been read and approved by all named authors.

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Statement on conflicts of interest

The authors declare no conflicts of interest.

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