

FINAL DEGREE PROJECT

Breaking down language barriers for better healthcare

Implementing a specialised translation application in
the emergency department to improve care
for patients with language barriers.

A MULTICENTRIC CLINICAL TRIAL

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1. ABSTRACT

TITLE: **Breaking down language barriers for better healthcare:** Implementing a specialised translation application in the emergency department to improve care for patients with language barriers.

BACKGROUND: The current growth in international mobility is leading to the creation of multicultural and multilingual societies, increasing the frequency of consultations where the doctor and patient do not share a common language. The language barrier prevents the establishment of essential doctor-patient communication, leading to inequity and negatively impacting the healthcare of these new patients. Although several resources are available to bridge the communication gap between professionals and patients who speak different languages, the actual effectiveness and feasibility of their routine implementation in emergency services has not been fully evaluated.

OBJECTIVE: The aim of this study is to evaluate and compare the degree of satisfaction with the communication proved during a medical emergency consultation between non-Catalan and non-Spanish speaking patients and doctors, according to whether or not a specialised language translation assistance application had been used. A secondary objective is to evaluate the satisfaction levels of the doctors conducting these consultations. Finally, we will analyse the time that patients have spent in the emergency department based on the resource use in their visits.

DESIGN AND SETTING: It has been designed to be a randomized, open-label, multicentric, prospective, controlled clinical trial. It will be conducted in the two reference emergency centres for the population in Salt, Santa Caterina Hospital and the Centre d'Urgències d'Atenció Primària Güell.

PARTICIPANTS: Patients over 18 years of age admitted to the emergency service with a priority level \geq III at triage, with a limited proficiency in Catalan and Spanish themselves and their companions.

METHODS: 180 participants will be enrolled using a consecutive sampling method during a seven days recruitment. Patients will be randomised in a 1:1 ratio into two groups: 1) Overcome the language barrier with the use of Universal Doctor Speaker® application; 2) Use others available resources to overcome it. At the end of consultation, participants and professionals will independently fill out a questionnaire, which is focus on the communication establish between them and their perceptions. Major outcome variable will be patients' satisfaction.

KEYWORDS: *Communication, Overcome language barrier, Emergency department, Language Translator Application, Universal Doctor Speaker®, Equitable healthcare*

2. ABBREVIATIONS

CEIC	Comité de Ética de Investigació Clínica
CUAP	Centre d'Urgències d'Atenció Primària
DCQ	Data collection questionnaire
DHR	Digital health record
ED	Emergency department
EU	European Union
IC	Informed consent
ICD	International Classification of Diseases
ICS	Institut Català de la Salut
ID	Identifier
Idescat	Institut d'Estadística de Catalunya
INE	Instituto Nacional de Estadística
LB	Language barrier
LLP	Limited language proficiency
LTA	Language translation application
MAT	Model Andorrà de Triatge
MI	Main investigator
NRS	Numerical rating scale
PI	Professional interpreter
PLAENSA	Pla d'enquestes de percepció, experiència i satisfacció d'usuaris del Servei Català de Salut
PrSQ	Professional satisfaction questionnaire
PSQ	Patient satisfaction questionnaire
SI	Secondary investigator
SoCMUE	Societat Catalana de Medicina d'Urgències i Emergències
UDS	Universal Doctor Speaker®
VAS	Visual analogue scale
WHO	World Health Organization

3. INTRODUCTION

3.1. Demographic Dynamics

The estimated number of international migrants worldwide has been increasing continuously over the last five decades, culminating in an estimated 281 million people residing in a country other than their birth country in 2020 (1).

In Catalonia, the foreign population has experienced a progressive increase. In 2005 it represented 11,42% of the population, a percentage that has risen to 16,32% according to the latest data from 2022 provided the Institut d'Estadística de Catalunya (Idescat) (2).

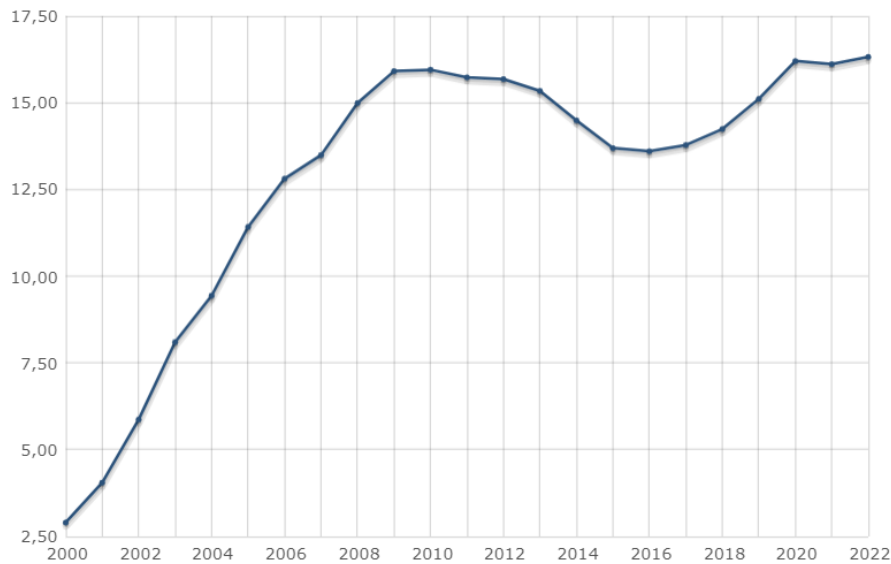


Figure 1. Representation of the evolution in percentage (%) of foreign population in Catalonia from 2000 to 2022, by Idescat (2)

This upward trend is also observed in the Gironès region, where the foreign population reaches 20,7% of the total residents. The municipality of Salt has the highest percentage, reaching 38,14% (3).

Immigration flows in Salt

The total population of Salt in 2022 was 32.517 inhabitants, of which 15.690 were born in Catalonia, 3.374 in the rest of Spain and 13.453 abroad. The foreign-born represented 41,37% of the municipality's total population. This contrast with the 5,87% in 2000.

A visual representation of the growth of Salt's population according to their place of birth - Catalonia, the rest of Spain or abroad - is shown in the following graph, obtained from Idescat (4).

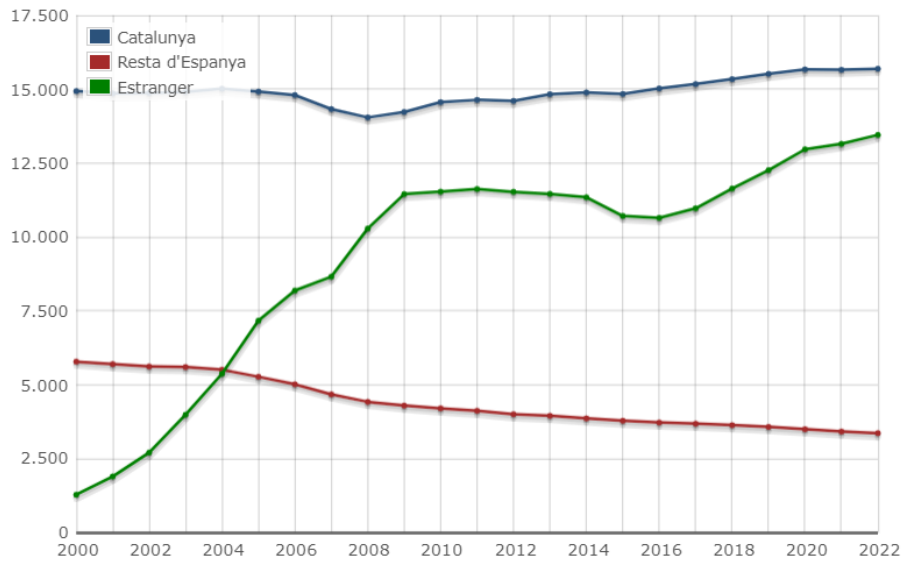


Figure 2. Graphic of the population of Salt according to birthplace from 2000 to 2022, from Idescat (4).

A more detailed analysis of the countries of origin of the immigrant population in Salts reveals that Morocco, Honduras and Gambia are the main countries of origin, representing 34,37%, 12,30% and 10,9% respectively of the total foreign population in the municipality (5).

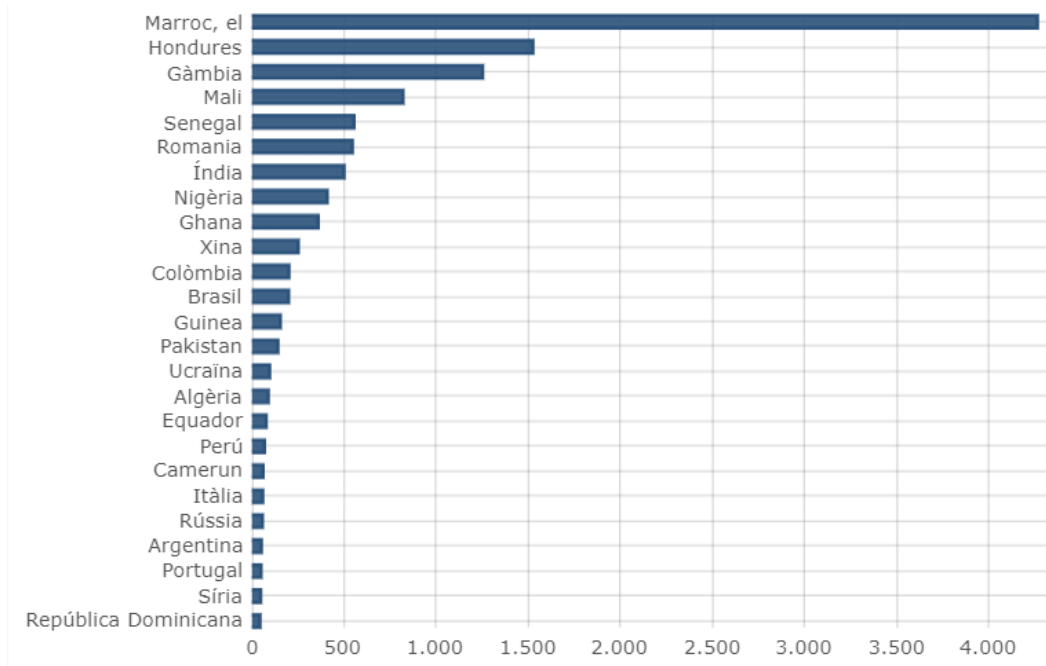


Figure 3. Chart of the immigrant population by origin country in Salt in 2022, reported by Idescat (5).

Having the knowledge of the officially recognised and most commonly spoken languages in the principal countries of origin of Salt's immigrant population is essential in order to obtain a complete and accurate understanding of the communication dynamics within the Salt community.

The following list collects the official languages of the top 10 migrants' origin countries (6):

- 1) **Morocco:** Arabic, Tamazight, French.
- 2) **Honduras:** Spanish.
- 3) **Gambia:** English.
- 4) **Mali:** Bambara; Mali has 13 national languages in addition to its official language.
- 5) **Senegal:** French.
- 6) **Romania:** Romanian.
- 7) **India:** Hindi, Bengali, Marathi... with a total of 22 officially recognized languages.
- 8) **Nigeria:** English.
- 9) **Ghana:** English.
- 10) **China:** Standard Chinese or Mandarin, plus other languages depending on the region.

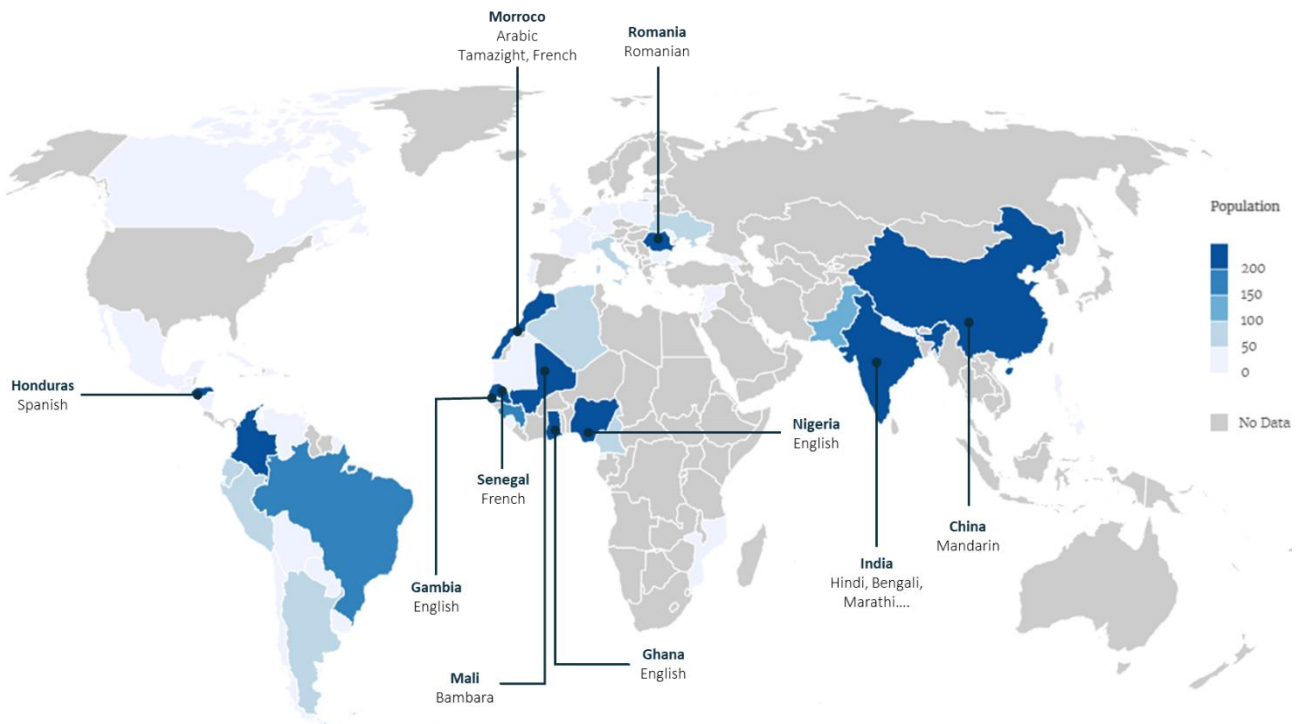


Figure 4. World map of the origin countries of immigrants in Salt, showing the languages of the top ten countries of origin.

3.2. Language barrier

Recognising the human right to health, World Health Organization (WHO) advocates holistic and individualised health care. This involves respecting individual autonomy and safety, such as ensuring basic rights and freedom to access quality healthcare. Encouraging a personalised model of healthcare that treats all patients fairly, equally and impartially (7).

The *Real Decreto-ley 7/2018, de 27 de julio, sobre el acceso universal al Sistema Nacional de Salud* was developed in Spain, in harmony with the principles advocated by the WHO. The decree aims to ensure that all individuals, regardless of their nationality or legal status, have equal access to healthcare in Spain. According to Article 3.1: *<< Las personas extranjeras no registradas ni autorizadas como residentes en España tienen derecho a la protección de la salud y a la atención sanitaria en las mismas condiciones que las personas con nacionalidad española, tal y como se establece en el artículo 3.1 >>* (8).

Effective communication between healthcare providers and patients is essential to achieve holistic and individualized healthcare and ensure equity for the entire population. It's important to find a common channel of communication between healthcare professionals and patients, and this can be particularly challenging for migrant patients due to the language barrier (LB) that often arise due to speaking different languages.

Analysis of competence in Catalan and Spanish

Catalonia has two co-official languages: Catalan and Spanish (9). To determine the population's proficiency levels in these languages, data from the most recent surveys conducted by the Idescat and the Instituto Nacional de Estadística (INE) were analysed.

In 2018, Idescat conducted the latest survey on the linguistic use by the population of Catalonia over the age of 15 (10). The survey evaluated the knowledge of the Catalan language based on nationality. The collected data, presented in the Figure 5, shows the correlation between the knowledge of Catalan in the areas of understanding, speaking, reading, and writing in correlation with the nationality of the Catalan population in 2018.

As might be expected, the population with Spanish nationality has a higher level of proficiency in Catalan in all areas than the foreign nationalities. It is worth noting that less than half of the foreign population can speak Catalan. This limitation could impede a clear understanding of medical concerns,

impede the exchange of vital information, and potentially affect the quality of the entire healthcare interaction for patients who do not know Catalan.

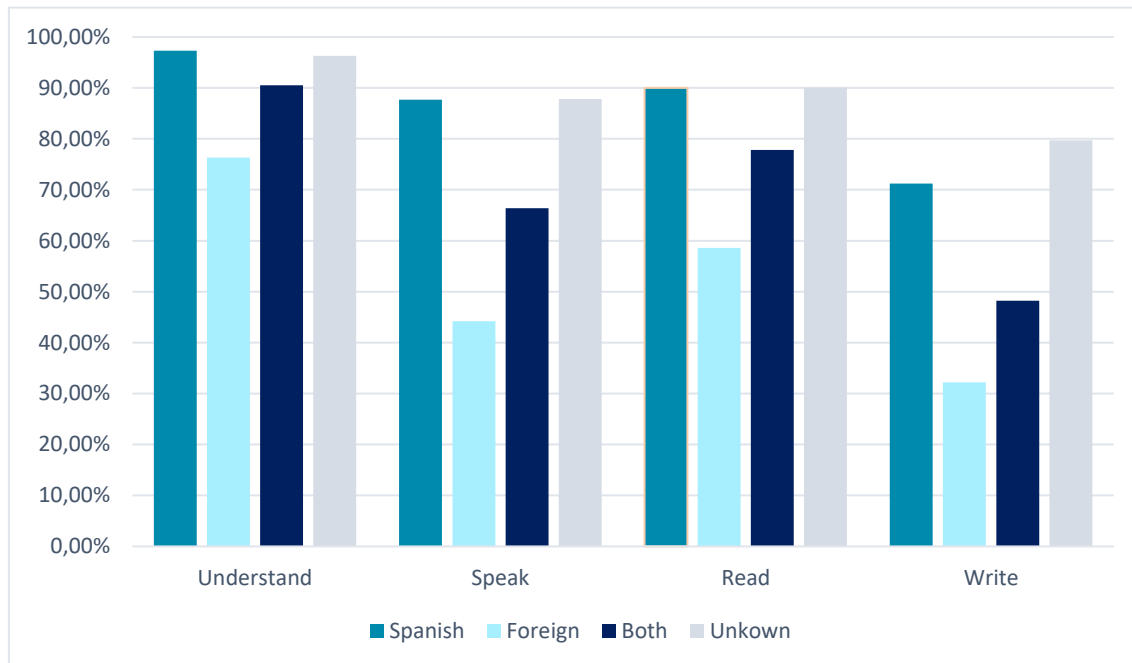


Figure 5. Population according to knowledge of Catalan and nationality. Catalonia 2018. Adapted from Idescat (10)

The INE conducted a survey in 2021 on the essential characteristics of the population and dwelling. The section on knowledge and use of languages revealed that 2,4% of the population born outside Spain and residing in the province of Girona do not understand Spanish at all, 6,7% cannot read it, 4% are unable to speak it, and 10,4% do not know how to write in Spanish (11).

It should be pointed out that Spanish is the official language of 21 countries in the world (Argentina, Bolivia, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Spain, Guatemala, Equatorial Guinea, Honduras, Mexico, Nicaragua, Panama, Uruguay, Peru, Puerto Rico, Dominican Republic, Uruguay and Venezuela) (12), which implies that a larger percentage of people already have a high level of knowledge of the language before starting the immigration process compared to Catalan. However, it is important to consider that the Spanish language spoken in each country has been adapted to its environment and inhabitants, which means that they have different lexicons and terminology. This can also lead to confusion and interfere with communication.

3.3. The Language Barrier's impact on health care

LB have a significant impact on health care, both for the patient and the system, and can drive to health inequalities (16). Research have found that LB can increase costs related to misdiagnosis and recurrent visits, as well as inefficient use of resources (17). This leads to a longer stay in the emergency department (ED) for this patient who shows a LB (18,19).

Patients that require interpreters face challenges such as less emotional support, routinely prolonged wait times, and have more compressed information and limited opportunities for follow-up questions compared to native speakers (20). This coincides with the conclusions of studies reviewing emergency health care, which found that patients needing interpreters reported lower satisfaction levels, inferior quality care, restricted diagnosis and treatment, and fewer follow-ups (21,22).

Implementing effective language services has been associated with improvements in communication, patient experience, healthcare outcomes, safety and the efficient use of resources (22–24).

Effective communication is fundamental for healthcare professionals and involves a cultural approach and understanding (13,14). It is worth noting that individuals from diverse cultural backgrounds may articulate pain and distress using culturally specific terms, expressions, or metaphors. This complexity can be challenging even for those with a high level of linguistic competence (15).

Concerning the patient's perspective, as highlighted in particular by Steinberg Emma M. et al study (25), individuals may feel that their language needs are a burden on their healthcare providers. Patients believed it was more effective and polite, minimised the doctor's workload and perceived less stigma and discrimination to 'getting by' on their own. However, this approach led patients to not expressing all their doubts and worries and leaving the consultation dissatisfied. Additionally, they neither understood the diagnosis, nor the purpose of the tests performed, nor how to carry out the recommended treatments properly.

Boudreaux and O'Hea conducted a literature review and found that patient satisfaction and likelihood of recommending emergency services to others were most significantly predicted by satisfaction with interpersonal relationships in the ED (26). This was mainly assessed on the basis of the quality and quantity of information received, with a notable negative impact associated with a sense of inadequate management of the LB. Other factors identified as being important predictors of satisfaction were perceived technical competence and perceived waiting times.

3.4. How the health system is addressing the language barrier

Communication is described as the social interaction that is established between a speaker and a receiver based on the exchange of information (27). It also enables individual to participate in society (28). It is when people have legal and health literacy that includes a certain capacity to understand, assess, address and communicate information about the care they receive, that they can truly oppose social injustice, either for themselves or for their families, in order to achieve health and wellbeing (29). Increasing the health literacy of immigrants enables them to have better access to adequate health care, promoting social justice by increasing social commitment, inclusion and full citizenship of immigrants (20).

No healthcare institution has provided guidelines or protocols for professionals to use when consulting with a patient whose language level is insufficient to conduct a proper medical history. Unclear procedures in health care can lead to potential risks, particularly in staff interactions with migrants, due to the lack of well-defined guidelines. This ambiguity can result in unconscious behaviours influenced by staff attitudes. In contrast, well-established routines offer benefits such as improved coordination, behavioural stability and the ability to perform tasks unconsciously. Clear guidelines and routines can be crucial for enhancing healthcare encounters and minimising the impact of unconscious biases on the care provided to migrants (30,31).

In everyday emergency medicine and in unpredictable situations, clinicians may find themselves in situations where they have limited linguistic and cultural knowledge, and in the absence of professional interpreters (PIs), patients have to rely on medically untrained or bilingual family members and/or healthcare workers. This can compromise the quality of care, leading to increased health inequalities within migrant communities and poorer health outcomes (20,25,32).

Professional interpreters/cross-cultural mediators

Prior literature reviews recommend the use of PIs, also referred to as cross-cultural mediators, to overcome LB and improve healthcare and satisfaction for people who do not speak the official language (24,33).

The presence of a PI can improve the quality of healthcare and outcomes for limited language proficiency (LLP) patients and their families. By being associated with decreased communication errors, increased patient comprehension, equitable healthcare utilisation, improved clinical outcomes and increased satisfaction with communication and clinical services for LLP patients (23,24).

Studies have shown that healthcare professionals prefer to work with PIs in situations involving communication barriers. In their perception, PIs ensure accurate and precise literal interpretation, maintain a professional approach, and remain neutral and objective. On the other hand, patients' perspectives differ, with reports suggesting that healthcare encounters with interpreters can be of limited quality and lack open communication. Patients tend to feel that their trust is betrayed and that the doctor-patient relationship is undermined. Additionally, they described experiencing time pressure during consultations when an interpreter is involved (20,25).

Interpreting practices present a particular challenge in the emergency care setting, which involves less structured with high-intensity activities, often requiring advanced technology, and all are delivered within a compressed time limit. The characteristics of ED make the arrangement of intercultural interpreting services challenging, as such services usually require scheduling in advance, potentially resulting in longer waiting times for patients and prolonged healthcare visits (20). Studies have reported that there is an under-utilisation of PIs in emergency care (34,35).

In contrast to other services in the hospital, the patients of EDs report limited access to language services, which exacerbates the difficulties they face in navigating unfamiliar healthcare environments. In many cases, these patients find support and comfort in the presence of family members, especially in unpredictable and short-term situations. This approach ensures effective communication between healthcare staff and relatives. It is important to note, however, that there may be potential drawbacks, such as compromised quality of interpretation due to confidentiality concerns and a possible lack of language proficiency (20,25) .

Translation applications

Studies have highlighted the proliferation of translation applications on the market (36,37). However, few have focused on the practical implementation of these applications in healthcare services, and particularly in the Spanish healthcare system.

Although there are great improvements in the quality of machine translators such as Google Translate, they are not yet considered sufficiently accurate for use in healthcare (38). Likewise, the ad-hoc translators currently available require a permanent connection to the Internet; and in terms of reliability issues, data confidentiality remains unresolved (39).

Furthermore, the recent literature reveals an increasing tendency for healthcare professionals to use mobile applications on personal devices to improve the delivery of clinical care to patients. This practice has been attributed to the greater accessibility and comfort offered by personal devices. Nevertheless, such practices often conflict with institutional policies and raise concerns about professionalism and patient privacy (40–43).

In light of these challenges, the study conducted by Hwang K et al. proposes one strategic solution (44). It suggests that health centres should provide professionals with equipment for using translation apps and, more generally, any mobile health apps. This approach aims to promote better acceptance and integration of these instruments into the routine of healthcare.

3.5. The available resources for Salt's emergency workers

- **Intercultural health mediation service** (45): The social health mediator acts as a bridge between the health professional and the migrant user, facilitating their relationship and creating a trusting environment. The service ensures equal and standardised access to health services for migrants. They are available in person, through writing or by telephone on the request of the corresponding health professional or the centre's admissions service. Sociolinguistic translation is provided and available in 22 languages.
- **Telephone translation service** (46): By calling 061 Salut Respon, professionals can have a straight line to the interpreting service and be speaking to an interpreter within 2 or 3 minutes. This service, accessible to all health professionals, addresses any language difficulties that may arise during consultations via a three-way call: the consultation (including the patient and the doctor), the 061 Salut Respon centre (that manages any problems that may emerge) and the interpreter of the requested language. Over 90 languages and dialects are currently available.
- **Online dictionaries of medical terminology**: Various official organisations have compiled lists of health-related terminology accessible online, offering translations of terms in different languages. Recommended by the Canal Salut of the Generalitat de Catalunya (47):
 - **HTA Glossary** (48): A support resource for health professionals and users, which provides a commonly recognised vocabulary related to health technologies. In English, German, Spanish, French and Russian.
 - **IATE (Interactive Terminology for Europe)** (49): The European Union's (EU) terminology management system used by its institutions and agencies. It aims to provide a web-based infrastructure for all EU terminology resources, thus improving the availability and standardisation of information. It provides data in the 24 official languages of the EU.
- **Online automatic translators and applications**: Generalitat's Canal Salut also recommends (47):
 - **Softcatalà's Translator** an online automatic translator for extensive texts between Catalan and various languages (50).
 - **Universal Doctor Speaker®** (UDS): Health translation programme, currently available in 17 languages, provided to health professionals by the Institut Català de la Salut (ICS). This has been the chosen as the reference LTA for this study.

3.6. Universal Doctor Speaker®

Universal Doctor Speaker® (UDS) is a programme created in 2010 by Catalan doctor Jordi Serrano Pons with the aim of improving communication between doctors and patients who do not speak the same language. It is available in web version as well as an application in the Apple iTunes and Google Play stores. Most notably, the application is highly accessible to providers who wish to use it, and is available to them free of cost (36,51).

The importance of actively engaging end-users in the entire development process of any new healthcare support instrument has been highlighted, a position supported by other articles (39,52). Furthermore, it is considered ideal for software developers to be involved from the beginning.

The application presents a structured menu which lists pre-formulated medical questions with potential answers and statements, organised into eight sections: Reason for the visit, Set of symptoms, Medical history, Allergies, Vaccinations, Physical examination, Diagnosis and Treatments. This design allows the app to be used at the most critical points in the healthcare encounter, including the patient interview, physical examination, diagnosis, treatment and care planning, and discharge.

The application is primarily composed of closed multiple-choice questions. It allows doctors to select the translations for the most frequent questions in a medical consultation, to which patients can mostly respond by using yes/ no answers. There are also some questions with multiple response options, particularly the ones about the duration of symptoms, and also a few open-ended types of questions. The questions are simultaneously presented in the two selected languages - the patient's and the doctor's - and they can also be listened to put loud in the patients' language.

The program is currently offered and available in 17 languages, which are Arabic, Catalan, English, French, German, Italian, Japanese, Mandarin Chinese Simplified, Moroccan Arabic, Norwegian, Polish, Portuguese, Brazilian Portuguese, Romanian, Russian, Somali, and Spanish. Of those, four are in the top eight languages spoken by the immigrant population in Salt.

The choice of UDS as the primary Language Translation Application (LTA) for this study was carefully considered. As recommended by Canal Salud (46), a trusted healthcare source, the application's adaptability is evidenced by its accessibility in multiple languages, including some of the most common languages of the immigrant population in Salt. The app's structured menu of pre-formulated medical questions, its compatibility with crucial healthcare aspects, and its ability to read questions aloud in the patient's language are in line with the study's focus on emergency care and patient satisfaction.

To summarize, its easy-to-use design, combined with the fact that it is an accessible and free resource, makes this programme a practical and efficient solution for healthcare professionals. And UDS not only fulfils the linguistic requirements of the study, but also addresses the aim of improving communication and, consequently, patient satisfaction in healthcare services.

Operation of the application

The following images have been taken of the application interface at several moments during a simulated consultation between a French speaking patient and a doctor who communicates in Catalan.



Figure 6. Selection of the language chosen by the patient in Universal Doctor Speaker®.

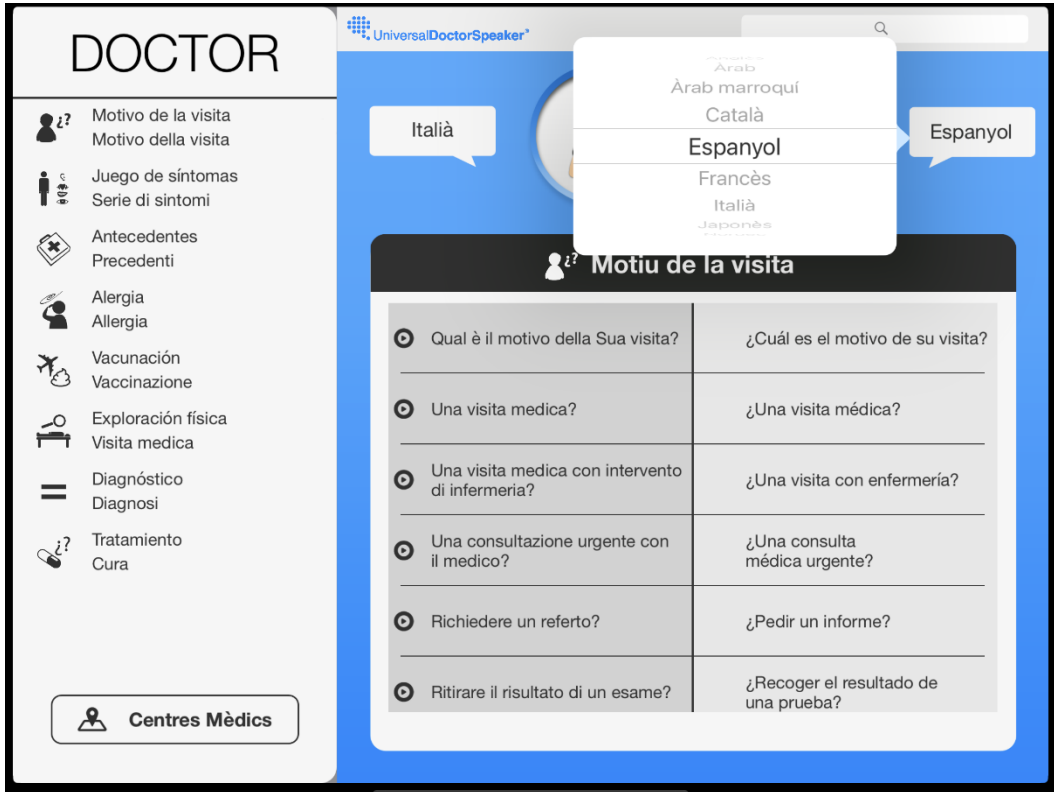


Figure 7. Doctor's preferred language selection in the application.

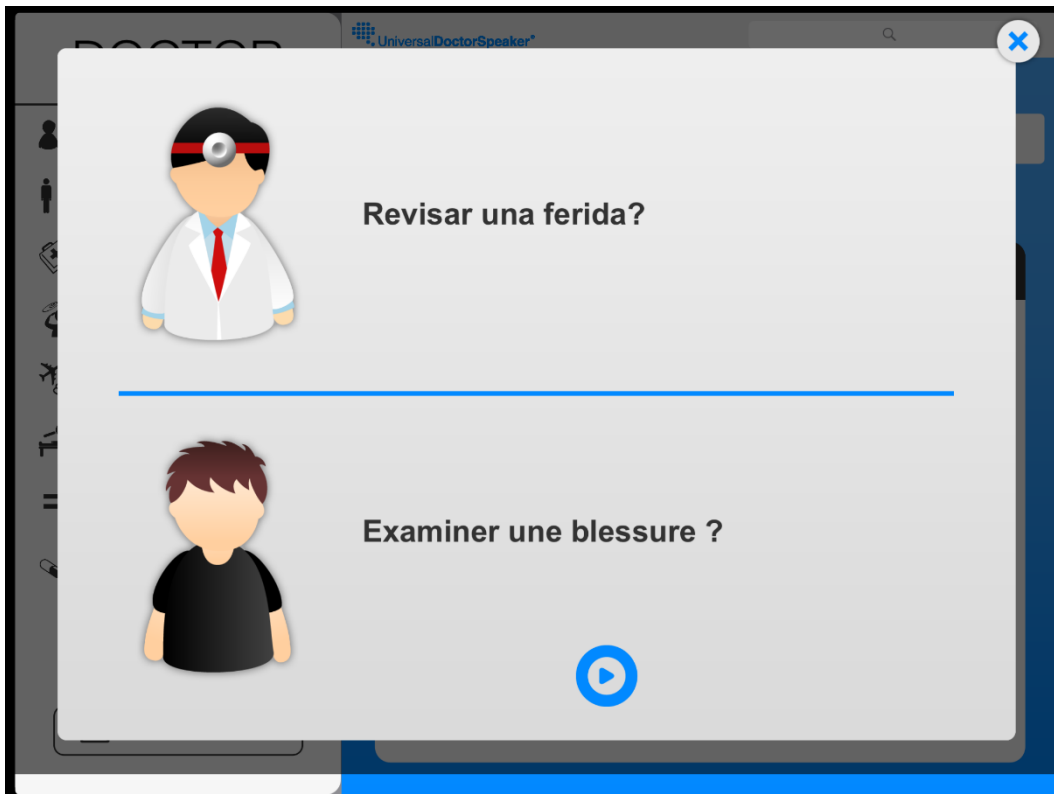


Figure 8. Example of request for reason for consultation.

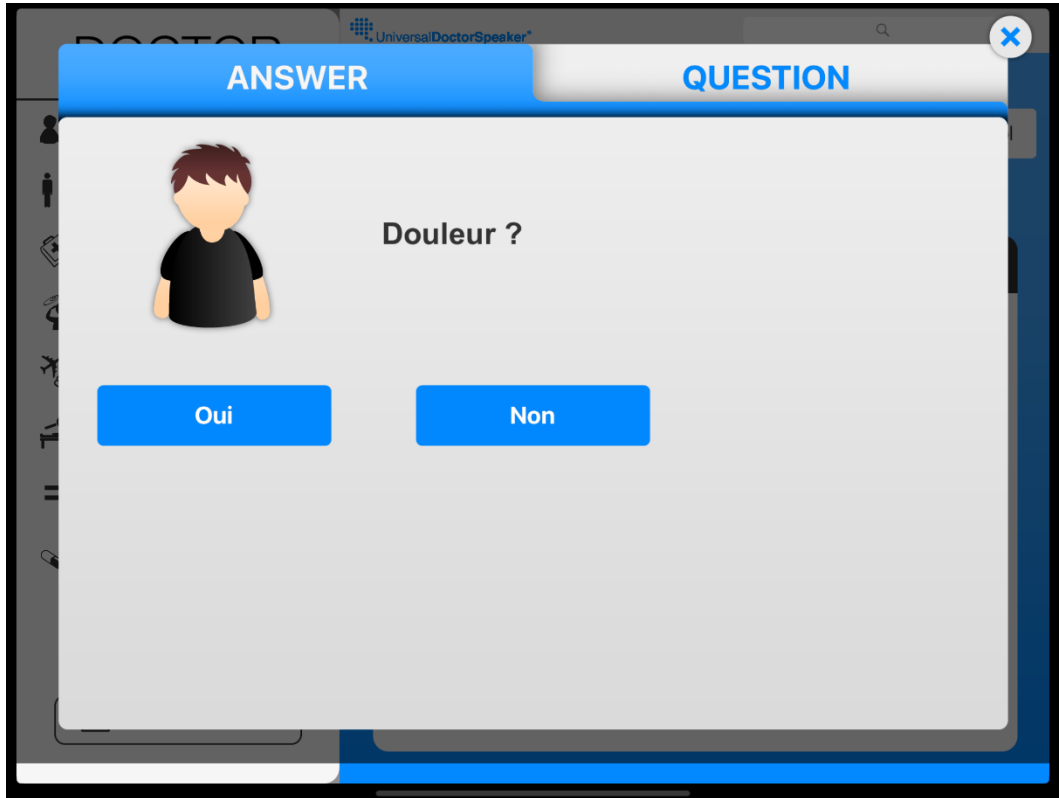


Figure 9. Yes/no question about pain being present.

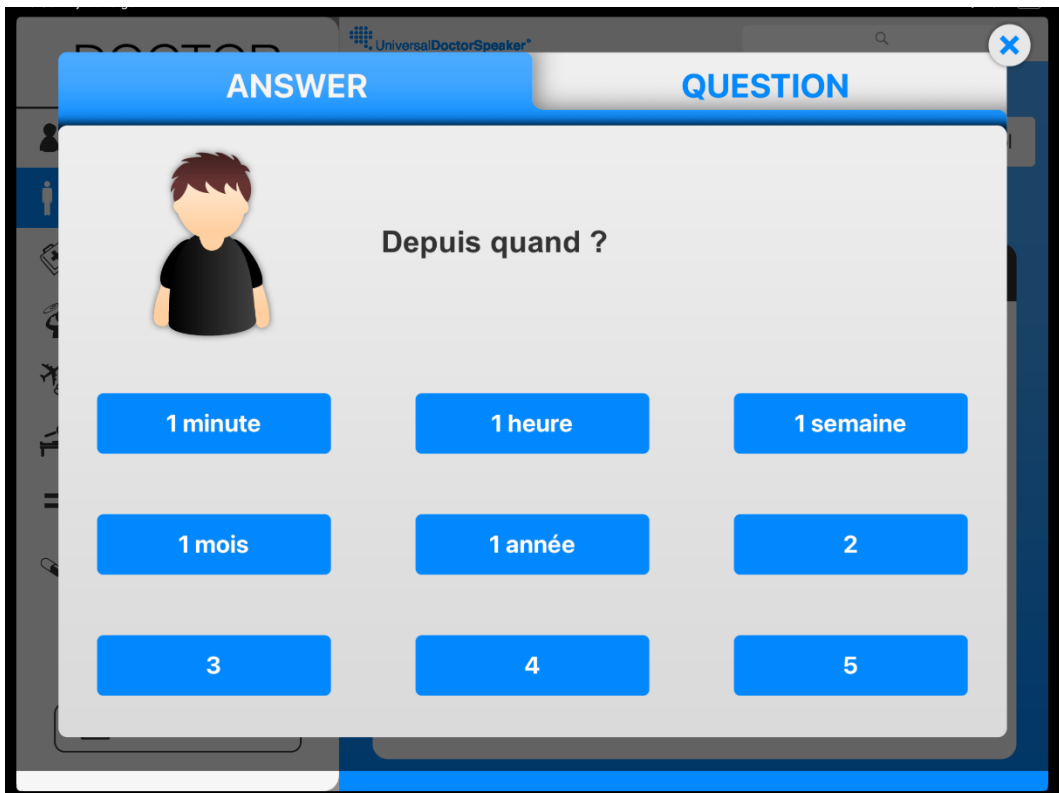


Figure 10. Multiple choice question about the duration of the symptom.

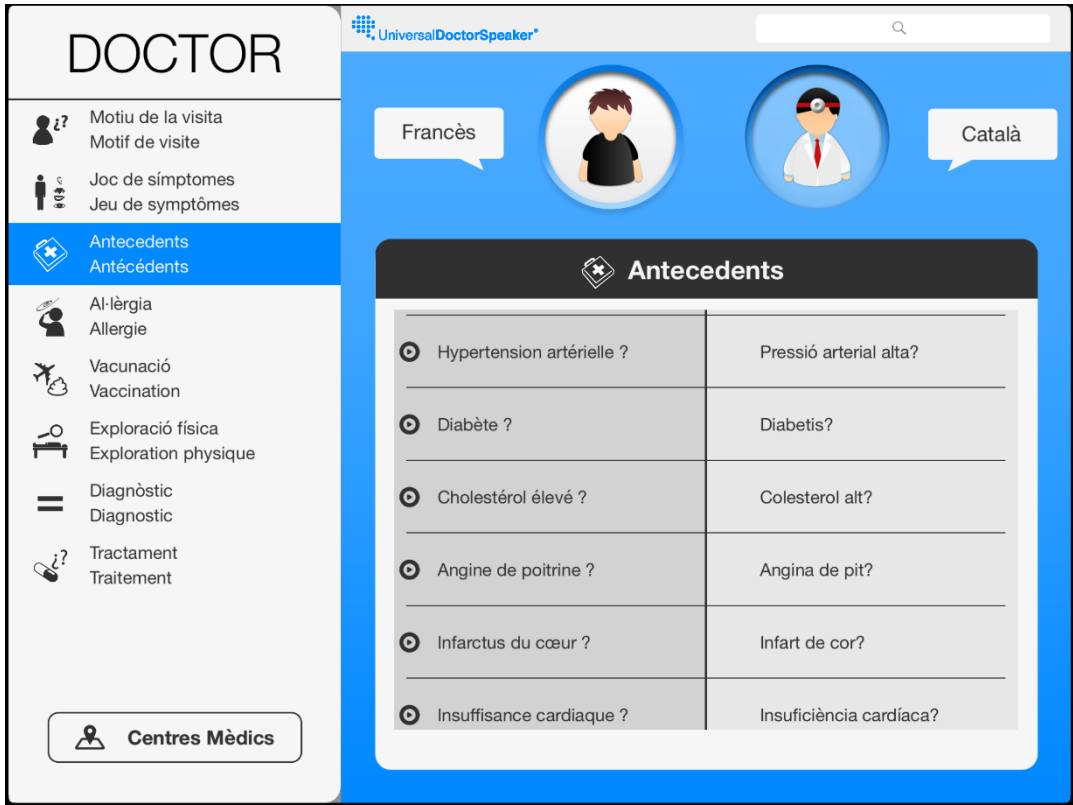


Figure 12. Some of the medical history that could be asked about in Universal Doctor Speaker®

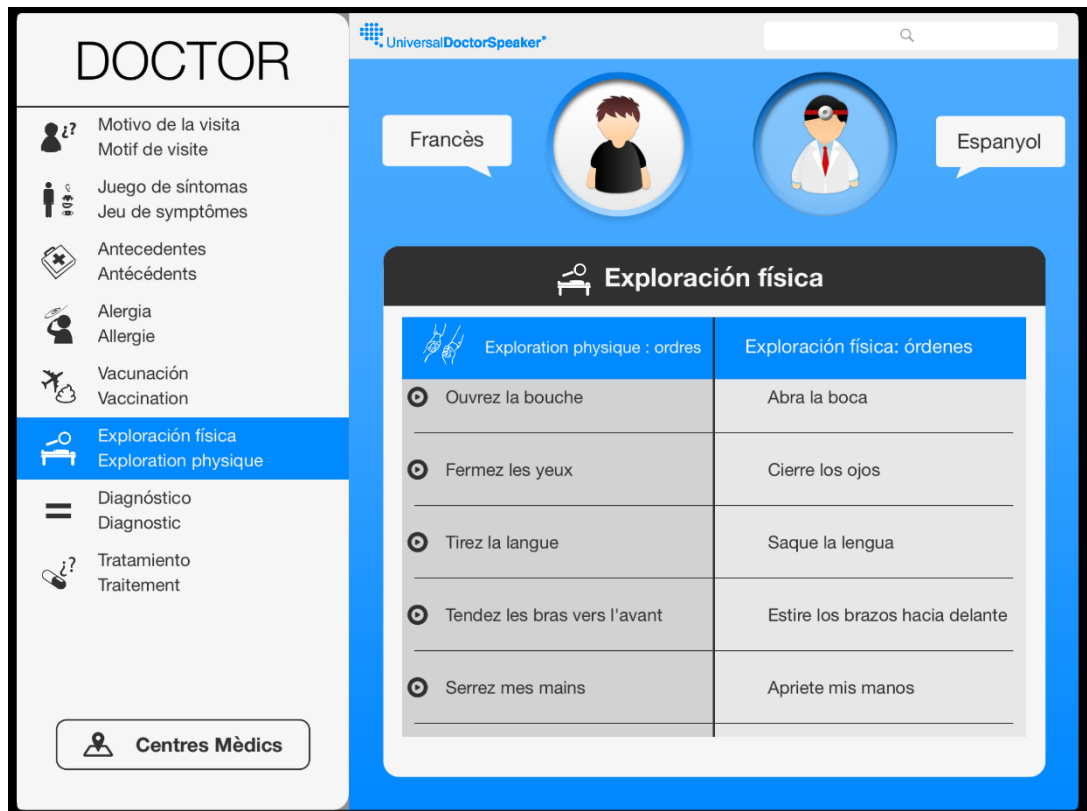


Figure 12. A series of physical examinations that may need to be performed.



Figure 13. Listing of possible diagnoses to translate by the application.



Figure 14. Options for treatment to be proposed.

4. JUSTIFICATION

In the last decades, the world has experienced a constant increase in the immigrant population. The municipality of Salt has registered a notable increase, having one of the highest proportions of immigrants in comparison to the total population of the Catalan territory, reaching 38.14% in 2022 (53). Additionally, an important proportion of these newcomers came from countries where the language and culture are significantly distinct from the Catalan national context (5). Such diversity requires that individuals need to take time to adapt, depending on their circumstances.

The unpredictable nature of emergencies requires people, including those with limited language skills, to seek medical care immediately. In these emergency situations, especially in multilingual communities, communicating effectively with healthcare providers becomes challenging. Overcoming the LB is critical to ensuring rapid and accurate communication for appropriate and time-efficient healthcare.

Although there are numerous studies that describe and analyse the challenges associated with LBs in medical consultations (16,21,22), there is a limited amount of literature that addresses potential solutions and effective measures to be implemented (44).

Many organisations support the use of intercultural mediation or interpretation services, which have been demonstrated to have a positive impact on the care of patients who have an LLP (24). However, in the emergency service, where there is a pressure to be fast and the flow of patients is extremely high, the use of these professional services by health workers is underutilised. This reticence is attributed mainly to the need for pre-planning and the resulting increase in waiting times for both practitioners and patients (34,35).

In these situations, healthcare professionals 'get by' with other non-reliable and non-recommended resources. We have observed that they typically use non-specialist translation programs, such as Google Translate (38); involve relatives or companions who may also not be fluent in the language and could compromise the patient's privacy; and some choose to continue without any assistance. All of these lead to unnecessary tests, longer hospital stays, patient disorientation and poorer aftercare, among other consequences (19).

This study aims to identify a resource that will not only be convenient and accessible for healthcare professionals but will also ensure that patients' privacy is protected. Moreover, it is important to avoid that patients perceive their language difficulties as a burden for the healthcare professional (25).

Considering the rising prevalence of the use of personal devices in professional practice (41–43), the study will investigate a specialised healthcare translation application recommended by respected institutions.

Currently, the market offers a wide range of LTAs specifically designed for healthcare environments (CALD Assist, Care To Translate, MediBabble, Systran...), and there are emerging studies comparing their technical characteristics (36). However, there is a lack of research evaluating the actual usefulness and effectiveness of these translation applications in daily clinical consultations (44).

The purpose of this resource would not be to replace the intercultural mediators in healthcare centres, rather to facilitate communication between doctor and patient in situations where they are not available or while waiting for them.

For this study, we chose the Universal Doctor Speaker® application as the reference LTA, principally because this is the application recommended by the Generalitat de Catalunya (47). Furthermore, the program is user-friendly, includes the majority of languages spoken by the immigrant population in Salt, is provided free of charge and can operate without an internet connection (51).

Let's break down language barriers for better healthcare!

5. HYPOTHESIS

5.1. Main hypothesis

The implementation of a specialised language translation assistance application will improve the satisfaction of patients who experience language barriers in their interactions with emergency medical professionals.

5.2. Secondary hypotheses

1. Healthcare professionals' satisfaction regarding interaction with patients decreases when they experience difficulties in establishing a conversation due to a language barrier.
2. Inadequate management of the language barrier could be contributing to increases the time that patients spend in the ED.

6. OBJECTIVES

6.1. Main objective

The primary objective of this study is to evaluate and compare the impact of implementing a specialised language translation support application (Universal Doctor Speaker®) to improve the satisfaction of patients who experience language barriers when interacting with professionals in the ED.

6.2. Secondary objectives

1. To evaluate the satisfaction of ED doctors in communicating with non-Catalan and non-Spanish speaking patients, depending on whether or not they use a specialised LTA (Universal Doctor Speaker®) to overcome the language barrier.
2. To compare the duration of ED visits for patients who presented a language barrier depending on the resource used to overcome it.

7. METHODOLOGY:

7.1. Study design

To investigate the main objective of this project, a clinical trial has been designed to follow with the parameters of a randomized, open-label, multicentred, prospective, controlled study.

This study has the purpose of comparing, as described in the main objective, the satisfaction with the communication achieved between LLP patients and the attending physicians in the ED of the Salt municipality. This comparison is based on whether LTA was used during the consultation or not. As mentioned earlier, this study uses UDS as the LTA.

All the eligible patients attending the triage area will be randomized in a 1:1 ratio to one of the following two groups:

- **Group 1:** Non-Catalan and non-Spanish speaking patients who, during the ED visit, will be assisted by the physician with the **UDS application**, in order to overcome LB.
- **Group 2:** Non-Catalan and non-Spanish speaking patients who, during the emergency consultation, the doctor will use any **other available resource** to overcome the LB.

At the end of the consultation, both the patient and the doctor will be requested to complete a questionnaire designed to evaluate their satisfaction with the communicative dynamics of the encounter. Patients will provide their answers by filling in a physical form, which will be deposited in a designated container in the admissions area. Correspondingly, doctors will give their feedback via an online questionnaire.

Regarding the masking method, an open approach was chosen because the interventions (use or not of UDS during the consultation) are evident to both the participants and the investigators.

7.2. Study setting

The study will be performed in the two 24-hour reference emergency centres serving the Salt's community: the Hospital Santa Caterina and the Centre d'Urgències d'Atenció Primària (CUAP) Güell.

Hospital Santa Caterina is the basic general hospital designated to provide urgent medical care to the population of Salt (54). To ensure efficient use of resources and a rapid response, less severe patients are often transferred to the Güell's CUAP. The Güell's CUAP operates as a primary care centre with the adequate equipment to deal with non-critical emergency consultations (triage level IV or V) 24 hours a

day, every day of the year (55). For this reason, it was considered appropriate to include both centres in the study.



Figure 15. Images of the entrances to Hospital Sant Caterina (left) and CUAP Güell (right).

7.3. Subjects selection

The study population will be composed by patients with a LLP in Catalan and Spanish, admitted to the ED of the participating institutions in the study with a triage level equal to or higher than three. It is required that patients have read the information document (ANNEX 1) about the study and have to sign the informed consent (IC) form (ANNEX 2) prior to participate in the study.

Limited Language Proficiency

To establish whether a user has limited language proficiency (LLP) in the two official languages, the definition proposed by the US Department of Health and Human Services has been adapted (56). According to the definition, persons with limited proficiency in a particular language are those who do not speak it as their native language and have a reduced ability to read, write, speak or understand it. As a result, they should be considered to be eligible for language assistance in relation to a certain type of service, benefit or encounter.

For the purpose of this study, patients with LLP will be defined as those who exhibit any of the following characteristics in the triage area:

- *Inability to comprehend Catalan or Spanish:* Patients who demonstrate a lack of understanding in either Catalan or Spanish.

- *Difficulties in speaking Catalan or Spanish:* Individuals who face challenges in speaking Catalan or Spanish to the point that they are unable to have a simple conversation.
- *Unable to coherently describe the reason for their consultation:* Patients who, due to their lack of knowledge of Catalan or Spanish, are not able to clearly communicate the reason for their consultation.

These criteria have been deliberately chosen as crucial factors to be considered in order to ensure effective communication and understanding of patients' healthcare needs. It is crucial to recognise their presence, as these factors contribute significantly to the development of LBs in the healthcare system.

How triage works?

Triage is a classification process that allows clinical risk management, enabling appropriate and safe management of patient flows when demand and clinical needs exceed available resources (57).

Currently, EDs use a model known as structured triage, in which classifies patients into diverse levels of priority. Each level determines an optimal time between arrival and care attention, ensuring that the most urgent patients receive assistance first, while others are re-evaluated before being seen by a physician (58,59).

The structural triage system implemented in the ED of Salt is the "Model Andorrà de Triatge" (MAT) (60). MAT was developed in 2000 by Dr. Josep Gómez Jiménez and colleagues, and in 2002, it was approved as the Catalan triage standard by the Societat Catalana de Medicina d'Urgències i Emergències (SoCMUE) (61,62). MAT is based on (62):

- Standardised 5-level triage, with a triage management software and a clinical decision support software in triage.
- A non-exclusive nursing triage model that prioritises patient urgency over all other considerations.
- Integrated into a continuous quality improvement system, with monitoring of triage quality indicators.
- Must be integrated into a global electronic medical record model.

In Salt's ED, triage is conducted by nursing personnel, with or without the assistance of a physician. The levels are determined on the basis of a scale of symptomatic categories according to the sentinel symptoms and diagnoses, as well as the discriminants of the urgency levels (physiological constants, evolution time, pain level, mechanism of injury, etc.), all performed with the assistance of clinical algorithms in electronic format (63–65).

The following table illustrates the triage structure used in the ED of Salt, associating the levels, severity and optimal waiting time (60):

Level	Colour	Rank	Description	Waiting time
I	Blue	Resuscitation	Immediate life threatening	Immediately
II	Red	Emergency	Elevated risk situation	20-30 minutes
III	Orange	Urgent	Need for complementary tests and haemodynamic stability	Less than 60 minutes
IV	Green	Less urgent	Haemodynamic stability, need to assess the need for complementary tests	3-4 hours
V	Black	Non urgent	Visit that can be arranged by pre-appointment / emergency at the primary care centre of reference	Over 4 hours

Table 1. Relationship between scales and severity levels used in the ED of Salt. Adapted from (60)

7.3.1. Inclusion criteria

- 1) Individuals who showed an LLP in Catalan or Spanish.
- 2) Patients who are classified in priority levels \geq III by the MAT system during triage.
- 3) Patients who can read and write in their native language or in a language provided in the LTA.
- 4) Adult patients of both sexes \geq 18 years of age.
- 5) Patients who voluntarily accept and sign the IC.

7.3.2. Exclusion criteria

- 1) Patients who are accompanied during the consultation by a relative or acquaintance over the age of 18 with a fluent knowledge of Catalan or Spanish.
- 2) Patients requesting emergency services for critical illness or acute distress, potential victims of sexual assault, and patients who require restraint measures.
- 3) Patients who need to be hospitalised or admitted to another centre for further diagnostic tests or to receive the prescribed treatment on discharge from the ED.
- 4) Patients whose reason for consultation is related to suicidal ideation or a severe mental health crisis.

- 5) Individuals whose native language or other languages in which they are proficient are not available in the translation application.
- 6) Patients who, for whatever reason, do not comprehend the study and, consequently, lack the autonomy to decide whether or not to participate.

7.3.3. Withdrawal of the study

Patients who agree to participate in the study must be committed to follow up that is stipulated in the protocol, and the professionals at the participating centres will encourage and assist them. Nevertheless, patients can be withdrawn from the study in certain situations.

Each participant who withdraws from the study must be declared and recorded in a “*Loss Record*” which includes the patient's data and the reason for dropout. The data obtained from the participant's withdrawn will be deleted from the definitive database.

Participants are able to withdraw from the study if any of the following events occur:

- Voluntary decision to leave the clinical trial by submitting the “Revocation for Consent” to this study (ANNEX 2). It is requested that the decision to withdraw from the trial be made in writing.
- Patients who at any time during clinical trial fulfil an exclusion criterion because this was developed after enrolment.
- Patients who do not complete accurate follow-up, meaning that some of their data may not be collected for proper analysis.

If withdrawal occurs, no further patients will be added to the clinical trial as the sample size for the clinical trial has already been established it.

7.4. Sampling

7.4.1. Sample size

The ICS has developed a validated questionnaire for the evaluation of the satisfaction and experience of patients in the emergency services at hospitals in Catalonia. The questionnaire is a crucial component of the Pla d'enquestes de percepció, experiència i satisfacció d'usuaris del Servei Català de la Salut (PLAENSA). Its main objective is to assess the quality of service and the degree of satisfaction of users of the different public health services, in this case hospital urgent care. The most recently conducted survey, in 2022, showed an overall patient satisfaction rating at 6.81 out of 10 (66).

Considering the limited availability of patient's satisfaction surveys, which were mostly in Catalan and Spanish and consequently did not really reflect the opinion of the target population of the study, it was decided to consider these results of PLAENSA as a reference to measure the baseline of patients' satisfaction.

A difference of 0.5 or greater between the levels of satisfaction of the two groups was considered relevant, considering that this variation could be significant (recognising that, for subsequent studies, it will be appropriate to verify that this improvement is dependable and significant).

The sample size calculation was conducted using the GRANMO online calculator. According to the main objective of the study, being a comparison of two discrete quantitative variables, the "two independent means" function was applied.

Accepting an alpha risk of 0,05 and a beta risk of 0,2 in a two-tailed test, **90** subjects are necessary in the first group and **90** in the second to recognize as statistically significant a difference greater than or equal to 0,5 units. The common standard deviation is assumed to be 1,1 (66). A drop-out rate of 15% has been anticipated (considering that there will be a proportion of patients who will not correctly complete the questionnaires).

7.4.2. Sample selection

The sampling method that will be applied in this study will be a **non-probabilistic consecutive** sampling. All patients receiving attention at the emergency triage of Santa Caterina Hospital and Güell CUAP will be offered to participate in the study, on the condition that they fulfil all the inclusion criteria and none of the exclusion criteria. The potential participants will be provided with a comprehensive explanation of the study and the IC will be presented and signed by them prior to the medical consultation.

Patient recruitment will be conducted in both centres until the required sample size, as detailed in the previous section, is achieved. It is estimated that the required goal will be reached within one week.

7.5. Variables

7.5.1. Independent variable

The independent variable for this study is “*Use of the Universal Doctor Speaker® in consultation*”. It will be expressed by the intervention group as *yes*, which used the LTA in the consultation, and the control group as *no*. It is a qualitative dichotomous variable.

7.5.2. Dependent variable

- **Dependent variable of the main objective:** The main dependent variable of the study is *Patients’ satisfaction*. It will be analysed as a discrete quantitative variable obtained from a satisfaction survey focusing on the communication established with the doctor in the consultation and the user's overall experience. To design the survey, it was selected and adapted questions from the PLAENSA questionnaire (66), which, as previously mentioned, aims to assess the general satisfaction of patients throughout their stay in the ED.

The new questionnaire has 9 items to be filled in each with 5 options. The lower the sum of the answers, the worse the patient's satisfaction will be.

- **Dependent variable of the secondary objectives**
 - Professionals’ satisfaction: Discrete quantitative variable extracted from a specific questionnaire to assess, from the professional's perspective, the degree of communication established during the consultation with patients who have a LB. A questionnaire of 8 questions has been designed, with each question rated from 0 to 5. In the end, the higher the sum of the different points, the greater the doctor's satisfaction regarding the doctor-patient interaction achieved.
 - Time in ED: It is a continuous quantitative variable that will be extracted from the Digital Health Record (DHR). Expressed in *minutes* it will measure the time that has elapsed since the patient's admission to the ED until the physician realizes the patient's discharge.

7.5.3. Covariates

Patient-related covariates

Covariates related to patient information are discussed below:

- **Age:** Continuous quantitative variable that will be expressed in *years* in an open-question.
- **Sex:** Qualitative dichotomous variable categorized as *Male* or *Female*.
- **Socioeconomic status:** in order to have a more complete picture of the socioeconomic factors affecting ED users, information obtained from educational level and occupation will be combined.
 - **Education level:** Polytomous qualitative ordinal variable in which the following different degrees are distinguished: *Without studies / Primary qualification / Secondary qualification / Diploma / Degree / Post-graduate*.
 - **Occupation:** Polytomous qualitative ordinal variable in which the next categories are differentiate: *Self-employed / Salaried worker / Pensioner / Student / Unemployed or looking for a job / Housewife / Other*.
- **Nationality:** Qualitative polytomous nominal variable, to be collected in open question format.
- **Time living in Catalonia:** Quantitative discrete variable, to be collected in open question format. Expressed in *weeks, months or years* depends on the case.
- **Language proficiency**

Language proficiency will be described as an ordinal polytomous qualitative variable. Taking as a reference the Common European Framework of Reference for Languages (67) in conjunction with the Interagency Language Roundtable scale (68), the following levels of language proficiency have been generally classified:

- **No proficiency:** cannot understand or communicate in the language.
- **Elementary proficiency (A1-A2):**
 - *A1:* Basic understanding of the most common phrases and expressions.
 - *A2:* Can communicate in simple, routine tasks requiring a simple and direct exchange of information.
- **Limited practical proficiency (B1-B2):**
 - *B1:* Can deal with most situations likely to arise during a temporary stay in an area where the language is spoken. Can describe experiences and events, dreams, hopes and ambitions.
 - *B2:* Can interact with a degree of fluency and spontaneity in the language. Can produce clear, detailed text on a wide variety of subjects.

- **Professional competence (C1-C2):**
 - C1: Can understand a wide range of demanding, longer texts and recognise implicit meaning. Can express ideas fluently and spontaneously.
 - C2 (Native or near-native proficiency): Can understand with ease virtually everything heard or read. Can summarize information from different spoken and written sources.
- **Pain control:** It is considered important to keep this variable in mind, since diverse studies have shown that patient satisfaction improves with higher pain control during the consultation (69,70). Moreover, patients whose pain is managed during their ED visit, experience a greater physician-patient relationship (71).

Pain control will be described as a discrete qualitative variable that will be obtained by comparing the pain experienced by the patient during triage with the perceived at discharge from the ED. To objectively evaluate pain, study participants will undergo the *numerical rating scale (NRS)* at the moment of arrival at the service and during discharge.

The NRS is a numerical version of the visual analogue scale (VAS). It is commonly presented as a horizontal line with an eleven-point numerical range (0 to 10), where zero represents "no pain" and the upper limit means "the worst pain you can ever imagine ". The NRS is a structured scale



Figure 16. Example model of a Numerical Rating Scale

designed to assess pain, improve communication with healthcare professionals, and track the evolution of pain through time (72–75).

Several studies highlight strong correlations between the NRS and other pain assessment instruments, as well as highlighting its high feasibility and good compliance. Unlike the VAS, which allows theoretically unlimited responses, the NRS provides a more discrete differentiation of pain levels (75–77).

- **Reason of consulting:** A polytomous nominal qualitative variable will be gathered from the diagnosis provided by the physician in the medical discharge report, following the ICD-10-ES coding system.

The International Classification of Diseases (ICD) is the WHO's reference classification for describing the health status of individuals in terms of diseases, lesions and reasons for consultation. The ICD can be defined as a system of mutually exclusive categories covering the entire range of diseases existing in the medical terminology (78).

In Spain, the most updated version is the ICD-10-ES of 2022. The ICD-10-ES is an alphanumeric classification system. It is organized into 22 chapters according to body systems or nosologically entities, which are then divided into categories and their corresponding subcategories that ultimately form a final code. A valid final code can have three, four, five, six or seven characters (79).

Professional-related covariates

Covariates referring to professional information are elaborated upon below:

- **Age:** Continuous quantitative variable that will be expressed in *years* in an open-question
- **Sex:** Qualitative dichotomous variable categorized as *Male* or *Female*.
- **Years experience:** Discrete quantitative variable, expressed in *years*, will be derived from the questionnaire.

		VARIABLES	DESCRIPTION	MEASUREMENT	CATEGORIES		
Independent		Use of the Universal Doctor Speaker® in consultation	Qualitative dichotomous	DHR or survey	<ul style="list-style-type: none"> · Yes · No 		
Dependent	Main	Patients' satisfaction	Quantitative discrete	Survey	0-10 score		
	Secondary	Professionals' satisfaction	Quantitative discrete	Survey	0-10 score		
		Time in ED	Quantitative continuous	DHR	- minutes		
Patients' Covariates		Age	Quantitative continuous	Questionnaire	- years		
		Sex	Qualitative dichotomous		<ul style="list-style-type: none"> · Male · Female 		
		Socioeconomic status	Education level		Qualitative polytomous ordinal	<ul style="list-style-type: none"> · Without studies · Primary qualification · Secondary qualification · Diploma · Degree · Post-graduate 	
			Occupation		Qualitative polytomous nominal	<ul style="list-style-type: none"> · Self-employed · Salaried worker · Pensioner · Student · Unemployed or looking for a job. · Housewife · Other 	
		Nationality	Qualitative polytomous nominal		-		
		Time living in Catalonia	Quantitative discrete		- weeks/ months/ years		
		Language proficiency	Qualitative polytomous ordinal		<ul style="list-style-type: none"> · No proficiency · Elementary proficiency · Limited Working Proficiency · Professional Working Proficiency 		
		Pain management	On arrival		Quantitative discrete	NRS	0-10 score
			On discharge		Quantitative discrete	NRS	0-10 score
		Reason of consulting	Qualitative polytomous nominal		ICD-10-ES	-	
Professionals' Covariates		Age	Quantitative continuous	Survey	- years		
		Sex	Qualitative dichotomous		<ul style="list-style-type: none"> · Male · Female 		
		Years of experience	Quantitative discrete		- years		

Table 2. Summary of study variables, measurement method and categories.

ED: Emergency department, DHR: digital health record, NRS: Numerical rating scale,

ICD: International classification of diseases

7.6. Study intervention

7.6.1. Enrolment

All patients who attend at the ED of one of the participating centres (see *Study Setting*) may be considered for recruitment, provided they meet with the inclusion and exclusion criteria described in the *Subject Selection* section.

At the triage area, a nurse will assess the patient's communication skills and will determine their level of proficiency. The proficiency level will be determined based on the explanation given in Catalan or Spanish for the reason for their consultation. If a patient is assigned as a triage level of III or lower and it is found to have LLP in Catalan or Spanish, they will be given a document containing all the languages available at the Universal Doctor Speaker® (ANNEX 3) to confirm their knowledge in one of the languages it provides.

If the patient demonstrates proficiency in one of the languages and also meets the other requirements, they will be considered a suitable candidate for the study.

They will then receive the informational document for participants (ANNEX 1) and IC form (ANNEX 2) in their selected language.

7.6.2. Randomization

Patients will be admitted to the study and subsequently randomised to a group once they have fully understood the study, its procedural details and their role in it, and have voluntarily agreed to participate by signing the IC. Triage personnel will be responsible for ensuring the proper execution of these steps.

Patient randomization will be carried out on a 1:1 ratio into one of the following two groups, using a randomisation computer program:

- **Group 1** will comprise of non-Catalan and non-Spanish speaking patients who will receive assistance from the physician, using the **LTA specifically chosen for this study** to overcome LB during the ED visit.
- **Group 2** will comprise of non-Catalan and non-Spanish speaking patients whose physicians will use **alternative available resources** to overcome LB during the ED visit.

Access to the consultation will be permitted once the patient has been randomly assigned to a group. Concurrently, the patient's DHR will be updated from triage to indicate that they have enrolled in the

trial and which group they have been assigned to, so that all professionals attending them will be informed.

To guarantee comprehensive anonymisation of patient data, strict measures will be implemented throughout the study. Each participant will be assigned a unique numerical identifier (ID) for exclusive use during the research period, ensuring privacy and secure data handling. This anonymisation process is essential to respect ethical standards and confidentiality in medical research.

7.6.3. Intervention

It must be pointed out that all emergency doctors will have received the information document for professionals (ANNEX 4) during their training for their participation in the study. Following a thorough review and clarification of any doubts, they will have signed the IC form (ANNEX 5).

By accessing the DHR, as previously explained, doctors will be informed of the patient's participation in the study and the specific group to where they have been allocated. This information is essential for adapting the consultation accordingly.

For patients assigned to Group 1, the clinician will need to prepare the tablet with the UDS application installed, as the chosen LTA, and launch the programme by entering the required login credentials.

In the case of patients in Group 2, any alternative resource to the UDS can be used. These may be for example contacting an intercultural mediator, attempting to communicate without the aid of any resource or seeking out another member of the emergency team who speaks the same language.

In order to maximise the efficiency of communication between patient and clinician, the selected resource should be used consistently throughout the consultation, in accordance with the assigned patient group. This requires a meticulous collection of a complete medical history, the performance of only essential diagnostic tests to confirm suspected diagnoses, and ultimately the formulation of the most accurate diagnosis. The purpose is to ensure that the prescribed treatment guidelines are precisely aligned with the identified diagnosis, facilitating a simplified and effective healthcare process.

7.6.4. Follow-up

At the conclusion of the consultation, the patient will be provided with the Patient Satisfaction Questionnaire (PSQ) (ANNEX 6) and the Data Collection Questionnaire (DCQ) (ANNEX 7) along with the

other documents handed out by the doctor, such as the prescriptions and the discharge report. These documents will be in the language chosen by the patient. The only visible identification will be the assigned ID to maintain anonymity.

Before leaving the consulting room, the patient should complete the DCQ in collaboration with the doctor. This form will be securely attached to the PSQ.

Regarding the PSQ, patients will have the option to complete it, either in the consulting room or in the admission area, wherever they feel most comfortable. Once all the forms have been completed, they must be deposited in a designated box that will be conveniently located at the Admissions Desk.

Physicians will be requested to complete the Professional Satisfaction Questionnaire (PrSQ) (ANNEX 8) at the end of a consultation and when the patient is discharged. At the time of closing the patient's DHR, a prompt will appear reminding them of the patient's participation in the study. This notification will also provide a direct link to access the PrSQ.

It is essential that physicians actively participate by completing the PrSQ to contribute to the overall evaluation of professional satisfaction within the study. To ensure that this is done, the consultation will not be able to be closed from the programme until the PrSQ has been completed. The form will only contain the patient's ID and it will be securely transmitted directly to the research team's database to ensure privacy.

7.7. Data collection

Gathering information

To evaluate the satisfaction of both patients and professionals in situations where LBs are present, specific questionnaires focusing on the perceptions of respondents about the communication established during consultations will be administered. In the absence of existing questionnaires covering the desired aspects, a set of specific questions were carefully designed for this study. By the start of the study, the questionnaires for patients' and professionals' satisfaction will have completed the validation process, ensuring their safety and reliability.

The PSQ, as described in the study intervention section, will be provided in printed form to make it more practical. Additionally, they will be attached to each patient's DCQ to ensure that the forms remain correlated. The only visible identification on these documents will be the ID generated for each patient during the randomization process, ensuring data protection and privacy.

The completed documents will be deposited in a secure and predetermined container, specifically designated at the Admissions Desk. A member of the research team will collect the documentation daily at a predetermined hour and upload it into the database.

Regarding the PrSQ, it has been designed to be accessible from an online platform, ensuring a convenient and optimized experience for professionals. Once completed, the responses will be sent directly to the database, anonymously and without any personal details, except for the patient's ID. This process not only improves accessibility but also facilitates the prompt integration of valuable professional data into the database.

Prior to beginning the definitive data collection, a pilot test will be conducted with a limited number of patients to assess the reliability of the instruments and to identify any data collection challenges. Any difficulties detected during this pilot test will be addressed and rectified appropriately.

Database Creation

As described in the *Study Intervention*, each patient will be assigned a unique ID during the randomisation process, which is crucial for ensuring confidentiality. This ID will be securely stored in an autonomous database, allowing for the possibility of de-anonymisation if required.

A computer scientist, independent of the research team, will meticulously construct an anonymous database that correlates patient IDs with data derived from their questionnaires. Additionally, the

healthcare professionals' responses associated with each consultation will be integrated. The process ensures the creation of a fully anonymous database, safeguarding the integrity of the research.

- The **DCQ** will serve as a source for a variety of valuable information, including:
 - *Personal information:* age, sex.
 - *Patient's demographic:* nationality, time residing in Catalonia, education level, occupation, and language proficiency.
 - *Clinical history details:* reason for consultation, pain levels on arrival and discharge.
- Data pertaining to patient satisfaction, encompassing both overall satisfaction and individual itemized assessments, will be extracted from the **PSQ**.
- The **PrSQ** will be used to evaluate global and detailed satisfaction. Personal information of professionals, including age, gender, and years of experience in the ED, will also be extracted for their analysis.

Collecting this information, the computer scientist will create a robust anonymous database, subsequently transferring it to the research team for further analysis.

Database and analysis

Within the working team, a designated investigator will be responsible for monitoring and controlling the quality of the collected data. This supervision will be frequent and regular in order to identify and resolve errors quickly. The creation of a solid database is essential to ensure the quality of subsequent data analysis.

Once the required number of subjects has been reached and the required data have been collected from each participant, the anonymous database will be transferred to the statistician. This is the stage where the statistician takes on the responsibility of analysing the data. The statistician will meticulously examine the data set, identify patterns, trends and significant correlations, and produce a detailed report. Lastly, the research team will interpret and connect the results to answer the objectives.

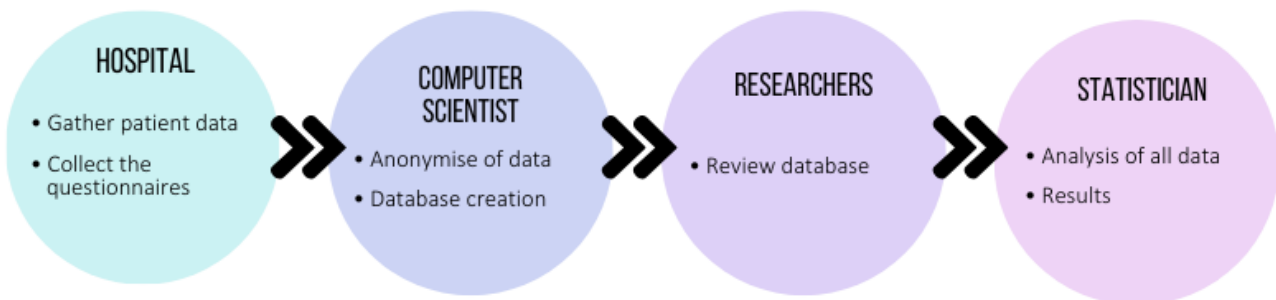


Figure 17. Summary of the data collection.

7.8. Flow diagram

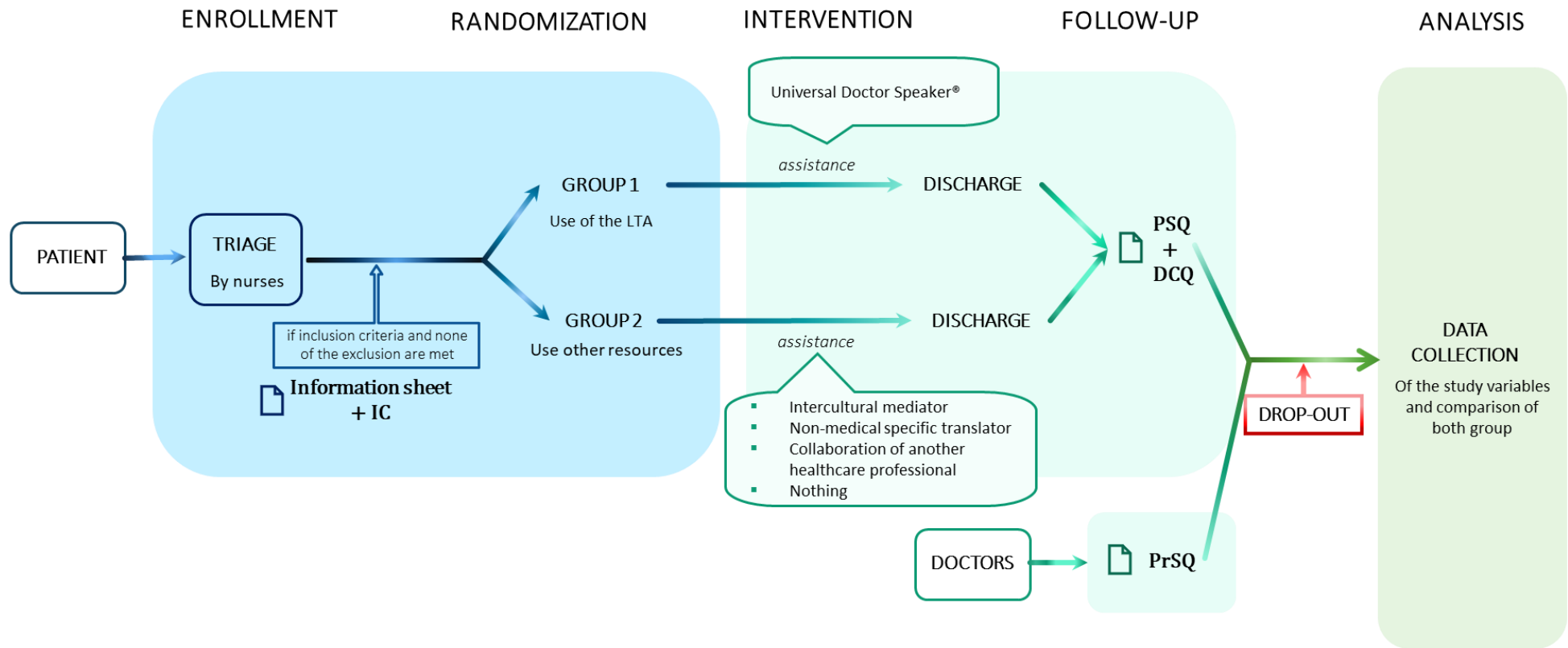


Figure 18. Study flow diagram.

IC: Informed consent, PSQ: Patient Satisfaction Questionnaire, DCQ: Data Collection Questionnaire, PrSQ: Professional Satisfaction Questionnaire

8. STATISTICAL ANALYSIS

The statistical analysis of the obtained data will be conducted in a blinded form by a statistical analyst, to ensure that no bias is involved.

The Statistical Package for Social Sciences (SPSS) software version 28.1 will be used for statistical analysis. A p value below 0.05 will be considered statistically significant and a 95% confidence interval will be defined for all analyses.

Descriptive analysis

Patients' satisfaction, the main dependent variable, will be summarised using **medians** and **interquartile range (IQR)** as it is a discrete quantitative variable. The same approach will be applied to the secondary dependent variable of professionals' satisfaction, also a discrete quantitative variable. Although the other secondary dependent variable, the time spent on ED, is a continuous quantitative variable, its distribution is asymmetric and, therefore, it will be summarized using the **median** and **IQR** as well.

These descriptive statistics will be stratified according to the use or non-use of the UDS app, and additionally stratified based on the covariates. Age will be categorized in quartiles.

Kaplan-Meier curves for the time spent on ED stratified by the use or non-use of the UDS app will be estimated and graphed.

Bivariate inference

The **Mann-Whitney's U test** will be applied to study patient and professional satisfaction (discrete quantitative variables), as well as the time spent on ED (with an asymmetrical distribution) based on the use or non-use of the chosen LTA in the consultation (dichotomous qualitative variable).

The survival curves for the time spent on ED stratified by the use of the UDS app will be compared using the **log-rank test**.

Multivariate analysis

In summary, multivariate models will be used to adjust the independent variables with the dependent variables according to covariates that may be potential confounding factors. The impact of this intervention on satisfaction will be determined using **Poisson regressions** for study patient and professional satisfaction, with adjustment for the covariables.

In the case of the time spent on ED, we will assess the effect of the intervention on a **Cox regression** controlling for all the covariables.

9. ETHICAL AND LEGAL CONSIDERATIONS

The study protocol has been developed in compliance with the ethical requirements stipulated in the **Helsinki Declaration of Ethical Principles for Medical Research Involving Human Subjects** signed by the WHO in October 2013.

The implementation of the protocol will not proceed until it has been approved by the **Comité de Ética de Investigació Clínica (CEIC) Institut d'Assistència Sanitària de Girona**. Any objection identified by the committee will be considered and implemented in the protocol.

The study must comply with the *“Ley 14/2007, de 3 de julio, de Investigación biomédica”*, which is based on the principles of integrity, dignity, and protection of human identity in all biomedical research that involves the intervention of human beings (80).

All professional members of the research team must sign a **statement attesting that they have read and approved the final protocol and agree with the national and international ethical aspects** of the clinical trial.

All enrolled subjects will be adequately informed about the study, its objectives, risks and benefits through an information document (see ANNEX 1)

In accordance with the *Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica*, individuals must voluntarily and freely accept and sign the IC approved by the CEIC and will be able to withdraw from the study at any stage without being judged, harmed or suffering any health consequences. If a participant chooses to no longer continue in the study, their data will be removed from the database.

During the collection of data, only the information necessary for the study will be collected (**minimisation principle**) and will be accessible exclusively to members of the research team and collaborators. The data and information will be used strictly for the purposes of the study. The professionals responsible for collecting and analysing the data must ensure the anonymity and privacy of patients in accordance with *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data*, in conjunction with *Ley Orgánica 3/2018, de 5 de Diciembre, de Protección de Datos Personales y Garantía de los derechos digitales*.

The **Principles of Biomedical Ethics by Beauchamp and Childress** (1970, reviewed in 2009) - Autonomy, Non-maleficence, Beneficence, and Justice - will be respected in this study:

- The principle of **autonomy**, referring to the right to self-determination, will be maintained by providing participants with comprehensive information to make decisions about their participation without being subject to repercussions.
- The principle of **non-maleficence** will be guaranteed in the study by ensuring that no test or procedure undertaken could compromise the well-being of participants. It is important to emphasise that the application has been designed to support consultation and not to substitute medical decision-making.
- The study complies with the principle of **beneficence** by exploring a more accessible resource that could facilitate the overcoming of the LB in emergency consultations. Furthermore, the programme has the potential to be used as a baseline for the implementation of equivalent instruments in other procedures and services, both within and outside of healthcare institutions.
- In the study the principle of **justice** will be respected by providing equal opportunities and access to all eligible patients who comply with the inclusion and exclusion criteria. All procedures will be performed in an equal manner for all patients, removing any potential for discrimination or exclusion.

In accordance with the ethical principles described, it has to be emphasised that the results of this study, whether positive or negative, will be **published transparently**. Our commitment to knowledge dissemination is firm, as we recognise that each result contributes to collective learning in the discipline. This commitment to transparency and knowledge sharing reflects our determination to advance understanding and promote continued progress in the area.

10. WORK PLAN

10.1. RESEARCH TEAM MEMBERS

The personnel who are involved in the various stages of this trial are as follows:

- **Main investigator (MI):** is the lead researcher responsible for designing the study protocol. By supervising the implementation of the protocol, the MI will ensure that it is correctly applied. Additionally, the MI actively participates in discussion of results, prepares the final report of conclusions, and promotes dissemination of results through publication.
- **Secondary investigators (SIs):** Each hospital will designate a doctor and a nurse to become SIs. Their responsibilities will include managing the professional training, ensuring compliance of the protocol in their respective centres, and facilitating coordination with the MI.
- **Nurses and doctors from the EDs:** Professionals from the emergency departments of each hospital play a crucial role in sample selection, patient data collection and other actions required for the trials. Their participation will complement their daily responsibilities in the hospital ED.
- **Professional Interpreters (PIs):** Interpreters, who are proficient in each of the available languages in the application, will be assigned to provide certified and official translations of all documents provided to patients. Their role is essential to guarantee that patients will be able to understand and engage in the trial.
- **Computer Scientist:** A data management professional with the appropriate experience will be recruited to design and create the anonymous database for the study.
- **Statistician:** An expert statistician will be engaged to perform the statistical analysis of the study. Their role is to extract significant findings from the data collected and to provide a detailed statistical report.
- **Other members:** Various support staff, including nursing assistants, admissions personnel, orderlies and professionals required for complementary testing, contribute to the successful execution of the study protocol.

10.2. STUDY STAGES

STAGE 1: BIBLIOGRAPHIC RESEARCH AND STUDY DESIGN (November 2023 – January 2023)

1. **Bibliographic research** (November - December 2023): A detailed bibliographic search and literature review was performed to obtain evidence regarding the current state of the field of study, which contributed to the identification of the principal areas to be addressed.
2. **Protocol elaboration** (December 2023 - January 2024): Following the definition of the objectives, the study protocol has been meticulously developed. In this document, the hypothesis, objectives, variables, type of study, population criteria (inclusion and exclusion), sample size and collection methods are described. In addition, details of data collection, work plan, timeline, budget and feasibility of the trial are exhaustively explained.

STAGE 2: ETHICAL APPROVAL (February - April 2024)

3. **Ethical evaluation and approval:** The protocol will be presented to the CEIC at the Institut d'Assistència Sanitària de Girona to guarantee compliance with fundamental ethical principles. Any concerns identified by the CEIC will be addressed and incorporated in the protocol.

STAGE 3: COORDINATION AND HEALTH PROFESSIONALS TRAINING (May - July 2024)

4. **Centre coordination** (May 2024): Once CEIC approval has been obtained, an information session will be organised for the participating centres to explain the study.

The SI group will be established. Along with the IM, they will define and review their roles during the study.

In addition, an online meeting will be arranged with each hospital's and service's lead personnel to explain the study protocol and timeline. Possible doubts or problems will be clarified at this point.

5. **Research Team Formation** (June - July 2024): Professional training sessions will be conducted via telematic meetings to ensure a standardised understanding of the protocol and procedures for the participating nurses and physicians, in order to promote homogeneity in data collection.

- 6. Sworn translation of documents** (June - July 2024): Certified translations of the different documentation of the study will be performed to guarantee accuracy. Documents will include the patients' information paper and satisfaction questionnaire, along with the IC and its revocation documents.

All these translated documents will be distributed to the study health centres.

STAGE 4: RECRUITMENT OF PARTICIPANTS, INTERVENTION, AND DATA COLLECTION (August 2024)

- 7. Sample recruitment:** The study will follow a non-probabilistic consecutive sampling method. Accordingly, migrants with a LB attending any of the study hospitals' EDs and meeting the inclusion and non-exclusion criteria will be invited to the study.

At triage, information documents will be provided, followed by the IC document to be signed.

- 8. Intervention:** After ensuring that the information papers and IC have been understood and signed, they will be enrolled in the study and randomised to one of the two groups.

Medical consultations will be performed as routine. Patients in group 1 will have the support of the application UDS, while those in group 2 will have use of other resources.

- 9. Follow-up and data collection:** Patient data and satisfaction questionnaires will be deposited in the admissions counter's box for subsequent collection and digitalisation by a SI from the respective centre.

The physicians will complete the satisfaction questionnaires online, which will be sent directly to the database.

The Santa Caterina Hospital's ED receives an average of 100 patients per day, including an estimated of 36 patients with the possibility of enrolling in the study. Meanwhile, at CUAP Güell, 22 patients out of the 60 attended daily are estimated to meet the eligibility criteria for the study. This indicates that the required sample size of 180 will be reached in a period of 4 days, to which a 3 days margin will be added.

If no exceptional situations are encountered, this phase can be completed in a period of 7 days.

STAGE 5: DATA ANALYSIS AND INTERPRETATION (September - December 2024)

- 10. Creation of the database** (September 2024): Expert statisticians will perform the required descriptive, bivariate and multivariate analyses of the anonymised data. A final report of the results will be prepared.

- 11. Statistical analysis** (October - November 2024): Carried out by an expert statistician, who will analyse the data collected by means of descriptive, bivariate and multivariate analysis. Subsequently, a report will be produced with the data obtained.

- 12. Results and conclusions** (December 2024): The research team will analyse, discuss and interpret the results from the statistician's report, ultimately drawing the conclusions of the trial.

STAGE 6: ARTICLE ELABORATION, PUBLICATION AND RESULTS DIVULGATION (January - April 2025)

- 13. Article writing, revision and publication** (January - February 2025): The MI will write the final article. This will be reviewed and edited by English corrector before being published.

- 14. Dissemination** (March - April 2025): The study's results will be published as a journal article and presented to the SoCMUE and the Sociedad Española de Medicina de Urgencias y Emergencias (SEMES). Additionally, the outcomes will be also presented during national and international congresses.

10.3. CHRONOGRAM

DATE	2023		2024												2025			
	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR
STAGE 1: BIBLIOGRAPHIC RESEARCH AND STUDY DESIGN																		
1. Bibliographic research																		
2. Protocol elaboration																		
STAGE 2: Ethical approval																		
3. CEIC approval																		
STAGE 3: Coordination and health professionals training																		
4. Centre coordination																		
5. Research Team Formation																		
6. Sworn translation																		
STAGE 4: Recruitment of participants, intervention, and data collection																		
7. Sample recruitment																		
8. Intervention																		
9. Follow-up and data collection																		
STAGE 5: Data analysis and interpretation																		
10. Creation of the database																		
11. Statistical analysis																		
12. Results and conclusions																		
STAGE 6: Article elaboration, publication and results divulgation																		
13. Article writing, revision and publication																		
14. Dissemination																		

Table 3. Chronogram of the study.

11. BUDGET

Personal expenses

- **Research team and staff:** The members of the research team and the emergency staff required to successfully conduct the consultations and the study will not receive any additional compensation. The study activities will be performed during their working hours at no extra cost. The following staff will be involved in the study: MI, SI, ED nurses and physicians, nursing assistants, admissions staff, orderlies, and professionals needed for complementary testing.
- **Coordinating and briefing meetings** will be conducted online for each group of professionals to focus on relevant information and address questions. As they will be done virtually, no additional costs will be associated.
- **Formation of emergency nurses:** An approximately 2-hour session will be provided for all emergency nurses who will be assigned to triage during their shift. The group will be divided into three smaller work groups to learn the necessary skills to identify patient inclusion and exclusion criteria. The instructor will be paid €30/hour and as the sessions will be online, there are no transportation costs.
- **Sessions to instruct doctors** on how to use the Universal Doctor Speaker® and correctly collect patient data for the study. These sessions will be conducted online in small groups, consisting in 6 sessions at various hours that will have an estimated duration of 1:30h. They will be led by specialised instructors and as there is no need to cover transport, a budget of 270€ is estimated for their implementation.

Subcontracted services

- **Sworn Interpreters:** The price per document for certified translation is €60, resulting in an estimated total cost of €2.520. We require translations of three documents - Patient Information documents, IC and Revocation, Patient Satisfaction Questionnaire - in 14 languages (the application covers 17 languages, but Catalan, Spanish and English are not included for translation).
- The **computer scientist** is responsible for creating the database, expected to require 10 hours. In addition, a meeting will be arranged with the MI and SIs, estimated to take 2 hours, to clarify the operation and data process before initiating meetings with the centres. The computer scientist will work a total of 12 hours at €30/hour, resulting in a total cost of €360.

- **Statistician:** Database analysis, including development and drafting of the final report, is calculated to require 50 hours at a rate of €40/hour, making a final cost of €2.000.
- Due to the fact that this is a low-intervention study, the **liability insurance** will be zero since the procedures that will be performed in the study do not differ in terms of patient risks from the usual ones.

Material costs

- **Printing** of the documents will be required, such as information pages for patients and professionals (4 pages each), IC and - if necessary - its revocation (2 pages), and PSQs (1 page). The cost of black and white copying will be €0,03/page, totalling €60.
- **Pens:** A box of pens will be provided to each hospital for borrowing by patients who need them to fill in the forms. This estimated cost for them will approximately €14.
- **Tablets:** Four tablets will be bought to install and run the UDS during the consultations. Each hospital will receive two devices. It is expected that the total cost will be €400.

Publication and dissemination costs

- **Linguistic correction:** To avoid any errors, the services of a linguistic editor will be solicited prior to submission of the article to the publication. A budget of €200 is reserved for this service.
- **Publication fees:** The principal findings will be published in two journal papers, preferably one national and one international. A publication charge of €1.500 is budgeted for each article.
- **National and international congress:** For dissemination of the results, the MI will present the results of the study at a national and an international congress at a cost of €750 and €1.500 for each application, correspondingly. The travel, accommodation and subsistence costs are also covered (an additional €250 and €500 respectively).

The sum of the expenses for the clinical trial, as estimated in the budget, would be a total of €13.504 and would cover the different stages of the research. A detailed summary of these costs is provided in Table 4 below.

	TYPE OF COST	UNIT COST	HOURS/UNIT	TOTAL
Personal expenses	Research team	-	-	€0
	Coordinating and briefing meetings	-	-	€0
	Formation of emergency nurses	€30/h	6	€ 180
	Instruction for doctors	€30/h	9	€270
Subcontracted services	Sworn Interpreters	€60/document	42	€2.520
	Computer scientist	€30/h	12	€360
	Statistical analysis	€40/h	50	€2.000
	Liability insurance	-	-	€0
Materials costs	Printing	€0,03/page (black and white)	≈2,000	€60
	Pens	€7/box	2	€14
	Tablets	€100/devices	4	€400
Publication and dissemination costs	Linguistic correction	€200/article	1	€200
	Article publication fees	€2.000/publication	2	€4.000
	National congress	€1.000/attendant	1	€1.000
	International congress	€2.500/attendant	1	€2.500
TOTAL				€ 13.504

Table 4. Budget summary for the study

12. FEASIBILITY

This multi-centre clinical trial is being implemented strategically in two health centres in the Salt region, considering their extensive experience in addressing the needs of the continuously growing immigrant population over the past decades. The choice of these centres also ensures rapid recruitment of the study's required sample size of 180 patients, estimating the entire study to take around **one and a half years to complete**.

Recognising the dynamic nature of EDs, characterised by the rotation of healthcare professionals and care unit staff on each shift, there is a requirement to ensure a standardised approach to the procedures and actions associated with the study. This will be reinforced by the implementation of **training for both nurses and physicians** to encourage a consistent and cohesive process across the trial period. Moreover, to ensure higher data quality, we will hire a **computer scientist** to head data management as well as a **statistician** to conduct rigorous statistical analyses.

To achieve the study's objectives, no additional tests will be performed other than those routinely performed based on the diagnostic suspicion of each patient in the ED. This design ensures that there is **no additional risk to patients participating** in the study compared to a regular ED visit.

The budget for conducting the research is structured to be **realistic and achievable**. Through careful management of costs such as staff training, data management and statistical analysis, the study will ensure an efficient use of the financial resources.

In summary, considering the information presented, we believe that the trial is not just achievable, it is likely to provide benefits that exceed any potential complications. We consider that **the trial is realistically feasible** and meets the essential criteria for successful implementation.

13. STRENGTHS AND LIMITATIONS OF THE STUDY

LIMITATIONS

The study may encounter **selection bias** because the patients who agree to participate may be significantly different from those who decline the invitation. Therefore, we will implement consistent recruitment strategies and emphasise to patients the voluntary nature of their participation in the study.

In Catalonia, there are **no official and validated questionnaires to assess doctors' difficulties and satisfaction** in communicating with patients who have a LB during their consultations. For this reason, a set of questions specifically focused on this issue has been developed and will be administered to the doctors participating in the study. The results will then allow the psychometric validation of this survey, so that it can be used in future studies.

The PSQ is susceptible to a significant measurement bias, which is **intercultural bias**. Patient satisfaction is influenced by each culture having different expectations and perceptions concerning their medical consultation. An attempt has been made to mitigate this effect through focusing the surveys on the evaluation of verbal communication between doctor and patient. In addition, the questionnaires will be translated by certified PIs to ensure that the meaning of the questions is not altered in any of the available languages.

Both questionnaires are subject to the **bias of honesty**; the reliability and veracity of the results depend on participants answering with complete honesty and sincerity. Anonymous surveys will be used and to participants will be guaranteed maximum confidentiality of their data throughout the study. Furthermore, participants will be encouraged to complete the questionnaire in a separate room without the presence of the doctor, in order to increase their privacy.

The Universal Doctor Speaker application is recommended by the authorities and covers a wide range of circumstances, however there are **certain functions that it cannot provide by the LTA**, such as voice recognition or text translation, among others. These are functions that could be proposed for implementation in the programme if the study results are positive and future integration of the application in consultations is considered.

The **absence of masking (open-label trial)** may lead to potential bias, such as bias due to deviation from the intended intervention, as neither the patient nor the attending professional can be blinded,

thus potential influencing on responses and behaviours. To reduce this effect in data analysis, the statistician will conduct the statistical analysis in a blinded setting.

Conducting the study in **two different healthcare centres**, despite having similar functions and organisation, may introduce variability in patient experience and satisfaction due to differences in infrastructure, professional attitudes or workflow. Pre-study training sessions will aim to homogenise and standardise procedures across all centres to mitigate this effect. In addition, all materials required for the study will be provided equally in both centres.

The clinical trial is focused on **short-term outcomes** such as patients' and professionals' satisfaction, as well as the impact of the LTA on the length of stay in the ED, without looking into long-term impacts. If the study results are positive, future research should explore longer-term effects of the application, such as improving adherence to treatment, reducing the number of visits for the same problem, and other effects.

STRENGTHS

No similar studies have been conducted in Spain to evaluate the effectiveness of resources in overcoming LBs when interpreters or intercultural mediators are inaccessible. Even where they are available, there has been **no evaluation of whether there are more effective and suitable options** for health professionals in the dynamic and high-pressure environment of the ED.

The **frequent rotation of emergency workers** and their alternating positions on each shift is a determining element in ensuring the validity and fidelity of our results. The regular changing of the triage nurses, at least three per day, minimises the risk of selection bias. Besides, having several doctors each day attending patients with the triage level under study will provide a variety of opinions and perceptions.

A further advantage of this study is that it has been designed to be **low-cost and to be carried out in a brief period of time**, facilitating its implementation in accordance with the protocol. The importance of cost-effectiveness and a short-term study is in line with practical considerations for a successful execution.

The study aims to provide the **perspectives of the non-Catalan and non-Spanish-speaking immigrant population about emergency consultations**, focusing in particular on the communication established with doctors. Official surveys conducted in Catalonia have not explored this aspect, because the questionnaires have generally been written in Catalan and Spanish.

The study will collect and **publish the satisfaction of healthcare professionals** during consultations where LBs are encountered. The majority of articles and hospital surveys focus mainly on user satisfaction and perception, overlooking the point of view of healthcare professionals. In addition, the training sessions and the study itself aim to increase the **awareness among healthcare professionals of the resources available** for effective communication when LBs are experienced.

And finally, if the study shows positive results, it could serve as a **foundation for future research**. This may include the evaluation of the use of LTA in other intra and extra hospital facilities, as well as the development of more extensive and competitive programmes. The potential positive outcomes could lead to further progress in addressing LBs in healthcare.

14. IMPACT ON HEALTH CARE SYSTEM

The principal expected impact of performing this study is the implementation of a resource that enables a better communication, provides a higher level of confidence and demonstrates effectiveness for non-Catalan and non-Spanish speaking immigrant patients attending EDs.

An improved understanding by healthcare professionals of the reason for consultation and the patient's current condition are expected to lead to the performance only the necessary and relevant tests as well as to decrease the patient's time spent in the service. Additionally, providing a clearly understandable explanation of the diagnosis and describing the treatment plan in detail will reduce patients' doubts, increase adherence to treatment, and ultimately improve patient's satisfaction.

The study aims to provide an opportunity for patients to express themselves and communicate during consultations without the need for a third person to intervene or represent a notable disruption to the usual operation of the service. Furthermore, it provides a more accessible and convenient resource for professionals to routinely incorporate into their consultations.

As previously mentioned, if the results are significantly positive, the implementation of the selected LTA or a similar programme could be considered for various situations in the ED and other hospital services, as well as in extra-hospital services such as ambulances, home care, and social services.

The prospect of developing a new LTA to expand the capabilities of the Universal Doctor Speaker® could also be explored, such as integrating voice recognition, suggestions for further questions depending on the answers given, the addition of more languages, or the incorporation of graphics or video, amongst other possibilities. The study has the potential to open the way for further applications and advances in language translation assistance systems.

Let's break down language barriers for better healthcare!

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16. ANNEXES

ANNEX 1 - Participant information document (English)

PARTICIPANT INFORMATION DOCUMENT

STUDY: Breaking down language barriers for better healthcare: Implementing a specialised translation application in the emergency department to improve care for patients with language barriers.

We address you to provide information about a study we are conducting, and we would like to invite you to participate. This study aims to assess satisfaction regarding doctor-patient communication in emergency consultations where a language barrier is present.

The study has been approved by the Clinical Research Ethics Committee and complies with current legislation and the principles of the Declaration of Helsinki.

Our intention is to ensure you receive adequate and necessary information so that you can freely decide whether or not to participate. Therefore, we kindly ask you to carefully read the following information sheet and consult with us to clarify any doubts that may arise.

Voluntary Participation

Your participation in this study is entirely voluntary, and you can change your decision at any time. If you choose to withdraw, you can revoke your informed consent without justification and without any consequences or harm to your healthcare.

STUDY DESCRIPTION

Relevance of the Study

Smooth communication between the doctor and the patient is fundamental for the success of any medical consultation. The language barrier, where the doctor and patient do not share a common language, hinders effective communication, creating what is known as a language barrier.

It has been studied that the language barrier has negative repercussions for both the patient and the healthcare institution, leading to increased patient dissatisfaction, unnecessary additional tests, and prolonged patient stay in the service.

Due to the limited information on the effectiveness of available resources to overcome the language barrier, this study aims to evaluate the implementation of a translation application in emergency consultations. This application is called Universal Doctor Speaker® and aims to facilitate the communication and create a positive experience for all parties involved.

Study Objectives

The main objective is to evaluate the satisfaction of patients who do not speak Catalan or Spanish regarding the communication established with their emergency doctor, depending on whether a translator assistance was used in the consultation or not.

Secondary objectives include assessing satisfaction from the perspective of the consulting professional, with or without the tool, and calculating the time patients spend in emergencies depending on the resource used to overcome the language barrier.

Characteristics required of study participants

Participants must be patients over 18 years old with limited knowledge of Catalan and Spanish, preventing effective communication in these languages. Additionally, their triage level should be III or higher (indicating situations without a probability of vital risk). Accompanying individuals should also face difficulties in maintaining a fluent conversation in both languages.

Participants must understand and sign a prior informed consent to participate in the study.

What your participation in the study involves

If you decide to participate and meet all the defined criteria, you will be assigned to one of the following groups during the consultation:

- Patients using UniversalDoctor Speaker® to facilitate communication.
- Patients using any other resource decided by the doctor to overcome the language barrier.

The consultation will proceed normally with one of the chosen resources. After its completion, along with the doctor, you will have to complete a form with some of your data. When leaving the room, you will be provided with a questionnaire to assess your experience in the consultation, focusing on the communication established with the doctor based on the resource used. You will need to submit the questionnaire along with a data form at the admissions desk.

With the collected data, an anonymous database will be generated, allowing for the study's objectives to be examined and conclusions drawn.

BENEFITS AND RISKS

What benefits will I get from my participation in the study?

Participation in the study will contribute to a better understanding of the opinions and experiences of immigrants in emergency consultations. It will serve as a foundation for improving the experience and healthcare of individuals facing difficulties expressing themselves in Catalan and Spanish.

What risks do I assume by participating in the study?

The developed tool is just an additional resource available to the professional during the consultation, posing no added risk beyond regular practices.

Is there any financial reward?

Neither you nor the research team members will receive financial compensation for participating in this study, and there will be no additional economic expenses.

PROTECTION OF PERSONAL DATA AND CONFIDENTIALITY

How is the confidentiality and protection of your data guaranteed?

Only necessary data for the study will be collected, and only study members will have access to them. All data and information will be used solely for the purpose of conducting the study. Professionals collecting and analyzing data will preserve the anonymity and privacy of patients, and they will sign a confidentiality agreement.

The entire process of data collection and analysis will comply with Regulation (EU) 2016/679 of the European Parliament and the Council, of April 27, 2016, regarding the protection of individuals concerning the processing of personal data and the free movement of such data (GDPR), and Organic Law 3/2018, on Data Protection and Guarantee of Digital Rights. Therefore, you have the right to exercise your rights of access, rectification, deletion, opposition, treatment limitation, and data portability (GDPR) by contacting the principal investigator of the project (main.invetigator@ais.cat).

By signing this document, you expressly consent to the processing of your data for research purposes within the framework of this project, in accordance with Article 6.1.a, 9.1.a of the GDPR. Satisfaction questionnaires and personal data sheets will be kept by the researchers for five years and then destroyed. You are informed of your right to withdraw consent for the processing of this data at any

time by email to main.invetigator@ais.cat, as well as your right to file a complaint with the Catalan Data Protection Authority against any actions by the Data Controller that you consider violate your rights.

DISSEMINATION OF RESULTS

Use of Study Results

There are no plans to disclose individual data beyond what is legally required. Once conclusions are drawn, the results will be published in scientific journals so that other healthcare centers can benefit from and implement the knowledge generated in the study. The anonymity of participants will be respected at all times.

QUESTIONS

Who should I contact if I have any questions or problems?

If you need to contact professionals from the research team at your hospital, you can send an email to this address main.invetigator@ais.cat or call 972 72 72 72 for prompt assistance.

We will ask for your authorization, and you can keep a copy of this document.

Thank you very much for your time and dedication.

Participant's Signature

Researcher's Signature

Name:
Date:

Name:
Date:

ANNEX 2 - Informed consent and Revocation of consent (English)

INFORMED CONSENT FOR PARTICIPANTS

STUDY: Breaking down language barriers for better healthcare: Implementing a specialised translation application in the emergency department to improve care for patients with language barriers.

I, (full name) _____, of legal age, with ID _____, declare that:

- I have read the informational sheet provided to me.
- I have been able to satisfactorily resolve any doubts that have arisen.
- I have received sufficient information about the study.
- I have spoken with (name of the researcher): -----

I also declare that I understand that my participation is entirely voluntary. I have the right to withdraw from the study whenever I want and at any time, revoking this consent, without any negative impact on my healthcare or my person.

In accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, regarding the protection of individuals concerning the processing of personal data, and Organic Law 3/2028, on Data Protection and guarantee of digital rights, I declare that I have been informed of:

- The existence of a database in which my personal data will be included.
- The purpose of its collection and the recipients of the information.
- The process of encoding the data.
- The availability of exercising the rights of access, rectification, cancellation, and opposition by writing to the owner of the database.

I freely give my consent to participate in the study ***“Breaking down language barriers for better healthcare: Implementing a specialised translation application in the emergency department to improve care for patients with language barriers.”***

Place, date/month/year:

Participant's signature

Researcher's signature

Name:

Name:

Date:

Date:

REVOCACTION OF CONSENT

I, (name and surnames) _____ with
ID number _____, declare that I revoke the previously signed informed consent to
participate in the study "*Implementing a specialised translation application in the emergency
department to improve care for patients with language barriers.*".

Place, date/month/year:

Patient's Signature

ANNEX 3 - Languages available at Universal Doctor Speaker®

AVAILABLE LANGUAGES AT Universal Doctor Speaker®

The language translation assistance app which will be used in the consultations is Universal Doctor Speaker® and is only available in a number of languages. If you are fluent in any of the following languages, please indicate to the nurse in front of you on the list below the language.

Thank you very much!

- Arabic (العربية)
- English
- French (Français)
- German (Deutsch)
- Italian (Italiano)
- Japanese (日本語)
- Mandarin Chinese Simplified (简体中文)
- Moroccan Arabic (العربية المغربية)
- Norwegian (Norsk)
- Polish (Polski)
- Portuguese (Português)
- Brazilian Portuguese (Português Brasileiro)
- Romanian (Română)
- Russian (Русский)
- Somali (Soomaali)

ANNEX 4 - Professional information document (Spanish)

DOCUMENTO DE INFORMACIÓN AL PROFESIONAL

ESTUDIO: Breaking down language barriers for better healthcare: Implementing a specialised translation application in the emergency department to improve care for patients with language barriers.

Nos dirigimos a usted porque nos gustaría informarle sobre un estudio que estamos realizando al que queremos invitarlo a participar. Este estudio pretende evaluar la satisfacción respecto a la comunicación médico-paciente establecida en consultas de urgencias donde se presente una barrera idiomática.

El estudio ha sido aprobado por el Comité Ético de Investigación Clínica y cumple con la legislación vigente y con los principios de la declaración de Helsinki.

Nuestra intención es que reciba la información adecuada y necesaria para que pueda decidir libremente si quiere o no participar. Por eso le rogamos que lea con atención la siguiente hoja informativa, y nos consulte para esclarecer las dudas que le puedan surgir.

Participación voluntaria

Su participación en este estudio es totalmente voluntaria y puede cambiar su decisión en cualquier momento. Si se da el caso, tendrá que revocar el consentimiento informado, sin necesidad de justificación y sin ninguna consecuencia o perjuicio en su asistencia sanitaria.

DESCRIPCIÓN DEL ESTUDIO

La relevancia de este estudio

Una comunicación fluida entre médico y paciente es la base del éxito de cualquier consulta médica. El hecho de que el médico y el paciente no compartan ningún idioma en el cual los dos tengan un buen dominio, causa que no puedan entablar una buena comunicación, y se establece la denominada barrera idiomática.

Ha sido estudiado y observado que la barrera idiomática comporta repercusiones negativas tanto para el paciente como para la institución sanitaria. Entre las cuales destaca, mayor insatisfacción del paciente, realización de pruebas complementarias innecesarias, prolongación de la estancia en el

servicio del paciente... En el caso de urgencias, estas se ven acentuadas al encontrarse con dificultades para contar con la ayuda de los servicios de las intérpretes interculturales, referentes para abordar la barrera idiomática en otros servicios.

Debido a la escasa información sobre la efectividad de los recursos disponibles para superar la barrera lingüística, este estudio busca evaluar la implementación de una aplicación de traducción en las consultas de urgencias. Esta aplicación se llama Universal Doctor Speaker®, y tiene el objetivo de facilitar la comunicación y crear una experiencia positiva por todas las partes implicadas.

Objetivos del estudio

El objetivo principal de este estudio es evaluar la satisfacción de los pacientes que no dominan la lengua catalana ni castellana respecto a la comunicación establecida con su médico de urgencias, según si en la consulta se ha usado o no un asistente de traducción.

Otros objetivos secundarios son evaluar la satisfacción respecto a la comunicación establecida desde el punto de vista del profesional que realiza la consulta, con o sin la herramienta. Y calcular el tiempo que los pacientes están en urgencias dependiendo el recurso usado para superar la barrera idiomática.

Características que deben tener los/las participantes del estudio

Pacientes, mayores de 18 años, que presenten un conocimiento limitado de Catalan y Castellano no permitiéndoles una buena comunicación en estas lenguas, y en triage su nivel de prioridad sea III o mayor (indicando situaciones sin probabilidad de riesgo vital). Así mismo, sus acompañantes también muestran dificultades para mantener una conversación fluida en los dos idiomas.

Deberán entender y firmar un consentimiento informado previamente para poder participar en el estudio.

En qué consiste su participación en el estudio

El paciente que decida participar en del estudio y cumpla todos los criterios decididos, en el momento de la consulta se le asignara en uno de los dos siguientes grupos:

- Pacientes que como herramienta para facilitar la comunicación usarán Universal Doctor Speaker®
- Pacientes que cualquier otro recurso decidido por el médico será usado para sobrepasar la barrera idiomática

Respetando el grupo que le haya sido asignado, el médico escogerá un recurso para superar la barrera lingüística y lo tendrá que usar a lo largo de toda la consulta. Una vez terminada, al paciente se le

facilitará un cuestionario en papel y se le indicará que tiene que ir al tablero de admisiones. Mientras, que al profesional le aparecerá en pantalla otro cuestionario centrado en valorar la comunicación establecida con el paciente según el recurso usado.

El cuestionario se enviará directamente al grupo encargado de la realización de la base de datos. Con el resto de los datos recogidos, se generará una base de datos anónima, que permitirá estudiar y sacar conclusiones respecto a los objetivos del estudio.

BENEFICIOS Y RIESGOS

¿Qué beneficios obtendré de mi participación en el estudio?

Su participación en el estudio ayudará a obtener un conocimiento mayor sobre la opinión y vivencias de las personas inmigrantes en las consultas de urgencias. Servirá de base para mejorar la experiencia y la asistencia sanitaria de todas aquellas personas que tengan dificultades para expresarse en catalán y castellano.

¿Qué riesgos asumo al participar en el estudio?

La herramienta desarrollada es solo un recurso más que tendrá cómo profesional a la hora de realizar la consulta, haciendo que no suponga ningún riesgo añadido al de las prácticas habituales.

¿Hay alguna recompensa económica?

Ni usted ni los miembros del equipo de investigación recibirán recompensa económica por participar en este estudio, pero tampoco tendrán ningún gasto económico adicional.

PROTECCIÓN DE DATOS PERSONALES Y CONFIDENCIALIDAD

¿Cómo se garantiza la confidencialidad y la protección de sus datos?

Solamente se recogerán aquellos datos necesarios para el estudio y únicamente los miembros que formen parte del estudio tendrán acceso a ellos. Todos los datos e información se utilizarán con el único fin de realizar el estudio.

Además, los profesionales que recojan y analicen los datos preservarán el anonimato y la privacidad de los pacientes, y deberán firmar un acuerdo de confidencialidad.

Todo el proceso de recogida y análisis de los datos se realizará en cumplimiento del Reglamento (UE) 2016/679 del Parlamento Europeo y del Consejo, de 27 de abril de 2016, relativo a la protección de las personas físicas en relación al tratamiento de datos personales y a la libre circulación de estos datos (RGPD), y la Ley Orgánica 3/2028, de Protección de Datos y garantía de los derechos digitales, y por

ello le comunicamos que usted podrá ejercer sus derechos de acceso, rectificación, supresión, oposición, limitación del tratamiento y portabilidad de datos (LOPD-GDD) contactando directamente con la investigadora principal del proyecto (aim.investigator@ias.cat).

Con la firma de este documento usted dará su consentimiento de forma expresa con el fin de que sus datos sean tratados con finalidades de investigación en el marco de este proyecto, de conformidad con el artículo 6.1.a, 9.1.a del RGPD. Los cuestionarios de satisfacción y las fichas de datos personales serán guardadas por las investigadoras durante cinco años y después destruidas.

Le informamos de su derecho a retirar el consentimiento para el tratamiento de estos datos en cualquier momento mediante la dirección de correo electrónico aim.investigator@ais.cat, así como de su derecho a presentar una reclamación delante de la Autoridad Catalana de Protección de Datos frente a cualquier actuación del Responsable del Tratamiento que considere que vulnera sus derechos.

DIFUSIÓN DE LOS RESULTADOS

¿Que se hará con los resultados obtenidos del estudio?

No sé prevén comunicaciones de datos de forma individual, más allá de las previstas legalmente.

Una vez elaboradas las conclusiones, se publicarán los resultados en revistas científicas. con el fin de que otros centros asistenciales puedan beneficiarse e implementar los conocimientos generados en el estudio. En todo momento se respetará el anonimato de los participantes.

DUDAS

¿Con quién debo contactar en caso de duda o problema?

Si necesita contactar con profesionales del equipo de investigación de su hospital, puede escribir un correo electrónico a esta dirección (aim.investigator@ais.cat) o llamar por teléfono al (972 72 72 72) y le atenderemos lo antes posible.

Le pediremos su autorización y podrá quedarse con una copia del presente documento.

Muchas gracias por su tiempo y su dedicación.

Signatura del/la profesional

Signatura del/la investigador/a

Nombre:

Nombre:

Fecha:

Fecha:

ANNEX 5 - Informed consent and revocation (Spanish)

CONSENTIMIENTO INFORMADO PARTICIPANTES

ESTUDIO: Breaking down language barriers for better healthcare: Implementing a specialised translation application in the emergency department to improve care for patients with language barriers.

Yo, (nombre y apellidos) _____, mayor de edad, con DNI _____, declaro que:

- He leído el documento informativo que se me ha sido entregado
- He podido resolver las dudas que me han surgido de forma satisfactoria
- He recibido información suficiente sobre el estudio
- He hablado con (nombre y apellidos de el/la investigador/a): _____

Declaró también que comprendo que mi participación es totalmente voluntaria. Que tengo derecho a retirarme del estudio cuando quiera y en cualquier momento, revocando el presente consentimiento, sin que este hecho repercuta negativamente en mi asistencia sanitaria ni en mi persona.

Conforme lo que establece el Reglamento (UE) 2016/679 del Parlamento Europeo y del Consejo, de 27 de abril de 2016, relativo a la protección de las personas físicas en lo que respecta al tratamiento de datos personales y la Ley Orgánica 3/2028, de Protección de Datos y garantía de los derechos digitales, declaro haber estado informado de:

- La existencia de una base de datos en la que se incluirán mis datos de carácter personal
- De la finalidad de su recogida y de los destinatarios de la información
- Del proceso de codificación de los datos
- De la disponibilidad de ejercer los derechos de acceso, rectificación, cancelación y oposición dirigiéndome por escrito al titular de la base de datos

Doy libremente mi conformidad para participar en el estudio "***Breaking down language barriers for better healthcare: Implementing a specialised translation application in the emergency department to improve care for patients with language barriers.***"

Lugar, día/mes/año:

Signatura del/la profesional

Signatura del/la investigador/a

Nombre:

Nombre:

Fecha:

Fecha:

REVOCACIÓN DEL CONSENTIMIENTO

Yo, (nombre y apellidos) _____ con
DNI _____, declaro que revoco el consentimiento informado previamente firmado
para participar en el estudio "*Implementing a specialised translation application in the emergency
department to improve care for patients with language barriers.*"

Lugar, fecha/mes/año:

Firma del participante:

ANNEX 6 - Patient Satisfaction Questionnaire (English)

PATIENT SATISFACTION SURVEY

- 1) How would you rate your overall experience in communicating with the doctor during your emergency room visit?
 - 1) Very dissatisfied
 - 2) Dissatisfying
 - 3) Neutral
 - 4) Good
 - 5) Excellent

- 2) How would you evaluate the clarity of the communication achieved with the doctor during your emergency room visit?
 - 1) Very poor
 - 2) Not clear
 - 3) Neutral
 - 4) Good
 - 5) Very good

- 3) How challenging was it for you that the doctor understood your symptoms and needs during the consultation?
 - 1) Very difficult
 - 2) Difficult
 - 3) Neutral
 - 4) Easy
 - 5) Very easy

- 4) When leaving the consultation and receiving discharge, did you understand the doctor's explanations about your diagnosis and treatment?
 - 1) No, I didn't understand anything
 - 2) No, I understood very little
 - 3) Neutral
 - 4) Yes, I understood most of it
 - 5) Yes, I understood everything

- 5) How did you perceive the doctor's willingness to listen and communicate with you, despite language complications?
 - 1) Poor
 - 2) Neutral
 - 3) Good
 - 4) Very good
 - 5) Excellent

6) How do you think your privacy was respected during the consultation?

- 1) Very bad
- 2) Bad
- 3) Good
- 4) Very good
- 5) Excellent

7) If any resource was used to overcome the language barrier, did you notice any difference in the time the doctor spent with you and how comfortable you felt?

- 1) More time and discomfort
- 2) More time, but more comfortable
- 3) Same time and comfort
- 4) Less time with less comfort
- 5) Less time with more comfort

8) Would you recommend using the same resource in the emergency room to another person facing the language barrier?

- 1) Definitely no
- 2) Would not recommend
- 3) Neutral
- 4) Yes, in certain situations
- 5) Yes, definitely

9) If the UniversalDoctor Speaker® app was used in the consultation, do you think the app adapted to your specific needs for medical communication?

- 1) Did not adapt
- 2) Slightly adapted
- 3) Neutral
- 4) Adapted
- 5) Totally adaptable

ANNEX 7 - Data Collection Questionnaire (English)

DATA COLLECTION QUESTIONNAIRE

“Breaking down language barriers for better healthcare: Implementing a specialised translation application in the emergency department to improve care for patients with language barriers.”

ADMINISTRATIVE INFORMATION		
Date:	Centre:	
Name data collector:		
PARTICIPANT INFORMATION		
Patient identification:	Age:	Sex: <input type="checkbox"/> Female <input type="checkbox"/> Male
Nationality:	Time living in Catalonia:	
Education level: <input type="checkbox"/> Without studies <input type="checkbox"/> Primary qualification <input type="checkbox"/> Secondary qualification <input type="checkbox"/> Diploma <input type="checkbox"/> Degree <input type="checkbox"/> Post-graduate	Occupation: <input type="checkbox"/> Self-employed <input type="checkbox"/> Salaried worker <input type="checkbox"/> Pensioner <input type="checkbox"/> Student <input type="checkbox"/> Unemployed or looking for a job <input type="checkbox"/> Housewife <input type="checkbox"/> Other	Language proficiency <input type="checkbox"/> No proficiency <input type="checkbox"/> Elementary proficiency <input type="checkbox"/> Limited Working Proficiency <input type="checkbox"/> Professional Working Proficiency
CONSULTATION INFORMATION		
Reason of consulting:		
Level of pain on arrival		
Level of pain on discharge		

ANNEX 8 - Professional Satisfaction Questionnaire (Spanish)

ENCUESTA SATISFACCIÓN PERSONAL

¿Qué recurso ha usado principalmente para superar la barrera idiomática en esta consulta?

- Mediadora intercultural
- Traductor no específico de medicina (p.ej. google translate, traductor del softcatalà)
- Pedir la colaboración de otro profesional sanitario que sabía que conocía el idioma
- Aplicación de UniversalDoctor Speaker®
- Ninguno
- Otro recurso

1. ¿Cómo calificaría su experiencia general en la comunicación con pacientes con barrera idiomática durante las consultas?

1. Muy insatisfactoria
2. Insatisfactoria
3. Neutral
4. Satisfactoria
5. Muy satisfactoria

2. En caso de haber usado algún recurso, ¿cómo calificaría la eficacia y facilidad del recurso usado en la consulta?

1. Nada efectiva
2. Poco efectiva
3. Neutral
4. Efectivo
5. Muy efectivo

3. ¿Cómo evaluaría la claridad de la comunicación lograda durante la consulta?

1. Muy mala
2. Poco clara
3. Regular
4. Buena
5. Muy buena

4. ¿Cómo de complicado le resultó entender las necesidades y síntomas del paciente?

1. Muy difícil
2. Difícil
3. Neutral
4. Sencillo
5. Muy sencillo

5. **¿En qué medida pudo explicar de manera efectiva el diagnóstico y tratamiento al paciente?**
 1. Mal
 2. Regular
 3. Neutral
 4. Bien
 5. Perfecto

6. **Si uso algún recurso en la consulta para sobrepasar la barrera idiomática, ¿Percibió una mejora de la eficacia de la consulta en términos de tiempo y comprensión?**
 1. No, alargó el tiempo de consulta y tampoco mejoró la comunicación
 2. No, alargó el tiempo de consulta o no mejoró la comunicación
 3. Neutral
 4. Sí, en cierta medida
 5. Sí, considerablemente

7. **¿Se sentiría cómodo comunicándose continuamente con este mismo recurso con los pacientes que presenten barrera idiomática en futuras consultas?**
 1. Muy Incómodo
 2. Incómodo
 3. Neutral
 4. Cómodo
 5. Muy Cómodo

8. **Si ha usado UniversalDoctor Speaker®, ¿Recomendaría su uso para mejorar la comunicación con paciente de barrera idiomática?**
 1. Definitivamente No
 2. No lo Recomendaría
 3. Neutral
 4. Sí, en ciertas situaciones
 5. Sí, definitivamente