

IMPROVING CLINICAL COMMUNICATION: A QUALITATIVE STUDY ON THE INFORMED CONSENT

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Abstract: *In the context of the Patient-Centred Care paradigm (Epstein et al., 2005; Suojanen et al., 2012) and the shift toward the psychobiological model (Dean & Street, 2015; Muñoz & García-Izquierdo, 2020), there is a growing demand for the patient to be an active agent in the management of their health. Clinical communication should be conveyed accurately and empathetically (Bellés Fortuño & García-Izquierdo, forthcoming), especially in complex legal genres such as the Informed Consent (IC). The research carried out by the Gantt research group up-to-date has revealed that there is no specific monitoring with the use of IC protocols in clinical practice. In this paper, we present the results of a qualitative pilot study with a group of practitioners from the Valencian Community (Spain). A focus group was conducted where the articulation of communication with patients was analyzed. The study tries to define the practical insights of using the IC to draw conclusions that can improve clinical communication. Results show that MPs generally consider that the IC process needs improvement, especially when considering closeness with patients to enhance communication.*

Key words: *clinical communication, patient-centred paradigm, textual genres, informed consent (IC), focus group.*

1. INTRODUCTION

In the context of the Patient-Centred Care paradigm (Epstein et al., 2005; Suojanen et al., 2012) and the shift toward the psychobiological model (Dean and Street, 2015; Muñoz & García-Izquierdo, 2020), there is a growing demand for the patient to be an active agent in the management of their health. In this context, clinical communication should be conveyed in an accurate and empathetic manner as therapeutic communication. Clinical communication should consider the context and the use of active listening (Bellés Fortuño & García-Izquierdo, forthcoming), especially in genres that are complex as to the information conveyed and the legal commitment, such as the Informed Consent (henceforth IC). This paper analyzes clinical communication by identifying practices during the IC process (including the written document). Health professionals' practices have been observed to detect strengths and weaknesses that must be addressed to improve clinical communication and patient and professional competences. Undeniably, the clinical setting has significantly changed with digital advances and technological tools. We have witnessed a subtle and abrupt need to do so due to the offspring of the COVID-19 pandemic. Nations currently suffer a substantial economic and social impact that affects health systems worldwide (United Nations, 2020). Telephone or online consultations are now much more regular than before the pandemic; patients are asked to develop their digital competences to deal with health administrations, bringing on the profile of a hyper-informed and empowered patient. In this transforming setting, clinical communication urges to be even more therapeutic. Aspects such as active listening, empathic communication, and management of emotions should not be left aside in every communicative event in the health setting (Bullington et al., 2019; Bellés Fortuño & García-Izquierdo, forthcoming).

With this post-pandemic scenario where the COVID-19 virus threatens to coexist with humans and positions National Health systems worldwide in the spotlight of citizenship, it is reasonable to smooth the relationship between patients and health professionals by improving clinical communication. The communicative acts between health professionals and patients and the textual genres they have to exchange during medical intercourse are several. However, the general objective here is to analyze and focus on the IC, a genre that health professionals and patients exchange prior to any medical interventions that may imply any risk to the patient's health or state of mind. Problems of IC comprehensibility may generally occur on the side of the patients since the IC genre includes

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medical but also legal information and terminology. Usually, the IC becomes a document that protects health professionals legally rather than an understandable and communicative text for the patient (Ay & Doğan, 2021; Matic et al., 2021).

According to Bossert & Strecht (2017), it is necessary to clarify the concepts of 'subjective' vs. 'objective' understanding and general understandability:

The comparison of different studies assessing understanding requires a common notion of what understanding entails and the application of comparable methods. In a systematic review of studies measuring understanding, Sand et al. (2010) show that several distinct concepts are covered by the term 'understanding.' Despite their varying conceptualizations, all the studies reviewed by Sand et al. (2010) aim to measure understanding objectively, i.e., by testing participants' knowledge or memory of certain facts. These studies do not generally evaluate how well the participants (subjectively) felt to have understood the IC document. For valid IC, however, IC documents should address prospective research participants' needs and demands. Therefore, to improve IC documents, it can be helpful first to identify text passages that are intrinsically hard to understand. Thus, it is also important to assess readers' own perception of the documents, e.g., whether they feel that they (subjectively) understood the given information and whether this information is adequate to come to an autonomous decision on their participation. (Bossert & Strecht 2017: 2)

Although the opinion of readers/patients needs to be considered, and as such, it has been addressed in previous research we have conducted (García-Izquierdo & Montalt, 2016; Muñoz & García-Izquierdo, 2020), in this study, a medical practitioner focus group (7 participants) has been gathered as the tool for analysis to resolve the following research questions (RQs): a) RQ1: Do medical practitioners see the need to improve the IC text to be more comprehensible to patients? and above all, b) RQ2: How can clinical communication improve in doctor-patient intercourse, according to physicians?

The present paper will first approach the IC genre and its functionality. Then, taking the focus group methodology as the basis of our research, we will present how a focus group of practitioners is exposed to a guided session to gather information about their views, usefulness, and insights about the improvements (if any) of the IC genre. The final section will present and discuss the most highlighting results from the focus group sessions.

1.1. Improving Clinical Communication: the Informed Consent (IC)

Care has been considered a secondary or accessory asset in healthcare. In contrast to this, Montalt and García-Izquierdo (2016: 81) propose a view in which communication is understood as a primary process, since the way we communicate is totally related to the way we experience reality. In Graig's opinion:

Communication [...] is not a secondary phenomenon that can be explained by antecedent psychological, sociological, cultural, or economic factors; rather, communication itself is the primary, constitutive social process that explains all these other factors. (Graig 1999: 126)

In the last decade, the so-called Patient-Centered Care (PCC) —Epstein et al. 2005; Suojanen et al., 2012, García-Izquierdo and Montalt, 2013—has been developed in the field of healthcare, which emphasises the need to pay attention to individuality and empower patients to actively participate in their own therapeutic process, thus overcoming the paternalism that has traditionally dominated healthcare. Only if patients receive adequate information —in quantity and quality— will they be able to take co-responsibility and make appropriate decisions (Montalt and García-Izquierdo, 2016). Moreover, the democratisation of access to information has increased the need to write texts that facilitate the transfer of medical knowledge to a broad, non-specialised and heterogeneous public (Muñoz-Miquel, 2012).

In this sense, as seen in the introductory section, the concept of comprehensibility plays a fundamental role, which has to do with conceptual complexity and how easy or difficult it is for readers to read and understand a text. It is a concept that includes not only formal aspects —such as linguistic, typographical and formatting issues— but also qualitative aspects, such as the quantity, relevance and organisation of information. Communication between doctors, patients and others needs to be brought closer together through strategies that improve both readability and clarity.

Many authors have highlighted the relevance of good communication in healthcare, both among healthcare professionals (Woods, D.M. et al., 2008) and between them and patients. There is also a consensus that communication skills are not innate and cannot always be improved simply through experience (Eklöf et al., 2014). Eklöf & Alborg (2016: 82) state that "good communication is an important resource in hospital units in terms of patient outcomes and safety as well as staff working environment and health."

In Brindley et al.'s opinion (2014):

What we say and how it is communicated can be a placebo (i.e., good communication can reduce pain and anxiety) or a nocebo (i.e., poor communication can increase pain and anxiety). [...] Communication is acute care medicine's most important nontechnical skill. It is how we exchange meaning, reduce complexity, address uncertainty, promote a shared mental model, inform, encourage, comfort, and challenge. Communication is central to the human experience of illness and includes the patient and doctor, the family or surrogate decision-makers, and the larger medical team (Brindley et al. 2014: 89-90).

In this sense, it is necessary to design new communicative tools for patients and professionals (Bellés-Fortuño & Molés-Cases, 2019). Communicative tools benefit healthcare staff and other professionals that develop their activity around clinical communication, such as translators, interpreters, or mediators in the healthcare setting (Montalt & Shuttleworth, 2012; García-Izquierdo & Montalt, 2013; Muñoz & García-Izquierdo, 2020). A healthcare setting should consider patients' perspectives, values, cultures, concerns, expectations, needs, feelings, ideas, or psychological contexts. In Hemberg and Sved's opinion (2021) not being understood and not understanding can be considered suffering related to care particularly in cases in which patients may feel unsafe, sad, ashamed, or alone. These researchers showed that language touches on a significant emotional dimension and helps preserve personal and linguistic identity. In Montalt & García-Izquierdo's opinion:

To achieve culturally competent systems and professionals, there is a need for healthcare education, which can be defined as the education that should be provided to health professionals, patients, and their relatives to help them live, both individually and socially, healthier lives by improving their physical, mental, emotional and social health. Increasing their knowledge about health, influencing their attitudes about caring for their well-being and ensuring that communication is carried out considering the cultural context in which healthcare education takes place are crucial aspects. (Montalt & García-Izquierdo 2022: 3)

Therefore, approaching the patient center stage in communication has been associated with positive outcomes such as patient satisfaction, higher treatment adherence rates, patient empowerment, and reduced health costs (Henriksen et al., 2008; Kristallidou, 2012). The IC is a complex textual genre that raises communication problems. Generally related to medical consultation, the IC genre is legally regulated and can have legal consequences. In addition, it is an evolving, written or spoken genre that may take multimodal shapes (Montalt & García-Izquierdo, 2016; Bellés-Fortuño, 2017). The IC could refer to a process with several steps: the patient receives oral input delivered by health professionals before signing a document in which she/he agrees to a particular intervention, treatment, or test.

Informed consent is formed by explaining in a detailed, understandable, and structured way why the intervention is needed, how the intervention will be done, the benefits that the person will receive from this intervention, and the possible harm that may occur due to the procedure, the process they will experience if they are not treated, and the alternative options in the treatment. The informed consent process is concluded by the patient's verbal and written notification of the decision (either approval or refusal) about the procedure, where the patient has read and understood the information presented in writing (World Medical Association, 2001).

There are many variations in the IC document; however, we could differentiate between two primary IC documents. a) a document for surgical interventions, and b) the IC for a clinical trial (Dankar et al., 2019). The study presented here focuses on the first type.

According to recent professional regulations, the IC should be explained orally, and when the risk is significant, written consent will be required. There are not, however, international ethical guidelines for clinical informed consent like those that have been developed to regulate human subject research (Glaser et al., 2020: 2)

In Spain, the legislation deals with the IC in several specific laws and regulations which consider its legal and ethical aspects (Article 10, Law 3/2001, May 28, *Regulating IC*; Law 41/2002, November 14, *Decalogue of Informed Consent*, 2016; the Central *Deontology Commission of the Collegiate Medical Organization*, development of Law 41/2002 on Patient Autonomy).

As highlighted by García-Izquierdo (2022), the elements that structure an IC and the formal requirements included vary from one jurisdiction to another. Still, according to legislation, every IC should consist of several premises to serve the purpose for which it is intended, such as the ones numbered below:

1. Every IC should have a voluntary character; it must clearly and repeatedly state that the person signing it is acting entirely voluntarily, without coercion or pressure, and he/she is fully aware of their actions. The possibility of revoking such a decision at any time and for any reason must also be stated under the same conditions.

2. The IC should include sufficient information in terms of *quantity* and *quality*. All information should be provided with enough detail and tone appropriate to the signatory's ability to read and understand it. The IC is a document that sets out the oral communication between the physician and the patient. All doubts should be clarified. The final decision must be valid and authentic. As with any legal process, it must be signed in the presence of a witness, and the relevant data must be verified to take effect. Any IC document must include a sworn declaration clause attesting to the signatory's signature and wishes.

Regardless of the premises listed above, there seem to be some problems that hinder IC comprehensibility in different languages and healthcare systems, and medical specialties (Glaser et al., 2020; Tazegül, 2022). Some of the most relevant problems can be read below:

- The administrative context where the IC is delivered needs more time for extensive document reading in hospitals and health care centres.
- Multimodality of the performative: The IC includes information from two complex fields (legal and medical).
- Multifunctionality of the written text: The IC should be expositive, argumentative, and performative.
- Variability of the document structure: A standardized IC document is lacking in the Spanish context. Instead, there are different types of ICs without a repetitive, regular arrangement.
- The functionality paradox: Does the IC offer the doctor or patient legal protection? (Bossert & Strecht, 2017).

So, as mentioned above, enhancing communication between health professionals and patients is needed to ensure comprehensibility. However, the research carried out by our research group has revealed that, despite the significant and undeniable progress made by the legislative and documentary standardization in Spain, the current situation shows no specific monitoring of the use of IC protocols in clinical practice.

In general terms, the *HIPOCRATES* research project carried out by our research group, GENTT, focuses on the Valencian context (public hospitals). It aims to understand the communication process of the IC in the doctor-patient relationship in the clinical context for improving medical attention and communication with patients from the doctor's perspective. In sum, the work done by GENTT during these years has aimed at: 1) Understanding how clinical communication with the patient is articulated in real hospital situations and 2) Defining how physicians perceive the IC process in their regular practice.

The research has been articulated at different stages and levels. Initially, a review of the state of the art of the IC as a process was addressed. Both quantitative and qualitative analyses have taken place using methodological tools: a quantitative analysis using corpora and different metrics for improving textual aspects of the IC has been studied. Later, the design and analysis of focus groups, interviews, and surveys with health care professionals (MP's and nurses), patients, and patient associations were included. Finally, some roleplay communication models have been produced to generate later audiovisual materials that can be used for pedagogical outcomes in clinical communication training. The general aim was to obtain information about improving the IC process.

In this paper, we present the results obtained from one of the qualitative studies, a focus group with some practitioners from the Valencian Community region in Spain. The objective is to triangulate the study results presented here and the general research results obtained to propose comprehensibility improvements in the IC process.

2. METHODOLOGY

We needed to delve into health professionals' opinions to improve the IC process. With that aim, the focus group included seven incentivized medical practitioners at different levels and job placements from the Valencian Community (Spain). We analyzed and observed how communication with patients is articulated and tried to define the practical insights of using the IC to draw conclusions that can improve clinical communication.

With this aim, we recruited a company that carries out market and social research and are specialist in working with focus groups. In this line, market research took place, where no type of medical research or biomedical or pharmacological data collection was done. The data about the participants included their contact for client communication; the data gathered has not been related to any specific medical trial discarding the implication of any bioethical committee. In this sense, and regarding the company recruited, they comply with the ethical code of ESOMAR for market and social research, the only one that applies to this research.

The variables considered for the selection of the practitioners participating in the research were: years of experience (more than three years practicing medicine), age, specialty (different specialties represented), monolingual and/or multilingual subjects, gender balance between male and female participants and with experience in various types of assistance (primary care, emergency, secondary care or palliative assistance to name a few). The study participants had all been selected from the national health service. Medical doctors working exclusively for private health institutions were excluded from the project. The participants represent a sample of practitioners working in the public health service in the Valencian Community (east coastal area in Spain); this region of Spain is a bilingual community where Spanish and Catalan are co-official languages. The variables mother tongue and level of competence in the two co-official languages of the autonomous region were considered relevant for the study. The language in which the IC is delivered to the patient, or the vehicular language used to explain the IC procedure, is appropriate for its comprehension and understanding, being an asset for clinical communication. Also, if practitioners could speak other foreign languages was a relevant variable that could affect the IC's delivery process and consequent understanding. It was also considered whether the participants had been trained in clinical communication and were part of a clinical teaching unit in a hospital or university.

The topics addressed during the focus group sessions were the genres of IC and medical consultation in a one-hour-and-half session conducted by a chairperson who acted as the moderator, guiding the group towards sensitive aspects to be analyzed. Concretely the session was distributed in 5 main sections specially shaped for this focus group and study (see Table below):

Table 1. Focus group session distribution.

Section	Set time
Introduction and warming up	10 minutes
Communication with the patient	30 minutes
The current IC	40 minutes
The ideal setting with the patient and the 'perfect' IC	10 minutes
Closing and farewell	5 minutes

During the session, the moderator poses some pre-established questions, and the participants give their opinions. Table 2 that follows illustrates the sections in which the session is structured, the contents and the questions addressed.

Table 2. Structure and questions of the discussion session.

Section	Content	Questions
Introduction and warming up	Objectives and methodology explained to participants	Some questions as:
Communication with the patient	<ul style="list-style-type: none"> · Importance of effective communication with the patient · Main values in communication. Comprehensibility and limitations · Perceptions on the use of the mother tongue 	<ul style="list-style-type: none"> · When you think of patient communication, what is the first thing that comes to your mind? · Is general communication the same as clinical communication? If not? What are the differences? · How do you deal with patients, what is the communication like, do they ask a lot of questions? · What are the main limitations/barriers in communication with patients? · What strategies do you use to talk to patients? · Who decides the language in which you communicate - you or the patient? · What role does the chosen language play in communicating with patients?

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Table 2, continued from previous page.

Section	Content	Questions
The current IC	<ul style="list-style-type: none"> Value and role of the IC in clinical practice Use of the IC in clinical practice. Writing and endorsement of information Languages in which the IC is provided Training 	<p>Working on an example of an IC “DIAGNOSTIC AND THERAPEUTIC COLONOSCOPY”.</p> <ul style="list-style-type: none"> What is Informed Consent? I would like you to quickly tell me what comes to your mind. - In what situations is the informed consent used? Do you really use it, are there any occasions when you decide not to use it, and why? What is the perception of this type of document among professionals? What document do you use: a document written by the hospital, by some health institutions, others, etc.? Is this document explained or given for the patient to read? Is it important for you that patients understand it or is it an administrative formality? In what language do you write these documents, and why? Have you ever had difficulties with comprehension due to Language issues? Have you received training on CI? What kind of training?
The ideal setting with the patient and the ‘perfect’ IC	<ul style="list-style-type: none"> Elements of editorial improvement Use of technology Improving the administration procedures 	<ul style="list-style-type: none"> What should be changed? What should you add or remove form the IC? What aspects would make these texts easier to understand? What should be changed in the procedures? Do you think the IC process is done well at present, and how could it be improved? What role should technology play in this? Should these types of documents be digitalised?
Closing and farewell	Research collaboration and acknowledgements	

It is worth mentioning that the session was conducted virtually during the COVID-19 lockdown in the Autumn of 2020. Some members of our research groups were given the possibility to attend and observe the session in ‘hidden chamber’ mode. The participants did not know we were watching, trying to minimize the observer’s paradox effect. The participants signed a consent form and agreed to be recorded and use the data for future private research, always keeping their anonymity. The aim was to gather helpful information to be processed regarding challenges, complexities, impediments, and needs of clinicians regarding language issues, textual comprehension, shared decision-making, or relevance of communication in the medical act.

3. RESULTS AND DISCUSSION

After analyzing the session and the answers obtained in the focus group with the medical practitioners, we could state that one of the questions on which everyone agrees is that trust is a very relevant aspect in every medical process, where a good part of the success of medical practice lies.

Initially, this study aimed at two research questions: a) RQ1: Do medical practitioners see the need to improve the IC text to be more comprehensible to patients? and above all, b) RQ2: How can clinical communication improve in doctor-patient intercourse?

In the following sections and in line with the aforementioned research questions, the most relevant findings are presented:

3.1. The need to improve the IC text to be more comprehensible to patients (RQ1)

According to practitioners, the IC itself, as it is known nowadays, does not give honest answers to the two main pillars of communication with the patient; it exclusively depends on what is said and how it is explained to the patient. There is a general feeling among the participants that the IC document by itself does not provide understanding. On the contrary, it is perceived as structurally complex, with technicalities and specific medical and legal terminology out of reach for the average patient unless some training or further practical explanations are given. From the ideas participants stated in the focus group, the IC is seen as a very formal and tedious document, static (only letter characters), rather than a visual, multimodal text; it is delivered to the patient at the end of the consultation when the patient sometimes feels overwhelmed. After all, according to participants' opinions, providing the IC and the IC document itself does not contribute to doctor-patient *closeness*.

3.1.1. Linguistic diversity

In addition, the concern of *linguistic diversity* arises, an issue that remains in the background and has yet to be directly treated, solved, or deeply analyzed in most cases. The study presented here is grounded on a bilingual region where two languages share officiality, Spanish and Catalan. Other languages coexist in the area since the Valencian Community receives migrants from all over the world but more concretely from countries such as Romania or Morocco. Considering the practitioners participating in this study and their statements in this bilingual setting, they have recognized that the IC document is usually given only in Spanish, despite working in an autonomous region with two co-official languages. Indeed, the templates or models on the website of the Autonomous Administration are in Spanish, Catalan, and English, but the reality is that only those printed in Spanish are used. When dealing with migrant patients or international foreigners, some hospitals deliver the IC document in English. However, stronger efforts are needed to translate the document into the patient's mother tongue so that the patient can have a more compelling reading (García-Izquierdo & Montalt, 2022). The priority is that the IC be signed by the patient, becoming a legal protection instrument for practitioners and health institutions. In the opinion of the physicians focus group, the IC should be available not only in Catalan and English but also in Arabic and Romanian, in line with the languages of the most common migrant population groups in the Valencian Community region. Language barrier issues have been externalized by Practitioners during the focus group session. As regards to practitioners, the language barrier does not seem to be such a handicap. They understand speaking a language different from the patient's one may hinder communication but there are other parameters that might be affected by effective communication. We can read some practitioners' opinions here below:

1. 10% of the population here is from Romania, and sometimes it is difficult to communicate with them.
2. I generally ask patients if they prefer Spanish or Valencian, speaking the patients' mother tongue tends to generate a more relaxed clinical atmosphere.
3. As I see it, the language does not limit clinical communication with the patient, at least it has never limited me. However, if the patient is not eager to favour communication and understanding, it definitely becomes quite difficult.

3.2. Improvements in Clinical communication may enhance doctor-patient intercourse (RQ2)

In this line, the results show that clinical communication needs improvement, and health professionals are conscious of patient misinformation.

According to the participants, *closeness* and *understanding* are vital aspects that foster trust in the doctor-patient communication and relationship. Listening, interpersonal contact, proximity, and empathy become binding actions to improve clinical communication in health professionals' opinions. We will see these two aspects in detail now.

3.2.1. Closeness

The participants considered closeness essential for the medical team to generate proximity with the patient. However, this is perceived as a challenging goal to accomplish in many cases due to the prioritization and hierarchical power roles assumed by society and practitioners. About this aspect, participants have recognized that the part of the nursing staff seems to be key here, considering that nurses accommodate better closeness with the patients; some excerpts transcribed from the focus group session corroborate this aspect:

4. One should always generate a feeling of support for the patient.
5. (...) the patient should always feel cared for and protected. They should feel we're close.
6. Our role should be caring, supporting, and listening...this greatly helps patients.

The physicians participating in the study allude to the impact that COVID-19 has had on communication with the patient. Above all, due to the lack of closeness and the coldness in the treatment imposed by distance, separation, remoteness, and 'telephone' consultations. It has been a significant barrier for many participants, mainly due to two aspects: a) the patients' level of tension, they have more doubts and less information (patient's anxiety), and b) because of the difficulty in transmitting calm and confidence on the part of the healthcare team. The clinical staff feels distant from the patient, either because of the new forms of Tele assistance (by phone) or the use of sanitary masks. The distance kept, the protective glass or methacrylate screens incorporated into the communicative event affect and restrict non-verbal communication, hindering the clinical communication flow. Moreover, the less literate a patient is and the less digitally trained, the more difficulties in comprehension and place for misunderstandings (Terblanche & Burgess, 2010; Pilegaard, 2016). Some physicians' personal opinions extracted from the focus group corroborate these ideas:

7. The level of studies and age greatly influence comprehension. Sometimes it is tough for an older person to understand something, just like it happens with foreigners.
8. The patient must understand what we explain...sometimes elderly patients come alone, and they don't understand what we are saying... medical terminology is complex.

In addition, this new form of teleconsultation by phone that the pandemic has brought about generates discomfort among the physicians interviewed; they state that when they inform and deal with patients on the telephone, they feel legally unprotected and unsupported by any current legislation. The participants argued that teleconsultation is not recorded, preventing participants' authentication. Medical doctors do not know to whom they are giving the information if this is the actual patient who should be treated, or if there is an impersonation fraud.

Along with closeness, understanding is another critical aspect that enhances good doctor-patient communication practices.

3.2.2. Understanding

According to the opinions of the participants in the focus group analysed, we have found some main barriers that might hinder understanding; they are listed below:

- Communication generally occurs in a context of great doubts, nervousness, tension, and fears on the patient's part, making attentive listening and clarity in receiving the message difficult.
- There is much information that patients cannot understand, and further, more straightforward explanations should be provided.
- The protocol followed in most consultations does not favor communication; the main handicap professionals mentioned is lack of time in the consultations and aspects such as visual contact with the patient. In the case of a phone consultation, there is a complete lack of eye contact with the patient. When the patient attends a regular onsite consultation, the distribution of the consultation setting (table, computer, distance, etc.) also affects communication success. Take, for instance, the computer screen between a doctor and a patient. It generates a feeling of alienation, not promoting fluent *communication*.
- Communication is constrained by bureaucratic procedures (filling in the patient's file, signing the IC, etc.)
- There is a large amount of information to be told. The information must be synthesized, adapted to each type of patient, and adjusted to the reality of each case.
- The patient imposes limitations on themselves to be concise or not to raise all doubts to the medical staff, being aware that the medical team's time is limited.

Some examples taken from the focus group answers and comments strengthen the ideas numbered (read examples below):

9. The informed consent document does not provide clear understanding, it is perceived as complex, with technicalities, very difficult to understand without specific training.
10. They (the IC document) are written with a lot of technical terms... some patients don't have a literacy level to understand the document, the IC itself is difficult for them.

11. It's important that the patients have time to read it (the IC), it is important they understand it for themselves.
12. The problem of time has always been there and it'll be. We are told to visit as many patients as possible, but what we wish is to have more time for our patients.

These six premises described above summarize the findings of the focus group's dialogues on clinical communication *understanding*. The complete IC process has also raised interest among participants; it will be analyzed in the next section.

3.2.3. Procedure

Regarding the IC procedure, the development of the document, and its implications, all the focus group participants, especially the younger professionals, recognized that this document has an excellent role and purpose. They highlighted the IC usefulness, particularly in the more invasive surgical specialties. However, professionals need help understanding why the IC must be signed 24 hours in advance according to the law. On many occasions, this legal premise cannot be accomplished, for example, in emergencies when there is no time before the urgent surgery or medical intervention, in other minor interventions or invasive tests such as CT scans or other MR imaging. Some practitioners differ about the value and use of the IC, especially those related to medical consultations. They argue that the IC should not have the same value in a surgical consultation as in primary care or a laboratory. They point out that waiting for the IC to be signed slows down some services, like in an operating room. If the document is not signed within 24 hours, surgeons cannot perform the intervention. As to the signature procedure, the organization and roles in the distribution of the IC differ among medical units. Sometimes the information is given, and the same doctor collects the IC. On other occasions, the administrative staff informs and collects the information for the MP.

The following excerpts extracted from the practitioners' group shoulder the ideas above mentioned.

13. The situation is the following... a patient with trochanteritis arrives, which is something rapidly sort out... and what do you do? You send the patient home with a piece of paper to sign it and ask them to bring it back to you signed? Bullshit! something you can solve in a minute, but you need to have consent... for a shoulder tendonitis? trochanteric bursitis?
14. Most times, especially when a patient has just been admitted, they haven't been explained anything and the patient signs the IC because they feel unwell... but the patient doesn't know what they have signed at all.

Archiving the IC documents signed worries practitioners too. During the focus group session, participants recognized that storing and archiving many ICs signed daily in hospitals is dull. Unfortunately, it is only sometimes done successfully since some ICs can get lost. To avoid this, some hospitals have already decided to digitize them (scanned) for storage, which facilitates their location and avoids the loss of documentation that can become very sensitive. Since the archiving procedure is not regulated by the state or autonomous government, it is up to hospitals or health centers to decide how to do this.

To this point, practitioners were asked about considering how technologically advanced electronic documents such as the e-consent could improve storage and archiving problems. Paradoxically, considering that the pandemic has favored the blossoming of electronic platforms and digitalized means of communication, the participants in the focus group had never heard of e-consent, nor about the current studies taking place about the e-consent by autonomous and national health systems in Spain. However, they all agreed to positively value this type of IC digital document use in the future.

15. I think that it should be electronic, as many other procedures are already electronically processed, papers can be misplaced. An electronic IC could be accessed easier.

The delivery and explanation of the IC are generally seen as tedious. The participants have stated that the IC procedure can slow down the effectiveness and quickness of the clinical process; however, they see it as mandatory and necessary, and following bioethical committees and medical societies regulations is crucial to keep a record of a patient's consent. As regards bioethical committees and medical societies, the physicians interviewed in the study showed their preferences towards those models of IC generated and developed by medical societies rather than those written by political entities (at local or national levels).

16. Those (ICs) issued by the medical societies have been written by specialists. Those published by political institutions, Ministry of Health or others are written by quality heads. We feel more confident with the ICs developed by medical societies.

17. The IC documents developed by medical societies include a greater variety of clinical procedures and tend to be more accurate... they are not so general.

When asked how patients react when the IC is delivered, the practitioners feel that the patient assumes the IC is a legal procedure. They do not read it thoroughly or take it as something fundamental may be due to ignorance, neglect, or unawareness. The signing of IC documents is a widespread practice, and if the IC is not signed, the patient cannot have access to the next step of their medical treatment, hindering their health improvement. Some of the interviewed participants, especially the younger ones, agreed with this idea and acknowledged that the patients only read the IC when the clinical staff highly recommends them. Patients rarely ask questions; those who query are usually more literate or patients who have had a bad experience with the sanitary system and look for any legal loophole.

18. I think that the patient assumes that it (the IC) is bureaucracy... it is something that is delivered at the end of the consultation and you assume that if you don't sign it, the surgery won't take place, that's it.
19. It is an internalized procedure, nearly all specialties have an informed consent and we cannot proceed if it is not signed. It may sound distant and careless, 'cause the informed consent is to inform the patient and protect him from everything that may happen while surgery and treatment; however, it is also a way of legally protecting the physician.

As seen from the main results obtained from the focus group, the IC process has some limitations and weaknesses that the participants in this study have argued.

The following section presents the most decisive conclusions and provides recommendations for clinical communication improvement regarding the IC procedure and clinical communication.

4. CONCLUSIONS AND FINAL RECOMMENDATIONS

The qualitative study presented here departed from the following research questions: a) RQ1. Do medical practitioners see the need to improve the IC text to be more comprehensible to patients? and b) RQ2. How can clinical communication improve in doctor-patient intercourse, according to physicians?

To reach our objective, a focus group with seven practitioners was organized, taking into consideration previously established parameters to have a heterogeneous group that could represent different medical profiles. The aim was to revise the process of the IC in clinical consultations and communication with patients. According to the results obtained and concerning the first RQ, MPs consider the IC document needs improvement. The document should be analyzed and assessed in detail so that its content can be reinforced rather than seen just as an act of signing. The IC document should be more lexically precise, with fewer medical technicalities and more accessible terminology for the patient (Muñoz & García-Izquierdo, 2020). Also, the document should be a much more multimodal means of communication. Visual elements could be added to textual ones, such as drawings or diagrams, aiming to offer a text with a clear and appealing design (Jefford & Moore, 2008; García-Izquierdo & Montalt, 2017). Accompanying the IC document with audiovisual elements also facilitates understanding and belittles the tediousness of the IC.

Regarding the second RQ and the improvement of clinical communication, the physicians interviewed highlighted the importance of generating closeness with the patients. Acknowledging the distinct patients' profiles and considering their origin, culture, religion, mother tongue, or educational level are vital aspects of making communication effective in the consultation and can aid the process of the IC delivery (Bridges et al., 2017; Carrese & Rhodes, 2000; Hemberg & Sved, 2021; García-Izquierdo & Montalt, 2022), as seen in section 1.1.

Explaining is vital in every consultation and even more while the IC is delivered. Here, enough time in advance for the IC to be read and signed should be given. The participants in this study mentioned how the short time available during the consultation needs to be optimized so that they must be instructive and simplify information as much as possible. Bioethical committees and medical societies should work together with governments and sanitary policymakers to find a way to generalize the many types of ICs currently existing; this would facilitate the IC procedure in the consultation and subsequently improve communication with patients. This joint work between clinicians and governments would minimize clinical document duplicates, avoid confusion, and generate greater credibility.

One crucial aspect observed in this study highlights the progress towards a more technological and digital clinical setting. Producing multimodal IC documents and including e-consent in the clinical setting is seen as something positive for improving doctor-patient communication. However, the paradox is served: Will the

e-consent improve doctor-patient communication? Are general patients trained and prepared for this digital genre, or will this further breach the relationship between clinicians and patients? Are future medical professionals trained to manage the digitalization of the healthcare system (Bellés Fortuño & Kozlova, 2012)? These aspects require the research community's attention and will undoubtedly be faced soon.

The role of the IC as legal protection for practitioners is undeniable, as all participants agreed. However, they consciously distinguish between the IC's legal objective and its informative role for patients. The IC is seen then as a legal consent form that usually needs to be more informed, succeeding partially in its purpose.

Another relevant underlying aspect that all the participants in the study suggested is the need for specific training about the IC document during their years of university training or professional career. The Spanish National Health Service does not provide such training, not even when surgical protocols are needed. However, according to the answers recorded from the focus group, such training seems relevant to health professionals, who state that this specialized training would benefit communication practices during the IC process, both with the patients and among the health professionals.

“While full bilingualism requires immersion and extended practice, many of us have rudimentary language skills that can be augmented. Fortunately, many universities offer courses that can be accessed by medical faculty” (Brindley 2014: 89).

In this sense, some countries already choose to incorporate communication training in the training of (future) doctors and the health system. Among the methods proposed for training, we can highlight *Dialog training* (DT), a model for communication training in healthcare settings that is designed to incorporate more open communication, greater trust and more awareness of norms and values (Grill et al., 2014; 2015).

Although the study presented here is limited to the country and region where it was conducted, the bilingual coastal area of the Valencian Community in Spain has revealed outstanding insights into the IC procedure and clinical communication as seen by cautiously selected practitioners.

Legislation of the IC, medical responsibility concerns, and clinical communication constraints, in written and spoken modes, confirmed the central claims of the focus group presented in this paper.

Studies such as the one presented here can contribute to governments developing their State Health policies, medical associations, ethics committees, health policymakers, and health professionals in general in improving their everyday duties. Moreover, other professions that may have yet to be directly included as health staff, such as mediators and/or interpreters, are also crucial as regards the clinical consultation and the delivery of the IC. They can also benefit from the insights of the current study.

The relevant findings of this research deserve further analysis in relation to the qualitative and quantitative studies already addressed by the GENTT research group. Prospective studies attempt to use the triangulation of this and other prior studies to make a feasible proposal for the amelioration of the IC document and other clinical documents for the public administrations in line with comprehensibility, readability, procedures and effective clinical communication.

NOTES

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CONFLICTS OF INTEREST

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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