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EXECUTIVE SUMMARY

Informed Consent process allows the subject to voluntarily decide his/her participation in a clinical trial. Generally, ICs are documents that are difficult to read, that do not include all stakeholders' perceptions and do not distinguish between subject's characteristics, (age, gender, demographic characteristics, etc.). This deliverable analyses the issues about gender and age.

MINORS

Research involving minors as subjects of research raises important questions regarding the participation of the child in the decision-making process.

Based on the fact that participation, understood as consent and/or assent in function of the legal relationship, is free and voluntary and is subject to a series of ethical and legal requirements, the decision making process becomes more sensitive due to the peculiarities of cognitive and moral development of the child.

Ethical and legal standards do not specify, in most cases, three of the key aspects in the decision-making process; information to be given to the child, how to assess the understanding of such information and how to assess the child's competence to make the decision.

The present systematic review of the literature has been oriented to find a response to these three key issues through a rigorous methodology in the search and treatment of information.

From the analysis of the information obtained we can observe that the exhaustiveness of the studies has not been high enough to be able to respond to each one of the aspects analyzed, with sufficient scientific evidence.

Regarding the information, we have been able to observe that in addition to being adapted to the age, the moral development of the minor and his emotional state must be individualized and continuous during the research study. There is no common pattern about the contents or the continent, as the range of situations surrounding each child may change in each case.

So, not only must we take care of what is said (quantity), but how it is said (method / format used), who says it (qualities of the person who reports), how often it says it (continuity and adaptation of information throughout the study) and what the minor wants to know or care about.

Giving information to the child without making sure he/she understood it would be tantamount to not giving any information. Therefore, it is necessary to check the understanding not only at the time of signing, but throughout the duration of the study. There is no method for evaluating validated understanding, since interviews and

questionnaires have been used with different structures and formats, without being able to reach a consensus. The studies that provide the most evidence use multimedia formats, on-line, images (comic) or video for presentation of information and evaluation of understanding, with positive results in some of them, especially in the section on risks. It is also observed that the lowest research subjects with health problems (cancer, HIV) tend to expect, by mistake, direct benefits of participation in research.

The comprehension of the information will be better if there is a good communicative relationship with the researcher and it is possible to discuss the information.

Understanding information and its integration by the child enhances the ability to make a coherent, free and autonomous decision. Determining this capacity is not an easy task, but four basic aspects must be evaluated: understanding of information, reasoning in the decision-making process, appreciation of the effects of participation and expression of a choice about participation.

At present, the reference tool is the MacCAT-CR that addresses these four blocks and has proven its validity and reproducibility. Although age cannot be a unique capacity requirement, it is the IQ that is the most influential variable. The scarcity of empirical data makes it necessary to carry out more studies with this tool. In the meantime, it is necessary to establish an effective relationship with the research team to determine the child's competence and ability to understand weigh risks and benefits and make a coherent and mature decision.

GENDER

This document goes over differences in communication by gender, taking into account all formats (verbal, non-verbal, writing and even using Internet). The methodology used has been a narrative review using different sources and databases such as Pubmed, Scopus, Web Of Science or Google Scholar; without limitation of date, but only considering documents written in English or Spanish.

The main paradigms in the study of gender differences in communications are presented, explaining the causes given to gender differences by each model, including the tendencies more extended nowadays, which highlight the importance of considering, by one side, gender as an activity that a person *does* rather than a characteristic that a person *has* and, by other side, the influence of other conditioning factors, apart from gender, in communication.

The findings in the field of gender differences in communication are frequently contradictory and the findings of one author are refuted by another. Even so, there are some differences that appear more often and most of them are related to the development of the role that society has assigned to men and women, so men usually have communicational behaviours

oriented to professional and public development, to transmit security, dominance, competitiveness, while women have communicational behaviours oriented to care, housekeeping and private development, looking tentative, caring and polite. These behaviours and stereotypes also influence the communicative behaviour in the relation physician-patient or in the use of social media and communication using ITCs. Even so several authors point out the existence of more similarities than differences between men and women; that the characteristics assigned to each gender style are not categorical and; that gendered styles are not assigned to one fixed gender and people can change from one to another depending on different situations (not all women must use the style typically assigned to them, and neither all the time, they can change from different styles, sometimes classically feminine and other times more archetypally masculine).

Accommodative behaviours have been associated with a positive evaluation of communication; in the field of relationship between physician and patient has been recommended to implement converge strategies, but cautiously and avoiding “overconverge” (for example to use “street language” during the clinical interview).

Most of the characteristics associated with female physicians have been evaluated by patients as positive and typical of a satisfactory experience. Usually physicians get more involved in communication with female patients.

There exist gender differences in the use of social media and in the eyetracking that should be taken into account when incorporating the use of ITCs to the IC process.

Most of the researchers found no significant differences in understanding of the IC form by gender, but the ones that found differences point out to a better comprehension by women.

Women indicate the characteristics that should have the professional who supplies information about the study: has to have knowledge of the study, appears secure and be able to answer the questions about the research; be accessible and available to give guide to the woman about the research; should have an attentive and accessible attitude, avoiding seeming arrogant. They prefer to receive the information in groups of women and individually (both complementary); and in written and orally format (also complementary). The conversation with the physician is very important and valued. To be able to decide about participating or not they should have information about risks and benefits, efficacy and possible side effects and inconveniences (short, medium and long term ones). They give more importance to the manner the information is provided (clearly and objectively to be easy understanding) than to the quantity, but too much information could be counterproductive. Use of audio-visuals contribute to improve the retention of the information and to assure that same information is provided to all potential participants.

TABLE OF MAIN RESULTS

Number	Short Description	Reference page
1	Gender is one of the conditioning of communication activities, but there are others that must be taken into account (biophysico-psychological, environmental, cultural patterns, socioeconomic-educational levels, shared behaviours)	20
2	Gender differences in communication are a controversial topic. Often, findings of one author's are refuted by others. Some researches point out that there are more similarities than differences between men and women. The differences are not categorical.	29
3	Some researchers point out that there aren't significant differences in understanding of the Informed Consent (IC) by gender. Others indicate that women have better comprehension.	50-51
4	There exist gender differences in the use of ITCs and in eyetracking	53-60
5	The communication physician-patient also presents differences by gender; most of them coincide with gender differences in non-clinical environments. Characteristics attributed to female physicians have been identified as more positive and satisfactory.	62-64
6	The oral explanation of the IC is a key factor for its understanding. Women prefer the IC to be presented in group and individually (complementary) and orally and writing (complementary).	62,70-71
7	Bento et al. studied the women's opinion about the IC process	69-72
8	To improve the understanding of IC is important to tailor it to the patient's characteristics	72
9	There are few scientific articles with high quality of evidence that help determine the information necessary for the consent of a child to participate in research	101
10	Assent must include at least: reason why is asked to participate; description of procedures; how might experience them; right to revoke participation at any time; decision of the child is free and voluntary; confidentiality	102, 103
11	It is recommended to individualize the information provided to the child, based on their age, emotional state, health status and what they want to know. Adapt the extension (short), language (simple without technicalities), format (multimedia).	103, 104
12	It is necessary to establish a good communication relationship between the minor, his / her parents and the research team	104
13	There are articles in the scientific literature that evaluate the understanding of assent information for research in minors, but without a consensus on the tool to be used. The use of questionnaires is common, but they are very heterogeneous.	105-109
14	It is difficult to determine the competence of a minor to participate in a process of assent in clinical research. The only tool validated today is the MacCAT-CR, but there are experts who value more discussion with the child and their parents to determine it.	109-113

TASK DESCRIPTION

Gender and age are two major factors to consider in the review of scientific literature in the field of IC. Identifying their different characteristics and needs is very important for proper development of the guidelines.

Because of the differences between both subjects (age and gender), this document is divided in two different parts, the first part is dedicated to gender adaptation, and concretely, gender differences in communication and its application to the IC; the second part is dedicated to the age, and specifically the topic of informed consent by minors (assent). Although they are part of the same deliverable, each part has its own introduction, methodology, results, conclusions, bibliography, etc.

In the case of age issues, the focus on minors is justified because it is a highly identifiable group with characteristics common to all of them, and also because they are considered as a vulnerable population and with legal differences compared with other age groups. Other age groups, such as elderly people, were considered, but only specific disease problems more common in that age range (such as dementia) were considered might affect the informed consent process, but not characteristics of the age group itself, they were discarded.

In the case of gender issues, it has been considered that the contents the IC should include doesn't differ essentially by the gender of the participant, unless some special cases as during pregnancy or breastfeeding, but these are included in the soft and hard law. Because of that, the differences analysed in this document are concerning to the style of communication, because they should be taken into account during the elaboration of the IC forms and the rest of the IC process.

The review about the informed consent by minors (assent) has been done using a systematic review while the review about gender differences in communication has been a narrative review.

A. GENDER ISSUES ASSOCIATED WITH THE ACQUISITION OF INFORMED CONSENT: GENDER DIFFERENCES IN COMMUNICATION.

A.1. INTRODUCTION

Gender is one of the main factors to consider in the field of the Informed Consent (IC) process. The contents that the IC should include don't differ essentially depending on the gender of the subject, but only special cases during pregnancy and breastfeeding are remarkable. There are differences by gender that must be taken into account to improve the IC process and its understanding, ensuring his/her autonomy in the decision taking about participating or not in the research, and as the H2020 says to *"integrate the needs and behaviours of women as well as men in research content"*⁽¹⁾.

The objective of this document is to analyse and explain the differences in communication by gender to be able to adapt the IC.

Which gender differences are considered?

The document includes differences about the patterns of communication, use of language, social media and Internet.

The document is not focused on the representation of women and men in different fields as publicity, cinema/TV, literature or linguistic. Neither on the use of non-sexist language, that is a very important aspect that must always be taken into account, as we will do in the entire project, but its analysis is not an objective of this document.

What contents can be found in the document?

In this document the differences following this index are analysed and explained:

1. Introduction
2. Sex VS Gender
3. Theoretical bases to the differences in the pattern of communication by gender:
 - Introduction
 - Main paradigms
 - Linguistic style accommodation
4. Differences in the patterns of communication by gender:
 - Motivation to communicate
 - Main characteristics of the different styles of communication

5. Gender differences in skills

- Gender differences in scholars: the PISA survey
- Gender differences in adults: the Survey of Adults Skills (PIAAC)
- Differences in gender comprehension of IC by gender

6. Online Gender Differences

- Gender differences in online communication
- Gender differences in online shopping
- Gender differences in social networking sites
- Gender differences in smartphone and texting
- Gender differences in eye tracking

7. The patient - physician communication

- Why is important?
- Gender differences in the relationship physician-patient

8. Women's opinions about the informed consent process

9. Conclusions

10. Recommendations for the gender approach in IC

11. Bibliography

What methodology has been used?

The information included in this document is the result of the analysis of papers and books founded in a narrative research done in different databases (Scopus, Pubmed, Web Of Knowledge, Scholar Google and Dialnet) and in guidelines and organisation webpages. The studies included are from the field currently known as studies of Language, Gender and Sexuality^{c, (2)}.

Important remarks:

There are two important ideas that Cameron⁽³⁾ says that we want to remark, because they are important to understand our point of view of the gender-related differences shown in this document:

1. The differences are not categorical and are based on the results of different studies that have found statistically significant differences between male and female trends or patterns.
2. The differences among each gender (age, socioeconomic status, ethnic and geographical origins, religious beliefs, etc.) must be taken into account, because they

^c This field includes the studies about the differences in communication between men and women.



influence on the behaviour and produces a variety of masculine and feminine styles in different contexts. These differences can be wider than those produced by gender.^d

^d This is one of the main ideas of the diversity paradigm that is explained in the section 3.1 of this document.

A.2. SEX VS GENDER

Sex and gender are two different concepts that have sometimes been used, wrongly, as synonymous. The Guidance on Gender Equality in Horizon 2020 ⁽⁴⁾ defines them as follows:

- **Sex** refers to *“biological qualities characteristic of women and men, boys and girls, in terms of reproductive organs and functions based on chromosomal complement and physiology. As such, sex is globally understood as the classification of living things as male and female, and intersexed.”*
- **Gender** is a *“socio-cultural process. It refers to cultural values and social attitudes that together shape and sanction “feminine” and “masculine” behaviours, and also affect products, technologies, environments, and knowledge.”*

The European Institute for Gender Equality (EIGE) ⁽⁵⁾ gives a more extended definition of gender and indicates that gender *“refers to the social attributes and opportunities associated with being female and male and to the relationships between women and men and girls and boys, as well as to the relations between women and those between men. These attributes, opportunities and relationships are socially constructed and are learned through socialisation processes. They are context- and time-specific, and changeable. Gender determines what is expected, allowed and valued in a women or a man in a given context. In most societies, there are differences and inequalities between women and men in responsibilities assigned, activities undertaken, access to and control over resources, as well as decision-making opportunities. Gender is part of the broader sociocultural context. Other important criteria for sociocultural analysis include class, race, poverty level, ethnic group and age.”*

Following the descriptions given above sex and gender differences have different contexts, referring sex to the biological and physiological characteristics and gender by the sociocultural context and the relations of power.

García, Jiménez and Martínez ⁽⁶⁾ highlight the following characteristics of the concept of gender saying that is:

- **Relational:** It doesn't refer to women or men in isolation; it refers to the relationships that are built socially between one and another.
- **Asymmetrical / hierarchical:** Differences between women and men aren't neutral; society gives more importance and value to the characteristics and activities associated with masculine gender and produce unequal power relations.
- **Changing:** Roles and relationships are modified over time and place, being susceptible to changes by interventions.
- **Contextual:** Gender relations are different depending on other characteristics, such as ethnicity, class, culture, etc.



- **Institutionally structured:** It refers not only to relations between women and men on a personal and private level, but also to a social system based on institutional values, legislation, religion, etc.

In this document the analysis is focused on gender issues, making reference to the ones that have its origins in the social aspects, not in the biological or physiological ones.

A.3. THEORETICAL BASES TO THE DIFFERENCES IN THE PATTERN OF COMMUNICATION BY GENDER:

A.3.1 INTRODUCTION

The relationship between communication and gender has been a topic that has aroused interest since long time ago^e, but it wasn't until the 1960's when the number of researches on this topic experimented a continuous increase. (7) In 1975 the relationship between gender and communication emerged as a differentiated investigation topic and from 1990's the increment of the studies in this field has been exponential. (8)

One of the effects of the rise of the studies about this topic has been the development of its own terminology, being especially important the creation of the term “*genderlect*” that is defined by the Encyclopedia of Language and Linguistics as “*A type of language usage that is prototypically associated with speakers of one gender*”⁽⁹⁾. The concept, which appears for the first time in the gender oriented sociolinguistic literature of the 1970s,⁽¹⁰⁾ has its origin on 1953 when Weinrich said that sex could be a relevant variable in language contact situations;^{(11) (12)} and in its traditional meaning contrast the male and female speech as two clearly different and stable gendered varieties.⁽¹⁰⁾ Authors like Glück, quoted by Motschenbacher, consider this term more appropriate than “*women's/men's language*”.⁽¹⁰⁾

During the last years, and particularly with the rise of the diversity paradigm, this concept has been widely criticised because of its dichotomy, and several researchers have wondered if it still being useful. Some authors refuse the term because they consider that to use it legitimates the masculine domination⁽¹³⁾ while others express that is inadequate to continue using the traditional approach to gendered variation, because it doesn't reflect the actual use of language done by men and women, but they still find the term ‘genderlect’ useful and suggest to redefine it. In this same way Motschenbacher⁽¹⁰⁾ indicates that “*the term ‘genderlect’ does not have to be dismissed entirely. It can be used in the knowledge that it plays a significant role in the performative construction of gender. This does not mean that all women and men use a female or male genderlect respectively. People have a multitude of speech styles at their disposal which they use depending on context*”, and propose to redefine the term genderlect in a postmodern way “*as standing for a linguistic style that performatively stages gendered language stereotypes*”.⁽¹⁰⁾

Tusón (14) doesn't use the term genderlect, she talks about different styles (the feminine style and masculine style) and, in the same direction that Motschenbacher, suggest the existence of two different discursive styles, and calling them feminine and masculine style

^e Otto Jespersen in his book *Language: Its Nature and Development* (1922) identify the first mentions to the differences in 1664, he indicated that “the first to mention their distinct sex dialects was the Dominican Breton, who, in his *Dictionnaire Caraïbe-français* (1664), says that the Caribbean chief had exterminated all the natives except the women, who had retained part of their ancient language.”

doesn't mean that all men must use all the typical traits of the masculine style, neither should all women the feminine style because these styles are just trends. She also points out that due to the characteristics of some men and women identity or different situations can use the traits usually assigned to the other sexual group.

Returning to the discussion on the appropriateness of using the term genderlect, Castellanos (15) argues that the term genderlect can still be useful because it brings us closer to understanding how the feminine and masculine identities are constructed. She defines genderlects as *"the differences of style between the feminine and masculine discourse, culturally conceived"*, so she highlights that the genderlects *"are not ascribable to men or women as biologically determined groups, but correspond to the cultural characterization of what types of expressions and attitudes are considered feminine or masculine in a specific sociocultural context, and therefore what types of behaviour are expected of men or women"*.

Poyatos indicates that gender is recognized as a conditioning of communication activities, but it is not the only one. He identifies the following conditioning factors of communicative activities: biophysico-psychological (such as ethnic group; gender; age; physiological, medical and emotional state; nutritional habits; psychological configuration); environmental (natural, modified, built and objectual environment; socioeconomic and educational background); cultural patterns (general cultural style; regional or subcultural groups; religious and moral values; relationships and role expectations; norms of etiquette and good manners; aesthetic values); socioeconomic-educational levels (from lowest socioeducational status to hyperrefined) and; shared behaviours (family and conjugal borrowings; borrowing from social models; social and occupational groups.⁽¹⁶⁾ It is important to take into account the influence all of them have on communication activities.

Poyatos⁽¹⁷⁾ also specifies that discourse has a basic triple structure: "what we say" (verbal language: the words); "How we say it" (paralanguage^f); "How we move it" (kinesics^g).

Independently of its format, the Informed Consent is a communicative act so it is important to analyse and understand the differences of communication by gender in order to adapt messages to each audience because, as Motschenbacher indicates, *"genderlects, therefore, provide resources for gendered identity performances which can be exploited strategically (for instance in advertising) or used as a form of ritualised practice (in people's everyday communities)"*⁽¹⁰⁾, and if fields such as advertising consider genderlects important probably it will be convenient to take it into account to make the messages more understandable and to bring people closer to medical research.

^f The Encyclopedia of Language and Linguistics defines Paralanguage as: "Relatively nonsystematic variations of tone of voice, e.g., nasalization or breathy voice used to a particular effect; sometimes also nonvocal phenomena such as eye movements, facial expressions, etc."⁽⁹⁾

^g The Encyclopedia of Language and Linguistics defines Kinesics as: "The study of the use of gesture, facial expression, and bodily movement as meaningful elements in a system of communication."⁽⁹⁾

A.3.2 MAIN PARADIGMS

Historically there have been different explanations to the gender differences that are represented in 4 main paradigms: the deficit model; the dominance approach; the difference theory; and a group formed by diversity, constructivist and performative approaches, which are more extended nowadays and are presented in this document all together because, independently of the denomination of each one, they have a lot of common points and we consider that it is the best for the purpose of this document.

A.3.2.1 The deficit model

The deficit model identifies women's language as inferior to that of men, which is considered as the norm.

The linguist Otto Jespersen did the first academic study on the differences between male and female language in 1922, in his book titled *Language: Its Nature and Development* (18), he analysed linguistic gender differences on several topics such as taboos, phonetics and grammar, vocabulary, choice of words, use of adverbs, frequency leaving exclamatory sentences half-finished or grade of formality. He suggested that there were two separate languages or dialects and he described women's speech as deficient compared to that of men, which was considered as the norm.⁽¹²⁾ Jespersen's theories have been very criticised by the feminist authors who consider them sexist, paternalist and self-flattering.⁽¹⁹⁾

Another main representative of the deficit model is Robin Lakoff⁽²⁰⁾, who uses the term "women's language" to reflect the double discrimination that women suffer with language: on the one hand the discrimination in the way women are taught to use the language (*talking like a lady*) and, on the other hand, the way the use of language treats women (*talking about women*). She indicates that both discriminations want to relegate women to some subservient functions and treat her as a non-serious person. She compared the lexicon and syntax of women's and men's speech^h, concluding that women's speech characteristics made it weak with an ineffective style and inferior compared to men's speech (the norm). Cameron⁽³⁾ identifies the following characteristics of women's speech in Lakoff's work:

- a) Preference for milder over more strongly tabooed expletives.
- b) Exaggerated politeness.
- c) Elaborate colour vocabulary.
- d) Use of empty adjectives ('lovely,' 'divine').
- e) Use of intensifiers ('so nice').
- f) Hedging to reduce the force of an utterance and/or the speaker's degree of commitment to it.

^h Because of its objectives, this document focuses only in the first aspect of the "women's language" that identifies Lakoff ("talking like a lady").

- g) Phrasing statements as questions, using rising intonation and/or end-of-sentence question tags.

Lakoff explains that many of these characteristics of the women's speech reflect insecurity and are produced by the male-dominated sexist society.⁽³⁾ In relation with this Hidalgo⁽¹²⁾ indicates that the *"deficit model"*, with the characteristics attributed to the *"women's language"*, emphasises the idea of female speakers' lack of confidence that is shown through *"hesitations, tag questions, rising intonation in declarative sentences, and epistemic modal markers."*

Uchida indicates that Lakoff's theories have been criticised, some critics questioned her methodology (based on unsystematic observations and intuition); others tested her hypotheses of *"women's speech"* getting contradicting results; and her concept of *"women's language"* has also been seen as confounding social status with sex. Even so she highlights Lakoff's contribution as *"one of the first and most influential works stating that it was inequality between the sexes in society that was reflected in language use, rather than the genetic inferiority of women"*⁽²¹⁾.

A.3.2.2 Dominance approach

The dominance approach explains the differences between the language of women and men as a reflection of social differences and power.

As Cameron says *"any difference in men's and women's ways of communicating is not natural and inevitable, but cultural and political"*⁽²²⁾.

This paradigm was constructed on the basis of the deficit model and especially from Lakoff's contribution; it rejects the linguistic superiority of men and explains the differences with the fewer assertive attitude of women as a result of the denial of their access to language of power.⁽¹²⁾ Fishman, quoted by Maltz and Borker, point out that the norms of behaviour ensure the maintenance of power and interactional control by men.⁽²³⁾

Zimmerman and West⁽²⁴⁾ indicate that men exercise in the conversational relations with women the same dominance and power that they exercise in other areas. This asymmetry of sex roles is reflected in different patterns of behaviour during conversational interventions between men and women (cross-sex conversations), as in the interruptions, silences or the support for partner developing topics.

Brown⁽²⁵⁾ studied, in a Mayan community, the relationship between communicative strategies and social status and how it was reflected in the politeness (more widespread among women), and she indicated that as a higher level of politeness is expected from inferiors to superiors, is predictable that women speak in a more formal and polite way, because of their secondary status relative to men. Cameron reaffirms the idea of the influence that gender power relations have on the linguistic by stating that *"men are 'less*

polite' not because they cannot use these strategies, but because in most situations they feel no need to"⁽²⁶⁾.

Fishman⁽²⁷⁾, in her analyses of gender's hierarchy in everyday interaction, realised that there were gender differences in the distribution of work in the conversations. Women tend to work more in the conversations and take a more active role insuring interaction than men (for example, asking more questions, using attention beginnings, doing support work when men are talking or doing active maintenance and continuation work in conversations); men are more likely to discourage interactions started by women than vice versa. She also realised that even women tend to work more in the conversations they usually have less successfully than men starting conversations or introducing topics; the explanation she gives to this effect is that men success because women do an effort in response to their attempts, while women fail because of the lack of men's capacity to do the interactional work. She points out that there is a *"division of labour in conversation"*, where women are the *"shitworkers"* that do the routine work and men are who control the process and get the benefit.

Other authors (as Bilious and Krauss; Herring, Johnson, and DiBenedetto; or Kollock, Blumstein, and Schwartz) show how different aspects in the communication reflect the hierarchical social differences by gender, as interruptions and overlaps; control of the turn taking and duration; topic selection; silences; or use of backchannels.⁽¹²⁾

A.3.2.3 Difference theory

The difference theory considers that gender differences in the communication are caused because men and women belong to two different subcultures, with different values, and this is reflected in the conversation.

This paradigm defends that men and women belong to two different subcultures and that affects to their communication behaviours,⁽¹²⁾ but even they have different rules of conversation and styles, both are equally valid.⁽²¹⁾ Gray refers it very well with the title of his book *Men are from Mars, women are from Venus*⁽²⁸⁾ that suggests that the differences between them are so wide as if they came from different planets⁽²⁹⁾; without going so far, Maltz and Borker⁽²³⁾ equate the difficulties in the communication between genders with the cross-ethnic communication. Mulac⁽³⁰⁾ indicates that the difference is in the way they use the language, not in the language they use, saying that *"There are two abiding truths on which the general public and research scholars find themselves in uneasy agreement: (a) Men and women speak the same language, and (b) men and women speak that language differently"*.

Tannen indicates that the origin of the differences is the education that boys and girls get during the childhood, she says that *"even if they grow up in the same neighborhood, on the same block, or in the same house, girls and boys grow up in different worlds of words. Others talk to them differently and expect and accept different ways of talking from them. Most important, children learn how to talk, how to have conversations, not only from their parents but from their peers"*⁽³¹⁾, she also emphasizes the importance of the games boys and girls play, and indicates

that the objectives, strategies and values of each kind of game makes them to acquire different gender appropriate behaviour. ⁽³²⁾ And points out that these cross-cultural communication differences produce frictions between men and women. ⁽³¹⁾

Maltz and Borker defend that rules of interacting in different situations are learned approximately at the age of 5 to 15 from peers of their own sex (that are with the ones that socially primarily interact). ⁽²³⁾ They also emphasize that the fact that boys and girls learn to use different genderlects, give them different rules and patterns of use and understanding of communication that produce the miscommunication between genders. ⁽³³⁾

Alami, in her analyses of Tanen's work, underlines that men and women speak different because they try to accomplish different things when they talk, and says that: *"Men approach conversation as a contest. Thus, they prefer to lead a conversation in a direction in which they can take central role by for example telling a joke, displaying information or skill, which Tannen calls "report talk" (public speaking). While most women's conversation is a way of establishing community and creating connection, which she calls "rapport talk" (private speaking)"* (33).

Mulac, Bradac and Gibbons ⁽³⁴⁾ consider that the *dominance approach* and the *difference theory* aren't exclusive and that each approach underlines different parts of a unitary process. This idea, which differs from the general tendency of considering both paradigms as contraries, has also been put into practice by other authors as Bogaers who combines both models in her research about gender differences in job interviews. ⁽³⁵⁾

Many authors critiqued the difference theory; Talbot shows the different critics that authors have done to this approach, pointing that *"the foremost concerns are the erasure of power and a tendency to overgeneralize, brought about by disregard for contextual considerations other than gender"* ⁽³²⁾. And she highlights that Thorne considers exaggerated the sex segregation in childhood; and Cameron points that the affirmations about the miscommunication between adults ignore issues of conflict over rights and obligations in times of social change. ⁽³²⁾ Uchida also criticises this approach because on the one hand she considers the idea of the different "cultures" too simplistic to account for all that happens in mixed-sex conversation; and on the other hand she considers inappropriate the dichotomization of "power" and "culture" as independent concepts because all social interaction occurs in the context of a patriarchal society. ⁽²¹⁾

A.3.2.4 Diversity, constructivist and performative approaches

Diversity, constructivist and performative approaches highlights the importance of considering, by one side, the gender as an activity that a person *does* rather than a characteristic that a person *has* and, by other side, other conditioning factors, apart from gender, in the communication.

Diversity, constructivist and performative approaches are nowadays the prevalent perspectives in the studies of Language, Gender and Sexuality; they break with the dichotomy between men's and women's language and with the assumption that all men and all women have the same linguistic behaviour, considering that old approaches reproduce gender stereotypes.^{(2) (3) (12)}

Acuña⁽²⁾ shows that the starting point of these paradigms is that societies and cultures establish predominant models of "*femininity*" and "*masculinity*" as signs of identity for women and men respectively; and the individuals can behave following this gender patterns or transforming (and challenging them) in a greater or lesser extent. Motschenbacher⁽¹⁰⁾ identify that there are "*hegemonic and non-hegemonic gender styles*", indicating that both of them are possible. The *hegemonic* are the ones that are stereotypically associated with femininity and masculinity in a culture; the non-hegemonic are subversives, as they deviate from what are considered coherent gender styles; and they only have significance in comparison to mainstream practices, because what is considered subversive in one context may be considered non-subversive in another, and vice versa.⁽¹⁰⁾

Butler⁽³⁶⁾ understands gender as "*performative*", as "*not something a person 'has' but something a person does*", so gender identity is a fluid construct rather than a natural given. Motschenbacher⁽¹⁰⁾, following this *performative* approach, emphasises his rejection to the idea that people speak a genderlect because of their demographic gender. In line with this approach, Acuña⁽²⁾ considers that is important to speak of "*masculinities*" and "*feminities*" reflecting the multiple forms of feminine and masculine identities. Cameron⁽³⁷⁾ indicates that Butler's performative concept of gender made researchers' attention to focus on the range of ways the resources of linguistic variation could be used to perform gender.

The *diversity* paradigm considers men and women as heterogeneous groups, with internal differences among them, that can be even bigger than the ones between genders^{(3) (12)}. As Cameron⁽³⁾ says "*people are after all never just men and women, but are always men and women of particular ages, classes, ethnic and geographical origins, occupations, social roles and statuses, and religious and political beliefs. The form gendered behaviour takes is inflected by these other dimensions of identity and experience*". She also emphasizes that linguistic variability can be used to produce a range of masculine and feminine styles adapted to different communities or contexts.

Motschenbacher⁽¹⁰⁾ identifies as a problem to consider gender as the only and independent conditioner for language variation and indicates that it interacts with other parameters as race, age, class or context; and indicates that if we find differences between male and female linguistic behaviour it doesn't mean that gender is the main and only factor that causes that difference. He proposes to focus on intra-gender diversity instead of the inter-gender difference and says that it will allow understanding that the linguistic behaviours of women and men have more similarities than differences. Poyatos⁽¹⁶⁾ also remarks the importance of

different conditioning of the communication activities and identifies them (see Figure 1 in the section 3.1).

Acuña ⁽²⁾ indicates that the adoption of this approach implies a change in the objectives of the researches, from exploring the differences in the ways of speaking and communicating by men's and women's, to analyse how communicative practices construct different versions of masculinity and femininity and which are the discursive resources involved in these processes and in which contexts acquire relevance. Cameron reflects it very well when she says *“In a gender difference framework, the fundamental question is, ‘how are women different from men?’ In a diversity framework, that question will immediately be met with another question: ‘which women and which men do you mean?’”*⁽³⁷⁾.

A.3.3 LINGUISTIC STYLE ACCOMMODATION

Once explained the main paradigms to explain the reasons of gender differences in communication, is important to know the strategies that individuals use to adapt their communication depending on the characteristics of his/her communication partners, with a special focus on the gender. For this purposes in this document is briefly explained the *“Communication Accommodation Theory”* (CAT)ⁱ. Watson and Gallois ⁽³⁸⁾ point out that one of the differences between this theoretical model to others of communication is that it takes the social identity, the personal identity or both into account that may drive the speech's partner motivation in a conversation.

Bylund, Peterson and Cameron explain that the CAT *“focuses on the ways individuals modify their communicative behavior as a result of their communication with each other (...) explains how behavioral strategies (e.g., rate of speech, eye contact, gestures) are utilized to accommodate speech and nonverbal behavior”*⁽³⁹⁾. Namy, Nygaard and Sauerteig indicate that people use accommodation to achieve particular social goals, as for example social approval or acceptance, attraction, affirmation of identity (group or individual), and the facilitation or regulation of discourse; to been able to accommodate is necessary to monitor the indexed characteristics of their interlocutors and adapt the own characteristics to them.⁽⁴⁰⁾

The CAT came up from the Speech Accommodation Theory (SAT) indicating how the accommodation not only involves the speech (as verbal language) but also includes the paralanguage, the kinesics and the different communication media (as speech, email or writing).⁽⁴¹⁾ The origins of the SAT were in the early 1970s with the aim of understanding the shifts in the speech styles, with a special focus on accents and dialects; in the 1980s

ⁱ CAT is just one of the several interpersonal communication theories that exist and it has been selected by the authors of the document because of its utility for this topic. For a brief overview of other useful interpersonal communication theories we recommend to read the article *“A practitioner's guide to interpersonal communication theory: An overview and exploration of selected theories”* written by Bylund, Peterson and Cameron⁽³⁹⁾

researchers used this theory in several contexts to examine how different social groups (basically focusing on the age and ethnicity/culture) use and perceive accommodation, by this time the theory was being re-named or re-conceptualized as the CAT (as said above). Since then the CAT has been developed and applied to different contexts, resulting in a useful theory to study the dynamics of interactions by examining the association between accommodative behaviours and different relational and identity outcomes and which can be applied to both interpersonal and intergroup interactions.⁽⁴²⁾

CAT proposes 3 different processes or approximation strategies that Soliz and Giles describe as follows:⁽⁴²⁾

1. Convergence: *“a strategy whereby individuals adapt their communicative behaviors in such a way as to become more similar to their interlocutor’s behavior. Typically, this is done to seek approval, affiliation, and/or interpersonal similarity as a manner of reducing social distance.”*
2. Divergence: *“leads to an accentuation of speech and nonverbal differences between the self and the other. Often (but not always) the motive behind divergence is precisely the desire to emphasize distinctiveness from one’s interlocutor, expressively highlighting contrasting group identities.”*
3. Maintenance: *“where a person persists in his or her original style, perhaps for reasons of authenticity or consistency, regardless of the communicative behavior of the interlocutor.”*

Muir, Joinshin, Cotterill and Dewdney⁽⁴³⁾ point out that accommodative behaviour has been associated with a positive evaluation of the communication, the individual, and the relationship, while nonaccommodation has been with negative evaluations. They indicate that:

- Convergence in speech or nonverbal behaviours facilitates the perception of similarity among interactants.
- Greater similarities in attitudes and personality are perceived when dyadic participants converged in pause duration.
- Convergence in nonverbal behaviours (as mimicking body language, facial expressions, or gaze) has been related with feelings of rapport among interactants.
- Verbal mimicry increases the perception of the speaker’s attractiveness.

Even the studies of Language, Gender and Sexuality only represents a small percentage of all the CAT-based research done (around 13,5% of them until December 2010)⁽⁴²⁾, there exist several researches that have studied the accommodation theory to gender-preferential language in different contexts (some of them as specifics as in e-mails⁽⁴⁴⁾, graffiti from toilets⁽⁴⁵⁾ or a medical visit).

Some authors indicate that the accommodation may be limited only to female speakers, who consciously or unconsciously accommodate their style when are with a male partner, while

others defend that both genders converge and even they do it in the same proportion.⁽⁴⁶⁾ Other authors show how gender-preferential style is more present in same-sex conversations than in mixed-sex conversations; and this can be explained by the accommodation (convergence) that men and women do to the gendered style of their partner in mixed-sex conversations. Accommodation in same-sex conversation also exists and it is erroneous to assume that the style used in a same-sex conversation is the “natural” one; in fact, as boys and girls usually spend more time in same-sex groups, they are more used to accommodate to the gender-preferential style of their own group, and they are also more motivated to do it to accentuate the similarities with the in-group members.⁽⁴⁴⁾ Other authors point out that, in mixed-sex conversations, men and women diverge from each other in their speech behaviours to stay consistent with traditional sex role stereotypes.⁽⁴³⁾

An example of the accommodation studies are the ones that found gender differences in vocal accommodation, indicating that women are more likely to accommodate than men, Namy, Nygaard and Sauerteig found this difference robust and they suggest that it is due to gender differences in the perception of indexical information (either because of a better perceptual sensitivity or because they pay more attention).⁽⁴⁰⁾

A.4. DIFFERENCES IN THE PATTERS OF COMMUNICATION BY GENDER

Turabian, Minier-Rodriguez, Moreno-Ruiz et al. ⁽⁴⁷⁾ indicate that gender differences in communication is a controversial topic, because some authors identify significant differences will others refuse them and say that there aren't differences. Even so, in the last decades the number of researches about differences between women and men behaviour have increase and there is an extended perception that there exist differences in the way men and women communicate and in the motivations to do it. Griffin highlights that after a long systematic research he found at least three cautions: ⁽⁴⁸⁾

1. There are more similarities than differences among men and women.
2. Greater variability of communication style exists among women and among men than between both groups.
3. Sex is a fact; gender is an idea.

This chapter contains a compilation of the differences between male and female trends or patterns found in several articles and books published but, as Cameron says, they are not categorical. ⁽³⁾ Another important idea is that, as Wallentin says, *"researchers bring their own preconceptions, or gender stereotypes, with them in their interpretation of data"* ⁽⁴⁹⁾ so is recommended to be cautious with the results.

A.4.1 MOTIVATION TO COMMUNICATE

Tannen points out that men and women have different motivations and needs to talk that influence the style of their speech. She indicates that *"more men feel comfortable doing "public speaking," while more women feel comfortable doing "private" speaking"* ⁽³¹⁾. In fact, she indicates that men are talkative in public and silent in private, whether women are silent in public and talkative in private, showing that men speak more than women in public arena and women more than men in private conversations. ^{(31) (50)}

Holmes indicates that most women enjoy talking and consider it important to keep in touch, so they use language to establish, nurture and develop personal relationships. While men understand language as a tool to obtain and transmit information; seeing the conversation as a means to an end. ⁽⁵¹⁾

In the same way, several authors point out that men are motivated to negotiate, maintain status, assert dominance, preserve their independence and to achieve utilitarian goals, while women use language as a way to form and maintain connection with others and negotiate relationships. ^{(31) (33) (50) (52)} As Griffin says *"girls learn to involve others in conversations, while boys learn to use communication to assert their own ideas and draw attention to themselves"* ⁽⁵⁰⁾.

Maltz and Borker identify the 3 major things done by boys and girls with speech: ⁽²³⁾

- Girls:

1. Create and maintain relationships of closeness and equality.
2. Criticize others in acceptable ways
3. Interpret accurately the speech of other girls.

● Boys:

1. Assert one's position of dominance.
2. Attract and maintain an audience.
3. Assert oneself when other speakers have the floor.

A.4.2 MAIN CHARACTERISTICS OF THE DIFFERENT STYLES OF COMMUNICATION

During more than 40 years different authors have study the communicative differences between men and women, and they have tried to identify the main characteristics more common in one and the other; Mulac, Studley and Blau indicate that male language is seen as more instrumental and commanding while female language is seen as more socially positive and accommodating.⁽⁵³⁾ Mulac, Giles, Bradac and Palomares point out that the women's style has been described as *"more hesitant, indirect, emotional, and uncertain"* than that of men that has been characterized as being *"more dominant, direct, and controlling"*⁽⁵⁴⁾.

Mulac, Bradac and Gibbons⁽³⁴⁾ did a literature review about gender-linked language differences and they identify 21 language features susceptible to be considered as indicative of the communicator gender; they separate the findings in 3 groups:

- Male language features: those found to be used more by male than by female communicators.
- Female language features: those found to be used more by female than by male communicators.
- Equivocal language feature: those found in some studies to be more indicative of males, and in others, more indicative of females.

From the 21 language features, 16 were identify as indicative of the communicator gender: 6 of the masculine style (reference to quantity; judgmental adjectives; elliptical sentences; directives; locatives; and "I" references) and 10 of the feminine style (intensive adverbs; references to emotions; dependent clauses; sentence initial adverbials; mean length sentence; uncertainty verbs; oppositions; negations; hedges; questions). About the other 5 language features (personal pronouns, tag questions, fillers, progressive verbs and justifiers) seems to don't be consensus and some studies associate them to a masculine style and others to a feminine one.

Another literature review about the characteristics associated with masculine and feminine communication styles, done recently by Weinberg, Treviño and Cleveland, they highlighted 4 key facets of each styles, about the masculine communication the 4 characteristics that they underlined were: assertive, egocentric, abstract and instrumental, while the 4 characteristics

of the feminine communication were: egalitarian, compassionate, concrete and relational.⁽⁵⁵⁾ Following tables synthesize their findings (tables A.1 and A.2):

Table A.1. Key facets of the gendered communication construct. Facet I: Masculine communication

Assertive	Communicate in a direct and assertive manner; communicating in a dominant, forceful, or aggressive way	Give orders in an attempt to control others (Weiss & Sachs, 1991); exhibit superiority, control by giving advice (J. T. Wood, 2013); aggressive and direct (Pearson, 1981); communicate in a way that is more forceful and authoritative (Mulac, 2006; W. Wood, Christensen, Hebl, & Rothgerber, 1997); assertive form of communication (Leaper & Ayres, 2007; Palomares, 2012)
	Dominate the conversation; interrupt others to gain command of the conversation	Communicate to assert control over others (Messner, 1997); compete for the <i>talk stage</i> or for conversational command; reroute conversations; challenge other speakers (J. T. Wood, 2013); talk often and at greater length than others (Mulac, 2006); dominating discussions (Borisoff & Merrill, 1985); usurp conversation (Tannen, 1990)
Egocentric	Emphasize and defend one's own thoughts and beliefs	Use communication to emphasize your ideas, opinions, and identity; preserve one's independence (J. T. Wood, 2013)
	Use communication to draw attention to oneself and to one's own ideas	Communicate to get attention and to stand out (Messner, 1997); use communication to attract and maintain others' attention and stand out (J. T. Wood, 2013); self-promotion (Tannen, 1994b)
	Use communication to establish and enhance one's own status	Communicate to compete for and maintain status (Messner, 1997); competitive (Leaper & Ayres, 2007); issue commands and compete for status (Goodwin, 1990); conversation as an arena for proving oneself and negotiating prestige (J. T. Wood, 2013)
	Use communication to assert one's authority	Communicate in a manner that is strong and ambitious (Kimmel, 2005); influences others (Palomares, 2012)
Abstract	Avoid disclosing personal information that might suggest weakness or vulnerability	Tendency to protect oneself from potential vulnerabilities by withholding or concealing personal information that may be construed as weakness (Saurer & Eisler, 1990)
	Use an abstract communication style, speaking in terms that are removed from concrete experiences	Impersonal (Newman, Groom, Handelman, & Pennebaker, 2008; Pearson, 1981); speak in abstract, general terms that are distanced from personal feelings and experiences (J. T. Wood, 2013)
Instrumental	Communicate in an instrumental way (as a means to accomplish goals)	Instrumental (Deaux & Major, 1987; Leaper & Ayres, 2007); communicate to accomplish goals (Messner, 1997); use talk to accomplish or achieve objectives (J. T. Wood, 2013)

Source: taken from "Gendered Communication and Career Outcomes: A Construct Validation and Prediction of Hierarchical Advancement and Non-Hierarchical Rewards"⁽⁵⁵⁾, with authorization of Frankie J. Weinberg.

Table A.2. Key facets of the gendered communication construct. Facet I: Feminine communication

Egalitarian	Employ a collaborative communication style	Foster cooperative and open-ended discussion (Campbell, 1993); cooperate with others (K. Robertson & Murachver, 2003; Weiss & Sachs, 1991)
	Communicate in a way that strives to establish equality among all participants	Use communication to establish egalitarian relations with others; establish equality and achieve symmetry (Ashcraft & Mumby, 2004; J. T. Wood, 2013)
	Communicate one's support for others	Demonstrate support to show understanding of others' situations or feelings (J. T. Wood, 2013)
	Communicate in a responsive way (e.g., by smiling or nodding)	Smile more frequently (LaFrance, Hecht, & Paluck, 2003); respond to others' ideas; nod or say "tell me more," or "that's interesting" (J. T. Wood, 2013); this type of responsiveness reflects a tendency to care about others such that they feel valued and included (Chatham-Carpenter & DeFrancisco, 1998), affirming the other person's position while also encouraging the other person to elaborate (J. T. Wood, 2013)
	Invite others to participate and encourage them to elaborate on their thoughts	Receptive (Pearson, 1981); include others and bring them into the conversation (J. T. Wood, 2013); use inclusive, nondirective language (Goodwin, 1990); engage in conversation to learn about others (F. Johnson, 1996); engage in participatory interaction in which participants respond to one another and build on each others' ideas (Hall & Langelier, 1988); conversational <i>maintenance work</i> —attempt to sustain conversation by inviting others to speak and by prompting them to elaborate their ideas (Taylor, 2002; J. T. Wood, 2013)
	Regard communication as a way to build rapport (harmonious connections) with others	Mindful of the <i>relationship level of talk</i> , with a focus on the relationship between communicators (MacGeorge, Gillihan, Samter, & Clark, 2003; J. T. Wood, 2013), conciliatory (Pearson, 1981); affiliative communication, promotes closeness (Leaper & Ayres, 2007; Palomares, 2012)
Compassionate	Communicate in a way that expresses empathy or sympathy toward others; understanding of others' perspectives	Concern with people and relationships (Spence & Buckner, 2000); communicate in a way that regards others' feelings and shows sensitivity to others (J. T. Wood, 2013)
	Communicate in a compassionate way; a way that is sensitive to the needs of others	Compassionately provide emotional support (Lilius et al., 2008; Miller, 2013); femininity is deferential (Spence & Buckner, 2000); employ tentative, provisional communication that allows others the opportunity to respond and express their opinions (J. T. Wood, 2013); use of tentative communication reflects the desire to maintain an open communication (Mills, 1999); polite (Pearson, 1981); consider others' points of view (Tannen, 1994a)
Concrete	Use a more concrete communication style, providing details, disclosing personal information, and using concrete reasoning	Utilize a personal, concrete style which includes details, personal disclosures, and concrete reasoning to cultivate a close, personal connection (Ashcraft & Mumby, 2004; Hall & Langelier, 1988; J. T. Wood, 2013). Share themselves via conversation (F. Johnson, 1996; Weinberg & Locander, 2013)
Relational	Communicate as a primary way to establish and maintain relationships	Communicate to create and maintain relationships; recognize that the communication process, more so than its content, is the heart of relationships; talk is the essence of relationships (J. T. Wood, 2013); promote closeness (Palomares, 2012); use words related to social processes (Newman et al., 2008)

Source: taken from "Gendered Communication and Career Outcomes: A Construct Validation and Prediction of Hierarchical Advancement and Non-Hierarchical Rewards"⁽⁵⁵⁾, with authorization of Frankie J. Weinberg.

Mohindra and Azhar⁽⁵⁶⁾ indicate that "men and women communicate on different levels and their communicational approaches are also different"; they summarize some of these differences in the following table (table A.3):

Table A.3. *Levels of Communication between Men and Women*

S.No	Men	Women
1	Men keep their problems to themselves and don't see the point in sharing personal issues.	Women are more likely to talk to other women when they have a problem or need to make a decision.
2	Men tend to relate to other men on one-up and one-down basis. Status and dominance is important.	They are more relationship oriented, and look for commonalities and ways to connect with other women.
3	Men focus on talking and providing information rather than asking questions. They share experiences as a way of being one-up.	They focus on building rapport, by sharing experiences and asking questions.
4	Men can have a disagreement, move on to another subject and go get a drink together	If women have a disagreement with each other it affects all aspects of their relationship.
5	Men build relationships while they are working on tasks with each other.	Get things done at work by building relationships.
6	Men move to solutions and problem solving right away.	Women want to talk about the problems and solve them collaboratively.
7	For men asking for help reflects an inability to achieve on one's own merit.	Offering help and advice is a sign of care.
8	Men listen to the main points. They are selective listeners.	They listen to each and every word; they show attentiveness through verbal and non-verbal cues.

Source: Taken from *"Gender Communication: A Comparative Analysis of Communicational Approaches of Men and Women at Workplaces"*.⁽⁵⁶⁾

A.4.2.1 The gendered styles: the reflection of differences of role. The "report talk" and the "rapport talk".

To show the main differences between the distinctive communication style of the public and private spheres, which have been related to how men and women tend to communicate, Tannen coined the terms *"report talk"* and the *"rapport talk"*. The main characteristics of these styles are:

- Report talk (public speaking): Griffin, Ledbetter and Sparks⁽⁵⁰⁾ define it as *"the typical monologic style of men, which seeks to command attention, convey information, and win arguments"* and points out that *"men use talk as a weapon"*. Eunson indicates that is a task-oriented talk that seeks to produce solutions.⁽⁵⁷⁾ Tannen explains that *"this is done by exhibiting knowledge and skill, and by holding center stage through verbal performance such as storytelling, joking, or imparting information"*⁽³¹⁾.
- Rapport talk (private speaking): Griffin, Ledbetter and Sparks define it as *"the typical conversational style of women, which seeks to establish connection with others"*⁽⁵⁰⁾. Eunson indicates that is a relationship-oriented talk that seeks to build understanding and empathy within a wider group.⁽⁵⁷⁾ Tannen points out that its emphasis is on displaying similarities and matching experiences.⁽³¹⁾

In a similar way than Tannen, connecting men's and women's style of communication with the ambit and role that society assign to each gender, Eagly and Carli indicate that women are

associated with communal qualities and men to agentic qualities, saying that *“women are associated with communal qualities, which convey a concern for the compassionate treatment of others. They include being especially affectionate, helpful, friendly, kind, and sympathetic, as well as interpersonally sensitive, gentle, and soft-spoken. In contrast, men are associated with agentic qualities, which convey assertion and control. They include being especially aggressive, ambitious, dominant, self-confident, and forceful, as well as self-reliant and individualistic”*⁽⁵⁸⁾.

A.4.2.2 Constructing the discourse

Tusón describes the differences between feminine and masculine style constructing the discourse, she highlights that in the feminine style is done in a shared way, with more involved and personalized style, whereas men have the tendency to summarize or reformulate what is being said and to use a more assertive style.⁽¹⁴⁾

She also indicates that feminine style is characterised by using more the second person and the first person of plural, to include the people they speak with; while masculine style use more the first person singular, third person and impersonal forms. Hirschman found this fact correlated with the stereotype that says that females usually talk more about their own experience and feelings while men use talk abstractly and generalize more.⁽⁵⁹⁾

Tusón also indicate that feminine style uses more often interrogative and exclamatory sentences and less frequently enunciative sentences than the masculine style. Feminine style also uses more indirect and less imposing forms and leaves more unfinished sentences than masculine style that uses more direct statements.⁽¹⁴⁾

Hirschman points out that most voluminous female speakers use more affirmative responses and fillers than most voluminous male speakers, she posits that this may be done to compensate their possible aggressiveness by increasing hesitancy and through greater responsiveness to the person she speaks with.⁽⁵⁹⁾

Hirschman also suggest that, when talking with somebody they don't know, women feel more comfortable and talk more easily to another woman than to a man, she didn't suggest any preference in males.⁽⁵⁹⁾

Mulac, Studley and Blau indicate that female speakers are more likely to begin the sentences using adverbs or adverbial sentences and to use longer sentences; while male speakers are more likely to make grammatical errors and use judgmental phrases.⁽⁵³⁾

A.4.2.3 Telling a story

Tannen indicates that men tell stories more often than women do and they do it more frequently speaking about themselves, whilst is more habitual in women than in men to tell stories referring to others. When men speak about themselves, sometimes they take the role of protagonist and antagonists, and usually they do it making them look good; when women

talk about themselves usually present them doing something foolish.⁽³¹⁾ ⁽⁵⁰⁾ Johnstone (mentioned by Tannen) found that the protagonist of men's stories, when is not about themselves, usually is about other men, being strange that they tell stories about women, while women stories are about themselves, men or other women.⁽³¹⁾

A.4.2.4 Telling jokes

Men usually tell more jokes than women, and they prefer to do it when they have an audience, doing it even when it includes people that they don't know well; men tell jokes usually to other men, but also to women or to mixed groups. Women usually prefer to do it in small groups (rarely more than three people) and the ones who tell jokes to large groups usually come from ethnic backgrounds in which verbal performance is appreciated; when women tell jokes usually is to other women, being strange that they tell them to groups of men and even less common to do it to mixed groups⁽³¹⁾.

A.4.2.5 Gossip and "sport-talk"

Gossiping is a term used mostly related to women's talk and usually in a pejorative way. Jones (quoted by Coates) uses this term in a positive sense and defines it as *"a way of talking between women in their roles as women, intimate in style, personal and domestic in topic and setting"*⁽⁶⁰⁾. Coates points out that the use of the term gossip brings the idea of a talk between women in a non-serious way, in contrast with the men's talk that is seen as a real talk and always serious; but the truth is that gossiping it is *"a process vital to everyday life and not restricted to women"*⁽⁶⁰⁾. In fact, a report published by The Guardian quoted a study indicating that *"some 27% of men, compared with 21 % of women, admitted making calls primarily for gossip, which 26% of men referred to as "keeping in touch". But when some were questioned in focus groups, this often proved to be "essentially a euphemism for gossip""*⁽⁶¹⁾.

Several authors have highlighted the importance of the gossip, for example Holmes indicates that *"gossip conveys information - about people, events, attitudes - as well as serving the cohesive social function of emphasising membership of the in-group and reinforcing solidarity between contributors"*⁽⁵¹⁾.

Cameron identifies *"sports-talk"* as a typical masculine conversational genre, and indicates that it has a similar purpose than gossip between women.⁽⁶⁰⁾ Several authors link the sports-talk with the gossip, for example Moss wrote an article in The Telegraph entitled *"Welcome back football, the great gossip mag for men. Prowess, professionalism, technique, talent? Forget it. Professional football has become the male equivalent of Hello! magazine"*⁽⁶²⁾ that shows how men gossip about all that involves football (live of the players, conflicts between them, what they say or post in the social media...). Johnson and Finlay, quoted by Coates, indicate the importance of talking about football and the importance of its role, saying that *"if female gossip is a way of talking which solidifies relationships between women, then talking about football would appear to serve a very similar purpose for men"*⁽⁶³⁾. Benwell indicates that men's lifestyle magazines also play this same role, and indicates that in both cases (men's

lifestyle magazines and football talk) the gossiping is limited to unknown and famous individuals, avoiding personal experiences and private sphere.⁽⁶⁴⁾ In fact this is one of the differences that Coates highlights between the men's talk that can be labelled as 'gossip' and women's gossip, because women's gossip is focus in the personal experience; other difference that she identifies is the competitive element that always appears in men's talk.⁽⁶⁰⁾

A.4.2.6 Choosing a topic

Johnstone, quoted by Tannen, found differences about the topic that men and women choose for their stories, women usually choose topics about community while men do it about contest. (31) Bischooping indicates that women talk more than men about people and relationships and appearances, while men do it more than women about social and political issues, work, money and leisure activities, especially sports.⁽⁶⁵⁾

Tusón indicates that usually women change the topic more often than men and they usually treat the topics from their own intimate experience, while men use to keep the same topic for longer and treat them from an external point of view.⁽¹⁴⁾ Nevertheless, Eunson points out that men change the topic more than women and he specifies that to change the topic women use more conjunction as "however", "but" or "and", while men use more interjections as "oh", "by the way" or "listen".⁽⁵⁷⁾

Fishman indicates that women try more often to introduce topics in the conversations than men but are less successful; these are considered tentative and discarded easily, while the topics proposed by men are seen as topics to be pursued.⁽²⁷⁾

A.4.2.7 Talking about troubles: "Trouble talk"

Tannen coined the term "*trouble talk*" and considered it as a particular type of rapport talk. She found that when women talk about troubles they seek for connection, reaffirm mutual interests, exchange points of view, share experiences and to get closer, as Alami⁽³³⁾ says "*I tell you my troubles, you tell me your troubles, and we are close*", they give sympathy and expect the same in response⁽⁶⁶⁾, without the necessity of looking for a solution, on the other hand men understand the trouble talk as a request for advice where the main aim is to look for a solution^{(31) (33) (50) (57)}. These different understanding of troubles talk bring different ways to respond, usually men do it giving advice, joking, changing the subject or giving no response while women respond more sharing a similar problem or expressing sympathy; these differences also bring up conflicts because, as Michaud and Warner say, "*when men respond to women's troubles talk by offering advice, women tend to feel that their feelings are being invalidated, their problems are being minimized, or that their partner is being condescending by telling them how to "fix" the problem. Conversely, when women offer sympathy to men, men may feel that they are being placed in a one-down or lower status position and being condescended to*"⁽⁶⁶⁾.

A.4.2.8 Minimal responses

Maltz and Borker identify differences of interpretation in the use of minimal responses in the conversation interaction between genders, such as nods and comments like “yes” or “mm hmm”, indicating that when women use it means something like “I’m listening to you; please continue”, and when men do it means “I agree with you” or “I follow your argument so far”, so the fact that women use minimal responses more is because they listen more often than men agree. This makes that⁽²³⁾:

- 1- *“Men who think that women are always agreeing with them and then conclude that it’s impossible to tell what a woman really thinks.*
- 2- *Women who get upset with men who never seem to be listening”*

Hirschman’s findings coincide with what Maltz and Borker said about women using more often minimal responses than men, but also point that they use them more when are speaking with another woman⁽⁵⁹⁾.

Nevertheless Fishman gives other sense to the use of the minimal responses by men, she says that *“male usages of the minimal response displayed lack of interest. (...) Such minimal responses are attempts to discourage interaction”*, women also do sometimes that use, but the most common use is as “support work” showing her participation and interest in the interaction and the speaker⁽²⁷⁾.

A.4.2.9 Hedges

Several authors have shown that women use hedge more frequently than men and this has influenced in considering women’s speech as “tentative”; Lakoff for example linked the use of hedges with unassertiveness and lack of confidence. However, Coates draws attention to the functions that use of hedges^j have, for example, she mentions that the hedge “you know” can be used to express confidence or uncertainty, and a research done by Holmes show that women use it more often to express confidence while men use it to express uncertainty. She also posits that the lower use of hedges by men is because of the choice of topics: men avoid sensitive topics and prefer to talk about impersonal subjects; indicating that the use of hedges is more usual (and very value) in sensitive topics because mitigates the force of what is said.⁽⁶⁰⁾

A.4.2.10 Silent, interruption and overlapping

Zimmerman and West⁽²⁴⁾ indicate that there is an asymmetry in the conversational relations between men and women and this was reflected in the patterns of interruption silent and support, and they observed that:

^j Coates defines “hedges” as a “linguistic forms such as *I think, I’m sure, you know, sort of and perhaps* which express the speaker’s certainty or uncertainty about the proposition under discussion”⁽⁶⁰⁾.

- Men interrupt more than women.^k
- Women fall silent (strategy of “silent protest”) when:
 - a) They are interrupted by men;
 - b) After a delayed “minimal response” by men;
 - c) Men overlap them.
- Men don’t fall in silence when they are interrupted by a woman.

Griffin et al. explain that when women start to speak before her conversation partner finished usually is to show her agreement, solidarity or to finish the sentence with what she thinks the speakers want to say, doing what Tannen called a “*cooperative overlap*”. This cooperative overlap is seen by women as a sign of rapport instead of an intent to control the conversation, but from men’s point of view any interruption is competitive, is a power move to control the conversation so the cooperative overlaps usually annoys them.⁽⁵⁰⁾

A.4.2.11 Asking questions

Several authors point out than women ask more questions than men, for example, Hirschman indicates that “*several of the female/male conversations fell into a question-answer pattern, with the females asking questions and the males answering, but not asking the females questions in return*”; she relates it to the role of women as facilitators of the conversation.⁽⁵⁹⁾ Fishman, in the same direction, points out that women usually work more in the conversations and take a more active role in insuring interaction than men, and she puts as example asking more questions.⁽²⁷⁾

Tannen⁽³¹⁾ indicates that this perception (women ask more questions than men) is not real and it depends on the sphere where the conversation is taking place, in private sphere women ask more than men, but in public sphere men are the ones who ask more, for example she says that in public lecturers “*men almost invariably ask the first question, more questions, and longer questions*”. She also points the differences about men’s and women’s questions, using an example of students asking her questions (she as an expert), she realised that women’s question were supportive or exploring while that of men were challenging.

Túson⁽¹⁴⁾ indicates that feminine style includes more questions “*echo*” (*isn’t it?, right?, huh?, don’t you think?..*) than the masculine style. On the same subject, Lakoff⁽²⁰⁾ thinks that tag-questions (*isn’t he?, don’t you?, isn’t it?...*) are more apt to be used by women than by men, and she explains that using these kind of questions speakers avoid to compromising and coming into conflict with the person she/he is speaking with, but also gives the impression of insecurity. Tannen⁽³¹⁾ indicates that people expect women to use tag-questions and when

^k Zimmerman and West identify the interruption as a “*violation of a speaker’s right to complete a turn*”, they also observed a lesser extent asymmetry in overlaps, that they understood as “*errors indigenous to the speaker transition process*”.

they have to guess the sex of the person speaking, they usually take the presence or absence of tags as an important clue (if tags are used they usually say that it is a woman and if there isn't they say that is a man); she also points out that women who use tag-questions and disclaimers are considered less intelligent than men who used them. Mulac, Bradac and Gibbons⁽³⁴⁾ identify the use of tag questions as an equivocal language feature, because some studies considered that men use them more often than women; that studies were in the context of an academic conference participation and in informal conversations between students. Crawford⁽⁶⁷⁾ also highlights that there is not a consensus about considering or not tag questions as a characteristic of a gendered style and describes Lakoff's claim as oversimplified.

Fishman⁽²⁷⁾ indicates that women use twice more often than men the kind of questions "D'ya know what?" that is a sequence Question-Question-Answer ("*D'ya know what?*" "*what?*" "*Blahblah (answer)*") very used also by children and that is a way of insuring rights to speak.

A.4.2.12 Paralanguage: Prosody

Túson⁽¹⁴⁾ describes the following prosodic characteristics of the feminine and masculine styles:

- Feminine style is distinguished by a more emphatic intonation, with a lengthening of the vowel and using more intonational modulations, while masculine style has a more staccato rhythm with fewer intonational modulations.
- Feminine style includes more changes of tone of voice than the masculine style, with tendency of using more acute tones.
- Feminine style use ascending endings whilst masculine style includes descending endings.

McQuiston and Morris indicate that is usual that women raise their voice's tone in response to a question, mainly at the end of the sentence, as in a question-like statement (for example, the man ask "What would you like to eat?" and the woman replies "A pizza?"), probably they do this to indicate support or to don't bring any inconvenience to the other person.⁽⁶⁸⁾

A.4.2.13 Vocabulary

As Túson⁽¹⁴⁾ describes there are differences in the vocabulary used in feminine and masculine style. Feminine style is characterised by the use of vocabulary related to private areas as family, home or affections, among others; by using more words that designate nuances as for example when referring colours; and to use more diminutives and words that express affection. On the other hand the male style characteristically uses vocabulary related to the public areas as politics, sports or work, among others; to use more coarse vocabulary as swearwords; and to use the augmentatives.

McQuiston and Morris indicate that women use more intensifier adverbs (as *very*, *really* or *vastly*) than men, and they think this can be to “*better express emotion and power*”. They also explain that its use usually seeks to emphasize an aspect of their statement or to give credibility to it. ⁽⁶⁸⁾

Eunson point out that men use more quantifiers (as *always*, *never*, *all* or *none*) than women, while women use more qualifiers (as *kind of* or *a bit*) than men do. He also highlights the aggression as other characteristic of the men’s style of communication and indicates that “*men may be more likely to use profanity/obscenity, and to use teasing insults and playful put-downs either as indicators of affection and intimacy or as threatening and controlling behaviour*” ⁽⁵⁷⁾.

A.4.2.14 Politeness

Many authors point out that women speak more politely than men and they use less ‘vulgar language’. For example, Lakoff indicates that “*women’s speech sounds much more ‘polite’ than men’s*” ⁽²⁰⁾ and considers that one aspect of this politeness is not to impose your mind/views/claims on anyone else, leaving an open decision and she notes that the use of tag-questions is very useful for this, as it doesn’t force agreement on the addressee.

As it has been written in the explanation of the dominance approach, several authors relate the more politeness of women as a reflection of the social differences and power. As we said before, Brown explains the more politeness of women because they are “*culturally relegated to a secondary status relative to men and since a higher level of politeness is expected from inferiors to superiors*” ⁽²⁵⁾. In the same direction Cameron ⁽²⁶⁾ points that men aren’t more polite because they feel that they don’t need it. Holmes also talks about the relationship between politeness and subordination and use it to explain the fact that women are more polite than men. She also differentiates two types of politeness: “*positive politeness that is solidarity oriented. It emphasises share attitudes and values (...). By contrast, negative politeness pays people respect and avoids intruding on them. Indirect directives (...) express negative politeness*” ⁽⁶⁹⁾.

McQuiston and Morris ⁽⁶⁸⁾, as Holmes ⁽⁶⁹⁾, indicate that women are more polite and men more directive in communication.

A.4.2.15 Compliments

Coates says that several researches indicate that women give and receive more compliments than men, she also offers some details about different studies that are summarise in the following points: ⁽⁶⁰⁾

- The majority of compliments are given by a woman to another woman, being not common the ones given by a man to another man. When a man gives a compliment usually is to a woman, in fact men use to give compliments to women more often than

vice versa. The compliments given by one woman to other are quite common and usually are about appearance, while between men usually are about possessions or skills and they normally avoid the ones about appearance (that are more common between gays).

- Women use more personalised compliments forms (with first or second person focus, e.g. I like your shoes or your hair looks good) while men preferred impersonal ones (third person focus, e.g. nice shirt!).
- Holmes indicates that *"compliments are remarkably formulaic speech acts. Most draw on a very small number of lexical items and a very narrow range of syntactic patterns"* and the patterns followed by men and women are similar, with differences in the forms *"What (a) ADJ[Adjective] NP[Noun Phrase]"* (e.g. What lovely earrings!) that is more used by women and the minimal pattern (e.g. Great shoes!) more commonly used by men.
- Herbert found that between two people with different status is expected that the person with higher status gives the compliment and the one with lower status accepts it.

A.4.2.16 Non-verbal communication

Mulac, Studley and Blau⁽⁵³⁾ point out that there are differences about how men and women use the nonverbal language, and these differences are consistent with gender stereotypes, as examples of these differences they mention that women tend to smile and gaze more, while men overlap more and tend to speak in longer sentences. Mohindra and Azhar⁽⁵⁶⁾ say that women are better interpreting non-verbal communication than men.

McQuiston and Morris⁽⁶⁸⁾ indicate that women smile more often than men do and they considered that they do it as part of their role, in fact men smile when they are happy or amused while women do it even if they don't feel any positive emotion. They also indicate that women usually nod more than men, as a signal of agreement. Men gesticulate more when are talking but they show less emotions, remaining more neutral, and even to seem more neutral they use facial expressions less often.

Tusón⁽¹⁴⁾ identifies some kinesics differences between the feminine and masculine styles. She indicates that in the feminine style the physical contact is smoother, being more usual actions like holding the arm while walking or kissing in the greetings and with more proximity when speaking. In masculine style physical contact are more sporadic and aggressive, with actions as blows, pats or hand clash in the greetings and keeping greater distance when speaking. McQuiston and Morris⁽⁶⁸⁾ indicate that women feel more comfortable than men in the side-by-side interaction.

Tusón⁽¹⁴⁾ also indicates that in feminine style the hands and arms gestures are usually done in a space closer to the body (with the forearm almost close to the chest) while in masculine

style the arm and hands gestures are wider. And in feminine style legs usually are together or crossed by knees while in masculine style legs are open or crossed with one foot on one knee.

Hall and Friedman ⁽⁷⁰⁾ indicate that there exist several differences on nonverbal behaviours and skills between men and women, mentioning *“smiling, gazing, nodding, expressiveness, self-touching, gesturing, use of verbal facilitators, interruptions, and accuracy in the decoding and encoding of nonverbal cues”* as example of these differences. Authors such as Henley suggest that these differences are explained by status/dominance differences, but Hall and Friedman argue that finding a parallelism between status and gender effects is not enough to infer a causal relation, and they suggest that these differences probably will be a product of socialization factors. They indicate that status can have different effect on men and women; in fact, they studied the differences in nonverbal communication taking into account status and gender, and found that higher status men used more facilitators and fewer interruptions and higher status women were more active nonverbally, which can be said as more “open”, confident, and supportive; they were characterized by being warmer and more expressive; more nodding, gazing, gesturing, and touching; and fewer facilitators.

McQuiston and Morris ⁽⁶⁸⁾ highlight the importance of the eye contact and how it reflects patterns of perceived social domination, and indicate that higher status people maintain the eye contact more when they are speaking while the lower status people do it more when they are listening to a person with higher status. Traditionally the role of lower status is associated with women and higher status with men. Mohindra and Azhar ⁽⁵⁶⁾ point out that men are not so comfortable as women with the eye contact, and they suggest that it can be because of the considerations about power, status and dominance; they also identify direct eye contact as an indication of emotion.

Is important to remember that there are differences not only in how men and women communicate, but also in how people communicate to them, also reflected in non-verbal communication, Hall and Roter ⁽⁷¹⁾ indicate as examples that people gaze and smile more to women or approach to them more closely. They suggest that in social interaction it seems that women are different stimulus than men, and they also point out that some behaviour, as smiling, gazing, some postures or tones are reciprocated.

Eunson, in his book *“C21 Communicating in the 21st century”* ⁽⁵⁷⁾, compiles the main gender differences in non-verbal communication from several authors (Lakoff; Glass; Tannen; Gray; Gamble and Gamble; Stewart, Cooper, Stewart and Friedley; Pearson, Turner and Todd-Mancillas; Trethewey)¹.

¹ Chapter 7, pages 14 and 15 (Table 7.2: Gender differences in non-verbal communication).

A.4.2.17 Written

Most of the differences already shown in the general communication differences also appear in written style.

Mulac, Giles, Bradac and Palomares⁽⁵⁴⁾ in a research about the gender-linked language effect^m studied the difference between men and women written style, the existence of genderlinked language stereotypes and the accommodation to the gender of the reader. To do so they asked the participants to describe different photos, first without any special instruction (gendered style), after other photos “as if you were a man” and “as if you were a woman” (genderlinked language stereotypes) and finally other photos “for a man” or “for a woman” (accommodation), from their findings they realize that:

- Gendered style: masculine written style includes more references to quantity; sentence initial adverbials; “I” references and elliptical sentences. Feminine written style uses more number of words and references to emotion.
- Genderlinked language stereotypes: masculine written style is considered to use more elliptical sentences, references to quantity and negations. While feminine written style is considered to use more references to emotion; judgmental adjectives; sentence initial adverbials and a bigger number of words.
- Accommodation: the analyses didn’t show any communication accommodation, so they didn’t found evidences of the accommodation of the text to the gender of the reader.

Eunson⁽⁵⁷⁾ points out that female writers focus more on relationship than on the task topics; they use the written channel in a similar way than the face-to-face or the telephone conversation, to build relationships, maintaining friendship and kin networks. Similar tends appear in the fiction and non-fiction texts where female writers use a more personal or involved style while male use a more informational and detached style.

Mulac, Studley and Blau identified for their research “*The Gender-Linked Language Effect in Primary and Secondary Students' Impromptu Essays*”⁽⁵³⁾ 19 language variables as potential predictors of writer’s gender. They also analysed previous empirical studies to determine whether these variables were considered indicative of male or female communicators, obtaining the following informationⁿ:

^m Mulac, Giles, Bradac and Palomares describe the gender-linked language effect as a “phenomenon in which transcripts of female communicators are rated higher on Socio-Intellectual Status and Aesthetic Quality and male communicators are rated higher on Dynamism”

ⁿ The original article can be consulted to see the researchers that have found each variable as indicative of male or female communicators.

1. Sentences:

- Mean length sentence (number of words/number of sentences). Four empirical studies found it more indicative of female communicators.
- Use of rhetorical questions (apparently don't expect any response). One empirical study found it more indicative of female communicators.

2. Clauses and phrases:

- Sentence initial adverbials (answering the questions How? When? Or Where? regarding the main clause). Two empirical studies found it more indicative of female communicators.
- Relative clauses (specify or qualify the words that convey primary meaning). Two empirical studies found it more indicative of female communicators and one of male communicators.
- Oppositions (retracting a statement and presenting one with the opposite meaning). Two empirical studies found it more indicative of female communicators.
- Judgmental phrases (personal evaluations more than descriptions). One empirical study found it more indicative of female communicators, while another one found it more indicative of male communicators.

3. Verb phrases:

- Action verbs (indicating movement or actions). One empirical study found it more indicative of female communicators, while another one found it more indicative of male communicators.
- Uncertainty verbs (indicating lack of certainty). Two empirical studies found it more indicative of female communicators.
- Progressive verbs (-ing forms). One empirical study found it more indicative of male communicators.

4. Modifiers

- Hedges/Softeners (indicate lack of confidence). One empirical study found it more indicative of female communicators.
- Intensive adverbs. Six empirical studies found it more indicative of female communicators.
- Justifiers (give a reason to a previous assertion). One empirical study found it more indicative of female communicators, while another one found it more indicative of male communicators.

5. Conjunctions

- Coordinating conjunctions (connects elements grammatically similar). One empirical study found it more indicative of male communicators.

- Subordinate conjunctions (connects elements grammatically different). One empirical study found it more indicative of female communicators.

6. References

- To emotion or feeling. Three empirical studies found it more indicative of female communicators.
- To quantity or place. Five empirical studies found it more indicative of male communicators.

7. Miscellaneous

- Grammatical errors. Two empirical studies found it more indicative of male communicators.
- Fillers (words used other than for their semantic meaning). Two empirical studies found it more indicative of female communicators and one of male communicators.
- Contractions (condense two words into one using an apostrophe to sign the omitted letters). They didn't find any previous study that considered it as indicative of writer's gender.

In the last 15 or 20 years different authors have tried to design algorithms to predict the gender of the writer of a text. Koppel, Argamon and Shimoni indicate that *"it is shown that automated text categorization techniques can exploit combinations of simple lexical and syntactic features to infer the gender of the author of an unseen formal written document with approximately 80 per cent accuracy"*⁽⁷²⁾, so they defend that there are differences in the way men and women write that reflects in the use of different kind of words (as prepositions, singular nouns or articles) or even the punctuation marks.

Ishikawa⁽⁷³⁾ did a research analysing of the written argumentative essays done by university students about two topics given and she found gender differences in language that suggest that *"male students tend to use more nouns related to social economic activities to convey information or facts about the given topics, whereas female students tend to use more pronouns, more intensifiers and modifiers, and words related to psychological cognitive processes so that they might convey their feelings and develop a good relationship with other people"*. Her study also included the following table that summarize the findings of the studies done by Koppel, Argamon and Shimoni⁽⁷²⁾; Argamon, Koppel, Fine and Shimoni⁽⁷⁴⁾; and Newman, Groom, Handelman and Pennebaker⁽⁷⁵⁾ (table A.4).

Table A.4. Summary of gender differences revealed by Koppel et al., Argamon et al. and Newman et al.

	Male	Female
Koppel et al.	noun specifiers (<i>that, one</i>)	negation (<i>not</i>), pronouns, prepositions (<i>for, with, in</i>), conjunction (<i>and</i>)
Argamon et al.	determiners (<i>a, the, that, these</i>), quantifiers (<i>one, two, more, some</i>)	pronouns (<i>I, you, she, her, their, myself, yourself, herself</i>)
Newman et al.	numbers, articles, prepositions (<i>on, to, from</i>)	pronouns (<i>I, my, me, she, their, them</i>), social words (<i>sister, friends</i>), psychological processes (<i>mad, uneasy</i>), verbs, negations, references to the home (<i>home, house</i>)

Source: Taken from "Gender Differences in Vocabulary Use in Essay Writing by University Students"⁽⁷³⁾

A.5. GENDER DIFFERENCES IN SKILLS

Several studies point out that men and women have different comprehension skills; some of these researches follow a biologist approach that puts the focus on the sex differences (biological and anatomic differences), while others are done under a gender perspective, explaining the differences as effects of social and cultural processes. In this document we focus only in the studies done under a gender perspective and we use as main references the PISA and the PIAAC survey, as there are some of the most quoted main referred criteria used in most of the studies.

Most of the studies in this field are done to scholar population and are based in the stereotypes and hold that males are better in mathematics and spatial tests, and females on verbal tests.⁽⁷⁶⁾

A.5.1 Gender differences in scholars: the PISA survey

The Organisation for Economic Co-operation and Development (OECD) has the Programme for International Students Assessment (PISA) that includes a triennial survey to 15-years-old students from different countries around the world; this survey assesses the acquisition of some key knowledge and skills, focusing on the core school subjects of science, reading and mathematics and it also asses the proficiency in an innovative domain, changing the specific topic in each survey, for example in the 2015 survey it was on collaborative problem solving. The PISA survey is one of the most widely used criteria for assessing the quality, equity, and efficiency of school systems and the skills difference among students⁽⁷⁷⁾.

The OECD did in 2015 a special report about gender differences using the data of the PISA survey (and punctually the Survey of Adult Skills), some of them are⁽⁷⁸⁾:

- Overall achievement: Is more likely that boys get lower achievers overall than girls, in fact a higher proportion of them don't arrive to the level of proficiency in any of the three main subjects (science, reading and mathematics). This probably is explaining because they spend less time studying and doing homework outside school.
- Reading: Girls usually have better skills than boys in reading; these differences are narrower when reading in digital format. A possible explication for these differences is that for enjoyment girls read more than boys, especially complex books as fiction, while boys spend more time than girls playing video games. Is important to remark the importance of reading proficiency, because is the base where all other learning is built; so it affects their performance in other school subjects, as Merisuo-Storm⁽⁷⁹⁾ indicates *"good readers are better students than poor readers in every subject area"*, and she also points out that habitual reading has a positive influence on writing and reading skills.
- Mathematics: Usually boys do it better in mathematics than girls. Girls are less confident in their ability to solve mathematics or science problems than boys and they

express strong feelings of anxiety towards mathematics more often. These differences disappear between boys and girls with similar levels of self-confidence in mathematics and of anxiety towards mathematics.

- Thinking like a scientist: Girls do it better solving mathematical or scientific problems when the task is similar to the ones that they routinely do in school, but they do it worse than boys when they are required to “think like scientists”. Boys usually have better results than girls when they have to apply their knowledge of science to a given situation, describing or interpreting phenomena scientifically and predicting changes. These differences may be related to the self-confidence that makes them to be less worried if they fail, that is essential in the trial-and-error processes that are necessary for learning mathematics and science.
- Cause of the differences: The OECD points out that these differences are caused by gender differences and not by sex ones saying that *“PISA shows that gender gaps in academic performance are not determined by innate differences in ability”*⁽⁷⁸⁾.

A.5.1.1 Other contributions to this topic

To explain these gender gap differences is also interesting to draw on the narrative review done by Meece, Glienke and Burg⁽⁸⁰⁾ about gender and motivation, where they highlighting the importance of stereotypes in the development of the skills, indicating that gender stereotypes have an important influence in the motivation-related beliefs and behaviours of boys and girls; usually boys have more favourable motivation to the areas of mathematics, science, and sports while girls have it to language arts and reading; even so the gender gap in motivation in mathematics and science use to decrease with the age, while gender differences in the conception of their reading and sporty ability appears early and continues over all the schooling. They also indicate that there exist gender differences in causal attribution patterns to the success in mathematics and sciences, indicating that boys are more likely to point that their success is because of their ability while women usually attribute it to the effort.

About reading habits, Lasarte⁽⁸¹⁾ indicates that girls read more books and magazines while boys read more newspapers, webs, blogs or forums; Merisuo-Storm⁽⁷⁹⁾ indicates that boys prefer comics and humorous books while girls prefer adventure books. In the survey Lasarte⁽⁸¹⁾ did to 300 students of 11-12 years old from Vitoria (Basque country) she realised that girls read an imaginary world more feminine than boys. Merisuo-Storm⁽⁷⁹⁾ point out that at early-age children start to differentiate between “girl book” and “boy book” and boys avoid to cross that gendered boundaries more than girls, and indicates that some groups of boys consider the school literacy as “un-masculine” with the adverse affect that it has to their reading habit and their reading and writing skills.

Lowrie and Diezmann⁽⁸²⁾ did a research using the Graphical Languages in Mathematics (GLIM) test with 317 Australian students (169 males and 148 females) aged 9-12 years, and they found that there are gender differences in the interpretation of graphics tasks and these are wider as the complexity of the task structure (connectivity between graphic, text and

contextual information) increases, observing that boys tend to be more skilled than girls on the most difficult tasks. They also found that boys outperform girls on map language (information represented on an axis and graphical languages that required movement between 2D and 3D representations).

A.5.2 Gender differences in adults: the Survey of Adults Skills (PIAAC)

The Survey of Adult Skills, is also a product of the OECD Programme for the International Assessment of Adult Competencies (PIAAC), this survey *“assesses the proficiency of adults in three information-processing skills essential for full participation in the knowledge-based economies and societies of the 21st century: literacy, numeracy and problem solving in technology-rich environments.”*⁽⁸³⁾ This and the PISA survey use a different conceptual framework, mainly because of the characteristics of the reference population, but they still enough similar to allow a qualitative comparison between them in the field of the gender gap.⁽⁸⁴⁾

The main results of this survey about gender differences are⁽⁸⁴⁾:

- Literacy proficiency: the gender differences found in the PISA survey (girls are more skilled than boys) became no significant among adults in most of the countries. In the countries that still a significant difference usually this is small, and in some countries men present better scores (as Turkey, Netherlands or Spain) while in others women have advantage (as Greece or Poland).
- Numeracy: gender differences in numeracy (shown in the PISA survey in a better ability of boys in mathematics) continue appearing in adults, and men still have better results than women in numeracy tests in almost all the participant countries.
- Problem solving in technology-rich environments: in this field the gender differences are very small, men tend to have just a little advantage.
- Relation with age: Both gender gaps (literacy and numeracy) appear to have a relation with the age:
 - In numeracy it seem to be wider among older adults (25-44 and 45-65 years) and narrower between young adults (16-24 years).
 - In literacy: The gender gap found in the PISA survey narrows with the age and arrives often to reverse in older adults.
 - The OECD indicates that *“in half the countries surveyed, there is no difference between young men and young women in their proficiency in numeracy, and they are equally proficient in literacy, with young women slightly more proficient in some countries.”*⁽⁸⁵⁾
 - The reason of these changes gives the impression to be caused by one hand, among the young adults, by the decrease of the gender gap in the access to the studies and, on the other hand, among the older adults, by higher

employment rates among men that gives them more opportunities to read, write and use problem-solving skills at work, improving them^{(78) (84)}.

A.5.3 Differences in gender comprehension of IC by gender

A systematic review and meta-analysis done by Tam, Huy, Thoa et al. found that gender had no effect on the proportion of participants who understood informed consent in clinical trials. By contrast other personal characteristics as age (older participants), health status (ill), educational level (lower) or country of origin (low-income) have been seen to have effect on the proportion of participants who understood informed consent in clinical trials. They also highlight that no significant changes in the understanding of any components have been founded in the last 30 years. Tam also point out that some simple measures as take care of the format, do it easily readable and take time to discuss it with the participants can be more effective than more complex measure to improve the understanding.⁽⁸⁶⁾

Due to the recent of this research and the methodology used not a lot of other studies non included in the systematic review done by Tam et al. have been found and the ones that have been point out in the same direction, for example Bergenmar, Johansson and Wilking did a questionnaire to 268 patients to measure the knowledge and understanding about cancer clinical trials among trial participants, and they found not differences in the understanding by gender but they also indicate non differences found by the rest of clinical and socio-economic factors studied. Is important to highlight that Bergenmar et al. found that the 'use of other information sources' and the 'time for information' (to have lasted for >30 min) as factors that where associated with a better perceived understanding.⁽⁸⁷⁾

Paris, Deygas, Cornu et al.⁽⁸⁸⁾ did a research to measure the impact of the modification of the IC form in terms of structure and readability in the participants' understanding in 481 patients in France (241 with the original IC and 240 with the improved one), and they realised that they were not significant differences in the understanding between both groups but the group with the improved IC documents decrease their enrolment. Some gender differences were found, that point to a better understanding by females in univariate analysis and, in multivariable analysis, gender (female) and educational level were associated with a better objective comprehension, this finding is not consistent with the review that Tam et al. did, but is in the same line of other researches that haven't been included in that systematic review, as the ones of Paris, Nogueira da Gama Chaves, Cornu et al.⁽⁸⁹⁾; Raich, Plomer and Coyne⁽⁹⁰⁾; or Morrow, Gootnick and Schmale (in IC for treatment)⁽⁹¹⁾.

Paris, Nogueira da Gama Chaves, Cornu et al.⁽⁸⁹⁾ did a research with 200 volunteers to compare the understanding of four versions of the Informed Consent Form (ICF), one unchanged and other three with different improvements (one with a systematic lexico-syntactic readability improvement; other one modified by a working group; and the last one modified by the working group followed by systematic lexico-syntactic improvement); and they found gender differences in understanding at baseline, when women presented better

comprehension scores than men, but as it was a secondary end-point they are cautious with this conclusion. About the improving of the comprehension by the methods used, they found that in phase I clinical trials all the improvement suggested were effective, without important differences between them, so they recommend using any of them, but not both at the same time. Non gender differences in the impact of the improvements were registered by the authors.

Morrow, Gootnick and Schmale⁽⁹¹⁾, studied the effect that giving more time to read the IC for a treatment (by taking it home) had in the understanding of a ICF, and they observed by one side that in the standard manner (without taking it home) women were better informed than men in most of the areas of the informed consent (procedures; purpose; discomforts and risks; appropriate alternatives; questions answered; diagnosis), founding not differences in the treatment area; and by the other side they found a positive effect of taking it home in the improvement of the understanding, especially in men that experimented a higher improvement in all the areas except questions answered where women improved more than them and treatment area, where they didn't improve. The antiquity of this research (published in 1978) makes to be very cautious with the results, but it has been included because it gives some ideas (as the effect of giving more time for the comprehension) and reflects the understanding in a first moment.

Knepp⁽⁹²⁾ did a research with 183 students to determine if they read the IC form comparing the frequencies in on line (remote access) or in laboratory (in person), the IC form used were approximately 1,75 pages long. He realised that usually people read it more when the procedure is done in the laboratory session than if they do it online at a remote location; he also found that, in person, women use to read it more often than men do, gender differences were not found in online sessions. He also points out that women were more caution to avoid manipulation than men and he consider that these findings can be related to the fact that women tend to use more written information sources than men or that they are more wary because historically they have suffered abuse more often in this field. In his conclusions he indicates that women prefer to do the IC process face to face, so they can receive more verbal information if needed. He also highlights that women usually are more information seeking.

Lobato, Bethony, Pereira et al.⁽⁹³⁾ evaluated the gender differences in the factors influencing the participation in clinical trial through a questionnaire administered to 143 volunteers (48 male, 95 female) in Brazil. They found that they were significant differences by gender; women tend to be more influenced by friends, partner, family, the researcher and altruism than men, demonstrating the influence of other factors besides the individual characteristics, as interpersonal relationships or social norms. They also hypothesize that the influence of the partner or family members is more notably in developing countries than in developed ones. Is interesting that, as Carpenter, DeVellis, Hogan et al.⁽⁹⁴⁾ indicate, female potential participants are more influenced by their partners to be involved in a clinical trial, but men trust more



their partners than women in other medical decision making as for example as source of medication information.

A.6. ONLINE GENDER DIFFERENCES

The Internet is resulting in a crucial communication strategy as it is the pathway for deliver information, provide entertainment and offer online tools. (95) The increasingly prevalence of social media, including online discussion, website forums, blogs, social networking sites, etc., has created a huge platform where the audience can publish and share their reviews on products, services and experiences. (96) Online gender differences refer to the different uses of the Internet between males and females. Back in the early stages of the Internet, there were significantly more men using the Internet than women. With the development and boom of the new technologies this has significantly decreased and nowadays researchers focus on the study of the different ways that women and men use the Internet. (97) However, we do not have to forget that the study of human's behavior will never be a precise science, so results will always be inconsistent and unpredictable.

A.6.1 Gender differences in online communication

Online discussion is a way of communication that has become of high importance in the last years for all citizens of the 21st century. (98)

Online discussion has appeared to be one of the tools used for communication in a lot of different environments. Thus, it is important for researchers to know the gender differences in online learning strategies and apply them to design better online discussion environments. (98)

Results from a study that compare university student's discussion strategies in online and face to face (F2F) contexts within the following factors: comprehension, interaction, elaboration and anxiety; showed that females tend to have better elaboration skills than male in online discussion contexts while in face to face context males and females seem to have similar levels of discussion strategies. Also, young females have higher Internet self-efficacy in online communication than young males, maybe due to their better online elaboration strategies. Regarding the change from F2F to online discussion methods, the study has shown that females are better adapters than male students because the females are more disposed to develop advanced interactive strategies to comprehend and elaborate ideas in online discussions, which may be related to the fact of women self- efficacy of using the Internet as a communication tool. Another important aspect is that online discussion strategies have shown to reduce both gender's anxiety due to less social pressure, interaction and expression. (98)

Focusing on the communication style in online discussion groups, there are a lot of different results depending on the study. Glasgow Caledonian University examined 197 introductory psychology students and show that significant gender differences were found in the use of many stylistic variables and interaction styles. Males were more likely to use authoritative language, using assertions, presuppositions and judging opinions, compared to females,

which were more likely to agree and support others. Also, females use more intensifiers such as “really” and “totally” in their postings, than males do. One of the aspects to highlight is that females made contributions in a more empathic way, containing personal experiences, emotions, and their own feelings, posting messages that are more attenuated. This may be related to findings from another study that show gender differences in the topic of interest, where females tend to talk more about their private lives, such as family, friends and that’s why their language is more likely personal, while men tend to talk about public lives, such as government and public figures. This is related to what it was said before in this document and previous research where women tend to use the internet as a communication tool while men use it as an information seeking tool. ^{(97) (98) (99) (100)}

Another variable of study is the Internet habit strength which has been found to be positively associated with online communication, with the characteristic of being stronger for females than for males. In other words, females with stronger internet habit strength tend to engage in online communication more than males do. However, there is still a gap in this association because research findings are inconsistent across different studies. ⁽¹⁰¹⁾

A.6.2 Gender differences in online shopping

Online shopping is becoming one of the most popular consumption choices accompanied by the emergence of e-businesses that have changed people’s social lifestyle point of view. The substantial growth of this type of purchasing has created great interest in understanding what impact people’s decision to buy or not online. In fact, there are studies that investigate the impact of online communication on online purchase and the gender variation on this impact. Consequently, a better understanding of online shopping attitude is critical to help business create and design effective websites that attract online customers. Gender difference in online shopping have been studied from different perspectives such as perceived risk of buying online, website usability and design, technology acceptance and attitude. ⁽¹⁰²⁾

Results have shown that the direction of attitude when shopping, is different between genders, where males often are goal-oriented shoppers motivated by convenience and females tend to be interest-driven and motivated by emotional and social interaction. It has also been found that communication does impact on online purchasing with more effect on women than men, but both had a positive effect. In this way, providing an online communication platform in an e-business website, can allow to social attributes and increase consumer behavior. ^{(95) (102)}

Moreover, three attitudinal components: cognition, affect and behavior; were examined through a survey of 80 students enrolled in an electronic commerce course. Results showed significant gender differences across the three attitudinal components. In general, women’s cognitive, affective and behavioral online shopping attitudes are lower than men’s, being cognition the lowest. Cognition of an object plays an important role in affect and behavioral intention towards that object. Thereby, women’s low cognitive attitude may explain the low

affection and behavioral attitude toward online shopping. Being that cognition refers to the evaluation of pros and cons of an object, this finding suggest that females are not sure about the benefits and risks of online shopping. In this way, business should focus on increasing women's awareness of the advantages associated with online shopping. Also, enhancing website design and making it more attractive improves the affective feelings and attitude towards online purchasing.⁽¹⁰²⁾

Research has also focused on examining gender differences in perceived risk of buying online and the effects of the word of mouth and recommendation of a friend. Following this line, results has shown that women are more concerned about the security and the perceived risks of buying online than men, even if they are experts in Internet usage. However, it has also been found that a recommendation of a friend has a greater effect on female's intention to buy online than it has for a male's, which results in a significant reduction in the perceived risk among women.^{(103) (104)}

Another study that examined the gender differences regarding the influence of inconsistent reviews on the internet, showed that females are more responsive to a mix of positive and negative reviews. As a consequent, females tend to shop more online in such circumstance than males, suggesting the idea of females considered as comprehensive information processors and males as selective information processors.⁽⁹⁶⁾

A.6.3 Gender differences in social networking sites

Social Networking sites supply a place for individuals to interact and stay in touch with other people, and are becoming a crucial part of everyday life.^{(105) (106)}

These websites have communication features that enable people to send instant messages, post photographs and messages, use the blog, send private messages, create groups, or play games, etc.⁽¹⁰⁵⁾

Language and communication through electronic sources such as emails, Facebook, and other social networking sites is being a subject of current study by a lot of researchers, especially in terms of gender differences. Examining how women and men react and accommodate to gender-preferential language in social networking sites is very important and have aroused great interest. Results from different studies have shown that more intensive adverbs, personal information, subordinating sentences, modals and compliments are used when writing to a female style-language user that is labeled with a female name, compared to a male style- language user labeled with a male name. On the other hand, more insults, opinions and adjectives were used when writing to a male style-language user. This suggests that, no matter what gender one person is, language style is changed according to which person you are writing to. However, another experiment was done with 33 females and 32 males communicating with users where their name label didn't necessarily match to the style-language they were using. (eg. A user called Laura using a male-style language). Results here

showed that participant's language was a consequence of both their own gender and the gender language-style from the user. Also, but with less influence, gender label had some effect on the participant's style-language. This suggests that although an individual's own gender affects to the communication style, the gender and style of the partner who you are communicating with, has a greater effect to use a gender-preferential language in electronic messages.^{(44) (99)}

The social context theory states that people tend to behave following stereotypes in front of a large and unfamiliar group, whereas in private communication this stereotyping behavior is reduced. In this way, public replies to Facebook status updates could be considered as a large and unfamiliar group communication; and private messages, as a one-to-one conversation with someone familiar. Gender differences in terms of public replies to Facebook status updates showed that females tend to reply more than males and using a more emotionally manner with a high level of support. However, these differences between males and females are not seen in private messages, supporting the social context theory, where in private, people behave less stereotypically and gender differences are reduced.⁽¹⁰⁶⁾ Another study also showed that Facebook users introduce themselves online in a less gender-stereotypical way compared to off-line contexts, and that this was seen more in women than in men.⁽¹⁰⁷⁾

It has been stated before that social media is used by the people as a network to connect and maintain social contacts, reflect their daily routines and activities, share information, discuss topics, etc. As this type of online communication is becoming more popular, an increase in women using these technologies is shown. In terms of Internet use and spent time online, women tend to be more socially users, interacting and connecting with others, and maintaining relationships, while men are more task-oriented users, focusing on gathering information and activities such as reading the news. In line with the fact that women use social networking sites to maintain relationships and connect with people, online video calls have also become one of the tools with a greater use in women than men. Regarding the overall use of social networking sites, the number of males and females that are Facebook users is variable depending on the study, so results are inconsistent. Additionally, it has been seen that men tend to use social networking sites for dating, meeting new people, learn about events, find job leads and make friends. Women, moreover, use these sites for posting pictures, comments and send messages; although they care more about their privacy and that's why they interact with people they already know and trust.^{(105) (108)}

Emailing is another way of online communication which women are more likely to use with their family and friends, than men. In addition, a lot of women have said that emailing has a significant role in their lives. On the other hand, men tend to use the email to collect information.⁽¹⁰⁸⁾

Gender has also been found to influence in information diffusion within social networks. It seems that men tend to receive a given message that could influence in social mobilization, more than women do.⁽¹⁰⁹⁾

Social media can also be a dangerous tool for adolescents in terms of online aggression or online bullying. In this way, there is also a gendered behavior which places adolescent girls to be more related to online bullying while boys are located in off-line face-to-face bullying.⁽¹¹⁰⁾

Regarding the profile picture, there has also been found gender differences. Women change more regularly their profile pages and give less personal information than men do. In fact, men are riskier with their photographs or information.⁽¹⁰⁵⁾ Also, compared to females, males tend more to have a profile picture of themselves alone. The male's motivations when choosing the profile picture are to look attractive, show how they are having fun and share unique moments. Also, men tend to show their status (wearing formal clothes or using objects). Female motivations are to look attractive, show how they are having fun, present special moments, but also protect their privacy, exhibit their interests and show their family relationships and emotions by smiling or giving eye contact without sunglasses. These results from different studies suggest the idea that, women are more diverse than men and that not only women think about showing their attractiveness, contrary to what Manago, Graham, Greenfield and Salimkhan investigated.^{(111) (112)}

Social media use can differentiate between high frequency users or low frequency users. When studying gender differences in this field, more high frequency users tend to be woman compared to the low frequency users, suggesting again, the women tendency of using social media to stay in touch and maintain their relationships.⁽¹¹³⁾

Instagram is another social networking site consisting on photo-sharing that has become nearly the most popular in the last 5 years. The main characteristic of this social network is the "hashtag". Hashtags are non-spaced words, sentences or expressions following the sign # that allow users to look for their interests, describe their pictures and gain visibility online. Gender differences are being studied to see how men and women use these hashtags. Research has found that in line with prior studies about gender attitude in computer-mediated communication, females tend to use more emotional and positive hashtags while men use more informative hashtags.⁽¹¹⁴⁾

Regarding instant messaging, some studies have shown that females tend to be more "talkative" with longer conversations, spending more time saying goodbye and using a larger number of emoticons, compared to males.⁽⁹⁹⁾

A.6.4 Gender differences in smartphone and texting

Young generations have grown up with cell phone access and has become an essential part of their lives, spending a considerable time texting or calling. Gender differences in this way of communication is also being studied by a lot of researchers.⁽¹¹⁵⁾

Smartphones are the new versions of mobile phones that have become very popular. They have millions of users and they offer a huge variety of applications (enjoyment, social, pastime, photography, etc.). Researchers are studying the risks of smartphone addiction and

whether these are different across genders. Some results have shown that female users are more likely to develop smartphone addiction by the effects of entertainment and pastime, while males tend to addict to smartphones by the effects of conformity, to avoid disapproval among their friends.⁽¹¹⁶⁾

Mobile phone usage can cause disruptions when driving or walking, learning in class, or during a face-to-face relationship. It has been found that females tend to spend more time using the mobile-phone to speak with their friends and family. Men, on the contrary, use them in a more informative way. Texting has also been found to be more used by women than men, especially to maintain their social interactions. It seems that this new way of communication by texting is eclipsing calling.⁽¹¹⁵⁾

Regarding the etiquette of cell phone use there are different beliefs between males and females. Overall, people think that texting is more acceptable than receiving or giving calls in a lot of different situations (public, intimate, interpersonal), except when driving. Regarding gender differences, men think that calls are more appropriate than women in all different situations, but for texting, men believed it is more appropriate than women only in public social situations. In other situations, no significant gender differences are found. Also, it is more likely within younger groups that females are more likely to text and call their mothers and fathers, than men do.⁽¹¹⁵⁾

A.6.5 Gender differences in eye tracking

Eye movement when reading a document is being a recent object of study for investigators that allow to map cognitive activities and provide information to improve effectiveness and efficiency on comprehension, science education, etc.⁽¹¹⁷⁾

Eye tracking is a technique used to follow eye movements and study the internal cognitive processes related to it. There are different variables used in the study of eye tracking such as location of fixation, gaze duration, regression (look back), pupil size, etc. Differences in location of fixation means differences of attention. Different gaze duration is related to the level of processing, being a deeper processing associated to a longer gaze duration. Regression is related to the working memory capacity and the reevaluation of the information already processed; and pupil size is related to the level of concentration. This technique is normally used in the fields of science education in order to provide teachers efficient ways of teaching their students, gaining knowledge about their cognitive abilities, but of course, it can be used to study many different fields.^{(117) (118)}

Eye tracking can also be used as a tool to study user behavior during online search, specifically to understand activities such as reading, scanning, processing of visual stimuli and cognitive load. There is great interest to find whether men and women have different preferences when viewing information either on a website or a paper document, or during online searching and how eye tracking can study these differences.⁽¹¹⁹⁾

Fixations are motionless gaze of 200-300 milliseconds where visual attention focus on a specific area and it has been related to intense cognitive processing ability. Saccades are rapid eye movements that last 40-50 milliseconds where almost no information is captured. Pupil diameter, gaze duration and number of fixations are metrics used to measure user engagement and mental processing. In this way, it has been shown that fixation frequency in a repeatedly area displays degree of importance and mean gaze duration shows complexity and task difficulty. Larger pupil size is related to cognitive load and concentration when viewing some components of a web-page in an online context. One research conducted with majors in communication focused on the study of ocular behavior on web pages using eye movement metrics. The websites chosen were categorized in 4 types: shopping, business, search and news, and the procedure selected 2 pages from each website; the home page and a specific page related to the website (e.g. If it's a news website, a news article.) Results showed that, generally, females had shorter mean gaze duration than males and that the first pages of the websites had longer gaze duration than second pages, suggesting that males do more cognitive effort and deeper processing and that first pages need more cognitive effort than second pages.^{(119) (120)}

Regarding online search tools such as Google, another study concluded that scanning patterns of the results page is more linear to males than females. In this way, females were more likely to make regressions and go back to already visited abstracts.⁽¹¹⁹⁾

Another study conducted in Spain to examine eye tracking when reading online news found that, when viewing the home page, females tend to read in a vertical manner while males read in a zigzag manner.⁽¹²¹⁾

Gender differences in attentional behavior considering text information or picture stimuli when looking at a website has also been studied using eye tracking. One study conducted with 120 subjects (60 women and 60 men) showed that, for the first ten seconds, the density distribution was clearly different between males and females. Women tend to focus on textual information more carefully while men pay more attention to photos or pictures, and they read less. This is supported by another study that stated that for male students it should be better to give graphical and picture explanations before the main text, while for females, it is better to give verbal explanations before graphics and pictures.^{(117) (122)}

Another study that scanned eye tracking in virtual navigation and orientation, showed that females tend to have longer fixations on the virtual environment and larger pupil diameter, which is associated to memory processing, while men tend to look to more space with shorter fixations and less pupil diameter.⁽¹²³⁾

Science performance and science problems solving have also been studied by different researchers through eye tracking to find gender differences. Overall, previous studies found no significant gender differences in science performance under untimed conditions. However, under timed conditions, science performance varies between males and females, being the

last ones at a disadvantage. In this way, females spent more time to solve a science-problem because they pay more attention to details and are more accurate. Men, on the other hand, focus on speed and solve the tasks more rapidly. Spatial working memory capacity of an individual influences in their science performance and has two components: phonological and visuospatial storage. The phonological is related to the temporary storage and process of verbal information while the visuospatial is related to the temporary storage and process of visual information. In this way, previous studies have shown that males have better visuospatial capacity than females, meaning that males have better skills to understand and memorize diagrammatic information in science, without the need to go back and make regressions to the diagrams. Eye tracking results from a study with students in Taiwan have shown that females have longer gaze duration and more fixation counts than males in textual information. While males tended to read only key pieces of the information provided by the diagram without reading it all, so in consequence, their gaze durations were shorter and fixations counts were less. ⁽¹¹⁸⁾

A.7. THE PATIENT - PHYSICIAN COMMUNICATION

A.7.1 Why is important?

The communication physician-patient is essential to create a favourable environment to talk about different health topics, including the health research and the proper explanation of the informed consent.

Several authors address the issue of communication in the clinical practice and/or the need of improving the communication skills of the physicians; for example:

- Turabian, Minier-Rodriguez, Moreno-Ruiz et al. say that *“communication is an important component of patient care, maybe the most important aspect of practice that health care professionals have to master. The physician-patient interview is the key component of all health care, particularly of primary medical care”*. They also indicate that good communication skills by the physician have been connected with positive outcomes (as patient and physician satisfaction or better levels of adherence to therapeutic recommendations).⁽⁴⁷⁾
- Ha and Longnecker highlight its importance indicating that *“doctors with better communication and interpersonal skills are able to detect problems earlier, can prevent medical crises and expensive intervention, and provide better support to their patients”*.⁽¹²⁴⁾
- Huang, Huang, Yang et al. also point out that the establishment of rapport between patient and physicians contributes to the patient’s satisfaction while a bad communication is a predictor of patient complaints, and they recommend that other countries follow the example of UK that requires to all they medical schools to examine the competence of the students in clinical communication.⁽¹²⁵⁾
- Ahmed and Bates⁽¹²⁶⁾ highlight the importance of and effective communication to improve health outcomes, as patient satisfaction; and they consider that an effective communication is *“patient-centered, informative and that promotes trust and confidence”*.

Other authors indicate its importance in the field of informed consent and/or clinical research; for example:

- Bento, Hardy and Osis indicate that Informed Consent is not only the signature of the form, and *“it is a process that begins at the first point of contact between the investigator and the potential volunteer and which continues throughout the study. This process consists of the investigator supplying information relating to the study, answering any questions and ascertaining that the person has understood the information he/she has been provided with, and allowing the volunteer, if he/she wishes, time to consult with other people”*⁽¹²⁷⁾; so improving communication between potential participants and physicians is of great importance. They also highlight the

important of a proper communication because if the participant doesn't understand the information well he/she won't be able to make an autonomous decision.

- Nishimura, Carey, Erwin et al. ⁽¹²⁸⁾, after a systematic review of 54 interventions and meta-analysis of 22 interventions, point out that the best way to improve comprehension of the IC is enhanced consent forms and an extended conversation between investigator and participant; and they emphasize the importance of improving communication skills.
- Hayman, Taylor, Peart et al. ⁽¹²⁹⁾ found that most useful information identified by parents who were invited to enrol their baby in a research project was the researcher's verbal explanation, a long distance from other sources of information as the written information sheet or the pamphlet, and they indicated that some studies highlight the positive effect that has an adequately information with the decision of participate in research for altruistic reasons.
- Stevens and Pletsch ⁽¹³⁰⁾ also indicate that the relationship between the patient and the health care professionals has a lot of influence in the decision to participate or not, even more than what can be written in the IC.

Ha and Longnecker ⁽¹²⁴⁾ identify the 3 main goals of physician-patient communication, which are: to generate a good interpersonal relationship; to smooth an exchange of information and; to include the patient in decision making. They also indicate that most complains that physicians receive are not because their clinical competency but because of issues of communication.

A.7.2 Gender differences in the relationship physician-patient

As Acuña ⁽²⁾ and Cameron ⁽³⁷⁾ point out, and has already been said in the section A3.2.4 *"Diversity, constructivist and performative approaches"*, the focus nowadays instead of been in the differences about men and women must be in the context and the type of men and women; so in this point the gender differences try to focus in the *"type of men and women"* (patients and physicians of both genders) and in a context (usually clinical conversations), but even in this case the differences are about styles and are not categorical.

Street ⁽¹³¹⁾ analyses the communication in medical encounters through the ecological perspective, and highlights the impact that contexts (media context, cultural-socioeconomic context, political-legal context, organizational context and interpersonal context) may have on the medical encounter. And explains that ecological model identifies two different sources of adaptive behaviour: the cognitive-affective factors (for adaptation based on strategic, attributional and relational considerations) and the partner's communicative actions. He also points out that several factors such as personality, identity, socialization and linguistic styles have been associated with communication differences; and, in the case of physicians-patient communication, a complex interaction of style, perception and adaptation must be taken into account. He suggests that gender differences in communication between patient and

physicians can be explained by factors as gender communication differences in other contexts; gender-based perceptions, attitudes, expectations and beliefs or; the partner's communicative actions. Even so, he indicates that males and females physicians still have more similarities communicating than differences and that gender differences in communication are usually more evident among physicians than among patients.

Hall and Roter ⁽⁷¹⁾ indicate that there are gender differences in communication between physician and patient, some of them due to the way physicians communicate and others because of the way patients treat the physician according to their gender. They indicate that the differences mainly correspond with the gender differences in communication by non-clinical population. Just as women are often more emotionally expressive, tend to have more positive and engaged non-verbal behaviors (such as smiling, nodding, and looking at a partner in conversation), and usually are more egalitarian in interpersonal relationships, female physicians tend to communicate with behaviors usually associated with positive effects to the patient; in fact it has been suggested that female physicians create a therapeutic milieu more favorable than male physicians. As example of the differences in characteristics of gendered communication in non-clinical population that also appear in clinical population, we can use the assessment that Holmes ⁽⁶⁹⁾ does when she indicates that male physicians use more imperatives (e.g. *"eat more fruit"*), while female physicians use less direct forms (e.g. *"maybe you could try fresh fruit for dessert"*).

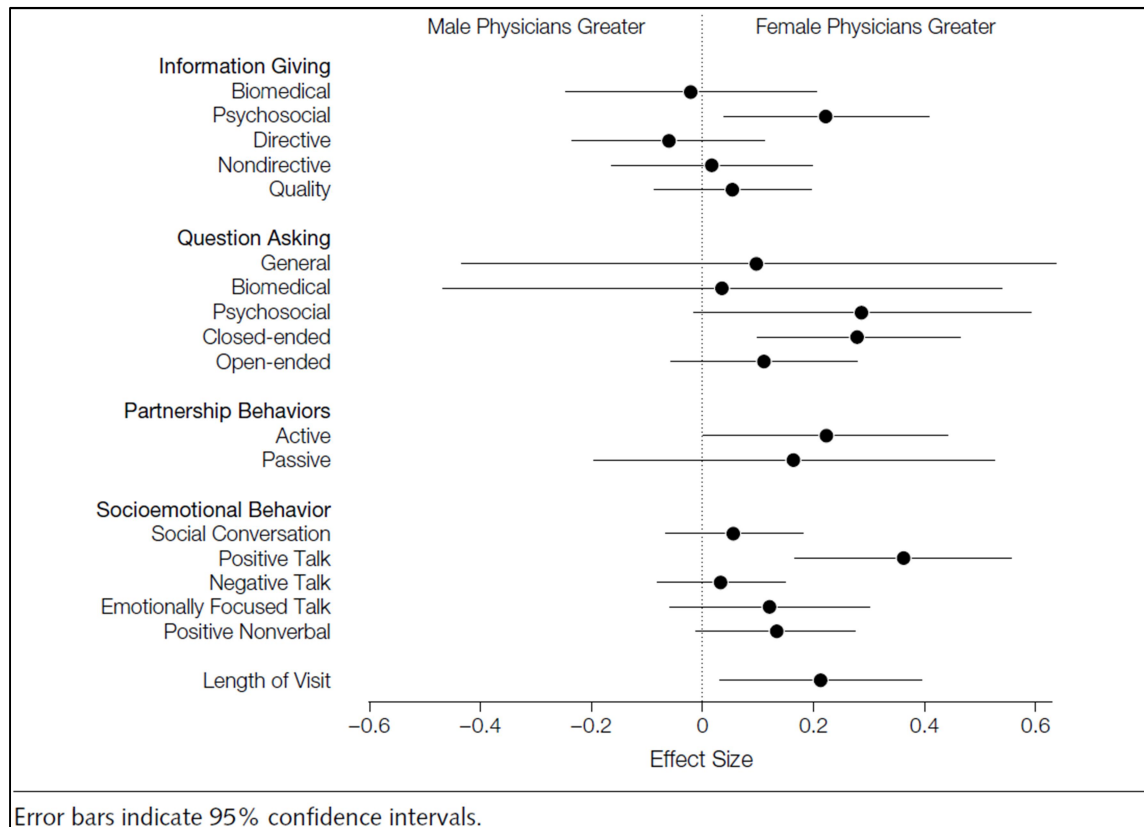
A.7.2.1 Physicians communication

Bertakis, Helms, Callahan et al. ⁽¹³²⁾ point out that there are gender differences in the way physicians communicate to their patients, indicating that female physicians engage in more positive conversations, build partnerships, ask more, and provide more information; and patients evaluate these attitude as positive, evaluating the experience as more satisfactory; this is more evident if the patient is a woman, in fact some studies indicate that female patients use to prefer to be attended by female physicians while male patients use to prefer to be attended by male physicians. In their research done with 250 new patients (118 males, 132 females) and 81 medical residents (48 male and 33 female) in California (USA) they found that female physicians spend more time discussing about the patient's family (medical and social matters, and current family functioning) and social context while men physicians spend more time with the history taking; they also registered a biggest satisfaction with the female physicians, but this can be in part explain because of the differences in the practice style, as patients usually feel less satisfy when the visit is very focused on history taking. So they suggest the importance of identifying the behaviors that are associated with a better patient's satisfaction and teach them to medical students.

Roter, Hall and Aoki ⁽¹³³⁾ did a systematic review of the literature and a meta-analysis to quantify the effect of the gender of the physicians on their communication with the patient during the medical visit, they considered 26 studies (23 observational studies and 3 large physician-report studies) described in 29 publications. They synthetize their findings as

“female physicians engage in significantly more active partnership behaviors, positive talk, psychological counseling, psychosocial question asking, and emotionally focus talk. There were no gender differences evident in the amount, quality, or manner of biomedical information giving or social conversation. Medical visits with female physicians are, on average, 2 minutes (10%) longer than those with male physicians” (figure A.1 show the results graphically).

Figure A.1. Estimated pooled gender effect sizes for categories of patient-physician communication in the meta-analyses done by Roter, Hall and Aoki.



Source: taken from *“Physician gender effects in medical communication: a meta-analytic review”*⁽¹³³⁾

They also conclude that female primary care physicians tend to use a style of communication more centered in the patient; they also point out that may exist differences in some patterns of communication between primary care physicians and some subspecialties (as obstetrics and gynecology).⁽¹³³⁾

Hall and Roter⁽⁷¹⁾ indicate that physicians communicate differently to male and female patients; generally they tend to become more involve with female patients. Physicians usually communicate more, give more information, build more partnership, direct more positive talk, emotionally concerned statements and disagreements with female than with male patients.

A.7.2.2 Patient communication

Turabian, Minier-Rodriguez, Moreno-Ruiz et al.⁽⁴⁷⁾ indicate that there are three groups of conditionings that influence in patients participation in medical interaction:

- The personal characteristics of the patient, as age, gender, ethnicity or education.
- The communication style of the physician as question asking, use of partnership-building or supportive talk.
- The clinical setting as the health condition or the medical specialty.

They did a study analyzing twenty consultations done by a male physician with eight male and twelve female patients, and found very small gender differences in communication, being only remarkable that interviews with women they (the patient women) were more supporting and registered less disagreement.⁽⁴⁷⁾

Hall and Roter⁽⁷¹⁾ did a meta-analytic review about how physician gender affects the patient communication in medical visits; they expected to find that, in general, patients treat the physicians as they treat them, following the reciprocity principle. The results they found are quite consistent between most of the studies, except with one or two studies on obstetricians-gynecologists that were removed in some analyses. The main results are:

- Patients talk more and give more biomedical and psychosocial information to female physicians.
- Patients promote more a partnership relationship with female physicians.
- Patient positive talk (including statements of agreement) is more common toward female physicians.
- Patients direct more anger or irritation toward male physicians (only one research studied the anger or irritation)
- Patients are more assertive with female physicians.
- There are non-significant differences in the amount of questions that patient ask by physician's gender; neither in social conversation (non-medical chitchat); patient negative talk (including disagreements); patient emotional talk (which included statements of concern, worry, and personal feelings); tendency of the patients to display more positive affect (as friendly, warm, kind) or to speak with anxiety to the physicians.

The principle of reciprocity is fulfilled in the greater tendency of the patients to have positive talk, give psychosocial information and build a partnership with female physicians. In the case of the biomedical information, may be patients give more information to female physicians because they use to ask more questions or because they do more efforts building a partnership.

In general it seems that patients feel more comfortable, committed, communicative, and assertive when talking to a female physician, what suggest that they feel more empowered. The evidences analyzed in this research show that it exist differences in the tone and content of the medical visit depending on the physician's gender.

Another observation that the authors do is that male and female patients communicate in different way. Feminine patients tend to have more emotionally concerned statements,

disagreements, and positive statements, and they usually do more questions to physicians than male patients.

A.7.2.3 Gender concordance and communication

Roter and Hall ⁽¹³⁴⁾ point out that some gender effects in communication between physician-patient in medical visits are stronger in same-gender dyads than in mixed-sex ones. They note that:

- Female dyads physician-patient are characterized by longest encounters and most equal contributions from both (patient and physician) to medical dialogue, with higher levels of psychosocial discussion, emotional exchange, and eye contact; and have lesser levels of physician verbal dominance. They also present more positive statements, head nodding, and interest cues than the rest of combinations.
- Male dyads physician-patient are characterized by shortest visit time and the highest level of physician verbal dominance.
- These differences appear to be consistent in most of the countries.

A.7.2.4 Accommodation in physician-patient communication

Communications between physician and patient has been seen as an unbalance relationship, where usually physicians have the power and the patients are the weak part, sometimes this power imbalance have brought situations where physician use a very clinical and complicated language for the patients, have dominating attitude or aloofness, causing in the patient a sensation of unsatisfaction. Physicians may accommodate their communication style to balance these relationship and increase patient's satisfaction.

A research done by Watson and Gallois ⁽³⁸⁾ with 134 participants that rated 16 descriptions of conversations on 13 items derived from the CAT, they identified the items that had higher rating in satisfying conversations than in unsatisfying; the first important conclusion is that they didn't find significant differences in the score given to the items, neither in the consideration of the conversation as satisfactory or unsatisfactory by gender. The items that were significantly better scored in satisfactory conversations than in unsatisfactory one, divided by areas, are:

- Discourse management:
 - "Treats patient as individual".
 - "Listen to patient's needs".
 - "Takes patient's views into account".
 - "Patient chooses topic".
- Emotional expression:
 - "Reassures patient".
 - "Show concern for patient".
- Interpersonal control:

- “Patient has control”.
- Assessment of behaviour:
 - “Typical health professional”.
 - “Health professional’s behaviour appropriate”.
- Outcome
 - “Pleasant conversation for patient”.

While the ones better scored in the unsatisfactory conversations than in the satisfactory ones were:

- Interpersonal control:
 - “Talks down to patient”.
 - “Health professional controls conversation”.

These show that participants think that patient should be taken into account and to also have an important role in the conversation, for example participating in the topic selection, and their relationship and emotional needs also have to be attended; but health professional still have to maintain his/her typical role, and the control has to be well balance, in fact, the over-control is seen as negative for communication.

In a more recent research, Ahmed and Bates ⁽¹²⁶⁾ indicate that the literature strongly recommends the physicians to accommodate towards patients and discourage the divergent communication. In their study with 310 patients they analysed the impact of different CAT strategies by the physician (taken from Watson and Gallois ⁽¹³⁵⁾) to the satisfaction of the patient. They realise that, in general, convergent communication improve the satisfaction of the patient, but not always, and depending on the different goals and areas, an accommodation strategy will be recommended:

- In the area of discourse management, that pursue to treat the patient as an individual, patients mostly prefer physicians to use the convergence in all four CAT strategies (“Treating the patient as an equal”; “Maintaining a good relationship with the patient”; “Treating the patient as an individual”; “Asking questions of the patient”) being more satisfied when the physician use this strategies.
- In the area of emotional expression, that seeks to understand and respond to the patient’s socio-emotional needs, patients prefer physicians who converge by “Reassuring the patient” and “Reducing the patient’s anxiety”. But for the third strategy “Showing liking for the patient” they prefer the ones that do it always or never, but not the ones who do it moderately.
- In the area of interpretability, with the objective of understand and respond to the informational needs of the patient; patients prefer physicians who convergence with the strategies of “expressing himself/herself clearly to the patient”, “checking to see if the patient understands” and in a lesser extent “looking comfortable with the patient” (in this last strategy, few patients prefer physicians to don’t use it). With the strategy

“Handling conversation competently”, patients prefer the physicians that always or never converge, more than the ones who do it moderately.

- In the area of interpersonal control, whose aim is to establish authority, expertise, and power in the clinical interaction. Patient prefer when physician controls the conversation (perform strategies of “Controlling conversation”; “Deciding on topics talked about”; “Talking down to patient”; “Intruding on patients’ privacy”) followed by the ones who cede control to the patient, but the most unsatisfied attitude is when the patient doesn’t know if the physician controls or cede the control over the conversation.

It seems that patients expect that the physician control the conversation, but they still want to keep their autonomy, be well informed and understand the content of the conversation (but using a proper language for the consultation). Ahmed and Bates also indicate that patients may perceive that the physician is not interested in their case or misunderstand their necessity of information if they perceive that they don’t converge at all; but they may feel that the physician are patronizing instead of making an effort to find common ground with the patient if they “*overconverged*” and use an everyday language in the consultation.⁽¹²⁶⁾

A.8. WOMEN'S OPINIONS ABOUT THE INFORMED CONSENT PROCESS

This section summarises the research done by Bento, Hardy and Osis concerning to women's opinion about the informed consent process⁽¹²⁷⁾ because:

1. with its qualitative methodology brings the information about the women's thoughts, their opinion, perceptions and feelings without suggested or close answers and allows to discuss in deep about each topic;
2. we didn't find any other study with these characteristics and so specific about the topic of the deliverable;
3. even it only presents the women's point of view, without comparing it with that of men, we consider it adjust perfectly to the objective of the document since the actual way of doing the inform consent process is predominantly masculine, as Lasarte says *"when we speak of gender we speak of the feminine, since the masculine is invisible and universal of pure omnipresent"*⁽⁸¹⁾.

Bento, Hardy and Osis⁽¹²⁷⁾ did a research analysing the opinion of women about the informed consent process in studies about contraceptive methods. They did eight focus groups and counted with the participation of 51 women, with ages between 18-49 years old, who were participating in a clinical trial in the area of women's health or had participated in the last 12 months and who lived in the metropolitan area of Campinas, Sao Paolo (Brazil), the date isn't specified but the article was published on 2008. The topics that they studied and their main findings are:

Professional who should supply the information about the study:

The person who invites the women to participate:

- Should be a member of the research team but preferably not the principal investigator, better if is not a physician and should have knowledge of the study, appear secure and been able to answer the questions.
- Will be the reference person during all the research, their link with the project, the one the women will look for advise, should be someone accessible, always available to give the guide the women may require about what to do and when to do it. *"This relationship should result in a real friendship that offers a greater sense of security to the study volunteers"*.

The authors indicate that, as the physician-patient relationship has been socially marked as a relation of power and physicians are considered to belong to an elite social and cultural class, some people may feel intimidate and feel inhibited to ask questions or questioning what the physician says, affecting their understanding and limiting their autonomy; and even if the researcher is not a physician there is always an unbalanced relationship were the volunteer is seen in a weak position.

Attitude of the professional

- Women indicate that the decision to participate or not will be influenced by the attitude of the professional, and they point out that when he/she has an arrogant attitude they feel as if they are “objects” or “laboratory rats”, while if he/she is attentive and accessible they feel more receptive to talk about the invitation and more comfortable to ask questions.

Is important to remark that women put the accent in aspects like politeness, accessibility, receptiveness instead of in aspects related to technical competence. Bento, Hardy and Osis indicate that Boltansky concurs in the same idea indicating that when people can't evaluate the technical competence of a physician they focus in his/her attitude, such as if is polite, patient, well-disposed or pleasant.

The way in which the information is given

Women indicate that:

- They would like to receive the information in groups of around 10 women and also individually (both, one complements the other). Indicating that to do it in group facilitates the exchange of information between them, while does it individually give them more freedom to ask or do comments that they can feel embarrass to do in a group. Some indicate that only with the information in group would be enough, because as all of them are women they won't feel ashamed to do any comment or question.
- The information should be given in written and orally format (complementary). Oral format favours an exchange of ideas and asking questions that give more security, but is important to do it as long as necessary and to feel that the woman has understood all the information given and has everything clear. Written informed consent form should include all the information given orally and is important to give it to the woman so she can access to the information again if she wants.

The authors explain that there are evidences about the improvement in the understanding in collective explanation versus individual, which may be caused because the information provider could use more time and use audio-visual aids. They also highlight the importance of give the time necessary to give and discuss the information.

Information that they would like to receive

- Women consider that to been able to decide about participating or not they should have information about risks and benefits, efficacy and possible side effects and inconveniences (short, medium and long term ones).

Quantity of information

- Women don't specify which amount of information they consider enough, the important thing for them is to have the information clear. They give more importance to the manner the information is provided (clearly and objectively to be easy understanding) than to the quantity. But they also point out that to have a lot of information to read may be counterproductive, because people usually don't have patience to read a lot of information, and it can be discouraging if the woman has difficulties to understand the information (what has to be especially considered in developing countries or in the ones with significant proportion of women with rudimentary reading skills).
- Some women prefer that the person providing the information reads it out to them while others prefer to read it themselves because it helps them to think more clearly.

There is an important controversy about this topic, because the principlist theory highlights the important of giving all the information to the potential participant to preserve the principle of autonomy, but usually it ends up in long ICF with detailed information about the study. Extensive ICF may be as prejudicial as to give little information, because both situations have the risk to reduce the emphasis on the relevant information to take an autonomous decision about participating.

Even so, we want to highlight the ending sentence that the authors use about this section in their article: *"There is evidence that volunteers decide whether to participate in a study before they read the consent form, after receiving oral instructions"*.

Teaching aids that may be used

- Women point out that audio-visuals (videos, posters, leaflets...) could contribute to improve the understanding and it can be specially appropriate to show in the film the procedures they will be submitted if they accept to participate if proceeds (is important to take into account that the study was about contraceptive). They also appreciate if contraceptive method and statements from women that are already using it are shown.
- They also consider useful to have some materials to take home, such as slides or information recorder on a cd/dvd/usb can be useful, so they can use it or share it with other women.

The authors indicate that other studies didn't find evidences about how use of audio-visuals improve understanding, but they point out other benefits of using them, such as that they contribute to a better retention of information or to assure that same information is provided to all potential participants.



As final remarks Bento, Hardy and Osis indicate that women don't consider the process of IC as a ritual mainly represented by the signature of the form and they understand it as a link between the potential volunteer and the investigator.

Other contributions

Stevens and Pletsch ⁽¹³⁰⁾ indicate that *"informed consent must be explained and obtained in a gender-specific and culturally competent manner"*, and they highlight the importance of taking into account factors that within the gender have impact on social context and health, as the ethnicity, class or country of birth. They also state the convenience of tailoring the IC to make it consistent with the beliefs, values and preferences of the potential participants.

A.9. CONCLUSIONS

A.9.1 About gender differences in communication

Gender differences in communication is a very controversial topic that has progressed from some studies and position that defend the existence of clear differences and presents women's language as inferior to that of men's, until approaches more extended nowadays that defend that there exist some differences between gendered styles, that are not assigned to one fixed gender and people can change from one to another depending on different situations (not all women must use the style typically assigned to them, and neither all the time, they can change from different styles, ones more feminine and others more masculine). Gender is considered only one of several conditionings of communicative activities and that understands that men and women are heterogeneous groups, where differences among them may be even bigger than the ones between genders.

Gender stereotypes seem to have an effect on the way men and women communicate, and the characteristics that have been associated with the masculine and feminine style enhance the development of the abilities and personalities that allow them to fulfill the roles assigned to each one of them by society, what Lasarte ⁽⁸¹⁾ calls the ethic of power -attributed to men- and the ethics of care -attributed to women-. These characteristics are, for example: security, dominance, competitive, person distant or oriented to professional and public development in the masculine style; and tentative, caring, polite, person close or oriented to care, housekeeping and private development in the feminine style. There exist also gender differences in the understanding of some communicative actions, such as minimal responses.

The way men and women communicate in same-sex and mixed-sex dyads or groups also differs and the "Communication Accommodation Theory" explain some of these differences, that are related to the modification of the communicative behaviour depending on the characteristics of the partner and the personal goals.

Even so, a lot of authors highlight that men and women have more common characteristics than differences; and the differences found are not categorical.

A.9.2 About gender differences in skills

Most of the studies in this field are done to scholar population and based in the stereotypes and hold that males are better in mathematics and spatial tests, and females on verbal tests. The studies also indicate that usually girls are more motivated than boys to read and are better when deal with routinely tasks, while boys feel less anxiety toward mathematics and are more able to resolve problems "thinking like scientists". When they arrive to adult ages, usually men have already improve their reading skills to the same level than women, but they still better with mathematics and with the interpretation of graphic tasks. Even so, most of the differences in old ages become from the development of tasks at work, that nowadays and because of the labour gender differences (vertical and horizontal segregation on the basis

of sex in the labour market), give more opportunities to men to practice and improve their skills reading and solving scientific and mathematic problems, getting advantage in both fields.

A.9.3 About gender differences with ICTs

New technologies have significantly increased in the last decade and gender differences have always been a subject of study. The different ways in which women and men use Internet is the topic where a lot of researchers are focusing their investigations. Although results are inconsistent between different studies, what is clear is that, there is still an existing gap between females and males regarding online contexts. This review collects information about gender differences in different online contexts: online communication, online shopping, social networking sites and texting. Information regarding eye tracking results in online situations is also collected.

Overall, females tend to use online discussion groups as a communication tool with their families and friends making contributions in a more empathic way, containing personal experiences and emotions. They are more likely to agree and support others. On the other hand, men tend to use an authoritative language in online discussion and judging opinions with a less personal involvement, using Internet as an information seeking tool.

Regarding online shopping, males tend to have a goal-oriented attitude and are motivated by convenience whereas females are motivated by emotional and social interaction to buy online. Results have also shown that females are more aware than males about the perceived risks and benefits of buying online, even though they are Internet expert users, suggesting they need to be more encouraged to buy, for example, by a friend's recommendation, which has a greater effect in women than it has in men. In addition, both genders are positively influenced by communication, meaning that when an online platform is present in an e-business website, consumer behavior increases.

Social Networking sites are also a platform where gender differences have appeared. In line with other online contexts, female users tend to reply public messages in social networks using a more emotional manner with a high level of support, compared to males. However, these differences are reduced when communicating by private messages, where gender-stereotypical language, decreases. Also, the uses of social networking sites differ between males and females. Males use them for dating, meet new people, gather information, find jobs... while females use them for posting pictures, comments, and communicate with their existing relationships. Moreover, online bullying is also more represented within adolescent girls, whereas boys are located on face-to-face bullying. Furthermore, profile picture is changed more regularly by women, being more diverse than men, and the hashtags also seem to be emotional and positive for women and informative for men, consistent with previous research and different contexts.

Texting has been found to be more used by women, especially to maintain their social relationships, and this way of communication is eclipsing calling. Also, men think that texting is more appropriate in public social situations than women do. No gender differences were found in thinking about being appropriate to text in private or interpersonal contexts.

Eye tracking has demonstrated different ocular movements between males and females when viewing a website, moving in a virtual environment, trying to solve a science problem or reading online news. These differences summarize in assumptions of females having shorter mean gaze duration than males when viewing a home page of a website, meaning that males do more cognitive effort. Also, females read the online news in a more vertical manner, whereas males tend to read in a zigzag way. Women tend to focus their attention in textual information while men pay more attention to photos and pictures. In this same line, diagram information is better understood by males, that have a better visuospatial capacity, when solving a science problem, with less regressions to the diagrams and shorter fixations, compared to females, that make more regressions and more fixation counts. Regarding virtual navigation and orientation, females tend to have longer fixations in the environment, paying attention to the details, while men look more to the environment in general with shorter fixations.

In conclusion, we are living in a technological world that is increasing very fast and although gender gap in online contexts has decreased significantly in the last decades, there will still be a gender attitude that comes intrinsically with the sex of the individual. Future steps should focus on trying to decrease this gap by offering tailored solutions to each gender, so both are in equal conditions within different online contexts.

A.9.4 About communication between physician and patient

The communication between physician and patient is a key issue in the relationship between them that has been related with better health outcomes and the patient's satisfaction. The need of increasing the physician's communicative skills has been suggested by several authors; being very importance to identify the aspects that can make the difference in interpersonal communication.

There are gender differences in communication between physician and patient, and they correspond mainly to general gender differences in communication, not being exclusive of the physician-patient relationship. Some of these differences are caused by how physicians communicate (his/her own gender and depending on patient's gender) and others because of the way patients communicate (his/her own gender and depending on physician's gender); in same-sex dyads some effects are stronger.

Some characteristics usually associated with female physicians have been evaluated by patients as positive and typical of a satisfactory experience. Usually physicians get more involved in communication with female patients.

Patients usually treat the physicians as they treat them, following the reciprocity principle; and they usually feel more comfortable, committed, communicative, and assertive when talking to a female physician. Patient's gender also influences their way to communicate.

Usually patients prefer the physician to accommodate their communicational behavior making the patient feel as an equal, taking him/her into account, taking interest on him/her, expressing clearly, reducing the patient's anxiety... but they also prefer the physician to continue having the control of the conversation and to don't "overconverge" using an everyday language.

A.9.5 About informed consent

Informed Consent process allows the subject to voluntarily decide his/her participation in a clinical trial. Generally, IC are documents difficult to read, that do not include all stakeholder's perceptions and do not distinguish between subject's characteristics, (age, gender, demographic characteristics, etc.)

Evidences show that IC forms are difficult to read⁽⁸⁸⁾ and its understanding hasn't improved in the last 30 years⁽⁸⁶⁾, hence the need to boost research in improving their understanding. In the present review, diverse analyses of factors that have influence in the comprehension of the IC have been found, as for example:

- The improvement of systematic lexico-syntactic readability improvement or the modification of the ICF by a working group, increase the comprehension in the phase I clinical trials.⁽⁸⁹⁾
- To have more time to read the ICF, by taking it home, improve the understanding, especially for men.⁽⁹¹⁾
- The oral explanation by the physician, taking his/her time and adapting the language to the patient, is really appropriate to increase the understanding.
- Patients who used additional information sources and the ones who had at least 30 minutes for receiving information registered better perceived understanding.⁽⁸⁷⁾
- Is more likely that people read the ICF complete in person than by remote access.⁽⁹²⁾

Tam et al. didn't find significant differences to understanding informed consent in clinical trial by gender⁽⁸⁶⁾, only few studies point to differences and in most cases reflect an advantage in understanding, or even in the frequency to read the entire ICF⁽⁹²⁾, by women. Even so, is important to consider that we didn't find studies that analyse the gender differences in comprehension with ICF adapted to gender. The effect of how accommodation and adaptation by gender can affect understanding of the IC, especially by women, or the impact it may have on decision-making about participation in research, has never been studied and we think is a field that should be considered. Accommodation may also make IC form or process more attractive and increase the proportion of people who read the whole IC.




Even there is an important controversy about the convenience of doing a gender adaptation of the IC, Stevens and Pletsch ⁽¹³⁰⁾ highlight the convenience of tailoring the IC to make it consistent with the gender of the participant, but also to his/her beliefs, values and preferences. This brings out the importance to consider the gender differences in communication and accentuates the need of continuing researching in this field.

Is important to remark the findings of some studies that identify the attitude or preferences of women around the IC process, for example Knepp found that women prefer to do the process face-to-face, are more caution to avoid manipulation and seek information more often than men ⁽⁹²⁾; or Bento, Hardy and Osis who did a research concerning to women's opinion about the informed consent process ⁽¹²⁷⁾.

A.10. RECOMMENDATIONS FOR THE GENDER APPROACH IN IC

First of all, there are six important ideas that should be remarked:

1. The adaptation of the IC forms in format “paper” is very difficult and costly and the evidence doesn’t show clear benefits that justify doing all this process (more research is need in this field) and we recommend to accommodate them for the moment only in cases that are addressed only to women. In other formats, as for example using the TICs or explained face to face this gender adaptation can be done easier.
2. The best way to improve the understanding of IC is to tailor it to the patient, having into account the gender, but also other determinants such as age or sociocultural level.
3. Gender differences in communication have been analyzed in this document. Gendered styles shown are useful, as tends, to guide the accommodation of the IC process to the patient’s style; but never have to be taken as categorical.
4. Convergent accommodation has a positive influence in the perception of the observer and has been associated with a positive evaluation of the communication, the individual, and the relationship.⁽⁴³⁾ Accommodation may contribute to make the text more comprehensible, taking into account the characteristics of the potential participant, and to improve the strategy of recruiting participants in research, especially increasing the participation of women, avoiding an important source of gender bias (under-representation of women, mainly in clinical trials) and contributing to incorporate gender perspective into health research. But it should be done cautiously and “overconverge” should be avoided.
5. The process of Informed Consent starts from the initial contact between the research team and the potential participant till the end of the research. It covers the Informed Consent forms and any actions (supply information, asking questions...) that provides the potential participant with better understanding and respect of their dignity and autonomy.
6. More research is needed to be done in this field.

From our findings we can suggest the following recommendations to improve the informed consent process, especially within vulnerable population under a gender perspective:

- Is very important to take care of the format, do the form easily readable and take time to discuss it with the participants.
- Informed consent should include more graphics (noncomplex) and pictures, which facilitate the comprehension of the main text.
- Both genders have seen to have less anxiety and social pressure in online contexts, compared to face-to-face. In this way, it may be useful to create an online platform where subjects can ask questions and write their concerns to the research team, in addition to the face to face appointment, that is essential to encourage the complete read of the ICF and to increase the understanding.

- Consider the eye tracking behavior, working on the design and order of information on the informed consent so that the first look and read at the document is more efficient.
- Taking into consideration that women usually are more emotional, the researcher should focus on these emotional feelings when offering the informed consent. In this way, when a clinical trial has women as the only population recruitable (pregnant women, adolescent girls), the way of communicating should be done following emotional guidelines.
- Avoid mathematic concepts and complex graphics in the ICF addressed to feminine participants to avoid to produce anxiety.
- Do the IFC as short as possible using a direct and impersonal style, when oriented to men.
- Take into account the gender differences in the interaction as, for example, in the use of minimal responses, cooperative overlap, physical distance, visual contact, etc.
- Follow the considerations from the research of Bento, Hardy and Osis ⁽¹²⁷⁾ about the women's opinion about the IC process (section A8 "women's opinions about the informed consent process"), taking into account that even women's preference is that the person who gives the informed consent won't be a physician, the European law indicates that the informed consent should be provided by a physician, so is important to consider the accommodation of language to break the distance between physician-volunteer. Other findings of that research were:
 - About the professional who should supply the information about the study: should have knowledge of the study, appear secure and been able to answer questions about the research; should be someone accessible, always available to give the guide the women may require about the research.
 - Attitude of the professional: attentive and accessible, avoiding arrogant attitude. Other studies remark that the characteristics usually attributed to female physicians have been identified as more positive and satisfactory, especially for women. So they should be taken into account and used as guide about how to behave.
 - The way in which the information is given: they prefer to receive the information in groups of women and individually (both complementary); and in written and orally format (also complementary). The conversation with the physician is very important and valued.
 - Information that they would like to receive: Women consider that to been able to decide about participating or not they should have information about risks and benefits, efficacy and possible side effects and inconveniences (short, medium and long term ones).
 - Quantity of information: They give more importance to the manner the information is provided (clearly and objectively to be easy understanding) than



to the quantity. But indicate that too much information could be counterproductive.

- Useful aids: audio-visuals (videos, posters, leaflets...) and some materials to take home, as slides or information recorder on a cd/dvd/usb. They contribute to a better retention of the information and to assure that same information is provided to all potential participants.

A.11. BIBLIOGRAPHY

1. European Commission. HORIZON 2020 - Work Programme 2016 - 2017 Science with and for Society. [Online].; 2016 [cited 2017 10 19. Available from: http://ec.europa.eu/research/participants/data/ref/h2020/wp/2016_2017/main/h2020-wp1617-swfs_en.pdf.
2. Acuña V. Conversación juvenil e identidad de género: despliegues de feminidad heterosexual en grupos de jóvenes veinteañeras. *Círculo de Lingüística Aplicada a la Comunicación*. 2017;69:3-33.
3. Cameron D. Gender. In: Brown K, editor. *Encyclopedia of Language & Linguistics* (Second Edition). Oxford: Elsevier; 2006. 733-9 p.
4. Directorate-General for Research & Innovation. *Guidance on Gender Equality in Horizon 2020* (version 2.0) Brussels: European Commission; 2016.
5. European Institute for Gender Equality (EIGE). *Gender Equality Glossary and Thesaurus*. [Online]. [cited 2017 July 18. Available from: <http://eige.europa.eu/rdc/thesaurus>.
6. García Calvente MdM, Jiménez Rodrigo ML, Martínez Morante E. *Guía para incorporar la perspectiva de género a la investigación en salud*. España: Escuela Andaluza de Salud Pública; 2010.
7. Guerrero S. Diferencias de género en evaluaciones de narraciones de experiencias personales en el habla juvenil de Santiago de Chile. Una aproximación sociolingüística. *Revista Signos*. 2011;44(75):18-32.
8. Prieto L, San Martín A. Diferencias de género en el empleo del discurso referido: aproximación sociolingüística y pragmático-discursiva. *Boletín de Filología*. 2002-2003; 39(1):269-303.
9. Thomason SG. Glossary. In: Brown K, editor. *Encyclopedia of Language & Linguistics* (Second Edition). Oxford: Elsevier; 2006.
10. Motschenbacher H. Can the term 'genderlect' be saved? A postmodernist re-definition. *GENDER LANG*. 2007;1(2):255-78.
11. Holmes J. Sex and language. In: Goebel H, Neide P, Stary Z, Wölck W, editors. *Contact Linguistics: An International Handbook of Contemporary Research* (Volume 1). Berlin: Walter de Gruyter; 1996. 720-5 p.
12. Hidalgo-Tenorio E. Genderlect. In: Naples N, Hoogland R, Wickramasinghe M, Wong A, editors. *The Wiley-Blackwell Encyclopedia of Gender and Sexuality Studies*. USA: Wiley-

- Blackwell; 2016. 1–4 p.
13. Gregori A. Contra el generolecto: una lectura crítica desde el constructivismo. In *Actas IV Congreso de Lingüística General*. Santiago de Compostela. 2004. 3681-9 p.
 14. Tusón A. Lenguaje, interacción y diferencia sexual. *Enunciación*. 2016;21(1):138-51.
 15. Castellanos G. Los estilos de género y la tiranía del binarismo: de por qué necesitamos el concepto generolecto. *Aljaba (Luján)*. 2016;20:69-88.
 16. Poyatos F. *Nonverbal Communication across Disciplines: Volume 1: Culture, sensory interaction, speech, conversation*. Amsterdam/Philadelphia: John Benjamins Publishing Company; 2002.
 17. Poyatos F. La Comunicación No Verbal como asignatura en Filologías Clásicas y Modernas. *Didáctica. Lengua y Literatura*. 2013;25:231-57.
 18. Jespersen O. *Language: Its Nature, Development and Origin*. London: Allen and Unwin; 1922.
 19. Torres Romo JJ. El constructivismo y las políticas del lenguaje: el habla de género. *Revista Mexicana de Ciencias Agrícolas*. 2015;2:347-55.
 20. Lakoff R. Language and woman's place. *Lang. Soc.* 1973;2(1):45-80.
 21. Uchida A. When "Difference" Is "Dominance": A Critique of the "Anti-Power-Based" Cultural Approach to Sex Differences. *Lang. Soc.* 1992;21(4):547-68.
 22. Cameron D. *On language and sexual politics*. Oxon (UK): Routledge; 2006.
 23. Maltz DN, Borker RA. A cultural approach to male-female miscommunication. In: Coates J, editor. *Language and Gender*. 1982. 417-34 p.
 24. Zimmerman DH, West C. Sex Roles, Interruptions and Silences in Conversation. In: Thorne B, Henley N, editors. *Language and Sex: Difference and Dominance*. Rowley: Newbury House; 1975. 105–29 p.
 25. Brown P. How and why are women more polite? Some evidence from a Mayan community. In: McConnell-Ginet S, Borker R, Furman N, editors. *Women and Language in Literature and Society*. New York: Praeger; 1980. 111–36 p.
 26. Cameron D. Sex/Gender, Language and the New Biologism. *Applied Linguistics*. 2009;31(2):173–92.

27. Fishman P. Interaction: The Work Women Do. Soc Probl. 1978;25(4):397-406.
28. Gray J. Men Are from Mars, Women Are from Venus. New York: HyperCollins Publishers; 1992.
29. De Francisco VP, Palczewski CH. Gender in communication: a critical introduction. 2nd ed. USA: Sage Publications; 2014.
30. Mulac A. The gender-linked language effect: Do language differences really make a difference? In: Canary D, Dindia K, editors. Sex differences and similarities in communication: Critical essays and empirical investigations of sex and gender in interaction. Mahwah (New Jersey): Erlbaum; 1998. 127-55 p.
31. Tannen D. You Just Don't Understand: Women and Men in Conversation. London: Virago; 1990.
32. Talbot M. Gender and Language. In: Brown K, editor. Encyclopedia of Language & Linguistics. 2nd ed. Oxford: Elsevier; 2006. 740-2 p.
33. Alami M. Approaches to Gender Studies: A Review of Literature. Journal of Applied Linguistics and Language Research. 2016;3(3):247-56.
34. Mulac A, Bradac JJ, Gibbons P. Empirical Support for the Gender-as-Culture Hypothesis: An Intercultural Analysis of Male/Female Language Differences. Hum Commun Res. 2001;27(1):121-52.
35. Bogaers IRWM. Gender in Job Interviews: some implications of verbal interactions of women and men. Int'l. J. Soc. Lang. 1998;129:35-58.
36. Butler J. Gender Trouble. Feminism and the Subversion of Identity. New York: Routledge and Kegan Paul; 1990.
37. Cameron D. Language, gender, and sexuality: Current issues and new directions. APPL LINGUIST. 2005;26(4):482-502.
38. Watson BM, Gallois C. Communication accommodation between patients and health professionals: themes and strategies in satisfying and unsatisfying encounters. International journal of applied linguistics. 1999;9(2):167-80.
39. Bylund CL, Peterson EB, Cameron KA. A practitioner's guide to interpersonal communication theory: An overview and exploration of selected theories. Patient Educ Couns. 2012;87:261-7.
40. Namy LL, Nygaard LC, Sauerteig D. Gender differences in vocal accommodation: the role

- of perception. *J Lang Soc Psychol.* 2002;21(4):422-32.
41. Green JA. Communication Accommodation Theory: Understanding Language Use in Social Interaction. [PhD thesis]. New Zealand: University of Otago; 2003.
 42. Soliz J, Giles H. Relational and Identity Processes in Communication: A Contextual and Meta-Analytical Review of Communication Accommodation Theory. *Annals of the International Communication Association.* 2014;38(1):107-44.
 43. Muir K, Joinson A, Cotterill R, Dewdney N. Characterizing the Linguistic Chameleon: Personal and Social Correlates of Linguistic Style Accommodation. *Hum Commun Res.* 2016;42:462-84.
 44. Thomson R, Murachver T, Green J. Where is the gender in gendered Language? *Psychol Sci.* 2001;12(2):171-5.
 45. Green JA. The writing on the stall: Gender and graffiti. *J Lang Soc Psychol.* 2003;22:282-96.
 46. Hancock AB, Rubin BA. Influence of communication partner's gender on language. *J Lang Soc Psychol.* 2015;34(1):46-64.
 47. Turabian JL, Minier-Rodriguez LE, Moreno-Ruiz S, Rodriguez-Almonte FE, Cucho-Jove R, Villarin-Castro A. Gender Differences in Verbal Behavior Style in Interviews in Family Medicine: Mars and Venus, or North Dakota and South Dakota? *J Women's Health Care.* 2017;6(2).
 48. Griffin E. A first look at communication theory. 8th ed. New York: McGraw-Hill; 2012.
 49. Wallentin M. Putative sex differences in verbal abilities and language cortex: A critical review. *Brain Lang.* 2009;108:175-83.
 50. Griffin E, Ledbetter A, Sparks G. A first look at communication theory. 9th ed. New York: McGraw-Hill; 2014.
 51. Holmes J. Women, Men and Politeness London: Longman; 1995.
 52. Leaper C, Ayres MM. A meta-analytic review of gender variations in adults' language use: talkativeness, affiliative speech, and assertive speech. *Pers Soc Psychol Rev.* 2007;11(4): 328-63.
 53. Mulac A, Studley LB, Blau S. The Gender-Linked Language Effect in Primary and Secondary Students' Impromptu Essays. *Sex Roles.* 1990;23(9):439-69.

54. Mulac A, Giles H, Bradac JJ, Palomares NA. The gender-linked language effect: an empirical test of a general process model. *Lang Sci.* 2013;38:22–31.
55. Weinberg FJ, Treviño LJ, Cleveland AO. Gendered Communication and Career Outcomes: A Construct Validation and Prediction of Hierarchical Advancement and Non-Hierarchical Rewards. *Communic Res.* 2015.
56. Mohindra V, Azhar S. Gender Communication: A Comparative Analysis of Communicational Approaches of Men and Women at Workplaces. *IOSR-JHSS.* 2012;2(1): 18-27.
57. Eunson B. *C21 Communicating in the 21st century.* 2nd ed. Australia: John Wiley & Sons; 2008.
58. Eagly AH, Carli LL. Women and the labyrinth of leadership. *Harvard Business Review.* 2007;85:63-71.
59. Hirschman L. Female-male differences in conversational interaction. *LANG SOC.* 1994;23:427-42.
60. Coates J. *Women, men and language: a sociolinguistic account of gender differences in language.* 3rd ed. London/New York: Routledge; 2013.
61. Ezard J. Mobile users 'ape monkeys'. *The Guardian.* 2001 December 5.
62. Moss C. Welcome back football, the great gossip mag for men. Prowess, professionalism, technique, talent? Forget it. Professional football has become the male equivalent of Hello! magazine. *The Telegraph.* 2015 August 13.
63. Johnson S, Finlay F. Do men gossip? An analysis of football talk on television. In: Johnson S, Meinhof U, editors. *Language and Masculinity.* Oxford: Blackwell; 1997. 130–43 p.
64. Benwell B. Male gossip and language play in the letters pages of men's lifestyle magazines. *J Pop Cult.* 2001;34(4):19-33.
65. Bischooping K. Gender differences in conversation topics, 1922-1990. *Sex Roles.* 1993;28(1):1-18.
66. Michaud SL, Warner RM. Gender differences in self-reported response to trouble talk. *Sex Roles.* 1997;37(Issue 7–8):527–40.
67. Crawford M. *Talking difference: on gender and language.* London(UK) & Thousand Oaks (CA): Sage; 1995.

68. McQuiston DH, Morris KA. Gender Differences in Communication: Implications for Salespeople. *Journal of Selling & Major Account Management*. 2009;9(1):54-64.
69. Holmes J. *An Introduction to Sociolinguistics*. 3rd ed. Harlow (England)/New York (USA): Pearson Longman; 2008.
70. Hall JA, Friedman GB. Status, gender, and nonverbal behavior: a study of structured interactions between employees of a company. *PERS SOC PSYCHOL B*. 1999;25(9):1082-91.
71. Hall JA, Roter DL. Do patients talk differently to male and female physicians? A meta-analytic review. *Patient Educ Couns*. 2002;48(3):217-24.
72. Koppel M, Argamon S, Shimoni AR. Automatically Categorizing Written Texts by Author Gender. *Literary and linguistic computing*. 2002;17(4):401-12.
73. Ishikawa Y. Gender Differences in Vocabulary Use in Essay Writing by University Students. *Procedia Soc Behav Sci*. 2015;192:593-600.
74. Argamon S, Koppel M, Fine J, Shimoni A. Gender, genre, and writing style in formal written texts. *Text*. 2003;23(3):321-46.
75. Newman ML, Groom CJ, Handelman LD, Pennebaker JW. Gender differences in language use: An analysis of 14,000 text samples. *Discourse Processes*. 2008;45:211-36.
76. Hyde JS. Sex and cognition: gender and cognitive functions. *Curr Opin Neurobiol*. 2016;38:53-6.
77. OECD. *PISA 2015 Results in Focus*; 2016.
78. OECD. *PISA in Focus Nº 49: What lies behind gender inequality in education?* 2015.
79. Merisuo-Storm T. Girls and boys like to read and write different texts. *SCAND J EDUC RES*. 2006;50(2):111-25.
80. Meece JL, Glienke BB, Burg S. Gender and motivation. *Journal of School Psychology*. 2006;44:351-73.
81. Lasarte G. Feminización del hábito lector [feminizing the habit of reading]. *Ocnos*. 2013;9:53-68.
82. Lowrie T, Diezmann CM. Solving graphics tasks: Gender differences in middle-school students. *LEARN INSTR*. 2011;21:109-25.

83. OECD Skills Studies. The Survey of Adult Skills: Reader's Companion. 2nd ed. Paris: OECD Publishing; 2016.
84. OECD Skills Studies. Skills Matter: Further Results from the Survey of Adult Skills Paris: OECD Publishing; 2016.
85. OECD. Skilled for life? Key Findings from the Survey of Adult Skills; 2013.
86. Tam NT, Huy NT, Thoa LTB, Long NP, Trang NTH, Hirayama K, et al. Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. Bull World Health Organ. 2015;93(3):186-98.
87. Bergenmar M, Johansson H, Wilking N. Levels of knowledge and perceived understanding among participants in cancer clinical trials – factors related to the informed consent procedure. Clin Trials. 2011;8:77–84.
88. Paris A, Deygas , Cornu , Thalamas C, Maison P, Duale , et al. Improved informed consent documents for biomedical research do not increase patients' understanding but reduce enrolment: a study in real settings. Br J Clin Pharmacol. 2015;80(5):1010-20.
89. Paris A, Nogueira da Gama Chaves D, Cornu C, Maison P, Salvat-Mélis M, Ribuot C, et al. Improvement of the comprehension of written information given to healthy volunteers in biomedical research: a single-blind randomized controlled study. Fundam Clin Pharmacol. 2007;21(2):207-14.
90. Raich PC, Plomer KD, Coyne CA. Literacy, comprehension, and informed consent in clinical research. Cancer Invest. 2001;19(4):437-45.
91. Morrow G, Gootnick J, Schmale A. A simple technique for increasing cancer patients' knowledge of informed consent to treatment. Cancer. 1978;42:793–9.
92. Knepp MM. Personality, sex of participant, and face-to-face interaction affect reading of informed consent forms. Psychol Rep. 2014;114(1):297-313.
93. Lobato L, Bethony JM, Pereira FB, Grahek SL, Diemert D, Gazzinelli MF. Impact of gender on the decision to participate in a clinical trial: a cross-sectional study. BMC Public Health. 2014;14(1156).
94. Carpenter DM, DeVellis RF, Hogan SL, Fisher EB, DeVellis BM, Jordan JM. Use and Perceived Credibility of Medication Information Sources for Patients with a Rare Illness: Differences by Gender. J Health Commun. 2011;16(6):629-42.
95. Chai C, Wu X, Shen D, Li D, Zhang K. Gender differences in the effect of communication

- on college student's online decisions. *Comput Human Behav.* 2016; 65.
96. Zhang KZK, Cheung CMK, Lee MKO. Examining the moderating effect of inconsistent reviews and its gender differences on consumer's online shopping decision. *International Journal of Information Management.* 2014; 34.
97. Zhang Y, Dang Y, Chen H. Research note: Examining gender emotional differences in Web forum communication. *Decision Support Systems.* 2013;55(3):851-60.
98. Tsai MJ, Liang JC, Hou HT, Tsai CC. Males are not as active as females in online discussion: Gender differences in face-to-face and online discussion strategies. *Australasian Journal of Educational Technology.* 2015; 31(3).
99. Fox AB, Bukatko D, Hallahan M, Crawford M. The medium makes a difference: Gender similarities and differences in instant messaging. *J Lang Soc Psychol.* 2007;26(4):389-97.
100. Guiller J, Durndell A. Student's linguistic behaviour in online discussion groups: Does gender matter? *Comput Human Behav.* 2007;23(5).
101. Ang CS. Internet habit strength and online communication: Exploring gender differences. *Comput Human Behav.* 2017;66.
102. Hasan B. Exploring gender differences in online shopping attitude. *Comput Human Behav.* 2010;26(4).
103. Garbarino E, Strahilevitz M. Gender Differences in the perceived risk of buying online and the effects of receiving a site recommendation. *Journal of Business Research.* 2004;57.
104. Lian JW, Yen DC. Online shopping drivers and barriers for older adults: Age and gender differences. *Comput Human Behav.* 2014;37.
105. Muscanell NL, Guadagno RE. Make new friends or keep the old: Gender and personality differences in social networking use. *Comput Human Behav.* 2012;28(1):107-12.
106. Joiner R, Stewart C, Beaney C, Moon A, Maras P, Guiller J, et al. Publically different, privately the same: Gender differences and similarities in response to Facebook status updates. *Comput Human Behav.* 2014;39:165-9.
107. Oberst U, Renau V, Chamarro A, Carbonell X. Gender stereotypes in Facebook profiles: Are women more female online? *Comput Human Behav.* 2016;60:559-64.
108. Kimbrough AM, Guadagno RE, Muscanell NL, Dill J. Gender differences in mediated communication: Women connect more than do men. *Comput Human Behav.*

2013;29(3):896-900.

109. Wang J, Madnick S, Li X, Alstott J, Velu C. Effect of Media Usage Selection on Social Mobilization Speed: Facebook vs E-Mail. PLoS One. 2015;10(9):e0134811.
110. Young R, Len-Ríos M, Young H. Romantic motivations for social media use, social comparison, and online aggression among adolescents. Comput Human Behav. 2017;75: 385-95.
111. Zheng W, Yuan CH, Chang WH, Wu YCJ. Profile pictures on social media: Gender and regional differences. Comput Human Behav. 2016;63:891-8.
112. Tifferet S, Vilnai-Yavetz I. Gender differences in Facebook self-presentation: An international randomized study. Comput Human Behav. 2014;35:388-99.
113. Scott CF, Bay-Cheng LY, Prince MA, Nochajski TH, Collins RL. Time spent online: Latent profile analyses of emerging adults' social media use. Comput Human Behav. 2017;75(311-9).
114. Gender and Instagram Hashtags: A Study of #Malaysianfood. In: Zhang Y, Baghirov F, Hashim H, Murphy J, editors. Conference on Information and Communication Technologies in Tourism RESEARCH NOTES; 2016.
115. Forgays DK, Hyman I, Schreiber J. Texting everywhere for everything: Gender and age differences in cell phone etiquette and use. Comput Human Behav. 2014;31:314-21.
116. Chen C, Zhang KZK, Gong X, Zhao SJ, Lee MKO, Liang L. Examining the effects of motives and gender differences on smartphone addiction. Comput Human Behav. 2017;75:891-902.
117. Yang F-Y, Huang R-T, Tsai I-J. The effects of epistemic beliefs in science and gender difference on university students' science-text reading: an eye-tracking study. International Journal of Science & Mathematics Education. 2016;14(3).
118. Huang P-S, Chen H-C. Gender Differences in Eye Movements in Solving Text-and-Diagram Science Problems. International Journal of Science and Mathematics Education. 2015;14(S2):327-46.
119. Lorigo L, Haridasan M, Brynjarsdóttir H, Xia L, Joachims T, Gay G, et al. Eye tracking and online search: Lessons learned and challenges ahead. Journal of the Association for Information Science and Technology. 2008;59(7):1041-52.
120. Pan B, Hembrooke HA, Gay GK, Granka LA, Feusner MK, Newman JK, editors. The determinants of web page viewing behavior: an eye-tracking study. Proceedings of the

- 2004 symposium on Eye tracking research & applications. ACM; 2004.
121. Alt64, AIMC. Estudio Eyetrack Medios España: Análisis del comportamiento visual de los internautas y la efectividad de la publicidad online. España; 2005.
122. Schiessl M, Duda S, Thölke A, Fischer R. Eye tracking and its application in usability and media research. *MMI-interaktiv Journal*. 2003;6:41-50.
123. Mueller SC, Jackson CP, Skelton RW. Sex differences in a virtual water maze: An eye tracking and pupillometry study. *Behav Brain Res*. 2008;193(2):209-15.
124. Ha JF, Longnecker N. Doctor-Patient Communication: A Review. *The Ochsner Journal*. 2010;10(1):38-43.
125. Huang CC, Huang CC, Yang YY, Lin SJ, Chen JW. The influence of gender on the communication skills assessment of medical students. *Eur J Intern Med*. 2015;26(9):670-4.
126. Ahmed R, Bates BR. To accommodate, or not to accommodate: Exploring patient satisfaction with doctors' accommodative behaviour during the clinical encounter. *J Commun Healthc*. 2016;9(1):22-32.
127. Bento SF, Hardy E, Osis MJ. Process for obtaining informed consent: women's opinions. *Dev World Bioeth*. 2008;8(3):197-206.
128. Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, McCormick JB. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. *BMC Medical Ethics*. 2013;14:28.
129. Hayman RM, Taylor BJ, Peart NS, Galland BC, Sayers RM. Participation in research: Informed consent, motivation and influence. *J Paediatr Child Health*. 2001;37:51-4.
130. Stevens PE, Pletsch PK. Informed consent and the history of inclusion of women in clinical research. *Health Care Women Int*. 2002;23(8):809-19.
131. Street Jr RL. Gender differences in health care provider-patient communication: are they due to style, stereotypes, or accommodation? *Patient Educ Couns*. 2002;48(3):201-6.
132. Bertakis KD, Helms LJ, Callahan EJ, Azari R, Robbins JA. The influence of gender on physician practice style. *Med Care*. 1995;33(4):407-16.
133. Roter DL, Hall JA, Aoki Y. Physician gender effects in medical communication: a meta-analytic review. *JAMA*. 2002;288(6):756-64.

134. Roter DL, Hall JA. Physician gender and patient-centered communication: a critical review of empirical research. *Annu Rev Public Health*. 2004;25:497-519.
135. Watson B, Gallois C. Nurturing communication by health professionals toward patients: a communication accommodation theory approach. *Health Commun*. 1998;10(4):343–55.
136. ClinicalTrials.gov. A service of the U.S. National Institutes of Health. [Online]. [cited 2017 07 20]. Available from: <https://clinicaltrials.gov/ct2/about-studies/glossary>.
137. CDC: Center for Disease Control and Prevention. [Online]. [cited 2017 August 29]. Available from: <https://www.cdc.gov/vaccines/terms/glossary.html>.
138. Applied Clinical Trials: The CDISC Glossary of Clinical Research Terminology. [Online].; December 2016/ January 2017. Available from: appliedclinicaltrialsonline.com.
139. "Glossary" Online Ethics Center for Engineering and Science 1/31/2006. [Online]. [cited 2017 August Wednesday 23]. Available from: www.onlineethics.org/glossary.aspx.
140. Horizon 2020- The EU framework Programme for Research and Innovation. [Online]. Available from: <http://ec.europa.eu/programmes/horizon2020/>.
141. Shivayogi P. Vulnerable populations and methods for their safeguard. *Perspectives in Clinical Research*. 2013 Jan-Mar;4(1).
142. Sheikh A, Halani L, Bhopal R, Netuveli G, Partridge RM, Car J, et al. Facilitating the Recruitment of Minority Ethnic People into Research: Qualitative Case Study of South Asians and Asthma. *PLOS Medicine*. 2009 October; 6(10).
143. Newington L, Metcalfe A. Factor influencing recruitment to research: qualitative study of the experiences and perceptions of research teams. *BMC Medical Research Methodology*. 2014;14(10).
144. McGartland Rubio D, Schoenbaum EE, Lee LS, Schteingart DE, Marantz PR, Anderson KE, et al. Defining Translational Research: Implications for Training. *HHS Author Manuscripts*. 2010 March;85(3).
145. López de Argumedo M, Reviriego E, Andríó E, Rico R, Sobradillo N, Hurtado de Saracho I. Revisión externa y validación de instrumentos metodológicos para la Lectura Crítica y la síntesis de la evidencia científica. Madrid: Plan Nacional para el SNS del MSC. Servicio de Evaluación de Tecnologías Sanitarias del País Vasco (Osteba). Informes de Evaluación de Tecnologías Sanitarias: OSTEBA Nº 2006/02;2006.
146. Durant RW, Wenzel JA, Scarinci IC, Paterniti DA, Fouad MN, Hurd TC, et al. Perspectives on Barriers and Facilitators to Minority Recruitment for Clinical Trials among cancer



Center Leaders, Investigators, Research Staff and Referring Clinicians: Enhancing minority participation in clinical trials (EMPaCT). Cancer. 2014;120(07).

147. The Tech Terms Computer Dictionary. [Online]. [cited 2017 August Wednesday 23. Available from: <https://techterms.com/>.

148. The Law Dictionary. [Online]. [cited 2017 August 29. Available from: <http://thelawdictionary.org>.

AGE ISSUES ASSOCIATED WITH THE ACQUISITION OF INFORMED CONSENT: THE MINORS CASE.

B.1. BACKGROUND/PURPOSE

The autonomy of the patient in the decision of participating in clinical research is of major importance, being the informed consent the document that allows the subject voluntarily decide to participate or not. But, what happens when the research involves minors?

Due to its consideration as a vulnerable population and its legal situation, the inclusion of minors in research is a great challenge and should be done with special care, being very important to identify their characteristics and needs. To know what to include in the assent, how to determine the degree of understanding and their competence to decide about the participation in the research are some of the questions that a researcher has to solve.

Regarding the last question, several studies highlighted MacArthur competence assessment tool for clinical research (MacCAT-CR) as a useful tool for assessing the minor's competence.

The aim of this systematic review is to evaluate the contents of the assent and informed consent by minors and whether the MacCAT-CR is a useful tool to evaluate the competence of the minor.

B.2. OBJECTIVES/ REVIEW QUESTION

B.2.1 MAIN OBJECTIVE

- Evaluate the assent and informed consent by minors.

B.2.2 SPECIFIC OBJECTIVES

- Describe the information that should include an informed consent by minors or assent in research.
- Analyse the minor's understanding of each content of the informed consent or assent.
- Evaluate whether MacCAT-CR is a good tool for assessing the competence of a minor to consent in research

B.3. MATERIALS AND METHODS

In order to respond to the objectives set in this task, and to evaluate the state of the art in the three specific objectives identified, a systematic review was carried out as an objective and rigorous methodology to accumulate evidence.

The implementation of a systematic review necessarily involves a series of phases described in the sections developed below and summarized in the flowchart of **annex B.6.1**.

B.3.1 FORMULATION OF THE PICO QUESTION

The review of the scientific literature in search of evidence requires a correct definition of the research question and the creation of a logical structure to improve the scope of the research.

The PICO strategy, whose acronyms correspond to the terms that should be included in this question, respond to: Population-Intervention-Comparison-Outcome.

The working group agreed on the following research questions that could answer the objectives of the proposed task:

- *What information is relevant to include in the assent / consent of children who want to participate in a research study?*
- *What do minors who decide to participate in a research study understand?*
- *How can we evaluate the competence of a minor to make the decision to participate in a research study?*

B.3.2 SEARCH OF RESEARCH STUDIES

A search strategy was designed in the PubMed database with the following keywords [MeSH/Keywords]:

- Population:
 - Child
 - Minors
 - Adolescent
- Intervention:
 - Informed Consent
 - Informed Consent by Minors
 - Consent Forms
 - Assent [All Fields]
 - Research
 - MacCAT-CR
- Outputs:
 - Decision Making

- Ethics
 - Ethics, Research
 - Ethical Theory
 - Principle-Based Ethics
 - Ethical Analysis
- Comprehension
 - Understanding

Different searches were done combining the keywords and taking into account a list of essential articles contributed by the members of the research team. After checking that the articles considered essential, appeared within the search, it was finally decided to work with the updated formula; making the search on July 10, 2017.

((("Informed consent"[Mesh] OR "assent"[All Fields]) AND "Ethics"[Mesh] AND ("Research"[Mesh] OR "Comprehension"[Mesh] OR "MacCAT"[TW])) OR ((("Informed Consent By Minors"[TW] OR "Consent Forms"[TW] OR "assent"[All Fields]) AND ("Ethical Theory"[TW] OR "Principle-Based Ethics"[TW] OR "Ethics, Research"[TW] OR "Ethical Analysis"[TW] OR "Comprehension"[TW] OR "Understanding"[TW] OR "Readability"[TW] OR "MacCAT"[TW] OR "Research"[TW] OR "Clinical research"[All Fields])) OR (("Ethics"[MeSH] OR "Comprehension"[MeSH] OR "MacCAT"[TW]) AND ("Informed consent"[Mesh] OR "assent"[All Fields]) AND "clinical research"[All Fields])) AND ((English[lang] OR Spanish[lang]) AND ("infant"[TW] OR "child"[TW] OR "adolescent"[TW] OR "minors"[TW])) AND ("2007/07/14"[PDat] : "2017/07/10"[PDat]))

After doing the general search it was necessary to review all the abstracts of the studies found to know if they really answered the research question. To that end, inclusion and exclusion criteria had been previously defined, which are reflected below.

B.3.2.1 CRITERIA FOR INCLUDING STUDIES IN THE REVIEW

- Type(s) of study design:
 - Experimental studies/ clinical research
 - Observational studies/ clinical research
 - Theoretical studies/ clinical research
- Type(s) of study participants / sub-populations:
 - Minors.
- Type(s) of interventions:
 - Informed consent by minors or Assent in clinical research.
- Type(s) of outcome measures
 - Contents of the Informed consent/Assent by minors.
 - Comprehension/Understanding of the information included in the Informed consent/Assent.
 - Benefits and harms of using MacCAT-CR
- Type(s) of publications

- Full text
- Abstracts
- Publication date (time period):
 - From 2007/07/14 to 2017/07/10 (last 10 years)
- Language(s):
 - English
 - Spanish

B.3.2.2 CRITERIA FOR EXCLUDING STUDIES FROM THE REVIEW

- Wrong type of study
 - Medical treatment and clinical practise won't be included because I-Consent is focussed on the Informed consent in clinical research.
- Wrong population
 - Researchers
 - Adults, parents, legal guardians
- Wrong purpose
 - When the objective of the study does not refer to the information that is of interest in the assent, or the level of understanding of the child or the assessment of their ability.
- Case Report
 - Singular cases won't be considered in this review.

B.3.3 SELECTING ITEMS

B.3.3.1 PRESELECTION PHASE

In the pre-selection phase, a blind peer review was carried out by reading the titles and abstracts of the articles resulting from the search, and taking into account the inclusion and exclusion criteria.

For that, the list of the studies founded were uploaded to the software Rayyan⁽¹⁾ to do the screening. Rayyan is a free web-tool designed to help researchers working on systematic reviews and other knowledge synthesis projects, and dramatically speeds up the process of screening and selecting studies.

Allows blind the review, access to the content of the article (title and abstract) from the same tool, detect duplicates and mark the reason for inclusion and exclusion as the reading is performed.

Pairs of reviewers screened and decided which studies meet the inclusion criteria. Disagreements were resolved through discussion in a group of three people in a verification phase.

The reasons for excluding articles have been recorded.

B.3.3.2 SELECTION PHASE

Reviewers extracted and analysed data independently and in duplicate from each eligible study. When the study design allowed it, the evaluation was done using standardized forms (OSTEBA FLC tools) and the online program (FLC 2.0)⁽²⁾. FLC 2.0 is a web application designed to support the development of systematic reviews of the scientific evidence providing tools for quality assessment of scientific studies and evidence synthesis.

Osteba (Basque Office Health Technology Assessment) has developed methodological instruments called FLC Tools to facilitate this process of Critical Appraisal and to synthesise the scientific evidence for researchers involved in a systematic review.

The critical appraisal process involves not only an assessment of the most important methodological aspects, but it also requires a detailed analysis of the aspects that contribute to the validity of a study. Reviewers resolved disagreements by discussion.

B.3.4 DATA COLLECTION AND CRITICAL READING.

Once the articles that were part of the review were selected, it was necessary to evaluate the internal quality of the studies using the Critical Appraisal Tools.

The data collection sheet (*Annex B.6.2*) consists of several sections that ask about the characteristics of the study. By including different types of study, a critical reading sheet was elaborated with different sections depending on whether it was a narrative review or was an empirical study, based on the proposals by the tool FLC 2.0.

The critical reading sheet leads the reviewer to enter the details of the study, collecting the data that produce the tables of evidence (*Annex B.6.3*).

A critical reading sheet was completed for each of the articles that had passed the 2nd selection phase. At this stage the same reviewers worked as in the selection stage of articles.

B.3.5 CRITICAL EVALUATION OF THE QUALITY OF STUDIES.

Based on the data obtained in the critical reading sheets, and following the quality pattern suggested by OSTEBA, a quality result has been applied, for the content being analyzed as well as for the methodology applied. The results obtained from the method described in each article along with the other criteria (research question, results, conclusions, conflict of interest), allowed to apply the "high", "average" or "low" quality assessment, as can be observe in the following table (table B.1).

Table B.1: Classification of Evidence (OSTEBA) by method and content.

	Method GOOD	Method FAIR	Method POOR
Rest of criteria GOOD	HIGH Quality	MODERATE Quality	LOW Quality
Rest of criteria FAIR	MODERATE Quality	MODERATE Quality	LOW Quality
Rest of criteria POOR	LOW Quality	LOW Quality	LOW Quality
Not classifiable: the study does not provide sufficient information to determine its quality			

When the study under analysis does not provide sufficient information to determine its quality, it has been considered "Not classifiable".

B.4. RESULTS

B.4.1 SEARCH OF RESEARCH STUDIES

In the last updated search on July 10, 2017 a total of 521 articles were obtained in PUBMED, which became 518 after solving the 3 duplicate articles. Seven articles from other databases were included as relevant to the research.

B.4.2 SELECTION OF STUDIES

As a result of the first blind selection phase, 412 of the 518 references were excluded. The main reason for exclusion was the population under study, because although the type of study was adequate and minors were participating, the analysis of the information was extracted from the parents or the researchers about the child's assent. In the same way, many of the studies were discarded by the type of study, because they referred to the assent in clinical practice.

Of the remaining 106 articles, in 16 occurred discrepancies and after being analyzed in groups, it was decided to reject them for not focusing on any of the three key points of consent: information, understanding and competence.

With the 90 articles included in this first screening, it was decided to carry out a second screening phase with the same reviewers and blind, after reviewing the criteria for inclusion and exclusion of articles. The result was the inclusion of 39 articles for in-depth analysis and full-text reading, and the remaining 51 were excluded.

The difficulty in selecting articles was due to the complexity of isolating the subjects under study from others directly related to research assent, such as the factors that influence the decision-making process of the child when he becomes a subject of research: mood, emotions, pressure, state of health, coercion, will, etc.

B.4.3 DATA COLLECTION AND CRITICAL READING

With the 39 articles that were finally selected to be included in this summary of the evidence, and the 7 extracted from other databases that contain relevant information, the data collection and critical reading sheets were completed, the result of which is presented in the tables of evidence (*Annex B.6.3*). The articles were grouped according to the content that could help to respond to each of the objectives.

After the critical reading, 4 of the 46 articles were found to refer to other aspects of the informed consent process, related to decision making, modified consent forms, and stages of moral development of the child.

It was observed that the 46 selected articles had a very different OSTEBA quality, as shown in the following summary table.

Table B.2: Summary of the quality of the evidence and content of the selected articles

	OSTEBA High quality	OSTEBA Moderate quality	OSTEBA Low quality	Not classifiable
INFORMATION	Tait, 2017-b	Dove, 2013 Tait, 2017-a	Twycross, 2008 Roth-Cline, 2013 Baker, 2013	Giesbertz, 2016
UNDERSTANDING	Unguru, 2010 O'Lonergan, 2011 Lee, 2013 Friedman, 2016 Vitiello, 2007*	Scherer, 2007 Miller, 2013 Miller, 2014 Poston, 2016 Blake, 2015 Coors, 2016 Murphy, 2007* Lally, 2014* Grootens, 2015*	Unguru, 2009 Blake, 2011 Chappuy, 2008 Fisher, 2016 John, 2008 Ott, 2013*	Massimo, 2009 (draft)
COMPETENCE	Hein, 2014	Raymundo, 2008 Monaghan, 2009 Larcher, 2010 Scherer, 2013 Hein, 2015-a Koelch, 2009 Koelch, 2010 Nelson, 2016*	Leibson, 2015 Alexander, 2015*	Hein, 2012 (draft) Hein, 2015-b (comments previous work) Hunter, 2007 (personal comments about Gillick competence)
OTHER THEMES		Swartling, 2011 (decision making)		Espejo, 2011 (moral development) Antal, 2017 (modified forms) Kumpunen, 2012 (information method)

*Additional records from other data bases

B.4.4 INFORMATION

Informed assent is a process that respects and promotes autonomy in the child's development, to show his/her opinion and decide on the health or illness processes that affect him/her. In this way the empowerment and development of their moral capacity for the autonomous exercise of future decisions is pursued ^(3, 4).

Although much has been written about assent in the last twenty-five years, there remain controversial aspects regarding this term, such as the quantity and quality of information to be provided to the child and what they really want and need to know, among others ^(5, 6).

All potential research subjects should be informed of the relevant aspects of the research, before being included in a research study, to protect their autonomy and voluntariness. Even non-competent people have the right to be informed.

In the case of minors, potential research subjects, it is necessary to select the quantity and quality of this information in the assent process.

B.4.4.1 METHODOLOGICAL ASPECTS

In the review carried out, only 7 articles analyze the information that is provided or should be given to the child during the IC process or assent. Of these, only 1 is of high quality, 2 of moderate quality, 3 of low quality and 1 not classifiable because of the lack of data after the critical reading as seen in Table B.3.

Except for an experimental study, the rest of studies are theoretical or observational. In the two studies involving minors and parents, an interview was used as method of data collection along with a semi-structured questionnaire with open questions.

Table B.3: Studies on the information of the assent, according to the quality of the evidence.

Author, year	Quality	Type of study	Nº subjects
Tait, 2017-b	High	Experimental studies/ clinical research	55 minors/55 parents
Dove, 2013	Medium	Observational studies/ clinical research	443 IC documents
Tait, 2017 -a	Medium	Observational studies/ clinical research	20 experts
Twycross, 2008	Low	Theoretical studies/ clinical research	Not applicable
Roth-Cline, 2013	Low	Theoretical studies/ clinical research	Not applicable
Baker, 2013	Low	Observational studies/ clinical research	20 minors/57 parents
Giesbertz, 2016	Not classifiable	Theoretical studies/ clinical research	Not applicable

B.4.4.2 RESULTS

Considering the definition proposed by Tait⁽⁷⁾ of "assent", we see that the importance of age-appropriate information is reinforced, taking into account the cognitive and emotional aspects of the child, as we observe in the following definition:

"Children who lack the legal authority to provide informed consent per state laws should provide their assent to participate in a research study unless they either lack the cognitive ability, their clinical condition precludes their ability to communicate a choice, or the research holds out the prospect of direct benefit that is only available in the context of the research. Assent is an interactive process between a researcher and child participant involving disclosure of cognitively and emotionally appropriate information regarding, at minimum, why the child is being asked to participate, a description of the procedures and how the child might experience them, and an understanding that participation in the study is voluntary. Children should understand that they can decline participation or withdraw from the study at any time. Assent requires that the child explicitly affirms his or her agreement to participate in a manner that reflects their age-appropriate understanding and that is free of undue influence or coercion. In the absence of an explicit agreement, mere failure of the child to object cannot be construed as assent."

It is important, according to Tait and agreed by a panel of experts using a Delphi technique⁽⁷⁾, to inform why he/she has been chosen to participate, the procedures to be submitted and how he/she might experience them, the benefits indirect if there is no expectation of personal benefit and voluntariness and the right to revoke at any time. The experts consider as a requirement for a meaningful assent, the understanding of this basic information and the child's awareness of how it would affect his/her personal situation.

But one thing is what bioethics experts and pediatric researchers decide, and another quite different is the information priority of children. Even their priorities may differ from what their parents or legal guardians think they might be interested in.

This is demonstrated in another study by Tait⁽⁸⁾ comparing research priorities among children, adolescents and their parents, where it was concluded that they differ in some aspects. The information priorities were analyzed using questionnaires about the hypothetical participation in a clinical trial. Both children and parents classified all elements of information (nature, purpose, procedure, direct benefits, indirect benefits, risks, voluntariness, right to withdraw) as important, but younger children (<12 years) placed more emphasis on knowing that their personal information will be kept confidential and less on knowing the purpose of the study and the benefits. Aspects that their parents considered to be very important. Adolescents give more importance in knowing what will be done to them, the direct benefits and the nature of the study compared to younger children, without having differences by sex.

For parents, informational priorities were higher if their child was between 13-17 years old and / or was a girl.

Of interest was that while parents seemed to focus more on the importance of real risks, children seemed more interested in the burden of participation, i.e. how much time it could take the participation and whether it would keep them away from their usual activities. Aspects that are not normally contemplated in the information provided to minors.

Previously, Roth-Cline⁽⁹⁾ had already sought evidence regarding the information to be contained in the children's assent. He noted that the regulations did not specify the information needed for the child, but the recommendations of the official bodies indicated that it should include information on the procedures to be carried out, the freedom to choose, the communication of the decision and the possibility to withdraw at any time, regardless of whether the parents are provided with more detailed information. The author concluded that the amount of information that a minor should understand should vary with the child's age and maturity without being able to state with scientific evidence the pieces of information to include in the assent.

Regarding the amount of information, Baker⁽¹⁰⁾ in a qualitative study using coded interviews conducted in 2013, attempted to identify how the IC quality of the children with cancer participating in a phase 1 trial could be improved. Of the interviews conducted to 20 children between the ages of 14 and 21, and those made to the parents, it was found that the most frequent suggestions were relative to the information given during the assent process. Information regarding the risks, benefits, purpose of the study, scientific bases that justify their participation, logistical problems in case of participation and all this through an honest communication, without technicalities, in a comfortable and individualized environment depending on the needs of the child and of his family. They also suggested that written information from the IC should be sent in advance, that other means be used (not only written) and that there should be a summary sheet with the key aspects that should be remembered during the course of the trial.

This individualization of assent according to the needs of the child has also been proposed by Giesbertz⁽¹¹⁾ in a theoretical study in which she attempted to answer the question of how content and the process of assent should be considered to be a personalized assent in the specific case of biobanks. Although the lack of data of that publication makes its quality unclassifiable, it is stated in that article that for the information to be individualized, it must begin with specific aspects and continue giving more information at the request of the child, using not only the means classical writings, but information technologies. That way we will verify that the child wants to know and wants to decide.

In an analysis of the thematic content of pediatric informed consent models performed by Dove in 2013⁽¹²⁾, he observed that only 30% use a specific model. Of the 443 IC models analyzed, 56% do not raise the possibility of dissent, 49% do not pose the possibility of a

future IC if they reach the age of majority, only 26% pose the potential risks from a point psychological, social or financial, 33% do not consider the indirect benefits and only 65% name the possibility of withdrawing at any time. All ICs referred to the right of the parents to access the child's information, but did not refer to the child's right to limit it. Confidentiality is specifically protected (coded) in 58% of documents and anonymized in 9%.

Beuchamp y Childress⁽¹³⁾ already established that in order for the communication process within the clinical relationship to be truly effective, one of the important elements was adequate exposure of the information. And it is precisely in the decision-making process that the most important thing is to foster an understanding of the information exchanged. Excess or lack of information should be avoided, as should the use of overly technical language, which could interfere with the processing and understanding of the language and lead to decision making without proper understanding.

Twycross⁽¹⁴⁾ attempted to establish a formula so that the information provided to minors involved in research was appropriate. Through meetings with experts conducted during the Research Society's International Nursing Research Conference, a consensus was reached on the format that the information should have:

- The information must have a manageable length, according to the age and development.
- It should not have a larger extension of an A4 double-sided sheet, as the detailed information can overwhelm the child.
- Information leaflets should be designed so that they can be read, but interactive enough to be involved in the process.
- Language should be appropriate to the child's age and development.
- Images and graphics can be used to increase understanding, but should be simple, clear and familiar.
- Do not just increase the font size of a format designed for older children.
- Information sheets should be printed on paper with the letterhead of the hospital or institution where the research is done.
- The brochures must contain the information necessary for the minor's decision.
- Always respect the confidentiality of data.

Many of these recommendations refer to aspects of readability, both linguistic (grammatical and lexical) and typographic (graphic characters), which will allow the child to read and understand it more easily.

B.4.5 UNDERSTANDING

Measurement of understanding of informed consent or assent requires an operational definition of what "understanding of informed consent" means. Using a Delphi method, Buccini⁽¹⁵⁾ proposed in 2009 a definition that takes into account three previous issues:

- What specific information of an IC should the participants know?
- What does "understanding" mean?
- What methods are there to verify understanding?

All this, together with the integration of new information in the subject's previous knowledge. With all this, she considered the understanding of IC as:

"Informed consent comprehension can be said to occur when the following conditions are met:

- There is evidence that a potential participant has integrated his/her current knowledge with the consent information;*
- The evidence occurs at the time the potential participant decides whether or not to take part in the research study;*
- At a minimum, the integrated consent information includes the consent requirements stipulated by national and international ethics regulations."*

This definition can be useful in putting forward methods or questionnaires to evaluate understanding.

The systematic review shows that these requirements are imperfectly met.

The methodological and content aspects of IC understanding studies in children and adolescents are reviewed below.

B.4.5.1 METHODOLOGICAL ASPECTS

In the review practiced there are 20 empirical articles of verification of the understanding of IC or of assent in minors. 5 of them have high quality, 9 moderate quality, and 6 low quality.

Six of the articles can be considered as clinical trials given the randomization of several IC models, with further study of their different understanding. The rest of the articles deal with open or closed questionnaires, or semi-structured interviews.

Given the wide variety of models it is difficult to draw conclusions. Following the formal aspects, 11 studies are conducted with healthy children or adolescents (for vaccine studies or for hypothetical future studies) and 7 with sick children participating in clinical trials for cancer, HIV and other diseases. Patients participating in cancer trials are Phase I, II or III, as well as post-marketing.

The lapse between the signing of the IC or assent to the investigation and the study of understanding is also very variable: in some cases the signature is immediate to the presentation of the IC, and in others it is up to 2 years later.

In 13 studies, a questionnaire is made with open or closed questions, with large differences in the number of questions, from 1 to 69, and with open or closed response options, responding in a Visual Analogue Scale, dichotomous (yes / no), with several possible answers, or with the Likert method (from "totally agree" to "totally disagree"). Its answer can be done with the help of the investigators. In 11 of the 13 articles the model of the questionnaire is provided. In other cases the interview is the basis of the analysis, usually with a predetermined structure.

Most studies do not report the year of completion of comprehension tests. Only four of the articles include an assessment of the Intelligence Coefficient of the children or adolescents studied, and in another, a test of literacy and numerical capacity as Lally used in her study⁽¹⁶⁾.

Table B.4: Studies on understanding, according to the quality of the evidence.

Author, year	Quality	Type of study	Nº subjects
Friedman 2016	High	Experimental studies/ clinical research	39
Lee 2013	High	Observational studies/ clinical research	123
O'Lonergan 2011	High	Experimental studies/ clinical research	170
Unguru 2010	High	Observational studies/ clinical research	37
Vitiello 2007*	High	Observational studies/ clinical research	295
Blake 2015	Medium	Experimental studies/ clinical research	120
Coors 2016	Medium	Experimental studies/ clinical research	195
Miller 2013	Medium	Observational studies/ clinical research	20
Miller 2014	Medium	Observational studies/ clinical research	61
Murphy 2007*	Medium	Experimental studies/ clinical research	187
Lally 2014*	Medium	Experimental studies/ clinical research	120
Poston 2016	Medium	Observational studies/ clinical research	4
Grootens 2015*	Medium	Observational studies/clinical research	101
Blake 2011	Low	Observational studies/ clinical research	33
Chappuy 2008	Low	Observational studies/ clinical research	29
Fisher 2016	Low	Observational studies/ clinical research	60
John 2008	Low	Observational studies/ clinical research	73
Ott 2013*	Low	Observational studies/ clinical research	33

* Secondary search

B.4.5.2 RESULTS

The studies of quality HIGH showed the following results:

Friedman⁽¹⁷⁾ in 2016, examines whether the use of two or seven questions during the on-line assent process in healthy gay or bisexual adolescents, for an on-line behavior study improves the understanding of the information in that assent. Two questions during the process,

relating to voluntariness and research risks, were repeated at the end of the assent process. The probability of correct response had an OR ranging from 3 to 10 in the groups that had encountered them during the assent phase, relative to the group that had only read the assent document. Conclusion: Reinforcement through questions interspersed in the process of assent improves their understanding in concrete aspects.

Lee⁽¹⁸⁾ evaluated the understanding of a modified document in text format with supporting images for a Hepatitis B vaccine trial (Experimental studies / clinical research) in the year 2013. The response to a 6-question questionnaire with dichotomous response (yes / no) showed that 56% of 123 young people between 12 and 17 years old answered all questions correctly. The best understood questions were those concerning randomization and the possibility of withdrawal from the study. The worst-understood issue was that of the blinding choice of vaccine.

O'Lonergan⁽¹⁹⁾ in 2011 studied the difference in understanding between a classic CI model in text format or a multimedia one for hypothetical imaging studies. A questionnaire of 8 questions after the IC process showed a better understanding among those who had used the multimedia model ($p < 0.009$), especially in relation to the sections of study procedures and risks. The study was done in parallel with the parents, and both the parents and the children had a better subjective impression of understanding than the questionnaire showed.

If the previous studies were hypothetical models in healthy population, Unguru⁽⁴⁾ in 2010 studied children with cancer through a questionnaire of 69 questions and with the help of an interviewer. Analyzes the degree of understanding about the Experimental studies / clinical research in which they are participating, and whose IC was signed more than 4 months earlier. In the understanding aspect, 70% of minors reported that the information provided at that moment was difficult or very difficult to understand, especially for the language used.

In MODERATE quality studies, two studies by Miller^(20, 21) and Poston⁽²²⁾ also use cancer patients. In the study published by Miller in 2013⁽²¹⁾ she uses a verbally administered structured interview after 6 days of the IC process for a Phase I Experimental studies / clinical research, on a questionnaire that deals with aspects of understanding and decision making. Overall, researchers have a good understanding of volunteerism and risk, although a significant percentage (30%) expected direct benefits. In the article that Miller published in 2014⁽²⁰⁾, also with interviews, she found a good understanding, with a value of comprehension difficulty of 1.94 (on a scale between 1, very easy to understand, and 10, very difficult to comprehend), comprehension which is believed to be facilitated by good communication with researchers.

Poston⁽²²⁾ finds a questionnaire with quantitative results, an understanding of 64 out of 100 possible points. The small number of participants ($n = 4$) prevents further conclusions.

Blake⁽²³⁾ in 2015 develops a clinical trial (Experimental studies / clinical research) to see if the understanding of a multimedia IC is better than a traditional model, for a hypothetical HIV vaccine. There is no difference in comprehension between both IC models.

Murphy⁽²⁴⁾ did a similar study in 2007 which compares the understanding of a simplified IC with images versus a standard one for a hypothetical study of HIV vaccine in adolescents conducted at three centers. The questionnaire of 19 questions was passed immediately after the live speech of the IC. Unlike the previous study, adolescents with the standard model correctly answered fewer questions than the simplified model (median 14 and 16 correct answers on 19, $p = 0.005$). The variables associated with better understanding were the IQ, the type of IC read, and the origin of the adolescent.

From the same group (ATN, Adolescent Trial Network for HIV / AIDS Interventions) is Lally's article⁽¹⁶⁾ that demonstrates a better understanding of specific aspects of IC such as "randomization" and "adverse effects" when completing information from a CI for a hypothetical HIV vaccine trial with a booklet explaining these issues with double messages (presentation of a misconception refuted with factual information).

A comic can also be a vehicle for information to get an acceptable understanding of the basics of research, as shown by Gootens-Wieger⁽²⁵⁾, in which a comic done by professionals about a hypothetical clinical trial in healthy children from 10 to 14 years old shown a comprehension above 65% in the eight sections considered essential in assent/consent to minors (voluntary, ineffective drug, withdrawal, randomization, placebo, side effects, anonymity, benefit uncertainty).

Finally, and within the MODERATE quality studies, the Coors article⁽²⁶⁾ studies the understanding of a specific IC model, that of a biobank in a sample of adolescents with substance use disorder. In this case, an improved IC model following a discussion process, and focused on current risks improved general understanding through a 6-question questionnaire.

But risks are not always as important to the adolescent as the aversion they may feel to certain procedures such as venipuncture. This is described by Scherer⁽²⁷⁾ in a theoretical study on the key issues related to the child's assent to research, which concludes that there are differences in the understanding between adolescents and their parents about the appreciation of risks and procedures.

The six LOW quality studies have some interesting aspects.

Blake⁽²³⁾ proposes to put more emphasis on the concepts of "randomization", "placebo", differentiation between clinical practice and research, after interviewing 33 healthy adolescents.

Chappuy ⁽²⁸⁾ in children with cancer or HIV, and also with guided interviews found worse understanding in aspects of procedures, possibility of alternative treatments, length of participation, right of withdrawal, and voluntariness.

Fisher⁽²⁹⁾ in sexual minority adolescents, and in the face of a hypothetical HIV vaccine, found an acceptable understanding behind the vision of an informative video on risks, benefits, and adherence, and proposes in a similar situation the possibility of self-consent informed.

In a study of healthy children who had participated in a study of a vaccine, done by John⁽³⁰⁾ in 2008, it is concluded that most children aged 6-8 do not have the ability to understand the factors surrounding a study research, with marked individual differences. Half of the 73 children who participated didn't know why they had blood drawn. Even after explaining and extracting them, 33% still without knowing the answer. Not so with the possibility of withdrawing from the study, which was understood by the majority from the beginning.

Finally, Ott⁽³¹⁾, member of the ATN group, found through interviews analyzed with a method based on grounded theory, improved understanding through the interviews themselves, although with incomplete understanding of aspects related to randomization and the need for placebo.

The review of the secondary literature focused on the systematic review and meta-analysis performed by Thanh Tam ⁽³²⁾ in 2015, with a bibliographic search until 2013, for understanding IC in adults and children. The three research articles she found and in which minors participate (Chappuy 2008, Miller 2013, and Unguru 2010) are also referenced in this study.

The article by Massimo⁽³³⁾ is rejected because, although it provides a model for analyzing the understanding of an IC, it is only a research project.

B.4.5.3 CONCLUSIONS

The measurement of the understanding of informed consent in research is done through questionnaires or interviews, none validated, and with a high subjective component. It is therefore urgent to have a validated tool, which can be applied in different types of clinical trials, to measure the understanding of informed consent and assent in children and adolescents, as Lepola states⁽³⁴⁾.

The studies analyzed show contradictory results regarding the application of improved models (with intermediate questions during the process, with multimedia tools, with improved models thanks to previous surveys ...) to improve the understanding.

Different scenarios (studies of hypothetical future clinical trials in the healthy population, or clinical trials in children and adolescents with serious illnesses) probably require different communicative tools on the part of the professionals involved, but in all of them the

importance of effective communication will be present in the IC process, as well as more readable, simplified, and sufficiently informed IC models to improve their understanding.

B.4.6 ASSESING COMPETENCE

It is analyzed here if the child has the capacity to understand the different aspects that entails their participation in a research study.

Logically this section is closely related and includes the above on understanding. In fact, it is the first section of a formal decision-making process called the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR).

The capacity, linked to the complementary term of competence, establishes a point or level in which it would be acceptable for the minor to have a voice in the decision to participate, according to Hein⁽³⁵⁾.

According to Katz⁽³⁶⁾ the capacity would be *"a clinical determination that addresses the integrity of mental abilities"* while competence would be the legal determination that deals with the social interest of restricting decision making when capacity is in doubt.

The capacity for autonomy is a continuous variable, but competence is dichotomous (whether or not it is competent), and therefore has a greater legal nuance according to Larcher⁽³⁷⁾. This author defines competence as *"the ability to understand nature, purpose and consequences and ability to decide"*.

An approach to the competence could be done with a battery of questions:

- What is the illness/condition and what are its effects?
- What treatments/investigations are necessary and why?
- When does this need to be done?
- What does the treatment mean to me, and how will it affect my life?
- What happens if I do not have the treatment?
- What are the alternatives and their effects?
- What are the practical consequences for me and my family on school and friends?

With this we see that the competence is contextual to the environment and to the situation that is sought to certify. Although the capacity required to agree to participate in a research study because of the risk involved is not the same, to assert itself in clinical practice, Monaghan⁽³⁸⁾ stated in a descriptive study with children aged 12-14 years that should use the exchange of information, the explanation and understanding of such information and the opportunity to ask questions as a basis for capacity assessment.

B.4.6.1 METHODOLOGICAL ASPECTS AND RESULTS

In the review done only 6 articles with empirical content that analyze a validated tool for the determination of the child's capacity to assent in clinical research have been found. This is the MacCAT-CR test.

Four of the articles are from two groups of authors. Hein has made the largest study using the MacCAT-CR tool, originally designed for adults. The authors redesigned it for use in minors, and added two more questions⁽³⁹⁾.

The MacCAT-CR test is a semi-structured interview that measures the 4 aspects to be evaluated in the determination of the competence of a subject:

- Understanding information.
- Reasoning in the decision-making process.
- Appreciation of the effects of participation in the subject.
- Expression of an election about that participation.

The test has two parts: 15-20 minute interview and a competition ranking.

The authors describe which factors are child-specific to make a judgment of competence: factors related to aspects of development (abstract thinking, cognitive social aspects, changing circumstances for child development, etc.), provision of information (adapted to age of the child, in small blocks, with multimedia support ...), and systemic influences (of parents, friends, and professionals).

The questions added by Hein et al.⁽³⁹⁾ were: "What do you think your parents will think about whether or not you take part in the study?" and; "What about your friends?".

Later they proved their validity in a study with 161 patients between 6 and 18 years who were participating in different clinical trials or observational studies. The application of the MacCAT-CR test in these patients sought two objectives: to study their reliability and validity in comparison to a clinical capacity assessment and to establish age limits of capacity or lack thereof⁽⁴⁰⁾.

For this, the minors were interviewed, with later analysis of the recording, and the authors established a clinical capacity criterion. This result was compared with clinical assessment. The authors found that the test was reproducible and valid, with a concordance with clinical assessment. Based on their results, they found that under 9.6 years the child was probably not capable, and that over 11.2 years was able, with the intermediate values being a gray zone of probable need for assessment on a case-by-case basis.

The same working group analyzes the factors that determine competition through a multivariate analysis of the previous study. It is not surprising that age and IQ are the variables that most influence capacity⁽⁴¹⁾.

Koelch et al. published two similar studies^(42, 43) with two small groups of adolescents with ADHD (with or without oppositional defiant disorder added). In the first study⁽⁴³⁾ they invited

them to participate in an open study on the understanding of a possible Experimental studies / clinical research, using the MacCAT-CR test. This use seemed more meant to measure understanding, appreciation and reasoning, than to a decision of competence or not: With this premise they found a more deficient understanding in the more abstract subjects (what is the final objective of an Experimental studies / clinical research, and what is the randomization and nature of the placebo).

In the 2010 publication⁽⁴²⁾, also involving a small sample with the same diseases, the MacCAT-CR test was passed to 12 adolescents and 12 parents to determine their competence to participate in an Experimental studies / clinical research with psychostimulants. From each minor the authors made a clinical assessment of competence, which was positive in all of them. MacCAT test scores for ability were better in parents than in minors. They didn't find correlation between capacity and IQ. The worst-understood items were those referring to the purpose of the study, nature of the placebo and possible absence of benefit for the patient).

Nelson in 2016⁽⁴⁴⁾ adapted the MacCAT-CR test to perform it during the informed consent process instead of after it, as usually done, and simplifies the contribution of information given. It also studies variables that may influence capacity. It studies 30 adolescents between 14 and 21 years old. They demonstrate a capacity similar to adults, although the variables studied, age, level of literacy, and socioeconomic level influence the degree of ability.

Alexander in 2015⁽⁴⁵⁾ studied 33 adolescents aged 16-19 years on a hypothetical HIV vaccine, through interviews with an ethnographic content analysis, and following the MacCAT-CR scheme with its four points (although without referring to it), found that all are competent to decide whether to participate in that hypothetical study.

Table B.5: Studies on competence, according to the quality of the evidence.

Author, year	Quality	Type of study	Nº subjects
Hein 2014	High	Observational studies/ clinical research	161
Hein 2015	Moderate	Observational studies/ clinical research	161
Koelch 2009	Low	Observational studies/ clinical research	19
Koelch 2010	Moderate	Observational studies/ clinical research	12
Nelson 2016	Moderate	Observational studies/ clinical research	30
Raymundo 2008	Moderate	Observational studies/ clinical research	59
Alexander 2015	Low	Observational studies/ clinical research	33

In addition to the MacCAT-CR, other authors have evaluated the possibility of using other models to assess the ability to consent. Thus, Raymundo⁽⁴⁶⁾ evaluated the moral development of a group of minors with an indicator of consent capacity, based on the Loevinger model of the Ego Stages and using the Souza questionnaire validated and adapted by the author. Raymundo concluded that the ability to understand and decide is gradually acquired, and not suddenly when a child reaches legal capacity. In fact, it is usually purchased before this. But

moral capacity is individual and varies with the person. It states that age, by itself, is not an adequate variable to measure the child's ability to decide, in the process of assent.

B.4.6.2 THEORETICAL STUDIES

Faced with the scarcity of empirical data, theoretical studies have been somewhat more frequent.

A first discussion is developed around the "Gillick competition". This concept comes from the *Gillick v West Norfolk & Wisbech Area Health Authority* and the Department of Health and Social Security⁽⁴⁷⁾ which established that, for clinical practice, the child under the age of 16 was considered competent when the physician determines it. That is useful in clinical practice to solve with agility situations in which there is a priori doubts about the competence of the minor to take of decisions, but according to Hunter⁽⁴⁸⁾ it would not be applicable to the investigation.

A Delphi study with 20 experts developed by Tait in 2017, studied the recommendation of the different methods to study the capacity⁽⁷⁾. Interestingly the experts leave the MacCAT-CR test in penultimate place. Table B.6 show the most valued items and its ranking.

Table B.6: Evaluate methods for assessing the child's capacity⁽⁷⁾.

ÍTEM	EVALUATE
<i>Discussion with both parents and children to find out their cognitive ability</i>	30
<i>Check feedback for understanding</i>	20
<i>Discussion with the child only to find out their cognitive ability</i>	10
<i>Use of general developmental models (eg, child or adolescent)</i>	10
<i>Based on age cut-off points</i>	5
<i>Use a short examination to find understanding</i>	0
<i>Using a standardized tool (b.p. the MacCAT-CR)</i>	0
<i>Only discussion with parents</i>	0

It is still argued whether age should be the sole or main criterion for defining competence for assent. Hein⁽³⁵⁾ defends the age criterion, but not Schrerer⁽⁴⁹⁾. Leibson's⁽⁵⁰⁾ review of IC in pediatric research, show how different authors suggest the age of 9 years as a cut between non-competition and competition, although this assertion is not shared by others.

B.4.6.3 CONCLUSIONS

Analysis of decision-making capacity for assent in children and adolescents remains controversial.

If the MacCAT-CR test, used in adults and modified for children and adolescents has proved valid, experts are still discussing whether to establish age competition, to use the MacCAT-CR test on each occasion or to use methods based on in interaction with the researcher and parents.

B.5. BIBLIOGRAPHY

1. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan- a web and mobile app for systematic reviews. *Systematic Reviews*. DOI: 10.1186/s13643-016-0384-4; 2016; Available from: <https://rayyan.qcri.org/>.
2. López de Argumedo M, Reviriego E, Andrío E, Rico R, Sobradillo N, Hurtado de Saracho I. Revisión externa y validación de instrumentos metodológicos para la Lectura Crítica y la síntesis de la evidencia científica. Madrid: Plan Nacional para el SNS del MSC. Servicio de Evaluación de Tecnologías Sanitarias del País Vasco (Osteba)2006.
3. Bustamante BJP, Díaz RG. Asentimiento y consentimiento informado en pediatría: aspectos bioéticos y jurídicos en el contexto colombiano. *Revista Colombiana de Bioética Universidad El Bosque*. 2013;8(1):144 - 64.
4. Unguru Y, Sill AM, Kamani N. The experiences of children enrolled in pediatric oncology research: implications for assent. *Pediatrics*. 2010;125(4):e876-83. Epub 2010/03/31.
5. Unguru Y. Making sense of adolescent decision-making: challenge and reality. *Adolescent medicine: state of the art reviews*. 2011;22(2):195-206, vii-viii. Epub 2011/11/24.
6. Unguru Y, Coppes MJ, Kamani N. Rethinking pediatric assent: from requirement to ideal. *Pediatr Clin N Am*. 2008;55(1):211-22.
7. Tait AR, Geisser ME. Development of a consensus operational definition of child assent for research. *BMC medical ethics*. 2017;18(1):41. Epub 2017/06/11.
8. Tait AR, Geisser ME, Ray L, Hutchinson RJ, Voepel-Lewis T. Disclosing Study Information to Children and Adolescents: Is What They Want, What Their Parents Think They Want? *Academic pediatrics*. 2017. Epub 2017/06/14.
9. Roth-Cline M, Nelson RM. Parental permission and child assent in research on children. *The Yale journal of biology and medicine*. 2013;86(3):291-301. Epub 2013/09/24.
10. Baker JN, Leek AC, Salas HS, Drotar D, Noll R, Rheingold SR, et al. Suggestions from adolescents, young adults, and parents for improving informed consent in phase 1 pediatric oncology trials. *Cancer*. 2013;119(23):4154-61.
11. Giesbertz NA, Melham K, Kaye J, van Delden JJ, Bredenoord AL. Personalized assent for pediatric biobanks. *BMC medical ethics*. 2016;17(1):59.

12. Dove ES, Avard D, Black L, Knoppers BM. Emerging issues in paediatric health research consent forms in Canada: working towards best practices. BMC medical ethics. 2013;14:5. Epub 2013/02/01.
13. Beauchamp T, Childress J. Principios de Ética Biomédica: Ed. Oxford University Press; 2001.
14. Twycross A, Gibson F, Coad J. Guidance on seeking agreement to participate in research from young children. Paediatric nursing. 2008;20(6):14-8.
15. Buccini L, Caputi P, Iverson D, Jones C. Toward a construct definition of informed consent comprehension. J Empir Res Hum Res Ethics. 2009;4(1):17-23.
16. Lally M, Goldsworthy R, Sarr M, Kahn J, Brown L, Peralta L, et al. Evaluation of an intervention among adolescents to reduce preventive misconception in HIV vaccine clinical trials. The Journal of adolescent health : official publication of the Society for Adolescent Medicine. 2014;55(2):254-9. Epub 2014/03/13.
17. Friedman MS, Chiu CJ, Croft C, Guadamuz TE, Stall R, Marshal MP. Ethics of Online Assent: Comparing Strategies to Ensure Informed Assent Among Youth. Journal of empirical research on human research ethics : JERHRE. 2016;11(1):15-20.
18. Lee S, Kapogiannis BG, Flynn PM, Rudy BJ, Bethel J, Ahmad S, et al. Comprehension of a simplified assent form in a vaccine trial for adolescents. Journal of medical ethics. 2013;39(6):410-2. Epub 2013/01/26.
19. O'Lonergan TA, Forster-Harwood JE. Novel approach to parental permission and child assent for research: improving comprehension2011 2011-1-1. 917-24 p.
20. Miller VA, Baker JN, Leek AC, Drotar D, Kodish E. Patient involvement in informed consent for pediatric phase I cancer research. Journal of pediatric hematology/oncology. 2014;36(8):635-40.
21. Miller VA, Baker JN, Leek AC, Hizlan S, Rheingold SR, Yamokoski AD, et al. Adolescent perspectives on phase I cancer research. Pediatric blood & cancer. 2013;60(5):873-8.
22. Poston RD. Assent Described: Exploring Perspectives From the Inside. Journal of pediatric nursing. 2016;31(6):e353-e65.
23. Blake D, Lemay C, Maranda L, Fortenberry J, Kearney MH, Mazor K. Development and evaluation of a web-based assent for adolescents considering an HIV vaccine trial. AIDS care. 2015;27(8):1005-13.

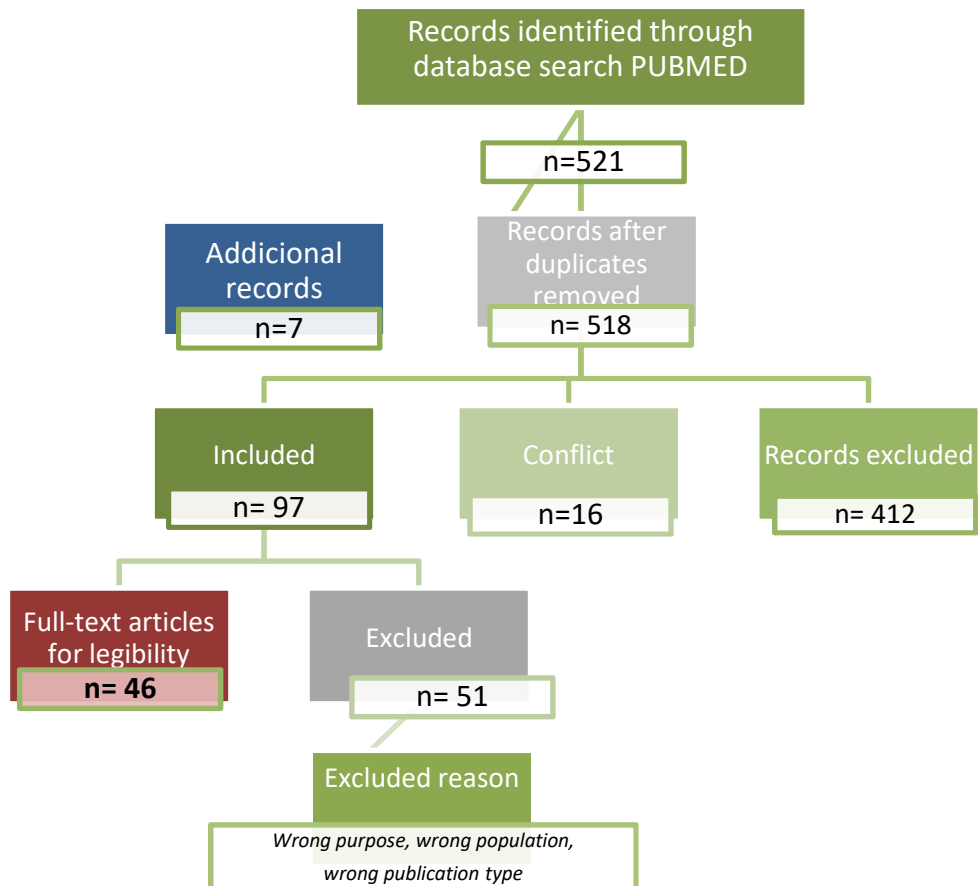
24. Murphy DA, Hoffman D, Seage GR, 3rd, Belzer M, Xu J, Durako SJ, et al. Improving comprehension for HIV vaccine trial information among adolescents at risk of HIV. *AIDS care*. 2007;19(1):42-51.
25. Grootens-Wiegers P, de Vries MC, van Beusekom MM, van Dijck L, van den Broek JM. Comic strips help children understand medical research: targeting the informed consent procedure to children's needs. *Patient education and counseling*. 2015;98(4):518-24. Epub 2015/01/24.
26. Coors ME, Raymond KM, Hopfer CJ, Sakai J, McWilliams SK, Young S, et al. Adolescents with substance use disorder and assent/consent: Empirical data on understanding biobank risks in genomic research 2016 2016-1-1. 267-71 p.
27. Scherer DG, Annett RD, Brody JL. Ethical issues in adolescent and parent informed consent for pediatric asthma research participation 2007 2007-1-1. 489-96 p.
28. Chappuy H, Doz F, Blanche S, Gentet JC, Tréluyer JM. Children's views on their involvement in clinical research. 2008;50(5):1043-6.
29. Fisher CB, Arbeit MR, Dumont MS, Macapagal K, Mustanski B. Self-Consent for HIV Prevention Research Involving Sexual and Gender Minority Youth: Reducing Barriers Through Evidence-Based Ethics. *Journal of empirical research on human research ethics : JERHRE*. 2016;11(1):3-14.
30. John T, Hope T, Savulescu J, Stein A, Pollard AJ. Children's consent and paediatric research: is it appropriate for healthy children to be the decision-makers in clinical research? *Archives of disease in childhood*. 2008;93(5):379-83.
31. Ott MA, Alexander AB, Lally M, Steever JB, Zimet GD, Adolescent Medicine Trials Network for HIVAI. Preventive misconception and adolescents' knowledge about HIV vaccine trials. *Journal of medical ethics*. 2013;39(12):765-71.
32. Tam NT, Huy NT, Thoa le TB, Long NP, Trang NT, Hirayama K, et al. Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis. *Bulletin of the World Health Organization*. 2015;93(3):186-98H. Epub 2015/04/18.
33. Massimo LM, Calcagno A, Battaglia T, Pistorio A. A project for the evaluation of awareness of under-aged patients involved in clinical trials. Development of the IGG-Awareness Scale. *Minerva pediatrica*. 2009;61(5):483-8.
34. Lepola P, Needham A, Mendum J, Sallabank P, Neubauer D, de Wildt S. Informed consent for paediatric clinical trials in Europe. *Archives of disease in childhood*. 2016;101(11):1017-25.

35. Hein IM, De Vries MC, Troost PW, Meynen G, Van Goudoever JB, Lindauer RJ. Informed consent instead of assent is appropriate in children from the age of twelve: Policy implications of new findings on children's competence to consent to clinical research. *BMC medical ethics*. 2015;16(1):76.
36. Katz AL, Webb SA, Committee On B. Informed Consent in Decision-Making in Pediatric Practice. *Pediatrics*. 2016;138(2).
37. Larcher V, Hutchinson A. How should paediatricians assess Gillick competence? *2010;95(4):307-11*.
38. Monaghan N, Morgan MZ. Consent of older children participating in BASCD coordinated dental epidemiology surveys in Wales 2009-1-1. 157-61 p.
39. Hein IM, Troost PW, Lindeboom R, de Vries MC, Zwaan CM, Lindauer RJ. Assessing children's competence to consent in research by a standardized tool: a validity study. *BMC pediatrics*. 2012;12:156.
40. Hein IM, Troost PW, Lindeboom R, Benninga MA, Zwaan CM, van Goudoever JB, et al. Accuracy of the MacArthur competence assessment tool for clinical research (MacCAT-CR) for measuring children's competence to consent to clinical research. *JAMA pediatrics*. 2014;168(12):1147-53. Epub 2014/10/16.
41. Hein IM, Troost PW, Lindeboom R, Benninga MA, Zwaan CM, van Goudoever JB, et al. Key factors in children's competence to consent to clinical research. *BMC medical ethics*. 2015;16(1):74.
42. Koelch M, Prestel A, Singer H, Schulze U, Fegert JM. Report of an initial pilot study on the feasibility of using the MacArthur competence assessment tool for clinical research in children and adolescents with attention-deficit/hyperactivity disorder. *J Child and Adol Psychopharm*. 2010;20(1):63-7.
43. Koelch M, Singer H, Prestel A, Burkert J, Schulze U, Fegert JrM. "...because I am something special" or "I think I will be something like a guinea pig": information and assent of legal minors in clinical trials--assessment of understanding, appreciation and reasoning. *Child and adolescent psychiatry and mental health*. 2009;3(1):2.
44. Nelson LR, Stupiansky NW, Ott MA. The Influence of Age, Health Literacy, and Affluence on Adolescents' Capacity to Consent to Research. *J Empir Res Hum Res Ethics*. 2016;11(2):115-21.
45. Alexander AB, Ott MA, Lally MA, Sniecinski K, Baker A, Zimet GD, et al. Adolescent decision making about participation in a hypothetical HIV vaccine trial. *Vaccine*. 2015;33(11):1331-7.

46. Raymundo MM, Goldim JR. Moral-psychological development related to the capacity of adolescents and elderly patients to consent 2008 2008-1-1. 602-5 p.
47. Great Britain. England. Court of Appeal CD. Gillick v West Norfolk and Wisbech Area Health Authority. The all England law reports. 1984;1985(1):533-59.
48. Hunter D, Pierscionek BK. Children, Gillick competency and consent for involvement in research. Journal of medical ethics. 2007;33(11):659-62.
49. Scherer DG, Brody JL, Annett RD, Turner C, Dalen J, Yoon Y. Empirically-derived Knowledge on Adolescent Assent to Pediatric Biomedical Research. AJOB Prim Res. 2013;4(3):15-26.
50. Leibson T, Koren G. Informed consent in pediatric research. Paediatric drugs. 2015;17(1):5-11.

B.6. ANNEXES

B.6.1 FLOW DIAGRAM



B.6.2 TEMPLATE FOR THE COLLECTION OF CRITICAL READING DATA

1. REFERENCE

- Bibliographic citation in Vancouver style
- Brief appointment. It is the one that appears in the summary table

2. STUDY

- Study design
- Goals
- Search period (if systematic review) and / or completion of the study
- Origin of the population; type of center and population
- Participating entities

3. REVIEWERS; people who perform the critical reading and date in which it is performed.

4. RESEARCH QUESTION

- Is the target population adequately defined?
☐ Yes ☐ No ☐ Partly ☐ N/Not applicable
- Is the intervention (s) being studied adequately defined?
☐ Yes ☐ No ☐ Partly ☐ N/Not applicable
- Is the intervention with which to compare or the effects to be studied adequately defined?
☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

The study is based on a clearly defined research question

☐ Good ☐ Fair ☐ Poor ☐ N/Not applicable

5. METHOD

a. SELECTION CRITERIA

- Is the method of selecting the participants / studies included in the review described?
☐ Yes ☐ No ☐ Partly ☐ N/Not applicable
- Are the inclusion criteria specified?
☐ Yes ☐ No ☐ Partly ☐ N/Not applicable
- Are the exclusion criteria specified?
☐ Yes ☐ No ☐ Partly ☐ N/Not applicable
- Were all selected cases / studies included in the study?
☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

v. Are the number of studies / participants included?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

vi. In short: are the inclusion and exclusion criteria adequate to be able to answer the question?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

vii. Is the search strategy / characteristics of the participants detailed?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

viii. In summary: is the bibliographic search sufficiently exhaustive and rigorous? Are the participants adequate?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

b. QUALITY OF STUDIES (IF SYSTEMATIC REVIEW)

i. Is the method used to evaluate the quality of studies described?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

ii. In summary: is the quality of the studies evaluated appropriately?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

c. EXTRACTION OF DATA (YES SYSTEMATIC REVIEW)

i. Is any form used for data extraction?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

ii. Is the information about the intervention and results clear for all relevant subjects and groups?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

iii. Are the number of reviewers mentioned?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

iv. In summary: the extraction of data is done rigorously?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

d. INTERVENTION (IF EXPERIMENTAL)

i. Is the study intervention well described?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

ii. Were the same variables measured and the same measurement scales used?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

iii. In summary, the intervention is developed in a rigorous way?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

e. TRACKING (IF EXPERIMENTAL)

i. Is the follow-up period indicated?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

ii. If losses occurred, indicate the number and characteristics of the losses.

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

iii. The method of collecting information is described

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

iv. In short, is follow-up adequate?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

The methodology (empirical study) used guarantees the internal validity of the study

☐ Good ☐ Fair ☐ Poor ☐ N/Not applicable

The methodology used (narrative review) for the selection and evaluation of individual studies is well described and adequate

☐ Good ☐ Fair ☐ Poor ☐ N/Not applicable

6. RESULTS

a. Is there a detailed description of the results?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

b. Are the number of studies and patients / participants included in the systematic review evaluated?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

c. Is the quality of the studies included in the review evaluated? In case the quality of the studies is evaluated, write down the results in this regard

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

d. Are the data from the studies included in the review well described?

☐ Yes ☐ No ☐ Partly ☐ N/Not applicable

Are the results correctly described?

☐ Good
 ☐ Fair
 ☐ Poor
 ☐ N/Not applicable

7. CONCLUSIONS

a. Do the findings give an answer to the objectives of the study?

☐ Yes
 ☐ No
 ☐ Partly
 ☐ N/Not applicable

The conclusions are based on the results obtained and take into account the constraints

☐ Good
 ☐ Fair
 ☐ Poor
 ☐ N/Not applicable

8. CONFLICT OF INTEREST

a. Is the source of funding mentioned?

☐ Yes
 ☐ No
 ☐ Partly
 ☐ N/Not applicable

b. Do the authors declare the existence or absence of any conflict of interest?

The results and conclusions are free from influences derived from conflicts of interest

☐ Good
 ☐ Fair
 ☐ Poor
 ☐ N/Not applicable

9. EXTERNAL VALIDITY

The results of the review are generalizable to the population and to the context of interest

☐ Good
 ☐ Fair
 ☐ Poor
 ☐ N/Not applicable

10. QUALITY OF THE STUDY

Taking into account the answers, the quality of the evidence provided by the study analyzed is assessed.

	METHOD OK	METHOD Medium	METHOD Wrong
Rest of criteria OK	HIGH Quality	MODERATE Quality	LOW Quality
Rest of criteria MEDIUM	MODERATE Quality	MODERATE Quality	LOW Quality
Rest of criteria WRONG	LOW Quality	LOW Quality	LOW Quality
Not classifiable: the study does not provide sufficient information to determine its quality			

The quality of evidence is:

☐ High
 ☐ Medium
 ☐ Low
 ☐ Unclassifiable

B.6.3 TABLES OF EVIDENCE.

All critical reading tables completed for the selected articles are listed below.

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Alexander 2015	<p>Design:</p> <p>An observational study with intervention, based on interviews and an analysis of ethnographic content, that focuses on the process (how is the ability of some adolescents to make a decision to enter a hypothetical clinical trial of an HIV vaccine).</p> <p>Goals:</p> <p>Examine the decision-making process of adolescents about their participation in an HIV vaccine trial</p> <p>Period of realization:</p> <p>Not known</p>	<p>Number of participants / group:</p> <p>33 adolescents aged 16-19</p> <p>Participating Features:</p> <p>Adolescents of both sexes of 16-19 years, HIV negative and with sexual activity with men, and with desire to participate. Recruitment in clinics, youth agencies and youth programs</p>	<p>Intervention:</p> <p>4 aspects treated in the interviews (they are the same as those of MacCAT-Cr):</p> <ul style="list-style-type: none"> - Understanding of relevant information. - Assessment of the situation itself. - Reasoning about options. - Election <p>Follow-up period:</p> <p>Do not</p> <p>Toll: Do not</p>	<ul style="list-style-type: none"> - Understanding of relevant information: Acceptable. - Assessment of the situation itself: They generally understood that the trial was an experiment, not a prevention measure. They discussed aspects of stigmatization. One more reason to participate acknowledged that it was monetary compensation. - Reasoning about the options: Most would like other people to participate in decision making (in order of frequency, peers, health, family, other adults). - Election: All participants felt able to make a choice. 	<p>They show that in the analyzed sample the adolescents have the capacity for an IC.</p> <p>They use the same guide as the MacCAT-CR, without naming it</p>	Not reproducible	Low

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Antal 2017	<p>Design:</p> <p>Observational study for the creation of a multimedia informed consent model in a clinical trial of childhood asthma, and its application. It seeks to increase understanding by reducing the cognitive load</p> <p>Goals:</p> <p>Describe the procedures used in designing and developing a multimedia platform to obtain parental consent and the child's consent for a controlled clinical trial to evaluate a treatment for asthma.</p> <p>Illustrate how five basic principles of multimedia learning were actively incorporated into the multimedia platform</p> <p>Evaluate understanding of parents and adolescents and satisfaction with the use of this platform.</p> <p>Period of realization:</p> <p>The evaluation of the platform, in 2017</p>	<p>Number of participants / group:</p> <p>Not applicable</p> <p>Participating Features:</p> <p>N / Not Applicable</p>	<p>Intervention:</p> <p>Use of a multimedia platform to obtain Informed Consent in asthma research. Comparison, for purposes of understanding, with a classic Informed Consent model. After viewing the video, an understanding questionnaire of 17 items, independently of parents and adolescents, is passed to the 4 days.</p> <p>Follow-up period:</p> <p>N / Not Applicable</p> <p>Toll:</p> <p>N / Not Applicable</p>	<p>In order to elaborate this multimedia, five basic principles of multimedia learning were taken into account: 1) Sensory modality: based on the cognitive learning theory, according to which people have independent channels to process visual and auditory information. 2) Coherence: Redundancy: subjects learn better from images + narration than from images + narration + Narration: better learning if there are signs in the image that show how the content is organized. written text5) Personalization: learning improves with a narrator who acts as a conductor. A video of 15 minutes, with 4 sections, is made interactive (the step to the next section is done after answering a questionnaire of 3 questions). It describes the formal characteristics of the platform and its elaboration (use of professionals of the image and of actors ...).</p>	<p>Studies of published electronic informed consent models do not capture all the components used in this study: Evidence-based learning principles for a CI multimedia format, a complex and real clinical trial, and the inclusion of both parents and minor , in the consent process.</p> <p>Limitations: do not study which of the 5 theoretical items used to make the video may be more important.</p> <p>Costs can be prohibitive. The clinical trials committee must be available for an iterative processing process.</p> <p>Your results (in future publications) will be interesting.</p>	<p>Description of the theoretical bases to develop a multimedia platform for Informed Consent in clinical research with minors. Description of the steps taken to prepare them.</p> <p>Description of the project to analyze your understanding.</p>	Low

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Short quotation: Baker 2013	<p>Design:</p> <p>Prospective observational study. It is the secondary analysis of data collected in a larger study in 6 pediatric cancer centers in the USA and that studied the communicative and understanding aspects of informed consent in a phase 1 trial. These data were collected through interviews with parents and adolescents who had already agreed to participate in those phase 1 trials.</p> <p>Goals:</p> <p>To identify the suggestions of parents and adolescents to improve the quality of IC in a phase 1 clinical trial.</p> <p>Period of realization:</p> <p>Not known</p>	<p>Number of participants / group:</p> <p>57 parents (72% mothers) and 20 children completed the questionnaire</p> <p>Participating Features:</p> <p>Partially Described</p>	<p>Intervention:</p> <p>85 families were invited to participate in phase 1 studies, and the IC interview was recorded. Subsequently, only those who had agreed to participate in the clinical trial were given a semi-structured interview. One of the questions was: "In your opinion, how can we improve the IC process in a phase 1 study?"</p> <p>The interviews were for parents and children between 14 and 21 years old.</p> <p>The analysis of the answers to the described question was by a qualitative method with analysis of the semantic content.</p> <p>Follow-up period:</p>	<p>There were 220 suggestions (parents) and 54 suggestions (children), which could be grouped into 21 codes. The most frequent suggestions were:</p> <ul style="list-style-type: none"> - Offer more information. - To offer an honest communication, without technicalities. - Individualizing the IC according to the needs of the patient and family. <p>All suggestions could be grouped into 3 groups:</p> <p>1- More information: more risk information, benefits, study purposes. Scientific basis for using this drug. Logistical problems in case of participation. Families also suggested changes in the IC model: not only written information, but by other means, the convenience of a CI summary sheet.</p> <p>2- Better structure and presentation of the IC process, mainly the convenience of sending written information of the CI in advance. They also suggested that the study be explained several times, have time to think about it, and interview in comfortable settings.</p> <p>3- Suggestions to the doctors who led</p>	<p>Provides opinions of parents and teens on the IC process: Above all, they insist on the need to use all the necessary time in IC, be honest, use more than one session, and be available to parents. We did not collect suggestions from families who refused to enter the clinical trial and could be different from the included group (all families had agreed to participate in the clinical trial).</p>	<p>Qualitative study on opinions of parents and adolescents who have agreed to participate in a phase 1 study. This group has another publication in the review (Miller 2013)</p>	Low

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			N / Not Applicable Toll: Two families	the process. Have a member of the medical team available for any questions that may arise. They also suggested that other non-medical professionals (nurses, chaplains, psychologists, social workers) should be involved in the process.			

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Short quotation: Blake 2011	<p>Design:</p> <p>Observational study. Interviews with groups of adolescents with opinions gathered on a text of assent previously read. Recording the interviews. Extraction of dominant themes.</p> <p>Goals:</p> <p>Establish the degree of understanding of the basics of a model of assent</p> <p>Period of realization: does not appear</p>	<p>Number of participants / group:</p> <p>33 adolescents (16 women, 17 men).</p> <p>Participating Features:</p> <p>Adolescents 15 to 17 years old, healthy, with English proficiency</p>	<p>Intervention:</p> <p>Group reading of a vaccine consent model, and further discussion.</p> <p>Follow-up period:</p> <p>N / Not Applicable</p> <p>Toll:</p> <p>N / Not Applicable</p>	<p>The topics discussed are divided into three groups:</p> <p>1.- Issues related to a research study: difficulty in differentiating research from clinical practice, difficulty in understanding terms such as "placebo" or "randomization".</p> <p>2.- Issues related to vaccines: difficulty in understanding how vaccines work (preventive and non-therapeutic use).</p> <p>3.- Topics related to a hypothetical HIV vaccine: difficulty in understanding the possibility of false positives.</p> <p>Other topics discussed: Need for more information on side effects. Importance of asking for parental consent before or after consent (before the parents in a case of chemotherapy, before the adolescents in a vaccine case).</p>	They verify the importance of insufficient understanding in models of research assent in adolescents	Although the population studied is highly skewed, limitations are found in the understanding of concepts used in research, the need to clarify the difference between research and clinical practice, and the importance of the order between parental informed consent and consent	Low

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<p>Short quotation:</p> <p>Blake 2015</p>	<p>Design:</p> <p>Experimental study. Prospective, randomized, non-blind trial with three groups of participants: with multimedia assent model, with questions and feedback (questions arise during the exposition, and answered before continuing), traditional model of assent with questions and feedback, and model traditional assent, without questions or feedback. After passing one of the models, they answer a questionnaire of 27 questions.</p> <p>Goals:</p> <p>Compare the understanding of assent (traditional model or multimedia model) measured in two ways: average correct answers in the questionnaire, and proportion of participants with a correct response rate greater than 80%. In addition, the rate of correct answers was compared by linear regression with the general school-level test (WRT-4).</p> <p>Period of realization:</p> <p>Not known</p>	<p>Number of participants / group:</p> <p>120 subjects aged 15-17 years; for each of the three groups (with sample size calculation) was 60 for group with assent on the web, and 30 and 30 for paper assent groups with or without questions. Each group was randomized using a randomization table.</p> <p>Characteristics of the participants:</p> <p>Origin of adolescents from 5 youth service agencies. Inclusion criteria: read and understand English</p>	<p>Intervention experimental group:</p> <p>They passed the web assent program first, then questionnaire and WRT-4.</p> <p>Control group intervention:</p> <p>The other two groups were read the assent model, clarifying doubts (to the subgroup with questions, they passed these). Then they did the questionnaire and WRAT-4.</p> <p>Follow-up period:</p> <p>Not applicable</p> <p>Post-randomization losses:</p> <p>N / Not Applicable</p>	<p>Magnitude of the effect (+ confidence intervals / p value):</p> <p>NO significant differences between groups in the comprehension questionnaire.</p> <p>Adverse effects:</p> <p>Not applicable</p>	<p>The initial hypothesis is not demonstrated, that an electronic model would improve understanding. The authors then analyze secondary aspects of the work</p>	<p>The non-confirmation of the hypothesis could be for several reasons: it is a theoretical model and not a real investigation. Staff who are aware of the classic assent may be different from a team of real-life researchers. They console themselves by saying that the multimedia model is no worse than the classic. In the conclusion do not focus on the important thing and is that the study does not confirm the previous hypothesis, that the electronic assent would be better.</p>	<p>Medium</p>

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Short quotation: Chappuy 2008	<p>Design:</p> <p>Observational study.</p> <p>Twenty-nine children in a cancer or HIV clinical trial were offered, with parental permission, the opportunity to complete a semi-structured interview to ascertain the understanding of prior informed consent.</p> <p>Goals:</p> <p>Examine children's understanding of informed consent for clinical trials of cancer or HIV.</p> <p>Period of realization:</p> <p>6 months. It does not indicate date of realization.</p>	<p>Number of participants / group:</p> <p>29 children interviewed (18 with HIV infection and 11 with cancer), aged between 8.5 and 18 years.</p> <p>9 of the 29 children had received a diagnosis and proposed IC less than 7 days earlier.</p> <p>Participating Features:</p> <p>Do not</p>	<p>Intervention:</p> <p>The intervention was a semi-directed interview by one of the authors (he did all the interviews) on the 9 aspects that should be included in an IC. This IC was supposed to have been asked for some time to participate in a clinical trial, regardless of whether they had agreed to participate or not.</p> <p>The CI elements that were questioned were: study objectives, study risks, potential self-benefits, benefits for others, procedures, possibility of alternative treatments, duration of participation, right of withdrawal, and voluntariness.</p> <p>A question was asked about each item and 0 or 1 was scored according to the answer. The sum of all the questions was therefore from 0 to 9 (final score).</p> <p>The decision to score 0 or 1 depended on the investigator, according to which he would agree with what was in the IC model.</p>	<p>The understanding of different elements of an IC was measured, the best ones being those referred to:</p> <ul style="list-style-type: none"> - Objectives of the study - Study Risks - Potential self-benefits. - Benefits for others. <p>The elements with the worst understanding were those referred to:</p> <ul style="list-style-type: none"> - Procedures - Possibility of alternative treatments - Duration of participation. - Right to withdrawal. - Voluntariness. <p>The information was</p>	<p>We found an incomplete understanding of elements included in an IC for minors. The understanding was related to the age and the time elapsed since the diagnosis. The elements of IC worse understood were those related to autonomy (possibility of alternative treatments, right to withdrawal, and voluntariness). The percentage of patients with adequate response was not high (58-62%), and lower than in other studies; the authors attribute it to the fact that in the latter the diseases at play were more serious than in other</p>	<p>It is not clear when minors are offered the IC document (although in Methods yes it says that the lapse between IC signature and interview, then in Results, does not appear). The interview was oral, and recorded, and the language of the questions adapted to the child's age</p>	Low

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			<p>Follow-up period: N / Not Applicable</p> <p>Toll: N / Not Applicable</p>	<p>considered adequate by 16 children.</p> <p>We correlated the understanding with age, with the existence of a time between diagnosis and application of IC.</p> <p>It does not say the average score of the entire population studied.</p>	studies.		

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Short quotation: Coors 2016	<p>Design:</p> <p>An experimental, prospective, with controls study that analyzes the understanding of the risks of a biobank with an improved IC model versus a standard one. For the realization of the improved IC model, a previous stage of analysis and quantification of the current risks of a biobank</p> <p>Goals:</p> <p>To determine whether improved Informed Consent describing the outstanding risks of a biobank increases understanding in adolescents with Substance Use Disorder (DSM-IV),</p>	<p>Number of participants / group:</p> <p>194, in Step 4</p> <p>Participating Features:</p> <p>Adolescents with Substance Use Disorder (some with other related pathology such as behavioral disorders) from a university treatment program. This study was offered independently of the proposed inclusion in the biobank. The controls were adolescent of the same sex and</p>	<p>Intervention:</p> <p>4 stages, each at the end of the previous one.</p> <p>Stage 1: Meeting to identify risks to biobank participants. The following risks were defined:</p> <ul style="list-style-type: none"> - Current risks: breach of security, genetic discrimination, unknown future uses, sensitive family information, change of opinion in the future, judicial use, uncertainty of benefits. - Future risks: Purchase of biobanks, among others. - Speculative risks: again, related to speculation. <p>With the current risks an improved IC model was made. A 10-question questionnaire with multiple responses was also developed to test the understanding of the risks, and a scale (Visual Analogue Scale, VAS), which measures a characteristic along a continuum (0-100), to measure highlighting the risks.</p> <p>Stage 2: Check whether participants understand risks as a prerequisite to ordering the importance of those risks.</p> <p>Stage 3: study and compare the participants' level of understanding of risks at the beginning of the study.</p> <p>Stage 4: compare a standard IC model for the genomic study with the standard IC model plus the improved</p>	<p>From Stage 2: Most respondents correctly answered the questionnaire (75-95% correct answers) and rated (by VAS) with more than 50% to 7 of the 8 current risks.</p> <p>Stage 3 (baseline understanding of risks): no differences between groups (adolescent patients of healthy adolescents, parents of one another and older adolescents and their siblings).</p> <p>From Stage 4 (comparison of the standard IC</p>	<p>The addition of an improved IC to a standard IC improves understanding in adolescent patients and parents of patients to the levels of understanding of their controls. It has been observed that quantifying the current risks through VAS allows the improvement of IC models.</p>	<p>Complex article focused on understanding the risks of an IC for a biobank in a particular population, adolescents with substance use disorder. A previous study of the importance they give to the current risks allows to improve the IC for comprehension purposes. The statistic is debatable (repeated t-tests)</p>	Medium

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	<p>compared to a standard informed consent model for genomic addiction research.</p> <p>Period of realization:</p> <p>Not known</p>	<p>racial group recruited through an Internet portal (Craiglist) in the areas coming from the cases. Parents of adolescent patients and adolescents old adolescent patients and siblings of adolescent adolescent patients.</p>	<p>model.</p> <p>In Step 2, measuring the importance of risks, the current risk information collected in Stage 1, and subsequently the questionnaire, and the visual scale to assess the importance of each risk (for each risk was considered only if the answers to the questionnaire were correct).</p> <p>The improved IC that was created only took into account the risks with an importance (VAS) greater than 50. In Step 3, baseline understanding of the risks, another independent group of participants (n = 165) were questionnaire without first passing the current risk information collected in Stage 1.</p> <p>In Stage 4, a third independent group of participants completed the questionnaire after receiving the standard IC only, or this plus the IC improved (n = 195). They describe how they calculated the "understanding of risk" through a score. At all stages, subjects were divided into 6 groups: adolescent patients, adolescent controls, parents of patients, parents of controls, former adolescent patients and siblings of former adolescent patients (and for Stage 4, each of the 6 groups were subdivided between those who received only the standard IC format and those who received the standard plus the improved questionnaire, without indicating how many cases in each subgroup).</p> <p>Follow-up period:</p> <p>Do not</p> <p>Toll: N / Not Applicable</p>	<p>format and Improved IC):</p> <p>The standard IC is better understood by adolescent controls than by adolescent patients (p = 0.005). The understanding of standard IC plus improved is the same in adolescent patients as in controls.</p> <p>Improved IC increases understanding in adolescent patients (p = 0.002).</p> <p>Improved IC increases understanding in parents of adolescent patients (p = 0.006) and siblings of older adolescents (p = 0.034)</p>			

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Short quotation: Dove 2013	Design: Observational study. Qualitative analysis of thematic content of pediatric informed consent models of academic centers and public bodies of Canada dated between 2008 and 2011. Six emerging issues are analyzed: 1) If the scope of the parental IC allows the consent, dissent or future consent of the child. 2) If the concept of risk and benefit incorporates the social and psychological perspective of the child. 3) Whether the possibility of withdrawal of the	Number of participants / group: 443 Informed Consents analyzed: 7 biobanks 4 of clinical trials 19 of genetic studies 11 longitudinal studies 17 observational studies Participating Features: Not applicable	Intervention: All selected CIs were analyzed using a modified qualitative method of thematic content. The information sought on emerging issues was presented in a table. Follow-up period: N / Not Applicable Toll: N / Not Applicable	1) Aspects related to consent: - 30% use a specific IC, while 42% use a generic IC (leave open the possibility of future uses of collected data / material). - 56% do not raise the possibility of dissent. - 49% do not raise the possibility of an agreement or consent in the future (if the research changes or the majority of the population reaches the age of majority) 2) Risks and benefits: - 26% pose potential risks from a social, psychological or financial point of view. - 67%	Since they were CIs of different types of studies, the variability of formats was expected. Thus, open IC formats are more likely in biobanks, since the samples are stored for a long time. With regard to risks, they remember that they go far beyond physical risks, and that Canadian law requires them to be taken into account. They also refer to research with more than "minimum risks", and therefore have to take into account all types of risks. Regarding the information of both the results of the study and of incidental findings, there is no consensus, especially in relation to genetic studies and biobanks. Limitations of the study: The study does	Study of IC models seeking to detect emerging problems of current IC models. They find many improveable aspects, which describe them in a table: Best practices for drafting paediatric research consent forms in Canada Emerging issue Best practices Scope of parental consent Broad consent · The possibility of future, unspecified research uses should be mentioned prior to obtaining consent and the consent form should be worded accordingly. When the child is considered to be legally able to provide consent, consent should be renewed, if feasible. · Where feasible, data and / or samples should be coded (not anonymised) in order to allow researchers to maintain contact with the child. Ability to dissent · The possibility of a child's right to dissent, provided there is an ability to understand the significance of research or his / her role in it, should be disclosed. Financial, social, and psychological issues · Consideration of potential harms must include physical as well as psychological, social or financial harms. Cumulative harms considered in assessing	Medium

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	<p>child is respected and to what extent withdrawal is permitted.</p> <p>4) Whether the information from the research results includes individual results and incidental findings.</p> <p>5) If doubts about privacy and confidentiality are resolved from the perspective of the minor and if the data are correctly identified.</p> <p>6) If custody and access to biological samples and data of the child are properly treated.</p> <p>Goals:</p> <p>1) Analyze how much information on</p>			<p>consider indirect benefits</p> <p>3) Extension of withdrawal:</p> <ul style="list-style-type: none"> - 65% name the possibility of the child withdrawing from the study. - The way of doing the withdrawal (destruction of data, samples, etc.) is only mentioned in 35%. - No CI mentions how to handle a possible disagreement between parent and child regarding withdrawal. <p>4) Information on results and incidental findings:</p> <ul style="list-style-type: none"> - This figure is not mentioned in 40% of ICs. Of those who mention the return of data, some offer 	<p>not focus on the understanding of IQs but rather on emerging ethical aspects (which I believe belong to the scope of information that should be included in the IC). There is no representation of CI models for qualitative research, nor for community research.</p>	<p>individual harms</p> <ul style="list-style-type: none"> · Cumulative harms should be considered. How? Benefit? is characterized · Risks and benefits should be considered from the child? S perspective. Withdrawal Ability for withdrawal <p>The child's ability to withdraw should be explicitly disclosed, as well as any circumstances that might limit the ability (eg if immediate withdrawal could harm the child). Extent of withdrawal</p> <ul style="list-style-type: none"> · The extent of the ability to withdraw should be explicitly disclosed (eg if data and / or samples are anonymised, the consent form should state that withdrawal is not feasible). Informational entanglement · The potential for a child and parents to disagree about whether to withdraw, and its potential impact on the research project, should be described. Return of research results and incidental findings The potential and process for returning research findings and incidental findings · The potential for disclosure of research findings and incidental findings, as well as its process (including disclosures and the possibility for entitlement to non-disclosure), should be described. Individual findings and incidental findings that have clinical significance should be communicated to the child and / or parents when either prevention or treatment is available during 	

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	<p>emerging issues is found in the CI sample analyzed.</p> <p>2) Evaluate the quality of that information using a structured list based on best practices.</p> <p>3) Proposal of improvements for the development of IC in minors.</p> <p>Period of realization: 2011</p>			<p>it individual and others, aggregates.</p> <p>5) Privacy and confidentiality:</p> <p>-All ICs refer to the right of parents to access information of the child (but do not refer to the right of children to limit it).</p> <p>- Identification is unspecifically protected in 33% of cases, coded in 58% (ideally), and anonymised in 9% of ICs.</p> <p>6) Custody and access of data / samples:</p> <p>- 42% of ICs referred to specific time periods of data / sample custody. 21% made no reference to this aspect.</p> <p>- 47% did not refer</p>		<p>childhood, and with adequate counseling provided. The interconnected nature of the potential risks and benefits of such communication should be disclosed. Duty to receive information</p> <p>· Parents should be aware that they will receive clinically significant information about conditions that are preventable or treatable during childhood. Privacy and confidentiality Parents? right to access information regarding their child</p> <p>· In research projects that collect and use particularly sensitive information, such as pregnancy status, drug use, or sexual history, consent forms should disclose what information will and will not be communicated to parents, and which information disclosure requires the child? S consent. Nomenclature for data / sample identifiability</p> <p>· Standardized sample identifiability terminology should be used: coded (including single-coded and double-coded), anonymised, and anonymous.</p> <p>· Biobanking or genetic research consent forms should state that anonymised or coded data and samples can not guarantee privacy. Retention of and access to data / samples Retention period (s) of data / samples</p> <p>· Consent forms should clearly distinguish between what is a legally required data / sample retention period and a retention period decided upon by the researcher. Access to data / samples</p>	

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				to possible transfers of samples / data to other locations. 40% said they could do so in the future.		<ul style="list-style-type: none"> · The policies and procedures for access to data and / or samples should be disclosed. · These policies and procedures should consider the privacy impact (both to the parents and child) of access to coded or anonymised information, including: organizational safeguards, technological measures, physical measures, and ethics oversight. · If feasible, researchers should disclose a method for listing all approved projects that are accessing the data and / or samples. 	

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Short quotation: Espejo 2011	<p>Design:</p> <p>Observational study, with three stages: to elaborate a scale of evaluation of the moral development for adolescents according to the stages of Kohlberg, evaluation of this scale comparing it with a already validated test (DIT test of James Rest), and comparison with the subjective average of the tutors of the cognitive ability and maturity of their students.</p> <p>Goals:</p> <p>Have a practical tool to assess the degree of moral development according to Kohlberg stadiums</p> <p>Period of realization:</p> <p>not applicable</p>	<p>Number of participants / group:</p> <p>60</p> <p>Participating Features:</p> <p>N / Not Applicable</p>	<p>Intervention:</p> <p>Elaboration of the scale. Application to 60 adolescents aged 14-15 years, together with the DIT scale, and subjective assessment of the tutor</p> <p>Follow-up period:</p> <p>N / Not Applicable</p> <p>Toll:</p> <p>N / Not Applicable</p>	Poor correlation between the three variables	N / Not Applicable	Does not seem useful for the I-Consent study	Not classifiable

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Short quotation: Fisher 2016	<p>Design:</p> <p>Observational study of the responses in groups of discussion of adolescents of sexual orientation minorities to questions related to a hypothetical study on prophylaxis pre-exposure to HIV.</p> <p>Goals:</p> <ul style="list-style-type: none"> - Be able to inform the local Clinical Trials Committees that there is capacity in these children to make informed self-consent. - Effect of the need for parental leave to make the decision to participate in such a study. - Attitudes about understanding the purpose of the study, risks and benefits, adherence and randomization. <p>Study if young people are empowered to raise doubts and</p>	<p>Number of participants / group:</p> <p>60 adolescents aged 14-17</p> <p>Participating Features:</p> <p>Sexual relations with men, HIV negative, Internet access, and domicile in USA</p>	<p>Intervention:</p> <p>Six groups were stratified by age, sex, and parental attitude towards their sexual identity, and the identities of the debate were anonymised. Sequential information and questions were sent to each group. Then a video was offered with information from the hypothetical study. An open questionnaire was made on the video, and the researchers planted several issues for discussion: paternal leave, randomization, privacy, and adherence to medication. Standardized information was extracted from the discussion groups for analysis.</p> <p>Follow-up period:</p> <p>N / Not Applicable</p>	<p>It only gives numeric data. Faced with the question of the need for parental leave, most answered that in that case he would not participate. There was an acceptable understanding of the risks and benefits of the study, of the need for daily adherence to treatment. There was a reasonable understanding of the need to know the study because it would be proposed that out of informed self-consent.</p>	<p>They meet the objective of demonstrating that young people aged 14 to 17 years of sexual minorities (almost all homosexuals and a few transgender) were able to understand the characteristics of a study of HIV pre-exposure prophylaxis, with a view to proposing to the Test Committees Clinical the possibility of informed consent.</p>	<p>Article with objectives different from those of the I-Consent. It could serve as an example of the need for consent in minors to specific problems</p>	Low

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	<p>consent voluntarily.</p> <p>- Study your ability for a responsible CI.</p> <p>Period of realization:</p> <p>2015</p>		<p>Toll:</p> <p>N / Not Applicable</p>				

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Friedman 2016	<p>Design:</p> <p>A randomized, prospective, randomized, three-arm, non-blind, experimental study conducted during a larger study to find out the behavior of young gay men on the Internet. Recruitment by Facebook.</p> <p>Goals:</p> <p>Study whether young, gay-oriented 14-17-year-old males improve their understanding of an online assent model by reinforcing with questions during the assent process.</p> <p>Period of realization:</p>	<p>Number of participants / group:</p> <p>Recruited 623 subjects. Excluded during the process 121 subjects.</p> <p>Final Groups:</p> <p>Group 1 (reading of assent): 158.</p> <p>Group 2 (reading of assent with 2 questions about him): 126 subjects.</p> <p>Group 3 (reading of assent with 7 questions about him): 114 subjects</p>	<p>Intervention experimental group:</p> <p>Group 1) Reading the document of assent and subsequent desire to participate.</p> <p>Group 2) Reading of the document of assent and answer to two questions about voluntariness and risks, and later desire to participate.</p> <p>Group 3) Reading of the document of assent and answer to a questionnaire of 7 questions (the previous two and 5 more) on the process of assent, and subsequent desire to participate.</p> <p>At the end of the study, the two questions from Group 2</p> <p>Control group intervention:</p> <p>Yes</p>	<p>Magnitude of the effect (+ confidence intervals / p value):</p> <p>The probability that the subjects in groups 2 and 3 correctly answered the two questions when they were questioned at the end of the study was of an OR between 3 and 10, compared to those in group 1. They do not say how much time passed between the first questionnaire and the second</p> <p>Adverse effects:</p> <p>N / Not Applicable</p>	<p>The addition of two questions about test risks and trial voluntariness, made during the assent process, improves understanding of the test (measured by correct answer of those same two questions at the end of the study, versus controls). This improvement of understanding is in exchange for more losses during the process of assent, if the subject is asked for a more active effort (answering the questions). Conclusion: If a computer support is used for an assent in which information is proposed with a more active interaction with the subject, understanding would be improved, but a way of not sacrificing the possibility of more losses would be sought (by that effort extra that the subject is requested).</p>	<p>He is interested in the demonstration that the more difficult the process, the more withdrawn, but that a very simple interactive consent process improves understanding</p>	High

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
	Not known	Characteristics of the participants: Partially	Follow-up period: N / Not Applicable Post-randomization losses: 27 in group 1, 61 in group 2, 81 in group 3				

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Giesbertz 2016	Design: Theoretical study Goals: It tries to answer the question how should the content and the consent process be to be considered a personalized assent, in the case of biobanks Period of realization: not applicable	Number of participants / group: N / Not Applicable Participating Features: N / Not Applicable	Intervention: N / Not Applicable Follow-up period: N / Not Applicable Toll: N / Not Applicable	1. Content of assent: - Information to be provided. - The information must be individualized - The information begins with specific aspects - Give more information at the request of the child. 2. Assent Process: - How to offer the information? Classic methods (personalized document and interview), plus information technologies -Adult's role. The parents modulate and help to a process in which the author gives great autonomy to the child: he does not see the assent as mere confirmation. - The assent itself: Verbal communication and information. Check that the child understands, wants to know,	Although assent will not always be obtained (children with little maturity, who reject, etc.), it must be actively sought, because it shows respect for the child, improves the quality of the biobank, and improves the child's commitment for future reconstitutions. Take into account the complexity of the biobank when insisting or not on the assent. The content and process of the biobank must be known to the local clinical trials committee. The process of assent must be flexible. See the custom assent as a commitment search.	It defends a vision of the assent in which the decision of the child is a priority, in front of alternative conceptions in which the assent is only the confirmation of the previous decision of the parents.	Unclassifiable

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
				<p>and wants to decide.</p> <ul style="list-style-type: none"> - Subjectivity of assent: the process can be modified by the researcher's own action. - Reaction of the child. How to interpret silence, as assent or as dissent? 			

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Grootens 2015	Design: Observational study with intervention. Goals: Development and test of a comic to explain aspects of the IC. Period of realization: does not appear	Number of participants / group: All students in 4 classrooms between 10 and 14 years old. N = 101 children aged 10-14 years. Participating Features: Do not	Intervention: Design of the comic by a cartoonist and a communicator, without the participation of minors. We moved to 4 classrooms for children from 10 to 14 years. Subsequently a questionnaire was made with open and closed questions. Then, a group questionnaire with open questions about the comic and its opinion of the process. Follow-up period: Do not Toll: Do not	Acceptable comprehension (greater than 65%) in the 8 basic areas of research (voluntary, ineffective drug, withdrawal, randomization, placebo, side effects, anonymity, benefit uncertainty). Children were satisfied with the format	A comic format can increase the understanding of an IC for a clinical trial in minors.	The use of simple and attractive methodologies for children can achieve acceptable understanding of the most relevant aspects of clinical research.	Medium

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Hein 2012	<p>Design:</p> <p>The article is the project description: it is a prospective cohort study that compares the competence through a professional assessment, with the MacCAT-CR instrument.</p> <p>Goals:</p> <ul style="list-style-type: none"> - To study the reproducibility of the MacCAT-CR to assess the competence of children in the CI of clinical trials. - To establish a reference standard from the MacCAT-CR score. - To estimate age limits of competence <p>Period of realization:</p> <p>does not appear</p>	<p>Number of participants / group:</p> <p>160</p> <p>Participating Features:</p> <p>Patients between 6 and 18 years old recruited from three Dutch hospitals to propose to participate in different clinical trials. The projects to be proposed were oncology, pneumology and pediatric ophthalmology</p>	<p>Intervention:</p> <p>The MacCAT-CR is compared with the subjective assessment of the baseline clinical investigator, and two experts who judge yes / no on the basis of the interview accompanying the Informed Consent request of the baseline clinical trial. The authors translate the MacCAT-CR, adding two questions: What do you think your parents will think about whether or not you take part in the study? And your friends ?, and With this they try to complete the consequences of social relations.</p> <p>Measurements:</p> <ul style="list-style-type: none"> - MacCAT-CR: total score, score of the different domains, and binary (yes / no) with respect to the competition. - Wechsler Nonverbal Scale of Ability (WNV) to determine intelligence. <p>Statistic analysis:</p> <ul style="list-style-type: none"> - Reliability (accuracy) of the MacCAT-CR test. 	THIS ARTICLE IS ONLY THE PROJECT. NO RESULTS	This would be the first empirical study at world level that seeks to establish a standard combined with the validation of a measuring instrument.	<p>This article is only the research project. A validated tool is used in adults to determine competence to consent to a research project, and is adapted for children (MacCAT-CR). The resulting tool will be passed to a sample of 160 children who are proposed to participate in different trials clinical trials. Competition as measured by MacCAT-CR will be compared to the judgment of the investigators by interviewing the subjects.</p> <p>Description of the MacCAT-CR: semi-structured interview that measures the 4 aspects to be evaluated in the determination of the competence of a subject:</p> <ul style="list-style-type: none"> - Understanding information. - Reasoning in the 	Unclassifiable

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
			<p>- Validity of the MacCAT-CR test in relation to the reference standard.</p> <p>- Interobserver reproducibility of the different tools used (MacCAT-CR reference standard test).</p> <p>Follow-up period:</p> <p>N / Not Applicable</p> <p>Toll:</p> <p>N / Not Applicable</p>			<p>decision-making process.</p> <p>- Appreciation of the effects of participation in the subject.</p> <p>- Expression of an election about that participation.</p> <p>Two parts on the test: 15-20 minute interview, and classification. The authors describe what factors are child-specific to make a judgment of competence: factors related to aspects of development (abstract thinking, cognitive social aspects, changing circumstances for child development, etc.), provision of information (adapted to age of the child, in small blocks, with multimedia support ...), and systemic influences (of parents, friends, and professionals).</p>	

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Hein 2014	<p>Design:</p> <p>Observational study.</p> <p>Patients 6-18 years of age who participated in several clinical trials or observational studies, and who were given the MacCAT-CR test that examines competence for assent. Prospective study.</p> <p>Goals:</p> <p>To test a standardized test of competence (MacCAT-CR test) as to its reliability and validity, and to estimate age cuts to assume competence in assent</p> <p>Period of realization:</p> <p>01 / 2012-01 / 2014</p>	<p>Number of participants / group:</p> <p>161 study patients, with different participation rates.</p> <p>Participating Features:</p> <p>Partially Described</p>	<p>Intervention:</p> <p>Application of the MacCAT-CR competence test, modified by the authors for use in children.</p> <p>Comparison with a competency assessment performed by clinical assessment, through a filmed interview, and analyzed later, blind to the results of the competition test.</p> <p>From this analysis of the recording, each researcher spoke about the competition (in 4 categories, most likely competent, probably competent, probably incompetent, and most likely incompetent).</p> <p>This assessment was the reference on which the MacCAT-CR test was measured</p> <p>Follow-up period:</p> <p>N / Not Applicable</p> <p>Toll:</p> <p>N / Not Applicable</p>	<p>Reproducibility and validity of the MacCAT-CR test for children: good (intraclass correlation coefficient between 0.68 and 0.92)</p> <p>Unidimensionality of the confirmed test (confirms the utility of the global test to determine competence, because each of the 4 components are related).</p> <p>Good agreement between the MacCAT-CR test and the standard to assess competition</p> <p>Value of the MacCAT-CR test to determine proficiency, greater than or equal to 35 points.</p> <p>Age cut off points for competition: 11.5 years (with limits of 9.6-11.2 years with 90% sensitivity and 90% specificity respectively)</p>	<p>The modified version of the MacCAT-CR test is accurate to determine competence in assenting in clinical research in minors, suggesting ages of use.</p> <p>Thus, under 9.6 years the child is likely to be incompetent, and over 11.2 years, it is likely to be competent.</p> <p>They suggest that in the period between the two, the test can be used to determine the child's competence.</p>	<p>This study shows age limits in which the competence to assent in minors is expected or not.</p> <p>Between 9.6 years (limit of incompetence) and 11.2 years (limit of competence) the proposed test could be used to define it individually.</p>	High

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
<p>Short quotation:</p> <p>Hein 2015 a</p>	<p>Design:</p> <p>Observational study.</p> <p>It is complementary to that of Hein 2014, which analyzes, with the same data from that study, the potential factors that determine the competence of the child for consent to research, and to what extent these factors explain the variation in competition judgments.</p> <p>Prospective study, case series, which analyzes the explanatory variables of the existence of competence to make Informed Consent in minors.</p> <p>Goals:</p> <p>Analyze, with the same data from the Hein 2014 study, the potential factors that determine the child's competence for consent to research, and to what extent these factors explain the variation in</p>	<p>Number of participants / group:</p> <p>161participants</p> <p>Participating Features:</p> <p>Participants from different clinical trials with different complexity and risk</p>	<p>Intervention:</p> <p>The competition was established exclusively by the MacCAT-CR test (dichotomous result, "competent" or "not competent"). The variables studied in relation to the competition were:</p> <p>Determining, "causal" variables: Age, sex, IQ, experience with disease, socioeconomic status, and ethnicity.</p> <p>Contextual variables (complexity of the decision, risk of the decision, paternal judgment on the competence of the minor and decision to participate by the minor).</p> <p>Statistical method: logistic regression. Contextual variables were analyzed after creating the best model.</p>	<p>- Association of variables with competence: all variables except sex, and experience with the disease were positively associated with competition according to the MacCAT-CR test.</p> <p>- Contribution of the different variables to the competition: only the age explained 56.4% of the variance. Age and Intellectual Coefficients accounted for 69.1% of the variance. The remaining variables (including the contextual ones) explained the 5.4% of the variance.</p>	<p>Age and IQ are the main explanatory variables for the presence of juvenile competition, measured using the MacCAT-CR test. The experience of the disease is not, according to this study, an important variable that determines the competence. Although in isolation the parental assessment of the competition is associated with competition according to the MacCAT-CR test, this assessment hardly contributes to the overall model. The authors recognize a limitation of having combined studies of high, medium and low risk and complexity (which in any case are quite subjective variables).</p>	<p>This study quantifies the importance of different variables in the measurement of children's ability to consent to research: Age and IQ are the most important factors. Age can be generalized and influence future social or legal changes in relation to the autonomy of the child, but the IQ would require a much more personalized assessment.</p>	<p>Medium</p>

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
	competition judgments. Period of realization: not applicable		Follow-up period: N / Not Applicable Toll: N / Not Applicable				

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	QUALITY OF EVIDENCE
Short quotation: Hein 2015 b	Design: Publication of comments on the work of Hein 2014 Goals: Not listed Period of realization: not applicable	Number of participants / group: Not applicable Participating Features: Not applicable	Intervention: Not applicable Follow-up period: Not applicable Toll: Not applicable	They differentiate two concepts: "capacity in decision making" to refer to the different levels of skills of the patient, and "competence", to refer to the degree of ability that a patient has to be able to make autonomous decisions. They insist on the need for empirical data and comment on the results of the application of a tool (the MacCAT-CR) to 161 children. From the results, they theorize. This tool analyzes the 4 aspects that measure the decision-making capacity that reflect competence standards: - Understanding of information. - Reasoning in the decision-making process. - Perception of the effects of that participation in the patient. Expression of an election about participation. It is a semi-structured interview that seems complex. It is known from the outset that in this test the four components are usually parallel in children, and independent in adults. When applied to a group of children, they find that there are two limits, 11.2 to define a child as competent, and 9.6, to define it as incompetent (with a gray area in the middle). They also find that competition does not vary for different severity of the clinical decision. With this data they are considered if the method of IC by the adult and assent in the child is the best method (on the one hand it leaves behind a demonstrated competence, and on the other, they have doubts about if they have escaped some aspect important to condition the validity of that result, still for another, these ages collide with the legislation of most countries). Ethical	The authors analyze the results of their own previous publication (Hein 2014) using a tool (MacArthur Competence Assessment Tools for Clinical Research, MacCAT-CR) to see from what age children would be competent for informed consent in clinical research . In this article they marked two limits: 11.2 to define a child as competent, and 9.6, to define it as incompetent (with a gray area in the middle). From the definition of normative judgment of competence: a child would be considered competent or well In spite of this they propose a selective implementation of the IC based on case by case and not by age, and, secondly, a dual IC. Authors' recommendations: - They do not recommend a selection on a case-by-case basis, but rather spend the age limits that they find in their work to request ICs for children (ie, over 11.2 years, the competent entry child would be considered) Cultural differences must be taken into account. Already in another point of the article they say that the CI to minors varies a lot between countries, being the one of accepting of smaller age the own Holland (its country), with twelve years, whereas the USA or would have of the majority of legal age (18 years). They therefore propose a dual consent, assuming the risk of a discrepancy between parents and minor. This dual consent would have two parts, one for parents and one for the child. Unresolved issues: - Until what age should dual consent be given? 16.18 years? - Extending those capacities to other areas of the	Unclassifiable

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	QUALITY OF EVIDENCE
				<p>aspects: This instrument has a problem. It does not measure emotional competence. Another problem is the possible change of values in the child that could affect his consent. Legal aspects: What is considered before conflicts with legality, which sets ages for competition. It would then establish the debate as to whether competition should be analyzed on a case by case basis, or presupposed according to the child's age. In relation to the best interest of the child, the authors suggest that if the child is able to overcome the items in the questionnaire, then he can give IC, and this, in turn, means that he is acting in his best interest. Developmental Aspects: Unlike adults, who are considered competent unless proven otherwise, children are considered entry incompetent. According to their study, the specificity to identify competence in children aged 11.2 years and over was 90%. In relation to who sees the most competent child, whether parents or professionals, literature is discordant, although it seems to predominate the view that parents assign more competence to children than professionals (perhaps because parents see it from an integrated point of view in the family, while professionals see it more from an independent point of view). to manage the impulsivity and the lack of vision of long-term consequences typical of the adolescent? There is no response at this time. On the other hand, there is agreement to consider the parents necessary for the development of a possible participation of a minor in an investigation (from creating the right environment to solving logistical problems)</p>	<p>public's life of the minor, such as civil, criminal, etc. - Need for more studies of MacCAT-CR to minors. - Need for more neurofunctional studies.</p>	

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Hunter 2007	Design: Theoretical Goals: Personal comments on the possibility of using the Gillick competition in research Period of realization: ns	Number of participants / group: Ns Participating Features: Ns	Intervention: Ns Follow-up period: Ns Toll: Ns	The Gillick competence assumes the maturity and ability to give informed consent on the part of a child under 16 years if the attending physician appreciates that it can be considered competent. This situation would be relatively clear in clinical practice but its application in research would be more doubtful. The researcher may not have the necessary skills to estimate the competence of a minor, and may also have a personal interest in research, in this case, when recruiting. The authors suggest that the Gillick competition should not be applied in research, since there may not prevail neither the non-maleficence nor the beneficence, and therefore not seek the best interest of the child, although there is an apparent respect for their autonomy. On the other hand, if it were applied in the investigation, we would give more priority to the autonomy of the child when making the decision, than in a possible beneficence or non-maleficence. According to the authors, if the Gillick competition were applied, there would be a possible collision between respecting the hypothetical rights of the minor to participate in an investigation and the possibility of causing harm. In two situations the Gillick standard could be used in research: when the investigation offers likely benefits to the participants, with few risks. The second, more debatable situation would be when the requirement of parental consent could threaten very important investigations. In this case the competition Gillick competition should be verified by non-research subjects.	In principle it does not interest for the systematic review. But somewhere there will have to introduce the issue of what is "minimum risk" in juvenile research	Unclassifiable

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: John 2008	<p>Design:</p> <p>Observational study, on the opinion of parents and minors regarding blood extraction, in a previous research on a vaccine</p> <p>Goals:</p> <p>Establish the relevance of asking healthy children to make a decision about their participation in an investigation.</p> <p>Period of realization:</p> <p>02 / 2005-08 / 2005</p>	<p>Number of participants / group:</p> <p>73 children and their parents, from an initial sample of 300 children who were included in the vaccine study</p> <p>Participating Features:</p> <p>Healthy children who had participated in a study of a vaccine started three years earlier.</p>	<p>Intervention:</p> <p>Intervention done on the day of the visit for blood collection for serology. The children were asked if they knew what they were going to that day for the consultation. The children were informed about the study of vaccines and about what they were proposed: to make a blood extraction for serology), with risks, advantages and disadvantages. Verbal assent was granted. Previously the parents had signed a formal consent. After the blood was drawn, the children were given a questionnaire to establish understanding about the vaccine study. Parents were given a questionnaire about their opinion regarding children's understanding of the study.</p> <p>Follow-up period:</p> <p>Do not</p> <p>Toll:nN / Not Applicable</p>	<p>71% knew they were going to have a blood test. More than half did not know why they were going to do the analysis. After the explanation and extraction, a questionnaire was made: 33% still did not respond or that the analysis had been done, although 29% answered that it was to see protection against a disease. 65/73 understood that they could withdraw from the study. The questionnaire to the parents showed that the opinion of the minor should be respected although some had previously proposed a persuasion. 75% thought that the decision to participate was exclusive to the parents.</p>	<p>Most children aged 6-8 are not able to understand the factors surrounding a research study, with marked individual differences. Discusses practical aspects to assess dissent by the child, which they propose must always be respected. They believe that the information to the child should be through the parents.</p>	<p>Study with unclear objectives, confusing methodology and non-concrete results (especially opinions).</p>	Low

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
<p>Short quotation:</p> <p>Koelch 2009</p>	<p>Design:</p> <p>A feasibility article on the use of MacCAT-CR in children with ADHD or ADHD plus challenging disorder who were asked to participate in a clinical trial or open study to study the understanding of such investigations.</p> <p>Goals:</p> <p>Explore the feasibility of providing research information for informed consent and how it is understood by children and parents</p> <p>Period of realization:</p> <p>Not applicable</p>	<p>Number of participants / group:</p> <p>N / Not Applicable</p> <p>Participating Features:</p> <p>19 minors from the two studies were selected (does not say selection criteria</p>	<p>Intervention:</p> <p>The MacCAT-CR test was used in minors and in parents separately. The children were also measured the IQ. Parental socioeconomic status was collected. Interviews to make the MacCAT -CR were recorded and then analyzed by two psychologists. A qualitative content analysis of these interviews was done, and an assessment of the parts of the MacCAT-CR.</p> <p>Follow-up period:</p> <p>Do not</p> <p>Toll:</p> <p>N / Not Applicable</p>	<p>-Comprehension: The issues related to the development of the study and the advantages, disadvantages and risks of the study were well understood. The primary purpose of an investigation was not well understood (it was thought to be the child's personal benefit). The concepts of placebo and randomization were not well understood. The concept of voluntary retreat without consequences was well understood.</p> <p>- Appreciation: Minors misunderstand what they have been proposed for in the study. Most thought it was to see if the medication could help them. They also thought they were not going to get a placebo.</p> <p>- Reasoning (reasons to accept or refuse to participate). Reasons to accept: hope for improvement, comfort (in the long-acting methylphenidate study), desire for exploratory behavior (try a new drug). Reasons for rejection: invasive procedures in the study, changes in the therapeutic group, and time expenditure.</p>	<p>The more abstract themes (primary objective of a clinical trial, randomization, and the nature of placebo) are misunderstood (often also by parents).</p>	<p>Exploratory and narrative study based on interviews</p>	<p>Low</p>

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	QUALITY OF EVIDENCE
Short quotation: Koelch 2010	<p>Design:</p> <p>Observational, pilot study to see the utility of the MacCAT test for the understanding of informed consent in a sample of 12 children with ADHD and oppositional defiant disorder (DSM-IV) and in their parents.</p> <p>Goals:</p> <ul style="list-style-type: none"> - To study the usefulness of MacCAT-CR in a population of children with ADHD plus oppositional defiant disorder to determine their ability to consent to participate in a clinical trial (atomoxetine vs placebo trial) - To compare possible differences in competence using the MacCAT test -CR between patients and parents. <p>Period of realization:</p> <p>Not known</p>	<p>Number of participants / group:</p> <p>12 minors, and 12 progenitors</p> <p>Participating Features:</p> <p>Children diagnosed with ADHD and oppositional defiant disorder according to DSM-IV criteria</p>	<p>Intervention:</p> <ol style="list-style-type: none"> 1.- Written information about the clinical trial provided 24 hours before the intervention. 2.- Clinical evaluation of an investigator on the competence of minors and parents for consent. 3.- Administration of the MacCAT-CR test separately to minors and parents. The interviews were recorded. Different professionals did the interview and valued the recordings to rate them. The score of the recordings were made by two independent psychologists, separately in the 4 areas according to the following score: - Understand information about the research project (5 subareas, each scored from 0 to 2) - Reason about potential risks and benefits of the choice made (3 subareas, each scored from 0 to 2) - Appreciate the nature of the election as well as the consequences of the election (3 subareas, each scored from 0 to 2). - Express a choice (1 subarea, scored 0 to 2). 4.- The agreement between professionals who made the scores was determined by intraclass correlations. 5- Other determinations: CI to the minors and 	<ul style="list-style-type: none"> - Clinical evaluation of the competition: all the minors and the parents were valued as competent. -Valoración of the test of MacCAT-CR: - Concorporation between professionals: excellent for the recordings of the minors (0.94-0.95), acceptable for those of the parents (0.7-0.83). - MacCAT-CR test scores for each of the sub-groups (minors vs. parents): Comprehension: 5.86 vs. 9.08 (for a maximum score of 10). Appreciation: 2.64 vs 4.96 (for a maximum score of 6). Reasoning 3.05 vs 4.63 (for a maximum score of 6). Expression of an election 1.77 vs 1.88 (for a maximum score of 2). Minors scored lower than parents. - Correlation with IQ: no 	<p>Pilot study given the small number of patients. Little agreement between a clinical assessment and the test result among the minors.</p> <p>Parents have better understanding than minors.</p>	Medium

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	QUALITY OF EVIDENCE
			<p>socioeconomic status of the parents.</p> <p>Follow-up period:</p> <p>Do not</p> <p>Toll:</p> <p>N / Not Applicable</p>	<p>correlation. There was better understanding in parents than in minors. Some items were especially difficult: purpose of the study, nature of the placebo, possible lack of benefit for the patient.</p>		

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
<p>Short quotation:</p> <p>Kupunen 2012</p>	<p>Design:</p> <p>Observational study evaluating two tools to obtain the assent of children in a study on food problems in children receiving chemo (Food Study). Design of the storyboard and the soup of letters: Graphic storyboard (for children 4 to 6 years): Children fill with drawings (stickers?) the gaps of a graphic story related to the project. Letter soup: a soup of letters with terms like "study", "participation", etc., and after discovering them, and making it clear that it is a game, you are invited to participate in what the game says, a study research. If they agreed to participate, a signal of withdrawal (verbal or non-verbal) was agreed.</p> <p>Goals:</p> <p>Analyze child-centered techniques to see usefulness in the process of assenting in research.</p> <p>Period of realization:</p> <p>Not known</p>	<p>Number of participants / group:</p> <p>14 children from 29 families who were participating in the Food Study.</p> <p>Participating Features:</p> <p>Do not</p>	<p>Intervention:</p> <p>Each child was offered one of two methods: 6 chose the soup of letters, 6, the graphic history, and 2, 10 and 12 years, a direct discussion. Evaluation by means of a thematic analysis of the field notes taken during the process, and analyzed by two independent researchers</p> <p>Follow-up period:</p> <p>Do not</p> <p>Toll:</p> <p>N / Not Applicable</p>	<p>Five topics were discussed:</p> <p>1.- Introduce the assent as a game.</p> <p>2.- Adopt a style of communication that will empower the child.</p> <p>3.- Avoid distractions during the process, especially clinical interruptions.</p> <p>4.- Take advantage of moments of concentration of the child.</p> <p>5.- Ensure voluntary.</p>	<p>The use of study-centered techniques allows for a process of assent in young children (up to 5 years old).</p>	<p>Description of child-centered methods that allow for their empowerment when applying for assent.</p>	<p>Low</p>

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Lally 2014	<p>Design:</p> <p>An experimental study in which a double message information technique (the message starts with frequent error information, along with the correct answer) improves the understanding of the concepts of placebo and randomization of an informed consent for a hypothetical study of HIV vaccine in adolescents. Three branches: basic IC information, an explanatory brochure with simple messages (presentation of factual facts associated with participation in the clinical trial), and an explanatory brochure with double messages (presentation of an erroneous concept refuted with factual information).</p> <p>Goals:</p> <p>Evaluate supplemental educational brochures designed to increase awareness in a clinical trial of an HIV vaccine through a persuasive message, focusing on those aspects that may be central to preventive misinterpretation. Investigate the possible association between understanding specific aspects of that clinical trial (randomization, untested efficacy, and interpretation of adverse effects) with impulsivity, health knowledge, and knowledge. basic math .</p>	<p>Number of participants / group:</p> <p>120 16-19 year olds from 4 sites participating in the ATN project.</p> <p>Participating Features:</p> <p>120 16-19 year olds from 4 sites participating in the ATN project. Inclusion criteria. Sexually active with men, and desire to participate in a clinical trial of these characteristics</p>	<p>Intervention:</p> <p>After signing the IC for this study they were given a questionnaire (IAQ part 1) (Interviewer Administered Questionnaire). The IAQ is a questionnaire that measures reading and math skills, impulsiveness, interest, and demographics. After completing this test they were all passed on to the pretended CI for a clinical trial on HIV vaccine. After him, he was randomized into three groups. The first, without supplementary information. The second, with a booklet with simple messages, and the third, with a booklet with double messages. Later they filled out the IAQ Part 2 with 10 questions that had to be answered with Likert responses (5 responses, from totally agree to totally disagree). There were also three questions about the desire to participate.</p> <p>Follow-up period:</p> <p>N / Not Applicable</p>	<p>Better understanding of the aspects of randomization and side effects by means of an ANOVA test between the group with supplementary information of double messages and the control group (only CI), but no less understanding in the aspect referred to the unproven efficacy. Regarding the second objective, it was found that there was better understanding with better literacy.</p>	<p>There is a better understanding with the use of a double message booklet. The use of explanatory booklets with double messages does not compromise the desire to participate (whereas the use of a brochure with simple messages diminished the desire to participate)</p>	<p>The methodology (double message explanatory booklet) is interested in improving understanding</p>	Medium

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
	Period of realization: Not known		Toll: N / Not Applicable				

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Murphy 2007	<p>Design:</p> <p>A randomized, open trial to study the understanding of two models of informed consent for a hypothetical HIV vaccine in adolescents</p> <p>Goals:</p> <p>-Develop a simplified model, with images, friendly to adolescents, of an IC model already tested in HIV vaccine studies (prototype HIVNET) .- Test this simplified model in groups of adolescents at risk.- Conduct a clinical trial among adolescents at risk of HIV to compare this simplified model with the standard, and see their degree of immediate understanding.</p> <p>Period of realization:</p> <p>November 2003-May 2004</p>	<p>Number of participants / group:</p> <p>263 subjects recruited. 187 completed the study (94 with standard IC and 93 with simplified).</p> <p>Characteristics of the participants:</p> <p>Origin, gender, race, sexual orientation</p>	<p>Intervention experimental group:</p> <p>Random assignment to standard or simplified format. Out loud reading. Video recording. After reading the ICs, the following tests were passed:</p> <ul style="list-style-type: none"> - understanding. 19 questions with multiple answers (3 answers) (provides definitions of questions). - memory of questions. 3 open questions about benefits, risks and experience of the visit - of willingness to participate: a question, if you did the study tomorrow, would you participate? - on HIV- cognitive measures, through two intelligence tests (K-BIT and WJ-R). <p>Control group intervention:</p> <p>the same</p> <p>Follow-up period:</p> <p>N / Not Applicable</p> <p>Post-randomization losses: Do not</p>	<p>Magnitude of the effect (+ confidence intervals / p value):</p> <p>The comprehension score (19 questions) was better in the group with the simplified CI format than with the standard (median scores of 16 and 14, with maximum possible of 19; $p = 0.0005$). In a multivariate model the variables associated with a better understanding were the C Intelligence, the type of IC and the place of the study.</p> <p>Adverse effects:</p> <p>N / Not Applicable</p>	<p>The improvement of the simplified CI does not know if it is by the addition of illustrations, by the simplified text, or by both.</p>	<p>Given the characteristics of the study, the items best and worst understood are the peculiar ones of the study, and the important thing is the improvement of the global understanding by simplifying and illustrating the IC model</p>	Medium

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Nelson 2016	<p>Design: Observational study with intervention</p> <p>Goals: Adapt the MacCat-CR test to adolescents. To verify with that test the capacity for consent for research in healthy adolescents. Examine developmental variables that influence the ability to consent to research.</p> <p>Period of realization: Not known</p>	<p>Number of participants / group: 30 adolescents 14-21 years old coming from adolescent clinics and community centers.</p> <p>Participating Features: Do not</p>	<p>Intervention:</p> <ul style="list-style-type: none"> - Collection of demographic data. - Realization of the REALM (Rapid Estimate of Adult Literacy in Medicine) test. - Reading of three models of informed consent for three hypothetical studies. - Performing the MacCAT-CR test (performed during the IC process, not after the IC process, as in adults): 23 questions that are evaluated according to the level of correction in the response, in 0.1, or 2. - Classification through FAS II (Family Affluence Scale) of the socioeconomic level. <p>Follow-up period: N / Not Applicable</p> <p>Toll: N / Not Applicable</p>	<p>30 adolescents (24 women and 6 men) between 14 and 21 years. Acceptable ability of the whole group (even the youngest had a capacity similar to that of adults). They found association of age, literacy and socioeconomic status in the three subsections of MacCAT-CR (understanding, appreciation, and reasoning). Aspects with worse understanding: that a clinical trial, in addition to effectiveness measures safety, and how to withdraw of a study.</p>	<p>The MacCAT-CR test, as adapted, is useful for measuring ability in adolescents, and is able to discriminate variables that influence their outcome such as age, literacy, and socioeconomic status.</p>	<p>Pilot study of the applicability of the MacCAT-CR test to healthy adolescents</p>	<p>Medium</p>

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Ott 2016	<p>Design:</p> <p>Observational study with intervention.</p> <p>Goals:</p> <p>To study the understanding of an IC against a hypothetical HIV vaccine, focusing on one aspect, the interpretive bias of IC that the adolescent can do, thinking that there is more probability of falling into the experimental branch, that this will be more effective, and that in this way unsafe sex will not be so risky.</p> <p>Period of realization:</p> <p>Not applicable</p>	<p>Number of participants / group:</p> <p>33 participants aged 16-19</p> <p>Participating Features:</p> <p>Adolescents of both sexes of 16-19 years, HIV negative and with sexual activity with men, and with desire to participate. Recruitment in clinics, youth agencies and youth programs.</p>	<p>Intervention:</p> <p>Assent of the minor without paternal consent. After reading an IC for a hypothetical HIV vaccine and a supplemental material on what is a clinical trial, and after participating in a questionnaire accepting that hypothetical investigation, a qualitative individual semi-structured interview was conducted for 30-60 minutes. Interviews recorded. Analysis of the interviews through a method based on grounded theory.</p> <p>Follow-up period:</p> <p>N / Not Applicable</p> <p>Toll:</p> <p>N / Not Applicable</p>	<p>5 essential aspects to be analyzed in a clinical trial on vaccines:</p> <ul style="list-style-type: none"> - Understanding how vaccines work. Incomplete understanding that a vaccine is preventive, non-curative, and not 100% effective. - Understanding what an experiment is. It was generally understood, in the sense that it was verbalized that the vaccine might not be effective. - Understanding what a placebo is. Overall, it was well understood, although one participant confused placebo with a placebo effect. Doubts as to the logic of using placebo. - Understanding what is randomization. Incomplete comprehension (only acceptable in 22 out of 33). In general, they included their own luck in the randomization process. - Understanding the need to maintain safe sex. In general, good understanding. 	<p>Adolescents were active in the IC information process. Interviews facilitated this understanding, clarifying concepts and providing feedback. The theoretical risk of unprotected sex bias from feeling the adolescent protected by the study process was not met in interviews. The authors acknowledge that a study of this type is difficult to generalize.</p>	<p>Low quality for poor reproducibility.</p>	<p>Low</p>

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Lee, 2013	<p>Design: Experimental, analytical study of intervention.</p> <p>Goals: - Evaluate the understanding of a simplified IC document, with a questionnaire of 6 questions V / F (available in English and Spanish), in possible participants of a clinical trial with Hepatitis B vaccines. - Evaluate the educational intervention of the researcher, on the improvement of the understanding of the information.</p> <p>Period of realization: It is not explicit</p>	<p>Number of participants / group: n = 123 young people aged 12-17 years</p> <p>Participating Features: Age</p>	<p>Intervention: An IC document was improved and simplified. This modification was reviewed and approved by a panel of ethical experts (Office of Human Research Protection), in order not to lose content. Readability: 6th grade + plain language + graphics that supported the key aspects. Available in English and Spanish. Translators were available if needed. All participants then read the simplified document with an investigator and filled out the Assent Form Comprehension Questionnaire (6 V / F questions). A researcher clarified areas not understood. Finally they signed the document</p> <p>Follow-up period: Do not</p> <p>Toll: Ns</p>	<p>Mean age 15.12 years, with range [12-17]. Male 62.6%, Hispanic 69.9%. 56% correctly answered the 6 questions, and 22% correctly answered 5 questions. 26% mistakenly believe that they will be given the vaccine they will receive (Q4), 21% mistakenly believe they are guaranteed participation in future studies (Q3) and 15% believe they will receive free medical care through the study. Questions about randomization (Q2) and study withdrawal (Q6) were comprised of at least 89%. The variables of age, sex, race, weight, sexual identity, sexual history, smoking, alcohol, marijuana, place of residence do not significantly influence comprehension. Only participants from Baltimore, Maryland, obtained better scores ($p = 0.0029$)</p>	<p>An important step in ensuring full understanding of the study is the evaluation of understanding through a questionnaire. The understanding of the information with a modified document is similar in all ages analyzed. The total understanding, of all the sections of information, barely exceeds 50%. Concepts such as randomization and right to revoke, are the best understood. Educational feedback in aspects not understood improves the understanding of information.</p> <p>LIMITATION: The educational level is not analyzed</p>	<p>It evaluates the understanding of a modified document in text format with supporting images, CI for adolescents [12-17 years] with an ad hoc questionnaire with 6 V / F questions.</p>	High

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Larcher, 2010	<p>Design: Descriptive, Review of the literature</p> <p>Goals: - Consider the ethical and legal nature of the competence to receive medical treatment - Provide practical guidance on how and by whom it should be evaluated - To determine the circumstances in which the assistance of a specialist is necessary</p> <p>Period of realization: N / Not applicable</p>	<p>Number of participants / group: 3 groups: over 18 years old, under 16 - 18 years old and under 16 years old</p> <p>Participating Features: Only specify age groups.</p>	Intervention: There is no intervention in this article	<p>NATURE COMPETITION: depends on the ability to understand nature, purpose and consequences and ability to decide. Competition is task-specific, impact on the child's future. It must be free of physical and mental influences. The capacity for autonomy is a continuous variable, but the competition is dichotomous (yes / no). The level of competence required for certain tasks is unknown, depending on the risk involved.</p> <p>TEST TO MEASURE COMPETITION: There is no single test, but it implies: the possibility of choosing that implies the ability to understand; the reasonable outcome of the election by making a decision that is considered correct and responsible; choice based on rational reasons, compatible with a life plan; ability to understand the need for treatment and its reasons, risks, expected benefits and alternatives, including non-treatment. It must also be able to retain information long enough; understanding, and not potential, and evaluate it</p> <p>HOW TO DEVELOP COMPETITION: Competence can be improved by sharing information that increases understanding of current treatment, its alternatives and the potential consequences of all options. Emotional</p>	<p>Although required by law, there is no single test to evaluate competition.</p> <p>It is necessary to evaluate competencies within the dynamics of working with children and families.</p> <p>Relationships based on trust, mutual respect and exchange of information should be encouraged.</p> <p>By adopting this approach, the need to dichotomize competition may be reduced.</p>	<p>Competence is related to COGNITIVE CAPACITY and EXPERIENCE and can be improved with education, incentives ...</p> <p>The participation of a psychologist or other third party should be considered in cases that pose serious difficulties in assessing competence or conflicts in complex decisions. Potential evaluators should have the necessary practical skills and understanding of the child in their social and medical situation. Assessments should be appropriate developmental, explore systemic influences and consider the child's emotional state, cognitive development, and ability to balance risks and benefits. The involvement of a psychologist or other independent third party should be considered in cases that raise serious concerns about competition, or involve complex decisions or conflicts between parties. In rare cases the courts may be involved.</p> <p>Proposal of questions to be answered: <i>Necessary information questions to be answered?</i> <i>What is the illness/condition and what are its effects?</i> <i>What treatments/investigations are necessary and why?</i></p>	Medium

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				<p>maturation includes developing the ability to consider the consequences of actions both for and for others. The children's personal experiences and their responses to it can provide them with a greater understanding than children of comparable age who lack such experience.</p> <p>COMPETITION EVALUATION: Physicians have legal responsibility, but other members of the multidisciplinary team may be able to do so. The assessment of competence must be individualized to a given context, although the ability to understand and evaluate risks is essential. Get relevant information about the child and his / her illness in advance. Allow enough time to decide. Check the level of development of the child to adapt the information. Explore external influences and emotional state that may compromise the child's ability. Evaluate cognitive development and its ability to assess risks and benefits.</p> <p>WHEN INVOLVING A PSYCHOLOGIST: In some teams, it is usual for the psychologist to evaluate competence with all the factors described above. At other times, it only participates when there is a conflict of decisions.</p>		<p><i>When does this need to be done?</i></p> <p><i>What does the treatment mean to me, and how will it affect my life?</i></p> <p><i>What happens if I do not have the treatment?</i></p> <p><i>What are the alternatives and their effects?</i></p> <p><i>What are the practical consequences for me and my family on school and friends?</i></p>	

REFERENCE	STUDY	POPULATION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Leibson, 2015	<p>Design: Bibliographical review of the literature</p> <p>Goals: This review addresses the historical, ethical, and legal aspects of IC for pediatric drug research.</p> <p>Period of realization: Ns</p>	<p>Number of participants / group: Bibliographic review NON-SYSTEMATIC</p>	<ul style="list-style-type: none"> - The authors (Lee, Ondrusek, Hein) suggest that in children between [9.4-11.2 years], IC can be justified if their competence is demonstrated. Under 9 years suggest that they are not competent. - Other authors suggest that there are no clear indications as to the age at which the child is able to nod. - Hein proposes the use of the MacArthur-CR to evaluate the capacity. - The essential components of IC in pediatric research are: freedom of choice, non-coercion with rewards, complete and understandable information (including drug, risks and potential benefits if any, procedures), in plain language - Information in writing - The amount of information must be decided for each protocol. Amount of reasonable information the patient wants to know - In a suitable format: multimedia, in group to favor interaction - Confidentiality. If this is not possible, please inform - Assent or agreement expressed by the minor and right to revoke at any time, of children who understand the purpose, risks and benefits. - The concept of "mature child" is not used in research as the interventions do not in many cases offer a direct benefit to the child. Instead in treatment yes. 	<p>The ethical peculiarity in pediatric research is what concerns the IC process. Changes in the lifestyle of adolescents necessitate the evolution in the consideration of the maturity of the children</p>	<p>It is a bibliographical review that addresses the evaluation of the CAPACITY of the child linked to age, understanding and reasoning.</p> <p>Provides guidelines on the essential components of IC in pediatric research</p>	Low

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Massimo, 2009	<p>Design: Monocentric study, transversal and descriptive survey project</p> <p>Objectives: To evaluate the degree of awareness of sick youngsters between 11 and 18 years of age with regards to the experimental trial they are undergoingTo estimate the proportion of patients with an acceptable level of awareness</p> <p>period of realization: 18 months</p>	<p>Number of participants / group: The minimum number of patients to be interviewed in this type of study will be 120, according to Machin and Campbell</p> <p>Participating features: No</p>	<p>Intervention: Semi- structured interview with 11 simple items. The form includes 2 sections: the first one is private and is reserved for the Hospital staff. It collects the patient´s personal information; and the second section includes 11 items for the patient´s awareness evaluation, which is given by a trained pediatrician. One single encounter which will last approximately one hour. It will take place no sooner than one month from the start of the protocol and no later than one year after.</p> <p>Follow-up period: 18 months</p> <p>Number of losses: N/Not applicable</p>	It´s a project. There is not results	There are not conclusionsThe model suggested implicitly demands that proper and factual information must be given to children and adolescents via simple dialog with the interviewer. It is the authors wish that this interaction, for all practical purposes, will become a routine part of hospital life, and that it will lead to an improvement in the patients and families quality of life	It is a project. The purpose is interesting, but it need to be evaluated.	Low

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Miller, 2014	<p>Design: Observational, descriptive and qualitative with recording of CI interviews. The ICC audio tapes were transcribed, anonymised, verified and loaded in NVivo 8 for encoding and analysis In addition, he included interviews with a group of 18 patients aged 14 - 21 a.</p> <p>Goals: -Describe the participation of children and adolescents by measuring physician-patient and parent-patient communication during the IC conference -Try if participation in IC discussions</p>	<p>Number of participants / group: n = 61</p> <p>Participating Features: Age, sex, type of cancer, years since diagnosis, duration of communication, role of physician, EC phase I</p>	<p>Intervention: Consent conferences were recorded, transcribed and coded for communication between patient - physician and patient - parent. CI in writing, in children aged 18 - 21a. Verbal or written assent, in children from 7 - 17a. Patients aged 14 to 21 years were interviewed to evaluate additional variables related to the decision</p> <p>Follow-up period: June 2008 - June 2011</p> <p>Toll: 3</p>	<p>- In the word count, it was observed that in 2 cases there was no doctor-patient communication, in 3 cases there was no parent-patient communication and in 10 cases there was no patient-parent communication.</p> <p>- The average proportion of communication from the doctor to the patient was 36%, from the father to the patient, from 1.76% and from the patient to the father it was 0.57%</p> <p>- 73.28% of the doctor's communication was to give information, 8.73% was to ask and verify, 7.34% socioemotional, 5.74% to establish the agreement and 4.8% was personal.</p> <p>Regarding the participation of the patient; was involved speaking in 43% of the communication, and gave</p>	<p>The majority of physician-patient communication consisted of providing information.</p> <p>The creation of a climate of trust and a social-emotional exchange, increases the satisfaction in the decision making.</p> <p>The difficulty to understand and the perceived pressure to participate were generally low in the subsample of patients aged 14-21 years. However, when physicians increase communication with their patients, they perceive that the information is easier to understand.</p> <p>It is possible that direct communication with patients is an indicator of other aspects of communication and may be related to the results of participation.</p> <p>The mean proportion of patient-to-physician communication was low.</p> <p>In 10% of cases, the patient was asked to sign the IC form without asking for an</p>	<p>Direct communication and creating a climate of trust between the physician and the child in the decision-making process of a Phase I clinical trial is very important in order to obtain a truly informed consent. It is not only important to give information, but also to talk about many other socio-emotional and personal aspects (emotional state, feelings, doubts, suggestions)</p>	Medium

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
	<p>increased with the patient's age</p> <p>- Examine whether participation was associated with patients' perceptions of the difficulty of understanding the information, the pressure to participate in the Phase I trial, and the difficulty in making the decision.</p> <p>Period of realization: 06/2008 - 06/2011</p>			<p>an opinion in 67% of the cases. In 10% of the cases, an opinion was not asked for, but he was asked to sign the IC. Regarding the age; the physician's communication was positively associated with the patient in the range of 18-21a, but communication from patient to physician was similar at all ages. Regarding the interview with the group of 14-21 a (n = 18); when physician-patient communication increased, patients perceived the information to be easier to understand. In the patient-physician communication, the difficulty of understanding, the perceived pressure or the difficulty of decision making did not influence.</p>	opinion about the trial or treatment.		

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Miller, 2013	<p>Design: Analytical, observational study</p> <p>Goals: - To examine the perspectives of adolescent patients about understanding and making decisions about a pediatric phase I cancer study.</p> <p>Period of realization: Jun 2008 - Jun 2011</p>	<p>Number of participants / group: n = 20</p> <p>Participating Features: Age [14-21a], Cancer, candidates for an EECC phase I, with sufficient cognitive capacity to be able to understand the information</p>	<p>Intervention: - Comprehensive interview focusing on four areas related to decision making on Phase I research: 1) understanding 2) the decision-making process, including the role of the adolescent, the impact of faith on decision and perceived pressure, 3) expectations regarding the effect of participation in the essay on the quality and duration of life 4) reasons to accept or reject the Phase I study. Participants answered closed questions about a verbally administered structured interview, which evaluated aspects of understanding and decision making about the Phase I study.</p>	<p>- 7 participants from [14-17a], and 13 participants from [18-21a]. - 75% were boys, mostly Caucasian (80%), with bone or soft tissue cancer (55%) followed by brain or CNS cancer (35%). - The mean number of years from diagnosis to participation in a phase I trial was 3 years on average. - UNDERSTANDING: After the IC lectures, 90% understood that it was not necessary to participate in the trial to be attended in the hospital, 90% understood that they could be withdrawn at any time and that the trial involved risks. 30% indicated that the trial would provide medical benefits, and 50% said "I do not know". - LEGIBILITY: The information provided was considered easy to understand (mean = 1.95 on a scale of [0 / very easy - 10 / very confusing]) - DECISIONS: 85% had the final word on the final decision to participate, considering that they are the most influential people on the decision (50%) and their parents (35%). Participants rated the opportunity to ask questions to the "high" doctor (M = 8.95 on a scale of [0 / not much-10 / lot].) Faith was important to the decision in 50%. (M = 2 on a scale [0 / without pressure - 10 / a lot of pressure].) The expected effect of their participation was investigated with questions 50% expected an improvement in their quality of life, and 80% expected them to last longer. The reasons that led them to participate were 75% of the cases, a</p>	<p>Section of conclusions very general. He speaks that the knowledge gained will help guide physicians and researchers to improve the IC process in Phase I and can be applied more widely to other potentially vulnerable subjects.</p>	<p>The investigation is limited to [14-21a], children with cancer participating in a phase I trial. Understanding the information is quite good, although under the benefits section there is a big misconception in the adolescents' belief of a benefit direct improvement in their quality of life and life span. The decision-making process seems easy enough, and most do not feel pressured</p>	Medium

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			<p>Follow-up period: jun 2008 - jun 2011</p> <p>Toll: Ns</p>	<p>potential positive clinical effect, including cure or 45% said because there was no other treatment option, 20% said to contribute to science or to help others.</p>			

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Monaghan, 2009	<p>Design: Descriptive, transverse.</p> <p>Goals: - Establish a more robust approach to obtaining the consent of 12- and 14-year-olds participating in surveys based on existing practice of "negative consent" and completing it with competent Gillick</p> <p>Period of realization: 2002-03 and 2004-05</p>	<p>Number of participants / group: Group 14 years (2002-03), n = 6393.</p> <p>Group 12 years (2004-05), n = 6749</p> <p>Participating Features: By age, yes. There are no more sociodemographic variables analyzed.</p>	<p>Intervention: 1st CI is requested to the parents by postal mail. 2° an intervention is made explaining to the children who are going to participate on the nature and purpose of the exploration. Doubts are resolved. 3° is carried out the exploration. 4th is an interview with 4 questions about his experience. Three questions with an answer YES / NO about understanding what the dentist would do, why he would explore his teeth and if he was treated well, and a fourth with an open answer about why he thinks he was not treated well.</p> <p>Follow-up period: 2002-03 and 2004-05</p> <p>Toll: 5 losses in the group of 14 years, and 17 losses in the group of 12 years</p>	<p>-The 10% of 12 years and 9% of 14 years, did not understand what the dentist would do (nature of the scan). -The 13.8% of 12 years, and 11.7% of 14a, did not understand the reason of the exploration (purpose of the exploration). -The 99.9% of both ages were satisfied with the way they had been treated. Those who were not satisfied indicated the reasons. - From the bivariate analysis, it is observed in children of 12a that only 83% understand the nature and the objective, and in the group of 14 a, 86%</p>	<p>- The use of the "competent Gillick" concept in Wales did not affect participation rates negatively. - There is still uncertainty about how dentists should assess the competence of children - Legislation presumes non-competition, and lets the dentist judge the competition - If only children who understood the nature and purpose of what was proposed were included, 15% could not have participated despite the opportunity to ask questions - The exchange of information, the explanation, the opportunity to ask questions as a basis for assessing the capacity</p>	<p>In Wales and England non-competent children are considered. An adult is considered competent in England and Wales if he is able to understand relevant information, withhold such information, weigh up such information to make the decision and communicate the decision. The law recognizes that the level of competence necessary to make a decision without risk is lower than that required in a more complex situation with different alternatives. It does not refer to research.</p>	Medium

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: O'Lonergan, 2011	<p>Design: A first descriptive study (survey) and a second analytical, experimental, randomized trial of understanding between traditional paper format, and the new multimedia format for two hypothetical research studies on dualenergy radiograph absorptiometry (DXA) and abdominal ultrasound.</p> <p>The general hypothesis was that children and their parents exposed to a multimedia permission / assent (P / A) process would have better understanding compared to those exposed to a traditional paper-based process.</p> <p>Goals: - Develop audiovisual descriptions of procedures and research rights for incorporation into a</p>	<p>Number of participants / group: A total of 194 pairs of child-parents (children 11 to 14 years): 24 pairs of child-parents in a pre-study on components of preference by survey and the effect on comprehension and 170 pairs of children-parents (340 participants) in a randomized trial in multimedia or paper for the assent in a hypothetical study</p> <p>Participating Features: Group surveys: age, marital status, employment, educational level, race, ethnicity and any medical diagnosis of the child.</p>	<p>Intervention: GROUP SURVEYS: 9 questions on the preference of the format (video, text, animated) and 10 comprehension questions (5 for each DXA / ultrasound procedure) on risks were analyzed, if the child has to wear hospital pajamas, how is the procedure and the part of the body to explore.</p> <p>RANDOMIZED CONTROLLED TRIAL GROUP: with the results of the first group, documents were designed in text and multimedia format with explanatory hyperlinks (3 hyperlinks on assent, which is an essay and right to revoke and 2 others with videos about the procedure and risks), for the hypothetical participation in a research study. The text with short sentences and appropriate to the age.</p> <p>We then analyzed the cognitive function of children with 2-subset Wechsler Abbreviated Scale of Intelligence and the parents a demographic questionnaire.</p>	<p>SURVEYING GROUP: Most of the study subjects prefer the video version of the DXA on the animated version and the paper (41 of 48 [85%]; $P < .0001$), and there were similar results for the description of abdominal ultrasound 38 of 47 [81%], $P < 0.0001$. There was no difference in the comprehension of children with the 3 versions, but the group of parental media had significantly improved overall comprehension ($P < .03$) compared to paper format.</p> <p>RANDOMIZED TESTING GROUP: children were within the range of normal intelligence for their age. Children exposed to the new multimedia format showed a better overall comprehension compared to the paper format ($P < .0009$), and</p>	Multimedia approaches to the decision-making process or assent can improve the general understanding of research involvement for children and parents. Better understanding of the specific components of the study can improve general understanding.	This article considers children > 7 years old, able to lend their assent. The hypothetical research study involves low-risk procedures, and the risks were not well understood. The use of a multimedia format (video, computer with explanatory hyperlinks in voice-over) improves the general understanding of information in children and parents in the process of assent.	High

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	<p>process of assent and then determine if the incorporation of these media improved the understanding of parents and children.</p> <p>- Compare the understanding between a multimedia permission / assent and a traditional process with text.</p> <p>Period of realization: Ns</p>		<p>With EVA [0 / I did not understand anything - 10 / I understood everything] analyzed how much they understood. In addition, questions were asked about the 8 essential elements of the consent process (objective, procedure, risk, direct benefit, indirect benefit, alternatives), and post-consent comprehension interview (PPCI) , right to revoke, voluntariness] that were recorded, transcribed and codified [0 / non-comprehension, 5 / correct but incomplete, 10 / correct and complete]</p> <p>Follow-up period: Do not</p> <p>Toll: Ns</p>	<p>there were very significant differences in the understanding of study procedures ($P < .0002$) and risks ($P < .0001$). The risks were not very well understood by the children, nor by the parents, but in all was better the score with the multimedia format.</p> <p>All children and parents overestimated their understanding.</p>			

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Poston, 2016	<p>Design: Descriptive, longitudinal of mixed methods. A QUANTITATIVE approach with the use of the Quality of Informed Consent Questionnaire (QuIC) with an adolescent population and their parents / guardians, and a QUALITATIVE approach with qualitative semistructured interviews with adolescents, their parents and physicians in the 48-72 hours of IC and consent for a clinical trial of pediatric oncology, and retention analysis of information 6-9 weeks after the initial IC.</p> <p>Goals: -Describe informed consent and consent experience in cancer research from the perspective of the participants: adolescents, their parents and their</p>	<p>Number of participants / group: 4 adolescents, 4 parents and 3 physicians</p> <p>Participating Features: ADOLESCENTS: 3 boys and 1 girl, African American, 12-18 years old, with myeloid leukemia (1), hodking lymphoma (1) and sarcoma (2). No previous research experience. Included in a phase III clinical trial of oncology.</p> <p>PARENTS: 4 African American women, 35-54 years old. Only one of them had previous experience with a research study.</p> <p>DOCTORS: 2 men</p>	<p>Intervention: 1^o Adolescents and their parents or guardians will participate in separate programs or qualitative interviews recorded in audio that last approximately one hour. Adolescents and their parents / guardians were asked to provide a description of their IC process and their subjective experiences. Seven key issues were analyzed; altruism, pressure, fear and lack of control, communication with the investigator, time and haste, protocol and memory.</p> <p>2 The subjects completed demographic data and the questionnaire (QuIC). The researcher completed the diagnosis of adolescent participants. 8 domains relevant to ICQ quality measurement with QuIC: Part A measures objective comprehension [1 / disagreement, 2 / unsafe, 3 / agree] and part B</p>	<p>QUANTITATIVE ANALYSIS COMPREHENSION (QUIC): in a scale of 0 to 100, where 100 is the maximum comprehension, TEENS obtained in part A (objective comprehension) obtained scores between 53 - 72, with a mean of 64.25. In part B (subjective comprehension) the scores were higher, between 60 - 89 with an average value of 79.25. In both parts, the scores were better in the female sex. The PARENTS obtained in the part A, lower scores between 47 - 70 with an average of 59, and in the part B higher between 86 - 100, with an average value of 93. This indicates a low level of objective comprehension of the essential elements of IC and assent, and a high subjective level of understanding.</p> <p>QUALITATIVE ANALYSIS (INTERVIEWS): ALTRUISMO, parents and children want to participate well by helping others, or by family pride and physicians to collect data for</p>	<p>QuIC could be used shortly after the discussion of IC and AI followed by qualitative interviews to explore the origin of participants' misunderstandings. The positive impression of the relationship with the researchers facilitated the experience of consent and assent. The participation of adolescents demonstrated the need to use a language they can understand, a high level of interaction and their involvement in the decision-making process. Researchers should know the adolescent and his / her particular situation well, and identify specific informational needs of each of them and their families</p>	<p>Little sample. Good method. Use of QuIC interesting. The qualitative interview shows many data that can not be collected through a standardized questionnaire.</p>	Medium

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	<p>medical providers. - Determining the understanding of key elements, memory and memory in detail time.</p> <p>Period of realization: Ns</p>	<p>and 1 woman, Caucasian, between 35-44 years old. They were the principal investigators of the trial and had prior experience in pediatric research and training in ethics and consent / assent in research.</p>	<p>measures subjective understanding [1 / do not understand at all 5 / I understand it very well] with final score of 0 - 100. Estimated time 7 minutes.</p> <p>3° A second qualitative interview with adolescents and their parents / guardians 6-9s after the end of the Induction Phase for the clinical trial on cancer</p> <p>Follow-up period: Do not</p> <p>Toll: Ns</p>	<p>the future.</p> <p>PRESSURE, adolescents and mothers felt overwhelmed with the vast amount of information and complex concepts. They emphasize complex language, very sophisticated.</p> <p>FEAR AND LACK OF CONTROL, adolescents and parents express fears and lack of capacity to manage oncological diagnosis, treatment options and decisions. Mothers express clear feelings of panic and lack of control, which they disguise in front of their children to protect them.</p> <p>COMMUNICATION WITH THE PHYSICIAN, is considered positive by adolescents and mothers. They used positive communication techniques and made them feel part of the conversation, emphasizing a patient-centered approach. Physicians noted their strategy of using plain language and physical signs that reflected differences in power between doctor, parent, adolescent, and nurse were eliminated.</p>			

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
				<p>TIME / PRESS, expressed frustration with the accelerated pace of decision making and pressure. They do not have time to process the information.</p> <p>MAP OF ROUTE, was explained by parents and adolescents with the order of activities and time schedule. This route map came from the doctor explaining the scheme of the protocol.</p> <p>MEMORY; mothers and adolescents described an inability to remember specific IC content and assent. The feeling of being overwhelmed and flooded with so much medical information was pointed out as the cause.</p> <p>ANALYSIS INTERVIEWS 6-9 WEEKS AFTER: Parents and teens struggled to remember details, but their feelings of fear had waned as they saw progress and reached milestones in protocol. They attributed this to their trust with the doctor</p>			

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Raymundo, 2008	<p>Design: Descriptive, cross-sectional study to evaluate moral development using the LOEVINGER MODEL OF EGO STAGES</p> <p>Goals: - To evaluate the moral development of a group of minors and a group of elders, using the classification system of moral development proposed by Loevinger as an indicator of the capacity of consent.</p> <p>Period of realization: Ns</p>	<p>Number of participants / group: 59 adolescents aged 14-18 years, and 60 patients aged > 60 years</p> <p>Participating Features: Partially</p>	<p>Intervention: Two psychologists, trained and prepared to use the instrument, identified possible participants in the waiting rooms of the consultations described, approached the patients, asked permission to speak with them and explained the research study related to the moral development of individuals and that it was anonymous. If they agreed to participate, they had to answer a 10-minute questionnaire, marking personal preferences. We used the Souza questionnaire validated in previous studies, and codified with the author's proposal. The instrument includes 30 states, distributed according to the Loevinger model with 9 possible answers each.</p> <p>Follow-up period: Ns</p> <p>Toll: Ns</p>	<p>SOCIODEMOGRAPHICS: the group of adolescents (n = 59) had a mean age of 16.08a, and 78% were students of low socioeconomic status. The mean age of the elderly group (n = 60) was 67.48a, mainly retired.</p> <p>YO DEVELOPMENT: adolescents, 15.3% conformist, 67.8% stage of consciousness and 16.9% autonomous stage. Of the elderly, 18.3% conformist, 61.7% stage of consciousness and 20% autonomous stage.</p> <p>No significant differences were found between the two age groups.</p>	<p>The ability to understand and decide, is gradually acquired, not suddenly when a child reaches legal capacity. Probably this capacity is acquired before legal. The moral capacity is individual and varies with the person. Age should be a relevant requirement, but it should not be the main determinant in the consent process.</p>	<p>The socioeconomic level of the participants was low, which may influence the level of moral development. It should be studied at other levels. It is also unknown whether sex or number of years influence. The ability to understand and decide does not depend exclusively on the age of the patient.</p> <p>Therefore, age alone is probably not a suitable variable to measure health decision making.</p>	Medium

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS
Short quotation: Roth-Cline, 2013	<p>Design: Literature review of the evidence regarding the IC of the parents and the assent of the children.</p> <p>Goals: -Review the evidence about the parents' IC and the children's assent, including INFORMATION, UNDERSTANDING and VOLUNTARIETY. -To highlight the differences between the child and the adolescent about the assent. -Consider the circumstances in which the parents' IC can be waived or the children's assent</p> <p>Period of realization: Ns</p>	<p>Number of participants / group: Evidence review. It does not indicate revised articles or search criteria.</p> <p>Participating Features: The review is made of two population groups: parents, children and adolescents.</p>	<p>PARENTAL PERMISSION: information on potential risks, benefits and alternatives. Willfulness. The permission of one of the parents is sufficient, as long as there is a minimal risk and with direct benefit to the child. Failure to do so requires the permission of both parents. A parent's perception of understanding at the time of decision may be high, although the parent may be unable to remember concepts in time. The criteria that improve the understanding of the key concepts are: that they can think clearly without being overwhelmed by emotion, education level, clarity in the disclosure of information, having a child in a previous study, age of the father, how they read the document of CI, the time they have to decide, amount of information. On the other hand, education, gender, social minority, lack of previous experience and lack of information are significantly associated with voluntariness. It also speaks of "continuous permission" throughout the different stages of the trial, to improve quality and the use of multimedia presentations to improve the perception and understanding of relevant information. CHILD ASSENT: The regulations specify factors to be taken into account to assess ability (age, maturity and psychological state). The regulations do not specify the elements of information necessary for the child, but according to the recommendations of the National Commission, the consent must include information on: procedures to be carried out, freedom to choose, communicate decision and possibility to withdraw. In order to obtain</p>	<p>The principle of respect for people requires that both the father and the child, if able, voluntarily choose to participate in the research.</p> <p>Parents should be provided with detailed information about the nature, objectives, risks, benefits and alternatives. Children who are capable, must agree to participate.</p> <p>The amount of information a child should understand must vary with the child's age and maturity.</p> <p>The age at which a child is able to assent may be less (5-7a) if it is understood as an expression of willingness to participate.</p> <p>The assumption evolves from a choice of young children depending to a large extent on the decision of parents, to joint decision making as the children mature, to a widely independent decision taken by an older adolescent with parental affirmation.</p> <p>More research on voluntarism is needed.</p> <p>We do not know the predictors of voluntariness nor the influence of family and medical</p>	<p>Parent IC and child assent contain components of information exchange, understanding, and willingness. How these three components are understood and operationalized should differ depending on the development level of the child</p> <p>The only empirical instrument to measure voluntariness is Decision-Making Control Instrument (DMCI).</p> <p>The instrument for measuring capacity, MacCAT-CR</p>	Low

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS
			<p>the agreement according to William Bartholome there are 4 essential elements: development of the appropriate understanding, revelation of the nature and procedures, evaluation of the influences that the child can have and their understanding of the information, and the will of the child.</p> <p>A more standard measurement to determine children's understanding is the MacCAT-CR: its use is feasible, acceptable time and excellent reliability in children. But there is no competition threshold (it should be in line with the relevance of the research and its risks) and its use has not been validated in a larger pediatric population.</p> <p>Evidence available suggests that the ability to understand medical decisions among adolescents older than 13 years is similar to that of adults.</p>	equipment		

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS
Short quotation: Scherer, 2007	<p>Design: Non-systematic bibliographic review</p> <p>Goals: -Review the literature related to knowledge, competence, will and economic compensation in the decision-making process in biomedical research with children, adolescents and their parents. Provide clinicians and researchers with an analysis of key issues related to voluntary consent for research and assent of the child.</p> <p>Period of realization: Ns</p>	<p>Number of participants / group: Bibliographic review. It also does not apply to the selection of articles.</p> <p>Participating Features: Ns</p>	<p>KNOWLEDGE: The majority of studies focus on researcher-patient communication. Regarding the empirical studies that exist, they say that written IC forms are tedious and difficult to read and understand by people who lack medical knowledge. Poor communication between adolescent and physician may occur when risks are described. In the case of children, most of the information on diagnosis and treatment is addressed to the parents, who filter and modulate it. Adolescents can attend more and may feel more responsibility for decision making when the study is presented directly to them and their parents will ask more questions when their child is not present. Parents and teens may be better informed with separate discussions.</p> <p>COMPETENCE: From a psychological perspective, there are several variables that can be used to judge an individual's cognitive abilities and the maturity of decision-making. An important consideration in the differential perception of risk between adolescents and adults may be the distinction between risk and aversion. Adolescents may need adult support when faced with participation in medical treatment decisions. The ratings of benefit parents and teens are fairly similar, although parents tend to be more hopeful in their BENEFIT perceptions, whereas parents and doctors are less concerned about the risk and aversion of venipuncture than adolescents. Both physicians and adolescents seem less concerned about the risks associated with</p>	<p>As pediatric asthma researchers recruit and enroll adolescents and parents in studies, they should be sensitive to the interpersonal process of establishing trust and credibility with both parents and adolescents.</p> <p>These interpersonal processes are not static and during the duration of the study</p> <p>More than a single conversation and consent signing event, discussions about research procedures, risks and benefits should occur on a regular basis throughout the duration of the studies among adolescents, participants and their parents.</p> <p>There are differences in understanding between adolescents and their parents about the appreciation of research risks and procedures, and compensation can be an influential factor in the decision-making process</p>	<p>Little-structured bibliographical review. It analyzes 4 key sections, but without giving any conclusive data. Each section ends by counting what they have obtained in asthma research, but without significant data. It seems more like a set of opinions.</p>	Medium

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS
			<p>experimental medication than parents.</p> <p>VOLUNTEERING: Many IRBs support the review of federal regulations to allow adolescents to independently consent to some types of research, including anonymous surveys, biomedical studies that only venous puncture, minor risk investigation at minor maturity, and drug-approved the FDA for pediatric patients. The Society for Adolescent Medicine (SAM) supports this position and has developed guidelines that articulate analyzes and recommendations of situations in which adolescents can ethically provide informed consent for participation in research. The degree of autonomy granted to adolescents varies culture, gender and age of adolescents. In general, young adolescents tend to differ or submit to parental authority, in mid-adolescence they begin to affirm, and try to exercise, greater control over personal choice. Adolescents are given more autonomy at a younger age than girls</p> <p>ECONOMIC COMPENSATION: Studies that require more time, effort, and discomfort usually offer greater compensation than they anticipate as "fair." Whenever financial compensation exceeds expectations, it is unethical. Avoid "overcompensation"</p>			

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS
Short quotation: Scherer, 2013	<p>Design: Review of a subsection of the empirical literature on adolescent consent</p> <p>Goals: - To determine the competence to assent to adolescents participating in clinical research on asthma and cancer - Assess the risk perceptions and benefits included in the protocols - Establish the effect of social and contextual variables on decision making - Relate it to psychological and social factors.</p> <p>Period of realization: Ns</p>	<p>Number of participants / group: Bibliographic review that does not specify the number of articles reviewed</p>	<p>It is a complex way in which research, protocol characteristics and family dynamics mediate the process of assent that adolescents and their parents participate when they approach participating in pediatric asthma research</p> <p>Studies on understanding risks and benefits suggest that adolescents and adults often perceive benefit from research where it does not exist. A positive relationship with a physician-researcher may improve research protocols for adolescents and parents, but medical researchers should also be aware about alerting parents and especially teens about the risks of participating in research, clarifying the differences between the discomfort and the risk of procedures, and articulate clearly the prospects of personal benefit</p>	<p>Given the variability in adolescent maturity, diversity of family decision-making styles and the logistics of seeking adolescent consent and parental permission, researchers should use flexibility in designing a process of assent.</p> <p>In cases of mature adolescents who make minimal decisions about participation in research, it is entirely reasonable to seek the assent of adolescents outside the presence of their parents. With less mature adolescents and more risky research, family-level adolescents consent / parent permission conferences may be more. The degree of financial compensation influences decisions to participate in research. This may be lower in studies of minimal risk. However, over and above the minimum risk studies that offer substantial compensation for participation in research requires a careful presentation of how the appropriate compensation will be distributed.</p> <p>At family conferences, researchers could increase teen participation by assuring parents, especially authoritative parents, that teens' views are vital to the research effort and teens to voice their questions, concerns and preferences.</p>	<p>Variability in the maturity of adolescents (diagnosis, previous experiences, cognitive area, neurological development, social-emotional area) and it is difficult to generalize a consent process.</p> <p>What seems clear, is that AGE can not be set as standard.</p> <p>It is also common, the difference in the perception of risk and benefit. If the perception is positive, and accompanied by financial compensation, the probabilities of assent are high.</p> <p>Family dynamics are also key in the decision-making process</p>	Medium

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Swartling, 2011	<p>Design: Qualitative study through free narrative interviews in focus groups. Interviews were conducted with the children participating in the ABIS study on DM1. It is a longitudinal study in which they entered at birth. Interviews are done with the cohort who was 10-12 years old at the time of data collection.</p> <p>Goals: -Explor the views of children under 10-12 years of age on medical research and participation in such research.</p> <p>Period of realization: Period of 8 months, between 2009-2010</p>	<p>Number of participants / group: n = 39 children.</p> <p>6 focus groups (1 group with 5 others with 6-7 children); 3 with no experience and selected at random by the teacher and 3 with experience in ABIS</p> <p>Participating Features: 3 groups without experience and 3 with previous experience in ABIS.</p> <p>20 women and 19 men.</p>	<p>Intervention: The interviews were digitally recorded and transcribed digitally, with each participant assigned a pseudonym. Field notes were also taken during interviews</p> <p>Each child was asked to: (1) Medical research (What is it and what do researchers do?) (2) Children and research (Why do children participate in research?) (3) Information and consent / consent / dissent (What do children want to know and decide if they are participating in the research?) (4) Data collection (What samples do researchers take and what do they do with them?) (5) Consequences of research (What do researchers find when children are involved in medical research?) (6) Risk of disease (What is risk taking and would you like to know?) Each topic was introduced by asking: "Can you think and tell me about ...? "</p> <p>The interviews were analyzed in three stages. In the first</p>	<p>5 topics:</p> <p>(1) knowledge about research and its importance. All groups considered IMPORTANT research and a positive image of researchers</p> <p>(2) a sense of altruism. There was a clear idea that the research was to "help" people (not just children) and everyone, regardless of their experience, believes it is important to share the data with others. Most stressed the importance of being informed of the final results. There was a homogeneous feeling that "A reward" could in some cases be good, but not in the "real" investigation, since it was then "bribe"</p> <p>(3) shared decision-making and the right to dissent; Age is important, and 10 years is an "appropriate" age in which they could understand information about the research and be able to participate in discussions even though they mention age 5-7 to start informing children about research. Most favored shared decision-making (family</p>	<p>Children are positive for research and when they participate, they want to be actively involved, take part in decision-making, and have their integrity and interests respected and protected.</p> <p>The process of informing children and making sure they understand what they are involved in is vitally important. This problem is even more important in prospective research.</p> <p>Appropriate information may be important to promote willingness to continue to participate in such studies.</p>	<p>Medical research on children is vital</p> <p>(1) ensure understanding of children's participation, (2) foster shared decision-making and (3) report on the final results.</p> <p>Information on research participation and outcomes should be appropriate for the age and maturity of the children.</p> <p>The five themes that emerged in focus group discussions are good starting points for discussions about children's participation in medical research:</p> <p>(1) knowledge about research</p> <p>(2) a sense of altruism, (3) shared decision-making and</p>	Medium

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			<p>step, we have made an account of each child's experiences and thoughts. In the second step, individual stories and interviews were analyzed in terms of "themes". both steps also use field notes. In the final step, two of us brought together the common themes of the groups approach, showing shared experiences.</p> <p>Follow-up period: Interviews were conducted for 8 months, between late 2009 and early 2010</p> <p>Toll: N / Not Applicable</p>	<p>decision) rather than individual consent. Many children preferred written information individually rather than using information technologies such as e-mail or websites</p> <p>(4) notions of integrity, privacy and access: all children were very positive in allowing other researchers to use their data in other research projects. Do not think they can be used for anything bad</p> <p>(5) Understanding the risk of illness and responsibility: All groups held that it was good to be informed about things that could make children sick, because then you could do something about it</p>		<p>the right to dissent</p> <p>(4) notions of integrity, privacy and access</p> <p>(5) understanding of disease risk and personal responsibilities.</p>	

REFERENCE	STUDY	POPULATION	INTERVENTION	RESULTS	CONCLUSIONS	COMMENTS	QUALITY OF EVIDENCE
Short quotation: Twycross, 2008	<p>Design: Qualitative study of working meetings held during the Research Society's international nursing research conference.</p> <p>Goals: -Provide good clinical practice in finding an informed agreement for children involved in research. -To know if it is possible to obtain IC from small children -Determining the researcher's commitment to the child -Know strategies for finding informed agreement for children to participate in</p>	<p>Number of participants / group: The number of workshops, or documents analyzed, is not known</p> <p>Participating Features: Ns</p>	<p>Intervention: Working meetings were held between members of the Royal College of Nursing's Research in Child Health and the UK Association of Child Health Nurse Researchers to discuss age-related issues to agree on research and strategies to be used by the investigators.</p> <p>Follow-up period: May 2007</p>	<p>- Children of ages 2 and above could claim to participate, with process adapted to them - Suggestions to establish relationship: Begin by explaining to the child who you are and how you are connected to your environment. Provide opportunities to meet the child (if they do not already know) and to get to know you. This makes it easy for the child to ask questions. Sit down and make eye contact with the child. Request permission to turn off the TV and minimize other interruptions and distractions where possible. Start by asking the child if he or she has been told something about the study. Be patient and demonstrate that you are prepared to wait for the child to think and speak, instead of thinking for him or her and jumping in too early. Always ask the child to clarify what he or she is trying to express rather than guessing what he or she means. Think about the types of questions that should be asked to be sure that the child has</p>	<p>-The values of respect, trust, clear information and good communication should exist when requesting consent in any type of project, regardless of the child's age - It is possible to obtain an informed consent to participate in a research study of children aged 18 months, provided that appropriate and attractive methods are used. - With young children, it is always necessary to obtain permission from the parent / guardian before approaching the child. - This is not a single procedure, but an ongoing process requires the researcher to commit to the child, using supportive materials such as information leaflets that have been prepared specifically for the minor child</p>	<p>It's a review article. The review methodology is not described, so the conclusions are not well supported. It picks up results from some random articles I imagine. Make suggestions without evidence.</p>	Low

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	<p>research</p> <p>-Establish a formula for information to be adequate</p> <p>Period of realization: May 2007</p>			<p>understood the research. (Open-ended questions are not always best suited to young children, as they may try to find the answer the adult is seeking.)</p> <p>Achieve a level of confidence in this first stage of a potential research relationship with a crucial child and is based on that researcher son who is really interested in what he or she has to say.</p> <p>- Strategies for assent: getting a good understanding of what will happen, what you want to achieve and the ability to decide to participate or not. To ensure that they understand it they propose several forms: one is asking questions at the end of the information, another is a table of activities as a game for the little ones, and in a fun way, another strategies is to let the child talk to others about the participation.</p> <p>- Formatting suggestions: The information should be kept to a manageable length, according to age and development. The sheet should not have more than one double-sided A4 page (detailed information sheets can overwhelm the participants). Brochures should be designed so that they can be read to the child but interactive</p>			

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				<p>enough to be involved in the process. The language used should be appropriate for the child's age and stage development. Images can be used to increase commitment, but appropriate for child development, prior learning and setting. Do not just increase the size of the typeface of an informational brochure originally designed for older children. Information leaflets should be printed on the letterhead of the hospital / institution where the research is conducted. Normal paper is not acceptable even for young children. Information leaflets must include the information required for consent, as established by NRES. This can mean being creative in the way you formulate the question or provide information or the child may not fully understand. If images or graphics are included, they should be simple, clear and familiar. Always respect the confidentiality of the data. If this is not the case, the child should be informed.</p>			

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Short quotation: Tait, 2017-a	Design: Based on current guidelines, a preliminary definition of ASENTIMIENTO was generated and Delphi Panel was sent, which included experts in bioethics and pediatric researchers, members of the Institutional Review Board, parents and individuals with regulatory / legal experience. For each subsequent review, the process of summarizing and reviewing responses was repeated until a consensus was reached. Goals: -Develop an	Number of participants / group: 20 participants in the Delphi panel: 11 pediatric research experts, 7 institutional review teams, 9 bioethics experts and 3 law experts Participating Features: 11 men and 9 women. All of them parents	Intervention: A PRELIMINARY DEFINITION is established: "An interactive process between a researcher and a participating child that involves an appropriate development, disclosure, discussion and understanding in which the child freely asserts his / her agreement to participate in a proposed research study but has a maturity or lack in the absence of an affirmative agreement, the mere failure of the child should not be construed as consent. " With this preliminary definition, 4 rounds were made with experts until reaching the final definition. The same was done with four constructs: the child's assent, information for young children (7-11a), information for older children / adolescents (12-17a), and requirements for meaningful consent	FINAL DEFINITION: " <i>Children who lack the legal authority to provide informed consent per state laws should provide their assent to participate in a research study unless they either lack the cognitive ability, their clinical condition precludes their ability to communicate a choice, or the research holds out the prospect of direct benefit that is only available in the context of the research. Assent is an interactive process between a researcher and child participant involving disclosure of cognitively and emotionally appropriate information regarding, at minimum, why the child is being asked to participate, a description of the procedures and how the child might experience them, and an understanding that participation in the study is voluntary. Children should understand that they can decline participation or withdraw from the study at any time. Assent requires that the child explicitly affirms his or her agreement to participate in a manner that reflects their age-appropriate understanding and that is free of undue influence or coercion. In the absence of an explicit agreement, mere failure of the child to object cannot be construed as assent.</i> "	The central consideration of assent as "Affirmative Agreement" was retained, but in each round of context revisions the importance of assent was added as an "interactive" process. It provided elements of information that were considered most important but also reinforced the importance of age-appropriate information that takes into account the cognitive and emotional aspects of the child.	The final definition is very dense, but it covers many important aspects. Regarding the information to be contained, there seems to be a consensus that you will be informed of: the procedures to be performed and how the child may experience them, the purpose of the study, that there may be no expectation of personal benefit but that their participation can help other children, that the study is voluntary, and that they can withdraw at any time.	Medium

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	<p>operational definition of assent to ensure that investigators, review boards and legislators consider the process of assent in the same way</p> <p>Period of realization: September 2015 - May 2016</p>		<p>Follow-up period: September 2015 - May 2016</p> <p>Toll: 13 losses; 8 did not respond and 5 responded that they did not</p>	<p>Consensus was also sought in 4 constructs, and the final results were:</p> <p>1 Assessment of the child's ability: it can typically be done with a discussion with the child alone or together with the parents to measure maturity and cognitive ability. Health status and previous experiences in decision-making should be considered.</p> <p>2 Information for young children (7 - 11 a) procedure to be performed and how it will be experienced, the objective of the study, indirect benefit if there is no expectation of personal benefit, voluntariness and right to withdraw at any time.</p> <p>3- Information for older children / adolescents (12 - 17a), the same information but in some cases will do so without the presence of parents.</p> <p>4- Requirements for meaningful assent: You must understand the basic information and be aware of how it would affect your situation. They must be free to decide without coercion or influence</p>			

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Short quotation: Tait, 2017-b	<p>Design: The child-parent dyads completed separate and independent surveys of the information (risks, benefits, etc.) they perceived as most important for the child to make decisions about participating in a hypothetical randomized controlled trial. Parents responded in the context of what information they believed their child (not themselves) thinks important</p> <p>Goals: -Compare research information priorities of children and</p>	<p>Number of participants / group: 55 father-child pairs. N = 110 participants</p> <p>Participating Features: The mean age of children / adolescents was 12.8 ± 2.7 years. and 46.2% were girls. The majority were mothers (78.4%). Demographics by race / ethnicity of parents were: White 84.3%, African American 7.8%, Asian 2.0%, and Hispanic 5.9%. The majority (83.9%) of parents education beyond grade and high school</p>	<p>Intervention: Two questionnaires containing identical information were developed; one for parents and one for children. The questionnaire for parents was written at approximately the 8th grade reading level and the questionnaire for grades 4 through 5 with an age-appropriate formulation, according to Flesch-Kincaid reading level. After consent / consent, parents and children were asked to imagine that the child was being recruited for a randomized controlled trial comparing a standard versus new investigational drug for intractable headache. This hypothetical trial required the child to provide several blood samples for the pharmacokinetic analysis and complete a diary related to their experience of pain. Participating children and parents read the research scenario and then answered several questions about the relative importance of knowing the details of the study, such as risks, purpose,</p>	<p>55 dyads of parents and children completed the surveys (n = 110). Cronbach alphas supported the internal consistency of the survey items for both the child ($\alpha = 0.75$) and the father ($\alpha = 0.80$). The intra-subject correlation coefficients between the items of the survey of children and parents were 0.75 (95% CI: 0.64-0.84, P Children and parents classified all items as significant (> 7 of 10) Although children put more emphasis on knowing that their personal information would be confidential and less on knowing the purpose of the study and the benefits compared to what the parents thought their child would perceive as important. Adolescents give more importance in knowing what they would do to them, the direct benefits and nature of the study compared to younger children. There was no difference between the information priorities of the boys and girls. For parents, informational priorities were higher if their child was older (13-17 years old) and / or a girl. There was no difference in the parents' perception of their child's informational priorities for race / ethnicity. Parents with higher education believed that their children</p>	<p>The results show that the information priorities of children and adolescents participating in an ECA differs from what their parents believe is important to them.</p> <p>Pediatric researchers can use this knowledge to ensure that parents do not confuse expectations / priorities with their child's and that children receive the information they need.</p>	<p>Of interest was that while parents seemed to focus more on the importance of real risks, children seemed more interested in the burden of participation, ie how long the study might take and whether it would keep them away from their usual activities and in the confidentiality of your data.</p> <p>When it comes to making the decision, about 60% of the children want it to be shared.</p> <p>While it is true, a small percentage would like to make the decision themselves</p>	High

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	<p>adolescents with information that parents believe is more important to their children</p> <p>-Determining who would want to make the decision to participate; the child alone, the parent alone or both</p> <p>Period of realization: Ns</p>		<p>benefits, etc. the questions were selected based on the literature on disclosure elements typically considered important by both parents and children.</p> <p>The importance of each piece of information (ie, risk, procedure, etc.) was rated from 0 to 10, where 0 = "I would not want to know (not important and 10 = "I really want to know "(extremely important). (ie, the child, parents, or both).</p> <p>Demographic information including age and gender of the child, race / ethnicity of the family, parent who completes the survey (mom / dad) and the highest level of parent training was also collected. A trained research assistant was present for parent and child surveys conducted separately and independently of each other and for younger children with any of the questions.</p> <p>Follow-up period: Do not</p> <p>Toll: Ns</p>	<p>would place greater emphasis on the importance of knowing procedures compared to parents with only one elementary or secondary school. Mothers with lower schooling believed that their children would put more emphasis on how long their child would be in the study compared to the more educated mothers. When asked who thought they would want to make the decision to participate in the headache study, both children and parents responded similarly. 64.2% of the children and 69.8% of the parents reported that they would want the decision to be shared. 11% of the children believed that their parents had to make the decision for them, while 5.7% of the parents thought that their children would want them (the parents) to make the decision for them. 34.5% of older children reported that they wanted to make the decision themselves compared to only 13% of the youngest children ($P = .079$). 10% of adolescents and 13% of the youngest children reported that they would like the father to make the decision for them</p>			

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Short quotation: Unguru, 2010	<p>Design: Recorded face-to-face interviews using the Consent Quality instrument (QuAs)</p> <p>Goals: -Determining what children (7-18a) with cancer involved in a clinical trial - Determine your preferences for inclusion in decision making</p> <p>Period of realization: January 2005 - September 2007</p>	<p>Number of participants / group: n = 37 children aged 7 - 19 a. 32 outpatient and 5 hospitalized children</p> <p>Participating Features: 37 children aged 7 to 19 years (mean: 13.6 years), 21 girls and 16 children. 70% immersed in a Phase III trial and 16% in Phase II. 38% take 12-24 months from the start of the protocol and 30% less than 4 months. During data collection, 38% had completed treatment and 62% were still in full treatment. All with a diagnosis of cancer.</p>	<p>Intervention: The 69-item QuAs instrument (open and closed questions) reviewed by 30 pediatric oncohematology patients familiar with the methodology of the research and child development trial. He was then evaluated by a scientist with experience in both bioethics and survey development. The instrument was pre-tested in a convenience sample of 4 patients with cancer and 4 between 7 and 16 years. Open-ended questions were included to facilitate a more nuanced understanding of children's views. The interviews were private, face-to-face, and audiorecorded, and lasted approx. 30 minutes. The children had the written questionnaire in hand and the researcher was reading aloud. Five dimensions of comprehension were evaluated: familiarity, knowledge (0-10), awareness (0-7), comprehension (6 intervention questions, randomization, risk / benefit,</p>	<p>FAMILY: 19% of the 37 children (51%) did not know or remember that their treatment was an investigation, although the terms "study" (95%), "research" (87%), "consent" , protocol (65%) ... 24% could not indicate which term best fit the type of research in which they were participating. KNOWLEDGE: in a range of [0-10], the mean was 5.7. 70% recognize that before participating, their doctor explained the ways they can treat their disease CONSCIENCE: in a range of [2-7], the mean was 4.8. Only 3 children could differentiate well between clinical treatment and research treatment. 41% do not know the purpose of the research in which they are participating. Only 5 children were able to correctly define the target. UNDERSTANDING: 70% said that information is "a bit difficult" or "very difficult" to understand, on a scale [1-3]. A minority replied that it was "easy to understand". 86% said they did not understand the language their doctor used. APPRECIATION: 89% say it is to generate knowledge, but 73% answered incorrectly about the risks.</p>	<p>Most children have a limited understanding of the research despite the doctors' explanations. Many children reported feeling they participate minimally in the decision to enroll in clinical trials. Tools to help researchers know that children understand what they agree upon when they agree to research and determining their preferences for inclusion in research can help make consent more meaningful.</p>	<p>Extensive participation of children in cancer trials. This study is with CHILDREN WITH CANCER. Few studies have examined the understanding of their disease and its treatment and the extent of their desire to be included in the decisions. They develop the quality-of-assent (QuAs) tool to assess which children with cancer enrolled in pediatric therapeutic oncology research protocols understand about research, their research-related treatment, and their inclusion preferences in making decisions about their watch</p>	High

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			<p>treatment efficacy, generalizable knowledge, and voluntariness + 5 additional purpose of the intervention) and appreciation (1-3).</p> <p>The children's preference for participation research was based on their responses to 5 domains of research related decision making: Decisional priority, Types of decisions, Role in decision to enroll in protocol, Preferences / Perceptions and Suggestions,</p> <p>The age of 14 was selected as the evaluation point for the component related to the instrument preferences.</p> <p>The interviews were transcribed literally and transcripts were checked against the audio tape.</p> <p>Follow-up period: January 2005 - September 2007</p> <p>Toll: Of 62 eligible patients, 37 completed the study</p>	<p>The assessment of the goal the 3 main reasons were "to help future children with cancer" (27 of 37 [73%]), "to improve personally" (22 of 37 [60%]) obtain and to help their physician to learning (43% [n = 16]). Children with Hodgkin's disease, germ cell tumors and leukemia greater knowledge and appreciation of the research than children with other cancers (P? .019 and P? .001, respectively), showing no relation to gender, age, protocol, months from the diagnosis and the termination or not of the treatment.</p> <p>PARTICIPATION IN DECISION-MAKING: Although all children wanted to participate in decision-making, 18 out of 37 (49%) did not have or do not remember having played a role in their decision to enroll, and 14 out of 37 (38%) they did not feel free to disagree with the inscription in the essay. The desire to make joint decisions was almost universal 97%. They felt pressured by their parents, the most common reason for signing up.</p> <p>Three-quarters (n = 28) would have liked to talk to other children enrolled in the research to help them understand what it means to be part of a study</p>		<p>out.</p> <p>Oral and written presentation is an effective method established to improve understanding</p>	

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Short quotation: Unguru, 2009	<p>Design: Critical review of the literature on assent. Opinion Article</p> <p>Goals: -Exploring the history of assent -Evaluate the central role of the evaluation of the understanding of the child -Determine the preference for participation in decisions related to your care -Describe the necessary components of meaningful assent.</p> <p>Period of realization: Ns</p>	<p>ELEMENTS OF THE ASSENT: must be independent of consent. The two concepts can not be equated. Importance that a child understands risks / benefits. To be valid, it should be contextual, taking into account the range of experiences the child experiences in the context of wider family relationships. The child's ability to make decisions must be respected. Finally, researchers should evaluate the quality and adequacy of children's understanding.</p> <p>CHILD'S ROLE IN THE SETTLEMENT PROCESS: Children do not need to understand the 8 components of the IC, when they agree to participate. You have to take into account what the child wants to know.</p> <p>Proposes the Assent Quality Questionnaire (QA) to assess what children understand and what they want to know.</p> <p>DECISION-MAKING MODELS: A multidimensional conceptual model, conceived of assent as a process. It establishes appropriate roles for children, parents and doctors and takes into account developmental factors, the individual and the context. Models based on autonomy, are based on adult IC and focus on competition, a legal term, rather than capacity, a term of development.</p>	<p>Assent strategies focus on knowledge of the child's cognitive abilities and decision-making skills. Appreciate what you understand and your preferences.</p> <p>It should be respected that some children feel comfortable in a limited role in decision making.</p> <p>Others want to be included in the decisions and expect parents to listen to them and keep them in mind.</p> <p>EFFECTIVE COMMUNICATION is a prerequisite for shared decision making, a strong foundation on which to base assent.</p>	<p>The guidelines are not intended to be universally applicable, as they require that the assent process be sufficiently malleable to accommodate the child's particular situation, family experiences and values.</p> <p>Guides should provide advice and a general framework.</p> <p>There must be consensus in key areas of assent:</p> <ol style="list-style-type: none"> 1) the need to appreciate the assent from a child's point of view 2) the importance of understanding the child and that he / she prefers to participate 3) the role of medical researchers creates the possibility of a very real ethical tension, which should be honest and frank community to children and parents 4) an adequate model of assent will only be practical and applicable if it is multifaceted and flexible in its conception of families. 	Low

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Short quotation: Vitiello 2007	<p>Design:</p> <p>Observational, prospective study with intervention</p> <p>Goals:</p> <p>To study the comprehension of a clinical trial in adolescents with depression (TADS Study) by means of a self-filled questionnaire at 6 weeks of randomization</p> <p>Period of realization:</p> <p>2003</p>	<p>Number of participants / group:</p> <p>295 adolescents aged 12-17 years (149 boys)</p> <p>Participating Features:</p> <p>The study consisted of treating adolescents with major depression with Fluoxetine, cognitive-behavioral therapy, both, or placebo (the pharmacological part was double-blind).</p>	<p>Intervention:</p> <p>Multiple answers questionnaire to see the level of understanding of IC items (12 questions, plus two open final questions on motivation to participate and level of agreement between the child and the parents). Questionnaire passed at 6 weeks of randomization.</p> <p>Text of the questionnaire in the article.</p> <p>Follow-up period:</p> <p>N / Not Applicable</p> <p>Toll:</p> <p>43</p>	<p>High rate of correct answers: 10.3 out of 12 adolescents, and 11.2 out of 12, parents. The worst-understood item was the nature of the project: "a clinical trial" was answered only by 63.6% of adolescents and 66.5% of parents (note this low percentage and the high percentage of other questions; go all at the same time). The group that received psychotherapy was the worst understood that it was an investigation.</p>	<p>Good understanding of the various IC items, except for the one that refers to their nature (which is a clinical trial), especially poorly understood in the group randomized to cognitive-behavioral therapy</p>	<p>Good understanding of various IC items and assent in adolescents in a clinical trial for depression. It can influence the legibility of the IC</p>	High