I.R.C.C.S. Ospedale San Raffaele

CLINICAL STUDY PROTOCOL

Study Code: ComPARE

Title: ComPARE: effective COMmunication in Perinatal cARE
Cross-sectional study

Principal Investigator: Prof. Massimo Candiani

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PROTOCOL SIGNATURE PAGE

Study Title: ComPARE: effective COMmunication in Perinatal cARE - cross-sectional study
Study Code: ComPARE
Protocol Version and Date: ver 1.1; 14/05/2026

The undersigned has read and understood all the aspects of the protocol detailed within this document and agrees to supervise and conduct the study in accordance with the protocol, the Declaration of Helsinki, Guideline for Good Clinical Practice ICH E6 (R3), and all applicable regulatory requirements.

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1. KEY STUDY CONTACTS

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2. SYNOPSIS

Study Identifier	ComPARE
Study Title	ComPARE: effective COMmunication in Perinatal cARE
Protocol Version and Date	Ver.1.1, 14/05/2026
Sponsor	IRCCS Ospedale San Raffaele
Co-Sponsor	Università Vita Salute San Raffaele
Funding Source(s)	N/A
Principal Investigator	Prof. Massimo Candiani
Study Description	Doctor–patient communication is recognised as "time of care" by Italian Law No. 219/2017 (5), as it represents the foundation for building a therapeutic alliance between the healthcare professional and the patient - an element essential for fostering trust and treatment adherence. Effective communication, grounded in mutual understanding and aimed at preventing misunderstandings, has been shown to play a crucial role in patient safety, autonomy, and overall quality of care (Berger, Boss, & Beach, 2017; Street, 2013). Acknowledging its relevance, recent research has increasingly turned to linguistic and pragmatic frameworks to investigate how miscommunication emerges in medical contexts and to identify strategies to prevent it (Crawford et al., 2017; Roberts et al., 2005; Roberts & Sarangi, 2005). Within the philosophy of language, the field of pragmatics provides particularly useful insights into communicative dynamics. Indeed, pragmatics explores how meaning depends not only on the literal content of what is said, but also on contextual elements such as speaker intentions,

presuppositions, and shared background knowledge (Consolandi et al., 2025). Building on this theoretical foundation, the Textual misUnderstanding Codebook ANalysis (TouCAN Codebook) was developed as a linguistic instrument designed to identify markers of problematic communication that may hinder mutual understanding. This tool was created through the analysis of 32 transcripts of consultations between patients with pancreatic ductal adenocarcinoma (PDAC) and their physicians, collected as part of the COMMUNI.CARE project conducted between February 2021 and April 2022 (Consolandi et al., 2020; Consolandi et al., 2024; Consolandi, 2024).

Comparable approaches grounded in philosophy of language, linguistics, or argumentation theory have been applied in other medical settings. However, to the best of our knowledge, no similar studies have explicitly focused on perinatal care. Yet, effective communication is equally fundamental in this context. The World Health Organization (2018) emphasises the importance of clear, respectful, and culturally sensitive communication between perinatal care providers and pregnant person. Such communication fosters a sense of respect, control, and satisfaction among pregnant individuals, ultimately leading to more positive perceptions of the care received (N.I.C.E., 2023).

The present study seeks to address this research gap. The focus of the study is the clarity, accessibility, and effectiveness of communication between healthcare professionals — specifically obstetricians and gynaecologists (OB-GYNs) and midwives — and pregnant individuals during prenatal consultations concerning vaginal birth after cesarean (VBAC). More specifically, the study aims (1) to evaluate the clarity and effectiveness of the information provided during these consultations, and (2) to explore the association between pregnant participants' level of understanding, and the presence of linguistic markers that may indicate potential sources of problematic communication and (3) to understand how the clarity and effectiveness of the information provided correlate with the pregnant people's decision on whether to have a VBAC or a new CS..

To pursue these aims, we will collect audio-recorded, naturally occurring conversations between pregnant people considering a vaginal birth after caesarean section (VBAC) and healthcare professionals (OB-GYNs and midwives). Data will be gathered at

IRCCS Ospedale San Raffaele during routinely scheduled VBAC counselling consultations, which take place twice a week in a clinical setting. These consultations typically last between 60 minutes and are specifically focused to discussing the feasibility of vaginal delivery after a previous caesarean section, including potential risks, benefits and clinical criteria.

VBAC constitutes a communicatively delicate topic because it is discussed with a pregnant person who have previously undergone a caesarean section, an invasive and often emotionally charged medical procedure. In this context, pregnant people may hold concerns or ambivalent attitudes toward both the possibility of a repeat caesarean and that of a vaginal delivery. For this reason, it is crucial that the information provided by healthcare professionals is clearly understood, so that patients can develop a well-informed awareness of the childbirth setting and of the options available to them. At the same time, effective communication requires healthcare professionals — particularly midwives and OB-GYNs — to accurately understand patients' preferences, expectations, and concerns, in order to support a genuinely shared decision-making process.

Once collected, the conversations will be transcribed verbatim and anonymised in accordance with ethical and data protection requirements. The TouCAN Codebook (Consolandi et al., 2025) will be used as the main analytical framework to examine the transcripts, with specific adaptations to account for the clinical and perinatal context of VBAC counselling. In particular, the codebook will be refined to capture domain-specific sources of misunderstanding related to risk framing, probabilistic information, and implicit normative assumptions. This analytical process will allow us to systematically identify and analyse instances of misunderstanding and communicative misalignment in VBAC-related decision-making interactions.

The application of the TouCAN Codebook will allow to objectively identify markers of misunderstanding within the conversation. However, to determine whether these misunderstandings are perceived by the pregnant person, the same day of the VBAC counselling consultation, immediately after the latter, it will be asked to the pregnant person whether they are willing to participate in a semi-structured interview called SSI-CLAR. This procedure has already been used in the CommuniCare study

	(Consolandi, 2020). The aim of the interview is to explore participants' perceived clarity of communication, tone, accessibility of language, and subjective understanding of the information received. Furthermore, after the consultation, to estimate the correlation between the clarity and effectiveness of the information provided and the pregnant people's decision on whether to have a VBAC or a new CS, information will be collected on whether or not the pregnant person has decided to undergone a VBAC or a CS.
Study Design	This is a cross-sectional and observational study on the accessibility, and effectiveness of communication between healthcare professionals — specifically obstetricians and gynaecologists (OB-GYNs) and midwives — and pregnant individuals during prenatal consultations concerning vaginal birth after cesarean (VBAC). The study involves pregnant people who are considering a VBAC and attending a scheduled prenatal outpatient consultation with an OB-GYN or midwife with expertise in VBAC. Before the consultation, a healthcare professional will inform participants about the aims and procedures of the study, emphasizing that it examines the clarity and effectiveness of communication during VBAC consultations. Written informed consent will be obtained prior to any data collection. Consent will cover the presence of an external observer during the consultation, the taking of field notes, audio recording of the visit, and optional participation in a subsequent semi-structured interview. During the consultation, the external observer will take field notes and, where consent is granted, record the audio of the visit. This figure serves a strictly observational and data-collection function: the recording of the interview, together with the systematic annotation of paraverbal and non-verbal elements, which an audio recording alone would not be able to capture and which are central to the linguistic and communicative analysis envisaged by the protocol. During the same day of the consultation and Immediately after that, the same external observer will conduct an SSI-CLAR

	interview lasting approximately 30 minutes. The interview will focus on participants' perceived clarity of communication, tone, accessibility of language, and subjective understanding of the information received. SSI-CLAR is a semi-structured interview administered orally and specifically adapted to the context of the clinical consultations. Its inclusion follows the procedures adopted in the CommuniCare study (Consolandi, 2020). Following the methodology adopted to analyse the interviews conducted in the CommuniCare study (Consolandi & Floris, 2026), the interview data will be analysed using thematic analysis as described by Bungay, Wright, and Bradbury (2009). This method, which consists of six phases of analysis, is particularly well suited to examining subjective meanings and patterns across qualitative datasets, as it allows researchers to explore both explicit content and underlying assumptions. The thematic analysis will follow a process of independent coding and collaborative synthesis to enhance the rigour and credibility of the findings (Nowell et al., 2017). Furthermore, after the consultation, to estimate the correlation between the clarity and effectiveness of the information provided and the pregnant people's decision on whether to have a VBAC or a new CS, information will be collected on whether or not the pregnant person has decided to undergone a VBAC or a CS.	
Primary Objective To evaluate the clarity and effectiveness of communication between healthcare professionals (OB-GYNs and midwives) and pregnant individuals during prenatal consultations concerning VBAC.	**Primary Endpoint** The primary endpoint is the level of misunderstanding in clinician–patient conversations, measured through systematic analysis of consultation transcripts using the TouCAN Codebook.	**Time point(s)** All data are collected on the same day of the prenatal consultation. Approximately 2 hours.
Secondary Objectives To assess whether there is a match or mismatch between the patterns of misunderstanding	**Secondary Endpoints** The degree of convergence or divergence between (a) the level and types of misunderstandings identified through TouCAN	**Time point(s)** All data are collected on the same day of the prenatal consultation. Approximately 2 hours.

identified in clinical conversations and patients' own perceptions of communication as reported in post-consultation interviews.	Codebook coding of consultations and (b) patients' perceived clarity and understanding as assessed via semi-structured interviews.	
Exploratory Objectives 1. To identify recurrent linguistic patterns of misunderstanding in prenatal consultations concerning VBAC and to generate hypotheses about how these patterns relate to clinician communication style and patient interpretation. 2. To understand how the clarity and effectiveness of the information provided correlate with the pregnant people's decision on whether to have a VBAC or a new CS.	**Other** 1. Descriptive mapping of the types of communicative misunderstandings observed across consultations. 2. The degree of convergence or divergence between (a) the level and types of misunderstandings identified through TouCAN Codebook coding of consultations, (b) patients' perceived clarity and understanding as assessed via semi-structured interviews and (c) the decision of the pregnant person to undergo undergone a VBAC or a CS.	**Time point(s)** All data are collected on the day of the prenatal consultation.

Study Population	A. Healthcare professionals from San Raffaele Hospital - both OB-GYNs or midwives specialised in VBAC. B. Pregnant people who have a scheduled VBAC counselling consultations at IRCCS Ospedale San Raffaele
Healthcare professionals' Inclusion Criteria	1. San Raffaele Hospital employed 2. OB-GYNs or midwives specialised in VBAC and leading the informative consultation with pregnant women 3. Italian speaker 4. Informed consent to study participation
Healthcare professionals' Exclusion Criteria	1. Not employed by San Raffaele Hospital 2. Not specialised in VBAC and not responsible for leading informational consultations with pregnant women 3. Not an Italian speaker 4. No informed consent to participate in the study
Pregnant people's Inclusion Criteria	1. Singleton pregnancies 2. Gestational age between 33 gw and 37 gw 3. Maternal age between 18 and 44 years 4. Italian speaker 5. History of caesarean section in a previous pregnancy 6. Written informed consent to study participation 7. Delivery at San Raffaele Hospital
Pregnant people's Exclusion Criteria	1. Multiple pregnancies 2. Gestational age not between 33 gw and 37 gw 3. Maternal age under the age 18 and over 45 years of age 4. Not italian speaker. 5. No history of caesarean section in a previous pregnancy. 6. Refusal to provide written informed consent for study participation. 7. Inability to provide valid informed consent due to severe cognitive impairment or psychiatric conditions. 8. Refusal of audio recording. 9. Conditions preventing participation in the post-counselling interview (e.g., clinical instability, language barriers without adequate support, or logistical constraints). 10. Delivery not at San Raffaele Hospital. 11. Presence of obstetric emergency or urgent clinical conditions requiring immediate medical intervention.
STUDY OBJECT	
DRUG	N/A

MEDICAL DEVICE	N/A
PROCEDURE	
Procedure(s)	1. Before the consultation, the healthcare professional will ask the participant whether she agrees to the presence of an external observer (an expert in philosophy of language and communication). The participant may freely refuse this request without any consequences for her care. 2. Before the consultation, an healthcare professional will inform the participant about the study, explaining that its objective is to assess the clarity and effectiveness of communication during discussions about VBAC and that participation is entirely voluntary. At this stage, the healthcare professional will request written informed consent to audio-record the consultation and to conduct the SSI-CLAR semi-structured interview after the visit, following the procedure of the COMMUNI.CARE project (Consolandi, 2020). If the participant provides written consent, an external observer will attend the consultation, take field notes, and audio-record the visit in accordance with the permissions granted. The participant may consent to the recording of the consultation while declining the SSI-CLAR interview, or vice versa. Participation in the SSI-CLAR interview is entirely optional. Even if the participant initially agrees to be interviewed, she may change her mind at any time before or during the interview and, in that case, no interview will be conducted. The participant may withdraw from the study at any point without having to provide a reason and without any consequences for her clinical care. 3. Audio-record of the consultation.
Additional procedure	The same day of the consultation, immediately after that, the external observer will conduct the SSI-CLAR interview, which will last around 30 minutes and will explore: • the participant's perception of the clarity and tone of the communication; • the accessibility of the language used; • the participant's subjective understanding of the information received.

	Furthermore, the same day of the consultation, immediately after that, to estimate the correlation between the clarity and effectiveness of the information provided and the pregnant people's decision on whether to have a VBAC or a new CS, information will be collected on whether or not the pregnant person has decided to undergone a VBAC or a CS.
Sample Size	A. 6 OB-GYNs and 6 midwives, both specialized in VBAC. B. 50 pregnant individuals who are considering a VBAC.
Statistical Design	The study adopts a primarily qualitative, observational design, complemented by a quantitative component with both explorative and modeling phases. Prenatal consultations will be transcribed and coded using the TouCAN Codebook to quantify misunderstandings. Inter-rater reliability of coding will be assessed prior to analysis. Patient-perceived communication quality will be assessed through post-consultation interviews and summarised descriptively. At the quantitative level, analyses will be structured in three complementary layers: (I) explorative descriptive and association analyses, including the Spearman's rho correlation between misunderstanding counts and perceived clarity score; (II) regression analyses of perceived clarity, including the linear mixed-effects model incorporating patient-level covariates and accounting for clustering by clinician; (III) exploratory, non-causal observation of delivery mode (VBAC vs CS) in relation to communication characteristics (misunderstandings and perceived clarity). It should be noted that the sample size is powered exclusively for the Spearman's rho correlation analysis; all other analyses — including the linear mixed-effects model and any logistic regression on delivery mode — are purely exploratory, underpowered, and not inferential. They are included for hypothesis-generating purposes only and should not be interpreted as establishing causal or predictive relationships. All quantitative analyses will be considered exploratory and hypothesis-generating. Results will be interpreted in the context of the study's qualitative findings, and emphasis will be placed on effect sizes and confidence intervals rather than solely on statistical significance.

Duration of the Study	Duration of enrollment: 2 years Duration of subject participation: 2 hours for participants Duration of total study period: 5 years

3. ABBREVIATIONS AND DEFINITIONS

3.1. Abbreviations

CIOMS	Council for International Organization of Medical Science
CRF	Case Report Form
CRO	Contract Research Organization
CTC	Clinical Trial Center
DPIA	Data Protection Impact Assessment
EC	Ethics Committee
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Conference on Harmonization
LVLP	Last Visit of Last Patient
MedDRA	Medical Dictionary for Regulatory Activities
OSR	Ospedale San Raffaele
PI	Principal Investigator
SmPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
TouCAN Codebook	Textual misUnderstanding Codebook ANalysis
VBAC	Vaginal Birth After Caesarean

4. BACKGROUND AND RATIONALE

Doctor–patient communication is recognised as an integral component of clinical care under Italian Law No. 219/2017, as it forms the basis for establishing trust, shared decision-making, and adherence to treatment. Evidence shows that clear and effective communication improves patient safety, autonomy, and satisfaction (Berger, Boss, & Beach, 2017; Street, 2013). Recent studies in linguistics and pragmatics have highlighted how misunderstandings in medical dialogue may arise from implicit assumptions, contextual cues, and non-literal meanings (Crawford et al., 2017; Roberts et al., 2005a; Roberts & Sarangi, 2005). The TouCAN Codebook, developed from consultations with patients affected by pancreatic ductal adenocarcinoma as part of the COMMUNI.CARE project, provides a structured method for identifying markers of potentially problematic communication through the lens of the philosophy of language (Consolandi et al., 2020; 2024; Consolandi et al., 2025).

Despite the recognised importance of respectful and clear communication in perinatal care (WHO, 2018; NICE, 2023), no comparable research has specifically examined communication practices in consultations concerning vaginal birth after cesarean (VBAC). These consultations require complex, risk-sensitive information to be conveyed in an accessible manner to ensure informed and autonomous decision-making regarding pregnancy and birth. The present study seeks to address this gap by evaluating the clarity, accessibility, and effectiveness of communication in consultations about VBAC, and by examining how these factors influence pregnant people's understanding.

The procedure under investigation is the standard prenatal outpatient consultation conducted by OB-GYNs or midwives with expertise in VBAC. No medicinal product or medical device is being tested. The consultation follows routine clinical practice and constitutes the standard of care. The intervention of interest pertains solely to the evaluation of communication practices, not to medical treatment itself.

The study will follow these steps:

1. Before the consultation, the healthcare professional will ask the participant whether she agrees to the presence of an external observer (an expert in philosophy of language and communication). The participant may freely refuse this request without any consequences for her care.
2. Before the consultation, the healthcare professional will inform the participant about the study, explaining that its objective is to assess the clarity and effectiveness of communication during discussions about VBAC and that participation is entirely voluntary. At this stage, the healthcare professional will request written informed

consent to audio-record the consultation and to conduct the SSI-CLAR semi-structured interview after the visit, following the procedure of the COMMUNI.CARE project. If the participant provides written consent, the external observer will attend the consultation, take field notes, and audio-record the visit in accordance with the permissions granted. The participant may consent to the recording of the consultation while declining the SSI-CLAR interview, or vice versa. Participation in the SSI-CLAR interview is entirely optional. Even if the participant initially agrees to be interviewed, she may change her mind at any time before or during the interview and, in that case, no interview will be conducted. The participant may withdraw from the study at any point without having to provide a reason and without any consequences for her clinical care.

3. Audio-record of the consultation.

After the consultation, the external observer will conduct the SSI-CLAR interview, to explore the participant's perceptions of clarity, tone, accessibility of language, and subjective understanding of the information provided. The interview will be conducted only if the participant has given her written informed consent before the consultation. Nonetheless, the participant may freely change her mind and decide to withdraw from the study at any moment. Furthermore, after the consultation, to estimate the correlation between the clarity and effectiveness of the information provided and the pregnant people's decision on whether to have a VBAC or a new CS, information will be collected on whether or not the pregnant person has decided to undergone a VBAC or a CS.

The prenatal consultations evaluated in this study follow established standards of care for counselling individuals considering VBAC. No deviation from clinical protocols will occur. The additional study components (recording of the visit and interview) are non-invasive, observational, and pose no risk to participants.

5. OBJECTIVES AND ENDPOINTS

Objectives	Endpoints	Time point(s)
Primary Objective To evaluate the clarity and effectiveness of communication between healthcare professionals (OB-GYNs and	**Primary Endpoint** The primary endpoint is the level of misunderstanding in clinician–patient conversations, measured through systematic analysis of consultation	**Time point(s)** All data are collected on the same day of the prenatal

midwives) and pregnant individuals during prenatal consultations concerning VBAC.	transcripts using the TouCAN Codebook.	consultation. Approximately 2 hours.
Secondary Objectives To assess whether there is a match or mismatch between the patterns of misunderstanding identified in clinical conversations and patients' own perceptions of communication as reported in post-consultation interviews.	**Secondary Endpoints** The degree of convergence or divergence between (a) the level and types of misunderstandings identified through TouCAN Codebook coding of consultations and (b) patients' perceived clarity and understanding as assessed via semi-structured interviews.	**Time point(s)** All data are collected on the same day of the prenatal consultation. Approximately 2 hours.
Exploratory Objectives 1. To identify recurrent linguistic patterns of misunderstanding in prenatal consultations concerning VBAC and to generate hypotheses about how these patterns relate to clinician communication style and patient interpretation. 2. To understand how the clarity and effectiveness of the information provided correlate with the pregnant people's decision on whether to have a VBAC or a new CS.	**Other** 1. Descriptive mapping of the types of communicative misunderstandings observed across consultations. 2. The degree of convergence or divergence between (a) the level and types of misunderstandings identified through TouCAN Codebook coding of consultations, (b) patients' perceived clarity and understanding as assessed via semi-structured interviews and (c) the decision of the pregnant person to undergo undergone a VBAC or a CS.	**Time point(s)** All data are collected on the same day of the prenatal consultation. Approximately 2 hours.

6. STUDY DESIGN

This study is based on the hypothesis that reducing the likelihood of misunderstandings during prenatal consultations concerning vaginal birth after cesarean (VBAC) leads to a higher level of patient understanding. More specifically, the study aims to

1. quantify the level of misunderstanding in clinician–patient communication using the TouCAN Codebook;
2. examine whether consultations characterized by fewer misunderstandings are associated with higher patient-perceived clarity and comprehension as assessed through post-consultation interviews.
3. understand how the clarity and effectiveness of the information provided correlate with the pregnant people's decision on whether to have a VBAC or a new CS.

This will be a monocentric observational cross-sectional study, conducted at OSR, involving pregnant individuals considering VBAC and healthcare professionals (OB-GYNs and midwives).

Eligible participants for healthcare professionals will be:

1. San Raffaele Hospital employed
2. OB-GYNs or midwives specialised in VBAC and leading the informative consultation with pregnant women
3. Italian speaker
4. Informed consent to study participation

Eligible participants for pregnant people will be:

1. Singleton pregnancies
2. Gestational age between 33 gw and 37 gw
3. Maternal age between 18 and 44 years
4. Italian speaker
5. History of caesarean section in a previous pregnancy
6. Written informed consent to study participation
7. Delivery at San Raffaele Hospital

The study requires: (1) completion of the scheduled outpatient visit with an OB-GYN or midwife experienced in VBAC, (2) the SSI-CLAR interview with the participant to assess their level of understanding of the information received and (3) the collection of information about the method of delivery, once it has taken place.

The consultation will be audio-recorded to allow subsequent linguistic analysis using the TouCAN Codebook. The SSI-CLAR interviews will also be audio-recorded to allow for subsequent transcription and thematic analysis. In particular, the analysis will follow the six-phase method described by Bungay, Wright, and Bradbury (2009), which is particularly well suited to examining subjective meanings and patterns across qualitative datasets, as it allows researchers to explore both explicit content and underlying assumptions. The thematic analysis will follow a process of independent coding and collaborative synthesis to enhance the rigour and credibility of the findings (Nowell et al., 2017). This type of analysis has already been performed in the CommuniCare study (Consolandi & Floris, 2026).

These data collection methods are designed to capture both subjective perceptions of communication quality and linguistic markers that may contribute to misunderstanding. Data will be collected during the routine outpatient prenatal visit and will continue to be gathered after delivery, specifically regarding the mode of birth (cesarean section or VBAC) and, in the case of cesarean section, the clinical indication. The study will last a total of 5 years, of which pregnant people's enrolment will last 2 years.

6.1. Study duration

Duration of enrollment: 2 years
Duration of subject participation: 2 hours for participants
Duration of total study period: 5 years

7. STUDY POPULATION

7.1. Study Participants

The study population consists of six OB-GYNs from OSR specialising in VBAC and six midwives from OSR specialising in VBAC — as well as 50 pregnant individuals who are considering VBAC.

7.2. Healthcare professionals' Inclusion Criteria

1. San Raffaele Hospital employed;
2. OB-GYNs or midwives specialised in VBAC and leading the informative consultation with pregnant women;
3. Italian speaker, in order to facilitate clear communication.
4. Written informed consent to study participation.

7.3. Healthcare professionals' Exclusion Criteria

1. Not employed by San Raffaele Hospital

2. Not specialised in VBAC and not responsible for leading informational consultations with pregnant women
3. Not an Italian speaker
4. No informed consent to participate in the study

7.4. Pregnant people's Inclusion Criteria

1. Singleton pregnancies
2. Gestational age between 33 gw and 37 gw
3. Maternal age between 18 and 44 years
4. Italian speaker, in order to facilitate clear communication and comprehension of study procedures.
5. History of caesarean section in a previous pregnancy
6. Written informed consent to study participation
7. Delivery at San Raffaele Hospital, to ensure uniformity in data collection.

7.5. Pregnant people's' Exclusion Criteria

1. Multiple pregnancies
2. Gestational age not between 33 gw and 37 gw
3. Maternal age under the age 18 and over 45 years of age
4. Not italian speaker, to avoid potential communication barriers during data collection and counseling.
5. No history of caesarean section in a previous pregnancy
6. Refusal to provide written informed consent for study participation.
7. Inability to provide valid informed consent due to severe cognitive impairment or psychiatric conditions.
8. Refusal of audio recording.
9. Conditions preventing participation in the post-counselling interview (e.g., clinical instability, language barriers without adequate support, or logistical constraints).
10. Delivery not at San Raffaele Hospital, to ensure consistency in data acquisition.
11. Presence of obstetric emergency or urgent clinical conditions requiring immediate medical intervention, which would interfere with the counselling process.

7.6. Screening Failures

In this study, *screen failures* are defined as participants who provide written informed consent to participate but are subsequently found, during screening procedures, not to meet one or more of the eligibility criteria for inclusion in the study.

For transparency and completeness of reporting, a minimal set of information will be collected for all screen failure participants. This will include basic demographic data (such as maternal age and gestational age at screening), details on the reason for ineligibility, and specification of the inclusion or exclusion criteria not met. Similarly, demographic data on the healthcare professional conducting the consultation will be collected, such as gender, age and professional status.

Screen failure data will be recorded in a dedicated log and stored securely in accordance with applicable data protection and ethical guidelines.

8. STUDY OBJECT

This is a cross-sectional study involving 50 pregnant people who are considering a VBAC and attending a scheduled prenatal outpatient consultation with an OB-GYN or midwife with expertise in VBAC. The study population includes 12 healthcare professionals from OSR. It does not involve the use of any medicinal products or medical devices, nor does it introduce any diagnostic or therapeutic procedures outside routine clinical practice. No drugs or medical devices are administered, prescribed, or evaluated as part of the study. Therefore:

1. No medicinal products are used for purposes outside the indications approved by the national Regulatory Authority.
2. No medical devices are used beyond normal clinical practice, and no additional or experimental devices are introduced.
3. The diagnostic and therapeutic pathways followed by participants are those already planned as part of their standard clinical care. The decision to treat or manage the patient is completely independent of the patient's inclusion in the study.
4. Assignments to diagnostic or therapeutic procedures are not influenced by participation in the study and are not based on any random allocation. Healthcare professionals retain full clinical autonomy in determining the most appropriate care strategy for each patient, in accordance with current national and international guidelines.

The study procedures consist of:

1. The completion of the scheduled outpatient consultation with an OB-GYN or midwife who has expertise in VBAC.
2. The SSI-CLAR interview with the participant to assess their subjective understanding of the information received.
3. The collection of information about the method of delivery, once it has taken place.

The consultation will be audio-recorded to allow subsequent linguistic analysis using the TouCAN Codebook (Consolandi et al., 2005): the summary table of the codebook can be found in Appendix E. The SSI-CLAR interviews will also be audio-recorded to allow for subsequent transcription and thematic analysis.

The use of interviews, observational field notes and linguistic analysis falls within procedures considered part of current clinical practice research, as they involve subjective evaluations and do not introduce any additional clinical risk.

If the participant does not provide written informed consent prior to the consultation, no audio recordings or field notes will be collected, and no data will be retained or analysed. If the participant requests to withdraw from the study, all data will be irreversibly deleted and will not be retained or analysed.

The outline for the SSI-CLAR semi-structured interview is provided in Appendix D. Following the methodology adopted to analyse the interviews conducted in the CommuniCare study (Consolandi & Floris, 2026), the interview data will be analysed using thematic analysis as described by Bungay, Wright, and Bradbury (2009). This method, which consists of six phases of analysis, is particularly well suited to examining subjective meanings and patterns across qualitative datasets, as it allows researchers to explore both explicit content and underlying assumptions. The thematic analysis will follow a process of independent coding and collaborative synthesis to enhance the rigour and credibility of the findings (Nowell et al., 2017).

8.1. Study object description

N/A.

9. STUDY PROCEDURES

C= clinical standard of care activities; R: research activities (activities done only for the participation in the study).

	Enrollment	**Baseline**	**Study Visit/Final Study Visit**
Day **Procedures**		1 (+/-1)	1 (+/-1)
Informed consent	R		
Demographics			R
Medical history	C		
Eligibility assessment	R		
VBAC consultation		C	
Registration			R
Interview			R
Labour's decision			R

9.1. Informed Consent

The investigator (in accordance with applicable regulatory requirements) and under the investigator's responsibility will ensure that each participant is fully informed about all relevant aspects of the study. Information will be provided in Italian and in clear, comprehensible language. Before the consultation begins, the healthcare professional (OB-GYN or midwife) will ask the participant for permission to allow the presence of an external observer during the consultation, to audio record the consultation and to participate to an interview after the consultation with the external observer. The external healthcare professional will explain the purpose of the study. Written informed consent will be requested before the consultation. The healthcare professional will provide the participant with full information about the study procedures, answer any questions, and then request written informed consent for the use of the collected data and participation in the subsequent SSI-CLAR interview. A copy of the signed and dated informed consent form will be given to the participant.

Participation in the study is entirely voluntary. Since the study is observational in nature, does not involve medical interventions, drugs, or medical devices, and poses no additional risks to participants, the presence of an independent witness is not required. Participants will be explicitly informed that they may withdraw from the study at any time, without providing a reason, and that withdrawal will not affect their medical care in any way. If the participant requests to withdraw from the study, all data will be irreversibly deleted and will not be retained or analysed.

The Informed Consent Form will be approved by the Independent Ethics Committee before the start of the study. The signed and dated consent form will be stored in the investigator's study file, and a copy will be provided to the participant.

9.2. Subject Recruitment and Screening

Participants will be recruited within the routine prenatal care pathway at OSR. Participants will be recruited within the routine prenatal care pathway at OSR. Clinical consultations and counselling concerning VBAC will be conducted by healthcare professionals according to standard clinical practice and will not be modified in relation to the study. Enrollment in the study will instead be managed by an external observer with expertise in philosophy of language and communication and independent from the clinical staff, who will identify potential participants on the basis of the clinical eligibility criteria already established in the care pathway. The external observer will provide information about the study and will obtain

informed consent for participation, without interfering with the clinical relationship or with the content of the healthcare counselling.

Eligible participants will be pregnant individuals aged 18–44 years, with a singleton pregnancy between ≤33 gw and ≥ 37 gw, who have a scheduled VBAC counselling consultations at IRCCS Ospedale San Raffaele . All participants must be Italian-speaking and planning to deliver at OSR. Patients who do not meet these criteria, who decline to participate, or who do not provide written informed consent will be excluded. In the screening phase, data sheet describing age and socioeconomic status, measured by the Hollingshead Index of Social Position (Hollingshead 1958), will be collected..

The healthcare professional involved will be both OB-GYNs and midwives specialised in VBAC and leading the informative consultation with pregnant women, They will be both San Raffaele Hospital employees and Italian speaker who have given the oral informed consent to study participation. In the screening phase, data sheet describing age, gender and professional role will be collected.

9.3. Subject Identification

A patient identification list will be kept, but the anonymity of participants will be guaranteed.

9.4. Baseline Assessments

Baseline assessments will be conducted prior to the evaluation of communication outcomes and will serve to describe the study population and contextualise the interpretation of the primary and secondary endpoints. These assessments do not involve any additional clinical procedures beyond standard prenatal care. The following baseline data will be collected sociodemographic characteristics of the participants.

These baseline assessments are non-invasive and consist solely of patient self-report and clinical data already collected as part of standard prenatal care. No new diagnostic or therapeutic procedures are introduced.

Baseline information will be used to:

- Characterise the sample,
- Ensure eligibility,
- Allow secondary analyses exploring whether sociodemographic or obstetric variables relate to communication clarity or understanding.

9.5. Visits and Follow Up

N/A

9.6. Definition of End of Study

According to the study design, the end of the study is defined as the date on which the information about the labour of the last participant is gathered after the labour. No additional participant contact will occur beyond this point.

9.7. Premature termination or suspension of a study

This study may be temporarily suspended or prematurely terminated by the authorized Sponsor representative or the PI at any site if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to study participants and investigator. If the study is prematurely terminated or suspended, the PI will promptly inform study participants and will provide the reason(s) for the termination or suspension.

10. DISCONTINUATION AND WITHDRAWAL

Participants can discontinue their voluntary participation any time without the need to provide any justification for their choice.

11. SAMPLE HANDLING

N/A

12. PATIENT SAFETY

Side effects are not expected.

13. DATA MANAGEMENT

13.1. Definition of source data and source documents

Source data for this study will consist of the original records and observations generated during the prenatal consultations and associated research procedures (audio recordings, field notes and semi-structured interviews). No investigational medicinal products or laboratory measurements are involved.

Source Documents include:

1. Sociodemographic information and obstetric history of the pregnant person involved in the study.
2. Demographic and professional role of healthcare professionals involved in the study.
3. Written informed consent forms
4. Field notes recorded by the external observer
5. Audio recordings of consultations
6. Interview notes and/or interview transcripts

Regarding data Storage and confidentiality:

1. Paper documents (e.g., consent forms, field notes) will be stored in locked, access-restricted cabinets.
2. Electronic data (audio files, transcripts, coded CRFs) will be stored on password-protected institutional servers compliant with GDPR and institutional data protection policies.
3. Identifying information will be stored separately from research data and linked only through a coded participant ID.
4. Electronic data systems used for storage and transcription are validated and comply with requirements for completeness, accuracy, reliability, and consistent performance.

A screening log will be maintained to record all individuals assessed for eligibility who do not enroll, including the reason for screen failure or non-participation.

13.2. Documentation of data in Case Report Forms (CRFs)

This study collects exclusively qualitative data through the audio recordings of consultations and the subsequent SSI-CLAR interview, along with basic demographic information. The latter will be collected and managed through an electronic Case Report Form (eCRF) implemented via REDCap (Research Electronic Data Capture), a secure, web-based platform designed to support data collection for research studies. REDCap ensures compliance with data protection standards and allows for accurate, structured recording of participant demographic data.

The Semi-Structured Interview SSI-CLAR will serve as the primary instrument for systematically collecting participant information relating to their understanding and perception of clinical communication. This interview tool ensures that data are gathered in a consistent and structured manner across all participants, allowing for rigorous and comparable qualitative analysis. All interview records will be completed in their entirety in a neat and legible manner to ensure accurate interpretation of the collected information. Transcripts of the consultations and interviews will be stored in appropriate folders in secure storage. Any corrections will be made by drawing a single line through the original entry, accompanied by the signature of an authorized researcher.

13.3. Data Recording and Record Keeping

The investigator shall arrange for the retention of Essential Documents for the Conduct of a Clinical study (e.g., patient files, other source data, and the Trial Master File/Investigator Site File) after the completion or discontinuation of the study according to institutional procedures and applicable laws.

13.4. Data Protection

The Investigator undertakes to:

- use the data only for the purposes of the foreseen analyses and within the limits established by the study and approved by the competent EC;
- store data in a secure network system;
- prohibit unauthorised third parties from accessing, even partially, data.
- guarantees to limit access to and processing of data only to its employees and collaborators who, upon appointment as an authorized person:
    1. need to process the data in order to carry out their work in relation to the study;
    2. have undertaken to maintain the confidentiality of the Data and of any information deriving from it or that is communicated to them.

If, within the context of the Study, the Investigator needs to make use of its own suppliers, the latter undertakes to appoint these subjects as Data Processors /Responsabili dei Trattamenti

with a specific agreement or other legal act suitable for this, before the start of any data processing by them, according to Regulation (EU) n. 2016/679, art. 28.

The Investigator also undertakes to adopt suitable measures to facilitate the exercise of the rights of the subject provided for by Regulation (EU) n. 2016/679, art. 15 – 22, including the rights of access, rectification, cancellation, limitation, opposition and portability, within 30 days of receiving the relative request.

In case the Investigator need to communicate the data outside OSR (the Data Controller /Titolare) in pseudonymized form, the Investigator will refrain from carrying out any activity aimed at identifying the identity of the subjects to whom such data refer. In the event, however, that the data could not be communicated in pseudonymized form by the Data Controller, the Investigator undertakes to adopt all the security and organizational measures aimed at protecting the confidentiality of the Data Subject).

Within 30 days following the end of the study, the Investigator undertakes to cancel the data communicated by the Data Controller or to make them irreversibly anonymous and to promptly communicate it in writing.

14. STATISTICS

Statistical and qualitative analyses will be conducted by the academic research team.

14.1. Description of Statistical Methods

The primary endpoint — the level of misunderstanding in clinician–patient communication — will be assessed through qualitative coding of consultation transcripts using the TouCAN Codebook. Coded misunderstandings will be quantified as counts (and, where appropriate, rates per consultation). Inter-rater reliability will be evaluated using Cohen's κ (or a multi-rater equivalent), and discrepancies will be resolved through consensus procedures.

From a quantitative perspective, analyses will be structured into three sequential components: (I) an exploratory analysis, where the secondary endpoint — the association between misunderstandings and patient-perceived communication quality — will be investigated using descriptive statistics and non-parametric correlation (Spearman's rank correlation) between (a) the number of coded misunderstandings, (b) a consultation-level score of perceived clarity derived from post-consultation interviews, and (c) patient decision regarding VBAC (trial of labour after caesarean vs elective repeat caesarean), which implies

an additional exploratory assessment of the association between perceived communication quality and patient decision; (II) a linear mixed-effects model that will be implemented to further investigate the relationship between communication characteristics and perceived clarity. The dependent variable will be the perceived clarity score. Fixed effects will include the number of coded misunderstandings and selected patient-level covariates (e.g., age, parity, and other relevant demographic or clinical variables). A random intercept at the clinician level will be included to account for the non-independence of consultations conducted by the same healthcare provider. This analysis will allow estimation of the adjusted association between misunderstandings and perceived clarity while accounting for potential confounding and within-clinician correlation; (III) a logistic regression model that will explore the association between communication characteristics and delivery outcomes. The dependent variable will be the occurrence of VBAC, defined as a binary outcome. Independent variables will include the number of misunderstandings, the perceived clarity score, and selected patient-level covariates. Where appropriate, clinician-level clustering may be accounted for through the inclusion of a random intercept or robust variance estimation. This analysis is intended to determine whether communication quality is associated with subsequent delivery outcomes.

All analyses are intended to explore potential associations without confirmatory inference. Model assumptions will be assessed where appropriate. If p-values are reported, they will be interpreted descriptively. The conventional significance level of $\alpha = 0.05$ will be used for exploratory inference. Analyses will be conducted using R or SPSS (version to be specified prior to analysis).

14.2. Sample Size Determination

The study is primarily designed as a qualitative investigation, aimed at in-depth analysis of communicative dynamics rather than hypothesis testing. However, a quantitative component is included to explore the associations between misunderstandings, perceived clarity and delivery outcomes.

The sample size for the whole quantitative section is based on the primary Spearman rank correlation analysis. Assuming a two-sided significance level of 0.05 and a statistical power of 80%, approximately 47 participants are required to detect a moderate monotonic association corresponding to a correlation coefficient of approximately 0.40 (see https://sample-size.net/correlation-sample-size/). We plan to recruit at least 50 participants with recorded consultations, which is sufficient to detect moderate-to-large associations of

this magnitude as well as to ensure thematic saturation in qualitative analysis. This range is also consistent with prior qualitative studies of clinician–patient communication (cfr. Consolandi et al. 2025).

14.3. Analysis Populations

Analyses will be conducted at the consultation level. The primary analysis population will include all enrolled pregnant participants whose VBAC consultation is audio-recorded and for whom a usable, anonymised transcript is available for TouCAN coding.

The secondary (integrated) analysis population will include the subset of these consultations for which a post-consultation interview is also completed, enabling comparison between transcript-based misunderstanding measures and patients' perceived communication quality.

Participants who decline or withdraw from the interview will remain in the primary analysis population but will not be included in the integrated analyses. Missing data (e.g., incomplete interviews or unusable recordings) will be reported descriptively; no imputation will be performed.

14.4 Statistical Design

The study adopts a primarily qualitative, observational design, complemented by a quantitative component with both explorative and modeling phases. Prenatal consultations will be transcribed and coded using the TouCAN Codebook to quantify misunderstandings. Inter-rater reliability of coding will be assessed prior to analysis. Patient-perceived communication quality will be assessed through post-consultation interviews and summarised descriptively.

At the quantitative level, analyses will be structured in three complementary layers: (I) explorative descriptive and association analyses, including the Spearman's rho correlation between misunderstanding counts and perceived clarity score; (II) regression analyses of perceived clarity, including the linear mixed-effects model incorporating patient-level covariates and accounting for clustering by clinician; (III) exploratory, non-causal observation of delivery mode (VBAC vs CS) in relation to communication characteristics (misunderstandings and perceived clarity).

It should be noted that the sample size is powered exclusively for the Spearman's rho correlation analysis; all other analyses — including the linear mixed-effects model and any logistic regression on delivery mode — are purely exploratory, underpowered, and not inferential. They are included for hypothesis-generating purposes only and should not be interpreted as establishing causal or predictive relationships.

All quantitative analyses will be considered exploratory and hypothesis-generating. Results will be interpreted in the context of the study's qualitative findings, and emphasis will be placed on effect sizes and confidence intervals rather than solely on statistical significance.

15. ETHICAL AND REGULATORY CONSIDERATIONS

This clinical study will be conducted in accordance with the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments established by the World Medical Assemblies, and the ICH guidelines for Good Clinical Practice.
This clinical study will be conducted in compliance with all international laws and regulations; national laws and regulations of the country in which the clinical study is performed; as well as any other applicable guidelines.

15.1. Responsibilities of the Investigator(s)

The Investigator(s) undertake(s) the responsibility to perform the study in accordance with this Protocol, Good Clinical Practice, and the applicable regulatory requirements. The Investigator is required to ensure compliance with the investigational product schedule, visits schedule, and procedures required by the protocol. The Investigator agrees to provide all information requested in the Case Report Form (CRF) in an accurate and legible manner. The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to study subjects without prior EC approval/favorable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted. The investigator must have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the study to conduct the study properly and safely.

15.2.Ethics Committee (EC) Approvals

This clinical study protocol as well as the Informed Consent are to be submitted to the appropriate Ethics Committee, and it is mandatory to obtain the written and dated approval, signed by the chairman with Ethics Committee(s) composition.
The clinical study the documents reviewed, the list of voting members and their qualifications, and the date of the review should be clearly stated on the written Ethics Committee approval.

15.3. Other Ethical Considerations

Even though this study involves a vulnerable population, specifically pregnant people, it is non-interventional and purely observational in nature; therefore, it does not introduce any additional risk beyond that associated with routine clinical care. No investigational procedures or interventions will be administered as part of the study. Participant safety and wellbeing will be of paramount importance and will be safeguarded throughout the study in accordance with established standard-of-care procedures, applicable regulatory and ethical requirements, and any additional protective measures deemed necessary.

16. GENDER MEDICINE IN RESEARCH PROTOCOL

The present study is intrinsically grounded in a gender medicine perspective, as it focuses on prenatal consultations concerning VBAC, conditions that exclusively involve individuals who are pregnant. In accordance with the Italian Plan for Gender Medicine and the SAGER Guidelines, the study adopts a clear distinction between sex (biological attributes associated with pregnancy) and gender (social and cultural dimensions that shape communication, expectations, and decision-making in healthcare interactions).

Although the clinical population necessarily consists of individuals with the biological capacity for pregnancy, the study acknowledges that pregnant persons may identify across a range of gender identities. For this reason, gender-inclusive terminology (e.g., “pregnant individuals” alongside “women” where appropriate) is used throughout the protocol and data collection instruments, and participants’ self-identified gender will be recorded when provided. No individual will be excluded on the basis of gender identity. The study population is therefore appropriate to capture both sex-specific clinical factors and gender-based communicative dynamics, in line with current evidence on person-centered maternal care.

Because the study does not test a medicinal product or therapeutic intervention, no sex-based dose adjustments or physiological-based stratifications are applicable. However,

data will be disaggregated by age, parity, socio-economic background, and (where available) gender identity, in order to assess whether these variables influence:

1. perceived clarity and accessibility of the consultation,
2. patient understanding of the information received,
3. levels of satisfaction and comfort during communication.
4. Patient's decision about the VBAC.

Recruitment, participation, dropout, and loss-to-follow up will be reported disaggregated by sex and gender identity whenever possible. Inclusion and exclusion criteria (gestational age, clinical diagnosis, language proficiency) are based on clinical and methodological considerations and are not expected to introduce gender-related biases.

17. QUALITY ASSURANCE AND QUALITY CONTROL

The study will be conducted in accordance with the current approved protocol, GCP, relevant regulations, and standard operating procedures. Investigators involved in the study will permit study-related audits, EC review, and regulatory inspections by providing direct access to all study records.

Study audits can be conducted by or on behalf of CTC, according to OSR quality standards. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents. Following written standard operating procedures, the auditors will verify that the clinical study is conducted, and data are generated, documented, and reported in compliance with the protocol, GCP, and the applicable regulatory requirements.

The Investigator should notify the CTC promptly of any inspection scheduled by any regulatory authorities and will promptly forward copies of any inspection reports received.

The study will be conducted in accordance with the current approved protocol, Good Clinical Practice (GCP), institutional standard operating procedures (SOPs), and all applicable regulatory requirements. All investigators and study personnel will be trained on the protocol and study procedures prior to initiation.

No Contract Research Organization (CRO) is involved in this study. Study oversight and coordination will be performed directly by the Reasearch team.

Study documentation, including source documents and electronic study records, will be made available for study-related monitoring activities, audits, Ethics Committee (EC) review,

and regulatory inspections. Data will be reviewed periodically to ensure completeness, internal consistency, and compliance with the approved protocol.

The Investigator will promptly inform the CTC of any scheduled inspection by regulatory authorities and will provide copies of any findings or reports received.

17.1. Deviation from study protocol

A deviation from the protocol is an unintended departure from the procedures or processes described in the protocol and approved by the EC.
The Investigator or designee must document and explain in the patient's source documentation any deviation from the approved protocol.
Every deviation from the study protocol must be specified and documented separately for each patient. The investigator should discuss the type and extent of deviation as well as the possible consequences for further participation of the patient in the study.

17.2. Surveillance for observational studies with additional procedure

N/A

18. FINANCE AND INSURANCE

18.1. Funding

N/A

18.2. Patient Insurance

Not necessary.

19. END OF CLINICAL STUDY

In accordance with applicable regulation, ICH GCP and SOPs, the PI shall notify the end of the clinical study within 15 days from the end of the clinical study and the reasons for such action.

19.1. Summary of the results of the clinical study

Irrespective of the outcome of a clinical study, within one year from the end of a clinical study, the PI shall submit a summary of the results of the clinical study.

20. INTELLECTUAL PROPERTY

The data intellectual property will be held by the OSR and UNISR for at least 25 years after the completion or discontinuation of the study.

21. PUBLICATION POLICY

Scientific dissemination of the study results (in anonymised form) will include publication in international peer-reviewed journals and presentation at national and international scientific conferences. Authorship will be determined according to standard scientific and ethical authorship criteria, taking into account: (1) contribution to the study design and conceptualisation; (2) participation in writing the study protocol; (3) involvement in data collection and/or data analysis; and (4) contribution to drafting and revising the manuscript.

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23. APPENDIX A: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Rationale	Study status	Details of Changes
1	1.1	14/05/2026	Clarification of data collection	Not yet recruiting	Modified the procedures regarding the collection of informed consent;

			procedures and data analysis procedures		added specifications concerning the personal information of healthcare professionals involved in the study to be collected, as well as the presence of the external observer during the consultation and the analysis procedures, through the addition of Appendix E..

24. APPENDIX C: LIST OF ENROLLING SITES

N/A

25. APPENDIX D: SSI-CLAR Semi-Structured Interview on Communicative Clarity in Medical Consultations

The following are some of the guiding questions that will be used during the semi-structured interview:

1. How do you view your communication with the doctor?
2. Has the doctor been thorough in communicating with you?
3. Were all of your questions answered, or do you feel you have any doubts left?
4. Was the language used understandable?
5. Do you agree with the following statement: *"Trust is the foundation of the doctor–patient relationship"*?
6. What are the criteria on which you decided to trust the doctor? Could you identify any key moments during the interaction?
7. In your opinion, when does a physician give his/her trust to the patient? In your specific case, when did this occur?
8. Following the conversation you just had, do you think she will opt for a vaginal delivery?

Since one of the criteria to participate to the study is to speak italian, the questions will be asked in italian:

1. Come valuta la comunicazione avuta con il medico?

2. Il medico è stato esaustivo nel comunicare con lei?
3. Tutte le sue domande hanno ricevuto risposta oppure ritiene di avere ancora dei dubbi?
4. Il linguaggio utilizzato è stato comprensibile?
5. È d'accordo con la seguente affermazione: "La fiducia è la base del rapporto medico-paziente"?
6. Quali sono i criteri in base ai quali ha deciso di fidarsi del medico? Riesce a individuare momenti chiave durante l'interazione?
7. Secondo lei, quando un medico concede fiducia al paziente? Nel suo caso specifico, quando è avvenuto?
8. A seguito del colloquio appena avuto, pensa che opterà per il parto vaginale?

26. APPENDIX E: Summary table of the TouCAN CodeBook

Textual Misunderstanding					
	Technical Jargon	**Medical Lexicon vs Common Lexicon**	**Treatment Plan Misunderstanding**	**Procedural Misunderstanding**	**Elusive Communication**
Explicit Textual Misunderstandings	*Definition*: The use of medical jargon, i.e., a highly specialised term by the healthcare professional that is not entirely understandable to the patient or	*Definition*: One of the two speakers implies a word used in everyday, non-specialized language but carries a different meaning in a specialized context, with a different	*Definition*: The patient explicitly asks for clarification about the physician's proposed therapeutic plan. *Direction*: patient →	-	-

	caregiver, but they explicitly ask for clarification about an unfamiliar specialised term. The healthcare professional provides the clarification. *Direction*: patient → healthcare professional. *Example*: Physician: it is a kind of tumour, but it is not like that, I mean, it is a diagnosis that… Patient: **Tumor and cancer, are**	meaning than the one intended by the recipient, but one of them asks for clarification. *Direction*: healthcare professional ↔ patient. *Example*: Patient: **Lesion…what does it mean?** ‘Cause… Physician: A lesion…a small ball… Patient: Ah…because when I hear “lesion” I may think about something that…that	healthcare professional *Example*: Patient: **But now for my problem…?!** Partner: He has already said that now there is chemo, and then… Patient: Ah, chemo…		

	they the same things? Physician: They are not, but forget the words now and follow me.	opens…like a wound. Physician: Lesion…lesion …a neoplasm, ok?			
Implicit Textual Misunderstandings	*Definition*: The use of medical jargon, i.e., a highly specialised term by the healthcare professional that is not entirely understandable to the patient or caregiver, but no one signals the ambiguity generated.	*Definition*: One of the two speakers implies a word used in everyday, non-specialized language but carries a different meaning in a specialised context with a different meaning than the one intended by the recipient, but no one signals the	*Definition*: The patient inquires about the physician's proposed therapeutic plan. *Direction*: patient → healthcare professional. *Example*: Physician: Ok, so now we can give you the prescriptions	*Definition*: The patient inquires about the next therapeutic steps, especially administrative procedures. *Direction*: patient → healthcare professional. *Example*: Patient: Since you told me that **you had**	*Definition*: It occurs when the doctor answers a patient's question without directly or pertinently addressing its content, instead shifting focus to a different topic or giving a generic response. *Direction*: healthcare

	Direction: patient → healthcare professional. *Example*: Patient: So, I thought that being an **experimental program** with rigid procedures… Physician: No, wait, the exams you took have nothing to do with the experimental program […] We are not doing experimental chemotherapy here.	ambiguity generated. *Direction*: healthcare professional ↔ patient. *Example*: Physician: Ok, any **allergies**? Partner: Yeah some seasonal allergies. Physician: Oh no, let's say allergies to drugs.	and organise everything. Patient: Thank you. So, if we have good results **you will try the surgery**, right? Physician: No, I have never talked about surgery, madam, no.	**already booked the appointment** … Physician: No, we give you the prescription, we cannot book the appointment for you.	professional → patient [1 exception]. *Example*: Patient: If we find out that I have this Gilbert's syndrome that doesn't allow me to take some chemos…**can I be included in another study with other drugs or…?** Physician: We will give you the standard treatment, I mean, the two treatments we are talking about are both standard treatments.