

D7.3 Patient empowerment

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Deliverable nature	Report (R)
Dissemination level	Public (PU)
Delivery date	30-04-2026
Version	1.0
Total number of pages	49
Keywords	Patient empowerment, AI acceptability

EXECUTIVE SUMMARY

This study aimed to assess the acceptability of artificial intelligence (AI) as a support tool in prostate cancer diagnosis and to identify the conditions under which its implementation is considered acceptable by patients and healthcare professionals. We employed a mixed-method design, combining a quantitative survey with $n=58$ patients (51 from Belgium and 7 from Italy) and a qualitative phase (interviews and focus groups) involving both patients ($n=16$) and physicians ($n=11$). Overall, the results indicate a generally positive yet cautious context for the integration of AI in clinical practice. Acceptance of AI is not unconditional and is shaped by multiple forms of uncertainty related to knowledge, responsibility, and the organization of roles within the patient–physician relationship.

Quantitative findings (patients only)

The quantitative phase shows that patients generally perceive AI as beneficial. A majority of respondents believe that AI can improve prostate cancer diagnosis, enhance the diagnostic process, and contribute to greater efficiency. Perceived benefits consistently outweigh perceived risks, and strong negative attitudes toward AI are relatively rare.

At the same time, behavioural intention to use AI in the diagnosis remains divided. While a substantial proportion of participants report willingness to use AI-based tools, an almost equally large group expresses uncertainty. Only a small minority explicitly rejects AI. This pattern suggests that attitudes toward AI are not polarized but rather characterized by conditional acceptance. Importantly, this uncertainty emerges in a context of high trust in healthcare systems and generally positive prior healthcare experiences. This indicates that the introduction of AI creates a new layer of uncertainty within an otherwise stable and trusted environment.

The analysis of concerns further shows that hesitation is not primarily driven by general distrust of technology. Instead, the most prominent concerns relate to the potential reduction of the human dimension of care, including fears of diminished interaction and reduced patient involvement in decision-making. Additional concerns relate to diagnostic reliability and governance issues, such as responsibility in case of errors and the clarity of regulatory frameworks.

Another aspect, willingness to share health data is generally high but strongly conditional. Participants emphasize the importance of privacy protection, clear limitations on data use, and trust in the institutions handling the data.

Qualitative findings (patients and physicians)

The qualitative analysis was conducted to unpack and further interpret the uncertainties identified in the quantitative phase. Three interrelated dimensions of uncertainty were identified: epistemic, ethical, and uncertainty related to social roles. These dimensions are connected through the central role of trust as a mechanism for managing complexity in medical decision-making.

Epistemic uncertainty concerns the status and reliability of AI-generated knowledge. Physicians question the quality, validity, and limits of AI outputs and emphasize the need for measurable performance indicators, validation procedures, and contextual interpretation. AI is not perceived as an autonomous source of knowledge but as a tool that requires human verification. For patients, epistemic uncertainty is primarily related to interpretation rather than accuracy. Medical information, including AI-generated outputs, is not considered meaningful in itself but becomes relevant only when explained by a physician. This highlights the importance of the physician as an intermediary in the production of understandable and trustworthy knowledge.

Ethical uncertainty is centered on responsibility, potential harm, and the conditions of acceptable AI use. Both patients and physicians strongly converge on the expectation that responsibility must remain with the physician, regardless of the use of AI. AI is not perceived as an actor capable of bearing responsibility. An important finding concerns the asymmetry in the perception of errors:

patients are more willing to accept errors made by physicians than those produced by AI. This reflects the role of the physician as a responsible agent who can explain and justify decisions. Ethical acceptability is therefore closely linked to maintaining human responsibility and control.

Uncertainty related to social roles addresses the potential transformation of roles within the patient–physician relationship. Physicians tend to reflect on possible changes in their professional role, including new tasks and interactions with AI. In contrast, patients emphasize the importance of preserving existing roles, particularly the central role of the physician.

Across both groups, there is a strong consensus that AI should function as a support tool rather than as a replacement for human expertise. The relational dimension of care — including communication, empathy, and the ability to adapt to individual patients — is considered essential and non-replaceable. At the same time, AI is seen as having the potential to reduce technical workload and thereby free up time for patient interaction.

Integrated interpretation

Taken together, the findings show that AI is not rejected but accepted conditionally. Acceptance depends less on the intrinsic characteristics of the technology and more on the conditions under which it is implemented.

A key transversal insight is that trust does not emerge directly from AI itself but from the framework in which it is embedded. This framework includes the presence of a responsible physician, the availability of validated and reliable outputs, and the possibility of explanation and dialogue with patients.

The results therefore suggest that the successful integration of AI in healthcare depends not only on technical performance but also on its alignment with existing epistemic standards, ethical principles, and social role configurations within the patient-physician relationship.

AI is accepted insofar as it supports these structures and remains under human control. Conversely, it becomes problematic when it is perceived as undermining responsibility, interpretability, or the human dimension of care.

DOCUMENT INFORMATION

Grant agreement No.	101095382	Acronym	FLUTE
Full title	Federate Learning and mUlti-party computation Techniques for prostatE cancer		
Call	HORIZON-HLTH-2022-IND-13-02		
Project URL	https://cordis.europa.eu/project/id/101095382		
EU project officer	Nihal YILDIRIM		

Deliverable	Number	D7.3	Title	Patient empowerment report
Work package	Number	WP7	Title	Collaboration, dissemination and exploitation
Task	Number	T7.3	Title	Patient empowerment

Date of delivery	Contractual	M36	Actual	M36
Status	version 1.0 <input checked="" type="checkbox"/> Final version			
Nature	<input checked="" type="checkbox"/> R <input type="checkbox"/> DEM <input type="checkbox"/> DMP <input type="checkbox"/> DEC <input type="checkbox"/> ETHICS <input type="checkbox"/> OTHER			
Dissemination level	<input checked="" type="checkbox"/> Public <input type="checkbox"/> Sensitive			

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Summary (for dissemination)	<i>This deliverable presents findings from a mixed-method approach combining a patient survey and qualitative interviews and focus groups with patients and physicians. Results show that AI in prostate cancer diagnosis is generally perceived positively but accepted conditionally. Patients and physicians view AI as a support tool rather than a replacement for human expertise. Its acceptability depends on trust, clear physician responsibility, reliable outputs, and preserving the human dimension of care.</i>
Keywords	<i>Patient empowerment, AI acceptability</i>

VERSION LONG			
Issue Date	Rev. No.	Author	Change
19-02-2026	0.1	Ekaterina Koshmanova	First draft
24-03-2026	0.2	Ekaterina Koshmanova	Added results, conclusions summary, references
28-04-2026	1.0	Ekaterina Koshmanova	Final version incorporating reviewers' comments

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1 Introduction

Artificial intelligence (AI) is increasingly integrated into clinical medicine to support diagnostic and decision-making processes across diverse healthcare settings (Hirosawa & Shimizu, 2025) and has the potential to enhance diagnostic accuracy, standardize interpretation of complex clinical data, and optimize patient care, while also reshaping workflows in healthcare systems (Topol, 2019).

Yet, the translation of AI systems from research environments into routine clinical practice remains challenging. Beyond technical performance, AI adoption is constrained by practical and ethical barriers, including data privacy, algorithmic bias, limited interpretability, workflow integration challenges, and concerns regarding accountability and patient consent (Aravazhi et al., 2025).

To address these challenges, privacy-preserving approaches such as federated learning have emerged, enabling collaborative model training across institutions without transferring raw patient data. By maintaining data locally while aggregating model updates, federated learning supports multi-centre AI development in compliance with data protection regulations and institutional requirements (Bartusik-Aebisher et al., 2026). Several recent European research initiatives, including the FLUTE project, have adopted such federated paradigms to develop and validate AI tools for clinical use.

However, even when technical and regulatory challenges are mitigated, successful implementation of AI into clinical practice ultimately depends on stakeholder acceptance. In general healthcare contexts, patients express positive attitudes toward AI, tempered by concerns about data privacy, transparency, accountability, and the preservation of human-centred care (Frost et al., 2024; Moy et al., 2024; Young et al., 2021). Among healthcare professionals, AI acceptance is shaped by task type, perceived clinical value, and anticipated impact on professional roles and responsibilities (Antes et al., 2021; Hua et al., 2024), and may be limited by distrust in AI and unclear regulatory standards (Hsieh, 2023). In (Asan et al., 2020) the authors identified key factors shaping trust in AI as a central psychological mechanism influencing physicians' willingness to use it—such as perceived reliability, interpretability, and prior experience—which are critical for successful AI integration into clinical workflows. Patients' trust, in turn, depends more on the patient-physician relationship and increases when AI operates under clear physician supervision (Esmailzadeh, 2020; Lennartz et al., 2021). Patients are therefore willing to consider AI as an assistive tool if human interaction is preserved, data transparency is ensured, and privacy is protected (Gundlack et al., 2025). Extending these findings, an integrative review of hospital-based AI implementation emphasizes the importance of organizational readiness, training, infrastructure, and concerns regarding professional autonomy as critical determinants of sustainable adoption (Lambert et al., 2023).

Given the increasing application of AI in prostate cancer diagnostics, it is essential to evaluate the acceptability of these tools among both patients and healthcare professionals, who are the ultimate end-users, as well as the conditions and barriers that may influence successful implementation in this specific clinical context. In prostate cancer, AI-assisted imaging and predictive models can enhance imaging analysis and cancer detection (Talyshinskii et al., 2024; Tun et al., 2025), improve detection of clinically significant tumours and optimize biopsy decisions (Morote et al., 2022). Such

approaches aim to enhance risk stratification while reducing unnecessary invasive procedures like biopsy, thereby improving the overall efficiency of the diagnostic pathway (Zhang et al., 2026).

Recent studies examining patient perspectives on AI in prostate cancer care indicate that trust and acceptance are higher when AI functions as a supportive tool alongside clinicians rather than autonomously (Fransen et al., 2025; Rodler et al., 2024). Focus group research further shows that men's expectations of AI combine hopes for improved diagnostic accuracy with concerns about patient-physician communication, with acceptance varying depending on whether AI is perceived as a tool, an advanced machine, or a replacement for the physician (Lysø et al., 2024). Additionally, it has been shown that prostate cancer patients with higher education and greater understanding of AI's potential are more likely to engage with AI based interventions, emphasizing the importance of patient education and communication to foster acceptance (Manolitsis et al., 2023).

Although a growing body of research has examined acceptability of AI in healthcare both in general and in the context of prostate cancer, most existing research investigates patients or clinicians separately, leaving a gap in understanding joint perceptions in real-world prostate cancer diagnostic workflows. These gaps highlight the need for context-specific, mixed-methods studies assessing AI acceptability among both patients and healthcare professionals in prostate cancer diagnostics.

Furthermore, understanding joint perceptions of AI in prostate cancer diagnostics is particularly important because these attitudes directly influence clinical interactions, decision-making processes, and the degree to which AI can be effectively integrated into patient care. In this context, examining patients' trust in their physicians and the healthcare system, the role of AI in supporting shared decision-making, and its potential to empower patients becomes essential to ensure that technological tools enhance patient-centred care and complement rather than disrupt the patient-physician relationship.

Patient-centred care has been conceptualized as an approach that promotes patient empowerment, autonomy, and active participation in care processes, including involvement in decision-making about diagnosis and treatment (Pulvirenti et al., 2014). However, involvement in the decision-making process exposes both clinicians and patients to uncertainty, as they must navigate complex information, probabilistic outcomes, and inherent limitations of medical knowledge. Clinicians routinely manage such uncertainty in their practice (Engebretsen et al., 2016; Greenhalgh, 1999), but when patients seek to actively participate in decisions, they encounter these same challenges firsthand.

As digital technologies and AI are increasingly introduced into clinical practice, traditional principles of clinical decision-making are challenged and reconfigured, as new forms of decision support influence how information is interpreted, how uncertainty is communicated, and how responsibility is shared between patients, healthcare professionals, healthcare institutions, and technological systems. While many studies focus on technical uncertainty, addressed through methods such as uncertainty quantification in prostate cancer imaging (Taguelmimt et al., 2025; Wahid et al., 2024), uncertainty in AI also extends to human and social dimensions. This includes how patients and healthcare professionals interpret and integrate AI recommendations, negotiate responsibility and agency, and manage communication in shared decision-making. AI can reduce certain forms of

uncertainty, particularly those related to limited information or cognitive constraints (Alli et al., 2024), but it may also introduce new uncertainties in decision-making processes. Prostate cancer screening and early treatment decisions are paradigmatic cases for shared decision-making, as benefits and harms vary by individual risk tolerance and values (Barry & Edgman-Levitan, 2012).

In light of these considerations, understanding both AI acceptance and the human and social dimensions of uncertainty is central to investigating how patients and healthcare professionals engage with AI in prostate cancer diagnostics. Despite rapid progress and growing evidence of the diagnostic effectiveness of AI in this field, a significant gap remains in understanding which factors facilitate or hinder the adoption of these technologies among stakeholders, particularly patients awaiting a diagnosis. Therefore, **the first objective** of this study was to assess the level of AI acceptance in prostate cancer diagnostics and identify key factors influencing the willingness of both patients and healthcare professionals to use such technologies in clinical practice. Moreover, while AI systems promise greater precision and risk stratification, they may also reshape how uncertainty is communicated and negotiated between patients and physicians. Accordingly, **the second objective** focused on how patients and healthcare professionals conceptualize and manage these human and social uncertainties in AI-supported prostate cancer diagnosis.

2 Objectives and research questions

General objective

To understand the acceptability of AI as support to healthcare providers in prostate cancer diagnosis, the willingness to provide data for clinical AI development, and the conditions for implementation that preserve or enhance the patient–physician relationship.

Specific objectives

- Determine acceptability of people with localized prostate cancer regarding AI-supported diagnosis and explore implementation conditions.
- Determine willingness to provide health data for clinical AI development and explore the conditions for this willingness.
- Explore acceptability of AI among healthcare professionals involved in prostate cancer diagnosis and identify perceived conditions and concerns.
- Describe the current patient–physician relationship in prostate cancer management and identify how AI could support this relationship.

Research questions

- What is the overall acceptability of AI as support in prostate cancer diagnosis among patients, and what factors explain variability?
- Which perceived risks (e.g., errors, privacy, loss of human contact) and benefits (e.g., accuracy, reassurance, speed) dominate attitudes?
- Under which governance conditions do patients accept providing health data for AI development?
- How do patients and healthcare professionals describe trust, communication, and responsibility in the diagnostic pathway?
- Which implementation conditions are required so that AI supports (rather than undermines) the patient–physician relationship?

3 Conceptual and theoretical frameworks

3.1 Acceptability of AI: constructs and determinants

The concept of acceptability of clinical AI is multifaceted and is not fully captured by generic technology acceptance models. For this project, acceptability is understood as a combination of perceived benefits, perceived risks, conditions of use, and the behavioural intention to accept AI-supported services in the prostate cancer diagnostic pathway.

Key determinants considered across the project include: perceived value (benefit–risk balance), trust in healthcare systems, social influence, prior exposure to similar tools, digital and health literacy, perceived technical knowledge, and the clarity of information provided about AI (intervention coherence).

3.2 Core dimensions shaping acceptability of AI

In line with the objectives of the study, acceptability of AI was approached as a multidimensional construct encompassing several interrelated dimensions that are recurrently discussed in the literature on AI in healthcare and patient perspectives on diagnostic technologies.

Key dimensions considered in this project include:

- Perceived benefits, such as improved diagnostic accuracy, better decision-making, increased efficiency of the diagnostic process, and potential reduction of unnecessary procedures;
- Perceived risks and uncertainties, including concerns about diagnostic errors, unexpected consequences, loss of control, and overall uncertainty associated with AI-supported clinical decisions;
- Conditions of use, referring to the circumstances under which AI is considered acceptable, such as the presence of healthcare professional oversight, clarity of responsibility, transparency, and appropriate regulatory safeguards;
- Social context and influence, including perceived attitudes of healthcare professionals and significant others toward the use of AI in prostate cancer diagnosis;
- Individual and contextual factors, such as trust in healthcare systems, prior exposure to digital or AI-based health technologies, perceived technical knowledge, and levels of health and e-health literacy.

Together, these dimensions provide a conceptual basis for understanding how patients evaluate AI as a support tool in the diagnostic pathway, without assuming that acceptability is driven by a single factor.

Willingness to provide health data

Willingness to provide health data for the development of clinical AI was considered as a related but distinct concept. While closely connected to acceptability of AI use in care, willingness to provide data reflects additional considerations linked to data governance, privacy, and trust.

In this project, willingness to provide health data is conceptualised as the balance between perceived benefits of data sharing for medical progress and improved care, and perceived risks related to confidentiality, misuse of data, and loss of control over personal information. This balance is shaped by the conditions under which data sharing is proposed.

These conditions include expectations regarding anonymisation, purpose limitation, transparency about data users, and the existence of appropriate governance and oversight mechanisms.

Understanding these conditions is essential, as willingness to provide data is not necessarily unconditional and may vary depending on how data use is framed and regulated.

3.3 Conceptual anchors for the qualitative phase: the patient–physician relationship

The qualitative phase of the study was anchored in conceptual models of the patient–physician relationship described in the medical and ethical literature, including paternalistic, informative, interpretive, and deliberative models. These models describe different ways in which decision-making authority, information exchange, and responsibility are distributed between patients and physicians.

These concepts were used as sensitising frameworks to explore how patients and healthcare professionals describe their current experiences of prostate cancer management, and how the introduction of AI as a diagnostic support tool might influence trust, communication, responsibility, and shared decision-making.

The qualitative phase also considered how the integration of new actors, such as digital tools and AI systems, may reshape traditional patient–physician relationships. This conceptual perspective supports a nuanced exploration of the conditions under which AI may support, rather than undermine, the relational dimensions of care.

4 Study design and overall approach

4.1 Design overview

The project is a cross-sectional observational, mixed-method sequential study with two linked phases. The quantitative phase provides a structured measurement of acceptability and willingness to provide data. The qualitative phase provides in-depth exploration of experiences and conditions, with particular emphasis on the patient–physician relationship.

4.2 Multinational setting

The study recruited participants in Belgium, Italy, and Spain. Each country followed local regulatory requirements and, where required, submitted study documents to the relevant ethics committee.

4.3 Overview of study workflow

- Submission of the protocol and supporting materials to the Ethics Committee
- Preparation of recruitment materials and REDCap instruments.
- Quantitative recruitment and data collection via self-administered online questionnaire.
- Optional collection of contact details in a separate instrument for those interested in qualitative participation.
- Development/refinement of qualitative interview guides based on literature on patient–physician relationship dimensions.
- Qualitative recruitment of patients and healthcare professionals; conduct of interviews and/or focus groups.
- Transcription and pseudonymisation; consolidation of datasets.
- Quantitative analysis, qualitative thematic analysis, and mixed-method integration.

5 Quantitative phase: methods

5.1 Population

Target population: adults with localized prostate cancer in participating countries.

Inclusion criteria: age \geq 18 years, localized prostate cancer diagnosis, informed consent

Exclusion criteria: inability to participate in the required language, metastatic disease at diagnosis, terminal illness, major cognitive impairment

5.2 Sampling strategy and sample size rationale

A volunteer sampling strategy was used. A formal statistical sample size calculation was not performed due to feasibility constraints and the multinational recruitment approach. The target was to recruit a minimum (50) and maximum (100) number of participants per country as defined in the protocol, balancing feasibility and the need for variability in participant characteristics.

Given the exploratory nature of acceptability determinants in a specific context, the emphasis was placed on collecting sufficiently diverse responses across countries and patient profiles, rather than on achieving a single powered hypothesis test.

5.3 Recruitment channels and procedures

- Posters and flyers (link + QR code) displayed in urology departments of the participating hospital network.
- Social media dissemination using visual materials adapted for online sharing.
- Distribution through patient associations (networks, mailing lists, facilities).
- Where authorised locally: direct invitation of eligible patients identified through hospital records (e.g., patients who underwent prostatectomy in a defined period).

Recruitment materials described the study purpose, voluntary participation, confidentiality, and how to access the questionnaire. Assistance could be provided to participants for accessing the online form (e.g., availability of a tablet/laptop), without influencing responses.

5.4 Data collection platform and instrument structure

The questionnaire was implemented using the REDCap platform, which is a software package designed for the overall management of studies, and which meets the regulatory requirements for health study hosts and supervised by the Clinical Trial Centre from CHUL. It also enables secure data capture with eligibility logic and validation rules. Participants first accessed an information and consent section. Consent was operationalised through mandatory statements that needed to be confirmed to proceed. Eligibility screening then ensured inclusion/exclusion criteria were met before the questionnaire sections were displayed.

A separate, unlinked REDCap form collected contact details for participants who volunteered to be contacted for the qualitative phase.

5.5 Questionnaire structure and analytical dimensions

The quantitative phase aimed to document patients' perceptions of AI as a support for healthcare providers in the diagnosis of prostate cancer. Data were collected using a structured questionnaire developed on the basis of existing literature on AI in healthcare and adapted to the prostate cancer diagnostic context.

The questionnaire covered several analytical dimensions reflecting key aspects of patients' perceptions:

- Understanding and perceived usefulness of AI in prostate cancer diagnosis, including perceived contribution to diagnostic accuracy, improvement of the diagnostic process, and potential cost reduction;
- Perceived risks and uncertainties associated with AI-supported diagnosis, such as uncertainty, unexpected consequences, potential losses, and overall likelihood of undesirable outcomes;
- Attitudes toward the use of AI-based tools, including willingness, uncertainty, or reluctance to use AI in the management of prostate cancer diagnosis;
- Specific concerns associated with uncertainty or reluctance, including fears related to diagnostic errors, reduced human interaction, decreased patient involvement in decision-making, data confidentiality, trust in AI systems, regulatory clarity, responsibility in case of errors, and potential increases in healthcare costs;
- Perceived social influence, including perceived expectations of significant others and healthcare professionals regarding the use of AI in prostate cancer diagnosis.

These dimensions were assessed using closed-ended questions, Likert-type scales, and conditional follow-up items, allowing a structured description of patients' perceptions.

Willingness to provide health data for AI development

The questionnaire also included a dedicated section addressing participants' willingness to provide their health data for the development of AI in the medical field.

Participants were asked whether they would agree to make their health data available for AI development, whether such agreement would be unconditional or dependent on specific conditions, and which conditions they considered important. Additional questions explored participants' perceptions of the risks and benefits associated with providing health data for this purpose.

This section provided insight into attitudes toward data provision and into the conditions under which participants consider data sharing acceptable.

Individual and contextual characteristics

To contextualise perceptions related to AI and data provision, the questionnaire collected information on participants' individual and contextual characteristics, including:

- sociodemographic variables (age, country of residence, education level, employment status, perceived household income);
- health-related context (self-rated health, treatment status, time since diagnosis, frequency of healthcare use);
- prior experience with AI-based health services;
- self-assessed technical knowledge and familiarity with AI;
- trust in healthcare institutions;
- health literacy and e-health literacy.

These variables were used to describe the study population and to support the interpretation of participants' responses.

Link with the qualitative phase

The quantitative findings informed the qualitative phase by identifying key perceptions, concerns, and conditions related to the use of AI in prostate cancer diagnosis. These elements were explored in greater depth during interviews and focus groups, with particular attention to communication, trust, responsibility, and the patient–physician relationship.

5.6 Participant code and withdrawal procedure

To support potential withdrawal while limiting identifiability, a structured participant code was used as described in the protocol. Participants could contact the principal investigator to withdraw consent, using this code to facilitate identification of their dataset record.

5.7 Data management, security and quality assurance

REDCap was used for secure storage and controlled access. Data exports were performed using role-based access permissions. Quality checks included: completion monitoring, missingness profiling, logic consistency checks, and review of free-text fields to remove inadvertent identifiers. An analysis dataset was created from raw exports and documented in an analysis log.

5.8 Statistical approach (overview)

Quantitative data were analysed using descriptive and exploratory statistics. Categorical and ordinal variables were summarized using frequencies and percentages. Acceptability of AI was measured as a three-level categorical variable (yes, yes under certain conditions, no). Given the small number of participants reporting non-acceptance of AI in their diagnostic pathway ($n = 5$) contrary to acceptance and uncertain acceptance, as well as unwillingness to share health data ($n = 5$), contrary to willingness ($n=28$) and willingness with conditions ($n=18$) regression analyses were not conducted for these outcomes. Quantitative analyses were thus restricted to descriptive statistics and exploratory association analyses.

Patterns of responses across survey domains (acceptability of AI, perceived benefits and risks, trust in AI and in healthcare professionals, familiarity with AI, and willingness to share health data) were examined to identify indications of uncertainty, such as conditional acceptance, coexistence of positive and negative expectations, and conditional data-sharing attitudes. These quantitative patterns were used to inform the qualitative phase and guided the development and refinement of the semi-structured interview guides.

Quantitative analyses were conducted using R software (version 4.5.0; R Foundation for Statistical Computing, Vienna, Austria).

6 Qualitative phase: methods

6.1 Design and rationale

The qualitative phase used semi-structured methods (focus groups and individual interviews) to deepen understanding of how AI should be implemented in prostate cancer diagnosis, with a focus on the patient–physician relationship.

Data were collected through both focus groups and individual interviews with people with prostate cancer, while healthcare professionals participated only in individual interviews.

The choice of format was guided by feasibility and participant availability while maintaining equivalent thematic coverage.

6.2 Study populations and eligibility

- adults with localized prostate cancer were eligible (criteria aligned with the quantitative phase).
- healthcare professionals involved in prostate cancer diagnosis and treatment (e.g., urologists, radiologists, radiotherapists) were eligible.

6.3 Sampling, sample size and saturation

Sampling was non-probabilistic and based on feasibility and information power. For each participant group, the planned number of participants was defined as a range (minimum to maximum), with the expectation that thematic saturation would be reached within this range. Data collection continued until thematic saturation was achieved, that is, until no substantially new themes emerged from successive interviews or focus groups.

Sessions typically lasted around one hour for individual interviews and up to one and a half hours for focus groups. Participants received a fixed compensation to cover costs related to participation, independent of the format of data collection.

6.4 Recruitment procedures

Patients were primarily recruited among those who expressed interest during the quantitative phase and agreed to be contacted via the separate contact form. Additional recruitment through clinical settings was used if needed. Healthcare professionals were recruited through targeted invitations and snowball sampling to reach diverse specialties involved in the diagnostic pathway.

6.5 Data collection tools and session conduct

Two semi-structured guides were developed, one for patients and one for healthcare professionals. Their development was informed by a targeted literature review on the patient–physician relationship and on AI acceptability factors.

The guides were iteratively refined over the course of data collection to incorporate emerging themes and to improve clarity and relevance of the questions. Sessions were moderated by a neutral facilitator and audio-recorded. Participants first completed a short characteristics questionnaire.

6.6 Topics covered

- Pathway experience (diagnosis to treatment): key moments, uncertainties, information needs.
- Communication and decision-making: roles, preferences, and perceived relationship model.

- Trust and accountability: expectations of physician responsibility and oversight.
- Perceived benefits and risks of AI: accuracy, reassurance, time, depersonalisation, overreliance, errors.
- Conditions for acceptable AI use: transparency, explanation, human control, performance communication, data governance.
- Impact of AI integration on the patient–physician relationship and on clinical decision-making: perceived changes in interaction, distribution of roles, and influence of AI on medical decisions.

6.7 Transcription, pseudonymisation and data storage

Audio recordings were transcribed and pseudonymised. Identifying details were removed or generalised during transcription. Transcripts and recordings were stored securely with restricted access. Any contact data used for scheduling were stored separately from research material.

6.8 Qualitative rigour and analytic process

All interviews and focus groups were audio-recorded and transcribed verbatim. Transcripts were analysed in the original language to preserve meaning and contextual nuance. Data were managed and coded using NVivo software (Lumivero, Version 15).

The analysis was conducted collaboratively by three researchers (EK, DK, and BV). Each transcript was independently coded by two members of the research team to enhance credibility, analytical consistency, and reflexive discussion. Coding discrepancies were resolved through team discussions until consensus was reached.

The analysis began with a theoretically informed coding framework derived from the study's focus on uncertainty. In the first stage, data were coded into four broad categories: epistemic uncertainty, ethical uncertainty, uncertainty related to social roles, and decisional uncertainty. This structure allowed systematic identification of how different forms of uncertainty were expressed within the patient–physician relationship in the context of AI-supported diagnosis.

As analysis progressed and findings were discussed in light of the quantitative results and the initial research question, it became apparent that trust functioned as a central, cross-cutting theme. Rather than appearing as a separate category, trust emerged as a mechanism through which participants managed complexity and uncertainty in clinical decision-making. Trust appeared to underpin shared decision-making processes, shaping how patients and physicians navigated uncertainty, balanced expertise and autonomy, and reached decisions together.

This led to a reorganization of the coding structure. The analytical focus shifted toward understanding decisional uncertainty in relation to trust, with three interconnected dimensions: epistemic uncertainty, ethical uncertainty, and uncertainty related to social roles. Conceptually, this reframing reflects the idea that clinical decisions rely on mechanisms of complexity reduction, primarily through trust, and that the introduction of AI tools in medical imaging may destabilize existing forms of epistemic, ethical, and role-based certainty.

In a subsequent phase, each researcher revisited previously coded segments to refine and develop subcategories within these domains. This stage was exploratory, and overlaps between categories were treated as analytically meaningful. Regular team meetings supported iterative refinement of the coding structure and ensured coherence between empirical material, emerging interpretations, and the study's overarching research question.

7 Ethical, regulatory and data protection considerations

Ethical approvals

The study was conducted only after the required ethics approvals were obtained. Each participating country followed its local requirements for submission and approval of the relevant phases.

Informed consent and participant rights

Participation was voluntary. Participants could withdraw at any time without consequences for their care or professional standing. Consent included information about the study purpose, procedures, data use, confidentiality, and recording (qualitative phase).

Confidentiality and GDPR compliance

Data were pseudonymised and access-restricted. Direct identifiers were stored separately from research data. Contact information collected for qualitative scheduling was separated from questionnaire responses. Data storage and processing complied with GDPR principles: lawfulness, fairness, transparency, minimisation, purpose limitation, security, and retention control.

Data retention and access governance

Retention periods and access rules are defined by institutional policies and approvals. Only authorised members of the research team have access to raw data. Any external sharing of de-identified datasets will require appropriate governance checks and approvals.

8 Results

8.1 Quantitative phase

This section presents the findings of the quantitative survey conducted among 58 patients (only fully completed questionnaires were retained for analysis). The results are organized into thematic domains corresponding to the structure of the questionnaire, including prior experience with AI, perceived risks and benefits, behavioural intention, data-sharing attitudes, and contextual factors influencing acceptance.

8.2 Sample Characteristics

The quantitative survey included 51 patients from Belgium and 7 patients from Italy. The mean age of respondents was 67.34 years (SD = 7.30). The majority of participants had completed non-university higher education (46.6%) or secondary education (34.5%). With regard to employment status, most respondents were retired (69.0%), reflecting the age distribution of the sample. Detailed demographic characteristics are presented in **Table 1**.

Table 1. Quantitative Sample Characteristics (N=58)

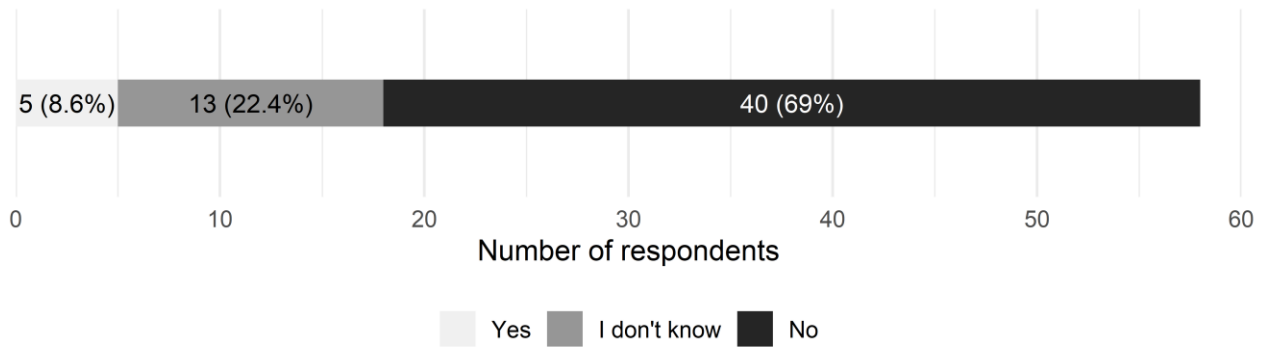
Variable	Category	n	%
Age (years)	Mean (SD)	67.34 (7.30)	—
Education level	Primary education	2	3.4
	Secondary education	20	34.5
	Non-university higher education	27	46.6
	University education	6	10.3
	PhD	3	5.2
Employment status	Retired	40	69.0
	Full-time employed	17	29.3
	Unemployed	1	1.7

8.2.1 Previous Experience and Healthcare Context

Among the 58 respondents, prior exposure to AI in diagnostic settings was limited. A majority (69%) reported no previous use of AI-based diagnostic tools, 8.6% indicated prior experience, and 22.4% were uncertain (**Figure 1**). This indicates that most participants evaluated AI in prostate cancer diagnostics without direct experiential reference. It should be noted that these responses reflect patients' self-reported awareness of AI use. Given the increasing integration of algorithmic systems

in clinical workflows, some respondents may have been exposed to AI-supported diagnostics without being explicitly informed.

Have you used AI in diagnostics before?

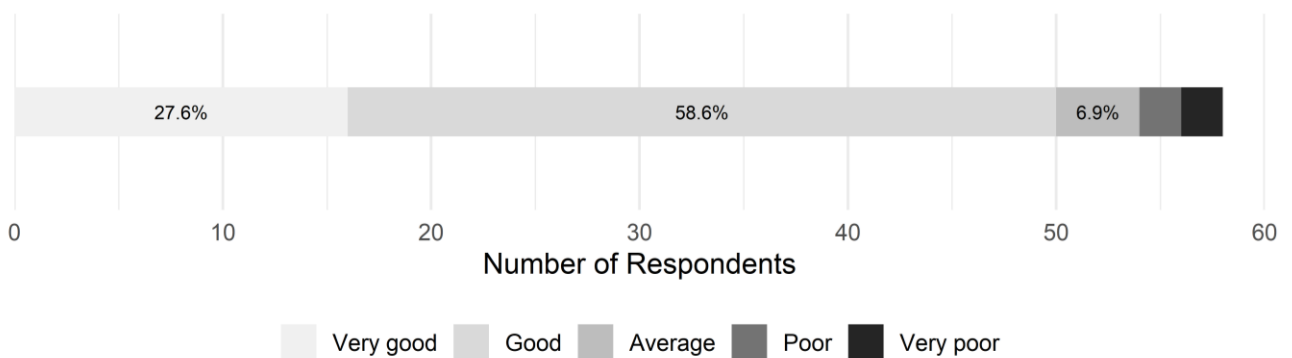


N = 58

Figure 1. Self-reported prior use of AI-based diagnostic tools (number and percentage of respondents)

At the same time, evaluations of previous healthcare experience were predominantly positive. In response to the question, “How do you evaluate your previous healthcare experience?”, more than 85% of respondents rated their experience as good or very good, while negative assessments were rare (**Figure 2**). Confidence in the healthcare system was correspondingly high. More than 70% of respondents agreed that healthcare institutions provide the best quality of medical care. A similar proportion agreed that, when treating medical problems, healthcare institutions place patients’ medical needs above other considerations, including costs (**Figure 3**).

How do you evaluate your previous healthcare experience?



N = 58

Figure 2. Previous healthcare experience

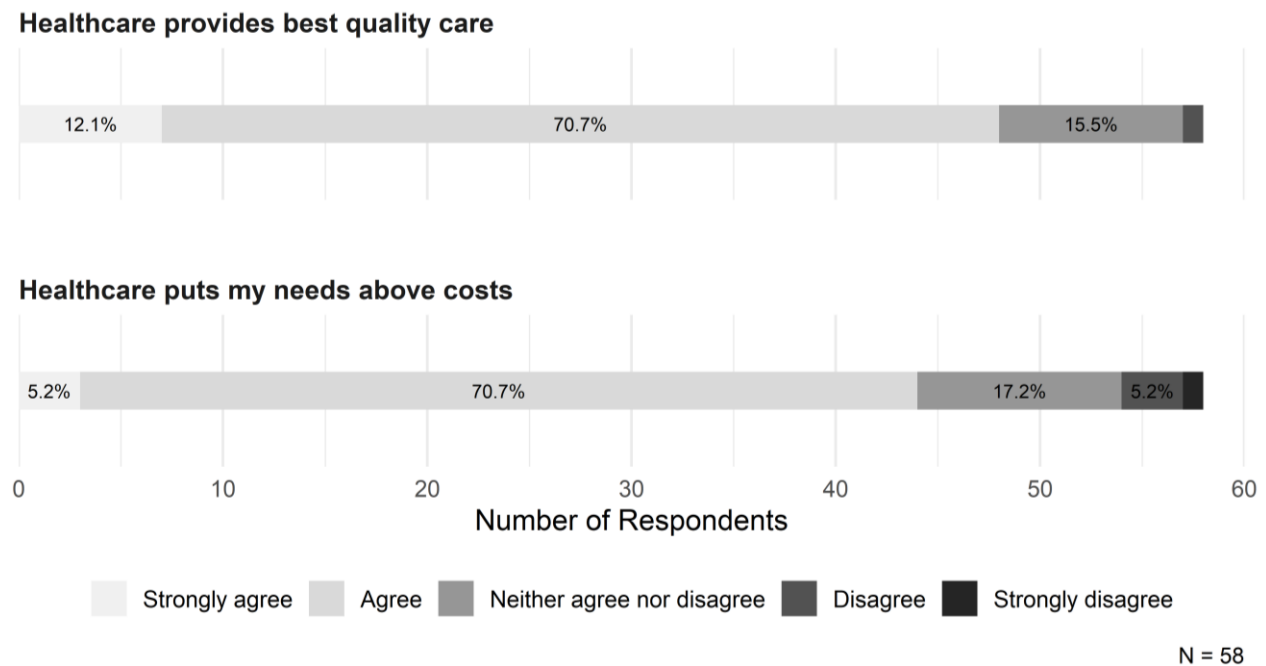


Figure 3. Confidence in healthcare system

The combination of limited experience with AI and high levels of trust in healthcare institutions raises an important question: why does uncertainty emerge when AI is introduced into an otherwise trusted healthcare context? Although respondents expressed strong confidence in conventional healthcare services, a noticeable proportion selected neutral or uncertain responses when evaluating AI-related items. This suggests that the introduction of AI creates a new layer of uncertainty within a generally confident environment.

The following sections therefore explore which specific aspects of AI—such as perceived risks, expected benefits, and potential changes in the patient-physician relationship—contribute to this emergence of caution and hesitation in an otherwise stable context of institutional trust.

8.2.2 Perceived Risks

Perceived risks associated with the use of AI-based tools in prostate cancer diagnostics were predominantly evaluated as moderate or low across all measured dimensions. When asked to assess the overall risk of using AI for diagnostic purposes, 41.4% of respondents selected “moderate,” while 24.1% and 25.9% rated the risk as “somewhat low” and “low,” respectively. Ratings of “high” or “very high” risk were reported by only a minority of participants (**Figure 4**).

Beyond the general risk assessment, respondents were asked to evaluate several distinct components of risk perception, including: (1) the degree of uncertainty associated with AI-based diagnostic tools, (2) the potential loss related to their use, (3) the probability of unexpected problems, and (4) the overall likelihood of adverse consequences. Across these dimensions, responses clustered primarily between “very low,” “low,” and “moderate.”

The degree of uncertainty was most frequently rated as moderate, indicating recognition of informational or situational ambiguity rather than perceived danger. Similarly, the potential loss associated with AI use was rarely considered high, suggesting that respondents did not anticipate severe negative outcomes in personal or clinical terms. The perceived probability of unexpected problems and adverse consequences followed a comparable pattern, with moderate ratings predominating and high-probability assessments remaining limited.

Taken together, the distribution of responses indicates that AI in prostate cancer diagnostics is not perceived as a high-risk technology by the majority of respondents. Instead, the findings reflect a calibrated and differentiated appraisal, in which uncertainty and potential drawbacks are acknowledged but not amplified into strong perceptions of threat. This pattern is consistent with cautious evaluation rather than categorical rejection.

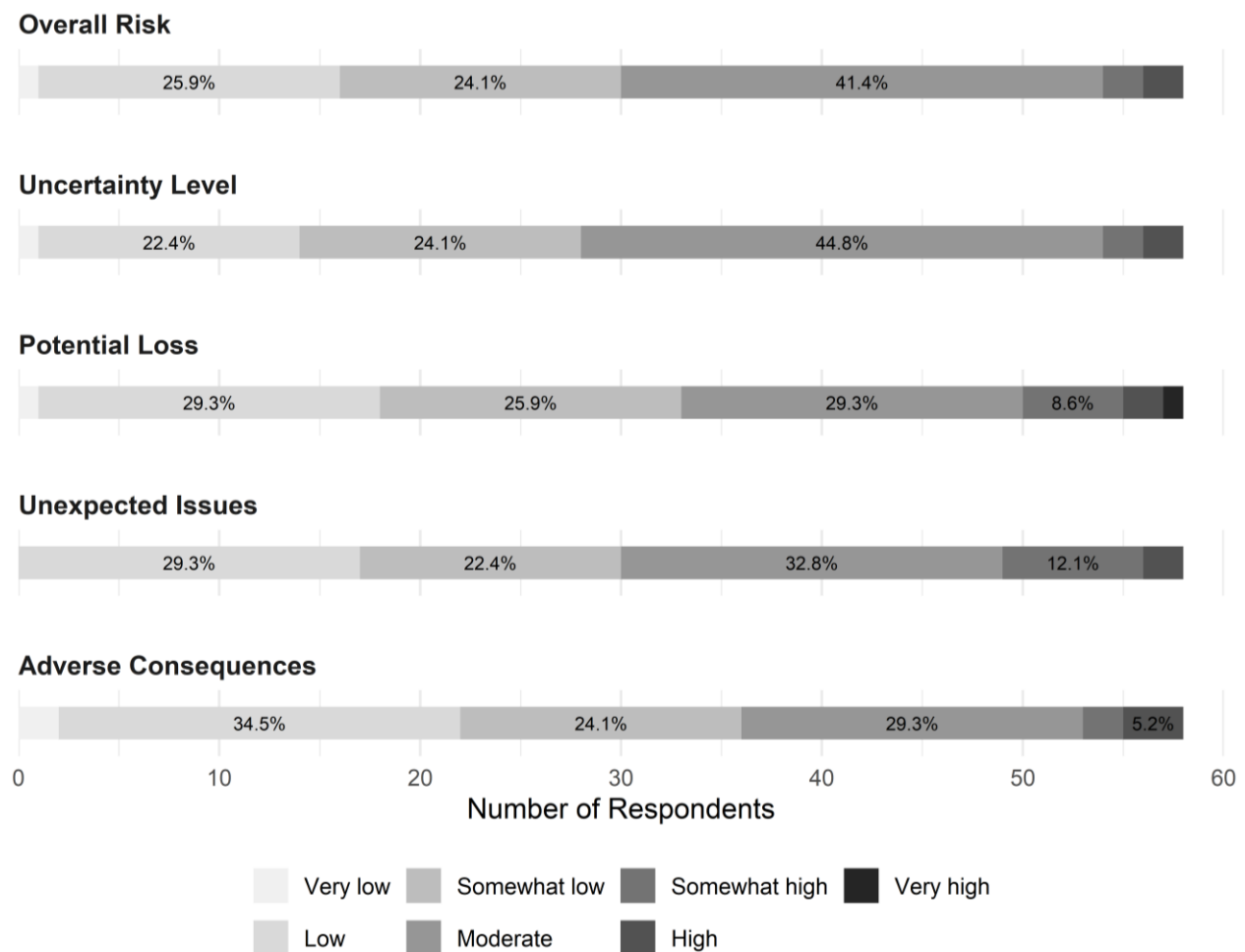


Figure 4. Perceived risk of AI in prostate cancer diagnosis

8.2.3 Perceived Benefits

In contrast to the multidimensional risk assessments described above, perceptions of potential benefits associated with AI-based diagnostic tools were consistently positive. Respondents evaluated several expected advantages, including improvement of prostate cancer diagnosis, advancement of the diagnostic process, diagnostic accuracy, and potential cost reduction.

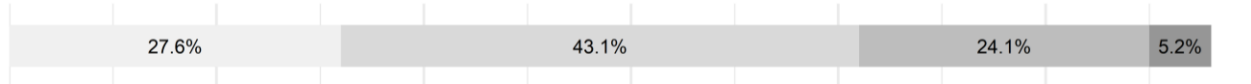
A substantial majority agreed or strongly agreed that AI could improve the diagnosis of prostate cancer (72.4%) and advance the overall diagnostic process (70.7%). Additionally, 62% of respondents considered AI capable of providing accurate diagnoses, while 56.9% agreed that AI implementation could contribute to reducing diagnostic costs (Figure 5).

I believe that tools based on artificial intelligence can:

Provide an accurate diagnosis of prostate cancer



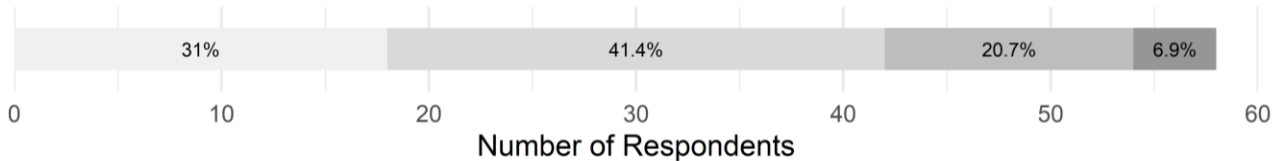
Advance the prostate cancer diagnostic process



Reduce the costs of prostate cancer diagnosis



Improve the diagnosis of prostate cancer



Strongly agree
 Somewhat agree
 Somewhat disagree
 Strongly disagree

Agree
 Neither agree nor disagree
 Disagree

N = 58

Figure 5. Agreement levels for AI benefits in prostate cancer diagnosis

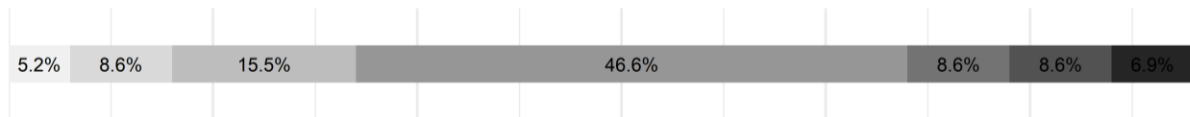
Across all benefit-related items, levels of disagreement were comparatively low, and neutral responses were less prevalent than in the risk assessment items. The distribution of responses indicates that expected performance gains—particularly in terms of diagnostic improvement and procedural advancement—are widely recognized.

Taken together, these findings suggest that perceived utility exceeds perceived risk. While respondents acknowledge elements of uncertainty and potential adverse consequences, anticipated improvements in diagnostic quality and efficiency appear to play a central role in shaping favourable expectations toward AI implementation in prostate cancer diagnostics.

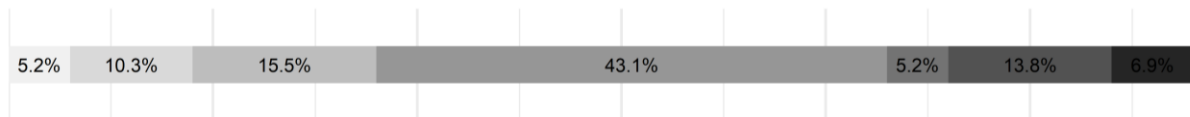
8.2.4 Social Influence

Perceived social endorsement of AI was moderate. Approximately 31% of respondents agreed that physicians support the use of AI in diagnostics, while around 26% perceived support within their social circles. However, a substantial share of participants selected neutral responses, indicating that social influence does not currently function as a strong determinant of acceptance (**Figure 6**).

My circle supports AI use



Important people endorse AI



Doctors support AI tools



Number of respondents

Strongly agree
 Somewhat agree
 Somewhat disagree
 Strongly disagree
 Agree
 Neither agree nor disagree
 Disagree

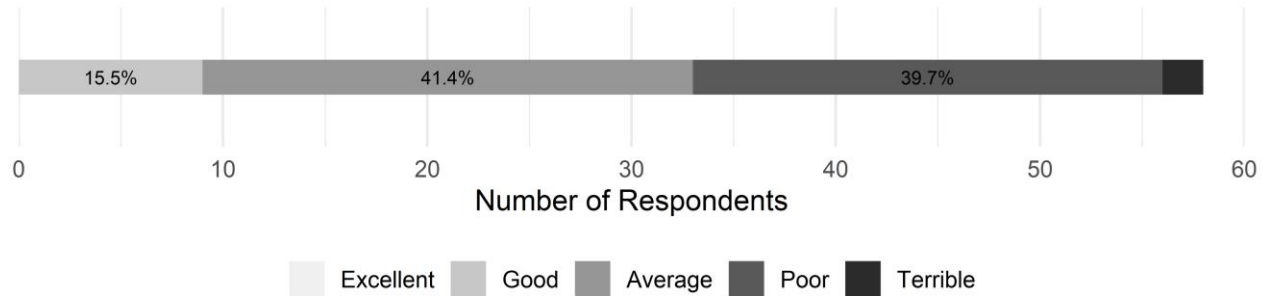
N = 58

Figure 6. Perceived social endorsement

8.2.5 AI Familiarity and Digital Competence

Self-assessed technical knowledge of AI was limited. The majority rated their knowledge as average (41.4%) or poor (39.7%), while only 15.5% reported good knowledge (**Figure 7**). General familiarity with AI concepts showed a similar distribution, with a considerable proportion indicating low or moderate familiarity (**Figure 8**).

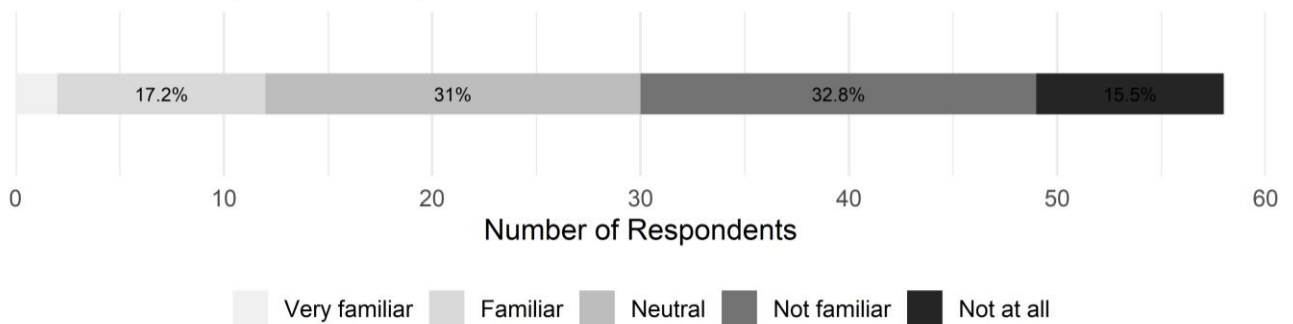
How do you evaluate your technical AI knowledge?



N = 58

Figure 7. Perceived technical AI knowledge

How familiar are you with the topic of AI?



N = 58

Figure 8. Perceived general AI familiarity

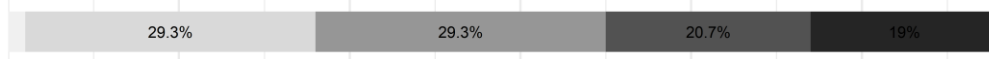
In contrast, indicators of eHealth literacy suggest functional digital competence. Between 43% and 50% of respondents agreed that they are able to find and use relevant health information online. Nevertheless, approximately one-fifth reported limited confidence in evaluating information quality, highlighting variability in critical digital skills (**Figure 9**).

EHealth literacy

I feel confident using information from the internet to make health decisions



I have the necessary skills to evaluate the health resources I find on the internet



I can distinguish high-quality from low-quality health resources on the internet



I know how to use the health information I find on the internet to help me



I know how to use the internet to answer my health questions



I know what health resources are available on the internet



I know where to find useful health resources on the internet



I know how to find useful health resources on the internet



0 10 20 30 40 50 60
Number of Respondents

Strongly agree Agree Neither agree nor disagree Disagree Strongly disagree

N = 58

Figure 9. Perceived EHealth literacy

Taken together, the results on social influence and AI familiarity provide additional context for understanding behavioural outcomes. Perceived social endorsement of AI was moderate rather than strong, suggesting that normative pressure in favour of adoption remains limited. At the same time, self-assessed AI knowledge and general familiarity were relatively low, indicating that many respondents evaluate AI from a position of partial understanding.

In contrast, eHealth literacy indicators suggest perceived digital competence, meaning that respondents are not digitally excluded but may lack specific AI-related knowledge. This combination—moderate social endorsement, limited AI familiarity, and adequate general digital competence—helps explain why uncertainty, rather than outright resistance, characterizes subsequent behavioural intentions.

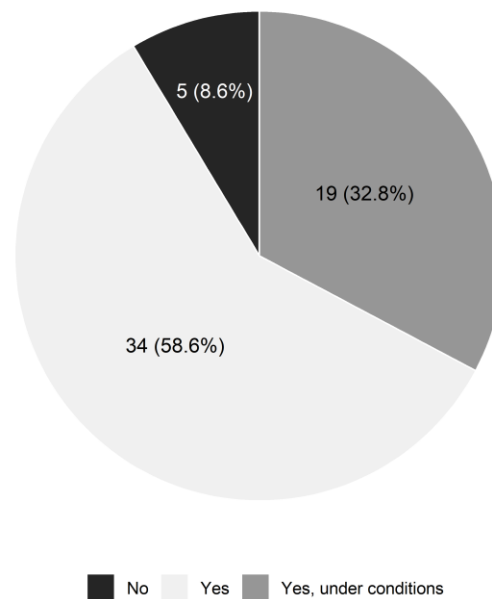
Against this background, the analysis now turns to two key behavioural indicators: willingness to share health data and willingness to use AI-based diagnostic tools.

8.2.6 Willingness to Share Health Data

Attitudes toward data sharing were generally favourable. A majority of respondents (58.6%) indicated willingness to share their health data for the development of AI in the medical field, while an additional 32.8% expressed conditional agreement. Only 8.6% declined to share their data (**Figure 10**).

Sharing of health data

I would agree to make my health data available for the development of artificial intelligence in the medical field



N = 58

Figure 10. Willingness to share health data

Open-ended responses provided further insight into the nature of these conditions. The most frequently mentioned requirements concerned strict protection of privacy and confidentiality, clear limitations on data use to medical or research purposes only, and assurances that data would not be shared beyond trusted healthcare institutions. Several respondents emphasized that data should be used exclusively within hospital settings or by professionals directly involved in patient care. Others specified that they would agree to data sharing only if access were restricted to institutions or actors they personally trust.

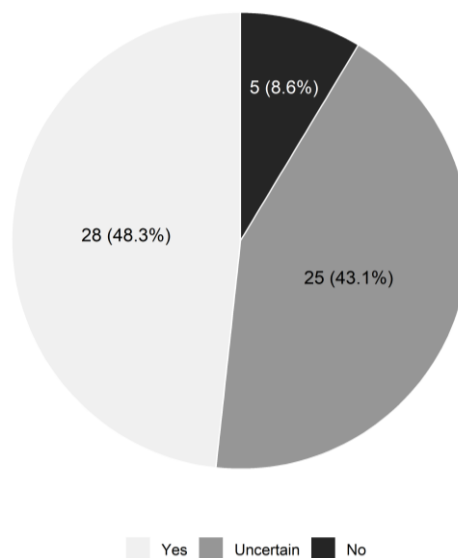
These findings indicate that willingness to share health data is closely linked to perceived control, transparency, and trust. Conditional openness appears to depend less on opposition to data-driven innovation per se and more on the assurance that governance mechanisms safeguard privacy, limit secondary use, and maintain institutional accountability.

The generally favourable attitudes toward data sharing suggest that respondents do not reject the principle of AI development in healthcare. Rather, their support appears conditional upon governance, transparency, and trust. This conditional openness provides important context for interpreting behavioural intention to use AI tools in personal diagnostic pathways.

8.2.7 Willingness to use AI and underlying concerns

With regard to behavioural intention, 48.3% of respondents indicated that they would be willing to use AI-based tools in the management of prostate cancer diagnostics. A substantial proportion (43.1%) reported uncertainty, while 8.6% expressed unwillingness to use such tools (**Figure 11**). Thus, approximately half of the sample demonstrated readiness to adopt AI, whereas the other half expressed hesitation or rejection.

I would like to use AI-based tools to manage my prostate cancer diagnosis



N = 58

Figure 11. Willingness to use AI tools in diagnostics

To further explore the structure of this hesitation, respondents who selected either “No” or “Uncertain” (n = 30) were asked to rate a series of potential concerns on a 10-point scale. The radar chart presents the mean scores across this subgroup (**Figure 12**).

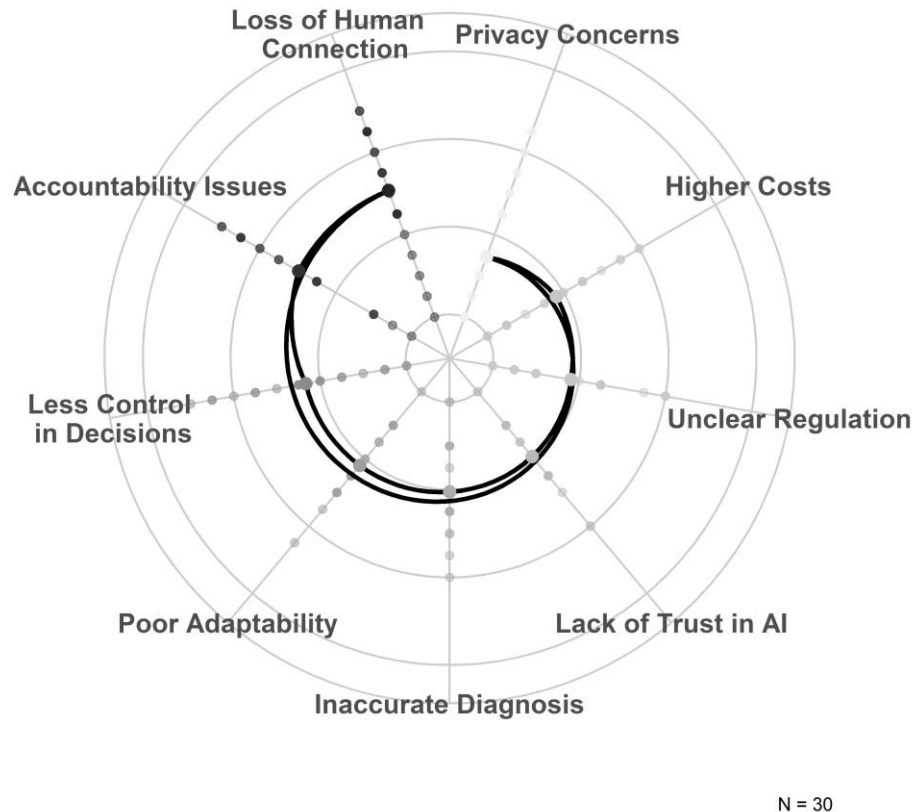


Figure 12. Concerns about the use of AI in prostate cancer diagnosis

The highest mean concern was associated with the perception that AI could reduce the human aspects of medical relationships. Respondents expressed apprehension that AI-supported diagnostics might weaken interpersonal interaction and diminish the relational dimension of care. Closely related to this concern was the fear that AI might place patients in a more passive role when making medical decisions about prostate cancer diagnosis.

Beyond relational concerns, respondents reported moderate levels of apprehension regarding diagnostic reliability, specifically the possibility that AI might provide inaccurate diagnoses or fail to adapt to specific and unforeseen medical situations. Issues of governance were also prominent: participants indicated concern about whether the safety and effectiveness of AI systems are clearly regulated and expressed uncertainty regarding who would be responsible if AI generated poor recommendations.

Concerns related to confidentiality of health information and general distrust toward machines using AI were present but comparatively less pronounced. Fear that AI implementation might lead to higher healthcare costs received moderate ratings within the subgroup.

Taken together, these findings suggest that reluctance toward AI adoption is not primarily rooted in generalized technological distrust. Rather, it reflects a combination of relational concerns (loss of

human interaction and patient agency), clinical reliability considerations (accuracy and adaptability), and governance-related uncertainties (regulation and accountability). The centrality of relational concerns indicates that preservation of the human dimension of care plays a pivotal role in shaping conditional acceptance of AI in prostate cancer diagnostics.

8.2.8 Summary of quantitative findings

Taken together, the quantitative results indicate a cautiously supportive environment for AI integration in prostate cancer diagnostics. Perceived benefits consistently outweigh perceived risks, institutional trust remains high, and explicit resistance is minimal. However, limited AI familiarity and a substantial proportion of neutral or uncertain responses suggest that acceptance is conditional and influenced by informational and experiential gaps.

These findings provided the basis for the subsequent qualitative phase of the study. To explore in greater depth the sources of uncertainty, trust formation, and expectations regarding AI-supported diagnostics, focus groups and semi-structured interviews were conducted with both patients and healthcare professionals. The qualitative component aimed to contextualize the survey patterns and to better understand the mechanisms underlying conditional acceptance identified in the quantitative analysis.

8.3 Qualitative Phase

This section presents the findings of the qualitative phase of the study, which consisted of focus groups and semi-structured interviews conducted with patients and healthcare professionals. The qualitative component was designed to further explore themes that emerged from the quantitative survey, particularly uncertainty, relational concerns, trust, and conditional acceptance of AI in prostate cancer diagnostics.

8.3.1 Participant characteristics

A total of 27 participants took part in the qualitative phase, including 16 patients and 11 healthcare professionals. Patient participants reflected a range of educational and employment backgrounds, broadly comparable to the quantitative sample. Healthcare professionals represented different clinical roles within prostate cancer diagnostics and had varying levels of professional experience. The demographic and professional characteristics of participants are summarized in **Table 2**.

Table 2. Characteristics of Qualitative Samples (N1 = 16, N2 = 11)

Patients			
Variable	Category	n	%
Age (years)	Mean (SD)	65.0 (6.4)	-
Professional status	Retired	11	68.8
	Employed	5	31.3
Education level	Primary education	2	13.3
	Secondary education	4	26.7
	Non-university higher education	7	46.7
	University education	2	13.3
	PhD	1	6.7
Physicians			
Variable	Category	n	%
Experience in prostate cancer care, years	Mean (SD):	10.4(6.7)	-
Gender	Male	8	72.7
	Female	3	27.3
Specialisation	Radiology	5	45.5
	Urology	4	36.4
	Radiotherapy	2	18.2
Previous use of AI in practice	Yes	7	63.6
	No	4	36.4

8.3.2 Overview of the qualitative analytical framework

The quantitative analysis provided an initial overview of patients’ attitudes toward the use of AI in prostate cancer diagnosis and highlighted several areas of uncertainty related to decision-making, responsibility, and professional roles. However, while the quantitative results allow the identification of general tendencies, they provide limited insight into how these uncertainties are experienced and interpreted by the actors involved.

To better understand the meanings underlying these patterns, a qualitative analysis was conducted. This approach makes it possible to explore how participants view the role of AI in medical practice and how they interpret its implications for clinical decision-making and professional relationships.

The qualitative material therefore complements the quantitative findings by examining how actors articulate the sources of uncertainty associated with AI and how these uncertainties relate to broader mechanisms structuring the patient–physician relationship.

Medical decision-making, including diagnosis, takes place in situations marked by uncertainty. Patients usually lack the medical expertise needed to independently assess diagnoses or treatment options, while physicians must often make decisions based on incomplete information. In the patient–physician relationship, trust plays a key role and helps reduce this complexity. It relies on implicit assumptions that physicians act according to ethical principles, possess relevant medical expertise, and occupy a socially recognized professional role. These assumptions facilitate cooperation between patients and physicians.

The introduction of AI into medical practice may challenge these established assumptions, particularly regarding the production and use of medical knowledge, responsibility for decisions, and professional authority. From this perspective, AI can introduce new forms of uncertainty into the patient–physician relationship. The qualitative analysis therefore examines how participants describe and interpret these uncertainties.

On the basis of this analytical perspective, the coding framework was organized around three dimensions of uncertainty – epistemic uncertainty, ethical uncertainty, and uncertainty of social roles organized around the central concept of trust (**Figure 13**)

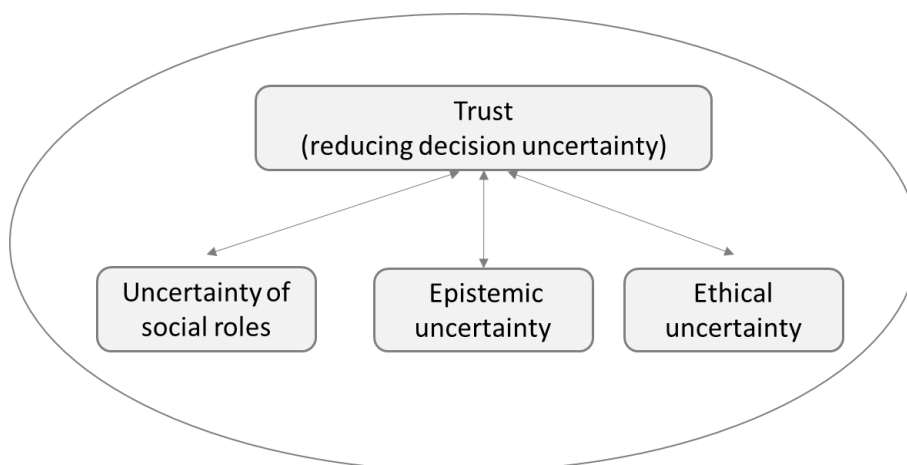


Figure 13. Analytical framework linking trust in medical decision-making with ethical, epistemic, and social role uncertainties

These three dimensions correspond to different ways in which the introduction of AI may destabilize the implicit certainties that structure the patient–physician relationship. Ethical uncertainty refers to questions concerning responsibility, legitimacy, and the moral implications of AI-supported decisions. Epistemic uncertainty concerns the production and interpretation of knowledge, particularly the status of AI-generated information within medical expertise. Finally, uncertainty of social roles addresses the possible reconfiguration of responsibilities and functions among physicians, patients, and technological systems.

The following sections present the results of the qualitative analysis according to these three analytical dimensions.

8.3.3 Epistemic uncertainty

Among **physicians**, epistemic uncertainty is primarily related to questions about the quality of knowledge produced by AI, the extent to which it can be trusted, and how its outputs can be aligned with clinical judgment. AI is considered potentially useful, but its outputs are not perceived as self-sufficient: they require validation, contextualisation, and human verification. In this sense, questions about knowledge are directly linked to the possibility of trusting technological tools in clinical practice.

In contrast, among **patients**, epistemic uncertainty does not primarily concern the accuracy of medical knowledge, but rather its comprehensibility, interpretation, and source. Participants focus less on the characteristics of knowledge itself and more on the conditions under which it becomes understandable and trustworthy. Trust is therefore not only related to the content of knowledge, but also to its accessibility in terms of understanding.

One of the central concerns among physicians is that AI systems always provide an answer, even in situations where uncertainty is inherent. This raises questions about whether such outputs can be trusted and on what basis they are produced. At the same time, it is emphasised that AI would be particularly valuable in “grey zones”, that is, situations of clinical uncertainty. However, precisely in these cases, it is currently perceived as insufficiently reliable. This limits the development of trust in AI in contexts where it would be most needed.

For most physicians, epistemic uncertainty is expressed through the need to understand how AI systems perform. This includes knowledge of accuracy, error rates, false positives, negative predictive value, and reproducibility. AI is therefore not seen as a source of ready-made knowledge, but as a tool whose value depends entirely on measurable and validated performance. These characteristics form the basis upon which trust in AI outputs can potentially be established.

It is also emphasised that AI systems may be highly sensitive but not necessarily specific. In particular, they tend to prioritise avoiding missed diagnoses, which can result in an increased number of false positives. As a consequence, AI-generated knowledge may be systematically biased towards over-detection, which complicates its integration into clinical decision-making and further limits trust.

This is closely related to the requirement for scientific validation. Knowledge produced by AI is not taken for granted and must be supported by clinical evidence. Without such validation, the epistemic status of AI remains weak, and its outputs cannot be fully trusted. As a result, trust in AI is contingent upon the existence of robust and recognised validation procedures.

A significant part of epistemic uncertainty also concerns the data on which AI systems are trained. Physicians repeatedly point to the importance of understanding the origin and quality of training data, as incomplete or biased inputs may lead to distorted outputs. At the same time, clinical interpretation is understood as going beyond image-based analysis, requiring contextual knowledge and professional judgment. Transparency regarding the sources of knowledge thus becomes another condition for trust.

In this regard, some physicians emphasise that medical knowledge cannot be reduced to algorithmic processing. The interpretation of medical images requires clinical experience, contextual understanding, and judgment that cannot be fully replicated by AI. Consequently, trust remains anchored in the physician as the holder of clinical expertise.

AI is therefore often described not as an autonomous source of knowledge, but as an additional layer of verification. It can function as a form of safety net, supporting decision-making without replacing the physician. In this context, trust in AI remains limited and embedded within a broader framework of trust in medical professionals.

Among patients, epistemic uncertainty is primarily expressed through difficulties in interpreting information. While patients may have access to medical reports or images, they often struggle to understand their meaning. The complexity of medical terminology and the lack of contextual explanation make such information difficult to use for independent decision-making, thereby limiting the possibility of trusting it directly.

Patients therefore emphasise that knowledge only becomes meaningful once it has been explained by a physician. The physician acts as an essential intermediary who translates complex information into an understandable form and relates it to the individual situation of the patient. Knowledge is thus not perceived as an autonomous output, but as something that emerges through interaction. Trust, in turn, is built within this interpretative process.

Patients also express doubts about the reliability of different sources of information. Information obtained from the internet or other non-professional sources is not trusted to the same extent as information provided by a physician. This highlights that trust is not only linked to the content of knowledge, but also to its source.

Overall, epistemic uncertainty among physicians is primarily related to the reliability, validity, and limits of AI-generated knowledge, whereas for patients it is associated with its interpretability and source. In both cases, AI-generated knowledge is not considered self-sufficient and must be integrated with human judgment, making trust a key mechanism in its acceptance within medical practice.

8.3.4 Ethical uncertainty

Among physicians, ethical uncertainty is primarily related to questions of responsibility, potential harm to patients, and the conditions under which AI can be legitimately used in clinical practice. In contrast to epistemic uncertainty, the focus here is not on the quality of knowledge, but on the consequences of its use and the distribution of responsibility for decision-making.

Among patients, ethical uncertainty is primarily linked to the need to preserve responsibility, maintain clear limits on the use of AI, and retain the human dimension of medical practice. Rather than discussing the redistribution of responsibility, patients tend to emphasise that responsibility should remain firmly anchored in the physician as the central actor.

Although responsibility was already addressed in relation to social roles, it reappears here as a central ethical concern. Physicians consistently emphasise that responsibility ultimately remains with them, regardless of the use of AI. At the same time, some participants point out a tension: while it might be desirable for developers to share responsibility, this is perceived as unlikely in practice. AI systems are often designed to minimise the risk of missing serious conditions, such as cancer, which leads to highly sensitive models. However, the consequences of using such systems, including potential errors, are borne by physicians rather than developers. This issue is closely intertwined with epistemic uncertainty, particularly regarding the likelihood of errors and how they can be managed.

A similar logic is observed among patients. A central theme is the necessity of having a clearly identifiable responsible actor. Patients emphasise that, regardless of the use of AI, medical decisions must remain the responsibility of a physician. AI is not perceived as an actor capable of bearing responsibility, and its use is considered acceptable only as long as final decisions remain under human control.

An additional important aspect concerns the asymmetry in the perception of errors. Patients indicate that they are more willing to accept errors made by a human physician than those made by AI. This difference is linked to the perception of the physician as a responsible agent who can explain, justify, and take responsibility for decisions, whereas AI lacks these capacities. As a result, errors produced by AI are seen as more problematic from an ethical perspective.

The risk of overdiagnosis constitutes another ethical concern. AI systems, particularly those designed to avoid missed diagnoses, may produce a higher number of false positives. This creates situations in which patients must be informed that a detected condition may not be clinically relevant or may not exist at all, raising questions about unnecessary anxiety and potential overtreatment.

In this context, the need for strict validation and control procedures becomes particularly important. Physicians emphasise that the use of AI is only acceptable when supported by robust evidence of effectiveness and safety. AI systems are expected to undergo clinical validation and to be approved by professional and institutional bodies. Ethical acceptability is therefore directly linked to the existence of recognised validation procedures, which also connects to broader epistemic concerns.

The question of informing patients about the use of AI also emerges as an ethical issue. Physicians express differing views: some consider disclosure as part of respecting patient autonomy, while others argue that patients are primarily concerned with outcomes rather than the tools used to achieve them. This creates a tension between transparency and the risk of overloading patients with complex technical information.

From the patients' perspective, being informed about the use of AI is not formulated as a strict requirement. What matters most is the result and its explanation. However, information becomes important when patients need to understand or discuss their situation. In this sense, ethical expectations are not centred on full transparency, but on the possibility of interpretation and dialogue with the physician, who remains responsible for the decision.

Both physicians and patients also raise concerns about the risk of "blind trust" in AI. There is a perceived danger that AI outputs may be treated as objective and unquestionable, potentially reducing critical engagement. This highlights the continued importance of the physician as the final interpreter and decision-maker.

Finally, some physicians point to the pressure associated with the implementation of AI in clinical practice. The adoption of new technologies may be perceived as inevitable or even obligatory, despite existing uncertainties regarding their reliability. This creates an additional ethical tension between the imperative to innovate and the responsibility to ensure patient safety. Patients, in turn, tend to perceive the introduction of AI as an inevitable development.

Overall, ethical uncertainty among physicians arises at the intersection of responsibility, potential harm, transparency, and institutional regulation. It reflects a mismatch between the increasing role of AI in decision-making processes and the continued concentration of responsibility on physicians, making the conditions of its use ethically challenging.

For patients, ethical uncertainty is less about the redistribution of roles and more about their preservation. Responsibility is expected to remain with the physician, the use of AI should be limited to a supportive function, and the human dimension of care must be maintained. In this context, the distinction between human and machine error plays a key role in reinforcing the central position of the physician as the bearer of responsibility and trust.

8.3.5 Uncertainty of social roles

With regard to social roles, physicians discuss both the existing distribution of roles (such as those of the physician, the patient, and the healthcare institution) and the potential transformation or preservation of these roles with the introduction of AI. Their reflections focus primarily on possible redistributions of roles, the expansion of the physician's role in certain areas, and shifts in responsibility.

This includes the emergence of new tasks, which may arise both organically and under the pressure of technological development. These changes concern not only the relationship between physicians and AI systems, but also the role of patients and institutional actors, including healthcare organisations, management structures, and, implicitly, the state.

Patients, by contrast, tend to frame social roles not in terms of redistribution, but in terms of the risk of their alteration or loss. While generally expressing a positive attitude towards the use of AI, they consistently emphasise that physicians may use various tools, whether or not this is explicitly communicated. However, the result, its interpretation, and the final decision are expected to remain with the physician.

Participants highlight the importance of preserving the physician's role as the central actor. A key concern is the potential loss of human contact. Human interaction, including empathy, communication, and non-verbal cues, is considered an essential component of medical care that cannot be replaced by technology.

Physicians almost unanimously stress that their role goes beyond collecting symptoms, making diagnoses, and prescribing treatment. They describe their work as involving listening to patients, understanding their narratives, and explaining medical situations and possible courses of action in a clear and accessible way. Communication is described as highly adaptive, tailored to the needs of individual patients. Some patients require detailed explanations, others come with many questions, while some prefer brief information. Particular importance is attributed to attentiveness and individualisation when communicating serious diagnoses and when explaining situations in which active surveillance, rather than immediate treatment, is appropriate.

Patients confirm the importance of this relational dimension, emphasising the need to “match” with the physician in order to build trust. This reflects the alignment between how patients receive information and how physicians communicate it. Both physicians and patients underline that physicians are able to take into account the emotional state of patients, a function that is not attributed to AI. In this sense, physicians also fulfil a partially psychological role, supporting both patients and their relatives. These aspects are considered central and not replaceable by technological systems.

At the same time, physicians, particularly radiologists, report a sense of pressure associated with the introduction of AI into clinical practice. They emphasise that the physician's role should not shift towards more technical or administrative tasks. On the contrary, AI is expected to reduce such burdens and allow physicians to devote more time to patient interaction. Patients express similar expectations, suggesting that AI could free up time for more meaningful human engagement.

The potential transformation of medical expertise is also discussed. Some physicians suggest that AI, trained on large datasets, could approach the level of highly experienced specialists. However, such views tend to be expressed by those with limited practical experience using AI. More experienced practitioners, particularly those already working with AI, express scepticism regarding its current usefulness.

A key issue in this context is again the distribution of responsibility. Physicians note that AI systems are often designed to minimise the risk of missing serious conditions, which leads to increased

sensitivity and a higher likelihood of detecting abnormalities that may not be clinically relevant. In the context of treatment, as opposed to diagnosis, final decisions are often made by patients, which introduces a partial redistribution of responsibility.

Related discussions address differences between more and less experienced physicians, as well as the possibility of AI functioning as a “third opinion”. However, even in such cases, AI is generally considered as an additional source of input rather than an equivalent to human expertise. Only a minority of patients express a preference for AI over physicians, while most continue to favour human judgment.

Overall, the vast majority of participants describe AI as a tool — an additional resource for analysis and support, rather than an independent actor. In this context, the physician assumes the role of a filter, mediator, and interpreter of information for the patient. Patients similarly emphasise the physician’s role as the final decision-maker, even in a context of increased information availability. While the use of AI in diagnosis is generally accepted, final decisions are expected to remain under human control.

The possibility of substitution is also discussed, particularly with regard to radiology. While some tasks are seen as potentially automatable, the complete replacement of physicians is generally considered unlikely.

Physicians further observe that patients are increasingly informed due to the accessibility of information, but also often more anxious. This is attributed to the difficulty of interpreting complex information and the dependence of AI outputs on the quality of input data. Patients confirm that, despite having access to information, they continue to rely on physicians as the primary interpreters. As a result, the patient’s role becomes simultaneously more active and more dependent on the physician.

Finally, both physicians and patients emphasise the importance of involving medical professionals in the development of AI systems. This includes not only providing medical expertise, but also shaping how systems are trained and what kind of outputs are expected. This expands the role of physicians beyond clinical practice, extending it into the domain of technological development and implementation.

8.3.6 Overall Synthesis of the qualitative findings

The qualitative analysis highlights that the introduction of AI in medical practice generates interconnected forms of uncertainty related to knowledge, ethics, and social roles. These dimensions do not operate independently, but rather jointly shape how AI is perceived, interpreted, and integrated into clinical settings.

Across all three dimensions, a central finding is that AI is not understood as an autonomous actor, but as a tool whose acceptability depends on the conditions of its use. In particular, its integration into medical practice is contingent upon its alignment with existing structures of responsibility, professional judgment, and patient–physician interaction.

For physicians, uncertainty primarily concerns the reliability, validation, and appropriate use of AI, as well as the implications for responsibility and professional roles. For patients, uncertainty is less about the technical properties of AI and more about its impact on understanding, trust, and the preservation of human interaction in care. Despite these differences, both groups converge on the expectation that physicians remain the central decision-makers and bear ultimate responsibility.

A key transversal insight is that trust does not emerge directly from the technology itself, but from the frameworks within which it is embedded. These include the presence of a responsible physician,

the availability of validated and reliable outputs, and the possibility of explanation and dialogue. In this sense, trust functions as a mechanism that enables decision-making in situations characterised by complexity and uncertainty.

Overall, the findings suggest that the successful integration of AI into healthcare depends not only on its technical performance, but also on its ability to fit within established ethical norms, epistemic standards, and social role configurations. AI is accepted insofar as it supports, rather than disrupts, these existing structures.

9 Quality assurance, limitations and risk management

9.1 Limitations

As a volunteer-based study, selection bias is possible, as participants with higher digital literacy or stronger opinions may have been more likely to engage. Furthermore, cross-country comparisons are significantly constrained by uneven recruitment efficiencies and regulatory delays. Specifically, the quantitative phase faced substantial recruitment challenges: while 9 participants were recruited in Italy, no data was collected in Spain due to administrative delays in obtaining Ethical Committee approval and subsequent recruitment difficulties. Consequently, the quantitative findings primarily reflect the Belgian context.

Regarding the qualitative phase, the results are based exclusively on Belgian data. Although a focus group was successfully conducted in Italy, the data could not be included in the final analysis; a technical failure during the recording process rendered transcription and subsequent formal analysis impossible.

Finally, as acceptability measures may be influenced by varying levels of AI literacy among participants, the interpretation of results will account for intervention coherence and the specific information provided during the study.

9.2 Risk management

- Privacy risk mitigation through data minimisation, pseudonymisation, and separation of contact details.
- Operational risks (recruitment and scheduling) mitigated via multi-channel recruitment and flexible choice of interviews vs focus groups.
- Analytical risks mitigated via transparent logs, and peer discussion of coding decisions.

10 Conclusions

This study provides a comprehensive assessment of the acceptability of AI in prostate cancer diagnostics and identifies the key conditions under which its implementation can be considered acceptable, trustworthy, and supportive of patient-centred care.

Overall, the findings indicate that AI is viewed in a generally positive yet cautious manner by both patients and healthcare professionals. Importantly, AI is not rejected as a technology; however, its acceptance is clearly conditional and depends on a range of contextual, relational, and ethical factors rather than on technical performance alone.

From the quantitative perspective, patients recognize substantial potential benefits of AI, particularly in terms of improving diagnostic accuracy, enhancing the efficiency of the diagnostic process, and supporting clinical decision-making. Across the dataset, perceived benefits consistently outweigh perceived risks. Nevertheless, this favourable perception does not translate into unequivocal willingness to use AI. A considerable proportion of patients express uncertainty, suggesting that acceptance is not hindered by fear of technology per se, but rather by uncertainty regarding the conditions of its use, especially within the clinical encounter.

The qualitative findings further elucidate the nature of this uncertainty by identifying three interrelated dimensions: epistemic, ethical, and social role uncertainty. These dimensions do not operate independently but are interconnected and structured around a central mechanism – trust.

A key insight of this study is that trust does not arise directly from AI systems themselves. Instead, it is embedded within existing healthcare structures, particularly the patient–physician relationship. AI is considered acceptable only insofar as it is integrated into this relational framework and does not undermine its core principles.

Across both patients and healthcare professionals, there is strong convergence on several fundamental expectations. First, the physician must remain the central decision-maker, retaining full responsibility for clinical decisions. AI is not perceived as an autonomous actor capable of bearing responsibility and is therefore only acceptable as a supportive tool. Second, responsibility for medical outcomes must remain clearly attributable to a human agent. Third, AI must operate under conditions that ensure interpretability, validation, and oversight.

Rather than diminishing the role of the physician, the introduction of AI appears to reinforce and transform it. The physician increasingly assumes the role of mediator, interpreter, and translator of complex information, including AI-generated outputs. In this context, AI does not replace clinical expertise but adds an additional layer of information that requires professional judgment to become meaningful for patient care.

For patients, one of the most salient concerns relates to the preservation of the human dimension of care, including communication, empathy, and individualized interaction. Hesitation toward AI is driven less by concerns about technological risks and more by fears of depersonalisation, reduced patient involvement, and weakened interpersonal relationships. This underscores the importance of maintaining and strengthening relational aspects of care as a central condition for AI acceptability.

In addition, attitudes toward data sharing reveal a generally high level of willingness to contribute health data for AI development, but this willingness is also conditional. It is strongly dependent on guarantees of privacy, transparency regarding data use, clear governance frameworks, and trust in the institutions managing the data. This highlights that data governance and institutional trust are integral components of AI acceptability.

Taken together, the findings suggest that the successful integration of AI into clinical practice depends not only on its technical capabilities but also on its ability to align with established epistemic

standards, ethical principles, and social role configurations in healthcare. AI is accepted when it supports these structures and remains embedded within them; conversely, it becomes problematic when it is perceived as challenging responsibility, interpretability, or the human dimension of care.

Ultimately, the study demonstrates that the key condition for AI acceptance is not its autonomy, but rather its integration into a human-centred system of decision-making. AI is perceived not as an independent agent, but as a tool that can enhance clinical practice, support physicians, and potentially enable more informed and engaged patient participation – provided that trust, responsibility, and meaningful human interaction are preserved.

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