Can Blood-Based Prostate Cancer Screening Be a Win-Win Situation for Insurance Companies, the Healthcare Industry, and Patients?

by

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Dedication

This thesis is dedicated foremost and above all to my loving parents, whose unconditional support, sacrifices, and endless motivation have been the pillars of my existence. Your integrity, diligence, and hard work values have defined my path and seen me through every trial.

To my wonderful wife, whose love, patience, and understanding have remained my biggest support throughout this project. Your support and belief in me provided me with the inspiration to continue advancing despite the toughest moments.

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ABSTRACT

Can Blood-Based Prostate Cancer Screening Be a Win-Win Situation for Insurance Companies, the Healthcare Industry, and Patients?

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This research investigates the potential of blood-based prostate cancer screening, particularly multi-cancer early detection (MCED) technologies, as a value-creating intervention for insurers, patients, and the broader healthcare industry in India. The study was driven by the growing economic and clinical burden of late-stage prostate cancer and the emerging promise of liquid biopsy-based approaches to transform preventive care.

A mixed-methods design was employed, combining a cost-benefit model with qualitative and quantitative data from a survey of insurance industry professionals. The cost-benefit analysis quantified financial savings for insurers under different sensitivity scenarios, while the survey captured stakeholder perspectives on adoption barriers, regulatory challenges, and broader industry implications. The results demonstrated that insurers could achieve substantial financial savings by integrating blood-based prostate cancer screening

into policy-linked health checkups, with projected savings ranging from ₹67 lakhs at 70% sensitivity to over ₹2 crores at 100% sensitivity. From a patient perspective, the findings underscored advantages such as reduced invasiveness, improved compliance, and earlier detection compared to conventional screening modalities. However, multiple obstacles emerged, including high upfront implementation costs, regulatory ambiguity, lack of actuarial models for preventive diagnostics, and infrastructure gaps within provider and laboratory networks. The study further highlighted that regulatory uncertainty and unclear reimbursement pathways remain central deterrents to adoption. Broader implications for providers, laboratories, and med-tech firms include the need for training, standardization, and alignment of innovation with payer requirements. Stakeholders emphasized the importance of policy reforms that balance innovation with oversight, including clearer approval pathways, standardized reimbursement models, and collaborative pilot programs. In conclusion, blood-based prostate cancer screening presents a promising win-win opportunity for insurers, patients, and the healthcare industry. Yet, realizing this potential will require coordinated policy interventions, regulatory clarity, and multi-stakeholder collaboration to overcome barriers and enable sustainable integration into India's healthcare ecosystem.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER I: INTRODUCTION

1.1 Introduction

Prostate cancer remains one of the most prevalent forms of cancer globally, posing significant health challenges and economic burdens on healthcare systems (Sung et.al, 2021). Traditional screening methods such as digital rectal examination (DRE) and prostate-specific antigen (PSA) testing have limitations in terms of accuracy, leading to overdiagnosis and overtreatment. A shift towards blood-based screening methods could offer a more accurate and less invasive alternative. Recent advancements in liquid biopsy technologies have paved the way for the identification of blood-based biomarkers associated with prostate cancer. Circulating tumor cells (CTCs), cell-free DNA (cfDNA), and exosomes have shown promise as non-invasive indicators of prostate cancer presence, progression, and response to treatment. Incorporating these biomarkers into routine screening could provide a more accurate and comprehensive assessment of an individual's prostate health.

The motivation behind this research stems from the pressing need to enhance prostate cancer screening efficacy while minimizing healthcare costs and patient burden. Adopting blood-based screening methods has the potential to revolutionize prostate cancer detection, offering improved accuracy, reduced invasiveness, and cost-effectiveness.

This research holds paramount importance for industry practice and knowledge advancement in several ways. Firstly, it addresses a critical gap in current prostate cancer screening strategies by exploring the feasibility and benefits of blood-based approaches. Secondly, it has significant implications for insurance companies, healthcare providers, and diagnostic technology firms, as successful implementation could lead to improved patient outcomes, reduced treatment costs, and enhanced competitiveness in the healthcare market. Overall, this research has the potential to reshape clinical practice, healthcare policies, and industry dynamics related to prostate cancer screening (Loeb, 2014; DiSantostefano and Lavelle, 2006).

1.2 Research Problem

Prostate cancer continues to be one of the most prevalent male cancers worldwide, and early diagnosis is essential to ensure successful treatment and enhanced survival rates. Standard screening techniques like PSA testing and digital rectal examination have their own limitations in terms of sensitivity, specificity, compliance, and overdiagnosis. New developments using liquid biopsy and blood-based screening provide a less invasive, theoretically more accurate approach. Nonetheless, implementation of these tests remains limited as of now due in part to the uncertainties concerning their cost-utility, clinical usefulness, and larger implications among healthcare stakeholders. There is an urgent research gap evaluating whether blood-based prostate cancer screening can serve the interests of three important stakeholders simultaneously: insurance companies (in terms of lower long term treatment expenses), the healthcare sector (in terms of better patient management and resource utilization), and patients (in

terms of earlier detection and less invasive treatments). Previous research in the field of blood-based prostate cancer screening has provided valuable insights into various biomarkers, diagnostic techniques, and their potential clinical utility (*Hanash et al., 2011*). Strengths of existing research include the identification of novel biomarkers with high sensitivity and specificity, paving the way for more accurate and personalized screening approaches. However, weaknesses persist, such as limited large-scale validation studies, heterogeneous patient populations, and variability in assay performance. Moreover, the translation of research findings into clinical practice and insurance coverage remains a challenge, highlighting the need for further investigation and evidence generation (*Bratt et. al., 2023*).

1.3 Purpose of Research

The purpose of this study is to critically assess whether the inclusion of blood-based prostate cancer screening can establish a mutually advantageous ("win-win") situation for insurance companies, the healthcare sector, and patients.

1.4 Significance of Study

The proposed research will employ a multi-faceted approach to achieve its objectives. Firstly, a comprehensive review of existing literature will be conducted to identify diagnostic platforms and clinical outcomes associated with blood-based prostate cancer screening.

Research methods will include statistical analysis, health economic modeling, and stakeholder consultations. Patient preferences, provider perspectives, and payer considerations will be integrated to develop a holistic understanding of the potential

benefits and challenges associated with blood-based screening implementation. In conclusion, this research aims to advance knowledge in the field of prostate cancer screening and contribute to improved patient care, healthcare resource allocation, and industry innovation.

1.5 Research Purpose and Questions

The objective of this research paper is to address the following inquiries:

- What are the systemic implications of blood-based screening for insurance companies, specifically on coverage policies, reimbursement strategies, and the general environment of healthcare spending?
- What are the quantifiable benefits to the insurers from lower cost spending for late stages of prostate cancer treatments, but in the meantime, enhancing the general health outcomes of policyholders?
- What are the identified obstacles and challenges to the integration of blood-based prostate cancer screening from the viewpoint of the insurance sector?
- What does it mean for the healthcare sector, with consideration for both healthcare providers, diagnostic labs, and medical technology vendors?
- What are the kinds of regulatory frameworks and procedures involved in overseeing blood-based prostate cancer screening tests, and what is their impact in terms of regulating insurance reimbursement and utilization?

CHAPTER II: REVIEW OF LITERATURE

2.1 Introduction

Blood-based prostate cancer screening holds significant potential in transforming the landscape of prostate cancer diagnosis and management (Trujillo et al., 2022). Prostate cancer represents a major health concern, being the second most common cancer among men worldwide and the fifth leading cause of cancer death (Bray et al., 2018). Early detection is paramount in improving survival rates and reducing mortality (WHO, 2017). Traditional screening methods have relied heavily on the prostate-specific antigen (PSA) test, which measures the level of PSA in the blood (Tikkinen et al, 2018). Elevated levels of PSA can indicate prostate cancer but may also result from benign conditions such as prostatitis or benign prostatic hyperplasia (Barry, 2001). This lack of specificity has led to significant challenges, including false positives, unnecessary biopsies, and overdiagnosis, which in turn can cause undue stress and lead to overtreatment (Pathirana, 2021).

In light of these limitations, the medical community has been exploring alternative methods for prostate cancer screening that are more accurate and less invasive. Blood-based biomarkers have emerged as a promising solution, with several potential advantages over traditional PSA testing (Balázs et al., 2021). These biomarkers include prostate cancer antigen 3 (PCA3), kallikrein related peptidase 2 (KLK2), Circulating

Tumor Cells (CTCs), and other molecular markers that could provide more specific indications of prostate cancer (Qu, Ren and Sun, 2014; Saini, 2016).

Blood-based screening methods could revolutionize prostate cancer diagnostics in multiple ways (Brito-Rocha et al., 2023). For insurance companies, more accurate screening could translate to cost savings by reducing the number of unnecessary treatments and procedures (Schnipper et al., 2012). For the healthcare industry, these methods promise to streamline clinical workflows, reduce patient burden, and improve overall efficiency. Patients, on the other hand, could benefit from less invasive testing, reduced anxiety from false positives, and more appropriate and timely treatments.

Despite the potential benefits, the adoption of blood-based prostate cancer screening is not without controversy. The cost of developing and validating new biomarkers is substantial, and there is ongoing debate regarding their cost-effectiveness compared to traditional methods (Thompson et al., 2004; Murphy et al., 2015). Additionally, ethical concerns about overdiagnosis and overtreatment persist, raising questions about the broader implications of widespread screening (Chou et al., 2011; Schröder et al., 2009).

This literature review aims to comprehensively examine the current state of blood-based cancer screening and its potential impact on insurance companies, the healthcare industry, and patients. It will delve into the main ideas, theories, and concepts surrounding this topic, highlight areas of agreement and disagreement, and identify gaps in the existing literature that need to be addressed. By synthesizing the available evidence, this review seeks to provide a balanced perspective on whether blood-based prostate cancer screening can truly be a win-win situation for all stakeholders involved.

2.2 Main Ideas, Theories, and Concepts

2.2.1 Prostate Cancer and Screening Methods

Prostate cancer screening aims to detect cancer early when treatment is more likely to be successful. The PSA test has been the conventional method, but it lacks specificity, leading to unnecessary biopsies and treatments (Munteanu et al., 2020). New blood-based biomarkers, such as prostate cancer antigen 3 (PCA3), kallikrein-related peptidase 2 (KLK2), CTCs, and others, are being investigated for their potential to improve screening accuracy (Qu et al., 2014; Lilja, et al., 2008; and Saini, 2016). One of the most promising developments in this field is the use of circulating tumor cells (CTCs) for prostate cancer screening (Ried et al., 2020). CTCs are cancer cells that have shed from the primary tumor into the bloodstream and are considered a hallmark of metastasis. The detection and analysis of CTCs can provide valuable information about the presence and progression of cancer (Alix-Panabières & Pantel, 2014; Ried et al., 2020).

2.2.2 Economic Implications for Insurance Companies

Insurance companies are deeply concerned with the cost-effectiveness of screening programs (Garg et al., 2013; Benoit & Naslund, 1997). Blood-based screening methods, if proven to reduce false positives and unnecessary treatments, could lower healthcare costs. Early and accurate detection can also mean less spending

on advanced cancer treatments, translating to better financial outcomes for insurers (Catalona et al., 1991; Chou et al., 2011).

2.2.3 Benefits to the Healthcare Industry

For the healthcare industry, blood-based screening methods could streamline diagnostic procedures, reduce patient burden, and enhance clinical decision making (Peralta et al., 2022). Laboratories and diagnostic companies could benefit from the development and commercialization of new tests, while hospitals might see reduced strain on resources due to fewer invasive procedures (Schröder et al., 2009).

2.2.4 Patient-Centric Advantages

Patients stand to benefit from less invasive, more accurate screening methods. Reduced anxiety from false positives, fewer biopsies, and the potential for earlier, less aggressive treatment options could significantly improve patient quality of life and outcomes (Klotz, 2010).

2.3 Areas Of Agreement And Disagreement Related To Blood-based Prostate Screening And Its Benefits To The Relevant Stakeholders

2.3.1 Agreement among Researchers on the Need for Improved Screening

There is a widespread consensus in the medical community on the necessity for improved prostate cancer screening methods (Lee et al., 2017). The limitations of the PSA test are well documented (Croswell et al., 2011). Despite its widespread use, the PSA test lacks specificity, leading to high rates of false positives and negatives. This inefficiency results in unnecessary biopsies and treatments, which

can cause physical, emotional, and financial burdens on patients (Barry, 2001; Catalona et al., 1991). The agreement extends to the potential benefits of newer, more accurate screening methods. Blood-based biomarkers, such as PCA3, KLK2, and circulating tumor cells (CTCs), are recognized for their promise in enhancing diagnostic accuracy. These biomarkers can potentially reduce false positives and provide a clearer indication of the presence and progression of prostate cancer (Lilja, et al., 2008; Saini, 2016).

Furthermore, there is a consensus on the need for early detection, which is crucial for successful treatment outcomes and improving survival rates. Improved screening methods that are less invasive and more reliable are viewed as essential advancements in the fight against prostate cancer. Overall, the medical community agrees on the importance of advancing beyond the PSA test to incorporate more sophisticated, accurate, and patient-friendly screening techniques (Schröder et al., 2009; Klotz, 2010).

2.3.2 Disagreement among Researchers on the Implementation and Cost Effectiveness

Despite the consensus on the need for improved prostate cancer screening, significant disagreements persist regarding the cost-effectiveness and implementation of new screening methods (Gómez Rivas et al., 2023). Critics argue that the development and validation of new biomarkers, such as circulating tumor cells (CTCs) and other blood-based markers, entail substantial financial investments, raising concerns about their cost-benefit ratio compared to traditional PSA testing (Thompson et al., 2004). Additionally, the integration of these

advanced screening techniques into routine clinical practice poses logistical challenges. These include the need for sophisticated technology, specialized training for healthcare providers, and standardized protocols for testing and interpretation. Ethical concerns also arise about overdiagnosis and the potential for overtreatment, which can lead to unnecessary medical interventions and associated risks for patients (Chou et al., 2011; Schröder et al., 2009). Thus, while the potential of advanced screening methods is acknowledged, their practical implementation and economic feasibility remain contentious issues.

2.3.3 Ethical Considerations and Overdiagnosis

The ethical implications of screening, particularly the risk of overdiagnosis and overtreatment, remain contentious. Critics argue that even with improved accuracy, widespread screening could lead to unnecessary treatments for cancers that may never cause symptoms or affect lifespan, thus causing more harm than good (Chou et al., 2011; Schröder et al., 2009).

2.4 Problems or Gaps in the Current Literature

2.4.1 *Insurance Coverage Policies, Reimbursement Strategies, and Healthcare Expenditures*

A critical gap in the current literature is the lack of comprehensive studies examining insurance coverage policies and reimbursement strategies specific to blood-based prostate cancer screening tests. While there is a general understanding that advanced screening methods can be more accurate, there is limited information on how these methods are perceived and covered by insurance companies.

Specifically, there is a need for detailed analyses of the cost structures, reimbursement rates, and economic implications for both insurers and patients. The broader landscape of healthcare expenditures related to the adoption of these tests is also underexplored. Understanding how these factors affect overall healthcare costs, patient out-of-pocket expenses, and the financial sustainability of widespread implementation remains a significant research gap (Febbo et al., 2024; Neumann et al., 2014).

2.4.2 Obstacles and Challenges from the Viewpoint of the Insurance Sector

From the perspective of the insurance sector, integrating blood-based prostate cancer screening presents several challenges that are not adequately addressed in the current literature (Cheng et al, 2018). Key issues include the initial high costs of these tests, the complexity of their implementation, and the variability in clinical outcomes. There is a lack of detailed studies exploring how insurance companies evaluate the cost-effectiveness of new screening technologies and the criteria they use to determine coverage. Additionally, the administrative and logistical challenges of integrating these tests into existing insurance frameworks, such as the need for specialized training and equipment, remain poorly understood.

2.4.3 Ramifications on the Healthcare Industry

The impact of blood-based prostate cancer screening on the healthcare industry is another area with significant gaps. While there is some discussion about the potential benefits, such as improved diagnostic accuracy and patient outcomes, there is limited empirical data on the broader ramifications. This includes how these

tests might affect clinical workflows, resource allocation, and healthcare provider practices. Furthermore, the potential for reducing or exacerbating healthcare disparities through the adoption of these technologies is an important yet underexplored topic. Comprehensive studies are needed to assess the systemic effects of integrating blood-based screening into routine practice (Siravegna et al., 2017).

2.4.4 Regulatory Frameworks and Procedural Requirements

The regulatory frameworks and procedural requirements governing blood-based prostate cancer screening tests are complex and evolving. However, the current literature lacks detailed analyses of these regulations and their practical implications. Studies are needed to clarify how regulatory bodies evaluate and approve new screening technologies, including the criteria for clinical validation, safety, and efficacy. Additionally, there is a need for research on how these regulatory requirements impact the development and deployment of new screening methods, including the timelines and costs associated with regulatory compliance (Gostin et al., 2009; Robson et al, 2010).

2.4.5 Impact of Regulations on Insurance Reimbursement Policies

Finally, there is a significant gap in understanding how regulations influence insurance reimbursement policies and the uptake of blood-based screening tests within the healthcare industry (Schroll et al, 2024). The interaction between regulatory approval and insurance coverage is crucial, as regulatory decisions can directly affect reimbursement rates and the willingness of insurers to cover new

technologies. Research is needed to explore how regulatory changes impact insurance policies and the broader adoption of blood-based screening tests.

2.5 Summary

To conclude this chapter, blood-based prostate cancer screening holds considerable promise for enhancing early detection and improving patient outcomes. By addressing the limitations of the traditional PSA test, such as its lack of specificity and high false positive rates, new biomarkers like PCA3, KLK2, and circulating tumor cells (CTCs) offer a more precise diagnostic approach. These advancements could lead to reduced unnecessary biopsies and treatments, thereby alleviating physical, emotional, and financial burdens on patients. The potential for these screening methods to lower healthcare costs and streamline clinical workflows makes them attractive to both the healthcare industry and insurance companies. However, the adoption of blood-based screening is not without challenges. High development costs, debates over cost effectiveness, and ethical concerns about overdiagnosis and overtreatment pose significant hurdles. Moreover, there are gaps in the literature regarding insurance coverage policies, reimbursement strategies, and the regulatory frameworks governing these new technologies. Comprehensive studies are needed to assess the economic implications, practical implementation issues, and the broader impact on healthcare systems.

Overall, while blood-based prostate cancer screening has the potential to be a win-win for all stakeholders, its successful integration into clinical practice will require

addressing these multifaceted challenges through further research and collaboration among healthcare providers, insurers, and regulatory bodies.

CHAPTER III: METHODOLOGY

3.1 Introduction

Blood-based prostate cancer screening holds much promise in changing the face of prostate cancer diagnosis and management (Trujillo et al., 2022). Prostate cancer is one of the leading health issues, ranking as the second most common cancer among men worldwide and the fifth leading cause of cancer death (Bray et al., 2018). Early detection is crucial in enhancing survival and reducing mortality (WHO, 2017). Traditionally, the most commonly employed screening methods include the PSA test, which detects the level of PSA in blood (Tikkinen et al, 2018). An increased level of PSA can indicate prostate cancer, but also is due to many benign conditions like prostatitis or benign prostatic hyperplasia (Barry, 2001). This has resulted in several major issues, such as false positives, unnecessary biopsies, and overdiagnosis, that can create undue stress and may even lead to overtreatment (Pathirana, 2021).

In view of these drawbacks, the medical world has been on the lookout for alternative screening methods for prostate cancer that are more accurate and less invasive. Blood-based biomarkers hold great promise, offering several advantages over the PSA test, which is traditional (Balázs et al., 2021). These biomarkers comprise prostate cancer antigen 3 (PCA3), kallikrein related peptidase 2 (KLK2), and Circulating Tumor Cells

(CTCs), among other molecular markers that might provide more defined prompts regarding prostate cancer (Qu, Ren and Sun, 2014; Saini, 2016).

Blood-based screening methods would transform the diagnosis of prostate cancer in many aspects (Brito-Rocha et al., 2023). For instance, more precise screening saves the insurance companies the unnecessary expenditure of treatment and procedures, thereby saving insurance companies from loss (Schnipper et al., 2012). To the healthcare sector, it provides a streamlined clinical workflow with a lightening burden for the patient, efficiency as well. This will lead to less invasive testing, lower false positive anxiety, and more appropriate and timely treatments for patients.

While blood-based prostate cancer screening holds a lot of promise, its use also sparks controversy. It's very expensive to develop and validate new biomarkers, which has become a contentious issue concerning whether such methods are cost effective compared to the more traditional ones (Thompson et al., 2004; Murphy et al., 2015). Furthermore, the issue of overdiagnosis and overtreatment will continue to be an ethical concern rather than other concerns for why screening should be performed (Chou et al., 2011; Schröder et al., 2009).

3.2 Importance for Industry Practice/Knowledge Advancement

This potentially offers blood-based prostate cancer screening a significant change in industry practices, moving the knowledge front of oncology and healthcare economics forward. Traditional PSA screening provides low specificity, meaning some will have false positives with resulting unnecessary biopsies and overtreatment (Etzioni et al., 2013). Development of integrative blood-based biomarkers includes CTCs, PCA3, and

KLK2 and these have more accuracy with much reduced invasiveness. Such breakthroughs may lead to earlier diagnosis, reduced burden of disease, and treatments better aimed toward optimal patient outcomes and quality of life.

These advanced screening technologies can enhance the clinical workflow of the healthcare sector, reduce unnecessary procedures, and increase the precision of diagnosis. This will ultimately save money, which would result in efficient use of resources and better delivery of health care services (Grossman et al., 2018). The insurance companies will save money from future cancer treatments and on all those diagnostic procedures that do not yield any useful information. It may lead to a more sustainable model of healthcare financing (Heijnsdijk et al., 2015). These breakthroughs are also very important for the overall scientific success in cancer biology and the development of targeted therapies, which are always inspiring innovations and progressions of discoveries in oncology research (Neal & Donovan, 2000).

3.3 Overview of the Research Problem

Current reliance on PSA testing for screening for prostate cancer is associated with a number of challenges. Although it has become popular, PSA testing is plagued by several limitations attributed to a lack of specificity. As such, there are many false positive results, inappropriate biopsies, and overtreatment. Studies have shown that PSA testing often detects low-risk cancers that may never have the potential to progress toward clinical significance, causing these patients to undergo invasive procedures with little benefit (Wolters et al., 2009; Pinsky et al., 2005). It leads to increased healthcare

costs, increased patient anxiety, and increased risk of harm through unnecessary invasive procedures (Etzioni et al., 2013).

So far, blood-based biomarkers promise to improve accuracy in diagnosis and patient outcomes. Still, their integration into clinical practice involves significant barriers as development and validation costs are high, their cost-effectiveness is uncertain, and regulatory hurdles abound. Ethical concerns include overdiagnosis and overtreatment, especially when new methods detect cancers that would not have gone on to cause symptoms or harm during the life of an individual (Draisma et al., 2009).

Second, how these novel screening techniques impact the insurance coverage policies, recharging policies, and the general health care system is less clear. Novel blood-based tests like PCA3 measurement, KLK2, and circulating tumor cells (CTCs) must undergo rigorous validation to ensure that such assays do offer a meaningful advantage over the established methods. Tests ought to demonstrate not only clinical value but also economic viability in such systems characterized by resources that are strictly confined (Heijnsdijk et al., 2015).

In this connection, a patient's consent and issues with data privacy surface. Similar to most other advances in medical science, building a culture of transparency as well as trust with patients is put atop the agenda. Patients need clear and easily understandable information from the test outcome implications, especially in this regard: false positives versus false negatives (Mottet et al., 2020).

On the other hand, practical steps for conducting blood-based prostate cancer screening require the handling of considerable logistical and systemic challenges. Some of these

include equal access to advanced screening technologies and integration of new tests into clinical workflows and adequate training of healthcare professionals in these technologies. The disparate infrastructures for healthcare across different regions also complicate these new methods of screening (Neal & Donovan, 2000).

This research addresses these gaps by evaluating the systemic impacts, benefits, and challenges of blood-based prostate cancer screening from the perspectives of insurance companies, the healthcare industry, and patients. Through a comprehensive analysis of these aspects, the study seeks to provide actionable insights and recommendations that can facilitate the successful integration of advanced screening technologies into routine clinical practice, thus improving patient outcomes and optimizing healthcare resources (Grossman et al., 2018).

3.4 Operationalization of Theoretical Constructs

Research methodology constitutes the foundation of any thesis, dictating the methodology employed to gather, analyze, and interpret data. Generally, methodologies are categorized as quantitative, qualitative, and mixed methods approaches.

Quantitative research entails gathering numerical data and using statistical methods to test hypotheses, find patterns, or measure variables. It comprises experimental designs, quasi-experimental studies, correlational research, and descriptive surveys, which are commonly employed when the goal is to measure the problem or assess causal links (Creswell, and Creswell, 2017). Qualitative research, on the other hand, is concerned with analyzing complex phenomena using non-numerical data like interviews, observations, and textual analysis. Methods like case studies, ethnography, grounded

theory, phenomenology, and narrative inquiry allow researchers to comprehend participants' experiences, points of view, and social environments in detail (Tisdell, Merriam and Stuckey-Peyrot, 2025). Mixed methods research integrates both quantitative and qualitative methods, permitting more thorough exploration of research questions. This method is especially useful when one approach will not adequately address the research problem's complexity (Creswell & Clark, 2017).

The study will consider a mixed method approach in evaluating the impacts of blood-based prostate cancer screening. This will include both qualitative and quantitative methods of data collection as well as analyses for the purposes of comprehensively evaluating the cost effectiveness, regulatory frameworks, and practical implementation challenges associated with these new screening methods. This will help to understand benefits that accrue when integrating the test, preferably through insurance companies before giving out the insurance cover to an individual.

3.5 Research Purpose and Questions

The distinct purpose of the study is to assess the systemic impacts of blood-based prostate cancer screening on the insurance companies, the health industry, and patients. The target recipients are insurance companies, patients, and the healthcare industry. The implications are to drastically lower the reimbursement load on insurance providers. By detecting potential risks to health before a policy is issued, insurers will be able to better evaluate the health status of the applicant and charge reasonable premium rates that are commensurate with the person's true risk level. This forward-

looking measure not only assists insurers in controlling long-term expenditures but also ensures the sustainability of healthcare coverage programs.

From the subject's point of view, participating in cancer screening during policy application can result in early malignancy detection, in many cases, at stages that are more amenable to cure, less harmful, and cheaper. Early detection not only increases clinical outcomes but also mitigates the emotional and psychological trauma inherent in late diagnosis of cancer. Financially, it can translate into reduced out-of-pocket payments for the patient and less of an economic strain on families. Overall, the strategy creates a win-win environment by aligning the interests of insurers with those of policyholders' well-being.

Specific Aims

- To reduce/lower the reimbursement load on the insurance companies by incorporating the blood-based cancer screening tests prior to policy disbursement.
- To identify the quantifiable benefits to the insurers from lower-cost spending for late-stage prostate cancer treatments
- To identify obstacles and challenges to the integration of blood-based prostate cancer screening from the viewpoint of the insurance sector

3.6 Research Design

The study will consider a mixed-methods approach in evaluating the impacts of blood-based prostate cancer screening. This will include both qualitative and quantitative methods of data collection as well as analyses for the purposes of comprehensively evaluating such impacts. This will help to understand the benefits that accrue when

integrating the test, preferably through insurance companies, before giving out the insurance cover to an individual. The blood-based prostate cancer screening test is going to be compared on different sensitivities (70%, 80%, 90%, and 100%). The following data are going to be collected:

- Percentage of health insurance claims of the total health insurance sold annually.
- Percentage of the claims related to cancer
- Average amount per cancer claim
- Average cost of the blood-based cancer screening test.

The data points will be considered for the Indian population only. Various sources for the data collection will be:

- Insurance Regulatory and Development Authority (IRDAI) website and handbook.
- National Health Authority of India Website and database.
- Different insurance company websites to get the average amount of claims.

Once I have the above data points, I will first calculate the total outflow by insurance companies as reimbursements without having the blood-based cancer screening test. Then I will work out the outflow by the insurance company as reimbursements, including blood-based cancer screening tests (at different sensitivities mentioned above). I will be able to know the net savings that the insurance companies may or may not get if they incorporate blood-based cancer screening in their health check-up before handling the insurance for the individual by having the two tables compared using Excel.

Qualitative research will help in understanding the deeper implications of implementing new screening technologies and provide a comprehensive view of stakeholders' perspectives.

Cost-Benefit Analysis Matrix Development

- Create a matrix to carry out an in-depth cost-benefit analysis for firms in the insurance and diagnostic/healthcare sectors. This matrix will reflect cost-saving benefits for insurance companies when they combine blood-based prostate cancer screening with their coverage for clients/policyholders.
- Cost Metrics Include costs related to screening tests, follow-up procedures, treatment of diagnosed cancers, and management of false positives/negatives.
- Benefit Metrics Include potential savings from early detection, reduced need for invasive procedures, improved patient outcomes, and long-term reductions in advanced cancer treatment costs.

Quantitative Data Analysis

- Descriptive Statistics Use descriptive statistics to summarize the data collected, including mean costs, standard deviations, and ranges for both traditional and blood-based screening methods. Excel will be for this purpose.
- Comparative Analysis: Perform comparative analyses to identify significant differences in costs and outcomes between the two screening approaches. To perform the comparative analysis in this research, I will employ the Cost-Benefit Analysis (CBA) framework.

Qualitative Data Analysis

Interviews

I will hold interviews with key stakeholders who are in the capacity of Managers and above within the insurance companies for extracting perceptions regarding perceived benefits and challenges of blood-based prostate cancer screening. The stakeholders will be reached through email and/or calls.

India has 57 insurers in total, 24 that insure life and 33 insurance the non-life (Acko, n.d.). I will interview employees from 3 - 4 companies of 24 life insurers. The sample size must expand until saturation of the data is realized. About five officers from each of the firms will be interviewed at the managerial level, and this will run to saturation.

3.7 Population and Sample Selection

For Qualitative data analysis, the study population includes employees from different insurance companies like Mercer Marsh Benefits India, Prudent Insurance Brokers Pvt. Ltd, HDFC Life, etc. A total of 11 employees were interviewed. A detailed questionnaire had been prepared for the interview. The questionnaire used has been attached as Appendix A.

3.8 Participant Selection

It is necessary to ground 14 questions in the questionnaire probing the Impact of Integrating Blood-based Cancer Screening into Health Checkups and Determining Implementation Challenges. The questionnaire will be shared with Managers and above in 3-4 insurance companies to know the significance/advantages of incorporating blood-based cancer screening tests in Health checkups before policy disbursements and

to know the challenges in integration. I will personally contact them to ask for their consent. After receiving confirmation from the participant about his/her desire to participate in the study, I will share with him/her the questionnaire (Google form) so that he/she can respond.

Daniel (2019) indicates that in a qualitative case study design, the researcher has to concentrate on choosing respondents who can articulate perspectives pertaining to the research question to attain data saturation. It is only after data saturation is attained that the study phenomenon will be purer and clearer. Any variables that, if known, would change the results of the study, all the overlapping data would likely cancel out the unknown problems (Daniel, 2019). He suggested that when beginning the interview process, to determine themes, it is simple to select a small sample and assess information, and then conduct additional interviews until no new themes or data are present.

Even with purposeful sampling, there could be a limitation because the researcher might exclude a quality sample from being included in the sample and miss capturing the entire necessary information to better investigate the study questions (Morse and Clark, 2019). However, these researched participants were selected intentionally to participate due to their having first-hand information on the insurance segment as well as challenges for implementation of new policies and frameworks.

3.9 Instrumentation

For the purpose of this study, two research instruments are adopted. For a qualitative study, a comprehensive secondary research will be conducted to get the following data points:

- Percentage of health insurance claims of the total health insurance sold annually.
- Percentage of the claims related to cancer
- Average amount per cancer claim
- Average cost of the blood-based cancer screening test.

Once the data points are collected, a detailed cost-benefit matrix will be developed to make analysis.

For a quantitative study, a questionnaire will be provided to the participants, and they will be asked to provide a response voluntarily.

3.10 Data Collection Procedures

For secondary research, a comprehensive review of documents, government websites, academic journals, etc., was conducted. These include the following:

- Insurance Regulatory and Development Authority (IRDAI) website and handbook
- National Health Authority of India Website and database

Once the data points are collected, a matrix will be developed to study the cost benefit analysis. There will be use of descriptive statistics to summarize the data collected, including mean costs, standard deviations, and ranges for both traditional and blood-based screening methods. Excel will be for this purpose. This matrix will reflect cost

saving benefits for insurance companies when they combine blood-based prostate cancer screening with their coverage for clients/policyholders.

For qualitative data analysis, the participants will be reached out to through email and/or calls and/or WhatsApp. Upon their consent to participate in the study, the questionnaires will be shared.

3.11 Data Analysis

The research uses both qualitative and quantitative methods of data analysis to fully respond to the research questions and make an evidence-based judgment on the feasibility and efficacy of blood-based prostate cancer screening. The double approach allows for both economic implications (through secondary data) and stakeholders' views (through primary survey data) to be analyzed rigorously.

3.11.1 Qualitative Data Analysis (Secondary Research)

The qualitative aspect is focused on secondary data analysis, where the institution and publicly available data will be harvested and analysed systematically. The following are the major data points that will be gathered:

- Total annual premiums on health insurance and the rate of policies that lead to claims
- Percentage of insurance claims related to cancer
- Average size of cancer-related treatment claims
- Estimated cost of a blood test for prostate cancer screening

These points of data will be abstracted from the following sources:

- National insurance regulatory bodies (e.g., IRDAI Annual Reports)

- Health economic surveys and actuarial analyses
- Peer-reviewed journals, white papers, and industry reports

After compilation, the information will be tabulated and normalized. A cost-benefit matrix will then be constructed based on this information. The matrix will simulate various screening scenarios, projecting possible cost savings to insurers under assumptions like:

- Early detection results in reduced treatment costs
- A certain percentage of policyholders are screened annually
- Decrease in late-stage cancer claim payments due to early intervention
- Sensitivity analyses would also be undertaken to assess the robustness of assumptions, including changes in screening uptake rates and the cost of tests.

3.11.2 Quantitative Data Analysis (Survey Research)

The primary data collected through stakeholder surveys will be analyzed using statistical techniques, with the objective of identifying trends, correlations, and levels of consensus among respondents. The following steps will be followed:

- Survey responses will be coded numerically for statistical processing
- Responses will be checked for completeness and consistency
- Data will be input into Microsoft Excel
- The responses will be reviewed and analyzed and will be categorized into themes, if necessary, using basic thematic analysis techniques.

Once both datasets (secondary data analysis and primary stakeholder insights through questionnaire) are analyzed, the results will be integrated to draw actionable

conclusions. This will involve validating the cost-benefit analysis for insurance companies, finding out the perception of the stakeholders involved regarding the incorporation of such a test, and the challenges faced in implementation.

3.12 Research Design Limitations

Although this study is aimed at offering a detailed assessment of the feasibility and potential value of introducing blood-based prostate cancer screening, some of the limitations that are inherent in its research design must be recognized. They could impact the generalizability, validity, or scope of the results and should, therefore, be taken into consideration while interpreting the findings.

3.12.1 Limited Availability and Reliability of Secondary Data

A central component of the qualitative analysis in this research is based on secondary data gathered from external agencies like public health organizations, insurance regulators, diagnostic labs, and peer-reviewed literature. The completeness and accuracy of such data are outside the control of the researcher, and inconsistencies can occur because of:

- Differences in reporting practices among organizations and nations
- Incomplete or out-of-date datasets
- Insufficiency of disaggregated data related to cancer claims and/or expenditure on cancer care

These variables might restrict the accuracy of the cost-benefit matrix and require the application of assumptions or estimates, which might not accurately account for all conditions encountered in real life.

3.12.2 Sampling Constraints and Response Bias in Survey

The primary data collection involves voluntary responses from professionals in insurance through an online questionnaire. This sampling method presents several limitations, like:

- The number of qualified respondents may be limited due to time constraints and availability, impacting the statistical power and representativeness of the results.
- Participants who choose to respond may have stronger opinions or vested interests in cancer diagnostics, leading to skewed results.

Even with these constraints, the mixed methods design implemented in this research provides a solid framework to examine the economic and strategic worth of blood-based prostate cancer screening. Although the findings must be interpreted in light of these limitations, they nonetheless provide valuable preliminary results that can be used to guide larger-scale research, pilot projects, and policy making in the future.

3.13 Conclusion

The Methodology Chapter presented the overarching research structure utilized to test if blood-based screening for prostate cancer can be an equally useful tactic for patients, the health industry, and insurance companies alike. As increasing focus has developed for cost-conscious, non-surgical, population-wide methods for cancer detection, methodological selection here is directed to present strategic and empirical analyses for the effectiveness of incorporating such screening within prevalent models of healthcare and insurance.

This study employs a mixed-methods strategy, integrating secondary data analysis and primary survey research. Secondary research assists in building a cost-benefit matrix by collating and summarizing key data points, such as cancer-related claim rates, treatment costs, and test prices. This is necessary for financial modeling of the implications of mass screening programs. Conversely, the survey part is meant to capture operational preparedness, stakeholder attitudes, and potential barriers to adoption from throughout the insurance industry.

Critical methodological components such as population and sample choice, measurement, and data analysis plans were specifically planned to be valid, pertinent, and practically useful for the findings. Although the research is plagued by some limitations such as limitations in the availability of data, dependence on assumptions in the cost model, and limited generalizability, the methodology adopted is adequate for yielding indicative findings that can inform further investigation and policy experimentation

CHAPTER IV: RESULTS

Chapter III discussed the methodology that will be used, along with the design and data collection methods, to validate the research findings. This chapter will focus on the results obtained from the research conducted for both qualitative and quantitative methods. For the ease of understanding, this chapter will present findings for qualitative and quantitative methods separately and then provide a comprehensive finding. The qualitative method, which is based on secondary analysis, answers the following research questions:

Will the insurance company benefit from incorporating the blood-based cancer screening test?

What are the potential benefits to individuals/patients of using the blood-based screening methods over the traditional screening methods available?

4.1 Will the insurance company benefit from incorporating the blood-based cancer screening test?

To answer the first question, I have developed the following matrix (Table 1: Savings for Insurance Company using Blood-based Cancer Screening Test) to find out whether there is any potential benefit to the insurance companies for incorporating the blood-based test to determine the policy coverage.

Savings for Insurance Company using Blood-based Cancer Screening Test					
		100% Sensitivity	**90% Sensitivity**	**80% Sensitivity**	**70% Sensitivity**
Sr. No.	**Description**	**Value**	**Value**	**Value**	**Value**
1	Number of Policies sold annually	10,000	10,000	10,000	10,000
2	Total number of health insurance claims (***24%*** *of the total policies sold*)	2,400	2,400	2,400	2,400
3	Number of claims related to cancer (***5.7%*** *of total health insurance claims*)	137	137	137	137
4	Average expenditure per cancer patient (in INR)	3,31,177	3,31,177	3,31,177	3,31,177
5	Total amount of cancer claims (in INR) (**Without** blood-based cancer screening test) **[A]**	**4,53,05,014**	**4,53,05,014**	**4,53,05,014**	**4,53,05,014**
6	Total number of claims detected by blood-based cancer screening test (at different Sensitivities)	137	123	109	96
7	Number of claims undetected by Blood-based cancer screening test (at different sensitivities)		14	27	41
8	Cost per Test (Blood-based cancer screening test) (In INR)	2,500	2,500	2,500	2,500

9	Total Cost for blood-based cancer screening test (for 100,000 policies) **[B]** (In INR)	2,50,00,000	2,50,00,000	2,50,00,000	2,50,00,000
10	Cost of undetected claims to the insurance company **[C]** (In INR)	0	45,30,501	90,61,003	1,35,91,504
11	Total cost to insurance company **[B+C]** (In INR)	2,50,00,000	2,95,30,501	3,40,61,003	3,85,91,504
12	**Total Savings** (In INR)	**2,03,05,014**	**1,57,74,512**	**1,12,44,011**	**67,13,510**

Table 4.1: Cost Benefit Framework: Savings for Insurance Company using Blood-based Cancer Screening Test (Author's work)

The matrix considered the following parameters.

i. Number of policies sold annually

This represents the total number of individual health insurance policies that have been written by insurance carriers in a specific year. It is an initial measure that will be used to estimate the potential coverage and effect of any suggested intervention i.e., adding a blood-based cancer screening test to the insurance process.

For the purpose of this analysis, information has been taken from the Insurance Regulatory and Development Authority of India (IRDAI) Handbook for Health Insurance 2023-24, which gives detailed industry-wide figures, such as policy issuance, gross premiums, net premiums earned, incurred claims, and incurred claims ratio. In particular, Part III, Sheet 67 of the handbook states that individual health

insurance policies worth INR 2,30,99,811 were sold during the financial year 2023-24.

Still, for the sake of simplicity and in order to enable feasible and representative calculations in this study, the number of policies has been scaled down to **10,000 policies**. This scaling does not detract from the integrity of the analysis since it is meant to illustrate proportional relationships and allow cost-benefit modeling that may be extrapolated later to realistic figures.

This assumption facilitates a more specific simulation of the economic and clinical consequences of introducing blood-based cancer screening at policy release, in a representative population.

ii. Number of Claims paid

This parameter is the number of health insurance claims filed and paid by insurers for a given period. It gives essential information on the insurers' claims burden and is the basis for estimating the possible effect of implementing preventive services, such as early detection of cancer using blood-based screening.

To calculate this figure, information has been obtained from the Insurance Regulatory and Development Authority of India (IRDAI) Handbook for Health Insurance 2023-24. The handbook reports that 54,59,284 claims were made and settled in the financial year of 2023-24, which represents about **24%** of total individual policies sold in this year (2,30,99,811 policies).

Using this industry standard claims incidence of 24%, the estimated number of paid claims resulting from this application of 10,000 normalized policies is **2,400**.

Such simplified modeling makes it possible to conduct proportional analysis and allow comparison of scenarios e.g., the deployment of blood-based cancer screening without sacrificing analytical precision. The 24% claim rate is used as a benchmark to determine how many policyholders use their health insurance on average over a one-year period, which is needed to evaluate the possible cost-benefit effect of interventions directed at lowering high-cost claims, i.e., those for cancer.

iii. Number of claims related to cancer

This metric represents the share of total health insurance claims that are specifically attributed to cancer-related treatments, such as hospitalization, chemotherapy, radiation therapy, surgery, and supportive care. Understanding the proportion of cancer-related claims is crucial for assessing the financial burden of cancer on insurance providers and for evaluating the potential benefits of preventive screening programs.

The percentage of claims attributed to cancer was determined through publicly available data sources. Approximately 5.7% of all health insurance claims filed in India during the financial year 2023-24 were related to cancer care (Business Today, 2024).

Applying this percentage to the estimated total of 2,400 claims (based on a normalized policyholder population of 10,000), the number of cancer-related claims is calculated as:

2,400 total claims × 5.7% = **137 cancer related claims**

This figure highlights the growing impact of cancer on health insurance systems. Despite representing a relatively small fraction of total claims, cancer-related cases typically incur significantly higher treatment costs and longer durations of care, leading to disproportionately high reimbursement amounts. This underscores the need for early detection and intervention strategies, such as blood-based screening, to help insurers manage risks more effectively while improving patient outcomes.

iv. Average expenditure per cancer patient

This measure is the average direct annual medical cost incurred for the management of a one cancer patient in India. It includes the entire gamut of costs associated with the treatment, such as diagnosis, hospital stay, surgery, chemotherapy, radiotherapy, drugs, and follow-up treatment. They are the immediate out of pocket costs of cancer treatment and do not include indirect costs like loss of productivity or caregiver burden.

The mean direct annual cost per cancer patient in India is estimated to be about **₹3,31,177,** as per a study by Prinja et al. (2023). The value is derived from data

gathered across a range of cancer care settings and is a composite costing that is generalizable to various types and stages of cancer.

This estimate is a key input to both health policy model planning and economic evaluation models, especially in the assessment of cancer prevention or early detection interventions like blood screening tests. It enables stakeholders, insurers, care providers, and policymakers to:

- Estimate the monetary burden of cancer treatment on insurance schemes and patients.
- Estimate the total cost burden of cancer-related claims over time.
- Compare costs in different scenarios, e.g., early versus late-stage diagnosis.
- Estimate likely savings from lower treatment intensity if cancers are diagnosed early.

Also, this cost reference point offers a starting point for measuring return on investment (ROI) on novel diagnostic technologies, to decide whether initial investments in diagnostics, such as multi-cancer early detection (MCED) tests, can lead to long-term insurance cost savings and better patient outcomes.

v. Total amount of cancer claims

This is the total cost incurred by insurance firms in paying for claims that are cancer-related. To calculate this amount, first, the number of cancer-related claims was ascertained as a percentage of the total number of insurance claims. From the

information presented, there were 137 cancer related claims, which translates to about 5.7% of the total number of 2,400 claims.

To find the average monetary value of these claims, the incidence of cancer (137) was multiplied by the average direct yearly cost per cancer patient in India, which is around ₹3,31,177 (as mentioned in point iv). This works out to a total amount of reimbursement of around **₹4.5 crores** (₹3,31,177 × 137), which is the average cost incurred by the insurance company for cases related to cancer in the period provided. This projection is indicative of the immense economic burden of cancer treatment on insurance providers and the need for early detection and preventive measures to control healthcare expenditures in the long term.

vi. Total number of claims detected by Blood-based cancer screening test (at different sensitivities)

This measure approximates the number of cancer cases that would have been detected by a blood-based cancer screening test, given that such a test had been applied to everyone at the point of policy implementation. It indicates the effectiveness of the test to detect cancer in different sensitivity levels, namely, 70% to 100%.

Sensitivity is the capacity of a test to identify individuals who have the disease accurately (true positives). Sensitivity increases, reducing false negatives, so more cancer would be detected. For purposes of analysis, various sensitivities (70%, 80%, 90%, 100%) have been used to reflect variations in performance in the real world.

The lower 70% sensitivity level has been chosen in accordance with generally acceptable clinical standards, according to which any screening test below 70% sensitivity can be insufficiently reliable for early detection (Bujang & Adnan, 2016). For each sensitivity level, detected claim numbers have been determined by multiplying the overall number of cancer claims (137) by the corresponding sensitivity percentage.

Example:

- At 70% sensitivity: 137 × 0.70 = 96 cases identified
- At 80% sensitivity: 137 × 0.80 = 109 cases identified
- At 90% sensitivity: 137 × 0.90 = 123 cases identified
- At 100% sensitivity: 137 × 1.00 = 137 cases identified

This discussion assists in demonstrating how the sensitivity of the screening test affects the number of cancers that might be detected prior to symptoms or claims, thus allowing for earlier intervention and potentially lowering treatment expenses.

vii. Number of claims undetected by Blood-based cancer screening test (at different sensitivities)

This parameter will estimate the number of cancer cases that would go undetected by the blood-based cancer screening test, contingent upon the sensitivity of the test. These are the false negatives people who have cancer but are not detected as such by the screening test. As such, these people are bound to be diagnosed later, when they develop symptoms, and will then make health insurance claims for the treatment of cancer.

To arrive at this figure, the overall number of cancer claims (as determined in point iii) is used as the numerator (137 claims). This is subtracted from the number of cases picked up by the screening test at different levels of sensitivity (determined in point vi).

For instance:

At 70% sensitivity, 96 are detected out of 137 cancer cases, leaving **41 undetected**.

At 80% sensitivity, 110 detected → **27 undetected**

At 90% sensitivity, 123 detected → **14 undetected**

At 100% sensitivity, all 137 cases were detected → **0 undetected**

This parameter is critical in measuring the residual risk that is still present even when a screening program has been put in place. It also sheds light on:

- The limitations of the test at different levels of performance.
- The economic implications to insurers as a result of undetected cases moving to more severe and expensive stages.
- The possible requirement for additional diagnostic approaches or confirmatory testing among those at increased risk.

By simulating gaps in detection at various sensitivities, healthcare planners and insurers can gain a greater appreciation of how enhancing test performance is associated with decreased long-term expenditures and enhanced clinical outcomes.

viii. Cost of the blood-based cancer screening test (Cost per test)

This is the unit cost of performing one blood-based cancer screening test on one person. For the needs of this study, a test cost of ₹2,500 has been taken as an average for every test. It incorporates costs for sample collection, laboratory testing, biomarker evaluation, reporting, and involved logistics.

The ₹2,500 figure is a rough estimate using the prevailing prices of sophisticated multi-cancer early detection (MCED) blood tests available in India. Real prices could differ based on the extent of the test (e.g., how many cancers are to be screened), the technology platform employed (e.g., next generation sequencing, methylation analysis, or CTC count), and whether the test is being presented as a part of a bundled preventive health package.

This per test expense is a key input in cost benefit and return on investment (ROI) calculations, since it enables the stakeholders to estimate:

- The screening cost of the entire target population (e.g., 10,000 policyholders)
- The cost per case of cancer detected at various sensitivity levels
- The cost offset potential, if early detection results in lower intensity of treatment and reduced hospital stays.

For example, screening 10,000 patients at ₹2,500 per patient yields the total cost of screening as ₹2.5 crores. This can then be compared with the estimated cost savings from early identification and foregone late-stage cancer claims in order to ascertain the economic feasibility of infusing such a screening program into the insurance model.

In conclusion, the ₹2,500 price is a key figure to simulate various scenarios of adoption and implementation of blood-based screening for cancer within the health insurance market.

ix. Total Cost for Blood-based cancer screening test

This parameter is the overall monetary investment made by insurance firms for carrying out a blood-based cancer screening program for all those applying for health insurance policies. An assumption here is that the screening test is carried out before the policy issuance, thus enabling the insurers to evaluate the risk of cancer at the time of onboarding.

Total expense is arrived at by taking the number of people screened (10,000 candidates in this case) and multiplying it with the expense per test (₹2,500, as specified in point viii). The total screening cost comes to ₹2.5 crores.

This initial investment allows insurance companies to:

- Screen high risk individuals or incipient cases of cancer prior to policy sanction.
- Take informed decisions in underwriting, such as:
    - Providing cover at modified or increased premiums to account for increased risk.
    - Delaying or excluding coverage in individual cases according to internal risk policies.
    - Referral for additional diagnostic evaluation where appropriate.

The strategic objective is to reduce the number of future high-cost claims by intervening sooner, hopefully cutting back on late-stage cancer diagnoses necessitating intensive, extended, and costly treatment.

Though this preventive strategy involves upfront investment, it could translate into significant long run cost savings to insurers through:

- Reduced incidence of high claim cancer cases
- More precise risk stratification of the insured membership
- Enhanced claims predictability
- And, at best, an improved and better managed insurance portfolio.

This measure also sets the stage for a cost benefit analysis by dividing the overall screening cost against the anticipated savings due to avoided or reduced cancer claims.

x. Cost of undetected claims to the insurance company

This is the monetary burden incurred by the insurer as a result of false negatives, i.e., those who actually have cancer but were not captured under the blood-based cancer screening test. These people would have tested negative in the pre policy screening process, been found eligible for regular coverage, and then subsequently made cancer related insurance claims as their condition advances and is clinically diagnosed at a later (and generally more costly) stage.

This expense is a byproduct of the sensitivity of the test, which quantifies to what extent the screening tool can identify actual positive instances of cancer. A test that

is less than 100% sensitive will always have some false negatives. Hence, this measure is computed by:

Cost of undetected claims = Number of false negatives × Average expenditure per cancer patient

For the purpose of this research, the computation is simulated at various sensitivity levels 100%, 90%, 80%, and 70% to represent various potential performance levels of the screening test. As sensitivity reduces, there are more false negatives and greater residual burden on the insurer from undiagnosed cancer progressing to claim inducing states.

For instance:

- At 100% sensitivity, all cases of cancer are identified → 0 undetected cases → ₹0 in undetected claims cost.
- At 90% sensitivity, 10% of the cases of cancer remain undetected → 14 undetected cases × ₹331,177 = ₹45.30 lakhs.
- At 80% sensitivity, 27 undetected × ₹331,177 = ₹90.61 lakhs.
- At 70% sensitivity, 41 undetected × ₹331,177 = ₹1.36 crores.

This parameter is important for insurers since it:

- Points out the remaining financial risk even after performing screening.

- Assists in assessing the trade offs between test expense, sensitivity, and effect on future claims.
- Assists in making choices about test selection, pricing models, and policy underwriting requirements.

Finally, this analysis allows for better estimation of cancer related liabilities and facilitates evidence based planning for preventive healthcare integration in insurance products.

xi. Total cost to the insurance company

This measure reflects the total cost incurred by the insurer as a result of having a blood-based cancer screening program. It is comprised of two main elements:

a. *Screening Costs*- initial investment made by the insurer for the purpose of giving the blood-based cancer screening test to all prospective policy applicants at the time of application. This is computed as:

Screening cost = Number of people screened × Cost per test

For instance, if 10,000 people are screened for ₹2,500 each, the cost of screening is ₹2.5 crores.

b. *Undetected Claims Cost (False Negatives)*- the cost of financial liability generated by undetected cancer cases due to less than perfect sensitivity of the test. These people, though screened and cleared, eventually develop cancer and claim reimbursement. This is estimated as:

Undetected Claims Cost = Number of undetected cancer cases × Average expenditure per cancer patient

It depends on test sensitivity (e.g., 70%, 80%, 90%, or 100%) and may have a significant effect on total insurer spending. The total cost at different sensitivities is mentioned in the table below.

Sr. No.	Sensitivity	Detected Cases	Undetected Cases	Undetected Claims Cost (INR) (In Lakhs)	Total Cost (INR) (In Lakhs)
1	100%	137	0	0	250
2	90%	123	14	45.30	295
3	80%	109	27	90.61	341
4	70%	96	41	136	386

Table 4.2: Total Cost Calculations (Author's work)

The overall cost to the insurance firm is therefore calculated as:

Total Cost = Screening Cost + Undetected Cancer Claim Cost

This parameter provides an overall estimate of the economic effect of adding blood-based cancer screening as part of the insurance enrollment process. It assists in:

- Measuring the monetary trade offs between early identification and residual risk

- Determining the feasibility and viability of embracing such preventive measures
- Measuring return on investment (ROI) by contrasting this overall expense with possible savings from reduced late stage cancer claims
- Guiding policy making on underwriting rules, premium rates, and long term health risk management.

Finally, this measure helps insurers to make informed decisions regarding the implementation and optimization of early cancer detection devices in their processes.

xii. Total savings

This is the parameter for the net financial gain or cost avoidance to the insurance company from adding a blood-based cancer screening test to its policy issuance process.

Literally, it quantifies how much the insurer saves by:

- Identifying early cancer cases, thus lowering the risk of costly late stage claims.
- Improving underwriting decision making, including adjusting premiums, deferring, or excluding coverage for high risk individuals identified upon screening.
- Preventing payments for claims that would otherwise have arisen if cancer had been undetected at the point of onboarding.

Total savings is calculated by comparing two scenarios i.e., (a) Without screening and (b) With screening. Without screening, is when the insurance company disburses

policies without conducting any cancer screening. All cancer related claims (137 in this study) are eventually reimbursed.

Total cost (Without Screening) = Cancer related claims × Average expenditure per cancer patient

Total cost (Without Screening) = 137 × ₹331,177 = ₹4.53 crores

With screening, is when the insurance company screens all individuals before onboarding or rolling out the insurance policies. As discussed in point number (xi) above, these factors in the screening cost and the cost for false negatives (undetected cancer claims). The total cost is mentioned in Table No. 2.

Total savings is derived by comparing the Total cost (without screening) and the Total Cost (with screening). The total savings at different sensitivities is calculated in the table below.

Sr. No.	Sensitivity	Baseline Cost without Screening (INR) (In Cr.)	Total Cost with Screening (INR) (In Cr.)	Total Savings (INR) (In Cr.)
1	100%	4.53	2.50	2.03
2	90%	4.53	2.95	1.58
3	80%	4.53	3.41	1.12
4	70%	4.53	3.86	0.67

Table 4.3: Total savings calculation (*Author's work*)

In conclusion, this analysis gives a structured evaluation of the economic implications of having a blood-based cancer screening test as part of the issuance process of health insurance policies. Through the examination of the major parameters such as number of policies sold, claims paid, percentage of cancer claims, average cost per cancer patient, and performance of the screening test at different sensitivities, we illustrate how early detection can practically influence cost management for insurers.

The information shows that although a one time investment is needed for conducting screening tests (at ₹2,500 per person), the long term cost savings are substantial. At greater sensitivities, the number of undiagnosed (false negative) cancer cases is reduced, thus lowering the expense of cancer claims when cancer appears at a later stage. Even with a conservative sensitivity of 70%, insurers do realize quantifiable savings, which only increase as test sensitivity increases.

The sum total to the insurer includes the cost of screening as well as the cost of silent claims. A comparison with the control cost arising in the absence of any screening will illustrate the sum total of savings ranging from around ₹67 lakhs to more than ₹2 crores, depending upon the sensitivity of the test. The results not only reflect the promise of preventive diagnostics to improve financial sustainability in the insurance industry but also reinforce a transition toward risk sensitive underwriting behavior.

In summary, the integration of blood-based cancer screening into the insurance onboarding process is an economical strategy that provides a win win situation,

improving early detection of cancer while maximizing claim outflows and enhancing the overall financial stability of insurers.

4.2 What are the potential benefits to individuals/patients of using the blood-based screening methods over the traditional screening methods available?

The potential benefits of blood-based screening over the traditional screening methods is mentioned in the table 4.4 below:

Criteria	Blood-based Screening (e.g., MCED)	Traditional Screening (e.g., Mammography, Colonoscopy, Pap smear)
Number of Cancers Detected (Brito-Rocha et. al., 2023)	Multiple cancers with one test	Typically detects one cancer type per test
Invasiveness (Mishra et. al., 2024)	Minimally invasive (simple blood draw)	Often invasive (e.g., colonoscopy, Pap smear)
Screening Frequency	Potential for annual or biannual use	Varies (some annual, others once every 5–10 years)
Detection Stage (Imai et. al., 2025)	Capable of detecting cancers at earlier, asymptomatic stages	Often detects cancer after symptoms or visible abnormalities appear
Patient Compliance (Gelhorn et. al., 2023)	High (due to convenience and ease)	Lower (due to discomfort, prep, or fear)
Accessibility (Carbonell et. al., 2024)	Can be offered in primary care or remote settings	Requires specialized facilities or trained personnel
Preparation Required (Carbonell et. al., 2024)	None	Often requires preparation (e.g., fasting, bowel prep)

Time Required (Carbonell et. al., 2024)	Few minutes (blood draw)	Varies; some require hours (e.g., colonoscopy appointments)
Radiation Exposure (Brito-Rocha et. al., 2023)	None	Some involve radiation (e.g., mammograms, CT scans, serum PSA testing)
Cost Efficiency (Long Term) (Kansal 2024)	Potentially cost saving by detecting cancers early	High costs are associated with late stage diagnosis and treatment
Population Coverage (Carbonell et. al., 2024)	Can include cancers without existing screening protocols	Limited to a few cancers with existing screening guidelines
Follow Up Needed (Lennon et. al., 2020)	Requires follow up imaging or diagnostic confirmation if positive	May provide immediate imaging or visual assessment

Table 4.4: Blood-based Cancer Screening vs. Traditional Screening Methods

For qualitative research, key stakeholders from the insurance sector were surveyed. The survey form includes 14 questions that are specifically designed to understand the understanding of the insurance sector with regards to the blood-based cancer screening test and the challenges that are faced or likely to be faced in incorporating the screening test

for policy disbursement. The survey will also help understand their views on potential steps that can be taken to incorporate the blood-based screening test into policy disbursement. A sample survey form/ Questionnaire can be referred to in Appendix A. The survey form was provided to the participants as Google Forms.

Basic Information

The survey form used in the qualitative study starts with the basic information, like name and the insurance company the participant is associated with. A total of 11 participants were surveyed from 4 different insurance companies. The distribution of the participants based on the insurance company they are associated with is illustrated below.

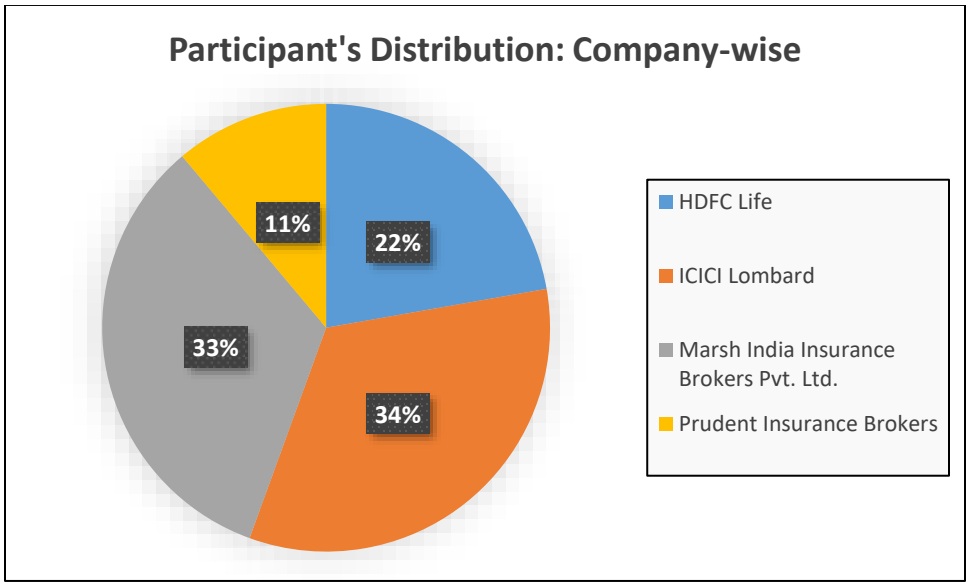

Figure 4.1: Participant's Distribution (*Author's work*)

Name of the Insurance Company	Number of Participants
HDFC Life	2
ICICI Lombard	3
Marsh India Insurance Brokers Pvt. Ltd.	3
Prudent Insurance Brokers	1

Table 4.5: Number of Participants (*Author's work*)

4.3 What are the systemic implications of blood-based screening for insurance companies, specifically on coverage policies, reimbursement strategies, and the general environment of healthcare spending?

One of the objectives of this study was to evaluate the state of knowledge among insurance stakeholders at present about blood-based cancer screening technology and how they perceive the wider systemic effects should such technology become included in regular health checkup packages offered to policyholders. The answers received exhibited certain trends in familiarity, strategic awareness, and perceived effects from an insurance policy and healthcare ecosystem viewpoint.

4.3.1 Familiarity with Blood-based Screening

Most of the insurance professionals interviewed represented by well known companies like Marsh India, Prudent Insurance, and other prominent brokerages said that they were "very familiar" or "somewhat familiar" with blood-based cancer screening technologies. To be specific, 80% of the respondents either had direct experience with or an educated idea about such technologies.

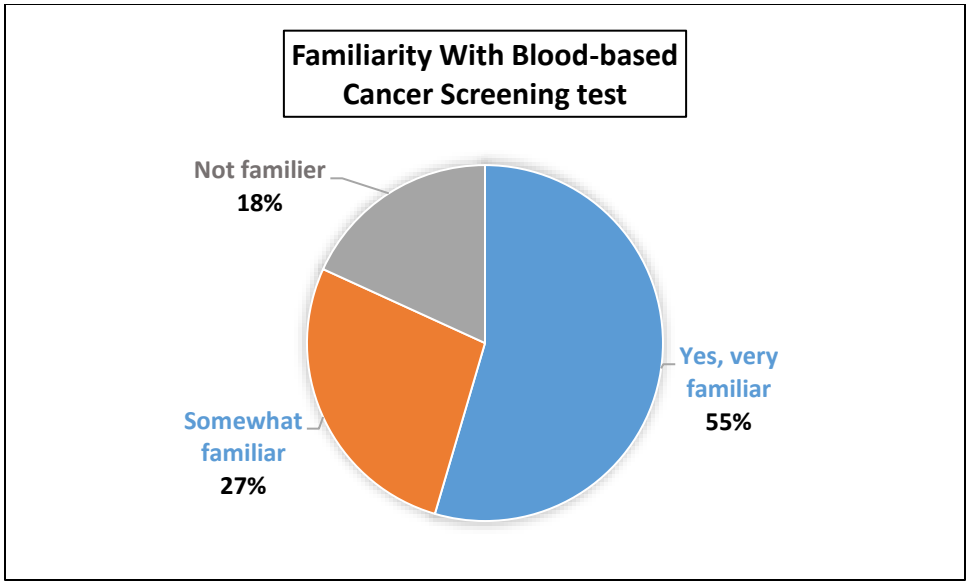

Figure 4.2: Familiarity with blood-based cancer screening test

(*Author's work*)

This degree of comfort, though not yet pervasive, suggests an increasing penetration of precision diagnostics into the awareness of insurance decision makers, particularly health benefits design and corporate wellness planners.

Also, when asked to rate their organization's level of awareness regarding advanced diagnostic technologies, a total of 90% of respondents selected either "moderate" or "high" awareness for their organizations. To elaborate this further, 3 respondents selected "high" awareness and 7 respondents selected "moderate" awareness. One respondent selected "low" awareness. The graphical illustration of awareness is shown in Figure 4.3 below.

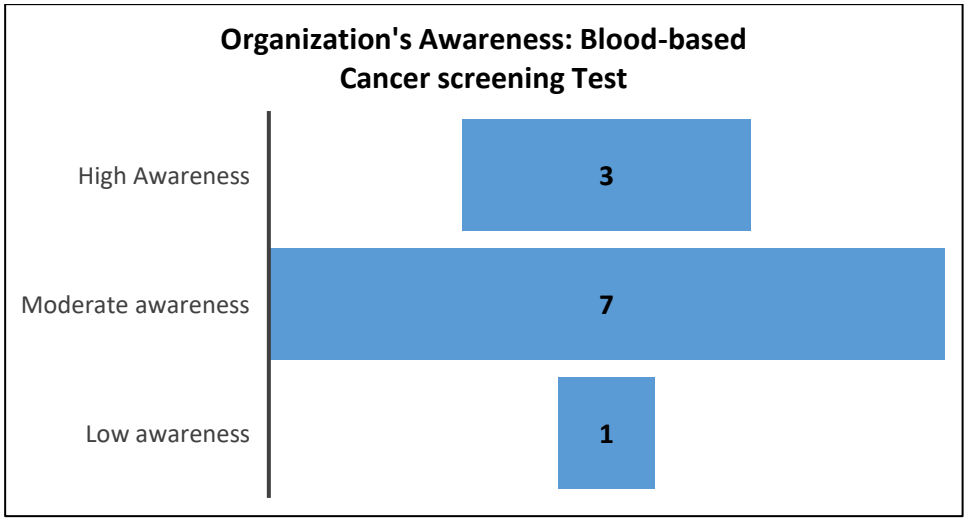

Figure 4.3: Organization's Awareness for Blood-based Cancer Screening Test

(*Author's work*)

This indicates that awareness is not an attribute exclusive to individuals but is starting to become institutionalized, a key prerequisite for policy innovation and benefit design.

4.3.2 Systemic Implications Identified by Stakeholders

Respondents were then prompted to consider the systemic implications that incorporation of blood-based prostate cancer screening could have, especially with regards to coverage policy, reimbursement, and the general environment of healthcare expenditures. The answers coalesced around a few central insights:

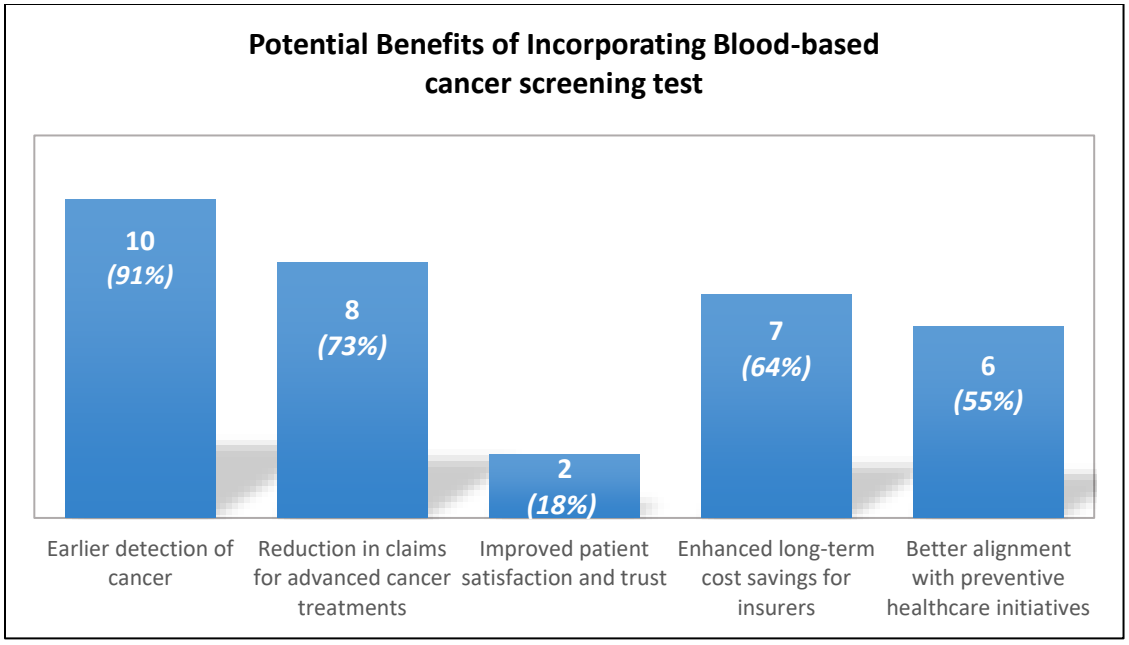

Figure 4.4: Potential Benefits of Incorporating Blood-based Cancer Screening Test (*Author's work*)

- *Move from Reactive to Preventive Models of Care* - Another common theme was that blood-based screening technologies fit with the industry's movement toward preventive care. The respondents (91%) observed that the early detection of cancers like prostate cancer at an early stage would contribute to a decrease in the number and severity of claims associated with late-stage diagnosis and aggressive treatments.
- *Long-term Cost Savings* - Some respondents (64%) recognized that while early adoption would mean costs for testing, integration, and training, they would be overshadowed by future/ long term savings in claims payments. The reasoning here is that late-stage prostate cancer typically means extended hospitalization, costly

therapies, and extended care expenses that could be avoided through early detection.

- *Risk Stratification Potential* - The respondents also pointed towards the scope for insurers to use a more risk-adjusted underwriting method of policy pricing. For example, screening information using blood could allow for more refined segmentation of policyholders in terms of cancer risk, with resulting in more customized and actuarially justified product design.
- *Increased Value Proposition to Insureds* - It was widely felt among many insurance experts that making this type of advanced screening a part of health examinations would greatly increase the perceived worth of insurance policies. This would contribute to greater involvement, increased renewal rates, and higher customer satisfaction, especially among health-aware or high-net-worth individuals.

4.3.3 Regulatory Uncertainty and Organizational Readiness

Though the anticipated benefits were robust, there were also indicative systemic issues, notably in terms of regulatory clarity. A majority (63%) felt that regulatory hurdles would play some role in the implementation of blood-based cancer screening tests in routine health checkups for policy disbursement.

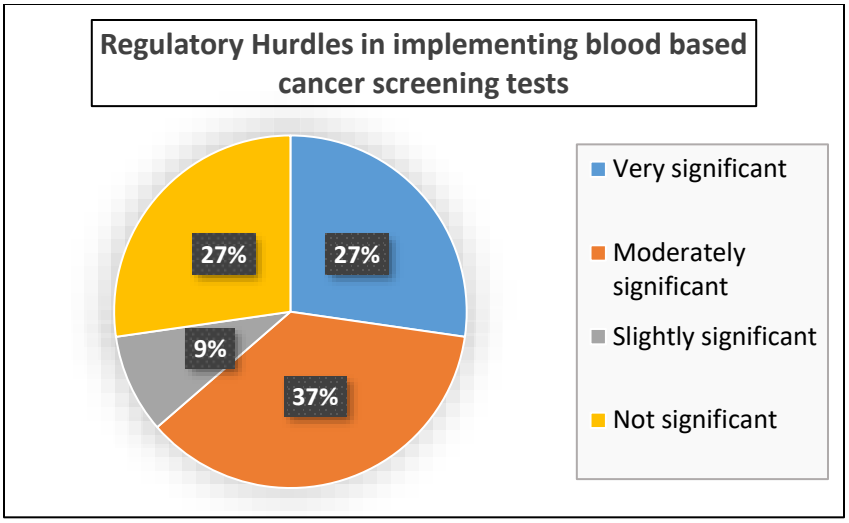

Figure 4.5: Regulatory Hurdles in Implementing Blood-Based Cancer Screening Tests (*Author's work*)

The insights from this section reveal that the insurance sector is moving into a period of thoughtful inquiry and guarded optimism. There is an unambiguous awareness of the systemic benefits that blood-based prostate cancer screening can provide, from enhanced claim management to fortified preventive care narratives. At the same time, the responses highlight the necessity for more robust & clear regulatory frameworks, actuarial models, and implementation protocols to enable mass adoption.

To summarize, overall awareness is building, institutional preparedness is developing, and system implications are better appreciated in terms of both risk reduction and customer value creation. These circumstances, in combination, provide a ground for piloting and incremental scaling of blood-based prostate cancer screening in insurance-backed health programs.

4.4 What are the quantifiable benefits to the insurers from lower cost spending for late stages of prostate cancer treatments, but in the meantime, enhancing the general health outcomes of policyholders?

Quantitative research was conducted to answer the question. For better and stepwise understanding the question is divided into two parts:

I. Will the insurance company benefit from incorporating the blood-based cancer screening test? If yes, what are the quantifiable benefits?

II. What are the potential benefits to individuals/patients of using the blood-based screening methods over the traditional screening methods available?

Both the above questions have been answered in depth in point 4.1 and point 4.2.

4.5 What are the identified obstacles and challenges to the integration of blood-based prostate cancer screening from the viewpoint of the insurance sector?

Although the overall perception by insurance experts for blood-based screening of prostate cancer was guarded optimism, they also outlined several operational, financial, infrastructural, and institutional impediments that might stymie implementation. These impediments, albeit not universally felt to be unbeatable, embody major considerations that must be overcome to facilitate the successful scaling and integration of such screening into insurance-backed health checkup schemes.

4.5.1 Financial and Cost-Related Barriers

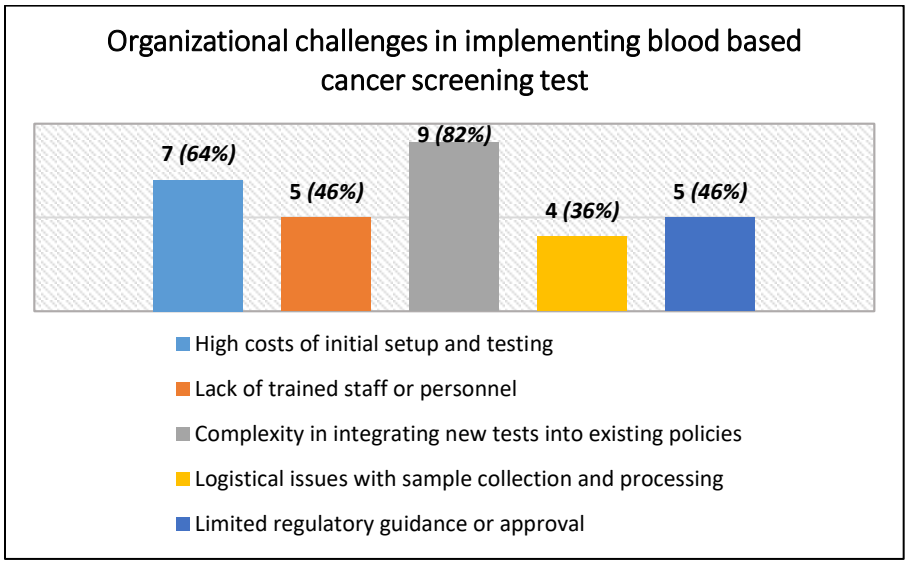

Figure 4.6: Organizational challenges in implementing blood-based cancer screening test (*Author's work*)

An overwhelming majority (64%) of those surveyed identified the prohibitively high initial expense of the screening test as the biggest obstacle. This is not just the explicit cost of each test, but even the implicit integration costs in terms of system upgrades, training insurance and healthcare staff, and administrative overheads.

In contrast to traditional screening (e.g., PSA or DRE), blood genomic or liquid biopsy testing uses sophisticated molecular methods that are more expensive because of proprietary technology, reagents, and quality controls required. Insurers were concerned that in the absence of clear cost-benefit trade-off knowledge, underwriting these tests on a large scale could result in greater premium pressure, particularly in price-conscious markets.

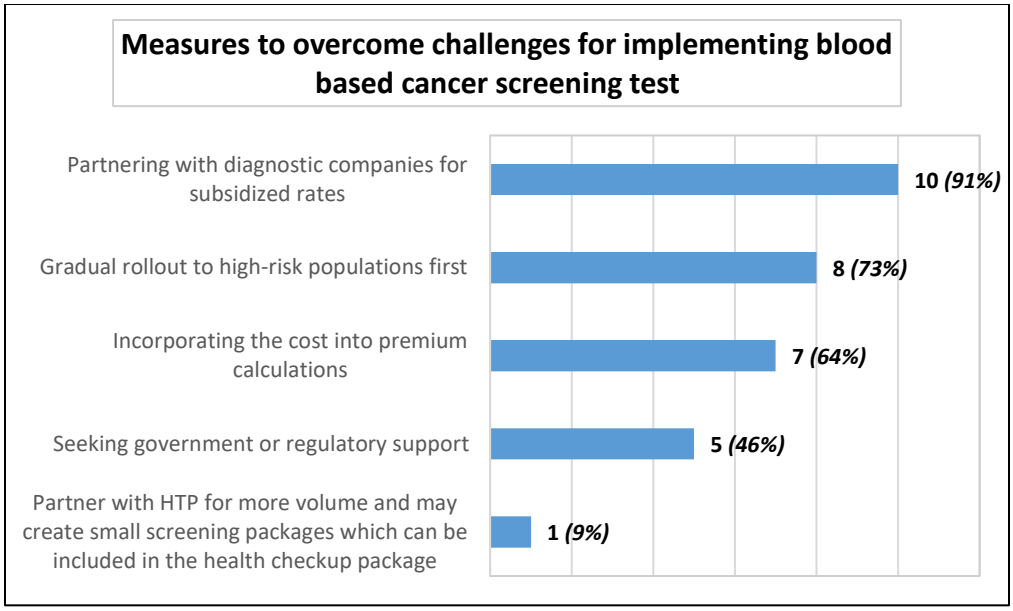

Figure 4.7: Measures to overcome challenges for implementing blood-based cancer screening test (*Author's work*)

To limit the above-mentioned challenges, the respondents proposed the following measures:

- Subsidization by early-adopting diagnostic firms (91%).
- Providing the test to high-risk population first and then gradually roll out to others (73%).
- Risk-tiered pricing by policyholder demographics and medical history (64%).

These options were considered possible routes to rendering the model economically feasible.

4.5.2 Operational and Workflow Integration Challenges

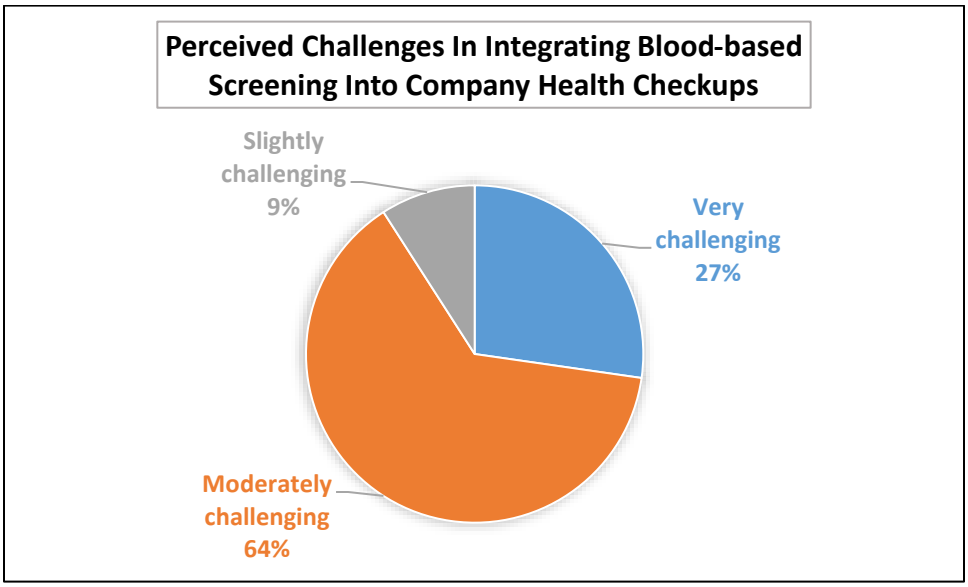

Figure 4.8: Perceived Challenges in Integrating Blood-Based Screening into Company Health Checkups (*Author's work*)

Another pressing concern raised was how complicated it would be to integrate blood-based screening tests into current insurance processes. Respondents indicated that the majority of insurance companies have standardized health checkup packages that are simple to process, monitor, and reimburse. Adding a new test, particularly one that is fairly recent and does not have standardized coding, would necessitate:

- Changes in checkup protocols,
- Customer service teams and panel doctors to be trained,
- Claim processing systems and electronic health records to be updated.

This would result in in-house resistance, longer turnaround times, and administrative backlog, especially in technologically inflexible companies. Further, for screening to

make a difference, a formal post-test care pathway (e.g., follow-up investigations or referrals) would also have to be planned out, again enhancing the complexity.

4.5.3 Logistical and Supply Chain Limitations

36% of respondents (Refer to Figure 4.6) were concerned about the collection, transport, and turnaround times of samples. Molecular tests based on blood generally demand cold chain facilities, validated phlebotomy, and high-quality laboratory processing that may not be equally available geographically.

Such limitations may:

- Limit equitable access,
- Lead to result delivery delays,
- Influence trust and user satisfaction.

Unless resolved through well-coordinated partnerships with diagnostic networks and phlebotomy laboratories, logistics would become a bottleneck for nationwide implementation.

4.5.4 Internal Buy-In and Strategic Alignment

82% of the respondents (Figure 4.6) noted that internal organizational resistance due to test complexity may be an issue. Implementing a new, clinically sophisticated test might involve cross-functional alignment of actuarial, medical underwriting, operations, claims, and sales staff. For most insurance companies, particularly those who specialize in group or retail health plans with narrow margins, such alignment is not likely to be forthcoming without the strong advocacy of leadership.

In addition, in the absence of explicit regulatory requirements or competitive imperative, firms may defer the initiative to more pressing product improvements or cost-reduction activities.

The results demonstrate unequivocally that though there is a definite strategic interest in the integration of blood-based prostate cancer screening, the way to implementation is studded with practical obstacles. These are:

- Financial limitations based on cost and pricing models,
- Operational complexity in workflow incorporation,
- Logistical limitations surrounding sample handling,
- Institutional inertia and ill-aligned priorities,
- And psychological or cultural resistance to embracing new diagnostics.

Acknowledging these obstacles is crucial to creating viable pilot programs and to framing collaboration models as among insurers, diagnostic providers, healthcare providers, and policymakers.

Proactively addressing these issues via cross-sector collaboration, shared cost structures, regulatory consistency, and education will prove central to converting initial interest into widespread adoption.

4.6 What does it mean for the healthcare sector, with consideration for both healthcare providers, diagnostic labs, and medical technology vendors?

Attaining successful integration of blood-based prostate cancer screening into insurance-based health checkup programs does not lie at the beck and call of insurance companies. Rather, it calls for an integrated, multi-stakeholder approach that includes healthcare

providers, diagnostic labs, med tech suppliers, and policy influencers. This part provides an analysis of the roles required from different stakeholders in the healthcare value chain, as outlined by respondents in the insurance industry.

4.6.1 Collaborative Models with Diagnostic Laboratories

A dominant theme throughout the answers was the necessity of cooperative partnerships with diagnostic laboratories (Figure 4.7). Several respondents cited such partnerships as critical to technical deployment and cost minimization. Diagnostic laboratories have a twofold role to play: first, by providing affordable test solutions in the form of subsidized models or negotiated price structures, and second, by guaranteeing accuracy, continuity, and operational effectiveness in sample collection, testing procedures, and output delivery.

Interviewees recognized diagnostic firms, particularly leaders in liquid biopsy and multi-cancer early detection technologies, as being well-positioned to close the clinical operational gap between screening innovation and insurance policy implementation. It is hoped that these collaborations not only optimize logistics but also enhance trust in the clinical validity and utility of the tests.

4.6.2 Role of Healthcare Providers in Awareness and Advocacy

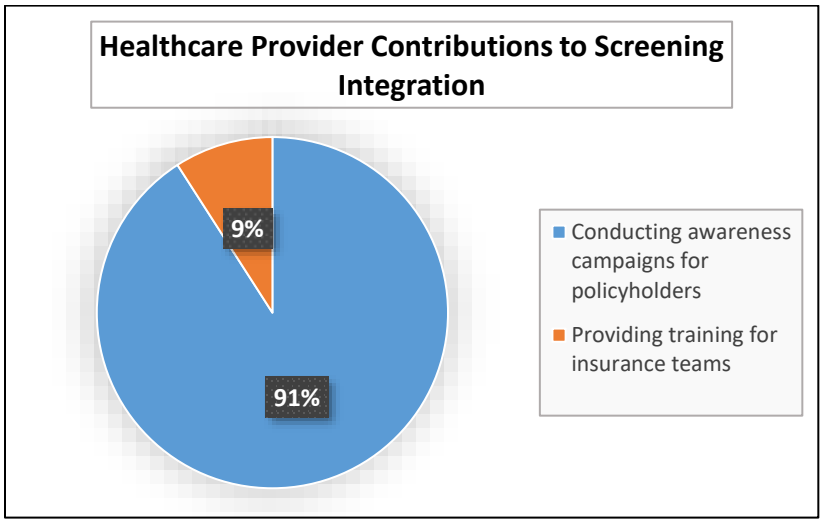

Figure 4.9: Healthcare Provider Contributions to Screening Integration

(*Author's work*)

The other key finding of the survey was the projected role of healthcare professionals, particularly specialists and physicians, in propagating patient education and uptake. The respondents (91%) indicated that general doctors, urologists, and oncologists would be important opinion leaders (KOLs) who could legitimize the clinical necessity and raise awareness of the value of early prostate cancer detection by blood-based screening.

In addition, healthcare professionals were recognized as key players in performing awareness campaigns aimed at policyholders. Such campaigns would be crucial in addressing suspicion, explaining that such tests are not invasive, and reaffirming the link between preventive screening and better long-term outcomes. In the absence of robust support from clinicians, insurance providers could struggle with encouraging take-up and use, even if coverage was extended.

4.6.3 Expectations from Med Tech and Platform Providers

The insurance stakeholders also placed significant emphasis on digital enablement and operational interoperability, the onus of which primarily falls on med tech vendors and health IT platforms. Some of the respondents suggested the implementation of mobile apps or online portals that would:

- Make test booking and scheduling easy,
- Offer automated reminders and notification of results,
- Allow data sharing between diagnostic labs, physicians, and insurers securely.

Specifically, among the respondents, one suggested creating an appointment booking app with built in time slot picker and digital consent management, which would heavily minimize operational hurdles and maximize the overall experience for insurance administrators and policyholders alike.

These technological interventions are likely to enhance workflow integration, minimize admin errors, and facilitate scalable deployment across geographies and partner networks.

4.6.4 Shared Responsibility for Cost and Education

Notably, the answers reflected a consensus that one organization alone should not be responsible for all the implementation work. Rather, a model of shared responsibility was preferred whereby:

- Diagnostic laboratories underwrite the test to stimulate early uptake,
- Insurers add screening to premium checkup schemes,

- Healthcare professionals reinforce clinical applicability through advice, and
- Regulatory or public health authorities may provide advice or co-funding incentives.

The respondents also underscored the value of training modules for insurance staff, preparing agents and corporate health administrators with sufficient knowledge to articulate the test's value to employers and individual policyholders. Education thus became a repeated sub-theme not just for patients but also for individuals tasked with productizing and marketing the offering within insurance frameworks.

To summarize, the statistics show that insurance stakeholders see a mutually reinforcing and complementary role for each partner in the ecosystem. The focus is on alignment of incentives early on, open communication channels, and technology facilitated service delivery. The healthcare industry isn't merely a provider of services in this system it's an engaged collaborator, tasked with facilitating clinical complexities, logistical design, and patient trust.

Overall, the healthcare sector's role is considered to be critical to the feasibility, credibility, and scalability of blood-based prostate cancer screening programs within the insurance market. Unless the value chain aligns, even a disease-valid clinically based screening device might not meet its full potential for lessening the burden of disease and maximizing healthcare expenditures.

4.7 What are the kinds of regulatory frameworks and procedures involved in overseeing blood-based prostate cancer screening tests, and what is their impact in terms of regulating insurance reimbursement and utilization?

One of the key aspects to consider with the adoption of any new medical technology, but especially within the context of the insurance system, is the potential influence of regulatory systems and the downstream effects on reimbursement qualification and utilization. Blood-based cancer screening, while facilitated by increasing clinical evidence and technological maturity, is still in a relatively nascent phase of mainstream regulation in most nations, including India. This section assesses the views provided by insurance experts on the state of regulation as of now, the associated risks and gaps perceived, and the necessity for policy clarity in order to facilitate sustainable implementation.

4.7.1 Perceived Significance of Regulatory Hurdles

When requested to rate the importance of regulatory barriers in incorporating screening based on blood in health checkups, 46% respondents (Figure 4.5) found that these were "not significant" or "slightly significant." Just one respondent placed regulatory problems under the bracket "very significant," implying that the insurance industry presently doesn't consider government regulation a significant stumbling block.

This feeling can be attributed to the nascent status of blood-based screening within the Indian regulatory framework, where limitations are few on paper, but proactive direction is similarly absent. Instead of outright prohibitions or bans, the lack of formal inclusion guidelines, standardized test pricing, and clinical recommendation protocols

is viewed as a soft obstacle that might be a barrier to uptake without proactive policy change.

4.7.2 Ambiguity in Reimbursement Policies

Another important theme underscored was the absence of standard reimbursement channels for sophisticated screening devices such as blood tests for cancer. In conventional insurance plans, reimbursement is usually linked to hospitalization or post-diagnosis therapy. Preventive care, particularly with new technologies, is rarely covered unless by mandate through group insurance policies or provided as part of value-added wellness packages.

Interviewees reported the complexity in integrating such new tests into existing policies (Figure 4.6). Hence, there is reluctance among insurers to completely underwrite these services until government regulators or industry associations (e.g., the IRDAI or National Health Authority) provide guidance that establishes the test's clinical and economic value.

4.7.3 Implications for Insurance Utilization and Innovation

The regulatory void has raised a scenario where use relies more on in-house innovation than on outside mandate. Participants from different organizations stated that pilots or pilot programs could even be launched by partnering with diagnostic companies, and/or initially rolling out the program to high risk individuals and/or partnering with Health Tech Partners (HTPs) for large scale screening (Figure 4.7)

But for mass adoption, particularly among middle-income and mass policyholders, regulatory approval and reimbursement facilitation are critical. Lack of this

infrastructure may limit innovation to niche markets and hinder mainstream penetration.

4.7.4 Calls for Government and Industry Action

Feedback (Figures 4.6 & 4.7) also came from a want for more transparency on the part of regulators and public health authorities. Participants emphasized the following potential benefits:

- National screening guidelines for cancer that include non-invasive blood-based tests.
- Ministry of Health or IRDAI-initiated pilot projects or public-private initiatives to assess cost-effectiveness.
- MCED (Multi-Cancer Early Detection) screening under tax savings in preventive health under Sections 80D/80DD.

Overall, the insurance sector does not perceive existing regulation as being inhibitive, but instead considers the absence of effective active policy infrastructure to be a source of inertia. The regulatory environment is perceived to be in an underdeveloped but not conflicting state, with considerable scope for cooperation between insurers, the government, and diagnostic providers.

For meaningful uptake and scale, there was consensus among respondents that reimbursement eligibility clarity, standardization of tests, and clinical endorsement will be required. In their absence, the incorporation of blood-based screening may continue to be limited to experimental or wellness-associated models, failing to realize the wider impact it might otherwise have.

4.8 Conclusion

Chapter IV presented an overall analysis of quantitative and qualitative results to determine the feasibility, advantages, and limitations of implementing blood-based prostate cancer screening for insurance health checkups. The quantitative cost-benefit model demonstrated quantifiable savings for insurers under different test sensitivities, with increased test sensitivity resulting in greater long-term savings. Even using conservative estimates, insurers achieved financial gains by decreasing late-stage cancer claims due to early detection.

Qualitatively, stakeholders from top insurance firms communicated growing acquaintance with blood-based screening technologies and recognized their systemic benefit in adapting towards preventive as opposed to reactive healthcare models. However, they also pointed to economic, operational, logistical, and regulatory challenges that need to be overcome for large-scale implementation.

Together, these findings confirm the hypothesis that blood-based screening can be a win for all parties insurers, providers, and patients if implementation is underpinned with strategic planning, coordination, and policy clarity.

CHAPTER V:

DISCUSSION

5.1 Discussion of Results

The findings highlight the twin benefit of incorporating cancer screening through blood tests in the insurance system: financial profitability for insurers and better patient outcomes. Quantitative results showed that as test sensitivity increases, insurers will save between ₹0.67 crores and ₹2.03 crores per 10,000 policies. Insurers achieve the savings through decreased cancer claims due to early diagnosis facilitated by screening.

From the qualitative side, the interviewed insurance professionals understood the long-term advantages of screening improved risk stratification, improved customer engagement, and potential to create innovative coverage designs. Yet they also highlighted the need to minimize costs, overcome resistance from within, and navigate regulatory ambiguity.

5.2 Discussion of Research Question One: Will the Insurance Company Benefit from Incorporating Blood-Based Prostate Cancer Screening Tests?

This study's cost-benefit analysis demonstrated that incorporating blood-based prostate cancer screening into insurance health check-ups can generate significant financial savings for insurers. At a sensitivity of 100%, insurers could save up to ₹2.03 crores compared to standard practice, with savings still evident (₹67 lakhs) even at a conservative 70% sensitivity (Table 4.1). These results highlight that preventive screening has the potential to offset high expenditures associated with late-stage prostate cancer treatment.

These findings are consistent with Heijnsdijk et al. (2015), who found that early detection programs reduced advanced-stage treatment costs in European populations. However, while their work modeled cost-effectiveness at a population health system level, the present study offers a microeconomic, insurer-specific perspective, providing practical insights into underwriting and policy design.

Moreover, this study's results align with Schnipper et al. (2012), who emphasized that preventive diagnostics could reduce the financial burden of oncology treatments on payers. At the same time, the concerns identified by Thompson et al. (2004) regarding the high development and validation costs of novel biomarkers are relevant here, as insurers in the present survey also cited upfront costs as a barrier to adoption. This convergence suggests that while the long-term financial benefits of blood-based screening are evident, near-term cost structures remain a challenge for implementation.

The insurer perspective captured in this study adds nuance to prior literature. Whereas Bratt et al. (2023) focused on biomarker performance and clinical validation, this research highlights regulatory uncertainty and actuarial integration as immediate barriers from the payer side. This suggests that the pathway to adoption is not only a question of scientific validity but also one of policy frameworks and financial modeling.

To sum up, this study supports the argument that blood-based cancer screening can deliver measurable financial benefits to insurers, consistent with international evidence, while also revealing stakeholder-specific challenges particularly upfront cost management and regulatory ambiguity that are underexplored in the existing literature.

5.3 Discussion of Research Question Two: What Are the Potential Benefits to Individuals/Patients of Using Blood-Based Screening Methods Over Traditional Methods?

The second research question examined the potential benefits of blood-based screening for patients compared with traditional screening methods. The results show that blood-based tests are less invasive, require minimal preparation, and may be performed in primary care settings, increasing compliance. Patients also stand to benefit from reduced false positives, earlier-stage detection, and lower anxiety compared to conventional modalities such as PSA and digital rectal examination.

These results are aligned with Klotz (2010), who emphasized the patient-centered advantages of reducing unnecessary biopsies and interventions. Similarly, Balázs et al. (2021) reported that novel biomarkers such as CTCs, cfDNA, PCA3, and KLK2 can improve diagnostic specificity, thereby sparing patients from invasive procedures. The findings also resonate with Carbonell et al. (2024), who highlighted accessibility benefits in rural and primary-care contexts.

However, the present study contributes additional evidence by quantifying the comparative benefits using a structured framework (Table 4.4). While earlier studies tended to focus narrowly on clinical accuracy, this research incorporates practical dimensions such as patient compliance, preparation time, and convenience, which are often neglected in cost-effectiveness analyses. This broader patient-focused framework helps bridge clinical research with health policy debates about screening acceptability.

At the same time, the findings diverge from Thompson et al. (2004), who questioned whether improved diagnostic tools necessarily translate into improved patient outcomes. The high compliance and acceptability rates identified here suggest that patient experience is a critical factor influencing the real-world effectiveness of screening programs.

In conclusion, the study reinforces existing evidence on the patient-centric advantages of blood-based screening while extending the literature by systematically framing these benefits beyond diagnostic accuracy. This positions blood-based screening not only as a clinical innovation but also as a patient-centered reform in cancer diagnostics.

5.4 Discussion of Research Question Three: What Are the Systemic Implications for Insurance Companies Regarding Coverage, Reimbursement, and Healthcare Spending?

The fourth research question explored the challenges and obstacles in integrating blood-based prostate cancer screening from the insurer perspective. The survey identified several recurring themes: high upfront costs of implementing screening programs, uncertainty about regulatory approval pathways, lack of actuarial models to incorporate preventive screening into policy pricing, and operational issues such as training and infrastructure readiness (Figure 4.6). Collectively, these barriers highlight that while insurers acknowledge the long-term benefits of blood-based tests, practical adoption remains hindered by systemic and financial uncertainties.

These findings are consistent with Murphy et al. (2015), who emphasized the substantial cost burden of developing and validating novel biomarker-based diagnostics. The concern that insurers expressed about initial capital outlays for widespread screening echoes this,

suggesting that even when tests show clinical promise, economic feasibility is a dominant determinant of adoption. Similarly, Cheng et al. (2018) reported that uncertainty regarding reimbursement policies for advanced diagnostics often discourages insurers from early adoption. The present study extends their conclusions by showing that this hesitation is not theoretical but actively shaping insurer decision-making in emerging markets like India.

At the same time, the findings diverge from the emphasis in Bratt et al. (2023), who positioned biomarker validation and assay standardization as the primary barriers to integration. In contrast, this study indicates that insurers are more concerned with regulatory ambiguity and actuarial uncertainty (Figure 4.6) than with the scientific performance of biomarkers. This divergence underscores the importance of distinguishing between clinical adoption barriers and financial or systemic adoption barriers (as identified in this study). It also suggests that the same technology can face different adoption hurdles depending on the stakeholder's perspective.

The study also aligns with Gostin et al. (2009), who argued that regulatory frameworks shape not only approval but also reimbursement and diffusion of technologies. Insurers in this research repeatedly emphasized that without clear guidance from national regulators, reimbursement decisions would be risky and potentially inconsistent. This reinforces the idea that regulation functions as a precondition for trust in adoption, particularly in markets where health technology assessment (HTA) systems are less developed.

Infrastructure and implementation challenges also emerged strongly. Respondents highlighted the lack of standardized screening protocols, insufficient training for underwriters and healthcare partners, and variability in laboratory capacity. These insights

resonate with Siravegna et al. (2017), who noted that logistical barriers can delay the clinical integration of liquid biopsy approaches, even when scientific validation is available. This study extends that argument by showing how infrastructure limitations directly affect payer willingness to reimburse a linkage often overlooked in prior clinical studies.

Finally, the responses revealed concerns about equity and access. Some insurers feared that implementing blood-based screening only for select high-value clients (e.g., HNIs) could exacerbate inequalities in healthcare access, a concern previously raised in Neumann et al. (2014) in the context of genomic diagnostics. This highlights the ethical dimension of integration, where insurers are caught between offering competitive value-added services and ensuring broad, equitable access to preventive care.

In summary, the obstacles identified in this study confirm existing evidence on cost and regulatory challenges while also extending the literature by foregrounding stakeholder-specific barriers. Whereas much of the academic debate centers on clinical performance and biomarker validation, this research demonstrates that insurers prioritize financial, regulatory, and operational readiness. These findings suggest that successful adoption will require a multi-pronged approach:

- Regulatory bodies must clarify approval and reimbursement frameworks,
- Actuarial models need to incorporate preventive testing more explicitly, and
- Infrastructure investments must be made to support standardized, scalable implementation.

5.5 Discussion of Research Question Four: What Are the Obstacles and Challenges to Implementation from the Insurance Sector's Viewpoint?

The fifth research question examined the implications of regulatory frameworks on insurance reimbursement and the adoption of blood-based prostate cancer screening. The findings from the survey indicated that regulatory uncertainty is one of the most significant deterrents to adoption, with 46% of respondents (Figure 4.7) emphasizing that without clear guidelines, insurers would hesitate to integrate these tests into routine policy-linked health checkups. This reveals that insurers view regulation not simply as a background factor but as a critical determinant of financial decision-making. These insights strongly support Robson et al. (2010), who argued that regulatory approval is not only a marker of safety and efficacy but also a signal to payers about clinical credibility. Similarly, Schroll et al. (2024) highlighted that reimbursement decisions in both public and private systems are tightly linked to regulatory endorsements, making regulatory frameworks an enabler of technology adoption. The present study empirically validates these arguments by showing that Indian insurers perceive regulatory approval as a prerequisite for coverage, even when preliminary cost-benefit models suggest financial savings.

At the same time, this study extends the literature by situating these concerns within the Indian healthcare landscape, where regulatory processes for advanced diagnostics are still developing. Unlike established systems in the US and EU, where agencies such as the FDA and EMA provide structured pathways for test approval, India's regulatory environment remains fragmented. For example, while the Central Drugs Standard Control Organization (CDSCO) oversees diagnostic approvals, there is no dedicated health technology

assessment (HTA) body equivalent to the UK's NICE that evaluates both clinical validity and cost-effectiveness. This structural gap magnifies insurer uncertainty, as companies lack a unified source of guidance to inform reimbursement policies. The results also diverge from the perspective of Neumann et al. (2014), who analyzed genomic testing reimbursement in developed health systems and found that insurers were primarily concerned with balancing premium costs with coverage benefits. In the Indian context, however, the barrier is more foundational without regulatory clarity, insurers are reluctant to even pilot reimbursement schemes. This shows that while insurers in mature systems debate how much to cover, insurers in India are still debating whether coverage is feasible at all.

Another important finding from this research is that insurers perceive regulation not only as a compliance hurdle but as a trust-building mechanism. Respondents repeatedly emphasized that clear regulatory approval would provide confidence for underwriting decisions and minimize reputational risks in case of patient disputes. This aligns with Gostin et al. (2009), who argued that regulation serves both a protective and legitimizing role in healthcare markets. The Indian case reinforces this dual role: approval assures insurers of test reliability while also protecting them legally and reputationally. Furthermore, this study highlights a gap in the existing literature concerning the interaction between regulation and actuarial modeling. Insurers in this research noted that they could not integrate screening into pricing strategies without regulatory certainty. This point expands on Schroll et al. (2024) by showing how regulation directly affects the feasibility of actuarial risk stratification, a linkage rarely documented in prior research.

Finally, respondents pointed to global regulatory precedents such as the FDA's approval of liquid biopsy-based tests for cancer detection as influential benchmarks. This suggests that Indian insurers look not only to domestic regulators but also to international trends to guide decision-making. However, they also noted that India's regulatory lag could create competitive disadvantages in adoption, reinforcing the urgency of developing local frameworks.

In summary, this study confirms prior evidence on the centrality of regulatory approval to reimbursement but extends the literature in three ways by:

- Situating the issue within India's fragmented regulatory environment;
- Framing regulation as a trust-enabler as much as a compliance mechanism; and
- Identifying the direct link between regulatory clarity and actuarial modeling.

Together, these contributions suggest that without regulatory reform, the potential financial and clinical benefits of blood-based prostate cancer screening may remain unrealized in insurance practice.

5.6 Discussion of Research Question Five: What Are the Implications for the Broader Healthcare Industry (Providers, Labs, Med-Tech Firms)?

The sixth research question examined the broader implications of blood-based prostate cancer screening for the healthcare industry, including providers, laboratories, and med-tech firms. The survey findings and cost-benefit modeling indicate that while insurers are critical stakeholders, successful adoption also requires systemic adjustments across the wider healthcare ecosystem.

For providers, the results suggest a shift in the role of clinicians from late-stage intervention to preventive care facilitation. Earlier detection made possible by blood-based screening means physicians will increasingly be tasked with counseling patients on early diagnostic results, determining appropriate follow-up, and managing patient expectations. This aligns with Mottet et al. (2020), who stressed the importance of physician-patient communication in prostate cancer diagnostics. However, unlike traditional screening programs that rely heavily on invasive procedures such as biopsies or imaging, providers will need to integrate liquid biopsy interpretation and confirmatory pathways into routine practice. This requires both training and workflow redesign, areas not yet extensively addressed in the literature.

For laboratories, the study highlights both opportunities and challenges. On the one hand, increased demand for blood-based screening will expand the scope of molecular diagnostic labs, creating new revenue streams. This is consistent with Siravegna et al. (2017), who observed that liquid biopsy technologies are reshaping laboratory medicine by enabling high-throughput, minimally invasive diagnostics. On the other hand, respondents in this study emphasized concerns about standardization and quality assurance, particularly in decentralized lab networks. This underscores a key divergence: while much of the literature focuses on assay sensitivity and specificity, this research points to operational readiness and quality control as equally important barriers to adoption in real-world practice.

For med-tech firms, the findings reveal a dual challenge. First, they must not only demonstrate clinical performance but also provide evidence of economic value to insurers and providers. This is in line with Balázs et al. (2021), who noted that biomarker innovation alone is insufficient without clear payer-oriented evidence. Second, med-tech firms face

the task of navigating fragmented regulatory pathways, particularly in emerging markets like India. Beyond these sector-specific implications, the results also highlight broader systemic consequences. Respondents pointed out that widespread adoption of blood-based screening would necessitate new referral pathways between primary care providers, laboratories, and oncology specialists. This resonates with Carbonell et al. (2024), who emphasized the need for integrated care models to fully leverage preventive diagnostics. Without such coordination, the benefits of early detection may not translate into improved patient outcomes, as delays in confirmatory testing or treatment could erode the advantages of screening.

Finally, the study revealed that innovation in this domain could reshape competitive dynamics within the healthcare industry. Providers who adopt blood-based screening early may gain reputational advantages as leaders in preventive care. Laboratories that invest in quality assurance and high-throughput platforms could establish themselves as preferred partners for insurers. Med-tech firms that succeed in aligning innovation with payer priorities may accelerate adoption across multiple markets. This is consistent with Balázs et al. (2021), who described how disruptive innovations often reconfigure industry hierarchies by favoring agile players over incumbents.

In conclusion, the implications of this study extend well beyond insurers and patients. Blood-based prostate cancer screening introduces a paradigm shift for the broader healthcare industry, requiring providers to integrate preventive counseling, laboratories to ensure standardization and capacity, and med-tech firms to align innovation with economic and regulatory realities. By emphasizing these system-wide effects, this study extends the

literature beyond clinical validation and insurer adoption, highlighting the interconnected roles of multiple stakeholders in realizing the promise of liquid biopsy-based screening.

5.7 Discussion of Research Question Six: What Regulatory Frameworks and Procedures Are Involved in Overseeing Blood-Based Prostate Cancer Screening Tests, and What Is Their Impact on Insurance Reimbursement and Utilization?

The seventh research question explored the policy and systemic considerations that influence the integration of blood-based prostate cancer screening, with a particular focus on regulation, reimbursement, utilization, and innovation. Findings from this study suggest that while insurers acknowledge the potential benefits of early detection, the broader policy environment will ultimately determine the pace and scope of adoption.

Survey responses emphasized that India's current regulatory framework for diagnostics is underdeveloped but not actively restrictive. Unlike the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA), which provide defined approval pathways for liquid biopsy tests, India's Central Drugs Standard Control Organization (CDSCO) has limited experience in handling advanced biomarker-based diagnostics. This gap creates ambiguity but also flexibility, since insurers and med-tech firms are not constrained by rigid frameworks. This observation echoes Neumann et al. (2014), who argued that regulatory immaturity in emerging markets can act as both a barrier and an opportunity for innovation. The present study adds to this by showing that insurers interpret regulatory gaps as risks rather than opportunities, highlighting a cautious industry mindset.

A consistent theme in the survey was uncertainty around how blood-based screening would be integrated into insurance benefit design. Respondents noted that current reimbursement

models are heavily treatment-oriented, with limited provisions for preventive diagnostics. This ambiguity discourages insurers from piloting new tests, despite evidence of long-term cost savings. These findings align with Robson et al. (2010), who observed that a lack of reimbursement clarity can stall adoption even when technologies demonstrate clinical validity. Unlike in countries where public health systems subsidize preventive tests, Indian insurers lack standardized benefit frameworks, leaving adoption decisions to individual companies. This structural uncertainty explains the "wait-and-see" attitude reported in this study.

The policy environment has direct implications for both utilization and innovation. Without clear reimbursement and regulatory guidance, utilization of blood-based screening will likely remain limited to high-net-worth individuals (HNIs) who can pay out-of-pocket. This risks reinforcing inequities in healthcare access, as noted by Gostin et al. (2009) in their discussion of innovation diffusion. On the innovation side, med-tech firms face weak incentives to invest in India if reimbursement and regulatory approval remain uncertain. This dynamic is consistent with Balázs et al. (2021), who found that unclear payer pathways dampen innovation incentives in biomarker development. By linking reimbursement ambiguity to both underutilization and innovation stagnation, the present study highlights a cycle of policy-driven inertia that is underexplored in existing literature.

Respondents across the study emphasized the need for policy reforms that address regulatory and reimbursement gaps. Insurers called for clearer CDSCO approval guidelines for diagnostics, alongside actuarial tools to integrate screening into premium models. Providers advocated for standard clinical pathways linking blood-based screening to

confirmatory diagnostics, while laboratories emphasized national quality assurance frameworks to standardize testing. Med-tech firms highlighted the need for public-private partnerships to support pilot programs and gather real-world evidence. These perspectives mirror the calls for multi-stakeholder collaboration raised by Schroll et al. (2024), but the present study grounds them in the specific context of India's insurance ecosystem, thereby offering concrete pathways for reform.

Finally, stakeholders consistently raised the importance of balancing innovation with oversight. While insurers recognized the financial benefits of early detection, they cautioned that unregulated proliferation of new tests could create risks of misdiagnosis, litigation, and reputational damage. This concern aligns with Thompson et al. (2004), who warned that premature adoption of under-validated diagnostics can backfire economically and clinically. At the same time, excessive regulation could stifle innovation, particularly for smaller med-tech firms. The findings therefore suggest that proportionate regulation clear, evidence-based, and flexible will be critical to balancing patient safety, insurer confidence, and industry innovation.

In summary, this study finds that India's current policy landscape for blood-based prostate cancer screening is characterized by regulatory underdevelopment, reimbursement ambiguity, and cautious insurer perspectives. These conditions suppress utilization and dampen innovation incentives, even as insurers recognize the technology's long-term potential. Stakeholders consistently call for reforms clearer regulatory pathways, standardized reimbursement structures, and collaborative pilot programs to unlock adoption. The challenge lies in balancing the need for innovation with the imperatives of

oversight, ensuring that early detection technologies benefit not only a select population but the broader healthcare ecosystem.

CHAPTER VI:

SUMMARY, IMPLICATIONS, AND RECOMMENDATIONS

This chapter summarizes the major findings of the study, distills the strategic and practical implications for stakeholders across sectors, and provides recommendations for policy formulation and future research. As the thesis has shown, blood-based prostate cancer screening using Multi-Cancer Early Detection (MCED) tests offers a critical chance to redefine the health insurance, healthcare delivery, and patient outcome landscape. Its implementation, however, hinges on the convergence of scientific breakthrough, regulatory preparedness, cross-sectoral collaboration, and economic feasibility.

6.1 Summary

The research aimed to provide an answer to the overarching question: Can blood-based screening for prostate cancer be a win-win for insurance companies, the healthcare sector, and patients?

The results support a resounding affirmative. A mixed-methods approach was used combining a quantitative cost-benefit model and qualitative stakeholder interviews to assess both financial and systemic consequences of including blood-based cancer screening within insurance models.

- For insurers, the quantitative model showed significant cost savings of ₹67 lakhs to more than ₹2 crores for every 10,000 policies, based on test sensitivity. Early detection drastically cuts high-cost cancer claims by detecting disease before it advances to costly, late-stage treatment.

- To patients, MCED testing provides ease, comfort, early detection, and enhanced survival rates particularly for difficult-to-detect cancers with no other screening option. The low invasiveness and one-test simplicity enhance compliance and access, especially in underserved populations.
- For the larger healthcare ecosystem, the research charted the functions of diagnostic laboratories (cost-sharing and quality management), medical professionals (clinical verification and follow-up), and med-tech firms (digital infrastructure and patient management). It also underscored that such technologies need to be integrated with regulatory certainty and joint action.

Although there are challenges remaining test expense, logistic constraints, internal insurer opposition, and policy standardization the research proved these obstacles could be overcome by strategic alliances, staged rollout, and favorable regulation.

6.2 Implications

The research conducted within this thesis has wider implications than lie with any one insurance policy or diagnostic technology. It represents a broader change in the way that risk is evaluated, health is governed, and financial security is provided in the case of non-communicable diseases such as cancer. The incorporation of blood-based prostate cancer screening particularly when utilized as a population-level preventive intervention has the power to transform the landscape of healthcare and insurance in the following important manners.

6.2.1 Implications for Insurance Companies

a. Evolution of Underwriting Models

In the past, underwriting health insurance has relied on age, medical record, self-reported risk factors, and even simple health examinations. Adding MCED tests to the underwriting process adds a new, data-driven layer of clinical understanding. With knowledge of molecular-level risk data on cancer even in clinically silent patients insurers are able to make better and more individualized risk judgments. This change can result in the development of risk-based models of pricing, whereby those who have early signs of disease might be provided with customized coverage options, subjected to a further investigation, or even referred to the correct care pathways prior to the issuance of a policy. This redefines underwriting as a preventive strategy for engagement rather than a reactive process.

b. Reduction in Long-Term Claims Liabilities

One of the most impressive discoveries derived from the cost-benefit model was the prospect of huge long-term savings. By identifying cancers at an early, more curable state, insurers can prevent huge payments for late-stage treatments, hospital stays, and prolonged therapies. The implication is clear: blood-based screening pays back in terms of prevention, allowing insurers to shift from reactive claims management to proactive risk prevention. This can go on to improve solvency margins, limit reinsurance costs, and stabilize premium rates.

c. Strategic Market Differentiation

As competition grows in the health insurance market, particularly in HNI and urban markets, insurers are looking for means to differentiate their products. MCED screening provides a strong competitive advantage announcing an insurance company's

inclination towards innovation, individualized healthcare, and customer wellness over the long term. By integrating screening into wellness plans or pre-policy checkups, insurers can make a more attractive value proposition, increase customer engagement, and promote better brand loyalty.

6.2.2 Implications for Healthcare Providers

a. Integration of New Diagnostic Modalities

Clinicians, especially generalists, urologists, oncologists, and family medicine physicians, will have to modify their screening procedures and clinical practices to incorporate blood-based MCED technologies. As more patients show up with results of such tests (either through health insurance schemes or self-implemented health checkups), doctors need to be ready to interpret the results, suggest follow-ups, and deal with patient anxiety or confusion.

b. Role in Driving Adoption

The work of healthcare professionals is not limited to interpretation; they play a vital part in legitimizing and promoting the application of MCED tests. Patient faith in physician advice continues to be one of the strongest adoption drivers, and in the absence of clinical acceptance, even the most sophisticated technologies will have problems scaling. Thus, providers will be instrumental in educating patients, instilling confidence in test results, and appropriate follow-up.

c. Expansion of Preventive Practice Models

With access to MCED results, healthcare providers can shift their practice from episodic illness treatment to ongoing preventive management. This includes

personalized cancer risk counseling, surveillance strategies, and patient-specific interventions significantly improving outcomes and reducing the burden of late-stage diagnosis.

6.2.3 Implications for Diagnostic Laboratories and Med-Tech Companies

a. Operational Scaling and Standardization

For diagnostic laboratories, the increasing need for MCED testing will necessitate swift expansion of testing capacity, such as investment in high-capacity equipment, quality control measures, bioinformatics pipelines, and trained staff. Laboratories must also strive to harmonize test methodologies and reporting formats to produce consistent results and foster interoperability among insurance partners.

b. Collaborative Pricing and Shared-Risk Models

Since affordability continues to be a challenge, particularly for bulk insurance rollout, diagnostic firms will have to become players in pricing innovation. This can include:

- Tiered pricing depending on the type of policy
- Subscription tests to gain access
- Shared-risk models where insurers and labs co-invest in preventive care programs

Such convergence will not only make testing more affordable but create long-term strategic alliances with insurers and healthcare providers.

c. Tech-Enabled Integration

Health IT and med-tech firms will be central to digitizing the patient journey, such as appointment scheduling, consent, delivery of results, and lab-to-insurer data exchange. Their platforms will be critical in making MCED testing efficient, secure, and scalable

particularly when working with large populations and geographically dispersed policyholders

6.2.4 Implications for Policymakers and Regulatory Bodies

a. Need for Preventive Health Policy Reform

The lack of official guidance regarding blood-based cancer screening precludes its inclusion in organized insurance programs. The policy makers are required to intervene to establish policies on reimbursement, clinical criteria for eligibility, and coding guidelines for MCED tests. This will enable:

- Consistent adoption across insurers
- Easier claim processing
- Clear consumer protections around consent and data privacy

b. Opportunity for Public-Private Partnerships (PPPs)

With India's large population and burden of cancer, the government can seize the day by collaborating with private players in terms of insurers and diagnostic operators via pilot projects, subsidies, and co-branded campaigns. These initiatives can be used as templates to provide equity-based screening initiatives to provide MCED access to the masses and not just to the elite.

c. Support for Evidence Generation

Policymakers and research organizations can facilitate long-term adoption by providing funding for outcome studies, real-world effectiveness trials, and economic impact analyses. This evidence base will be critical to securing regulatory approvals, policy mandates, and public trust.

6.2.5 Implications for Patients and Society

a. Shift Toward Preventive, Personalized Healthcare

For patients, the message is empowerment: the power to catch cancer early using a quick, non-invasive test, even before they show symptoms. This encourages a culture of responsible health ownership, eliminates fear of late detection, and enhances the survival rate.

b. Improved Health Equity

If scaled up, MCED tests, particularly when coupled with insurance and public health support, can bridge the diagnostic gap for those with poor access to conventional screening technologies (e.g., colonoscopies, MRIs). This can drive more equitable health outcomes between urban, rural, and underserved populations.

c. Reduced Financial and Emotional Burden

By finding cancer at an earlier stage, families and patients are relieved of the emotional damage, financial hardship, and interruption of lifestyle related to late-stage disease. Not only that, but also out-of-pocket health costs are diminished, particularly in the face of no universal cancer coverage.

6.3 Recommendations for Future Research

Although this research presents a robust case for integrating blood-based prostate cancer screening into insurance models, there are still many areas where additional work is both needed and worthwhile. Most importantly, there is an urgent need for longitudinal real-world evidence (RWE) to confirm and underpin the results of this research. Observational studies following policyholders over a few years comparing unscreened versus screened

cohorts would provide strong evidence of real-world reductions in late-stage cancer diagnosis, claim payouts, treatment expenses, and survival rates. Such actual-world experience would bolster the argument for wholesale take-up and enable insurers to further develop predictive risk models.

Simultaneously, there is a requirement to investigate the behavioral and psychological effect of early cancer detection on patients. Although screening via the blood is physically non-invasive, a positive test result might induce anxiety, fear, or confusion, especially in those without symptoms. Studies into patient reactions, adherence to follow-up, and the influence of physician counseling or computer interventions would serve to maximize the assurance that screening programs are not merely medically effective but also psychologically supportive and ethically acceptable.

The integration of MCED technologies into insurance processes also poses important ethical and legal concerns regarding informed consent, patient data privacy, and fairness in underwriting. The future studies need to consider how to best convey test results, whether such results can be utilized in risk stratification without leading to discrimination, and how patient autonomy can be maintained within insurance environments. Secondly, as India introduces data protection legislations like the Digital Personal Data Protection (DPDP) Act, research has to be conducted to assess insurers' and diagnostic service providers' readiness for compliance with respect to sensitive medical information.

Yet another area of potential exploration is comparative policy research. Analyzing how nations such as the United States, United Kingdom, and others are reimbursing and regulating MCED tests can provide valuable insights for Indian stakeholders. Tax

incentives' variances, insurance mandates' differences, and public health adoption approaches could be lessons to adopt in India's regulatory roadmap and assist in creating a world-aligned best-practice guideline.

Practically, implementation science will play a key role in informing how MCED screening is implemented across various healthcare settings. This involves assessing models for rural roll-out, mobile collection units, staff training, and incorporating into current wellness programs. Public-private partnership models able to align diagnostic labs, insurers, and health ministries can also be tested to explore cost-effectiveness, infrastructure readiness, and population health impact at scale.

At the same time, the function of med-tech platforms and digital health tools should be examined. These consist of booking and consent patient-facing portals, AI-based cancer risk prediction models, and insurer-lab data-sharing platforms. Investigation in this field would guarantee that technology is employed to streamline workflows, improve patient engagement, and facilitate secure, scalable delivery of screening.

Future economic modeling should also be extended beyond prostate cancer. MCED tests are capable of detecting more than 50 types of cancer, most of which have a much greater mortality cost and healthcare burden. Cost-benefit analyses based on cancers like pancreatic, ovarian, or colorectal alone or in bundled screening strategies could provide a bigger picture of the economic potential of early detection and underwrite multi-cancer insurance strategies.

Finally, equity-based research is necessary to ensure that the payoff from blood-based screening extends to high-income, urban centers only. Research needs to probe willingness

to pay across various demographic groups, adoption in Tier 2 and Tier 3 cities, and inclusion in public health insurance programs such as Ayushman Bharat. There needs to be an attempt to assess community-based models of screening through frontline health workers, mobile van-based units, and government subsidies.

Consequently, the potential for blood-based prostate cancer screening in the future and more general MCED integration hinges on a cross-disciplinary research agenda in clinical, behavioral, ethical, economic, and implementation science. Those studies will be central to informing policy, directing industry practice, and maximizing the potential for early detection innovations to enhance an efficient, ethical, and equitable healthcare system.

6.4 Conclusion

This thesis aimed to respond to an essential question at the nexus of insurance economics and healthcare innovation: Can blood-based screening for prostate cancer be a win-win scenario for patients, the healthcare sector, and insurance companies? Based on a mix of quantitative cost-benefit analysis and qualitative stakeholder insights from insurance, the research has shown that the response is a resounding and evidence-based yes but with significant qualifications that need to be addressed in order to realize the full potential of this innovation. From an insurance viewpoint, the research has discovered that the use of blood-based screening, specifically multi-cancer early detection (MCED) tests, as a policy issuance aspect can greatly minimize high-value claims as well as optimize portfolio predictability. It means that the technologies are not only medically beneficial but are also economically sound and fit in with insurers' increasing move towards preventive and data-intensive models of underwriting. For individuals, MCED screening provides earlier

detection, enhanced survival, and a less painful, more convenient diagnostic process most notably in comparison to invasive or organ-specific conventional screening methods. The advantages are especially significant in a nation like India, where delayed-stage cancer diagnosis is still common and healthcare resources are under strain.

Outside of the insurers' and patients' immediate benefits, the study has implications for the larger healthcare system. Diagnostic laboratories, physicians, and med-tech firms each have essential roles to play in making MCED screening operationally feasible, clinically justified, and technologically compatible. In addition, the study stressed that without regulatory environments to ensure standardization, reimbursement, and ethical oversight, MCED screening implementation will be piecemeal and out of reach for the populations most likely to benefit from it.

Notably, although the research verifies the strategic and social utility of blood-based screening, it also acknowledges that implementation issues—financial, logistical, ethical, and regulatory—are issues to be dealt with by concerted, multi-party action. These include actual-world pilot projects, innovation in pricing, education of providers, and policy change, all informed by sound future research. Achievement will necessitate cooperation between public and private sectors, alignment of incentives, and firm dedication to equity and ethics. Overall, blood-based prostate cancer screening is more than a diagnostic revolution; it is a defining moment to revolutionize the detection of cancer, risk management, and protection for health. With responsible application and backing from evidence and policy, it has the potential to revolutionize medicine from reactive and expensive to proactive, individualized, and preventive. As the world—and India—works

to make cancer less of a burden and healthcare better, this strategy could very well be the foundation of a wiser, more equitable, and more sustainable future.

APPENDIX A

SURVEY COVER LETTER

Subject: Request for Participation in Research Survey on Blood-Based Cancer Screening

Dear *(Participant's Name)*,

I am currently pursuing my doctoral studies, and my research focuses on **"Exploring the Impact of Integrating Blood-Based Cancer Screening into Health Checkups and Identifying Implementation Challenges."**

As part of this research, I have developed a brief questionnaire aimed at professionals in the insurance and brokerage sector to better understand industry perspectives on the inclusion of blood-based cancer screening in preventive health programs.

I would be truly grateful if you could take 5 minutes to complete the survey using the link below:

Link: https://docs.google.com/forms/d/e/1FAIpQLScEPBrlVMnGh2Dq2kAFEDFUG-qyenjs7ACESA3zDp1NX7v29Q/viewform?usp=sharing.

Your insights will play a valuable role in shaping evidence-based recommendations and addressing real-world implementation challenges. If possible, I kindly request you to share this with colleagues or peers in your network who may also be in a position to contribute.

Thank you in advance for your time and support.

Warm regards,

Jigar Pandya

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APPENDIX B:

QUESTIONNAIRE/ SURVEY FORM

1. Are you familiar with blood-based prostate cancer screening?
    - Yes, very familiar
    - Somewhat familiar
    - Not familiar
2. How would you rate your organization's awareness of advanced diagnostic technologies like blood-based cancer screening?
    - High Awareness
    - Moderate awareness
    - Low awareness
    - Not aware
3. What potential benefits do you foresee from integrating blood-based prostate cancer screening into health checkups? (Select all that apply.)
    - Earlier detection of cancer
    - Reduction in claims for advanced cancer treatments
    - Improved patient satisfaction and trust
    - Enhanced long-term cost savings for insurers
    - Better alignment with preventive healthcare initiatives
    - Others
4. How significant do you believe the financial impact of integrating this screening will be for your organization?

- Highly significant (major cost savings)
- Moderately significant (some cost savings)
- Minimal impact (neutral effect on costs)
- Negative impact (increase in costs)

5. What is your perspective on the potential for blood-based screening to reduce the need for invasive procedures?
    - Highly likely
    - Somewhat likely
    - Unlikely
    - Unsure
6. How important is the inclusion of advanced screening technologies in enhancing the value of health checkups for policyholders?
    - Very important
    - Moderately important
    - Not important
7. What are the primary challenges your organization might face in implementing blood-based screening tests? (Select all that apply.)
    - High costs of initial setup and testing
    - Lack of trained staff or personnel
    - Complexity in integrating new tests into existing policies
    - Logistical issues with sample collection and processing
    - Limited regulatory guidance or approval

- Others

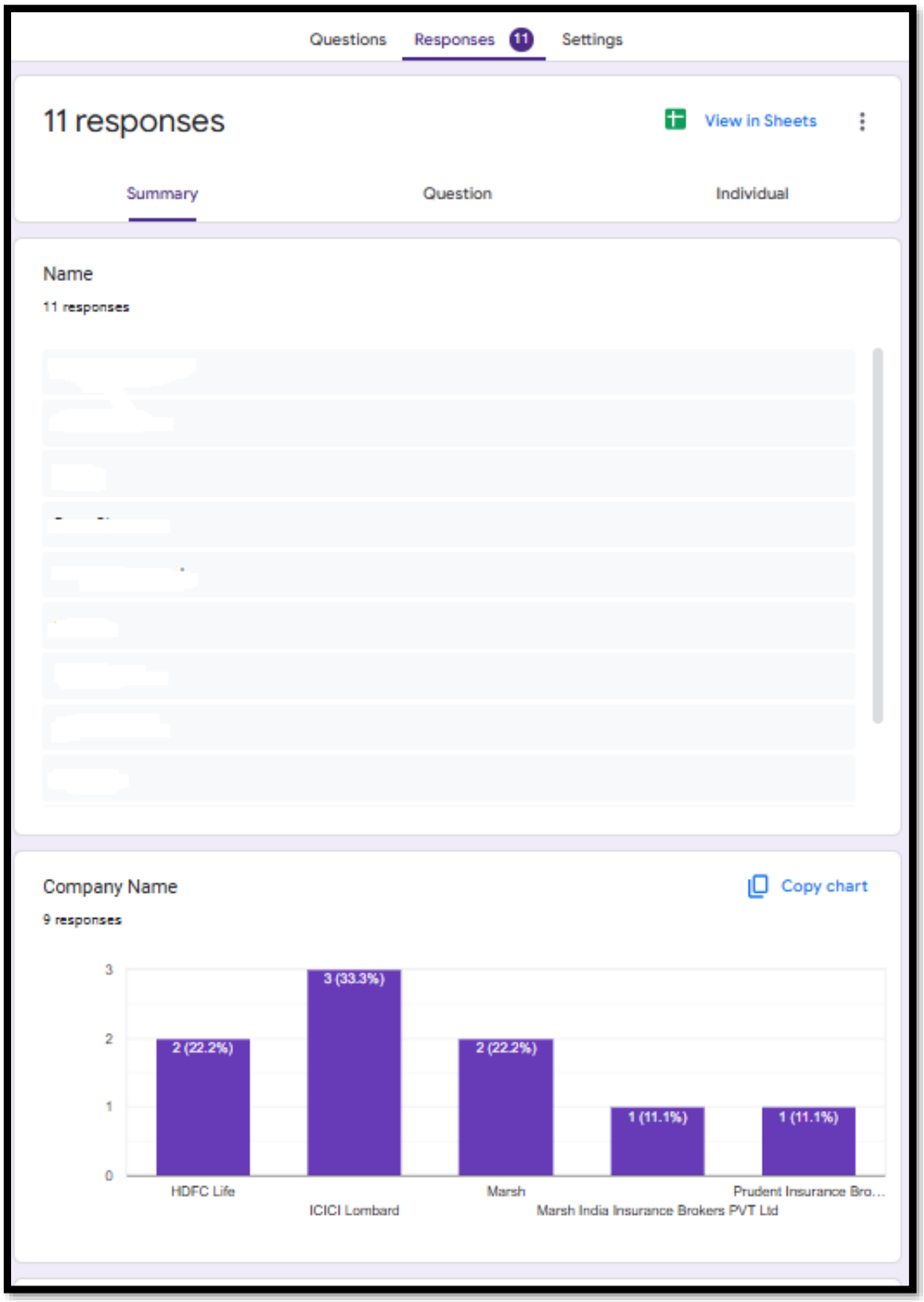
8. How challenging do you think it will be to incorporate blood-based screening into your company's health checkup workflows?
    - Very challenging
    - Moderately challenging
    - Slightly challenging
    - Not challenging
9. How significant are regulatory hurdles in implementing blood-based screening in health checkups?
    - Very significant
    - Moderately significant
    - Slightly significant
    - Not significant
10. What measures would help address the cost challenges of implementing blood-based screening? (Select all that apply.)
    - Partnering with diagnostic companies for subsidized rates
    - Gradual rollout to high-risk populations first
    - Incorporating the cost into premium calculations
    - Seeking government or regulatory support
    - Others
11. How can healthcare providers support the integration of blood-based prostate cancer screening?

- Conducting awareness campaigns for policyholders
- Providing training for insurance teams
- Offering streamlined workflows for sample collection and processing
- Ensuring timely delivery of results

12. What steps would help mitigate operational barriers to implementation? (Select all that apply.)
    - Developing detailed operational guidelines
    - Providing staff training and education
    - Collaborating with diagnostic labs for streamlined services
    - Using technology platforms for process automation
    - Others
13. Do you believe integrating blood-based prostate cancer screening into health checkups is feasible for your organization?
    - Yes, with minimal adjustments
    - Yes, but only with significant changes
    - No, it is not feasible currently
    - Unsure
14. What additional factors should be considered to ensure the successful adoption of this screening technology?

APPENDIX C:

PARTICIPANT RESPONSES



Questions Responses 11 Settings

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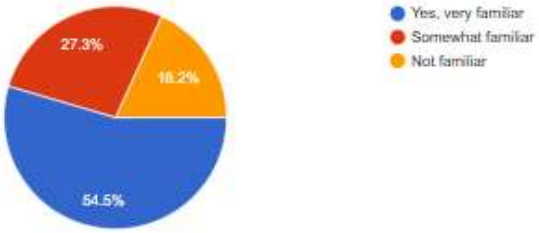
Are you familiar with blood-based cancer screening?

11 responses



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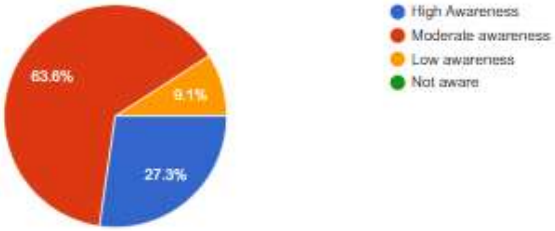
How would you rate your organization's awareness of advanced diagnostic technologies like blood-based cancer screening?

11 responses



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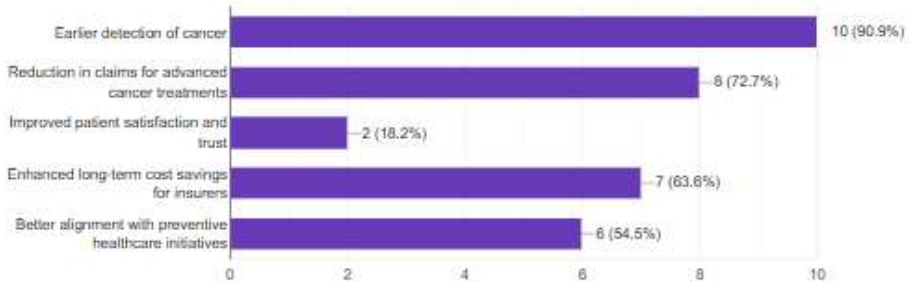
What potential benefits do you foresee from integrating blood-based prostate cancer screening into health checkups? (Select all that apply.)

11 responses



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Questions Responses 11 Settings

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How significant do you believe the financial impact of integrating this screening will be for your organization?

11 responses

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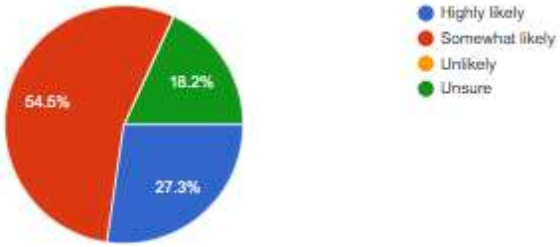
What is your perspective on the potential for blood-based screening to reduce the need for invasive procedures?

11 responses



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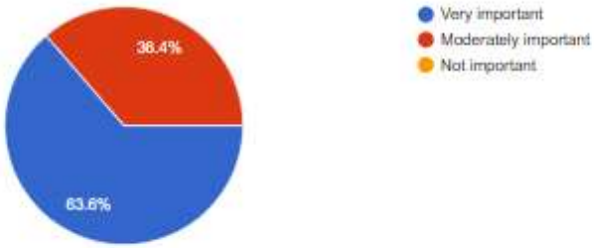
How important is the inclusion of advanced screening technologies in enhancing the value of health checkups for policyholders?

11 responses



Questions Responses 11 Settings

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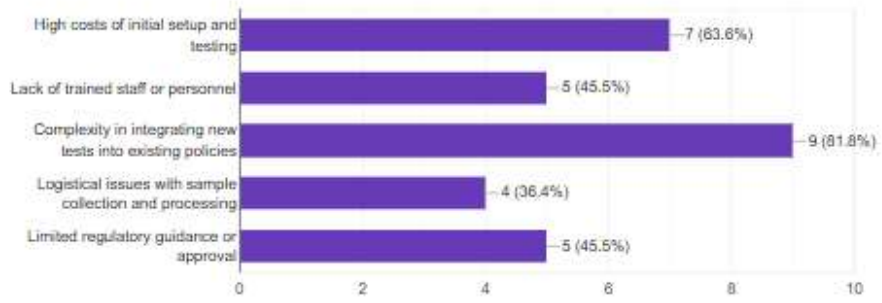
What are the primary challenges your organization might face in implementing blood-based screening tests? (Select all that apply.)

11 responses



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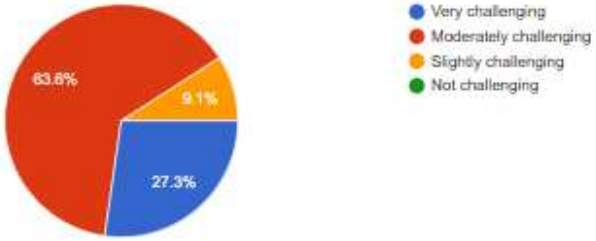
How challenging do you think it will be to incorporate blood-based screening into your company's health checkup workflows?

11 responses



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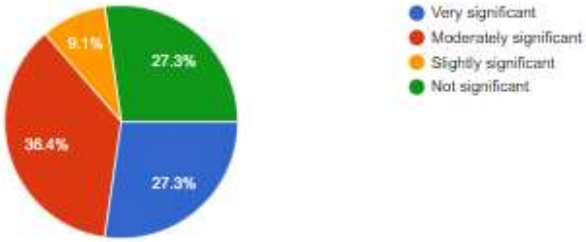
How significant are regulatory hurdles in implementing blood-based screening in health checkups?

11 responses



Questions Responses 11 Settings

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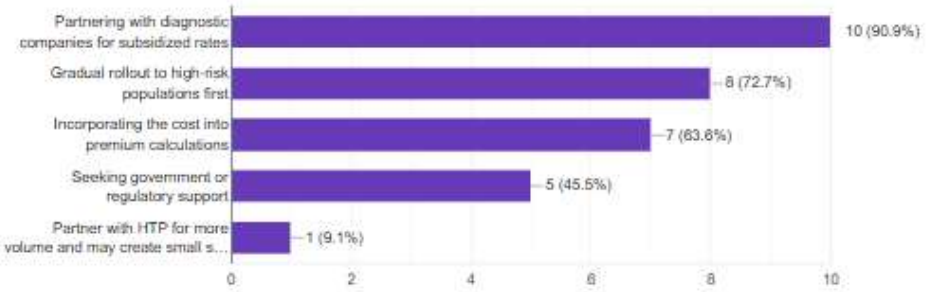
What measures would help address the cost challenges of implementing blood-based screening? (Select all that apply.)

11 responses



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How can healthcare providers support the integration of blood-based prostate cancer screening?

11 responses

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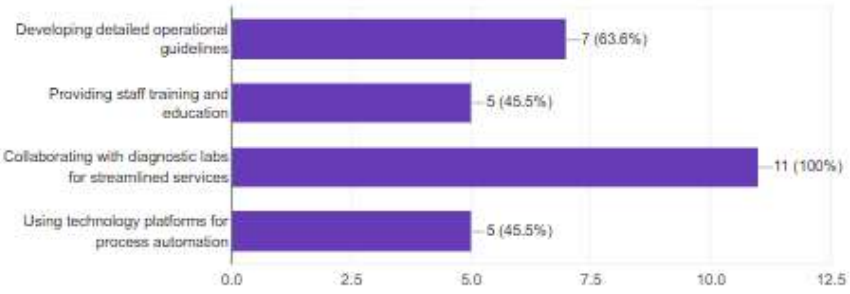
What steps would help mitigate operational barriers to implementation? (Select all that apply.)

11 responses



Questions Responses 11 Settings

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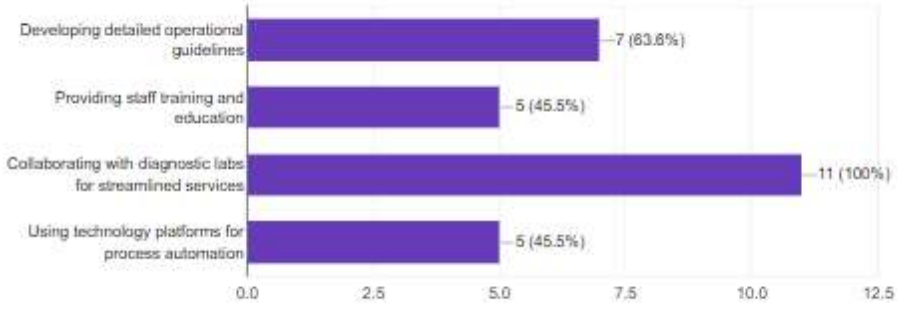
What steps would help mitigate operational barriers to implementation? (Select all that apply.)

11 responses



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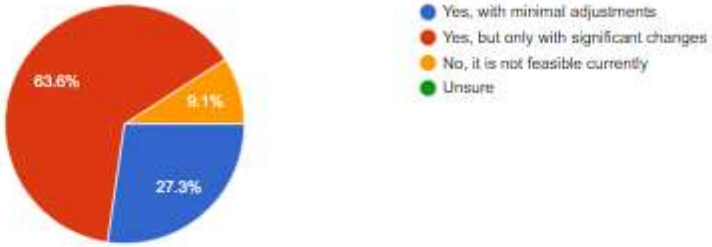
Do you believe integrating blood-based prostate cancer screening into health checkups is feasible for your organization?

11 responses



What additional factors should be considered to ensure the successful adoption of this screening technology?

4 responses

Awareness of need of implementation.

Increased awareness , clear treatment pathways in case of positive test report and operational ease for sample collection Pan India

App to book appointment with slots which is missing in DCG

Na