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Beyond the Horizon: The Critical Determinants Shaping Value-Based Pricing Adoption for European Prescription Drugs

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Abstract

The expenditure on prescription medications forms a significant and growing portion of total healthcare spending. Value-based pricing (VBP) has surfaced as a possible approach to control the rising costs associated with pharmaceuticals. Nevertheless, despite in-depth conversations about value-based frameworks, implementing these models has presented difficulties, resulting in low adoption rates and frequent unsuccessful implementation. In this study, we conducted empirical research to investigate the various factors that influence the successful adoption of VBP for prescription drugs in Europe. To gather quantitative data, we administered a survey to 333 professionals working in drug manufacturing, payer organizations, pharmacies, and hospitals. Using the conceptual model and the ADANCO software, we examined seven direct and four indirect hypothesized relationships. The results revealed that five constructs, namely health information technology, value measurement, perceived behavioral control, perceived social norms, and drug selection intent impacted the adoption of VBP, mediated by contractual intent and organizational intent.

Keywords: value-based pricing, prescription drugs, health information technology, drug pricing

1. Introduction

Prescription medications are designed to address a wide range of health conditions, including hypertension, cancer, and dermatitis. These drugs offer several benefits, such as alleviating different levels of discomfort and improving overall quality of life. The price of these medications can be quite high, mainly because of factors such as the seriousness and complexity of the disease, substantial research costs, and the need to replace less expensive drugs with more costly alternatives to enhance their efficacy (Lakdawalla, 2018).

In contrast to conventional pricing methods that often relied on a cost-plus margin approach to set product prices, modern theories recognize that pricing strategies should be grounded in the changing needs and perspectives of customers. The pioneering approach of value-based pricing (VBP) considers the perceived value that a product offers to patients and insurance companies (Vlaanderen et al., 2019). There is a compelling requirement for the adoption of VBP in Europe, encompassing the evaluation of elements such as therapeutic advantages, patient results, cost-efficiency, and the broader influence on healthcare systems.

Nonetheless, the implementation of VBP in Europe has produced diverse outcomes. Italy and Spain have notably embraced VBP, while regions like the UK and elsewhere tend to gravitate towards a more straightforward approach of providing discounts (Carlson et al., 2017). Several obstacles impede the full-scale implementation of VBP for prescription drugs. Certain challenges emerge within organizations, such as the expenses linked to data collection (Adamski et al., 2010) and inherent complexities associated with accurately quantifying the value or impact of a prescription drug (Dabbous et al., 2020). Concurrently, inter-organizational challenges surface, encompassing issues such as negotiating value metrics between healthcare payers and pharmaceutical manufacturers (Makady et al., 2019) as well as contract periods (Michelsen et al., 2020). Additional complexities arise from market-related factors, including

fragmented healthcare systems as highlighted by Gonçalves et al. (2018), adherence to nation-specific data privacy regulations, and the lack of a robust legal framework as noted by Neumann et al. (2011). These factors hinder the smooth exchange of patient information.

There are several research gaps identified in this area of study. Firstly, there is a pressing need for a systematic examination of the barriers to VBP adoption. This would involve consolidating a comprehensive catalog of associated risks and pertinent factors, as these risks are scattered across the literature, often with limited explanations (Hou & Neely, 2018). Secondly, it is imperative to synthesize the findings derived from existing research to lay a foundation for future inquiries, potentially addressing the fragmentation observed in the literature concerning VBP. Research on the barriers to VBP is an evolving field, and there is a need for forthcoming investigations to corroborate prior findings and to explore obstacles within different contexts, distinct from those previously examined (Alipour & Ho, 2020; Seeley et al., 2018). Finally, it is crucial to conduct additional research to strengthen assertions regarding the attitudes and behaviors of payers in the context of adopting VBP (Goble et al., 2017).

The primary objective of this study is to identify the obstacles that impede the adoption of VBP and analyze them from the diverse perspectives of various stakeholders, including pharmaceutical companies, healthcare providers, payers, and regulators. By doing so, we intend to shed light on the root causes of the disparity in adoption rates. The insights gleaned from this research hold the potential to be instrumental in shaping strategies aimed at surmounting these barriers, thereby facilitating the broader acceptance and effective implementation of VBP for prescription drugs.

Building upon the gaps evident in current research and the problem statement outlined, we have identified two distinct research objectives:

- To examine the barriers and facilitators influencing the implementation of VBP for prescription drugs in European healthcare systems.
- To assess the relative impact and significance of various factors contributing to the adoption of VBP for prescription drugs within five European healthcare systems.

2. Literature Review

Prioritizing cost-efficiency becomes crucial for a healthcare system dealing with an ongoing rise in pharmaceutical expenditures, while also dealing with limitations on healthcare resources. Forecasts suggest that prescription medication expenses are projected to surge by an average of seven percent annually until the year 2025 (National Health Expenditure Projections 2015-2025, 2015). In light of this situation, there has been a renewed focus on devising effective approaches to implementing a VBP strategy in Europe. The objective is to attain the best possible results that are meaningful for patients, all while either sustaining or lowering expenses (Cattel & Eijkenaar, 2020; Lotvin et al., 2014; Yu et al., 2017). However, there are several obstacles in the way of fully integrating VBP for prescription medications. Numerous studies emphasize the need for further research from the perspectives of both healthcare payers and prescribers regarding the adoption of VBP (Jommi et al., 2023; Seeley et al., 2018). Moreover, it is imperative to increase the pool of respondents in studies focusing on the adoption of VBP. This expansion is necessary to bolster the strength of findings and enrich the insights derived from previous research efforts (Goble et al., 2017).

The secondary review under consideration consists of information that was previously acquired and originates from external sources. In the initial phase of our research, we embarked on a comprehensive review of existing literature, predominantly drawing from secondary sources. This in-depth examination entailed the systematic evaluation of a diverse range of articles published on well-established global platforms, including, but not restricted to, Frontiers in Pharmacology, Value in Health, PharmacoEconomics, and Applied Health Economics and Health Policy. We took great care to meticulously collect these articles from reputable platforms such as ScienceDirect, PubMed Central, EBSCOhost, Google Scholar, and ProQuest Central. These articles played a pivotal role in our research, assisting us in pinpointing crucial research gaps, particularly by shedding light on their limitations and the prospects they presented for further investigation. Our review primarily centered on articles published between 2016 and 2023. The literature review we present encapsulates a synthesized and coherent summary of the insights gleaned from this extensive collection of articles.

2.1 Conceptual framework

In this study, we examine the adoption of VBP for prescription drugs (AD) as the dependent variable. The independent variables under investigation include Health Information Technology (HI), Value Measurement (VM), Drug Selection Intent (DI), Perceived Behavioral Control (BC), and Perceived Social Norms (SN). Additionally, we consider mediating variables, namely Contractual Intent (CI) and Organizational Intent (OI).

2.1.1 Health Information Technology

Health Information technology (HIT) encompasses applications and solutions used for electronically generating, maintaining, analyzing, storing, and transmitting data. Alternatively, it aids in the diagnosis, treatment, and management of medical conditions (Nesheva, 2019). HIT encompasses any clinical information technology system that captures patient data within an electronic health record (Heart et al., 2016). This facilitates the aggregation of data, resulting in fresh insights aimed at enhancing healthcare quality, efficiency, and cost savings. The existence of a framework for gathering vital data to support performance-based agreements has proven advantageous for Italian health authorities in effectively implementing these arrangements. This practice has been recognized as an exemplary model of a public-private partnership (Maskineh & Nasser, 2018).

On the flip side, prior research has identified substantial barriers, including an insufficient data infrastructure and significant administrative or initial expenses, that hinder the implementation of VBP within healthcare institutions (Garrison et al., 2013; Gonçalves et al., 2018; Nazareth et al., 2017). The current method of generating electronic records tailored to specific research requirements may become unsustainable due to factors such as administrative complexities and the availability of data aligned with research objectives (Makady et al., 2019). Healthcare systems frequently fall short in capturing the level of system integration required for specific medical conditions or patient subgroups. For many payers, linking compensation to specific outcomes will demand improvements to their existing infrastructure, which incurs costs. Challenges related to HIT concerning VBP are evident, particularly in Europe. Pauwels et al. (2017) conducted an extensive literature review to collect insights regarding the regulatory framework and implementation of VBP across Europe. The study's findings indicated that arrangements involving manufacturers covering nonpharmaceutical expenses face implementation challenges, primarily because payers often lack the necessary systems or data to support such agreements. Novartis, known for successfully introducing several risk-sharing initiatives, advocates practical strategies for addressing access-related issues. However, they underscore the importance of carefully evaluating the additional data collection burden in relation to the value gained from additional evidence (Antonanzas et al., 2019). Improvements to the IT infrastructure have the potential to enhance the ability to collect and track patient data. However, the ongoing challenge lies in effectively analyzing, storing, and sharing data while adhering to regulatory requirements.

This study leverages the gaps and insights derived from the literature review to assess the impact of HIT on adoption, specifically focusing on aspects of interoperability, patient reported outcomes (PRO), and implementation costs.

H1: HIT significantly influences contractual intent during VBP adoption for prescription drugs

H2: HIT significantly influences VBP adoption for prescription drugs mediated by contractual intent

2.1.2 Value Measurement

Value measurement consists of two key components: defining the appropriate value and measuring it according to established standards. The measurement of value or outcomes involves the process of evaluating the ultimate effects of a drug, ensuring the precision and practicality of data collection, and determining the appropriate duration for assessment (Zeldovich & Alexandrowicz, 2019). Among the frequently employed outcomes within VBP agreements are laboratory findings, hospitalization frequency, and metrics related to adherence (Mahendraratnam et al., 2019). The Quality Adjusted Life Year (QALY) integrates various aspects of health, including lifespan and various facets of life quality. Health authorities in England acknowledge the complexities associated with quantifying and evaluating the QALY concerning healthcare (Reddy et al., 2020). Seeley et al. (2018) conducted a comprehensive literature review, analyzing 90 articles related to value-centered contracts. All participants in these research studies emphasized a crucial step in the process, which involves defining the measurement of value and ensuring its availability within existing databases. This additional information provides insights into how medications perform in Real-World Evidence (RWE) studies compared to clinical trials, which often adhere to strict eligibility criteria and variables like disease stage and concurrent illnesses. In

cases of diseases with expedited review pathways, these trials may operate within condensed three-year timelines. In contrast, VBP can provide data spanning longer durations and more comprehensive outcome measures, such as the incidence of heart attacks rather than solely considering cholesterol levels. This approach reduces uncertainty for payers and recognizes genuinely innovative pharmaceuticals. Once the various aspects of value are identified, the next step involves quantification. In some cases, existing measurement scales may suffice like QALYs. However, for alternative considerations, VBP may require the development of customized measurements. The process of obtaining real-time data and subsequently analyzing it may result in significant costs and administrative burdens, a concern highlighted by certain health plans as a deterrent to the implementation of VBP for prescription drugs.

This study leverages the gaps and discoveries arising from the literature review to assess the impact of value measurement on adoption, focusing on aspects including the definition of outcomes, the utilization of real-world evidence, and government regulations.

H3: Value measurement significantly influences contractual intent during VBP adoption for prescription drugs

H4: Value measurement significantly influences VBP adoption for prescription drugs mediated by contractual intent

2.1.3 Contractual Intent

In the context of VBP, contractual intent relates to the expected befits from VBP in comparison to pricing models based on volume or competition. Pandey & Jhamb (2021) conducted an empirical study to examine the choices and application of prevailing organizational strategies. The findings indicated a preference for VBP over the other two models, although its implementation did not match this preference to the same degree. Hinterhuber (2008) conducted a two-phase empirical inquiry and deduced that, despite the potential benefits of VBP, more than 80% of companies continue to rely heavily on pricing methods primarily rooted in costs or competitive price benchmarks. This disjunction between aspirations and practical application primarily stems from an insufficient understanding of the customer value associated with this pricing approach. To achieve successful VBP implementation, organizations must adeptly recognize and communicate the comparative merits of their offerings. This entails gaining a deep understanding of the needs and preferences of drug manufacturers and payers, conducting thorough market research, analyzing competitors' offerings, and positioning their contracts as superior in terms of value. In a study, Dunlop et al. (2018) carried out a quantitative research with a focus on payers, aiming to uncover the perspectives and motivations influencing the adoption of VBP contracts. A substantial portion of the respondents expressed a preference for such arrangements over simple discounts, especially when they resulted in more significant cost reductions or improved uncertainty management. This sentiment was consistent across Europe. Nevertheless, attitudes toward these contracts varied depending on professional roles. Hospital pharmacists believed they would gain greater influence if presented with substantial cost savings, whereas national/regional payers indicated that their control would be augmented through more effective risk management within these agreements (Thanimalai et al., 2021).

In this study, the gaps and discoveries arising from the literature review are leveraged to examine the impact of contractual intent on adoption, specifically concerning aspects of risk-sharing, dynamic terms, and the allocation of budgets.

H5: Contractual intent significantly influences VBP adoption for prescription drugs in Europe

2.1.4 Perceived Behavioral Control

Ajzen (2020) emphasizes that Perceived Behavioral Control (PBC) is linked to one's beliefs about the availability of necessary resources and the likelihood of engaging in a behavior. It also considers internal and external factors that could hinder the execution of that behavior. This concept comprises two essential aspects: self-efficacy and controllability. Self-efficacy refers to the perceived level of difficulty in adopting an innovation and an individual's confidence in their ability to succeed in doing so. In contrast, controllability deals with external factors and the belief in whether one has personal control over performing the behavior or if it is primarily influenced by uncontrollable external factors (Shibly et al., 2022). When an individual holding a role in an organization exhibits a strong sense of PBC, it indicates a heightened belief in their ability to successfully carry out a specific action, specifically, the adoption of VBP as emphasized in this study. Brugger et al. (2015) conducted interviews to delve into the softer factors that affect the complex decision-making process at multiple levels when it comes to VBP. The feedback obtained from the participants consistently demonstrated a genuine dedication to VBP and a willingness to put forth their best efforts. Nevertheless, they expressed concerns

regarding the irregular nature of the assessment process, both internally and externally within the organization. PBC plays a dual role in influencing adoption, both directly and indirectly through organizational intent. In an organizational context, where the decision to adopt VBP is not entirely under an individual's voluntary control, PBC emerges as a significant predictor of adoption through the organization's intent. This is because the link between intention and adoption hinges on the individual's ability to translate their intentions into actions, with the support of the organization (Irimia-Diéguez et al., 2023).

In this study, PBC is represented by sub-variables, self-efficacy and controllability, which are derived from previous studies.

H6: PBC significantly influences organizational intent during VBP adoption for prescription drugs

H7: PBC significantly influences VBP adoption for prescription drugs mediated by organizational intent

2.1.5 Perceived Social Norms

In the Theory of Planned Behavior, social norms fall under the category of subjective norms. This category encompasses the perceived encouragement, influence, or expectations originating from individuals considered significant, including policymakers (Doekhie et al., 2020). In reality, subjective norms wield an impact on individuals who are adopting certain behaviors, motivating them to act in a manner they believe is expected by influential individuals. The significance of social influence escalates when individuals sense pressure emanating from significant figures in their lives (Oktavianus & Bautista, 2023). Social norms encompass a couple of pivotal scenarios: injunctive and descriptive (Ajzen, 2020). The former refers to beliefs regarding the approval or disapproval of a specific adoption by influential individuals, while the latter pertains to the belief that these influential figures themselves engage in the adoption. In the context of this study, the focus has primarily been on injunctive norms. It's worth noting that the adoption of VBP remains relatively limited in the European region. As a result, the descriptive norm or the influence exerted by competing pharmaceutical companies or payers may not carry significant relevance at this point. Regarding the adoption of VBP, social norms encompass the perception of support or pressure from various stakeholders, including patient advocacy groups and policymakers. These norms, as elucidated in the literature, can manifest in various forms, such as 1) a team culture that prioritizes patient needs (Keyworth et al., 2019); 2) endorsement from patient advocacy groups (Hughes & Barnes-Holmes, 2013), and 3) support from government and policymakers (Callenbach et al., 2023). In a research endeavor centered on the adoption of VBP in countries affiliated with the Organization for Economic Cooperation and Development (OECD), the OECD Secretariat carried out interviews with a panel of three experts (Performance-Based Managed Entry Agreements for New Medicines in OECD Countries and EU Member States, 2019). The adoption of value-based agreements (VBAs) was, according to these specialists, primarily prompted by the combined influence of public expectations and the pharmaceutical industry. As a result, social conventions have the potential to enhance the overall strategic direction of an organization. Research conducted through meta-analyses on collaborative decision-making has indicated that social norms exerted the most significant influence on the intent to act among healthcare professionals (Thompson-Leduc et al., 2015).

This thesis leverages the identified gaps and insights derived from the literature review to assess how social norms impact adoption within the realms of government policymakers and patient advocacy groups.

H8: Perceived social norms significantly influence organizational intent during VBP adoption for prescription drugs

H9: Perceived social norms significantly influence VBP adoption for prescription drugs mediated by organizational intent

2.1.6 Organizational Intent

Intent involves holding optimistic expectations for favorable outcomes (Ajzen, 2020). It affects the willingness of every member to allocate resources, including financial, temporal, reputational, and emotional investments, to bolster the potential for effective performance (Valdez-Juárez & Castillo-Vergara, 2021). Organizational intent signifies a company's inherent commitment to skillfully navigate the demands, challenges, pressures, and opportunities within the corporate landscape. It stands as an assessment made by the organization's workforce regarding their collective abilities, common purpose, and resilience. Essentially, organizational intent embodies a belief in the capacity to attain the desired level of adoption (Masana & Muriithi, 2019). Companies embarking on the transition to VBP have deliberately designed initiatives with the goal of fostering organizational confidence. This approach seeks to accelerate the buy-in of team members and enhance their eagerness to embrace change (Liozu, 2017). With heightened confidence, individuals jointly

possess the belief in their capacity to produce the desired results and achieve objectives. For the successful execution of VBP, payer organizations must engage in partnerships with pertinent parties to garner their backing, as is the case with other initiatives involving healthcare delivery system or payment reform. This approach aids in attracting a larger patient base, which holds significant importance for pharmaceutical manufacturers. In a health outcome-based agreement, where manufacturer rebates or payments may be tied to predefined clinical outcomes, involving physicians is likely a necessity. Nevertheless, physicians might demonstrate hesitancy in collecting and transmitting patient outcome data unless an incentive is offered (Moody & Mdycebp, 2016). Organizational intent serves as the essential catalyst that sustains the momentum of the change process and encourages the required mobilization within organizations as they transition to VBP. This study leverages the gaps and insights derived from the literature review to assess how organizational intent impacts adoption in terms of determination and decision-making.

H10: Organizational intent significantly influences VBP adoption for prescription drugs in Europe

2.1.7 Drug Selection Intent

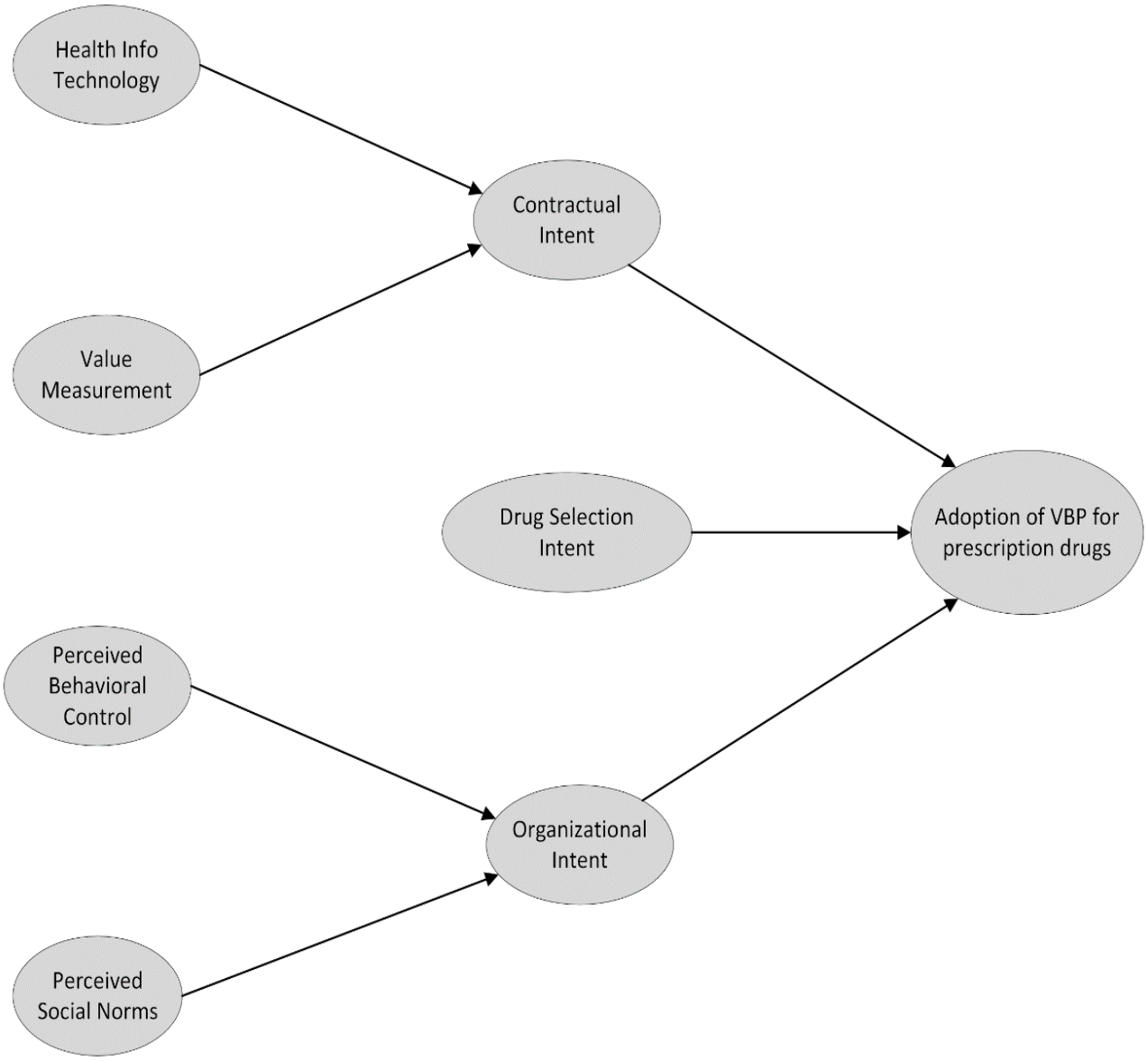
The type of prescription medication plays a crucial role in influencing the adoption of VBP. Some therapeutic domains are inherently more conducive to VBP adoption than others. For instance, in the realm of diabetes treatment, the presence of clearly defined markers and biomarkers, as well as easily measurable outcomes like A1C levels, positions it differently from other therapeutic areas. Drug selection in this context is evaluated across three primary categories: clinical value, economic value, and the stage of drug maturity. Starting with clinical value, disease areas such as oncology and related fields are inherently better suited for VBP adoption when compared to diabetes. While VBP can be applied to any drug given the availability of pertinent data, therapeutic domains like oncology are particularly attractive due to the potential for extended years of life or enhanced quality of life years. Furthermore, VBP finds its most favorable application in drugs that address unmet needs or cater to chronic conditions where the value generated is less tangible. This observation aligns with the findings of Trueman et al. (2010) , which also underscore that VBP are notably well-suited for therapeutic domains characterized by substantial unmet needs. Additionally, the market price or economic value of a drug plays a pivotal role in determining the adoption of VBP. They hold greater significance for high-cost drugs, particularly within therapeutic areas such as oncology and immunology, while their relevance diminishes in the context of diabetes treatment. It's worth noting that the same drug could experience varying degrees of VBP adoption, depending on whether it serves a high-priced therapeutic area, like obesity, as opposed to diabetes. This perspective is corroborated by Jommi et al. (2021) , who emphasized that even though VBP leans on value frameworks, a comprehensive understanding of investments in research and development related to the economic value of a drug remains essential. Lastly, the duration a prescription drug has been on the market is a vital factor to consider when contemplating the adoption of VBP. Newer drugs are generally more amenable to VBP arrangements when contrasted with matured drugs. However, it's worth noting that government policies may also seek to incorporate mature drugs into the VBP framework. This notion is further substantiated by the perspectives of industry experts, as revealed in a study conducted by Jommi et al. (2023). Their research indicates that VBP agreements are more responsive to emerging evidence on drugs at the time of their launch and prove advantageous when the outcomes of these drugs are still uncertain or not firmly established.

H11: Drug selection intent significantly influences VBP adoption for prescription drugs in Europe

2.1.8 Dependent Construct: Adoption of VBP for prescription drugs in Europe

Numerous researchers have highlighted that the increasing enthusiasm for VBP is grounded in the fact that it accrues the most substantial benefits among a spectrum of pricing methodologies (Blonda et al., 2021). Research outcomes have consistently affirmed that VBP emerges as the most favorable pricing approach in the contemporary business landscape (Ingenbleek, 2007). VBP exhibits a positive correlation with the success of new products, a contrast to cost or competition-based pricing. Furthermore, VBP plays a pivotal role in the effective optimization of value while operating within the confines of the allocated budget (Jommi et al., 2023). This study assesses adoption of VBP in the context of patient access, patient outcomes, and treatment cost. As a summary, Figure 1 depicts the conceptual framework for the study.

Figure 1: Conceptual Framework



3. Methods

The central aim of any quantitative study is to determine the theory's ability in explaining or predicting the observed phenomena of interest through the utilization of a survey (Gay & Airasian, 2000). The questionnaire is crafted with the expectation that it will effectively capture a range of participants' perspectives and experiences, aligning with its design.

The aim of this study is to assess the hypotheses derived from the conceptual model, enhancing previous discoveries. The research design, analysis unit, scales, and measurements were formulated within the framework of the survey. A pre-test phase preceded the main study, and the data collection process is elucidated. The construction of the quantitative questionnaire drew upon insights from the academic literature review and qualitative insights. The selected data analysis methodology was Partial Least Squares Structural Equation Modeling (PLS-SEM), and it was executed using ADANCO software.

The survey has been designed to encompass a wide-ranging population with a connection to the pricing of prescription drugs. This population comprises professionals spanning various sectors, including payers/insurance companies, pharmaceutical firms, healthcare practitioners, pharmacists, healthcare consultants, administrators, and academia. It's important to note that the survey participants occupy diverse roles within their respective industries. The sampling details

are highlighted in Figure 2.

Figure 2: The Sampling Process

The Sampling Process	
Sampling frame	Professional associations, industry organizations, regulatory bodies, academic institutions, and consulting organizations from United Kingdom, Sweden, Italy, France, and Spain
Sampling technique	Stratified purposive sampling
Sampling Size	333
Time frame	April- June 2023

The main study questionnaire comprised a total of 25 questions, encompassing demographic inquiries as well. For the pilot study, Microsoft Forms was employed, while Zoho Forms was utilized for the primary investigation. These platforms were selected due to their user-friendly interfaces, cost-effectiveness, streamlined distribution capabilities, and their capacity to consolidate and track data within a spreadsheet.

4. Results

4.1 Demographics

The selection of survey respondents was carried out meticulously, with a deliberate effort to ensure a well-balanced representation across different strata. The survey questionnaire garnered responses from a diverse array of organizations, encompassing payers, pharmaceutical manufacturers, healthcare professionals, pharmacies, and consulting firms.

Out of the 333 participants, the distribution was as follows: 44% of responses originated from the UK, while approximately 13-15% came from France, Spain, Italy, Sweden. Among the respondents, 29% were affiliated with insurance companies, and 23% represented healthcare professionals. The remainder consisted of 7% from drug manufacturing companies, 6% from pharmacies, and 5% from healthcare consultancies. Regarding roles, 58% of participants held non-management positions, 19% served as middle managers, 10% as team leaders, and 6% as senior managers. An additional 2% occupied top-level executive roles, while 2% worked as independent consultants in the healthcare industry. By encompassing respondents with varying levels of expertise, the researchers aimed to investigate how differing levels of knowledge influence attitudes and intentions toward adoption (Huneke et al., 2004). It's important to note that the survey did include an exclusion criterion based on respondents' knowledge levels of value-based pricing. If a respondent indicated that they had "No knowledge", the survey was terminated, and their responses were not collected. Among the 333 responses received, the breakdown of respondents' self-assessed knowledge levels was as follows: 15% considered themselves experts, 32% claimed to possess intermediate knowledge, 29% reported having basic knowledge, and 24% indicated they had limited knowledge.

These demographics distributions are represented in Figures 3-6.

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Figure 3: Demographics: Location

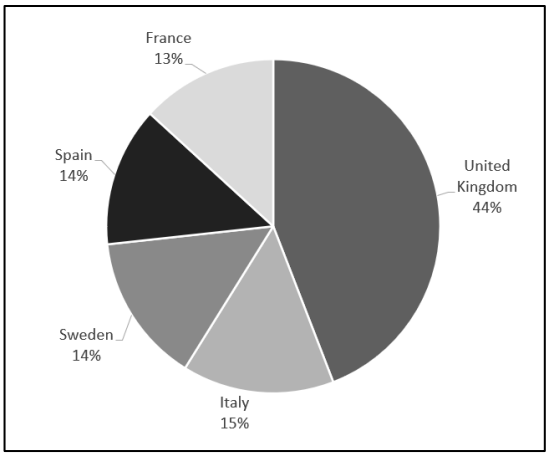


Figure 4: Demographics: Role

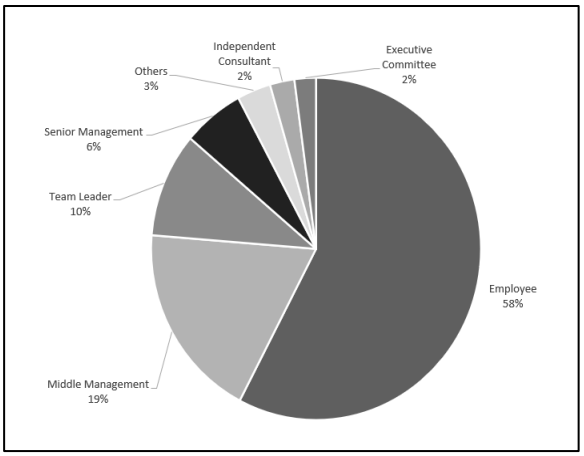


Figure 5: Demographics: Organization Type

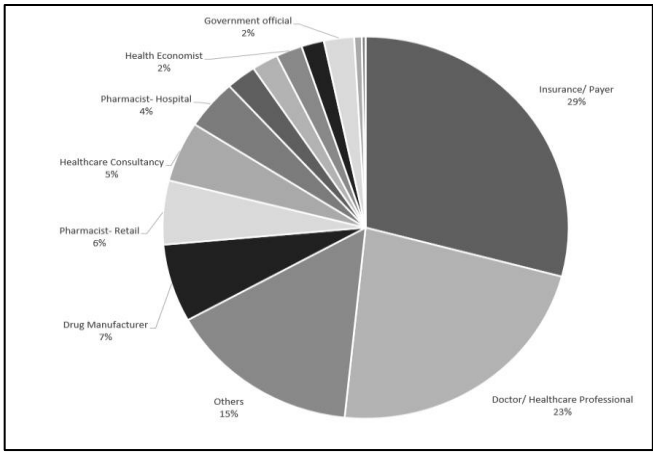
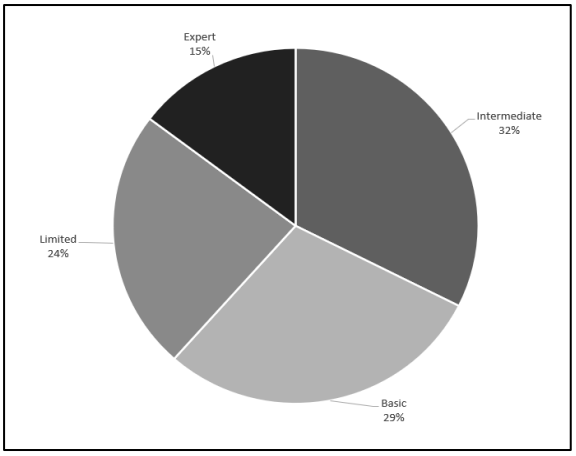


Figure 6: Demographics: VBP knowledge



4.2 SEM model

The findings from the analysis demonstrate that the constructs employed in this study exhibited strong internal reliability and consistency. This was evident as all constructs possessed Cronbach's Alpha values exceeding 0.64. Additionally, the constructs displayed rho_A values surpassing 0.8, and indicator reliability values above 0.5, collectively indicating a high degree of reliability. Furthermore, the Average Variance Extracted (AVE) value for the constructs exceeded 0.6, underscoring robust convergent validity. Collinearity among variables is typically indicated by a Variance Inflation Factor (VIF) value exceeding 5. However, the results indicate that all variables had VIF values below 5, signifying the absence of collinearity among the indicators. The Fornell-Larcker Criterion confirmed that each factor's value exceeded the strongest correlation that variable had with other variables within the model. This affirms that the various constructs are distinct from one another. Wright (1934) posited that indicator loadings of 0.8 or higher are indicative of the strongest impact, while loadings falling within the range of 0.5 to 0.8 suggest a moderate impact. All indicator loadings were found to be statistically significant and medium to high impact. All reliability and validity tests, along with loadings are mentioned in the Appendix (Figures 8-13).

The coefficient of determination, denoted as the R^2 value, serves as an indicator of the proportion of variation in the dependent variable(s) that can be effectively explained by the predictors (as shown in Figure A1). In this context, the R^2 value for employee retention is calculated to be 0.62, signifying that approximately 62% of the variability in employee retention can be accounted for by the variables considered in the model. This suggests a substantial explanatory power. SRMR is the square root of the discrepancy between residuals of the sample covariance matrix and the assumed model and its value less than 0.08 is considered acceptable (Dijkstra & Henseler, 2015; Hair, 2009; Hooper et al., 2007). The findings indicated that the model's SRMR value is 0.0638 and it can be concluded that the data exhibited coherence with the combined factors and composites within the measurement model.

Furthermore, the structural model (Figure 7 under Appendix) was scrutinized using the bootstrapping technique, involving 5000 sampling iterations across 333 observations to derive path coefficients and t-values. Based on the resulting analysis, it can be inferred that DI (t=7.6932, p=0.0000), OI (t=6.7248, p=0.0000), and CI (t=6.2294, p=0.0000) exert a strong influence on adoption, thus confirming hypotheses H11, H10, and H5. Similarly, HI (t=7.5978, p=0.0000) and VM (t=7.6613, p=0.0000) significantly impact CI, affirming hypotheses H1 and H3. OI is notably affected by BC (t=6.8444, p=0.0000) and SN (t=6.4023, p=0.0000), thus confirming hypotheses H6 and H8.

The indirect effects are highlighted in Appendix under Figures 14-17. HI (t=4.6885, p=0.0000) and VM (t=4.8806, p=0.0000) indirectly influence adoption through their mediation of CI, thereby confirming hypotheses H2 and H4. Similarly, BC (t=5.1944, p=0.0000) and SN (t=4.2793, p=0.0000) indirectly influence adoption by way of their mediation of OI, affirming hypotheses H7 and H9. Table 1 shows the results and inference of the direct and indirect effects of the variables.

Table 1: Direct and Indirect Effects Inference

Hypothesis	Effect	Original coefficient	t-value	p-value (2-sided)	Result
H1	Health Info Technology -> Contractual Intent	0.3927	7.5978	0	Significant and Positive
H2	Health Info Technology ->Contractual Intent-> Adoption	0.1189	4.6885	0	Significant and Positive
H3	Value Measurement -> Contractual Intent	0.3605	7.6613	0	Significant and Positive
H4	Value Measurement ->Contractual Intent-> Adoption	0.1091	4.8806	0	Significant and Positive
H5	Contractual Intent -> Adoption	0.3027	6.2294	0	Significant and Positive
H6	Perceived Behavioral Control -> Organizational Intent	0.3735	6.8444	0	Significant and Positive
H7	Perceived Behavioral Control -> Organizational Intent-> Adoption	0.1037	5.1944	0	Significant and Positive
H8	Perceived Social Norms -> Organizational Intent	0.3818	6.4023	0	Significant and Positive
H9	Perceived Social Norms -> Organizational Intent-> Adoption	0.106	4.2793	0	Significant and Positive
H10	Organizational Intent -> Adoption	0.2777	6.7248	0	Significant and Positive
H11	Drug Selection Intent -> Adoption	0.3771	7.6932	0	Significant and Positive

5. Discussion

An array of variables influencing the adoption of VBP for prescription drugs has been elucidated, substantiated by references to prior research. A comprehensive set of seven variables, namely HIT, value measurement, PBC, perceived social norms, contractual intent, organizational intent and drug selection intent, was identified through a meticulous examination of existing literature. The descriptions revealed that the uptake of VBP by European organizations is not solely determined by attributes within an organization but is instead influenced by a multitude of inter-organizational and market-related factors, which are intertwined with the behavioral intentions of stakeholders.

There is a necessity to focus on foundational building blocks for adopting VBP, namely HIT, value measurement and contractual intent. HIT significantly influences contractual intent in the adoption of VBP. This result substantiates the earlier findings of Adamski et al. (2010) and Makady et al. (2017) indicating that HIT, encompassing its implementation and associated costs, plays a pivotal role in the requirement for improved system integrations and reduced implementation

costs, ultimately contributing to the enhancement of VBP contract development. HIT exerts an influence on the adoption of VBP, with its impact mediated through contractual intent. This finding corroborates earlier research by Holleman et al. (2019), Michelsen et al. (2020), J. S. Yu et al. (2017), emphasizing that achieving data interoperability necessitates modifications in the internal processes and systems of both payers and drug manufacturers. European healthcare systems need to focus their efforts in building inter-connected, robust, and cost-effective data infrastructure.

The measurement of value has a discernible impact on contractual intent in the context of VBP adoption. This outcome reiterates the earlier findings put forth by Hospodková et al. (2023). Their conclusions highlight that both payers and drug manufacturers perceive an enhanced sense of control within the VBP framework when they leverage RWE derived from existing technical infrastructure, including registries and hospital claims, which constitutes a crucial component of value measurement. Value measurement exerts an influence on the adoption of VBP, with its impact being mediated through contractual intent. This perspective aligns with the assertions made by Boscolo et al. (2020) and Holleman et al. (2019), who contended that well-defined value definitions play a significant role in influencing VBP adoption. Thus, the current findings are consistent with prior research, underscoring the importance of accurately defining outcomes to affect contract structure, which, in turn, ultimately impacts the adoption of VBP.

The significance of contractual intent in influencing the adoption of VBP is noteworthy. This finding aligns with previous observations made by Alvino et al. (2020), Barrett & Stephens (2017) and ROGERS et al. (2008) , which emphasized the direct impact of the relative advantage of an innovation on its adoption. Furthermore, it acknowledges the insights of Hinterhuber (2008) regarding the necessity of understanding the relative advantage of VBP to enhance its adoption for prescription drugs. Consequently, companies are required to meticulously craft appropriate contractual terms to facilitate the adoption of VBP.

Post the foundational setups, it is required to focus on change management within the organization through PBC, perceived social norms and organizational intent. PBC indeed has an impact on organizational intent. This finding serves to affirm the earlier observations made by Ajzen (2020) , highlighting the influence of PBC on organizational intent. Furthermore, it reiterates the conclusions drawn by Brugger et al. (2015), indicating that stakeholders' perceived control affects the structure of the outcome evaluation process, both within and beyond the organizational boundaries. PBC also exerts an impact on the adoption of VBP, with this influence being mediated through organizational intent. Ajzen (2020) has previously highlighted that PBC indirectly affects actual behavior or adoption through its influence on intent. These present findings align with the conclusions of prior studies. Therefore, it underscores the significance of offering stakeholders appropriate controls to enhance their willingness to implement VBP, ultimately contributing to increased adoption rates.

The impact of social norms on organizational impact, as highlighted by this outcome, confirms the earlier findings of Ajzen (2020) regarding the influence of social norms on organizational effects in the context of innovation adoption. This observation also echoes the conclusions drawn by Blay et al. (2018) and Thompson-Leduc et al. (2015), who identified this construct as having the most significant effect on behavioral intention. The impact of social norms on actual behavior, mediated by organizational intent, as demonstrated by this outcome, reaffirms the earlier assertions of Ajzen (2020) that social norms influence actual behavior through their mediation by organizational intent. This finding is also in line with the research by Cluley et al. (2022), which noted that external factors play a role in driving organizations toward increased patient and public engagement, thereby contributing to broader acceptance and public engagement in the context of VBP adoption.

Positive organizational intent reinforces increased actual behavior, as evidenced by this outcome, thus corroborating the earlier assertions made by Ajzen (2020) regarding the motivating influence of organizational intent on actual behavior. These findings also parallel the research by Danzon et al. (2015) and Steinbrenner (2019), which documented that organizational decisions stimulate collaboration among a wide array of stakeholders, encompassing healthcare providers, payers, regulators, and patients.

Finally, drug selection intent certainly impacts adoption, as indicated by this outcome, thus reaffirming the earlier conclusions drawn by J. J. Carlson et al. (2010) that stakeholders' (particularly payers) attitudes towards VBP adoption are subject to change, particularly for products with a substantial budget impact, such as those addressing chronic diseases and oncology. It is imperative for participating organizations to select the right drug for VBP contracts for its success.

6. Conclusions

The concept of VBP is undeniably crucial in establishing equitable and transparent pricing reflective of the therapeutic worth of prescription drugs. However, its practical implementation encounters notable challenges. This study seeks to unveil the obstacles impeding VBP adoption and scrutinize them from the viewpoints of various stakeholders, including pharmaceutical companies, healthcare providers, payers, and regulators, in order to elucidate the underlying causes of the adoption gap. Notably, it was observed that HIT, value measurement, PBC, perceived social norms, and drug selection intent significantly influence adoption. Additionally, the relationships among these factors are mediated by organizational intent and contractual intent.

7. Limitations and suggestions for further research

The primary study was centered on five European countries: Italy, France, Spain, the UK, and Sweden. To enhance the broader relevance of future research, it may be beneficial to include a more diverse range of countries. The literature review was limited to English-language sources. Future studies could consider incorporating local languages to obtain a more comprehensive perspective. Additionally, the study did not directly incorporate patient viewpoints, as the primary focus was on the reimbursed market. Nevertheless, it would be intriguing to involve patients in future research to enrich the scope of investigation.

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Appendices

Figure 7: Graphical representation of the model

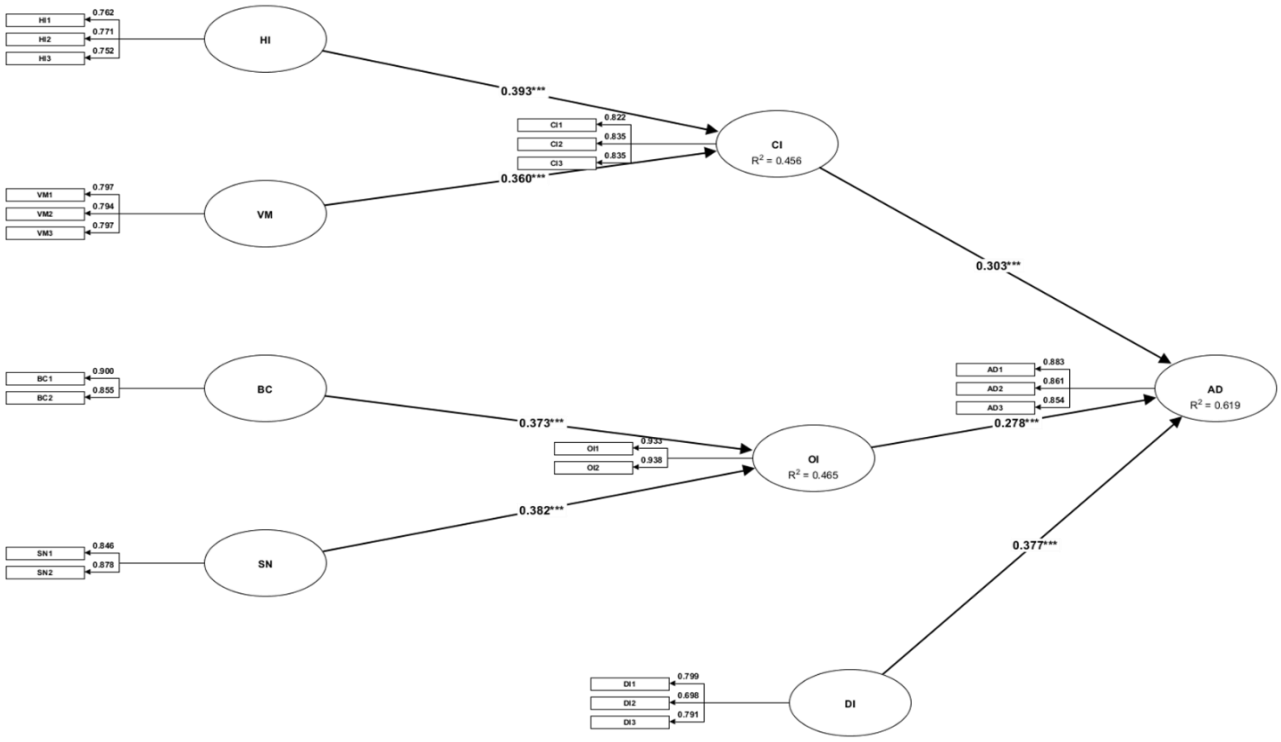

Figure 8: Construct Reliability

Construct	Dijkstra-Henseler's rho (ρA)	Jöreskog's rho (ρc)	Cronbach's alpha(α)
AD	0.8336	0.8999	0.833
DI	0.6506	0.8074	0.6426
OI	0.8585	0.9336	0.8577
CI	0.7764	0.8699	0.7757
HI	0.6381	0.8056	0.638
VM	0.7104	0.8382	0.7104
BC	0.7192	0.8706	0.7048
SN	0.66	0.8526	0.6551

Figure 9: Convergent Validity

Construct	Average variance extracted (AVE)
AD	0.7498
DI	0.5838
OI	0.8754
CI	0.6902
HI	0.5801
VM	0.6333
BC	0.7709
SN	0.7431

Figure 10: Discriminant Validity: Fornell-Larcker Criterion

Construct	AD	DI	OI	CI	HI	VM	BC	SN
AD	0.7498							
DI	0.4528	0.5838						
OI	0.3633	0.2081	0.8754					
CI	0.4274	0.312	0.2554	0.6902				
HI	0.279	0.2684	0.1716	0.3742	0.5801			
VM	0.2937	0.2568	0.1232	0.3589	0.3693	0.6333		
BC	0.2184	0.1752	0.3768	0.1939	0.1326	0.0802	0.7709	
SN	0.326	0.1931	0.3806	0.2349	0.1675	0.1571	0.3964	0.7431

Figure 11: Loadings

Indicator	AD	DI	OI	CI	HI	VM	BC	SN
CI1				0.8219				
CI2				0.8355				
CI3				0.835				
HI1					0.762			
HI2					0.7708			
HI3					0.7521			
VM1						0.7966		
VM2						0.7939		
VM3						0.7969		
BC1							0.9001	
BC2							0.8553	
SN1								0.8462
SN2								0.8776
OI1			0.9332					
OI2			0.938					
DI1		0.799						
DI2		0.6978						
DI3		0.7913						
AD1	0.8828							
AD2	0.8609							
AD3	0.8537							

Figure 12: Indicator Reliability

Indicator	AD	DI	OI	CI	HI	VM	BC	SN
CI1				0.6755				
CI2				0.698				
CI3				0.6972				
HI1					0.5806			
HI2					0.5941			
HI3					0.5656			
VM1						0.6345		
VM2						0.6302		
VM3						0.635		
BC1							0.8102	
BC2							0.7316	
SN1								0.7161
SN2								0.7701
OI1			0.8709					
OI2			0.8799					
DI1		0.6384						
DI2		0.4869						
DI3		0.6262						
AD1	0.7794							
AD2	0.7412							
AD3	0.7288							

Figure 13: Indicator Multicollinearity

Indicator	AD	DI	OI	CI	HI	VM	BC	SN
CI1				1.5772				
CI2				1.5826				
CI3				1.6332				
HI1					1.2466			
HI2					1.2713			
HI3					1.2354			
VM1						1.3964		
VM2						1.3736		
VM3						1.3931		
BC1							1.4208	
BC2							1.4208	
SN1								1.3111
SN2								1.3111
OI1			2.2925					
OI2			2.2925					
DI1		1.3408						
DI2		1.1908						
DI3		1.2941						
AD1	2.0845							
AD2	1.9131							
AD3	1.831							

Figure 14: Influence of Health info technology on adoption through contractual intent

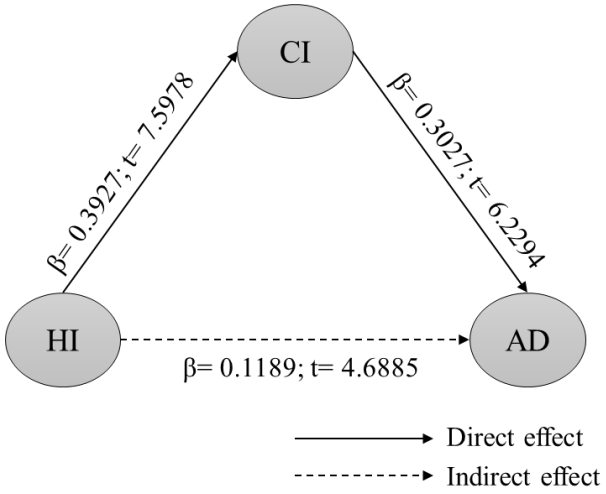

Figure 15: Influence of value measurement on adoption through contractual intent

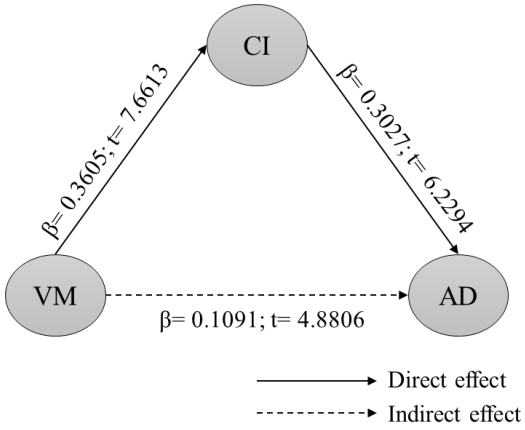

Figure 16: Influence of perceived behavioral control on adoption through organizational intent

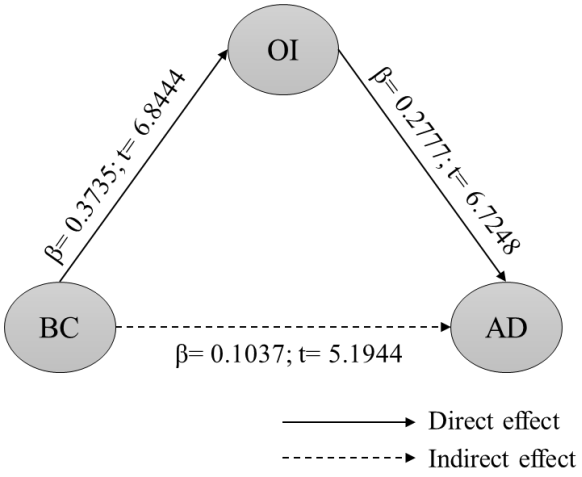

Figure 17: Influence of perceived social norms on adoption through organizational intent