UTILIZATION OF WEARABLE DEVICES FOR ENAHNCING REAL-TIME ADVERSE DRUG REACTIONS (ADR) MONITORING THROUGH PHARMACOVIGILANCE IN IRELAND

A thesis submitted in partial fulfilment of the requirements for the MSc in Pharmaceutical Business and Technology

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CANDIDATE DECLARATION

I hereby certify that the content I am submitting for evaluation as part of the MSc in Pharmaceutical Business & Technology program is original to me and is based on my own study and/or research. I have also acknowledged all sources and materials used in its creation. Furthermore, I certify that I have never plagiarized—not even from other students—or copied someone else's work in whole or in part.

Signed :

Date :

Supervisor – Philip Byrne

Signed :

Date :

ACKNOWLEDGEMENT

I thank Almighty God for giving me the confidence and the presence of mind throughout this endeavor and completing this project without any problem.

The success and final outcome of this project required a lot of guidance and assistance from many people and I am extremely privileged to have got this all through the completion of the project. All that I have done is only due to such supervision and assistance and I would not forget to thank them.

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List of Abbreviations

Abbreviation	Full Form
ADRs	Adverse Drug Reactions
AEs	Adverse Events
AEFIs	Adverse Events Following Immunizations
AF	Atrial Fibrillation
AI	Artificial Intelligence
API	Active Pharmaceutical Ingredient
API	Application Programming Interface
BP	Blood Pressure
CRS	Comfort Rating Scale
DHT	Digital Health Tool
DL	Deep Learning
ECG	Electrocardiogram
EHRs	Electronic Health Records
EMA	European Medicines Agency
EU	European Union
FAERS	FDA Adverse Event Reporting System
FDI	Foreign Direct Investment
GDPR	General Data Protection Regulation
GVP	Good Pharmacovigilance Practices
HCPs	Healthcare Professionals
HF	Heart Failure
HPRA	Health Products Regulatory Authority
HRV	Heart Rate Variability
ICT	Information and Communications Technology
IDA	Industrial Development Agency
IoMT	Internet of Medical Things
IoT	Internet of Things
MAE	Mean Absolute Error
MAPE	Mean Absolute Percentage Error
MI	Myocardial Infarction
ML	Machine Learning
MoE	Margin of Error
NLP	Natural Language Processing
PIDM	Programme for International Drug Monitoring
PPG	Photoplethysmography
PV	Pharmacovigilance
SAHPRA	South African Health Products Regulatory Authority
SUS	System Usability Scale
WHO	World Health Organisation

ABSTRACT

This dissertation explores the potential of wearable devices to revolutionize pharmacovigilance by enabling real-time monitoring and detection of adverse drug reactions (ADRs). A utilitarian approach is used, emphasizing the practical application of technology to enhance patient safety and drug development. The research employs a mixed-methods approach, combining quantitative surveys and qualitative responses. The surveys, distributed electronically across Ireland, assess consumer perceptions of wearable devices and pharmacovigilance practices.

Key findings highlight the potential of wearables to improve ADR detection. However, challenges such as data security, privacy concerns, and user engagement need to be addressed. The research concludes by recommending strategies for responsible and effective implementation of wearable technology in pharmacovigilance practices, including establishing robust data security measures, obtaining informed consent from patients, and developing user-friendly wearable devices.

The study contributes to the advancement of patient safety and drug development by exploring the potential of wearable technology in pharmacovigilance. By implementing the recommendations outlined in this study, healthcare professionals can leverage this technology to improve patient outcomes and medication safety.

A survey was conducted to assess patient attitudes and understanding of wearable technology in Ireland. The results revealed that a significant portion of the population (98.01%) uses smartphones daily and expresses interest in new technologies (99%). Smartwatches (77.22%) and activity trackers (29.70%) emerged as the most popular wearable devices. While a substantial number of respondents already use wearables (58.41%), ethical considerations and data privacy concerns were also evident.

The analysis suggests that wearable devices, particularly smart clothing or accessories, hold promise for detecting ADRs due to their ability to track a wider range of physiological data points. However, concerns regarding data accuracy, security, and fairness in access necessitate the development of robust regulations and ethical guidelines.

Overall, the findings indicate that wearable devices have the potential to become valuable tools in pharmacovigilance, but further research and development are crucial to address ethical concerns and ensure responsible data practices.

CHAPTER 1 : INTRODUCTION

1.1. OVERVIEW

This research considers the use of real time monitoring of adverse events (AEs) in pharmacovigilance by leveraging wearable devices, particularly within the context of Ireland's robust pharmaceutical industry. The aim of this research is to explore the potential of wearables in pharmacovigilance, focusing on their ability to detect and report adverse events in real time.

This dissertation aims to identify opportunities for improved adverse event detection, reporting, and analysis, while considering the challenges this brings along with outlining future directions for technology-driven pharmacovigilance (for example continuous real-time monitoring, personalized pharmacovigilance, predictive analytics, and immersive virtual experiences).

This research has the potential to revolutionize patient safety for personalized medicine use and expedite drug development. By exploring these elements, we can tap into the potential of devices and ultimately shape the trajectory of pharmacovigilance in the years to come. This research will examine how the experts; public and potential customers [patients] perceive such advancements.

1.1.1 INTRODUCTION TO WEARABLE TECHNOLOGY

An object attached to, or implanted into the human body with electronics and computers integrated into it is referred to as wearable technology, also known as wearable devices (Wright and Keith, 2014). A wearable device is typically worn as an accessory with an implant that has an interface to carry out basic functions while still serving its original aesthetic purpose (Wilson and Laing, 2018). These gadgets perform many of the same tasks as our laptops and cellphones and more because they have sensory and scanning features like biofeedback. They also come in the form of jewelry, headbands, watches, clothing, or more intrusive items like smart tattoos and microchips that can be inserted into the body and used for a variety of functions in all facets of life (Wright and Keith, 2014).

Technology has greatly enhanced people's quality of life and revolutionized the healthcare industry. The measurement of physiological and biochemical activities in the body, such as blood oxygen saturation and protein levels, has advanced due to ongoing technological innovation, enabling their determination outside of hospital laboratories (Chiauzzi *et al.*, 2015).

Wearable technology, part of the Internet of Things (IoT), is a rapidly growing field that uses electronic devices to gather, transmit, and analyze patient health data. It has the potential to improve healthcare outcomes, reduce costs, and increase patient participation. Applications include fitness trackers, smartwatches, ECG monitors, blood pressure monitors, and biosensors. The market is expected to grow significantly, with Deloitte Insights predicting a growth of over 440 million units in 2024. The technology is expected to encourage preventive healthcare, increase patient engagement, and lower healthcare costs (Alshahrani, 2023)

A variety of technological advancements have been made in recent years concerning the multipurpose use of wearables, like fitness bands and smartwatches. These include paying for goods and services that support the cashless policy (such as FitPay) and monitoring bodily vital signs like heart rate, sleeping patterns, and the number of calories burned, to name a few. Due to their features, wearable technology has proven beneficial in a variety of industries, including healthcare, entertainment, and education (Wright and Keith, 2014). The application of wearable technology to detect adverse drug reactions (i.e., signal detection) will be the main focus of this study.

1.1.2 PHARMACOVIGILANCE

Pharmacovigilance encompasses a diverse set of actions, now deeply embedded in every phase of drug development. The World Health Organisation (WHO) defines pharmacovigilance as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem” (WHO, 2024). In other words, pharmacovigilance plays an important role in signal detection of adverse drug reactions (ADRs) and hence ensuring the safety of medicinal products. In Ireland, committed to safeguarding public health, the HPRA proactively gathers and analyzes diverse sources of information on drug safety, such as patient reports, published studies, large-scale population data, and additional clinical trial outcomes. They continuously scrutinize new safety information and promptly take appropriate regulatory measures to ensure the safety of medications. Reporting suspected adverse events is only one method of spotting potential new adverse reactions (i.e., a signal), which can also be found in additional sources, like new information from clinical trials, publications and social media to mention some. Once a signal has been detected, additional analysis and information are required to determine its significance. Therefore, pharmacovigilance plays a critical role in drug development, epidemiological studies, future research, and the advancement of medical understanding. Enhancements in medication safety or comprehension will eventually result in better patient care (HPRA, 2014).

1.1.3 THE LOCATION – IRELAND

Many small and large pharmaceutical companies can be found in Ireland. The main sectors of the pharmaceutical industry that these businesses are in are as follows:

- Biopharmaceuticals (Biotechnology)

- Medical Devices & Diagnostics

- Solid/Oral Finished Dose Pharmaceuticals

- Active Pharmaceutical Ingredient (API)

With a history that dates back to the 1960s, for a net employment gain of 24,019, IDA Ireland reported job gains of 32,426 and losses of 8,407 in total. 242 investments total—89 expansions and 103 new name investments—were awarded to IDA Ireland in 2022. Regional locations accounted for 127 projects or 52% of all investments. Ten of the top ten pharmaceutical companies in the world are among the approximately 75 pharmaceutical companies that Ireland is proud to have (IDA Ireland, 2023).

The given data is relevant to the research purpose as it provides data on IDA Ireland's effectiveness in attracting foreign direct investment (FDI). This data helps analyze the impact of IDA Ireland on employment in Ireland, the level of activity and potential economic impact, and the focus on regional locations. The data also highlights IDA Ireland's success in attracting pharmaceutical companies, which can be used to support the research questions.

With over 80,000 individuals currently employed in the life science industry, Ireland is a hub of activity for job seekers in this particularly buoyant field. In 2021, the Biopharmaceutical and

Chemical industry alone shipped goods worth €106 billion, or 67% of all goods exported during that year. According to Jane Lyons, (country manager of PhamaLex Ireland), *"Ireland is internationally recognized as a destination of choice for the life science sector".* It is home to nine of the top ten MedTech businesses and 24 of the top 25 Biotech and Pharma companies worldwide (Daly, 2022).

Ireland's strong position in the life science industry is evident in its large and growing workforce. The Biopharmaceutical and Chemical industry contribute significantly to the Irish economy, indicating a stable and well-funded sector. Ireland's recognition as a leader in the life science sector attracts top companies from around the world, offering a variety of job opportunities with reputable employers. This makes Ireland an attractive destination for job seekers in the life science industry.

Figure 1: Pharmaceutical industries in Ireland & its location (Creaner, 2024)

1.1.4 WEARABLE DEVICES INTEGRATION INTO PHARMACOVIGILANCE

Patient safety involves protecting patients from errors, injuries, accidents, and infections, as well as capturing and understanding other adverse events. Reporting adverse events helps prevent poor patient outcomes. Pharmacovigilance involves monitoring the effects of drugs and medical devices, including the detection, assessment, and understanding of adverse events (˚Aserød, 2017).

Pharmacovigilance has evolved significantly in recent years, with patients playing a crucial role in identifying and describing adverse drug reactions. This has been facilitated by the integration of information and communications technology (ICT), allowing patients to upload their reports online. This has led to the potential for data sharing via online forums and search engines (Berrewaerts *et al.*, 2016).

This highlights the significance of the research, which focuses on pharmacovigilance by leveraging wearable technology to detect ADRs.

1.2 AIMS AND OBJECTIVES OF DISSERATATION

Wearable technology with activity tracking and physiological sensors has the potential to enhance pharmacovigilance systems through real-time monitoring and early ADR detection. However, there are potential limitations such as underreporting, delayed detection, and lack of real-time data.

Regulatory implications and ethical considerations need to be addressed, as well as selecting suitable devices. Technical feasibility and data integration should be assessed, considering factors like accuracy and reliability.

Patient engagement and real-time data integration should be considered, and AI and machine learning algorithms could be used to analyze wearable data and predict ADRs. Recommendations for technology-driven pharmacovigilance include continuous real-time monitoring, personalized pharmacovigilance, predictive analytics, and immersive virtual experiences.

The objectives of this research are to :

1. Assess the existing pharmacovigilance systems and processes in the pharmaceutical industry, highlighting strengths and areas that can benefit from technological advancements.

2. Examine pharmacovigilance regulations, identify gaps, and propose ethical standards (such as purposeful data collection, transparent data sharing, data security, and privacy) for wearable devices, ensuring patient autonomy and informed consent in wearables-based monitoring.
3. Research the wearable devices that might be suitable for ADR detection.
4. Investigate and evaluate the technical feasibility of using these wearables for monitoring and detecting adverse events, as well as the accuracy and reliability of the health data collected.
5. Assess patient adoption of wearables for health monitoring and adverse event reporting, examining factors influencing engagement and integrating real-time data into existing databases.
6. Outline recommendations for technology-driven pharmacovigilance (continuous real-time monitoring, personalized pharmacovigilance, predictive analytics, immersive virtual experiences)

1.3 RESEARCH QUESTIONS

1. What are the current Pharmacovigilance Practices used in the Pharmaceutical Industry?
2. What are the Regulatory Implications and Ethical Considerations for new technologies being used in Pharmacovigilance?
3. What types of wearable devices are suitable for ADR detection?
4. How to access data for adverse event detection from these wearables?
5. How do patient engagement and acceptance affect the real-time data integration into the pharmacovigilance system from wearables? (user engagement metrics such as device usage, data completeness, user feedback, and acceptance surveys such as adoption rate, satisfaction level, and intent to continue using)

The use of wearable devices in healthcare has opened the way for their use in pharmacovigilance. The use of wearable devices can be a form of solution to real time monitoring of adverse events. This research aims to explore how wearables devices can be incorporated in pharmacovigilance systems.

1.4 SIGNIFICANCE OF THE RESEARCH

The research explores real-time ADR detection using wearables, aiming to improve patient safety and drug development while aligning with utilitarian ideals. It assumes potential solutions lie in technological advancements such as AI, machine learning, and wearable technology. The study emphasizes data privacy and ethics, balancing technological benefits with ethical principles like informed consent and patient autonomy. It also advocates for patient-centered care, prioritizing autonomy, values, and experiences in healthcare decision-making. The use of real-time data and evidence-based approaches aligns with the philosophy of evidence-based medicine, which emphasizes using the best available evidence for clinical practice.

This approach addresses various ethical, social, and practical aspects of using wearables for real-time ADR detection. Balancing utilitarianism with individual rights, addressing the ethical implications of emerging technologies like AI and machine learning, and implementing robust data security measures are essential for maintaining trust and ethical conduct. The use of real-time data and evidence-based approaches strengthens the validity and generalizability of the research.

1.5 ACCESS AND RESEARCH ETHICS ISSUES

- Obtaining informed consent from participants will be crucial for accessing and using their wearable data ethically.
- Data anonymization and encryption measures will be essential to protecting participant privacy. Participants will be fully informed about how their data will be collected, stored, and used.
- The research will comply with relevant data privacy regulations and ethical guidelines, such as GDPR in the EU.

1.6 STRUCTURE OF THE RESEARCH

Surveys will be used to learn about people's common values and preferences. Every individual who uses wearable devices will be a potential contributor to the survey. After the data is gathered, it will be utilized to evaluate the objectives. As part of the research, the ethical guidelines will also be evaluated. The research will follow a mixed-methods research strategy, combining both quantitative and qualitative approaches.

The research aims to explore the use of wearables for real-time ADR monitoring in pharmacovigilance, focusing on current practices, technology feasibility, patient engagement, and potential implications. Data collection will involve analyzing existing literature, surveys, technical evaluations, and statistical methods to identify trends and correlations.

The proposed conceptual framework incorporates both quantitative and qualitative elements, outlining a logical progression through various stages of analysis.

The research aims to triangulate findings from both quantitative and qualitative analyses to gain a comprehensive understanding of the potential and challenges of using wearables for ADR monitoring in pharmacovigilance. The research will draw conclusions based on the combined analysis and propose recommendations for responsible and effective implementation of this technology in pharmacovigilance practices.

CHAPTER 2 : LITERATURE REVIEW

2.1 WEARABLE DEVICES –

Wearable technology, part of the Internet of Things (IoT), is a rapidly growing field that uses electronic devices to gather, transmit, and analyze patient health data. It has the potential to improve healthcare outcomes, reduce costs, and increase patient participation. Applications include fitness trackers, smartwatches, ECG monitors, blood pressure monitors, and biosensors. The market is expected to grow significantly, with Deloitte Insights predicting a growth of over 440 million units in 2024. The technology is expected to encourage preventive healthcare, increase patient engagement, and lower healthcare costs.

The research article by (Alshahrani, 2023) explores wearable healthcare technology, including smartwatches and fitness trackers, and its growing market. Technology is gaining interest due to its potential for better healthcare outcomes. Wearables can be used for basic health monitoring, chronic disease management, and early detection of conditions. Benefits include promoting preventive healthcare, increasing patient engagement, lowering medical costs, and reducing workload for healthcare providers. The future of wearables in healthcare looks promising with advancements in technology leading to more accurate monitoring and improved data analysis (Alshahrani, 2023). The paper provides a clear overview of wearable healthcare technology; however, some gaps were noted such as lacks in data on health outcomes, specific populations, privacy and security concerns, cost-effectiveness, and long-term user engagement. It could benefit from a deeper exploration of specific aspects, mentioning credible sources for market growth statistics and potential future advancements. Challenges such as data security, user privacy, and accuracy need to be addressed.

Future advancements in wearables and digital health programs are expected to play a significant role in disease management, prevention, and personalized care. Despite challenges such as the technological limitations and potential limitations in wireless charging and battery life, which could impact the accuracy and usability of these devices, the study by (Smuck *et al.*, 2021) suggests that wearables have the potential to transform healthcare delivery with careful planning and implementation. It also mentions the potential for wearables to be integrated into clothing, potentially improving compliance, and the possibility of using wearables for disease diagnosis and treatment monitoring in the future. Similar studies mentioned in the paper written by (Smuck *et al.*, 2021) include assessment of ownership of smart devices and the acceptability of digital health data sharing and secondary care provider attitudes towards patient-generated health data from smartwatches. (Smuck *et al.*, 2021)

Key Features of successful digital health programs involving wearables
• Clearly defined problem and disease state • Integrated system of healthcare delivery • Technology support bar and service • Personalized experience • Enhanced end user experience • Aligned payment and reimbursement models • Clinician champions and stakeholder support

Table 1: Key features of Wearables (Smuck et al.*, 2021)*

A review by (Vijayan *et al.*, 2021) explores the potential of wearable sensor technology in healthcare, focusing on its applications in monitoring physiology, activity levels, and sleep patterns. These sensors can be used to monitor chronic conditions, improve rehabilitation outcomes, and remotely track patients. They are often more accurate and convenient than traditional methods like questionnaires and clinical tests, and can collect data in a person's natural environment, providing a more complete picture of their health. Deep learning algorithms can be used to analyze data from wearable sensors and identify patterns that can improve healthcare.

Figure 2: Types of wearables (Vijayan et al.*, 2021)*

Despite challenges such as accuracy, security, and privacy, the benefits of wearable sensors outweigh these challenges, making them increasingly popular in healthcare (Vijayan *et al.*, 2021). While wearable sensor technology has the potential to revolutionize healthcare by providing more accurate, convenient, and personalized care, it requires further research and analysis to fully understand its potential and its limitations.

(Mattison *et al.*, 2022) carried out a systematic review which discusses the potential of wearable technology in managing chronic diseases. It reviews 30 articles on how wearables like Fitbits and smartwatches impact health outcomes in people with chronic diseases. The results were mixed, with some showing positive effects and others showing no effect. Some studies suggested that wearables could improve pain scores, increase physical activity levels, and improve sleep quality in certain conditions. However, more research is needed on the long-term effects and cost-effectiveness of wearables (Mattison *et al.*, 2022). The review provides valuable insights into the current state of research on wearables for chronic disease management, but the mixed results highlight the need for further research in this area.

(Lu *et al.*, 2022) conducted a systematic review which examines the use of wearable medical devices in healthcare, focusing on clinical applications. The study was conducted using scientific databases from 2015 to 2019, examining studies on health monitoring, chronic disease management, disease diagnosis and treatment, and rehabilitation aiding. The results show that wearable devices can be worn on the head, limbs, or torso and are used in various healthcare areas such as health and safety monitoring, chronic disease management, disease diagnosis and treatment, and rehabilitation. However, wearable devices may not be comfortable or user-friendly for everyone, and privacy and security concerns about data collected by these devices need further research. The paper concludes that while wearable devices have the potential to play a major role in healthcare, more research is needed to explore their full potential and address current limitations (Lu *et al.*, 2022).

The research paper by (Huhn *et al.*, 2022) discusses the increasing popularity of wearable devices in health research due to their unobtrusive nature, comfort, and ability to collect data over long periods in natural settings. The scoping review included 179 studies using affordable, consumer-grade wearable devices to measure vital signs such as heart rate, sleep duration, and physical activity. Most of the studies were observational and focused on large populations in global health research. The most common wearable devices used in the studies were Fitbits, ActiGraph (research-grade), and Polar Electro. Wrist-worn devices were the most popular, followed by hip-worn and chest-worn devices. The most frequent applications of wearable devices in health research included correlations between wearable data and other physiological data, method evaluations for wearables, population-based research, experimental outcome assessment, predictive forecasting, and exploratory analysis of big data sets.

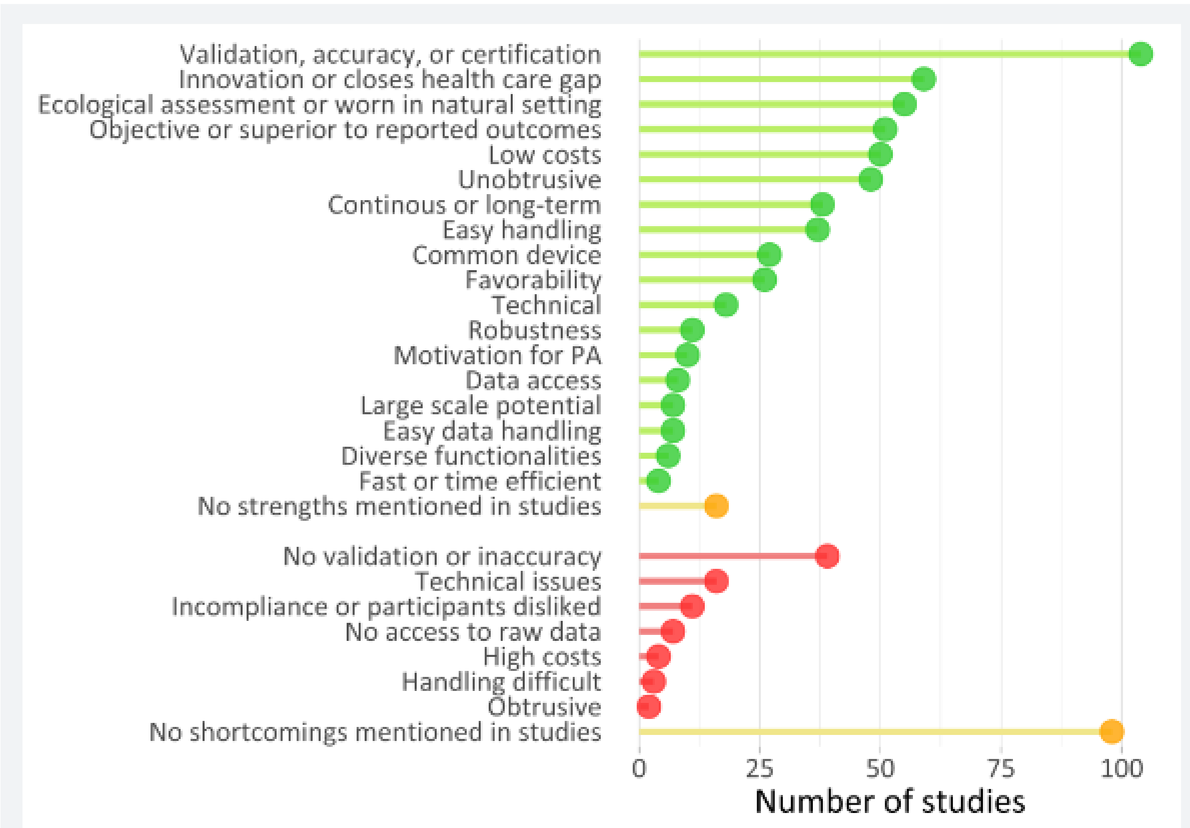


Figure 3: Strengths and weakness of wearables (Huhn et al., 2022)

The paper by (Huhn *et al.*, 2022) concludes that wearable devices have a wide range of potential applications in health research and can be used to study various health conditions. However, there are also limitations to wearable devices, such as accuracy and validation. The paper offers a comprehensive overview of how affordable wearable devices are being used in health research, focusing on commercially available, affordable wearables used for health research. The paper also highlights trends in wearable use, such as the increasing popularity of wrist-worn devices and the growing focus on global health research (Huhn *et al.*, 2022).

The research article by (Guan *et al.*, 2022) explores the use of wearable devices, specifically smartwatches, to monitor side effects following COVID-19 vaccination. The study analyzed data from participants in Israel who received second and third doses of the BNT162b2 mRNA vaccine and compared it with self-reported questionnaires on side effects.

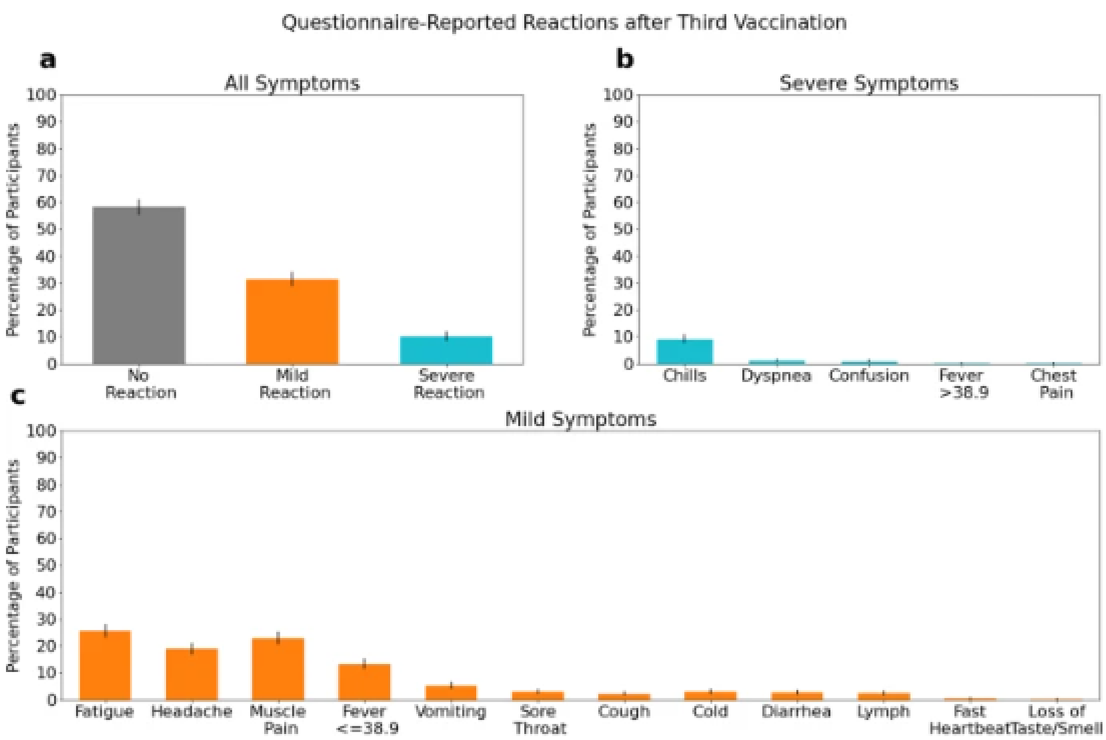


Figure 4: Symptoms as reported in questionnaires (Guan et al.*, 2022)*

The findings from *(Guan* et al.*, 2022)* study showed that wearable devices were more sensitive than questionnaires in detecting physiological changes associated with vaccination. Even participants who reported no side effects showed a significant increase in heart rate and stress measure in the 72 hours following vaccination.

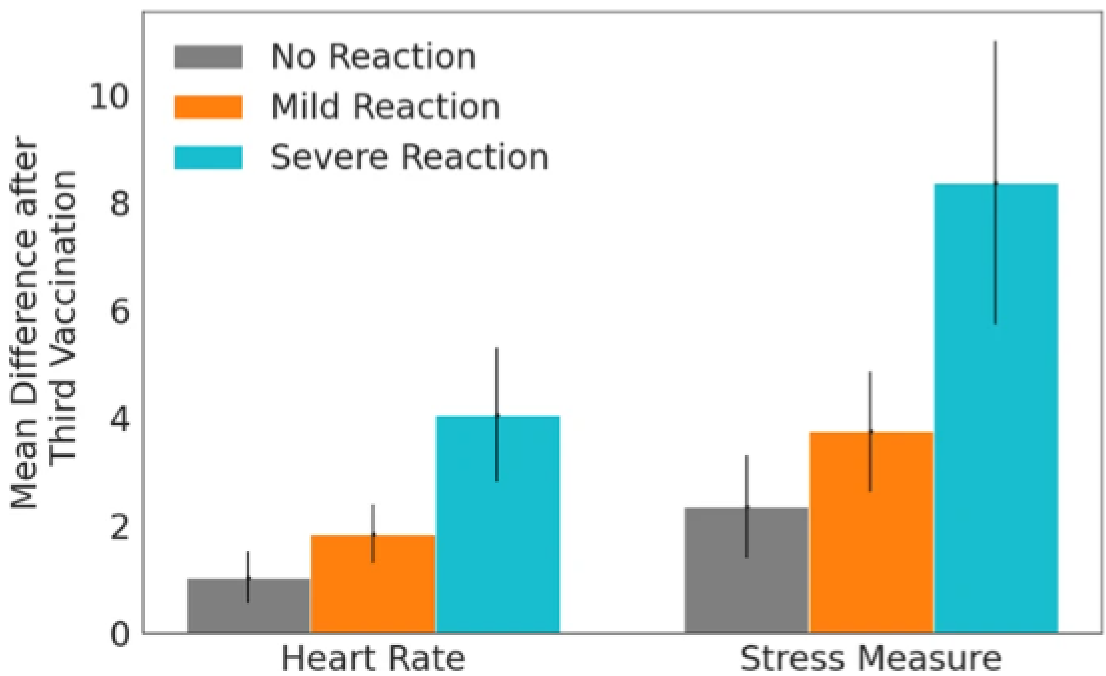


Figure 5: Change in heart rate and stress measure in smartwatch (Guan et al., 2022)

Wearable data from the devices correlated with the severity and duration of reported symptoms. Benefits of wearables include continuous monitoring, earlier detection of side effects, and potential improvement in clinical trials by identifying abnormal reactions sooner. However, (Guan *et al.*, 2022) study's limitations include its focus on a specific smartwatch model (Garmin Vivosmart 4), reliance on self-reported questionnaires, and potential bias in self-reported data.

Future directions include exploring using wearables to monitor side effects for other vaccines or health conditions and combining wearable data with self-reported information for a more comprehensive picture. The study suggests that wearable devices hold promise for more objective and sensitive monitoring of COVID-19 vaccine side effects, potentially improving vaccine safety surveillance and clinical trials. (Guan *et al.*, 2022)

The thesis by *(Kaur, 2021)* mentions that healthcare sector, particularly in Nordic countries, has been slow to adopt emerging technologies to optimize health efficacy. Wearable devices are however emerging as a promising technology for clinical trials, offering easier and more attractive ways for patients to participate. These devices can generate real-world data that can improve patient monitoring in clinical trials. However, challenges such as patient safety, measurement reliability and validity, and data privacy and integrity need to be addressed.

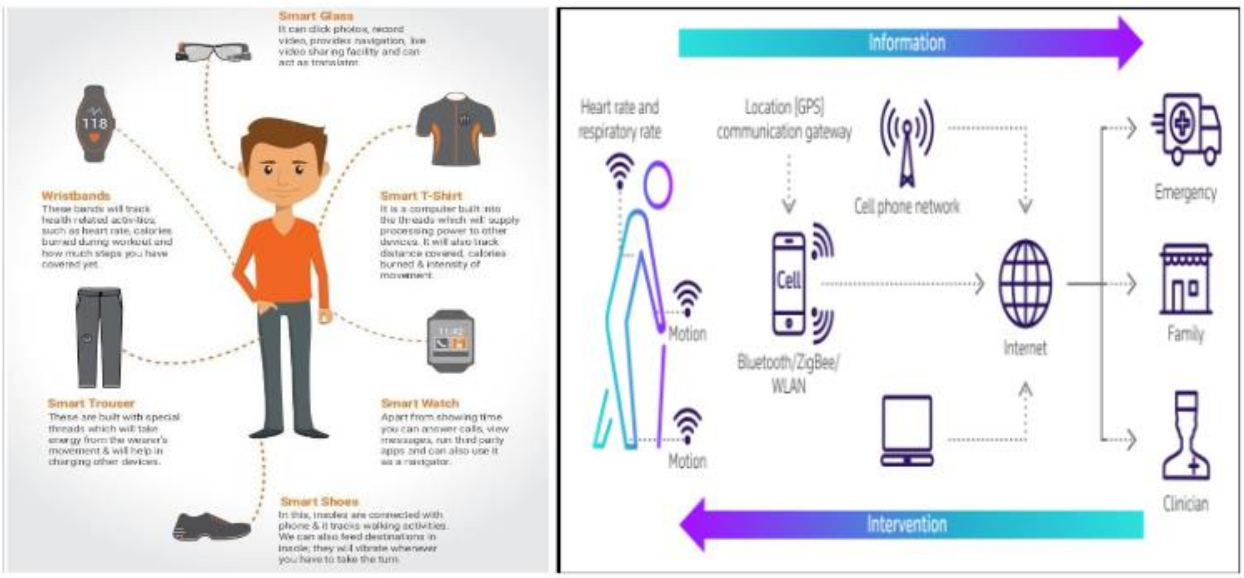


Figure 6: Wearables based health Monitoring System (Kaur, 2021)

The thesis by (Kaur, 2021) explores the potential of wearable remote patient monitoring in clinical trials. It highlights the relevance of wearable technology in improving clinical trials and patient-centric healthcare, especially during the COVID-19 pandemic. The thesis also highlights potential benefits like increased patient access, real-world data collection, and early disease detection. (Kaur, 2021)

(Sanches *et al.*, 2023) carried out a systematic review and meta-analysis which explores the potential of wearable devices to measure heart rate variability (HRV) to identify and predict COVID-19. Traditional methods like ECGs and Holter monitors provide detailed HRV measurements but can be uncomfortable and restrict daily routines. Wearable devices, like smartwatches or chest straps, offer continuous monitoring with a trade-off in precision. Recent studies have shown a link between reduced HRV and COVID-19. The study reviewed 9 existing studies and found that wearable devices like Fitbits and smartwatches using photoplethysmography (PPG - which uses light to measure how much blood the heart is pumping under the surface of the skin) technology can measure HRV. The study also found evidence that HRV decreases in people with COVID-19 compared to healthy individuals. Some studies suggest that wearable devices may detect a decrease in HRV before symptoms appear, which could be helpful for early detection of COVID-19. (Sanches *et al.*, 2023)

The research paper by (Dobson *et al.*, 2023) explores the use of wearable devices in health research, particularly for mental health conditions like anxiety. Wearables collect continuous, passive, and real-time data, which can be used to develop interventions and monitor patients remotely. They can also be a valuable tool for self-management of health. However, there are several limitations to wearables, including digital inclusion (which ensures everyone has access to and skills to use information and communication technologies, including the internet and digital literacy), data access and privacy concerns, ethical implications. The strengths of wearables include their ability to collect continuous, passive, and real-time data, making them useful for mental health monitoring and interventions. The paper suggests that researchers and policymakers should be transparent about their data collection practices and implement policies to protect privacy and data ownership. Additionally, wearable companies should be more transparent about their algorithms and data practices. (Dobson *et al.*, 2023)

The review by (Abd-alrazaq *et al.*, 2024) examines the effectiveness of wearable AI in detecting and predicting stress among students. The study aims to assess the effectiveness of wearable AI in diagnosing and predicting stress among students. Researchers conducted a systematic review and meta-analysis, searching 7 electronic databases for relevant studies on stress detection or prediction in students. A meta-analysis of 6 studies showed that wearable AI has promising accuracy (around 86%) in detecting stress in students. However, the accuracy varied depending on factors such as the number of stress classes, type of wearable device, and data set size. The research suggests that wearable AI has the potential to be a valuable tool for detecting stress in students, but more research is needed before it can be widely used in real-world settings. (Abd-alrazaq *et al.*, 2024)

(Kargarandehkordi *et al.*, 2024) carried out a prospective cohort study which explores the use of machine learning (ML) to predict stress-induced spikes in blood pressure (BP) in real-time, focusing on personalized models built from data collected through wearable devices like Fitbits. The study aims to develop personalized ML models to predict BP spikes using wearable sensor data, allowing for real-time monitoring and potential interventions for stress management. The research involved recruiting participants with diagnosed hypertension and self-reported stressful lifestyles, wearing Fitbits and Omron HeartGuide BP monitors for four weeks, and using a mobile app called CardioMate to collect data and prompt BP measurements. Self-supervised learning techniques were used to train the models.

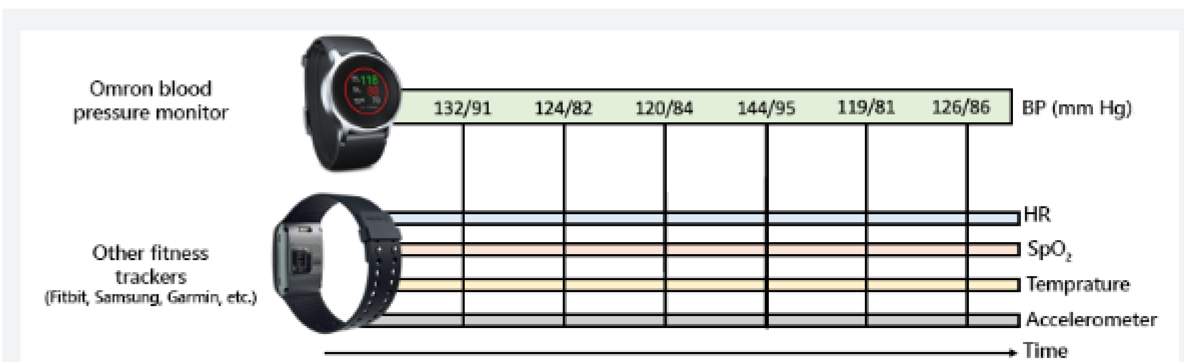


Figure 7: Wearables to collect BP and HR (Kargarandehkordi et al.*, 2024)*

The output in (Kargarandehkordi *et al.*, 2024) study shows promising results for personalized ML with limited labeled data. Future work includes complete participant recruitment and data collection and developing and evaluating personalized ML models for BP prediction. The research paper highlights the potential of personalized AI models using wearable devices to address the limitations of current methods for diagnosis and intervention. (Kargarandehkordi *et al.*, 2024)

The study by *(Choi, 2024)* aimed to compare self-tracking health practices, eHealth literacy, and subjective well-being among college students with and without disabilities. A cross-sectional online survey was conducted with 702 participants, 83 with disabilities and 619 without. The survey assessed self-tracking practices, preferred tracking tools, eHealth literacy (using the eHEALS scale), and subjective well-being (using the FS scale).

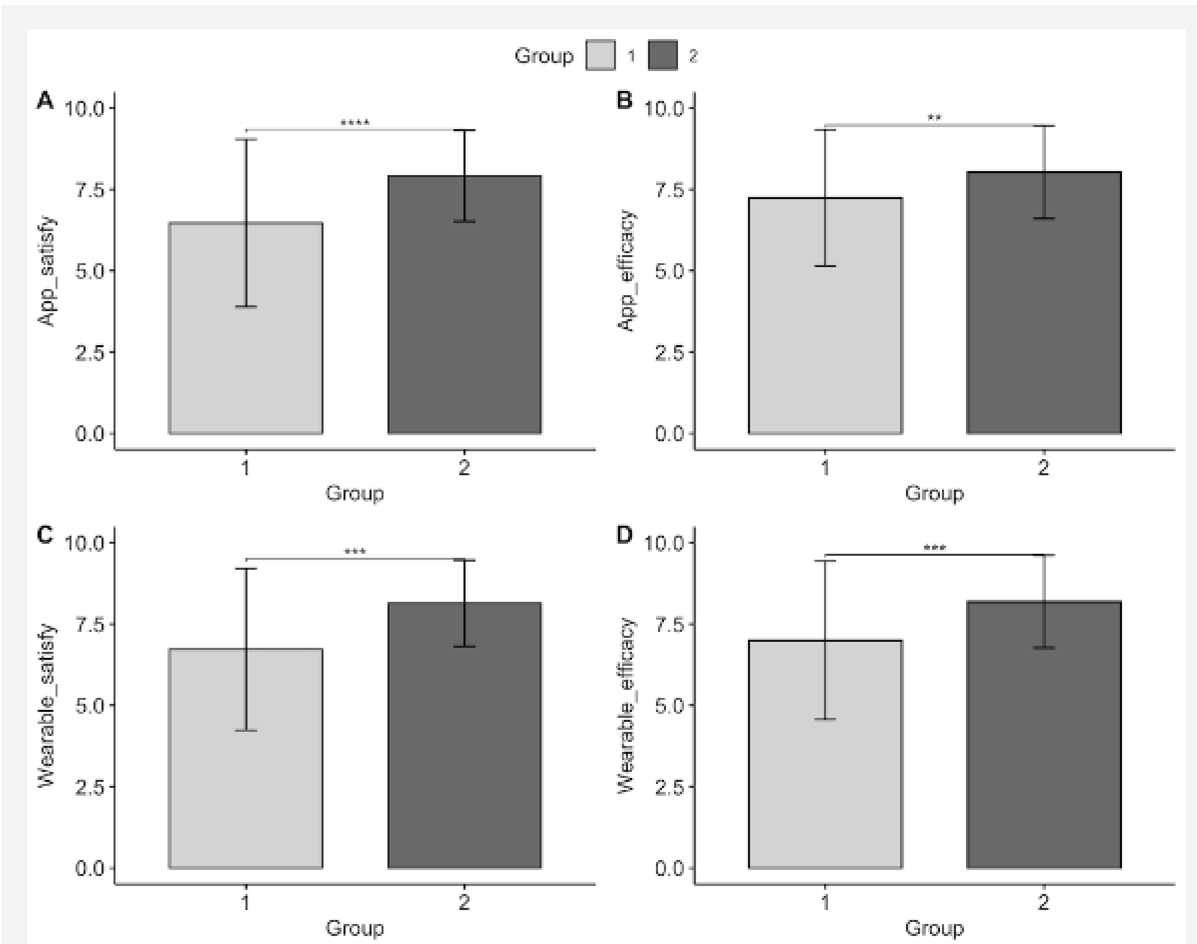


Figure 8: Comparative analysis of different variables between two groups (Choi, 2024)

Results of (Choi, 2024) study showed that over 80% of participants self-tracked their health. Students with disabilities were more likely to use laptops/desktops and track heart rate, while students without disabilities preferred tablets and tracked food intake/calories. Students with disabilities reported lower satisfaction and perceived efficacy with smartphone apps and wearable devices for health tracking. Common reasons for not self-tracking health included forgetting, lack of perceived usefulness, and difficulty tracking. Students with disabilities had lower eHealth literacy and subjective well-being scores compared to students without disabilities. Regression analysis showed that disability status, self-tracking practices, and eHealth literacy significantly predicted subjective well-being. The study highlights potential benefits of digital health technologies for self-care management in young adults and emphasizes the importance of designing accessible health apps and wearables for users with disabilities (Choi, 2024). In conclusion, this study provides valuable insights into the self-tracking practices of college students with and without disabilities.

The research paper by (Dixon *et al.*, 2023) discusses the potential of smartphone and wearable device data for population health research. It argues that while these devices collect significant health data, large-scale studies have not been conducted. The paper highlights the need for this data to answer critical research questions in areas like arthritis, diabetes, and mental health. The authors discuss the requirements for using this data, including issues like selection bias due to device ownership and data harmonization across different devices. They emphasize the importance of public trust and engagement in the research process.

The paper by (Dixon *et al.*, 2023) proposes solutions such as establishing an interdisciplinary research community and securely linking patient-generated data with national healthcare data sets. They believe this will allow researchers to answer many important questions while maintaining public trust. (Dixon *et al.*, 2023)

The research paper by *(Chang* et al., *2023)* explores the ethical implications and factors influencing the adoption of healthcare wearables in an omnichannel healthcare supply chain environment. It finds that wearables facilitate communication between patients and healthcare providers.

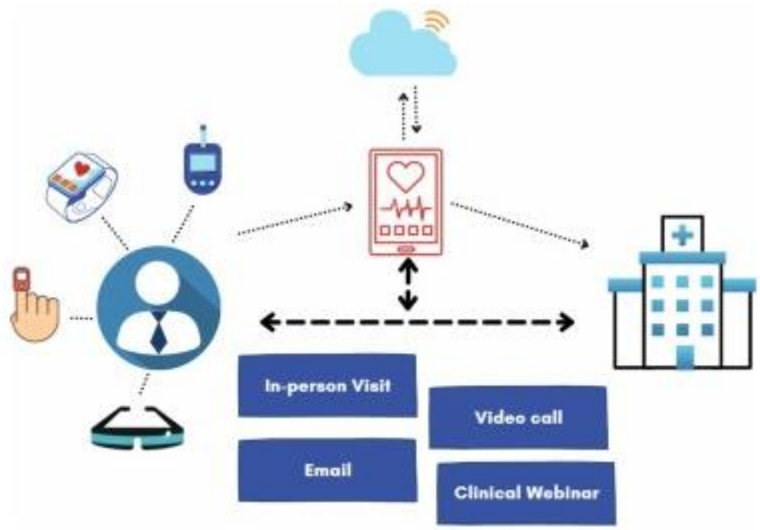


Figure 9: Wearables in the Healthcare Omnichannel Environment (Chang et al.*, 2023)*

The study by (Chang *et al.*, 2023) proposes a framework integrating traditional statistical and machine learning approaches to analyze large amounts of data related to wearable usage in the omnichannel healthcare supply chain. It highlights the potential of wearables in transforming healthcare delivery but emphasizes the need to address ethical concerns and user adoption barriers. The research paper offers valuable insights and proposes a new direction for investigating wearables in healthcare. (Chang *et al.*, 2023)

The research paper by (Ferguson *et al.*, 2021) presents a robust protocol for a Cochrane Review on the effectiveness of wearable smart devices in detecting atrial fibrillation (AF) in adults without prior arrhythmia diagnosis. The review aims to evaluate the effectiveness of these devices in adults without prior arrhythmia diagnosis. The review includes a comprehensive search strategy, rigorous methodology, predefined subgroup analysis, and the GRADE approach for quality assessment. However, it has limitations, such as excluding implantable cardiac monitors and non-smart wearables like Holter monitors, potentially overlooking valuable data.

The protocol demonstrates a well-designed Cochrane Review focusing on providing high-quality evidence on wearable technology's role in AF detection. (Ferguson *et al.*, 2021)

The research paper by (Virginia Anikwe *et al.*, 2022) provides a comprehensive review of mobile and wearable sensors for health monitoring systems. Sensors are classified into homogeneous (one type), dual (two types), and heterogeneous (multiple types), with heterogeneous sensors being most effective due to their ability to combine data from various sources. The system architecture involves data collection, transmission, pre-processing, feature extraction, analysis, and evaluation using machine learning algorithms. These sensors are used in various health monitoring applications, including human activity and posture monitoring, sleep disorders, fall detection, depression and mood swings, Parkinson's disease management, cardiac diseases, and coronavirus disease detection and contact tracing. The paper highlights the future potential of integrating these sensors with the Internet of Things (IoT) and Internet of Medical Things (IoMT) for improved healthcare delivery. (Virginia Anikwe *et al.*, 2022)

The development and validation study by (Yoo *et al.*, 2024) explores the feasibility of using electronic health records (EHRs) for postmarket surveillance of wearable devices that provide atrial fibrillation (AF) prediagnoses. Traditional methods for monitoring these devices after their release are limited, and EHRs are designed for billing purposes and lack standardized terms to capture wearable use. The proposed solution is to develop a system to analyze unstructured clinical notes in EHRs and identify mentions of AF prediagnoses received through wearables. The methodology involves defining rules to identify relevant text patterns in notes, training a labeler model to probabilistically label notes based on these rules, and fine-tuning a large NLP classifier to improve detection accuracy. A retrospective cohort study was conducted to compare characteristics of patients with and without wearable prediagnoses. Results showed that the labeler model achieved high accuracy and acceptable recall in identifying relevant notes. The fine-tuned classifier further improved recall while maintaining good precision. The system identified a significant number of patients (2279) who received AF prediagnoses from wearables. Patients with prediagnoses tended to be older, male, White, and have higher scores on a risk assessment tool for stroke. They were also more likely to be prescribed anticoagulant medications and eventually receive a confirmed AF diagnosis compared to those without prediagnoses. This study demonstrates the potential for EHR-based surveillance of wearable AF prediagnoses, but further research is needed to validate these findings in larger populations (Yoo *et al.*, 2024). The approach offers a scalable and cost-effective way to monitor the real-world use of wearables and assess their impact on patient care.

The review by (Mikhail *et al.*, 2023) explores the potential of smartwatches for atrial fibrillation (AF) detection, highlighting their user-friendliness and cost-effectiveness. The research shows promising accuracy (93.5-98.25%) for smartwatch ECG in detecting AF. However, challenges such as user interface complexity for older adults and limited research on smartwatch effectiveness during daily activities are highlighted. The paper suggests smartwatches can speed up diagnosis and reduce mortality, but further investigation is needed to establish a causal link. Critics suggest that 2018-2023 is a recent enough timeframe for such a rapidly evolving field. Additionally, the paper does not address the concern of patients with undiagnosed AF who might be alarmed by a smartwatch notification. (Mikhail *et al.*, 2023)

2.2 ADR & PHARMACOVIGILANCE –

Pharmacovigilance, the science of monitoring the safety of medicines and vaccines. It emphasizes the importance of detecting, assessing, understanding, and preventing adverse effects of medicines. The World Health Organization (WHO) Programme for International Drug Monitoring (PIDM) promotes global medicine safety by setting standards and coordinating reporting networks. Underreporting is a common challenge in pharmacovigilance, and MedSafetyWeek is an annual campaign to raise awareness of Adverse Drug Reactions (ADRs) and national reporting systems. Social media and online sources are explored to complement traditional methods of monitoring medicine safety. (WHO, 2024)

The review article by (Agrawal *et al.*, 2023) discusses the history and importance of pharmacovigilance, the science of monitoring the effects of drugs after they have been released to the market. The concept of pharmacovigilance dates back to 1848 when a young girl died after receiving chloroform anesthesia, leading to investigations into the safety of anesthesia. Pharmacovigilance is important because it helps to identify and assess the risks of drugs that may not have been identified during clinical trials, ensuring that the benefits of a drug outweigh the risks.

The article by (Agrawal *et al.*, 2023) describes the main objectives of pharmacovigilance include monitoring the effects of drugs during clinical trials and after they have been released to the market, monitoring the quality of drugs, identifying health risks involved in the administration of certain drugs, and encouraging the safe, rational, and efficient use of drugs. The article concludes by discussing the future of pharmacovigilance in India. (Agrawal *et al.*, 2023)

The chapter by (Al-Worafi, 2020) discusses the significance of pharmacovigilance (PV) in ensuring medication safety and improving patient outcomes. It covers the history, objectives, and application of PV to vaccines, herbal medications, and self-medication. The chapter also highlights the challenges faced by developing countries in implementing PV practices and suggests recommendations for improvement. (Al-Worafi, 2020)

The document summarized by (SAHPRA, 2022) is a guideline for healthcare professionals on reporting adverse drug reactions (ADRs) and adverse events following immunizations (AEFIs) to the South African Health Products Regulatory Authority (SAHPRA). The purpose of the guideline is to help healthcare professionals monitor the safety and effectiveness of medicines and encourage reporting of suspected ADRs, AEFIs, and product quality issues. The guideline provides information on ADRs, AEFIs, and pharmacovigilance, how to identify ADRs/AEFIs, what information to include in an ADR/AEFI report, when to report ADRs/AEFIs, and how to report ADRs/AEFIs (e.g., mobile app, online form). (SAHPRA, 2022)

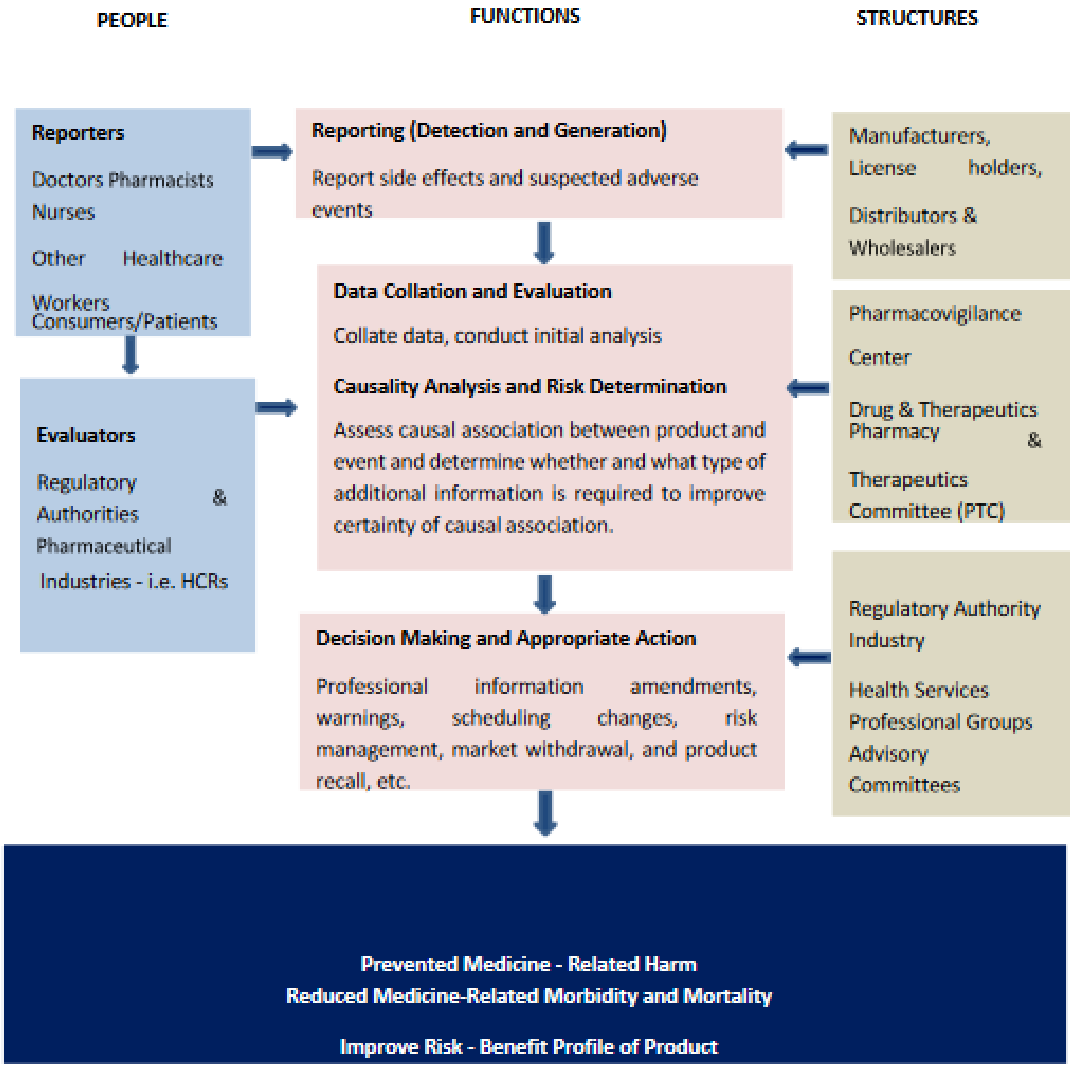


Figure 10: professional groups & their functions (SAHPRA, 2022)

The review by (Zatovkaňuková and Slíva, 2023) analyzed the impact of different countries' laws and approaches to pharmacovigilance on reporting of adverse drug reactions (ADRs). Data from six countries such as US,Canada, UK, Japan, China etc. since 2010 was analyzed. All countries required drug manufacturers to report ADRs, but healthcare professionals' obligations varied. The number of ADR reports per person increased in all studied countries, with the US having the highest reporting rate, possibly due to government efforts. China, though starting later, surpassed some other countries. The study suggests that improving pharmacovigilance systems and sharing best practices internationally could lead to better drug safety monitoring (Zatovkaňuková and Slíva, 2023). Overall, the study provides a starting point for understanding the influence of pharmacovigilance systems on ADR reporting.

The research article by (Fossouo *et al.*, 2022) discusses the importance of pharmacovigilance, which involves monitoring the safety of medicines post-release. Traditional methods are deemed insufficient, and a more proactive approach is needed. Community pharmacists, due to their accessibility and expertise, are well-positioned to contribute to pharmacovigilance efforts. The chapter proposes integrating pharmacovigilance systems with electronic health records to improve data collection, reporting, and patient safety. In summary, pharmacovigilance plays a critical role in ensuring medication safety, and integrating pharmacovigilance systems with electronic health records and clinical data management systems can enhance this role. (Fossouo *et al.*, 2022)

The review article by (Satwika *et al.*, 2021) explores the potential of advanced technologies in improving pharmacovigilance, the monitoring of drug safety. Traditional methods like clinical trials and spontaneous reporting are insufficient, but the rise of social media and mobile apps has created a vast amount of data that can be mined for insights. The study emphasizes the importance of combining these new methods with traditional ones for earlier detection of adverse drug reactions, which can improve overall drug safety, especially for vulnerable populations.

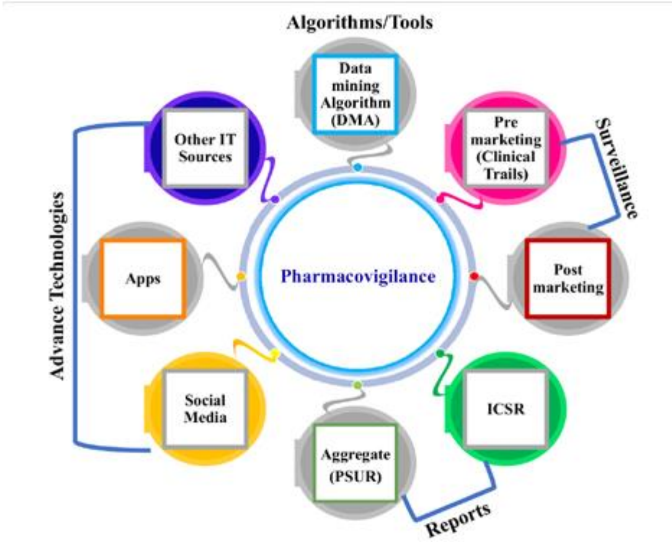


Figure 11: Advanced framework components to boost pharmacovigilance system (Satwika et al.*, 2021)*

The article by (Satwika *et al.*, 2021) addresses the need for better methods for detecting adverse drug reactions (ADRs) in healthcare and highlights the potential of social media and mobile app data in pharmacovigilance. The paper's strengths include relevance, acknowledging the potential of social media data, and a combined approach. However, it could benefit from a more critical analysis.

The review on pharmacovigilance by (Lavertu *et al.*, 2021) emphasizes the importance of monitoring drug safety after approval to identify rare side effects and those affecting specific groups. It highlights the various established, emerging, and experimental systems used in pharmacovigilance, including published case reports, spontaneous reporting systems like FAERS, electronic health records (EHRs), social media data, and experimental systems like mobile apps.

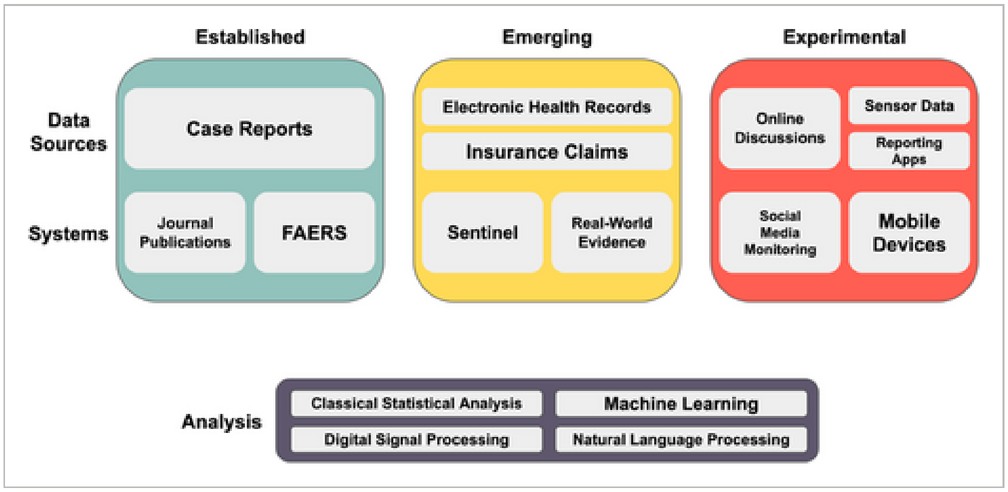


Figure 12: overview of pharmacovigilance methods at a varying stages of development (Lavertu et al., *2021)*

The paper by (Lavertu *et al.*, 2021) highlights the challenges and future directions of pharmacovigilance, such as integrating diverse data sources, developing robust methods for analysis using artificial intelligence, and collaborating with experts from various fields. It also emphasizes the need to address ethical considerations and data privacy when using social media data. (Lavertu *et al.*, 2021)

The paper "Automated Signal Detection in Pharmacovigilance: A Review of Recent Developments" by *(Wadhwa* et al., *2021)* discusses the advancements in automated systems used to detect potential risks associated with medications. Pharmacovigilance is crucial for public health monitoring, and it involves collecting and analyzing data on adverse drug reactions (ADRs) to identify potential risks. Traditionally, this process relied on manual review, which was time-consuming and labor-intensive. Automation offers benefits such as faster processing of data, increased efficiency in detecting signals, and allowing human experts to focus on high-level tasks. However, there are no universal standards for automated pharmacovigilance systems, and regulatory bodies need to develop guidelines for data analysis and validation. Training for staff is necessary to implement and manage these systems effectively. Current automation methods include large databases like VigiBase, EudraVigilance, and FAERS, which collect ADR reports, and statistical algorithms analyze data to identify potential signals. Human experts review flagged signals for confirmation.

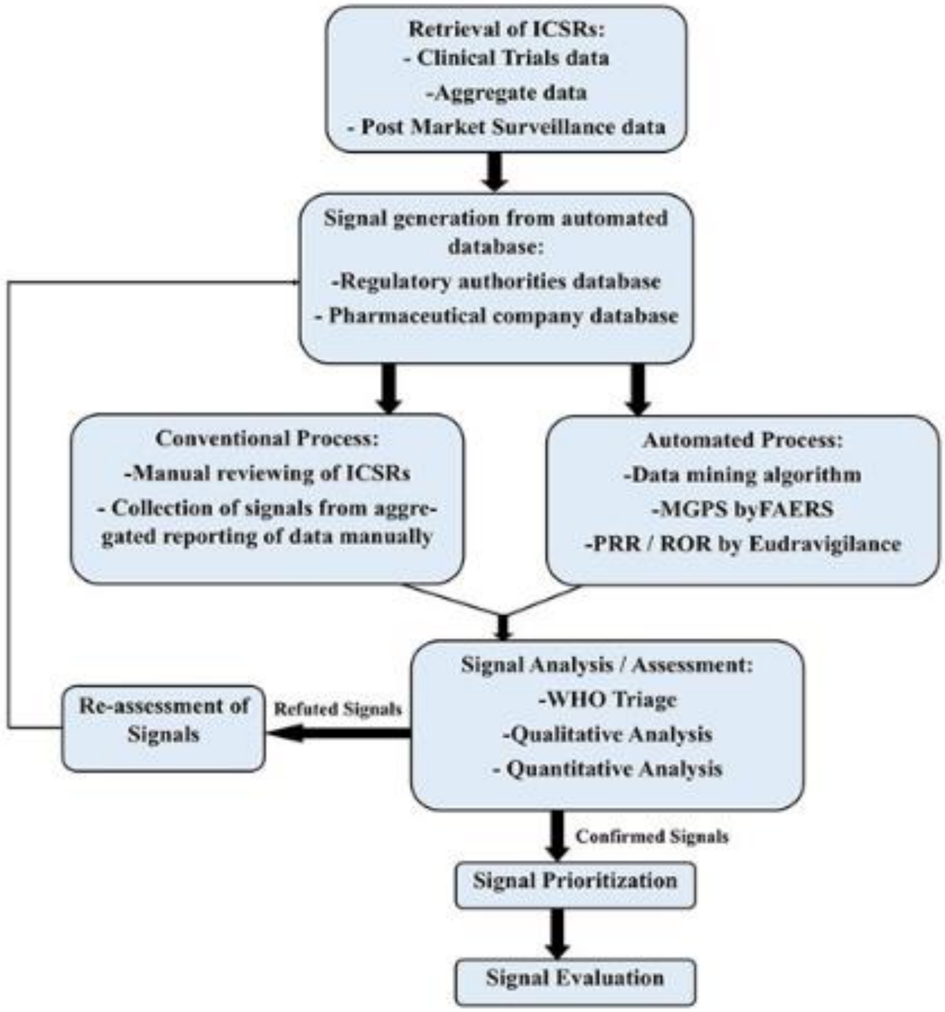


Figure 13: Overview of Pharmacovigilance process (Wadhwa et al., 2021)

The future of automation is promising, with Machine Learning and Artificial Intelligence potentially improving signal detection. Collaboration between industry and regulatory bodies is essential for developing robust automation systems. In conclusion, automation is transforming pharmacovigilance by enabling faster and more efficient detection of potential drug risks.

However, challenges remain regarding standardization, training, and the optimal balance between automation and human oversight. (Wadhwa *et al.*, 2021)

The research paper "Monitoring the Safety of Medicines and Vaccines in Times of Pandemic" by (Rocca and Grundmark, 2021) addresses two main challenges faced by pharmacovigilance during the COVID-19 pandemic: increased uncertainty due to novelty and the massive amount of data generated by large-scale vaccination programs. Traditional methods of pharmacovigilance, which rely on single-case causality assessment, are less effective in this context. Some experts advocate for a population-level approach, focusing on statistical analysis of large datasets to identify potential safety signals, while others emphasize the importance of clinical expertise and in-depth investigation of individual cases.

The optimal approach suggested by (Rocca and Grundmark, 2021) study likely involves a combination of both strategies, but resource allocation is a challenge. Large-scale vaccination programs have led to a surge in spontaneous adverse event reports, making existing pharmacovigilance systems unequipped to handle this data volume efficiently. Data quality can also be an issue, as reports may be incomplete or inaccurate. There is a need for more resources to process and analyze the data, including trained personnel and advanced technologies. The paper by (Rocca and Grundmark, 2021) argues that pharmacovigilance needs to critically reflect on its epistemological foundations, particularly the role of qualitative evidence in a world dominated by evidence-based medicine. It emphasizes the importance of serendipity and responsive networks in promoting the discovery of unexpected safety risks. Investing in clinical expertise and in-depth case analysis, alongside technological advancements, is crucial for building a resilient pharmacovigilance system. (Rocca and Grundmark, 2021)

The research paper "Digital Biomarkers for Post-Licensure Safety Monitoring of Drugs and Vaccines" by (Garcia-Gancedo and Bate, 2022) explores the potential of digital biomarkers to enhance safety monitoring of drugs and vaccines post-approval. Traditional methods, which rely on subjective reports from healthcare providers and patients, are limited in their accuracy and reliability. Digital biomarkers offer continuous, objective data on a patient's health, including heart rate, activity level, sleep patterns, and weight changes. This rich data could enable earlier detection of safety issues and provide a more comprehensive understanding of how medications affect patients.

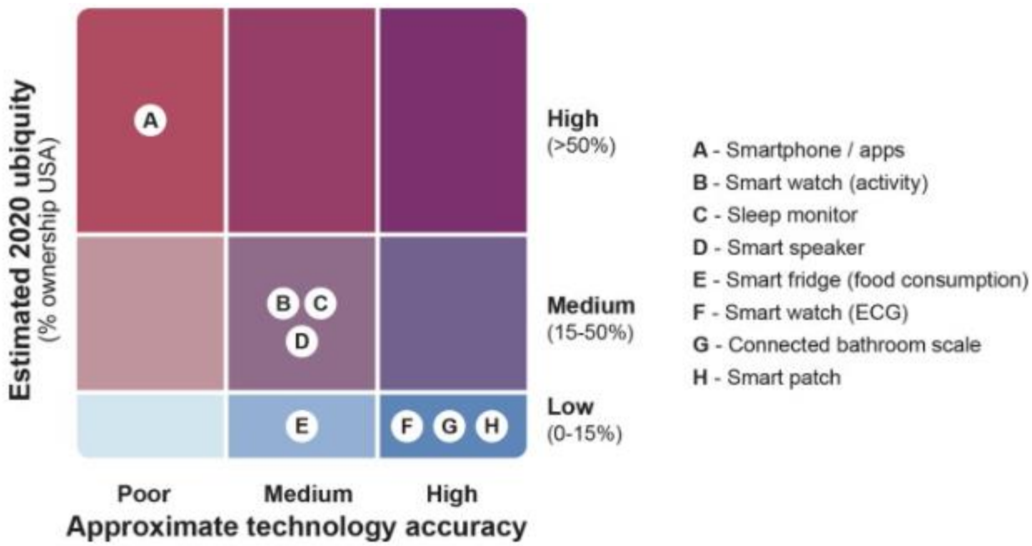


Figure 14: Examples of digital health tools (Garcia-Gancedo and Bate, 2022)

However, challenges such as data quality, standardization, and privacy concerns need to be addressed before digital biomarkers can be widely used for safety monitoring. The paper by (Garcia-Gancedo and Bate, 2022) highlights the strengths of digital biomarkers, such as providing richer, more objective, and continuous data than traditional methods. It also provides supporting case studies that demonstrate how digital biomarkers can be used for various safety monitoring purposes. (Garcia-Gancedo and Bate, 2022)

This research article by (Nazir Ahmed Kazi and Kolhar, 2021) presents a smartwatch-based system called CardioWatch (SCW) designed to monitor heart rate variability (HRV) in patients with myocardial infarction (MI) living alone. The system aims to identify abnormal HRV as a potential warning sign of cardiac arrest and other complications. The problem is the high mortality rate for MI patients living alone due to lack of timely medical attention.

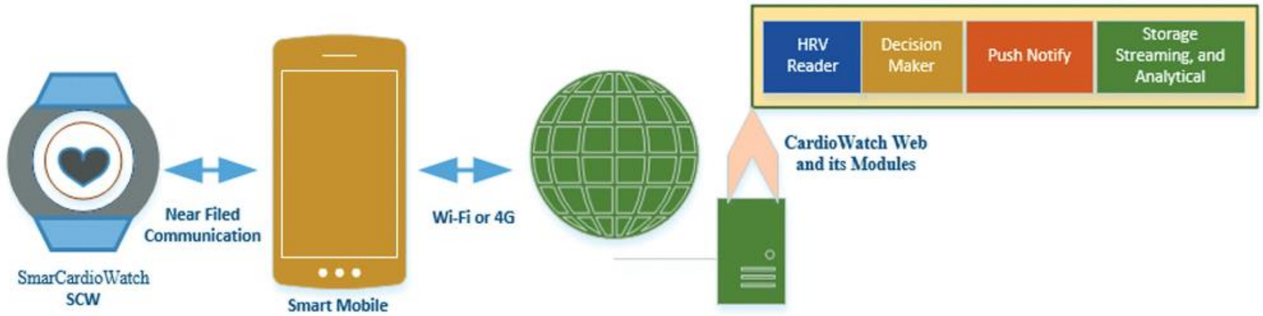


Figure 15: Architectural overview of proposed framework of CardioWatch (Nazir Ahmed Kazi and Kolhar, 2021)

The SCW system consists of an HRV reader, decision maker, container, and streamer. It was tested using machine learning (ML) and deep learning (DL) techniques on a dataset from the UC Irvine Machine Learning Repository (a collection of databases, domain theories, and data generators that are used by the machine learning community for the empirical analysis of machine learning algorithms), with DL achieving high accuracy (0.99) in MI detection. Other ML techniques were also evaluated with promising results. The SCW system has the potential to improve the quality of life and survival rate for MI patients living alone, but further development and validation are necessary before widespread adoption. (Nazir Ahmed Kazi and Kolhar, 2021)

The review conducted by (Di Giovanni *et al.*, 2022) explores the challenges of integrating digital health data into the pharmaceutical and medical device industries. The data generated by digital health tools could be crucial for understanding the safety and effectiveness of drugs and devices. However, current regulations lack clear guidance on how to use this data, making it difficult for companies to understand their responsibilities and compliance with regulations. The paper suggests that companies should develop a data management strategy that considers the purpose of collecting the data, its value, and how it aligns with their goals. It also recommends conducting a detailed assessment of their projects to identify their obligations regarding this new type of data. The paper highlights the importance of digital health data and its potential value in understanding the safety and efficacy of medical products (Di Giovanni *et al.*, 2022). However, it also highlights the regulatory gap and suggests practical approaches for data management and project assessment.

The prospective interventional clinical study by *(Kirszenblat and Edouard, 2021)* discusses the accuracy of the Withings ScanWatch wrist-worn device in measuring pulse oxygen saturation (SpO2) levels. The study involved 14 healthy participants who wore the ScanWatch on both wrists and a finger pulse oximeter. Blood samples were taken while participants inhaled gas mixtures with different oxygen concentrations. SpO2 readings from the ScanWatch were compared to blood oxygen levels measured from the blood samples (SaO2). The results showed a strong correlation between SpO2 measured by the ScanWatch and SaO2 from blood samples. There was a small bias (average difference) between ScanWatch and SaO2 readings.

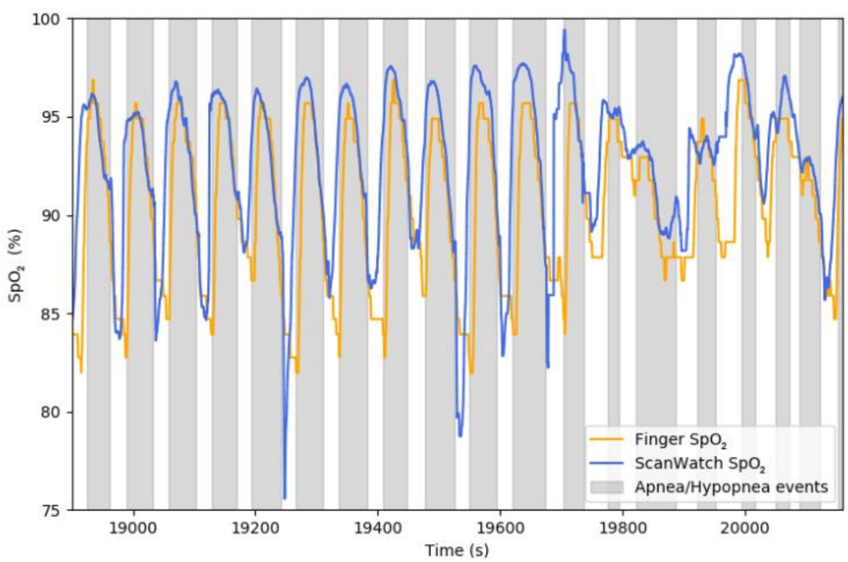
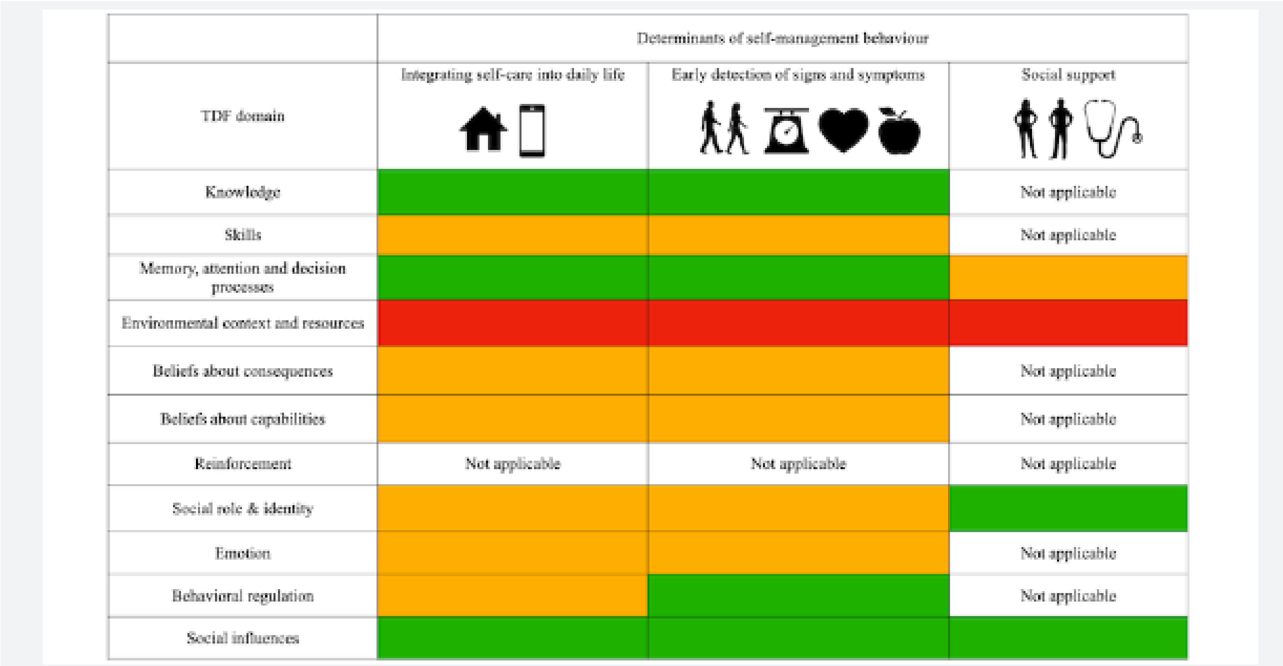


Figure 16: SpO2 measured by Scan Watch & finger pulse oximeter (Kirszenblat and Edouard, 2021)

The study suggests that Withings ScanWatch shows promise as a device for measuring SpO2 levels with adequate accuracy, suggesting it may be a reliable alternative to finger pulse oximeters for monitoring SpO2 levels. (Kirszenblat and Edouard, 2021)

The research paper by (Alen *et al.*, 2024) explores the use of smartwatches for detecting tremors in Parkinson's disease patients. Key findings suggest that smartwatches can identify tremors missed in routine assessments, particularly low-amplitude tremors. The authors suggest that integrating smartwatch data in assessments could improve tremor documentation and enable better monitoring of tremors at home over time. However, the study focuses on comparing routine tremor documentation with smartwatch data, not diagnosis. The study includes a large group of participants with Parkinson's disease and healthy controls, and validates the smartwatch system against a gold-standard seismometer. (Alen *et al.*, 2024)

This mixed method study by (Keogh *et al.*, 2024) aimed to evaluate the usability and adherence of a digital health tool (DHT) designed to support self-care behaviors in people with heart failure (HF). The study involved 19 participants who used DHT for 6 months. The key findings showed that patients wore the Fitbit device for an average of 86.2% of the days and weighed themselves for 73.7% of the days, suggesting good acceptance of the monitoring aspects of the DHT. The study did not detect significant improvements in self-care behaviors as measured by two questionnaires. However, interviews revealed that participants felt more aware of their health due to the DHT, and some adjusted their routines (e.g., walking more) based on the information provided. The System Usability Scale (SUS) score indicated that the overall usability of the DHT was not acceptable, and participants found the app information to be too basic and desired features like blood pressure monitoring.



TDF domain	Determinants of self-management behaviour		
	Integrating self-care into daily life	Early detection of signs and symptoms	Social support
Knowledge			Not applicable
Skills			Not applicable
Memory, attention and decision processes			
Environmental context and resources			
Beliefs about consequences			Not applicable
Beliefs about capabilities			Not applicable
Reinforcement	Not applicable	Not applicable	Not applicable
Social role & identity			
Emotion			Not applicable
Behavioral regulation			Not applicable
Social influences			

Figure 17: Impact of each theoretical domains framework component on self-management of heart failure (Keogh et al., *2024)*

The study by (Keogh *et al.*, 2024) found that the motivation was high among participants to use the DHT, and the Comfort Rating Scale (CRS) results indicated that the Fitbit was very comfortable to wear. Patients still relied heavily on healthcare professionals (HCPs) for managing their HF, but they felt the DHT empowered them to discuss their progress with HCPs. Notably, participants appreciated the remote monitoring aspect and the calls they received from HCPs if the system flagged any concerns (Keogh *et al.*, 2024). Overall, the study highlights the potential of DHTs to support HF self-management.

The research paper "Factors Affecting Public Willingness to Share Personal Health Data for Third-Party or Secondary Uses" by (Baines *et al.*, 2024) examines the factors affecting public willingness to share personal health data with third parties. The study involved searching six databases for relevant studies published between 2011 and 2021, including 135 studies. The results showed that privacy and security concerns were the most common barriers, with people being more hesitant to share sensitive data like mental health information. The type of data being shared also mattered, as people are more comfortable sharing with healthcare providers or researchers than with commercial companies. People are less likely to share data if they don't see a clear benefit or believe the main purpose is for profit. Enablers for sharing data included trust in the data user and the way data will be handled, transparency about how data will be used, control over what data is shared and with whom, and clear benefits from sharing data, such as improved healthcare or research discoveries. The research suggests that public support for sharing personal health data is conditional. People are more likely to share data if they trust how it will be used and if they see a clear benefit. By addressing privacy concerns and being transparent, healthcare providers and researchers can encourage greater public participation in data sharing initiatives. (Baines *et al.*, 2024)

The prospective clinical trial carried out by (Helmer *et al.*, 2022) aimed to investigate the accuracy of consumer-grade fitness trackers in measuring heart rate against a clinical gold standard, electrocardiography (ECG), in hospitalized patients after moderate to major surgery. The findings showed good overall accuracy, with all four fitness trackers exhibiting high correlation and concordance coefficients with ECG. The mean absolute error (MAE) was low across devices, and the mean absolute percentage error (MAPE) was below 5% for all trackers. Potential biases were identified, including age, arrhythmia, obesity, and wrist circumference, which affected Garmin and Apple Watch trackers. Fitness trackers had slightly higher dropout rates compared to the clinical gold standard (TPO), with dropout rates ranging from 1.2% (Garmin) to 8.3% (Fitbit). Similar factors also increased dropout rates for some trackers. The study concluded that consumer-grade fitness trackers showed promising results for continuous heart rate monitoring in hospitalized patients, but observed deviations were generally small and not clinically significant. The study excluded critically ill patients and those who required immediate intensive care. The fitness trackers used consumer-grade firmware, reflecting real-world user experience (Helmer *et al.*, 2022). The study offers valuable insights into the accuracy of consumer-grade fitness trackers for measuring heart rate in a controlled setting, but limitations like sample size and focus on resting heart rate highlight the need for further studies in more diverse populations and under various activity levels.

2.3 SUMMARY –

This literature review explores the potential applications of wearable devices in healthcare, focusing on patient engagement and pharmacovigilance. Wearables can improve healthcare outcomes, reduce costs, and increase patient participation by providing health monitoring, chronic disease management, and early detection of conditions. Benefits include promoting preventive healthcare, increasing patient engagement, lowering medical costs, and reducing workload for healthcare providers. Challenges include data security, user privacy, accuracy, battery life, and user compliance.

Patient engagement is enhanced by wearables tracking health metrics and providing insights into daily behaviors, improving patient engagement in preventive healthcare and chronic disease management. Pharmacovigilance can be revolutionized by wearables providing real-time patient data, which can be used to identify potential side effects, improve medication adherence, and personalize treatment plans. Wearables can be integrated with electronic health records (EHRs) for data collection and analysis.

Challenges include data privacy and security concerns, and regulatory frameworks need to be developed to ensure data validity and reliability. Further research is needed to explore the full potential of wearables in pharmacovigilance and identify effective integration methods.

2.4 CONCLUSION –

This research will explore the potential of wearable technology, including fitness trackers, smartwatches, and medical sensors, to improve healthcare delivery. These devices offer applications in chronic disease management, preventive healthcare, and patient engagement. They promise improved health outcomes, lower healthcare costs, and increased patient involvement. However, further research is needed to fully understand the effectiveness of wearables, including data on long-term health outcomes, specific populations, user engagement, privacy, security, and cost-effectiveness.

Future advancements include better battery life, more accurate sensors, and integration with AI. Additionally, wearables have the potential for mental health monitoring and interventions due to their ability to collect continuous, real-time data. Post-market surveillance of medical devices can also be achieved through wearable technology.

Despite the potential, challenges such as data security, user privacy, and integration with existing healthcare systems remain. Regulatory frameworks need to be established to ensure data validity and reliability. Further research is needed to unlock the full potential of wearables in pharmacovigilance and identify effective methods for integrating them into the healthcare landscape.

2.5 CONCEPTUAL FRAMEWORK –

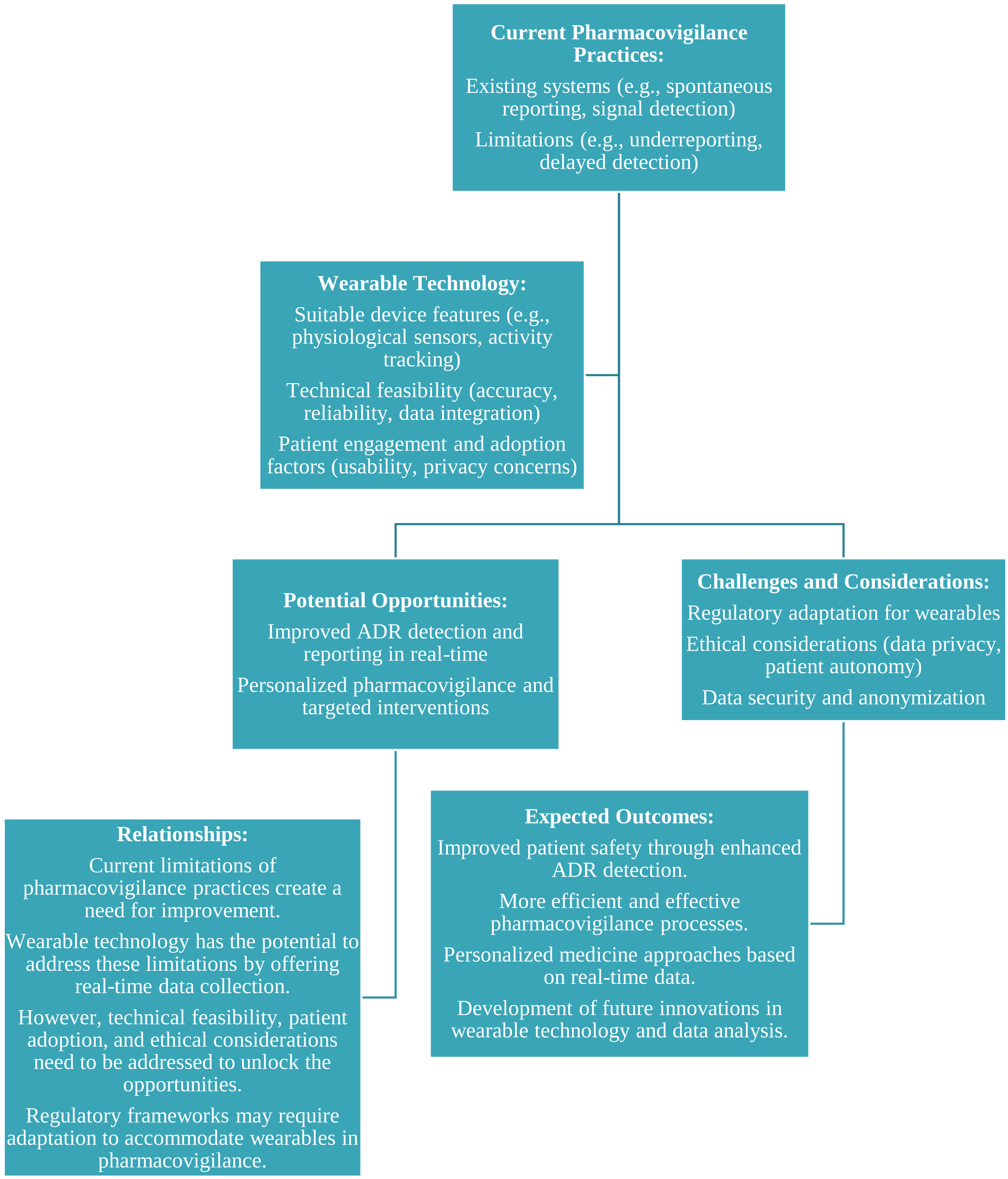


Figure 18: Conceptual Framework

The conceptual framework outlines the potential of wearable technology to revolutionize pharmacovigilance by enabling real-time monitoring and early detection of adverse drug reactions (ADRs). However, it acknowledges challenges such as underreporting, delayed detection, data privacy, and regulatory frameworks.

The framework proposes that wearable technology with physiological sensors and activity tracking can enhance pharmacovigilance by facilitating real-time monitoring and early ADR detection. However, ethical considerations, data privacy, and patient autonomy need to be addressed for successful implementation.

Future research directions include developing standardized data formats for wearable-collected health data, evaluating the accuracy and reliability of different wearable devices for ADR detection, exploring artificial intelligence and machine learning for real-time data analysis and ADR prediction, investigating strategies to improve patient engagement and adoption of wearables for health monitoring and ADR reporting, and advocating for flexible regulatory frameworks.

CHAPTER 3 : RESEARCH METHODOLOGY

3.1 OVERVIEW –

Philosophy	Utilitarianism
Approach	Mixed Methods (Quantitative & Qualitative)
Strategy	Survey
Data Collection Methods	Questionnaire distributed online
Structure	7 sections with 33 questions
Time Horizon	Cross-sectional
Participants	People currently living in Ireland

This research aims to explore the potential and challenges of wearable technology in pharmacovigilance through utilitarian approach. The methodology involves using mixed methods, including quantitative surveys and qualitative responses, with a short-term focus on existing practices and future directions.

Data collection methods include surveys and questionnaires to assess patient engagement with wearables.

Secondary data sources include existing literature on pharmacovigilance, wearable devices, and related regulations, as well as reports and data from regulatory agencies like EMA and HPRA.

Participants in the study include people who use wearable devices and healthcare professionals involved in pharmacovigilance programs. Data analysis will involve statistical analysis of surveys to identify potential ADR patterns.

Data sources include surveys and questionnaires administered to public and healthcare professionals and secondary data from existing literature on pharmacovigilance, wearable devices, and related regulations. Data analysis will use statistical tools to identify trends and correlations between variables.

3.2 RESEARCH PHILOSOPHY –

The research is guided by two main philosophical approaches: pragmatics and evidence-based medicine. The research focuses on Pragmatism which emphasizes the practical application of wearable technology to enhance patient safety and drug development using wearable devices. It aligns with evidence-based medicine, which uses the best available data for clinical practice and prioritizes real-time data and evidence-based approaches to strengthen findings' validity. The research also acknowledges the importance of ethical considerations, balancing technological benefits with informed consent and autonomy. This combination of philosophies makes the research actionable and impactful, ensuring the findings are grounded in robust evidence and based on practical solutions.

The survey provided both quantitative and qualitative data, which were analyzed and used to draw conclusions for the research. The questionnaires have different questions that provide qualitative information reflecting the topic's processes and effectiveness. The study ensured no bias or interference of personal interest, using only the collected data. The online questionnaire reduced interaction with participants, reducing the risk of any influence on the data's outcome.

3.3 RESEARCH APPROACH –

The research used a mixed methods approach to meet the objectives of the study. Online surveys were distributed electronically across Ireland, allowing respondents to fill out questionnaires. The aim was to understand consumers' perceptions of wearable devices and pharmacovigilance practices. The inductive approach was used, and both qualitative and quantitative data were collected. The primary research data was analyzed and compared with literature to provide recommendations for future use of wearable devices by pharmacovigilance professionals. The findings were used to conclude the research.

3.4 RESEARCH STRATEGY –

The research aimed to identify the level of implementation of wearable technologies in the pharmacovigilance system in Ireland and assess the readiness and willingness of consumers to use this technology.

The literature review reveals a lack of research on consumer perceptions and challenges affecting the implementation of wearable technology in Ireland, indicating that no studies have been conducted on how Irish society views this technology or obstacles preventing its adoption.
To gather data, the researcher used questionnaires, which were designed to be easy to understand and follow. The questionnaire had seven sections with 33 structured questions aimed at determining general perceptions of the willingness of consumers or patients to use wearable devices for monitoring adverse drug reactions (ADR) through the pharmacovigilance system. The questionnaires were electronically dispatched through MS Forms and sent to different people without any input from the author to eliminate bias. The first section of the questionnaire included a letter to the respondent obtaining informed consent and ensuring data storage in line with the General Data Protection Regulation (GDPR). Participants were required to agree to participate in the survey.

3.5 SAMPLE SIZE CALCULATION –

The margin of error in a survey is a crucial factor to consider. A margin of error of 5% - 8% is a common choice, while a confidence level of 90%, 95%, or 99% is also common. A higher confidence level requires a larger sample size. The response distribution is 50% for each question, with 50% being the largest sample size.
The formula used to calculate the sample size is as follows -

$$n = (Z^2 * p(1-p)) / (MoE)^2$$

Each part of the formula represents:

- **n:** This is the sample size - the minimum number of participants needed in the survey.
- **Z:** This represents the z-score corresponding to the desired confidence level. Since confidence level = 95%, Z = 1.96 (commonly used value).
- **p:** This is the estimated proportion. A common approach is to use p = 0.5, which represents the greatest uncertainty (50% one way, 50% the other).
- **MoE:** This stands for Margin of Error, expressed as a decimal. In this case, the margin of error is 8%, so MoE = 0.08.

Framing the equation with the values

n = (1.96 ^ 2 * 0.5 * (1 - 0.5)) / (0.08)^2

n = (3.8416 * 0.25) / 0.0064

n ≈ 149

The recommended sample size is 149 for this study, as a larger sample with a large response rate is more likely to get a correct answer than a large sample with only a small percentage of respondents responding. The sample size doesn't significantly change for populations larger than 20,000. The response distribution is 50% for each question, and hence the recommended sample size is 149. (Raosoft, 2024)

3.6 DATA COLLECTION METHOD –

A survey was carried out to gather opinions from the study participants. Each question on the survey questionnaire sought feedback from the study population regarding wearable technology use under the study's various objectives.

Structure of the Questionnaire -

The questionnaire was divided into seven sections, containing a total of 33 questions.

Section 1 - Two questions in this section were intended to confirm that the participants had given their consent to participate in the study and that they had fully understood its objectives and purpose, which made sure that the participant was allowed to take part in the study.

Section 2 - This section had four questions and was designed to categorize the participants according to their gender, age, field of work, and experience in pharmacovigilance.

Section 3 - Eight questions covering the introduction to wearable devices comprised the third section, which also established the participant's relationship with technology. The purpose of the questions was to ascertain how often and what factors influence the adoption of these wearable devices. The questionnaire assessed patient interest and experience with wearable devices for health monitoring and reporting adverse events, focusing on general technology use, device preference, usage duration, perceptions, and motivations.

Section 4 - The objective of the fourth section, "current pharmacovigilance practices," was to ascertain the participants' familiarity with pharmacovigilance practices, focusing on identifying uncommon, chronic, and overall adverse drug reactions (ADRs). Four questions make up this section, asking participants to express their familiarity with the types of adverse drug reactions (ADRs) and side effects of the medications they take. The participants were asked about the challenges of identifying these types of side effects. Current methods may make it difficult to identify uncommon, chronic, mild, and mimic symptoms of aging or other illnesses. The questionnaire suggests that technological advancements could improve pharmacovigilance by making it easier to detect these types of side effects.

Section 5 - This section assessed awareness of regulations, ethics, and concerns surrounding wearable devices in healthcare, specifically for pharmacovigilance. It addressed concerns about wearable health data accuracy, potential breaches, and inclusivity. It emphasized the importance of informed patient consent, strong security measures, and transparency in data usage. The section also focused on opinions on ethical data collection and patient privacy in health research and monitoring with wearables. It had five questions, of which three were closed-ended and two were open-ended.

Section 6 - This section assesses the use of wearable devices in detecting Adverse Drug Reactions (ADRs). It had five questions, two of which were about rating the usefulness of different wearable categories, focusing on specific data points like heart rate or sleep patterns, and three open-ended questions encouraging suggestions for additional devices or data points. The aim is to gather information on the potential of wearables to monitor the side effects of medications.

Section 7 – The final section explored patient engagement with wearables for health monitoring and reporting side effects. It focused on strategies like comfort, user-friendliness, affordability, education, and incentives. It also addressed potential barriers like privacy, technical knowledge, cost, and data accuracy. It had five questions, two closed-ended and three open-ended, which focused on suggestions for making patients feel more comfortable and confident using wearables for their health.

The literature review provided justification for the study purpose and objectives, and almost all the questions in the survey were framed in such a way that they fulfilled the study objectives.

3.7 TIME HORIZON –

Data was gathered through surveys at predetermined intervals because the study was completed in a short amount of time. A particular concept or interest that was popular among a cohort at a given moment was being evaluated and understood by the researcher. It was therefore determined that the study was cross-sectional.

3.8 SOURCES & SELECTION OF PARTICIPANTS –

The author created a questionnaire for a study in Ireland, which was distributed via the internet using MS Forms. Participants were obtained through LinkedIn and the author's contacts, and the form was shared with their contacts in Ireland. The total number of participants was 63, ranging in age and occupation.

The author reached out to participants mainly through social media platforms. The study's aim and purpose were explained to participants. The author also consulted friends and former colleagues in Ireland. The quantitative study used convenient and snowball sampling methods, with participants filling out the survey electronically, ensuring no bias or influence on responses.

3.9 INCLUSION & EXCLUSION CRITERIA –

The questionnaire was only available to people living in Ireland who have used or are considering using wearable technology. In addition, anyone working in the field of pharmacovigilance was included. There were no other inclusion or exclusion criteria established. In addition, following their reading of the questionnaire's introduction, participants were asked if they understood and wished to continue participating; if they selected no for the response, they were immediately removed from the survey.

3.10 ETHICAL CONSIDERATIONS –

The goal and purpose of this study were explained to every participant. It was explained to the participants that they had the right to both participate in and withdraw from the study. Extreme caution was taken when crafting the survey questions to ensure that participants would not be required to divulge any personal or organizational information. The questions were perfectly within the parameters of the research goals. It was explained to the participants that they were free to leave the study at any time without facing any consequences and that their involvement in it was entirely voluntary.

3.11 CONCLUSION –

A combination of data collection methods was employed for this study. Open-ended and closed-ended questionnaires were used to collect data using a combination of quantitative and qualitative methods from Irish consumers. These techniques are consistent with the pragmatism research philosophy as a whole. Overall, the insights, perceptions, and opinions that were obtained from the data analysis and correlation with the researcher's literature review from the secondary research helped address the research questions. In the chapters that follow, the main conclusions and analyses are covered in detail.

CHAPTER 4 : FINDINGS AND ANALYSIS

An online survey was conducted to explore the potential of wearable devices in pharmacovigilance, focusing on their ability to detect and report adverse drug reactions (ADRs) in real-time. In this survey, 101 people responded based on inclusion criteria. The data analysis followed a two-step approach: Section 1 focused on descriptive statistics to understand the data's distribution and characteristics, while Section 2 employed inferential statistics to draw conclusions about the population from which the data was drawn.

In the descriptive part, author will describe the responding population with respect to baseline characteristics namely their understanding of research purpose, consent for the participation, age, sex, profession, and experience in pharmacovigilance. In the inferential part, i.e., during the analysis stage, various sections will be assessed for the knowledge of wearable devices, pharmacovigilance, and patient adoption. These sections will then culminate in an evaluation based on the established objectives.

Following are the result obtained from the study survey:

4.1 INTRODUCTION QUESTIONS

The questionnaire included two introductory questions, outlining the study's objectives, and allowing participants to contact the author with any questions or concerns. Participation was voluntary, and participants could withdraw at any time. Question 1 was a required question to confirm understanding of the study's purpose. All 101 respondents completed the survey, indicating they had read and understood its purpose by selecting "yes." Participation was voluntary and open to all participants.

I have read and understood the above information	Frequency	Percent (%)
Yes	101	100.000

Table 2: Frequencies for I have read and understood the above information

The second question in the introduction aimed to confirm consent for participants in the research, which was required. The survey was distributed to people living in Ireland. Participants who did not want to continue with the survey left.

I agree to participate in this research	Frequency	Percent (%)
Yes	101	100.000

Table 3: Frequencies for I agree to participate in this research

4.2 DEMOGRAPHICS DETAILS OF THE STUDY POPULATION (QUESTION 3 TO 6)

A total of 101 people answered the questionnaire in total, and the information gathered from these answers was examined. There were 47 male participants and 53 female participants, and one participant chose not to reveal gender. The majority of participants were young adults, ranging in age from 18 to 30, and the majority of responses came from the pharmaceutical industry, students and other sources mainly finance, 45 people had some experience in pharmacovigilance (0-2 years).

Variable	**Category**	**Frequency**	**Percent (%)**
Gender	Male	47	46.53
	Female	53	52.47
	Prefer not to say	1	0.99
Age (in years)	18-30	83	82.17
	31-40	9	8.91
	41-50	2	1.98
	51-60	5	4.95
	61 and over	2	1.98
Profession / Field of Work	Healthcare	14	13.86
	Pharmaceuticals	20	19.80
	IT	14	13.86
	Sports & Fitness	0	0
	Government Bodies	2	1.98
	Students	30	29.70
	Other	21	20.79
Experience in Pharmacovigilance (in years)	0-2	45	44.55
	3-5	1	0.99
	6-10	3	2.97
	11-15	0	0
	16+	2	1.98
	NA	50	49.50

Table 4: Summary of participants demographics (Question 3 to 6)

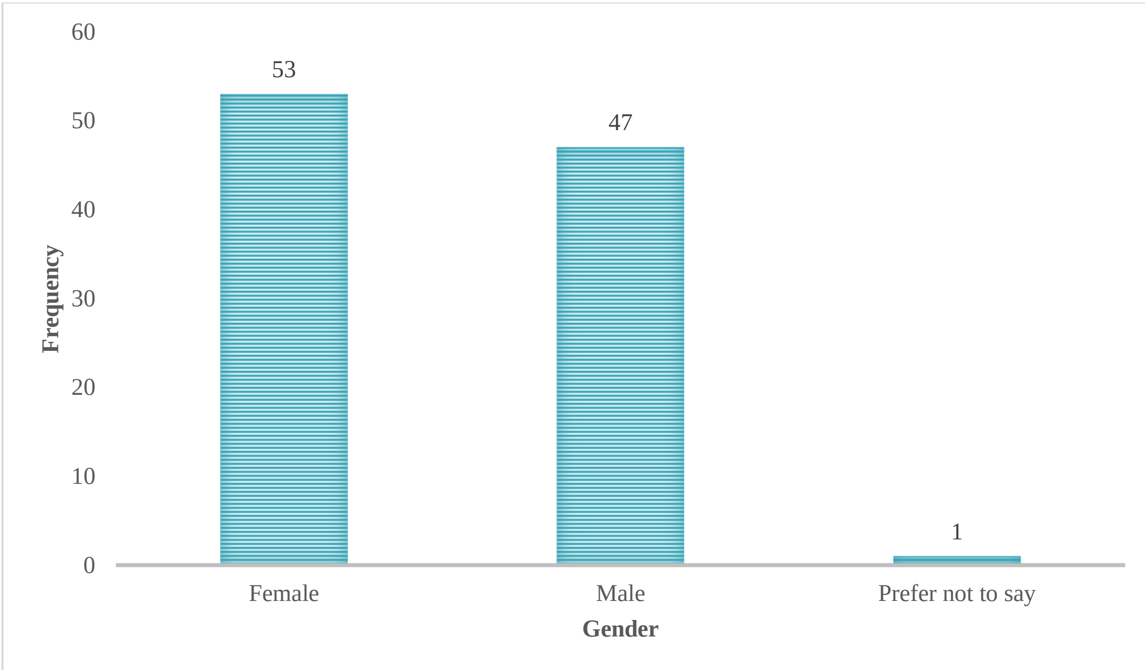


Figure 19: Distribution of Gender

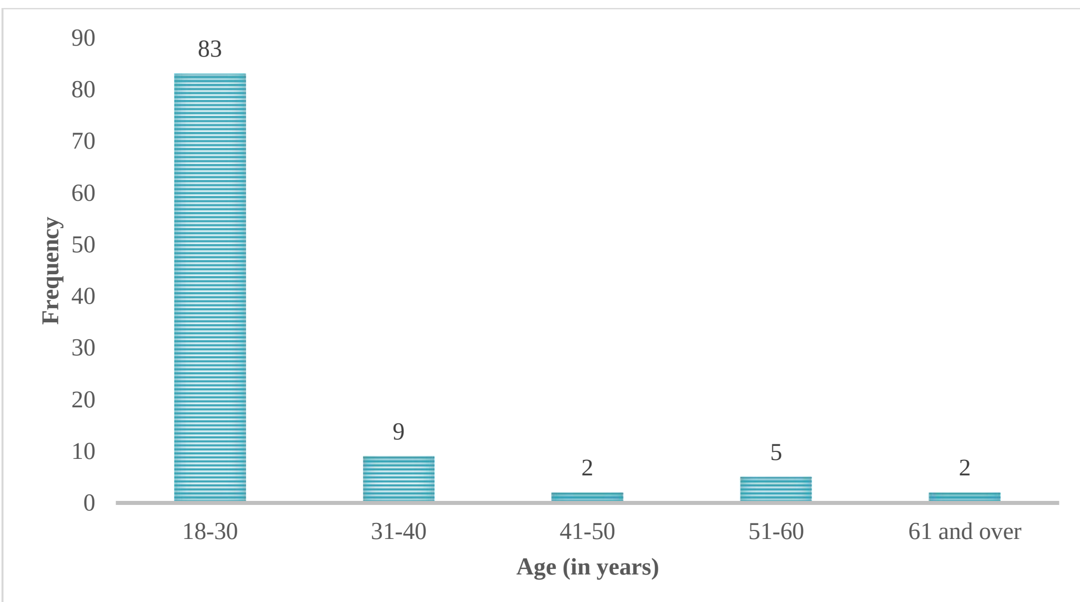


Figure 20: Distribution of Age (in years)

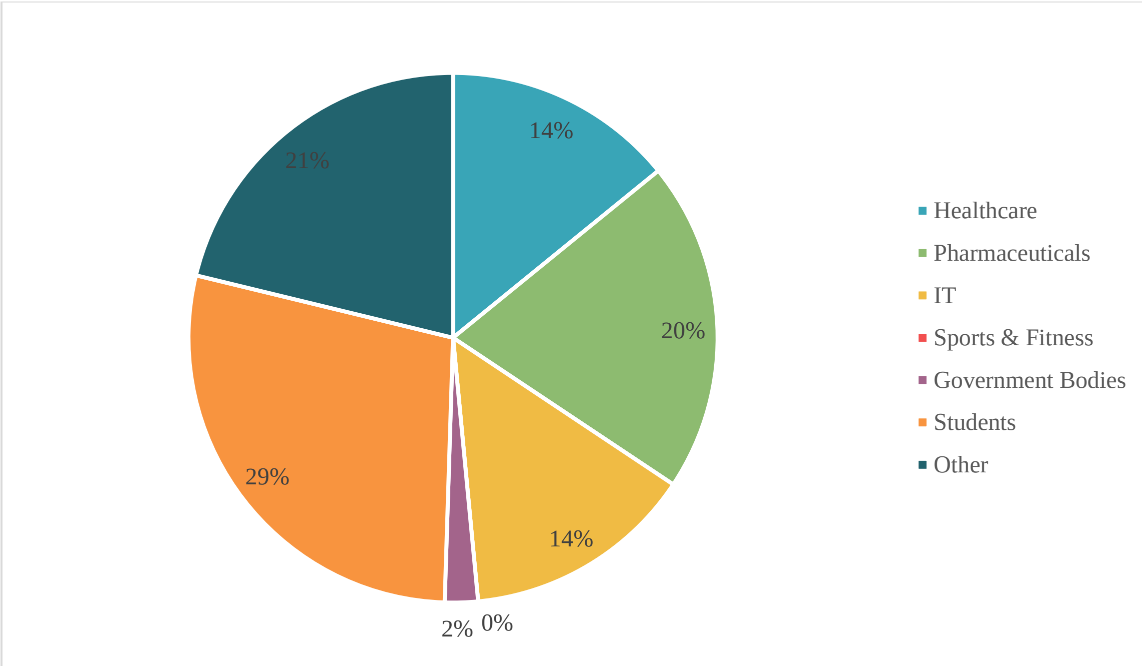


Figure 21: Distribution of Profession / Field of Work

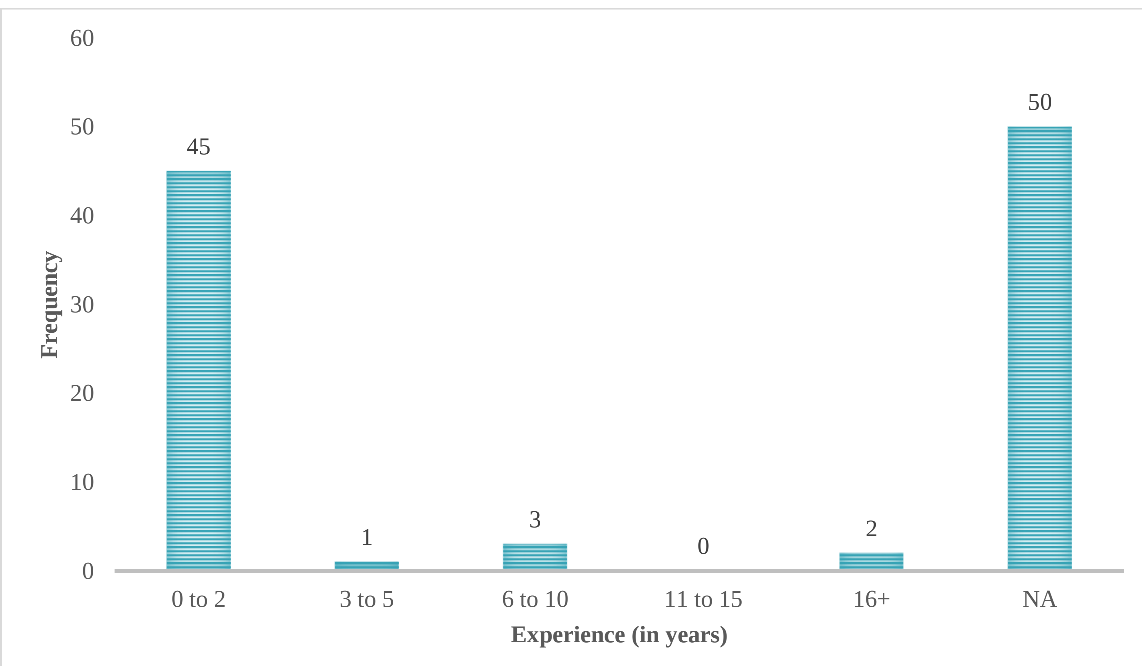


Figure 22: Distribution of Experience in Pharmacovigilance (in years)

4.3 INTRODUCTION TO WEARABLE DEVICES (QUESTION 7 TO 14)

The purpose of this questionnaire section was to ascertain the prevalence of smartphone and wearable technology use in Ireland in order to understand the technological sophistication of the country's population.

Question 7, 8 and 9

The purpose of these questions was to find out how eager participants are to try new technology and what their experiences have been using wearables and mobile phones. 99 participants, or 98.01%, reported using their phones on a daily basis. The majority of participants (100) stated that they enjoy learning about new technologies. Additionally, 59 participants still use the wearables that 58.41% of the respondents reported having used, and 13 individuals owned the device but had given it up. Out of the participants, 16 individuals (15.84%) have not used wearables but express interest in doing so, while 12.87% have not used them at all.

Variable	**Category**	**Frequency**	**Percent (%)**
Using phone is an integral part of my daily routine	Yes	99	98.01
	No	2	1.98
I enjoy learning about new technology	Yes	100	99
	No	1	0.99
Have you ever used a wearable device?	Yes, I am still using it now	59	58.41
	Yes, but I abandoned it	13	12.87
	No	13	12.87
	No, but I am interested	16	15.84
	No, and never wanted to use one	0	0

Table 5: Experience with mobile phones, technology and wearables (Question 7 to 9)

Given that the majority of people in Ireland either use or are prepared to use mobile phones and wearable technology, the analysis above demonstrates that these phenomena are not new to Irish society. It is encouraging for the acceptance of wearable devices in the field of pharmacovigilance to monitor and report ADRs that they are also interested in acquiring new technologies.

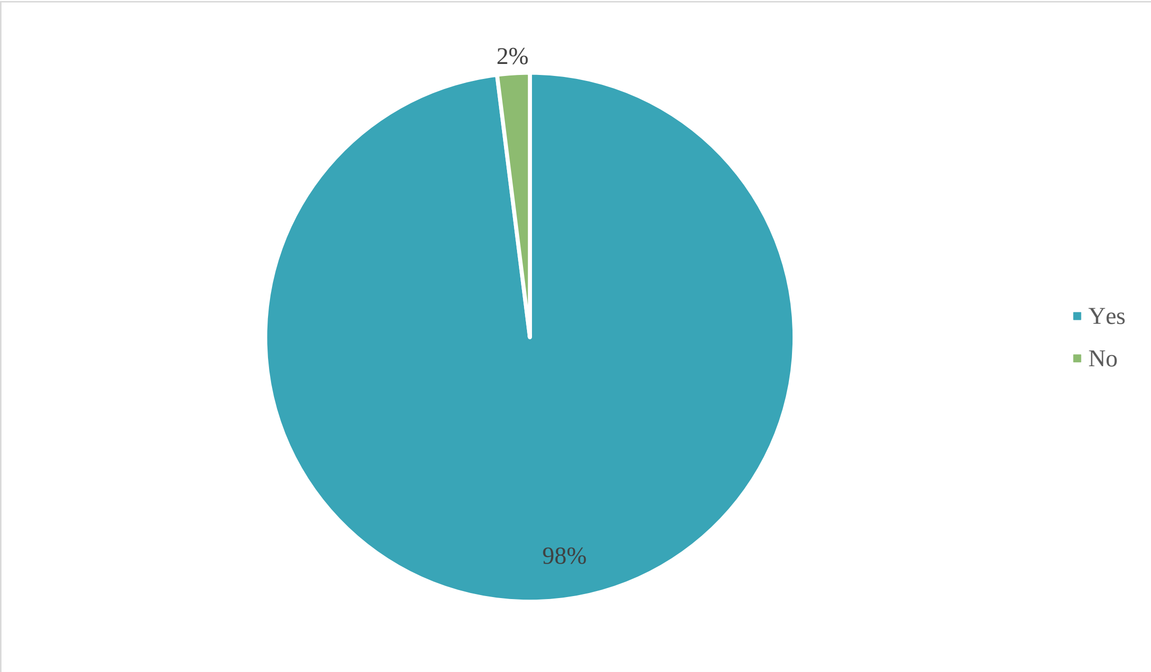


Figure 23:Distribution of Using phone is an integral part of my daily routine

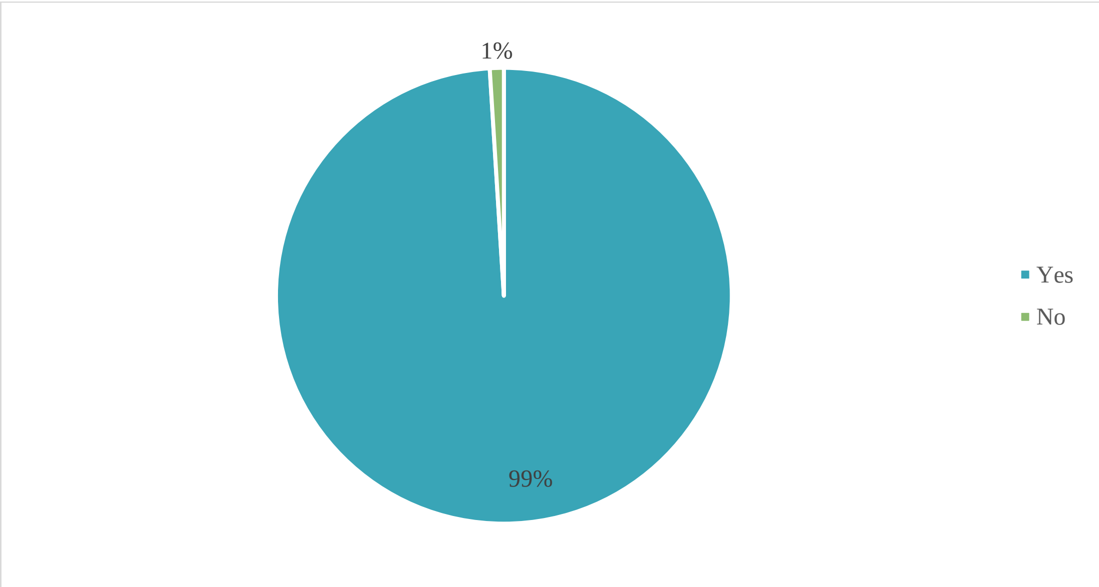


Figure 24: Distribution of I enjoy learning about new technology

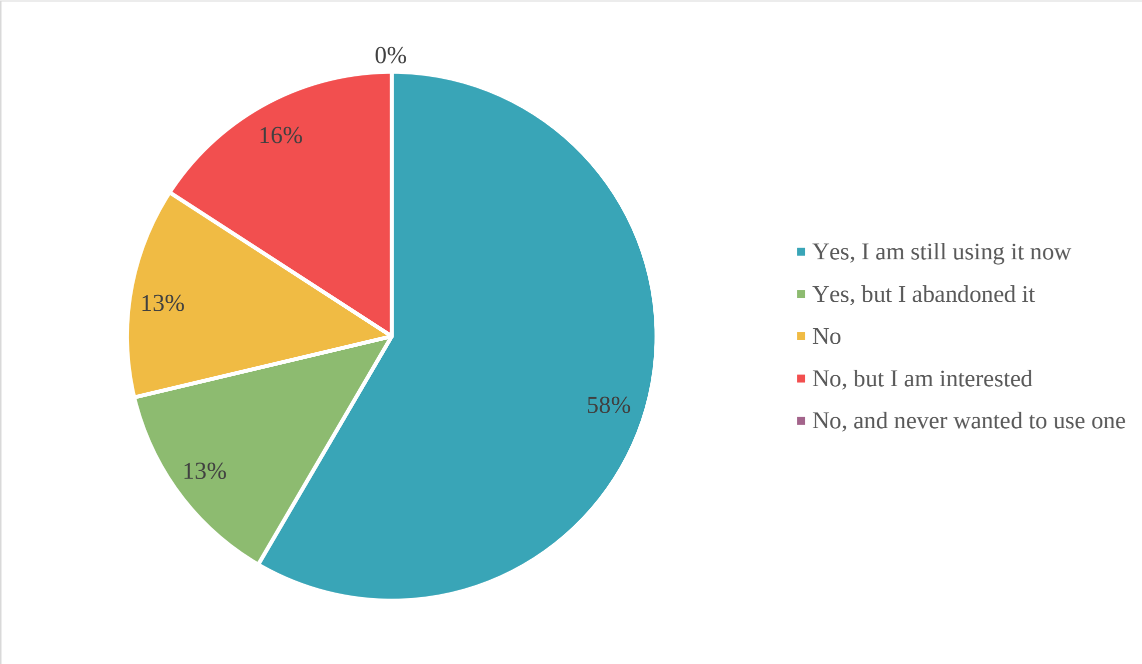


Figure 25: Distribution of Have you ever used a wearable device?

Question 10

This is a follow-up question designed to help identify the most popular and widely accepted wearable technology among Irish people. In Ireland, smartwatches (77.22%), activity trackers (29.70%) are the top 2 most desired and utilized wearable devices. Some respondents even suggested use of mobile phones.

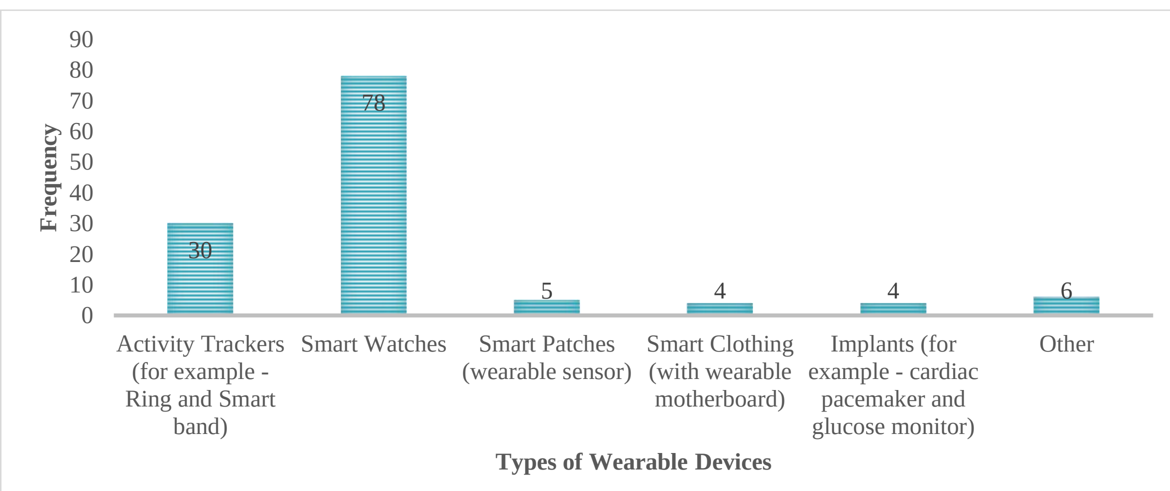


Figure 26: Wearable devices popularity in Ireland

Question 11 & 12

The information obtained from these questions is useful in determining the wearable device owner's frequency of use as well as when they first began using it.

Of the participants, 26 have owned a wearable device for more than two years, 23 have owned it for 1-2 years, 9 respondents have owned it for 7-12 months, and 6 have owned it for 1-6 months. 7 individuals have owned the device for less than a week, and those who have never owned the device were not covered by the question.

Variable	**Category**	**Frequency**	**Percent (%)**
How long have you been using your wearable device?	1-2 years	23	22.77
	1-6 months	6	5.94
	7-12 months	9	8.91
	Less than 1 week	7	6.93
	Not applicable	30	29.70
	Over 2 years	26	25.74
How often do you use your wearable device?	Always	21	20.79
	Never	11	10.89
	Not applicable	17	16.83
	Often	25	24.75
	Rarely	16	15.84
	Sometimes	11	10.89

Table 6: Frequencies for Usage of Wearable devices

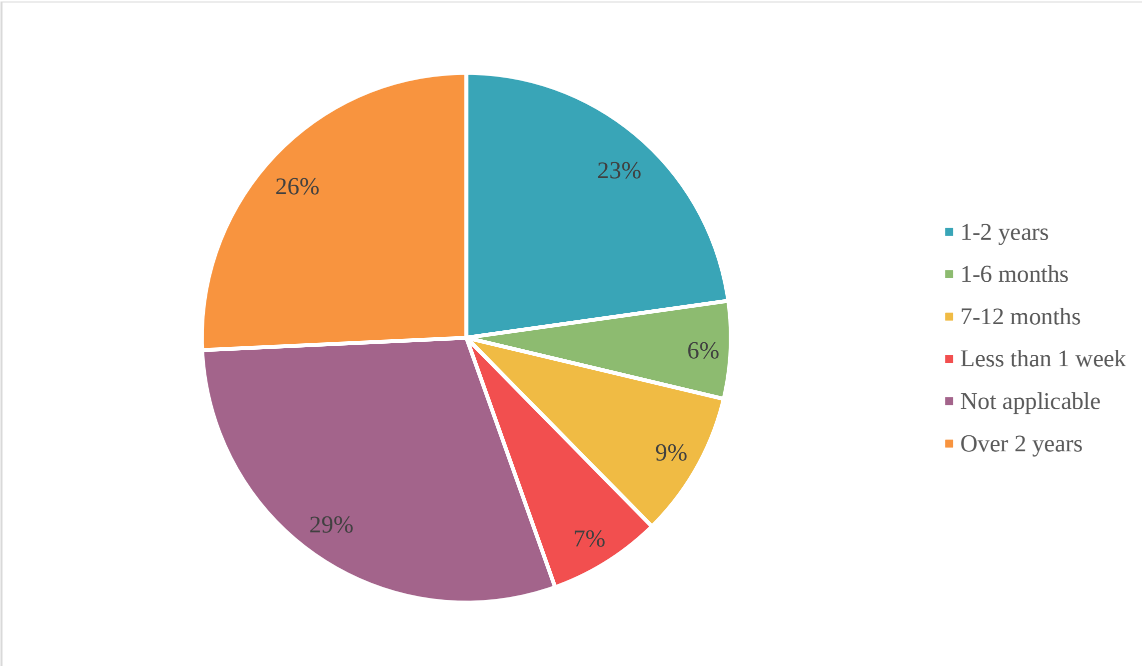


Figure 27: Length of using wearable device

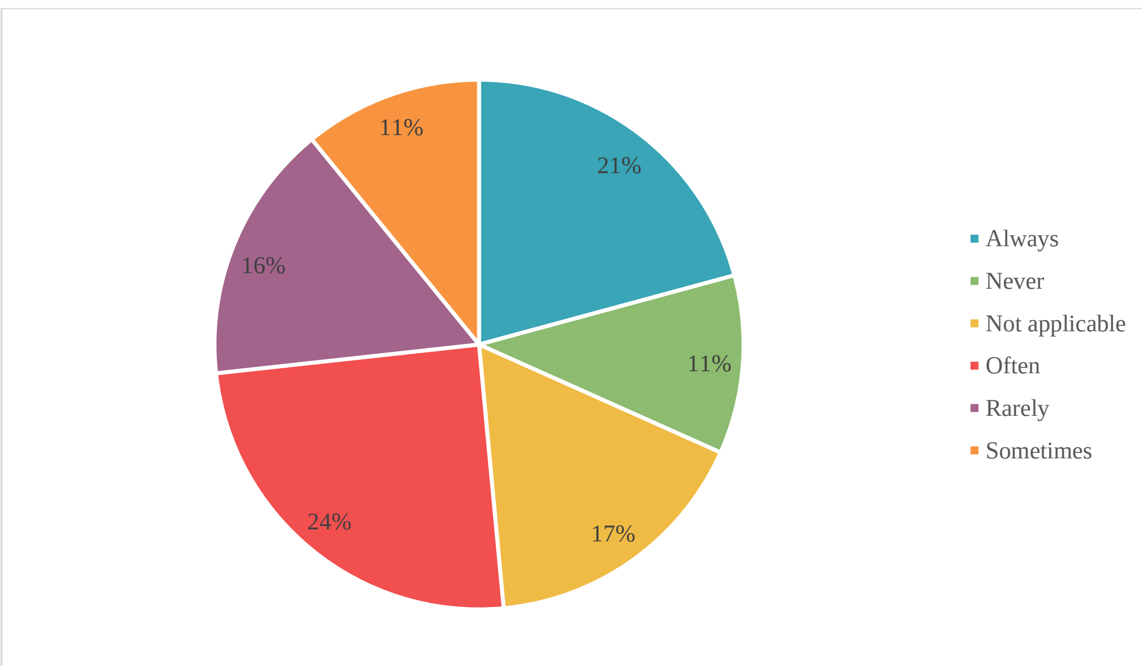


Figure 28: Frequency of use of wearable device

According to the data, a significant number of wearable device owners use them regularly, regardless of how long they have owned the device.

Question 13 & 14

The question 13 aids in figuring out how Irish society feels about wearable technology.
54 respondents think wearable technology is very helpful in promoting physical health, and many respondents (58) thought wearable technology was very simple to use.

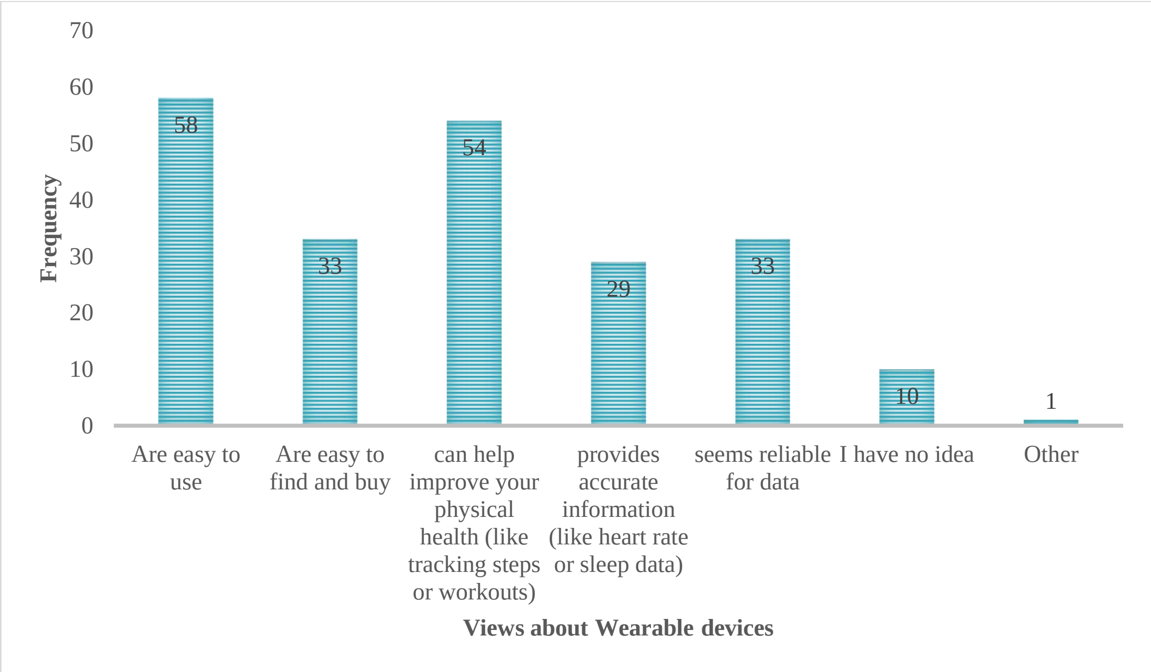


Figure 29: Views about Wearable devices

The information gathered from question 14 is used to ascertain what factors participants consider when making wearable device purchases. The majority of respondents (52.47%) claimed that social media and the internet had the most influence. The next most frequent factors were word-of-mouth and advertisements, with 26.73% and 22.77% of the total, respectively.

Additional factors include:

- Research purposes

- Fitness and Health

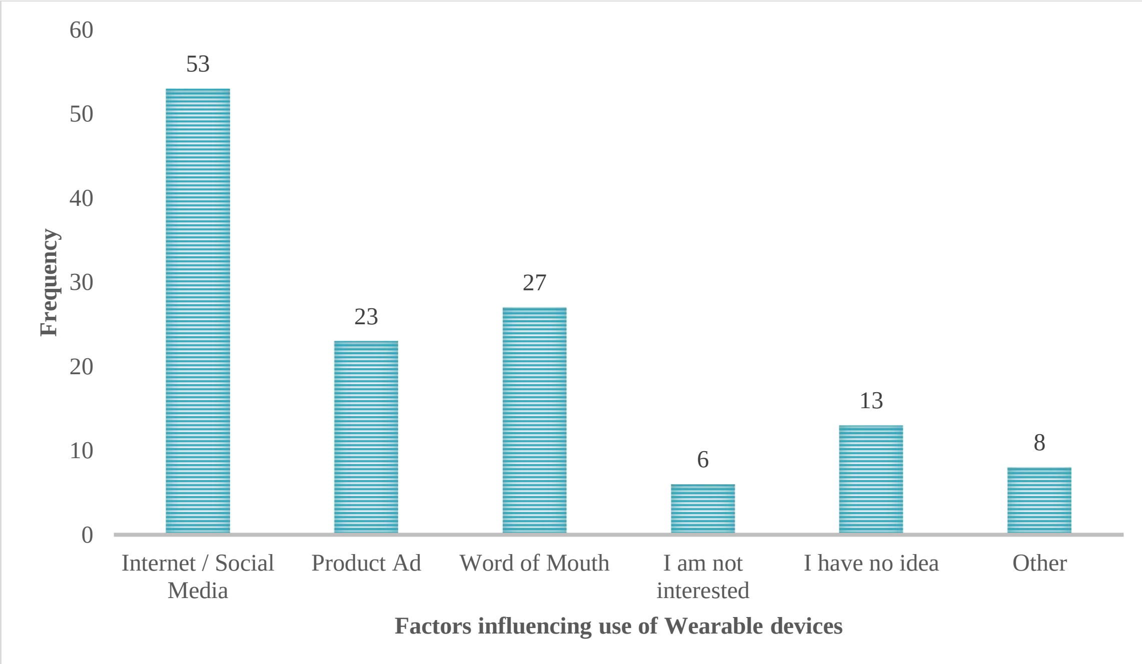


Figure 30: Factors influencing use of Wearable devices

4.4 CURRENT PHARMACOVIGILNACE PRACTICES (QUESTION 15-18)

This section helps examine the knowledge of pharmacovigilance practices in Ireland which is useful for the determination of consumer views on the ability and acceptability of wearables to monitor and report ADRs.

Pharmacovigilance is the science of monitoring, detecting, assessing, understanding, and preventing adverse reactions from medications. It involves tracking real-world effects, analyzing reactions, understanding the cause, and preventing them through warnings, prescribing guidelines, or removal from the market.

Question 15, 16 and 17

The questions explore the difficulty in identifying side effects of medications. They focus on uncommon side effects, chronic side effects, and adverse drug reactions (ADR). Uncommon side effects are those not experienced by most people, chronic side effects are those causing long-term health problems, and ADR is the difficulty in identifying any negative reaction to a medication.

Variable	Category	Frequency	Percent (%)
How easy is it to find uncommon side effects of medications?	Very Easy	5	4.95
	Easy	19	18.81
	Neutral	40	39.60
	Difficult	26	25.74
	Very Difficult	11	10.89
How difficult is it to identify chronic side effects from a medicine?	Very Easy	5	4.95
	Easy	22	21.78
	Neutral	34	33.66
	Difficult	31	30.69
	Very Difficult	9	8.91
How difficult is it to identify ADR from a medicine?	Not at all difficult	6	5.94
	Difficult	16	15.84
	Neutral	51	50.49
	Somewhat difficult	18	17.82
	Very difficult	10	9.9

Table 7: Identification of side effects

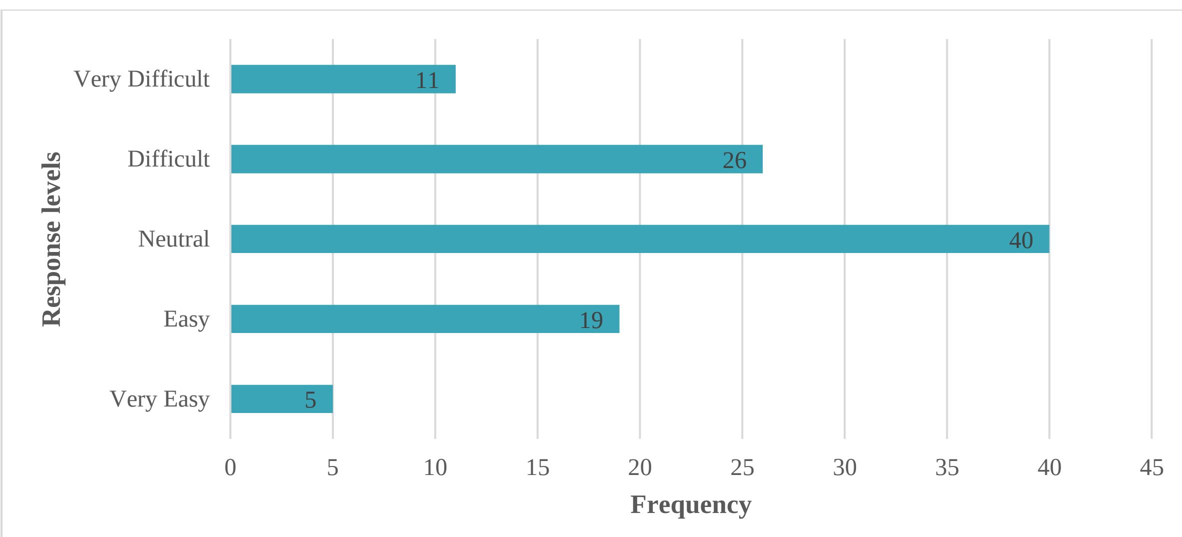


Figure 31: Response for uncommon side effects of medications

Neutral and difficult appear to be common in this response. Uncommon side effects are less frequent and often unreported, making it challenging to identify them.

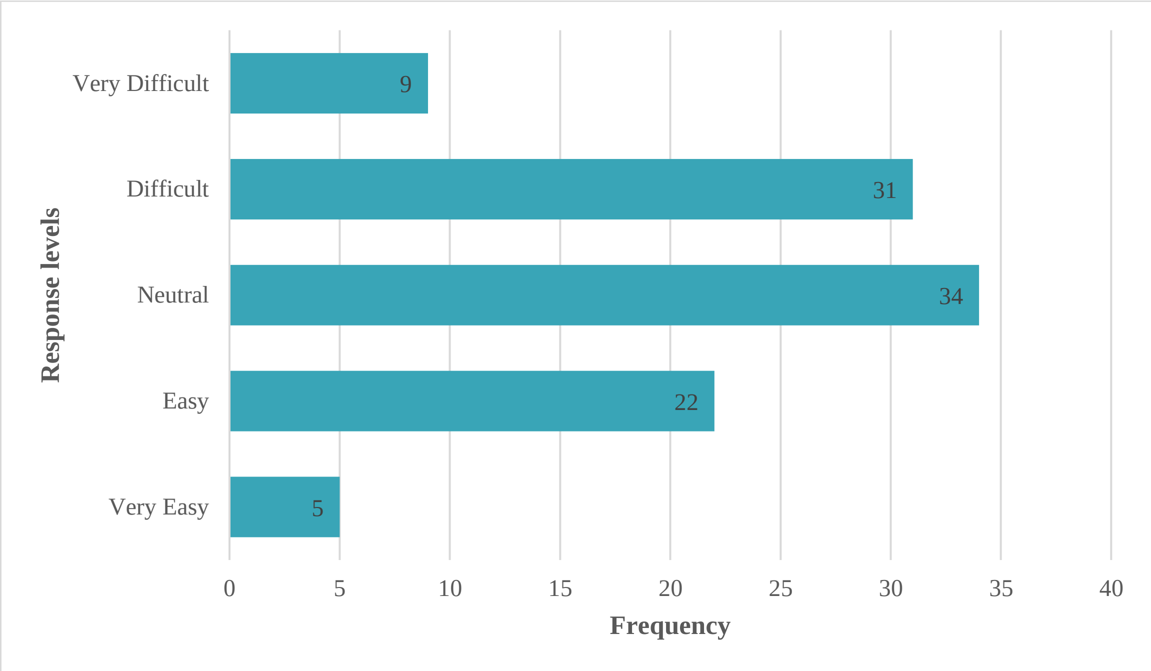


Figure 32: Response for chronic side effects from a medicine

Neutral and difficult appear to be common in this response. Identifying chronic side effects from medication is a complex issue due to time, subtle symptoms, multiple factors, and limited testing. It's an ongoing process requiring careful observation by patients and healthcare providers.

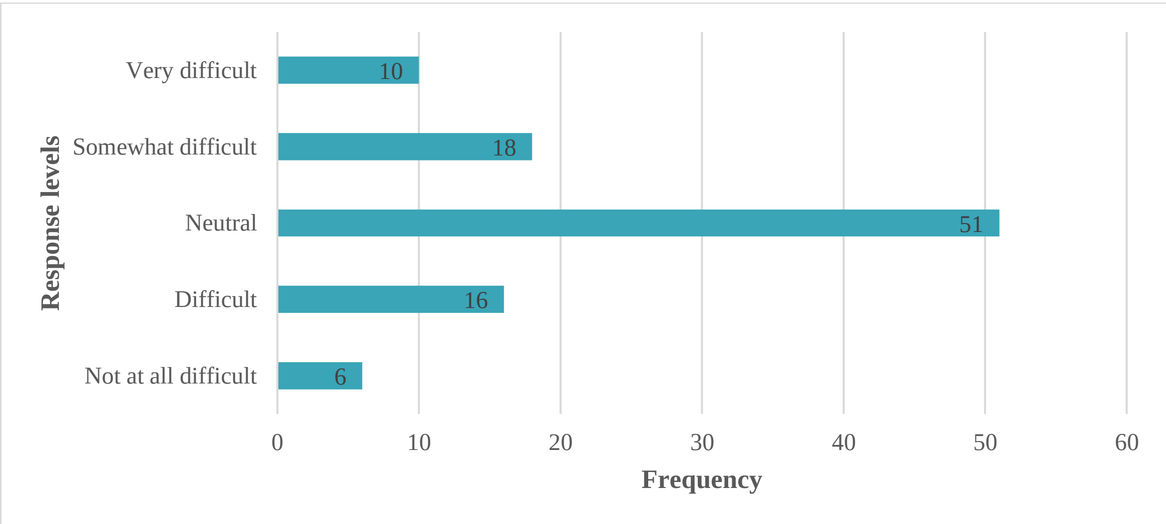


Figure 33: Response for ADR from a medicine

Neutral and somewhat difficult is the common response for this question. Identifying adverse drug reactions (ADRs) from a medicine is neutral and somewhat difficult due to similar symptoms, multiple factors, delayed reactions, making it crucial for patient safety.

Variable	**Category**	**Value**	**df**	**p**
How easy is it to find uncommon side effects of medications?	χ^2	38.954	20	0.078
	N	101		
How difficult is it to identify chronic side effects from a medicine?	χ^2	30.035	20	0.069
	N	101		
How difficult is it to identify ADR from a medicine?	χ^2	29.904	20	0.071
	N	101		

Statistically significant at P<0.05

Table 8: Chi-Squared Tests for Question 15, 16 and 17

Statistical analysis of following questions using chi-squared test showed there is statistical significance ($p<0.05$) in identification of side effects and ADR.

Question 18

The question highlights the most challenging side effects of medications, including subtle, long-lasting, and potentially mimicking health problems. These side effects are difficult to identify and report, posing challenges for doctors and patients.

Category	Frequency	Percent (%)
Mild and easily ignored effects. (e.g., slight headache)	52	51.48
Effects that take a long time to appear / chronic. (e.g., fatigue after months of use)	66	65.34
Effects that could also be from other things like getting older or being sick. (e.g., joint pain)	33	32.67

Table 9: side effects hardest for doctors and people to spot and report

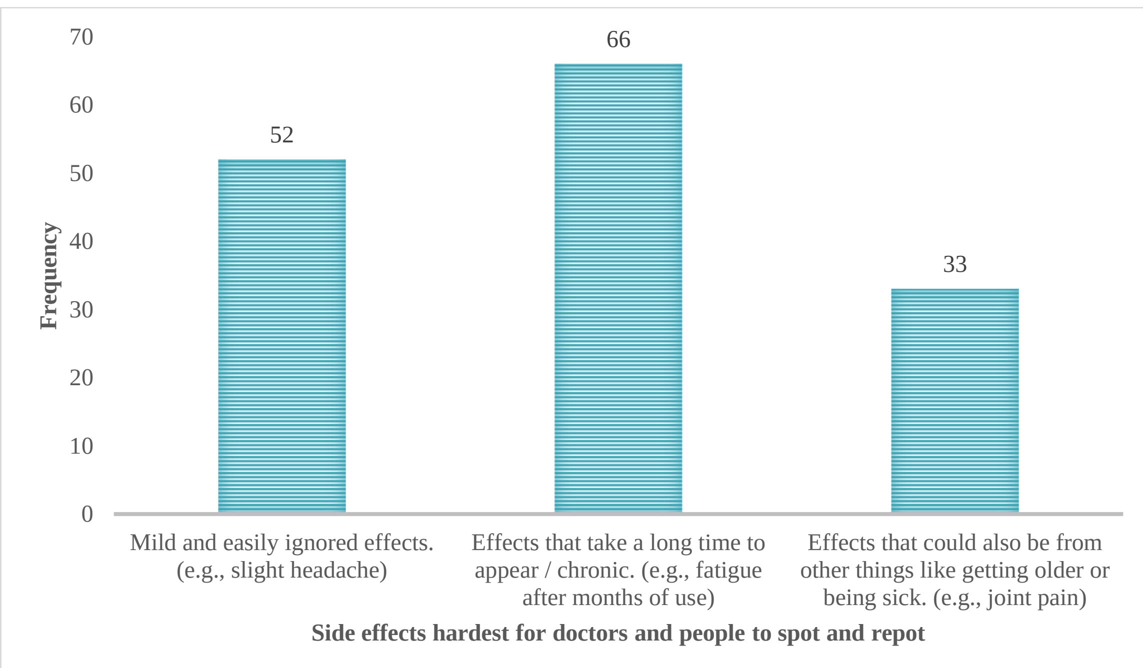


Figure 34: side effects hardest for doctors and people to spot and report

The graph and responses suggest it's not easy to detect the side effects of the medications and hence here wearable devices can play an important role in monitoring and reporting of these events.

4.5 REGULATORY AND ETHICAL CONSIDERATIONS (QUESTION 19 TO 23)

This section explores the ethical use of wearable devices in healthcare, specifically for pharmacovigilance. It gauges familiarity with regulations and ethical guidelines, and questions concern data accuracy, reliability, and fairness. It emphasizes the importance of informed consent, strong security measures, and transparency for patients. The section also asks open-ended questions about ethical data collection and patient privacy when using wearables for health research and monitoring.

Question 19

The responses revealed that 72% of respondents are not very familiar with the regulations and ethical guidelines surrounding the use of wearable tech in healthcare. The majority of respondents are not familiar with the use of wearable devices, with 43.56% not familiar at all, 29.70% somewhat familiar, 20.79% moderately familiar, 3.96% very familiar, and 1.98% extremely familiar.

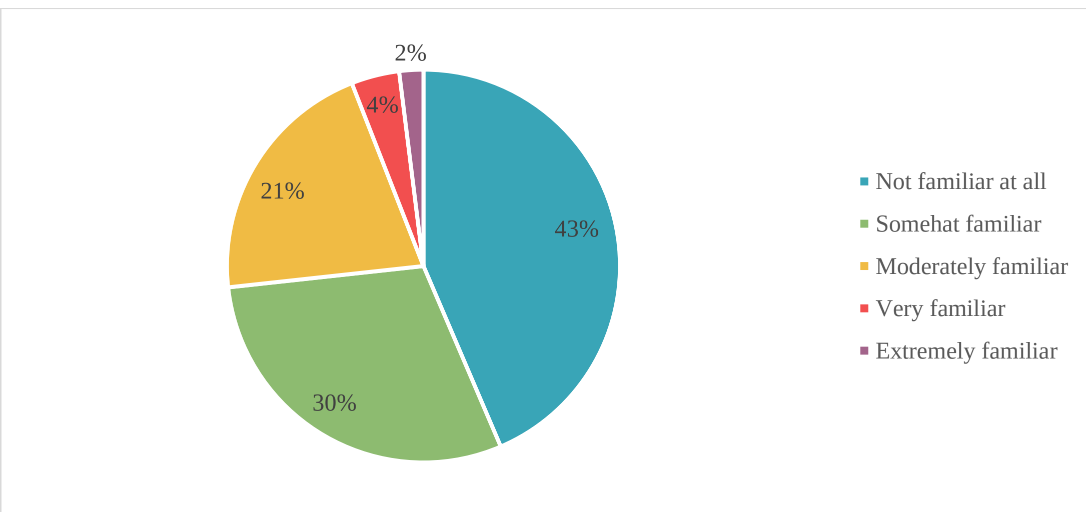


Figure 35: Familiarity with regulations & ethical guidelines surrounding use of wearable devices in healthcare

This suggests that there is need for education related to these guidelines in the population which can in turn generate good quality of life and reduce the fatality with side effects and ADRs.

Question 20

The question has 3 statements which explore the potential drawbacks of using wearable devices for pharmacovigilance, including concerns about data accuracy and reliability, potential data breaches and misuse of information, and fairness and inclusivity. It asks respondents to rate their level of concern for the accuracy and reliability of data collected by wearable devices, the risk of data breaches and misuse, and the potential for not everyone having equal access to wearable devices or the data being representative of the entire population due to affordability or technical limitations.

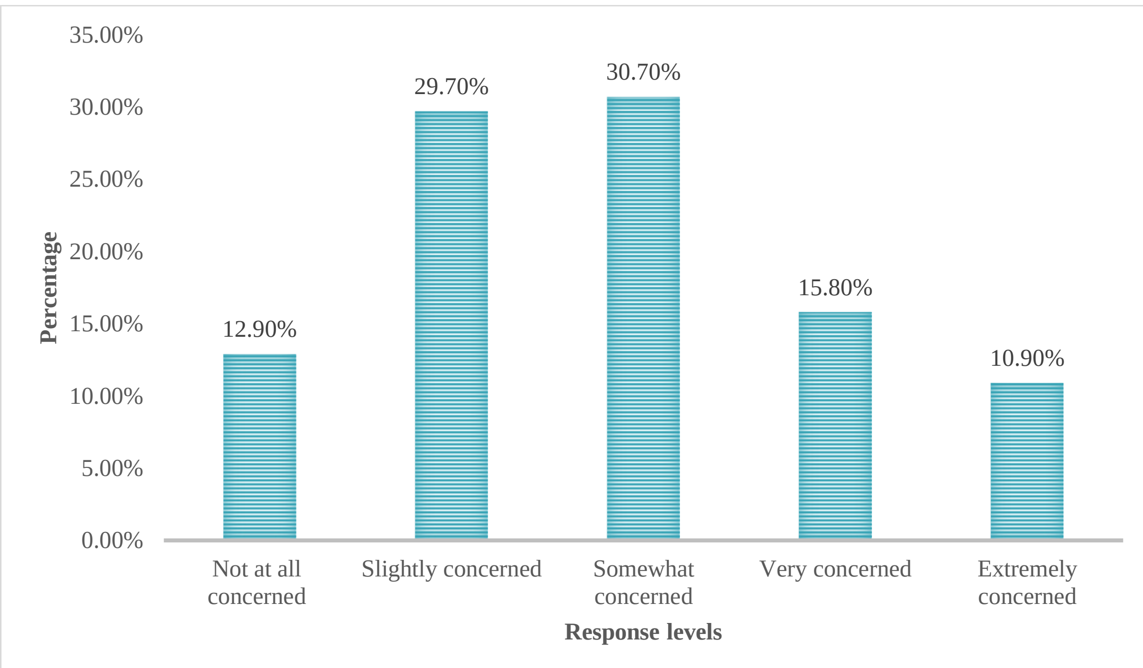


Figure 36: Views about the accuracy and reliability of data collected from wearable devices

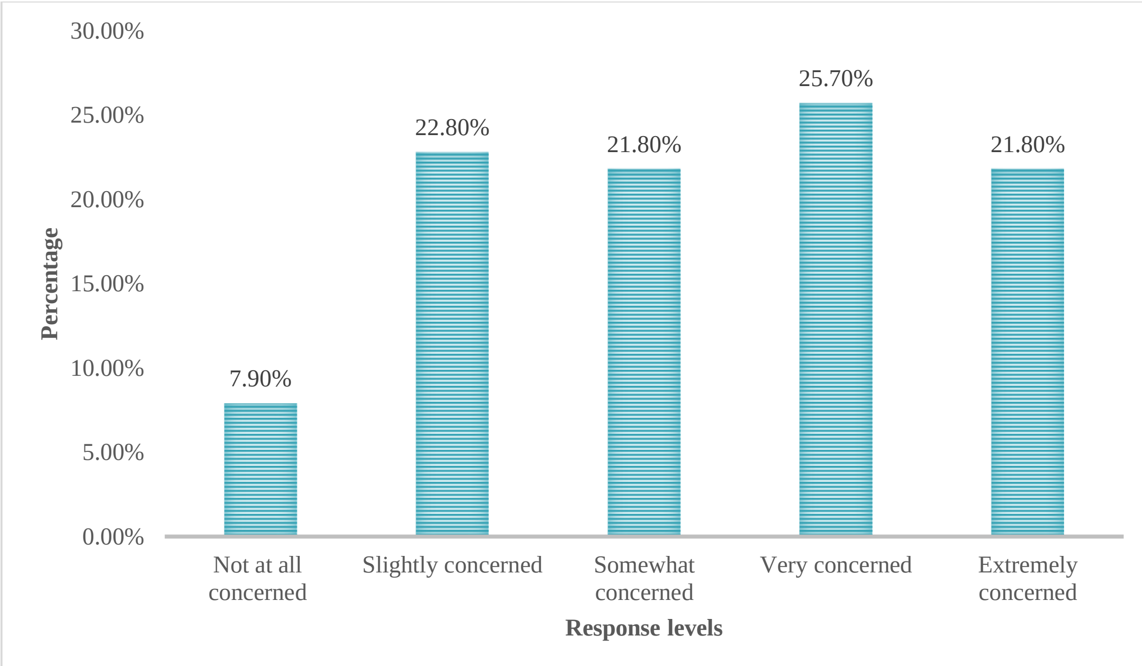


Figure 37: Views about the potential for data breaches and the misuse of patient information from wearable devices

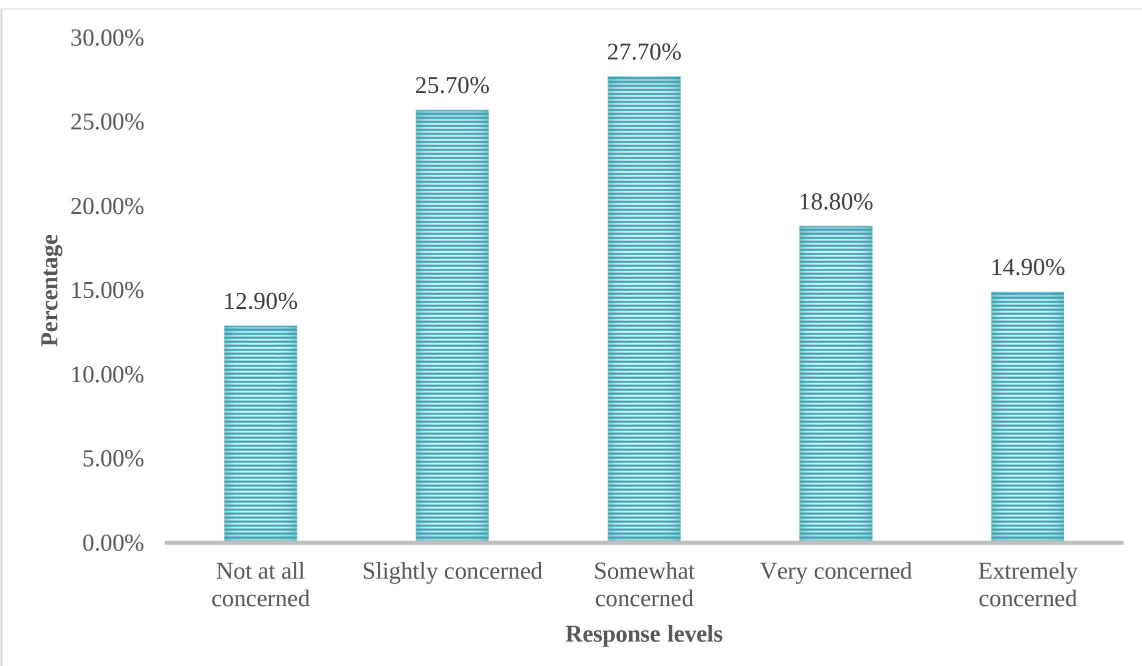


Figure 38: Views about the fairness and inclusivity of using wearable technology in healthcare, considering access and limitations for certain populations

The graphs above represent the views of the study population which suggests that there is need for regulatory considerations in case of wearable devices used in healthcare or in monitoring and reporting of ADRs.

Question 21 & 22

The question has 3 statements which emphasize the importance of privacy and data security in healthcare wearable devices. It emphasizes the need for patients to be informed and have control over their health data collected by these devices. Patients should be clear about the data being used and have the right to choose whether or not to participate in data collection. Robust security measures are crucial to protect patient data from unauthorized access. Data collection should be limited to what is necessary for the wearable device's intended purpose, and patients should be transparently informed about how their data is being used. The question underscores the ethical and legal significance of data privacy and security in healthcare wearables.

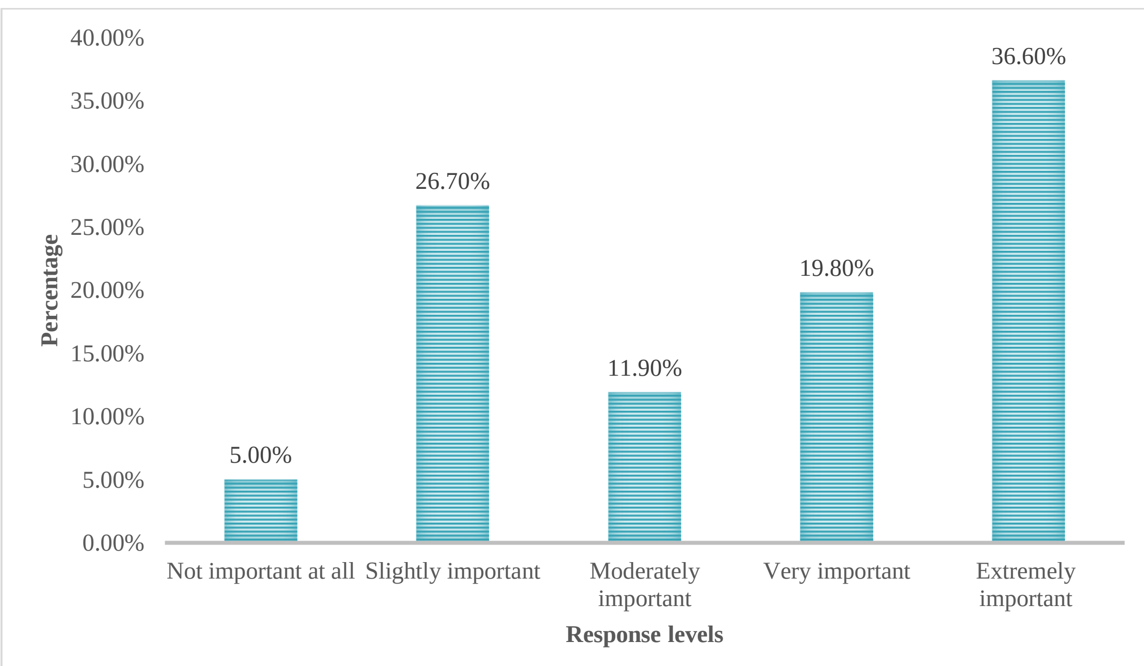


Figure 39:Views about the patients clearly understand how their data is being used and the right to choose whether or not to participate

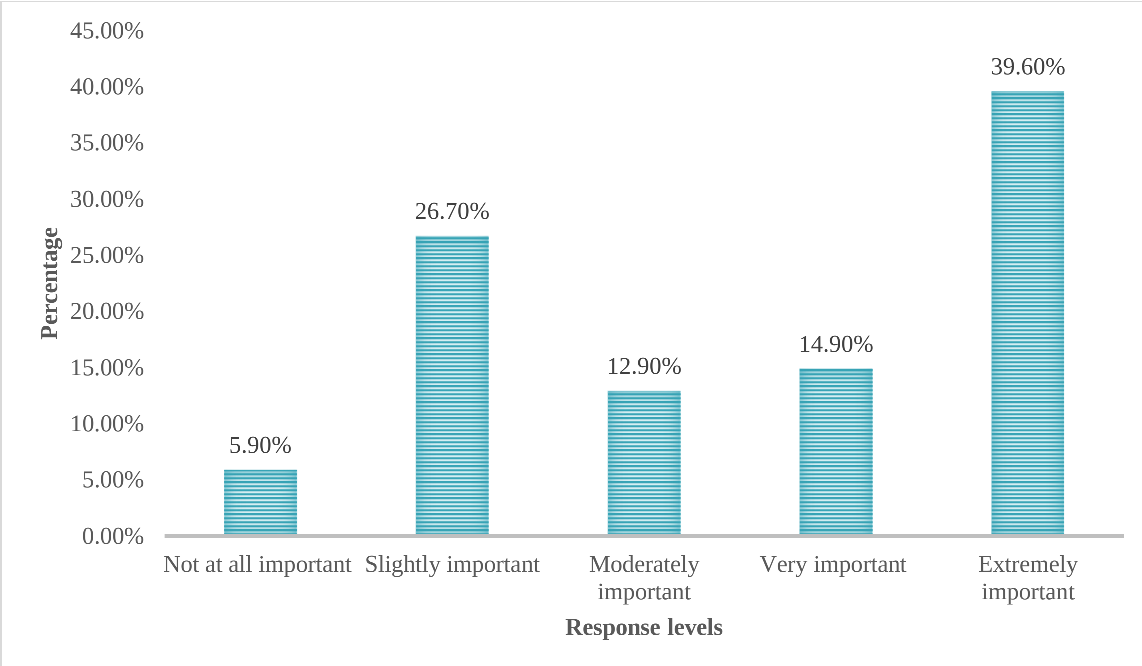


Figure 40: Views about strong security measures in place to protect patient data from unauthorized access

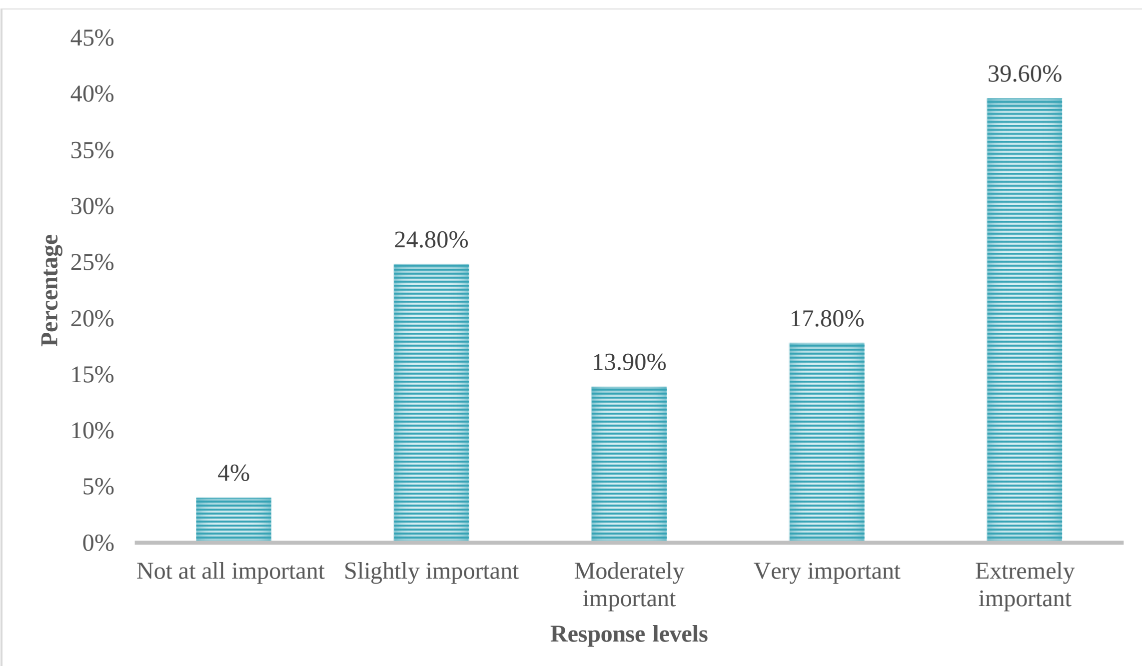


Figure 41: Views about data collected and used only for the specific purposes it was intended for, with clear transparency for patients

The graphs above represent the views of the study population which suggests that there is need for ethical considerations in case of wearable devices used in healthcare or in monitoring and reporting of ADRs. Also, the population suggested full compliance with GDPR with regards to data collection in case of wearable devices.

Question 23

The question seeks perspective of the study population on the importance of protecting patient privacy and ensuring ethical data collection when using wearable devices in health research and monitoring. It emphasizes the need to track health data ethically and without compromising patient privacy, as wearable devices collect sensitive health information. Strong privacy measures are crucial for conducting such research effectively. As this question is open-ended, it gives qualitative response rather than a quantitative response.

Some responses to the open-ended question **"In your opinion, what are the most important things to consider ensuring ethical data collection and patient privacy when using wearable devices for health research and monitoring?"** are as follows –

"All should be clearly explained to the patients in layman's terms, they must confirm they understand."

"The complete data collected for the user should be completely controlled by the user himself, as to where, when and how the data can be used under his knowledge."

"To get the information in a correct way and the person know where information is being transferred"?

"Patient consent and awareness on the use is the most important matter."

"Data safety"

"Are they going to use my info against me?"

"How the patient recognizes the side effect"

"Data protection"

"Data security is really a concern I feel."

"Optimum usage of data with fair policies"

"Privacy by design and privacy by default should be the root of any wearable devices which step into the market. I believe the privacy factor should not be an afterthought. It should be integrated into a device rather than apply the principles of data privacy or security later on. Additionally, one has to keep in mind the device is going to be used by every spectrum of age. One should give more attention to privacy when making a device for elders as they might not understand privacy and security issues as an adult can."

"Regulation and standards"

"Any potential markers that may have an effect in the future on the patient to be monitored by the system and prevent future diseases."

"Informed Consent; patients should be aware of how their information will be used and have the right to control its use & should be paired strict transparency and accountability standards."

"To ensure you are well informed of any data collection before use."

"Name , date of birth, IP address, should not be asked for, instead ask for nickname or username, ask for age group only not DOB, IP address once used will allow the data collector to keep linking it for other purposes and at some stage data breach may occur and easy for hackers, in general only generic data to be asked for."

"Always Protect Privacy of Patients and It's Most Important"

"Heart rate monitor"

"Users data privacy, transparency and the necessity to ensure that users have given informed consent to the processing of their personal data."

"Never sell the data to third parties."

"It is advisable to share data for the R &D, at the same time one should not fall into trap of corporate agenda. Nowadays more and most money-making propaganda are in healthcare platforms."

"Data collected can be used for R & D, but it could be misused for corporate interest."

"Review by correct medical specialist. Feedback to patient."

"The company who produce the device should have a good track record."

"Patient satisfaction Accuracy of data"

"Information should not be misused, and collection should be done with the consent of the patient."

“Consent forms should be clear, and patients should be informed about potential risks and privacy options. De-identification techniques can also be used.”
“It's not easy.”
“Making sure patient takes data away anytime they want ? Or make it anonymous.”
“Ethical issues”
“Their mind set should be cleared that they don’t have any serious problems.”

The responses to the study on wearable device data collection and privacy emphasize the importance of transparency, control, and responsible data practices when collecting health information through these devices.

Key concerns include patient privacy, transparency and security, data usage, patient well-being, and additional considerations such as privacy by design, use of privacy controls, patient satisfaction, and data accuracy. Patients should be informed about the collection, use, and storage of their data, and have complete control over their data. Data collection should be minimized, using anonymization and avoiding unnecessary personal identifiers. Regulations and standards should be in place to govern data collection practices, and data should be used for the stated research purpose, with data anonymization or pseudonymization being crucial to protect patient identities. The responses also emphasize the importance of patient satisfaction and data accuracy. However, some responses were unclear or not applicable to the question, and some responses did not provide specific details.

4.6 WEARABLE DEVICES FOR ADR DETECTION (QUESTION 24 TO 28)

This section focuses on different types of wearable devices and their data points for detecting, understanding and reporting ADRs.

Question 24 & 25

The questions ask to evaluate the effectiveness of different wearable devices in detecting adverse drug reactions (ADRs). The three types of wearable devices considered are smartwatches, implantable devices, and smart clothing or accessories. Smartwatches track basic health metrics like heart rate, sleep patterns, and activity levels. Implantable devices monitor health data continuously, while smart clothing or accessories embed sensors to track health information. The questions are to determine which wearable option would be most helpful in detecting ADRs.

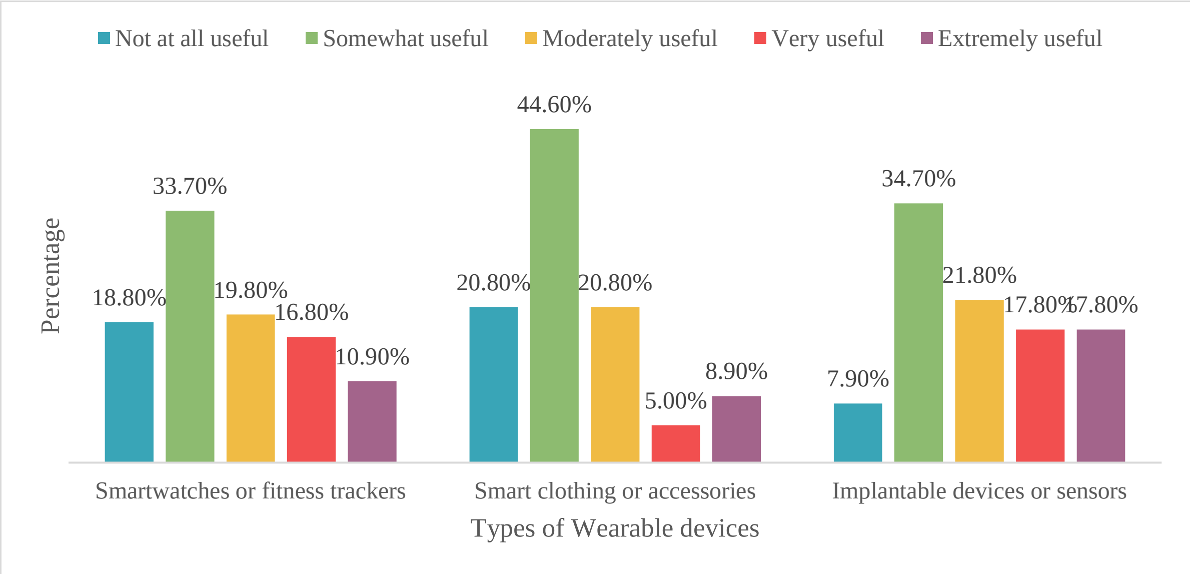


Figure 42: Views about types of wearable devices suitable for detecting ADRs

The responses from study population suggested that Smart clothing or accessories was suitable for detection of ADRs, and Smart watches or fitness trackers and Implantable devices or sensors were on the second position in the list.

Variable	**Category**	**Value**	**df**	**p**
Smartwatches or fitness trackers	χ^2	19.311	12	0.013
	N	101		
Smart clothing or accessories	χ^2	40.695	12	<.001
	N	101		
Implantable devices or sensors	χ^2	9.409	12	0.052
	N	101		

Statistically significant at P<0.05

Table 10: Chi-Squared Tests for Question 24 & 25

Statistical analysis of following question using chi-squared test showed there is statistical significance ($p<0.05$) for different wearable devices which are suitable for detecting ADRs.

Question 26 & 27

The questions explore the potential of wearable devices to identify and report adverse drug reactions (ADRs). It aims to determine the value of each data point in determining if a medication might be causing any side effect. The data points include vital signs like heart rate, blood pressure, sleep patterns, skin temperature, and blood sugar levels.

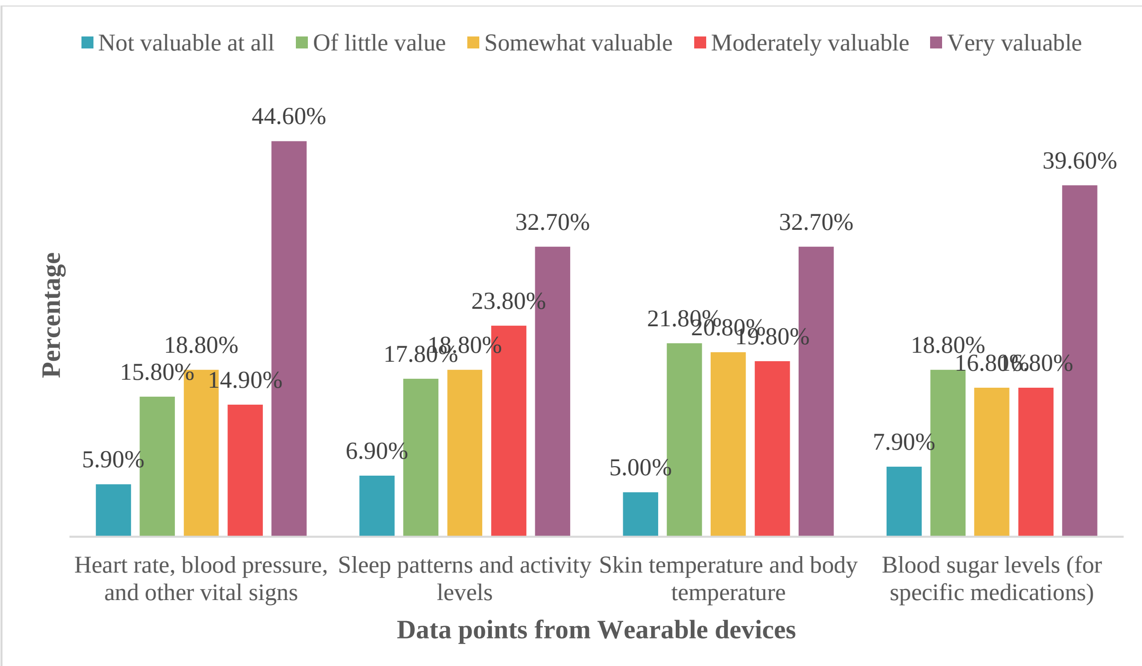


Figure 43: Views about the data points from wearables for understanding and reporting ADRs

The responses from study population suggested that all the data points might play significant role in understanding and reporting ADRs.

Question 28

This question is open-ended, which seeks to identify new wearable devices or methods of collecting health data that could be beneficial in identifying and understanding adverse drug reactions (ADRs). While wearable devices can detect adverse reactions to medications, there are other types of wearable devices or data that could be even more effective in detecting these reactions. This is crucial as more information about medication effects can lead to safer medication use.

Some responses for the open-ended question **"Aside from the options listed, can you think of any other types of wearable devices or data points that could help detect and understand ADRs?"** are as follows –

"Temperature band. Oxygen levels in blood."
"Stress levels throughout the day and night would also help better understand someone's health."
"Brain waves/ Neural activity"
"Temperature Probe. Weighing Scales. Oxygen Levels in Blood"
"Wearable devices like EDA sensors, voice analysis devices, movement and gait analysis, sleep trackers, smart clothing with biometric sensors, non-invasive blood glucose monitors, and environmental sensors can be used to detect and understand Adverse Drug Reactions (ADRs), but their effectiveness depends on the specific ADR being monitored and requires further research and development."

The responses to the question on wearable devices for detecting adverse drug reactions (ADRs) suggest a range of potential new devices and data points. These include visuals, stress monitoring, brain activity tracking, and other sensors like electrodermal activity sensors, voice analysis, movement analysis, sleep trackers, smart clothing with biometric sensors, non-invasive blood glucose monitors, and environmental sensors. Some responses expressed uncertainty or acknowledged limitations, while others acknowledged the need for further research. The findings suggest that exploring additional data points beyond current wearables could be beneficial for ADR detection, but the effectiveness of these new approaches depends on the specific ADR being monitored.

4.7 PATIENT ENGAGEMENT (QUESTION 29 TO 33)

This section focuses on different types of strategies for patient engagement about wearable devices for detecting, understanding and reporting ADRs and barriers which might affect patient adoption of wearable devices.

Question 29 & 30

These questions aim to determine the effectiveness of various strategies in encouraging people to use wearable devices for health tracking and reporting adverse drug reactions (ADR). The criteria include comfort, user-friendliness, affordability, clear information about benefits, and incentives for use and reporting. The goal is to determine if people are more likely to use wearables if they are easy to wear, enjoyable, and not too expensive. Additionally, there might be chance that rewards or prizes could motivate people to use wearables and report side effects.

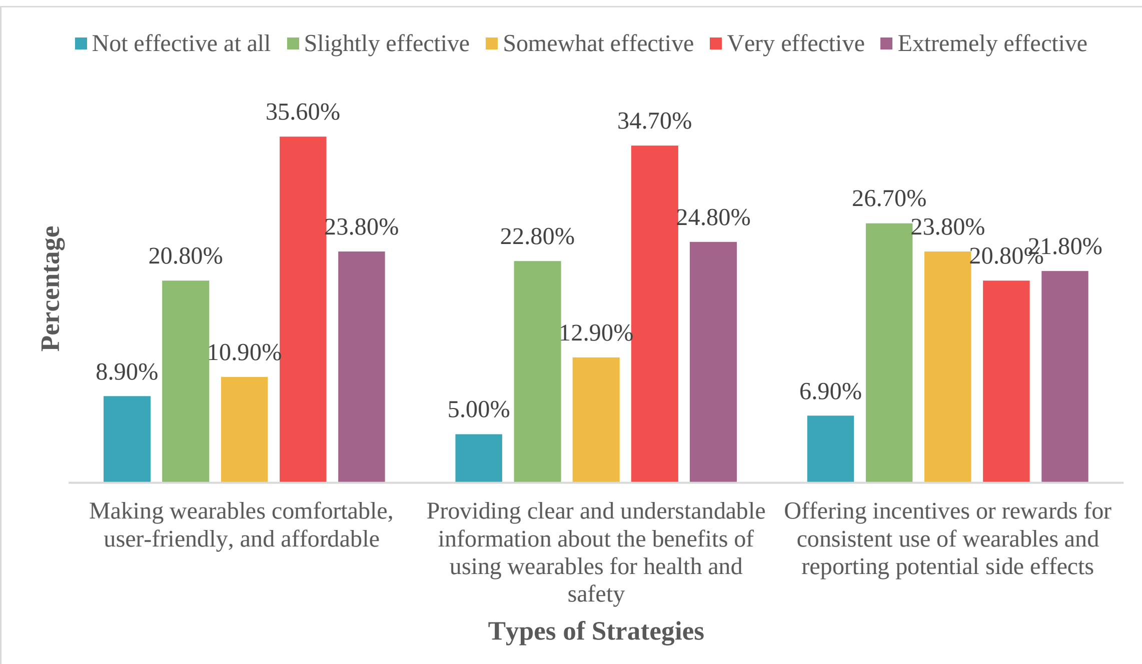


Figure 44: Views about the following strategies in encouraging patients to use wearables for health monitoring and ADR reporting

The responses suggested that making wearables comfortable, user-friendly, and affordable might encourage patients to use wearables for health monitoring and ADR reporting. While the second most common strategy was providing clear and understandable information about the benefits of using wearables for health and safety.

Also, some responses suggested –

"Free - For example some companies offer free hearing aids to anyone over 65."

"Promoting wearable devices through health care professionals as patients have a lot of trust in their physicians/ pharmacists."

The responses suggest two strategies for promoting wearable use for health monitoring and ADR reporting: offering wearables for free, similar to free hearing aids, and promoting wearables through healthcare professionals. The cost barrier could incentivize people to try wearables, while the trust patients have in their doctors and pharmacists could increase patient adoption. These responses offer alternative ideas for promoting wearable use.

Question 31, 32 & 33

The question asks how much each factor might hinder patients from using wearable technology for health purposes. Factors include concerns about data privacy and security, lack of technical knowledge or difficulty using the technology, the cost and accessibility of wearable devices, and concerns about the accuracy and reliability of data collected from wearables. Patients may be concerned about the theft or misuse of their personal health information, as well as the difficulty in using the devices due to their technical skills or the confusion they may cause.

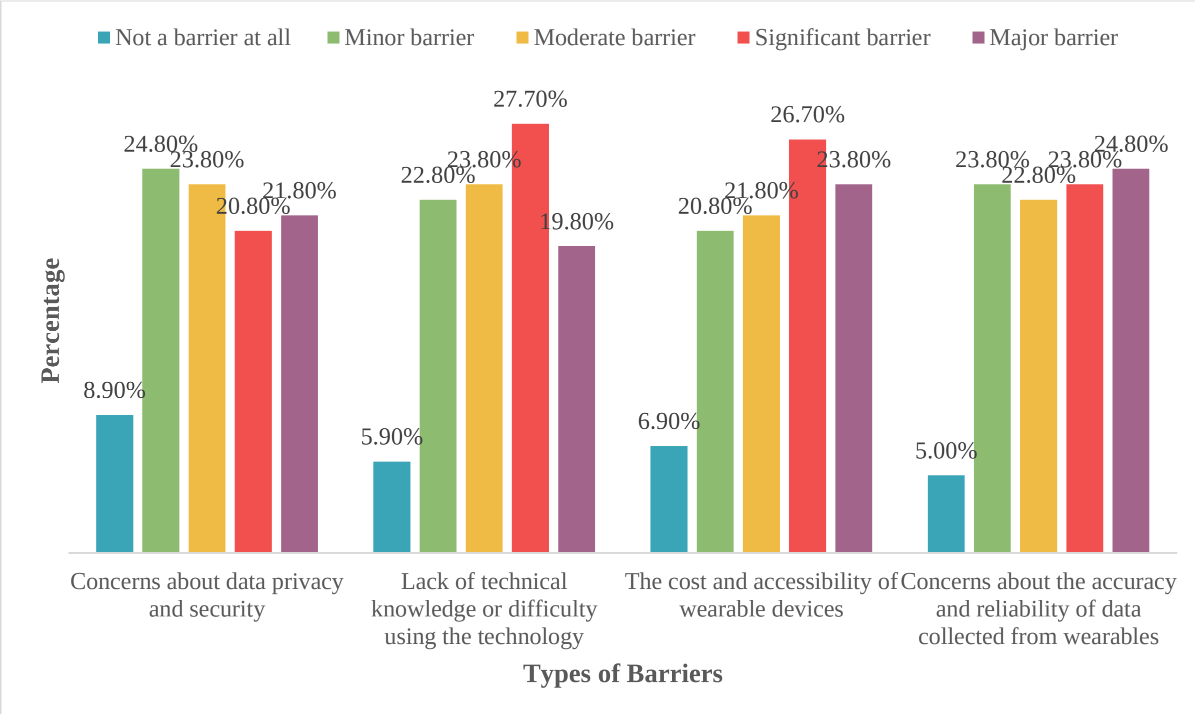


Figure 45: Views about the barriers to patient adoption of wearable technology

The responses suggested that lack of technical knowledge or difficulty using the technology acts as a barrier to patient adoption of wearable technology. While the second most common barrier was cost and accessibility of wearable devices.

Some responses from open-ended question **"what are the most important aspects to address to encourage patients to feel comfortable and confident using wearable technology for their health and safety?"** are as follows –

"Risks from wearing them if any."

"Purpose What it does How it works What it monitors How it monitors How is the data managed How is it presented / reviewed Benefits."

"Firstly, it would be the cost that drives people away from buying wearables Secondly, transparency about the technology and counselling patients with complete and clear knowledge make them confident to try the devices."

“Awareness of wearables and their major effect on user’s lifestyle, transparency on the data usage and taking acknowledgment of the user before using the same data for future use.” “The need to Track their health.”

“Provide sufficient information to understand the proper usage of the technology developments for their future.”

“Ease of use”

“Clear understanding and easy to manageable device”

“Data security”

“To tell them more about the benefits of the device with the data along with keeping their privacy and security in mind. One great example is falling detection in Apple watches as it is proven to be a success with elders living alone.”

“By avoiding data sharing with any marketing related companies trying to push their medication or wearable devices.”

“Helping patients to understand that active, vigilant use of wearable devices could potentially minimize the impact of health care on their routines; reducing the need for patients to invest time in booking appointments with health care professionals, plan their schedule around such appointments, or commit time and money for appointment-related travel.”

“There are no common factors. Society affordability and concerns are generally accounted for suggesting.”

“Simple explanations in layman's terms .”

“In our day data protection seems to be an ongoing topic , so highlighting via all the channels that all data is secured and used correctly might help the cause a bit”

“Low cost Easily accessible Easy maintenance Privacy”

“Educate the patient regarding the wearable devices. Explain the pros and cons.”

"To make patients feel comfortable and confident using wearables for health and safety, three key aspects should be addressed: transparency, user-friendliness, and seamless integration with healthcare systems. Clear communication about the wearable's purpose, benefits, privacy concerns, and user-friendly interfaces can help patients feel empowered to manage their health."

"If the data can be used for their personal health journey, as much as the broad study. So their treatment can be adapted to their own needs, I think, would encourage the use of these technology."

The responses reveal several barriers to wearable technology adoption, including cost, data privacy, and security concerns. Patients often find wearables unaffordable, fearing misuse of their information. Lack of technical knowledge or difficulty of use also contributes to these barriers. Patients also seek transparency about how wearables work, data collection, and usage. Data management and security are crucial, emphasizing secure handling and avoiding third-party sharing without user consent. Patients need to understand the benefits of wearables for their health and well-being. Integration with existing healthcare systems is essential for adoption. However, some respondents' express concerns about the accuracy of data collected by wearables. The responses conclude that addressing cost, data privacy, and user-friendliness is essential for overcoming these barriers and building trust with patients.

4.8 SUMMARY

The study aimed to investigate the potential of wearable devices in pharmacovigilance, specifically their ability to detect and report adverse drug reactions (ADRs) in real-time. A total of 101 participants responded to the questionnaire. The analysis of the data revealed the following: The majority of the participants (98.01%) reported using their phones daily. Almost all respondents (99%) expressed interest in learning about new technologies. 58.41% of the participants reported currently using wearable devices, while 15% expressed interest in using them in the future. Smartwatches and activity trackers were identified as the most popular wearable devices in Ireland. A significant number of wearable device owners wear them regularly. There is a general lack of familiarity with the regulations and ethical guidelines surrounding the use of wearable tech in healthcare (72% of respondents were not very familiar).

Concerns were raised about data accuracy, reliability, potential breaches, and misuse of information. The importance of patient privacy and data security was emphasized. Smart clothing or accessories were viewed as the most suitable wearable device for detecting ADRs. Several new wearable devices and data points were suggested for potentially improving ADR detection, including temperature sensors, stress monitors, and brain activity trackers. Making wearables comfortable, user-friendly, and affordable was seen as a way to encourage patient use. Lack of technical knowledge and cost were identified as the main barriers to patient adoption. Transparency, user-friendliness, and integration with healthcare systems were highlighted as key factors for building trust with patients. In conclusion, the study suggests that wearable devices have the potential to be a valuable tool in pharmacovigilance. However, there are several challenges that need to be addressed, such as data privacy, security, and user adoption.

CHAPTER 5 : CONCLUSIONS AND RECOMMENDATIONS

5.1 CONCLUSION BASED ON RESEARCH QUESTIONS, PRIMARY AND SECONDAY RESEARCH –

1. **What are the current Pharmacovigilance Practices used in the Pharmaceutical Industry?**

Ireland, like many developed countries, follows strict Pharmacovigilance (PV) practices to ensure the safety of medications throughout their lifecycle. The European Medicines Agency (EMA) provides a guideline on good pharmacovigilance practices (GVP) – Module VI (Rev 2) (EMA, 2017), which outlines the legal requirements and processes for collecting, managing, and submitting reports of suspected adverse reactions (ADR) to medicinal products.

The GVP has strengths such as standardization, comprehensiveness, multiple sources, clear definitions, and electronic submission. However, it also has areas for improvement, such as under-reporting, data quality, signal detection, and limited scope.

Technological advancements can address these limitations by providing a more complete picture of a patient's medical history and medication use, automating the analysis of large volumes of text data from various sources, allowing patients to report ADRs directly, using mobile apps, using machine learning algorithms to analyze large datasets, and using blockchain technology to create a secure and transparent system for tracking medication use and identifying potential safety issues.

By utilizing these technological advancements, pharmacovigilance systems can become more efficient, comprehensive, and timely in detecting and evaluating potential ADRs, ultimately improving the safety of medicinal products. The use of electronic health records (EHRs), natural language processing (NLP), mobile apps, machine learning algorithms, and blockchain technology can help improve the efficiency, comprehensiveness, and timely detection of potential ADRs.

The text on pharmacovigilance practices by (Waller and Harrison-Woolrych, 2017) provides a solid foundation for understanding the core principles and processes of pharmacovigilance. The text also includes a section on ethical considerations and examines potential future directions in the field. However, it has a limited focus on technological advancements, lacks specificity on Ireland, and may be overwhelming for those unfamiliar with pharmacovigilance.

The text assesses existing pharmacovigilance systems and processes, highlighting strengths such as standardized practices, multi-source data collection, risk management strategies, and global collaboration. However, it also highlights areas for improvement with technological advancements, such as data integration and mining, electronic reporting systems, AI-powered tools, real-world data integration, and natural language processing. By embracing these advancements, pharmacovigilance systems can become more efficient, proactive, and capable of identifying even rare or complex safety issues.

In conclusion, the text provides a valuable resource for understanding pharmacovigilance practices, but it should be incorporated with information on technological advancements to make it more relevant to contemporary practices.

Also, the survey done by the author resulted in assessing the knowledge of current pharmacovigilance practices in the study population, which clearly states that majority of the population is unfamiliar with the regulations and find it difficult to spot and report side effects and ADRs.

2. **What are the Regulatory Implications and Ethical Considerations for new technologies being used in Pharmacovigilance?**

Ireland's pharmacovigilance system is governed by the European Union (EU) framework, with the Irish Medicines Agency (HPRA) responsible for implementing these regulations. According to (HPRA, 2024) New technologies must comply with EU regulations, including the General Data Protection Regulation (GDPR) and pharmacovigilance legislation, which include data privacy, security, transparency, auditability, patient privacy, data ownership, algorithmic bias, and equity and accessibility. The HPRA provides resources and guidance for stakeholders involved in pharmacovigilance activities, and consulting with them is recommended before implementing any new technology in this domain. Public trust and transparency are essential for building public trust in the use of new technologies for pharmacovigilance.

Ethical review may be required depending on the nature of the technology and its interaction with patient data. By carefully considering these regulatory implications and ethical considerations, Ireland can leverage new technologies to enhance pharmacovigilance while safeguarding patient privacy and promoting responsible data use. The HPRA could develop specific guidance for implementing new technologies, increase public awareness and trust in the use of new technologies, and establish an independent body to oversee the use of new technologies in pharmacovigilance.

The author, through quantitative and qualitative analysis has determined that study population is not familiar with the ethical and regulatory considerations for new technologies being used in Pharmacovigilance. Also, the population is concerned about various potential issues with using wearable devices in pharmacovigilance.

3. What types of wearable devices are suitable for ADR detection?

Wearable devices have the potential to be valuable tools for adverse drug reaction (ADR) detection, but their suitability depends on the type of ADR they can monitor and the data they collect. Some types of wearable devices include physiological monitors, smartwatches and fitness trackers, biosensors, and smart clothing.
Physiological monitors track vital signs like heart rate, blood pressure, respiration rate, and oxygen saturation, useful for detecting ADRs that cause changes in these parameters. Smartwatches and fitness trackers monitor heart rate, sleep patterns, activity levels, and skin temperature, but may not be as sensitive or accurate as dedicated medical devices. Biosensors monitor biological markers in sweat, tears, or interstitial fluid, potentially detecting early signs of ADRs by monitoring changes in biomarkers associated with organ function or inflammation.

Smart clothing infused with sensors tracks physiological parameters but has similar limitations in data accuracy.

Overall, wearable devices offer a promising but evolving approach to ADR detection, but their effectiveness will depend on improvements in data accuracy, integration with electronic health records, and the development of robust data analysis algorithms.

The survey was conducted, and the responses suggest that people are interested in using wearables for ADR detection and monitoring. Smart clothing or accessories were viewed as the most suitable wearable device for detecting ADRs and Smartwatches or Fitness trackers as the second most common wearable devices. Several new wearable devices and data points were suggested for potentially improving ADR detection, including temperature sensors, stress monitors, and brain activity trackers.

4. How to access data for adverse event detection from these wearables?

Accessing data from wearables for ADR detection involves several steps, including obtaining informed consent from patients, collecting relevant data, using Application Programming Interface (API) integration, developing a secure mobile app, and securely storing collected data in the cloud. Data security and privacy are crucial, with strong encryption, anonymization, and compliance with relevant regulations.

Data integration is essential, ensuring seamless integration with electronic health records (EHRs) for a holistic view of patient health. Standardization of data formats across wearables and EHRs facilitates efficient analysis. Technical feasibility is crucial, with API availability and data integration being complex due to data format variations and privacy restrictions. Real-time vs. retrospective analysis depends on the use case, and sensor accuracy may be limited by wearable sensors. User factors and algorithmic analysis require careful development and validation to ensure accuracy.

Addressing challenges involves standardizing wearable data formats and API interfaces, developing machine learning algorithms specifically trained on wearable data for ADR detection, and educating users on proper wearable use and data collection practices. While technical challenges exist, advancements in wearable technology, data integration, and algorithm development hold promise for using wearables as a valuable tool for ADR detection. However, careful consideration of these limitations and ongoing research are crucial for ensuring the reliability and accuracy of this approach.

5. **How do patient engagement and acceptance affect the real-time data integration into the pharmacovigilance system from wearables?**

Patient engagement is crucial for successful real-time data integration from wearables into pharmacovigilance systems. High patient engagement leads to increased data volume, improved data quality, and enhanced patient safety. However, low wearable adoption can hinder data collection, create inconsistent data, overload pharmacovigilance systems, and cause alert fatigue.

Strategies to enhance patient engagement include education about the benefits of wearables for ADR detection and pharmacovigilance, transparency and control, user-friendly interfaces, and incentives. Adoption of wearables for health monitoring and ADR reporting is influenced by perceived benefits, user-friendliness, data privacy concerns, cost and accessibility, and integration with healthcare systems.

To increase patient adoption, focus on specific patient needs, simplify data interpretation, address privacy concerns, offer integration with existing apps, and develop partnerships with healthcare providers. Real-time data integration with existing databases like Electronic Health Records (EHRs) presents challenges such as data standardization, interoperability, and data security.

The survey was done, and the study population raised concerns about data accuracy, reliability, potential breaches, and misuse of information. The importance of patient privacy and data security was emphasized. . Making wearables comfortable, user-friendly, and affordable was seen as a way to encourage patient use. Lack of technical knowledge and cost were identified as the main barriers to patient adoption. Transparency, user-friendliness, and integration with healthcare systems were highlighted as key factors for building trust with patients.

By addressing patient concerns, promoting engagement, and overcoming technical challenges, real-time data integration from wearables can become a valuable tool for improving pharmacovigilance and patient safety.

In conclusion, the study suggests that wearable devices have the potential to be a valuable tool in pharmacovigilance. However, there are several challenges that need to be addressed, such as data privacy, security, and user adoption.

5.2 CONTRIBUTIONS AND LIMITATIONS OF THE RESEARCH –

This study aimed to break new ground by exploring the use of wearable devices for pharmacovigilance for monitoring and reporting ADRs, specifically in Ireland. Unlike prior research that focused on general applications of wearables in healthcare, this investigation delved into public perception and technical challenges of wearable devices for pharmacovigilance.

The research employed an online survey (n=100) assessed public views and user acceptance of these novel systems in Ireland. While the initial goal included evaluating the effectiveness of wearable devices for pharmacovigilance, resource limitations prevented access to clinical trial data.

The study also acknowledges a sample bias towards younger individuals due to surveys conducted online and lack of knowledge of pharmacovigilance in the study population hindered access to clinical trial data also, due to the limited timeline of the research the author could not attain the expected sample size (n=149). These limitations, along with the predominance of young postgraduate participants, necessitates further research with a larger and more diverse sample to achieve generalizable findings.

5.3 RECOMMENDATIONS FOR PRACTICE AND FUTURE RESEARCH –

The study explores the potential of wearable devices for pharmacovigilance in Ireland, focusing on monitoring and reporting adverse drug reactions (ADRs). It recommends several recommendations for practice, including public education campaigns, user-centered design and development, collaboration with stakeholders, addressing sample bias, and securing funding for larger, more diverse studies.

To address sample bias, it is suggested to employ diverse recruitment strategies and consider alternative data collection methods. Further research should focus on the accuracy and reliability of wearable data for detecting and reporting ADRs and exploring the potential of wearable devices for personalized pharmacovigilance and risk stratification.

Future research on wearable devices for pharmacovigilance in Ireland can be strengthened by expanding the sample size and diversity, assessing wearable data integration, evaluating wearable effectiveness for ADR detection, investigating user experience factors influencing long-term engagement, and analyzing the current regulatory landscape in Ireland regarding the use of wearables for pharmacovigilance.

User experience factors should be investigated, and qualitative research should be conducted to understand user concerns, preferences, and motivations regarding wearable use for ADR monitoring. Strategies should be developed to promote user adherence and data collection compliance over extended periods.

Regulatory and ethical considerations should be considered, as well as the need for ethical and responsible implementation of wearable technology in pharmacovigilance practices. By addressing these areas, future research can provide a more comprehensive understanding of the feasibility, effectiveness, and user acceptance of wearable devices for pharmacovigilance in the Irish context, ultimately contributing to the development of robust and efficient pharmacovigilance systems that improve patient safety and medication use.

5.4 REFLCETIONS –

The research on wearable devices for pharmacovigilance in Ireland has revealed a complex relationship between technological potential, public perception, and real-world limitations. The limited sample size and focus on younger demographics highlight the need for further studies to bridge the gap between technological innovation and societal readiness. The experience emphasizes the importance of considering both technical feasibility and human factors in healthcare solutions. The author is eager to contribute to the research for effective implementation of wearable pharmacovigilance for public health.

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APPENDICES

Survey form

An analysis of utilization of wearable devices for enhancing real-time adverse drug reactions (ADRs) monitoring, through pharmacovigilance in Ireland

* Required

Introduction

Dear Respondent,

This questionnaire is being carried out by Iram Naz Ansari, a MSc student in Griffith College, Dublin, Ireland. This research is in the fulfilment of a master's degree in Pharmaceutical Business and Technology at Griffith College Dublin.

The survey will take approximately 10 minutes to complete.

This survey aims to understand how people in Ireland use wearable devices. We're interested in everyone's opinion—people who already use them, those who might be interested, and even experts in the field. We want to find out if people in Ireland are open to using wearable devices to track their health and share information with healthcare providers.

The research aims to look at the existing and future use of wearable devices (such as the smartwatches) in improving real-time monitoring of adverse drug reactions as part of pharmacovigilance in Ireland.

Participation in this research is completely voluntary, and your response will be treated with uttermost confidentiality in that your identity will not be connected through the data of this questionnaire. All data generated from this will be stored in line with the General Data Protection Regulation (GDPR).

Thank You.

1. I have read and understood the above information. *

○ Yes

○ No

2. I agree to participate in this research. *

○ Yes

○ No

Demographics

3. Gender *

- ○ Male
- ○ Female
- ○ Prefer not to say
- ○ Other

4. Age (in years) *

- ○ 18-30
- ○ 31-40
- ○ 41-50
- ○ 51-60
- ○ 61 and over

5. Profession / Field of Work *

- ○ Healthcare
- ○ Pharmaceuticals
- ○ IT
- ○ Sports and Fitness
- ○ Government Bodies
- ○ Students
- ○ Other

6. Experience in Pharmacovigilance (in years) *

- ◯ 0-2
- ◯ 3-5
- ◯ 6-10
- ◯ 11-15
- ◯ 16+
- ◯ NA

Introduction to Wearable Devices

7. Using phone is an integral part of my daily routine *

- ○ Yes
- ○ No

8. I enjoy learning about new technology *

- ○ Yes
- ○ No

9. Have you ever used a wearable device? *

- ○ Yes, I am still using it now
- ○ Yes, but I abandoned it
- ○ No
- ○ No, but I am interested
- ○ No, and never wanted to use one

10. What type of wearable device do you use / are interested in using? (Pick all that apply) *

- ☐ Activity Trackers (for example – Ring and Smart band)
- ☐ Smart Watches
- ☐ Smart Clothing (with wearable motherboard)
- ☐ Smart Patches (wearable sensor)
- ☐ Implants (for example – cardiac pacemaker and glucose monitor)
- ☐ Other

11. How long have you been using your wearable device? *

◯ Less than 1 week

◯ 1-6 months

◯ 7-12 months

◯ 1-2 years

◯ Over 2 years

◯ Not applicable

12. How often do you use your wearable device? *

◯ Never

◯ Rarely

◯ Sometimes

◯ Often

◯ Always

◯ Not applicable

13. Wearable devices? (tick the relevant boxes) *

☐ are easy to use

☐ are easy to find and buy

☐ can help improve your physical health (like tracking steps or workouts)

☐ provides accurate information (like heart rate or sleep data)

☐ seems reliable for data

☐ I have no idea

☐ Other

14. What makes you want to use wearable devices (tick the relevant boxes) *

- [ ] Internet / Social Media
- [ ] Product Ad
- [ ] Word of Mouth
- [ ] I am not interested
- [ ] I have no idea
- [ ] Other

Current Pharmacovigilance Practices

15. How easy is it to find uncommon side effects of medications? *

- ○ Very easy
- ○ Easy
- ○ Neutral
- ○ Not easy
- ○ Not very easy

16. How difficult is it to identify chronic side effects from a medicine? *

- ○ Very easy
- ○ Easy
- ○ Neutral
- ○ Difficult
- ○ Very difficult

17. How difficult is it to identify ADR from a medicine? *

- ○ Not at all difficult
- ○ Difficult
- ○ Neutral
- ○ Somewhat difficult
- ○ Very difficult

18. Which kind of side effects are the hardest for doctors and people taking medication to spot and report? (Pick all that apply) *

- ☐ Mild and easily ignored effects. (e.g., slight headache)
- ☐ Effects that take a long time to appear / chronic. (e.g., fatigue after months of use)
- ☐ Effects that could also be from other things like getting older or being sick. (e.g., joint pain)

Regulatory and Ethical Considerations

19. How familiar are you with the regulations and ethical guidelines surrounding the use of wearable devices in healthcare? *

- ◯ Not familiar at all
- ◯ Somewhat familiar
- ◯ Moderately familiar
- ◯ Very familiar
- ◯ Extremely familiar

20. How concerned are you about the following potential issues with using wearable devices in pharmacovigilance?
(Please rate each statement individually) *

	Not at all concerned	Slightly concerned	Somewhat concerned	Very concerned	Extremely concerned
The accuracy and reliability of data collected from wearable devices	◯	◯	◯	◯	◯
The potential for data breaches and the misuse of patient information from wearable devices	◯	◯	◯	◯	◯
The fairness and inclusivity of using wearable technology in healthcare, considering access and limitations for certain populations	◯	◯	◯	◯	◯

21. How important is it to ensure the following aspects when using wearable devices in healthcare?
(Please rate each statement individually) *

	Not important at all	Slightly important	Moderately important	Very important	Extremely important
Patients clearly understand how their data is being used and have the right to choose whether or not to participate	○	○	○	○	○
Strong security measures are in place to protect patient data from unauthorized access	○	○	○	○	○
Data is collected and used only for the specific purposes it was intended for, with clear transparency for patients	○	○	○	○	○

22. Other (Please specify)

23. In your opinion, what are the most important things to consider to ensure ethical data collection and patient privacy when using wearable devices for health research and monitoring?

Wearable Devices for ADR detection

24. How useful do you think the following types of wearable devices would be for detecting adverse drug reactions (ADRs)?
(Please rate each device individually) *

	Not at al useful	Somewhat useful	Moderately useful	Very useful	Extremely useful
Smartwatches or fitness trackers	○	○	○	○	○
Smart clothing or accessories	○	○	○	○	○
Implantable devices or sensors	○	○	○	○	○

25. Other (Please specify)

26. How valuable would the following data points from wearables be for understanding and reporting ADRs?
(Please rate each data point individually) *

	Not valuable at all	Of little value	Somewhat valuable	Moderately valuable	Very valuable
Heart rate, blood pressure, and other vital signs	○	○	○	○	○
Sleep patterns and activity levels	○	○	○	○	○
Skin temperature and body temperature	○	○	○	○	○
Blood sugar levels (for specific medications)	○	○	○	○	○

27. Other (Please specify)

28. Aside from the options listed, can you think of any other types of wearable devices or data points that could help detect and understand ADRs?

Patient Engagement

29. How effective do you think the following strategies would be in encouraging patients to use wearables for health monitoring and ADR reporting?
(Please rate each statement individually) *

	Not effective at all	Slightly effective	Somewhat effective	Very effective	Extremely effective
Making wearables comfortable, user-friendly, and affordable	○	○	○	○	○
Providing clear and understandable information about the benefits of using wearables for health and safety	○	○	○	○	○
Offering incentives or rewards for consistent use of wearables and reporting potential side effects	○	○	○	○	○

30. Other (Please specify)

31. How big of a barrier do you think the following factors could be to patient adoption of wearable technology?
(Please rate each statement individually) *

	Not a barrier at all	Minor barrier	Moderate barrier	Significant barrier	Major barrier
Concerns about data privacy and security	○	○	○	○	○
Lack of technical knowledge or difficulty using the technology	○	○	○	○	○
The cost and accessibility of wearable devices	○	○	○	○	○
Concerns about the accuracy and reliability of data collected from wearables	○	○	○	○	○

32. Other (Please specify)

33. In your opinion, what are the most important aspects to address to encourage patients to feel comfortable and confident using wearable technology for their health and safety?