OPINION OF BLIND & VISUALLY IMPAIRED PATIENTS & CARETAKERS ON BRAILLE LABELLING ON MEDICAL CARE PRODUCTS PACKAGING IN INDIA

by

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OPINION OF BLIND & VISUALLY IMPAIRED PATIENTS & CARETAKERS

ON BRAILLE LABELLING ON MEDICAL CARE

PRODUCTS PACKAGING

IN INDIA

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Dedication

I dedicate this thesis to my wife Nasreen Hoda, who let me play, be myself and daydream at the cost of my time for her. Unconditionally, she supported me throughout this journey. To my mother, Shamim, who gifted me the mind set of purpose, growth and always encouraged me in all circumstances. My younger brother, Dr Athar has shown me the way to live life with firm determination while utilizing my potential. My father Mr M H Khan who always silently supported me with his trust in me. My in-laws, Mr. S A Hoda and Mrs Zahida Hoda who give me so much love and always believe in all my efforts. To all the participants in my study who believed that this country will be a better place to live for all disabled people as integral part of society. At last and most important, to my dearest daughter Zoya and my dearest son, Zayan who kept their patience showing maturity beyond their ages on my non availability for them during my study waiting for their father to be a better evolved person than earlier and become a little useful to society.

Acknowledgement

Overall, on this doctoral journey, I wish to thank many people who supported me. First, I would like to extend my heartfelt thanks to my supervisor Dr Josip Burusic for his continuous advice, support, comments during my dissertation journey. Thanks a lot, Dr Josip. This would have not been possible to complete my dissertation research work without your able guidance. Secondly, I would like to thanks Dr Vijay Shankar Sharma, Head of Department, Shakuntala Misra National Rehabilitation University, Lucknow, UP, India and Mrs. Amita Dubey and Alok Sigh from NAB (National Association of Blind), state branch, Lucknow, UP, India for providing me opportunity to come across a set of people who hold the strong will, full of enthusiasm to live life, the BVI (Blind and visually impaired) individuals who have taken the charge to lead their life at parity and social inclusivity.

ABSTRACT

OPINION OF BVI (BLIND & VISUALLY IMPAIRED) PATIENTS & CARETAKERS ON BRAILLE LABELLING ON MEDICAL CARE PRODUCTS PACKAGING IN INDIA

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Dissertation Mentor: Dr Josip Burusic

Visual impairment has become a global issue, which is leading to various difficulties and has been significantly affecting BVI (Blind and Visually impaired) individuals life quality. As per literature review there are around more than 285 million people with visual impairment in the world and out of which around 90% live in developing side countries of the world. In India, currently there are around 12 million blind people which is making it a home to one third of the world's blind and visually impaired population.

This study was conducted involving 60 BVI (blind and visually impaired) individuals, 30 caretakers, and 42 pharmaceutical industry professionals to assess the need, viability, and implications of implementing Braille labeling on medical and healthcare packs. The primary aim was to validate the hypothesis that Braille labeling would enhance the independence of BVI patients in managing their healthcare need,

reduction in accidental misuse, influence on purchase decision and its importance. In study, 42 out of 60 BVI mentioned a significant enhancement in independence, while 18 reported a somewhat enhanced experience; inclined towards enhancement of Independence. All 60 participants agreed that Braille labeling would significantly reduce accidental misuse of medicines; very strong indication of need to reduce accidental misuse of medicines. Furthermore, 58 respondents out of 60 believed that Braille labeling would positively influence purchase decisions even with marginal increase in cost, a strong input for industry. Regarding importance (need) of Braille labeling, 39 out of 60 BVI individuals deemed it very important, with 21 considering it important; indicates the need. The study also revealed through both BVI and caretakers that the primary challenge faced by BVI individuals was the identification and differentiation between similar packs. Moreover, caretakers also indicated that Braille labeling would increase independence (29 out of 30). Similarly, 19 out of 30 caretakers believed that Braille labeling would positively influence purchase decisions.

Assessed the opinions of 42 industry professionals, major operational challenges identified included high-cost implications (by 69%), regulatory compliance (by 33.3%), production process modifications (by 45.2%), and challenge in availability of Braille experts (by 52.4%). Also, key technical challenges operations such as printing technology limitations (by 66.7%), quality control (by 45.2%), accuracy (by 50%), training and skill development of staff (by 64.3%) and space constraints on labels (by 54.8%) were also highlighted, no impact on design and aesthetics (by 47.6%), somewhat impact aesthetics and design (by 42.9 %). Overall, industry challenge is big & needs a model like public private partnership. All industry participants expressed lack of required level of communication regarding Braille labeling on medical pack in India with no existing

policy.

Overall, BVI populations indicates the dire need of such a tool like Braille labelling to gain independence while industry has its own challenges. A comprehensive discussion in country is needed to address both the sides, social inclusivity of BVI (Blind and visually impaired) individuals to access healthcare needs and in parallel address Industry challenges.

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CHAPTER I:

INTRODUCTION

1.1 Introduction

Visual impairment has become a global issue, resulting in various types of complications which is affecting quality of patient's life. There are around 285 million people with blindness and visual impairment across the world out of which around 90% are living in developing countries(Shetty et al., 2021). A BVI (blind or visually impaired) individual in general faces countless challenges in their daily activities including proper medication safety and efficacy(Almukainzi et al., 2020). Vision loss risk increases many folds with age due to chronic eye diseases and aging(Wong et al., 2020). This is concerning that the proportion of the elderly is going to increase from 617 million (8.5% of world's population) to around 1.6 billion (17%) by year 2050 (Wong et al., 2020). People living in developing world are 5 to 10 times more likely to go towards blindness than people living in substantially industrialized countries("World Sight Day," n.d. 2002). As per data showed in Vision Atlas around 1.1 billion people are living with vision loss(Voss and Haslam, n.d.2020).

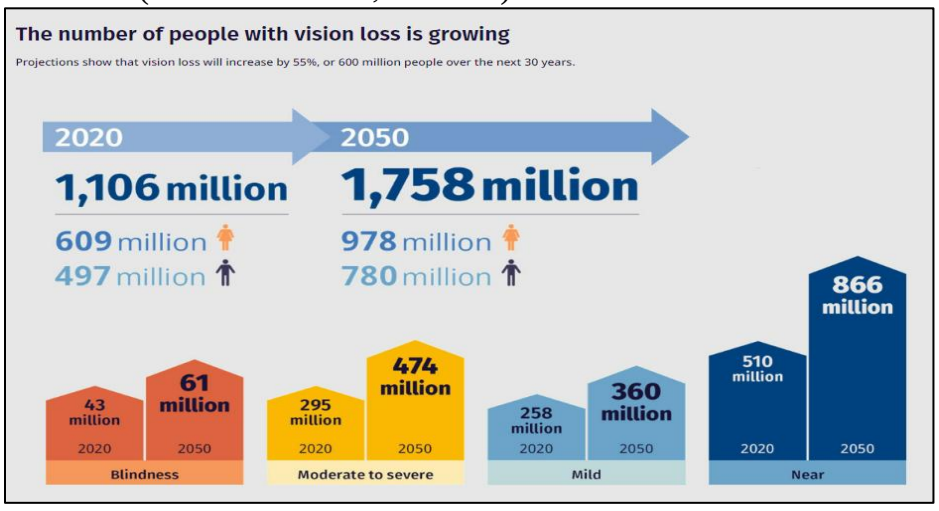


Figure1
Showing possible progression in vision loss

Below figure shows prevalence of all vision loss by GBD (global disease burden) Super Region 2020

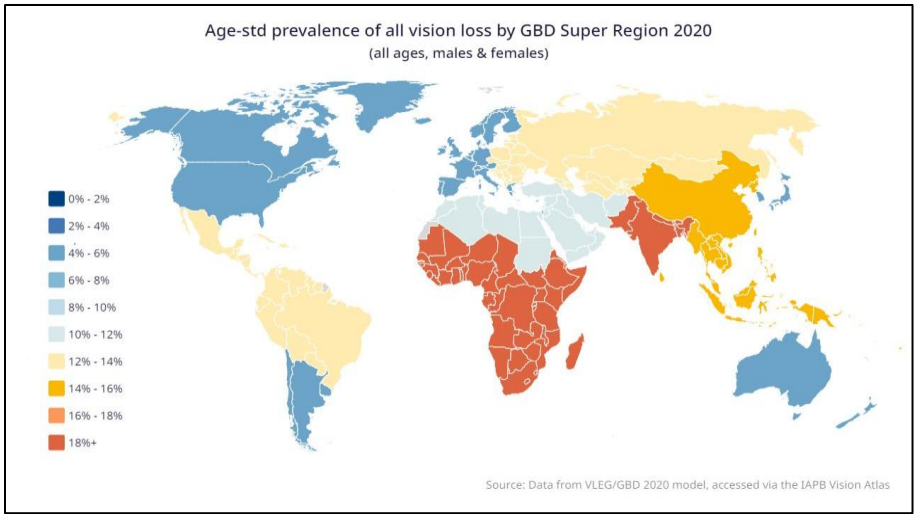


Figure 2.
Showing prevalence of all vison loss

The prevalence of visual impairment of standardized by age is shown across the 21 regions in Figure 2. The prevalence in regions of the world which are poorer is more than 4 times than that seen in the regions with high-income (Ackland, P.et al, 2017).

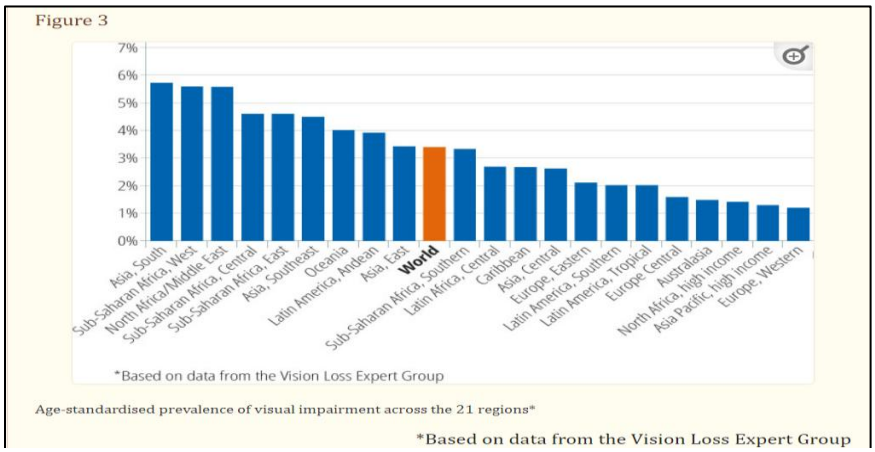


Figure 3
Showing standardized prevalence across 21 regions

In India, currently there are around 12 million blind people which is making it a home to one third of the world's blind and visually impaired population(Tosi et al., 2020). As per IAPB (International Agency for the Prevention of Blindness) data from VLEG/GBD 2020 model, below are the affected numbers of blind and varied degree of visually impaired people.

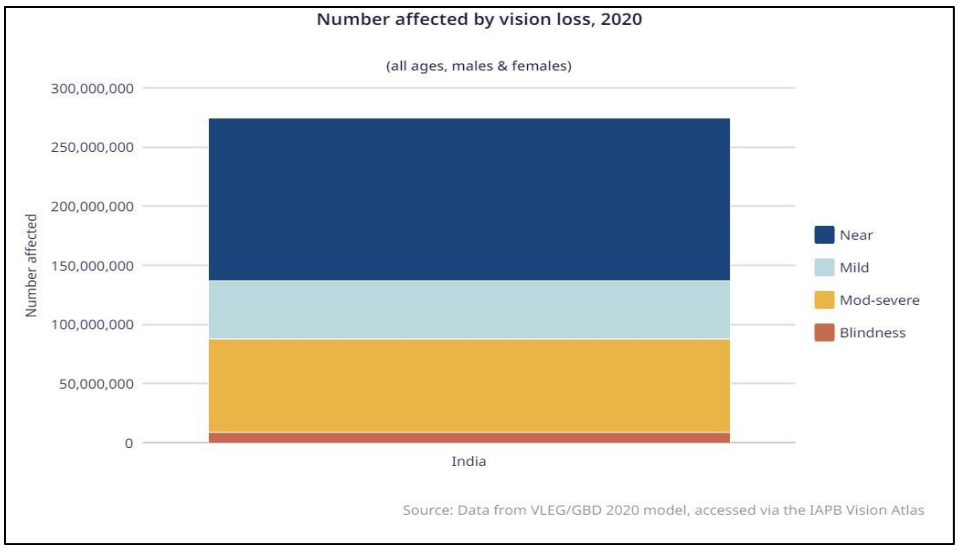


Figure 4
Showing number of affected people for blind and vision impairment in India

India's national policy demands for social inclusiveness & better quality of life and there has been little work done on the need of having Braille labelling on medical & healthcare products packaging to access to products, minimize medication errors as per WHO's objective and give independence to BVI (Blind & Visually impaired) patients hereafter called BVI patients or individuals or subjects.

Different governments in the world have made the use of Braille on medical packaging mandatory to better meet the requirements of the visually impaired in their

countries(“Usage of Braille Packaging,” 2017). The National Policy of India considers that People with disabilities are valuable human resource for the nation and seeks to create an environment providing protection of their rights, equal opportunities and participation in society (“Govt of India, Act 2016,” n.d.). Indian drug authority discussed the proposal in 2020 and a recommendation was given to constitute a sub-committee which will examine the issue in detail for any further consideration.

In recent years, the rights and needs of individuals with visual impairments have garnered increased attention worldwide. In India, as the movement towards inclusivity is yet to gain momentum, one crucial aspect needs to be examined is the accessibility of medical care products for the blind and visually impaired (BVI) population. One apt solution which may be suggested is the implementation of Braille labelling on medical care products packaging. This study delves into the opinions of BVI patients and their caretakers (families, instructors, teachers) regarding the implementation of Braille labelling, exploring its potential benefits and challenges.

With an estimated 12-15 million visually impaired individuals in India, ensuring access to essential medical care products is of paramount importance. Braille, a tactile writing system, has long been recognized to empower individuals with visual impairments to read and comprehend written information. By incorporating Braille labelling on medical packaging, there is potential for enhanced independence and safety for BVI patients in terms of reduction of accidental misuse.

The perspective of BVI individuals and their caretakers on Braille labelling is critical in understanding the practical challenges and impact of implementation of braille

on packs. Their firsthand experiences and insights can shed light on the efficacy of Braille labelling in facilitating the understanding and proper use of medical care products, fostering a more inclusive healthcare system.

One significant challenge faced by the BVI community in India is the accessibility of vital healthcare information. Without access to clear and concise instructions on medical care products, BVI patients may face unnecessary risks or dependence on others for assistance. Braille labelling presents an opportunity to address this disparity and promote equitable access to healthcare resources.

However, to implement Braille labelling effectively, several factors must be considered, including standardization, cost-effectiveness, and adherence to regulatory guidelines. It is critical to assess the potential advantages of Braille labelling against the practical challenges of integrating it into existing medical packaging processes.

Understanding the opinions and preferences of caretakers, who are playing a vital role in managing the healthcare requirements of BVI patients, is equally essential. Their perspective on the ease of handling Braille-labelled medical products and their perception of the impact on patients' well-being and gain in independence can offer valuable insights into the overall acceptability of this initiative.

The Indian government's commitment to building an inclusive society for persons with disabilities, including those with visual impairments, has seen the introduction of various policies and initiatives. Exploring the opinions of BVI patients and their caretakers on Braille labelling aligns with this commitment and can contribute to the

formulation of evidence-based policies that accommodate to the precise requirements of the BVI community.

Beyond the potential of benefits to BVI patients, Braille labelling on medical care products could also promote awareness and empathy among the wider public, fostering a more inclusive society. Understanding the perspectives of all stakeholders involved will aid in assessing the social impact and effectiveness of this accessibility measure.

The technological advancements and innovation in packaging industries offer new possibilities for incorporating Braille labels seamlessly. Collaborative efforts between healthcare providers, manufacturers, and the BVI community can pave the way for an effective and sustainable implementation of Braille labelling on medical care products.

The exploration into the opinions of BVI patients and their caretakers on Braille labelling may suggest a step towards creating a healthcare system that truly prioritizes accessibility and inclusivity for all. By fostering a platform for dialogue and understanding, we can collectively work towards building a more inclusive future for the country's BVI community.

The results of this research work may offer an overview to pharmaceutical companies to gauge the necessity for adaption of Braille labelling for medical & healthcare products packaging for BVI population which is simple and effective way of improving the life quality and attaining freedom for BVI patients with Braille literacy. It may serve as an important information for Industry and government to take appropriate

decision for this cost and effort intensive initiative for Industry and further the compliance adherence for Regulators providing benefit to BVI population.

1.2 Research Problem

The actual numbers of blind or visually impaired people will continue to increase and various helping aids are continuously explored. In reports it has been seen that there are around 5.2 million medical errors in India, annually(Reddy, 2017) and the associated cost with medication errors is estimated to be $42 billion USD globally(Shetty et al., 2021). Medication without harm was launched in March 2017 under WHO's third global patient safety challenge to find solutions in reducing medication errors.

Literature review results of studies have indicated that use of Braille improves literacy in the visually impaired. The Braille system is the only known system through which Blind or visually impaired individuals can read, learn, and write. On one hand few studies have shown the effectiveness of successfully moved out prescription with Braille as an efficient method in attending the key issues to medication safety with the visually impaired people. On the other hand, there have been numerous assistive technological devices for BVI (blind and visually impaired) individual to support timely and accurate medication but most of them have only been piloted and not widely commercialized. Cost and availability may be a limitation, but explorations are still ongoing; future may be brighter with affordable solutions. The arrival of assistive technologies based on smartphones promotes ease of use and usability and independence resulting in improved life quality but yet poses several challenging opportunities(Khan and Khusro, 2021).

Various studies have highlighted the importance of assistance as social situations in recent past like COVID-19 pandemic has educated us that with sudden interruption of support and assistance to BVI group of individuals may have a serious impact on their well-being, livelihood, daily living activities, socio-economic conditions and finally compromise on the life quality and may even risk their lives.

India has approximately one third of blind population and has an inclusive national policy for disabled. Braille may be a basic skill tool to manage quality of life with independent medication, health care product administration. Visually impaired or blind people face myriad difficulties in living their everyday life. This is particularly true when there are no facilities available to meet their special needs. Only few studies have investigated the difficulties encountered by BVI individuals in country and their needs in relation to their medicines administration. Therefore, is need of research in Braille labelling requirements on medical and healthcare packaging from the viewpoint of end user (BVI), direct caregiver and blind school instructors/ teachers to read the feasibility.

More specifically, the below research questions need to be attended are:

What is the perspective of BVI (blind and visually impaired) individuals and their caretakers/instructors regarding the need/ importance of Braille labelling on medical care products packaging in India, and how does it impact their healthcare experience in terms of gaining the independence in administration of medication, reduction in accidental misuse of medication, and overall well-being of BVI patient?". Assess through their opinion the influence on their purchase decisions with inclusion of Braille labelling?”

This research problem aims to delve into the opinions, preferences, and experiences of BVI patients and their caretakers regarding the adoption of Braille labelling on medical care products in India. It seeks to explore the potential benefits, challenges, and the overall impact of Braille labelling on healthcare accessibility and inclusivity for the BVI community.

This study also aims to get the industry perspectives through experts regarding the potential challenges in adapting the Braille labelling on packs.

Also, it will be of great importance to read the direction of country policy on Braille labelling on medical packaging is gauged this juncture to study the current situation on this upcoming issue.

1.3 Purpose of the Research

The research purpose on the topic "Opinion of Blind & visually impaired patients & caretakers on Braille labelling on medical care products packaging in India" is to gain a broad understanding of the perspectives and experiences of BVI individuals and their caretakers, instructors, teachers regarding the implementation of Braille labelling on medical care products packaging. The research aims to explore the prospective benefits and associated challenges with Braille labelling and its impact on the healthcare experience, independence, and overall well-being of the BVI community in India.

The objectives of the research are as follows:
Assessing Accessibility: This research seeks to evaluate the current accessibility of medical care products for BVI patients in India and understand the difficulties they

encounter in using products with conventional packaging lacking Braille labels. This assessment will provide insights into the existing barriers and limitations faced by the visually impaired population when accessing essential healthcare resources.

Understanding Awareness and Understanding of Braille: The study aims to gauge the familiarity and comprehension of Braille as a tactile reading system among BVI patients and their caretakers. By understanding their level of learning and understanding, researchers can assess the potential effectiveness of Braille labelling as an accessible solution for medical care products.

Identifying Practical Challenges and Benefits: By gathering the perspectives of BVI patients and their caretakers, the research aims to identify the practical challenges they face when using medical products without Braille labelling. Additionally, it aims to explore the probable benefits of Braille labelling, like improvement in independence, safety, and ease of use, which may enhance the overall healthcare experience for the visually impaired population.

Evaluating Purchasing Behavior: The research aims to examine how the presence of Braille labelling on medical care products packaging influences the decision-making process and purchasing behavior of BVI patients and their caretakers. Also, what is their view if there is a marginal increase in cost of product. This evaluation may provide key insights on the impact of accessible labelling on product selection and usage patterns.

Exploring the practical challenges posed to Pharmaceutical Industry: The study seek out to study the operational and technical challenges of Industry as it may require huge investments and technical changes in entire production and supply chain.

Exploring the status and direction of Regulation in country: The study seeks to explore the status and direction of thinking of regulators on policy for braille labeling of medical packaging to make Braille part of the Indian healthcare system and promoting accessibility and inclusivity for the visually impaired through Braille labelling.

The purpose of this research work is to provide valued data and key insights that can inform policymakers, healthcare providers, and pharmaceutical manufacturers in making informed decisions regarding the implementation of Braille labelling on medical care products packaging. The research work aims to contribute to advancement of an broad healthcare environment that takes care to the requirements of all individuals, regardless of visual impairment, promoting equitable access to healthcare resources and improving the overall life quality for the BVI population of the country in India.

1.4 Significance of Study

This research study on the "Opinion of Blind & visually impaired patients & caretakers on Braille labelling on medical care products packaging in India" holds prominence due to the following reasons:

Enhancing Inclusivity & Accessibility: This study may give insights to address a critical aspect of healthcare accessibility for the BVI community in India. Understanding the views and preferences of BVI Individuals and caretakers regarding Braille labelling can

lead to the progress of more inclusive products packaging with Industry participation, enabling better access to essential healthcare for the BVI population.

Empowering BVI Patient-Centric care: By exploring the perceptions of BVI patients and caretakers, the study may highlight the importance of patient-centered healthcare. Understanding their needs and predilections in terms of accessible labelling can help manufacturers design products that cater to the unique requirements of BVI individuals, promoting independence & empowerment.

Evidence based Policies: The study may provide valuable insights to lawmakers and regulators. Evidence-based data on the impact of Braille labelling can aid in the formulation of policies that foster the integration of accessible packaging in the healthcare area, contributing to the creation of a more inclusive healthcare ecosystem system in India.

Aid in improving decision making: By evaluating how the existence of Braille labelling influences decision-making and purchasing behavior, the study may focus the significance of accessible packaging in facilitating informed healthcare choices for BVI individuals and caretakers. This insight may encourage companies to adopt Braille labelling to augment BVI population engagement and satisfaction.

Safety of Patients: The research can shed light on the potential safety benefits of Braille labelling, as BVI individuals and caretakers can accurately recognize medical care products and follow usage information independently. Improved adherence to medication regimens and proper use of healthcare care products can positively impact patient

outcomes and reduce healthcare-related risks like reduction in accidental misuse of medicinal products.

Awareness: Through this study, the public and healthcare area professionals can gain a immersed perception of challenges faced by BVI individuals in gain access to medical care. Enhanced awareness and empathy can lead to greater support for initiatives that promote inclusivity and accessibility for the BVI community.

Collaboration and Innovation: The study can encourage collaboration between healthcare professionals, companies, and NGOs/organizations serving the BVI community. By identifying logistical & economic challenges, the research can inspire novel solutions and partnerships aimed at making Braille labelling a standard practice in the healthcare industry.

Global Relevance: As inclusivity and accessibility are global concerns, the outcomes of the study can have some suggestions beyond India's borders. Other countries with similar challenges in healthcare approachability for BVI individuals can draw some awareness from this research and apply relevant strategies in their environments.

Overall, the implication of the study lies in its ability to back to a more inclusive medicines & healthcare ecosystem in India. By augmenting the voices of BVI patients and caretakers, the research may drive positive change, enhance medication & healthcare experiences, and overlay the way for a more equitable and accessible future for the BVI population in the country.

1.5 Research Questions

The aim of this Study is to investigate and understand the experiences, opinions, and preferences of BVI (blind and visually impaired) individuals and caretakers regarding the application of Braille labelling on medical care products packaging in India.

Key Research Questions:

BVI (Blind and Visually impaired) Subjects:

Main questions-

- The research needs to validate the hypothesis that implementation of Braille labelling on medical & healthcare packs will enhance independence of BVI patients in managing their healthcare needs and administering medications?
- Validate the hypothesis, that Braille labeling on medical & hralthcare care products packaging will reduce accidental misuse (by BVI individuals)
- Validate the hypothesis that introduction of Braille labelling on medical care products packaging will influence the purchasing behavior of BVI patients even with marginal increase in price?

Sub questions-

- What are the perceptions of BVI patients (with Braille literacy) about the current accessibility of medical care products in context to India?
- Figure out the the practical issues faced by BVI patients in using medical care products that lack accessible labelling?

Caretakers of BVI:

Main questions-

- Validate the hypothesis that implementation of Braille labelling on medical & healthcare packs will enhance independence of BVI patients in managing their healthcare needs and administering medications?
- Validate that the introduction of Braille labelling on medical care products packaging will influence the purchasing behavior of caretakers even with marginal increase in price?
- Validate that it is important to have Braille labelling for BVI patients on medical packaing

Sub questions-

- Validate that it is challenging for BVI patients to identify/ differentiate the medical products

Industry experienced professionals:

Sub questions-

- What are the main Operational challenges the medical care product industry might face in implementing Braille labeling on packaging in India?
- What technical challenges might companies encounter when integrating Braille labeling into their packaging processes?
- Will Braille labeling affect the overall design and aesthetics of medical product packaging?
- Has Industry started any interactions with blind or visually impaired patients or their caretakers regarding Braille labeling on medical care product packaging?

Policy Makers:

Sub question-

1. Are there any existing policies or regulations related to Braille labeling on medical packaging in India? Or is there any direction to make any policy?

Addressing the above research questions will contribute to a broad perception of the opinions and experiences of BVI individuals and their caretakers considering Braille labelling on medical care products packaging. Industry responses will highlight the practical challenges in implementation by business. The findings will inform policymakers, healthcare professionals and manufacturers in their efforts to create a more inclusive healthcare environment catering to the unique needs of the BVI population in the country.

CHAPTER II:

LITERATURE REVIEW

2.1 Theoretical Framework

Urie Bronfenbrenner developed an Ecological Systems Theory which provides a framework to understand human development in context to various environmental systems. The theory can be applied to assess the opinions of BVI (blind and visually impaired) individuals regarding Braille labeling in India on medical packs by considering multiple levels of influence. This theory stresses the importance of considering multiple interacting systems that influence individual development and experiences. The Ecological Systems Theory consists of five interrelated levels, each contributing to the understanding of the complex dynamics shaping the perspectives of BVI Individuals and caretakers on Braille labelling acceptance and implementation for improvement in quality of life.

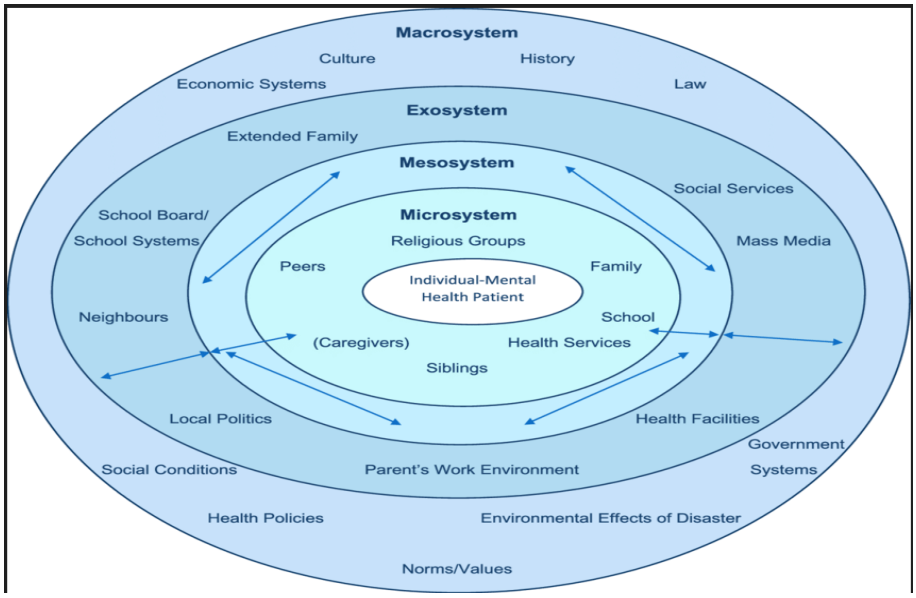


Figure 5
Bronfenbrenner's ecological systems theory diagram (Niederer, et al. 2009)

Below is overview on how this theory can be used in this assessment study:

Microsystem: This level denotes the immediate surroundings in which the individual interacts directly. In this case, it includes the BVI individual's interactions with medical packs and its labeling. Assess how the presence or absence of Braille labeling impacts the BVI individuals directly. This could involve conducting surveys or interviews to understand their experiences and preferences regarding Braille labeling and its impact.

Mesosystem: This level involves the interactions between different microsystems. Study how the availability of Braille labeling on medical packs interacts with other aspects of the individual's environment, such as their interactions with healthcare professionals or caretakers. Understanding how Braille labeling fits into their broader self-healthcare experiences that can provide insights into its effectiveness and importance.

Exosystem: This level involves the broader social settings that indirectly influence the BVI individual. Consider societal attitudes towards accessibility and inclusion for BVI people with impairments. Explore how policies, regulations, and industry standards regarding accessible medical packaging affect the availability and quality of Braille labeling on product packs.

Macrosystem: This level encompasses the broader cultural and societal norms, values & ideologies. Gauge how cultural beliefs and attitudes towards visual disability and accessibility impact the importance placed on Braille labeling in the given healthcare settings. Consider how societal perceptions of visual disability influence the provision of accessible healthcare resources.

Chronosystem: This level involves the dimension with respect to time and how the person and their environments alter over the lifetime. Consider how changes in technologies, healthcare practices, or advocacy efforts over time have influenced the availability and effectiveness of Braille labeling on medical packs. Assess any advancements or trends that may have impacted the accessibility of healthcare information for BVI individuals.

Applying the Ecological Systems Theory here to assess the opinions of BVI (blind and visually impaired) individuals regarding Braille labeling on medical packs to acquire a comprehensive understanding of the multifaceted factors those have influenced their experiences and preferences. This holistic approach can advise required efforts needed to improve inclusivity and accessibility in healthcare settings to key stakeholders.

2.2 Literature Review

A BVI (blind, visually impaired) person in general faces challenges throughout in their day to day activities including proper medication safety and efficacy (Almukainzi et al., 2020). The risk of loss of vision enhances multifold with age due to aging processes & chronic eye diseases (Wong et al., 2020). This is concerning that the proportion of the elderly will increase from 617 million (8.5% of population of the world) to around 1.6 billion (17%) by the year 2050 (Wong et al., 2020). People who are living the developing world are 5 to 10 times more likely to go blind than people who are living industrialized countries ("World Sight Day," n.d.2002). Currently, India holds around 12 million blind people which is making India home to 1/3rd of the world's blind population (Tosi et al., 2020). The liability on caregivers of BVI individuals is worsened by competing priorities and their own increasing age(Pur et al., 2022).

This literature review begins with exploring the advancements done for making BVI patients' life easy (1) Use of Braille on medical packs to assist BVI patients (2) Use of Assistive technologies for assistance to BVI patients (3) Position of Govt policies in various countries for use of Braille as mandatory on medical packs. It showcases the aspects of utilized assistance to BVI patients and its significance in making their life normal. Eventually, it shows that the literature review focuses on use of Braille and other technological assistance to BVI patients, with a special focus on India geography.

The stated search that was utilized for this literature review was gathered by conducting various searches within known standard electronic databases. Databases explored include, ResearchGate, Google Scholar, Taylor & Francis & Springer. These searches were conducted using the terms such as Braille, Braille labelling, Braille on medical packaging, Braille labelling in India. Moreover, the lists of citation from the dissertations, articles and journals, which were acquired through these searches were used to examine additional sources.

Background

Blindness and Visual impairment affect around 285 million people across the world, which is going to result as a high public health burden(Awad et al., 2020). When eye sight is reduced or absent, these individuals may not be able to read, identify and understand information on standard printed medical labels. This limitation in visual ability puts them in the same or enhanced risk than the general population for medicine related difficulties associated with improper use of medicines, such as concomitant administration of medicines being consumed at wrong dose. The approach used most

commonly by BVI individuals to read medicines label is by some other person (e.g., caregiver) reading it, which creates high degree dependency and challenges self-determination and overall well-being. Especially, for individuals who use to be self-sufficient before suffering from this medical condition. These people may feel more vulnerable & diminished as they play a less active role in addressing their health. In a study by Khare et al., (2016) it is stated that caregivers who assist persons with visual impairment often neglect their own needs, which results in depression & burden. Efforts of rehabilitation, which are directed to only disabled, seldom direct to the caregiver.

Different governments in the world have made the use of Braille on medical packaging mandatory to better satisfy the requirements of the visually impaired in their countries ("Usage of Braille Packaging," 2017). The National Policy in India recognizes that people with disabilities are valuable human resource for the country and emphasizes to create an setting that provides them the protection of their rights, equal opportunities and full involvement in society ("Govt of India, Act 2016," n.d.). Indian drug authority has reviewed the proposal on Braille labelling when a representation was made in 58th virtual meeting of DCC (drugs consultative committee) which was held through web conference on 14th July 2020 at CDSCO (HQ)) for discussion on the proposal concerning the issues faced by the blind and visually impaired individuals to read the labels. After in depth deliberation, committee recommended to constitute a sub-committee to examine the issue for its further considerations.

India's national policy calls for social inclusiveness & better quality of life and there has been little work done on the need of having Braille labelling on medical & health supplements packaging to access to medical and healthcare products, minimize

medication errors as per WHO's larger objective and give independence to BVI (Blind & Visually impaired) patients hereafter called BVI patients.

There are various types of aids or support systems implemented or studied as covered below:

Use of Braille on medical packs to assist BVI patients:

In a recently released brochure by "The National Council on Disability (NCD)" highlights best systems for making prescription medicine container labels available to Blind or visually impaired people. U.S. Access Board stakeholder panel recommends, the brochure to be designed to help pharmacists provide their patients with access to drug label information. "Even though every pharmacy may not have a braille printer or be able to provide large print immediately, pharmacists should know what resources are available, especially if they have a regular customer who is blind or has low vision," said Pomerantz. Often, pharmacists can make arrangements in advance so they can keep a sufficient supply of the right kind of accessible labels, he added. (Erickson, 2016)

In an article by Barnett et al. (2017) it is summarized on how to support visually impaired people to interact with the pharmacy, administer the medicines safely and effectively, helping them get the best benefit from their medication. It is important that everyone with vision loss can take their medicines safely, including ability to read dispensing labels and all storage instructions. In a survey conducted in 2015 on registered blind and partly sighted adults in the UK which was undertaken by the RNIB (Royal National Institute of Blind People), 9 out of 10 blind and partly sighted people mentioned that the information on medicines pack was impossible to read or quite difficult. Pack labels must be provided in an accessible manner; however, this is not routinely

considered or provided currently in pharmacies. NHS England introduced in August 2016 AIS (Accessible Information Standard), which requires that the information and communication requirements of visually disabled individuals are proactively addressed under NHS healthcare, which includes dispensing of medication. Going forward information on compliance on pharmacy with the AIS is available supporting organizations that provide publicly funded social care or NHS. This confirms that visually disabled individuals, receive information in manner which they can recognize.

Johnson (2018), mentions in his study done for device making braille labels with embossing (precision alignment) that Braille labels are a technologically simple and that can allow people with visual impairment to independently recognize spaces and objects in their homes, workplace, and schools. For an adult, the functional skill essential in the workplace are identifying objects such as boxes, file folders and medicines. He mentions that labels in Braille leads to daily enhanced efficiency.

Bashyal et al. (2019) conducted a cross-sectional descriptive study in 120 blind people using a program at various centers like hostels, blind associations, colleges located in Nepal to study the difficulties during medication. In their search for the most characteristic solution of medicine administration problems among the visually impaired population, most of the participants suggested alphabet for Braille labelling (35.8%) followed by distinguishing mark on drug packaging (20%). Likewise, 15.8% of people also assumed that an extra explanation by pharmacist could add to resolve their problems. Similarly, they also got recommendations for information given in an audio format (14.2%), and 6.7% said development of mobile app drug reader could be more effective. They also got the advice for medicines use data pamphlets in the Braille alphabet (5.8%)

and Telephone helpline (1.7%).

In a review study by Menditto et al. (2020) where he researched the medicines administration compliance as a increasing concern for public health & poor adherence to treatment that has been associated with poor outcomes on health with higher costs for affected patients. Improving compliance needs interventions to consider the qualities of the individual regimen of therapy as per needs of the patients. He mentions that packages meeting patient needs have been designed, like encouraging to remember to take the medication in time or assist interpreting the labels by using braille label.

Almukainzi et al. (2020) conducted a study which was cross-sectional run through close and open-ended questionnaires with 215 blind or visually impaired individuals, above 18 years of age who were separated throughout different cities within Saudi Arabian kingdom. This research was carried out to investigate the medicines administration pattern in severely blind and visually impaired individuals to gauge the need for Braille labelling on medicines packaging distributed to these patients. The study stressed the need of applying Braille labelling to medicines packs prescribed to the blind and visually impaired. He says that these individuals were facing many challenges in their attempts for self-medication. Also, the current regulations concerning the supply of medications to this visually impaired population do not adequately meet the needs of these patients. A reconsideration for revision of the current policies regarding the application of Braille labelling to medicines pack is reasonable. This study was concluded asserting that use of Braille labelling on medicine packs medicines may minimize medications errors, improve treatment regimes, and promote independence through self-administration of medications in these individuals.

In a questionnaire-based observational study carried on 100 blind or visually impaired patients who were Braille literate (aged ≥18 years) by Shetty et al. (2021). The questionnaire in this study consisted of 8 items capturing patient details on the medicines administration management in addition to a personal interview with them. It was run twice to each individual at baseline and at the end. Braille prescription included details regarding medicines, instructions, their dosages, expiry dates, and any major side effects. The prescription development was easy and quick with an average completion time of 1 hour. Finally, it was observed that most of the study individuals aged between 30-40 years (n = 80) and mostly were males (78%). At baseline, 73% of respondents encountered challenges with self-administration of medicines in comparison to 17.5% at end-line. With Braille prescription, only 5% informed of taking a wrong dosage in comparison to 46.2% at baseline. Individuals missing a dose was significantly reduced after using Braille prescription (43.7% vs. 7.5% respectively) as routine. Finally, it was concluded that research study successfully has rolled out Braille prescription as an efficacious tool in addressing the key challenges to safety with the blind and visually impaired patients.

SAHEL et al. (2022) conducted a study to investigate the Impact of innovative packaging with respect to the attitudes and intensions of purchase of blind and visually impaired individuals in Algeria. The purpose of this study was to evaluate the impact of innovative Braille-labelled medicines packaging on the attitudes and intention of purchase of blind and visually impaired consumers. They implemented qualitative & quantitative approach. The findings showed them for validation of their hypotheses; Packaging for medicines labelled in the Braille system has a positive impact on the attitudes of blind & visually impaired consumers. Packaging for medicines labelled in

Braille has a positive impact on intension of purchase blind and visually impaired consumers. Attitudes have a positive impact on the purchase intention of blind and visually impaired consumers. The results enabled them to emphasize the views of chemists & doctors showing the importance of introduction of Braille labelling into the design of drug packaging.

Use of Assistive technologies to support BVI patients:

There have been numerous studies to explore assistive technological devices for visually impaired and blind individuals to support accurate and timely medication.

In a study (Lee et al., 2018) it shows that visual impairments reduce individual's capability to run day to day activities such as medicine administration. While the people with sight can use their vision to smoothly identify & locate their medicines, the visually impaired rely on someone's assistance to complement their need. Thus, getting appropriate support at the right time is crucial to avoid the misuse of medicines. Based on the results of the discussion in an interview, a medicine recognition model and braille embosser system for Android smartphones was developed. By using a picture of a medicine with a built-in camera, the CNN-based recognition model classifies 11 types of drugs with 99.6% accuracy. Additionally, a braille embosser having low cost, can connect via Bluetooth to one's smartphone and can print the categorization results as a braille label for identification in future without a smartphone use.

Ho et al., (2000) has shown in their study that products like ScotchTM (Braille) Labeler and Magnetic Strip Recorder were developed to aid the visually impaired, but these are costly and require Braille literate person. On the other hand, E-Label is less

expensive and accommodates virtually all individual visually impaired person knowing Braille or not, because it works on basis of person's own voice recording for label. This is essential for independent living, and very crucial when it comes to medication labelling.

According to Lumb and Nyamweya, (2020) to ensure access and use of correct dosage, simple tips and techniques can be shared or used while dispensing medications to visually impaired patients to help them handle their medications better. To help them identify/ differentiate their medicines, palpable Braille-inspired marks can be made on their medication’s packs/containers. They may use 3D markers, non-toxic white glue, rolled adhesive tape.

In this study (Sahu et al., 2020) a camera-based text reading framework which is assistive is proposed for blind people to read the label text from the medicine prescription in their daily lives. In this system, the camera functions as main vision capturing the image of given prescription. To differentiate the prescription image from its complex background, region of interest (ROI) image was proposed as a motion-based method. Then characters as text are identified by OCR (optical character recognition). These extracted texts gets converted into an audio output which uses the text to speech.

Awad et al., (2020), for the first time, used 3D (three-dimensional) printing to create printlets which were orally disintegrating printlets suited for patients with blindness. These Printlets were designed as Moon patterns on their surface with Braille, allowing individuals in identification of medicines when separated from their original packs. Different shapes of Printlets were manufactured to offer further information, such as indication of medicines or its regimen of dose. Despite these patterns are present the

printlets reserved its originally designed mechanical properties and given dissolution characteristics like disintegrating within ~5s, which avoids the need for water and enabling self-administration. Moreover, blind person verified the readability of the printlets. Largely, this practical & approach novel may reduce errors in medicines administration to improve adherence to regimen in patients with blindness.

In another study (Wong et al., 2020) exploration of the potential of 3D (three-dimensional printing) technology in producing a 3D medicine label for visually impaired individuals for ease in their administration of medicine. Variations of dosing instructions, label wordings and identifiers on medicines were designed with suggestion to guidelines by the American Foundation for visually impaired people. Symbols and shapes were used as instructions for dosing and identifiers for individual's medical conditions. Designs of prototypes were created with graphics computer via drafting software and 3D printed by using acrylonitrile butadiene styrene. Then feedback was taken from 5 people with normal sight and 4 visually impaired persons. Target organs symbols-based medicine identifiers were used. There is enormous potential for producing 3D medicine labels for patients with rapid innovations in 3DP technologies.

Also, many other technologies aiding to read labels directly or understand Braille matter has been in market. Hsu, (2020) states that braille technology that has assisted existed for long time with the intention of assisting the visually impaired in operating common activities like writing, reading and communicating. These technologies are pointed to help those who are blind or visually impaired to better adapt to the normal visual world. However, an evident difference exists in present technology when it arrives to two-way communication between the non-blind and blind, technology permits non-

blind individuals to recognize the braille system. This study presents a innovative approach to transform images of braille into English text by using a CNN (convolutional neural network) model and a ratio character segmentation algorithm. The accomplishment of the CNN model produced a predictive accuracy of 98.73% on the set of test. The functionality performance of this AI based detection system could be examined through accessible user interfaces.

Sahu et al., (2020) in her research study proposed a camera-based assistive text reading framework for blind or visually impaired people to read the labels with text from the medicine prescription daily. Audio Output by OCR feasibility is verified. Additionally, this method can successfully resolve the problem of Understanding prescription initiated by the visually impaired people with a great impact on them.

Shashidhar et al., (2021) in their study had proposed a device which is capable of recognizing a tablet with an image of the tablet's blister and the name of the tablet is voiced. SQLite Database management system was employed where database of ten drugs that are commonly used by individuals was saved for testing. SQLite serves as a client-server database system and not as an engine for client server database. Relatively, it is integrated into the final product. It can be changed according to the need of the patient. The SIFT algorithm is used to identify & detect local images. Feature point localization, feature point identification, feature descriptor generation & orientation assignment are the 4 stages of the SIFT algorithm.

Position of Government policies in various countries for use of Braille:

In EU, Directive 2004/27/EC with amendment of Directive 2001/83/EC which includes changes to the package leaflet & label requirements. Through this guidance it is interpreted that the requirements for Braille on the packs, and the requirements for the leaflet are to be made available in manner for the partially sighted and blind as per Article 56a (European Commission., 2005).

In an article by Sharma, (2013) Kanetkar says, The regulation in EU has been the guiding aspect for pharmaceutical companies to initiate braille for any medicinal product for human consumption. The directive in EU defines this ‘as any substance or combination of substances presented as having properties for treating or preventing disease in human beings. This regulation has since shown the path for countries who are quickly pursuing similar suit. All legislation in EU relating to pharmaceuticals is covered under the European economic area (Liechtenstein, Iceland and Norway) have also applied this directive. Even countries like US, Brazil, and Canada have employed a mandate for braille labelling on all medicinal packaging. The markets for export like North America and EU have braille-compliant medicines packs, in line with the European Union mandate (2005) and Can-Am Braille (2009).

Botta, (2018) in an article says that the U.S. still considers it to be an optional guideline unlike all the EU countries where braille is mandatory on medicines packs.

When the European Union treaded last decade to order mandatory braille packs on products, including medicinal products, there was a outbreak of activity throughout the pharmaceutical supply chain in the US as packagers, manufacturers, dispensaries,

distributors began putting plans in place to bring equipment as capabilities onboard to handle braille labelling, expecting the US to follow the EU model.

A working group of the US Access Board, an organizing body among federal agencies representing people who have disabilities has issued a non-binding guidance and means of access on braille label, however, FDA has not issued any mandatory requirements which was welcomed by Industry. Such government mandates will likely pose regulatory challenges.

According to Botta, (2018), response from an FDA spokesman, to an information request from Medicinal Processing, said that the authority "would be open to reviewing braille labelling on a drug product if a sponsor were to submit for review," pointing to the drug Hetlioz which was earlier approved with braille labelling for strength and brand name by FDA.

According to Kibirkštis et al., (2011), it has been a legal obligation to integrate legible Braille on medicine packs, since 2005 in most of countries, even including Lithuania. This enables the visually impaired to smoothly participate into the society. In Braille system it uses raised dots which can be read by touch by blind person. Braille can be developed in 3 ways, using digital embossing and printing. In Pharmaceutical packaging embossing is most common in the production. Medication packs, like most of other packages, go through transport and handling during their life cycle, therefore damage may occur due to various mechanical factors. Braille is read by touching the dots on the pack, which is exposed to various mechanical factors, therefore deformation properties of paperboard are particularly important; which varies depending on

parameters, like type of material & composition etc. It is critical to make the reasonable choice from a options of paperboard types, and to form adopt appropriate parameters of Braille. Furthermore, during the process values of the parameters can be altered.

According to Demyanenko et al., (2016) as per the Order no. 722 vide 25 Aug 2010 of the Ministry of Public Health of Ukraine for drugs label with Braille "About approval of the labelling of medicinal products with Braille font", which was enforced on 26 Nov 2010 for requirements for drug labelling, considering the Directive of the Parliament and Council of Europe vide N 2004/27/EC from 31Mar 2004. Braille labelling is applied to the secondary packaging of pharmaceutical products and should be exhibited in Ukrainian language and by the additional request by applicants in Russian or any other language. Braille labelling includes name of the drug; dose of the active ingredients; dosage form.

In another article by Labetska and Kotmalova, (2022) on Modern Technologies for marking pharmaceutical packaging according to European Union standards, medicines must be marked in Braille for the safe use of medicines by visually impaired patients. In 2010, a law came into force in Ukraine requiring manufacturers to apply Braille marking to the secondary packaging of medicinal products. The name of the drug, the dose of the active substance and the dosage form are indicated in Braille on the consumer package. The main ways to apply Braille characters on the pharmaceutical packaging are: embossing on secondary and primary packaging (on plastic containers); screen printing; inkjet printing with UV and thermal varnishes; use of self-adhesive labels (stickers)

In India a representation on Braille was made in 58th virtual meeting of DCC (drugs consultative committee) held via web conference on July14th, 2020 at HQ of FDA for deliberation on the proposal regarding issues faced by the BVI (blind or visually impaired) people to read medicinal products like tablets or capsules strips where committee was apprised that, a representation has been received, wherein the issues faced by BVIs (Blind or visually impaired) patients in reading the strips of tablets is emphasized. It was stated that strips of the tablets or capsules are not available with Braille labelling and hence it is very difficult by the blind or visually impaired people to identify the medicine. Hence, it was requested that a requirement shall be made to label the drugs with Braille inscriptions. Committee was also told that, this matter was deliberated with the stakeholders of industry in a virtual meeting held on 23 Jun 2020 to devise a procedure on this context. Industry stakeholders presented that it is challenging to provide necessary information on the medicines label in Braille due to space constraints etc. Further, industry presented its limitation on its awareness whether internationally such practices are well adopted and at this stage such proposal is very difficult to adopt. After detailed deliberation, committee suggested to constitute a sub-committee to examine the issue in thorough details for any further thought.

According to Yadav et al., (2021) organizations and regulatory authorities play a essential part in setting the requirements of regulatory procedures related to medicine development in a country. Each country has its owned governing body for regulations, that is, liable for policy drafting, implementing regulations, as well as suggesting guidance to facilitate the evolution, granting of licenses, and handle registration of medicines. The pharmaceutical industry in India is one of the most structured industries. In this known regulatory scenario, agencies play a role of vital importance because of the

continuous changes and with due pressure placed on regulators to assert a continuous availability of quality medications at an cost-effective price to the Indian public. As per regulatory requirements for new medication approval Braille code is not required on pack labelling.

2.3 Summary

Visual impairment has become a global issue, which leads to various difficulties and substantially impact patient's life quality. There are around 285 million people with blindness or visual impairment across the world, out of which around 90% live in developing part of the world. A BVI (blind or visually impaired) person normally faces countless challenges throughout their day-to-day activities including proper administration of medication addressing efficacy and safety. The actual numbers of people poor eyesight or blind continue to increase and several helping aids are constantly being explored.

Reports exhibit that annually, about 5.2 million medical errors happen in India and the related cost with medication such errors has been estimated to be $42 billion US dollars globally. Medicine administration without harm was launched in March 2017 under WHO's Third Global Patient Safety Challenge to look for solutions for the challenges that healthcare system faces in reducing the errors in medication. The aim is to reduce medication-related harm by 50%, globally within next 5 years.

This literature review covers the available advancements for making BVI patients' life easy like use of Braille on medical packs to assist BVI patients, assistive

technologies for assistance to BVI patients & how various countries government are forming policies in various countries for use of Braille as mandatory on medical packs.

Braille is the globally widespread writing and reading system for visually impaired and blind people. The Braille system was founded by Louis Braille (1809 – 1852), in 1825 who himself was blind and lived in France. Braille itself is not a language but it's just another way to write and read a language. Braille contains of arrangements of dots, making up the letters of the numbers, alphabet & the punctuation.

Studies have shown the validity of using Braille to improve literacy in the visually impaired. Braille is the only known system through which people with visual impairment or blindness can read, write and learn. Few studies have shown the effectiveness of successfully rolled out prescription using Braille as an efficient method in attending the key challenges to medicines administration safety with the blind or visually impaired persons.

On the other hand, there have been numerous assistive technological devices for visually impaired and blind individuals to support timely and accurate medication but most of them have only been piloted and not widely commercialized. Cost and availability may be a limitation, but explorations are still ongoing, and future may be brighter with affordable solutions.

Various studies have highlighted the importance of assistance as social situations in recent past like COVID-19 pandemic has taught us that a sudden interruption of assistance to these susceptible groups of individuals will have a grave impact on their

health and overall wellbeing in daily life activities, livelihood, socio-economic and finally pose a challenge their life quality and may even put them in danger for lives.

India has one third of blind population and has an inclusive national policy for disabled. Braille may be a basic skill tool to manage quality of life with independent medication, health care product administration. People who are severely visually impaired or blind face numerous problems in their daily lives. This is particularly true there are no facilities are provided to meet their special needs. Only few studies have investigated the problems faced by BVI (blind and visually impaired) individuals in India and their needs in relation medication.

In terms of Policies governments have recognized the gravity of situation and according to the stages of development authorities are drafting policies and implementing, however deep country level requirements need to be gauged. Organizations and regulatory authorities in countries play very a essential role in addressing to the needs of regulatory procedures related to drug development in country.

European Union has directive for pharmaceutical packs mandating the use of braille label and most of the countries have already executed it, pharmaceutical companies in India did not follow suit. US Access Board, which is a coordinating body among federal authorities representing people with all disabilities has issued a non-binding guidance note and other few means of access over braille, however FDA did not issue obligatory regulations. Other countries in region have been varied stages in adapting the regulations.

Indian National Policy highlights to avail barrier-free atmosphere enabling disabled people to move about freely and safely and use the facilities within the constructed conditions. The aim of obstacle free design is to provide a setting that supports the independent working of individuals so that they can contribute without much assistance, in daily activities.

National policy also encourages research enabling improvement of life quality of disabled persons, any research studies will be supported on their cultural and socioeconomic context, possible cause of such disabilities, early childhood education intervention methods, user-friendly aids and uses and all matters linked with disabilities which will meaningfully alter the life quality and civil society's ability to act to their worries. Family member’s consent is mandatory wherever persons with such disabilities are involved to such research initiatives.

In India introducing Braille on all medicines packaging has not been received well due to the cost being a major deterrent in relation to poor socioeconomic conditions. One of the challenges with Braille for labelling is that it takes up a lot of space and therefore only some information can be given.

In an article Sharma, (2013), MK Banerjee voices that Braille on medicinal pack is a pricey option, apart from lack of regulations, price plays an important role. In response to a query posed on whether Indian pharmaceutical companies are lagging far behind in accepting advanced packaging technologies, MK Banerjee, Director, C&I (Global), Essel Propack explains that he believes that Indian companies are quite aware of these technological gaps and new scientific requirements to produce new generation

packaging material for Pharmaceutical industry. On the other hand, price control regulations are impeding investments in new manufacturing plants and new machines to produce newly developed packaging material. Cost of new advanced technology must be connected-in to fall within the formula of price control.

In an article (Sharma, 2013), Kanetkar states that there are only few pharmaceutical companies that are considering to adapt these technologies. Braille label on pharmaceutical packs is not a FDA mandate in India. The government of India is taking ongoing steps towards initiating braille script on pharma packs through government and non-government agencies. In India only few blind or visually impaired people can read braille. Since the braille on pharma packs is not mandatory in India, the technological advancements as well as learning of the visually impaired and blind in braille is minimal. There are 3-folds industrial level challenges for braille or pharmaceutical packaging. Initially, there is an extra cost in improving the packaging line machinery and be braille compliant. Then, braille dots height need to be sufficient enough to be easily read, but not that high that it punches holes in the packaging. The company must ensure that braille dots are not missing or malformed on surface, while ensuring accurate spacing between the dots. And at last, control over quality is particularly significant in braille packaging, one misplaced dot may lead to costly lawsuits, product recalls and tarnish the brand image in big way. Hence Industry needs sufficient inputs for successful implementation.

Conclusion

Through this review of literature, it can be concluded that we are primarily focused on understanding the utility of Braille prescription in patients to study reducing

medication errors through customized Braille prescription studies and some studies on Braille or text reading technologies. Only few studies have tackled the issues of safety and medication usage pattern in visually impaired and blind patients, or the need to use Braille labelling over medicines packs distributed to these patients. People with visual disabilities are more exposed to pandemic and endemic conditions than people without visual disability. Not much research in India has been done in Braille labelling requirements on medical packaging.

Through this research it is intended to demonstrate that if there is need of Braille labelling on medical and healthcare products packaging to improve medical care access effectively to BVI (Blind & Visually impaired) patients and hence quality of life (Independence, self-esteem & inclusivity). Mandatory implementation of Braille labelling needs to be gauged with broader picture of readiness of BVI population and if other technological advances are making way to serve the purpose better then adapting cost and efforts intensive Braille labelling initiative.

What is missing from the past studies is assessment of the need of Braille labelling on medical or healthcare products in India. There is need of research in Braille labelling requirements on medical and healthcare packaging from the viewpoint of end user (BVI) or direct caregiver by validating the hypothesis that Braille labelling will enhance their independence, help in reduction of accidental misuse of medicines and it is very important tool for BVI population.

Overall, outcome of this study may provide the inputs to industry to assess the need to adapt Braille labelling on medical and healthcare products packaging to improve

medical access effectively to BVI patients and hence quality of life and government to think in the direction of Braille labelling policy including motivational measures for industry to adopt the same.

CHAPTER III:

METHODOLOGY

3.1 Overview of the Research Problem

Here the research problem focuses on exploring the impact on variables like gain in independence, reduction of accidental misuse of medicines, influence on purchase decisions, and importance with adaption of Braille labelling on medical packaging through the study of opinions and perspectives of blind and visually impaired (BVI) individuals and caretakers regarding Braille labelling on medical & healthcare products packaging in India. Outcome of research will indicate if implementation of Braille labelling on medical products has the potential to considerably impact healthcare accessibility and inclusivity for the BVI community. Understanding the attitudes and experiences of BVI individuals and caretakers towards Braille labelling is critical for stakeholders in taking decisions in upgrading to a more inclusive healthcare environment. Also, another viewpoint needs to be deeply understood i.e. challenges which Industry may face in adopting to this initiative in their production process.

Key aspects of the research problem**:**

Accessibility to healthcare resources: The research problem results may help in addressing the issue of healthcare accessibility and safety use to reduce accidental misuse for the BVI(blind and visually impaired) individuals in India. It seeks to understand how the presence of Braille labelling on medical care products packs can enhance the independence & safety of BVI patients when managing their healthcare needs.

Impact on purchase decision-making:

The research problem delves into how the availability of Braille labelling influences the decision-making process of BVI individuals and caretakers on buying when choosing medical & healthcare products. It explores whether Braille labelling affects their preferences and usage patterns.

Inclusivity & Empowerment:

By studying the opinions of BVI individuals and caretakers, the research problem stresses to explore the value of Braille labelling availability for inclusivity and empowerment for the visually impaired community. It seeks to identify how Braille labelling is a need which can positively impact their healthcare experiences, parity and overall well-being.

Industry practical challenges:

The study considers the practical challenges faced by BVI individuals when using medical care products without accessible labelling. Identifying these challenges like identification & differentiation in similar packs can inform prospective improvements in product packaging design, label information and accessibility. On the other hand, what are the practical challenges posed in front of pharmaceutical industry to swiftly implement this initiative addressing a social cause.

This research problem targets to contribute to the generation of evidence-based strategies that promote the widespread adoption of Braille labelling on medical & healthcare products packaging in India. By addressing the needs and preferences of the BVI community, the study seeks to expand healthcare accessibility, improve patient-centric care, and adopt a more inclusive healthcare environment in India.

3.2 Theoretical Construct's Operationalization

Operationalization of theoretical construct involves defining and measuring the concepts or variables derived from the "Ecological systems theory" to evaluate the opinion of the BVI population, caretakers and experienced industry professionals regarding Braille labeling on medical packaging.

Ecological Systems Theory: Applying here ecological systems theory in this context in understanding the interaction between environments and individuals, emphasizing how the current social ecosystem in India is impacting the perceptions of Braille labelling on medical packs for BVI (Blind and visually impaired) individuals.

Identification of Theoretical Constructs: key constructs within the ecological systems theory relevant to this study:

- Microsystem: Immediate environments such as home or workplace.
- Mesosystem: Interactions among microsystems.
- Exosystem: Outside settings or environments that indirectly influence individuals, such as societal attitudes and policies.
- Macrosystem: Broader cultural and societal contexts.
- Chronosystem: Advance tecnologies and other aids

This involves defining specific variables and indicators that represent each construct:
Microsystem: Here we will study if communication and discussions are going on as information flow on Braille labelling on medical packs within individual's immediate living environment, including their home, schools, and workplace.

Mesosystem: Here we will study if any cross communication or information flow is present for awareness on Braille labelling on medical packs in society.

Exosystem: Here we will study the societal attitudes and policies related to accessibility of medical packs, Braile labelling for blind and visually impaired individuals.

Macrosystem: Here we will study broader cultural norms and values regarding disability rights and accessibility of medication .

Chronosytem: Literature review outcomes and during Interview observations will contribute to this input on accebility support.

Measurement Instruments:

The instruments or methods that will be used to measure each construct.:

- Interviews through semi-structured questionnaires to assess opinions and preferences regarding Braille labeling on medical packaging & to explore challenges related to accessing medical information.
- Observations of participants interactions through their opinions on Braille-labeled packaging aiding ease in their lives making them feel independent and inclusive.

Data Collection Procedures: Data will be collected through Structured interviews with BVIs, caretakers and survey questionnaire with Industry experienced professionals to collect their opinions.

Plan for analysis of data: The collected data need to be analyzed to address the questions of research or hypotheses. This will involve qualitative analysis of interview transcripts and survey data.

Reliability & Validity: The reliability and validity of the data collected for operationalized constructs through measurement instruments may be checked with inter-rater reliability assessments.

Limitations: This research study will cover small cohort, acknowledging any potential constraints associated with the operationalization of theoretical constructs and data collection methods.

3.3 Research Purpose and Questions

The aim of this research is to do exploration and understand the opinions, preferences, and experiences of BVI (Visually impaired and blind) patients and their caretakers regarding the implementation of Braille labelling on medical care products packaging in India. The study targets to assess the effect of Braille labelling on healthcare accessibility, patient safety, decision-making, and whole well-being of the blind or visually impaired community in India. By investigating these perspectives, the research takes to contribute to the development of a more inclusive healthcare system that caters to the unique requirements of BVI individuals.

Main Research Questions:

For BVI (Visually impaired and blinds) Individuals

1. The research needs to validate the hypothesis that implementation of Braille labelling on medical & healthcare packs will enhance independence of BVI patients in managing their healthcare needs and administering medications?

2. Validate the hypothesis, that Braille labeling on medical & healthlthcare care products packaging will help in reduction of accidental misuse of medication (by individuals who are visually impaired or blind).
3. Validate the hypothesis that the introduction of Braille labelling on medical care products packaging will influence the purchasing behavior of BVI patients even with marginal increase in price?
4. Validate that it is important to have Braille labelling for BVI patients on medical packaing.

For caretakers:

1. Validate the hypothesis that implementation of Braille labelling on medical & healthcare packs will enhance independence of BVI patients in managing their healthcare needs and administering medications?
2. Validate that the introduction of Braille labelling on medical care products packaging will influence the purchasing behavior of caretakers even with marginal increase in price?
3. Validate that it is important to have Braille labelling for BVI patients on medical packaing

Sub-questions of research:

1. What are the perceptions of BVI patients (with Braille literacy) about the current accessibility of medical care products in Indian context?
2. Explore the practical problems encountered by BVI patients in using medical care products that lack accessible labelling?
3. Do you as caretakers feel that it is challenging for BVI patients to identify/ differentiate the similar medical products

4. From Industry perspective, what are the main operational challenges the medical care product industry might face in implementing Braille labeling on packaging in India?
5. From Industry perspective, what are few technical challenges might companies encounter when integrating Braille labeling into their packaging processes?
6. Will Braille labeling affect the overall design and aesthetics of medical product packaging?
7. To your knowledge, has industry communicated or started any interactions with blind or visually impaired patients or their caretakers or NGOs or heard from Indian drug authorities regarding Braille labeling subject on medical care product packaging in India?
8. Are there any existing policies or regulations related to Braille labeling on medical packaging in India?

With answers to these research questions, the research targets to generate valuable insights that can be used by policymakers, healthcare providers, and manufacturers to take informed decisions regarding the adoption of Braille labelling on medical care products in India. The research will provide contribution to the advancement of a healthcare ecosystem which is inclusive and addresses the needs of all disabled individuals, despite of visual impairment, fostering equitable access to healthcare resources to improve the life quality for the BVI community.

3.4 Research Approach & Strategy

Research method utilized in this study is literature review and opinion survey with structured questionnaires through the interviews and direct online data collection. The perceptions of Braille labelling on medical care & healthcare packaging will be studied

from BVI (Blind and Visually impaired) population and caregiver's opinion for variables like Independence, reduction in accidental misuse, importance, and influence on purchase decisions to have access, parity, and quality of life. Applied approach is qualitative. A qualitative method is considered to be a naturalistic which is interpretative approach relating to the understanding the meanings which people usually attach to experiences (decisions, actions, beliefs, values, etc.) within their own social worlds(Snape and Spencer, 2003). The descriptive approach used to collect data from or about people to describe, compare, or explain their feelings, knowledge, values and behaviors is known as survey research(Fink, 2019). To explore the research questions initially Mixed Methods Approach was thought of but considering the challenge that BVI (blind and visually impaired) population can't respond to openly distributed survey's easily and need assistance hence, qualitative approach was finalized as its feasible and convenient with data collection with face-to-face interviews and telephonic interviews through questionnaires and observations. It is very pertinent to use qualitative methods approach for this study for research because it is to learn in the field is about challenges faced by a specific set of population due to visual impairment or blindness and it is needs to be investigated that the particularity of application of Braille labelling on medications helping in independence & safety of use. The particularity in this study may be achieved by conducting structured qualitative interviews with a set of Blind and Visually impaired people and caretakers. This will help to achieve in-depth insights directly from affected population and experienced caretakers as qualitative research. Also, help from NGOs or collaboration group may be taken if there is any challenge in accessibility to subject group arises. Inputs on policy on Braille labelling will be taken from policy makers (drug authority-CDSCO, India) with email or telephone and thorough check on official authority website where all applicable country policies are available for public and

industry to follow as current reference. Opinion of atleast 30 experienced Industry professional will be taken on the potential operational & technical challenges faced by industry to implement Braille labelling on medical care and healthcare packaging.

3.5 Data Collection Methods

Collecting data from blind and visually impaired patients and caretakers on Braille labelling on medical care products packaging in India requires a thoughtful and inclusive approach. Since the target audience faces unique challenges, it's essential to use data collection methods that cater to their needs. Below are proposed methods:

1. In-person Interviews: Conduct face-to-face interviews with interested participants to collect indepth insights into their opinions, preferences, and challenges related to Braille labelling on medical products. Make sure the interviews are conducted in a private and comfortable setting.
2. Phone Interviews: Offer phone interviews as an alternative for those who may find it challenging to participate in person. Provide any necessary assistive technologies or resources during the phone call to accommodate the participants' needs.
3. Interviews (for Care Givers): Conduct face to face interview or telephonic interview as per the comfort and availability of people.
4. Create online survey questionnaires for experienced industry professionals to provide their opinions.
5. Collaboration with NGOs and Support Groups: If need be, partner with local NGOs or support groups that cater to BVI (blind and visually impaired) individuals. They can help in connect with potential participants and ensuring the data collection process is inclusive.

3.6 Data Analysis

This study will use thematic analysis method, which is a flexible and widely used method for analyzing qualitative data set, particularly in interview-based research to recognize patterns, insights & themes from data collected through interviews.

The deeper understanding will be provided by qualitative findings about the reasons behind survey responses and throws light on the experiences, perceptions, and aspirations of the subject participants. Collected data will be organized and coded systematically to facilitate analysis.

Analysis will start by generating initial codes by identifying and labeling meaningful portions of data that portray key concepts, ideas, or patterns within the interviews. Coding will cover both explicitly stated content and underlying meanings or interpretations within the data.

We will organize and collate similar or related codes into potential themes and will Look for patterns, similarities, or recurring concepts across the data. A preliminary list of themes will be created based on the grouped codes where each theme will represent a coherent pattern or idea that emerges from the data.

Then themes will be revised and refined from the preliminary list of themes. Themes will be merged, split, or reframed as needed to ensure they are distinct, comprehensive, and reflective of the interview content.

Then clear themes will be defined by articulating its central concept by

developing a concise and descriptive name for each theme that capture its essence. Ensuring that each theme is meaningful, relevant, and grounded in the interview data.

Themes will be mapped out for reltionships using visual tools such as mind maps or diagrams. This can help visualize connections, hierarchies, or overlaps between themes. Thematic map will be reviewed to ensure coherence and clarity in the arrangement of themes.

Thorough review of the themes will be Conducted to refine and finalize themes. Seek input from colleagues or peers to validate the identified themes and ensure their robustness.

Finalized themes will be documented the in a coherent narrative that synthesizes the key findings from the thematic analysis. quotes from the interview will be provided to support each theme and demonstrate its relevance. Interpret the themes in relation to the research objectives, existing literature, and broader implications.

We will imply peer debriefing or member checking to increase the trustworthiness & validity of the results.

Triangulation: We will consider incorporating multiple sources of data, such as interviews with BVI (blind & visually impaired) individuals, interviews with caregivers, educators, instructors and collected observations in relevant settings, to enrich the study findings and enhance credibility.

3.7 Population and Sample

Population: The population for the opinion survey comprises BVI (blind and visually impaired) Individuals, caretakers residing in India and experinced industry professionals. This includes persons who are completely visually impaired and blind. Caretakers are included as they may have valuable understandings into the needs, perceptions and experiences of the BVI they support. Industry experts to opine on challenges posed to industry to adopt Braille labelling. Indian drug authority to revert on any Braille labelling policy if exists.

Sample Size: The arrive to determination of appropirate sample size which depends on numerous factors which includes the margin of error, level of confidence desired, and the heterogeneity of the population. As there is no fixed percentage for the prevalence of visual impairment in India, it is challenging to estimate the exact population size at a given time point.

To achieve a representative sample that can provide meaningful and statistically valid results, a larger sample size is generally recommended but considering the particularity of BVI (blind and visually impaired) population segment, which is small in numbers, diversity of experiences and perspectives among BVI patients and their caretakers, problem at hand, a sample size of atleast 30 to 100 participants may be appropriate. For this study, around 60 BVI individuals, 30 caretakers & atleast 30 experienced industry professionals will be considered for participation.

3.8 Recruitment and Participation

To reach potential participants, researcher will collaborate with healthcare facilities, support organizations, training centers, schools, universities for the visually impaired, dedicated to visually impaired and blind individuals, caretakers & online data. It is essential to make the survey/ questionnaire accessible, offering multiple formats, including online forms, phone interviews, to accommodate different needs.

Moreover, researcher will obtain due permissions from involved institutes, and informed consent from all subject participants to ensure their voluntary participation and promising confidentiality and anonymity in data collection and reporting.

By employing a carefully selected and representative sample, the survey will yield valuable insights into the opinions and experiences of BVI patients and their caretakers regarding Braille labelling on medical care products packaging in India. The findings from this sample may generate a better understanding of healthcare accessibility for the visually impaired community and inform strategies for improving healthcare experiences in India.

3.9 Participant Selection

Participant Selection Criteria: Participants should include individuals who are visually impaired or blind, ranging from individuals with complete blindness to those with varying degrees of visual impairment. Caretakers of visually impaired individuals should also be included in the sample.

Age: The sample will capture a diverse range of ages 18 years onwards to capture insights from both younger and older visually impaired individuals and caretakers.

Geographic Diversity: Participants should be recruited from different locations to ensure

a broad representation of opinions and experiences.

Language Proficiency: The survey interview will be conducted in the required languages to accommodate participants' language preferences and ensure inclusivity.
Diversity of Settings: Participants will be recruited from various settings, including rehabilitation centers, blind schools, and open society.
Duration of Visual Impairment: Participants who have experienced visual impairment for different durations, including congenital, acquired, and progressive cases, should be included as per availability.
Caregiver relationship: Caretakers will be integrated in the sample, representing various caregiver relationships, such as parents, siblings, spouses, instructors, teachers or professional caregivers.
Experience with Braille: The sample will include individuals with familiarity and experience with Braille as a tactile reading system.
Accessibility Needs: All efforts will be made to accommodate the accessibility needs of participants, providing options for accessible survey formats, such as questionnaires & interviews in required language.
Informed Consent: Participants must provide informed consent to ensure their voluntary participation and willingness to share their opinions.

Above criteria will be adhered to the participant selection, the opinion survey will capture a diverse range of perspectives, experiences, and opinions from blind and visually impaired patients and their caretakers & Industry experienced professionals. The inclusion of participants with different backgrounds and characteristics will enrich the data and provide a comprehensive understanding of the topic, allowing researcher to

carve out meaningful conclusions and make learnt recommendations to enhance healthcare accessibility for the visually impaired community in India.

3.9.1 Instrumentation

To gather data on the opinions of blind and visually impaired (BVI) individuals and their caretakers regarding Braille labelling on medical care products packaging in India, comprehensive questionnaire instruments will be employed through interviews. The questionnaires will consist of various question types to capture different aspects of participants' attitudes, perceptions, aspirations, and experiences.

Demographic Information:

Age- Open-ended question to capture the age of the participant.

Gender- Multiple-choice question with options for male, female, and other.

Visual Impairment duration- Multiple-choice question to identify participants with visual impairement duration.

Caretaker role- Multiple-choice question to determine the participant's role as a caretaker in ecosystem.

Measure attitudes towards Braille Labelling through Likert-scale questions: Participants will rate their agreement with statements related to the usefulness, practicality, independence, safety, purchase decision and importance of Braille labelling on medical care products packaging.

Awareness and Usage of Braille: Multiple-choice questions: Participants will indicate their familiarity with Braille as a reading system and whether they have encountered medical care products with Braille labelling.

Impact on healthcare accessibility through open-ended questions: Participants will be encouraged to share their experiences and perspectives on how Braille labelling affects their independence, safety, and accessibility to medical care products.

Decision-Making and Usage Patterns through Likert-scale questions: Participants will rate their likelihood of choosing medical products with Braille labelling over those without Braille labelling in various scenarios.

Practical Challenges: Participants will be asked to identify specific challenges they face when using medical care products without Braille labelling.

Accessibility Preferences: Participants will indicate their preferred formats for surveys and any specific accessibility needs they have.

Informed Consent: Participants will provide informed consent at the beginning of the survey, confirming their voluntary participation and agreement to share their opinions.

Interview Administration: Researcher will deploy the survey instrument as questionnaire with a combination of Likert-scale, multiple-choice and questions which are open-ended.

Accessibility Considerations: Reasercher will ensure to accommodate accessibility needs of participants by providing assistance or alternative survey formats as required.

Quality Control & Data Validation: Apply data validation checks to make sure the

accuracy and integrity of responses. Monitor survey completion to detect any potential errors or incomplete submissions.

Data Anonymity and Confidentiality: Ensure to all participants that all responses will remain anonymous and confidential throughout the research process.

Data Recording: Record and store survey responses securely and in a manner compliant with data protection regulations.

Ethical Considerations: Comply with ethical guidelines and obtain necessary approvals from schools or rehabilations centres

Subgroup Analysis: Conduct subgroup analysis to explore variations in opinions basis specific features, such as age, level of visual impairment, or caregiver relationship. This analysis will help identify unique challenges and perspectives within different subgroups.

Data Visualization: Key findings will be presented using graphs, charts, and tables to visually represent survey results and highlight significant patterns and trends. Visualizations will be used to illustrate the distribution of responses to Likert-scale questions and other categorical variables.

The analysis will provide valuable insights to inform policy, practice, and interventions aimed at enhancing healthcare accessibility and inclusivity for the visually impaired community.

3.9.2 Limitations of Research Design

Bias in Sampling: The survey study may suffer from sampling bias due to the challenges of reaching a truly representative sample of blind and visually impaired patients and their caretakers in India. Participants who are more connected to healthcare facilities or support organizations might be overrepresented, leading to potential limitations in generalizing the findings to the broader population of visually impaired individuals in India as Braille literacy itself is a major issue.

Bias in self Self-selection: While participation in the survey is purely voluntary, there is a risk of bias in self-selection. Participants who hold sound opinions or experiences related to Braille labelling may be more likely to participate, leading to potential overrepresentation of certain viewpoints and experiences.

Bias in Social desirability: Subject participants might feed socially wanted responses, especially in self-report surveys or face to face inteviews. They may feel inclined to present self and their viewpoints in a positive light, leading to potential bias in the data.

Language and Literacy Barriers: Participants with limited literacy or language barriers may find it challenging to participate in the survey, potentially excluding certain subgroups of the visually impaired population.

Recall bias: Participants might struggle to recall specific instances or experiences related to Braille labelling, which could affect the accuracy and completeness of their responses.

Subjective interpretation of open-ended responses: Thematic analysis of qualitative data is subjective and might vary based on the researchers' interpretations, potentially

introducing bias in the analysis process.

Limited contextual information: The opinion survey may not capture the full context and complexities of participants' opinions and experiences related to Braille labelling on medical care products packaging.

Lack of longitudinal data: The opinion survey provides a view of participants' opinions at a specific point in time, but it may not capture changes in experiences & attitudes over time.

Cultural and regional variations: The survey's findings may not fully account for cultural and regional variations within India, as perceptions and experiences related to Braille labelling might differ across diverse communities.

Limited caretaker perspectives: While including caretakers in the survey provides valuable insights, their perspectives might not entirely represent the encounters and opinions of visually impaired individuals themselves.

Despite these limitations, the survey will present valuable understandings into the opinions and experiences of BVI (blind and visually impaired) individuals and caretakers regarding Braille labelling on medical care products packaging in India. Researcher acknowledges and will try to address these limitations while interpreting and discussing the opinion survey's findings. All possible efforts will be taken to improve accessibility, reach, and representation to enhance the study's validity and reliability in the given

context.

3.9.3 Conclusion

In conclusion, the methodology employed in the opinion survey on "Opinion of Blind & visually impaired patients & caretakers on Braille labelling on medical care products packaging in India" will provide valuable perceptions into the perspectives and experiences of the visually impaired community regarding Braille labelling. By adopting a qualitative method of research, the research aimed to capture qualitative data to acquire a comprehensive knowledge of the research problem.

The survey questionnaires for interviews to be successfully applied with a diverse sample of blind and visually impaired patients and their caretakers in the most populous state, Uttar Pradesh of India in selected institutions. The inclusion of different levels of visual impairment, age groups, and caregiver relationships should contribute to a richer dataset, enhancing the applicability and generalizability of the findings.

The qualitative analysis, specifically the thematic analysis of `both closed ended & open-ended responses to provide rich and nuanced understandings into the issues faced by visually impaired and blind individuals when using medical care products without Braille labelling. Moreover, the narratives shared by participants should shed light on the practical implications of Braille labelling on healthcare accessibility and their overall quality of life.

However, the methodology also has its limitations. Sampling and self-selection bias may affect the representativeness of the sample, limiting the generalizability of the

findings. Additionally, the subjective nature of qualitative analysis may introduce the potential for researcher interpretation bias in the identification of themes.

Despite these limitations, the survey will serve as a valuable preliminary point for recognizing the importance of Braille labelling accessibility in healthcare for the visually impaired community in India. The data collected from this survey can serve to inform policy proposals and healthcare systems aimed at promoting inclusivity and patient-centered care.

Researchers can build upon these findings through future studies, employing longitudinal designs and exploring the impact of Braille labelling on specific medical care products. Addressing the limitations and continuing to ensure accessibility for visually impaired participants will further enhance the rigor and validity of research in this area.

In conclusion, the survey's methodology may provide a solid footing for recognizing the opinions and experiences of blind and visually impaired individuals and caretakers regarding Braille labelling on medical care packaging in India. The study will influence to the broader discussion on healthcare accessibility and the development of inclusive practices for the visually impaired community, fostering positive change and improved healthcare experiences for all individuals.

CHAPTER IV:

RESULTS

4.1 Introduction

This research study presents the results of data collection through the face-to-face interviews and telephone interviews among a cohort of 60 individuals comprising both blind and visually impaired subjects. We also investigated into the experiences and perspectives of 30 caretakers of BVI individuals through face to face and telephonic interviews, pointing to shed light on the challenges and opportunities for the BVI population as a second layer of information to strengthen the findings & observations. This research effort was undertaken with the utmost ethical considerations, having obtained due permissions from the Institutions, Shakuntala Misra National Rehabilitation University, Lucknow, UP, India and NAB (National Association of Blind), state branch, Lucknow, UP, India. By uncovering the findings, we want to inform stakeholders to think about support services, interventions, and policies aimed at enhancing the support available to BVI (blind and visually impaired) individuals while in parallel acknowledging industry challenges to explore mitigation.

Below are the outcomes derived from the collected data, throwing the light on the diverse experiences, challenges, and aspirations of blind and visually impaired individuals.

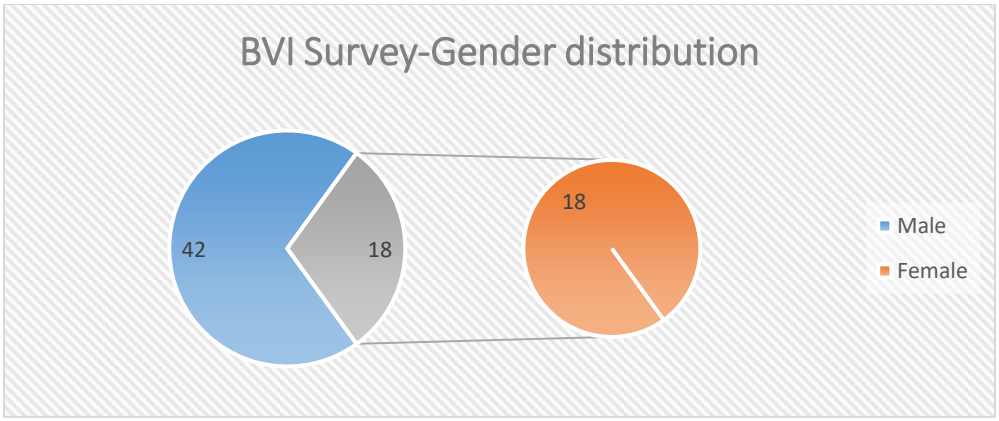


Figure 6
Showing gender distribution of 60 BVI individuals interviewed

With a total of 60 BVI individual's interviews selected randomly in a training school setting & telephonic interviews of which 42 male and 18 female participants contributed their viewpoints, this finding shed light on the multi-layered nature of challenges experienced by both genders in handling their medication regimens. By analyzing the perspectives shared by both genders across different age groups, we may aim to detect commonalities and unique concerns as patterns, themes & observations.

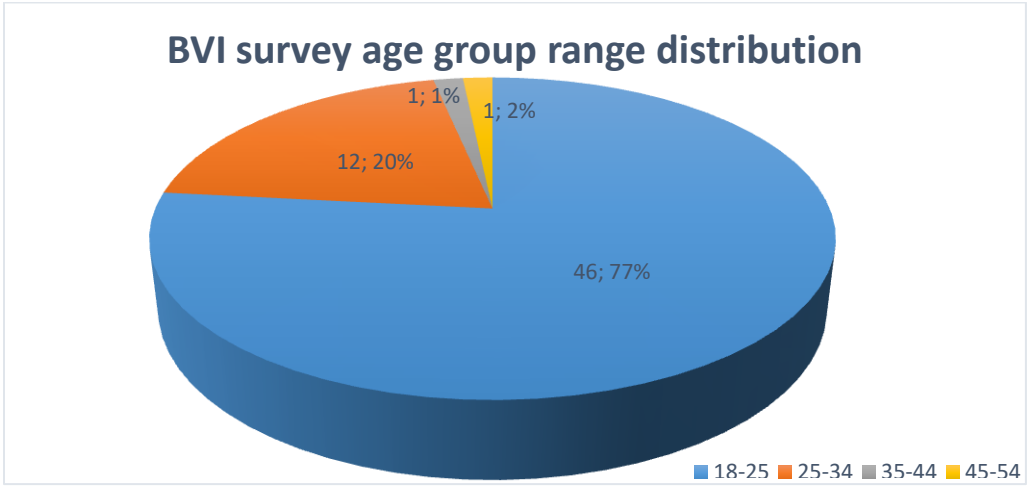


Figure 7
Showing the distribution of age group for interviewed BVI individuals.

While conducting this study, we came across that mostly the subjects were college attendees between age group18-34 years which gave a sense that this age group & their caretakers understand the importance of Braille training and other social skills development to lead their life as inclusive part of society. Almost all individuals of both genders were active, knowledgeable, highly participative, and inquisitive for these interviews and clearly expressed that they came across for any such initiative for the first time where someone is enquiring about their difficulties in administration of medication.

Explicitly, we sought to understand the scattering of people based on the onset of their visual impairment and its correlation with the acquisition of Braille education. By elucidating this relationship, we aimed to perceive the patterns in the age at which individuals acquire Braille literacy, thereby some information can be provided for initiatives aimed at enhancing educational support for the BVI community as Braille education as a need; going to be a big ask for uniform implementation of any such support system in society to be served through braille. It may create a big positive impact.

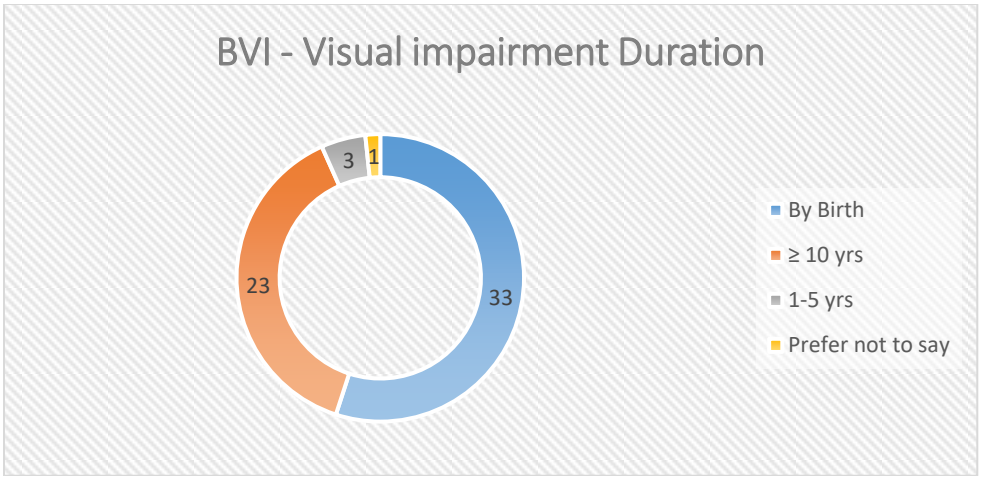


Figure 8
Showing the onset of duration of acquisition of blindness

In this section of the report, we present the findings derived from inquiries into the duration of visual impairment among survey participants, distinguishing between those who were suffering from visual impaired or blind from birth and those who acquired their condition later in life. As a finding we saw that more than 50% individuals were blind by birth and around 38% acquired the blindness or visual impairment for more than 10 years. So if we co-relate this prevalence with the above age group distribution then it comes out that mostly blindness is occurring at the early stages of life, hence any interventions on Braille awareness and education are needed from early stages to gain the benefits for significant duration in lifetime of BVI individuals.

Medication management is a critical aspect of healthcare for individuals across various demographics, including those with visual impairments. In this study, we examined the prevalence of medication consumption among blind and visually impaired individuals and the challenges they encounter in identifying and accessing their medications effectively. The findings presented here are derived from a survey conducted among 60 participants within this demographic area, shedding light on their experiences and perspectives regarding medication usage and accessibility.

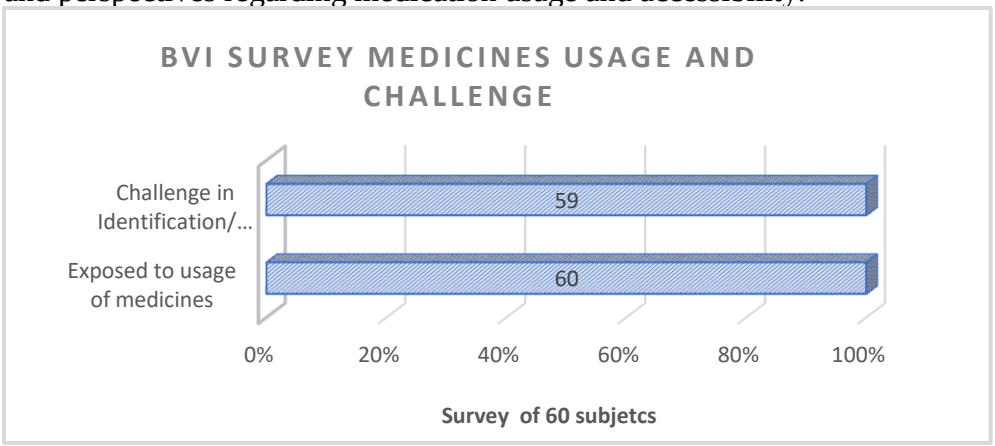


Figure 9
Showing BVI individuals with medication exposure and specific challenges

Results indicate that 100% interviewed individuals, 60 out of 60, reported consuming medications regularly or consumed at one point of time for a range of health conditions, spanning from common ailments to more serious medical concerns. This qualifies this cohort to undertake this opinion survey. This high prevalence underscores the magnitude of knowing and attending the unique needs and challenges faced by BVI (blind and visually) impaired individuals in managing their medication regimens effectively.

Furthermore, the survey revealed that an overwhelming majority of participants almost 98%, with 59 out of 60 respondents, expressed facing challenges in the identification, differentiation, and access of their medications. These challenges may stem from various factors, including inaccessible medical packs, identical packs, inadequate labeling and support on external assistance for medication management. The findings underscore the urgent need for interventions and support mechanisms aimed at improving medication accessibility and management for blind and visually impaired individuals. By addressing the identified challenges, healthcare providers, policymakers, and advocacy groups can work collaboratively to enhance the overall healthcare experiences and outcomes for this population.

Industry's view through experienced professionals opinion is also very important here to understand the perception and practical challenges in adaptation of Braille labelling on medical & healthcae packs in India.

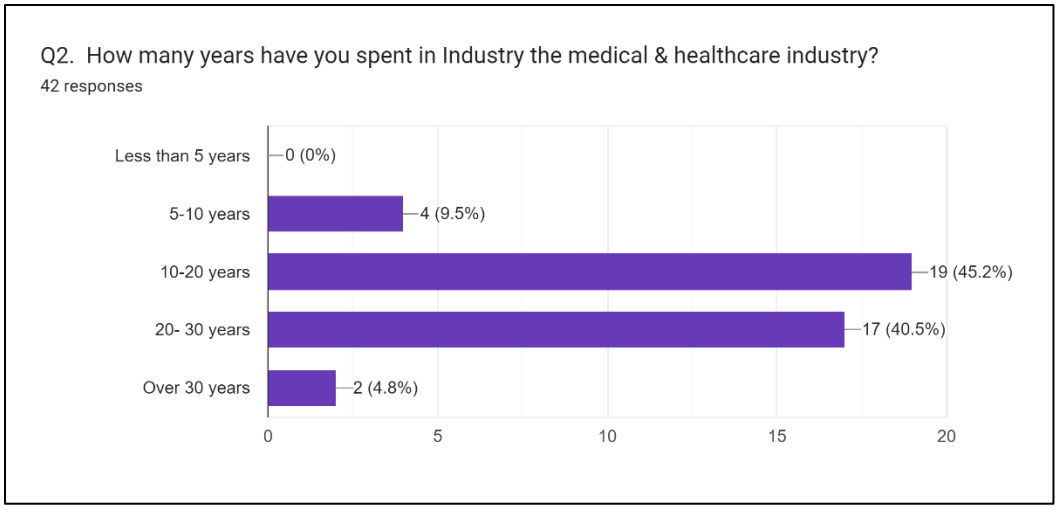


Figure 10
Showing the experience of Industry professionals

Opinion was collected through a structured survey questionnaire from 42 (target 30 professionals) pharmaceutical Industry professionals who deeply understand the importance of label and its implication on patients and regulations. Range of experience was minimum 5 years to over 30 years, so that professionals are in a position to opine appropriately .

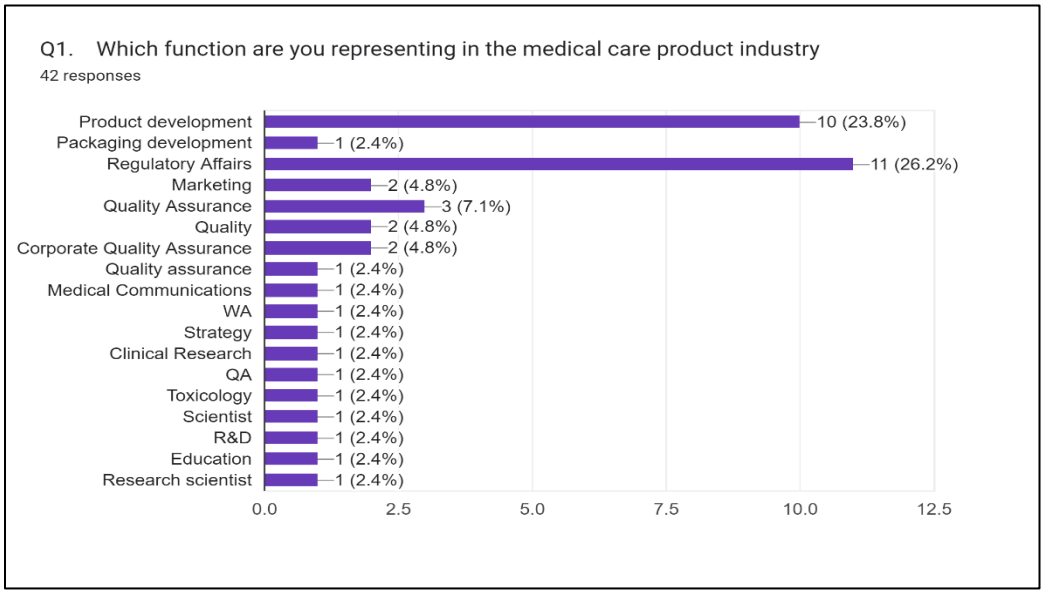


Figure 11
Showing the Industry professional functional diversity

Response was sought from key functions (Product development, Quality Assurance and Regulatory Affairs and few other functions) in the pharmaceutical industry who deal with the design, technical content, compliance and complexity of drug labels.

In the subsequent sections of this report, we delved deeper into the specific challenges reported by participants so that potential strategies and recommendations for mitigating these obstacles can be explored.

Through a comprehensive analysis of the interview & observation data as qualitative analysis, we aim to provide specific thematic patterns, themes providing insights that can advise policy decisions and drive initiatives aimed at nurturing greater inclusivity and accessibility in medication management for BVI individuals.

4.2 Research question one

For BVI (Visually impaired and Blind) Individuals:

Validate the hypothesis that implementing the Braille labelling on medical & healthcare packs will enhance independence of BVI individuals in managing their healthcare needs and administering medications?

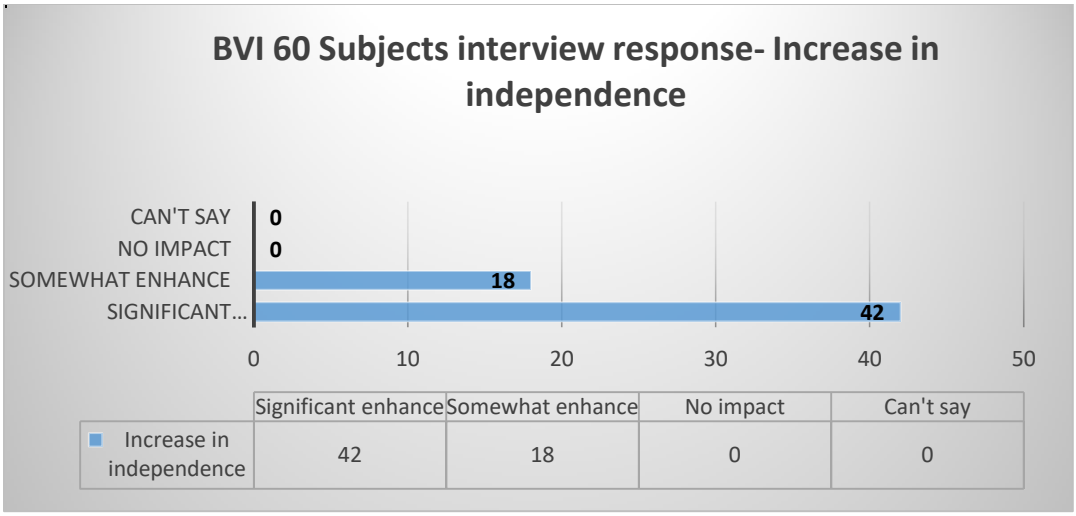


Figure and table 12
Showing response of BVI subjects on independence.

Data collected from interviews from 60 subjects in figure 12 shows on perception of enhanced independence speaks that 42 out of 60 see it as significant enhancement while 18 out of 60 see it as somewhat enhanced. Overall, enhancement of independence was perceived.

4.3 Research question two

For BVI (Visually impaired and Blind) Individuals:

Validate the hypothesis, that Braille labeling on medical & healthcare care products packaging will reduce accidental misuse by BVI individuals.

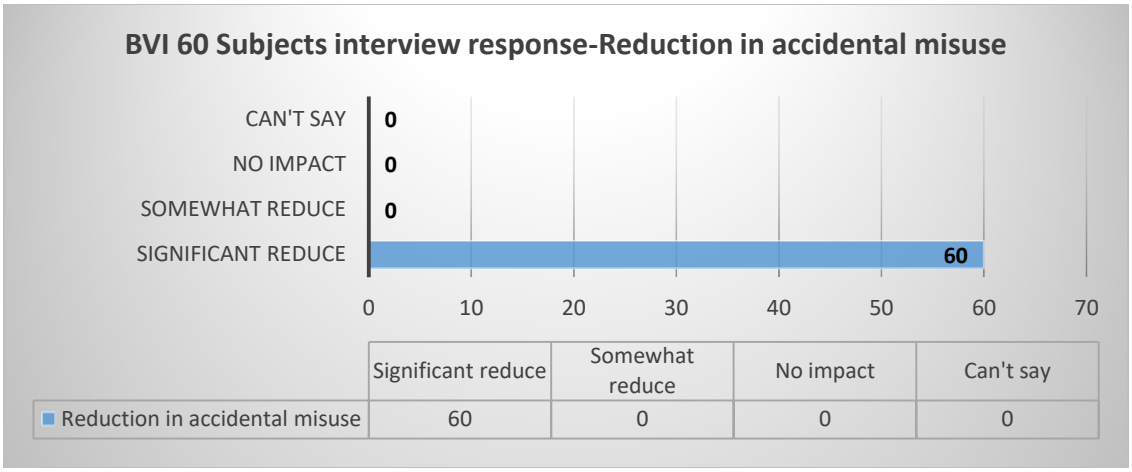


Figure and table 13
Showing response of BVI subjects on reduction in accidental misuse

Data collected from interviews from 60 subjects in figure 13 shows on perception of reduction of accidental misuse says that 60 out of 60 see it as significant reduction in accidental misuse.

4.4 Research question three

For BVI (Visually impaired and Blind) Individuals:

Validate the hypothesis that the introduction of Braille labelling on medical care products packaging will influence the purchasing behavior of BVI patients even with marginal increase in price?

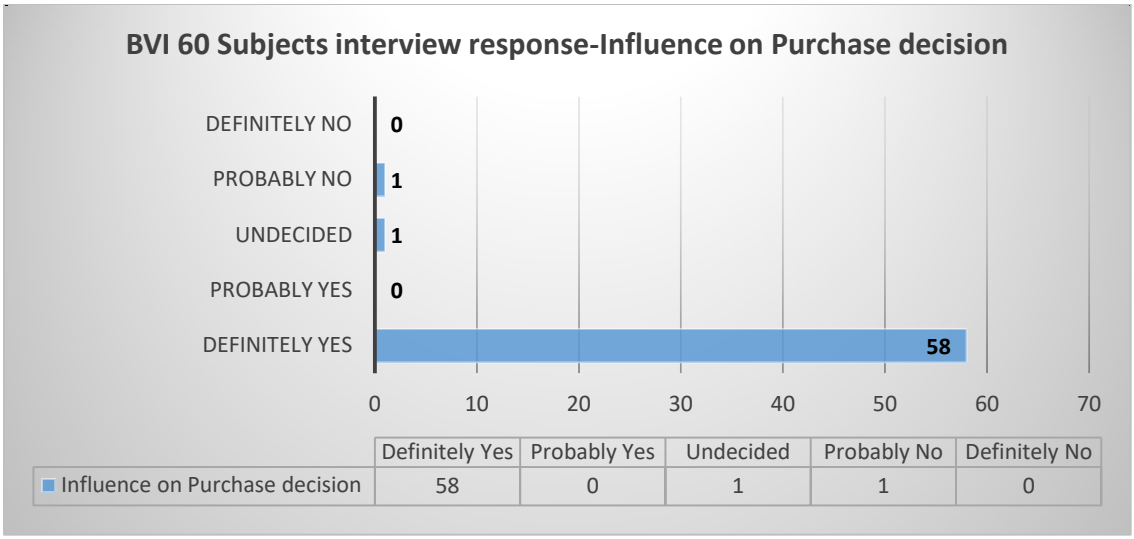


Figure and table 14
Showing response of BVI subjects on influence on purchase decision

Data collected from interviews from 60 subjects in figure 14 show on perception on influence on purchase decision says that 58 out of 60 see it as definite factor to positively influence the purchase decision. Only 2 out of 60 were doubtful.

4.5 Research question four

For BVI (Blind and Visually impaired) Individuals:

Validate that it is important to have Braille labelling for BVI patients on medical packaing

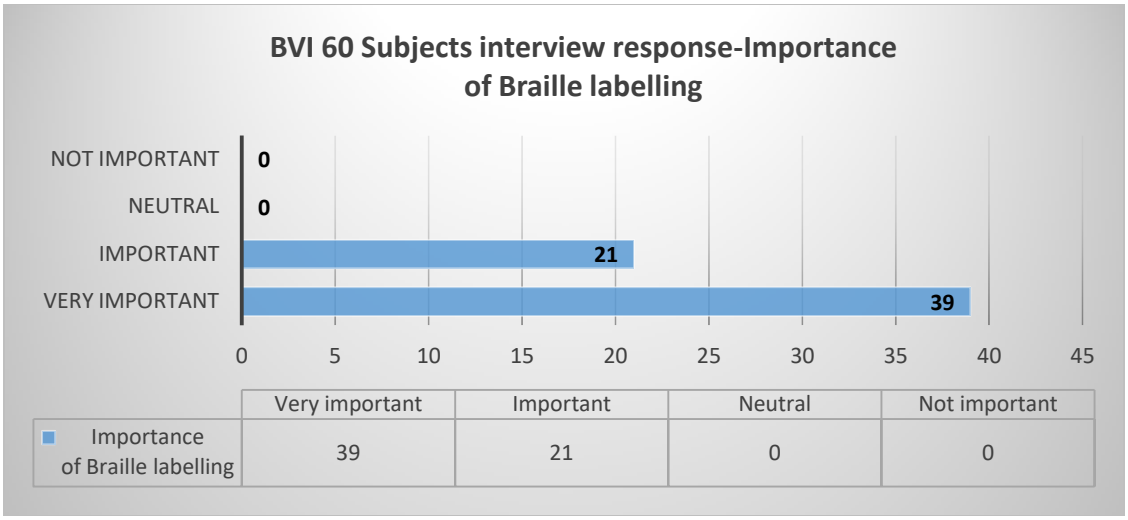


Figure and table 15
Showing response of BVI subjects on importance

Data collected from interviews from 60 subjects in figure 15 show on perception on importance of having Braille labelling on medical packs, 39 out of 60 see it very important while 21 see it as important, which talks of high demand of Braille label application as aspiration to resolve their problems.

4.6 Research question five

For Caretakers:

Validate the hypothesis that implementation of Braille labelling on medical & healthcare packs will enhance independence of BVI patients in managing their healthcare needs and administering medications?

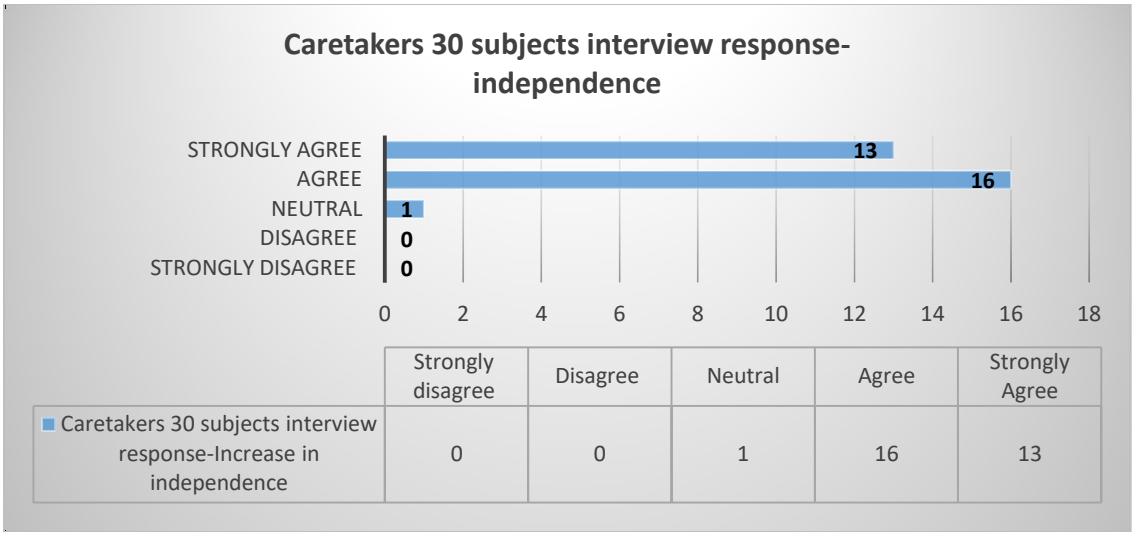


Figure and table 16
Showing caretakers response on independence of BVI individuals

Data collected from direct interview from 30 subjects in Caretakers in figure 16 shows on perception of enhanced independence speaks that 13 out of 30 strongly agree while 16 out of 30 agree with only 1 subject being unsure.

4.7 Research question six

For Caretakers

Validate that the introduction of Braille labelling on medical care products packaging will influence the purchasing behavior of caretakers even with marginal increase in price?

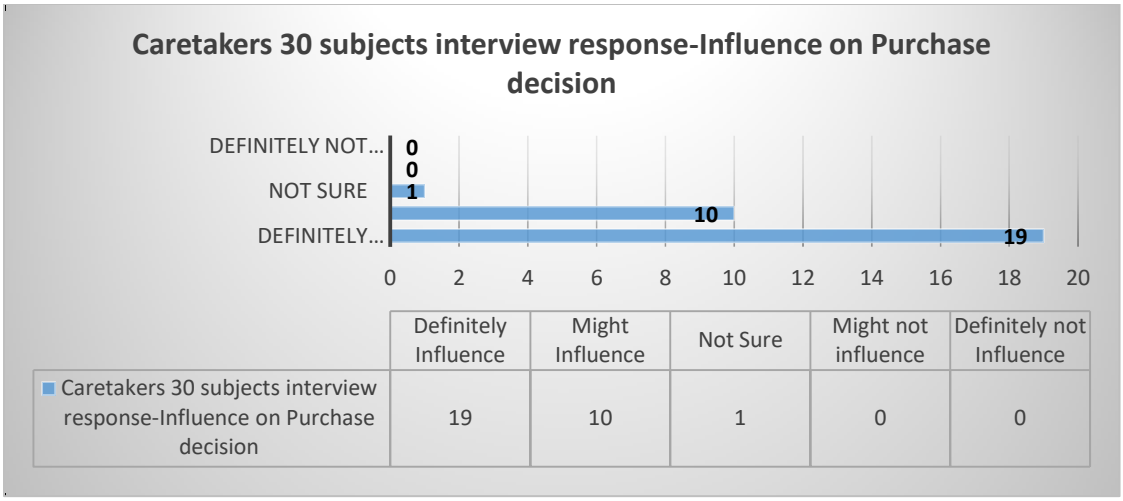


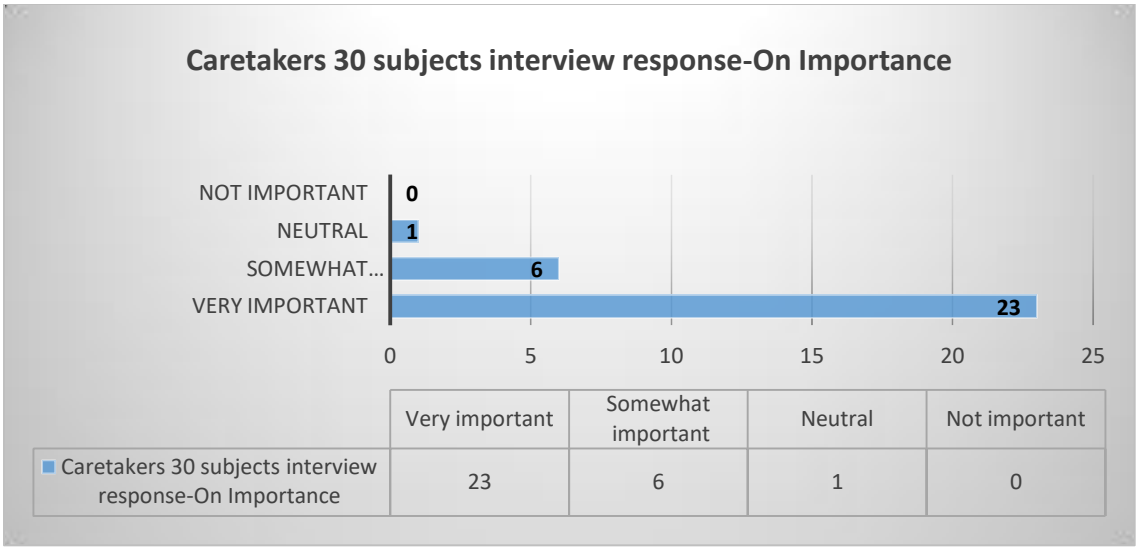
Figure and table 17
Showing response of caretakers on influence on purchase decision

Data collected from direct interviews from 30 caretakers in figure 17 show on perception on influence on purchase decision says that 19 out of 30 see it as definite factor to positively influence the purchase decision, while 10 out of 30 see it as might influence with only 1 subject being unsure.

4.8 Research question seven

For Caretakers

Validate that it is important to have Braille labelling for BVI patients on medical packaing



	Very important	Somewhat important	Neutral	Not important
Caretakers 30 subjects interview response-On Importance	23	6	1	0

Figure and table 18
Showing response of caretakers on importance

Data collected from direct interviews from 30 caretakers in figure 18 show on perception on importance of having Braille labelling on medical packs, 23 out of 30 see it very important while 6 see it as somewhat important, with only 1 being unsure which indicates high demand of Braille implementation on label.

The responses from BVI and caretakers were measured based on Likert scale questions showing the mean and standard deviation as below:

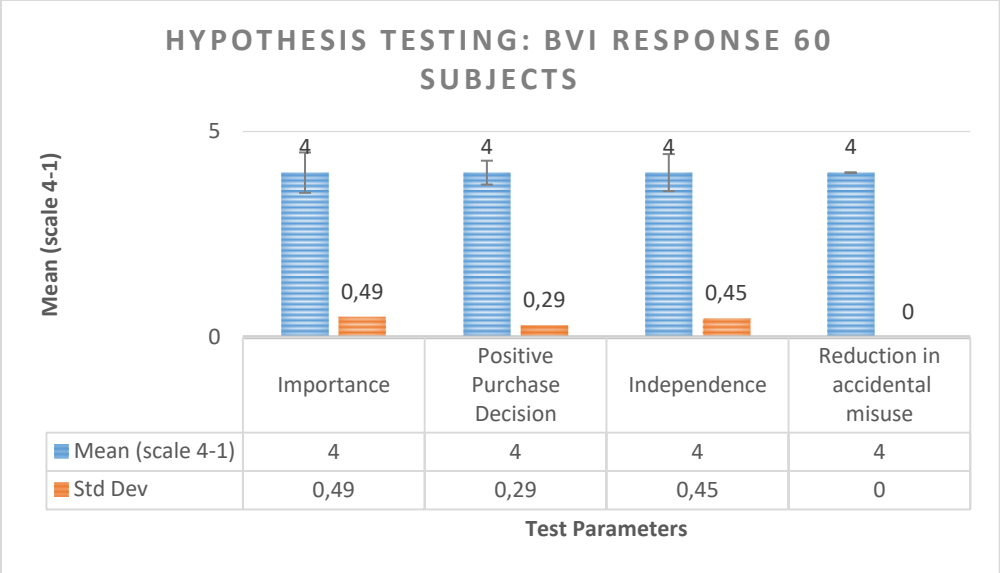


Figure and table 19
Showing standard deviation and mean based on response of BVI individuals

The study results mean and standard deviation in the above graph show the distribution of responses received from BVI individuals for hypothesis parameters- Importance, Positive purchase decision, Independence, and Reduction in accidental misuse, measured on a scale of 1-4 (where 4 being high positive and 1 being on lower side).

Above mean of four indicates that, on average, the responses received from the BVI individuals lean to be closer to the upper end of the scale (4). This suggests a positive skew in the data, with more responses grouping towards the higher end of the scale.

The above measures of standard deviation showing that how the dispersion is indicated for the responses around the mean. With a standard-deviation of 0-0.49 in above table for relevant parameters, the responses are relatively closely gathered around

the mean of 4. This implies that there is reasonably very little variations in the responses, with most falling within a narrow range close to the mean.

The slim spread of responses nearby the mean suggests a high level of consistency among the BVI individuals towards positive direction in their ratings for testing parameters- Importance, Positive purchase decision, Independence and Reduction in accidental misuse showing a clear need of Braille labelling on medical and healthcare packs.

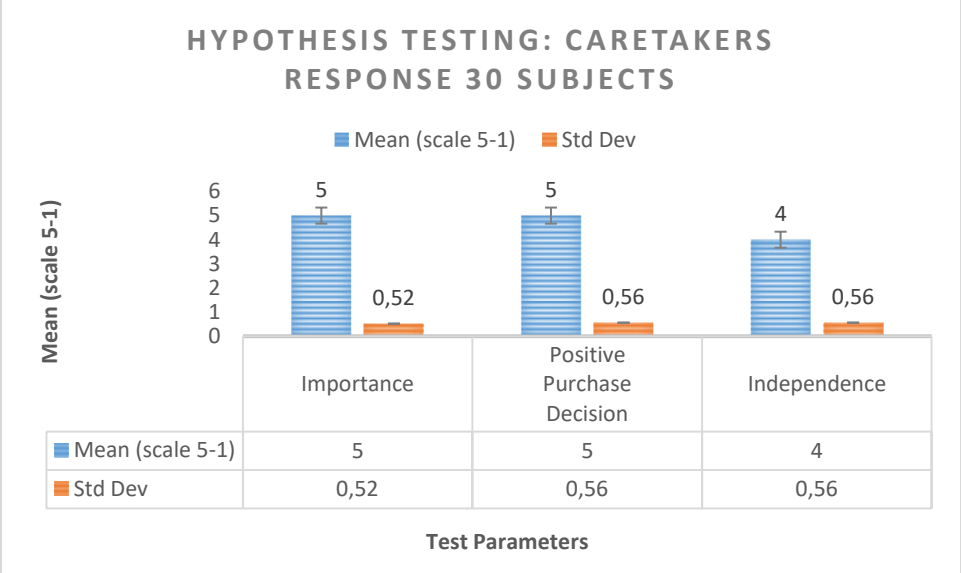


Figure and table 20
Showing mean and standard deviation based on response of caretakers

The study results mean and standard deviation in the above graph show the distribution of responses received from caretakers of BVI individuals for hypothesis parameters- Importance, Positive purchase decision & Independence measured on a scale of 1-5 (where 5 being high positive and 1 being on lower side).

The mean of 5 for importance and positive purchase decision and mean of 4 on Independence indicates that, on average, the responses received from the caretakers of BVI individuals lean to be closer to the upper end of the scale (5). This suggests a positive skew in the data, with more responses grouping towards the higher end of the scale.

The measure of above standard deviation shows the dispersion of the responses near the mean. With a standard deviation of 0.52-0.56 in above table for respective parameters, the responses are reasonably closely clustered around the mean of 5. This implies that there is comparatively little variations in the responses, with most falling within a narrow range close to the mean.

The thin spread of responses nearby the mean suggests a high level of uniformity among the caretakers towards positive direction in their ratings for testing parameters- Importance, Positive purchase decision and Independence showing a clear need of Braille labelling on medical and healthcare packaging. Both BVI and caretakers' responses indicate towards the need of having Braille labelling on medical packaging.

4.9. Other research sub questions for deeper insights

For BVI, Caretakers & Industry experts

- What are the practical challenges faced by BVI patients in using medical care products that lack accessible labelling?

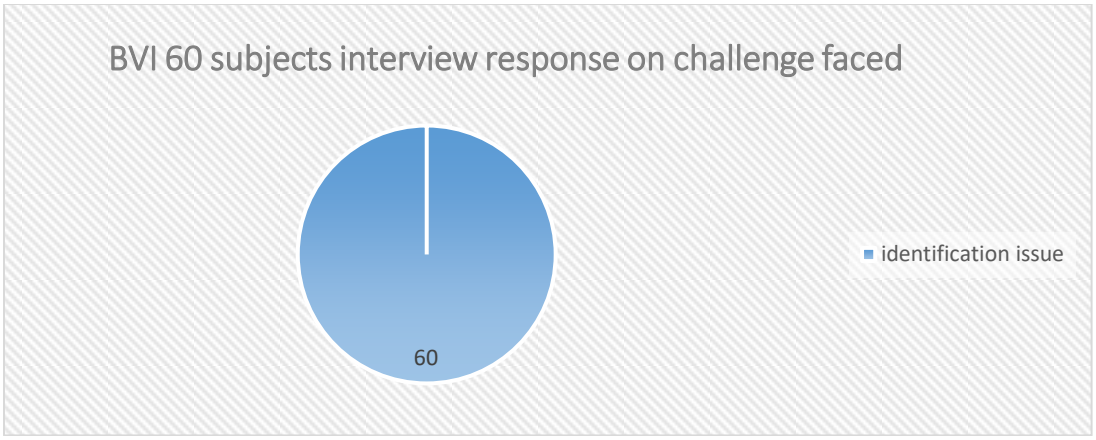


Figure 21
Showing response of BVIs on challenges faced

Data collected from direct interviews from BVIs in figure 19, all 60 BVI subjects expressed that it is very difficult for them to identify and differentiate similar packs to administer the medication and always need assistance.

- Check with caretakers is it challenging for BVI patients to identify/ differentiate the medical products

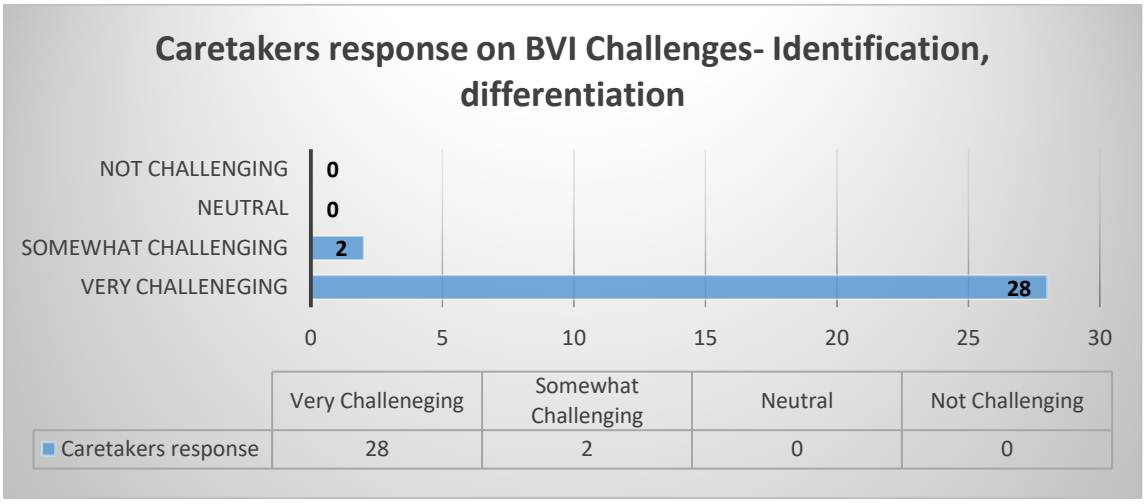


Figure and table 22
Showing response of caretakers for observed challenges

Data collected from interviews from caretakers, 28 out of 30 caretakers expressed that it is very difficult for them to identify and differentiate similar packs to administer the medication and always ask for assistance.

- What are the main challenges the medical care product industry might face in implementing Braille labeling on packaging in India?

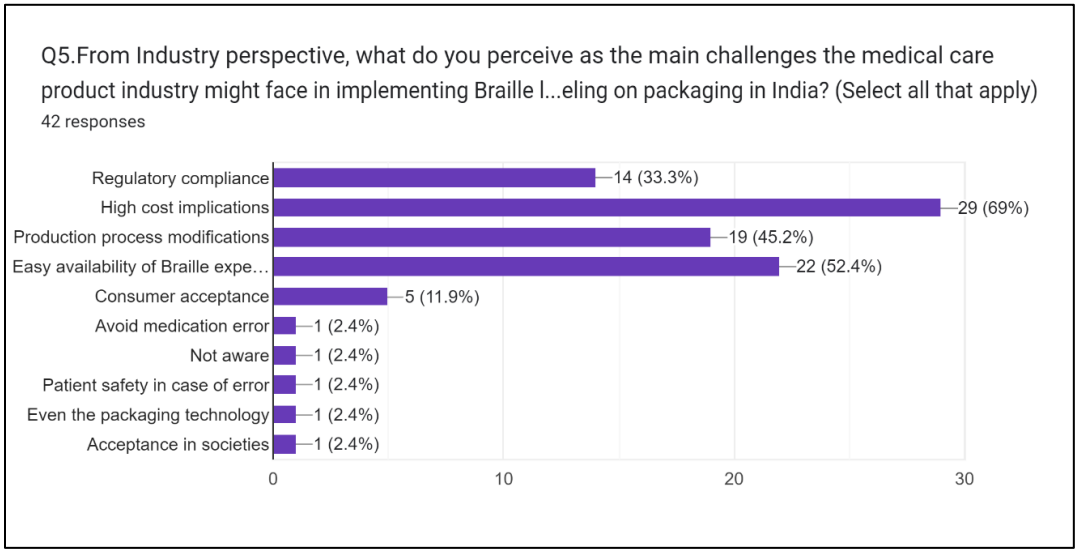


Figure 23
Showing response of Industry professionals on operational challenges

Data collected through online survey questionnaire from 42 Industry experienced professionals, majorly 33% say regulatory compliance will be a challenge, 69% say it will have high-cost implications, 45% say need of production process modification needed, 52% see the scarcity of Braille expert needed for implementation, 11.9% see the challenge of consumer acceptance.

- What technical challenges might companies encounter when integrating Braille labeling into their packaging processes?

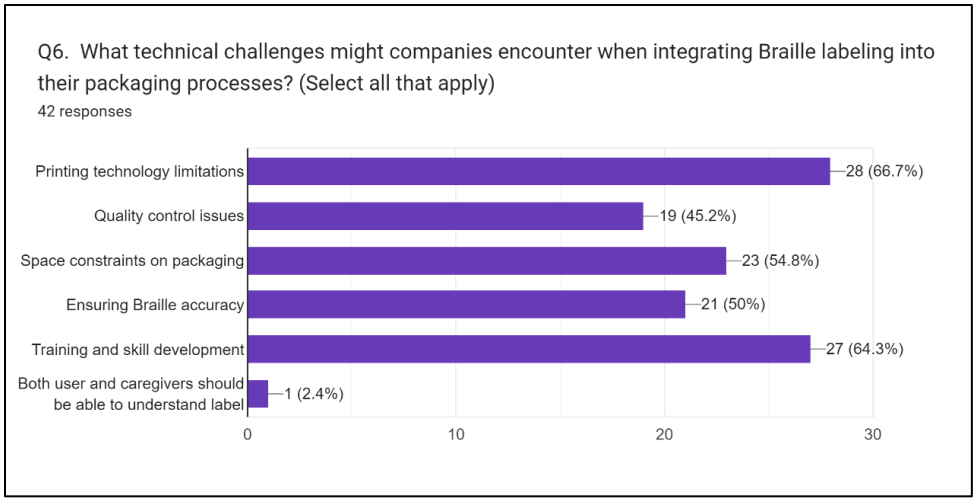


Figure 24
Showing response of Industry professionals on technical challenges

Data collected through online survey questionnaire from 42 Industry experienced professionals, majorly 66.7% say limitations of printing technology online will be a challenge, 45.2% see quality control issues, 54.8% see the limitation of space constraints on label, 50% see the challenge pf accuracy, 64.3% see the challenge of training & skill development.

- Will Braille labeling affect the overall design and aesthetics of packaging?

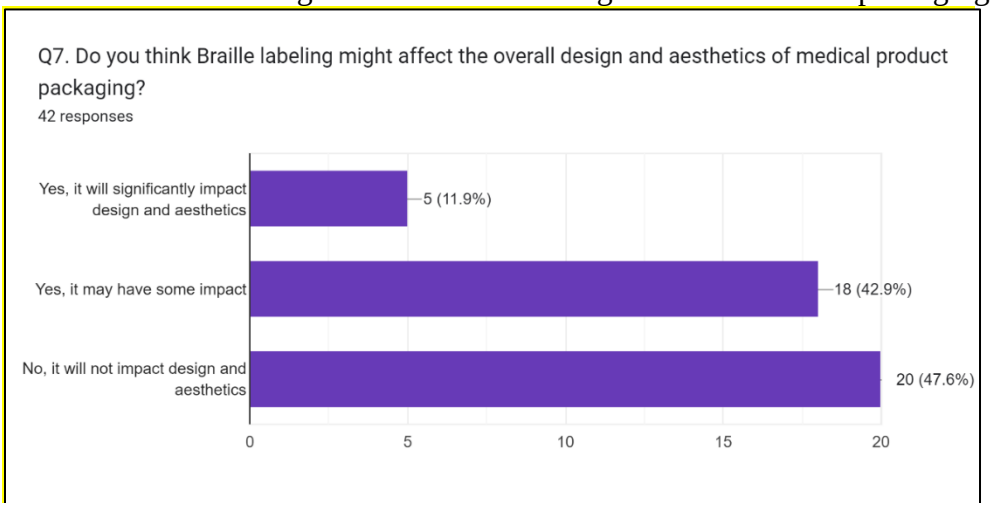


Figure 25
Showing response of Industry professionals on design and aesthetics

Data collected through online survey questionnaire from 42 Industry experienced professionals pack aesthetics majorly 47.6% see no impact on design and aesthetics, 42.9 % say it may somewhat impact while only 11.9% see it significantly impacting aesthetics and design.

- Has Industry started any interactions with blind or visually impaired patients or their caretakers regarding Braille labeling on medical care product packaging?

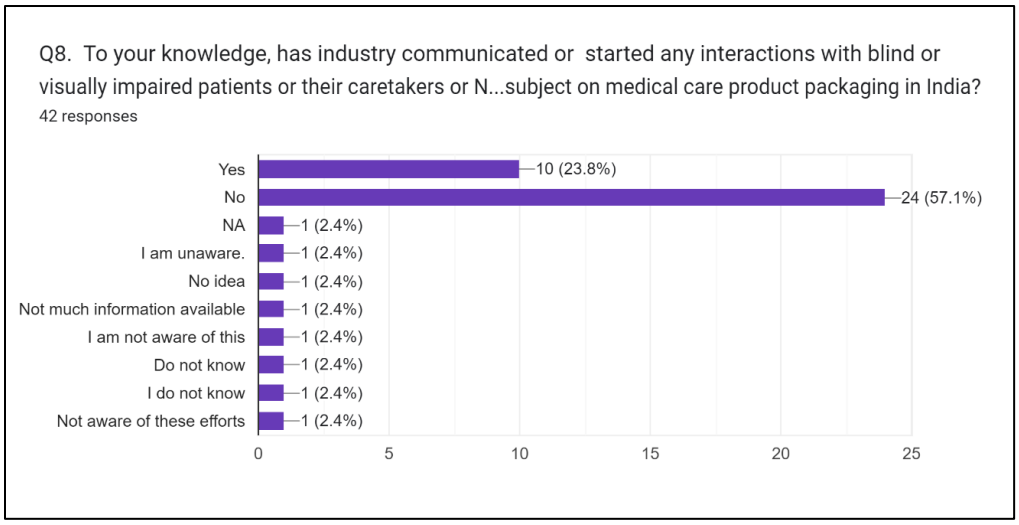


Figure 26
Showing response of Industry professionals on social communications.

Data collected through online survey questionnaire from 42 Industry experienced professionals on awareness on communication between industry and society and government and society, 57.1% say no communication in place, 23.8% say yes about communication but most of these have exposures for generic medicines exported to Europe where Braille labelling is a mandatory requirement. Rest expressed no awareness which construed to no communication.

- Are there any existing policies or regulations related to Braille labeling on medical packaging in India? Or is there any direction to make any policy?

An email has been sent to CDSCO (central drugs standards control organization), an India drug authority to check about the policy status but no response received so far, despite reminders. However, over the phone it was communicated that there is no policy as of now in drug regulations for Braille labelling on medicines packaging. Also, a thorough search on official regulatory authority website has not shown any existing policy on Braille labelling, neither any draft policy is circulated at this stage.

So, overall, the study revealed an agreement among BVI individuals and caretakers' responses that Braille labeling significantly enhances their independence in managing their healthcare needs. These findings underscore the importance of accessibility in healthcare packaging, as it empowers individuals with visual impairments to navigate medication regimens and healthcare instructions confidently and independently. Another significant finding is the unanimous agreement among participants (BVI) that Braille labeling would substantially reduce accidental misuse of medications enhancing safety. This is a critical aspect of BVI patients' safety, particularly for individuals who rely on medicines for managing chronic conditions. The study indicates that Braille labeling positively influences purchase decisions for healthcare products. This suggests that consumers, including BVI individuals and caretakers, focus on accessibility features such as Braille labeling when selecting medical and healthcare products. These finding have implications for both manufacturers and policy makers in terms of product design aiding BVI population for social parity & inclusivity in access to medication. Both BVI individuals and caretakers identified challenges related to pack

identification and differentiation as highlighted. This highlights the practical difficulties faced by BVI individuals when accessing medication information and underscores the need for accessible labeling solutions such as Braille labelling.

On the other hand, industry experienced professionals identified various challenges associated with implementing Braille labeling, including high-cost implications, regulatory compliance, and technical limitations on production lines and technology. These challenges reflect practical considerations that manufacturers must address when developing and implementing accessible packaging solutions.

The absence of any government policy regarding Braille labeling on medical and healthcare pack and the lack of communication between industry stakeholders, government authorities, and the public highlight systemic barriers to accessibility in healthcare packaging impacting accessibility. Addressing these gaps requires organized efforts from policymakers, industry stakeholders, advocacy groups, BVI population, caretakers, and healthcare professionals to prioritize accessibility and inclusivity in healthcare packaging policy.

4.9.1 Summary

A comprehensive study was conducted involving BVI individuals, caretakers, and pharmaceutical industry specialists to assess the need, viability, and implications of implementing Braille labeling on medical and healthcare packs. The primary aim was to validate the hypothesis that Braille labeling would enhance the independence of BVI patients in managing their healthcare needs and administering medications, reduction in accidental misuse, influence on purchase decision and importance of Braille labelling.

Among the BVI subjects, 42 out of 60 mentioned a significant enhancement in independence with implementation of Braille labeling, while 18 reported a somewhat enhanced experience, so overall indication is largly inclined towards enhancement of Independence.

Additionally, all 60 participants agreed that Braille labeling would significantly reduce accidental misuse of medicines, which is a very strong indication of need to reduce accidental misuse of medicines. Furthermore, 58 respondents out of 60 believed that Braille labeling would positively influence purchase decisions even with marginal increase in cost, should be considered as a strong input for industry to think of a participative model along with government creating some positive stimulus creating a feasible environment for adaption of Braille labelling. Regarding the opinion on importance (need) of implementing Braille labeling, 39 out of 60 BVI individuals deemed it very important, with 21 considering it important, which almost states that 100% of interviewed individuals clearly indicate the need. The study also revealed that the primary challenge faced by BVI individuals was the identification and differentiation between similar packs.

To strengthen our findings caretakers of BVI individuals corroborated these findings, with 28 out of 30 confirming the challenge of pack identification. Moreover, caretakers indicated that Braille labeling would increase independence, with 13 strongly agreeing and 16 agreeing out of 30 individuals. Similarly, 19 out of 30 caretakers believed that Braille labeling would definitely positively influence purchase decisions along with other 10 caretakers stating might influence.

When assessing the opinions of industry professionals, major operational challenges identified included high-cost implications (69%), regulatory compliance (33.3%), production process modifications (45.2%), and challenge in availability of Braille experts for implementation (52.4%). Also, key technical challenges which will be posed with daily operations such as printing technology limitations (66.7%), quality control (45.2%), accuracy (50%), training and skill development of staff (64.3%) and space constraints on labels (54.8%) were also highlighted, 47.6% see no impact on design and aesthetics, 42.9 % say it may somewhat impact while 11.9% see it significantly impacting aesthetics and design. Overall, the challenge for industry is big and needs a stimulus or a model like public private partnership (PPP- need exploration)

Furthermore, industry professionals expressed that there is a lack of communication regarding Braille labeling (76.2%) with relevant authorities or the public.

Additionally, there is currently no existing policy regarding Braille labeling with health authorities.

4.9.2 Outcome based of ecological systems theory.

This study applied the ecological systems theory perspective regarding the issues faced by the BVI population in identifying and differentiating medications, exacerbating the risk of accidental misuse, and hindering independence due to the absence of braille labeling on medical packaging, lack of policy support, and highly disconnected social communication. Outcome of this exercise is explained with figures below.

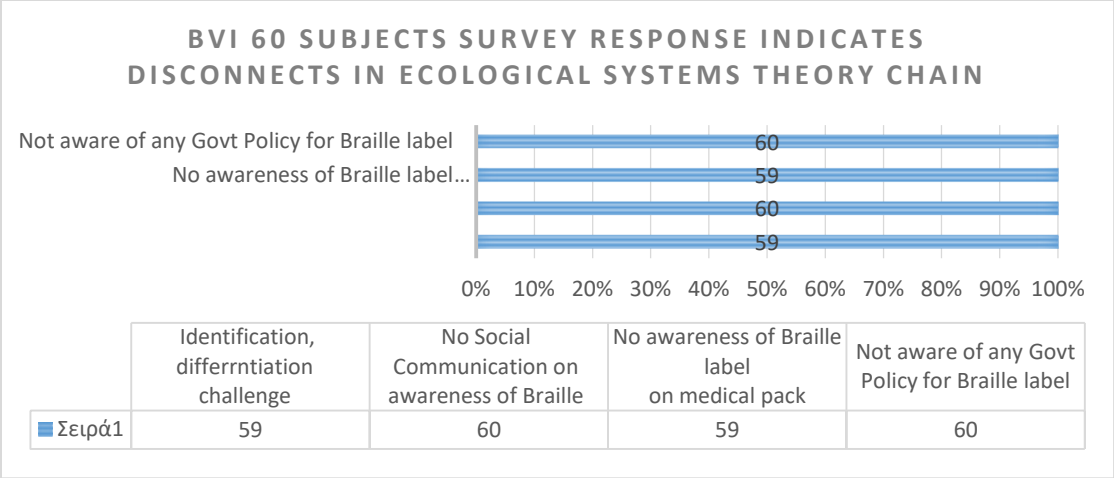


Figure and table 27
Showing response of BVI subjects on awareness & challenges

Data collected from interviews from BVI subjects on challenges, any awareness of products with braille labelling, any social communication with industry or government and any policy existence on Braille labelling. Almost the full cohort of 60 expressed that there are challenges, no awareness on any available product in India with Braille, no social communication, and lack of awareness on any existing policy on Braille labelling on medicines packaging.

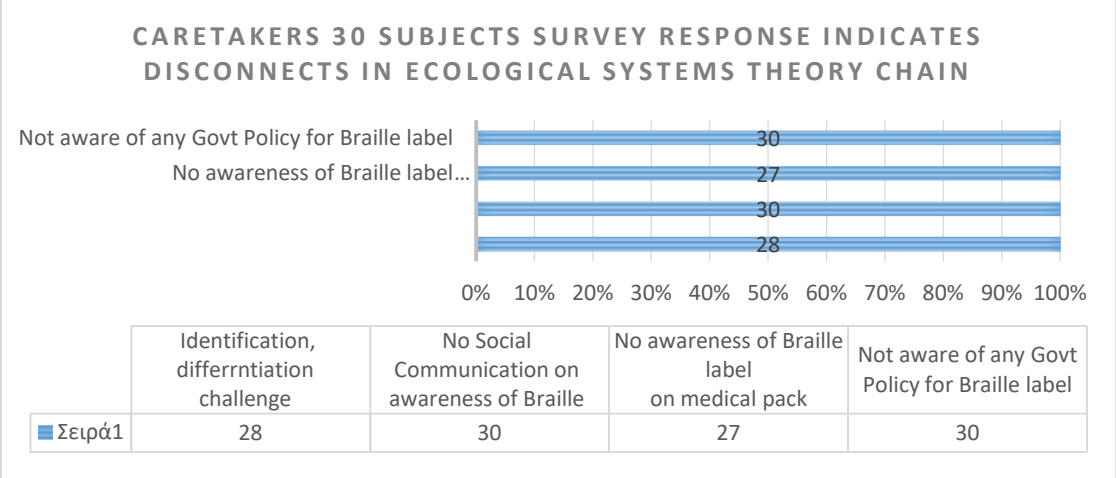


Figure and table 28
Showing response of caretakers on challenges of BVIs

Data collected from interviews from caretakers on challenges, any awareness of products with braille labelling, any social communication with industry or government and any policy existence on Braille labelling. Around 90-100% cohort of 30 expressed that there are challenges, no awareness on any available product in India with Braille, no social communication, and no awareness on any existing policy on Braille labelling on medicines packaging.

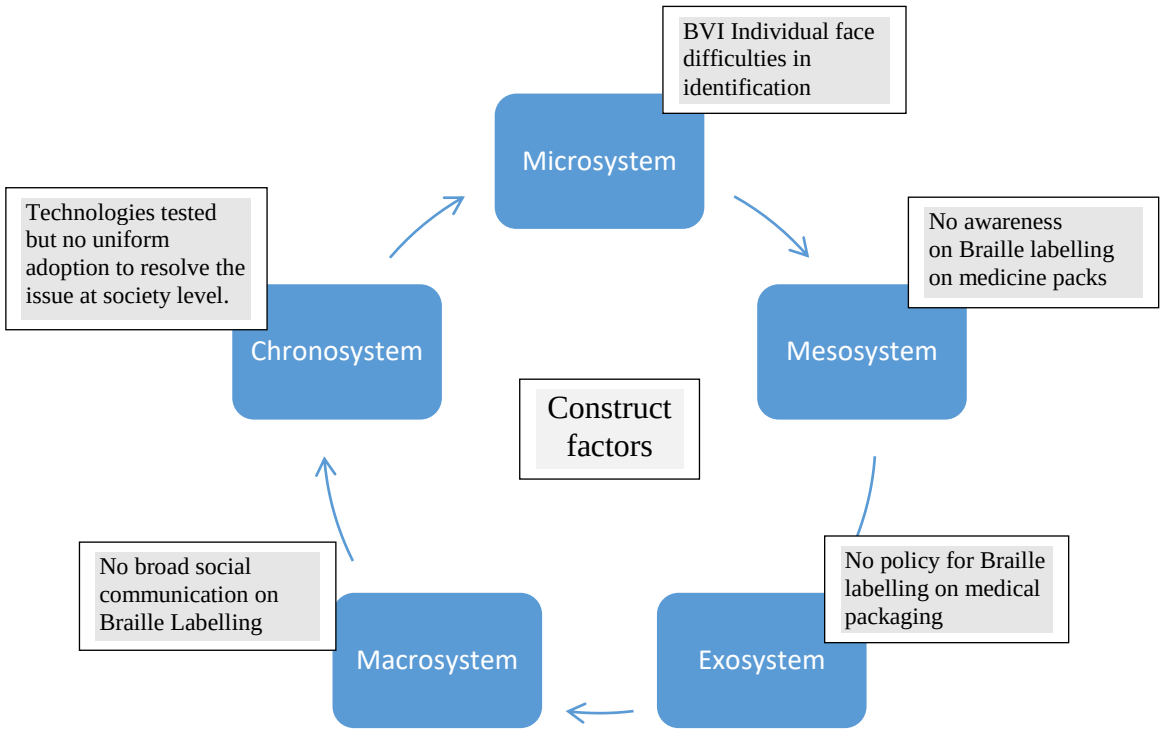


Figure 29
Depicting status of factors on awareness & use Braille labelling in ecosystem.

A qualitative approach was employed to analyze the insights from individuals within the blind and visually impaired population, caretakers, experienced industry professionals and policymakers through a semi-structured interviews and discussions to collect viewpoints. Below were the observations:

Microsystem: BVI individuals clearly indicated the challenges in identifying and distinguishing similar pack medicines, which was further endoresed by caretakers. This impedes their ability to manage their medication regimen independently and correctly. This limitation increases the risk of accidental misuse and compromises their overall health outcomes and hence they seek timely medical assistance making them highly dependent.

Mesosystem: Interviewed BVI population clearly mentioned that there is no any awareness of any policy existence nor any such communication from authorities. BVI population challenges are enhanced due to lack of policy support as there are no existing regulations calling for mandatory braille labeling on medical packaging.

Exosystem: It was observed that either there is no social communication or very limited social communication is happening regarding accessible medication packaging which contributes to the isolation of blind individuals in managing their healthcare needs and quality of life.

Macrosystem: With no active social communication and the overarching societal ignorant attitudes has somewhat marginalized the BVI population in having access to essential healthcare needs, awareness for any such possibility. Through qualitative analysis, it was found that the blind population expresses a high aspiration for Braille labeling, citing its potential to enhance independence, mitigate the risk of medication errors, and positively influence their purchasing decisions.

Chronosystem: Many advance technologies are tested like mobile apps and other label reading devices but there is no scalable solution adopted which leaves the BVI population with no uniform viable, cost effective soltion.

The above observations underscore the complexity interplayed between the individuals, interpersonal, institutional, and societal factors greatly influencing the medication accessibility for the BVI population. Addressing the mentioned challenges requires a well-rounded approach involving policy reforms, highly amplified social communication content & strategies, and inclusive design principles in healthcare packaging for Braille labelling. From an ecological systems theory perspective, ensuring equitable access to medication labeling for the blind population necessitates concerted efforts at multiple levels of influence. Hence, the application of Braille labeling on medical packaging emerges as a critical intervention to address the multilayered challenges faced by the BVI population in accessing the medications. Beyond mere convenience, Braille labeling represents a evident step towards achieving social parity and promoting inclusivity in healthcare. Policymakers, pharmaceutical companies, and healthcare stakeholders must collaborate to ensure the widespread adoption of Braille labeling, thereby empowering the BVI community and advancing equitable healthcare access for all.

4.9.3 Emerged Patterns

The qualitative analysis of the data provides several profound patterns in the study.

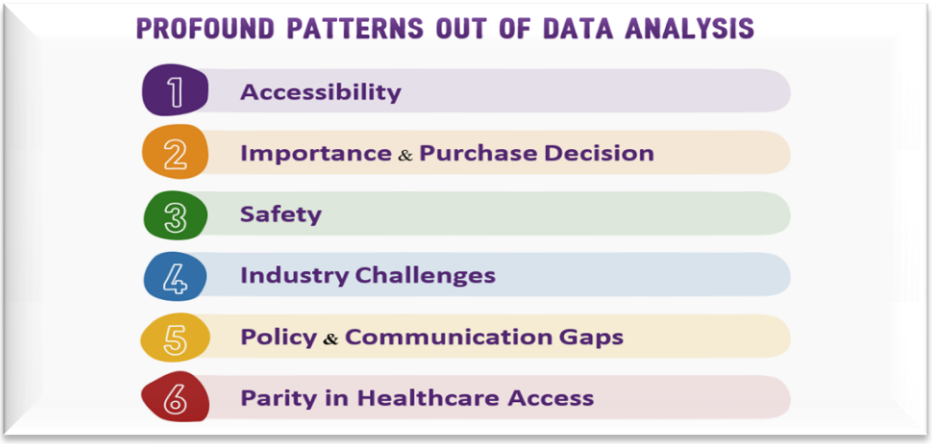


Figure 30
Showing profound observed patterns

Accessibility:

The unanimous agreement among blind and visually impaired (BVI) individuals regarding the significant enhancement of independence suggests that accessibility features such as Braille labeling can profoundly empower individuals with disabilities. By providing access to essential healthcare information, Braille labeling enables BVI individuals to take greater control of their health and well-being. This is supported by 42 out of 60 subjects stating significant enhancement. All 60 BVI subjects confirmed that Braille labeling would significantly reduce accidental misuse of medicines. Caretakers also validated the potential positive impacts of Braille labeling. A notable portion agreed that it would increase independence (13 out of 30 strongly agreed, 16 agreed), influence purchase decisions positively (19 out of 30), and considered it very important to have Braille labeling (23 out of 30). Both BVI individuals and their caretakers identified the challenge of identifying and differentiating between similar packs as a significant issue. This highlights the practical necessity for Braille labeling.

Importance & Purchase Decision:

A considerable number of both BVI subjects and caretakers emphasized the importance of implementing Braille labeling. Among BVI subjects, 39 out of 60 considered it very important, and among caretakers, 23 out of 30 resonated the same sentiment. The positive influence of Braille labeling on purchase decisions reflects a growing recognition of inclusive healthcare product designs. As BVI individuals increasingly prioritize accessibility features, manufacturers should consider inclusivity in their product offerings to meet the needs of a disabled population. A unanimous positive opinion was given by all 58 BVI respondents regarding the influence of Braille labeling on their purchase decision.

Safety:

The recognition of Braille labeling to reduce accidental misuse of medications and healthcare products stresses the importance of safety and patient-centric care for BVI individuals. Implementing Braille labeling not only enhances accessibility but also contributes to improved medication adherence and overall benefits of healthcare outcomes.

Practical Industry Challenges:

Industry professionals identified various operational and technical challenges associated with adapting Braille labeling on medical packs. These include high cost implications, regulatory compliance, production process modifications, availability of Braille experts, printing technology limitations, quality control, accuracy, staff training, and space constraints on labels. The challenges identified by industry professionals regarding the implementation of Braille labeling present opportunities for innovation and collaboration. Addressing issues such as cost implications, regulatory compliance, and

technical limitations requires creative solutions and partnerships across sectors to advance accessibility in healthcare packaging.

Social communication & policy gaps:

The lack of policy and communication gaps on Braille labelling on medical packaging among key stakeholders highlight systemic difficulties to ease of access in healthcare packaging. Addressing these gaps requires highly coordinated efforts to advocate for policy formulation, enhance awareness, and foster collaboration among society, government, and industry stakeholders to promote inclusive medical packaging. The study findings suggest a need for the development of policy and regulations regarding Braille labeling in medical & healthcare products. Additionally, there is a clear requirement for amplified communication between industry stakeholders, regulators, and the public regarding the implementation and benefits of Braille labeling. Overall, the qualitative analysis underscores the importance and potential benefits of Braille labeling for BVI individuals in managing their healthcare needs, while also highlighting the significant challenges that need to be addressed for successful implementation by the industry.

Parity in healthcare access:

The study emphasizes the perception that ease of access is not purely a matter of convenience but a underlying aspect of parity in healthcare access. By emphasizing accessibility features such as Braille labeling, stakeholders can contribute to reducing disparities in healthcare access and improving health outcomes for all individuals including BVI individuals, regardless of disability status.

4.9.4 Identified themes.

Based on emerged patterns through analysis of the Opinion of BVIs Caretakers & Industry professionals below themes have been derived regarding Braille labelling- *Independence, Risk Reduction, Importance, Purchase decision & Inclusivity.*

Figure 31
Derived themes

Theme 1: Independence

The theme of enhanced independence with Braille labelling emerged prominently throughout the interviews, with participants expressing a strong need for products that enhance their independence and self-reliance. Most of participants emphasized the importance of assistive technologies that enable them to perform daily tasks independently, without relying on care takers & external assistance. For instance, one participant remarked:

I value products that allow me to navigate my environment without constant assistance & being able to use a medicine pack which enables me to read that gives me the freedom to access information on my own.

Participants described how Braille labelling inclusion contribute to their sense of independence, empowering them to engage more fully in various activities of daily life.

Theme 2: Importance

Importance of having Braille labelling emerged as another critical theme in participants' discussions, reflecting their worries about navigating their environments with increased accuracy. BVI individuals emphasized the importance of Braille labelling on medical products that prioritize access, differentiation of & safety features.

I heavily rely on assistance of relatives to access healthcare needs. Features like braille labelling are very important allowing me to use my medication as an when I want.

Theme 3: Risk Reduction (for accidental misuse)

BVI individuals emphasized the need for products that minimize potential risks and ensure their physical well-being, underscoring the role of safety considerations in their decision-making process.

All BVI participants also discussed the significance of products that mitigate the risk of accidental misuse, particularly in contexts where they may be more vulnerable to situation where they are taking potent medications pose high risks. They emphasized the importance of clear and accessible interfaces, privacy settings, and safeguards. As one participant articulated:

For sure braille labelling will help me identify & distinguish the right medicine reducing the chances of wrong medication, we really felt the need in covid times when less or no assistance was around.

Participants emphasized the need for products that empower them to maintain control over their information and mitigate the potential consequences of accidental misuse.

Theme 4: Purchase Decision

The theme of positive purchase decision reflects participants' considerations and criteria when evaluating and selecting assistive technologies for their daily needs like medications etc. Participants described factors such as usability, affordability, effectiveness, and compatibility with their individual needs and preferences like Braille label. They emphasized the importance of conducting thorough research, seeking recommendations, and engaging with trial periods or demonstrations before making a purchase decision. As one participant stated:

Being blind and not rich, I prioritize products that offer value for money, user-friendly interface, braille presence on medicine label will influence my purchase decisions, as it enables me to act on my own.

Participants highlighted the significance of making informed choices to ensuring products they select align with their goals, preferences, and expectations.

Theme 5: Social Inclusivity

The theme of inclusivity underscores the obligation for society & government intervention to address policy gaps & help in tackling industry challenges surrounding Braille labeling. Amidst concerns including high costs, regulatory compliance, production process modifications, availability of Braille experts, printing technology limitations, quality control, accuracy, staff training, and space constraints on labels, there

arises a critical need for inclusive measures to uplift self-esteem and enable independence in BVI population.

Being blind, i always depend on assistance and keep on waiting for assistance to avail my medication, sometimes i miss the medication. Braille will be a beneficial tool for us to handle the medicine like other who can see, never heard on any policy from government.

By proactively addressing these obstacles, governments can foster an environment conducive to innovation and collaboration within the industry. Such interventions would not only enhance accessibility for visually impaired individuals but also stimulate advancements in Braille labeling technologies and practices, thereby promoting a more inclusive society.

4.9.5 Key Insights

Key insights have been derived from above themes for stakeholders to plan actions to bring better outcomes for BVI (blind & visually impaired) individuals based on the provided themes:

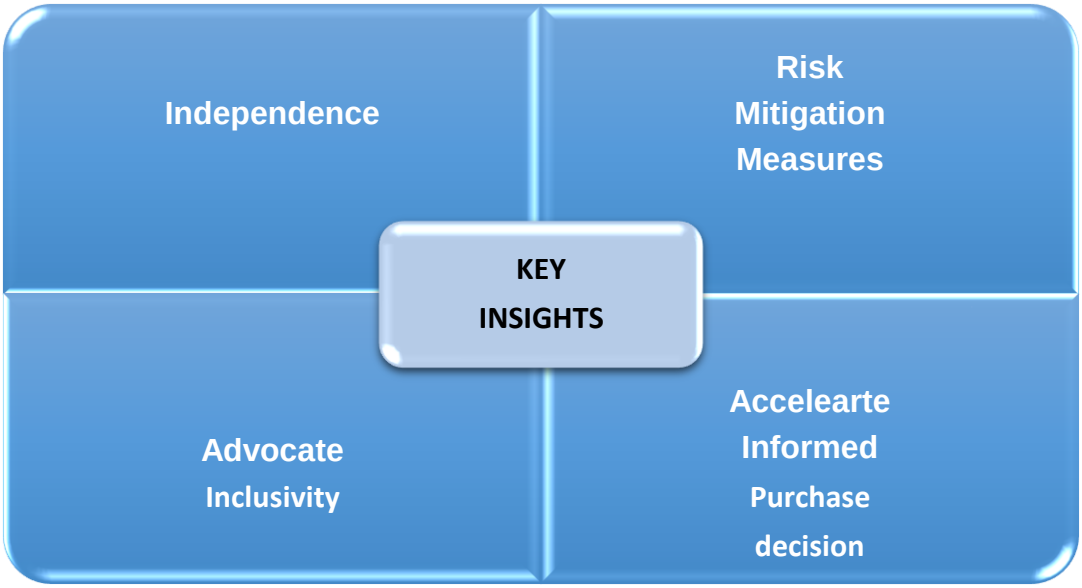


Figure 32
Key identified insights

Independence is Vital**:**

Stakeholders should prioritize the development of easy, cost-effective assistive technologies on medical packaging that enhance the autonomy and self-reliance of BVI individuals. Technology like Braille labeling enable them to perform tasks like easy medication access and independent administration, thereby reducing dependency on caretakers' assistance. Study data suggests that there is a critical need for products with Braille labelling as it significantly contributes to the independence and safety of BVI individuals. Incorporating Braille labelling on products is not just a matter of easy accessibility; it will be a fundamental aspect of safety and independence for BVI population. Stakeholders must admit the importance of Braille labelling as a standard feature across all medical products to facilitate easy navigation and differentiation of similar packs, thereby promoting easy medication access, inclusivity, and autonomy.

Risk mitigation measure for accidental misuse:

Stakeholders must prioritize the development of products with clear and accessible interfaces like Braille labelling by empowering BVI individuals to gain control over their required information on medicines pack, stakeholders can mitigate the potential risk of accidental misuse in medication.

Accelerate informed purchase decisions:

Stakeholders should provide resources for thorough research, recommendations, and trial periods to empower visually impaired individuals to make informed purchase decisions. Usability, affordability, effectiveness, and compatibility with BVI individual needs and preferences should be key considerations. This empowers BVI individuals to make informed purchase decisions based on conducive factors such as usability, affordability, and compatibility with their specific needs, thereby supporting positive outcomes and satisfaction.

Advocate inclusivity:

Government & Industry intervention is required to evaluate the rationale in the light of social inclusivity. Both stakeholders must collaborate to address policy gaps and industry challenges surrounding the Braille labelling on medical packs. By implementing inclusive measures such as subsidizing production costs with Braille label, promoting wider Braille training atmosphere, and incentivizing any such innovation for social cause, stakeholders can ensure that visually diminished individuals have reasonable access to essential products and services, fostering a more inclusive society for all. Public private partnership (PPP) model can be an idea to test.

4.9.6 Conclusion

The data obtained for this study through direct interviews with BVI individuals, caretakers and experienced industry experts is highly skewed and no traditional statistical tools may be applicable, hence it's important to present the results and observations in a clear and meaningful way. A clear description of complete dataset, including the variables measured and the nature of the skewness observed is captured above. The reason behind the skewness observed in the data might be due to inherent characteristics of the population being studied which is not having an easy aid to access medical care by themselves in the absence of any uniform measure serving their needs.

The thematic analysis shown in above figure 30 revealed six profound patterns- Accessibility, Importance and Purchase decision, Safety, Industry Challenges, Policy and communication gaps & Parity in healthcare access.

These patterns were refined into five overarching themes figure 28- Independence, Reduction of accidental misuse, Importance, Purchase decision & Inclusivity that condense participants' perspectives and priorities regarding Braille labelling. These themes underscore the importance of designing and developing products that empower blind individuals to lead independent, safe, and fulfilling lives, while also addressing their specific needs and concerns.

So, these overarching themes in figure 30 were further condensed to valuabale insights for stakeholders as Independence, Risk Mitigation Measures, facilitate Informed purchase decisions & Advocate inclusivity.

The study stresses the importance of prioritizing accessibility and inclusivity in

healthcare packaging through Braille labelling to ensure equitable access to essential medications and healthcare information for all individuals, regardless of visual impairment. Alongside making it adaptable with positive policy stimulus for industry is also a need.

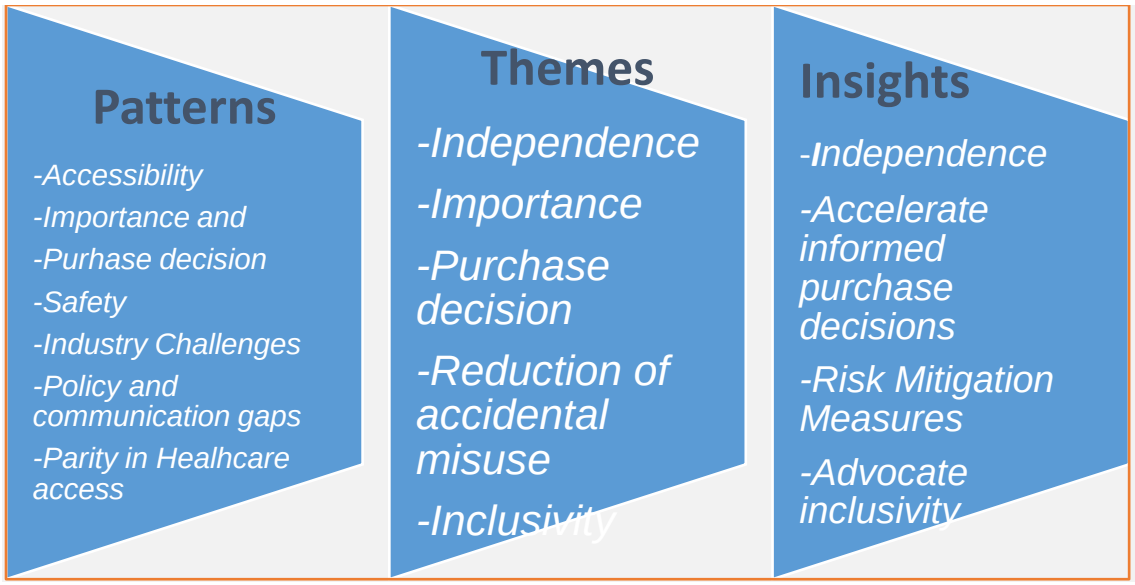


Figure 33
Showing derived pattens, themes and insights

Overall, the study stresses the value of cooperation between stakeholders to address the identified challenges and promote the adoption of Braille labeling on medical and healthcare packs. By working together to overcome barriers and advocate for inclusive design practices, stakeholders can ensure equitable access to essential healthcare information for individuals with visual impairments, ultimately improving healthcare outcomes and enhancing quality of life by leveraging on above emerged patterns, themes, and key insights in figure 32 identified based on study data analysis.

In conclusion, the findings from the study provide compelling evidence in support

of implementing Braille labeling on medical and healthcare packs. The overwhelming consensus among BVI individuals and caretakers, underscores the significant benefits of Braille labeling.

However, while the benefits to BVI population with Braill labelling are evident, challenges infront of pharmaceutical manufacturing industry remain such as high costs, regulatory compliance, supply of Braile experts and technical limitations are essential to be addressed for effective execution. Furthermore, the lack of effective communication within the social ecosytem on Braille labelling on medical packs for awareness and need and lack of policy regarding Braille labeling highlights the need for active collaboration between industry stakeholders, government authorities, healthcare professionals, careatakers and BVI individuals to facilitate its implementation.

CHAPTER V:

DISCUSSION

5.1 Discussion of Results

The results of the study highlight several key findings regarding the potential of implementation of Braille labeling on medical and healthcare packs, as well as the implications for BVI (blind and visually impaired) individuals, caretakers, and industry.

5.2 Research question one

For BVIs (visually impaired and blind Individuals) on enhanced independence

The outcomes of the study indicate a notable level of support for this hypothesis among the subjects surveyed. Out of the 60 participants surveyed, 42 expressed that the implementation of Braille labeling would significantly enhance their independence. This indicates a strong positive perception among most of the participants. Additionally, 18 out of the 60 subjects believed that Braille labeling would somewhat enhance their independence. While this number is lower than those who found it significant, it still demonstrates a considerable level of support for the hypothesis. These findings suggest that there is a clear demand and potential benefit for integrating Braille labeling on medical and healthcare packs for BVI patients. By providing accessible information through Braille, BVI individuals can be empowered to take greater control of their healthcare management, including medication administration. Improved independence in managing healthcare needs not only enhances the quality of life for BVI patients but also promotes their self-esteem, overall well-being, and health outcomes. The study results further strengthen the demonstration done by Almukainzi et al. (2020) by conducting a cross-sectional study which concluded that Braille label use on medicines may improve regimes of drug treatment, decrease medicines errors, and promote independence in these

persons through self-administration of medications.

However, it's vital to note that this study represents a specific sample and may not be generalizable to all BVI populations. Further research and implementation efforts are warranted to fully assess the effectiveness and broader implications of Braille labeling in healthcare settings.

5.3 Research question two

For BVI (blind and visually impaired) Individuals on reduction of accidental misuse.

Strong perception on reduction of accidental misuse was supported by unanimous agreement among all 60 subjects interviewed. This overwhelming consensus suggests a strong potential for Braille labeling to address a critical accessibility issue in the healthcare sector. The findings indicate that Braille labeling holds promise as an effective solution to mitigate accidental misuse among individuals with visual impairments. By providing tactile information directly on the packaging, Braille enables users to independently identify and correctly utilize products, reducing the risk of errors or adverse consequences associated with misuse. Moreover, the unanimous endorsement of Braille labeling underscores its potential impact on enhancing the safety and autonomy of individuals with visual impairments in accessing essential medical and healthcare products. This aligns with the principles of inclusivity and accessibility in healthcare, promoting equitable access to information and services for all individuals, regardless of ability. These results are aligned with the findings of an observational study by Shetty et al. (2021) where it was finally concluded that Braille use on prescription was as an efficient method in focusing the key issues to medicine safety with the visually impaired.

Further research and implementation efforts could explore the practicality and effectiveness of integrating Braille labeling across a broader range of medical and healthcare products.

5.4 Research question three

For BVI (blind and visually impaired) Individuals on purchasing behavior even with marginal increase in price?

The overwhelming majority of blind patients surveyed (58 out of 60) expressed a favorable opinion towards the introduction of Braille labeling on medical product packaging. This indicates a strong initial acceptance of the concept among the target demographic. The interview results suggest a strong positive inclination towards the introduction of Braille labeling on medical product packaging among blind patients. While the hypothesis proposes a potential influence on purchasing behavior, further research is warranted to validate this assumption and explore the broader implications of accessibility enhancements in healthcare packaging. The results are showing similar patterns in attitude in a study by SAHEL et al. (2022), where findings allowed them to justify the hypotheses; Packs for pharmaceutical products labelled in Braille has a positive effect on the intension of purchase of visually diminished and blind individuals.

5.5 Research question four

For BVI (blind and visually impaired) Individuals on importance of braille labelling

Braille labelling on medical packs plays a crucial role in ensuring accessibility and independence for blind or visually impaired (BVI) patients. The importance of this feature lies in its ability to provide essential information about medications, dosage

instructions, and potential hazards directly to those who rely on touch to navigate the world. Interview conducted among 60 individuals with visual impairment, 39 respondents emphasized the "very important" nature of Braille labelling, while 21 considered it "important." This overwhelming majority underscores the critical need for accessible packaging in the healthcare sector. For BVI individuals, accessing vital medical information independently can be challenging without tactile aids like Braille. Traditional packaging often relies heavily on visual cues, leaving blind individuals reliant on others for assistance, which can compromise their autonomy. In conclusion, the overwhelming support for Braille labelling on medical packs among BVI individuals highlights its undeniable importance in promoting accessibility, independence, and inclusivity in healthcare. This was earlier highlighted in various studies in literature review as well that the importance of such assistance with simple tools like Braille label on packs will be highly supportive in social situations in like in recent past COVID-19 pandemic where unexpected interruption of support system and help to these groups of persons had a serious impact on their health.

5.6 Research question five

For caretakers on enhanced independence of BVI individuals

The implementation of Braille labeling on medical and healthcare packs will strengthen the independence of visually impaired (BVI) individuals in managing their healthcare and administering medications. Findings from caretakers further indicate broad support, with 13 out of 30 caretakers strongly agreeing and 16 agreeing, while only 1 remained neutral. These results suggest a promising avenue for improving healthcare accessibility and autonomy among BVI individuals.

5.7 Research question six

For caretakers on their purchasing behavior for their BVIs relatives with marginal increase in price

Based on caretaker responses, 19 out of 30 affirmed that Braille labelling would definitely have a positive influence on their purchase decisions, while 10 expressed that it might influence their decisions. This suggests a strong inclination towards the adoption of Braille labelling among caretakers, potentially outweighing concerns about marginal price increases.

5.8 Research question seven

For caretakers on importance

Braille labeling on medical and healthcare packaging is crucial for visually impaired (BVI) patients. The validation stems from a opinion interviews from direct caretakers, where 23 out of 30 respondents stressed the significance of Braille labeling as "very important," while the remaining 6 respondents regarded it as "important." This vast consensus underscores the critical need for Braille labeling on medical packaging to enhance accessibility and ensure the safety and autonomy of BVI patients in managing their healthcare needs.

5.9 Other Research Sub questions for deeper insights

For BVI, caretakers and Industry experts

- What are the practical challenges faced by BVI patients in using medical care products that lack accessible labelling?
- Check with caretakers Is it challenging for BVI patients to identify/ differentiate the medical products

- What are the main operational challenges for the medical care product industry might face in implementing Braille labeling on packaging in India?
- What technical challenges might companies encounter when integrating Braille labeling into their packaging processes?
- Will Braille labeling affect the overall design and aesthetics of packaging?
- Has Industry started any interactions with blind or visually impaired patients or their caretakers regarding Braille labeling on medical care product packaging?
- Are there any existing policies or regulations related to Braille labeling on medical packaging in India?

This study results involving blind and visually impaired (BVI) individuals, caretakers, and pharmaceutical industry experienced professionals to assess the need, acceptance, viability, and implications of implementing Braille labeling on medical and healthcare packs. The study revealed that the primary challenge faced by BVI individuals (all 60 BVI individuals) was the identification and differentiation between similar packs. To strengthen our findings caretakers of BVI individuals corroborated these findings, with 28 out of 30 confirming the challenge of pack identification.

When assessing the opinions of 42 industry professionals, 69% see major operational challenges identified included high-cost implications, 33.3% see regulatory compliance issues, 45.2 % mentioned production process modifications will be needed, and 52.4% expressed challenge in availability of Braille experts for implementation and consistent compliance. Also, key technical challenges which will be posed with daily operations such as printing technology limitations opined by 66.7%, quality control issues seen 45.2%, accuracy issues by 50%, training and skill development of staff was

expressed by 64.3% and space constraints on labels by 54.8% were also highlighted. Out of 42 Industry experienced professionals on pack aesthetics 47.6% see no impact on design and aesthetics, 42.9 % say it may somewhat impact while 11.9% see it significantly impacting aesthetics and design. Furthermore, industry professionals expressed a lack of communication regarding Braille labeling (76.2%) with relevant authorities or the public.

Additionally, there is currently no existing policy regarding Braille labeling on medical or healthcare packs.

CHAPTER VI:

SUMMARY, IMPLICATIONS, AND RECOMMENDATIONS

6.1 Summary

The research study was meticulously designed, employing both face-to-face and telephonic interviews with a well-crafted semi-structured questionnaire to gather substantial data for validating hypotheses. Participation from BVI (blind and visually impaired) individuals, caretakers, and industry professionals provided valuable insights into braille labeling requirements and challenges for its implementation, enhancing the productivity of study.

6.2 Implications

The suggestions of the research study are important for several stakeholders. Firstly, the findings can inform policymakers and industry professionals about the specific requirements and challenges associated with implementing braille labeling, thereby facilitating the development of more effective policies and strategies. Secondly, the understandings acquired from BVI individuals and caretakers can provide to the construct of more inclusive & accessible products & policies. Additionally, the research stresses the importance of active engagement from diverse stakeholders in addressing medication accessibility issues, emphasizing the need for collaborative efforts to create meaningful solutions. Overall, the study underscores the potential for improving accessibility and inclusivity through targeted interventions with simple tools like Braille labelling as informed by observed evidence and participants strong inputs.

6.3 Future research recommendations

Basis the observations & outcomes of the study on braille labeling and its implications, several suggestions for future research in India may be as below:

- Need for a comprehensive cost-benefit evaluation for the economic sensibleness of employing Braille labeling in pharmaceutical industry in India. This analysis should delve into potential cost-effective measures and long-term gains to justify investment and addressing a major social cause.
- It is crucial to conduct a thorough compliance assessment aspect to understand the regulatory landscape and identify gaps. To strengthen smooth enforcement mechanisms ensuring extensive adoption of braille labeling in pharmaceutical industry in India.
- Study perceived challenges related to expertise availability for braille labeling requiring research into skill development programs and potential incentives for professionals to be available with skills.
- Additionally, investigating consumer perceptions and behaviors on a larger cohort towards braille labeling can provide insights into factors influencing acknowledgement and purchase decisions, particularly among blind individuals and caretakers.
- Develop tailored implementation strategies considering challenges like cost constraints and compliance issues is essential. Case studies and pilot projects can help identify effective approaches for successful braille labeling implementation in diverse contexts.

6.4 Conclusion

In conclusion, the comprehensive research study on braille labeling has explained significant gaps in healthcare accessibility for a particular BVI population and

highlighted the pressing need for its implementation on medicines and healthcare packaging in India.

Despite the challenges identified by industry professionals regarding high cost, compliance, and expertise availability, the study has underscored the immense potential for need of Braille labelling for a big social cause to bring parity for BVI individuals in healthcare access. By working on key insights from the study- *Independence, risk mitigation measures, facilitate informed purchase decisions & advocate inclusivity*, a workable solution through technological innovations, tailored strategies, and conducive policies, there exists a pathway towards overcoming these obstacles and realizing a smooth and successful integration of Braille labeling. Through collaborative efforts and commitment to accessibility, industries can not only enhance their products but also foster inclusivity and independence for BVI individuals which is going to contribute as one of the highest populations in the world for visual disability in India, thus needs active intervention.

Ultimately, embracing Braille labeling may not only represent a legal and ethical obligation but also a transformative opportunity to create a more reasonable and inclusive society for all.

APPENDIX A

COVER LETTER

Date:

Zafar Parvez Khan

Research Student, Swiss school of Business Management (SSBM), Geneva

Address: 1004, Bhumika Residency, Roadpali, Navi Mumbai

Contact- email: zafar.khan@hotmail.com , Mob: +91 7506218317

Subject: Request to Participate in a Survey on Braille Labelling on Medical Care Products Packaging

Dear Sir,

Hope this letter finds you doing well. I am Zafar Parvez Khan, a Doctorate Student at Swiss school of Business Management (SSBM), Geneva. I am conducting research on the topic of "Opinion of Blind & visually impaired patients & caretakers on Braille labelling on medical care products packaging in India." The objective of this study is to acquire valuable experiences into the perspectives and experiences of blind and visually impaired (BVI) patients and their caretakers regarding Braille labelling on medical care products packaging.

Your participation in this survey is of utmost importance, as it will help us understand the challenges and benefits associated with Braille labelling implementation in the healthcare sector. Your valuable input may contribute significantly to the

development of a more comprehensive healthcare approach that caters to the unique needs of the visually impaired community in India.

Participating in this Opinion survey for research work is entirely voluntary, and all replies will remain **anonymous** and confidential. Your personal data will not be communicated with any external parties, and the data collected will be used solely for research purposes.

The Interview will take about 15-20 minutes for completion.

We understand the demands on your time and sincerely appreciate your willingness to share your insights. Your contribution to this research will help make a meaningful difference in the lives of BVI patients and their caretakers.

Should you have any inquiries or concerns about the evaluation or the research, please do not hesitate to call me. Thank you in advance for your time and cooperation.

With warm regards,

Zafar Parvez Khan
Student, Swiss school of Business Managemnt (SSBM)
Geneva

APPENDIX B

INFORMED CONSENT

Zafar Parvez Khan

Research Student

Swiss school of Business Management (SSBM), Geneva

1004 Bhumika residency, sec 20, Roadpali

Navi Mumbai, India-410218

zafar.khan@hotmail.com

+91 7506218317

[Date]

Subject: Informed Consent for Participation in the Interview/ Survey on Braille Labelling on Medical Care Products Packaging

Dear [Participant's Name],

Hope this letter finds you very well. I am Zafar Parvez Khan, research student at Swiss School of Business & Management. I am conducting a research study on the topic of "Opinion of Blind & visually impaired patients & caretakers on Braille labelling on medical care products packaging in India."

Purpose and Procedure:

The aim of this opinion survey is to gather valuable perceptions into the opinions and experiences of blind and visually impaired (BVI) patients and their caretakers regarding Braille labelling on medical care products packaging. The survey will involve

answering questions related to your perspectives on Braille labelling, its practicality, and its impact on healthcare accessibility for the visually impaired community in India.

Participation:

Your contribution in this Inteview/ Opinion survey is entirely voluntary. You hold the right to refuse to take part or withdraw from the survey at any time without any penalty or loss of benefits.

Confidentiality:

All responses collected during this Interview will remain anonymous and confidential. Your personal data will be kept secure and will not be shared with any external parties. Data obtained from the survey will be used only for study purposes and will be reported in aggregate form.

Risks and Benefits:

The Inteview survey poses no risks, and it is not expected to cause any harm to participants. By participating, you will participate to the progress of knowledge in the field of healthcare accessibility for the visually impaired, potentially leading to the development of more inclusive healthcare practices.

Contact Information:

For any questions or concerns about the survey or the research, you may contact me at email address or phone number.

Consent:

Proceeding with the Interview/ opinion survey, you are providing your voluntary consent to participate in this research study. Your completion and submission of the survey will be considered as an indication of your informed consent.

Thank you for your participation in this research. Your valuable contribution will make a substantial impact on the improvement of healthcare accessibility for the visually diminished community in India.

Sincerely,

Zafar Parvez Khan
Student, Swiss school of Business Managemnt (SSBM)
Geneva

APPENDIX C

INTERVIEW GUIDE

Interview Guide: Opinion Survey on Braille Labelling on Medical Care Products Packaging in India

Introduction:

Thank you for your agreement to participate in this opinion survey interview. My name is Zafar Parvez Khan, and I am carrying out a research study on the topic of "Opinion of Blind & visually impaired patients & caretakers on Braille labelling on medical care products packaging in India." The aim of this interview is to gather valuable insights into your opinions and experiences regarding Braille labelling on medical care products packaging. Your contribution in this interview is entirely voluntary, and all information shared will remain anonymous and confidential. If need arises, I will request for your consent to record the interview for accurate data analysis.

Section 1: Background of participant

- Can you please start by telling about yourself? (e.g., your name, age, occupation, and any other relevant information you are comfortable sharing)
- How long has been your visual impairement,? (Please specify the duration)

Section 2: Braille Labelling Awareness and Perception

- How familiar are you with Braille as a tactile reading system?
- Have you encountered medical care products with Braille labelling in the past? If yes, please share your experience with using these products.

- What are your thoughts and opinions about Braille labelling on medical care products packaging? Do you believe it enhances accessibility for the visually impaired community?

Section 3: Impact on Healthcare Accessibility

- In your opinion, how does the presence or absence of Braille labelling on medical care products packaging affect the independence and safety of visually impaired individuals in managing their healthcare needs?
- Do you believe Braille labelling facilitates the proper use of medical care products for visually impaired patients? Is it important?

Section 4: Decision-making and Usage Patterns

- How does the availability of Braille labelling influence your or the visually impaired individual's decision-making process when selecting medical care products?
- If Braille labelling were more widely available, how likely would you be to choose products with Braille labelling over those without it? Please elaborate on your response.
- Will you buy the medicines with braille labelling with marginal incraese in cost?

Section 5: Challenges and Recommendations

- In your experience, what are the practical challenges faced by visually impaired individuals when using medical care products without accessible labelling?
- Do you have any suggestion for Braille labelling on medical care products implementaion for the visually impaired community in India?

Conclusion:

Thanks for sharing your valuable experiences & insights with us today. Your contributions will play a significant role in increasing our knowledge on Braille labelling on medical care products packaging and its impact on healthcare accessibility for the visually impaired community. Is there anything else you would like to add or share before we conclude?

End of Interview: Thank the participant for their time and willingness to participate in the research study.

APPENDIX D:

QUETIONNNAIRE FOR BVI

(Blind and Visually impaired Individuals)

Date: **Name(optional):** **Place:**

1.What is your gender?

- Male
- Female
- Prefer not to say

2. What is your age?

- Under 18
- 18-24
- 25-34
- 35-44
- 45-54
- 55-64
- 65 or over

3. How long have you been with blindness or visually impairment?

- Less than 1 year
- 1-5 years
- 6-10 years
- More than 10 years
- I prefer not to answer

4. Do you use any medical care products or used in past for managing any of your health or medical condition?

- Yes
- No
- Prefer not to say

5. Do you have difficulties in locating and identifying the medical care products you need or you could locate it easily?

- Yes
- No
- Not applicable

if yes, please briefly mention what obstacles do you face when trying to locate and identify medical care products independently:

……

6. Are you aware of any accessible or specialized medical care products designed for individuals with Blindness or visual impairment?

- Yes
- No
- Not sure

7. Are you aware that medical care products often have Braille labels for blind and visually impaired individuals?

- Yes
- No

8. If Yes, how familiar are you with Braille as a tactile reading system?

- Very familiar
- Somewhat familiar
- Not familiar at all

9. If yes, how confident are you in your ability to accurately interpret and understand Braille labels on medical care products? (Scale- 4-1)

- Very confident- 4
- Confident-3
- Somewhat confident-2
- Not confident-1

10. Do you understand the purpose of Braille labelling on medical care products packaging?

- Yes, I understand it completely
- Yes, but I have some doubts
- No, I'm not sure
- No, I don't understand it at all

11. In your opinion, In India do you feel it is important to have Braille labeling on medical care products packaging for individuals who are blind or visually impaired? (Scale: 4-1)

- Very important-4
- Important-3
- Neutral- 2

- Not important-1

12. In your opinion, what potential benefits can be associated with the implementation of Braille labelling on medical care products packaging for BVI patients?

- Increased independence
- Enhanced safety
- Can’t say
- Improved ease of use
- Other (please specify): _____

13. Would Braille labelling on medical care products packaging influence your purchasing decisions? (Scale: 4-1)

- Definitely, yes-4
- Probably yes-3
- Probably no-2
- Definitely no-1

14. If Yes, would you be more likely to purchase medical care products with Braille labelling for your healthcare needs with marginal cost increase?

- Yes
- No
- It depends on other factors_____

15. How do you think the presence of Braille labelling would affect the independence of blind and visually impaired individuals in managing their healthcare needs and administering medications? (Scale: 4-1)

- Significantly enhance independence. -4
- Somewhat enhance independence- 3
- No impact-2
- Can’t say-1

16. How do you think Braille labeling on medical care products packaging could enhance your independence in managing your healthcare needs?

- Increased ability to identify and use products independently
- Enhanced confidence in product selection and usage
- Easier access to essential medical information
- Other (please specify): _____

17. In your view, in what ways could Braille labeling contribute to the safety of blind and visually impaired individuals in using medical care products?

- Reduction in accidental misuse or ingestion of incorrect products
- Improved understanding of dosage and usage instructions
- Increased overall safety in handling medical care products
- Other (please specify): _____

18. How do you think Braille labeling contribute to the reduction of accidental misuse in using medical care products for blind and visually impaired individuals? (Scale-4-1)

- Significantly reduce in accidental misuse -4

- Somewhat reduce in accidental misuse – 3
- Can’t say-2
- No impact-1

19. Is there anything else you would like to share regarding Braille labelling on medical care products or your experiences?

---

20. Have you heard anything about Braille labeling on medical packaging from Govt or any other source?

- Yes
- No

21. If you are willing to participate in further discussions or interviews related to this topic, please provide your email address or preferred contact method:

……..

Thank you for participating in this survey. Your feedback is invaluable in understanding the perspectives on this important topic.

APPENDIX E:

QUETIONNNAIRE FOR CARETKERS

Date: **Name(optional):** **Place:**

1. What is your gender?

- Male
- Female
- Prefer not to say

2. What is your age?

- Under 18
- 18-24
- 25-34
- 35-44
- 45-54
- 55-64
- 65 or over

3. What is your relationship to the blind or visually disabled patient?

- Parent
- Spouse
- Sibling
- Friend
- Other (please specify): _____

4. Are you aware of Braille labelling on medical care products in India?

- Yes
- No

5. How familiar are you with Braille as a tactile reading system?

- Very familiar
- Somewhat familiar
- Not familiar at all

6. Do you understand the purpose of Braille labelling on medical care products packaging?

- Yes, I understand it completely
- Yes, but I have some doubts
- No, I'm not sure
- No, I don't understand it at all

7. In your view, how challenging is it to identify or differentiate medical care products for the Blind patient? (Scale- 4-1)

- Very challenging-4
- Somewhat challenging-3
- Neutral-2
- Not challenging at all-1

8. Do you think the inclusion of Braille labeling on medical care products packaging is an important addition for blind or visually impaired individuals and their caretakers? (scale-5-1)

- Very important-5
- Somewhat important-4
- Neutral-3
- Somewhat not important-2
- Not important-1

9. Do you believe that increasing the availability of medical care products with Braille labelling would enhance the independence and well-being of individuals with visual impairments? (scale-5-1)

- Strongly disagree-1
- Disagree-2
- Neutral-3
- Agree-4
- Strongly agree-5

10. In your opinion, what potential benefits can be associated with the implementation of Braille labelling on medical care products packaging for blind or visually disabled patients?

- Increased independence
- Enhanced safety
- Improved ease of use
- Other (please specify): _____

11. Would Braille labeling on medical care products packaging influence your decision to purchase a particular product for a blind or visually impaired individual you are caring for? (scale-5-1)

- Definitely influence-5
- Might influence-4
- Not sure-3
- Might not influence-2
- Definitely not influence-1

12. Is there anything else you would like to share regarding Braille labelling on medical care products or the challenges faced by blind or visually disabled patients?

---

13. Have you heard anything about Braille labeling on medical packaging from Govt or any other source?

- Yes
- No

14. If you are willing to participate in further discussions or interviews related to this topic, please provide your email address or preferred contact method:

_____

Thank you for participating in this survey.

APPENDIX F:

QUETIONNNAIRE INDUSTRY PROFESSIONAL

Experienced Pharma Industry professionals view

Hello Friends, Please complete this questionnaire, I am conducting a research on Braille labelling on medical packs feasibility study through opinion survey from Blind and Visually Impaired individuals and caretakers

Name (optional)

Short answer text

Q1. Which function are you representing in the medical care product industry *

- [ ] Product development
- [ ] Packaging development
- [ ] Regulatory Affairs
- [ ] Marketing
- [ ] Other...

Q2. How many years have you spent in Industry the medical & healthcare industry? *

- [ ] Less than 5 years
- [ ] 5-10 years
- [ ] 10-20 years
- [ ] 20- 30 years
- [ ] Over 30 years

Q3. Did you come across Braille Labelling options for Blind & Visually disabled population on medical care packaging in India? *

- [ ] Yes
- [ ] No
- [ ] Other...

Q4. From an industry perspective, what is your view on incorporating Braille labeling on medical care products for Blind population in India? *

Short answer text

Q5.From Industry perspective, what do you perceive as the main challenges the medical care product industry might face in implementing Braille labeling on packaging in India? (Select all that apply) *

- [ ] Regulatory compliance
- [ ] High cost implications
- [ ] Production process modifications
- [ ] Easy availability of Braille experts to design content
- [ ] Consumer acceptance
- [ ] Other...

Q6. What technical challenges might companies encounter when integrating Braille labeling into their packaging processes? (Select all that apply) *

- [ ] Printing technology limitations
- [ ] Quality control issues
- [ ] Space constraints on packaging
- [ ] Ensuring Braille accuracy
- [ ] Training and skill development
- [ ] Other...

Q7. Do you think Braille labeling might affect the overall design and aesthetics of medical product packaging? *

- [ ] Yes, it will significantly impact design and aesthetics
- [ ] Yes, it may have some impact
- [ ] No, it will not impact design and aesthetics

Q8. To your knowledge, has industry communicated or started any interactions with blind or visually impaired patients or their caretakers or NGOs or heard from Indian drug authorities regarding Braille labeling subject on medical care product packaging in India? *

- [ ] Yes
- [ ] No
- [ ] Other...

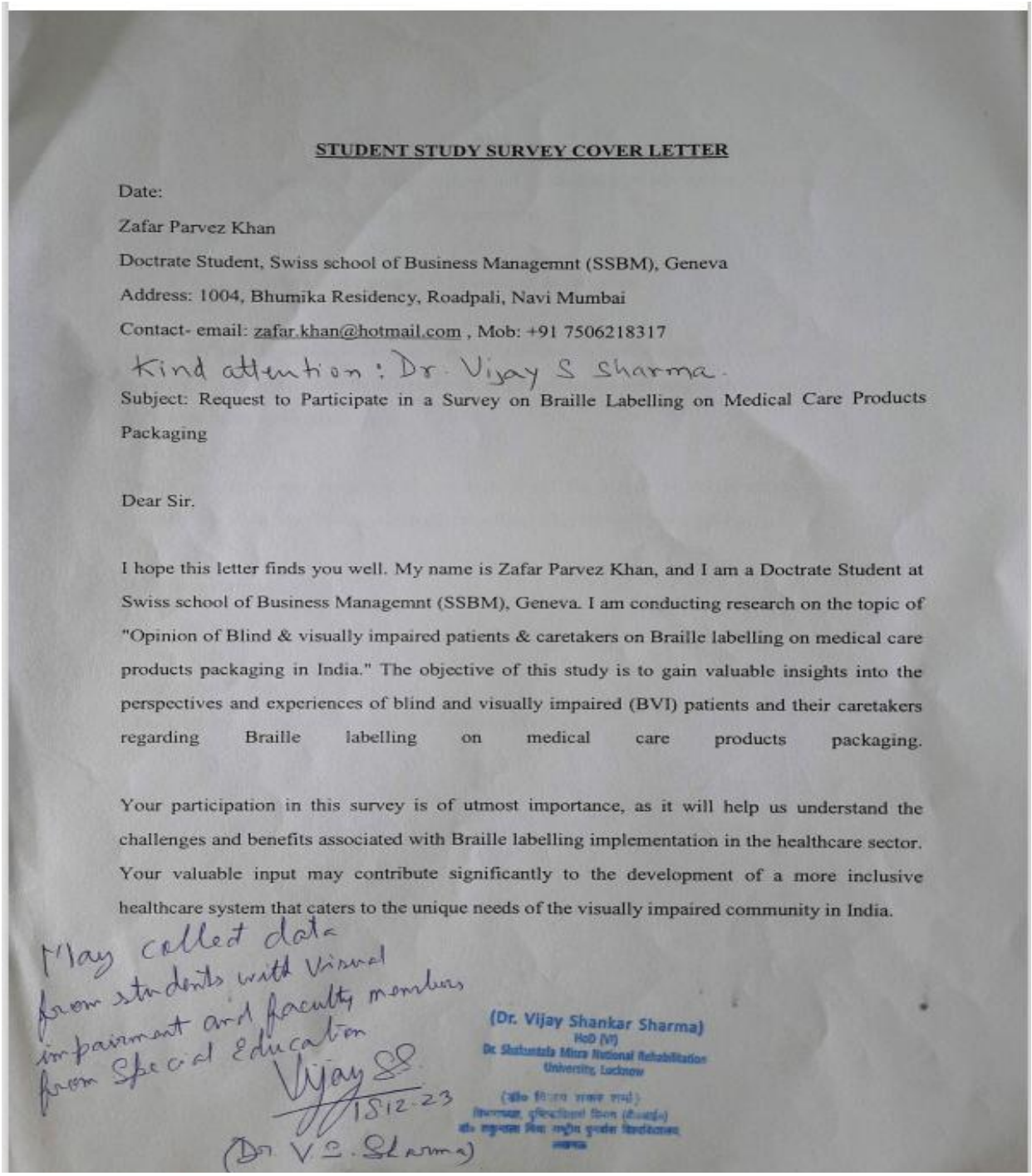
Q9. Is there anything else you would like to share regarding the future of Braille labeling on medical care product packaging in India *

Short answer text

APPENDIX G:

INSTITUTE 1 PERMISSION

SHAKUNTALA MISRA UNIVERSITY, LUCKNOW, UP, INDIA



STUDENT STUDY SURVEY COVER LETTER

Date:

Zafar Parvez Khan

Doctrate Student, Swiss school of Business Managemnt (SSBM), Geneva

Address: 1004, Bhumika Residency, Roadpali, Navi Mumbai

Contact- email: zafar.khan@hotmail.com , Mob: +91 7506218317

Kind attention : Dr. Vijay S Sharma.

Subject: Request to Participate in a Survey on Braille Labelling on Medical Care Products Packaging

Dear Sir.

I hope this letter finds you well. My name is Zafar Parvez Khan, and I am a Doctrate Student at Swiss school of Business Managemnt (SSBM), Geneva. I am conducting research on the topic of "Opinion of Blind & visually impaired patients & caretakers on Braille labelling on medical care products packaging in India." The objective of this study is to gain valuable insights into the perspectives and experiences of blind and visually impaired (BVI) patients and their caretakers regarding Braille labelling on medical care products packaging.

Your participation in this survey is of utmost importance, as it will help us understand the challenges and benefits associated with Braille labelling implementation in the healthcare sector. Your valuable input may contribute significantly to the development of a more inclusive healthcare system that caters to the unique needs of the visually impaired community in India.

May collect data from students with visual impairment and faculty members from Special Education

Vijay S.
15.12.23
(Dr V S. Sharma)

(Dr. Vijay Shankar Sharma)
HoD (VI)
Dr Shakuntala Misra National Rehabilitation University, Lucknow

Participating in this survey is entirely voluntary, and all responses will remain **anonymous** and confidential. Your personal information will not be shared with any external parties, and the data collected will be used solely for research purposes.

The survey will take approximately 10-15 minutes to complete

We understand the demands on your time and sincerely appreciate your willingness to share your insights. Your contribution to this research will help make a meaningful difference in the lives of BVI patients and their caretakers.

Should you have any questions or concerns about the survey or the research, please do not hesitate to contact me. Thank you in advance for your time and cooperation.

With warm regards,

Zafar Parvez Khan

Student, Swiss school of Business Managemnt (SSBM)

Geneva

APPENDIX H:

INSTITUTE 2 PERMISSION

FROM NAB STATE BRANCH, LUCKNOW, UP, INDIA

19-12-2023

STUDENT STUDY SURVEY COVER LETTER

Date:

Zafar Parvez Khan

Doctrate Student, Swiss school of Business Managemnt (SSBM), Geneva

Address: 1004, Bhumika Residency, Roadpali, Navi Mumbai

Contact- email: zafar.khan@hotmail.com , Mob: +91 7506218317

Kind Attn: NAB UP State, Ms. Amita Dubey.

Subject: Request to Participate in a Survey on Braille Labelling on Medical Care Products Packaging

Dear Sir,

I hope this letter finds you well. My name is Zafar Parvez Khan, and I am a Doctrate Student at Swiss school of Business Managemnt (SSBM), Geneva. I am conducting research on the topic of "Opinion of Blind & visually impaired patients & caretakers on Braille labelling on medical care products packaging in India." The objective of this study is to gain valuable insights into the perspectives and experiences of blind and visually impaired (BVI) patients and their caretakers regarding Braille labelling on medical care products packaging.

Your participation in this survey is of utmost importance, as it will help us understand the challenges and benefits associated with Braille labelling implementation in the healthcare sector. Your valuable input may contribute significantly to the development of a more inclusive healthcare system that caters to the unique needs of the visually impaired community in India.

NAB UP State Branch Lucknow
1710, 1st Floor, Lekhraj Dollar
Indira Nagar, Lucknow - 226016

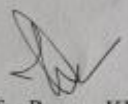
Participating in this survey is entirely voluntary, and all responses will remain **anonymous** and confidential. Your personal information will not be shared with any external parties, and the data collected will be used solely for research purposes.

The survey will take approximately 10-15 minutes to complete

We understand the demands on your time and sincerely appreciate your willingness to share your insights. Your contribution to this research will help make a meaningful difference in the lives of BVI patients and their caretakers.

Should you have any questions or concerns about the survey or the research, please do not hesitate to contact me. Thank you in advance for your time and cooperation.

With warm regards,



Zafar Parvez Khan
Student, Swiss school of Business Managemnt (SSBM)
Geneva

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