Medication use patterns in the visually impaired in Saudi Arabia and the importance of applying Braille labeling

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Background: A visually impaired person typically faces countless challenges throughout their daily activities. These challenges can include medication safety and efficacy. Few studies have addressed the issues of safety and pattern of medication usage in visually impaired patients, or the need to apply Braille labeling to medications dispensed to these patients.

Objective: To explore the medication use pattern in severely visually impaired and blind patients living in Saudi Arabia, and to evaluate the need for Braille labeling on medication dispensed to these patients.

Method: The merits of the proposal and its alignment with national regulations were evaluated and the study was approved by the Institutional Review Board (IRB). This cross-sectional study was conducted through open- and closed-ended questionnaires that were distributed to 215 visually impaired people, aged 18 years and above, dispersed throughout different cities within the kingdom.

Result: The sample population was equally distributed in terms of sex. The majority of the participants were young with a college degree. More than half of the participants were unable to identify the name, dose, expiry date, instructions and interactions of their medication, and the respondents usually relied on their caregivers. 91% of the respondents agreed that application of Braille labeling on their medications would improve the quality of their therapy and help them overcome some of their difficulties.

Conclusion: This study investigated medication usage patterns in the visually impaired in Saudi Arabia. These patients face considerable challenges to any efforts to self-administer their own medication and are heavily reliant on caregivers. The current methods for dispensing medications to this population, (and current regulations) do not sufficiently meet their health information needs. The study highlighted the necessity of applying Braille labeling to medicines prescribed to the visually impaired. A reconsideration of the current regulations regarding the application of Braille labeling to medications is warranted. The addition of technology to the printed Braille labeling can advance the pharmaceutical care services provided and improve the life quality of patients.

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1. Introduction

Visual impairment is a worldwide health problem that significantly influences the personal, economic, and social life of an individual. Approximately 1.3 billion people around the world are living with some form of vision impairment that varies from mild impairment to totally blind. The International Classification of Diseases classifies people who present visual acuity worse than 6/60 as having a severe distance vision impairment, and people who are presenting visual acuity worse than 3/60 as blind (WHO, 2017). Globally, around 217 million people have moderate to severe vision impairment, and 36 million people are blind (WHO, 2017). In Saudi Arabia, the number of severely visually impaired/blind people is approximately 236,000 individuals (General Authority for statistics, 2017). These individuals have special needs that cannot be ignored. The visual difficulties that impact
their everyday living activities can be extended to affect medication safety and efficacy. Due to their disability, this population is unable to differentiate between medication names or colors. The visually impaired are unable to read the usual drug leaflets explaining doses, expiry dates, and appropriate storage conditions of their medications. Consequently, accidental medication errors are anticipated, especially among those who are practicing polypharmacy (Han et al., 2017). Despite the high prevalence of visual impairment world-wide, a review study that explores the health information needs of visually impaired world-wide, a review study that explores the unique health information needs of this group (Beverley et al., 2004). The study found that most of the previous studies had looked at the everyday life style of the visually impaired but not to their unique needs, for example, details of medication usage and drug safety. Furthermore, the review study reported that there were only a limited number of studies that actually involved the point of views of visually impaired patients (Beverley et al., 2004).

A recent study involving 100 visually impaired individuals in Malaysia aimed to identify common problems that visually impaired people are facing in using their medications (Han et al., 2017). Using interview questionnaires, the researchers found that 89% of the respondents were unable to read the prescription labels, 75% did not know the expiry date, and 58% did not even know the name of their medications. The authors concluded that health information provided to visually impaired individuals was of poor quality and of insufficient quantity (Han et al., 2017).

To the best of our knowledge, there is only one published study concerning blind patients and their medication usage in Saudi Arabia (Kentab et al., 2015). That study aimed to understand the medication usage of 95 blind patients in Saudi Arabia and the challenges they experienced in taking their medications (Kentab et al., 2015). The authors found that the most common challenges encountered by blind patients were linked to drug identification (75%), dose recognition (82%), and identification of expiration date (92%). They also found that a large number of patients had to rely on sighted caregivers to properly administer their medications (Kentab et al., 2015). Thousands of blind people have utilized Braille in their native languages as an effective way of learning (Rajasenathipathi et al., 2010). The Braille system, which was founded by Louis Braille, is the only known system through which individuals with partial or total loss of sight can learn, read and write (Khidri et al., 2014). Braille is a system of raised dots which form words that can be read with the fingers. Braille is not a language, rather, it is a coding system which can be used to write and read many languages, including Arabic, Chinese, English, and Spanish (Fig. 1) (Khidri et al., 2014). We believe that use of Braille for medications that are dispensed to the visually impaired could ease the difficulties described by these patients and facilitate correct, self-administration of their medications.

The objectives of this study are to explore the pattern of medication usage of severely visual impaired and blind patients living in Saudi Arabia, and to investigate the demand for applying Braille labeling on drugs dispensed to these patients.

2. Method

The merits of the proposal and its alignment with national regulations were evaluated and the study was subsequently approved by the Institutional Review Board (Registration Number 17-0056) of Princess Noura University, Riyadh, Saudi Arabia. This was a cross-sectional study conducted through open- and closed-ended questionnaires, which began with a consent statement for participation in order to be able to continue the survey. The survey was made available online through a Google Docs link sent to participating blind associations in different cities in Saudi Arabia and submitted to blind influencers on social network sites. The sample data included 215 blind individuals, who are over 18 years old. The questions included five main domains: demographic information, medical status, medication usage pattern, an assessment of the difficulties in handling medications, and suggested ways to improve treatment with medications. The questions were formed and selected after reviewing previous related published studies, conducted in Saudi Arabia, South Korea, Thailand, and Malaysia (Han et al., 2017; Kentab et al., 2015; Lee and Lee, 2018; Riewpaiboon, 2009). The study was conducted over a period of two years 16/4/2017–16/5/2019.

The demographic questions included gender, age, region of living, inception of blindness, and education level. The questions related to medical status asked about current and past diseases and/or any medical condition that needed to be treated with prescriptions and/or over-the-counter medicines. The medication usage pattern questions examined the past and current medications and approaches used by the visually impaired to recognize and differentiate medicine names, usage instructions, expiry dates, and proper storage conditions. The fourth domain was focused on assessing the difficulties that visually impaired people faced in managing their medications, including dose accuracy, caregivers’ reliance, and incidences of errors in medication. The last domain investigated the necessity of using Braille labeling, Braille reading ability, and asked for proposals for methods to overcome the challenges of taking medications and to improve medication safety and efficacy for visually impaired patients.

3. Result

Our sample was almost equally distributed between male respondents (50.2%) and female respondents (49.8%). The majority of the participants were young (18–29 years old), and only 34% were above 30 years of age (Table 1). Most of the respondents (about 70%) had a college degree and they were all blind since birth. With regards to geographic distribution, 41% of respondents live in the eastern region of the kingdom, 34% live in the Middle region, and 9% live in other parts of the Kingdom (Table 1).

Only about 19% of our sample had a chronic disease diagnosis, and most of them had no diagnosis. About 27% of the respondents confirmed that they were taking medications frequently, 27% were taking medications sometimes, 12% rarely, and 34% did not take medications. However, about 75% of the individuals were being concomitantly administered more than one drug (while 25% had not).

Regarding medication usage pattern, 54% of the respondents received their medications from the pharmacy with a normal-

Fig. 1. The embossed letters and numbers in Braille system.
Table 1
 Respondents demographical distribution.

| Variable          | Percentage (n = 215) |
|-------------------|----------------------|
| Gender            |                      |
| Male              | 50.2%                |
| Female            | 49.8%                |
| Age (years)       |                      |
| 18–20             | 19.5%                |
| 21–24             | 21.4%                |
| 24–29             | 25.1%                |
| 30+               | 34%                  |
| Onset of blindness|                      |
| Since birth       | 69.3%                |
| Last 1–4 years    | 12.6%                |
| Last 5–9 years    | 7%                   |
| More than 10 years| 11.2%                |
| Living region     |                      |
| West              | 40.9%                |
| Middle            | 33.5%                |
| East              | 9.3%                 |
| Other             | 16.3%                |
| Education level   |                      |
| Primary school    | 4.2%                 |
| Middle school     | 4.2%                 |
| High school       | 20.9%                |
| University degree and above | 70.7% |

Table 2
Summary of main techniques mentioned by visually impaired to identify their medications.

- Identify the size and the shape of the (tablets, capsules, or bottles) by touching the external packaging.
- Identify the surface roughness of the drugs or/and the containers.
- Smelling the product odors.
- Adding marks such as adding a raised sticker or tearing part of the carton box.
- Printing braille sticker on each medicine container.
- Using audible record for each medication prescription.

sight companion, 25% were dependent on caregivers to receive their medications, and 21% of them received their medications alone. When we asked how they could identify their medicines, about 51% of them said they depend on caregivers to identify their medications. The remaining respondents relied on different coping techniques; for example, storage of their medications in different places (30%), identification of the size by touching (the outer boxes or bottles) or determining the surface roughness of (tablets, capsules), smelling the medications, and adding markers such as a raised sticker or tearing a part of the carton box. Some respondents got help reading the label in the first instance and then printed and attached a Braille label on the medicines; 5% of respondents said they could not identify their medications at all (Table 2).

With regard to dosage recognition, most of them relied on caregivers (71%), a smaller percentage could not detect the dose (4%), and many of the remainder (21%) created coping techniques, as previously mentioned, such as adding touchable markers (Fig. 2).

In relation to the drug instructions, such as times of dose, food requirements, and other drug interaction, 92% of the respondents said they depend on others to provide this information. Of the remainder, 5% of respondents were unable to recognize any information, and 2% simply relied on guesswork.

With regard to determining the drug expiry date, the vast majority of the respondents relied upon a sighted caregiver (90%), however, 8% could not determine it, and 2% relied on their own estimations.

To understand how visual disability affects medication usage and to estimate the incidence of medication errors, we asked our participants if they have ever took a drug by mistake. The majority of the respondents said they had never mistakenly taken a drug (62%). However, 22% of respondents confirmed that they had mistakenly taken a drug and a further 16% suspected that they had. With regards to a mistaken drug dose, 53.5% of respondents stated that this had never happened, 27% assumed that it had, 16% confirmed that they had indeed taken an incorrect dose at some time, and 3% were assured that it had happened very often. Moreover, 9% of respondents admitted that they had accidentally taken expired drugs, and 30% thought they might have taken expired drugs (61% did not believe this had ever happened).

In the domain that focused on using braille labeling, we asked our participants about the ideal way to dispense medications to the visually impaired. The majority of respondents recommended the use of Braille labeling (86%), 11% thought that medicines should be dispensed in the presence of a seeing companion, and 3% thought with assistance of technology (Fig. 3). When we asked our sample if they could read Braille letters, 89% assured us that they could, while only 11% could not (Fig. 4). When asked if Braille labeling could improve the quality of therapy and avoid the above mentioned challenges, 91% agreed (and 9% disagreed) that Braille labeling could improve the quality of therapy (Fig. 5).

It should be noted that although 24% of respondents had received at least one medication with Braille labeling, 76% had never received any medication with Braille labeling. We finished the survey with open ended questions asking participants to suggest any other way, rather than Braille labeling, to overcome the difficulties, improve treatment quality, and minimize the errors in dispensing medication to the blind and visual impaired. Interestingly, about 46% of respondents insisted that Braille labeling in English and Arabic was the key (not only on drug labeling but also on the drug leaflets and containers). While 20% of respondents had no other suggestions, the remaining respondents suggested various other techniques, such as mobile applications that can convert text to voice, the use of audible devices, sending the labels and instruction by Email to the patients, adding touchable marks to the containers, and using different container sizes and shapes.

4. Discussion

Severely visually impaired/blind people face countless difficulties in living their everyday lives. This is especially true when no facilities are provided to meet their special needs. Very few studies have examined the difficulties faced by these individuals and their requirements in relation to the administration of medications. Many studies have shown the validity of using Braille to improve literacy in the visually impaired (Khidri et al., 2014). Braille is a system written with embossed letters and numbers which the visually impaired can touch, and consequently, read and learn from (Khidri et al., 2014). We hypothesized that the use of Braille for labeling medications is a necessity for these patients. Therefore, in this study, we investigated medication usage patterns in severely visually impaired and blind patients living in Saudi Arabia. Moreover, we examined the perceptions of a representative sample of this group and assessed their needs regarding Braille labeling on drugs dispensed to them.

This study was accomplished using a questionnaire survey submitted to a sample of visually impaired individuals around the
The survey contained questions regarding demographic information, medical status, medication usage patterns, difficulties in handling medications, and, finally, the necessity of applying Braille on medication labels (and/or other ways to improve medication recognition).

We found that visually impaired patients struggle in recognizing their drugs, doses, and expiration date. The results of our study broadly align with the outcomes of Kentab et al. (2015). Additionally, our study found that these patients encountered difficulties in knowing when and which foods to avoid, and in knowing which drugs may interact with their medications. This study, in agreement with the Kentab study, found that about half of the respondents (54% and 46%, respectively) depend on a caregiver for obtaining their medications. This was mainly due to a lack of the facilities required to meet their needs. A dependence on others to

Fig. 2. The participants were facing hard time in recognizing drugs dose independently.

Fig. 3. The visually impaired proposed systems to dispense medications for them.

Fig. 4. The ability to read Braille system in our sample.

Fig. 5. The majority of participants thought that applying Braille is the best way to solve the problems they faced in taking their medications.
help them to identify their medications pushed many of the respondents into creating self-coping strategies of varying effectiveness (Table 2). This dependency on others to identify their medications and had subsequently made Braille stickers on the medicine containers by themselves. Also, in the answers to the open-ended questions in our survey, many of these patients believed Braille labeling would allow them independence in getting their medications. Hence, applying the Braille system to medicine labels to help patients with visual disability is a necessity.

The results of our study showed that 89% of respondents are able to read Braille. Teaching Braille to the visually impaired in Saudi Arabia started in 1958 in the evening classes of ordinarily schools (Battal, 2016). In the 1960s, the ministry of education in Saudi Arabia expanded the care of special education services and established the first school, Al Nour “The light”. In this school, books for the visually impaired were printed in the Braille system (Battal, 2016). The school aimed to improve the quality of life for blind people through literacy. As the number of schools for the visually impaired grew, they have all taken on the name (Al Nour) in honor of this first institution. The Braille system is now well recognized by the visually impaired around the kingdom. Therefore, the majority of our sample consider that applying Braille is a requirement in drug labeling.

Since 2005, Braille is a requirement for all pharmaceutical product packages granted marketing authorization in Europe. The requirements included medicines that had marketing authorization prior to this date, and all were required to comply by 2010 (European Commission, 2005). The Guide to Labels and Leaflets of Human Medicines issued by the European Union (EU) requires the product name, strength, and the dosage, to be expressed in Braille format on the packaging, without any abbreviations (Health Products Regulatory Authority HPRA, 2020). It also requires that the marketing authorization holder must ensure that the package leaflet is available on request in Braille format. The only exception was if the medications have to be administered by healthcare professionals (Health Products Regulatory Authority HPRA, 2020).

In the United State (US), use of Braille letters on pharmaceutical drug products is not a mandate of the Food and Drug Administration (FDA). On the other hand, the committee of the United States Access Board issued guidelines to advise industry on including Braille on packaging across the US (Connors et al., 2015).

A requirement for Braille code in medication packaging has been applied in the Gulf Cooperation Council (GCC) countries. In 2015, United Arab Emirates (UAE) required pharmaceutical companies to state the name and concentration of medicines using Braille on all packaging produced for the UAE market. The Braille must be included on the packs in Arabic and English Braille (Chaudhary, 2015). The Saudi Food and Drug Administration (SFDA) also gave special consideration to using the Braille system, especially, for medicines where the target population may include a larger proportion of visually impaired patients (SFDA, 2011). However, our study showed that only 24% of the participants have ever received medications with Braille.

In South Korea, pharmaceutical regulations regarding packaging recommend Braille be applied on over-the-counter packaging. Despite this recommendation, a study conducted in South Korea examining the usage of Braille labeling by community pharmacists (using a sample of thirty-six community pharmacies), found 77.8% of the pharmacies never used braille stickers (Lee and Lee, 2018). This demonstrates the necessity of establishing a mandatory legal ruling on pharmacies and pharmaceutical drug companies, compelling the use of Braille labels on medicines provided for visually impaired patients.

Because numerous countries around the world provide recommendations for using Braille letters on medicine packaging, some pharmaceutical manufacturers have applied Braille on the medication packages for their products both internationally and locally, this includes MERC®, Bayer®, Aljazeera®, and RiyadhPharm®. However, applying Braille on drugs labels requires some significant considerations. First, Braille currently is only implemented on outer/secondary packaging to clarify the trade name, generic name, strength, and expiration date (Fig. 6). However, the system is not applied to primary packaging of the capsules or tablets (for example, on the aluminum foils), nor on ampules or bottles, and this is important if medication errors are to be minimized (European Commission, 2005). Also, additional necessary information, such as drugs, foods, or beverages interactions are missing (Zuo et al., 2013). Similarly, warnings, contraindications, and possible drugs side effects in Braille are still missing in these regulations. Our open-ended questions had many comments about the need for such information by visually impaired patients.

According to the labeling requirements in the Code of Federal Regulations, the cGPM (current good manufacturing practice) of labeling,” Labels “refer not only to the drug names and strength but also to all the accompanying package insert or other product literature for dosage form and other information such as special consideration, contraindications, storage instructions, and the expiration date (21CFR PART 201, 2019). However, all of this information is missing in the Braille language provided. Thus, extending the requirements for Braille code to a full leaflet is vital.

A second important consideration when applying Braille in only the outer package, is the system relies on embossed dots, and any damaged or missing dot can completely change the meaning. The damage may occur between the time the dots are embossed on the drug packaging and the time that the package reaches the patient. This necessitates applying Braille to the primary packaging, or changes to how the packages are handled in the supply chain, or, preferably, printing Braille labeling at the time of dispensing. Applying Braille labeling at the time of dispensing is important, especially considering that pharmacists do not dispense the drug in its original container (as in hospital pharmacies). Moreover, applying Braille in the prescription labeling of drugs at dispensing time allows the pharmacist to individualize the drug dose, frequency, and duration for each patient, according to his/her case. Finally, as Arabic is the spoken language of Saudi Arabia, translating the labeling to Arabic Braille for the visually impaired people living in Saudi Arabia is a must.

There are many technologies on the market that can leveraged to assist visually impaired patients. These technological aids can be either devices (audible digital devices) or software applications, e.g. screen or code reading software. For instance, ScripTalk® by EnVision America, Inc., an audible prescriptions reader device that can read any medication prescription after placing the container in the device (Fig. 7). The software requires mobile applications or barcode readers that translate the conventional label screen to a Braille screen by scanning the medication barcode or by recognition of a medication box in an image. Other devices depend on Near Field Communication (NFC) technology that connects the data between a mobile phone and an NFC tag attached to a medication (AlZuhair et al., 2014; Garrido et al., 2012; Isomursu et al., 2009). However, many of these technologies do have their limitations and they do not provide full support for people with visual
disabilities (Laabidi et al., 2014). Most of the technologies available on the market support English readers. The results of our study show that only about 3% of the participants have ever used such tools, possibly, because they are unaffordable for many patients.

Braille labeling is more reliable than other methods, as the sensitivity of the adjunct tools is not an issue. However, technology can provide an additional source of information supplementary to the ordinary printed Braille labeling and this can be of great value to visual impaired patients, and may help visually impaired patients who can read Braille and also those who do not. Almuzaini et al have reviewed different technologies from the literature that can be used for the identification of medications, and discuss the advantages and disadvantages of each approach (Almuzaini and Abdullah-Al-Wadud, 2018). The QR code is possibly the leading approach because QR readers are freely available, and the codes can easily be printed on the medication box (Al-Quwayfili and Al-Khalifa, 2014; Almuzaini and Abdullah-Al-Wadud, 2018; Tekin et al., 2013). The SFDA have implemented new legislation requiring pharmaceutical products seeking marketing authorization in Saudi Arabia to have QR codes added to the packaging (Fig. 8). Pharmacists and patients can scan the code via a smartphone application, giving them full access to all the necessary information concerning medicine usage, recent warnings, registration status, expiry date, and price (SFDA, 2017). The regulation requiring that a QR code connected to the drug database be printed on the packaging should be extended to include information in Braille, which can then be simply read by a Braille screen on smartphones (Hayhoe, 2013). With additional features like a sound guide to find the QR code (Tekin and Coughlan, 2009, 2010), and an audible reading of the information in Arabic (Al-Shamma and Fathi, 2010), an extended regulation could avoid the concerns discussed above (regarding printing only Braille during manufacturing and prescription labeling). Consequently, this would greatly enhance pharmaceutical services provided to these patients in this region.

5. Conclusion

This study described medication usage patterns in the visually impaired in Saudi Arabia. These patients face many challenges in their efforts to self-administer their medications. The current rules and regulations concerning the dispensing of medications to this population do not sufficiently meet the needs of the patient. This study highlights the demand for applying Braille on manufacturing packaging and on prescription drug labeling for the visually impaired. A reconsideration of the regulations regarding the application of Braille labeling on medicines should be made. Using Braille on drug labeling can improve drug treatments, minimize medications errors, and promote independence in these individuals (by facilitating self-administration). The addition of technology and an electronic system to the printed Braille labeling can significantly advance the pharmaceutical care services provided and improve the quality of life of visually impaired/blind patients in Saudi Arabia.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.
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