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The impact of simulated visual impairment on medication use process: A study with healthy volunteers

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ABSTRACT

Background: Visual impairment may be caused by various diseases and can impact the safe use of medications. It is therefore important that healthcare professionals consider these challenges to facilitate the correct administration of medications by visually impaired patients.
Objective: To determine the category of visual impairment beyond which it becomes impossible to identify medication boxes, to read patient information leaflets, expiration dates, and dosage instructions.
Methods: Visual impairment was simulated with glasses on healthy volunteers who had to identify and read different elements on medication boxes and leaflets. The participant eligibility was confirmed through the administration of five ophthalmological tests designed to quantify functional vision. Data were analyzed using a within-subject repeated measures ANOVA.
Results: Ninety-two simulations were conducted. This study indicates that for a simulated moderate visual impairment, 81 % of participants lacked access to the medication names and doses, 75 % lacked access to the full expiration date, and 60 % were unable to read the leaflets. Additionally, a simulated moderate visual impairment resulted in a reduced reading speed of 44 words per minute. The low contrast of the writing on medication boxes makes identification more difficult.
Conclusions: This simulation study demonstrated that it became impossible to identify medication boxes from a severe visual impairment onwards, while it was no longer possible to read leaflets and expiry dates from a moderate visual impairment onwards. Consequently, it is necessary to ensure that the patient has strategies to identify medications, particularly if the packaging exhibits low contrast and small print.

1. Introduction

Low vision refers to any visual impairment (VI) that cannot be corrected by glasses or contact lenses.[1] VI is characterized either as a reduction in various visual functions, or by a functional disability to carry out tasks of daily living.[2,3]

To standardize the definition of VI, the World Health Organization (WHO) has established a classification comprising six categories of VI.[4] According to this classification, a person is considered visually impaired when their visual acuity is less than 3/10, meaning they can see at 3 m what a person with normal vision can see at 10 m.[4,5] In epidemiological surveys, VI is typically assessed according to this classification based on the visual acuity.[6,7] However, in clinical practice, other parameters such as visual field, color perception, or contrast sensitivity are also taken into consideration. Table 1 shows the categories of VI established by the WHO based on the visual acuity of the better eye.[4]

The concept of functional disability is defined as a limitation in the ability to perform the tasks required for independent living.[2,9,10] These tasks are divided into two groups: activities of daily living (ADL), which relate to the basic tasks of daily living (e.g. eating or washing), and instrumental activities of daily living (IADL), which relate to more complex tasks. The management of medications is considered an IADL.[2,9,10] A number of studies have demonstrated that age and vision loss have a negative effect on medication management.[3,11] Consequently, people with VI face greater challenges in managing their medications due to reduced access to dosage labels.[12–14] Indeed, reading dosage labels is a complex task that requires a high degree of precision,[15,16] and the legibility of the text depends on multiple factors including size, font, and contrast.[17] The legibility of dosage labels is important to ensure that patients take their medications in an appropriate manner and to prevent

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medication errors.[18] In this regard, specific recommendations have therefore been made in the United Kingdom[19] and the United States,[20,21] with the aim of improving the legibility of labels. These recommendations pertain particularly to the size of the characters, the typography, the organization of the information on the labels, and the increase in white space. Nevertheless, Leat et al.[22] and Latham et al.[23] found that an important proportion of current dosage labels did not adhere with these guidelines. According to some studies, visually impaired patients may also experience difficulty in reading expiration dates,[24] doses,[25] and patient information leaflets,[26,27] and identifying them.[28,29] The name and dose of some medications are written in Braille on the boxes. However, only 0.27 % of patients with VI worldwide are able to use it.[30] In addition, a study indicated that 24 % of visually impaired patients were unable to distinguish their tablets.[13] Another study showed that some visually impaired patients misdoes or take the wrong medication.[31] Therefore, vision is utilized at various levels in the management of medications, including visual acuity for reading dosage labels, leaflets or letters/symbols on boxes, and contrast sensitivity for distinguishing between tablets of the same color or with non-contrasting identification marks.[32]

It is often unfeasible for pharmacists and physicians to select appropriate packaging with accessible information for visually impaired patients. Consequently, it is necessary for these healthcare professionals to consider these difficulties and implement compensatory strategies to ensure that the quality of care provided remains uncompromised. Nevertheless, no study has yet evaluated which categories of visual impairment necessitate adaptations. As a result, the objective of the study was to determine the category of VI described by the WHO beyond which it becomes impossible to identify medication boxes and to read patient information leaflets, expiration dates, and dosage instructions. This would facilitate the inclusion of visually impaired patients in healthcare.

2. Methods

2.1. Study design

The methodology entailed the execution of VI simulations on a cohort of healthy volunteers. Indeed, the research was conducted exclusively with healthy volunteers to assess the impact of a simulated VI, while avoiding the confounding effects of VI-associated disorders and compensatory systems (e.g., touch) that may be developed by VI individuals. In general, if VI has occurred over several years, the individual would benefit from an adaptation period and would therefore be better able to recognize cues to facilitate the identification of medications.[33] Moreover, patients with congenital visual impairment sometimes have associated disorders (e.g. intellectual impairment) that may affect their ability to identify medications.

Currently, there is no standard protocol for simulating a VI in persons with normal vision.[34] Therefore, glasses were created with Lapeyre® FE100, FE030, FE010, FE005, FE001, FE000 Ryser occlusion filters (lapeyregroup.com) to simulate the different categories of VI described by the WHO and achieve the visual acuity corresponding to each category. A total of seven pairs of glasses were developed for the study. The first pair of glasses served as a control simulating normal vision with a visual acuity of 10/10. The following six pairs of glasses were created to simulate the categories of VI described by the WHO with visual acuities of 3/10, 1/10, 1/20, 1/50, light perception, and no light perception, which represents absolute blindness (complete blackness). A validation of the simulation glasses was conducted by an ophthalmologist using the Snellen test. The researcher initially conducted the test in binocular vision at a distance of 5 m to assess her distance visual acuity (reference: 10/10). Each pair of glasses was then worn by the researcher to evaluate distance visual acuity using the same parameters. A number of filters were superimposed on certain pairs of glasses to simulate visual acuities corresponding to categories defined by the WHO. Furthermore, the effect of Ryser filters on contrast sensitivity was assessed through the utilization of the Pelli-Robson test. The results of the Pelli-Robson test for the validation of the simulation glasses are in alignment with the findings in the literature.[8] Table 1 shows the validation of simulation glasses.

Additionally, a pilot study was conducted to determine the feasibility and duration of simulations under real conditions with eligible candidates, as well as to develop a smooth data collection process. To achieve this, the same protocol as described below was employed, enabling its adoption for the entirety of the study without modification. The mean duration of each assessment in the study was 51 min (SD 7).

2.2. Selection criteria and recruitment of participants

The study included healthy French-speaking volunteers aged of 18 and over, who did not have VI and did not wear glasses due to practical reasons related to the use of simulation glasses (contact lenses were allowed). Participants were also required to not have any chronic treatments, except for the contraceptive pill, and have no prior knowledge of Braille. The study excluded students who had already undertaken courses on the subject of medications. This reduce the risk of participants having prior knowledge of the medications used in the study.

The participants were recruited on a voluntary basis and using the snowball method. A poster was distributed via an online publication on social networks, inviting people to contact the research team through the telephone number or email address indicated on the poster to arrange an appointment at their earliest convenience. The required sample size ($n = 78$) was determined previously using G*Power® software based on specific parameters related to the statistical test used (effect size = 0.14; $\alpha = 0.05$; $1 - \beta = 0.95$; number of groups = 1; number of measures = 7). This effect size of 0.14 was calculated using an η^2 of 0.02, indicating small effects, and selected on the basis of Cohen's conventions.[35]

A non-invasive quantification of functional vision (without administration of medications, such as eye drops) was carried out using five

Table 1
Categories of visual impairment according to the World Health Organization and validation of simulation glasses.

Categories (WHO)	Type of damage	Type of VI	VA of the better eye (Decimal notation)		VA simulated by glasses (Decimal notation)	CS (logCS) *
			Lower than	*Greater than or egal to*		
Control (C)	Normal vision		–	8/10	10/10	2.10
Category 0 (C0)	Perceived loss	Mild VI	5/10	3/10	5/10	1.80
Category I (C1)	Low vision	Moderate VI	3/10	1/10	1/10	1.05
Category II (C2)		Severe VI	1/10	1/20	1/20	0.60
Category III (C3)	Legal blindness	Profound VI	1/20	1/50	1/50	0.15
Category IV (C4)		Severe blindness	1/50	LP	LP	0.00
Category V (C5)		Absolute blindness	No LP		Complete blackness	0.00

CS: contrast sensitivity, LP: light perception, VA: visual acuity, VI: visual impairment, WHO: World Health Organization. * A score of 2 means normal CS, a score less than 1.5 indicates VI, and a score less than 1 indicates a visual disability.[8]

ophthalmological tests to determine the eligibility of the recruited volunteers for the study (**Appendix A**). These tests assessed visual acuity (Snellen and Parinaud tests), central visual field (Amsler grid), and color vision (Ishihara plates and 15 Hue test). Participants who did not fully validate all five ophthalmological tests according to inclusion criteria described in Table 2 were excluded from the study.

2.3. Selection criteria for study material

The study is limited to medications marketed in Belgium and was divided into four parts: identifying medication boxes (part 1), reading expiration dates (part 2), reading patient information leaflets (part 3), and reading dosage instructions (part 4).

2.3.1. Part 1 Identifying medication boxes

The medication boxes (**Appendix B**) were selected based on the font size of their name and dose. Five different font sizes were identified with x-heights of 2 mm, 4 mm, 6 mm, 8 mm, and 10 mm, respectively. One box was selected for each font size within each category of VI (5 boxes/category). Consequently, medication boxes were different for each category of VI to eliminate any potential memory effects. Different color contrasts have also been selected, including black or white writing on a colored background. All generics and contraceptive medications were excluded.

2.3.2. Part 2 Reading patient information leaflets

The leaflets were selected based on the font size (x-height: 2 mm), and included a scientific vocabulary, with medication and pathology names that could be more complex to read. The leaflets were distinct for each category of VI (2 leaflets/category). Furthermore, different sections of the leaflets were used. These sections were delineated by the use of frames in color, which facilitated the process.

- **Section 1** "What information should be known prior to the administration of this medication?": This section was used to evaluate **reading speed** and was framed in blue. Each piece of text selected comprised an average of 160 words.
- **Sections 2 and 3** "What are the possible side effects" and "How should this medication be stored": Theses sections were used to evaluate **rapid information searches** and were framed in yellow. Three questions for each category were drafted regarding these two sections.

2.3.3. Part 3 Reading expiration dates

Expiration dates were also selected based on their font size. One equivalent font size (x-height: 2 mm) was chosen for all medication boxes. Expiration dates, written in black on a white background, were different for each category of VI to eliminate the memory effects (1 expiration date/category).

2.3.4. Part 4 Reading dosage instructions

Four sheets with instructions for medication use (dosage and administration method) (**Appendix C**) were written in *Arial* font, a simple and standard font recommended for use with low vision.[36] Eight different font sizes were employed for each sheet: A12.5 (x = 2.33 mm), A16 (x = 2.91), A20 (x = 3.64), A25.5 (x = 4.65), A32 (x = 5.81), A40 (x = 7.27), A50 (x = 9.16), and A64 (x = 11.64). The medications were different for each font size and for each sheet. Dosages and administration methods of each medication were established based on the PHIL tool available on the website of the Belgian Pharmaceutical Association.

The same medication boxes, expiration dates, patient information leaflets, and sheets with instructions for medication use were used for all participants.

2.4. Data collection

The study comprised two stages. In the first stage, the participant's functional vision was quantified, and a paper evaluation grid was completed. The second stage involved the four parts of the simulation study.

2.4.1. Part 1 Identifying medication boxes

For each medication box, participants were required to provide the speciality name, molecule dose, and box color, starting from the largest font size to the smallest. All colors within the same range were accepted. For example, for the box of *Claversal*® (mesalazine), the accepted denominations included green, blue, turquoise blue, and turquoise green. A score was assigned to participants based on their performance to identify the name (1 point), dose (1 point), and color (1 point) of five medications. As a result, a total score (/15) was calculated for each participant in each category of VI.

2.4.2. Part 2 Reading patient information leaflets

Participants were instructed to read passages from the leaflets and answer to questions to evaluate reading speed and rapid information searches. To assess reading speed, participants were required to read the entirety of the selected passage and were timed. The time (in minutes) and the number of words omitted or skipped were recorded. A score was awarded according to the reading speed interval: 0 wpm (0 point), < 30 wpm (1 point), 30–40 wpm (2 points), 40–50 wpm (3 points), 50–60

Table 2
Characteristics of volunteers recruited (n = 102).

Parameters	Pilot study (n = 3)	Simulations (n = 92)	Excluded volunteers (n = 7)
Gender	**M**: 33 % (n = 1) **W**: 67 % (n = 2)	**M**: 46 % (n = 42) **W**: 54 % (n = 50)	**M**: 100 % (n = 7) **W**: 0 % (n = 0)
Mean age	30.33 years (SD 10.41)	25.74 years (SD 5.68)	39.63 years (SD 13.29)
Snellen test	VA = 10/10 (SD 0.00)	VA = 9.8/10 (SD 0.48)	**V29**: VA = 2.8/10 **V64**: VA = 3.7/10 **V63**: VA < 6.6/10 **V64**: VA < 6.6/10
Parinaud test	VA = 9/10 (SD 0.00)	VA = 9/10 (SD 0.00)	
Amsler grid	No distortions: 100 % (n = 95) No blotches: 100 % (n = 95)		**V64**: Distortions identified
Ishihara plates	14 plates read: 33 % (n = 1) 15 plates read: 67 % (n = 2)	13 plates read: 9 % (n = 8) 14 plates read: 37 % (n = 34) 15 plates read: 54 % (n = 50)	– **V54**: Protanopia detected **V76**: Deuteranopia detected
15 Hue test	No simple inversion: 100 % (n = 3)	No simple inversion: 50 % (n = 46) 1 simple inversion: 50 % (n = 46)	**V99**: Protanopia detected **V25**: 3 simple inversions **V63**: 3 simple inversions

M: man, VA: visual acuity, W: woman.

wpm (4 points), 60–70 wpm (5 points), 70–80 wpm (6 points), > 80 wpm (7 points). To evaluate rapid information searches, participants were instructed to read the pertinent sections of the leaflets and provide the correct response once they had identified it in the text. A score was assigned to participants based on their ability to answer the questions correctly (1 point/correct response). As a result, a total score (/10) was calculated for each participant in each category of VI.

2.4.3. Part 3 Reading expiration dates

Participants were asked to provide the month and year of the expiration dates. A score was assigned to each participant based on their performance to identify the month (1 point) and the year (1 point) of the expiration dates. As a result, a total score (/2) was calculated for each participant in each category of VI.

2.4.4. Part 4 Reading dosage instructions

Participants were required to read the different dosage instructions, beginning with the smallest font size and progressing to the font size that allowed for easy and complete reading. A complete reading included information on dosage and method of administration. The smallest font size that could be read by the participants was noted.

The simulation glasses were worn by each participant in order of opacity, from the least opaque (control, normal vision) to the opaquest (category V, absolute blindness). All the simulations were carried out in the same environment and with the same lighting, to minimize the effect of the environment. Parts 1 and 3 were performed at a fixed distance of 40 cm, and at free distance when the identification or reading became too complex. Parts 2 and 4 of the study were performed at a reading distance chosen by the participant. All the parts were realized one after the other for each category of VI to minimize the number of manipulations with the simulation glasses. The data collection process for each part was terminated when identification or reading became too complex or impossible. Data were recorded in grids using an Excel spreadsheet.

Appendix D contains the data collection table of the study with the selection and score calculation criteria set out above.

2.5. Data analysis

The data obtained from the quantification of functional vision were presented in the form of mean and standard deviation values or percentages.

A score for each participant, as well as a mean score and a standard deviation (SD) were calculated for each category of VI in parts 1 (score /15) and 2 (score /10) in the Excel spreadsheet. A within-subjects repeated measures ANOVA was performed on the mean scores using IBM® SPSS 29 Advanced software. Before conducting the statistical analysis, the conditions for applying the model were verified, including the data independence within each category, residuals normality and data sphericity. It was found that the latter condition was not met. To address this issue, the Greenhouse-Geisser test was used to interpret the ANOVA. In addition, a Bonferroni post-hoc test was used to compare the means in pairs to determine which mean differed significantly from the others. A p-value of less than 0.05 was deemed to be statistically significant. Moreover, mean reading speeds and standard deviations were calculated for part 2 of the study with the following formula: Reading speed = (Number of words – Number of words omitted/skipped)/ reading time.

The number of participants who identified one, two or no elements of the expiration dates and who read the different font sizes for parts 3 and 4 respectively were recorded. The data was then subjected to percentage calculation and graphical representation using the Microsoft Excel® software.

2.6. Ethic approval

The Ethics Committee of the Faculty of Psychology and Educational Sciences of the University of Mons approved the study protocol (file number: *220422TM*). The risk identified for the study is the discomfort associated with wearing simulation glasses. To reduce this risk, the time spent wearing glasses has been limited as much as possible. All participants provided an informed consent. This consent document served to reiterate the established regulations concerning data confidentiality and the participants' prerogative to withdraw from the study at any time. Participant names were pseudonymized during the data collection phase

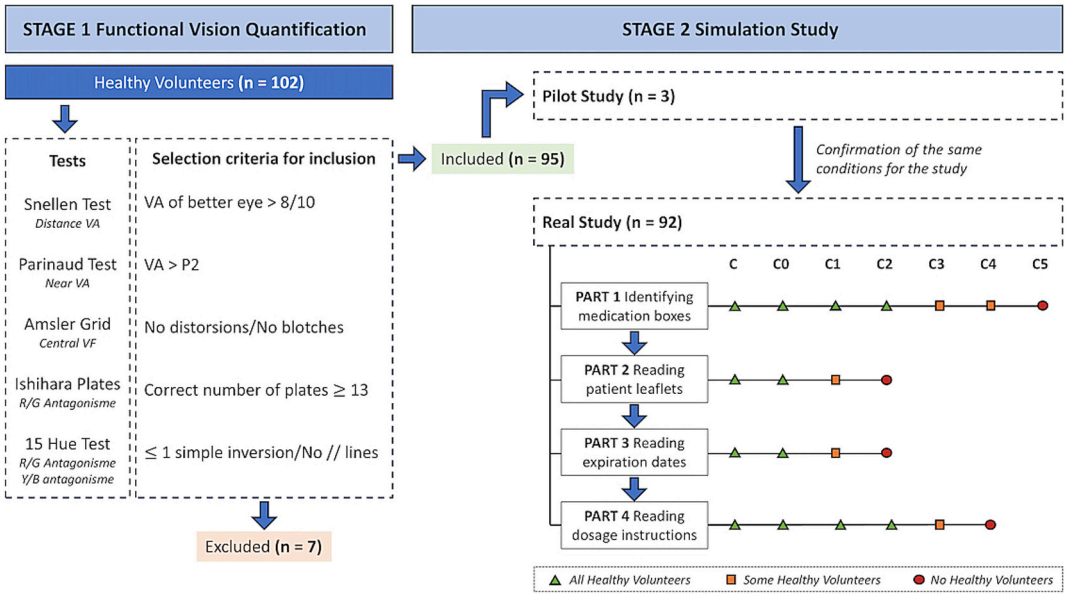

Fig. 1. Detailed process of the study. The present process encompasses two stages of the study: the quantification of functional vision and the simulation study. The colored triangles, squares, and circles represent the category of visual impairment up to which the healthy volunteers were able to perform identification or reading. Notably, a red circle was placed for one volunteer who demonstrated reading proficiency for severe visual impairment (CII), as their performance was not indicative of the overall sample. R/G: red/green, VA: visual acuity, VF: visual field, Y/B: yellow/blue, //: parallel. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

using a convention with the letter V for "volunteer" followed by a number assigned in the order of the simulations conducted. No other personal data was collected during the course of this study.

3. Results

The study process is detailed in Fig. 1. The study was carried out over a seven-months period, from October 2022 to April 2023, and involved 102 healthy volunteers. Three volunteers participated in the pilot study, while 92 aged 18 to 46 years contributed to the actual data collection. Seven volunteers did not validate all the inclusion criteria defined for the quantification of functional vision (Fig. 1) and were therefore excluded from the study. Table 2 presents the characteristics of volunteers recruited.

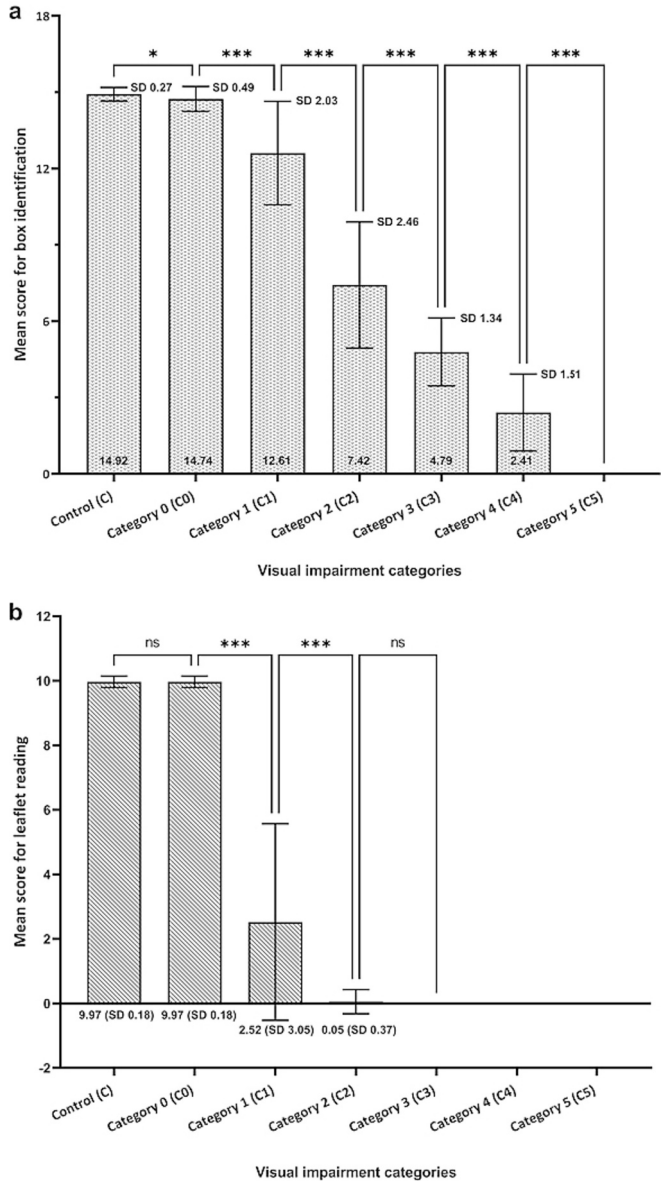

Fig. 2. The impact of simulated visual impairment on the ability **a)** to identify medication boxes, and **b)** to read patient information leaflets. Indeed, the null hypothesis H_0 for this test stated that there was no difference between the means, indicating that the VI had no effect on the independent variables studied. In this case, *p*-value is less than 0.001, which means that the null hypothesis can be rejected. This implies that there is a statistically significant difference between the means, or that at least one mean differs from the others. * = significant difference between 0.05 and 0.01; ** = significant difference between 0.01 and 0.001; *** = significant difference < 0.001; ns = non-significant difference.

3.1. Part 1: Identifying medication boxes

Fig. 2a presents the results for the identification of medication boxes. These results demonstrate a significant impact of simulated VI on box identification ($F_{6,91} = 1865.84$, $p < 0.001$), as evidenced by a decline in mean score as VI category rise. Specifically, to ascertain the category of VI that exhibited the most significant effect, the Bonferroni test was employed. While a decline in score was evident across all categories of VI, the most significant mean difference was observed between categories I and II (5.19, $p < 0.001$, $CI_{95} = [4.33; 6.05]$), with the least significant mean difference noted between the control and category C0 (0.19, $p = 0.03$, $CI_{95} = [0.01; 0.36]$). In summary, the results indicates that box identification becomes increasingly complex starting from a severe VI (category II).

3.2. Part 2: Reading patient information leaflets

Fig. 2b presents the results for the reading of leaflets. These results demonstrate a significant impact of simulated VI on leaflets reading ($F_{6,91} = 1507.52$, $p < 0.001$), as evidenced by a decline in mean score as VI category rise. Specifically, the Bonferroni post-hoc test revealed that there were no significant differences between the means of the control and category C0 (0.00, $p = 1.000$, $CI_{95} = [-0.07; 0.07]$), as well as between the means of categories II and III (0.05, $p = 1.000$, $CI_{95} = [-0.07; 0.17]$). Nevertheless, a decrease in the mean score was observed between categories I and II (2.47, $p < 0.001$, $CI_{95} = [1.49; 3.45]$), while a significant decrease was observed between categories 0 and I (7.45, $p < 0.001$, $CI_{95} = [6.44; 8.45]$). Notably, reading the instructions became unfeasible for categories III, IV, and V. In summary, the results indicates that leaflet reading becomes increasingly complex starting from a moderate VI (category I).

Table 3 presents the data on reading speed. While all of 92 participants with normal vision (control) or simulated mild VI (category 0) were able to read almost the entire patient information leaflet extracts, only 38 of them were able to read a small part of the leaflet with simulated moderate VI (category I). As the simulated VI increased, the mean reading time increased and the mean reading speed decreased from 189 wpm for normal vision (control) to 42 wpm for severe VI (category II).

3.3. Part 3: Reading expiration dates

All participants (100 %) were able to provide a complete reading of the expiration dates (month and year) during simulations of control and category 0. However, for category II to V, it was no longer possible to identify the month and year. The results for category I (moderate VI) need to be presented with more details. Specifically, only 25 % of volunteers were able to read the month and year of the expiration dates, while 22 % of them were able to identify only one element (either the month or the year). For the majority of volunteers (53 %), reading the expiration date was impossible.

3.4. Part 4: Reading dosage instructions

The dosage instructions reading was only assessed for the category that showed an identification or reading problem in the other parts of the study (from category I). It was not possible for participants to read the medication dosage instructions in categories IV and V. Fig. 3 details the results for categories I, II, and III. In category I, the reading threshold was set at *Arial* 12.5 for 65 % of volunteers. In category II, the results were scattered across all the font sizes evaluated. Particularly, for 40 % of volunteers, the reading threshold was set at *Arial* 40. In category III, the smallest font size that volunteers were able to read was *Arial* 40.

Table 3
Reading speed data.

Category of VI according to WHO	Number of words in the leaflet extract	Number of volunteers who were able to read the leaflet extract	Mean number of words read by volunteers	Mean time to read the leaflet extract (*sec*)	Mean reading speed (wpm)
Control (C) Normal vision	167	92	166 (SD 1.04)	52.76 (SD 8.23)	**189 wpm** (SD 29.40)
Category 0 (C0) Mild VI	157	92	156 (SD 1.42)	55.39 (SD 11.01)	**169 wpm** (SD 33.50)
Category I (C1) Moderate VI	153	38	45 (SD 64.50)	61.55 (SD 87.40)	**44 wpm** (SD 25.81)
Category II (C2) Severe VI	160	1	1 (SD 13.35)	1.98 (SD 18.98)	**42 wpm** (SD 6.14)
Category III (C3) Profound VI	171				
Category IV (C4) Severe blindness	161		No more reading possible.		
Category V (C5) Absolute blindness	159				

Sec: second, VI: visual impairment, WHO: World Health Organization, wpm: words per minute.

However, 61 % of volunteers were unable to read *Arial* 64.

4. Discussion

This study demonstrates that simulating a VI in healthy volunteers affects their ability to identify boxes and read expiration dates, patient information leaflets, and written dosage instructions of medications marketed in Belgium.

More specifically, this study aimed to determine the category of simulated VI at which the identification of medication boxes and the reading of expiration dates, leaflets, and dosage instructions become impossible for the majority of participants. Indeed, only 22 % of participants in category 0 (mild VI) could not access to all identifying information on the medication boxes (name + dose), compared with 80 % in category I (moderate VI) and 99 % with in category II (severe VI). With regard to the colors of the boxes, only 30 % of participants in category III (profound VI) were unable to identify all the colors, compared with 92 % in category IV (severe blindness). Additionally, 75 % of participants in category I lacked access to all the information on the expiration date (month + year) while, 60 % of participants in category I were unable to read the leaflets, in contrast to 99 % in category II. The results for reading of dosage instructions were more variable.

The ability to identify medication boxes and read expiration dates, patient information leaflets, and written dosage instructions depends on the reading performance. Indeed, the act of reading is a complex process that is influenced by a multitude of factors. These include both visual factors[37] and non-visual factors, such as motor coordination, linguistic comprehension, and cognitive competence.[37] These factors refer to a person's intrinsic abilities.[38] Reading difficulty is often cited as one of the most common signs observed in low vision clinics.[38] Moreover, a study by Leat et al.[39] showed that reading medication information was the main objective for the patients questioned.

This study shows that severe VI (category II) corresponds to the category of VI at which identification of medications becomes challenging. Although a reduction in the mean score was observed for moderate VI (category I), this was not considered limiting as it was mainly due to the difficulty of identifying the boxes of *Temsta*® (lorazepam) and *Loramet*® (lormetazepam). Indeed, the font type and contrast

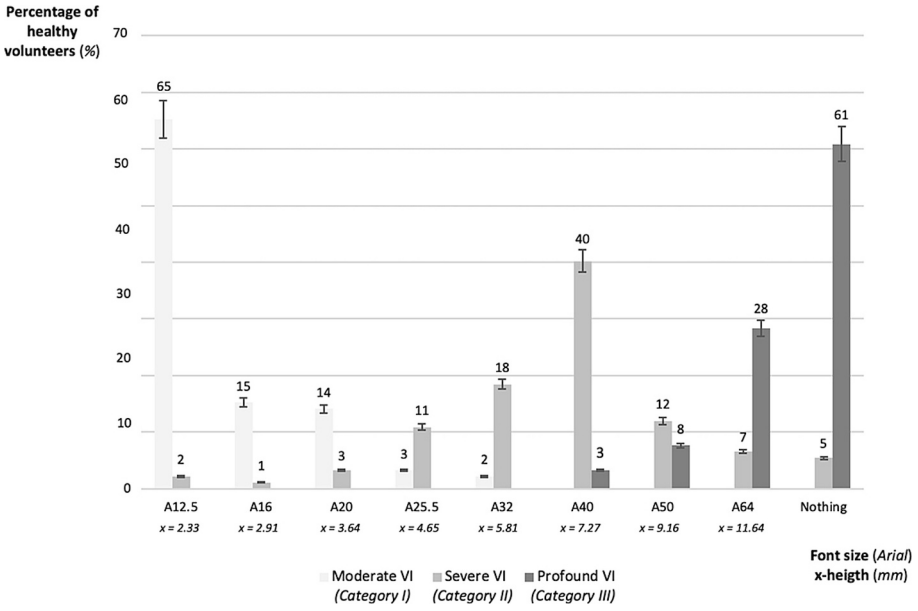

Fig. 3. Percentages of healthy volunteers who were able to read the different proposed font size for simulated moderate, severe and profound visual impairment. The font under consideration was *Arial*, ranging from size *Arial* 12.5 to *Arial* 64. The x-heights (in millimeters) corresponding to each size of the *Arial* font were also indicated. VI: visual impairment.

used (white writing on a yellow background [16 % theorical contrast][40] or orange [60 % theorical contrast][40]) for the design of these boxes were not appropriate for identification during a simulation of VI. The identification of *Azopt*® (brinzolamide), written in smaller characters, was facilitated by the use of a more readable font and optimal contrast (black writing on a white background). In accordance with the recommendations set forth in the Guide to Good Coloring Practice,[40] a theorical contrast of at least 70 % is recommended to enhance readability. To circumvent this issue, the medication boxes to be distributed according to each category of VI could have been randomly assigned. In cases of simulated severe blindness, the majority of participants were still able to perceive color, although not all colors could be identified due to their presence on a small part of the boxes (cf. Appendix A, Category IV). One study tested the impact of color differences on the identification of eye drops.[41] The results showed a 64 % improvement in the correct identification of medications based solely on the analysis of the color of identical bottles.[41] This suggests that the use of boxes with distinct colors could help patients to identify their medications according to their visual abilities.

Furthermore, the simulation study shows that moderate VI (category I) is associated with an increased difficulty or even inability to read patient information leaflets and expiration dates. This was evidenced by a reduction in reading speed, quantified in wpm. The mean reading speed was of 44 wpm (SD 21), compared to 193 wpm (SD 29) for normal vision. In general, a reading speed below 80 wpm is considered to be slow, while above 160 wpm is considered to be fluent.[42] Going further, Whittaker and Lovie-Kitchin[17] identified three slower reading rates based on clinical experience in people in low vision, including spot reading (44 wpm). The reading of participants who were able to read with a simulated moderate VI (category I) can therefore be described as spot reading, adequate for many everyday tasks, such as reading labels. Only one participant was able to read with a simulated severe VI (41 wpm). A study has shown that visually impaired people read at a slower speed than those without VI. Indeed, Rokiah and Zainora[38] found that 63 % of visually impaired students read at a slower speed than their peers without VI. Similarly, Latham et al.[23] demonstrated that a simulated moderate VI (category I) was sufficient to induce a slow reading speed ($<$ 25 wpm) for the reading of dosage labels. Reading speed reflects the dynamic nature of reading and depends on the level of difficulty of the reading material,[37] as well as the ability to recognize words.[43] Factors such as the length and complexity of words can therefore influence reading ability. In this simulation study, it was observed that few participants who were able to read leaflets with a simulated severe VI were able to identify only a few words. It is also important to mention that certain medication or pathology names in the patient information leaflets were more difficult to read. The reduction in reading speed may also be attributed to the small font size used for writing leaflets. It is essential to consider that while visual acuity defines the smallest font size for legible reading, a larger font size is often required for smooth and efficient reading.[37] Moreover, the low contrast of the expiration dates written on the boxes and the small font size used to write them, may have made them difficult to locate and read.

Finally, the simulation study demonstrates a great variation in font sizes that can be read by healthy volunteers for written dosage instructions. This depends on the font used, the category of VI, and also the particular skills needed for reading and comprehension as described above. However, 65 % of volunteers were able to read *Arial* 12.5 with a simulated moderate VI (category I). These results are similar to those obtained in a study conducted by Latham et al.[23] Indeed, this study demonstrated that with a simulated moderate VI (category I), only 20 % of participants were able to read sufficient information on a typical label (*Arial* 9), while 80 % of them were able to read labels written with large characters (*Arial* 12). This study also showed that label accuracy improved with larger characters.

In addressing the identification and reading difficulties experienced by visually impaired patients, healthcare professionals may propose several solutions. One such solution is assistive products, as evidenced by the research conducted by Almuzaini et al.,[44] who examined the use of text readers for medication management, and by Virgili et al.,[45] who demonstrated that reading devices, such as optical and electronic magnifiers, can enhance reading speed and quality of life for individuals with vision loss. Focus groups have been conducted with community pharmacists to identify assistive products that could be readily integrated into pharmacy practice.[46] In this study, it was also proposed that community pharmacists repackage medications into small sachets with a readable label (in large print, raised print, or readable with an assistive product). Adapted medication schedules could also be proposed when necessary, and individualized interviews could be conducted to offer a medication box identification exercise.

5. Future considerations

The results presented are based on a simulation study. It must be acknowledged that the results obtained for patients with genuine visual impairment may differ. Indeed, the study did not account for the possibility that younger participants may have utilized accommodations to complete the various tasks, which would not have been a feasible option for older people. The results are therefore not relevant to older people (e.g. people with presbyopia). They may also not be generalizable to people with aged-related macular degeneration (central scotoma imposes additional restrictions on performance that are not taken into consideration in this study). Consequently, the sample of healthy volunteers may not be representative of the heterogeneity of the visually impaired population. Given the various limitations of this study, further work on more specific groups of patients such as those with age-related macular degeneration or older patients is required to clarify the generalizability of the results presented.

Only a limited number of font size and font type for dosage instructions could be tested. Other combinations of styles/sizes and layouts could be tested. For example, the *Luciole* font, which was specifically designed for individuals with VI[47] could be the subject of future studies.

Finally, it would be beneficial to formulate and implement recommendations for healthcare professionals to incorporate visually impaired individuals into healthcare services. The preliminary phase in implementing these recommendations involves enhancing awareness among healthcare professionals regarding the issue. It is noteworthy that the development of training programs, whether university-based or postgraduate, on VI could serve as a catalyst for this awareness process.

6. Conclusions

This simulation study demonstrated that it became impossible to identify medication boxes from a severe visual impairment onwards, while it was no longer possible to read leaflets and expiry dates from a moderate visual impairment onwards. To ensure an individualized approach for patients with moderate visual impairment (category I) and above, healthcare professionals require appropriate recommendations and tools. The results indicate that it is more challenging to identify medication names when contrast is low. It may be worthwhile to recommend to pharmaceutical companies that they use optimal color contrasts and larger fonts on medication boxes, especially for the names of medications, their dose, and for highlighting expiration dates. Nevertheless, this is not always the case, and thus pharmacists must exercise heightened vigilance when dispensing medications with low-contrast names to visually impaired patients, and if necessary, ensure that the patient has implemented strategies to identify the box. Furthermore, the font size used to write patient information leaflets and dosage instructions needs to be addressed. These adaptations could facilitate medication identification and information access for visually impaired people.

CRediT authorship contribution statement

Théodora Merenda: Writing – original draft, Visualization, Methodology, Investigation, Formal analysis, Conceptualization. **Fanny Depasse:** Writing – review & editing, Methodology, Conceptualization. **Stéphanie Patris:** Writing – review & editing, Validation, Supervision, Conceptualization.

Declaration of competing interest

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

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Appendix A. Supplementary data

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