

# The Safety Gap

Safety and Accessibility of  
Medicines and Medical Devices  
for people with sensory  
impairment

A report commissioned by the Patient Safety  
Commissioner

Patient Safety  
Commissioner  
**Listening to Patients**



## The Safety Gap

# Foreword



The safety of a medicine relies on the 6 Rs – that it is the right person, right medicine, right route, right dose, right time and the right to decline.<sup>1</sup> The WHO Medication without Harm campaign, ‘Know, Check, Ask’ highlights the need for patients to be seen as partners in their care, with the appropriate level of information and knowledge to be kept safe.<sup>2</sup> But despite these campaigns, it is estimated that there are 237 million medication errors each year in England.<sup>3</sup>

For patients with sensory impairment, including people with sight loss or hearing loss, there are greater barriers to access the knowledge and information about medicines and medical devices needed to stay safe. This impacts on more than 2 million people living with sight loss in the UK<sup>4</sup> and over 18 million adults in the UK who are deaf, have hearing loss or tinnitus.<sup>5</sup> As a General Practitioner, I know from my clinical practice that patients with sensory impairment may find it difficult to use medicines and devices and this was backed up by correspondence from patients to me as the Patient Safety Commissioner (PSC). Gaps in patient information were highlighted further in my work as part of the task force on developing an electronic patient information leaflet (ePIL).

In this project we focused on the needs of patients with sight loss and diabetes, as sight loss can be a consequence of diabetes and patients with diabetes may use medicines and medical devices as a matter of daily routine. During the course of this project we published the Patient Safety Principles<sup>6</sup> which set out ways to help design and deliver care with the patients’ perspective in mind. This project speaks to a number of the principles including creating a culture of safety where patients are at the heart of everything, where we treat people equitably and identify and act on inequalities. The Principles set out that we should identify and mitigate risks, be transparent and accountable and use information and data to drive improved care and outcomes.

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- 1 [Discussing and planning medicines support | Quick guides to social care topics | Social care | NICE Communities | About | NICE](#)
  - 2 [Medication Without Harm](#)
  - 3 [237+ million medication errors made every year in England | BMJ](#)
  - 4 [Learn more about sight loss statistics across the UK | RNIB](#)
  - 5 [Prevalence of deafness and hearing loss – RNID](#)
  - 6 [Patient Safety Principles – Patient Safety Commissioner](#)

I would like to thank Professor Margaret Watson for her expertise and huge commitment to this work. I would also like to thank all the patients who attended focus group and contributed to the research. It's only by listening to the views and voices of people with lived experience that we are able to gain insights that will make improvements to patient safety and to the accessibility of medicines and medical devices.

I would also like to thank all those organisations who have been part of this work, and by doing so, have been able to understand ways that, making changes which may appear small, can have huge positive impacts on the lives of those that we care for. In particular I would like to thank the Boots branches in Westfield Stratford and the Stratford Centre for hosting me and my team and for the innovations that are helping to support the needs of patients with sight and hearing loss. I would also like to thank the RNIB, the RNID, Diabetes UK and the Thomas Pocklington Trust for their exceptional work and help to amplify these findings so that we can avoid patients coming to harm.

When we get it right for people with additional needs we will make it better for everyone.



**Professor Henrietta Hughes OBE FRCGP**

## A. Introduction

The Patient Safety Commissioner (PSC), Professor Henrietta Hughes, amplifies the views and voices of patients in relation to the safety of medicines and medical devices. The report of Professor Margaret Watson highlights serious gaps and deficiencies in the way that people with visual and/or hearing impairment or loss (referred to as sensory impairment) are able to access and use medicines and medical devices safely.

This executive summary sets out some of the background of the work and the recommendations and observations that the PSC wishes to make as a result of the findings of Professor Watson's Report.

### The work of the Patient Safety Commissioner

The PSC is an independent appointment whose has two primary roles set out in legislation. The first is to promote the safety of patients with regards the use of medicines and medical devices. The second is to promote the importance of the views of patients on those same issues.

The PSC is supported by a small team of civil servants, who helped scope the initial project plan, as well delivery of the project.

Throughout the study, the team has benefitted enormously from the advice, support, and input of Diabetes UK, the RNIB, the RNID and the Thomas Pocklington Trust.

In addition, the PSC appointed Professor Watson as the researcher for this project in Summer 2024. Professor Watson conducted this research through her consultancy, Watson Research and Training Limited. (She also holds a Professorial position with the University of Strathclyde). We want to extend our thanks to her for all her work in undertaking the study and writing the accompanying report.

### What does the report cover?

The report presents the results of a short-term study to explore the challenges experienced by patients with sensory impairment in relation to their safe and effective access to and use of medicines and medical devices.

Professor Watson's report contains five chapters:

1. Background
2. Current context
3. Overview of existing research
4. The study
5. Discussion and findings

Chapter 4 is where Professor Watson sets out the findings for our engagement with patients (via focus groups) and our key informants survey that we sent out to interested organisations and bodies.

The PSC has used the findings set out in Chapter 5 of Professor Watson's report as her evidence base for a set of recommendations and observations that we have included at the end of this Executive Summary.

### **Why has the PSC undertaken this project?**

The PSC started her post in September 2022. Since her appointment, she has focussed on a wide range of concerns that patients have raised with her.

As with all her work, the origin of this project lay in a conversation with patients. The PSC held a meeting with the RNIB in March 2024 – as part of her programme of regular engagement with patients and patient representative organisations. In that conversation, they flagged the persistent challenges that those with visual loss or impairment face when accessing healthcare information. They flagged the existing, collaborative research undertaken with other charities in this space around the barriers to implementation of the NHS Accessible Information Standard (AIS). They also raised the specific issues around medicines and medical devices – citing the inaccessibility of glucose readers – as one example. These concerns echoed those of individual patients who had contacted the PSC via our correspondence route.

Work then began to publish the PSC's business plan for 24/25. When considering how to choose from our longlist of possible projects to undertake with our limited resource, we examined a number of areas:

1. Alignment with the PSC's remit, strategy, and Patient Safety Principles.
2. What areas will present us with the best opportunities to maximise our impact in terms of improving outcomes for patients.

In terms of remit, the topic of this report sits firmly within the core of her remit around the safety of medicines and medical devices. In terms of our strategy, one of its three pillars is 'to support initiatives which amplify all patient voices and empower patients to make informed decisions about their care.' Underneath this pillar sits our specific aim of calling for 'informed consent and supported decision making so all patients are fully informed about the benefit, risks and alternatives when a medicine or medical device is used.'

The overlap of the scope of this report and this part of our strategy is clear. As Professor Watson sets out in her report,

For any patient to use a medicine as it is intended, they must first of all have sufficient and accessible information to make an informed choice regarding whether to use it and the anticipated benefits and risks of using it.

Finally, the PSC published the Patient Safety Principles in October 2024. These Principles are designed to inform the work of the health and care system – but also the work of the PSC. The full list is set out below:

1. Create a culture of safety.
2. Put patients at the heart of everything.
3. Treat people equitably.
4. Identify and act on inequalities.
5. Identify and mitigate risks.
6. Be transparent and accountable.
7. Use information and data to drive improved care and outcomes.

This project is particularly relevant to advancing principles (2), (3), (4) and (5).

In terms of the second consideration – maximising opportunities to influence – we noted that a refresh of the NHS AIS was forthcoming, along with the potential introduction of mandatory information standards under the Health and Care Act 2022. We also noted the developments in MedTech for the purposes of managing diabetes – including the approval of the National Institute for Health and Care Excellence (NICE) of hybrid closed loop technology – also known as the artificial pancreas – in December 2023, presenting a unique opportunity to influence the procurement and rollout of this technology.<sup>7</sup>

On the back of this, the PSC included the headline of this project in her business plan for 24/25, published in April 2024.<sup>8</sup>

### **Defining the scope of the project**

Once the project was included in the 24/25 Business Plan, it was necessary to refine down the scope of the project to match our timescales and resources.

We developed an initial proposal around diabetes and accessibility. This was because we were aware of the overlap between sight loss and diabetes, as well as the recent expansion of the medical technology available to manage the condition. As a result of the resource available – and keen not to replicate existing work completed by charities – we decided to focus on medicine and medical devices, as opposed to the whole clinical pathway.

We are grateful during this phase of the project for the insights of the RNIB and Diabetes UK, who helped us test our initial proposal.

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7 [NICE recommends life changing technology is rolled out to people with type 1 diabetes | NICE](#)

8 [Business Plan FY 2024-25 – Patient Safety Commissioner](#)

From the RNIB, we learnt that diabetic retinopathy is commonly referenced in their community Facebook groups, including in relation to accessibility issues around needles and talk back blood glucose monitors.

Diabetes UK also shared with us some initial feedback from colleagues of specific known issues around continuous glucose monitoring (CGM) devices and patient information leaflets. They also confirmed that they receive a substantial number of queries to their helpline from people with diabetes experiencing sight loss asking advice on which CGM, pump, pen or other device could suit their needs.

### **Key research questions**

After the scoping phase was complete, the PSC and internal team set the following research question to Professor Watson:

- What barriers to patient safety (specifically in relation to medicines and medical devices) exist for patients with sensory impairment?
- How do these barriers specifically manifest in relation to patients who have diabetes and are visually impaired? Are there areas of good practice in this area that we can learn from?
- What should the health system do to overcome these barriers?

## **B. Specific issues outside the scope of the main report**

There are a number of issues that we encountered during our engagement for the project that do not fit neatly into Professor Watson's report, but which the PSC wanted to discuss:

### **Resources for pharmacy staff and patients**

The PSC and a member of her team were delighted to complete a visit to two Boots stores in November 2024 to meet with some of their staff and see some of their work around accessibility.

After the visit, Boots provided the PSC with some further information, guidance and tools that their staff have access to. This includes a Medicines Support Tool, which can be used by the staff members to structure and record a conversation around needs and potential solutions. Potential solutions included in this document include large A4 print labels for those having difficulty with reading labels or identifying medicines and pill presses for patients who have difficulty in removing their medication from blister packs.



We acknowledge that a large provider such as Boots has significantly greater resources at its disposal than independent community pharmacists, and so would continue to encourage the sector to work together on sharing resources. Whilst the NHS Specialist Pharmacy Service (SPS) has produced guidance for staff, we could not see any national guidance from the NHS targeted at patients.

### **The accessibility of prescription exemption certificates**

The PSC raised the issue discussed in Professor Watson's report on page 1 concerning prescription exemption certificates.

The PSC raised this discrete issue – preserving the confidentiality of the participant – with the NHS Business Services Authority (NHSBSA), who administer medical exemption certificates that entitle the holder to free NHS prescriptions.

The PSC was grateful for the response of their Chief Executive, Michael Brodie, who thanked the team for raising the issue with him. In his response, he conceded that the current application process does not easily cater for requesting a large print or visually accessible form/certificate upfront as it remains a largely analogue service on paper sent via the GP. He flagged ongoing work by the NHSBSA to move away from an application-based model to one where a flag could be added to GP systems to automatically generate a medical exemption certificate where a relevant medical condition is diagnosed.

NHSBSA are also examining for the right conditions to make this an enduring certificate and not one that has to be reapplied for every five years. This would do away with the need for the letters altogether. Their CEO committed to continue to work with the PSC on these issues and, as such, the PSC has not made this issue the subject of one of her recommendations or observations.

## **C. Recommendations and observations to improve patient experience**

The following recommendations and observations have been informed by the primary and secondary evidence presented in Professor Watson's report.

To support these recommendations and observations, the PSC herself also commits to:

1. Raising these issues as part of her engagement with DHSC's MedTech Programme Board in her role as an advisor to that Board.
2. Highlight the importance of improving the accessibility of the health and care system for those with sensory impairment as part of her engagement with the 10 Year Plan.
3. Raising these issues as part of regular engagement with MHRA

## Recommendation 1

The MHRA needs to review – working alongside patients – whether their current guidance and regulations for the licencing and packaging of medicines goes as far as is possible to enable their safe use by those with sensory impairment.

## Recommendation 2

The ABPI, MHRA and DHSC should work together to restart work – alongside published milestones – to digitise paper-based patient information leaflets via the existing UK Electronic Patient Information Task Force (ePIL). As part of this restart, ePIL – working with patients – should examine how to maximise the benefits of this work for patients with sensory impairment.

## Recommendation 3

NHS England’s Diabetes Programme Team should launch a patient reference group to assess, understand and mitigate the barriers and enablers to the safe and effective roll-out of medical devices and other education programmes for the management of diabetes (such as DAFNE) for those with sensory impairments.

## Recommendation 4

DHSC and NHS England need to ensure the work announced to improve and expand the NHS App in ‘Reforming elective care for patients’ includes an assessment – conducted with the input of patients – to determine whether further accessibility improvements are required, especially for people with visual impairment.

In a number of other areas, the PSC wants to make observations to a number of bodies – highlighting the outcome without specifying the solutions, in keeping with the ethos of the recent Health Services Safety Investigations Body (HSSIB) report ‘Recommendations but no action: improving the effectiveness of quality and safety recommendations in healthcare.’<sup>9</sup>

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9 Recommendations but no action: improving the effectiveness of quality and safety recommendations in healthcare

## Observation 1

A patient's medical record needs to include a prominent flag of accessibility needs and detailed information about these needs to ensure that the healthcare professional can provide any required reasonable adjustments. All relevant healthcare professionals – including community pharmacists – must have sufficient access to these patient records and flags.

## Observation 2

Healthcare professionals, particularly community pharmacy personnel and others involved in the direct supply of medicines and medical devices, must have sufficient funding to support the additional time and resources required by to undertake assessments of patient needs and provide the required 'reasonable adjustments' for medicines and medical devices.

## Observation 3

With the anticipated increase in prevalence of sensory impairment amongst the general population, further guidance is required to promote evidence-based practice by health and social care professionals in terms of the medicine journey of people with sensory impairment. It is also crucial that there is provision of training to healthcare professionals (ideally within the undergraduate curricula) regarding the needs of people with sensory impairment.

## Observation 4

People with experience of sensory impairment should be included in the design of medical devices, as well as user information and instructions to accompany their supply and use. Manufacturers need to provide more resources to facilitate the demonstration of the effective use of medical devices, especially for people with visual impairment.



# Listening to Patients

## Safety and Accessibility of Medicines and Medical Devices

A report commissioned by the Patient Safety Commissioner, from Prof MC Watson,\* Watson Research and Training Limited.

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# Executive Summary

## Rationale and Background

This Report presents the results of a short-term study to explore the challenges experienced by patients with visual and/or hearing impairment or loss (hereafter referred to as sensory impairment) in relation to their safe and effective access to and use of medicines (hereafter referred to as their medicine-related needs) and medical devices. The study focussed in particular on the experience of patients with visual impairment who have diabetes and concludes with findings based upon the results derived.

## Aims

The study addressed the following questions:

1. What barriers to patient safety (specifically in relation to medicines and medical devices) exist for patients with sensory impairment?
2. How do these barriers specifically manifest in relation to patients who have diabetes and are visually impaired? Are there areas of good practice in this area that we can learn from?
3. What should the health system do to overcome these barriers?

## Methods

The primary data that were generated were derived from three sources:

- Focus Groups involving individuals with visual impairment or loss, including people with diabetes.
- Key Informant responses to an electronic survey.
- Medicines and Healthcare Products Regulatory Authority (MHRA) Yellow Card reports.

Additional information (secondary data) was derived from the results of a literature search conducted by The Knowledge Centre, Department of Health and Social Care (DSHC) in August 2024. This primary data collection for the study was undertaken between September to December 2024.



## Results

Three focus groups comprising 11 participants were conducted online to explore the experience of people with visual impairment regarding the challenges they experienced with medicines and medical devices. Eight participants had diabetes of whom six had Type 1 Diabetes Mellitus (T1DM) and two had Type 2 DM. The average age of participants was 50 years (range: 35 to 66 years) and six were female. Five lived alone of whom four had T1DM and visual impairment. Survey responses were submitted from third sector organisations representing people with sensory impairments and diabetes, industry representatives, and health services representatives. The search of MHRA Yellow Card reports identified 169 submissions from patients who reported a past medical history which included a vision disorder. These reports were then reviewed to identify the nature of the vision disorder (historical or current) and for any relevance of the adverse event to readability or packaging. Four reports were found to be regarding issues with packaging readability or product quality and were related to patients with an existing history of sight loss, blindness or other visual impairment.

This study used a combination of primary and secondary data to address the three research questions stated in Chapter 1. This chapter presents the discussion of the results in terms of the first and second research questions (including examples of good practice) and concludes with recommendations for future practice (research question 3).

## Barriers to Patient Safety for Patients with Sensory Impairment

A wide range of barriers to patient safety was identified in terms of patients with sensory impairment in general and more specifically patients with diabetes and sensory impairment. Barriers and challenges were identified at along all stages of the medicine journey. Many of the barriers were associated with access to information, primarily written (including digital), but also verbal in terms of communication during consultations and accessing support services. The evidence suggests a lack of training and hence awareness of healthcare professionals regarding working with people with sensory impairment.

Multiple barriers were identified in terms of the use of medical devices and technology to support people with T1DM with few devices having the accessibility required for individuals to operate them without the assistance of others.

## Impact of Barriers on Patients with Diabetes and Visual Impairment

People with diabetes, particularly those who use insulin, need to be able to understand how to manage their diabetes effectively and safely, to prevent acute problems due to hypoglycaemia and hyperglycaemia, and to minimise

the risk of longer term complications e.g. (further) visual impairment, renal and cardiovascular problems. To do so, they need timely access to training that is delivered in accessible formats. People with diabetes who have been unable to access timely training about the management of their condition will be at risk of inadequate management of their diabetes and at higher risk of developing longer-term problems associated with diabetes.

People with diabetes and sensory impairment, particularly those with visual impairment, experience substantial burden on a daily basis to manage their condition in a safe and effective manner. They experience anxiety and fear associated with the risk of incorrect medicine supply and use. Whilst the use of technology for some aspects of diabetes management has been life-changing, the operation and management of diabetes-specific devices and technologies is problematic for many because the design of devices fails to meet the accessibility needs of people with diabetes and sensory impairment.

The results indicate that the principles of medicines optimisation (RPS 2013) are not being met for people with sensory impairment, particularly those with diabetes and visual impairment. A lack of person-centred care for people with these conditions means that they will achieve sub-optimal benefit from their medicines and medical devices and experience higher risk and harm from their medicines.

## **Examples of Good Practice**

Few examples of good practice were identified during the PSC Study. The development of NaviLens codes (or similar) is promising in achieving greater accessibility of information about medicines and their safe and effective use.

## **Findings/conclusions**

The primary and secondary evidence presented in this report has highlighted areas where change is needed.

1. Accessibility needs and preferences for medicines and medical devices of people with sensory impairment should be assessed using standardised tools and reviewed at appropriate intervals.
2. People with sensory impairment should be offered and have timely access to translation services for health and social care consultations e.g. British Sign Language (BSL) translators for consultations with GPs and Diabetes Management Team.

3. Medical, pharmacy and other health and social care records to include prominent flag of accessibility needs and detailed information about these needs. A clinical code arising from the “reasonable adjustment flag” is insufficient by itself and should be accompanied by relevant explanatory detail.
4. Guidelines are needed to promote evidence-based prescribing for people with sensory impairment.
5. Pharmacists and other pharmacy personnel/health professionals involved in the supply of medicines need to be aware of the importance of informing people with visual impairment and especially people with visual impairment and diabetes when any changes are made to the medication regimen.
6. A funding review is needed to support the additional time and resources required by healthcare professionals, particularly community pharmacy personnel (or others involved in the direct supply of medicines and medical devices), to undertake systematic assessments and provide “reasonable adjustments” for medicines and medical devices.
7. The NHS app needs to be proactively and regularly reviewed and improved in terms of accessibility, especially for people with visual impairment. Improvements are needed in relation to ‘onboarding’ of people to the app and with their prescription medicines.
8. Helpline personnel i.e. for manufacturers of insulin pumps and other relevant devices, should be trained to work effectively with people with visual impairment.
9. Clear guidance is needed for people with diabetes regarding the appropriate and safe disposal of the medical devices and related paraphernalia.
10. Medicine information and packaging must be offered in accessible formats. The NaviLens codes (or equivalent) should be introduced on medicine packaging and for product information leaflets for all medicines.
11. Prescription exemption certificate expiration date reminders (and other health-related notifications) need to be sent to individuals in an accessible format.
12. Resources should be developed for use by people with sensory impairment as well as health and social care providers, to facilitate the demonstration of the effective use of medical devices, especially for people with visual impairment.

13. All health and social care professionals to have sufficient access to patient records to ensure awareness and documentation of “reasonable adjustment flags”.
14. Strategies are needed to increase awareness regarding the medicine-related needs of people with visual impairment in general and more specifically people with visual impairment and diabetes.
15. Guidelines are needed to promote evidence-based practice by health and social care professionals in terms of the medicine journey of people with sensory impairment.
16. Provision of protected funded training time for community pharmacists and their teams is needed to increase their awareness of the needs of people with sensory impairment and/or diabetes, and the resources available to meet their needs.
17. Provision of training to health and social care professionals (ideally within the undergraduate curricula) regarding the needs of people with sensory impairment.
18. People with sensory impairment should be made aware of the importance of disclosing their sensory needs and preferences about medicines and medical devices so that these can be documented within their shared medical record.
19. People with sensory impairment should be made aware of the importance of the need to authorise community pharmacists to have access to their medical record.
20. The “Diabetes structured education and self-management support course” (and other routine education and training events delivered via the NHS) needs to be accessible to people with sensory impairment and to be provided to people with sensory impairment in a timely manner.
21. People with experience of visual (and hearing) impairment should be included in the design of insulin pumps and CGMs, as well as user information and instructions to accompany their supply and use.
22. Medical devices that are to be assessed for regulation by the MHRA should be evaluated in terms of their accessibility prior to approval.

## **Acknowledgements**

We are extremely grateful to the individuals and organisations who gave their time so generously to support and participate in this study.

# Glossary

Term	Definition
<b>ABPI</b>	Association of the British Pharmaceutical Industry
<b>ABHI</b>	Association of British HealthTech Industries
<b>Assistive Technologies</b>	“Products, systems, and services that help people improve or maintain their functioning in areas like cognition, communication, hearing, mobility, self-care, and vision” (WHO 2024d).
<b>CGM</b>	Continuous glucose monitor/ing: a device that measures glucose levels at any time.
<b>CHM</b>	Commission on Human Medicines (advises ministers on the safety, efficacy and quality of medicinal products).
<b>CPE</b>	Community Pharmacy England
<b>DMO</b>	Diabetic Macular Oedema
<b>Hybrid Closed Loop (HCL) System</b>	Sometimes referred to as an ‘artificial pancreas’. Includes a CGM and an insulin pump to monitor and manage blood glucose levels.
<b>HCPs</b>	Health care professionals
<b>HSSIB</b>	Health Service Safety Investigations Body
<b>Medical Device</b>	“any article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose” (WHO 2024)
<b>Medicine Management</b>	“The entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care” (Audit Commission 1994).
<b>MedTech</b>	Medical technologies are “products, services or solutions used to save and improve people’s lives” (MedTech Europe 2024).

<b>Term</b>	<b>Definition</b>
<b>MHRA</b>	Medicines and Healthcare Products Regulatory Agency
<b>NPA</b>	National Pharmacy Association
<b>OCR</b>	Ocular Character Recognition
<b>PSC</b>	Patient Safety Commissioner
<b>RCN</b>	Royal College of Nursing
<b>RNIB</b>	Royal National Institute of Blind People
<b>RPS</b>	Royal Pharmaceutical Society
<b>SMS</b>	Short Message Service (also known as a text message)
<b>T1DM</b>	Type 1 Diabetes Mellitus
<b>T2DM</b>	Type 2 Diabetes Mellitus
<b>WHO</b>	World Health Organisation

## Chapter 1:

# Background

## Background

### Medicines, Medical Devices and Patient Safety

Medicines are the most commonly used healthcare intervention (RPS 2013). To be used safely and achieve their therapeutic effect, they need to be used in the manner in which they were intended. For any patient to use a medicine as it is intended, they must first of all have sufficient and accessible information to make an informed choice regarding whether to use it and the anticipated benefits and risks of using it. If they do decide to use the medicine, patients then have to:

- remember to use it
- know when to use it
- know where to find it
- know how to use it
- be able to access it
- be able to administer it

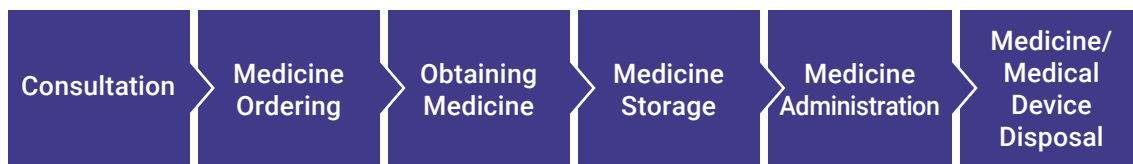
In addition, patients should be aware that if they experience an adverse reaction with a medicine (or medical device) that they can report this using the Yellow Card Scheme provided by the Medicines and Healthcare products Regulatory Agency (MHRA) (2024a).

Medical devices are any “article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose” (WHO 2024). Many medical devices are used in conjunction with medicines i.e. to facilitate administration, storage, monitoring, and all medical devices that are used in the United Kingdom are regulated by the MHRA. All of the same considerations set out above in relation to medicines apply to medical devices in terms of patients requiring sufficient and accessible information to make an informed choice regarding whether to use the device and the anticipated benefits and risks of using it.

In the UK, an estimated 16.5% of hospital admissions are medicine-related, many of which are preventable (Osanlou 2022). The World Health Organisation (WHO) Global Patient Safety Challenge, ‘Medication Without Harm’, was launched in 2017 in recognition of the harm caused by unsafe medication

practices and medication error (WHO 2017). Whilst the Challenge did not specifically address medicine-related harm experienced by individuals with sensory impairment, these patient populations are likely to be at higher risk of medication-related harm as a result of their sensory function and its impact upon their 'medicine journey' (Figure 1) (Fuzesi 2024). For example, patients with visual impairment are likely to need alternative strategies to identify their medicines e.g. larger font or braille labels, magnifiers to read labels and information leaflets.

**Figure 1 The Medicine Journey**



### Sensory Impairment

People with sensory impairment or loss can experience substantial challenges with the safe and effective use of their medicines (Al-Husein 2019, Smith 2019, Fuzesi 2024). The PSC study focussed upon visual impairment, including people with partial or total loss of visual function as well as congenital (i.e. from birth) and/or acquired visual impairment. In addition, the study included some exploration of the medicine-related needs of people with hearing impairment (partial or total, congenital and/or acquired), to illustrate and emphasise the additional considerations that relate to this population.

### Visual Impairment – number affected

Globally, an estimated 2.2 billion people have a near or distance vision impairment (WHO 2024a). In around half of these cases, vision impairment could have been prevented or has yet to be addressed. Most people with vision impairment/blindness are aged over 50, however, it can affect people of all ages. In the UK, over 2 million people have some form of visual impairment but only about 320,000 people are registered as blind or partially sighted (RNIB 2021). By the middle of this century, the number of people living with sight loss in the UK will double to 4 million (RNIB 2021). The major causes of visual impairment (RNIB 2021) are:

1. Age-related Macular Degeneration AMD (23%, number affected (n) =488,000)
2. Cataract (19%, n=394,000)
3. Glaucoma (7%, n=151,000)
4. Diabetic Retinopathy (see Visual Impairment and Diabetes) (5%, n=97,000)



*Pezzullo et al (2018)* estimated that sight loss and blindness (due to multiple causes) in the adult population in the UK cost an average of £15.8 billion (in 2013) comprising healthcare and other (indirect) costs.

### **Hearing Impairment – numbers affected**

Deafness and hearing impairment affect one fifth of the global population, equating to over 1.5 billion people (WHO 2024b). By the middle of this century, over 700 million people will have disabling hearing impairment (WHO 2024b). In the UK, 18 million adults are affected by deafness, hearing impairment or tinnitus equating to one in every three adults (RNID 2024). The risk of hearing impairment increases with age: the majority (80%) of people aged 70 and over, and more than half of all adults aged 55 or over, have some form of hearing impairment (RNID 2024).

### **Sensory Impairment and Medicines and Safety**

As referenced above, medicine-related errors are one of the most common avoidable causes of healthcare harm. There is also a growing body of evidence about the specific medicine-related needs of people with sensory impairment (Al-Husein 2019, Smith 2019, Fuzesi 2024) and the implications in terms of medicine safety and harm if these needs are unmet. Much of the evidence has been derived from studies with older people, however, the implications are relevant to most if not all adult individuals with sensory impairment.

People with sensory impairment, especially visual impairment, are at risk from medicine-related harm especially if their medicine-related needs are unmet i.e. in terms of providing information in an accessible format or providing medical devices that are suitable for use by someone with limited visual function. Harm can arise due to multiple reasons including incorrect dosage (over or under) and inappropriate administration. In addition, harm can arise due to other patient, health (or social) care professional or process errors. For example, during the study by Smith et al (2019) which included interviews with people aged 65 years and over with sensory impairment, one interviewee reported consuming double the recommended dose of medication because they were unaware of the increased strength of medication that they had been supplied.

*“I was complaining to my wife about feeling really lightheaded and that sometimes can be symptomatic of a hypo coming on... ‘Are you sure you’ve been taking your medication right?’ she said and I said, ‘I don’t know... so I got it out and bingo they had reintroduced the 4 mg tablets and I was taking 8 (4 mg) tablets a day instead of 8 (2 mg) tablets so my blood pressure just went right down.”*

Another interviewee (from the same study) received another patient's medicines in error (and fortunately did not administer them):

"I've actually had the wrong medicine supplied to me...and I was just about to take some tablets and [wife name] says to me 'what's that you've got now?' and I said 'it's my medicine' that I was put on... and she said 'that's not what you're on' and we looked at the packages. It wasn't even for me it was for a guy in the village three miles down the road."

The study by Alhusein et al (2019) included this example from a pharmacist of a medication dosage error for a patient with hearing impairment.

"I told him to take eight tablets, all at once, every day for five days. His carer was with him who also repeated it, then he went away home and had [took] it all at once and took them all ..because all he heard was "all at once"."

In the study by Fuzesi et al (2024), a participant with visual impairment reported being given the wrong inhaler.

"I was given once the wrong dose of [drug name] inhaler.. somebody lifted the wrong lot, put them in and .. I got them. . when I looked .. I thought this is not right."

The above examples provide insight into the type of errors (all of which were avoidable) and harms that can arise due to medicines and patients with sensory impairment.

## What is diabetes and the link with visual impairment?

### Diabetes

Diabetes Mellitus (hereafter referred to as diabetes) is a disease that causes the body to produce insufficient insulin. The result is persistent hyperglycaemia i.e. excessive amounts of blood glucose. Approximately 5.6 million people in the UK have been diagnosed with diabetes (Diabetes UK, 2024). Of these, approximately 1 in 10 have Type 1 Diabetes Mellitus (T1DM) and 9 in 10 have Type 2 Diabetes Mellitus (T2DM) (Diabetes UK, 2024). For people with T1DM, their pancreas produces no or insufficient insulin and for people with T2DM, their pancreas produces insufficient insulin, or their body does not use insulin effectively. In 2021/2, diabetes cost the UK £14 billion, including £10 billion in direct NHS costs equating to 6% of the entire NHS budget (Hex, 2024). The majority (~60%) of direct costs are associated with complications arising from diabetes (see below).

## Visual Impairment and Diabetes

Diabetes is one of the major causes of visual impairment in the UK (RNIB 2021). In this report we consider some of the challenges that people with diabetes and visual impairment face in relation to medicines and medical devices, but of course, those challenges are also relevant to people with visual impairment due to other conditions. Nearly half (48%) of people with T1DM and around 28% of people with T2DM have Diabetic Retinopathy (a condition that affects the retina and can cause blindness) (Mathur 2016). The risk of Diabetic Retinopathy for people with T1DM increases with age and is also higher in specific regions in the UK (Mathur 2016). The rate of Type 2 Diabetes is higher in South Asian and Black ethnic groups compared with white populations (Pham 2019, Mathur 2016) and people from these ethnic groups also have higher rates of Diabetic Retinopathy (Sivaprasad 2012). For people with T2DM, the risk of Diabetic Retinopathy also increases with age, and is higher in specific regions of the UK. In addition, the risk of Diabetic Retinopathy is higher in men as well as people with lower socio-economic status (Mathur 2016). People with diabetes are also at risk of other vision-related conditions, which include a 2-to-5 times higher risk of cataract and double the risk of open-angle glaucoma, compared with individuals who do not have diabetes (National Eye Institute 2024).

### Why is managing blood glucose important for patient safety?

Diabetic control is typically measured using HbA1c (glycosylated haemoglobin A1c), which is derived from a blood test and provides an estimate of how well the diabetes has been managed over the past 90 days (Eyth & Naik 2023). The risk of Diabetic Retinopathy is increased for people with higher levels of HbA1c i.e. people whose diabetes is less well-managed (DCCTRG 1993). Other long term complications of diabetes are also associated with higher levels of HbA1c including kidney and nerve damage (DCCTRG 1993) as well as cardiovascular disease (Lachin 2014). Blood glucose can be managed using dietary control, medicines and monitoring. The effective management of blood glucose can help to reduce the risk of vision loss due to diabetes, particularly Diabetic Retinopathy, as well as the other long term health conditions described above.

### Medicines for the management of Diabetes

People with diabetes typically manage their condition with dietary control and medicines. The type of medicine(s) that they use depends upon their type of diabetes. For example, T1DM is typically managed with insulin which is either given by injection at different points throughout the day or is administered continuously via a pump. Insulin is a high risk drug i.e. it is a medicine that has a “high risk of causing injury or harm if they are misused or used in error. Error rates with these medications are not necessarily higher than with any other medicines, but when problems occur, the consequences can be more significant” (APhA 2007). The dose of insulin needs to be titrated to each

individual person's needs based upon multiple factors including the previous and anticipated consumption of carbohydrates. Incorrect titration can result in hypoglycaemia (low blood sugar) which, if left untreated can result in loss of consciousness, coma and potentially death. Hyperglycaemia (high blood sugar) can also occur if insufficient insulin is used. Insulin can either be administered as a sub-cutaneous (beneath the skin) injection using syringes or insulin pens or can be given using a pump. The six Rs of insulin treatment are "Right patient, right insulin, right dose, right time, right device and right way" (Diabetes UK, 2020).

People with T2DM whose condition cannot be managed effectively by dietary control, usually manage their diabetes with one or more medicines that are taken by mouth as tablets. These are oral hypoglycaemic medicines (Box 1) and they act by lowering blood glucose. Some people with T2DM also require insulin to manage their diabetes. (Some people with T1DM also use oral hypoglycaemic medicines in combination with insulin to manage their blood glucose level). Oral hypoglycaemic medicines can also be high risk because of the risk of hypoglycaemia if food has not been consumed or if too high a dose has been used.

### Box 1 Oral Hypoglycaemic Medicines

**Alpha glucosidase inhibitors** e.g. Acarbose

**Biguanides** e.g. metformin

**Dipeptidylpeptidase-4 inhibitors (Gliptins)** e.g. Alogliptin, Linagliptin, Saxagliptin, Sitagliptin, Vildagliptin

**Glucagon-like Peptide-2 Receptor Agonists** e.g. Dulaglutide, Exenatide, Liraglutide, Lixisenatide, Semaglutide.

**Meglitinides** e.g. Repaglinide

**Sodium Glucose Co-Transporter 2 Inhibitors** e.g. Canagliflozin, Dapagliflozin, Empagliflozin, Ertugliflozin,

**Sulphonylureas** e.g. Gliclazide, Glimepiride, Glipizide, Tolbutamide

**Thiazolidinediones** e.g. Pioglitazone

People with diabetes often have multiple health conditions (co-morbidities) which require treatment with multiple medicines, often referred to as polypharmacy (SPS 2022). A recent systematic review (Remelli 2022) identified studies that had explored the extent to which older people with T2DM experienced "polypharmacy" and concluded that there are high rates of polypharmacy in older people with diabetes which are associated with higher rates of hypoglycaemia, falls, hospitalisation and death.

## Medical Devices used for the Management of Diabetes

The management of diabetes often involves the use of multiple medical devices with different functions and purposes, which is another reason why the Patient Safety Commissioner wanted to focus on diabetes as a condition in this study. Some devices are used to monitor blood glucose whilst others are used to administer insulin (and other medicines). The main types of medical devices used by people with diabetes are summarised below. This is not an exhaustive list.

### Glucose Monitoring and Monitors

People with diabetes need to monitor their blood glucose levels and the frequency of monitoring varies depending upon the type of diabetes they have, their nutrition and physical activity and current health status.

#### Finger-Prick Test

A finger-prick test can be undertaken using a finger prick device which uses a lancet (needle) to create a drop of blood which is placed upon a testing strip and then inserted into a blood testing meter. The meter then measures the amount of glucose in the blood sample. For people with diabetes who have visual impairment, the use of the finger-prick test can be problematic or impossible if they do not have sufficient visual function to use the lancet, place the blood drop on the strip, insert the strip and/or read the blood glucose level on the monitor. Talking blood glucose meters are medical devices that have been developed to assist people with visual impairment by saying when the blood sample is being tested and the result. Manual dexterity is still required to place the testing strip in the meter and a finger-prick is also required to obtain a blood sample.

(NB: People with T1DM might also monitor their ketone levels using similar methods to those described above for glucose monitoring. Ketones are substances that accumulate if the body has insufficient insulin and are typically measured using a drop of blood on a testing strip which is then placed in a meter.)

#### Continuous Glucose Monitors

Continuous glucose monitors (CGMs) are medical devices that enable individuals with diabetes to monitor their glucose levels on a continuous basis. CGMs usually comprise two components: a sensor that is attached to the body which monitors the amount of glucose in the body's cells (called interstitial fluid); and a device that receives or reads the glucose level (this information can also be sent to smartphones). Flash Glucose Monitors are CGMs that require to be scanned by a reader or smartphone intermittently to access the glucose level.

## Insulin Administration

Insulin is currently only available as a liquid formulation and needs to be injected into the body to be effective. Injections can be administered using syringes or insulin pens, or by using insulin pumps.

### Syringes, Syringe Readers, Magnifiers and Pens

Some syringes have readers which display a digital reading of the volume of solution. Magnifiers can be added to syringe barrels to facilitate reading calibration markings and thus increase the accuracy of the measured dose. Insulin pens are commonly used devices that use either replaceable or non-replaceable cartridges that contain insulin (Diabetes UK 2024a). Pens typically use needles that need to be attached prior to each injection. The exact dose of insulin can be dialled up using a pen: many pens make an audible 'click' for each unit of insulin dialled up, enabling people with visual impairment to count the clicks to check their dose prior to administration. There are many advantages and disadvantages to the use of pens versus syringes, but these are beyond the scope of this report.

### Insulin pump – Closed Loop Systems

A closed loop system (sometimes referred to as an artificial pancreas) usually comprises an insulin pump that is connected to a continuous glucose monitor. The two elements are linked either through software on a phone or within the pump. Doses of insulin are released throughout each day and night according to blood glucose readings. Hybrid closed loop systems are regulated and can also be purchased. In 2023, NICE announced that hybrid closed loop systems would be available to people with T1DM that fulfilled specific requirements (NICE 2023). The criteria did not include people with visual impairment. Several hybrid closed loop systems are currently regulated (by the MHRA) for use in the UK (Diabetes UK 2024). ("DIY" closed loop systems are an alternative to hybrid systems; however, they are not regulated and are not available through the NHS).

## Apps

A wide range of Apps is available for use by people with diabetes. The purpose of the Apps varies with some providing information e.g. carbohydrate content, whilst others monitor glucose levels (including those used with systems described above) and provide advice regarding insulin dose requirements. Some Apps are for use by people who are newly diagnosed with diabetes rather than those with longer established diabetes. Apps work on different operating systems, i.e. Android and/or smart devices e.g. iPhone.

**Summary**

This chapter provided a summary of the topics covered by this report including patient safety, medicines and medical devices, the challenge of sensory impairment in the context of the safe and effective use of medicines and medical devices, and diabetes, visual impairment and the medicines and devices used for the management of this condition.

## Chapter 2:

# Current Context

This chapter presents the current context in terms of legislation, regulation and guidance regarding medicines, medical devices, disability in general and sensory impairment more specifically. It is informed by a literature search conducted by The Knowledge Centre, Department of Health and Social Care) in August 2024 (DHSC 2024).

## **Legislation, Regulation and Guidance related to Medicines, Medical Devices and Disability (including Sensory Impairment)**

The United Nations Convention on the Rights of Persons with Disabilities (UNCRPD) (UN 2006) published its Convention on the Rights of Persons with Disabilities, hereafter referred to as the Convention, which states that:

**“Persons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others.”**

Article 25 of the Convention relates specifically to health:

**“Persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability.”**

In 2014, the UNCRPD published Article 9 Accessibility (UN 2014) which stated that:

**“Health care and social protection would remain unattainable for persons with disabilities without access to the premises where those services are provided. Even if the buildings where the health-care and social protection services are provided are themselves accessible, without accessible transportation, persons with disabilities are unable to travel to the places where the services are being provided. All information and communication pertaining to the provision of health care should be accessible through sign language, Braille, accessible electronic formats, alternative script, and augmentative and alternative modes, means and formats of communication.” (UN 2014)**

The UK ratified the UNCRPD in 2009 (EHRC 2020).



European law requires all medicines to have their name in braille on the packaging (Council Directive 2004/27/EC, Article 56(a)). In the UK, Regulation 259 of the Human Medicines Regulations states that:

**“The name of a medicinal product must also be expressed in Braille format on the outer packaging of the product (or, if there is no outer packaging, on the immediate packaging of the product).”**

Regulation 259 also states that the manufacturer “must ensure that the package leaflet is made available on request in formats suitable for blind and partially-sighted persons.”

In the UK, the Equality Act (2010) was introduced to protect people from discrimination and harassment associated with protected characteristics which include disability (UK 2010). This act places legal responsibilities on service providers (amongst others) to meet the needs of people with protected characteristics by making “reasonable adjustments” when required.

To help facilitate better compliance with the Equality Act (particularly across NHS and social care services), a “reasonable adjustment flag” has been developed for use in the National Care Records Service (NCRS) (in England) (Personal Communication NHSE 16/12/24) (NHSE 2024) which enables health providers to document adjustments made locally which can then be shared through the central record. The reasonable adjustments are defined using clinical codes e.g. communication codes, but “highly individualised bespoke adjustments for patients” can also be documented in the system. There has been low uptake of the flagging system to date, however, greater linkage with other systems is planned from 2025. The extent to which health and social care providers have access to this system depends upon the compatibility of their systems and the extent of access to patient records – the latter might act as a barrier for use by community pharmacy personnel (see later).

In 2016, NHS England introduced a new information standard, the Accessible Information Standard (AIS), which sets out how organisations should ensure that disabled people and people with impairments or sensory loss get information they can access and understand, and any communication support they need from health and care services. All organisations that provide publicly funded NHS care or adult social care are expected to follow this standard. Commissioners of NHS or social care must also have due regard to this standard in line with the requirements of the Equality Act 2010 (NHSE 2016).

NHS England introduced the AIS because “despite the existence of legislation and guidance ... in reality many service users continue to receive information from health and social care organisations in formats which they are unable to understand and do not receive the support they need to communicate” (NHSE 2017). It was, therefore, felt that a bespoke standard was required to drive improvements for patients who may require additional support to understand the information being provided to them. The scope of organisations to which

the AIS applies is wide – and includes all providers of NHS care or treatment, independent contractors providing NHS services including pharmacy services and adult social care bodies.

There are two weaknesses in the current AIS. First, organisations are only required to ‘have regard’ to the AIS. Second, neither the MHRA nor the Department of Health and Social Care have to assess whether their legislation, rules and guidance support delivery of the AIS, as they are not within the scope of the AIS – although they have more general obligations under the Equality Act 2010, as referenced above.

The extent to which this standard has been applied, and the timeliness of its application has been assessed and demonstrates variable and inconsistent practice – as discussed in Chapter 3. In 2025, however, the Department of Health and Social Care plans to commence the process for implementing Section 95 of the Health and Care Act 2022. Once this section is commenced, it will allow for the publication of mandatory information standards which would require health and social care providers to comply with such standards rather than, as now, have regard to them. The commencement of this section has long been called for by patient representative organisations on the basis that it would strengthen the levers available to NHS England to increase compliance with the AIS by providers.

In 2023, the Professional Record Standards Body (PRSB) published Diabetes Information Standards (PRSB 2024) which cover a broad range of areas and aims to standardise the way information on people with diabetes is collected, stored and shared. The standards include codes to note impairments and communication preferences.

The MHRA is responsible for the licensing of medicines and the regulation of medical devices in the UK. The EU Medical Devices Directive Essential Requirements (which currently apply in Great Britain) provide that when designing and manufacturing a device, manufacturers are required to consider “mental and physical conditions of intended users” as part of their risk management and that “consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users” (EU MDD).

In 2019, the MHRA published “MHRA Guideline for the Naming of Medicinal Products and Braille Requirements for Name on Label” (MHRA 2019): the requirement for Braille is set out in Regulation 259, of the Human Medicines Regulations 2012 (Gov.uk 2012) which states that:

**“The name of a medicinal product must also be expressed in Braille format on the outer packaging of the product (or, if there is no outer packaging, on the immediate packaging of the product).”**

The requirement that a patient information leaflet in an alternative format is made available on request is rather limited. It imposes no requirement on the quality or timeliness with which that patient information leaflet is provided after being requested by the patient. The MHRA Best Practice Guidance on Package Leaflets recommends that Marketing Authorisation Holders ensure that they can provide the statutory information in any format that may be requested by the user and references large print, audio and Braille versions as alternative formats (MHRA). There are no specific legislative requirements around minimum font sizes, although guidance recommends 9pt for patient information leaflets and 7pt for labels as minimum sizes. The RNIB recommends font size 14 (RNIB 2023). In 2023, the MHRA published updated guidance on the provision of information leaflets in formats suitable for people with visual impairment (MHRA 2023).

In 2013, the Royal Pharmaceutical Society (RPS) published good practice guidance for health professionals in England, titled “Medicines Optimisation: Helping patients to make the most of medicines” (RPS 2013). This guidance was endorsed by NHS England, the Royal College of General Practitioners (RCGP), Royal College of Nursing (RCN), the Association of British Pharmaceutical Industry (ABPI) and the Academy of Medical Royal Colleges. The core of Medicines Optimisation is the need for a person-centred approach in addition to four main principles:

1. Aim to understand the patient’s experience
2. Evidence based choice of medicines
3. Ensure medicines use is as safe as possible
4. Make medicines optimisation part of routine practice

There is a growing body of evidence of the medicine and medical device-related experiences of people with sensory impairment (Principle 1) (The empirical research undertaken for this Project provides additional information, particularly in relation to people with diabetes). In terms of Principles 2 and 3, a recent scoping review (*Morrison et al, under review*) sought to identify guidelines and resources that were relevant to prescribing for older people with sensory impairment (visual and/or hearing impairment). No guidelines were identified. The review identified a gap in evidence-based resources to support health professionals when prescribing for older people with visual and/or hearing impairment. An additional scoping review (*Asante et al, under review*) sought to identify assessment tools that could be used with older people with sensory impairment to assess their “Medication Self-Management Capacity”. The review identified 17 studies, 13 of which included an assessment of visual function in relation to medicine use e.g. an individual’s ability to read the label on a medicine container. One tool also included an assessment of an individual’s

hearing function. None of the tools identified were developed specifically to assess sensory function specifically associated with 'medicine management' (Audit Commission, 1994).

## **Summary**

Despite international and national legislation, regulation and guidance, the accessibility of medicines and medical devices for people with sensory impairment remains relatively neglected, suggesting the current frameworks are not delivering the required outcomes for patients. In Chapter 3, evidence is presented regarding existing challenges experienced by people with sensory impairment, many of which relate to accessibility of information.

### Chapter 3:

# Overview of Existing Research

This chapter presents a summary of evidence derived from existing research around the topics relevant to the current Patient Safety Commissioner Study. The chapter content is informed by the aforementioned literature search conducted by The Knowledge Centre. It includes a summary of the evidence about the medicine-related challenges primarily of people with visual impairment, with additional information presented regarding hearing impairment.

## Medicine-related Challenges of People with Sensory Impairment

In 2015, the RNIB published 'My Voice 2015', derived from the experiences of over 1200 blind and partially sighted people in the UK (RNIB 2015) which documented that blind and partially sighted people reported having health conditions (in addition to the condition affecting their vision) (called co-morbidities) with 40% having one condition, 24% had two and 16% had three or more. Many of these co-morbidities are treated with medicines. My Voice identified several factors that influenced an individual's ability to manage their medicines e.g. age, the amount of functional vision, the age at which sight loss occurred or started, and the presence of additional disabilities (RNIB 2015).

Several evidence reviews have been published that report the medicine-related needs, challenges, preferences of, and solutions for, people with visual impairment (Killick 2018, Cooper 2023). Whilst these reviews are not limited to people with diabetes, the results are relevant to people with diabetes who have visual impairment. A scoping review of the pharmaceutical care needs of people with sensory loss (including visual and/or hearing impairment or loss) (Killick 2018) included 11 studies. The review demonstrated that compared with people with no sensory loss, people with these types of sensory loss have lower levels of medication-related knowledge and are at higher risk of medicine-related harm. The same review also identified that communication with health professionals was problematic for people with hearing loss, with written information being provided by pharmacists to try to address this challenge.

The following evidence is presented to illustrate the different stages of the aforementioned patient journey (Figure 1). In addition to the journey stages, there are elements that run across all parts of the journey including information and communication.

## Consultation

People with sensory impairment often do not disclose their impairment to health professionals (Al Husein 2018, Basma 2024, Merenda 2024). Even when health professionals are aware of sensory impairment, there is a dearth of evidence regarding what modifications are made e.g. with prescribing behaviour, to facilitate the safe and effective use of medicines by people with sensory impairment. In a study with 15 primary care-based prescribers (including general practitioners (GPs), nurses, pharmacists) in the UK (Morrison et al 2024, unpublished), only two reported having undertaken any training specific to people with sensory impairment. Furthermore, there is evidence that pharmacists and other pharmacy personnel have undertaken limited if any training regarding the medicine-related needs of people with sensory impairment (Al Husein 2018, Basma 2024, Merenda 2024). Only one training resource has been identified to promote awareness of the medicine-related needs of people with sensory impairment, specifically older people “Supporting Medicine Use by Older People with Visual and/or Hearing Impairment” (Future Learn 2023). This free online resource is available to anyone with internet access and comprises lay language, closed captions and BSL translation to enhance the accessibility of this resource.

Whilst community pharmacy personnel seldom report systematic approaches to identifying patients with visual (and hearing) impairment (Al Husein 2019, Merenda 2024), a new initiative called FLAG-ME Vision is being evaluated in community pharmacies in England to identify people with visual impairment and to document this information in their pharmacy records (FLAG-ME 2024).

## Ordering

People with sensory impairment have identified a range of challenges associated with ordering their medicines (Smith 2019). The type of challenge is often associated with the type of sensory impairment. People with hearing impairment have difficulty using telephone ordering of medicines and people with visual impairment report difficulty with the use of online ordering systems (Fuzesi 2024).

## Obtaining (Supply)

In the UK, prescription medicines are usually supplied from community pharmacies with patients (or their representative) either visiting the pharmacy to collect their supply, or the medicines being delivered directly to the individual's home by the pharmacy delivery service (RNIB 2015). In-person collection is associated with inconvenience for some people with sensory impairment. People with visual impairment report that navigating through pharmacy premises can be challenging due to narrow aisles causing problems if using a guide dog or cane, which can knock products off shelves (Smith 2019). People with visual impairment have reported concerns about privacy and personal safety when collecting medicines because pharmacy personnel typically ask

for confirmation of their name and address before handing over the medicines, and people with visual impairment are aware that other people in the area will hear this information and that they have a visual impairment and thus are at risk of personal attack (Smith 2019). People with hearing impairment report being anxious about missing notification that their medicines are ready for collection because they cannot hear their name being called (Al Husein 2018).

Community pharmacy personnel have identified that their lack of awareness of the presence of visual impairment is a barrier to the supply and counselling to people with visual impairment (Basma 2024, Al Husein 2019). A lack of education, training and resources was also identified as limiting pharmacist effectiveness when supplying medicines to people with visual impairment (Basma 2024, Al Husein 2019).

### **Storage (at home)**

People with visual impairment often curate their medicines using personalised bespoke systems, which do not always reflect appropriate storage conditions (Fuzesi 2024, Ling 2017). The study by Fuzesi (2024) included several participants who stored their medication in specific areas within the home to reflect the timing of doses. For example, one participant kept all their 'morning' medicines on the beside cabinet which acted as a prompt but also was convenient, facilitating administration on waking. Another participant placed their morning medicines on the top shelf of a kitchen cupboard, from right to left, reflecting the order in which they would be administered. Lunchtime medicines were placed on the middle shelf in the same order and nighttime medicines were placed on the lowest shelf, again using the same order. Medicines are often removed from their original packaging and labelling, to facilitate use (Fuzesi 2024, Ling 2017). This can be problematic if information is needed about the medicine e.g. the dose, and/or if the packaging needs to be checked to determine whether any changes have been made e.g. different strength, manufacturer, etc.

### **Administration**

For medicines to be administered in a safe and effective manner, the patient needs to remember when to use the medicine, how to use it (by accessing information provided on the label and information sheet), how much to use and be able to use the medicine in the manner in which it is intended, which includes gaining physical access to the dosage form e.g. tablet, and/or the use of the administrative device e.g. syringe/needle. There is substantial evidence of difficulties experienced by people with visual impairment in accessing and checking their medicines prior to administration (RNIB 2015, Fuzesi 2024).

## Disposal

Medicines and medical devices e.g. syringes, needles, sensors, that have been used, expired, or which are no longer needed, should be disposed of in a safe and effective manner to protect individuals, animals and the environment. Very little evidence has been identified regarding the specific needs of people with visual impairment in terms of medicine and medical device disposal (Ling 2017). Participants in the SIPA2 Study (Fuzesi 2024) reported returning medicines to their local community pharmacy for destruction. This is the ideal method for destruction or disposal of medicines that are no longer used or needed and all community pharmacies in the UK are contacted to provide a medicine disposal service regardless of whether the medicines were obtained from that pharmacy or not.

## Accessibility of Medicine-related Information

In the UK, every medicine that is dispensed is required by law to be labelled and for the label to include the name, dosage, formulation and strength of the medicine. It also includes the dosage instructions and other information, e.g. the name of the patient and the date on which the medicine was supplied. The aforementioned My Voice report reported that 45% of respondents either found it impossible to read the medication instructions or that this was quite/very difficult (RNIB 2015). People who were registered blind were more likely to say it was impossible to read medication instructions compared with people registered as partially sighted.

Several studies have explored strategies to improve the legibility of medicine labels for people with visual impairment. *Leat et al (2016)* tested the effect of larger print and dosage instructions with numbers written as words in uppercase as well as being highlighted.

In addition to the medicine label, other written information is provided with each prescription medicine supplied. Every licensed medicine has a patient information leaflet (PIL) (unless the relevant information for safe use of the medicine can be accommodated on the outer packaging) which summarises the key facts about the product, why it is used (indication), the dose, likely side effects, as well as incompatibilities with other medicines or substances (contra-indications). In 2023, the RNIB published a report (Ali 2023) on Accessible Health Information much of which related to accessible medicine information (and packaging, see later). Half of the respondents aged 62 years and over lived alone. Older people and people with visual impairment are more likely to live alone (ONS 2024, Lincoln & Lindsay 2024) and as such, they have limited if any options available to them to directly access written medicine-related information.



A multifaceted study in the US explored the extent to which accessible medicine information was available for people with visual impairment (Nguyen 2024). A total of 39 manufacturers were contacted to explore the extent to which they provided accessible medication guides or alternative formats to their standard information resources. None of the manufacturers provided accessible medicine information resources. The information guides for the 50 most commonly used medicines were downloaded and assessed for accessibility using a standard checklist. There was substantial variation in the accessibility of the guides with some evidence of good practice in terms of the use of high contrast between text and background, full spelling of acronyms and the use of bold or italic font to emphasise points of importance. The majority of guides used tabulated presentations which were not compatible with screen readers. The final component of the study was to explore the experience of 699 adults with visual impairment (defined as the need to use a screen reader) to identify barriers to obtaining accessible written medicine-related information from pharmacies or other healthcare settings. The majority (>72%) of respondents had asked another person (carer, family member) to help with accessing medicine information and 82% needed help to read written information about medicines. Specific barriers included an inability to read paper-based information, confusion due to inadequate communication and personnel lacking the ability to support people with visual impairment. Suggestions regarding improvements that could be made to medicine information resources included the use of different formats e.g. Braille, audio, voice-to-text, larger print size, trained personnel, enhanced communication and having a “dedicated individual with the health care setting to assist patients with disabilities” (Nguyen 2024).

## Braille

There are around 20,000 braille users in the UK, and whilst this constitutes only 7% of all people who are registered blind (RNIB 2015), their ability to access and read braille is crucial in terms of the safe and effective use of medicines. There are multiple anecdotal reports of medicine labels being applied during the dispensing process which cover braille information. This occurs despite Schedule 24 of the Human Medicines Regulations stating “any statutory information, including Braille” must not be covered by the pharmacy/dispensing label (Gov.uk 2012a). In addition, braille users have suggested that the inclusion of expiry dates and formulation type e.g. capsules, tablets, is information that they would wish to have included in braille. A novel study conducted by *Protopapa et al (2014)* explored the use of 3D printing of the medication name in braille onto the actual tablet. The utility and generalisability of this approach is likely to be limited given the wide range of generic medicines available and the anticipated expense of providing personalised printing for individual patients.

## Assistive Technologies including Medical Devices

For the purpose of this report, 'assistive technology' is defined as "products, systems, and services that help people improve or maintain their functioning in areas like cognition, communication, hearing, mobility, self-care, and vision" (WHO 2024d). The My Voice report highlighted the generational divide in the use of technology with lower levels of use of computers and smartphones in people aged 75 years and over (RNIB 2015).

Medical technologies are products, services or solutions used to save and improve people's lives (MedTech Europe 2024) and a 'medical device' is "any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, materials or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose" (WHO 2024c). In the UK, the MHRA provides guidance on the management of medical devices (MHRA 2021).

A scoping review of assistive technologies and strategies to support the medication management of individuals with hearing and/or visual impairment (Cooper 2023) included 17 studies which tested technologies and devices to use with phones (n=6), eye drop administration (n=5), touch-to-speech (n=2), glucose monitoring (n=1) and magnifying technology (n=1). The majority of studies (n=10) evaluated early prototypes and whilst most participants were able to operate the devices and reported them to be useful, few of the evaluations involved the intended end-users of the technology i.e. people with sensory impairment.

Another scoping review (Espirito-Santo 2024) was conducted to identify and evaluate digital solutions available to informal caregivers for improving medication adherence. Only four studies were included which evaluated mobile apps, SMS messaging, and wearable devices. The studies reported improvements in medication adherence. None of the studies included participants with sensory impairment specifically.

## Summary

This chapter provided an overview of the substantial and growing body of evidence about the experience of people with sensory impairment with their medicines and medical devices. This information was used to inform the Patient Safety Commissioner Study reported in Chapter 4, which explored the specific challenges experienced by people with visual impairment and diabetes in terms of their medicine and medical devices.

## Chapter 4:

# The Patient Safety Commissioner Study

This study was conducted from September to December 2024. The primary data that were generated were derived from three sources:

- Focus Groups involving individuals with visual impairment or loss, including people with diabetes.
- Key Informant responses to an electronic survey.
- MHRA Yellow Card reports.

## Focus Groups

A series of focus groups was conducted to learn directly from people with visual impairment and loss, particularly those with diabetes, about their medicine-related challenges.

Focus group participants were recruited using a variety of methods and with the involvement of different organisations: Diabetes UK, Thomas Pocklington Trust and the RNIB. Participants were provided with an information sheet (Appendix 1) and consent form (Appendix 2) both of which were available as standard or large text format, as well as an audible version, to increase accessibility to these documents. A topic guide (Appendix 3) was developed, informed by the literature, to be used to standardise the questions asked and topics explored during each focus group. Each focus group was led by one moderator (MW) and all discussion was digitally recorded. The online focus groups were conducted using MS Teams and the automated transcript of each group was used for the analyses. Each transcript was checked for accuracy and corrected prior to analysis. Due to limited resources and time constraints, the analysis was undertaken by one researcher (MW).

Three focus groups comprising 11 participants in total, were conducted online to explore the experience of people with visual impairment regarding the challenges they experienced with medicines and medical devices. (One of the groups was originally scheduled for in-person attendance but had to revert to online participation due to anticipated industrial action with the public transport system). Eight participants had diabetes of whom six had T1DM and two had T2DM (Table 1). The average age of participants was 50 years (range: 35 to 66 years) and six were female. Five participants lived alone of whom four had T1DM and visual impairment.

The results of the focus groups discussions in terms of medicines and medical devices are presented to reflect the medicine journey (Figure 1) where relevant, with additional themes described thereafter.

Table 1 Focus Group Participant Characteristics

Participants (N=11)	Lives Alone Y/N	Visual Impairment/Loss	Diabetes History	Medical Devices & Assistive Technology Used
1_1	Y	Severe sight impaired	T1DM	Insulin pens and pumps Optical readers Smartphones Apps
1_2	N	Severe sight impaired (congenital). Braille reader	N/A	
1_3	N	Visual impairment commenced 10 years ago. Now registered as severe sight impaired. Guide dog user. Has 6% vision in one eye and more but 'patchy' in other.	T1DM (for 28 years)	Hybrid closed loop with Dexcom CGM
2_1	N	Severe sight impaired (30 years) due to degenerative optic nerve. Guide dog user. Able to read some braille. Hearing impairment.	N/A	Injectables
2_2	Y	Sight lost (15 years). Uses long cane.	T1DM (since age 7)	
2_3	N	Severe sight impairment	T2DM	

Participants (N=11)	Lives Alone Y/N	Visual Impairment/Loss	Diabetes History	Medical Devices & Assistive Technology Used
2_4	Y	Congenital (genetic). Registered blind with 6/60 sight. Has dyslexia. Does not use cane or guide dog and does not read braille.	N/A	Magnifier. Binoculars.
2_5	Y	Tractional retinal detachment. 70% vision loss, 30% vision in one eye only, mainly peripheral loss.	T1DM	
3_1	N	Registered severely sight impaired (2024) and sight impaired (2016-24). High myopia i.e. sees well 'close up'. Cataracts in one eye. Braille reader. Uses long cane with ball on the end.	T1DM for 28 years	Freestyle Libre
3_2	N	Severely sight impaired. Macular oedema. Diabetic retinopathy. Cataract operation – one eye with very little sight. Other eye – receives monthly injections.	T2DM	Insulin pen CGM Inhaler & Volumatic. WiZoom
3_3	Y	Eye problems since 2021/2 including diabetic retinopathy, diabetic macular oedema. Vision “quite good” except in low light conditions. Wears glasses for distance.	T1DM for 29 years.	Dexcom (self-funded until supplied via the NHS) Tandem pump.

1=FG1, 2=FG2 3=FG3 F: Female M: Male T1DM: Type 1 Diabetes Mellitus T2DM: Type 2 Diabetes Mellitus N/A: not applicable  
NHS: National Health Service

NB: Additional information about characteristics e.g. age, gender, medicines, is not presented to preserve the anonymity of the participants.

## Consultations

The participants were asked whether they had disclosed their sensory impairment to the healthcare providers with whom they interacted so that consultations and interactions could be tailored to accommodate their needs. One participant (a white cane user) stated that the personnel in his general practice were aware of his visual impairment, however, he was aware that this information was not always on other computer systems.

Several participants reported making no formal disclosure stating that because they used visible indicators e.g. guide dog, long cane, they expected healthcare personnel to be aware of the meaning of these items. One participant stated that pharmacy personnel didn't realise the implications of visual or hearing impairment because despite using a long white cane they did not modify their behaviour to support her needs. The value of disclosure was queried by one participant due to frequent staff turnover and stated that pharmacy personnel awareness of her visual impairment would depend upon who is on duty.

## Ordering

Whilst repeat prescription medicines can be ordered using the NHS app, participants reported that it was not sufficiently accessible for people with visual impairment and as such, medicines had to be ordered by phone.

**“It isn't accessible enough and that's why I actually will request medication over the phone. Most surgeries are more than actively trying to dissuade people from doing it to the point where you actually, you know, there is now a legitimate a genuine barrier that when you ring in and ask for a repeat prescription, you usually have to sort of front load the conversation with a very hasty hello, I'm one of your blind customers. Could I please possibly request my repeat prescription now? Don't cut me off because I can't do it on the app. You know, you almost do the kind of gabble a lot of nonsense just to get your repeat prescription.”**

In addition, the effective use of apps required appropriate **“onboarding”** i.e. the introduction of users to apps including their installation.

## Obtaining (Supply) and Storage

Participants seldom mentioned pharmacy personnel in the context of supply or medicine-related information. None of the participants reported discussing their medicine-related needs with pharmacy personnel. One participant cautioned against excessive training for pharmacy personnel (in relation to supporting people with visual impairment) to avoid *“two minute lectures”*. Some participants suggested that they didn't engage with pharmacy personnel

because they felt it would place excessive burden on personnel. Several participants had their medicines delivered directly to their homes from the pharmacy whilst others collected them in person.

Participants in all three focus groups emphasised the importance of being aware of any changes that had been made to their medicine regimens e.g. a different generic medicine of an existing treatment, changes in insulin vials (shape, size), etc. They relied on the shape and colour of tablets/capsules and/or the packaging for medicine identification.

**“When it’s happened in the past, ...my first indication is something as simple as you know that doesn’t .. feel like the last boxes I had or you know the packaging feels particularly different or the shape of this pen has .. changed....You then have to find a way to verify ...that something hasn’t been done in error before you take the medication. .. I got a box of insulin injector pens and it was completely different to the style shape .. format of what I’d been used to using for many a long, long time”.**

**“I’ve been on the same three medications – amlodipine, atorvastatin and perindopril – I can’t remember .. how many years now... I’m not sure I’ve had the same box twice”.**

An example was given of when the vials of insulin had been changed and the time spent on checking whether the product that had been supplied was correct.

**“I’ll use an OCR, ocular character recognition, software on my phone; various apps that read text and labels, to scan the boxes and just pick out the name of the medication so that I know ..what ones in each in each box”.**

### Incorrect Supply

Several participants described being supplied with incorrect medicines. In one case, they had been supplied with somebody else’s medicines. One participant had been given wrong medicine because it had a ‘sound alike’ name and looked similar to what she was expecting. This participant only became aware of the error when a member of the public commented on how brightly coloured the medicine box was, which made the participant realise that it was incorrect. Another participant stated that pharmacy personnel **“need to be extra careful”** when supplying people with visual impairment and diabetes (because of the consequences of incorrect supply and/or other medicine error).

### Administration

Many of the concerns discussed by the participants related to accessibility to medicine-related information as well as the accessibility of medical devices.



### Accessibility of Information and Medication Packaging

The layout, format, direction, and colour of information was flagged as important in terms of medicine and related information. Information not only needs to be accessible but the instructions for the use of devices need to make sense to someone with visual impairment e.g. it is insufficient simply to make inhaler instructions accessible, the information needs to include how a person with visual impairment should use the device. Many participants were unable to read or gain access to information about their medicines and this included being able to read or access medicine label information, as well as more detailed information from the medicine packaging and/or patient information leaflet (PIL). The importance of written information being presented in an accessible format was discussed in terms of:

**“the language of position, direction, texture, layout” and that “from a non-visual perspective it does not come naturally to the general population and there is huge room for .. consultation for education on those on those matters”.**

Participants reported being unable to read expiry dates especially those which are indented rather than printed. Braille users described experiences of dispensing labels being placed over braille information, making it inaccessible.

The use of different brands and thus different packaging caused confusion and uncertainty as well as concerns about safety. Participants reported using smartphones to check the accuracy of their medicine supply. Medication packaging challenges were identified in relation to foil strips of tablets or other solid dosage forms, because they were identical to the touch and therefore it was difficult to differentiate between them.

Some medicine packaging involving boxes was reported as being difficult if not impossible to open without damaging the box and as such, boxes could not be re-closed securely and the contents would fall out and/or mix with other medicines in the same area creating risk of incorrect administration.

**“The number of resealable ..cardboard boxes has gone down in the last few years, and that means that ..blind people, ..the ability to drop, lose, kick medication around the bedroom has gone up. That would be a very simple innovation that could come back into medication design ..if you have to tear cardboard to open it and then you can’t reseal a box securely, then the stuff’s going to go missing and you’re going to suddenly find yourself short. The implications of that, you know, could be quite far reaching.. the implications are always more complicated than they.. look at face value”.**

**“the three antiepileptics I take are regularly in boxes that I basically have to damage in order to get at the drug and so there is always a risk of dropping some.”**

One participant reported being fined because he had not renewed his prescription exemption certificate. The reminder had been sent to him in an inaccessible format.

**“I actually ended up being fined because my .. exemption certificate had expired. And I ... didn’t receive an accessible reminder of any description that it was due to expire”.**

### Accessibility of Medical Devices and Technology

Many participants reported the use of medical devices and other forms of technology to support their medicine use, particularly participants who used insulin. This included sensors for monitoring blood glucose, insulin pumps, smartphones to link sensors and pumps as well as for integral reading software i.e. to read medicine labels and other written information.

The use of smartphone apps for ocular reading and checking names of medicines and information was often cited.

**“iPhone usage is probably the single most important innovation for a blind person in my lifetime”.**

**“Technology’s certainly a help in a lot of ..general situations, but you know medication-wise as well .. you know ..the glucose monitors.. sync up with your phone which then works with the inbuilt screen reading software so that you can actually, .. read ..your glucose level from that and use the .. logs and make notes and stuff in there so you can share the information with your consultant.”**

### Glucose Monitoring and Insulin Administration

Glucose testing strips were reported as difficult and often impossible to use by people with diabetes and visual impairment. One participant with T2DM did not monitor their glucose because their visual impairment prohibited the accurate co-ordination of their blood sample onto the testing strip. This meant that the participant waited until they became symptomatic (e.g. rapid heart rate), whereupon they would consume chocolate and other high sugar food to correct their hypoglycaemia (low blood sugar levels). This participant believed that they were not eligible for CGM, perceiving that this technology is only available to people with T1DM. One of the participants also suggested that eligibility for insulin pumps varied by ICB (Integrated Care Board) and led to a **“postcode lottery”** for people with diabetes. Variation in the availability of insulin pumps and eligibility for access was discussed by another participant who had sufficient visual function currently to operate her pump, but was fearful that if her vision deteriorated further, that the pump would be withdrawn.

**“If I went back on injections like it sounds really dramatic but I think I would probably end up in hospital and potentially even die a lot younger if they took my insulin pump away.”**

She also suggested that if people could start using pumps as soon as possible then they could enhance their familiarity with using these devices before their visual function deteriorated further.

**“If we made them [insulin pumps] accessible at the beginning we could literally save people’s lives and .. it sounds really dramatic but for us ..Type 1 [sic] .. it really is.. life or death. If we don’t take our insulin, we will die”.**

Whilst CGMs and insulin pumps were considered to have revolutionised diabetes management, participants frequently cited lack of accessibility of information which was necessary for their effective use and maintenance.

**“One of the things we’ve highlighted to the hospital is.. that the .. pumps that they ordinarily dish out, the automated insulin delivery, are not suitable for people with impairments.”**

One participant who used Libre2 in combination with an app on her phone discussed the challenge of accessing different formats of information. She had sufficient visual function to read her “numbers” i.e. blood glucose level, but not to see the scale. She also mentioned that she was unable to insert the sensor into her arm and relied upon her partner to perform this task.

Suggestions were made regarding improving the accessibility of pumps including:

**“Magnification software on the pump itself would be helpful, and inverted colours would be helpful as well. Again, .. currently these aren’t built in.”**

One participant who lived alone described the ongoing challenge of managing her diabetes on her own in terms of the technology and dexterity required.

**“It’s really difficult when you’re changing your cannula and your insulin because you’ve only two hands, and unless you’ve got someone there to help you all the time, you have to change your insulin every three days on this particular pump. I found it difficult when priming the insulin because the insulin is the same colour -it’s clear, clear colour .. and the tubing is a clear colour – so there’s no contrast and you’re trying to prime it and get any air bubbles out and I find that really tricky. ..Do we change the colour of the tubing .. I’m not sure if that would work, .. it would have to be trialed, but just to make us see those bubbles a bit better.”**

In terms of colour and colour contrast of medical devices and equipment, one participant shared a photo of her “diabetes hardware” stating that it comprises:

**“Black lead, a black plug, a black finger pricker, a black PDM [personal diabetes manager] that controls the pump and it comes all nicely packaged in you guessed it, a black bag! This is very difficult for those**

with poor sight who need high contrast. Even the skin to protect the PDM is also black. If this was a bright colour it would really help but they [say] that is not an option”.

**Figure 2 Image of diabetes devices used by a participant**



Ordering ‘diabetes consumables’ was also a challenge for people with visual impairment because the items were ordered from different companies i.e. their CGM sensor was provided by one company and the insulin pump by another company. This added to the burden of diabetes management.

Accessing support from manufacturers’ helplines or support services was often problematic because participants were asked to provide information about serial numbers and other information which required to be read and reported to the helpline personnel; information that was often inaccessible to people with visual impairment.

Whilst insulin pens originally revolutionised diabetes treatment, their use by people with visual impairment was noted as being problematic for several (modifiable) reasons. Substantial dexterity is needed to remove needle caps and place needles onto pens. The use of clear caps was deemed to be unhelpful. People were reliant upon the audible clicks of the ratchet, as well as the movement of the dial, however, one participant who was on a high dose of insulin struggled with ensuring the use of accurate doses.

**“My insulin pens are my real worry. I have prefilled injection so I have to put the needle on the top, screw the needle onto the top which has a clear cap. So not only can I [not] see the cap, when I put it down anywhere or if I drop it on the floor, I’m lost. The needle is so fine to screw that onto the thing.. I said to the diabetic centre when I was up there last my last appointment is there anything you can help me with because I cannot see the numbers at the bottom where you dial the pen**

so I have to take 54 [units] I have to do 27 each side of my tummy. .. So some days it it could be under. I mean, you're counting, you know. And then you have to think about something and then oh no, back to square one. You know. So now I just kind of turn it twice in a little bit in the hope that I've got 27.

## Disposal

Participants discussed the disposal and environmental impact of the medical devices supplied for the management of diabetes. One participant described retaining all the plastic needle covers and caps at home because she didn't know what to do with them and she couldn't use them due to her visual impairment. The disposal of sensors was discussed with one participant querying whether it was appropriate to dispose of them in sharps boxes because they contained batteries and could perhaps be recycled.

## Medicine Safety and the Burden of Visual Impairment and Diabetes

People with visual impairment, especially those with diabetes, experience substantial burden due to their medicines on a daily basis. This includes extensive accuracy checks especially to ensure that any perceived changes with medicines or medical devices were safe and intended, and also ongoing vigilance and checking with diabetes management.

**"We have to make multiple medical decisions on the [insulin] dosage that .. we take. So every, .. day is .. completely different for us."**

**"When you can't see in any given day when you want some downtime means ..spending God knows how much time ..doing things that no one else has to do. And that's an implication of sight loss even if it doesn't look like it. ..The time implication is considerable. I know that medical implication is more important, but there is a time one as well."**

Avoidance of error and harm was a major concern for most participants.

**"I've learned to be very cautious".**

**"It's a worry. It's a massive worry for me to have sight loss and not necessarily be able to know what I have in my hand".**

One individual who had two forms of tablets and two different insulins highlighted that they need to be able to differentiate between the two types.

**"I need to know I'm taking the right medication using the right product".**

Participants mentioned anxiety and fear associated with medicine changes and checking.

**"I have been known to check individual tablet strips as well because they'll usually have a label on them to confirm".**

Participants relied substantially on the shape and feel of medicines and tablets to check whether they were using the correct ones.

**“The first thing I thought was, oh, have they sent me the wrong ..box of insulin..? But it was only through again reading the .. printed information on the packaging with an app and I then actually did manage to double check with someone so before I needed to actually use it, to set my ..mind at ease that it was just a change of packaging, it wasn’t a different medication, it wasn’t a different concentration or anything else. It was just they happened to change the packaging ... So it’s the most important thing ..knowledge that you are taking what you think you are taking.....If the packaging changes or if the supplier changes. I need to know that it’s the equivalent or the same ..as I’m used to because I need to judge whether it will have the same effect”.**

Most participants reported concerns about their safety in terms of incorrect medicine supply and or administration. Several participants gave examples of medicine-related errors that they had experienced. Participants varied in their preferences and resources for checking the accuracy of medicine supply. Some participants were willing and satisfied with using ocular reading tools to check their medicines however at least one participant preferred to rely upon a human being.

Many participants reported using the same community pharmacy regularly for their medicine-related needs. None reported having had a specific discussion with pharmacy personnel about their needs in terms of their medicines in the context of their visual impairment and the options for accessible information. Assumptions were made by participants that information from their medical records would be transferred to their pharmacy records in relation to their visual impairment. It should be noted, however, that not all health and social care professionals have access to medical records. For example, community pharmacists can access a ‘summary care record’ (SCR) for patients that give permission to do so, or without permission if there is reasonable justification i.e. in the event of an emergency. The amount of information available via the SCR is variable and might not include information regarding “reasonable adjustments flag”.

### **High Risk Medicines**

Several participants used high risk medicines including insulin and anti-epileptic medication. Seven participants used insulin which needs to be titrated daily to optimise blood glucose management and minimise adverse effects requiring people with diabetes to be ever vigilant:

**“If things go wrong they can go very wrong very quickly”.**

Some participants used oral hypoglycaemic medicines which can be regarded as high risk if used inappropriately. Two participants in FG 1 used antiepileptic medication for the management of epilepsy. Several antiepileptic medicines

are considered to be high risk medicines because the dose and blood levels need to be titrated carefully to derive a therapeutic effect i.e. fewer or no seizures, with minimal toxicity. None of the participants used Category 1 anti-epileptic medication i.e. where the “patient should be maintained on a specific manufacturer’s product” (BNF 2024).

### **(Lack of) Person-centred Care**

Two participants recounted examples of where their specific wishes, needs and abilities were not addressed by health professionals. In the first example, the participant was not permitted to try to administer a newly-prescribed medicine herself because of her visual impairment, which she described as “*insulting*”. The second example was a participant who was unable to administer a medicine independently (alternative options were available where independence could have been maintained) and felt “*degraded*” when he had to ask a neighbour to administer it to him.

#### **Example 1**

The female participant had visual impairment (but not diabetes), who used injectable medicines, and who valued her independence. She described a situation where she was prescribed a new injectable medicine, but the hospital consultant (as well as the manufacturer of the medicine) stated that her husband had to administer it.

**“I like to be able to control .. things myself, I don’t want to wait on somebody else who might not be here anyway.”**

**Interviewer:** Who were they that weren’t happy about you doing it?

**“The consultant and the...company that’s providing the medication.”**

**Interviewer:** So, he would have preferred your husband to be administering ..the injection for you...to what extent were you involved in that discussion?

**“So we’re fully involved in it, but they were quite adamant that I wouldn’t be able to do it because of my visual impairment. I think that’s more of a concern, you know, because I couldn’t see properly ... which I suppose in some ways is insulting.**

**“My husband did do it for the first few months and then I said, well, this is silly show me how to do it and I’ll do it.”**

## Example 2

The second example was a male participant (see also Case Study 3) who required injectable weight loss medication. He was severely sight impaired, had T2DM and lived with his wife.

**“They swapped them injections... it was challenging. When it was you expected to look for this little number one and twisted dial to another ..and then look for the liquid to about 5mls of liquid. And when you can't see, that's obviously not viable to be doing stuff like that. ..It just wasn't viable to give them to somebody who can't see what they're doing, really”.**

**Interviewer:** To what extent was there any discussion about what would work for you and how you would manage?

**“There wasn't any discussion. It was ‘that's what you're having, because that's what we can get’”.**

**Interviewer:** Who was that consultation with?

**“.. one of the practise nurses .. Since that situation ..we swapped surgeries to the one we're at now”.**

**Interviewer:** And did you swap do because you've moved house or because it's a different level of care?

**“It was better care”.**

**Interviewer:** And what does better care look like and feel like for you?

**“Talking to you properly and understanding your needs.. It's not .. wanting special care, it's just understanding where you are and what you need. ..Instead of just saying ‘that's yours, away you go we'll see you later then’ talk through things and see if you can manage. Can you use? It's not a case of you don't have to, if my wife was out, I'd have to get someone else to do the injections for me. But the other surgery didn't seem to worry about that...”.**

**Interviewer:** And so how does that make you feel?

**“More annoyed than anything....to give somebody who can't see, someone that you can't physically do [it] yourself seemed a bit strange to me. That didn't make a lot of sense”.**

**Interviewer:** Yes.. Did you get a sense that they were relying upon .. somebody else helping you?

**“Yeah. Yes, definitely. Yeah, they're definitely thought someone would do it for me. I remember wife or even have to get a neighbour to do it once because that was the only way we could do it”.**



**Interviewer:** And how did that make you feel was having to get a neighbour to do it?

**“Oh, it’s not really embarrassing, but you shouldn’t have to go asking a neighbour to come and inject you into your stomach because you can’t see what you’re doing yourself. It’s a bit ..degraded [sic] in a way. That was how it was. That was why we swapped [changed general medical practice]”.**

## **Other Challenges Experienced by People with Visual Impairment**

The challenges associated with people with visual impairment learning how to use products or technology was highlighted. For example, one participant worked with a third sector organisation to develop methods of informing people with visual impairment about how to use COVID-19 tests and more recently how to use the FIT (faecal immunochemical test) below testing kit. Health care professionals were perceived to be unaccustomed to explaining the use of medical devices to people with visual impairment e.g. inhalers.

People with diabetes need to monitor their carbohydrate consumption as part of their blood glucose management. A lack of accessible nutritional information on food packaging was identified as a barrier to diabetes management.

## **Summary**

This section presented a summary of the findings of the three focus groups conducted specifically for this Study. The results were presented to reflect the medicine journey and additionally, the Medicines Optimisation framework (RPS 2013). The following section presents the results of the Key Informant Survey.

## **Key Informant Survey Results Related to Visual Impairment**

The Patient Safety Commissioner’s team conducted a survey of key informants in organisations and agencies relevant to the topics addressed by this Project. The survey was emailed as an attached document to – where possible – named individuals and comprised 13 questions (Appendix 4) similar to those included in the Focus Group topic guide. The survey was completed (wholly or in part), or relevant information was supplied by representatives from the following organisations:

- Association of British HealthTech Industries (ABHI)
- Association of British Pharmaceutical Industry (ABPI)
- Community Pharmacy England (CPE)
- Health Services Safety Investigations Body (HSSIB)
- Healthwatch England

- Medicines and Healthcare products Regulatory Agency (MHRA)NHS England (Diabetes Programme Team)
- National Pharmacy Association
- RNIB
- RNID
- SignHealth

A summary of the survey responses is presented below.

### Trade Associations for Medicines and Medical Devices

Association of British HealthTech Industries (ABHI)

People with visual or hearing impairment may need to access visual aids (spectacles, contact lenses) and hearing aids (cochlear implants, wearable aids). People with some clinical conditions (e.g. diabetes) may be more prone to visual impairments and need access to devices specific to their condition (e.g. glucose testing).

Devices regulation tends to be very broad to cover the very diverse range of devices, their characteristics, performance and intended use. Sitting alongside regulation are standards that can cover more detail than legislation. In addition, authorities may decide to issue guidance to support the legislation. Such guidance can be more specific than legislation or standards.

From a very quick, initial review, UKCA regulation has no specific requirements around people with disabilities. EU CE legislation is a little more specific:

**“In eliminating or reducing risks related to use error, the manufacturer shall: (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).”**

A relevant harmonised standard – BS EN ISO 62366 *“Applicability of usability engineering to medical devices”* – covers users with disabilities:

**“When developing and applying USABILITY goals during the design PROCESS, the MANUFACTURER needs to consider the specific characteristics of the intended USER PROFILES. This might include USERS with disabilities, (e.g. impaired vision, hearing or touch). The MANUFACTURER also considers the associated HAZARDS and RISKS.”**

MHRA Guidance on applying human factors to medical devices expects manufacturers to understand user profiles including hearing and vision.

**“Understanding should include but is not limited to: user profiles: a description of the users (e.g. gender, age, height, education, experience, hearing, vision, computer literacy, values, motivations, culture, any anthropometric and biomechanical considerations, disease state)”**

In 2012, the MHRA wrote guidance for Notified Bodies on the review of devices for self-testing that included provisions for people with visual impairment testing their blood glucose, but it looks as if this was withdrawn.

The ABPI did not complete the survey. A representative did however provide information regarding electronic Patient Information Leaflets (ePILs) (Appendix 5).

### **Community Pharmacy Organisations (CPE, NPA)**

Responses were received from CPE and the NPA. Both organisations highlighted the lack of government funding to provide services to reflect the Equality Act 2010 legislation. The Drug Tariff (standardised rates of reimbursement for community pharmacy services) states that “a contribution for provision of auxiliary aids for people eligible under the Equality Act 2010” is included in the single activity fee for prescriptions – for each dispensed medicine, however the CPE stated that due to funding cuts to community pharmacy services “there is no real funding for community pharmacies to comply with their responsibilities under the Equality Act”.

In terms of improving the accessibility of medicines and medical devices for patients with a visual and/or hearing-impairment, CPE has previously issued guidance (2015, 2016a, 2017) regarding the Accessible Information Standard 2015 and the Equality Act 2010 and its implications for pharmacy professionals in terms of making ‘reasonable adjustments’ to ensure persons with disabilities can access pharmacy services. The website includes a statement “Pharmacy contractors have an important role to play in ensuring NHS funded services are accessible to all, and pharmacy teams already make efforts to provide information to people in formats that they can understand and appropriate support to help them to communicate” (CPE, 2016b). The CPE also states that pharmacy teams:

**“should, as a matter of normal routine practice, ask patients about any accessible information and / or communication needs they may have and ensure that information is recorded on their notes”**

**and,**

**“make reasonable adjustments to ensure that people receive information in a format they can understand. The adjustments you make should be reasonable – but this does not mean that the patient must always receive information in their preferred format. What is important is that they can access and understand the information.”**

The CPE suggested that recent regulatory changes are likely to result in the greater use of original pack dispensing, which might benefit braille users because of the legal requirement for original packs of medicines to include braille information.

The NPA has previously produced resources to support pharmacy teams on complying with the Accessible Information Standard, and in implementing the Equality Act 2010 in terms of the reasonable adjustments that could be made to assist people with a disability receiving goods and services. This organisation also reported providing up-to-date information on the requirements of the Accessible Information Standard and gave examples that included the “use of large print labels, ensuring that medicine box labels are not applied covering up braille writing on the packaging, availability of hearing loops, talking monitored dosage systems, checking to see if the patient has social care support/ carer support”. They acknowledged that a “one size fits all approach” was not appropriate and promoted a person-centred approach.

In terms of ordering, the NPA advised that community pharmacy teams could assist people with sensory impairment by ordering their medicines from their general practice, however, in most areas this is not permitted. In terms of the delivery of prescription medicines to people’s homes, there is no NHS/ Government funding for this service.

The NPA stated that patients also need support with labels (on how they need to specifically take their medicine) that are applied to original containers that may have braille but also to plain carton boxes or medicine bottles when different quantities of medicines are required to be supplied. They advised that there is a lack of adequate technologies, access to, and support from NHS/Government to implement audio/large print labels. There was a lack of a joined-up systems approach to tackle this situation as well as inadequate access to relevant information about individual patient’s requirements. The NPA suggested that having a standardised approach throughout community, primary and secondary care, as well as social care, would benefit patients and HCPs. For example, using the same approved provider for braille labelling. This way the patients know what to expect and HCPs know it is a reliable and assured provider. They recommended that the providers should be NHS/Government funded to ensure patients receive care that reflects standardised accessibility requirements. In terms of medical devices, the NPA suggested that talking monitored dosage systems exist but are expensive and can be difficult to use or implement. Improvements in service design were needed in terms of gauges that could be read by people with visual impairment and having audible clicks on medical devices.

Finally, the NPA suggested that there might be potential for a community pharmacy toolkit to assist with complying with the Accessible Information Standard.

### **NHS England, Diabetes Programme Director**

The NHSE response from the Diabetes Programme Director, referenced discussions with the PSC that have focussed on “engaging people with lived experience in the implementation of diabetes technologies – in particular Hybrid Closed Loop (HCL) technologies”. “NHS England works proactively with HCL suppliers to include eight systems “in a single national procurement framework and to agree NICE recommended cost-effective prices. This is to provide greater choice. Industry suppliers have expressed a desire to work collaboratively with us through the ABHI to look at ways we can reduce inequalities in terms of technology access”. The respondent noted the lack of evidence around these technologies when used by people with sensory impairment and a need for “greater professional awareness of evidence of good practice”.

### **Health Services Safety Investigations Body (HSSIB)**

The HSSIB response mentioned their involvement in equality impact assessments to determine whether their work has a positive impact on people with protected characteristics (which would include people with disability e.g. sensory impairment). Specific challenges related to medicines and/or medical devices would be investigated if identified. In addition, the HSSIB described the formation of the International Patient Safety Organisations Network (IPSON) in 2023, the purpose of which is to bring countries together that have an active patient safety organisation. IPSON meets quarterly and to date has not considered the challenges of patient safety in relation to medicines and medical devices, their use by people with sensory impairment, or their use by people with diabetes and visual impairment. They offered the opportunity to discuss these challenges at a future meeting of IPSON.

### **Voluntary and Third Sector Organisations (HealthWatch, RNIB, RNID, SignHealth)**

#### **Healthwatch England**

The HealthWatch England response provided links to several documents of relevance to the survey including their *Harnessing digital technology to prevent or manage ill health report* (HealthWatch 2023) that highlighted the risk of digital exclusion of people with sensory impairment from health services e.g. virtual appointment systems. In addition, they suggested that “Regulation 259 of the Human Medicines Regulations could be brought into line with the revised Accessible Information Standard to ensure that patient rights to accessible information about medicines matches those in health services.” They also signposted to the Healthwatch Cumberland (2023) publication, *Disability Voices: Digital Divide Report*, which included a case study with a male individual who had macular degeneration. The case study did not include reference to medication; however, it illustrated benefits and challenges of digital technology. The report also included a recommendation to “Advertise the financial support

that people living with disabilities can access to purchase digital technology/equipment that would improve their daily quality of life and support them in obtaining this support.”

## RNIB

The RNIB provided an extensive response (the full response is available in Appendix 5) which summarised the wide range of activities the organisation has undertaken that are relevant to the medicine-related needs of people with visual impairment or loss. These activities include advocacy for increasing the accessibility of medicine packaging and patient information leaflets (PILs) particularly Braille on medicine packaging (including collaboration with PharmaBraille), and accessible PILs (in a variety of formats) and extended XPILs (enhanced digital versions of PILs).

The RNIB collaborates with commercial organisations to improve accessibility of information. For example, they worked with Haleon, a pharmaceutical company, to transform barcodes into audio-encoded labels which, when used in combination with the Seeing AI app, enable users to scan the codes and access spoken information about the medicine. They also worked with Kellogg’s, Aunt Bessie’s and Procter and Gamble (P&G) to improve access to information of Consumer-Packaged Goods (CPGs).

Whilst the RNIB does not support the use of QR codes, it is working with Unilever, and Zappar (a UK-based company), to develop Zap Vision Accessible QR codes (AQRs) and NaviLens codes (<https://www.navilens.com/en/#navilens-section>) for navigation (See Example 1 below). There is considerable scope for more widespread use of **accessible** QR codes for medicine packaging and PILs. These types of codes do not rely upon the user to be in immediate proximity of the code, nor do they need the camera to be aligned with the code. The use of AQRs for medicines would enable access to information in different formats, as well as more comprehensive information e.g. expiry dates, batch numbers, and translation into other languages, including BSL.

### Example 1 Assistive Technology, Medicine Information and Packaging (original information provided by key informant from RNIB)

*Cinfa*, a Spanish pharmaceutical company that produces 1500 products, has been collaborating with NaviLens and the Spanish government to facilitate access to medicine information for people who are blind or partially sighted. Every medicine package produced by Cinfa will include a NaviLens code that will provide “vital medicine information” about the product (Figure 3). In addition, the packages will have a GS1 DataMatrix health code which will store and deliver essential information.

People wishing to use the system will be required to download the free NaviLens app. Users of the app will then point their camera towards the medicine package, and the following information will be read aloud:

- The name of the medicine
- Active ingredient
- Expiry date
- Batch number
- Serial number

The Spanish Medicines Agency, the government body responsible for ensuring the safety and effectiveness of all medicines, approved the use of these codes on Cinfa products in Autumn 2024. An illustration of the use of the system can be viewed here: <https://www.youtube.com/watch?v=mehDPhd-cgk>.

**Figure 3 Example of NaviLens codes on medicine packaging**



## Key Informant Survey Results Related to Hearing Impairment

The RNID and SignHealth provided extensive responses to the survey questions. The full responses are presented in Appendix 5.

The RNID highlighted that communication was primary barrier to safe and effective access and use of medicines by people with hearing impairment. The response suggested that reasonable adjustments were often not in place for people with hearing impairment during consultations where medicines were prescribed or reviewed and that this had safety (and effectiveness) implications because the patient was not fully informed about their medicine. They cited a report that stated that 77% of respondents to a survey never or rarely received information in alternative formats when interacting with health or social care professionals. The same survey reported that 81% of respondents had an appointment where their communication needs were not met. The RNID response highlighted the lack of interpreters for people who are deaf and that they use of family members to interpret is a breach of confidentiality and privacy. The quality of interpretation with informal interpreters is often lacking because of the complexity of terminology that is discussed. The response also highlighted the challenges that people with hearing impairment experience with phone or other non in-person consultations, as well as in-person consultations where masks are worn. They suggested that service providers had “poor awareness of how to aid lip-reading”, that professionals were impatient with individuals who had impaired hearing, that people with hearing impairment did not hear their name being called at reception, and that hearing loops often were unavailable or staff were unfamiliar with their use. The RNID response highlighted barriers to the safe and effective use of medicines and medical devices at all stages of the medicine journey, as well as the implications and likely consequences for people with hearing impairment resulting from these challenges.

A representative from SignHealth who is deaf and has T1DM emphasised the implications of inadequate communication between health and social care professionals and the safety implications for people with diabetes and hearing impairment/loss. She highlighted the lack of interpreter services during consultations with her GP which meant she had incomplete information about her medicines, how to use them effectively, and potential side-effects. The DAFNE (Dose Adjustment For Normal Eating) course was criticised for its lack of accessibility for Deaf/deaf people. The response also discussed sound alerts that were used with several medical devices for diabetes management, which were unhelpful for people with hearing impairment. Whilst manufacturers of these devices provide alternative vibration alerts the vibration alert setting must be turned on to be effective. Written materials were seldom if ever presented to accommodate the different language style and comprehension of people who are Deaf/deaf, as well as people for whom English is not their native language



and are overly complex and use terminology that will not be accessible to all individuals who are hearing impaired, particularly those who require interpretation services.

## **MHRA Yellow Card Reports**

The MHRA provided information regarding spontaneous adverse event reports that had been made to the Yellow Card Scheme\* (MHRA 2024a), which were associated with people who reported a vision disorder within the past medical history section of their report. The search identified 169 submissions from patients who reported a past medical history which included a vision disorder. These reports were then reviewed to identify the nature of the vision disorder (historical or current) and for any relevance of the adverse event to readability or packaging. Four reports were found to be regarding issues with packaging readability or product quality and were related to patients with an existing history of sight loss, blindness or other visual impairment.

\*The Yellow Card scheme collects and monitors information on suspected safety concerns involving healthcare products, like a side effect with a medicine. The scheme relies on voluntary reporting of problems to a healthcare product by the public (including patients, parents and carers) as well as from healthcare professionals. A reported reaction does not necessarily mean it has been caused by the medicine, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental. Information collected through the Yellow Card Scheme is an important tool in helping MHRA monitor medicine safety. Yellow Card reports of suspected ADRs are evaluated, together with additional sources of evidence such as worldwide literature, in order to detect previously unidentified hazards or side effects.

## **Summary**

This chapter presented the results of the primary data collection for this Study which included focus groups, key informant responses to an electronic survey and yellow card reports to the MHRA. The results identify numerous and varied medicine and medical device-related challenges experienced by people with visual impairment, diabetes, and hearing impairment. Chapter 5 presents the discussion of these results in the context of safety and people with sensory impairment in general, and then more specifically in relation to people with diabetes and visual impairment, examples of good practice and recommendations for future practice.

## Chapter 5:

# Discussion and Recommendations for Practice

This study used a combination of primary and secondary data to address the three research questions stated in Chapter 1. This chapter presents the discussion of the results in terms of the first and second research questions (including examples of good practice) and concludes with recommendations for future practice (research question 3).

## **Barriers to Patient Safety for Patients with Sensory Impairment**

A wide range of barriers to patient safety was identified in terms of patients with sensory impairment in general and more specifically patients with diabetes and sensory impairment. Barriers and challenges were identified at along all stages of the medicine journey. Many of the barriers were associated with access to information, primarily written (including digital), but also verbal in terms of communication during consultations and accessing support services. The evidence suggests a lack of training and hence awareness of healthcare professionals regarding working with people with sensory impairment.

Multiple barriers were identified in terms of the use of medical devices and technology to support people with T1DM with few devices having the accessibility required for individuals to operate them without the assistance of others.

## **Impact of Barriers on Patients with Diabetes and Visual Impairment**

People with diabetes, particularly those who use insulin, need to be able to understand how to manage their diabetes effectively and safely, to prevent acute problems due to hypoglycaemia and hyperglycaemia, and to minimise the risk of longer term complications e.g. (further) visual impairment, renal and cardiovascular problems. To do so, they need timely access to training that is delivered in accessible formats. People with diabetes who have been unable to access timely training about the management of their condition will be at risk of inadequate management of their diabetes and at higher risk of developing longer-term problems associated with diabetes.

People with diabetes and sensory impairment, particularly those with visual impairment, experience substantial burden on a daily basis to manage their condition in a safe and effective manner. They experience anxiety and fear

associated with the risk of incorrect medicine supply and use. Whilst the use of technology for some aspects of diabetes management has been life-changing, the operation and management of diabetes-specific devices and technologies is problematic for many because the design of devices fails to meet the accessibility needs of people with diabetes and sensory impairment.

The results indicate that the principles of medicines optimisation (RPS 2013) are not being met for people with sensory impairment, particularly those with diabetes and visual impairment. A lack of person-centred care for people with these conditions means that they will achieve sub-optimal benefit from their medicines and medical devices and experience higher risk and harm from their medicines.

### **Examples of Good Practice**

Few examples of good practice were identified during the PSC Study. The development of NaviLens codes (or similar) is promising in achieving greater accessibility of information about medicines and their safe and effective use.

### **Findings/conclusions**

The primary and secondary evidence presented in this report has highlighted areas where change is needed.

1. Accessibility needs and preferences for medicines and medical devices of people with sensory impairment should be assessed using standardised tools and reviewed at appropriate intervals.
2. People with sensory impairment should be offered and have timely access to translation services for health and social care consultations e.g. BSL translators for consultations with GPs and Diabetes Management Team.
3. Medical, pharmacy and other health and social care records to include prominent flag of accessibility needs and detailed information about these needs. A clinical code arising from the “reasonable adjustment flag” is insufficient by itself and should be accompanied by relevant explanatory detail.
4. Guidelines are needed to promote evidence-based prescribing for people with sensory impairment.
5. Pharmacists and other pharmacy personnel/health professionals involved in the supply of medicines need to be aware of the importance of informing people with visual impairment and especially people with visual impairment and diabetes when any changes are made to the medication regimen.

6. A funding review is needed to support the additional time and resources required by healthcare professionals, particularly community pharmacy personnel (or others involved in the direct supply of medicines and medical devices), to undertake systematic assessments and provide “reasonable adjustments” for medicines and medical devices.
7. The NHS app needs to be proactively and regularly reviewed and improved in terms of accessibility, especially for people with visual impairment. Improvements are needed in relation to ‘onboarding’ of people to the app and with their prescription medicines.
8. Helpline personnel i.e. for manufacturers of insulin pumps and other relevant devices, should be trained to work effectively with people with visual impairment.
9. Clear guidance is needed for people with diabetes regarding the appropriate and safe disposal of the medical devices and related paraphernalia.
10. Medicine information and packaging must be offered in accessible formats. The NaviLens codes (or equivalent) should be introduced on medicine packaging and for product information leaflets for all medicines.
11. Prescription exemption certificate expiration date reminders (and other health-related notifications) need to be sent to individuals in an accessible format.
12. Resources should be developed for use by people with sensory impairment as well as health and social care providers, to facilitate the demonstration of the effective use of medical devices, especially for people with visual impairment.
13. All health and social care professionals to have sufficient access to patient records to ensure awareness and documentation of “reasonable adjustment flags”.
14. Strategies are needed to increase awareness regarding the medicine-related needs of people with visual impairment in general and more specifically people with visual impairment and diabetes.
15. Guidelines are needed to promote evidence-based practice by health and social care professionals in terms of the medicine journey of people with sensory impairment.
16. Provision of protected funded training time for community pharmacists and their teams is needed to increase their awareness of the needs of people with sensory impairment and/or diabetes, and the resources available to meet their needs.

17. Provision of training to health and social care professionals (ideally within the undergraduate curricula) regarding the needs of people with sensory impairment.
18. People with sensory impairment should be made aware of the importance of disclosing their sensory needs and preferences about medicines and medical devices so that these can be documented within their shared medical record.
19. People with sensory impairment should be made aware of the importance of the need to authorise community pharmacists to have access to their medical record.
20. The “Diabetes structured education and self-management support course” (and other routine education and training events delivered via the NHS) needs to be accessible to people with sensory impairment and to be provided to people with sensory impairment in a timely manner.
21. People with experience of visual (and hearing) impairment should be included in the design of insulin pumps and CGMs, as well as user information and instructions to accompany their supply and use.
22. Medical devices that are to be assessed for regulation by the MHRA should be evaluated in terms of their accessibility prior to approval.

# Case Studies

The following case studies were derived from focus group participants' experiences. These case studies illustrate the many challenges experienced by people with visual impairment, especially people with diabetes, in relation to their medicines and medical devices. The case studies could be used as a resource by organisations and institutions to raise awareness of these challenges and to derive solutions to promote enhanced safety for these patient populations.

## Case Study 1

- 35 year old female; lives with husband.
- Visual function has deteriorated over previous 10 years. Now registered severely sight impaired with less than 10% vision in one eye and better but "patchy" vision in the other eye. Guide dog user. Uses long cane too when necessary.
- She also uses folic acid and levetiracetam (for the management of epilepsy).

Type 1 Diabetes Mellitus ~ 28 years. Uses hybrid closed loop system which connects an insulin pump with CGM. When she started on her first insulin pump, she had better visual function. The contract for her first insulin pump was for 4 years and in 2011 she had no visual impairment. By 2015 i.e. the end of the first contract, she had begun to develop visual impairment. Her current insulin pump is provided by one supplier, and the sensors are provided by different company.

This lady reports anxiety about being supplied with incorrect medication. This has happened previously and has made her more diligent now with checking accuracy of medicine supply. Her preference is not to use apps but to ask a sighted person to help her check either in person or on Facetime call with a relative. She is very concerned that her insulin pump will be withdrawn from her if her vision deteriorates further i.e. making it inoperable. She commented that she anticipates that her life expectancy will be reduced if she can no longer use her pump.

## Case Study 2

- 45 year old female; lives alone.
- Severely sight impaired – sight loss occurred 15 years ago.
- Uses long cane

Type 1 Diabetes Mellitus (since age 7) – uses insulin pens (and antihypertensive medication).

Insulin pen clicks help her to measure her insulin dose. She uses Libre with an Android phone to monitor her blood glucose to avoid the need for finger pricks. She reported attending a Libre training session with 30-35 other people during which videos were shown with no audio-description, so she felt this “totally ignored special needs” of people with visual impairment. She had listened to the videos in advance to prepare for the training session.

She reported being “told off” by health professionals (diabetic team) to avoid being “so well-controlled”. She felt that she was treated with “total ignorance from professionals” i.e. they advised less rigid management of her diabetes whereas she wanted to manage it as well as possible to avoid or minimise the risk of developing further problems – this was motivated by her sight loss due to the disease at age 30.

She highlighted a lack of availability of talking blood glucose meters and that only a few android phones have compatibility. She also described using Google to access a talking blood glucose meter for her friend who has learning disabilities and was newly diagnosed with diabetes.

### Case Study 3

- 53 year old male; lives with wife.
- Severe sight impairment.

Type 2 Diabetes Mellitus – uses metformin and gliclazide.

He cannot perform manual blood glucose measurement because cannot see strips and cannot place blood drop accurately on testing strip. He was advised that he is not eligible for Libre and as such, he does not test his blood glucose and only becomes aware of hypoglycaemia when his heart begins to race whereupon he eats chocolate.

The practice nurse at his previous general practice prescribed injectable weight loss medication that required self-assembly (needle attachment) prior to administration. He was unable to use the medicine independently because of his visual impairment. He had to rely upon his wife assembling and administering the injection. On one occasion when his wife was unavailable, he had to ask a neighbour to assemble and administer the injection to him. He reported that he felt it was “degrading” to have to ask his neighbour to do this.

This experience motivated the patient to change general medical practice so that he could access “better service/care” and where they “talk to you properly” and understand his needs. His weight loss medication was changed to a version that does not require self-assembly.



# Appendices

# Appendix 1 Declaration of Interest: Professor Margaret C Watson

Category/Name	Relevant interest (if any)
Current Employment	<p>Founder/Director: Watson Research and Training Limited.</p> <p>Professor of Health Services Research and Pharmacy Practice, University of Strathclyde (0.5 wte)</p>
Appointments (voluntary or otherwise) e.g. trusteeships, directorships, local authority membership, tribunals etc	2024 National Institute for Health and Care Research (NIHR) Research Support Service (RSS) Hub (delivered by Imperial College London and Partners)
Membership of any professional bodies, special interest groups or mutual support organisations	<p>Fellow of the Royal Pharmaceutical Society (2019)</p> <p>British Geriatric Society (2023-)</p> <p>Associate Member of the Association of Coaching (2019-)</p> <p>Royal Pharmaceutical Society of Great Britain (Membership number: 81110) (MRPharmS) (1987-)</p> <p>General Pharmaceutical Council (Membership number: 2034020) (2010-)</p>
Any commercial/financial/legal connection or interest in the pharmaceutical and medical devices industry sector or any other body or organisation of interest to the Redress project	I am a registered pharmacist and therefore have a professional interest in medicines but this is not associated with any commercial, financial or legal connections to the pharmaceutical industry or medical device industry.
Gifts or hospitality offered to you by external bodies and whether this was declined or accepted in the last twelve months	I received a £50 gift voucher from the University of Cardiff for the delivery of a seminar in December 2024. The topic of the seminar was entirely unrelated to this report.

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Category/Name	Relevant interest (if any)
Any contractual relationship with the Redress Project and/or parties of interest	I was contracted by the Patient Safety Commissioner to undertake the research that informed this report, as well as to conduct the research and present the findings in this report.
Any other interests that are not covered by the above	I have funding from the Dunhill Medical Trust to undertake research related to medicine-related challenges of older people with sensory impairment and the supervision of PhD students whose projects are related to these topics. Several of the academic outputs from this research programme are included and referenced in this report. Invited speaker: Pharmacy Show, Birmingham, 2024. Travel and subsistence costs were reimbursed. No fee was paid.

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# Appendix 2 Focus Group – Participant Information Leaflet

## Participant Information Leaflet

This work is supported by The Patient Safety Commissioner, Dr Henrietta Hughes

### **Title of Study: Medicines and people with visual impairment or loss**

#### What is the purpose of this research?

This study aims to explore the experience of people with visual impairment or loss and medicine-related challenges and solutions.

#### Why have you been invited to take part?

You have been invited to take part because you indicated your interest in this study.

#### What does participation in this study involve?

You will be asked to take part in a focus group, which is a group discussion. The focus group will be no longer than 90 minutes. It will be audio-recorded, and notes will be made by the researcher (the researcher is Margaret Watson who has been commissioned by the Patient Safety Commissioner to undertake this research). Some focus groups will be conducted online, and one will be conducted in London in November. You will only be asked to participate in one focus group.

You can leave the focus group at any time, and you do not have to answer a particular question if you do not want to.

#### Do you need to take part?

No. Participation is voluntary. You can withdraw from the study up to 24 hours after the focus group has taken place without having to give any reason, and without disadvantage to yourself. At this point data will have been anonymised, and it is not possible to remove it from the study.

### What are the benefits in taking part?

There are no specific benefits to participation. Your involvement will help our understanding of the medicine-related needs of people with visual impairment or loss. Your views will help inform any recommendations that the Patient Safety Commissioner decides to make to government and healthcare bodies to improve patient safety and experience.

### What are the potential risks to you in taking part?

We do not anticipate any risk in participating in this study.

### Who will have access to the information?

Only members of the research team will have access to the information you provide. All personal data will be processed in accordance with the provisions of the Data Protection Act 2018 and UK General Data Protection Regulation (UK GDPR). During transcription, your identity will remain confidential and any personal data such as your name and/or employment details will be removed and replaced with a unique identification number. Only anonymised data will be reported in the study results, and you will not be identifiable from this.

### Where will the information be stored and how long will it be kept for?

Research data will be transcribed, uploaded, and stored on a password-protected folder. Consent forms will be kept for the duration of the study, after which time your contact details will be permanently deleted. Handling, processing, storing, and destroying of data will be in accordance with government policies and procedures. Once the recordings have been transcribed, they will be destroyed.

### What will happen to the results of the research study?

The results of the study will be included in a public report from the Patient Safety Commissioner and will be used to raise awareness and drive improvements amongst individuals and organisations regarding the medicine-related challenges of people with visual impairment or loss. The results might also be presented in peer reviewed publications, articles, collaborations, projects, or presentations.

Thank you for reading this information – please ask any questions if you are unsure about what is written here.

### What happens next?

If you would like to participate, please sign, and return the attached Consent Form.

If you have read this information sheet and do not wish to be involved in the study, you need do nothing and thank you for your attention. If you have any questions on any aspect of your involvement in this study, please contact:

Should you have any questions, please contact Andrew Biden, the project manager in the Office of the Patient Safety Commissioner:

Email address: [pscenquiries@patientsafetycommissioner.org.uk](mailto:pscenquiries@patientsafetycommissioner.org.uk)

Work phone: 07590 254752

<https://www.patientsafetycommissioner.org.uk/>

# Appendix 3 Focus Group – Consent Form

## Consent Form for Focus Group Participants

This work is supported by The Patient Safety Commissioner

### **Title of Study: Medicines and people with visual impairment or loss**

**Please read the following statements and sign below if you agree.**

I have read and understood the Participant Information Leaflet on the above study.

I have had an opportunity to discuss the details with a researcher.

I confirm the researcher has answered any questions to my satisfaction.

I consent to being audio-recorded as part of the study, and understand recordings will be retained until they have been transcribed and checked, after which they will be destroyed.

I understand that any information recorded in the research will remain confidential and no information that identifies me will be made publicly available.

I understand that anonymised data (i.e., data that do not identify me personally) cannot be withdrawn once they have been included in the study.

I understand that my participation is voluntary and that I am free to withdraw from the study at any time without having to give a reason or consequences.

I consent to being a participant in the study.

**Participant signature:**

**Date:**

**Participant name:**

**Researcher/Witness signature:**

**Date:**

**Researcher/Witness name:**

# Appendix 4 Focus Group Topic Guide

## Focus Group Topic Guide

Thank you for joining this group discussion. We are going to be discussing if you have any difficulties with medicines and/or medical devices and if so, whether this is during consultations when a medicine or medical device is prescribed, or when you want to order or obtain medicines or medical devices, any difficulties with storing medicines, remembering to use medicines/medical devices, how to use them, actually using or administering them, and then disposing of them once they are no longer needed or they have expired. We also want to know about the information that you need for your medicines and/or medical devices and whether and how you access this information.

Before we start, I'd like to go through some "ground rules" – these help to make sure everyone has an opportunity to share their experience and opinions.

- Firstly, we would like to record this session so that we have access to your answers after today and this will enable us to analyse them and write a report. Could you indicate by raising your hand if you consent to us recording this discussion?
- We ask that you treat all the information that is discussed today in a confidential manner, that is, that you don't discuss what other participants have said with people who not involved in today's discussion.
- There are several people in this discussion so it would be helpful if we have one person speaking at a time. You might not agree with what someone is saying but please be respectful of other people's opinions.
- I will ask a series of questions, and I'd like you to answer based upon your experience and opinion. There are no right or wrong answers. If I have not stated the question clearly enough, please ask me to rephrase it.
- Does anyone have any questions or concerns before we start?

To begin, I'd like to go round the group and ask you to introduce yourself, so this might include the types of medicines and medical devices that you use (if you are comfortable to do so), whether you have any visual impairment or loss, and anything else that you think is important to share in relation to your medicines and medical devices.



I'm now going to ask general questions about your medicines and medical devices.

- What if any difficulties do you have in relation to your medicines and medical devices?
- What impact do these difficulties have on you?
- With whom have you discussed these difficulties?
- Who helps you to manage your medicines and medical devices?
- Are the people who provide health and or social care services to you aware of your visual impairment or loss?
- What are your opinions of the packaging that is used for your medicines (and medical devices)?
- Information about medicines is provided in the information leaflet, label, and can often be provided verbally too. What difficulties do you experience with medicine-related information?
- How do you typically access information about medicines or devices?
- Are there any other devices or appliances (sometimes called assistive technology) that help you with any aspect of your medicines?
- What would help you with your medicines and medical devices?
- Do you have any questions for us about this project?

# Appendix 5 Key Informant Questions

## Patient Safety Commissioner – Key Informants Questions (List 2)

Note – it may help respondents structure their answers if they consider the 5 stages of the medicine or medical device journey:

1. Ordering.
2. Obtaining/collecting.
3. Storing.
4. Administering/using.
5. Disposal.

Each stage will generate different questions for patients that they need to be put in a position to answer if they are going to take their medication and/or use their medical device safely and effectively. These questions include:

1. What is the name of this medication or medical device and what is it for?
2. What are the risks and possible side-effects?
3. When should I take this medication or use this medical device?
4. How much of this medicine should I take each time?
5. What should I do if I have side-effects?
6. Can this medicine or medical device interact with my other medications or medical devices?
7. How long should I take each medication or use this medical device for?
8. How do I receive and be able to understand the results of a medical device?
9. Am I taking medications or using medical devices that I no longer need?

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## Questions

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Question 1	<b>What is your name (and, if relevant, the name of your organisation)?</b>
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Response

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Question 2	Have you/your organisation completed or published any relevant work, research, or reports in this space? If so, please could you provide us with the relevant links. Unless otherwise stated, we will assume that we can reference any work cited in the report.  More generally, how do you work with patients with a visual and/or hearing-impairment to understand their experiences of medicines and medical devices accessibility?
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Response

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Question 3	How and where do you seek to improve the accessibility of medicines and medical devices for patients with a visual and/or hearing-impairment into your organisation's current work?  Do you have any specific levers – legislative or otherwise – to drive forward improvements in this area?
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Response

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Question 4	What are some of the challenges in driving forward these improvements?
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Response

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Question 5	Do you wish to offer any views on the current accessibility of the labelling, packaging, and patient information sheets for medicines and/or medical devices for patients with a visual and/or hearing-impairment?
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Response

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Question 6

The current legislative requirements – as set out in Regulation 259 of the Human Medicines Regulations – require that:

The product name in Braille is presented on the carton for all licensed medicines that are directly handled by patients.

The patient information leaflet is made available on request in formats suitable for blind and partially sighted patients. This includes Braille, large print or audio versions of the leaflet.

How effectively do these requirements meet patients' needs?

How could these requirements be improved?  
What, if any, would be the risks of making any changes in this space?

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Response

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Question 7

Are there any other changes in legislation, regulation, or professional practice that you think would offer benefits in terms of medicines and medical devices accessibility for patients with a visual and/or hearing-impairment?

What, if any, would be the risks of making any changes in this space?

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Response

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Question 8

Do you have any examples of creativity/best practice in terms of medicines accessibility for patients with a visual and/or hearing-impairment – either that relates to diabetes, or broader?

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Response

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Question 9

Do you have any examples where things are not working as effectively for patients with a visual and/or hearing-impairment when accessing/using medicines – either that relates to diabetes, or broader?

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Response

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Question 10                      Do you have any examples of creativity/best practice in terms of ensuring accessibility of medical devices for patients with a visual and/or hearing-impairment – either that relates to diabetes, or broader?

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Response

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Question 11                      Do you have any examples that show where things are not working as effectively for patients with a visual and/or hearing-impairment when accessing and using medical devices – either that relates to diabetes, or broader?

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Response

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Question 12                      Are there any countries/jurisdictions which England could learn from in terms of delivering accessibility improvement in the areas of medicines and/or medical technology for patients with a visual and/or hearing-impairment? If so, what enabling factors do these countries/jurisdictions have?

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Response

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Question 13                      Do you have any further comments that would help inform the Commissioner's report?

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Response

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\* Adapted from: Fuzesi P, Broadfoot K, Lennon M, Jacob SA, Macaden L, Smith A, Welsh T, Watson MC. The Burden of Managing Medicines for Older People With Sensory Impairment: An Ethnographic-Informed Study. *Gerontol Geriatr Med.* 2024 May 16;10:23337214241253410. doi: 10.1177/23337214241253410. PMID: 38765919; PMCID: PMC11100380.

\*\*Adapted from '**5 Moment for Medication Safety**.' World Health Organisation (2019).

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# References

- Alhusein N, Macaden L, Smith A, Stoddart KM, Taylor AJ, Killick K, Kroll T, Watson MC. 'Has she seen me?': a multiple methods study of the pharmaceutical care needs of older people with sensory impairment in Scotland. *BMJ Open* 2018;**8**:e023198. doi: 10.1136/bmjopen-2018-023198
- Alhusein N, Killick K, Macaden L, Smith A, Stoddart K, Taylor A, Kroll T, Watson MC. "We're really not ready for this": A qualitative exploration of community pharmacy personnel's perspectives on the pharmaceutical care of older people with sensory impairment. *Disabil Health J.* 2019 Apr;**12**(2):242-248. doi: 10.1016/j.dhjo.2018.10.006. Epub 2018 Oct 26. PMID: 30392961; PMCID: PMC6436755.
- Ali, M.M. Accessible Health Information (2023). Royal National Institute of Blind People. London, UK.
- American Pharmacists Association (APhA), Medication Errors. 2nd ed 2007, Washington DC, American Pharmacists Association.*
- Asante E, Morrison B, Watson MC, Lennon MR. Assessment Tools for Medication Self-Management Capacity in Community-Dwelling Older Adults with Sensory Impairment: A Scoping Review (BMC Geriatrics, under review)*
- Audit Commission (Audit Commission 1994). A Prescription for Improvement – Towards more Rational Prescribing in General Practice, Audit Commission/HMSO, 1994.
- Awad, A.; Yao, A.; Trenfield, S.J.; Goyanes, A.; Gaisford, S.; Basit, A.W. 3D Printed Tablets (Printlets) with Braille and Moon Patterns for Visually Impaired Patients. *Pharmaceutics* **2020**, *12*, 172. <https://doi.org/10.3390/pharmaceutics12020172>
- Cooper L, Fuzesi P, Jacob SA, Kamalakannan S, Lennon M, Macaden L, Smith A, Welsh T, Broadfoot K, Watson MC. Assistive technologies and strategies to support the medication management of individuals with hearing and/or visual impairment: A scoping review. *Disabil Health J.* 2023 Oct;**16**(4):101500. doi: 10.1016/j.dhjo.2023.101500. Epub 2023 Jun 29. PMID: 37481354.
- CPE (2015). <https://cpe.org.uk/wp-content/uploads/2015/08/PSNC-Briefing-039-15-Accessible-information-standards-WG-FINAL-03-08-15-.pdf> (Accessed 11/24)
- CPE (2016a). <https://cpe.org.uk/wp-content/uploads/2016/01/PSNC-Briefing-001.16-Equality-Act-2010.pdf> (Accessed 11/24)

CPE (2016b) [https://cpe.org.uk/wp-content/uploads/2016/04/Community-Pharmacy\\_Accessible-Information-Standard\\_April-2016.pdf](https://cpe.org.uk/wp-content/uploads/2016/04/Community-Pharmacy_Accessible-Information-Standard_April-2016.pdf) (Accessed 11/24)

Department of Health and Social Care (DHSC) (2024). Evidence search: An overview of literature available on accessibility requirements for medicines and MedTech under legislation, regulation, and best practice guidance in the UK and internationally – including in the United Nations Convention on the Rights of Persons. The Knowledge Centre, August 2024.

CPE (2017). <https://cpe.org.uk/wp-content/uploads/2020/07/PSNC-Briefing-060.17-Equality-Act-2010-A-quick-reference-guide.pdf> (Accessed 11/24)

Diabetes Control and Complications Trial Research Group (DCCTRG). Nathan DM, Genuth S, Lachin J, Cleary P, Crofford O, Davis M, Rand L, Siebert C. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med*. 1993 Sep 30;329(14):977-86.

Diabetes UK (2024). <https://www.diabetes.org.uk/about-us/about-the-charity/our-strategy/statistics#:~:text=We%20estimate%20that%20more%20than,by%20167%2C822%20from%202021%2D22>. (Accessed 09/24)

Diabetes UK (2024a). Insulin Pens. <https://www.diabetes.co.uk/insulin/diabetes-and-insulin-pens.html> (Accessed 12/24)

Diabetes UK (2020) <https://www.diabetes.org.uk/for-professionals/get-involved/news-and-updates/tips-for-insulin-safety#:~:text=Right%20patient%2C%20right%20insulin%2C%20right,right%20device%20and%20right%20way>.)

<https://www.diabetes.org.uk/guide-to-diabetes/diabetes-technology/what-is-diabetes-technology>

Diabetes UK (Diabetes UK 2024). Closed loop systems (artificial pancreas). <https://www.diabetes.org.uk/about-diabetes/looking-after-diabetes/technology/closed-loop-systems> (Accessed 12/24)

Equality and Human Rights Commission Guidance (2010). The United Nations Convention on the Rights of People with Disabilities Equality and Human Rights Commission Guidance. What does it mean for you? [https://www.equalityhumanrights.com/sites/default/files/uncrpdguide\\_0.pdf](https://www.equalityhumanrights.com/sites/default/files/uncrpdguide_0.pdf) (Accessed 09/24)

Equality and Human Rights Commission (EHRC) (2020). UN Convention on the Rights of Persons with Disabilities (CRPD). <https://www.equalityhumanrights.com/our-work/our-human-rights-work/monitoring-and-promoting-un-treaties/un-convention-rights-persons#:~:text=CRPD%20is%20an%20international%20human,eliminating%20disability%20discrimination> (Accessed 01/25)

EU MDD (European Medical Devices Directive) Essential Requirements Medical Device Regulation, Category Archives: Z – Annex (1) I – General safety and performance requirements – CHAPTER 1 – General requirements <https://www.medical-device-regulation.eu/category/chapter-1-general-requirements-2/> (Accessed 02/25)

Espírito-Santo, M.; Santos, S.; Estêvão, M.D. Digital Solutions Available to Be Used by Informal Caregivers, Contributing to Medication Adherence: A Scoping Review. *Pharmacy* **2024**, *12*, 20. <https://doi.org/10.3390/pharmacy12010020>

Eyth E, Naik R. Hemoglobin A1C. [Updated 2023 Mar 13]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK549816/> (accessed 10/24)

FLAG-ME Vision (2024) <https://healthylongevitychallenge.org/winners/patient-safety-research-centre-empowering-older-people-to-avoid-medication-related-harm-a-co-produced-community-pharmacy-solution/> (Accessed 12/24)

Future Learn (2023) Supporting Medicine Use by Older People with Visual and/or Hearing Impairment. <https://www.futurelearn.com/courses/supporting-medicine-use-by-older-people-with-sensory-impairment> (Accessed 09/24)

Fuzesi P, Broadfoot K, Lennon M, Jacob SA, Macaden L, Smith A, Welsh T, Watson MC. The Burden of Managing Medicines for Older People With Sensory Impairment: An Ethnographic-Informed Study. *Gerontol Geriatr Med.* 2024 May 16;10:23337214241253410. doi: 10.1177/23337214241253410. PMID: 38765919; PMCID: PMC11100380.

**Gov.uk** (2012) The Human Medicines Regulations 2012. UK Statutory Instruments 2012 No. 1916 PART 13, CHAPTER 1, Requirements for packaging and..., Regulation 259. <https://www.legislation.gov.uk/uksi/2012/1916/regulation/259> (Accessed 02/25)

**Gov.uk** (2012a) Schedule 24. Packaging information requirements. <https://www.legislation.gov.uk/uksi/2012/1916/schedule/24> (Accessed 02/25)

**Gov.uk** (2022). Information standards. Health and Care Act 2022, UK Public General Acts, 2022 c. 31, PART 2, Section 95, Information standards. (Accessed 12/24)

Healthwatch Cumberland (2023). Disability Voices: Digital Divide Report. <https://healthwatchcumberland.co.uk/wp-content/uploads/2024/02/Draft-Digital-Divide-report-1.pdf> (Accessed 11/24)

HealthWatch England (2023). Harnessing digital technology to prevent or manage ill health. <https://nds.healthwatch.co.uk/reports-library/harnessing-digital-technology-prevent-or-manage-ill-health> (Accessed 11/24)



Hex N, MacDonald R, Pocock J, et al. Estimation of the direct health and indirect societal costs of diabetes in the UK using a cost of illness model. *Diabet Med.* 2024; 41:e15326. doi:[10.1111/dme.15326](https://doi.org/10.1111/dme.15326)

British National Formulary (online) London: BMJ and Pharmaceutical Press <http://www.medicinescomplete.com> (Accessed 10/24)

Kentab BY, Barry HE, Al-Aqeel SA, Hughes CM. A systematic review of pharmacists' interventions to support medicines optimisation in patients with visual impairment, *International Journal of Clinical Pharmacy*, 10.1007/s11096-019-00907-2, **41**, 6, (1400-1407), (2019).

Killick, K., Macaden, L., Smith, A., Kroll, T., Stoddart, K. and Watson, M.C. (2018), A scoping review of the pharmaceutical care needs of people with sensory loss. *Int J Pharm Pract*, 26: 380-386. <https://doi.org/10.1111/ijpp.12456>

Knowledge Centre, The. Evidence search: An overview of literature available on accessibility requirements for medicines and MedTech under legislation, regulation, and best practice guidance in the UK and internationally – including in the United Nations Convention on the Rights of Persons. 29th August, 2024. , UK: The Knowledge Centre, Department of Health and Social Care.

Lachin JM, Orchard TJ, Nathan DM., DCCT/EDIC Research Group. Update on cardiovascular outcomes at 30 years of the diabetes control and complications trial/epidemiology of diabetes interventions and complications study. *Diabetes Care.* 2014;37(1):39-43.

Lincoln & Lindsay Blind Society. Facts and Figures. <https://www.llbs.co.uk/facts-and-figures/#:~:text=At%20least%20one%2Dthird%20who,working%20age%20are%20in%20employment>. (Accessed 2024).

Lind M, Pivodic A, Svensson A, Ålafsdóttir A F, Wedel H, Ludvigsson J et al. HbA1c level as a risk factor for retinopathy and nephropathy in children and adults with type 1 diabetes: Swedish population based cohort study *BMJ* 2019;366:l4894

Ling, Z.-H.; Yow, H.-Y.; Mohd, M.-B. Medication-handling challenges among visually impaired population. *Arch. Pharm. Pract.* **2017**, 8, 8–14. [yellow indicates not yet cited in chapter(s)]

Mathur R, Bhaskaran K, Edwards E, et al. Population trends in the 10-year incidence and prevalence of diabetic retinopathy in the UK: a cohort study in the Clinical Practice Research Datalink 2004–2014. *BMJ Open* 2017;7:e014444. doi:10.1136/bmjopen-2016-014444

MedTech Europe (2024). Facts & Figures 2024. <https://www.medtecheurope.org/wp-content/uploads/2024/07/medtech-europes-facts-figures-2024.pdf> (Accessed 12/24)

Merenda T, Denis J, Patris S. Pharmaceutical care for visually impaired patients: a qualitative study of community pharmacists' needs and professional experience. *Int J Clin Pharm*. 2024 Jun;46(3):665-674. doi: 10.1007/s11096-023-01684-9. Epub 2024 Feb 26. PMID: 38407693.

MHRA 2021 (Medicines and Healthcare products Regulatory Agency). Managing Medical Devices Guidance for health and social care organisations. January 2021. [https://assets.publishing.service.gov.uk/media/6089dc938fa8f51b91f3d82f/Managing\\_medical\\_devices.pdf](https://assets.publishing.service.gov.uk/media/6089dc938fa8f51b91f3d82f/Managing_medical_devices.pdf) (Accessed 09/24)

MHRA. Best practice guidance on patient information leaflets (PILs) [https://assets.publishing.service.gov.uk/media/5fe086c18fa8f5149718d66a/Best\\_practice\\_guidance\\_on\\_patient\\_information\\_leaflets.pdf](https://assets.publishing.service.gov.uk/media/5fe086c18fa8f5149718d66a/Best_practice_guidance_on_patient_information_leaflets.pdf) (Accessed 02/25)

MHRA (2024a). <https://yellowcard.mhra.gov.uk/> (accessed 10/24)

MHRA (2024b). Medicines: packaging, labelling and patient information leaflets. <https://www.gov.uk/guidance/medicines-packaging-labelling-and-patient-information-leaflets> (Accessed 09/24).

MHRA (2024c). <https://www.gov.uk/guidance/medicines-packaging-labelling-and-patient-information-leaflets#braille-on-labelling-and-in-pils> (Accessed 09/24)

MHRA (2023) <https://www.gov.uk/government/publications/patient-information-leaflets-for-blind-and-partially-sighted-patients/compliance-with-regulation-259-of-the-human-medicines-regulations-2012-provision-of-patient-information-leaflets-in-formats-appropriate-for-blind> (Accessed 12/24)

Morrison B, Asante E, Lennon MR, Watson MC. A scoping review of guidelines and resources to promote evidence- based prescribing for older people with sensory impairment. Primary Health Care Research & Development (under review)

Morrison B, Asante E, Lennon MR, Watson MC. Prescribing for Older People with Sensory Impairment: A Qualitative Interview Study with Independent Prescribers in Primary Care (unpublished. In preparation 2024).

National Eye Institute (2024). Diabetic Retinopathy <https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/diabetic-retinopathy> (Accessed 09/24)

National Institute for Health and Care Excellence (NICE 2023). Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes. <https://www.nice.org.uk/guidance/ta943> (Accessed 12/24)

Nguyen C. Improving health equity: Evaluation of accessible written medication information for patients with visual impairment. *J Am Pharm Assoc* (2003). 2024 May-Jun;64(3):101879. doi: 10.1016/j.japh.2023.06.023. Epub 2023 Jul 7. PMID: 37422111.

NHS England (2017). Accessible Information: Specification v.1.1. <https://www.england.nhs.uk/wp-content/uploads/2017/08/accessible-info-specification-v1-1.pdf> (Accessed 01/25)

NHS England (2024) Reasonable Adjustments Flag <https://digital.nhs.uk/services/reasonable-adjustment-flag#how-the-reasonable-adjustment-flag-works> (Accessed 12/24)

ONS (2024). Office of National Statistics. National life tables – life expectancy in the UK: 2020 to 2022. <https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/lifeexpectancies/bulletins/nationallifetablesunitedkingdom/2020to2022#:~:text=Life%20expectancy%20at%20birth%20in%20the%20UK%20in%202020%20to,from%2083.0%20years%20for%20females.> (Accessed 12/24)

Osanlou R, Walker L, Hughes DA, et al. Adverse drug reactions, multimorbidity and polypharmacy: a prospective analysis of 1 month of medical admissions. *BMJ Open* 2022;12:e055551. doi: 10.1136/bmjopen-2021-055551

Personal Communication: NHS England (16/12/24) and Patient Safety Commissioner, Reasonable Adjustments and National Care Records Service.

Pezzullo, L.; Streatfeild, J.; Simkiss, P.; Shickle, D. The economic impact of sight loss and blindness in the UK adult population. *BMC Health Serv. Res.* **2018**, *18*, 63.

PharmaBraille <https://www.pharmabraille.com/> (Accessed 11/24)

Pham TM, Carpenter JR, Morris TP, Sharma M, Petersen I. Ethnic Differences in the Prevalence of Type 2 Diabetes Diagnoses in the UK: Cross-Sectional Analysis of the Health Improvement Network Primary Care Database. *Clin Epidemiol.* 2019;11:1081-1088 <https://doi.org/10.2147/CLEP.S227621>

PRSB (Professional Record Standards Body) (2023). Diabetes Information Standard. <https://theprsb.org/standards/diabetesinformationstandard/> (Accessed 02/25)

Protopapa C, Siamidi A, Sakellaropoulou A, Kolipaka S, Junqueira LA, Tabriz AG, Douroumis D, Vlachou M. 3D-Printed Melatonin Tablets with Braille Motifs for the Visually Impaired. *Pharmaceuticals (Basel)*. 2024 Aug 1;17(8):1017. doi: 10.3390/ph17081017. PMID: 39204122; PMCID: PMC11357011.

Remelli F, Ceresini MG, Trevisan C, Noale M, Volpato S. Prevalence and impact of polypharmacy in older patients with type 2 diabetes. *Aging Clin Exp Res*. 2022 Sep;34(9):1969-1983. doi: 10.1007/s40520-022-02165-1. Epub 2022 Jun 20. PMID: 35723858; PMCID: PMC9464133.

RNIB 2015. My Voice. The views and experiences of blind and partially sighted people in the UK. <https://www.rnib.org.uk/professionals/health-social-care-education-professionals/knowledge-and-research-hub/reports-and-insight/my-voice/#:~:text=My%20Voice%202015%20provides%20a,person%20in%20the%20UK%20today.&text=This%20is%20the%20only%20survey,not%20a%20one%2Doff%20event>. (Accessed 12/24)

RNIB (Royal National Institute of Blind People) (2021). Key information and statistics on sight loss in the UK. <https://www.rnib.org.uk/professionals/health-social-care-education-professionals/knowledge-and-research-hub/key-information-and-statistics-on-sight-loss-in-the-uk/> (Accessed 09/24)

RNIB 2023. [https://www.rnib.org.uk/documents/1643/Clear\\_Print\\_guidance\\_2023.docx](https://www.rnib.org.uk/documents/1643/Clear_Print_guidance_2023.docx) (Accessed 02/25)

RNIB 2024. Exploring knowledge about accessibility of medication information and its management.

RNID (Royal National Institute for Deaf People). (2024) <https://rnid.org.uk/get-involved/research-and-policy/facts-and-figures/prevalence-of-deafness-and-hearing-loss/> (Accessed 09/24)

Royal Pharmaceutical Society (RPS), 2013. Medicines Optimisation. Helping patients to make the most of medicines.

<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Policy/helping-patients-make-the-most-of-their-medicines.pdf> (Accessed 09/24)

SENSE (2024). Blindness and visual impairment. <https://www.sense.org.uk/information-and-advice/conditions/blindness-and-visual-impairment/#:~:text=The%20leading%20cause%20of%20visual,age%2C%20the%20macula%20wears%20out>. (Accessed 09/24)

Sivaprasad S, Gupta B, Gulliford MC, Dohia H, Mohamed M, Nagi D, et al. (2012) Ethnic Variations in the Prevalence of Diabetic Retinopathy in People with Diabetes Attending Screening in the United Kingdom (DRIVE UK). *PLoS ONE* 7(3): e32182. <https://doi.org/10.1371/journal.pone.0032182>

Smith A, Macaden L, Kroll T, Alhusein N, Taylor A, Killick K, Stoddart K, Watson M. A qualitative exploration of the experiences of community dwelling older adults with sensory impairment/s receiving polypharmacy on their pharmaceutical care journey. *Age Ageing*. 2019 Nov 1;48(6):895-902. doi: 10.1093/ageing/afz092. PMID: 31389566; PMCID: PMC6814090.

Specialist Pharmacy Service (2022). Understanding polypharmacy, overprescribing and deprescribing. <https://www.sps.nhs.uk/articles/understanding-polypharmacy-overprescribing-and-deprescribing/#:~:text=Polypharmacy%20refers%20to%20the%20prescribing,medicines%20that%20are%20clinically%20required.> (Accessed 09/24)

United Kingdom (UK) Public General Acts (2010) The Equality Act 2010, Section 20, Duty to Make Adjustments. <https://www.legislation.gov.uk/ukpga/2010/15/section/20> (Accessed 12/24).

United Kingdom (UK) Statutory Instruments (2012). The Human Medicines Regulations 2012, Section 259. Packaging requirements: information for blind and partially sighted patients. <https://www.legislation.gov.uk/uksi/2012/1916/regulation/259> (Accessed 12/24).

United Nations (UN) (2006). Convention on the Rights of Persons with Disabilities. <https://www.ohchr.org/en/instruments-mechanisms/instruments/convention-rights-persons-disabilities> (Accessed 09/24)

World Health Organization (WHO) (WHO 2024). Medical Devices. <https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices#:~:text=What%20are%20medical%20devices%3Fbody%20for%20some%20health%20purpose.> (Accessed 12/24)

World Health Organization (WHO) (WHO 2024a). Blindness and vision impairment. <https://www.who.int/news-room/fact-sheets/detail/blindness-and-visual-impairment> (Accessed 09/24)

WHO 2024b. Deafness and hearing loss. <https://www.who.int/news-room/fact-sheets/detail/deafness-and-hearing-loss> (Accessed 09/24)

WHO 2024c. Medical Devices. [https://www.who.int/health-topics/medical-devices#tab=tab\\_1](https://www.who.int/health-topics/medical-devices#tab=tab_1) (Accessed 12/24)

WHO 2024d. Assistive Technology. <https://www.who.int/news-room/fact-sheets/detail/assistive-technology#:~:text=Overview,political%2C%20economic%20and%20social%20spheres.> (Accessed 12/24).

WHO 2017. Global Patient Safety Challenge: Medication without harm. <https://www.who.int/initiatives/medication-without-harm> (Accessed 09/24)

Zappara (2024) <https://www.zappara.com/zapvision/> (Accessed 12/24)

