Department of Health & Social Care

National Voices

Patient views on medical devices prescribed to them outside of hospital in England

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Executive summary

In November 2024, the Department of Health and Social Care (DHSC) commissioned National Voices to deliver a research project to better understand patient experience of the 60,000 medical devices prescribed under Part IX of the NHS Drug Tariff. The aim of this research project was to develop an understanding of the features patients most value within medical devices that are listed on Part IX of the Drug Tariff, so that this can be considered in future categorisation and assessment by DHSC. This work will compliment the specific patient voice that will be provided for the Independent Assessment Panels going forward.

Between November 2024 and March 2025, National Voices gathered 679 survey responses and conducted interviews or focus groups with 66 people with experience of medical devices. This report details the key feedback gathered from participants, divided into the following 7 categories:

- wound and skin care
- gastrointestinal and urological care
- respiratory and airway management
- lymphoedema, support and therapeutics
- sexual, reproductive and pelvic health
- diabetes, glucose monitoring and insulin delivery (during the time of reporting this category was renamed to 'point of care testing and hypodermic equipment')
- oral, dental, ear, eye and nasal care

Using the insights captured, DHSC and National Voices have worked together to identify next steps the department itself will take, as well as recommendations to medical device manufacturers and people within integrated care systems who make decisions on which devices from Part IX of the Drug Tariff to make available locally.

Despite the breadth of devices and diversity of individuals engaged with throughout this project, 5 cross-cutting themes emerged:

1. Patients want and expect medical devices to help them live their lives to the fullest

One person told us, 'You don't want to feel like you're dying of this thing. You're living with it, and you want to live properly'. From being able to swim to being able to have sex, from being able to leave the house to being able to use a device without relying on a carer, people felt like medical devices shouldn’t get in the way of them living their lives.

2. Appearance, comfort and fit matter

One person said, 'The day they put [medical shoes] on me I cried. I felt like lymphoedema took everything from me.' Others described devices causing them pain or making them feel that people were staring at them. While the aesthetic and fit of devices sometimes wasn’t considered important by manufacturers and prescribers, they often meant a great deal to those who use devices.

3. One size doesn’t fit all, so patient choice is important

In some areas, there was a strong consensus on what device features were best, but in others it was clear that different device features worked well for different people. For example, we heard that while some people with stoma bags preferred filters to aid with odour control, other people preferred bags without filters as they felt that filters were not effective and increased the likelihood of leaking.

4. It is important that medical devices respond to the needs of the diverse groups of people who use them

This presented itself in lots of different ways - as one example we heard feedback that a number of devices were only made available to people in a beige colour or white skin tone, which was alienating for people from racial and ethnic minority groups. We also heard that device design often did not meet the needs of people with limited dexterity or sight loss.

5. High quality and accessible information is important for patients to make choices about the right device for them

When people received high quality information in a format that worked for them, they were often able to get the best device for them and had a good understanding of the strengths and limitations of their choice. However, we heard of many instances where people were given incomplete or inaccessible information. For example, one man who had a prostatectomy for prostate cancer told us that the only information he was given about it was a DVD. Another participant told us that they thought there was only one stoma bag available, and they didn’t realise they had any choice.

Background and context

In November 2024, DHSC commissioned National Voices to deliver a research project to better understand patient experience of medical devices prescribed under Part IX of the NHS Drug Tariff. National Voices is a coalition of health and social care charities in England who advocate for more equitable and person-centred health and care, shaped by the people who use and need it the most. The organisation has more than 200 members covering a diverse range of health conditions and communities, connecting them with the experiences of millions of people.

Part IX of the NHS Drug Tariff lists medical devices (also known as appliances or products by patients) that are appropriate for prescription outside of a hospital setting, for example, wound care products, stoma bags and catheters. Manufacturers and distributers wishing to supply a medical device or appliance for NHS prescribing must first seek approval from NHS Prescription Services for inclusion of that device or product in Part IX of the Drug Tariff. This means that devices which do not feature on Part IX of the Drug Tariff cannot be prescribed by primary care clinicians (however there are other ways to supply medical devices in the community outside of the Drug Tariff). Clinicians are able to prescribe over 60,000 medical devices in primary care settings.

Following a targeted consultation that took place between October 2023 and January 2024, DHSC are updating the way medical devices listed on Part IX of the Drug Tariff are categorised and assessed to make it easier for clinicians to compare similar devices to each other. Currently, the 2 deciding factors, once the product has been checked for safety and quality, that determine which devices are available for prescription in primary care are:

- clinical appropriateness (in a primary or community care setting)
- cost effectiveness

The Drug Tariff in its current iteration makes it challenging for clinicians to compare relevant devices because of the:

- lack of categorisation
- omission of feedback from people who use the devices

This means that people are less able to have a say on which devices they are prescribed, thus limiting the likelihood that their devices will meet their needs. This report explores why it is important for people to have access to devices that not only meet their medical needs but also allows them to live day-to-day with as little disruption as possible.

The 7 categories of medical devices and products are:

- **wound and skin care**
- **gastrointestinal and urological care**
- **respiratory and airway management**
- **lymphoedema, support and therapeutics**
- **sexual, reproductive and pelvic health**
- **diabetes, glucose monitoring and insulin delivery (during the time of reporting this category was renamed to 'point of care testing and hypodermic equipment)**
- **oral, dental, ear, eye and nasal care**

DHSC commissioned National Voices to deliver this research project to better understand people's experiences of using medical devices. DHSC intend to improve experiences of medical devices through:

- changing the way products and medical devices are available for prescribing in primary and community care
- improving awareness of the different medical devices people can choose from

Using the insights captured from this project, the DHSC and National Voices have worked together to:

- identify the next steps the department will take
- make recommendations to medical device manufacturers and people who make decisions on which devices from Part IX of the Drug Tariff to make available locally

Methodology

The research team took a mixed-methods approach to meeting the research objectives and the project was delivered in 4 stages:

Patient mapping

The patient mapping stage involved:

- conducting a rapid desktop review of existing evidence
- holding scoping conversations with experts
- capturing insights from patient and inequalities charities
- finalising recruitment quotas

Survey

The survey stage involved:

- disseminating the survey to the target audience through trusted intermediary voluntary, community and social enterprise (VCSE) organisations
- gathering and processing more than 600 survey responses

Focus groups and interviews

The focus groups and interviews stage involved:

- developing tailored topic guides by condition area
- hosting 6 focus groups, bringing together insights from 53 patients
- conducting 14 in in-depth interviews

Analysis and reporting

The analysis and reporting stage involved developing the report highlighting key features of devices and patient information needs based on feedback and findings from the survey, focus groups and interviews.

Project scoping

National Voices invited all VCSE organisations from its membership to feed into the design of this project. Thirteen VCSE members participated in an online event to help ensure that the survey was:

- designed in a way that would be inclusive to people with experience of using a wide range of devices across the 7 categories outlined above
- suitable for public audiences within VCSE partners' networks

Involvement of lived experience

The research team worked with Katie-Rose Stone, a Lived Experience Partner, at 2 points throughout the project. Lived Experience Partners are people with significant lived experience of health and care who act as strategic advisors to National Voices on engagement projects - helping to rebalance power, create space for productive conversations and to achieve outcomes which create real benefits for patients. In this project, Katie-Rose supported at 2 stages:

- in the design of the survey and topic guides used in focus groups and interviews
- in the thematic analysis.

Katie-Rose offered strategic advice on how best to enable participation from people who use medical devices and worked with the team to provide additional context to the emerging findings based on her experiences as a patient.

Survey design and dissemination

The survey was designed collaboratively, with DHSC providing the categories of devices and products as part of the amended Part IX Drug Tariff taxonomy. The draft survey was then shared with VCSE organisations and with Katie-Rose (Lived Experience Partner) for feedback, before being finalised and disseminated through:

- National Voices members' newsletters and other communication channels
- VCSE organisations who have been engaged in improving Part IX of the Drug Tariff.

To encourage people to complete the survey, DHSC offered a random prize draw with 4 chances to win £250.

In total 679 people responded to the survey over the course of 6 weeks, with the majority of respondents (419) providing feedback on gastrointestinal and urological care devices or products. Table 1 below provides a breakdown of response rates per category of medical device.

Questions asked, other than demographic questions, were:

- which medical devices or products have you used?
- how long have you been using this device or product for? If you are no longer using it, how long did you use it for?
- how often do/did you use this device or product?
- what do you think are the most important features of the product or device? (for example, the coating provides ease of use, the base plate of the stoma bag does not irritate my skin).
- which features, if any, make the medical device or product easy to use?
- which features, if any, make the medical device or product hard to use?
- what features would make you switch to an alternative medical device or product? (for example, the device or product was reusable and not single-use)
- what information would have been useful when you first started using these medical devices and products?

Table 1: amount of feedback per category

Device category	Amount of feedback provided
Gastrointestinal and urological care devices and products	419
Lymphoedema, support and therapeutics devices and products	165
Diabetes, glucose monitoring and insulin delivery devices and products	67
Wound and skin care devices and products	32

Oral, dental, ear, eye and nasal care devices and products	28
Respiratory and airway management devices and products	25
Sexual, reproductive and pelvic health devices and products	20
Total	756

The total number of device category selections is higher than the number of individual survey respondents because people were encouraged to share feedback on as many devices as they wanted.

It should be noted that because people self-reported on the devices they use, not all of the devices that survey respondents shared their views on are listed on Part IX of the Drug Tariff. For example, people with diabetes shared their views on continuous glucose monitoring sensors which feature on the Drug Tariff alongside insulin pumps which do not. For the most part, the authors of this report opted to not include feedback on devices that do not feature on the Drug Tariff to avoid any confusion, but the feedback was shared with DHSC colleagues through alternative channels. We have been clear when patient feedback on devices not listed on the Drug Tariff is provided.

Focus group and interview recruitment

The majority of focus group participants were recruited through the survey. After completing the survey, respondents had the opportunity to register their interest in taking part in a focus group to discuss their experiences of medical devices in more detail. Due to a low number of responses we were unable to recruit enough participants to host focus groups for users of:

- oral, dental, ear, eye and nasal care devices
- sexual, reproductive and pelvic health devices

However, one oral, dental, ear, eye and nasal care device user was recruited to take part in an in-depth interview.

The lack of survey responses from people who use these devices could be due either to:

- the fact that there are a relatively small number of devices that fall within this category

- people who are prescribed these devices don't self-identify as patients who use medical devices like someone using a stoma bag, for example

Furthermore, the distinction between a medical device and medication is less obvious for products such as eye and ear drops or nasal sprays. This means that people who use these devices may have wrongly assumed that their experiences are not relevant to this project and therefore decided to not complete the survey.

The research team opted to deliver in-depth interviews rather than focus groups with sexual, reproductive and pelvic health device users instead due to the potentially sensitive nature of the topic. These participants were recruited through:

- the survey
- a professional market recruitment agency

During the analysis we also identified groups in the population who were more likely to have specific challenges with particular medical devices and/or the information provided alongside medical devices and so recruited an additional 5 interview participants through VCSE organisations. These participants included:

- one participant experiencing digital exclusion
- 2 participants with a learning disability
- one participant with a visual impairment
- one participant with limited dexterity

We were only able to recruit one participant who uses oral, dental, ear, eye and nasal care devices for an interview within the timeframe of the project. We recommend that DHSC proactively engage these device users in future work. Table 2 below provides an overview of participant numbers and type of engagement across device categories.

Table 2: participant numbers and type of engagement across device categories

Device category	Engagement type	Number of participants
Wound and skin care	Focus group	10
	In-depth interview	1
Gastrointestinal and urological care	Focus group x 2	15
	In-depth interview	1

Respiratory and airway management	Focus group	5
	In-depth interview	1
Lymphoedema, support and therapeutics	Focus group	12
Diabetes, glucose monitoring and insulin delivery	Focus group	11
	In-depth interview	1
Oral, dental, ear, eye and nasal care	In-depth interview	1
Sexual, reproductive and pelvic health	In-depth interviews	8
Total		66

In terms of demographic diversity of focus groups and in-depth interviews, our aim was to have representation from at least 2 participants per focus group from each of the following groups:

- disabled people
- people with experience of multiple long-term conditions
- people experiencing socioeconomic inequality
- people belonging to a racial or ethnic minority group

We were able to gather demographic monitoring information for 53 out of 66 people who participated in focus groups and in-depth interviews. However, not all participants answered all questions. On each of these demographic themes, we found:

- of the 46 people who answered the question 'Do you have any physical or mental health conditions or illnesses lasting or expected to last 12 months or more?', 43 people said yes. This gives us confidence that we had strong representation of both disabled people and people with experience of multiple long-term conditions
- of the 53 people who answered the question, 'Which option best describes your ethnic background?', 11 people chose backgrounds other than ‘White’, including:
    - Indian
    - African
    - Pakistani
    - Bangladeshi
    - Caribbean

- Mixed - White and Asian
- Mixed - White and Black Caribbean.

This represents over 20% of those who shared demographic information - marginally higher than the share of these groups in the wider population (18.3% in the 2021 census). This gives us confidence that people from racially and ethnically diverse groups had the opportunity to share their experiences, but further research is needed to confirm whether views shared are representative of these populations.

We were unable to monitor for socioeconomic status due to data protection limitations on this survey.

For more detailed analysis of demographic data for the focus groups and in-depth interviews, including on gender, sex, sexuality, age, disability, race and ethnicity, refer to appendix B.

Focus group and interview delivery

All primary research was delivered online, apart from the interview with one digitally excluded participant which was delivered over the phone. A topic guide was used to structure the focus groups and interviews, ensuring consistency in the focus of the questions and alignment with the research objectives. The topic guides covered the following 3 sections:

- introductions, including the types of devices that participants wanted to discuss
- people's experiences of devices, structured chronologically from prescription to current usage
- patient information needs

This structure mirrored the design of the survey, allowing the research team to explore people's experiences in a conversational setting.

Limitations of the project

Digital exclusion

The requirement for people to have access to and the ability to use an internet connected device to participate in the survey and focus groups or interview may have limited responses. Although using online research and communication tools meant that the research team was able to gather a large amount of insights in a short period of time, people without access to an internet connected device and people who experience accessibility issues will have struggled to share their views on medical devices despite the survey being screen reader compatible. We plan to address this through additional interviews with people experiencing digital exclusion and people with diverse communication needs.

Demographic underrepresentation

As is common with surveys of this nature, there was an underrepresentation of people from ethnically diverse communities and people aged 18 to 24 in the survey. This meant that the experiences of these cohorts were not prevalent in the findings. We aimed to address this by ensuring representation in the focus groups and in-depth interviews. The younger participants who took part in focus groups did share views on their experiences of using medical devices that differed enough from older cohorts to suggest that further research is needed with younger people. Only by increasing the demographic diversity would a stronger picture be formed of how ethnicity and race may result in differences in the prescription of medical devices, and ongoing support for the individual using such devices. This would require a more targeted approach and/or a larger scale project to achieve. In addition, the inability for the research team to track whether survey participants are experiencing socioeconomic inequality and subsequently to explore whether living in poverty impacts people's experiences of medical devices is missing from this research.

Range of devices

The practical barriers associated with the scale and diversity of devices means that any single research project would be unlikely to be able to capture patient experiences of every medical device on the Drug Tariff. Any single research project would also be unlikely to be able to capture the views of a representative sample of people from groups experiencing inequality for every medical device on the Drug Tariff.

Self-selection

Survey respondents self-selected the medical devices they chose to share insights on. For example, within the gastrointestinal and urological care device category, individuals may have only shared insights on using a certain brand of stoma bag. However, they may have previously used alternative brands and so compare their current brand to these other devices, but this context is not provided for the research team in the survey. Similarly, they may also use washers alongside their stoma bags but have chosen not to share these insights. The survey was designed this way because providing a drop-down list of all the devices for respondents to select from was not realistic due to the very high volume of devices, and the process of categorising the devices was still ongoing as this project was being delivered.

The remainder of this report summarises feedback shared by participants through the survey, focus groups and interviews. The structure of the feedback follows the 7 device categories outlined above.

Wound and skin care

This section explores:

- dressings
- bandages
- topical treatments
- supportive and retentive products
- skin protection and adhesives

People use wound and skin care devices to:

- protect wounds
- prevent infection
- control bleeding
- absorb excess fluid
- provide a suitable environment for any wound to heal, typically after surgery, injuries, cuts, abrasions, or burns

Care can be self-managed at home, or by a specialist nurse.

Dressings

Medical dressings are designed to protect wounds, promote healing, and prevent infection. Twenty-two people provided feedback on dressings.

Key features valued most by participants

There were several key features which were most valued by respondents of wound and skin care products.

1. Absorbency and leak prevention, such as an absorbent core which helps the dressing to hold fluids

2. Skin protection and allergen considerations, ensuring materials used do not irritate the skin

    - "The only dressing that does not irritate me and also works as a dressing (waterproof, stays on for more than a few hours, adheres well, removes easily)"

3. Ease of use for those needing to change dressings between nurse visits

4. Support the wound healing environment and minimise infection risk

- "It kept my dressings vacuumed, promoting healing and minimising the risk of infection"

- "Includes silver, which is antibacterial"*

*Note that the above lists features perceived by patients to be valuable. However, people should be aware that silver and other antiseptic dressings can cause antimicrobial resistance. These products should not be used unless there is an infection. Additionally, many anti-microbial dressings are allergens. antimicrobial/bacterial dressings used without infection prevents the inflammatory stage of healing. There is much research to show that silver shows toxicity and antimicrobial resistance. Only use under clinician's advice.

Features that make the device easy to use

1. Ease of application and good adhesion to alleviate the burden associated with frequent dressing replacement.

Respondents noted simple application and removal as a key feature which make devices easy to use, highlighting a “simple pull off tab” and “easy application and easy removal”.

- "It adheres well, is waterproof, can be left on for up to a week"

2. Non-adherent properties which prevent injuries when changing dressings

3. Cut-to-size feature:

Finally, the user-friendly, cut-to-size feature made dressings customisable for respondents, and the user-friendly design ensures that they are appropriately applied:

- "Guards that you peel off so you can stick it one side at a time"

- "User friendly individual gauze swabs, easy to tear adhesive tape"

Features that make the device hard to use

1. Poor adhesive quality:

As with dressings being easier when adhesive quality was strong, respondents noted that dressings were hard to use when adhesive quality was poor:

- "The fact that it did not stay on skin"
- "Due to area of the wound, it is hard to stick the dressing to the skin sometimes"

2. Not tailored to the individual:

- "The dressing is too large for my wound so requires folding or cutting to size, this can be messy as the iodine gets on your hand"

3. Difficulty of application:

Respondents also noted the complex application of dressings as a difficult feature:

- "It takes some time to get used to it to get the right tension"
- "It is a little tricky to apply and has an extra top layer that has to be removed"

During application, and once applied, respondents noted that "the fragile nature make it [dressings] easily prone to tearing".

4. Allergens:

And finally, one participant shared challenges they faced with allergic reactions to different dressings.

Features that would encourage switching to an alternative device

1. Affordability and availability:

A more affordable dressing was noted multiple times by those purchasing dressings privately as a reason for switching. Respondents also noted frustrations with availability issues regarding prescriptions and pharmacies.

However, users should be aware that dealing with the cause of the wound is the most important thing. Purchasing what is perceived to be a 'higher quality' dressing may not be the right solution.

2. Improved performance:

Improved performance, for example a better ability to handle wetness and leakage, and improved conformity to irregular wound shape, would also give individuals reason to switch to an alternative dressing. Similarly, larger sizes with better adhesion, and smaller dressings with less wastage were also noted as reasons to switch.

3. Hypoallergenic alternatives:

Finally, those with severe allergies noted that they would switch if there were better hypoallergenic alternatives, with some people sharing their need for specifically skin-sensitive options.

Bandages

Bandages are a strip of woven material, which are used to protect an injured part of the body. They are commonly used to bind up a wound.

Key features valued most by participants

1. Absorbency:

Participants noted several valuable key features of bandages, the first of these being absorbency, particularly of bandages containing cotton:

2. Basic physical properties:

The length and width of the bandage, along with elasticity and adjustability were key features:

- "The elastic material allows the bandage to provide consistent compression, which helps reduce swelling and supports the injured area"

3. Breathability:

The breathability of bandages, and recognition of the non-irritating materials were also noted:

- "The bandage is breathable, which prevents skin irritation"
- "Latex free and non-irritating"

Features that make the device easy to use

1. Material quality:

Several features make bandages easy to use according to the insights shared by participants. The first of these is the quality of materials, resulting in elasticity and conformity to wounds.

- "Its elasticity allows it to stretch and conform to the shape of the injured area, this made it simple to wrap around my leg"
- "The fact that it seems to cling to dressings better"

2. Pre-folded design:

Respondents praised a pre-folded design stating it helped with easy and fast application.

3. Individual bandages:

And finally, one user noted the "individual sterile bandages" made use of the product easier. However, it should be noted that unless the bandage is touching the wound, it does not need to be sterile.

Features that make the device hard to use

1. Fraying of products:

Respondents shared that a few features make bandages harder to use. Two respondents shared that the fraying and loose ends of the product makes it difficult to use:

2. Difficulty of application:

Difficulty applying bandages was also noted, as respondents struggled to achieve the correct level of tension, or needed assistance when applying the product:

- "Getting the right level of tightness can be tricky. If wrapped too tightly, it can restrict blood flow, but if too loose, it may not provide enough support"
- "Two pairs of hands make the holding in place of this bandage easier to apply on top of dressings"

The difficulty of application also leads to individuals becoming dependent on others, as shared by one focus group participant, who "was told my husband can do the bandages so I am able to take showers and my husband can do the change." This indicates a shift in the dynamics of care and the need for support, which can create feelings of dependence and vulnerability.

3. Allergy concerns:

One focus group participant also shared concerns regarding allergies to bandages, where a bandage was irritating her skin and it was making her eczema worse. This was a silver dressing that contained coconut, but she has a coconut food allergy. Although she was asked about allergies by her consultant; nobody knew this bandage contained coconut. She used this for almost 3 months, before her consultant researched the bandage online and found out about the coconut oil.*

*It is difficult to comment on specific cases without knowing the full information, however it should be noted that using silver dressings for this length of time can also cause eczema, anti-microbial resistance and toxicity.

Features that would encourage switching to an alternative device

1. Breathability:

Respondents noted that they would consider switching product if the alternative bandage had better breathability to reduce sweating and skin irritation and was more adaptable, for example if it had adjustable straps.

2. Environmental considerations:

Respondents would also switch if an alternative product was more sustainable and was reusable.

Finally, it was noted that respondents would switch if advised to do so by their nurse or doctor.

Topical treatments

A topical treatment is a medication which is applied directly to the skin or mucous membrane. They can treat a variety of skin conditions, as well as pain or other problems in specific parts of the body. Six people gave feedback on topical treatments.

Key features valued most by participants

1. Stoma base plate compatibility:

Topical treatment consistency to avoid interfering with the adhesive properties of a stoma base plate was highlighted as a key feature for people who use topical treatments between the base plate of their stoma bag and their skin.

2. Allergy and skin irritation considerations:

In addition, allergy and general skin irritation considerations were understandably noted of value, as users look for problem-free topical treatment use which would not inflame the skin.

Features that make the device hard to use

1. Difficulty of application:

Two of the topical treatments were noted as hard to apply on wounds. For example, one respondent described that the thickness made it hard to spread on a dressing.

Features that would encourage switching to an alternative device

1. To avoid skin irritation:

One respondent mentioned allergies as a reason to switch, with another noting poor effectiveness and side effects. The latter individual described stopping using medicated honey because "It made my wound bed very wet and left skin macerated. Worked only on a very short-term basis".

2. Improved consistency:

One focus group participant also switched to using an off-the-shelf item, instead of their prescribed lotion, as they did not like the consistency.

3. Availability

Respondents also shared that they would like to use a specific product but can only obtain it through district nurse sample packs, stating "it is like gold dust".

Supportive and retentive products

Supportive and retentive products support the healing, or self-management of a wound. No clear brand names were shared for supportive and retentive products. Of the 6 people who provided feedback, the majority of respondents shared their experiences of using either compression socks or compression stockings.

Key features valued most by participants

1. Comfort, relief, and ease:

Research showed that comfort, relief, and ease of use are the most valued features for supportive and retentive products.

Features that make the device easy to use

1. Ease of fastenings:

The first feature identified which makes supportive and retentive products easier to use was easy to use fastenings:

- "Sticky straps to fasten the bands around legs"

2. Complimentary products:

Complimentary products and devices, which aid in the application of such garments, were also seen as beneficial.

Features that make the device hard to use

1. Fit:

Based on respondents' insights, several challenging features were identified. Firstly, the fit and tightness of garments:

- "When new, can be taxing to fit"

More broadly, a respondent shared poor fit issues generally make garments harder to use (compression stockings). Tension adjustments were also viewed as a challenging feature:

- "The adjustment of tension needed for legs"

Features that would encourage switching to an alternative device

Most respondents shared that they would not switch to an alternative device, with one individual noting that they would "always use same one [as] its customised". Only one respondent mentioned that they would consider switching to "stockings with zip fasteners" if available.

Skin protection and adhesives

Skin protectants are barriers that protect skin from irritation. Skin adhesives help keep supportive and retentive products in place. There were just 2 respondents who shared use of skin protection and adhesives.

Key features valued most by participants

Respondents shared that they most value that treatments "help to keep my compression stockings from falling down", and "prevent infection and sooth the skin helping it to heal".

Features that make the device easy to use

Although the 2 skin protection and adhesives had different application formats, namely roll on and a squeezy tube, respondents noted that they find such formats a key feature for ease. The respondents shared no negative features of either product.

Wound and Skin Care patient information needs

Accessible information needs

The VCSE organisations that represent the needs of those who fed into this project during the scoping phase made it clear that any information designed to improve awareness of or improve the ability to use a medical device must take into consideration diverse communication needs. The Accessible Information Standard provides guidance on meeting the information and communication support needs of patients, service users, carers and parents with a disability, impairment or sensory loss and was flagged as a useful resource for device manufacturers.

Practical advice

Those with wound and skin care needs tended to want practical guidance from clinicians on how to use wound and skin care devices safely and independently where appropriate. In particular, people wanted practical advice on how to apply or remove bandages or dressings; and information on what to do when experiencing a potential allergic reaction or other unwanted side effects arising from an interaction with other medicines.

- "Some potential allergies and interactions with medications"
- "Proper guidelines on how to use and remove it easily without the health attendant assistance"
- "Information about signs of improper use such as numbness, tingling, or increased swelling"

Personal wellbeing advice

People felt it would be helpful to understand the emotional and psychological impacts of having to use wound and skin care devices that can arise from things such as social isolation; fear and concern; or the loss of a sense of agency.

Device availability

Supply, availability and procurement information was also requested by people to help them navigate the seemingly complex prescription process. This information is especially important to those who have been negatively affected by an inappropriate supply of wound and skin care devices which has caused unwanted outcomes such as disruption to their daily lives and/or worsening of their condition.

- "To be able to order in advance, and advice for what would happen if there was supply issues."
- "How to obtain them. I.e. having to phone community hub rather than doctors"

Some respondents wanted information on the full range of medical devices available for their condition or injury, in order for them to make an informed choice.

- "To be informed about the range of products available to me. Again healthcare professionals making decisions for me rather than in collaboration with me"

Treatment decision information

A small number of respondents highlighted that they wanted to be involved in shared decision-making when it came to being prescribed their medical devices and wanting "to be more involved in making [a] decision on what would be the best dressing for my wound rather than being told by the district nurse".

One focus group participant explained how they were given a Negative Pressure Wound Therapy device without being explained what that would fully entail. They woke up from the surgery very surprised to see the dressing across their chest with a pump attached to it. Because of the lack of consultation in the run up to the procedure, the patient did not receive any information to prepare them for living with a Negative Pressure Wound Therapy device. Post-operation they were given a single leaflet which provided very little detail, including the fact that the noise from the pump would potentially prevent them from sleeping. The focus group participant had to wait for more than a week before being given more detailed information about the device.

- “Once I understood what the dressing was and what it was for, that it created a vacuum on the wounds, improved healing, it was easier to understand."

Information formats

Printed information materials such as leaflets, as well as in-person conversations were both mentioned by focus group participants as the ideal format for meeting their information needs. In particular, people were interested in learning from the lived experiences of their peers who may be using similar devices.

The wound and skin care device user with a learning disability shared that they would have benefitted from having a chaperone present who could support them through their procedure but also be a second pair of ears for when the doctor was describing how to redress the wound independently.

- "It would be helpful to have something like a chaperone to come with me. Even though I’ve got a mild disability that would have been helpful to have someone hold my hand, help me get through the pain barrier. I go into a child state when these things happen. If I had a chaperone that person would be another listening ear."

The same person would have also benefited from being signposted to follow-up support to help them with applying the bandages at home.

- "I’ve had problems with my hands because I have terrible tremors but managed to sort it out. If I had really bad tremors I would need someone to come in for the next 3 weeks. And I don’t have a clue who I could ask for that help."

2. Gastrointestinal and urological care

Ostomy products

A stoma bag and urostomy serve different purposes, though both are types of ostomies:

Regular Stoma Bag (Ileostomy/Colostomy):

- Used for collecting digestive waste
- Connected to either the large intestine (colostomy) or small intestine (ileostomy)
- Collects solid or semi-solid waste
- Uses different types of pouches designed for faecal matter
- Can be located on various sides of the abdomen depending on the type

Urostomy:

- Specifically for diverting urine
- Created when the bladder is removed or bypassed
- Typically produces clear, sterile urine
- Requires special urostomy pouches with anti-reflux valves
- Usually located on the right side of the abdomen

Ileostomy and colostomy bags

Three hundred and two people provided feedback on ileostomy and colostomy bags, with respondents sharing a wide range of brands and types of stoma products. Associated products highlighted include adhesive sprays and wipes, disposal bags, barriers rings, and stoma powder.

Key features valued most by participants

1. Skin-friendly adhesive and baseplate:

Based on the data, there are several critical features that users consistently identify as most important for stoma bags. Firstly, the vast majority of respondents appreciated a skin-friendly adhesive, baseplate and flange. Participants emphasised that ideally these would be non-irritating to the skin yet have strong adhesion to prevent leaks. A handful of respondents shared the importance of special materials added into baseplates believed to aid skin healing.

2. Leak prevention:

Respondents also appreciated leak prevention of bags, noting that a proper fit around the stoma is crucial. It was emphasised that convex plates help with hernias and securing a good seal, while a strong adhesive maintains integrity during activities such as swimming and exercise.

- "Secure fit to my skin, doesn't irritate my skin, easy to empty and seal back up, doesn't leak"

- "Reliability in sticking and preventing leakage. Good skin adhesion without damaging skin. Good fit around stoma"

One focus group participant shared:

- "I've never had a leak in 3 years. My stoma nurse said there's no reason why anybody with a stoma should leak. If you have the right stuff, you shouldn't. It's that simple"

3. Comfort and discretion:

The importance of a bag with a slim profile which doesn't show under clothing was emphasised, as was the importance of bags which are comfortable to wear with minimal rustling noise. Odour control through effective filters was also identified as a vital feature to remain discreet by several survey respondents. However, this view is not unanimously held, with a focus group participant and several survey respondents noting their preference for a filter-less bag due to a lack of effectiveness of the filter. We were also separately contacted by an individual who shared screenshots of a social media group, whereby a number of stoma bag users had shown the same interest, indicating that some people prefer a product without a filter.

- "Doesn't leak, doesn't rustle, doesn't look hideous, is discreet under clothing, is right size, and is opaque"

- "I like the fact that it doesn't look like an ugly, old fashioned stoma bag. I am young (30s) and am so pleased I can have a modern looking bag that doesn't make me feel super self-conscious or old or ugly"

- "Why [has] every company has taken away the choice of having a filter-less bag? The smell and odour seep through the filters."

- "The filter, which I've been told helps to release gas, doesn't ever do that. This is my only fault with the bags is it could do with a discreet way of expelling air from the bag as it becomes very uncomfortable when full of air and you cannot bend or lay on your side when it's full of air."

4. Ease of use:

Finally, ease of use was a broader key feature for respondents, noting that it was important that bags are easy to apply and remove, have a flexible flange and secure adhesive. Some respondents also shared their preference for pre-cut options for easier application.

- "A product that ensures that waste goes into the bag, rather than sitting around the stoma (pancaking or leaks)"

The right thickness and durability of the flange, to ensure that the flanges don’t break down quickly, are also appreciated. Respondents also noted the need for clear visibility for easier application, and an easily customisable shape, which individuals can cut to tailor to their needs.

- "The flange is the right thickness and doesn't break down too quickly."

Features that make the device easy to use

1. Base Plate and Adhesive Features:

Respondents shared that a pre-cut base plate encourages simpler application. Likewise, a flexible flange and secure adhesive that adheres quickly to skin; as well as easy-to-separate backing paper were emphasised as features that allow for easier application.

- "Tab on the side of the base plate enables the pouch to be easily separated from cover to attach stoma bag to skin"

2. Viewing and fitting features:

A number of viewing and fitting features were also quoted by respondents as making products easier to use:

- "Viewing window to guide over the stoma make it easy to place correctly and not damage the stoma"

- "The rings in the baseplate help to cut out a template"

3. Comfort and practical features:

Comfort and practical features were also noted as important when looking at the ease with which a product is used. For example, a hidden Velcro tab which is still easily accessible to drain the bag.

- "Wearing a 2-piece has been so helpful as I am not disturbing my skin daily. I can change my bag at night so I can sleep so much longer"

4. Additional support features:

A handful of additional support features were noted by respondents ensuring the product is easy to use, such as adhesive remover ('glue release') and elastic tape.

Features that make the device hard to use

Based on the survey responses, several key challenges make these medical devices difficult to use.

1. Adhesive and Skin Issues:

Respondents shared that some bags could cause irritation around the stoma, with others sharing experiences of bags coming unstuck, and requiring additional strips.

- "The bags can cause skin irritation around the Stoma"
- "As my skin is quite sore the bag comes unstuck at the point and I need to use strips"

One focus group participant noted the extent of the detriment of skin irritations, and ultimately rashes, caused by poorly fitting devices.

- "It's not just a rash and you don't understand this unless you've got a bag. If you've got a rash under your bag, then your bag doesn't stick. And if your bag doesn't stick, then that means waste is coming out onto you. And if that's happening, then you can't leave the house. You can't go to work. You can't look after your children. You can't do any of the normal things in life. It's not just "oh, you've got a little rash". It's like saying, "oh, you've got a rash, and so you're going to poo yourself constantly all day. Just go off and go to work." And then it's acidic, the poo that's coming out is burning your skin. So you just get caught in that cycle."

2. Design and Physical Comfort:

It was noted that hard plastic components can be uncomfortable and visible under clothing. Likewise, the 'neck' of the product can be difficult to clean when draining the bag. Respondents also shared that belt loops can add extra bulkiness.

- “I don’t wear skirts or tights, have to change what I wear cause of the leg bag.”

- "My current bag is really hard to keep clean when draining. The 'neck' is quite short and wide and I always end up dirty"

3. Application Challenges:

Some respondents shared difficulty with positioning the stoma bag, especially for those with different shaped abdomens and stomas. Some respondents also find it challenging to cut the hole to the right size.

> "I use a mirror but because the stoma is below my bust and on a rounded stomach, getting it properly around an 'innie' stoma, even with a convex base plate isn't always easy"

4. Material and Durability Issues:

Concerns were shared regarding the material and durability of some stoma bags, with respondents finding some bags flimsy, difficult to separate from the backing paper and noisy, rustling like a bag of crisps. Durability concerns were also shared, with some bags only lasting 2 days.

Features that would encourage switching to an alternative device

A handful of factors would encourage those who use ileostomy and colostomy bags to consider switching to an alternative stoma bag.

1. Improved Material and Design Features:

Respondents would switch if there was a device with better fit and comfort, as well as made of quiet materials and being less rigid at the chute for emptying the bag.

- "If it fitted around the shape of the area"

- "Quieter bag, longer usage of flange"

- “If you are trying to be discreet, no one’s stomach rustles like a supermarket carrier bag.”

- "Less rigid chute for emptying the bag"

2. Enhanced Performance:

An improvement surrounding leakage of stoma bags would encourage individuals to switch, as would longer-lasting adhesion, and less pancaking of the stoma bag.

- "Better at preventing leak/seepage"
- "Less pancaking. Good fit to prevent leaks around stoma and hernia"

Two focus group participants shared that they had already switched bags due to high output and leakage:

- "I had sort of issues on both occasions actually so they had the flat bags and both times I've needed a change to convex just because of really high output and dealing with leaks."
- "I was having a problem with leaks and then I just swapped to a convex bag, which I didn't even know existed. And it's changed everything. It's so good. I think that would have been a lot more helpful because again, I just thought it was a one bag and that's what you're stuck with really."

The fear of leaks had a colossal effect on people's quality of life, with one focus group participant sharing "I still have leaks which is always devastating. It's been 13 years now. It's still devastating". The self-consciousness and anxiety that arises from leakage was also noted by focus group participants, with individuals expressing concerns about odours and visibility.

3. Aesthetic Improvements:

Aesthetic improvements, such as being less noticeable under clothes, and having a wider variety of colour options, would also encourage respondents and participants to switch product.

- "The way it looks; it looks like a typical NHS product, beige. Looks horrible and feels horrible. And makes me feel horrible. It looks like my granny has gone to a shop and bought her granny knickers. That sort of colour and look. Comes down to how it affects your mental health, if you feel like it doesn’t look right it is going to affect you mentally when you’re out and about."
- " I think there should be more range of colours especially in other brands as colours are limited."

One focus group participant also noted a desire for normalcy, as evidenced by the excitement over aesthetic choices, sharing that "When [supermarket and clothing brand] came out with black pants and bright cerise ones, I went mad and bought them because they're exciting... You don't want to feel like you're dying of this thing. You're living with it, and you want to live properly".

4. Skin tone considerations:

One focus group respondent highlighted the prejudice surrounding providing devices in some skin tones and not others.

> "Bags should be made to racial groups and skin colour, really prejudicial to not have bags that match people’s skin tone"

Notably, many respondents expressed reluctance to switch, with comments like "I wouldn't use a different product" and "I'm too nervous to swap to anything different as it took a while to find one that worked this well". Most people explicitly rejected reusable options, stating "I would not accept a re-usable bag. Personal hygiene is crucial for self-image and for perception by others" despite the reduced environmental impact.

Urostomy bags

Based on the 99 responses, several brands and types of urostomy bags are used.

Key features valued most by participants

There were a handful of key features shared by respondents which emerged as the most important for urostomy products.

1. Skin Protection and Comfort:

The first of these was a base plate which doesn't irritate skin and provides good adhesion. Some products use special additives like ceramides or honey to protect skin.

2. Leak Prevention:

Secondly, respondents appreciated a secure fit and reliable adhesion to prevent leaks.

Convex design helps prevent leaks for certain stoma types.

- "That it's convex and helps to prevent leaks as the stoma stands 'proud'"

3. Ease of Use:

Broader ease of use was also noted as an important feature, with simple application, easy-to-use tap features, and pre-cut holes all contributing to this.

4. Compatibility with Other Devices:

Good connection with night drainage bags was also named as a vital feature, as was sufficient tube length for day and night use.

- "Making sure I have a short tube during the day with straps that can hold it to my leg and a long tube at night so that I can turn over in bed"

5. Durability:

And finally, durability was noted as a key feature of urostomy bags. Some users noted the need for longer-lasting base plates that don't break down quickly, and similarly people appreciated the ability for maintenance of adhesion even when the bag is full.

- "Stays secure even when bag is full (very heavy)"

Features that make the device easy to use

1. Pre-cut and fitting features:

A number of features make urostomy bags easier to use, the first of these being pre-cut holes and a 2-piece system, contributing to an improved fit.

- "Getting them pre-cut by machine ensures a smooth aperture and good fit"

- "2 piece means I can navigate the flange/base plate properly"

2. Adhesion and removal properties:

Respondents also noted the importance of good adhesion, and easy removal with "removal spray".

- "Reliable sticking to skin so the products work with hardly any leaks"

3. Tap/drainage features:

People also appreciated a tap feature, particularly those living with reduced dexterity. Likewise, a secure attachment of night drainage bags to the urostomy bag brought some respondents confidence in the product.

4. Visibility and application:

Clear visibility during application also encouraged ease of use of urostomy bags.

- "I can see just where I am placing it - I always change my pouch in front of a magnifying mirror"

5. Comfort features:

Finally, comfort features were noted by respondents as making urostomy bags easier to use. These included a smaller area of adhesive to reduce the chance of irritation; easy application; and a product which is not bulky.

Features that make the device hard to use

Based on the survey responses, several key challenges make urostomy devices difficult to use.

1. Base Plate and Adhesion Issues:

The first of these is problems with base plates not sticking properly, and sizing issues, which can lead to leaks, resulting in anxiety and mental wellbeing challenges for users.

- "Sometimes I find the base plate does not stick or the pouch is prevented from draining into the catheter bag and the base plate explodes from the skin and I am left soaking wet and in need of a change of clothes and a wash"

- "I have to change it every 2 days as the urine dissolves the back of the base plate. It leaks if left longer"

- "Nervous about cutting it too small and damaging stoma"

One focus group participant shared the challenges of poor-quality adhesives, resulting in extensive leaks:

- "The first time I had a really big leak outside, I was in somebody's house and it was really hot and […] the chair was almost soaked. And they all thought there was something wrong with me instead of the adhesive, because that's really what had happened. The adhesive had failed because of the sweat and the heat. Lots of people just think of this as, oh, you know, you're on your last legs, you're only needing these things for a short period of time. You don't have to think about it. We just need people to stop and think we're people we have lives outside of the bathroom and we would like to carry on doing it with the modicum of success that we're managing so far."

2. Incompatibility Problems:

Respondents also found frustration regarding compatibility issues between the products of different manufacturers.

3. Design Limitations:

A lack of customisation was also shared as making urostomy bags harder to use, as were "fiddly" drainage taps and concerns regarding urostomy pouches twisting. Likewise, respondents faced challenges surrounding quick filling and visible bulging of urostomy bags.

- "The urostomy pouches now do not have the clips included to stop the pouches twisting"
- "Fills quickly and visibly bulges"

One participant also noted that the urostomy flange they use is "Not pliable like some other brands when applying to the skin".

Features that would encourage switching to an alternative device

Understandably, following on from features which make products more challenging for individuals to use, several key features would encourage people to switch to an alternative urostomy product.

1. Better Skin Care and Reduced Irritation:

Respondents would appreciate a product which was less irritating, ideally with a hypo-allergenic plate and adhesive.

2. Longer-Lasting Products:

Longer lasting, more durable products, would also be appreciated by respondents.

- "A pouch which didn't need changing for at least a week but felt comfortable"
- "Possibly a longer lasting wafer that does not break down after 1 1/2 - 2 days"

3. Environmental Considerations:

Sustainability of products, such as reusability, was also noted as a reason to switch by a handful of individuals.

- "I prefer reusable night bags to single use ones - not good for the environment."
- "[There is] massive plastic waste in the landfill – if there's a more eco-friendly version I would pick that."

One focus group participant shared that they "worry about the amount of waste I'm producing. Fill a black rubbish bag every week and goes straight to landfill... Can something be done to ameliorate waste we are producing?" This concern illustrates the broader implications of medical device use beyond individual health.

4. Design Improvements:

Finally, design improvements would encourage respondents to switch to an alternative product. These improvements include a slimmer tap and cap, a flatter profile, and a waterproof, more durable exterior, to allow for activities such as swimming.

- "More flexible base plate but with coloured base for easier siting"
- "Waterproof exterior as I swim twice a week"

5. Financial concerns:

One focus group participant also shared feelings of guilt regarding the financial burden on the NHS. Another shared, "I have a large amount of guilt about using all the supplies I do and the cost that NHS is spending on me."

Stoma irrigation

Stoma irrigation is a system of bowel management for a colostomy in which water is introduced into the bowel to stimulate muscular contractions and passage of faeces. This option can allow for a smaller colostomy bag or a cap instead of a standard bag.[1]

Key features valued most by participants

1. Design and Physical Characteristics

- "Secure seal on the irrigation sleeve"

Features that make the device hard to use

1. Fit

- "Remains fiddly to fit securely around stomach"

2. Discontinuation of favoured devices

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[1] https://www.bladderandbowel.org/stoma/irrigation-and-your-stoma/

Long-term concerns were also shared by respondents, both regarding themselves physically and discontinuation of products.

- "[Brand] have stopped manufacturing the pump so it is likely a time will come when it breaks down that I will have to return to a gravity system which is much less convenient"

Features that would encourage switching to an alternative device

1. Environmental Considerations:

Respondents noted that environmental considerations would encourage them to switch product, both regarding reusable components, such as adhesive sleeves, and in regard to impact of disposal.

- "Reusable adhesive sleeve to reduce plastic waste"
- "If it was easier to clean after each use"

Trans anal irrigation appliances

Bowel irrigation involves using medical devices to introduce warm water into the bowel via the anus and rectum. This process causes muscular contractions which encourage the bowel to empty. There were 17 respondents who provided feedback in this category.

Key features valued most by participants

A number of key features were noted as important for respondents regarding using trans anal irrigation products.

1. Ease of Use and Operation:

The first of these was ease of use and operation, including automated functionality, intuitive setup and operation, and self-management capability.

- "Not a pump it does it for me with the press of a button"
- "Intuitive. Easy to set up"

2. Design and Physical Characteristics:

Several design and physical characteristics were also noted as important, including portability and weight and water containment functionality (see features that make the device easy to use).

3. Effectiveness and Reliability:

Effectiveness and reliability also contributed to the reassurance these devices provided, giving respondents peace of mind, and causing minimal side effects.

- "Peace of mind knowing that all waste material has gone and (unless ill) [I] will not be caught out during the day."

4. Safety and Comfort:

Safety and control were also noted as important features, with respondents appreciating ease of insertion, and speed and efficiency.

Features that make the device easy to use

1. Automated Functions:

A handful of features also make irrigation products more user-friendly. The first of these included automated functions, and clear information with products, which allow for easier use and self-management.

- "Straight forward instructions and the catheter balloon was good "

2. Portability and Design:

Respondents also noted the benefits of irrigation product portability and design, with water container features specifically highlighted.

- "Lightness of the machine"

- "The water container needs to be easy to fill and needs temperature guide"

Features that make the device hard to use

Several concerns were shared regarding difficulties using irrigation products.

1. Equipment and Setup Issues:

The first of these was equipment and setup issues, with emphasis given to water container problems and complexity of the system caused by multiple tubes.

- "The opening of the water container too small for an older person, my son adapted an empty disinfectant bottle which has made life so much easier."

- "Cone and container are in my view poor now compared to a few years ago. The water container needs to be simple to fill during irrigation."

2. Physical Challenges:

Physical challenges were also noted with respondents finding catheter insertion particularly difficult at times.

- "I worry about damage to bowel, bulky to transport"

3. Technical Issues:

Respondents also raised challenges surrounding technical issues, with particular emphasis given to battery failure and noise.

- "It's very noisy and this can cause sensory overwhelm which then means the day is harder"

Features that would encourage switching to an alternative device

1. Safety improvements:

Safety improvements would encourage individuals to switch product.

- "Safer to use long term better shape in rectum"

Notably, some respondents and participants shared that there were no adequate alternatives available or that they weren't aware of other options on the market.

Wipes, sprays and deodorants

Forty-five respondents provided feedback on wipes, sprays, and deodorants, often sharing their views of a combination of these devices at once.

Adhesive removers

Adhesive removers for stoma bags are products that help remove stoma bags and any remaining adhesive residue. They are an important part of stoma care, helping to protect skin from irritation and damage.

Key features valued most by participants

Based on the data, respondents shared a handful of key features regarding adhesive removers.

1. Skin protection and damage prevention, lending to effective removal:

- "The adhesive remover does not irritate skin. The use of the adhesive remover spray prevents damage to the skin which used to be caused by trying to remove the adhesive without the adhesive remover spray"
- "The medical adhesive remover spray makes the removal of the stoma bag easy to remove without damaging the skin. The medical adhesive remover wipe, removes any residual glue from my skin"

2. Speed, convenience, and versatility:

- "Spray is much better to use as you don't need to faff about with little sachets of a wipe/liquid in a sachet. By the time you get it out, your stoma can become active. Spray is much better for speed"
- "The spray is easy to use as you can use it in any position, even upside down as it has bag on valve technology"

Features that make the device easy to use

Respondents found a handful of further features lend to easier use of the product. These include the design of the product, including the spray bottle format, valve technology lending to versatile application, and a convenient size.

Features that make the device hard to use

Very few respondents shared challenges with the product. The main issue mentioned was the product sometimes being "dry". Most users indicated no problems with adhesive removers, with many explicitly stating "None" or "N/A" when asked about difficulties. Several users specifically praised how easy they were to use.

Features that would encourage switching to an alternative device

Very few respondents mentioned specific features that would make them switch from their current adhesive removers. The main reasons cited were:

- "If it didn't help me to remove my device"
- "A product that meant you could use less sprays to achieve the easy removal of the stoma pouch"

Barrier spray

Barrier sprays in stoma care are used:

- to provide a barrier film over the skin to prevent skin damage in the event of a leakage and
- to reduce skin damage from stripping the adhesive away where there has been damage to the skin.

Key features valued most by participants

From the insights respondents shared, several key features of barrier sprays emerge. Each of these features were also noted as lending to ease of use of the product.

1. Skin protection, coating effectiveness, and non-irritability:

- "Protects the skin and allows better adhesive contact"
- "The spray coating provides the right amount of protection for my skin"

2. Flexibility in format, lending to ease of application, was also appreciated:

- "Choice of spray or wipe"
- "It is easy to apply"

3. Quick-drying properties:

> "Dries quickly, doesn't irritate my skin and protects my skin"

Features that make the device hard to use

Very few issues were reported with barrier sprays. The main difficulty mentioned was that spray can tops are too tight. Most users reported no difficulties with barrier sprays, with many explicitly stating "None" when asked about features that make the product hard to use.

Features that would encourage switching to an alternative device

Very few respondents mentioned specific features that would make them switch from their current barrier sprays. The few mentioned reasons included "a better product for protecting my skin". The issue with spray can tops being too tight suggests that easier-to-open packaging could be a potential feature for switching.

As with features that make the device hard to use, most respondents indicated they were satisfied with their current barrier sprays, with many explicitly stating "None" when asked what would make them switch.

Lubricating Deodorants

Deodorants can be in the form of drops that go in a stoma bag or a spray to use in the air when changing a bag. Some areas of the NHS no longer allow these to be prescribed.

Lubricating deodorants can help mask odour but have a primary function of lubricating the bag so the output goes to the bottom to prevent pancaking. Pancaking is where the consistency of the stool causes it to stick at the top of the bag instead of dropping down which can cause leaks and smell from the filter.

There is only one detailed response about lubricating deodorants for their stoma bag. They noted that it:

- Neutralises odour which helps reduce anxiety about emptying the bag in public
- Comes in convenient sachets that fit in their bag and are easy to open
- Helps prevent isolation by making them more comfortable going out
- Also functions as a lubricant to prevent "pancaking" and leaks

Separately, a focus group participant shared frustrations with accessing deodorants on the NHS:

- "I can smell it and it makes me very self-conscious that other people might be able to, so my urology nurse just advised me to get some deodorant and just spray around it. But why should I have to do that? So, I do do that. But I do also suffer with lots of UTIs. I get the cost is a problem, but [this is] cost over somebody needing other stuff to feel comfortable with a stoma."

Stoma bag accessories

Within stoma bag accessories, 19 respondents shared insights regarding rings and seals, and flange extenders. Most of these devices are used daily and serve the primary functions of skin protection, leak prevention, and secure fitting of stoma bags.

Rings and seals

Rings and seals for stoma bags are designed to protect the skin around an individual's stoma. These are also sometimes referred to as 'washers'. These medical devices help to fill in uneven skin surfaces and improve the fit of the skin barrier, helping to prevent leakage of stoma output and increase the wear time of a stoma bag.

Key features valued most by participants

According to the insights shared, a number of features were seen as important by respondents. These features also lent to ease of use.

1. Skin Protection and Comfort:

The first of these was skin protection and comfort, with respondents preferring products that both prevent skin irritation and provide healing properties.

2. Leak Prevention and Security:

Respondents also shared that leak prevention and security gave peace of mind.

- "Makes for a secure fit between skin and baseplate"
- "Provides support for my stoma which is positioned at an angle. I was experiencing numerous leaks before the seals were introduced. Helped greatly"

3. Adaptability and Fit:

Mouldability and versatility were key design features favoured by ring and seal users.

4. Ease of Application:

Finally, respondents shared that a simple application process is also key for ring and seal use.

- "You just pull off front and back protection, stick onto the stoma bag"
- "Concentric shape makes it easy to apply to the bag"

Features that make the device hard to use

Two main issues were reported to make rings and seals difficult to use:

1. Packaging problems:

- "The harder plastic container with 5 rings in is difficult to open with arthritic fingers"
- "Opening the packaging each ring comes in"

2. Skin sensitivity:

- "My sensitive skin reacts to the device"

3. Product Availability

The importance of knowing about product availability was also appreciated, with one user noting it "took ages to find this" product, suggesting earlier information about washer options would have been helpful.

However, it's worth noting that several users reported no difficulties, with responses like "None" and "Nil" when asked about features that make the product hard to use.

Features that would encourage switching to an alternative device

The main reason respondents would make the switch to alternative rings and seals is for improved packaging:

- "If it was in a different plastic casing"

However, as with features that make the product harder to use, many users expressed satisfaction with their current products and specifically stated they wouldn't switch.

Flange extenders

Flange extenders are adhesive strips used to increase the adhesive area and stop the flange edge from lifting.

Key features valued most by participants

Respondents shared the following key feature of flange extenders, which also made the products easier to use:

Fit and Security:

Respondents noted that these products help them to achieve a close fit with the bag.

- "Provide extra protection to the skin and help the bag get a close fit."

Features that make the device hard to use

Some respondents told us it was difficult to correctly place extenders.

Indwelling urinary catheters

An indwelling urinary catheter is a flexible tube inserted into the bladder, sometimes referred to as a Foley catheter. The catheter is held in the bladder by a water filled balloon.

Urine is drained through a tube connected to a collection bag, which can either be strapped to the inside of the person's leg or attached to a stand on the floor. Indwelling catheters are used when a patient cannot empty their bladder naturally resulting from urinary retention, incontinence or after surgery.

Key features valued most by participants

1. Coating and lubrication for comfortable insertion and reduction of pain.

2. Design and ease of use, such as prevention of leaks from good connectors.

- "Easy to connect, usually"
- "Right material, good connectors"

3. Infection prevention.

Several users emphasized the importance of features intended to reduce the risk of a UTI. Patients perceive that the easier the catheter is to use the less likely they will get an infection from the process.

- "The silver coated has been a huge relief as I have issues with blocking, UTI and pain upon withdrawal and insert with the non-coated ones. "

4. Do not get blocked as sediment can pass through.

Features that make the device easy to use

1. Clear tubing to monitor sediment levels.

Features that were noted as ensuring easier use of catheters included clear tubing to allow for monitoring of sediment levels; and drainage holes that improve flow and help prevent blockages.

- "The tube is clear so that I can see the level of sediment coming from my bladder"

2. Easy to connect, good method of attaching to bed

Features that make the device hard to use

1. Design issues such as difficulties attaching night bags. Frustrations were shared regarding the design of the urine bags, and difficulties attaching night bags. Likewise, respondents found that the poor discharge design and design around size also made the products more challenging to use.

- "The stop valve at the bottom of the bag leaks albeit slowly, but the design is not effective."

Features that would encourage switching to an alternative device

1. A catheter that is more comfortable and is less painful to replace.

2. A product with better infection prevention.

In line with features that made products more valued, respondents would consider switching if a product with better infection prevention were available, with one specifically suggesting "[bacterio]phage coated catheters or impregnated catheters for those suffering frequent UTI".

Intermittent urinary catheters

An intermittent catheter is temporarily inserted into the bladder and removed once the bladder is empty. These catheters are inserted several times a day, for just long enough to drain the bladder, and then removed. People using these should be taught how to insert the catheter themselves. One end of the catheter is either left open-ended, to allow drainage into a toilet, or attached to a bag to collect the urine. The other end is guided through the urethra until it enters the bladder and urine starts to flow.[2]

Key features valued most by participants

1. Coating and lubrication for comfortable insertion and reduction of pain

For both indwelling and intermittent catheters, respondents valued as essential comfortable insertion and reduction of pain. Respondents perceived that coating and lubrication can help with this and perceived that these features helped to prevent trauma to the urethra and reduce the risk of Urinary Tract Infections (UTIs). However, some users are allergic to certain coatings, making labelling of specific materials crucial.

- "Self-lubricating. Coating allows comfortable insertion. Doesn't irritate urethra"

- "The coating prevents trauma to my urethra, which is critical as I have no sensation. This also helps reduce the amount of UTIs I get compared to other products I used to use."

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[2] https://www.nhs.uk/tests-and-treatments/urinary-catheters/types/

2. Ease of use

Several users referred to getting the size, coating and firmness correct to make intermittent catheters easier to use.

- "Easy to open and coated for application"
- "Sheathed catheter to allow for no touch technique"
- "The handling aid allows me to catheterise without touching the coating."

3. Discreet and compact

Respondents noted that discreet packaging makes devices easier to carry and dispose of while using in public spaces.

- "Easy to use, comfortable, coating helps it to be pain free, discrete to carry with you"
- "Packaging is really important e.g., catheters rolled up to fit into pockets" (intermittent catheter)

Features that make the device easy to use

1. The right size, coating and firmness to aid insertion.

2. Features designed to aid flow and reduce blockages.

- "I need male length catheters and it has 4 extra-large draining holes which helps with flow and mucus."

3. Integrated components

Respondents appreciated integrated components, including sterile water sachets to enable safe catheterisation (intermittent catheter), and simple connection systems for urine bags (intermittent / indwelling catheters).

- "The included sterile water sachet means I can catheterise anywhere safely - at home, at work, on holiday, at the gym, my kids sports centre, friends' houses, cafes, bars, restaurants. Everywhere able-bodied people take for granted!"

Features that make the device hard to use

Based on insights shared by respondents, a handful of key challenges make the catheters difficult to use.

1. Connection port for urine bag could be a bit bigger to accommodate different urine bags.

Frustrations were shared regarding the design of the urine bags, and difficulties attaching night bags. Likewise, respondents found that the poor discharge design, and design around size and portability also made the products more challenging to use.

- "Discharge end not designed for clean flow and tends to spray urine"
- "The overall size and weight of a 2 weeks supply makes for added weight and bulk especially when travelling abroad"

2. Not firm enough.

3. A difficult procedure generally, especially outside the home.

One respondent shared that "as a woman you need 3 hands to use them". Another respondent shared difficulties regarding location and facility constraints.

  - "The procedure itself is tricky but the product requires you to be next to a sink and a loo at the same time!"

- "If there is no mirror on [the] wall [it is] difficult to start to enter it into the urethra due to body shape"

A visually impaired interview participant shared that the packaging that their self-catheter comes in can be challenging to open.

- "The packaging isn’t the easiest thing to open – you have to twist it and I wouldn’t have known that unless I was shown."

4. Cannot control the flow.

Features that would encourage switching to an alternative device

1. Reusable device if there is a way to prevent infection and is comfortable

2. More compact and discreet packaging for disposal

3. The design of drainage holes/something more efficient at draining the bladder

4. One designed with more patient involvement

Respondents said they would consider switching to a reusable intermittent catheter if the process was not more complicated and if the research supported infection control.

More broadly, better design features, such as more discreet design and improved design features including for the design of drainage holes and designs considering women's body shapes were also noted. One visually impaired interview participant would switch to an integrated self-catheterisation system which did not require them take the additional step of attaching the bag once the catheter was inserted.

Absorbent pads for incontinence

Absorbent pads help individuals maintain personal hygiene and quality of life by absorbing leaks. Fourteen respondents shared insights regarding absorbent pads. It should be noted that research participants explained that these products are purchased privately for the most part. Absorbent pads for incontinence are not provided through Part IX of the Drug Tariff but we know the feedback is valuable and relevant to the audience of this report.

Key features valued most by participants

Based on the survey responses, the most important features of absorbent pads for incontinence include absorbency and leakage prevention; comfort and skin protection; and discretion and fit (including odour control and size variety).

- "Must be fully absorbent and comfortable. Ideally not obtrusive."
- "Does the job, comes in a range of sizes, so can request bigger ones when needed"

Features that make the product easy to use

A number of design features made absorbent pads easier to use, including securement properties, a pull-on design, variety in sizing and absorption, secure fastening and comfort, and the design of width and adhesion / fixation strips.

- "Sticky base to adhere to clothing."
- "Pull-on style makes it easy to use and they're not particularly bulky so not visible under clothes"
- "Secure fastening to underwear, soft feel against skin."

Features that make the product hard to use

1. Poor design features:

Respondents noted a number of design features which made products more challenging to use. These included bulkiness and visibility, leaks, and adhesion problems, which were experienced by 2 respondents choosing to use off-the-shelf products.

- "Too bulky and leaks doesn't stay in place"
- "The pads that don't stick properly"

2. Poor quality of prescribed pads:

Quality issues around pads prescribed was also noted as a challenge.

- "Limitations in availability and willingness for prescriber to offer best choice for patient"
- "The ones I get free from the NHS are not quite the same as the ones that can be purchased - they don't adhere to underpants as well"

3. Disposal challenges:

Some respondents also noted disposal challenges of products, with one noting that "many male toilets do not have places to dispose of the absorbents". Finally, another respondent noted challenges around skin irritation.

Features that would encourage switching to an alternative product

Respondents shared that they would switch to a product if it were "slimmer and more comfortable", but with the same level of absorption. Equally, they would appreciate better adhesion and odour control. Some respondents would switch to more environmentally friendly options if available.

Gastrointestinal and urological patient information needs

Accessible information needs

The VCSE organisations that represent the needs of those who fed into this project during the scoping phase made it clear that any information designed to improve awareness of or improve the ability to use a medical device must take into consideration diverse communication needs. The Accessible Information Standard provides guidance on meeting the information and communication support needs of patients, service users, carers and parents with a disability, impairment or sensory loss and was flagged as a useful resource for device manufacturers.

Respondents who use gastrointestinal and urological devices expressed a desire for:

- practical guidance on how to live with the related conditions;
- information on the various additional products and accessories that can improve the effectiveness of the products available;
- information on how to navigate the prescription fulfilment process;
- information on support services and resources.

Practical guidance

The main information gap participants requested was knowing that different medical devices are available to them, and that they can get better results through trial and error. This was especially relevant for the fit and placement of stoma bags, which is different for every body shape and can also change over time and should be reassessed on a regular basis.

- "That there were other options available - I thought there was just one stoma bag and it was an NHS one - I didn't realise it there were different companies and bags "
- "The need to try lots of products before finding the ones which work best for you."

Many participants raised concerns that without receiving this information early in their medical devices journey, they wasted a lot of time living with a medical device that was not fit for purpose and therefore negatively affected their physical and mental wellbeing. In many cases people described how they ultimately found the device that worked best for them through word of mouth rather than via a medical professional in the NHS.

- "I was given a leaflet and told to order from the one Stoma nurse gave me. Information about other suppliers and types of bags would have saved me a year of needing help."
- "There's one bag that I was never told about, but it was kind of through word of mouth and Facebook support groups"

People also wanted practical advice on how to ensure that colostomy and urostomy bags stay in place to avoid leaks, as this presents the biggest challenge when living with an ostomy device. Leakages have a hugely detrimental effect on person's wellbeing, both physically through the risk of rashes and infection, as well as emotionally due to embarrassment.

Some survey respondents were initially not made aware that leaks are not a normal part of using a stoma and are a sign that the current medical devices are not functioning properly.

- "The hole in the base plate needs to [be] a snug fit but not tight around the stoma so as not to cause leaks or soreness."
- "How to avoid leaks and prevent soreness and infection."
- "That leaks mean something is wrong and that there are plenty of alternatives to help."

On intermittent catheters there were requests for

- "Information aimed at late teens young adults on catheters, silly things like can you still have sex and do normal things."
- "Recommendation from other patients"
- "Better instructions on how to use them"

Additional products and accessories

Respondents and participants said that they would have benefited from information on the range of accessories available to them to improve the chances of their stoma bag functioning properly. "What healing products are in the flanges and the benefits of this."

- "[Information on] additional adhesive products like elastic tape strips"

Being made aware of the range of bags and accessories that make living with a stoma more manageable from the outset could reduce the number of negative experiences that people go through.

Managing prescriptions

One of the biggest differences between people who have recently been prescribed a gastrointestinal or urological care device and those with years of experience is the level of familiarity with the prescription fulfilment process. Participants described how once they are prescribed a device, they simultaneously become patients, self-advocates and supply chain managers which can be very confusing, especially for people who have been prescribed a device more recently. This is particularly an issue when people want to discuss switching to an alternative device with their health practitioner.

- "When I asked at the GP [to switch to an alternative stoma bag] and they said, 'oh, who do you already use?' So it's like you're already funnelled into one provider and you’re not told how to access a different provider… it is confusing"

Several people requested information on how to navigate the prescription fulfilment process through education on what role Dispensing Appliance Contractors (DAC) play; the relationship between device manufacturers and DACs; and the differences in how long it takes to get a prescription fulfilled based on geography, prescriber and DAC.

Support services and resources

Respondents expressed desire for "more info on the reality of living with an ileostomy and bags. Warts and all. What I might struggle with or find different" and where to turn to for support to help overcome the emotional impacts of living with a stoma bag. A large portion of gastrointestinal and urological care device users who took part in the survey and focus groups described benefitting from accessing peer support networks, often hosted by local NHS or VCSE organisation. Respondents suggested being sign-posted to these resources during the initial prescription process would allow people to access support networks early on in their stoma journeys.

Perceptions of industry influence over prescribing decisions

A small number of focus group participants and survey respondents raised concerns that the information they were receiving on the range of available device brands was not impartial due to the influence of branding and marketing efforts from manufacturers, and the fact that a manufacturer can sponsor stoma nursing roles. This perceived lack of impartiality made some participants concerned that they had been encouraged to continue using a medical device that wasn't the best one for them.

- "Some stoma departments are stuck on certain sponsor products to the severe detriment of many patients, not informing them of alternatives and not letting them change."
- " [I want] good advice rather than discover that stoma nurses are sponsored and not employed by NHS, therefore they are biased to a particular company, this is not made transparent to the patient"

Information formats

There was no strong consensus on how respondents said that they would like to receive information about their devices. People provided a wide range of suggestions as to how they would like to receive information: in several ways:

- Through leaflets that have been codesigned with people with lived experience.

> "Would be helpful to have patient created leaflet from a patient’s point of view, having top tips e.g. don’t be afraid to keep trialling bags until you’re as happy as you can be."

- Through direct contact with people who have lived experience with stomas either online or in person.

- Via comprehensive pre-operative education, including the opportunity to see and test devices before surgery to help reduce anxiety.

- Through video demonstrations showing best practices and specific techniques like attaching night bags.

- Through better post-discharge follow-up support, as some felt "abandoned" after initial stoma nurse visits.

- Through detailed explanations from doctors about how to use devices accurately, especially for first-time users. Many respondents emphasised the importance of having someone walk them through the process, particularly at the beginning when everything can feel overwhelming.

In the interview with the participant living with a visual impairment, they explained that a physical demonstration with a nurse was the only accessible way for them to learn how to self-catheterize.

- "I never had to use [a self-catheter] in my life, didn’t even know they existed. When I went onto self-catheters I had a nurse show me how to do it which was a great experience. It was hand over hand so I knew what to do."

Relying on written or video/audio instructions alone would not allow most visually impaired people to access information on how to safely and effectively use gastrointestinal and urological devices.

3. Respiratory and airway management

There are a wide range of respiratory and airway management devices included in Part IX of the Drug Tariff, for example, inhalation meters, peak flow meters, spacers and many more. However, survey respondents and focus group participants only provided feedback on spacers.

The limitations of the reach of the survey meant that not all patient groups responded within the timeframe, resulting in limited responses for respiratory and airway management. Equally, some people who use these devices don't identify themselves as a medical device user and therefore did not respond to the survey.

Spacers

Just one survey respondent and one interview participant shared their experiences of using a spacer - a tube-shaped device that fits on an inhaler's mouthpiece and allows for ease of delivery of medicine into the lungs. People with asthma, and children and adults who have trouble coordinating the "press and breathe" technique when using an inhaler, may choose to use a spacer. The interview participant who shared their experiences of using a spacer has limited dexterity in their hands due to arthritis, which makes using their inhaler more difficult.

Key features valued most by participants

The survey respondent shared that the most important feature of the spacer is the size, ensuring it is portable and compact. For the person living with arthritis, the ability to use an inhaler without having to coordinate pressing the button and simultaneously inhaling was the most important feature.

- "I'm not very coordinated, pressing down on the inhaler with limited dexterity is difficult in a controlled way."

Features that would encourage switching to an alternative device

Both participants agreed that they would switch to an alternative device if it was smaller and therefore easier to carry. One participant explained that they would often opt to leave their spacer at home if they did not want to bring a larger bag with them. The fact that manufacturers suggest transporting the spacer in its own bag to avoid scratching it added to participants' reluctance to bring the spacer with them.

- "It's quite large – I want to take inhaler in my bag. It's quite fragile too, it can't get scratched. It says carry it in a fabric bag to protect the device. That's a factor because it makes it very bulky."

The interview participant with limited dexterity also found that cleaning and maintaining the spacer is challenging because it needs taking apart and then putting back together which requires a high degree of coordination.

While survey respondents and focus group participants only provided feedback on a limited number of medical devices listed on Part IX of the Drug Tariff, they did provide feedback and insights on a number of medical devices which are not listed on Part IX of the Drug Tariff, but are prescribed in other NHS settings or available privately. This includes insights on Positive Airway Pressure (PAP) Therapies, Nebulisers and Domiciliary oxygen therapies. We have taken the decision to publish these within the report. You can find details on them below.

Positive Airway Pressure (PAP) Therapies

Positive Airway Pressure (PAP) therapy refers to a treatment method for sleep apnoea that uses a machine to deliver pressurised air through a mask, keeping the airway open during sleep by preventing it from collapsing and allowing for normal breathing. These medical devices are generally prescribed though the NHS to those who experience sleep apnoea, and work by maintaining airflow by applying gentle pressure to the upper airway throughout the night. Eight people provided feedback on their use of PAP therapies including CPAP, BiPAP, AutoPAP machines and EPAP devices.

Key features valued most by participants

1. Comfort and Discreetness:

Participants noted that the most valued key feature centred around the comfort of the device, noting that it should be comfortable, and the mask should have a suitable fit. Further to this, users noted that they appreciated the machines could be used at home and are quiet because of the need to use the devices every day.

- "Quiet machine and comfortable mask"
- "Reliable and quiet"
- "Easy to use, the mask fit is highly important"

Features that make the device easy to use

1. Ease of Control:

Mostly, participants shared insights into the ease with which they were able to control their PAP therapy devices, and ability for a medical team to access the machine where necessary:

- "It starts and stops itself"
- "Controls are simple, switch on and use, medical team can access via remote monitoring"

Features that make the device hard to use

1. Face Mask Discomfort

There was an overwhelming response surrounding discomfort of the face mask. The majority of respondents who use PAP therapy devices shared frustrations about the general discomfort, and more specifically, discomfort around the nose and ears:

- "Mask fit and comfort"
- "The mask tends to make my ears sore"
- "Discomfort around the nose"

2. Difficulty of Replacing Masks:

Two survey respondents also highlighted difficulty regarding repairing or replacing masks, and how this causes a great deal of disruption in their lives.

- "If mask needs replacing can take several days to organise which means you are unable to sleep until new mask arrives. [The] Hospital refuses to give patients spares until needed."
- "Difficulty getting replaced or repaired if breaks"

3. Poor Design:

The user of one product emphasised that the machine is too bulky, and their preference would be to have a more compact machine. And finally, one user of a BiPAP machine noted their frustration with the noise the machine makes and that it leaves them with a dry throat.

Features that would encourage switching to an alternative device

Respondents noted that they would be encouraged to switch to an alternative if it had a more comfortable mask. They also noted that a battery backup would be appreciated, to prevent any issues that may occur due to power cuts.

Nebulisers

A nebuliser is a small machine that turns liquid medicine into a mist that can be inhaled. Nebulisers are used to treat infections, relieve symptoms of lung conditions like asthma, clear airways, loosen phlegm, and deliver treatment during radiotherapy or palliative care.

At the time of writing, NHS.uk states that "while the medicines used with a nebuliser can be provided on prescription, the nebuliser device itself is not always available on the NHS. In some areas, a local respiratory service may provide the device without charge but, if this is not an option, you may have to pay for a device".

Of the 3 respondents who use nebulisers, none shared specific brand names of nebulisers. People in the focus group shared that they had a 'heavy duty' nebuliser prescribed by the NHS, and a 'handbag' nebuliser, which they had purchased themselves.

Key features valued most by participants

A couple of respondents shared that they appreciated the smaller size of the nebuliser they had acquired privately. However, this smaller size was not available via the NHS and therefore came at an expense to the individual.

- "It is portable so [I] can carry [it] in [a] handbag if going out"

Features that make the device hard to use

1. Size and Design:

All individuals who used a nebuliser shared their frustration with the size of the device supplied by the NHS on prescription. They felt that little thought had been given to the portability, and ultimately liveability, of the device, which makes it difficult to travel and carry around. Those who had chosen to purchase a smaller nebuliser privately had a ‘heavy duty’ nebuliser for use at home, and a ‘handbag’ nebuliser for travelling.

- "Massive nebuliser to carry round, and carrying something else that’s heavy doesn’t help"
- "[It] is heavy to carry into London, especially when you go on public transport"

Respondents and participants often found themselves struggling with the size and weight of such products, which can impact their mobility and ability to engage in daily activities. For instance, one person noted, "If I wanted to leave house, there's no way I could leave the house... [I would] have to get patient transport to hospital to take machine in or get another part," highlighting the logistical challenges posed by bulky equipment.

2. Maintenance:

Participants noted the impracticality of maintaining the device, due to the cleaning regime and servicing needs:

- "Have to take it back for servicing"
- "Practicality of maintaining it"

Further to this, focus group participants expressed frustration over the lack of proper training and guidance on how to use their prescribed devices. One participant stated, "You get a leaflet which gives you some stick man or some sort of idea how to use it, but you don't know if you're actually using it correctly." This underscores the importance of effective education and support in ensuring that people can use their devices properly.

Features that would encourage switching to an alternative device

Understandably due to the bulkiness of the device, individuals would switch if a more compact device were offered, which was easier to travel with.

Domiciliary oxygen therapies

Domiciliary oxygen therapy, also known as home oxygen therapy, is a treatment that involves breathing in oxygen-enriched air through a mask or tube. Individuals with chronic pulmonary or cardiac diseases often need oxygen therapy after being discharged from the hospital.

While domiciliary oxygen therapy is available external to the NHS, the NHS advises that individuals should only use home oxygen therapy if a GP or specialist has prescribed it. Two respondents to the survey shared use of domiciliary oxygen therapies, namely an oxygen compressor and oxygen cylinder.

Key features valued most by participants

They key featured identified by respondents using domiciliary oxygen therapies, were the ease of use, and quietness of the machine.

- "The sound with the one I have you can barely hear it "

Features that make the device easy to use

Users noted that the 2 features that make the device easy to use include its manoeuvrability due to being on wheels; and the easy-to-read controls.

Features that would encourage switching to an alternative device

Neither respondent mentioned any features which made the devices hard to use, nor would they consider switching device.

Respiratory and airway management patient information needs

Accessible information needs

The VCSE organisations that represent the needs of patients who fed into this project during the scoping phase made it clear that any information designed to improve awareness of or improve the ability to use a medical device must take into consideration diverse communication needs. The Accessible Information Standard provides guidance on meeting the information and communication support needs of patients, service users, carers and parents with a disability, impairment or sensory loss and was flagged as a useful resource for device manufacturers.

Individuals who use respiratory and airway management devices want clear, accessible information on how to use, maintain and manage their medical devices; as well as information on potential risks and side effects.

Device usage and maintenance

Focus groups participants requested information on replacement and servicing needs: "When does this need replacing, when does this need servicing?", as well as information on how to dispose of their respiratory and airway management devices once they are no longer usable.

- "Where you can dispose of them?"

This is especially important for people who want to minimise their ecological footprint by recycling as much as possible.

Receiving training on how to use medical devices increases the likelihood that people will use them as recommended.

- "If you want 100% adherence to your medication... you need to be using it right."

Information formats

Respondents expressed varying preferences for how they would like to receive information, with suggestions including:

- Video instructions: "Why not video the person showing you how to use it so you’ve got your own recording?"

- QR codes linking to online materials: "Should info leaflets have a QR code that links to online materials for support?"
- Accessible written materials: "All material for the public should be at this level which is easy using AI."

4. Lymphoedema, support and therapeutics

As part of our research into lymphoedema, support and therapeutics, participants shared insights on support and compression garments and lymphoedema garments; application devices; and automated compression pumps.

Support and compression garments / Lymphoedema garments

Lymphoedema is a failure of the lymphatic system that leads to swelling, skin and tissue changes and a predisposition to infection. Compression garments are tight-fitting garments that help reduce swelling and improve blood flow and can be used to treat lymphoedema. Lymphoedema garments are designed to contain swelling, improve shape, skin and tissue changes, reduce incidence of infection and provide symptom relief. A lymphoedema specialist or healthcare professional can prescribe and fit individuals with compression and lymphoedema garments, which can then be used at home to improve comfort and quality of life.

One hundred and thirty-four people provided feedback on support and compression garments, and 94 people gave feedback on lymphoedema garments. Participants shared a wide variety of brands used for support and compression garments, and lymphoedema garments.

Key features valued most by participants

1. Comfort and Wearability:

Comfort and wearability were noted as key features that people would like to see from their support and compression, and lymphoedema garments. Those who had experienced this noted the impact it had on their mental wellbeing and confidence.

- "Ease of application, all day comfort when on, appearance, efficacy"
- "Anti-slip coating, which keeps it in place and stops it falling down"

Features that make the device easy to use

1. Comfort:

Comfort was identified as the most valued feature for lymphoedema, support and therapeutics devices. Those who had received made-to-measure lymphoedema garments with fastenings said they worked better for them (particularly Velcro fastenings); and found these features made their garment easier, and more comfortable, to use. One respondent who used compression stockings for their lymphoedema, also noted the benefits of a footless stocking.

- "The fact that it is made to measure, and is of a firm elasticated construction"
- "Material is thinner than other gloves and feels nice on my skin"
- "The Velcro on the straps allows me to easily adjust the tightness of the leg wrap & using the [brand] frame to put on the protective stocking on my own"
- "Comfortable [and] easy to put on and remove, do not damage fragile skin"
- "The fact that the stocking is footless makes it easier for me to get on, and it is a lot more comfortable than a closed toe option"

Features that make the device hard to use

1. Application:

Participants highlighted difficulties with putting them on, and therefore reliance on others and the subsequent lack of independence this results in them having.

- "Very hard to get on and in the summer months very hot and uncomfortable"
- “I struggle for 30/40 mins to put on current compression tights and cannot put shoes on easily or my ankle boots with zips. If my son [is] at home, he assists with pulling up zips”
- "My husband puts my hosiery stockings on as I can’t do them myself"

One focus group participant also noted how use of garments can change dynamics within personal relationships. They shared, "It’s affected my relationship because he’s become my carer", highlighting how newfound dependency on their partner to care for them can alter their personal connection.

2. Discomfort:

Once on, many participants also shared that the garments are uncomfortable, with some being too tight, rubbing, and gathering. This occurs to a greater extent for those with support and compression garments, as lymphoedema garments tend to be made to measure, but also happened for a handful of individuals using lymphoedema garments. This ongoing, daily discomfort also resulted in skin issues and conditions such as hard skin forming due to poorly fitting garments; as well as pain, skin irritation and breakdown.

One respondent shared that removal of the garment can be uncomfortable due to a skin condition they also have.

- "Fabric gathers end hurts behind the knees. Surface non-slippery hence trouser legs ride up and stay up"
- "Occasionally product has flaws in stitching which can irritate the skin"
- "Over the course of the day some compression garments become very uncomfortable"
- "The seam under your foot creates hard skin"
- “The tops of the stockings do not work, they crease and cause soreness, restricting circulation"
- “Rely on measurements submitted to [brand] by hospice lymphoedema specialist but method used is very low tech (tape measure)"

3. Maintenance and Disruption:

Respondents also shared the maintenance issues and disruption that the garments have on their daily life, as it impacts what clothes they are able to wear, and the need to clean garments each day to keep them hygienic and looking clean. They also shared that garments can shrink with washing.

- "Being prescribed only 2 pairs of tights twice yearly is not enough for washing [and] drying regularly so I used to hold onto 'old but undamaged' tights so I had daily change for work"
- "The need to replace and wash each day"
- "Impacts clothing (sleeves are tight) especially coats"

4. Aesthetic considerations:

People described often feeling self-conscious about their appearance due to the garments. A focus group participant remarked, "I go to the office and people stare at me... I asked the NHS what I can do, but the options all look like medical shoes and are ugly." This indicates the importance of considering the emotional impact of the appearance of medical devices.

The argument for more aesthetically pleasing options came through strongly from respondents; another focus group participant expressed, "There is a massive disconnect between users and manufacturers around wanting more design options." This desire for better design reflects a broader wish to feel accepted and 'normal' in social contexts, exemplified further by another participant who shared "The day they put [medical shoes] on me I cried. I felt like lymphoedema took everything from me."

Additional challenges for people with existing conditions

When understanding an individual's garment preference, it is important to recognise that they may have multiple long term conditions which have the potential to influence their garment choice. For example, an individual with arthritis shared that they have difficulty manipulating garments during application due to joint pain and reduced dexterity.

- "Even with the adjustable Velcro for the wraps I do still suffer pain in my thumbs due to bad arthritis whilst trying to put them on"
- "[I] have arthritis now so cannot struggle with trying to get a pair of ill-fitting compression tights on. Due to this I am not wearing compression tights at home, only when going out which obviously is making lymphoedema worse"

This experience was shared with other respondents and participants with varying mobility challenges, with individuals losing their independence due to the need for a family member or carer to aid them in putting on their garment. Once participant shared that his day started when his carer arrived and could put on his garment, and ended when they took it off and left, as he was unable to do this himself and was therefore dependent on others for daily compression management. Exploring application devices with those who use them, such as the butler donning aid , would help individuals in gaining back their independence where mobility allows.

Features that would encourage switching to an alternative device

Overall, participants and respondents were more likely to switch garments if an alternative was to be more ‘liveable’. Most notably, if the garments were more comfortable, both physically and for confidence, in a lighter or thinner material, causing less friction and with better shaping, and in a more natural looking colour, and this comfort was maintained throughout the day, the participants would look to switch. If the garments were more liveable, and required less maintenance, for example could be washed in the washing machine, and lasted longer as to not require as frequent replacements, participants would also look to switch.

Application devices

Application devices exist to make it easier to put on compression and lymphoedema garments. Four people provided feedback via the survey for these. In the focus groups, participants spoke very highly of their experiences of using application devices, suggesting that more could be done to raise awareness of the existence of these devices with relevant patient groups.

Key features valued most by participants

Participants shared that the overall ease of use and wider design of application devices are the most valued features, noting that a “good coating” is vital to ensuring that garments are held in place. Further to this, it was recognised that easy dismantling and adjustable poles ensure that the device is adaptable and allows for the individual to travel as they wish. Participants also noted that the device being easy to clean is key to maintaining hygiene of the product.

- "It is easy to use and the coating on the metal helps hold the stockings place so I can put them on"
- "Can be easily dismantled for travel packing"
- "Adjustable poles to pull up the stocking"

Features that would encourage switching to an alternative device

Despite noting that they appreciate the portability of some devices, participants noted that they would rather a “less bulky” device too. The preference for a device that lasts longer, particularly one that maintains its effectiveness beyond the current one-month period, was also noted. At present, devices can lose their coating, which aids in keeping the stocking in place as an individual applies them, within roughly one month. If this coating was to be more durable, not only would the device last longer but there would be less waste.

Automated compression pumps

An automated compression pump for lymphoedema is a machine that uses air to squeeze a swollen limb to help reduce swelling and pain. It's also known as an intermittent pneumatic compression (IPC) pump or pneumatic compression therapy (PCT) device. Although these devices are not on Part IX of the Drug Tariff nor prescribed for home use on the NHS, people may buy these privately to use at home, or sometimes use them in hospitals. 11 people provided feedback on automated compression pumps.

Key features

A number of participants and respondents who use automated compression pumps shared that the features which were most valued and make the device easy to use are general ease of use, and comfort.:

> "Comfortable and relaxing"

Features that make the device hard to use

In contrast, some found the pumps cumbersome - described as having "sheer bulk, stiff inflexible material".

Portability and set-up issues were also identified as features which made the pumps hard to use:

- "Unfortunately not very portable - could not take on holiday"
- "Don't find it particularly easy to get set up"

One participant also shared that it "takes significant time each day to get the benefits".

And finally, participants found that there is poor accessibility to sourcing the pumps, citing cost as a barrier, with clinical pumps costing between £1,080 - £3,100, and noting their frustration that pumps are not available on the NHS. As highlighted many individuals buy their devices privately for home use, and some may access pumps during hospital visits. However, most users who purchased their pumps privately appear to use their devices daily or weekly, with treatment durations ranging from less than 6 months to over 5 years.

Lymphoedema patient information needs

At the point of prescription, those who use lymphoedema support and therapeutic devices want information on how to use and maintain or dispose of their devices; the various types of devices available; what lymphoedema is and how it is caused; and how and when to seek support.

Accessible information needs

The VCSE organisations that represent the needs of those who fed into this project during the scoping phase made it clear that any information designed to improve awareness of or improve the ability to use a medical device must take into consideration diverse communication needs. The Accessible Information Standard provides guidance on meeting the information and communication support needs of patients, service users, carers and parents with a disability, impairment or sensory loss and was flagged as a useful resource for device manufacturers.

Practical guidance

The most commonly requested information was instructions on how to use lymphoedema devices, since it is a condition that many people manage themselves daily. Due to the design of support and compression garments, many respondents and participants find it difficult to put them on and remove them.

- "More information on different tips to be put the product on"

Being able to apply and remove the garments more effectively not only saves the person time and reduces their discomfort or frustration, but it also helps keep the devices in good condition and therefore ensure their effectiveness. This is especially important for made to measure garments which are less easily replaced.

- "Hacks to remove without feeling like you're breaking or stretching the garment"

Respondents and participants also wanted advice on caring for lymphoedema and support garments, because they are often used daily for long periods of time and therefore need to be washed.

- "Simpler instructions on how to look after the garment in terms of washing and drying."

Enabling patient choice

People would have wanted information on the full range of compression and support garments available to them as well as accompanying accessories to help with applying and removing the garments. In particular, some would have found it beneficial to be offered several samples of garments to try simultaneously, and in person, rather than prolonging the process of trial and error over a period of months or only being able to view options online.

- "Various samples to try as opposed to 1 then wait a few weeks to try another. It’s been 6 months now and I end up buying my own"
- "Any information as I wasn’t provided with any. Plus it would have been nice to had made to measure right away instead of having to go through tons of generic socks made for old people that didn’t suit me or fit."

Seeking support

Because lymphoedema is a chronic condition, many individuals highlighted the importance of being able to spot the signs when additional support may be needed from clinicians, such as requesting replacement garments when they have become less effective.

- "Information on what to do if your compression isn't holding the swelling and getting new garments quickly"

Participants also suggested that people should be encouraged to contact their lymphoedema clinician if they feel like their garments are not functioning properly or if they notice any signs of deterioration in their condition.

- "Reassurance to tell patient to ring in if there's anything wrong with the garment immediately."

Information about the condition

Some people received very little information about what caused their lymphoedema and how to manage the condition. This can exacerbate the negative impacts of living with lymphoedema as people are less well equipped to proactively manage their symptoms.

- "I knew nothing about genital lymphoedema. It would have been helpful to have been taught self lymphatic drainage."
- "It would've been useful to know a little bit about lymphoedema at the time I had my lymph nodes removed. By the time I understood my leg was swollen and it was too late to get the best outcome"

Respondents and participants also requested clarity around the implications of living with lymphoedema and the impact it can have on their daily life in order to help them prepare for the potential physical and emotional challenges.

- "I've been wearing these garments for 30 years next year. There was less choice years ago so I think probably the only useful information would have been to be prepared that you'll be a patient for life and you'll need to wear these each day."

Information formats

Most people requested physical demonstrations on how to use the medical device because of the need to apply and remove the garments. These demonstrations could be provided either in person or via an instructional video.

- "Didn't know how to use the white waist belt in [brand] tights until I met a nurse who knew. No info in [the] leaflet or website."
- "Physical and visual demonstration either in person or via video."

A few people felt they would have benefited from much more in-depth training on how to manage their condition holistically, rather than only relying on the compression garments. As above, this type of information provision would benefit from attendance in-person.

- "A course to dedicated to self-care. This would include a few sessions being shown by nurse and then doing lymphatic drainage until I could do correctly, bandaging if required and then easiest method of putting on compression tights. This would be over a series of approx. 6-8 weeks not a one hour appt as was given many years ago"

Other suggested information formats included support from other lymphoedema support garment users; and QR codes for easy access to educational resources.

5. Sexual, reproductive and pelvic health

The research team was only able to deliver a small number of interviews due to the very low number of survey responses providing insights into the patient experience of sexual, reproductive and pelvic health devices. As a result, this report only shares the experiences of people who use vacuum pumps and intrauterine devices.

Vacuum pumps

Vacuum therapy is non-invasive method of producing an erection for people who suffer from erectile dysfunction. They do this by sucking blood into the penis, with the rubber band maintaining that erection. They do not increase blood flow. In Peyronie's disease there is some evidence that they reduce the extent of any bend. Constriction rings are used to maintain the erection. The findings below are based on 3 survey responses and 2 interviews. People are often prescribed a vacuum pump after undergoing treatment for prostate cancer as erectile dysfunction can be a side effect of both radiotherapy and prostatectomy.

Most important features of the device or product

For prostate cancer survivors, the most valued element is the ability to achieve an erection and help maintain penile length. Both interview participants explained how without frequent rehabilitation the penis can atrophy which can lead to further emotional distress. It should be noted that these medical devices do not have a role in the prevention or treatment of incontinence; it is pelvic floor exercises that can support bladder function. Urinary incontinence is a side effect of radical prostatectomy.

- "If you’ve had a radical operation, when they remove the prostate you can lose up to an inch, and you can get shrinking through radiotherapy. And the pump can restore the penis size back to near pre-operation or treatment size."
- "The issue with NHS is they’re lousy with telling you the best exercises to get bladder back to full working function through pelvic floor exercises and penile health exercises."

For the participant with Peyronie's disease, the most important feature is the ability to straighten the penis.

Features which make the device or product easy to use

From a practical perspective, the simple operation; having different sleeve sizes available; and the ability to use the pump with one hand were all mentioned by participants as making the device easy to use.

Features which make the device or product hard to use

Participants told us that using the device requires a good level of dexterity in the hands, which can be challenging for some people, although a mechanised version is available. It was generally felt by participants that relying on the constriction rings for maintaining an erection for the purpose of sexual intercourse is not very effective both physically but also emotionally because it removes the spontaneity from the experience and can be uncomfortable.

- "Pointless erection rings. The device is good for penile health, i.e., getting regular blood engorgement but attempting to use the subsequent erection with a constriction ring is not practical and definitely not enjoyable."

Features that would encourage switching to an alternative device or product

Participants noted that the devices last about 5 years before needing to be replaced and one survey respondent suggested that a device that was less prone to breakage would be beneficial. This was the only feature mentioned that would encourage switching to an alternative device.

Intrauterine devices

Intrauterine devices (IUDs) are contraceptive devices placed inside the uterus, typically to prevent pregnancy. Only some IUDs are available through Part IX of the Drug Tariff, for example, the copper coil, which works by releasing copper into the womb. Hormonal IUDs which work by releasing the hormone progestogen are available on the NHS under other arrangements. Once inserted by a medical professional, the copper coil lasts for 5 or 10 years depending on the type before needing to be replaced. We held 5 interviews with people who have experience of using an IUD and received 2 survey responses.

Most important features of the device or product

Participants noted that the semipermanent nature of IUDs means that people are less prone to having unwanted pregnancies compared to the likelihood of forgetting to use other contraceptives such as birth control pills.

- "It was really the convenience for me, I'm not a fan of taking pills, I think I will miss them and for family plans it's just harder to remember."

For some people, the fact that the copper coil does not introduce any new hormones into their body was an important feature. This was especially important for people who experience anxiety or are prone to mood swings.

- "So I chose the non-hormonal one which is the copper one for the simple reason, I'm quite a moody person probably my personality so I thought having a hormonal one is not what I need."

- "Because I do […] suffer with anxiety, I do feel like a lot of the pills and other things that are hormone based they affect my mood."

Features which make the device or product easy to use

Participants liked the fact that their IUDs required no effort or maintenance after insertion, which made them very practical. In general, participants felt that the IUD was easier to use than other forms of contraceptive because they were not required to continue attending appointments or remembering to take a pill to stay effective.

- "I found [the contraceptive injection] really tedious. I just want to know that I'm protected and don't have to think about it"

Features which make the device or product hard to use

A number of participants found the process of accessing an IUD slow and cumbersome, for example, having to wait weeks for an appointment and then being disappointed that they would only get information at that appointment and not get the IUD itself fitted.

All participants mentioned that the fitting procedure was unpleasant at best and painful at worse, with some participants experiencing spotting for a few weeks after.

- "Just uncomfortableness and a bit of spotting really"

One survey respondent had an especially negative experience during the fitting procedure during which her blood pressure dropped and she experienced nausea and vomiting.

Several participants who were previously on other forms of contraception (for example, contraceptive pills) mentioned that because the copper coil is non-hormonal, their periods came back which was uncomfortable.

- "I think from coming off the contraception where my periods had stopped completely and then to have the coil fitted to start having periods again, I think that took a little bit of getting used to"

- "Made periods v heavy, painful and prolonged"

One participant was told she "may bleed for 1 to 2 weeks," but experienced 5 weeks of continuous bleeding after the fitting:

- "I ended up having to phone the doctor and say, ‘Is this normal?’ and they kind of snapped at me - ‘Well, of course it’s normal!’ I was just going off what I had been told."

The same participant described bleeding 3 weeks out of 4 for 9 months before deciding to have the IUD removed and described the impact it had on her life:

- "The expense of period products adds up—having to use them almost all the time. My love life stopped, quick. It didn’t put a strain on anything for us, but I could see how it would in some relationships."

Another participant shared information on the impact more painful and heavier periods had on her:

- "I tend to bleed out a lot quicker so like within an hour or an hour and a half my tampon will be full whereas before, I never noticed that - I could change it like once every 3 hours on the heaviest day whereas now it's like once every hour.. they weren't really painful and they weren't really very heavy periods but now they are."

It is recommended that people who have an IUD fitted check that the device hasn't moved once per menstrual cycle. One participant left their appointment unsure of how to do this and during the interview expressed that doing this feels difficult.

- “The only thing is that the nurse advised you can check for strings yourself and that’s always something I’ve wondered but not checked myself, it’s weird.”

Features that would encourage switching to an alternative device or product

No participants expressed any interest in switching to an alternative device.

Overall participants expressed an interest in switching to an alternative device that provided the same functionality but also reduced period flow and duration, and cramping. However, in general, participants highlighted that it was important to them that they would like to use a hormone-free device.

- "[My periods] weren't really painful and they weren't really very heavy periods but now they are."

Sexual, reproductive and pelvic health device information needs

The patient information needs for both devices differ hugely because of the fact that both devices are prescribed and used in completely different circumstances. Using an IUD involves a consultation with plenty of time to consider the different contraceptive options; is reversible; and requires seeing a medical professional to insert and remove the device. Conversely, a vacuum pump is the only non-invasive option for rehabilitation post prostate cancer or to reduce curvature of the penis; and is used without clinical supervision, and ideally on a regular basis.

People who use vacuum pumps described how they received none-to-little in-person guidance on how the use the pump which made using it more intimidating.

- "Apparently, you’re meant to get a demonstration at a clinic but that didn’t happen for me, it just got dispensed at an ordinary chemist. It arrived with a DVD, which luckily, I had a DVD player for it. That was the last of my contact with a health professional in regard to using the pump."

Prostate cancer survivors felt that medical professionals should be explaining to their patients that regular use of the vacuum pump is important for rehabilitation but fail to do so because of the uncomfortable nature of the topic.

- "The manufacturers market the pump as a sexual performance device, and most people think the only reason to have an erection is for sex – but don’t realise that there’s a health management element to having an erection. Medical people know this but don’t have that conversation because of the uncomfortable conversations around erections."

Prostate cancer survivors also requested more information on the physical changes they may experience as a result of undergoing radiotherapy or a prostatectomy and the subsequent emotional impacts.

- "There’s too much focus on saving a life but not enough on what it’s like to live afterwards."

IUD users requested information on what to expect during the procedure; warning signs that something has gone wrong after the procedure; what to expect once the device has been inserted; and what the removal procedure entails. In particular it was suggested that any challenges around removing the device should be made clear to patients.

- "Mention more of the risks of what can happen over time; what can happen to your body and the coil over time as the years go by which could maybe make it a little bit more difficult to remove."

For the most part participants received their information from the internet beforehand; from friends and family; or from a leaflet and conversation with a clinician during their appointment.

- "When I had my first appointment, the nurse gave me a leaflet with every type of contraception, the pill, IUD, different types of pill, patch, the implants, condoms everything and it tells you how it works."

6. Diabetes, glucose monitoring and insulin delivery

Continuous Glucose Monitoring (CGM) sensors

Continuous glucose monitoring sensors (CGMs) are wearable devices that track an individual's glucose levels over time. It can help to manage diabetes by providing real-time information about glucose levels. Forty one people shared feedback on CGMs.

Most important features of the device or product

1. Health Management and Personal Safety:

The most commonly cited important feature is the ability to continuously monitor glucose levels and alert the user to changes in glucose levels. Respondents described a range of benefits from this functionality, namely:

Managing their health:

- "Keeps me alive - warning me of low or high BG levels (hypo or hyper)"

Preventing medical emergencies:

- "I can see at a glance my blood sugar levels, I am alerted to oncoming low and high levels so they can be treated before becoming problematic"

Supporting people to make better short-and-long-term decisions about food consumption and insulin dosing:

- "The fact it provides continuous glucose data to enable both immediate decision making (food, insulin) and longer term trend identification"

2. Physical Design and Comfort:

The second most commonly mentioned key feature was good design, making the devices easy to use and therefore reducing the negative impact on quality of life.

The lack of physical harm during the application process when compared to using a lancet:

- “The product not causing any harm upon insertion”; "Easy to apply, it generally does what it should"; "The easy insertion device".

The fact that using a CGM sensor does not require the user to draw blood was especially important for the interview participant with a learning disability, who had a fear of needles.

- "If you don’t like needles it’s not a good thing. So I tend to use my monitor just to test my ketones and use my continuous blood monitor using [brand device] which connects to me phone to monitor blood sugar levels"

Several users specifically highlighted comfort aspects:

  - “Small size and discreet design makes it comfortable to wear”
  - "Doesn't get in the way during daily activities"
  - "Comfortable to wear and easy to forget it's there"

3. Accuracy and Reliability:

Accuracy was highly valued, however a small number of respondents complained that they found their devices to not be accurate all of the time. This is explored in more detail below when discussing features that make the devices hard to use.

- "Once the sensor is inserted, I can pretty much rely on its accuracy"
- "The accuracy has been consistent and reliable for me over multiple sensors"
- "Readings match well with finger prick tests when I've double-checked"
- "The trend arrows are very accurate in predicting where my glucose is heading"

Features which make the device or product easy to use

1. Mobile App Integration and Digital Features:

Almost all respondents appreciated the seamless integration of smartphone apps, allowing them to easily read and interpret their readings and access additional functionality. The fact that this process is automated is especially valuable.

- "User friendly app, linked to phone, ease of use"
- "Can be programmed to sound alarms and alerts when necessary"

- "Blood glucose levels sent automatically to phone"
- "Readings sent every minute to my mobile phone via Bluetooth"
- “[blood glucose] readings instantly available on my phone and, through a third-party app, on my [smart] watch”

The interview participant with a learning disability explained how the fact that their CGM sensor and accompanying app was sending readings directly to their diabetes nurse meant that they were no longer required to keep a record of their blood sugar levels to bring to check-ups.

- "That’s the other good thing about having it on my phone – with the finger prick you had to make a note of blood levels but with the sensor you don’t because the results go straight to the hospital."

Features which make the device or product hard to use

While for the most part respondents spoke positively about their CGMs, several issues make the devices hard to use.

1. Accuracy and Calibration Issues

Several respondents encountered connectivity issues leading to a drop in accuracy. This can be due to the CGM sensor itself failing, or the need to keep the phone and sensor in close proximity.

- "Frequently not close enough to actual [blood glucose levels] to rely on for insulin dosing"
- "Too many sensors fail and are sometimes not sufficiently accurate"
- "Unable to calibrate readings, it has tendency to give me false low readings"
- "Sometimes the sensors fail (signal loss and false low readings)"
- “Needing to be in close proximity of your mobile phone or needing to carry it with you all the time”

2. Physical Application Challenges

A small number of practical issues make the devices inconvenient to use, such as the CGM sensor detaching from the skin, or the need to frequently replace the sensor.

- "The adhesive can become loose over time. Not enough testing has been done by the manufacturer to be certain that some activities may affect the sensor"

- “The sensor sometimes falls off but far less frequently now and can always be replaced.”

A few respondents mentioned having difficulty with applying the CGM sensor due to dexterity issues:

- “I don't have the strength now to unscrew the applicators”

- "Transmitter needs to be inserted into sensor which means I need help from another person"

3. Social and Lifestyle Impact

Some focus group participants also noted challenges related to their work environments and social activities. For instance, one participant mentioned, "[I'm] told I can't have my phone out at work," which affects their ability to monitor their devices effectively. Additionally, there are travel considerations, as noted by another respondent: "storage, when you go on holiday" needs special planning. One participant highlighted the risk that relying on access to a smartphone can create if they enter a diabetic coma in public.

- "The only thing that can be challenging with the sensor is if I’m away from home and had low blood and was going into diabetic coma no one could get into my phone because I’ve got a password on my phone."

4. Confusing data visualisations on the app

One interview participant with a learning disability found the use of graphs and different data visualisations to be confusing, preferring instead to only use the simple numerical display on the home page.

- "Sometimes I get a thing like that (line graph) which I don’t understand – so I tend to just keep it on the first bit of the app which gives me the number. I know 5 or below is under, over 10 is high. I’ve got this written down so I know."

Features that would encourage switching to an alternative device or product

1. Longer Lasting CGM Sensors:

While most said they are not considering switching, respondents predominantly mentioned wanting to have longer lasting sensors which could be used for longer than a fortnight. Some respondents were also interested in a sensor that is not single use.

- “Sensors only last for 14 days it would be nice if it lasted a month I would change to this”
- “Longer life i.e. one sensor lasting say a month rather than 14 or 15 days”
- “The product is single-use and requires changing every 14 days”

2. Integrated Monitor and Insulin Pump Device:

Some respondents said they had already switched to an integrated monitor and insulin pump device:

- “Integration with an insulin pump - which is why I have now changed to the hybrid closed loop system”

3. Dual monitoring functionality

One participant said that they would switch to an alternative monitor if it was able to monitor their blood sugar and ketone levels simultaneously, removing the need to use testing strips altogether.

Reusable insulin pens

Reusable insulin pens are used to treat diabetes by delivering insulin into the body. Eighteen people shared insights on these.

Most important features of the device or product

Respondents consistently emphasised the importance of features that enhance accuracy of dosage, provide dose verification and time of last administration, and integrate with digital health platforms.

- “Solidly made, accurate, does half units and has a dose memory on top.”
- “The latest models record insulin delivery which can be downloaded to the phone App”
- “Being able to upload dose details to [adjoining brand app] and 1/2 unit capability”
- “Storage of time and amount of last dose, downloadable to CGM records”.

Features which make the device or product easy to use

1. Physical Design and Portability:

Respondents appreciated devices that were well designed and easy to use. In particular, the ease with which the plunger is actioned was highly praised.

- "Convenient to use and to carry"
- "Portable, half unit delivery, smooth action on depressing the plunger"
- “Easy to hold, when you press the plunger you don’t have to keep your thumb pressed down”

2. Simple Operation:

Ease of basic functions was highlighted:

- "Easy to insert a new cartridge"
- "Clear dial”

Features which make the device or product hard to use

Very few respondents had anything to say here, the few comments related to inconsistent communication between the insulin pens and the brand app; and the physical design of the carrying case.

- “Communication between pen and [adjoining brand app] very hit and miss”
- “Occasional cracked cartridge when stored or in use”
- “Silly little elastic pen holder that’s too tight to get the pen into in the case.”

Features that would encourage switching to an alternative device or product

Respondents would consider switching if an alternative device had the ability to automatically record insulin administration to an app.

- “Record of doses and time administered. Diabetes becomes a habit and there have been many times over the years that I can’t remember whether I have taken a dose as it’s so automatic to do it”
- “Pens which link to my sensor phone app to allow dosage registering.”

Detection Products and Lancets

Lancets are small, needle-like medical devices, used to prick the skin in order to collect a few drops of blood on a paper testing strip, allowing an individual to test their blood sugar levels using a blood glucose meter. The 30 people who shared using detection products and lancets listed a wide variety of different device types and manufacturers. Respondents listed brand names less often with detection products and lancets compared to other diabetes and glucose monitoring devices and products in the survey. Respondents often did not differentiate between the individual components but rather gave feedback on the testing kit (detection strips, lancets and blood glucose monitors) as a whole with the various components used in conjunction with each other.

Most important features of the device or product

The most important features of the devices identified by respondents and participants were mainly features which made them convenient and fast to use, limiting disruption to daily life. Examples include:

1. Dispensing of Test Strips:

- “Test strips are in a cartridge which moves on automatically after each test. This is a lot easier than having to get out a strip from a pot, which can be fiddly with limited dexterity.”
- “Individually wrapped strips means they remain sterile until use, including inserting into monitor as I only remove lower half when ready to put the blood on”

2. Need for Small Blood Sample:

- “Quick and easy to use, requires little blood”

3. Efficacy of Lancet Technology:

- “Easily produces a sterile needle each time”
- “That it pierced the skin first time”

4. Device Portability:

- “Compact device complete with case to carry all its associated accessories”

Features which make the device or product easy to use

When respondents described features which make the devices easy to use, they often described features which make it simple to collect and read the results from their blood glucose meters. This includes the size of the display on the device itself, or the ability to interpret the data once connected to an app:

- “Big display”
- “Easy to read display and compact design"
- “The display is big enough to see without glasses which is great in the night if needed and when swimming”
- “Big screen, connectivity to a mobile and integration with third party apps”
- “Provides a Bluetooth link to allow 3rd party apps to receive (and subsequently interpret) data”

Features which make the device or product hard to use

In general respondents shared positive comments about their detection products and lancets, and the way these products work together with their blood glucose meters.

The most common complaints involved the process of extracting a blood sample and then applying that to the testing strips:

- “Can be awkward to get the blood drop on to the correct place on the continuous strip in the cassette”
- “Finger pricks are less convenient than using CGM”
- “Hard to get enough blood onto the strip, individual wrapping is hard to remove”
- “Given a very short time to put blood on strip after inserting strip to monitor.”
- “Fiddly for those like me with fat fingers.”

Features that would encourage switching to an alternative device or product

Features that would encourage respondents to switch to an alternative device included: a means of reducing the pain and burden of drawing blood; improved readability of the meters; and better packaging of strips.

- “The only thing I would change is a smaller needle as the constant monitoring makes my fingers really painful as I suffer with fibromyalgia the pain is magnified.”

- “The meter is very good, the only thing I'd change about it is to have a light that shines along the test strip so that it can be used at night more easily without needing to turn a light on.”

- “More strips in each box, 10 don't last long”

- “Boxes dispensed with very short expiry dates, meaning we are wasting lots of strips”

Diabetes, glucose monitoring and insulin delivery device information needs

Continuous Glucose Monitoring sensors (CGMs) are some of the most technically advanced medical devices featured on Part IX of the Drug Tariff. Understanding and managing blood glucose levels can also be complex. This means that people want clear, consistent information about their devices and how to use them. This is especially the case for those who are using CGM sensors that are compatible with a mobile app as a receiver. Having glucose information on a mobile phone provides additional functionality to using a self-contained receiver device (such as data sharing and follow capacity) but creates another layer of complexity. To overcome this, people requested comprehensive demonstrations on how to insert the sensors; how to connect their CGM and set up accounts; and how to interpret their blood glucose readings.

- "It would have helped to have a diabetes specialist nurse to show me how to insert the sensor"

While many research participants reported they had received adequate training, those who did not felt this was due to a lack of capacity amongst clinicians.

- "Healthcare professionals often lack time and training to properly explain devices."

- "Healthcare professionals have so little time to spend going through the ins and outs of all the devices that are available."

Respondents and participants also wanted practical information on how to minimise the impact of diabetes on their lifestyle, such as considerations when travelling abroad.

Accessible information needs

The VCSE organisations that represent the needs of those who fed into this project during the scoping phase made it clear that any information designed to improve awareness of or improve the ability to use a medical device must take into consideration diverse communication needs. The Accessible Information Standard provides guidance on meeting the information and communication support needs of patients, service users, carers and parents with a disability, impairment or sensory loss and was flagged as a useful resource for device manufacturers.

The interview participant with a learning disability mentioned that one device their diabetes nurse offered them did not come with Easy Read instructions and therefore they were ultimately prescribed an alternative device with Easy Read instructions. This indicates that providing information in an accessible format will and should influence prescribing decisions.

- "So we looked at [one CGM] but there was no Easy Read that went with it. But the [alternative CGM] did, so my mum and nurse suggested we go with [the alternative CGM] as they have the Easy Read which the nurse put on my phone."

7. Oral, dental, ear, eye and nasal care

As part of our work around oral, dental, ear, eye and nasal care, we predominantly explored respondents' thoughts on eye drops, ear care, and oral care.

Eye drops

If eye drops achieve its intended purpose by physical means such as lubricating, and any medicinal ingredient plays a supporting role, they are usually classified as medical devices. If the main effect of the eye drops relies on a pharmacological, immunological or metabolic action then it's a medicinal product. Eye drops are topical, meaning you put them directly on the surface of your eyes.

It should be noted that whist the majority of eye drops fed back on are not featured on Part IX of the Drug Tariff, we have included the insights shared by respondents as the feedback can be applied to eye drops that are featured on the Drug Tariff.

Of the 11 survey participants who shared insights on eye drops, 7 shared further details on the brand of their eye drops.

Key features valued most by participants

Based on responses, respondents value the following key features of eye drops:

1. Appropriate Design and Usability:

- "The container is large enough to hold in arthritic hands"
- "Easy to carry in pocket or handbag"
- "Convenient single dose vials"

2. Treatment Effectiveness:

- "Eases dry eye condition"
- "Appears to stop increase pressure"

Features which make the device or product easy to use

Respondents described a handful of beneficial features regarding eye drops, which make the product easier to use.

1. Ease of Administration:

- "The bottle is flexible enough to facilitate administration of the eyedrops"
- "Easy to squirt"

2 Self-contained Design:

- "It is all self-contained"

Features which make the device or product hard to use

Several challenges were identified by used which make the product harder to use.

1. Difficulty of Extraction:

- "The plastic of the bottle that you squeeze to release the drops is quite hard and you end up having to squeeze the bottle so hard, you can get more than one drop in the eyes"
- "Plastic vials too hard, making it difficult to administer drops. Twisting off the caps of these single dose vials leaves a sharp edge which could cause injury"

2. Self-administration Difficulties:

- "Putting drops in myself"
- "Hard to put drops in"
- "Difficult to apply correctly"
- "Hard to use tough to squeeze drops"

Features that would encourage switching to an alternative device or product

The key feature respondents said would make them consider switching product was ease of application. This included a better bottle design with an improved delivery system, and broadly easier application methods.

- "Easier method of putting in drops"
- "A softer plastic bottle to give more control over the administration of the eye drops"
- "Better delivery system"

> One interview participant requested an eye drop bottle that accurately dispenses a pre-determined number of eye drops to ensure the right dose is given." I just wish sometimes you could tell if you had the right amount of drops, it dispenses the right amount automatically like the Flash floor cleaner – so you know you’ve got the right amount in."

Oral care

Dry mouth, also known as xerostomia, can be a result of side effects from some medications, oral thrush or cancer treatment. Examples include dry mouth products such as mouthwashes, and oral film forming agents. 3 respondents shared insights regarding oral care, all of which were regarding mouthwash.

Key features valued most by participants

Respondents valued the effectiveness and taste of the products:

- "That it works and I don't have to keep applying"
- "It provides the moisture in my mouth to overcome dryness"
- "Tastes lovely and actually works"

Features that would encourage switching to an alternative device or product

The cap was identified by one user as a difficult feature, and they noted they would switch for a flip lid. Another respondent shared that the product is not always easily available in pharmacies, and they would switch if a prescription for an alternative product was more accessible on the NHS.

Oral, ear and eye care patient information needs

People only requested practical information on how to use their devices, although it should be noted that the overall response rate to these products in the survey was relatively low.

- Instructions for proper usage and administration - "A good information leaflet on correct usage"
- Hygiene and contamination prevention - "Tips on keeping the bottle clean and how to avoid contamination (not touching the tip to the eye or skin)"
- Safety warnings - particularly regarding single-use vials which can have "sharp edge which could cause injury

Accessible information needs

The VCSE organisations that represent the needs of patients who fed into this project during the scoping phase made it clear that any information designed to improve awareness of or improve the ability to use a medical device must take into consideration diverse communication needs. The Accessible Information Standard provides guidance on meeting the information and communication support needs of patients, service users, carers and parents with a disability, impairment or sensory loss and was flagged as a useful resource for device manufacturers.

Recommendations and next steps

The recommendations generated from this research are designed to ensure that people have access to the medical devices they need to live as fully and independently as possible. There are 3 audiences for these recommendations and next steps:

- DHSC
- device manufacturers
- people who make decisions about which medical devices from Part IX of the Drug Tariff will be prescribed

Planned next steps for DHSC

In response to the findings of this report, DHSC plans to:

- conduct a survey to see what additional support local decision makers may need to make decisions around which devices to make available in their area, for example, by making an easy-to-digest resource on what matters to patients about devices. This would help reduce unwarranted regional variation in access to devices.
- ensure a wide range of choices of device are available through Part IX of the Drug Tariff.
- incentivise manufacturers to reduce inequalities experienced by device users by introducing a 'value add' component to the Quality Evaluation Framework for Part IX of the Drug Tariff. This rewards manufacturers that provide evidence that their product is designed to address health inequalities through provision of case studies addressing access and/or usage issues for specific populations.
- design future patient engagement on medical devices in a way that maximises the opportunity for groups experiencing inequalities to be heard and that enables meaningful participation.
- explore if improvements can be made to ensure information on allergens and ingredients is easy to find for medical device users and people making prescribing decisions.
- improve information available to patients on the medical devices available and the prescribing and dispensing process.

- ensure patient voice is threaded through the Part IX Drug Tariff Independent Assessment Panels.

Recommendations for device manufacturers

In response to this report, device manufacturers should:

- consider how to develop a stronger understanding of what matters to device users (beyond their immediate health and care needs) and incorporate this into device design and re-design, including considerations such as portability, aesthetics, independence, comfort, fit and more.

- work with people experiencing inequalities to co-design improvements and/or a more varied device offer.

- commission accessibility testing of existing and new devices with disabled people, for example, people with sight loss and people with limited dexterity. This includes ensuring that packaging is safe as possible for people with a sensory impairment.

Recommendations for people who make decisions about which medical devices will be prescribed

- ICBs and those involved in making formularies of recommended devices for prescribing should take into account the wider social, sensory and emotional needs of device users when deciding which medical devices to make available. This should include designing patient input to include consideration of groups experiencing inequalities. This might result in certain medical devices with added features being made available to people with specific requirements to reduce health inequalities.

- Consider how any information provided to device users can help to raise awareness of and signpost people towards peer support around devices.

- Ensure they are meeting the needs of groups experiencing inequalities and complying with the Equality Act 2010 and Public Sector Equality Duty when making decisions about which devices are made available for prescription locally.

Not all medical devices are on formularies and so nurse prescribers and Dispensing Appliance Contractors influencing prescriptions should:

- ensure patients always receive information on choices available to them and information on any rights they have to exercise these choices.

- ensure that aesthetics and patient choice are factored into prescription decision-making.

Resources from the Patient Safety Commissioner

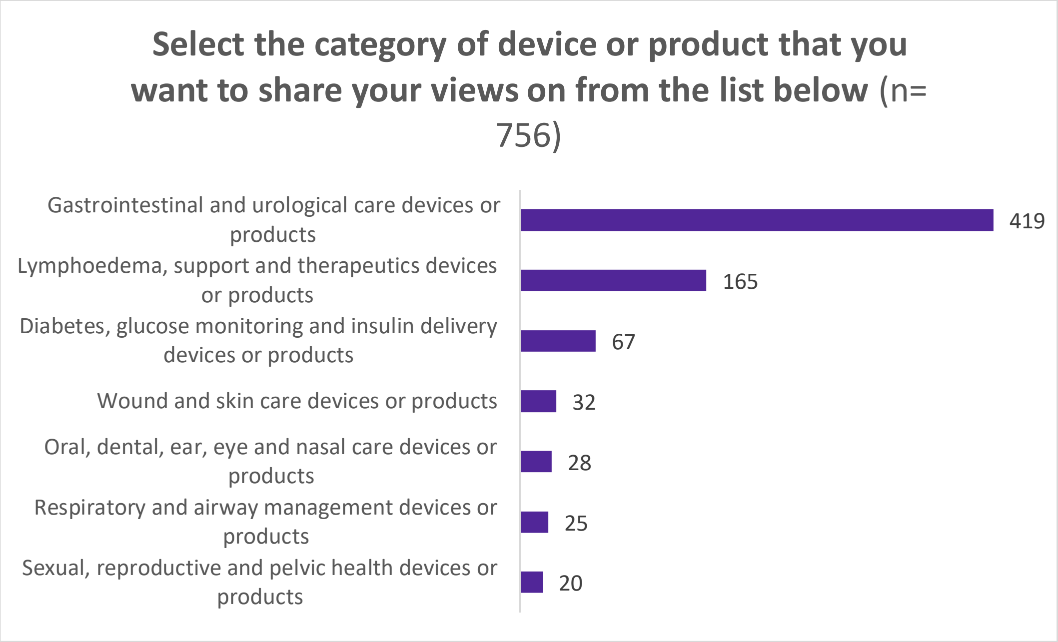
In addition to these recommendations for specific audiences, National Voices and DHSC recommend that anyone involved in supporting access to medical devices should refer to the Patient Safety Commissioner's report The Safety Gap and aim for alignment with the Patient Safety Commissioner's Patient Safety Principles.

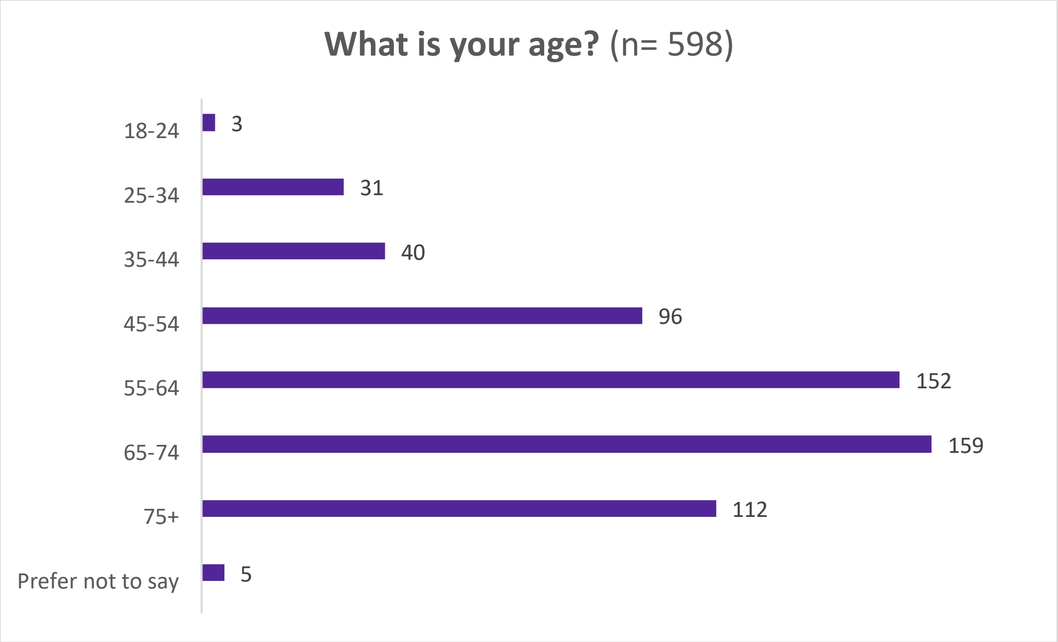
Appendices

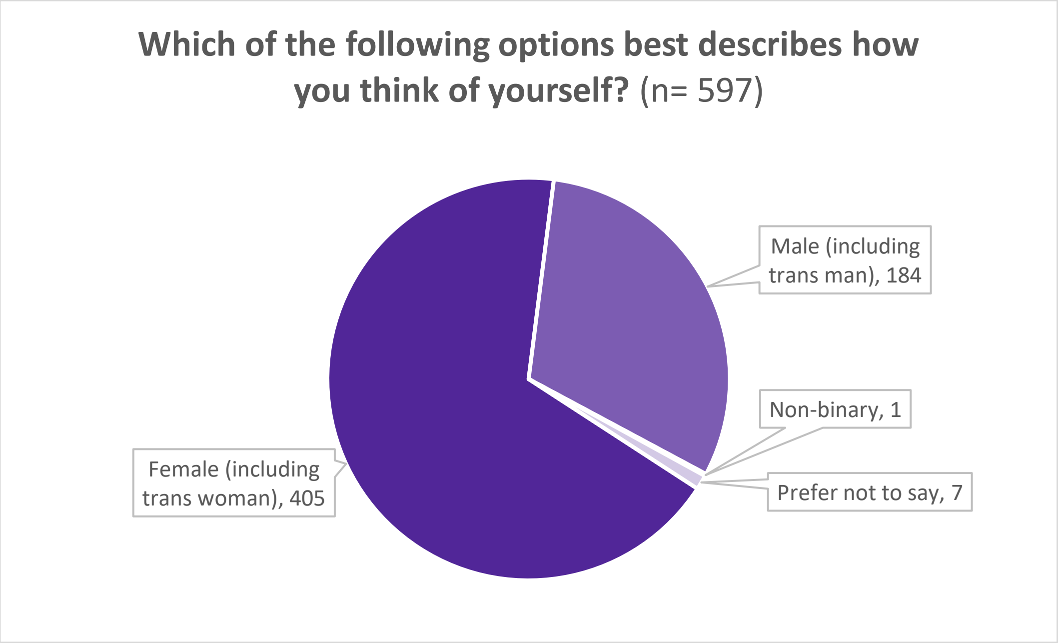
Appendix A

Profiles of survey respondents.

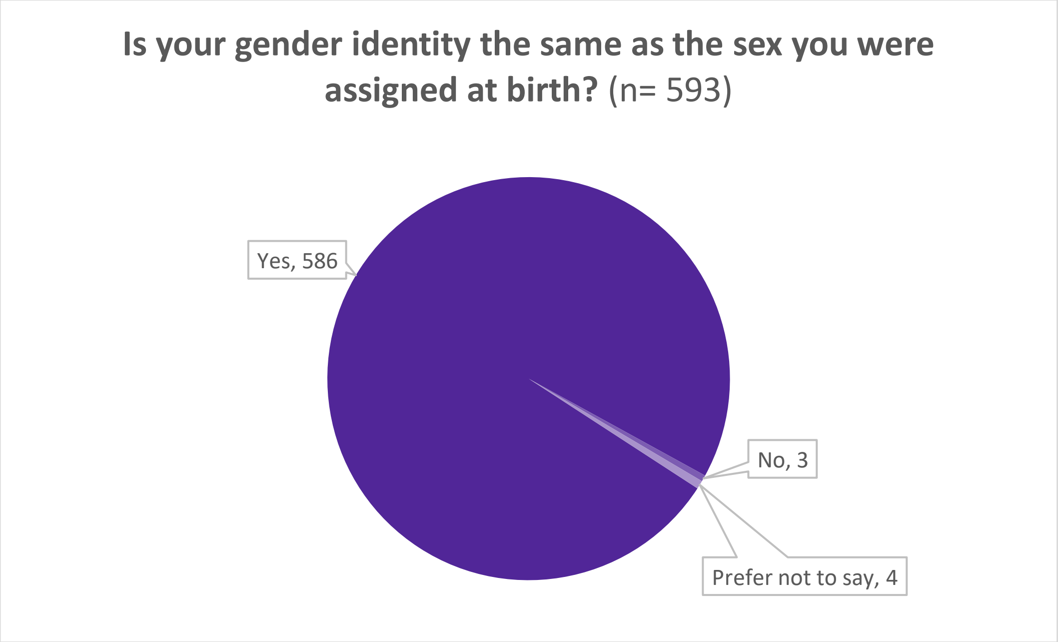
Select the category of device or product that you want to share your views on from the list below (n=756)



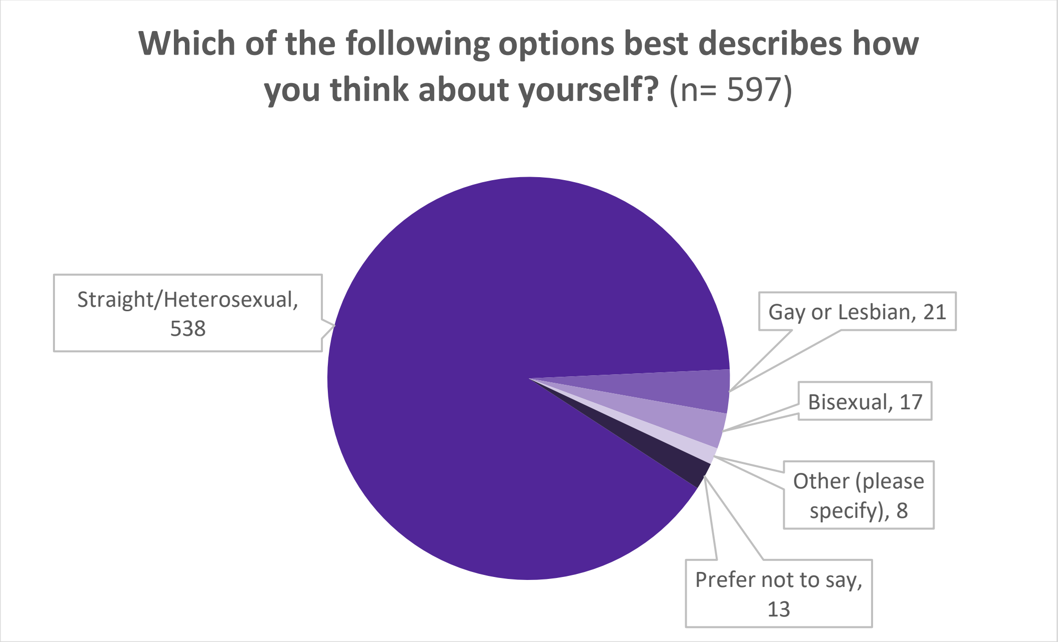


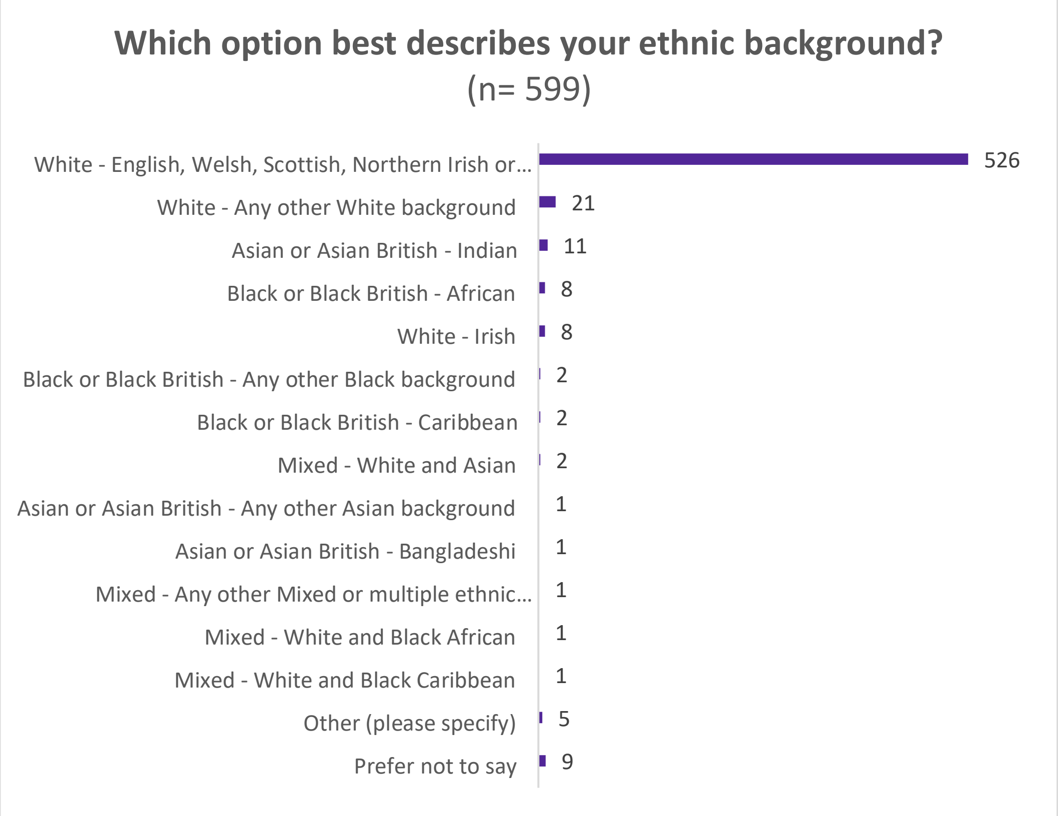


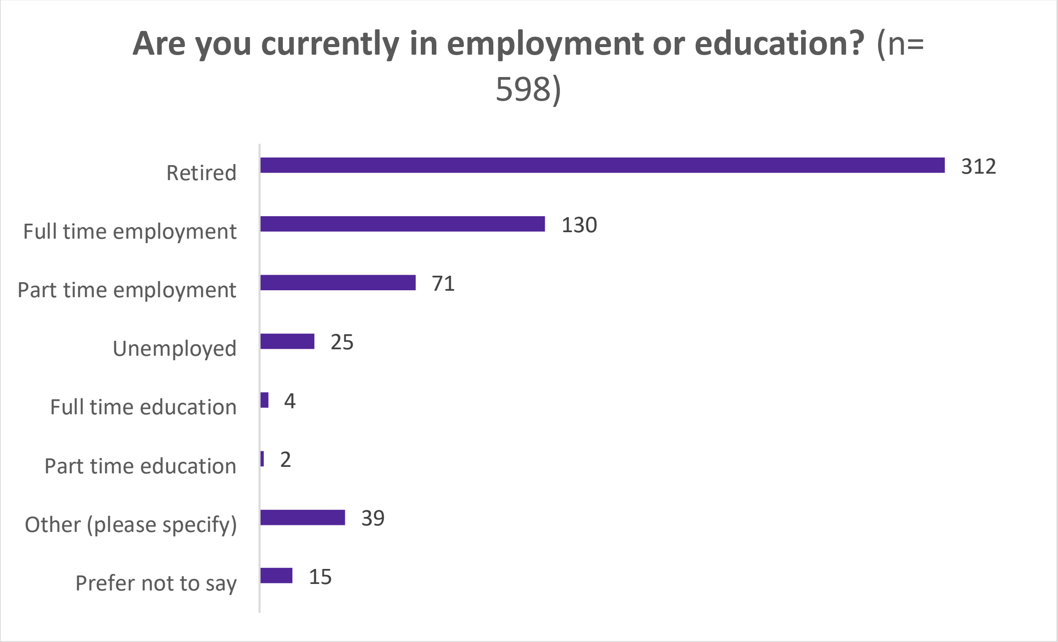
Which of the following options best describes how you think of yourself? (n= 597)



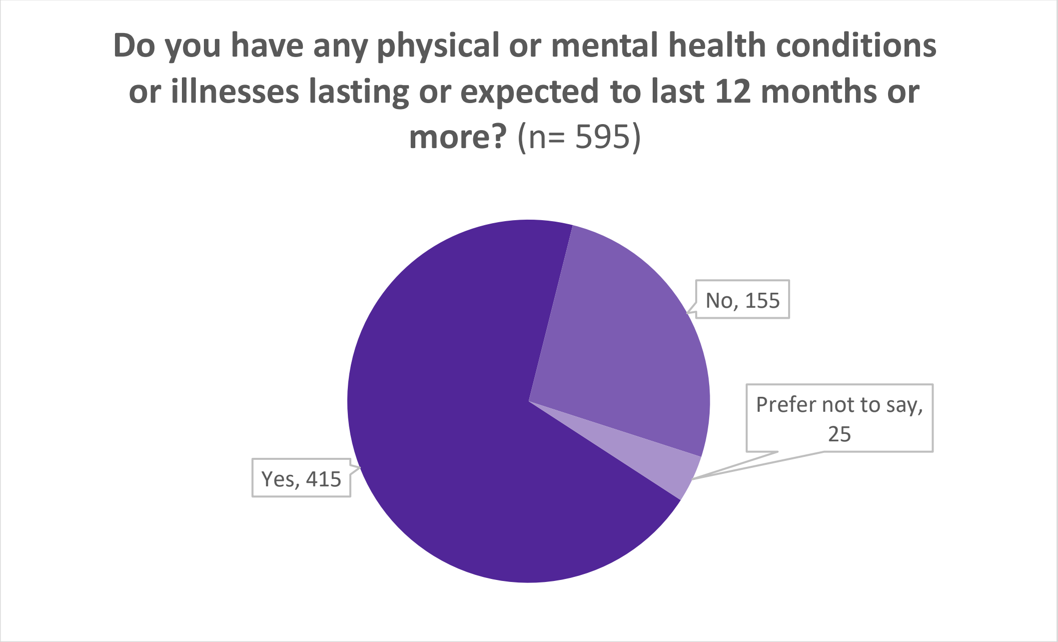
Is your gender identity the same as the sex you were assigned at birth? (n= 593)

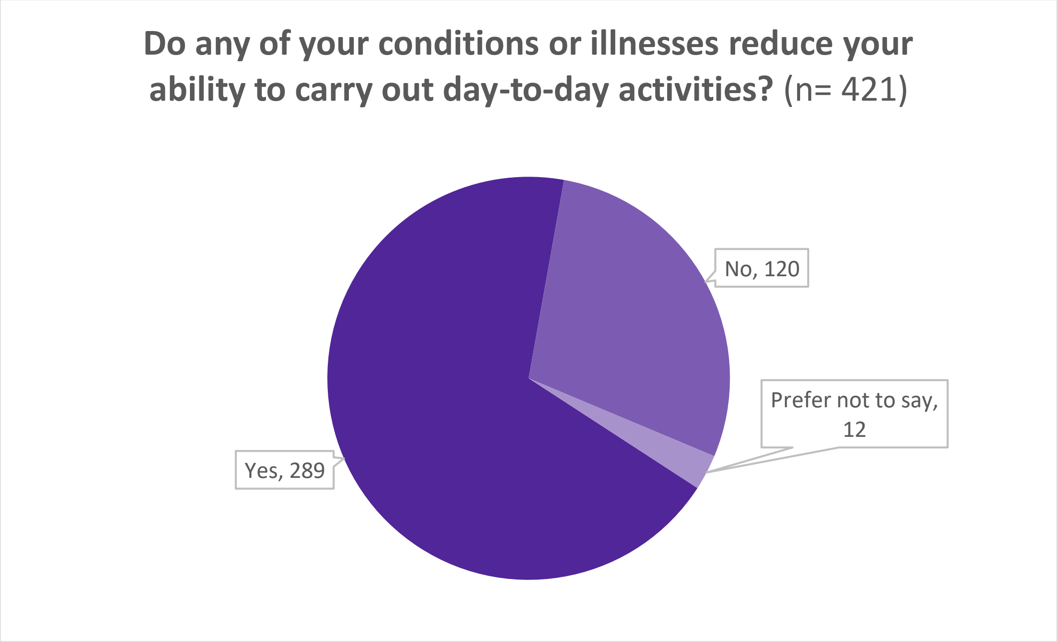

Which of the following options best describes how you think about yourself? (n= 597)
Straight/Heterosexual, 538
Gay or Lesbian, 21
Bisexual, 17
Other (please specify), 8
Prefer not to say, 13


Which option best describes your ethnic background? (n= 599)
White - English, Welsh, Scottish, Northern Irish or…
526
White - Any other White background
21
Asian or Asian British - Indian
11
Black or Black British - African
8
White - Irish
8
Black or Black British - Any other Black background
2
Black or Black British - Caribbean
2
Mixed - White and Asian
2
Asian or Asian British - Any other Asian background
1
Asian or Asian British - Bangladeshi
1
Mixed - Any other Mixed or multiple ethnic…
1
Mixed - White and Black African
1
Mixed - White and Black Caribbean
1
Other (please specify)
5
Prefer not to say
9



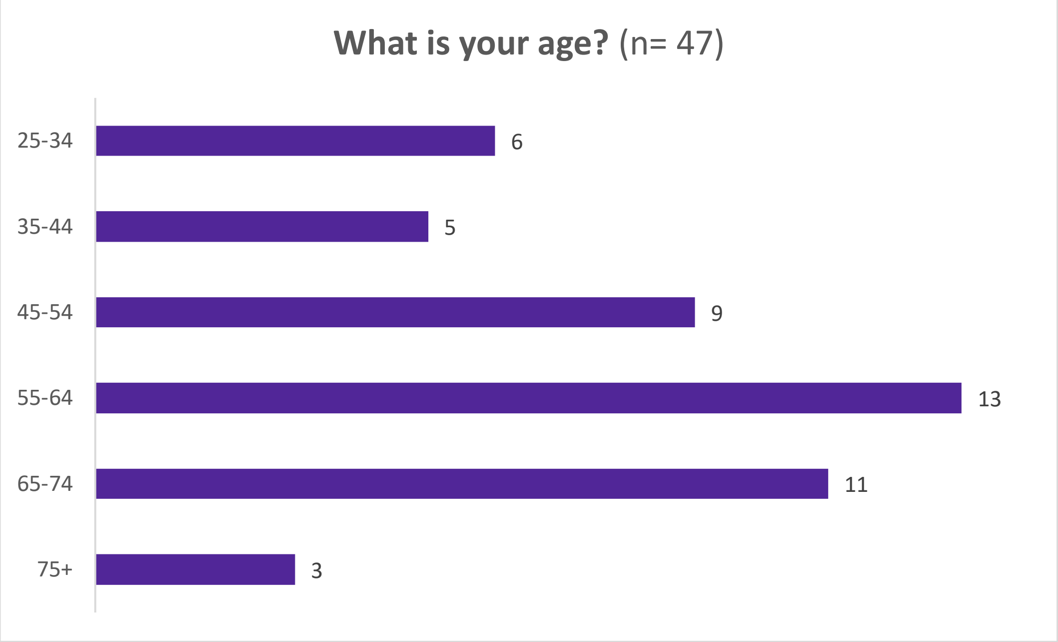
*25 of the people who responded 'other' are not in work due to a health condition or disability. Five people are self-employed. The remaining are not in employment but have caring responsibilities and/or are unemployed.

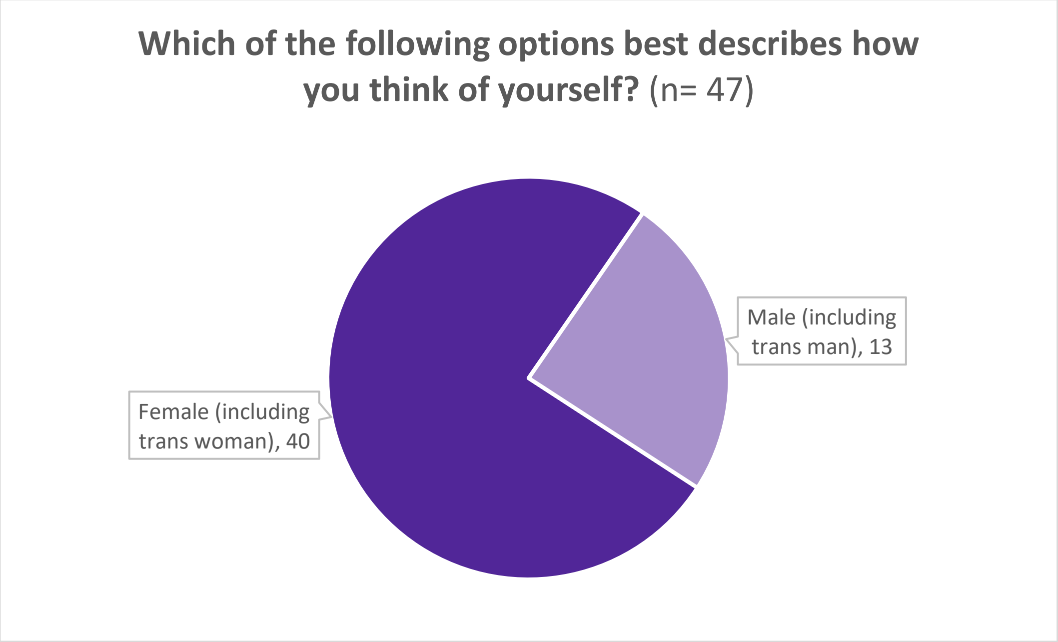


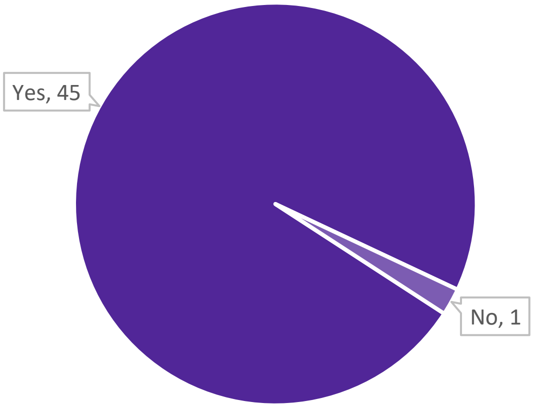

Do any of your conditions or illnesses reduce your ability to carry out day-to-day activities? (n= 421)
No, 120
Prefer not to say, 12
Yes, 289

Appendix B

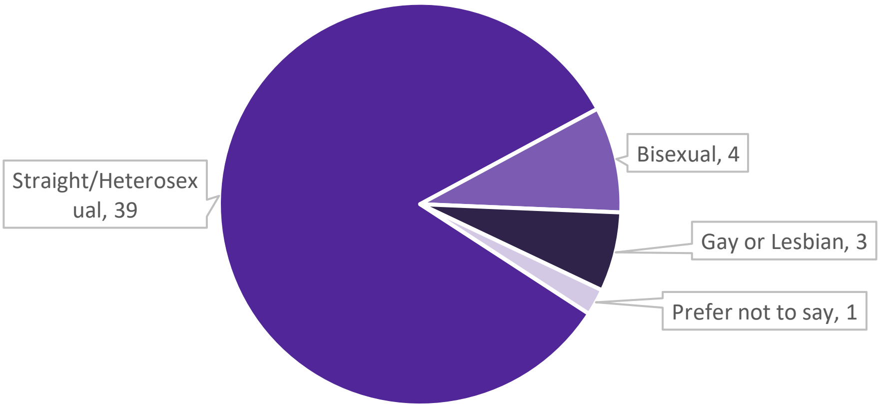
Profiles of focus group and interview participants



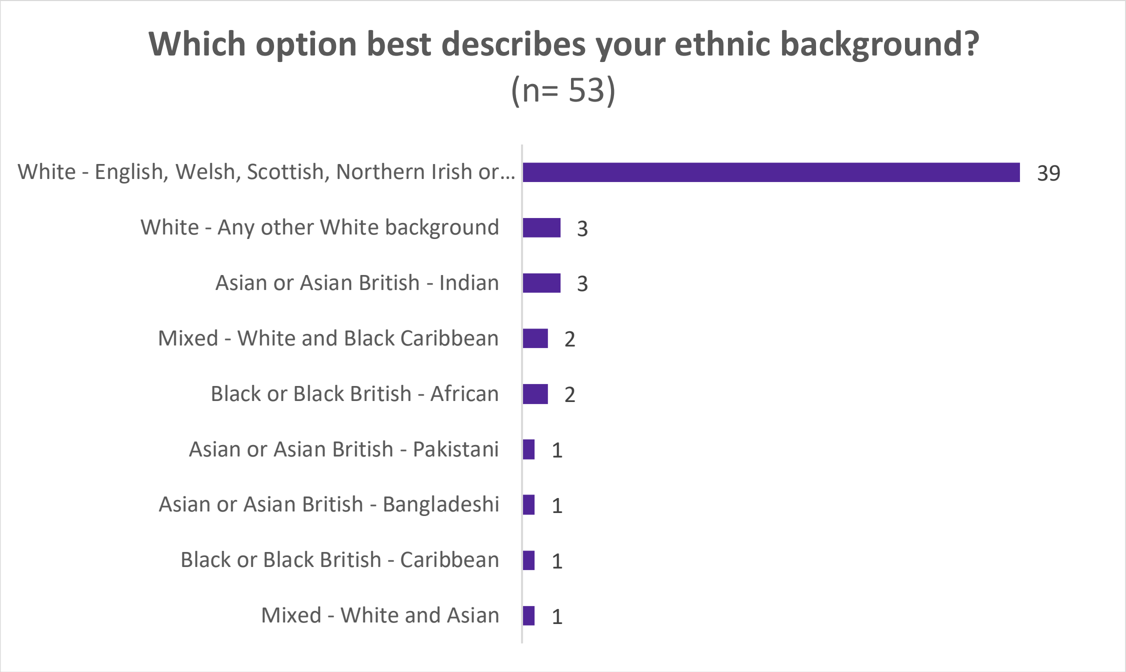


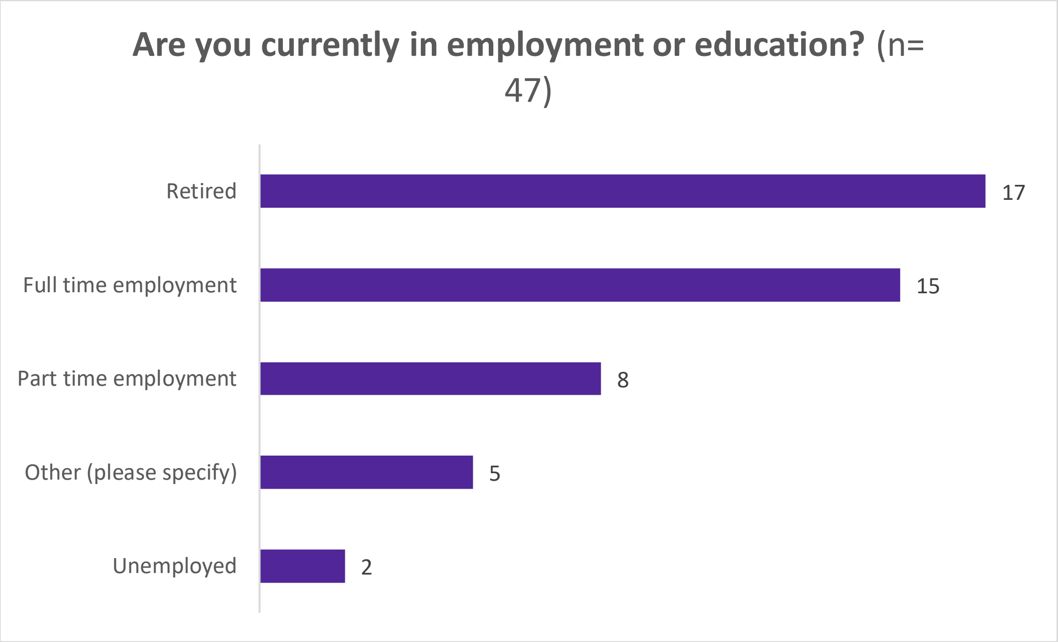


Is your gender identity the same as the sex you were assigned at birth? (n= 46)

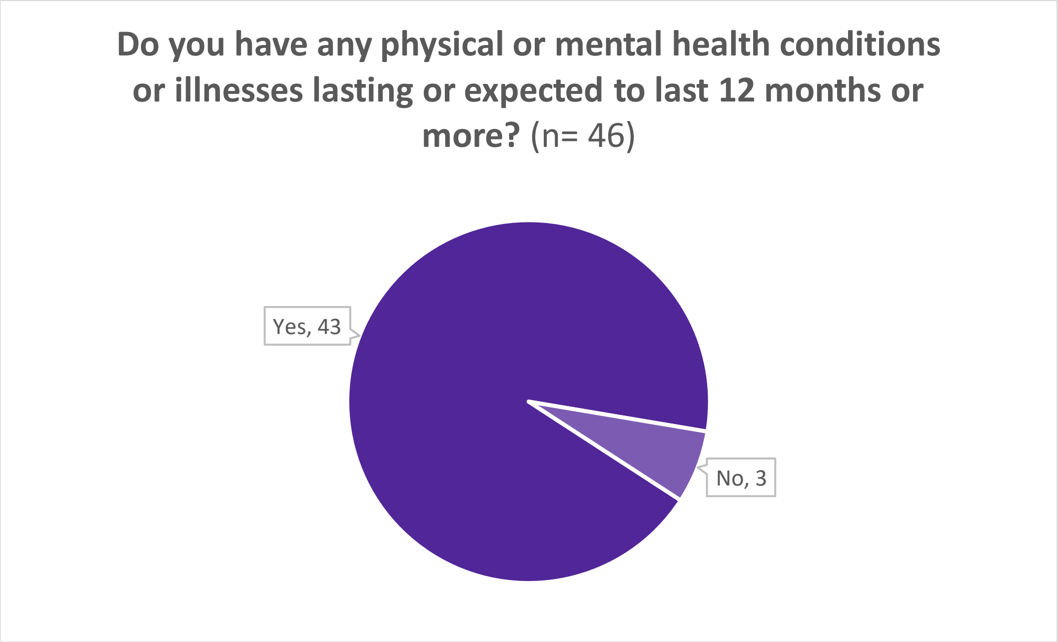


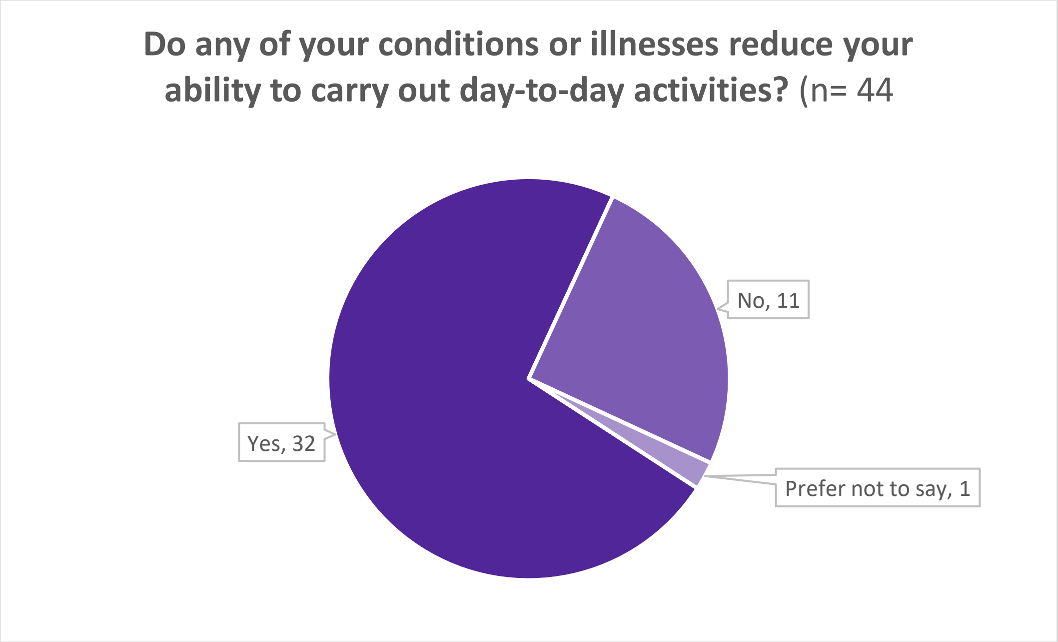
Which of the following options best describes how you think about yourself? (n= 47)





*4 of the people who responded 'other' are not in work due to a health condition or disability. One is self-employed.


Do you have any physical or mental health conditions or illnesses lasting or expected to last 12 months or more? (n= 46)
Yes, 43
No, 3


Do any of your conditions or illnesses reduce your ability to carry out day-to-day activities? (n= 44
No, 11
Yes, 32
Prefer not to say, 1