Healthcare Improvement Scotland

Gathering Views Report on Implanted Medical Devices

Patient views about information relating to the implanted medical devices used in their care

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Section 1: Executive summary

The Medical Devices and Legislation Unit (MDLU) within the Scottish Government has developed Scotland's first Medical Devices Policy Framework and Action Plan. The policy Framework's purpose is to take forward policies that aim to improve patient safety and outcomes in the context of medical device use in Scotland. Furthermore, the Framework seeks to enhance the availability of medical device information and system wide data to empower patients in making informed choices about their treatment and care.

The Scottish Government commissioned Healthcare Improvement Scotland to undertake a Gathering Views exercise to support the implementation of the Medical Devices Policy Framework, and to deepen policy insight into people's experiences of living with an implanted medical device[1]. Since the commissioning of this work, the Framework and initial Action Plan have been developed by Scottish Government, and this Gathering Views work, which was already underway, was found to align in particular with Theme 3: Improving the information available to patients about medical devices used in their care.

The Gathering Views exercise was undertaken during July and August 2023 across all NHS board areas in Scotland. Individual interviews took place via telephone calls, video calls and in face-to-face settings. The work involved gathering people's views on their experience of living with an implanted medical device. This report outlines the feedback from participants as well as the key areas they highlight for improvement. To note, during these interviews, participants were asked to recall details and relied on their memory to answer the interview questions. Therefore, the findings reflect the participants' perceptions at the time and their narratives at the time of interview.

A total of 65 people from across Scotland took part in this exercise over an eight-week period. Interviews were organised through engagement offices using links through local contacts, NHS services and third sector organisations. A mix of participants from all demographics were sought, collecting views from urban, rural and island communities and a diverse range of individuals. Equality monitoring information about the participants is provided in Appendix 3. The participants had a range of devices, and many had multiple devices, however the participants' devices do not reflect the full range of implanted medical devices.

Key findings from this work include:

- **Information before the procedure**: For a large proportion of their devices, participants got information from their medical team before the procedure, covering many important elements. However, many didn't receive all the aspects of information, noticed

[1] The definition of an "Implanted Medical Device" used for this Gathering Views exercise means anything embedded into the body to be used in a patient's diagnosis, treatment, or care. These may also be known as "implants", and can include, for example, pacemakers or joint replacements. Devices are also referred to as "implantable" in the Medical Devices Policy Framework and Action Plan, and in some places in this report.

inconsistencies in the information they received, and had further information needs, for example the device type and longevity, and around the procedure, recovery and potential risks.

- **Setting expectations, understanding risks, and providing consent**: For many of their devices, participants had enough information to help set their expectations, understand benefits and risks, and provide fully informed consent. However, for some of their devices, this was not the case, and participants discussed inconsistencies and further information needs.
- **Information after the procedure**: for over half of their devices, participants said they would have wanted to get further information from their medical team after getting the device. For most of their devices, participants did receive post-procedure information from their medical team, for example who to contact if there were issues. For half of their devices, participants said they got information about the actual device type and for over a third of their devices, participants also got an implant card. However, for some of their devices, participants did not get any information after the procedure or there were issues with the information they did receive.
- **Feedback processes**: For half of their devices, participants said they had not been asked to provide feedback about their experience, and participants had only been asked to provide feedback for around a third of their devices. For just under half of their devices, participants said they did not know how to provide feedback.
- **Further information sources**: For over half of their devices, participants were not signposted to further information sources by their medical team and did not have a discussion about this. For more than half of their devices, participants did look for further information, from a range of sources and in different ways.
- **Multiple devices**: People who receive one implanted medical device as part of their care may be more likely to receive further devices, highlighting the need to consider this aspect when planning and delivering care and support for these patients, including when considering their information needs.
- **Tracking system**: Participants have positive views about a potential implanted medical device tracking system and can see a range of benefits for both staff and patients, including enhanced communication and increased access to information.
- **Priorities and key considerations**: priorities and key considerations discussed by participants included:
    - the importance of addressing information needs in shaping the overall patient experience, with participants often linking their overall positive experience with having satisfactory information
    - getting the right information, the right way, and adopting a person-centred approach so information suits people's needs and preferences
    - ensuring information is provided and available through a range of methods and avenues
    - considering the role of people's "independent research" and patient initiative

- existing differences and inconsistencies in information provided between different procedures, which have significant impact on the participant experience and could lead to unequal outcomes for patients, for example between different devices, between initial and replacement procedures, or between less and more high-risk procedures, and
- the perceived impact of the COVID-19 pandemic.

Findings and conclusions are presented in full in this report.

Recommendations are presented in summary in this executive summary. Further details around the recommendations and specific aspects to consider are provided in Section 5.

For Scottish Government

Recommendation 1: Consider the findings in this report to guide the implementation of Scotland's first Medical Devices Policy Framework, and work towards addressing health inequalities and barriers which may be more prominent among certain groups of the population.

Recommendation 2: Continue to work on the development and implementation of an electronic implanted medical device tracking system through the NHS Scotland Scan for Safety Programme.

Recommendation 3: Consider how to support NHS boards on a national, 'Once for Scotland' basis to provide all patients receiving an implantable medical device with the right information, at the right time, in the right way, both before and after receiving their implant, based on their needs and preferences. Work towards improving consistency in the information provided to patients around their implanted medical devices and related procedures and processes.

For wider consideration

Recommendation 4: Consider how NHS boards and local organisations can best address patient information needs and ensure that information processes around implanted medical devices are person-centred.

Recommendation 5: Consider how feedback processes can be improved within the patient journey of people with implanted medical devices, and how routine feedback may help ensure a person-centred approach in addressing patients' information needs.

Recommendation 6: Consider further exploring the barriers to patients fulfilling their information needs around implanted medical devices.

Section 2: Background

Healthcare Improvement Scotland aims to improve health and care for the people of Scotland. Our vision is a health and care system where:

- people can access safe, effective, good quality, person-centred care when they need it
- services are informed by the people of Scotland and based on evidence that works, and
- those delivering care have support to innovate and improve.

Healthcare Improvement Scotland – Community Engagement & System Redesign is committed to supporting the engagement of people and communities in the development and design of health and social care services.

The Medical Devices and Legislation Unit (MDLU) within the Scottish Government has developed Scotland's first-ever Medical Devices Policy Framework and Action Plan. The Framework's purpose is to take forward policies that aim to improve patient safety and outcomes in the context of medical device use in Scotland. Furthermore, the Framework seeks to enhance the availability of medical device information and system wide data to empower patients in making informed choices about their treatment and care.

In January 2023, the Scottish Government commissioned us to undertake a Gathering Views exercise. This work aims to build on the findings from earlier patient insights work taken forward by the MDLU, including a literature review carried out by Healthcare Improvement Scotland in 2022 which highlighted that information on patient views around implantable devices in Scotland is sparse. The feedback from this Gathering Views exercise will be used to support the implementation of Scotland's first Medical Devices Policy Framework, and to deepen policy insight into people's experiences of living with an implanted medical device[2], in particular around Theme 3: Improving the information available to patients about medical devices used in their care.

For this exercise, we engaged with 65 members of the public, who:

- have, or have recently had in the past, one or more implanted medical devices (contraceptive devices are not included in this work)
- got the device from 2018 onwards
- got the device through NHSScotland, not privately nor abroad, and
- got the device through planned care, not as part of urgent care.

[2] The definition of an "Implanted Medical Device" used for this Gathering Views exercise means anything embedded into the body to be used in a patient's diagnosis, treatment, or care. These may also be known as "implants", and can include, for example, pacemakers or joint replacements. Devices are also referred to as "implantable" in the Medical Devices Policy Framework and Action Plan, and in some places in this report.

Participants were considered eligible if they had enough time before getting their device to receive information and have discussions with their medical team, which was a key focus of this engagement.

To build upon the Scottish Government's existing knowledge base, we conducted targeted engagement within a diverse demographic across Scotland, including:

- both rural and urban communities
- all sexes and genders
- a broad spectrum of age groups
- diverse religions and cultural backgrounds
- people living with a disability, and
- low-income households.

While sincere efforts were made to engage with people from different religions and backgrounds, we acknowledge the limitations of our engagement in terms of numbers from LGBT+ communities and from minority ethnic backgrounds and religions. We remain committed to ensuring inclusivity in future engagement initiatives.

We focused on engaging with people who had been living with their implanted medical device for at least five years, including cases where the device was subsequently removed. Additionally, people with multiple devices were included in the exercise. Details on the range of devices that participants had are presented in Section 4.

Section 3: Approach

Healthcare Improvement Scotland – Community Engagement & System Redesign has developed an approach called Gathering Views[3]. This aims to gather lived experience views on specific subject areas to inform the development of health and care policy and services.

Gathering Views exercises are not undertaken as formal research, nor as formal public consultation. The engagement is intended to supplement work undertaken by Scottish Government or other commissioners, consider new or different ideas, and make recommendations based on the findings. Further information on our Gathering Views processes can be found on our webpage.

The question set (Appendix 1) was developed to help us to gather people's views, insights, and experiences about living with an implanted medical device. A total of thirteen questions, with supplementary questions, were presented.

An information sheet was provided for the participants as well as a consent form to take part in the work, and all participants provided written or verbal consent in advance of the interview (Appendix 2).

Equality monitoring questions were in the form of a questionnaire (Appendix 3). Participants could complete the survey either before or during the discussions, via email or paper copy. This achieved a 75% response rate and equality monitoring information is provided in Appendix 4.

Recruitment methods were agreed based on the scope and aims of this work. We carried out this engagement over an eight-week period, collecting extensive and in-depth responses. The aim was to engage with different people across Scotland who have a range of implanted medical devices, to obtain insights from people's experiences. The focus was not on obtaining a representative sample.

We undertook 65 interviews, with most being with individual participants, however, one involved a participant accompanied by their spouse. Three interviews were with parents of children who have an implanted medical device. Most interviews were via video call, three interviews were done in person, and one via telephone. Following a qualitative approach with quantitative elements, and aligned with the objectives of this work, the aim was to collect rich and meaningful feedback from a wide demographical range of people from across Scotland.

To note: To ensure clarity, quantitative findings in this report are presented including the sample number (N), which, in most cases, refers to the number of participants' devices discussed, as opposed to the number of participants. The sample size differs between

[3] On behalf of the Scottish Government and Healthcare Improvement Scotland, views are gathered from members of the public across a variety of health-related topics.

questions, as participants may have discussed a different number of devices. Figures and tables also include overall N numbers, and present findings in terms of sample numbers and percentages where appropriate to ensure clarity. Qualitative findings do not include participant numbers, as discussed in the section outlining our approach.

The questions covered the following areas:

- about the implanted medical device
- information received before getting the medical device
- information received after getting the medical device
- feeding back on the participant's experience
- the implanted medical device tracking system, and
- what matters to you.

The themes that emerged from the questions can be found in the feedback and recommendations section of this report, as well as recommendations that were identified during the analysis process. Where appropriate, we have used anonymised quotes from participants to illustrate what we heard. Quotes are not associated with any identifiable characteristics, such as location.

This piece of work adopted a mixed methods approach, and the analysis process was undertaken in three stages, as this exercise collected both qualitative and quantitative data: 1) The quantitative aspect utilised closed questions, and these are reported using participant numbers, percentages, and figures where appropriate; 2)The qualitative aspect used open questions, with responses analysed separately from the quantitative data, using thematic analysis. Qualitative findings are presented by discussing themes and examples of participant responses, focusing on the content of the responses and not the number of respondents. However, when it is helpful to understand how prevalent particular views were, we say "many" or "some" participants had this view. When saying "most" this means the majority of the participants; when saying "some" this is less than half and more than one or two participants; when saying "many" this is more than "some" but less than half, as shown in Figure 1; 3) The quantitative and qualitative findings were combined to form a more holistic picture of participants' views and experiences. Findings in this report are presented as such, with qualitative findings complementing, explaining, and enriching the quantitative findings. The recommendations were developed to address key points in these findings and are linked to the views and experiences shared with us during this work.

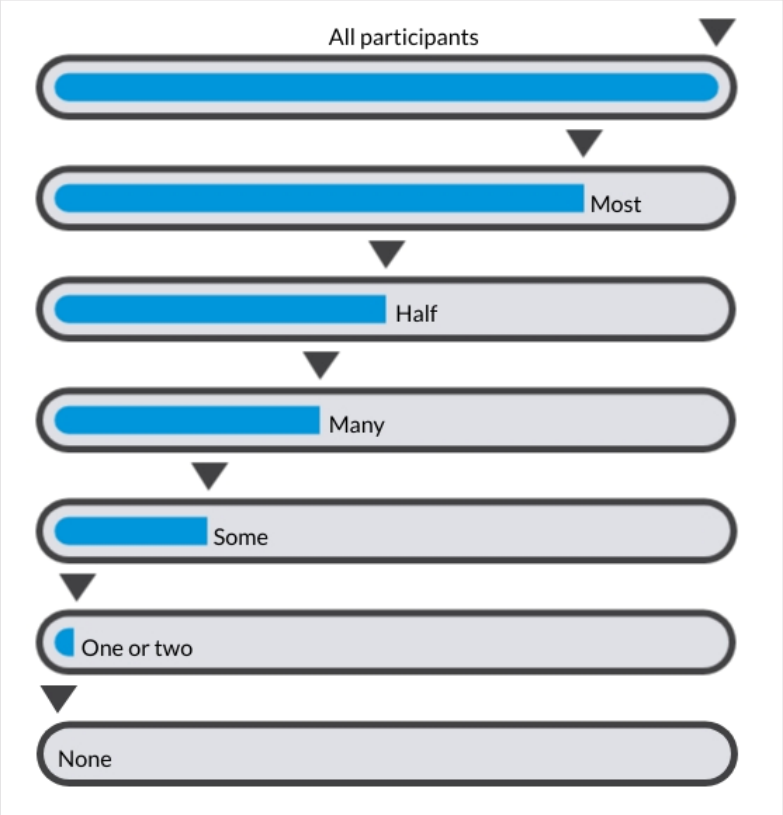


Figure 1: Visualisation of how qualitative findings are semi-quantified in certain places in this report

The interviews were informative for both participants and interviewers given the complexity of the subject. Participants provided comprehensive feedback, and to ensure clarity and understanding, an information briefing was shared with all participants before the interviews took place.

3.1. Limitations and influencing factors

It is important to highlight certain limitations and influencing factors around this work, to provide context and inform the reader's understanding and interpretation of the findings, conclusions and recommendations outlined in this report.

We mostly used a qualitative methodological approach for this Gathering Views exercise, while also incorporating certain quantitative aspects, through combining closed questions with open, explorative questions during the interviews. This was adopted as an appropriate and pragmatic approach to obtain a good understanding of, for example, the proportion of participants' devices for which they received an implant card, as well as obtaining in-depth insight into participants' experiences and perceptions by asking focused, open questions that encouraged participants to share their stories and narratives. The resulting limitations and influencing factors are further explained within this section.

These findings are based on interviews with participants who have, or have had, implanted medical devices. During these interviews, participants were asked to recall details and relied

on their memory to answer the interview questions. These findings highlight what participants perceived at the time and remembered at the time of interview. The findings are not a definitive or necessarily 'true' reflection of what information was, or was not, given to participants. According to the mainly qualitative methodological approach employed for this piece of work, the findings reflect the participants' "truths" at the time and their narratives at the time of interview, tightly linked with the individual participants' contexts. Due to this, participants' responses may, at times, seem contradictory, however they reflect their views and perceptions.

Individual participants' contexts and understanding may also have influenced their understanding of the interview questions. This is especially relevant when thinking about the "medical team" and how this is defined and understood. Some participants saw their medical team as broad, including medical staff from a range of services, for example, including their GP. Others identified it as being very specific, for example, a consultant and device technician. This difference will have influenced participants' answers in questions, such as whether they received information from their medical team. However, in outlining participant responses overall in such questions, any relevant issues become clear.

The wide range of implanted medical devices and individual circumstances and conditions included in this piece of work added to the complexity and diversity of findings. For example, some procedures discussed by the participants were described as being delivered by way of a walk-in service, whereas others require a great deal of ongoing support and sustained effort on behalf of the patient to recover and gain the most from the intervention. The diversity of participants, similarly, should be considered as an influencing factor. A broad range of demographic characteristics, as well as diverse socioeconomic backgrounds mean that participants' experiences may be influenced by further aspects, such as health inequalities, which may have shaped the participants' responses and overall patient experience. While including a diverse group of participants was one of the initial objectives of this Gathering Views, which adds value to the importance and nuance of these findings, it could make it more challenging to get a broader overview. It is also important to note that while participants did have a range of implanted medical devices, the participants' devices don't reflect the full range of devices.

It is notable, furthermore, that many participants in this work had more than one device, whether these were two or more different devices, or one device that had been replaced one or more times. While this enabled participants to reflect on multiple experiences, producing rich data, it is possible that having been through more than one procedure, participants were more likely to have different expectations and make comparisons between their experiences. Furthermore, this work focused on the participants' experiences with their devices, therefore may not reflect the range of people's experiences nor the range of available implanted medical devices.

These findings are intended to offer insight and direction for improvement and further exploration. However, caution should be exercised if these findings were to be generalised.

Section 4: Findings

This section provides context to this work by describing the participants in terms of the range of implanted medical devices and the year participants received them. It then outlines key points and themes from all the feedback collected through this Gathering Views exercise. Conclusions and recommendations based on these findings are outlined in section 5.

4.1 The participants' devices

For this Gathering Views exercise, we interviewed 65 members of the public who either currently have or have had one or more implanted medical devices in the recent past[4]. Participants received most of their devices from 2019 onwards.

4.1.1 The range of participants' implanted medical devices

The participants had a range of implanted medical devices, shown in Table 1 and Figure 2. 26 participants (40%, N=65) had more than one device, amounting to an overall 89 devices between all participants. It is important to note, however, that the participants' devices do not reflect the full range of implanted medical devices available.

Device type	Number of participants with this type of device	Percentage of this type of device compared to overall number of participants' devices (N=89)
Joint replacement	21	24%
Lens replacement	16	18%
Pacemaker	12	14%
Heart Valve	10	11%
Implant in blood vessel e.g. stent	10	11%
Implanted defibrillator	7	8%
Implanted stimulator	3	3%
Cochlear implant	2	2%
Breast implants	1	1%
Other devices	7	8%

Table 1: Device range

[4] Contraceptive devices were excluded from this work due to the scope of the activity.

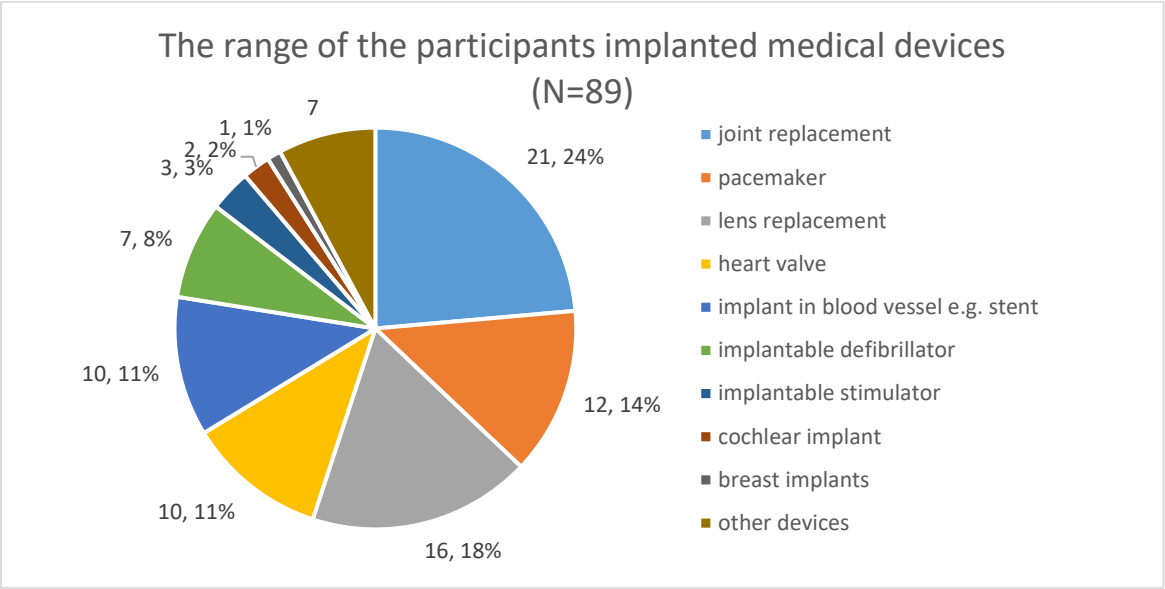


Figure 2: The range of participants' devices

The seven devices categorised as "other" in Table 1 and Figure 2 include: portacath for infusion treatment, bone-anchored hearing aid, telemetric device and programmable shunt, insulin pump, metal pins/metal plate, cardiac resynchronisation therapy device with defibrillator (CRT-D), pig heart valve, and penile implant.

4.1.2 When the participants got their implanted medical devices

Participants got or replaced most of their devices in the last five years, since 2019 (73, 73%, N=99). Participants got or replaced some of their devices between 2014 and 2018, and seven of their devices had been received before that[5], as shown in Table 2 and Figure 3.

Year of getting or replacing the device	Number of participants	Percentage (N=99)
Before 2014	7	7%
2014	4	4%
2015	3	3%
2016	3	3%
2017	5	5%
2018	4	4%
2019	11	11%
2020	14	14%
2021	16	16%
2022	15	15%
2023	17	18%

Table 2: The range of years that participants got their devices

[5] Table 2 and Figure 3 show the years that participants' devices were received or replaced. They include information on 99 devices (N=99) as some devices have been replaced. As participants may not choose to discuss all their devices when responding to the interview questions, the number of participants' devices discussed in each question varies. This variation is indicated by including the sample (N) number in each question.

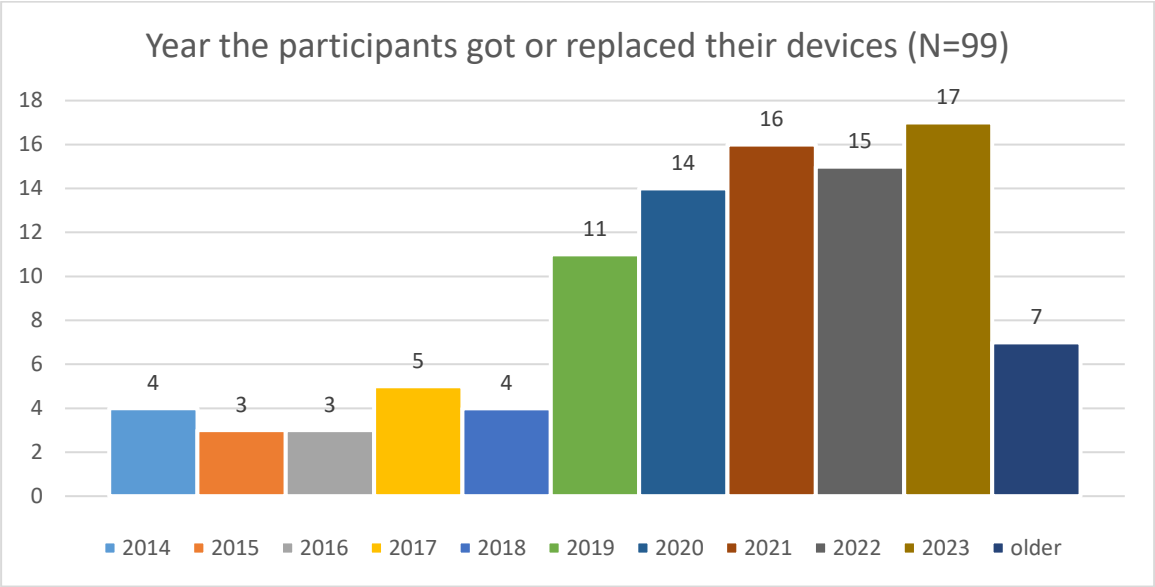


Figure 3: The range of years that participants got their devices

While the interviews focused on participants' devices received or replaced since 2018 specifically, participants at times discussed older experiences.

4.2 Key findings and feedback

This section outlines the key findings from all the feedback collected through this Gathering Views exercise.

4.2.1 Information from the medical team before getting the implanted device

When asked if they were given information from their medical team before getting the implanted medical device, participants said they received information for more than half of their devices (43, 59%), as shown in Figure 4.

However, for nearly a third of participants' devices (22, 30%) they said no, and for eight (11%) they were unsure (N=73). For some participants, this differed between their devices.

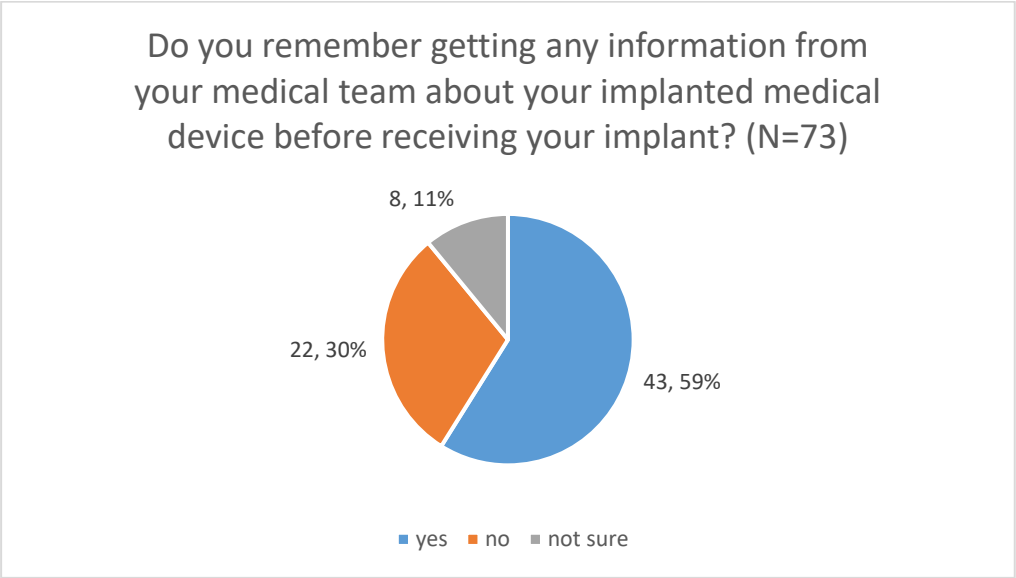


Figure 4: Getting information from the medical team about the device before getting the implant

Information participants got from their medical team before getting their device and experiences around this

As shown in Figure 5, for around half of their devices, participants said they did get information on the type of the proposed device (38, 55%, N=69) and on device longevity (33, 49%, N=68). For over a third of participants' devices (27, 41%, N=66), participants got information about potential problems. For some participants, this differed between their devices.

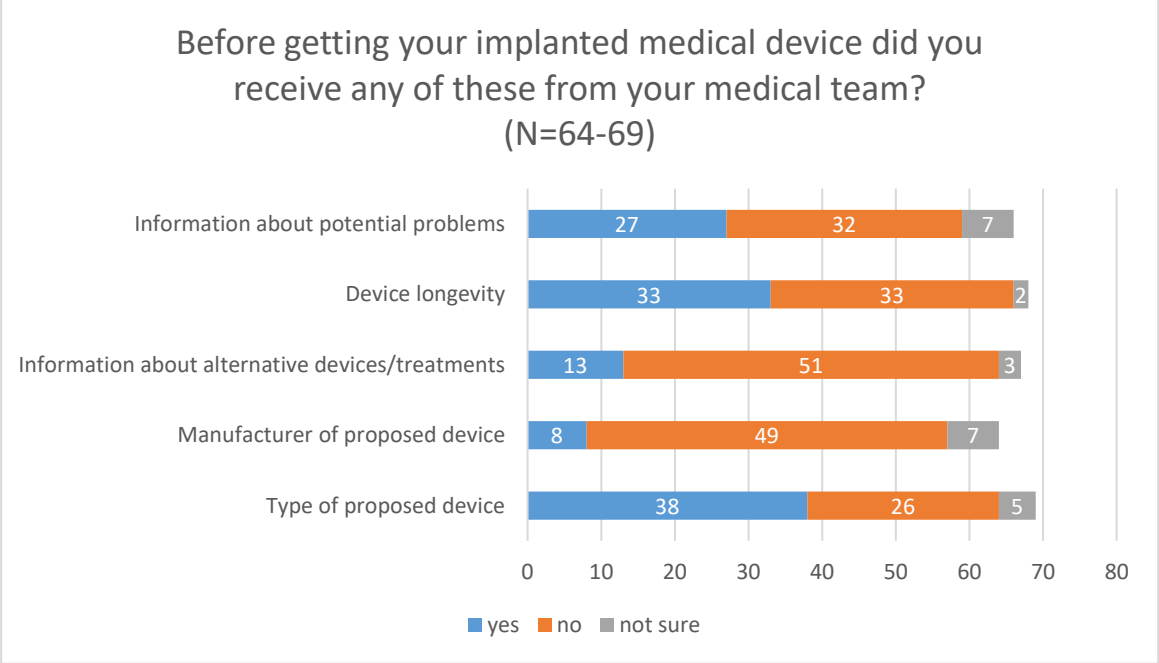


Figure 5: Information that was received from the medical team before the procedure

Information and staff support

Many participants described being provided with a comprehensive amount of information before getting their devices. Some participants felt that their medical team provided them with an in-depth explanation and a comprehensive overview, including an explanation of risks and benefits. Words used to describe staff regarding their support included being "excellent", "supportive", "honest", and "marvellous". Participants mentioned feeling looked after, having frequent contact with the medical team and an open door for questions and concerns, and feeling that the clinicians were honest, realistic, and direct. Participants said that staff gave them clear explanations and were available. Some participants were put at ease and reassured by individual staff and their medical team when they felt apprehensive about their procedure, and one participant felt that all the information they were provided with helped them to make an informed decision about their implant. One participant said, "the support of services, disciplines and dedication was sometimes quite humbling", and another said about staff that "they're a caring bunch of people".

Information content and ways of providing information

Participants mentioned receiving written information in the form of letters; booklets; leaflets or brochures; being given a contact telephone number to ask questions; having a discussion with a consultant or their medical team about their implant (in person or online); and follow-up appointments; or a discussion with the surgeon on the day of the procedure.

Most described their medical team mainly delivering information verbally. Some mentioned getting clear explanations of the device and the procedure, as well as information about expected recovery and aftercare, being offered a choice on the type of implant, information on risks and side-effects, and being able to ask questions. Some participants were being monitored by staff before their procedure. Some participants felt they received a full explanation including the statistics for success and failure, any risks, and the possibility of further surgery if needed. For example, a participant had concerns about potential issues around the fitting of the device, but they were reassured once this was fully explained to them by the medical team.

Some patients attended in person settings, such as clinics, workshops and a "joint replacement school", where they could meet with all staff involved and other patients. One participant was offered a simulator prior to getting their device fitted, providing the evidence needed for them to make the decision to proceed with the procedure. The participant noted that they found this very helpful. A participant was offered to participate in a clinical trial, which helped them decide on their implant. A further participant took part in a workshop with other patients to learn about their device, which they were very happy with.

One participant appreciated being able to take along a family member to an appointment, who was able to ask questions on their behalf, and others felt they were given the opportunity to ask questions and raise concerns verbally. One participant was offered time with a translator, which they found helpful. One participant noted that the contraindications

(reasons why an implant could not be used) were very clear in the manual they received, and how important they felt it was to receive this information. One participant, whose daughter was planned to have an insulin pump installed, described the many meetings they had with dietitians. They were given training on how to work the pump and calculate carbohydrates, and were tested on this to ensure understanding. This parent explained they speak little English and worried about understanding all of this but were supported by a translator attending the meetings. Another participant emphasised how much they appreciated the in-depth and detailed information they received, specifically about how their new device varied from the old one.

Some participants were advised to contact either their local health board, a consultant, or their medical team if any issues arose. Another participant was given a card with details of the local ambulatory unit to contact if there was an issue. A further participant advised that they receive emails with any reported issues from the manufacturer of their implant.

One participant felt that, as devices gradually become more commonplace, the medical team would have more knowledge available to them to inform patients of risks. Another participant felt reassured as data is transmitted directly to the hospital from their device, so any potential problems would be picked up by the hospital.

Information participants did not get from their medical team and experiences and challenges around this

Participants said that for most of their devices they did not get information about the manufacturer of the proposed device (49, 77%, N=64), nor information about alternative devices or treatments (51, 76%, N=67), as shown in Figure 5. Some participants noted that there was only one type of implant available for their particular procedure, so they wouldn't expect information on alternative devices or treatments. For some participants, this differed between their devices.

Many participants felt they received minimal or no information, and many felt they lacked specific information about their procedure. Some participants said that they were given some information but not all. For example, they knew about their procedure but not the actual device itself. Some participants thought that there was a lack of supporting services around newer procedures and devices, suggesting that this may change as procedures become more commonplace.

One participant commented that they felt the amount of information required is dependent on the type of implant being fitted. From participants' responses, it can be observed that patients tended to receive less information when procedures were at shorter notice and not planned long in advance. However, there were still participants that received a limited amount of information about all aspects of the procedure and device, despite long-term planning. One patient highlighted that they received more information after the device was implanted than before.

It is important to note however, that for some participants, not receiving information was not an issue and it did not influence their experience. Two participants were just grateful to be receiving the device to maintain their health. One mentioned that "knowing what type of device wouldn't really matter to me" and the other patient thought that the "requirement of information is very different depending on the device" and that something like a pacemaker requires more monitoring by staff and awareness of what to do if something goes wrong.

Information needs regarding information content

Device type, number, and alternatives: One patient commented that they felt "in the dark" when it came to knowing what type of device they were to receive. Another participant felt that the choice of implants on offer to them was very limited given the complex procedure, and another said they felt their decision was rushed and that they would have liked more time to consider alternatives. One participant was unaware that their implant was numbered and only found this out when looking at their medical records following surgery.

Device longevity: Some participants said they had to explicitly ask about device longevity themselves, as this information wasn't offered to them. Not having been told about device longevity, some other participants simply assumed their implant was permanent. For example, some thought that there would be no replacement available if the device failed, some felt that the question around longevity didn't apply to their specific implanted device, or they had been told that their implant shouldn't need replacing but that there were "no guarantees". Two participants felt they were not advised on device longevity due to them being elderly, and they assumed that the medical professionals thought that longevity wasn't relevant to them due to their age. One participant explained that they felt they had to search for support on their own as their cardiac nurse had said there was limited support available due to their age and because they had not experienced a heart attack. One participant who asked about this, was told their own life expectancy, leaving them shocked and in denial.

The procedure, recovery, and aftercare: Participants also noted not knowing about the process, for example, what testing after the procedure would look like, or what would happen during the procedure. Many mentioned having to ask for information rather than it being offered. A participant said that patients are roughly told what is going to happen, but it isn't until it happens that people know. A further participant highlighted the importance of knowing how long you will have to wait for your procedure, especially when in pain and discomfort. One participant felt that they didn't receive advice on how the implant could affect their lifestyle, for example, not being able to drive for some time or the implant affecting hotel keys (magnetic stripe cards). A participant said:

"I never sat down with a person to tell me what the next few months in my life would be like, and I would have liked that."

Risks and potential problems: While many received information on the potential problems that could occur with their implanted device, some felt this was only explained to them on the day of their surgery. One participant commented that a lot could go wrong with their

particularly complex implant, and they felt that more thought should have gone into potential risks.

Information needs regarding ways of providing information

Many of the patients had to rely on their own knowledge of their devices and many found information online. For example, one person who had been a surgical nurse in the past knew a lot about hip replacements but insisted that "the complexity of it was worse than I thought. Most advice I got online was pretty sketchy and I didn't think that was good enough". Someone else said "I asked what I 'could not' do and the response was 'as long as you don't go gardening'. Nothing else much at all with regard to eye aftercare. I had to look it up afterwards online when I got home".

One participant noted that, although they received information verbally, they felt they would have benefitted from having this in a written format to reference at a later date. One participant felt supported for one aspect of their implanted device, but not regarding the setting up of the equipment, and also found it a struggle to get ongoing support for this.

Needs around staff and communication approaches

Some participants said that staff communication was insufficient, poor and caused mistakes and inaccuracies. For example, one participant said that the only thing they were told was that they required a device. Another explained how major decisions about their surgery were unclear and made them uneasy, as the surgeons were still deliberating what to do at the last minute. Someone else said that there was a significant difference in the quality of service between their GP and hospital, with the GP coming out as "poor".

Some participants felt that the medical staff were rushed and didn't have the time for explanations prior to the surgery, leaving them feeling a bit rushed, anxious, and unprepared. One participant said that "the whole experience was traumatic". One participant was left feeling confused, as they were led to believe the device would be one type when they were actually fitted with something different, and another described how their referral was lost twice within the system. A participant was advised they should use exercise to improve their condition, which they felt was incorrect and led to a delay in their implant being fitted, leaving them in considerable pain up until the procedure. One participant wished they had met with the doctor in advance to discuss their requirements, as they just assumed the doctor would make the right choice for them. They said:

"I would have liked to have seen the doctor beforehand. I just totally put my trust in him."

The role of information provided by the medical team before getting the implanted device to help understand what might happen and know what to expect

Positive experiences of the information helping to understand what might happen and knowing what to expect

For over half of their devices (41, 58%, N=70), participants confirmed that the information they received from their medical team before getting the implanted device was enough for them to understand what might happen after getting the device and to know what to expect, as shown in Figure 6.

Many participants said that the information they received was clear, concise, and sufficient, and some said they felt supported, not judged, and given opportunities to ask questions. Some participants also noted they had been given details on the risks involved, including the benefits for the person. One participant described a positive conversation with their medical team, saying:

"They asked about equipment I have in the house and what I might need. I needed to get a seat at the right height (to support hips after surgery). The seat was delivered the day after my operation."

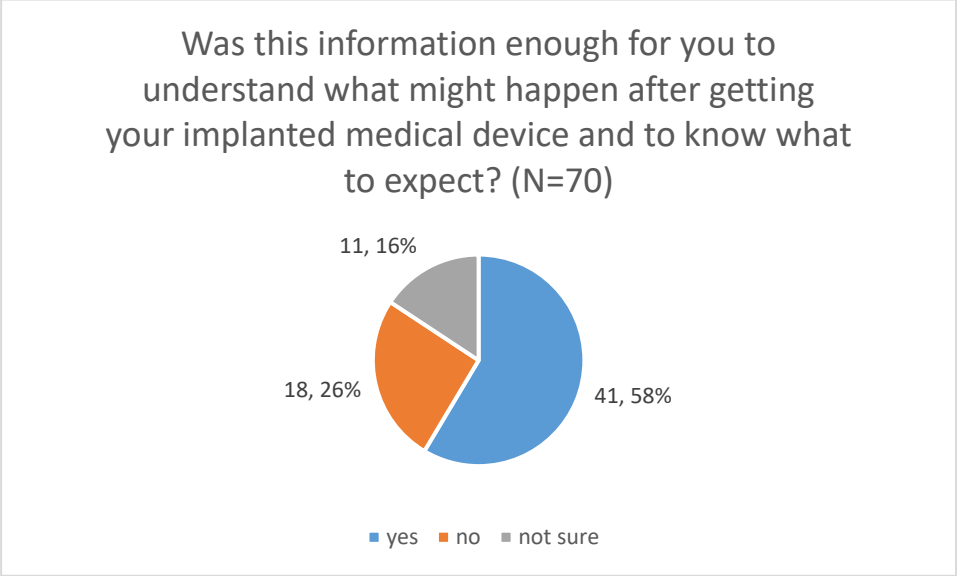


Figure 6: Information from the medical team before the procedure and understanding what might happen and knowing what to expect

Issues around the information being enough to understand what might happen and knowing what to expect

For eighteen of their devices (26%) participants said that the information was not enough to understand what might happen and to know what to expect, and for 11 (16%) they were unsure (N=70), as shown in Figure 6. For some participants this differed between their devices.

Some participants felt that the information was not enough, with some saying the information was not forthcoming or of a more generic nature than expected. The focus was

on the operational procedure and not specific to their implanted device. Some other participants felt they did not receive information around risks involved before their procedure. Two participants said:

"It would have been nice to have something to read",

and

"It was a lot more complex than I expected. The information was sketchy, and I was completely unprepared."

Some participants described feeling rushed, anxious, and unprepared, with one participant saying that "the whole experience was traumatic". They said:

"As it was not face-to-face, I felt it was a bit rushed. It didn't bother me too much, as I wanted them done badly, but there was no information about the actual device."

On the opposite end of the scale, a small number of participants felt they received too much information in advance, which, for some, heightened anxieties around the procedure.

The role of information provided by the medical team before getting the implanted device to help understand benefits and potential risks

Positive experiences of the information helping to understand benefits and potential risks

For most of their devices (58, 82%, N=71), participants confirmed that the information they received from their medical team was enough for them to clearly understand the benefits and potential risks around getting the implanted device at the time, as shown in Figure 7.

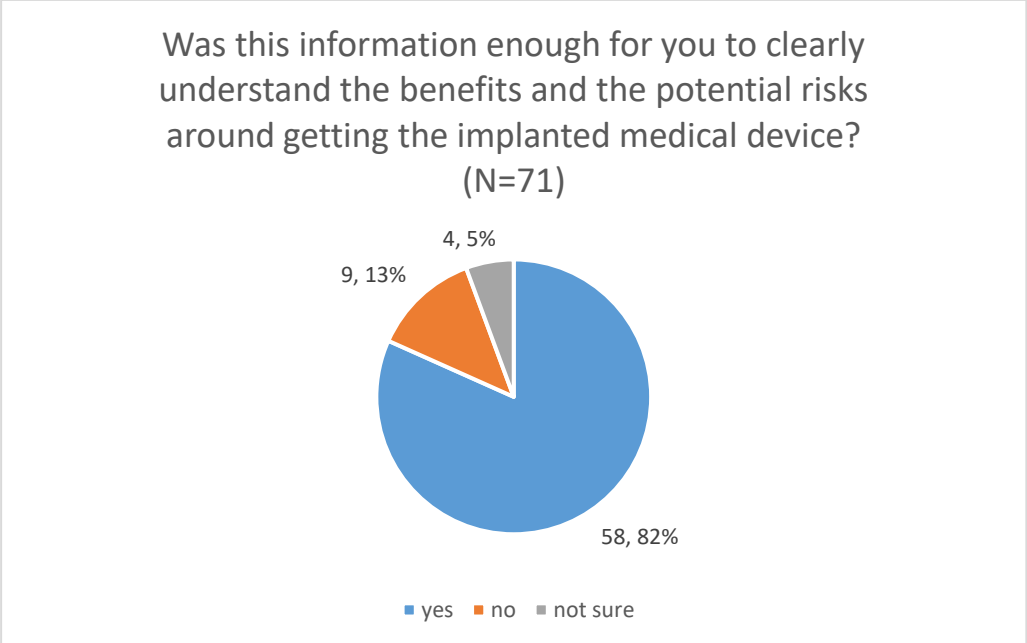


Figure 7: Information from the medical team before the procedure and understanding the benefits and risks

Some participants praised the information they received from staff, feeling that the information was balanced and comprehensive, with an increased focus on risks. One said:

"If anything, (there is) a bias to give dangers of having hip replacement."

Another participant said that, in their view, there are risks with every procedure, but said:

"The consequences were staring me in the face if I didn't get it, I would suffer a heart attack."

Issues with the information being enough to help understand benefits and potential risks

On the other hand, for nine of their devices (13%) participants said that the information was not enough to understand benefits and potential risks, and for four (5%), they were unsure (N=71), as shown in Figure 7. For some participants, this differed between their devices.

Some participants felt there was too much information and not enough about the risks. For example, one participant didn't realise how much pain they would be in after the procedure. The timing and level/amount of information was also mentioned, with some participants saying that it was a lot to take in. Two participants mentioned that it would have been beneficial to them to have heard how similar operations had gone.

For some participants who had multiple implanted medical devices, the information they received for each device around benefits and risks varied significantly, for example, some participants said they had received a lot of advice and information for one device, but not much at all for the other.

Some participants said they never received any information on neither benefits nor risks, and some felt that staff were too busy and overwhelmed to give them their full attention. One participant mentioned the lack of information from staff about any follow-up appointment, and another felt that the onus was on them to ask more questions of the team, which they did not. Another participant said:

"I knew I would always need it [as has had issues with hip since birth], but I underestimated it. I blamed myself for being underprepared."

The role of information provided by the medical team before getting the implanted device for participants to give fully informed consent

Positive experiences of the information helping participants to give fully informed consent

For most of their devices (60, 87%, N=69), participants confirmed that the information they received from their medical team was enough for them to give their fully informed consent to receive the implant, as shown in Figure 8.

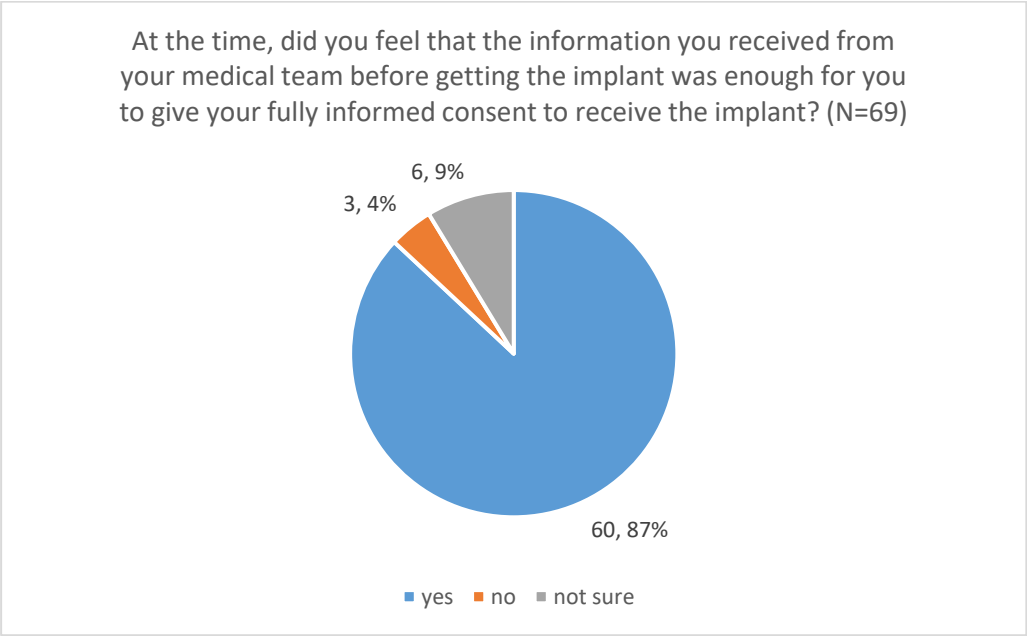


Figure 8: Information from the medical team before the procedure and giving fully informed consent

Many participants were positive about this, saying they had enough information, at the right level, that it was clear and explained well to them with no ambiguity, so they felt able to give their fully informed consent. Some noted that risks and benefits were clearly discussed in order for them to provide consent, however, some others said that only risks were discussed. Some participants said that they provided consent as they trusted the advice given by clinicians. One said they "trusted staff implicitly" and another discussed the "thorough job the hospital did at giving me such a high level of information".

Some other participants explained they knew the procedure was necessary so were grateful for having it, so didn't question the need for more information and weren't concerned about making an informed choice. One said:

"I'm sure there would have been more information I could have been given, but I didn't miss not having this."

Some participants discussed how they were not concerned about consent, since they thought there was very little to no choice around providing consent, as they required the implant to stay alive. One said:

"I really had no option; without the device I could die."

Two participants felt that they perhaps didn't receive enough information either due to the timing of the procedure and it needing to be done fast, or them simply not receiving the information, but said that this wouldn't have deterred them from providing consent.

Issues with the information being enough to help participants give fully informed consent

Participants said that the information was not enough to do this for only three of their devices (4%) and for six (9%) they were unsure (N=69), as shown in Figure 8. For some, this differed between their devices.

While most of the participants seem to have been happy at the time to give consent, some commented that in hindsight they would have benefitted from more information. For example, one said:

"I signed because I knew that I needed the procedure, but I am not sure I understood fully what I was signing."

Some participants said that they hadn't been asked, or did not recall being asked, for consent. A small number of patients said that risks were not discussed at all. Some participants expressed a wish for more information, in particular around the actual device, as they felt discussions around consent at the time focused mainly on the procedure. One participant said it would have been helpful to have an interpreter with them to help them understand the information and provide consent, but this was not offered. One participant said they received a different implanted device than what had been discussed, and they were not aware of this possibility. Another participant explained that they had been referred to Macmillan Cancer Support but that they had not consented to this, as they did not want additional support.

Further information needs to be able to provide fully informed consent

When asked what other information would have been useful to help provide their consent, participants said they would need to receive more clear and detailed information at an appropriate level, and at the right time, to not add to their anxieties. Some highlighted wanting to have a better understanding of the procedure itself and what to expect after the procedure. Some participants mentioned needing to share appropriate information with patients, for example, not discussing costs and funding, unless necessary.

Suggestions for further information that would help provide consent included:

- a leaflet detailing the procedure
- a demonstration video
- signposting to useful links, for example, charities or peer support groups
- having a peer support buddy, as "learning from other patients' experiences would be good"
- information on next steps, post-operative recovery and expectations
- longer term information
- information on alternative options and choices of devices and treatments available, and
- information about pain relief availability and timing.

Although many indicated that not having this information did not deter them from having the procedure, most participants suggested that they would have benefitted from having this information, they would have felt more supported, and this would have eased their anxiety and stress.

The timing of receiving the information and the level of information was also mentioned. Some participants said that it was a lot to take in prior to operation or when feeling anxious. One participant spoke to their consultant 10 weeks prior to their procedure with no other communication taking place. One said:

"I think maybe if they had spoken beforehand about pain relief and that it was OK to say if you felt you needed more, I might have felt more relaxed."

Some participants said face-to-face discussions would have been better to get information prior to giving consent, and some participants highlighted that having in person discussions, and being able to ask questions, had been very beneficial for them to understand and give consent.

Two participants said that having family or friends with medical knowledge was useful to ask the right questions.

One participant, for whom English is not their first language, felt that they would have benefitted from having an interpreter present when receiving information prior to the procedure, as due to stress and worry, it was hard to focus and understand.

4.2.2 Information from other sources before getting the device

Discussion with the medical team about where to find further information

For over half of their devices (46, 65%, N=71), participants said that they did not have a discussion with their medical team about where they could find more information before getting their medical device, as shown in Figure 9.

For less than a third of their devices (20, 28%), participants said that they did have this discussion with their medical team, and for five of their devices (7%) they were unsure (N=71), as shown in Figure 9. For some participants, this differed between their devices.

Some participants said they were happy with the information they had received from the medical team, one saying "I was so well informed by the team".

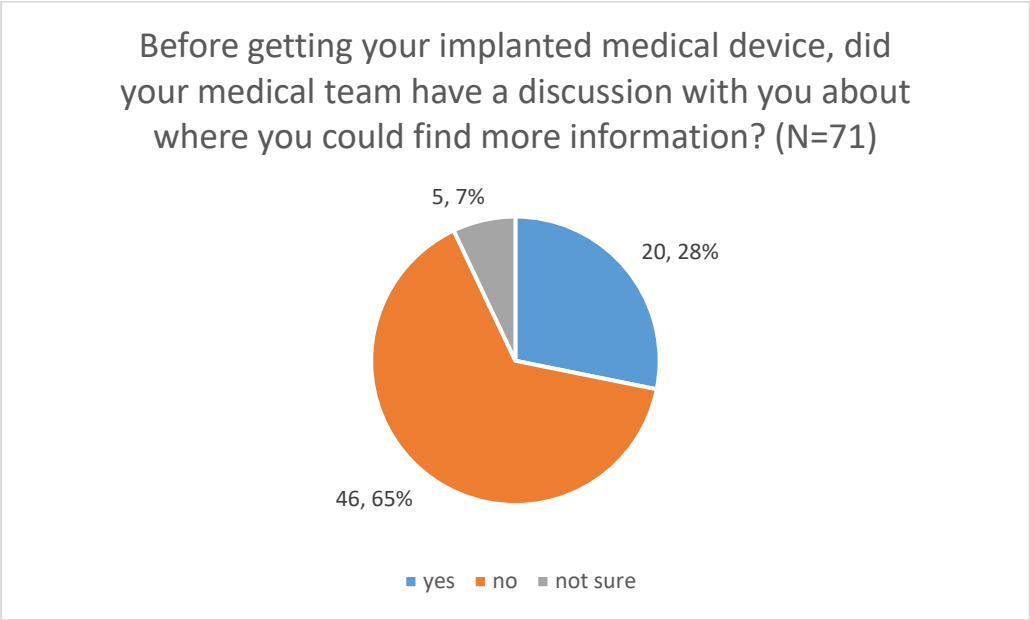


Figure 9: Discussion with the medical team about where to find more information

For over half of their devices, participants confirmed that did look for more information in addition to what they got from their medical team (43, 61%, N=71), as shown in Figure 10.

Most discussed searching for further information in a range of ways, for example, looking online, asking family and friends, and also speaking to further healthcare professionals. It is also interesting to note that one participant explained they had looked for further information, not for themselves, but to share with their family and address their concerns, highlighting the importance of information not only for patients but for those around them.

On the other hand, for over a third of their devices (28, 39%, N=71), participants said they did not look for further information, as shown in Figure 10. For some participants, this differed between their devices.

Most said they had no suggestions about where to look elsewhere for information and many said they did not seek further information at all, because they did not feel the need, or because there was not enough time to do so. Some participants stated that they were too unwell to look for more information before their procedure, or that there was not enough time to look for information prior to the procedure.

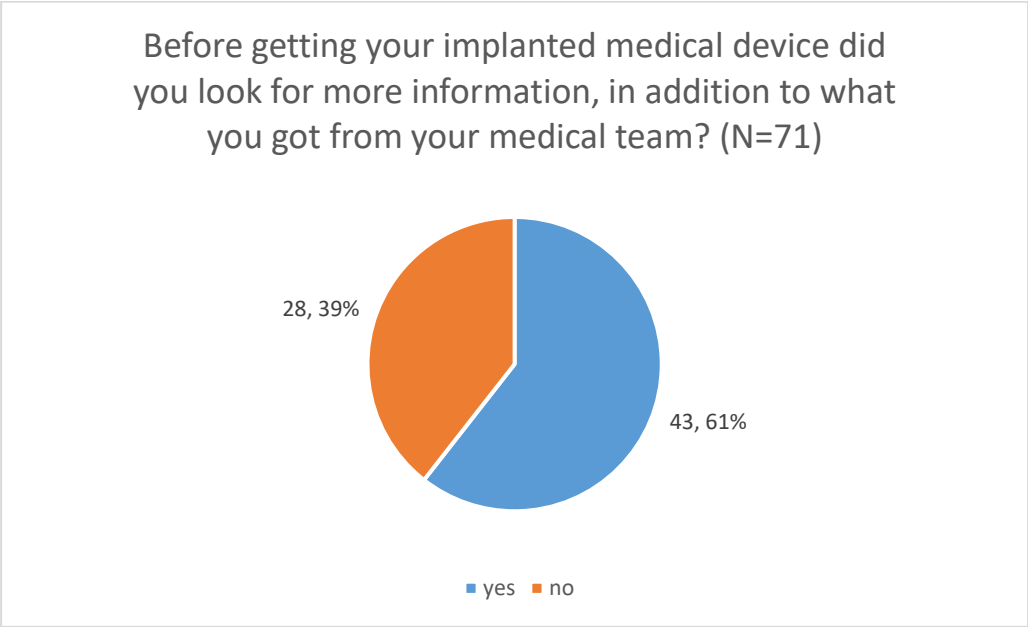


Figure 10: Seeking information beyond the medical team before getting the procedure

Further sources of information signposted by the medical team

For most of their devices where participants had a discussion with their medical team about where to seek additional information, participants were advised to use the NHS Inform website (13, 19%, N=68) or their GP or local specialist clinic (10, 15%, N=67), as shown in Figure 11.

For a small number of participants' devices, participants were advised to look for further information through charitable organisations (6, 9%, N=67), other health organisations (2, 3%, N=66), and professional associations or Royal Colleges (2, 3%, N=66), as shown in Figure 11. For some participants, this differed between their devices.

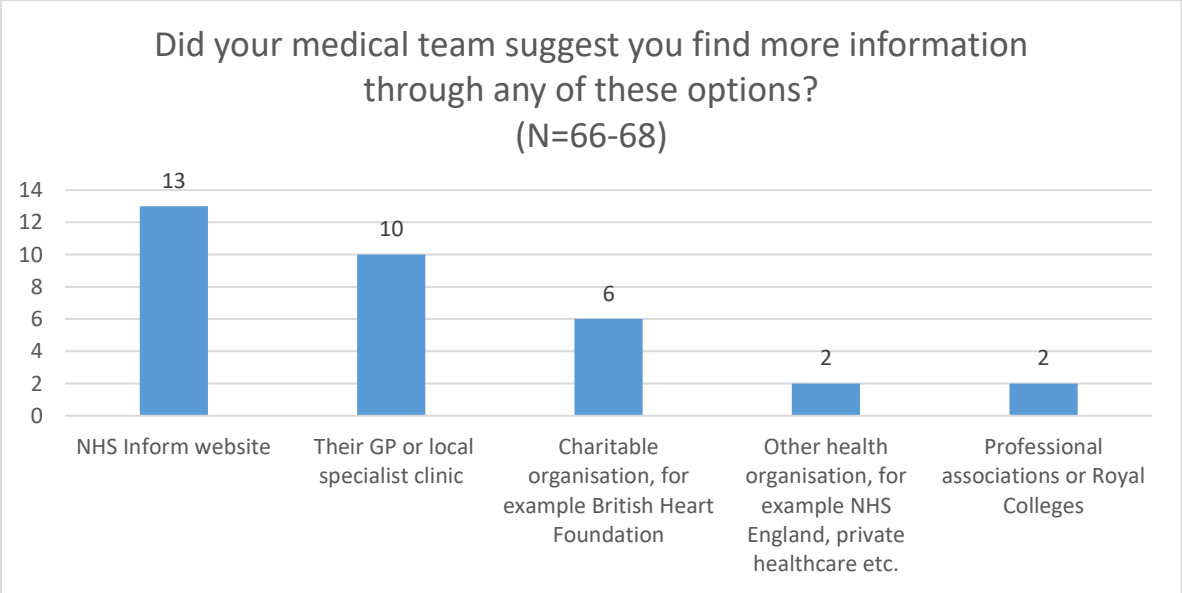


Figure 11: Medical team suggestions on where to look for more information before getting the device

Many participants were signposted to resources such as the British Heart Foundation, the Maggie's Centre, Macmillan Cancer Support, and third sector organisations. Many participants were advised to search for more information on the internet or through YouTube, for example how the device works, etc. Many said this was helpful, for example, one participant sourced information about the device manufacturer on YouTube in Polish, their first language. Two participants mentioned being signposted to the NHS Inform website, but not being given any other suggestions beyond that. Another said they were directed to an NHS website with support from a physiotherapist. One participant attended a talk on having a hip replacement, which was also an opportunity to ask questions. One participant was advised to download an app to support them with managing their diabetes.

Issues around being signposted to further sources of information by the medical team

Many participants discussed concerns regarding finding information online. One participant was surprised that they were not signposted to more specific sources of information and said that looking for information online can be overwhelming, especially when coming across information that is not specific to the UK. One participant noted specifically that it is important to keep a check on what information people look at because it can cause anxiety. The suggestion to look for more information online was also an issue for a small number of participants who said they don't have access to the internet and would not readily look for information online. One participant said:

"I had to access it (this information) myself so I would have liked for the information to have been given to me by professionals. I felt like I didn't want to bother them regarding aftercare. It's fine because I can access the internet, but a lot of people can't."

A participant said they felt that the clinicians don't like patients having too much knowledge beforehand, saying "I don't get the impression medical teams like you looking up information as you take extra baggage into the theatre".

Further sources of information used by participants

Friends, family, and peer groups

Many participants mentioned using friends, family, and peer groups to find further information. Two participants specifically mentioned having a family member that was a medical professional; the one said that their family member was a source of additional information, but the other said they felt the medical team assumed the patient could ask their relative for more information, so they didn't provide suggestions on where to look for further information. Another participant said they had good support from family and friends.

Other relevant professionals

Some participants got further support and had discussions about where to get information from other professionals beyond their medical team. One participant said they were signposted to further information, not by their medical team, but by the optician, and another got support from a Cognitive Behavioural Therapy (CBT) practitioner. A participant had a consultation with an Occupational Therapist, who told them about the Pain Society of Scotland. A participant highlighted their positive experience with the outreach team, saying they noted the value of their efforts in taking information and services direct to the entire local community. They noted that, previously, there hadn't been similar multi-disciplinary support, saying that "this is impressive". On one occasion, a participant said that they had been signposted to further information by their local authority.

Independent research

Some participants said they took their own initiative to search for information online or to look for support groups. One participant said:

"I found the information myself – and I think they (the clinicians) thought I would because of my profession."

Many participants throughout these interviews showed an in-depth understanding of medical language and their procedures. This may be seen as evidence of them actively seeking to understand as much as possible about their treatment and how to support their own recovery.

Online and "offline" resources

Most participants sought further information by looking online, and many looking at NHS online resources specifically. Some looked for further information through medical publications, including research papers, and NICE and SIGN guidelines, but others simply mentioned online materials and sources without specifying what these were. Many accessed the device manufacturer websites, and some observed that these often seemed to be based in the United States. Most participants felt that these websites were good at providing comprehensive information, often highly illustrative, and containing technical information. Two participants mentioned relevant video content on YouTube but without further identifying the nature or origin of this material.

Other sources of online information discussed by the participants included third sector groups and organisations with a remit connected to the participants' needs. Third sector sources were also found to be useful in signposting participants to peer groups and other sources of information. Peer support groups and others with lived or living experience of the procedure or condition were discussed as being helpful, both as valued sources of additional information and for providing insight into what it was like for a person going through a particular procedure. One participant stated that they had used a website in their native language (so not NHS nor UK-based) to find more information to ensure they did not miss or

misunderstand vital information concerning their procedure and treatment. Social media were also discussed as helpful to find more information, particularly through groups comprised of people with lived or living experience of the participants' procedure or condition. One participant used a comparison website to find out other people's experiences with their surgeon.

While most that sought further information did this online, many participants discussed their concerns around this. For example, one participant who used a device manufacturer website to find more information, said they found the information to be inaccessible, and even had the potential to cause worry to people by being too technical. This echoed a wider concern shared by several participants about finding information on the internet. Participants discussed their concerns around the quality and consistency of online information, and two participants added that not all the information found online could be equally trusted, and that it sometimes was difficult to tell the high-quality information from more dubious content. Some also felt that the information they would have wanted, for example, in relation to a new or unusual procedure, was not available online, or they could not find it. Participants also observed that searching online can provide so much information that it becomes difficult to manage the sheer volume of material and decide what is relevant, accurate, and appropriate and what is not. One felt that having access to such a large amount of information could make people feel worse, for example, by highlighting potential outcomes, which might not, in actuality, be relevant to the patient.

Participants also tried to find out online where they could find more information in "offline" formats, such as printed materials and details of organisations, or groups relevant to their procedure or condition that could be contacted directly. Some sought further information in person, from friends and relatives, and one participant said they got information from "the clinical trial" they were involved in, which also enabled them to go to their local hospital for a check-up rather than the specialist hospital.

Further information needs before getting the device

The device, the process, and impact on participants' lives

Many participants looked for information about and around their device and procedure, often in digital form. They looked at aspects such as the procedure itself, information about the device they had not discussed with the medical team, the healing process, the recovery and rehabilitation process, and the expected impact on their lives. For example, they considered factors like their ability to drive a vehicle or to continue working. For the participants this could include descriptions of the procedure and the implications of having it performed (for example, on NHS Inform), medical guidelines (for example, by NICE and SIGN), relevant medical and scientific publications, guides, blogs, and information in audio-visual formats directly relating to their condition (for example, on YouTube).

Some expressed what seemed to be a concern around what the procedure would mean for their future ways of living and how and whether they felt they could trust the ability of the health services to accompany them on their journey into an uncertain future.

One participant was surprised to find themselves conscious throughout the procedure, as they had not had any discussions or advice about being under local anaesthetic and observing the process. They said:

"don't know why I found that surprising",

and

"the drill sound was chilling, scary".

One participant said they would have appreciated more discussions around what life was going to be like after the procedure, and would like to have understood how immobile they were going to be. A participant who received a penile implant discussed their annoyance, as in getting the implant their penis size had reduced by 30% and they had not been told this in advance.

One participant felt it would have been helpful to have clarity around timescales and know where they were on the waiting list[6]. Due to lack of clarity on this, they had to take time off work, which disrupted their life. Another participant was advised at the "2 week before-op health check" that their holiday needed to be cancelled.

The right information

Participants noted, the need to receive the right information, in terms of the content, context and format. For example, a deaf participant had to have their son help answer questions when they received written information, and also sought help from their lip-reading group. Another participant was signposted to information, all of which was based in the United States (US) and centred on the North American context.

Peer support and lived/living experience

Many also sought insights from people with lived or living experience, interested in finding out about others' experiences and how it impacted on their lives over time. Many also sought further information about their device through manufacturer websites. However, many noted that devices were often manufactured in the US, and observed that, while information was presented well, it was presented differently to how they would expect in the UK. Participants also noted that it would have been helpful to have information about support groups and how to find them.

[6] The importance of clarity around waiting time processes is also highlighted in our Gathering Views work focusing on Waiting Times Guidance.

4.2.3 Information from the medical team after getting the implanted device

Information participants got from their medical team after getting their device and experiences around this

For most of their devices (51, 70%, N=73), participants confirmed that they received information from their medical team after getting their implanted device, as shown in Figure 12.

For most of their devices, participants confirmed that they got information from their medical team on who to contact if there are issues (55, 81%), who to contact about recovery, rehabilitation, and next steps (50, 74%), and information about how the process went (43, 63%). For half of their devices, participants said they got information about the actual device type (34, 50%) (N=68), as seen in Figure 13.

For over a third of participants' devices, participants said they got an implant card (28, 41%), information about the actual device manufacturer (27, 40%), and serial number (25, 37%) (N=68), as seen in Figure 13.

When discussing information received after getting their device, many participants mentioned particular roles more specifically, such as physiotherapists and physiotherapy teams, nurses, surgeons, consultants, and GPs and, where relevant, many also mentioned getting information from opticians, audiology teams, radiographers or X-ray staff, and device technicians. Some participants mentioned getting information from their medical team in general.

Most participants received information after their procedure during routine or planned contact points, shortly afterwards. Many also explicitly referred to printed materials including implant cards, leaflets, booklets, or letters containing information and guidance about the device itself, device maintenance where required, aftercare, exercise regimes and medication. However, some participants reported having to proactively seek out information, for example, by asking a healthcare professional, often a more senior member of staff, such as a surgeon or consultant, for the information they wanted, as it was not provided.

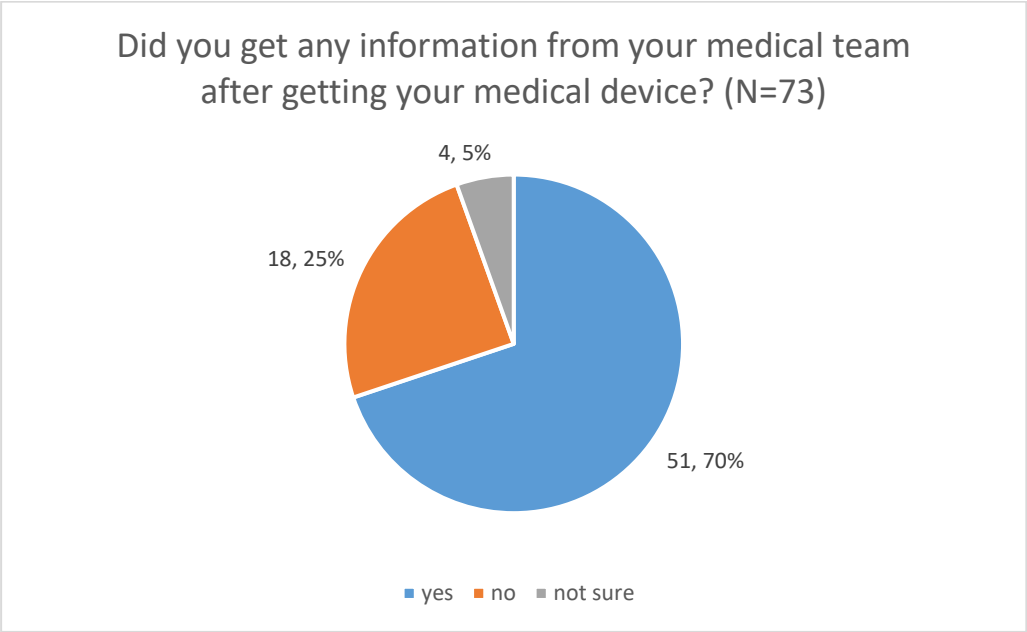


Figure 12: Getting information from the medical team after getting the device

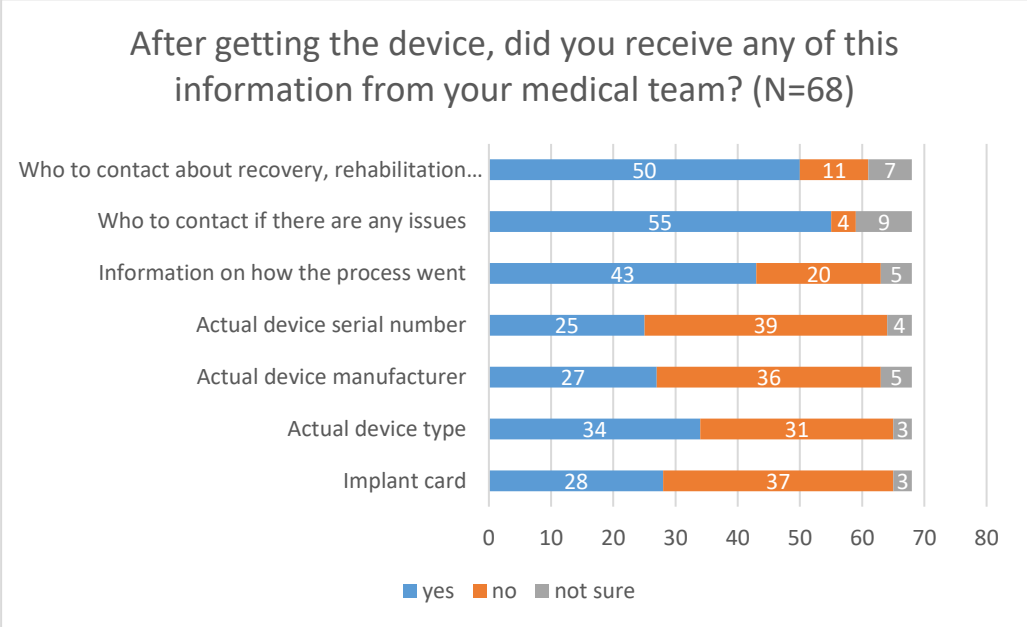


Figure 13: Information that was received from the medical team after getting the device

When asked about what information they received after their procedure, some participants said they were satisfied with the information they were given and that it was comprehensive, and some noted that they were able to ask their medical team questions. Two participants said they had received information before the procedure that proved to be useful after they got their implant.

Information participants received after the procedure included advice about exercise or physiotherapy, medication, what they should avoid doing, next steps, how to take care of themselves and what to be aware of, information on long-term effects and possibilities, how the procedure went, and contact details, for example, for a specialist nurse. Some

participants discussed getting information at their follow-up appointments with a specialist, nurse, or technician, taking place at home or at their local hospital or services. One participant described attending rehabilitation appointments, physiotherapy and meeting their practice nurse after getting their procedure. Another participant watched an animation video after the procedure, which they found helpful, and someone else was signposted to the manufacturer website. Another participant said they were given a replica device to practice and diary to complete to reflect on their learning, which they found useful. One participant said they were given access to an app and asked to download it before the procedure, as it would be helpful after the procedure.

Information participants did not get from their medical team and experiences and challenges around this

For less than a third of participants' devices, participants said they did not get any information (18, 25%) and for four (5%) they were unsure (N=73), as shown in Figure 12. For some participants, this differed between their devices.

For 39 of their devices (57%), participants did not remember receiving the actual device serial number, for 37 (54%) they did not get an implant card, for 36 (53%) they did not get information on the actual device manufacturer, and for 31 (46%) they did not get information on the actual device type (N=68), as shown in Figure 13. For some participants, this differed between their devices.

Influencing factors

Participants' experiences regarding information after their procedure varied, and some participants thought this could be due to a range of factors, including that some procedures were simpler than others, with some requiring increased levels of ongoing support towards recovery, which, in practice, meant there were differences in the level of information needed after the procedure. Some participants thought that the information they received may have depended on the type of device, with one saying, for example, that there probably is more information about devices such as a defibrillator than for a stent.

Communication challenges

Some participants said they cannot remember or are unsure about the information given after their procedure. For example, one participant took a note of contact details they were given at the time, but currently are not clear what these were for as it was not explained. Some said that the information they got was out-of-date and the medical terminology used felt inaccessible and difficult to relate to. Furthermore, some participants highlighted experiences of poor communication. One participant felt they had been "pushed out the door" because staff were too busy, saying:

"They were so, so busy, it's unbelievable".

One participant discussed how they had tried to ask questions but failed to get any answers and felt there was no discussion about the implants. Two participants said the specialist hospital did not make the referral to local physiotherapy as advised, so they had to contact physiotherapy themselves, and another mentioned disconnect between local and national teams. One further participant explained how they had to move between health boards and found it challenging to receive and manage their medical information due to this. Two other participants experienced poor pain management due to delayed or lack of communication. One participant had an unexpected issue once they got back home and did not understand what was happening, resulting in being readmitted to hospital. Another participant discussed how the nurse they had the contact details for was on maternity leave, but they had not been given an alternative contact and, thus, struggled to make contact with the department. One participant felt they had been questioned in a racist manner.

Information on how the procedure went

Some participants stated that they were informed immediately after their procedure how it went. However, they noted that no details or other information were given to them at that time. Some participants noted that they had no recollection of the period immediately after the procedure and therefore cannot be certain what information was given or not.

Implant card

Many did not remember receiving an implant card, and, of those who said they did, there were still differences to what they received. Some did receive a “credit-card-sized card”, which they keep in their wallet, and one noted they had been advised to carry it with them at all times. However, others got an A4 sheet of paper, which some participants said they felt was too big to keep with them. One participant shared concerns about this not looking “official”, while others said they were worried about it being misplaced or damaged. Another said it would be better to have this as a card, and that it could also have a barcode for them to access information through, ensuring that the information would be kept up to date. Some participants said they had not had anything like an implant card, as they were told it was not necessary.

Device information

Some were not given details directly by the medical team, but said they have this information on the device packaging, the device manual, or on the device itself, if accessible. Some participants said they did not receive any details about the device at all, and one participant said they had not thought to ask about device details, such as the device manufacturer. One participant highlighted that they were unaware lenses, for example those used in cataract surgery, have a number and they were confused about the different types of information given depending on the type of device received. One person said they did not feel like it was necessary for the patient to know details such as the device manufacturer, and one participant said:

"I got everything to do with me and my recovery but not about the actual device. I know it's in there and it's doing its thing!"

Who to contact about issues

Most participants were told to contact their local hospital if there were any issues with their device, and for some, there was further clarification, for example, needing to contact their local cardiology unit. Some were told to contact their surgeon or consultant directly or via a secretary. Some were told to go directly to their GP; however, one participant said their GP was initially helpful but they lacked knowledge about the specific device, which affected their follow-up care. Two participants said they were advised to contact their local specialist nurse. One participant was advised to go directly to the hospital if any issues arose, but they believed this was due to the pandemic at the time, and that that wouldn't necessarily be the standard process. One participant was advised to attend an out of hours clinic so contact could be made with the manufacturer. One participant noted that they received their eye test results and a phone number to contact after the procedure if there were issues. Some did not specify who they were told to contact but confirmed they did receive this information.

On the other hand, some participants noted that they were not given contact details at all, nor advice on where to go if there were issues, especially when thinking about potential issues in the long-term.

What to expect and next steps

Many participants said that they were informed about what to expect in the days and weeks following the procedure, and were given information such as about rehabilitation, stitch removal, follow-up appointments, referral to physiotherapy, and medication. One participant explained they were given information from the surgical team and audiology department, as their device required input from both teams. One participant said they were given a discharge letter that also went to their GP, but they were surprised that this was the only follow-up. Another participant said it would have been helpful to receive a "dos and don'ts leaflet", as they had not been advised around everyday tasks, such as driving or household tasks resulting in issues with their shoulder.

Safekeeping of information on medical devices

For just under half of their devices (32, 48%), participants confirmed that they still have the details of the implanted device they might have been given by their medical team, as shown in Figure 14.

However, for over a third of participants' devices (29, 43%), participants said they do not have the details they were given, and for six of their devices (9%) they were unsure (N=67), as shown in Figure 14. For some participants, this differed between their devices.

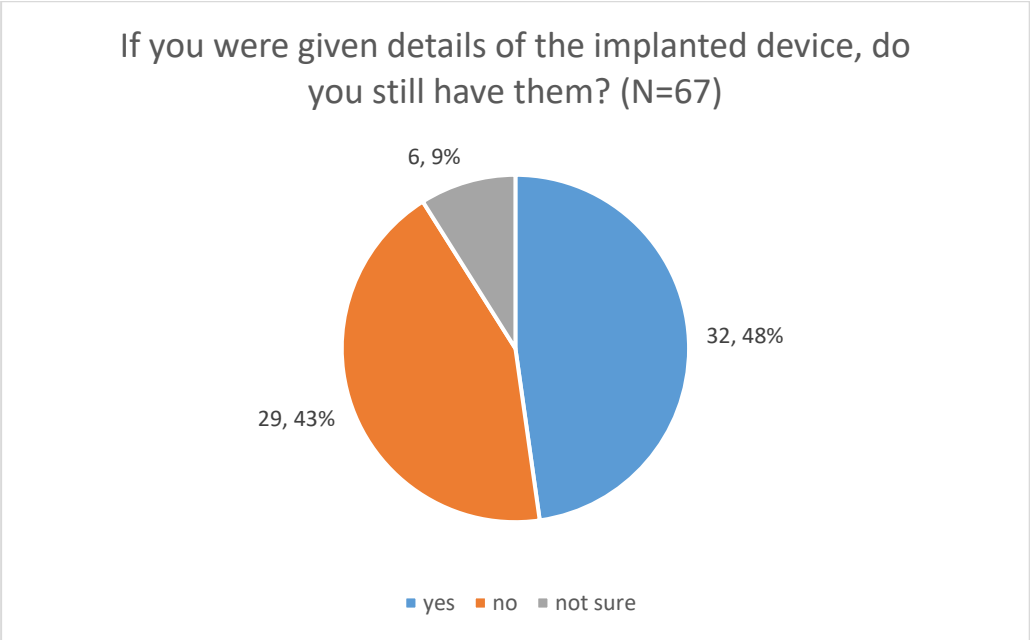


Figure 14: Safekeeping of information on medical devices

It is important to note that some participants said they did not remember getting any information about their devices after the procedure, and the information they got focused mainly on their recovery and future treatment. Some said that they didn't feel it was necessary to get information about the device, as they were straightforward procedures. For example, one participant reported not receiving any written information about their devices when getting implanted devices for their eyes and shoulders.

Enablers and barriers for information safekeeping

Many of those who still had details about their devices received them in the form of a booklet or information sheet that was issued at discharge and with the device. For some, this information was on a credit-card-sized card, including the date of the procedure, the serial number of the device, and information on what to do in the case of an emergency. For some of their devices, information is also recorded on the device packaging, making it easier to retain. On the other hand, some participants only received verbal information regarding their devices at the time of the procedure, which would mean they would have to retain this through memorising, making this a challenge.

Some said they had received detailed information both verbally and in writing about their devices, which made it easier to hold on to. However, as highlighted in other questions, many participants did not receive information or certain aspects of information at all.

Information received from the medical team after the procedure on how to take care of themselves and the device

Positive experiences around receiving information from the medical team after the procedure to know how to take care of themselves and the device

For most of their devices (52, 74%, N=70), participants confirmed that they did receive clear and understandable information and advice from their medical team about the expected recovery process and how to take care of themselves and, if needed, the implanted medical device after the procedure, as shown in Figure 15. Most participants said that the information they were given was clear and understandable and that they felt they could ask further questions and have follow-up enquiries about their recovery. One participant said:

"All the information was comprehensive in the booklet and gone through at the clinic with plenty opportunity to ask questions".

And another participant said:

"Just before being discharged, they went through everything so that was very thorough. I wasn't at all concerned about it."

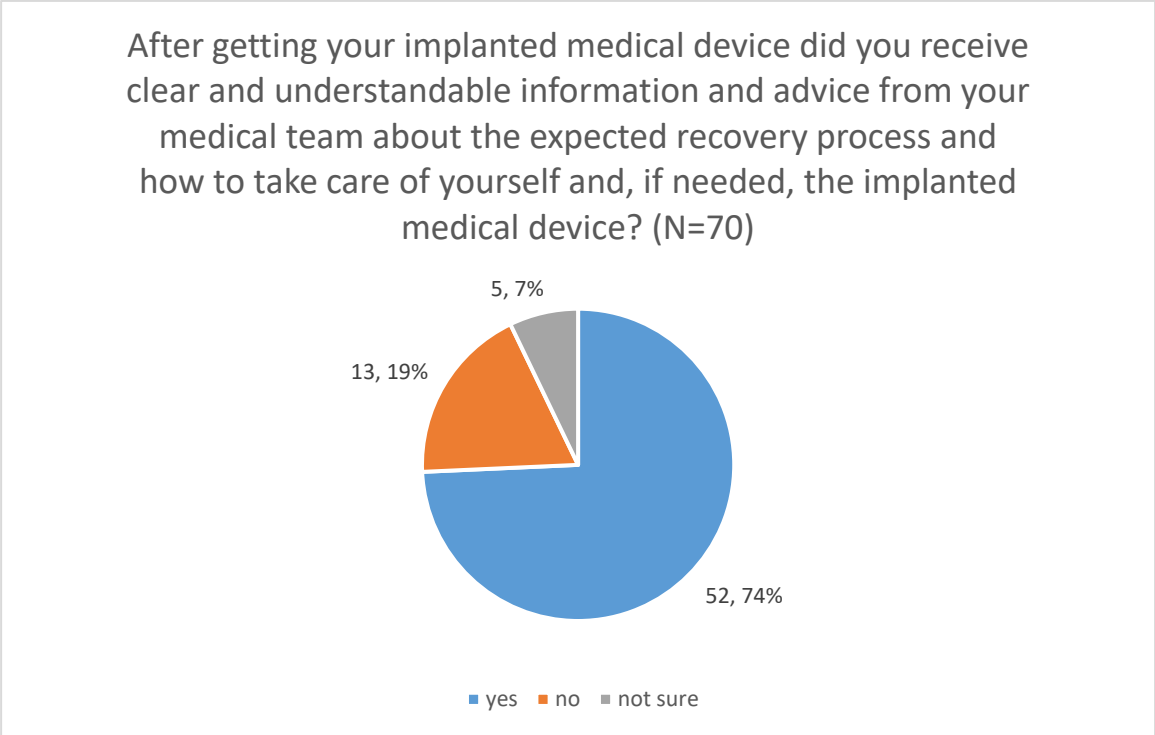


Figure 15: Information from the medical team after getting the device and knowing about recovery and how to take care of oneself and the device

Issues around receiving information from the medical team after the procedure to know how to take care of themselves and the device

While most received this information, participants' responses highlighted that many received information about their aftercare but not about how to take care of the device, and some received more detailed information about recovery than others.

However, for thirteen of their devices (19%) participants said they were not given this information at all, and for five (7%) they were unsure (N=70), as shown in Figure 15. For some participants, this differed between their devices.

Some said they received no information regarding recovery, even though some did get information about the device. Some participants explained that they would have appreciated more information from their medical teams on both their recovery and how to take care of their medical devices if appropriate. Some participants also highlighted that they didn't feel they needed this sort of information, as they had been through similar procedures in the past, or due to their procedures being straightforward in terms of recovery and the implanted device itself.

Further information needs after the procedure

For over half of their devices (42, 59%, N=71), participants said that there was other information they would have wanted to get from their medical team after getting the device, as shown in Figure 16.

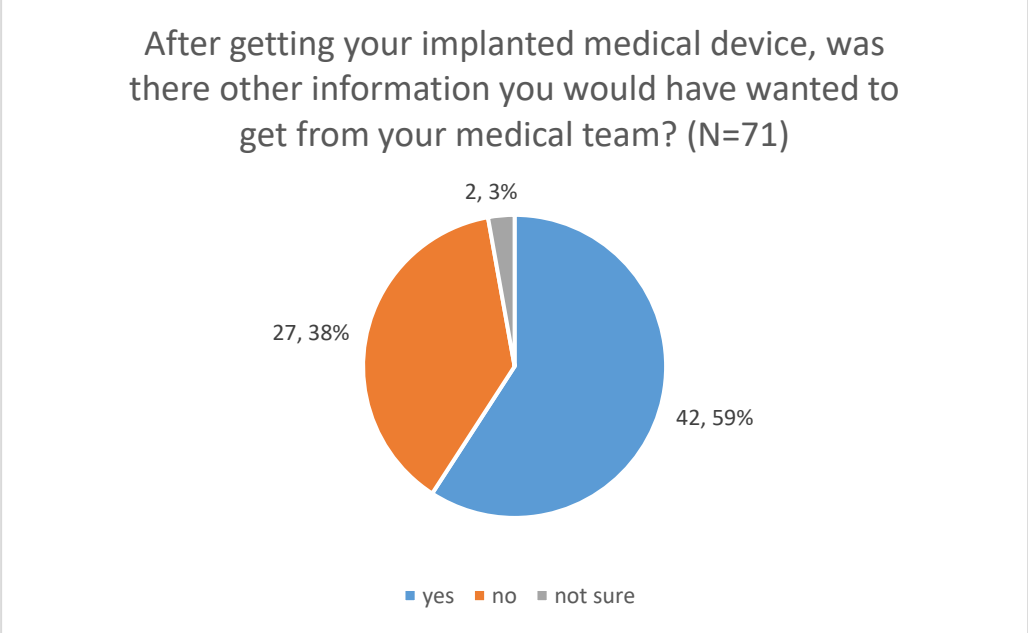


Figure 16: Further information needs after the procedure

Many participants said they would have wanted more information from their medical team following their procedure, including about their treatment and recovery and their medical device. Some participants discussed wanting more information about their aftercare, treatment, and recovery, with pain management and wound treatment after the procedure being a frequent concern. Participants said they would appreciate if this was in writing, with one participant saying:

"If your pain is not controlled, you can't do anything, and it has an impact on your mental health and psychologically. An information sheet about pain relief would have been useful."

Another participant said they:

"would want to know more about the recovery and what's normal and abnormal. It would have been good to know about key milestones for your recovery. Also, to have had additional appointments between having the operation and the 2-year full recovery stage, just in case you have any concerns. It's not good to have to go through the system again."

Participants had different views about whether they needed further information. Some discussed wanting more information about their device and expectations around this seemed to vary depending on the type of device, for example, information regarding heart valves or defibrillators being more sought after than information regarding lenses. Some said that it would have been helpful to have a more realistic understanding of what to expect after the procedure, and to meet the medical team on a regular basis to monitor progress and provide reassurance. One participant said they felt alone and depressed due to this not taking place.

On the other hand, for over a third of participants' devices (27, 38%) participants said they did not want further information, and for two (3%) they were unsure (N=71), as shown in Figure 16. For some participants, this differed between their devices. For some participants, this had to do with them feeling that they had been given adequate information by their medical team and did not require anything further.

4.2.4 Providing patient feedback on experiences of implanted medical device processes and procedures

Participants' experiences of providing feedback on their experience with their medical device

Negative experiences, issues, and challenges around providing feedback

For half of their devices (35, 50%), participants said they had not been asked to provide feedback about their experience, and for nine (13%) they were unsure (N=70), as shown in Figure 17. Furthermore, for just under half of participants' devices (28, 46%), participants said they don't know how to provide feedback about their experience. For 11 of their

devices (18%) participants were unsure whether they knew how to provide feedback or not, as shown in Figure 18 (N=61).

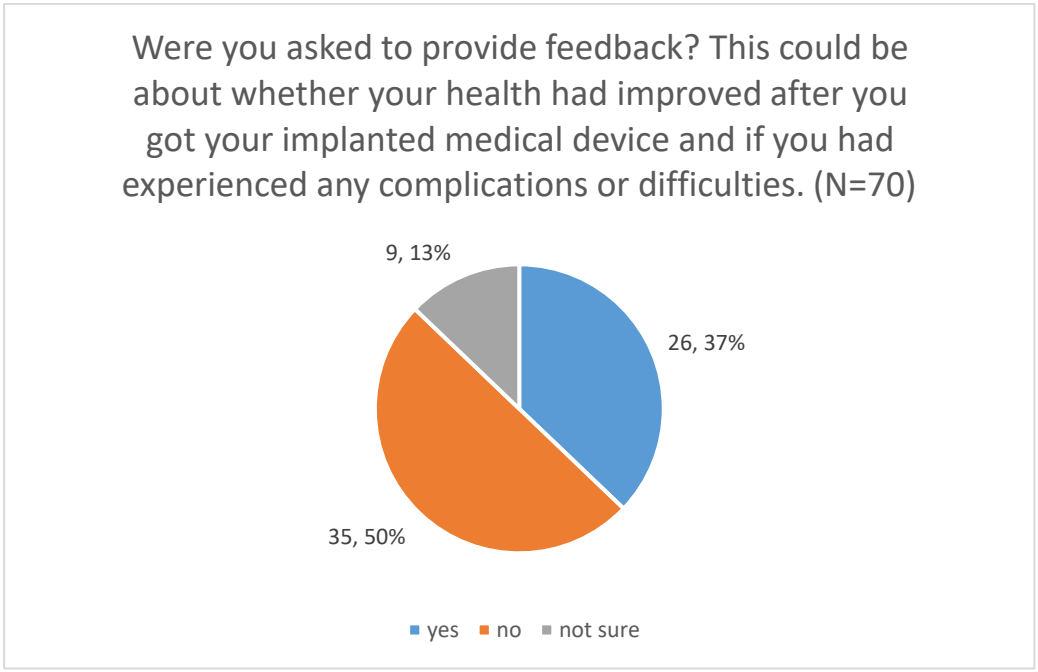


Figure 17: Being asked to provide feedback after the procedure

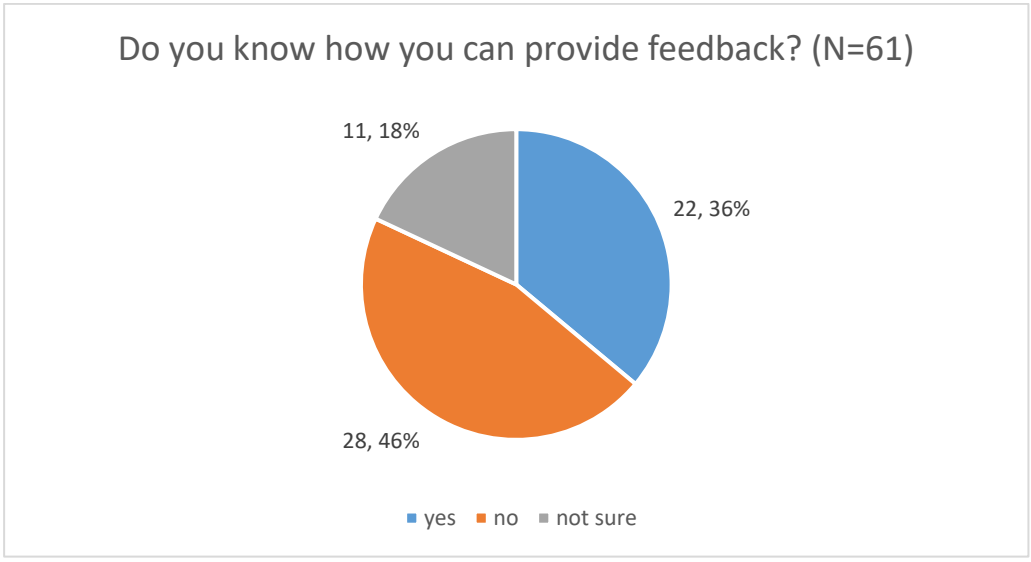


Figure 18: Awareness of how to provide feedback

Some participants stated that they were not aware they could give feedback, they did not know who to provide feedback to, nor how to go about it, but if they had been asked or known how to give feedback, they would be happy to. For example, one participant explained how they would have liked to have discussed an issue with their treatment with their clinician, saying:

"I'd have liked to have spoken with him again, as I feel like he just lengthened my wait for treatment by saying this (referring to a communication issue which led to delay)".

Some also felt that if they wanted to provide feedback, they would be able to find out how. For example, a participant said they would "take the bull by the horns and try to talk to my GP", though some others said they felt their GP was difficult to get in touch with.

Two participants noted that they did not remember being asked to provide feedback but would have been comfortable to do so if they wanted to as they felt listened to throughout the process. Two participants were unsure if they had been asked to provide feedback.

One participant said they had been asked for feedback following a previous procedure in 2014 but had not been asked to do so for the current device that they got in 2019. Another participant highlighted that they had been asked to provide feedback through an online questionnaire when getting a procedure done privately but had not been asked for feedback when they got a procedure through the NHS. Another participant explained how they fed back about how unwell they felt, only for their concerns to be dismissed and to be told that:

"I had to live with it and that 1 in 5 of these things didn't work and I happened to be one of the five. I went back to the GP and mentioned this, and the GP then organised another appointment with the consultant. I think my GP had spoken to him, as by this time he had changed his tune."

One participant said they might have been given an online link before the procedure, potentially a link to Care Opinion. The other participant discussed being involved in drug research and having appointments with a cardiac nurse and cardiologist as opportunities to give feedback.

One participant said that they were still experiencing pain following their procedure but had not fed that back to their GP.

One participant attended an exercise class and was encouraged to feed back, however, they are still trying to source who to feed back to. One participant explained they don't like providing feedback, as it feels like a "tick-box exercise".

One participant expressed concern for those who would be unable to feedback, for example, younger or older patients "who can't speak for themselves", and some other participants felt that the pandemic hindered feedback processes.

Positive experiences around providing feedback

For over a third of participants' devices (26, 37%) participants said they had been asked to provide feedback (N=70), as seen in Figure 17. For just over a third of participants' devices (22, 36%), participants confirmed they do know how to provide feedback (N=61), as seen in Figure 18. For some participants, this differed between their devices.

Most participants who said they know how to provide feedback, noted that they would do so via the service who carried out the procedure. Some participants explained that they were happy to use Care Opinion to provide feedback.

When asked about feedback opportunities, many discussed their follow-up appointments and associating giving feedback with being asked how they were getting on following their procedure. Some participants said they felt like the follow-up appointments provided them with the opportunity to give feedback on the process, though some said that they weren't specifically asked to provide feedback. Two participants mentioned tools they were given access to in order to provide feedback, for example, a recovery app and a daily diary. These provided participants with opportunity to reflect and feedback on how their recovery was going. One participant said they were given the opportunity to feed back but they chose not to. One participant advised they still provide ongoing feedback to their consultant, as they are still being seen regularly. One participant advised they regularly contact their consultant and relevant service via email.

Participant thoughts around potentially providing feedback routinely about their experience

Positive views on potentially providing feedback routinely and how this could be done

For most of their devices (45, 66%, N=68), participants confirmed that they would like to be able to routinely feedback about their experience, as shown in Figure 19. Participants said, for example, "definitely yes" and "if it helps somebody, absolutely". Participants explained how they felt that sharing their own lived experience would benefit others, such as reassuring others about the process, about what to expect or what to be aware of, and how to live their life with an implant. They also thought that providing feedback to staff would help improve processes and information in future.

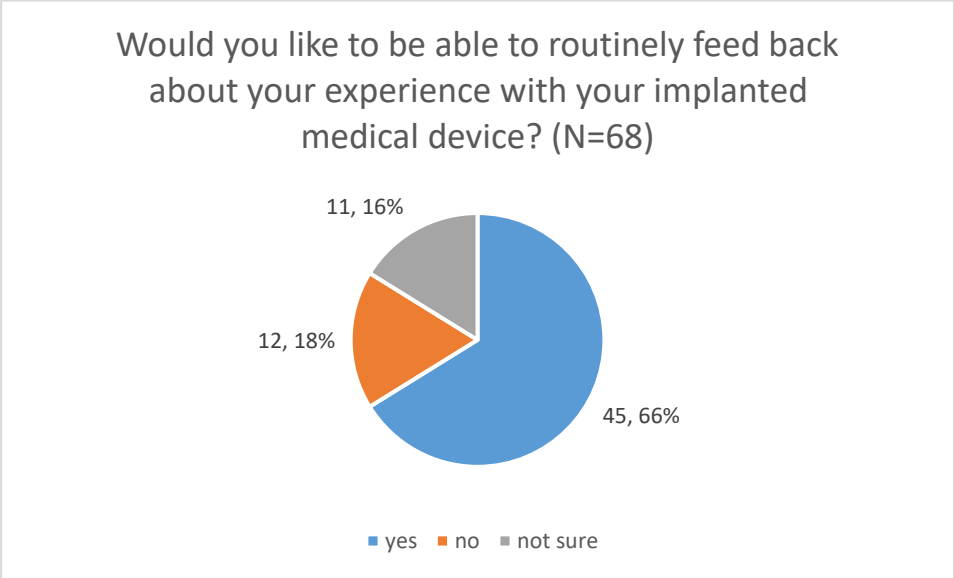


Figure 19: Views on providing feedback routinely

Some participants discussed aspects they would have liked to provide feedback on. For example, one participant mentioned being told to watch a specific series of videos on YouTube about recovery and aftercare. However, they remembered feeling that these

videos were unrealistic, and explained that they would have liked to feed that back to the medical team at the time.

One participant noted that feedback needs to be clearly defined, so it is clear what the purpose is and how it would be used, also ensuring that participants are informed of the difference their feedback has made. They said:

"it's important to be informed as to what is done with this feedback as well as defining what is meant by feedback".

Another participant noted that opportunities to provide feedback need to be available to all and highlighted that there must be "offline" avenues for this as well; not everyone uses online tools or has access to the internet.

Negative views around potentially providing feedback routinely

However, for 12 of their devices (18%) participants did not want to feed back routinely and participants were unsure for 11 (16%) (N=68), as seen in Figure 19. For some participants this differed between their devices.

Some participants explained that they wouldn't want to provide feedback routinely as they thought that adding additional mechanisms for feedback would add more pressure to the system, discussing how staff and services are overstretched. A small number of participants did not want to provide routine feedback due to either personal circumstances or because a significant amount of time had passed since their procedure. One participant said: "now I'm recovered, I don't really feel like I have to. I might have done at the time", and another said: "it would have been helpful at the time".

Ways of providing feedback

Overall, feedback from participants highlights the need for a variety of methods to be available for patients to provide feedback, to address people's preferences, needs, as well as potentially being more relevant at different times in their patient journey. Ways of providing feedback that were discussed included:

- In person: most participants thought that discussions in person and face-to-face were the best way to provide feedback.
- Online: many participants discussed providing feedback online, mentioning a range of methods, such as online meetings, Care Opinion, or email.
- Surveys and questionnaires: most participants discussed surveys and questionnaires as good options to collect feedback, and they mentioned both doing these online and in written form and circulated via post. Two participants mentioned that including questions with scales in surveys would be a helpful way to ask for feedback.
- Over the phone: some participants discussed phone calls as a good way to provide feedback. However, some noted that it can be difficult for people to record conversations that way.

- Over videocall: some participants discussed giving feedback over a videocall, potentially in a one-to-one or group discussion.
- Routine feedback at follow-up appointments: some participants discussed wanting to provide feedback during their routine check-up and possibly increasing their check-ups to quarterly or biannually, recognising that this may depend on the type of device one has.
- Sharing lived experience: participants discussed, as in previous questions, the value of sharing lived and living experience, and learning from others. They also noted that there does not seem to be a clear way in which to share their experience with others. One participant highlighted the need to hear about lived experience from younger people, as they felt this would have benefitted them at the time.
- Simulated training or test patient: two participants noted this method as a good mechanism to provide feedback, particularly for new staff to understand the patient journey around getting an implanted medical device.
- Holistic approach: one participant noted that a more holistic approach would improve feedback processes and lead to improvement. For example, one participant said, "I'm very thankful to the consultant, but there's nowhere in the system where anybody else knows that I think he's brilliant. He knows because I told him", suggesting that they would like their feedback to be part of a more streamlined and impactful process.

4.2.5 Views on an implanted medical device tracking system

Potential benefits of a tracking system

Most participants agreed that a tracking system for implanted medical devices would be a good idea and helpful to have, and that it would minimise costs and improve efficiency. Most thought that it would benefit them and others to know that they could access such a system, and that this was also being used by medical staff. Participants felt reassured that such a system would allow tracking of potential issues with their device, giving them peace of mind knowing that such a tracking system was in use and that they could be contacted if there was an issue. However, one participant noted the need to potentially use other means of communication as well when there is an issue with a device, for example, being notified via text message. Some participants felt that having all this information easily accessible would save staff time by alleviating delay in treatment or recall of a device. One participant noted that such a system would be helpful due to the large number of implanted devices being used and the challenges in getting necessary information about implants and procedures in some cases. They said:

"I think it would be excellent and beneficial for everybody. You need that information and I think you should be told it. With heart valves, pacemakers etc., people are given more information about the implants because they are life threatening. But there are thousands of

hip replacements getting done and we have very little information about replacements and implants given to us with our operations."

Some participants saw a tracking system as a good way to ensure access to as much information as possible and having it all in one place. Some participants thought it would be good to have this information on an app, especially since, as one participant discussed, all medical records are already online. Participants said that, having all this information in one place and easily accessible, would be particularly helpful when moving between countries. One participant explained that this would be really helpful in the case of an emergency, for emergency staff to access it, or where patients may have to relay information about their device to medical staff. Another participant thought it would be beneficial for those who may not be able to retain large amounts of information, for example, people with cognitive difficulties. One participant said that they could see the merit in having this information and having a standard approach across the board on how this information is stored, saying:

"All basic information in one place would be good, people won't have to be using different sources to look for information."

Requirements, expectations and barriers to a tracking system

While recognising potential benefits, participants also discussed what they would need and expect of a tracking system to ensure these benefits. Participants highlighted that the system would need to be robust and secure, especially around confidentiality and privacy, and that they would need to clearly understand how the data and information would be used.

When asked what information they would want to find on a tracking system, participants mentioned they would want to find information about:

- the device used in their care
- how long the device is expected to last (device longevity)
- device functionality
- information about recall, potential risks, or whether there are any problems with the device
- benefits of having this information, and
- information on how to provide feedback.

Nearly all participants wanted to know what their device was made from, the device manufacturer, how it works, the device serial number, etc. Most participants said they wanted to know how long the device or battery would last for, whether it would need replaced at some point, and when. Many participants also said it would be good to know if something went wrong with the device and that devices could be recalled through the system. One said they would appreciate knowing what to do if there was a recall and would

like to be sent a text message to tell them to visit the database or contact a clinician. They said:

"Most patients would be happy to know what to do if there was a recall. Patients wouldn't have to go into the database, they would be sent a text message to check that site and contact a clinician about a recall."

One participant said they just wanted to know that the device was continuing to function as it should be, with another wanting to know if there are any improvements or firmware updates for their device.

Some participants felt it would be good to know about different devices and how they perform, with perhaps before and after pictures. Some participants highlighted that, having this information in digital form and all in one place would make it easier to access, though they again noted that ensuring confidentiality was very important to them.

One participant mentioned knowing about the device's reliability would be helpful.

One participant thought that a tracking system would be beneficial, but that they would need to understand more about it. One participant wanted to know what benefit this information would be to them, as this wasn't clear.

Two participants felt they wouldn't benefit from a tracking system and wondered why anyone would want to track their device. Another participant felt this type of system could frighten some people.

4.2.6 Priorities, key considerations and what matters most around information provided about implanted medical devices and relevant procedures and processes

A person-centred approach to information around implanted medical devices

Participants highlighted the importance of the way in which information is provided. They noted that information needs to be accessible, user-friendly, and communicated well. While this was important to participants, preferences on how to receive information differed, highlighting the importance of using a range of means to communicate with patients. For example, some thought there should be more leaflets and that they should cover a variety of conditions and be widely available. Some participants highlighted the importance of a more person-centred approach. One participant commented that they received much more written information when they got a procedure done through private healthcare in comparison to their NHS experience. However, another said they felt that leaflets are impersonal, and two participants explained they would prefer a more tailored and personal approach to the information they received. One participant thought it would be beneficial for staff to be trained to have a brief discussion with patients about their procedure prior to

surgery. Another participant added that an important aspect would be to ensure that patients are listened to, as their concerns about issues with their pacemaker had been dismissed by clinicians in the past, even though they were experiencing concerning side-effects. The participant explained that patients react differently to devices and that staff should listen to the patient and trust their experience and symptoms over technology.

This person-centred approach must also consider differences in information needs, as participants' responses highlighted that patients want different levels of information and at different times. As one participant said in their feedback, "ignorance is bliss".

Obtaining information through a range of methods and avenues

Participants, throughout the interviews, highlighted that different methods of receiving information may be helpful in different contexts and for different people, and emphasised the importance of this. Participants consistently said that all information should be available in different formats, for example, verbal and written, online and offline. They discussed getting information verbally from clinicians, reading information leaflets, using digital apps for pre-care and post-care, and receiving text messages. Furthermore, while most were positive about their interactions with staff, there was a feeling that staff interaction was limited. Some wanted more opportunities to ask questions, signalling that in person support and opportunities to ask questions are valued as a form of obtaining information as well.

Many participants discussed the importance of peer support and being linked in with other patients who have had similar experiences, as well as family, friends, and support groups. Some participants noted that they would have found it useful to have an opportunity to speak with people with lived experience of their device, before and after the procedure, but did not get that option, and didn't know where to find that kind of information.

One participant said that the hip replacement group they had attended provided more support and information than the hospital, and that they benefitted from having a "sounding board" to voice concerns, rather than feeling as though they were annoying the medical staff.

The role of "independent research" and patient initiative

Some participants didn't feel well informed and instead relied on their own research or information from friends who had undergone a similar procedure. For example, one participant felt they had to take the process into their own hands, bypassing their GP and emailing consultants directly in order to get a diagnosis. A further participant discovered that an incorrect device was listed on their referral letter and notes, which was only picked up when they mentioned this to the nurse prior to the procedure being carried out. They said:

"I had picked up on it but potentially could have received the wrong device!"

Another participant recounted their experience, where both themselves and their spouse needed a knee replacement. When discussing their knee replacement with their consultant, they were told they would be getting a new type of device, as the older type had a high rate of failure. However, their spouse had not been advised about that and was indeed going to initially be given the old type of device, until they challenged this through providing clinicians with a printout of the report outlining the device failures. To ensure the spouse received the right type of device they had to ensure they were seen by a different health board and in a different location, as in their original location the older device was still being implanted. The participant expressed concerns about this, and the fact that their circumstantial awareness of the issue, due to their personal situation and context, highlighted that others are disadvantaged. They also said that, by not having had information such as the manufacturer's name or the specific device details, they would not have been able to find out about these failures if the consultant had not discussed it with them.

Differences and inconsistencies in information provided between different procedures or in replacement procedures

It was common for participants to have had more than one device or replacement of their devices. In almost all cases, how much information they received varied between different procedures. Most of the participants that had replaced their implanted devices noted they did not get as much information compared to those getting an implant for the first time in order to understand what to expect and what might happen. Echoing previous responses, participants said they felt there was an assumption by the staff or service that they would know what to expect having had a device before. One participant said this was understandable and they felt staff would have provided more information if needed or asked for. Other participants, however, have noted that they didn't feel this expectation was fair as they still needed the same information, and they may have forgotten or misplaced the information given at the time of the previous procedure.

Some participants noted that they received information before their procedure for their first implant, but minimal or no further information was provided for subsequent implants. They felt it was assumed that they already had all the information they needed from the first implant, and that staff "assumed you know the gist". One participant did note that they had a discussion with their consultant on the improvements and differences between their old device and the replacement device prior to surgery. Two participants, however, said they received more information before receiving their second device than their first, or that they had two different devices and received more information about one device than the other. One participant highlighted the importance of providing up to date, enough, and correct information every time a patient receives a device or goes through a procedure. They noted that many things change in time, not only technology but ways of working, multi-disciplinary approaches, and information, and it is important to keep improving things.

One participant was told that the information and support they would receive was limited due to their situation. In this case, they had not had a heart attack and therefore would receive less support than others who had a similar device but had had a heart attack, which they felt was not appropriate and left them confused.

Perceptions around the impact of the COVID-19 pandemic

Several participants thought that the pandemic had a negative impact on the level of information they received prior to their procedure and many spoke of the “impact COVID had” on appointments and waiting times. Some participants felt that the pandemic led to delays in both appointments and waiting times and that this also negatively impacted on the level of information they received prior to their procedure, although one participant felt they received their operation quicker than anticipated during the pandemic.

One participant noted that all procedures were halted due to the pandemic, which resulted in a backlog and delay in receiving their implant.

The pandemic seemed to have had a significant impact on some participants’ experiences prior to receiving their devices. At one person’s initial appointment, during the first week of lockdown "the doctor seemed on edge and told me to do my exercises and I'll be fine in 6 weeks. To me this was the wrong information”; this patient then waited in pain for six months before having to chase up the hospital for a consultation. One participant explained how they had to have their knee replacement consultation online on Zoom and they were only given an overview of the situation. One participant suggested that the pandemic might have been the reason for having received limited information.

Participants discussed the perceived impact of the pandemic on communication between departments, needing to make repeated phone calls to get a consultation, getting poor service from GP practices and having difficulties in getting advice, and not knowing what the surgery would involve. A participant likened their experience to a “factory process”.

One participant noted their aftercare was impacted as the implanted device was fitted during the pandemic, however primary care services were still unavailable at that point, and they missed out on correct aftercare. One participant commented that they had to wait for three years to have their current implant replaced due to the pandemic.

Some participants also felt that the pandemic hindered patient feedback processes.

The importance of information for the overall patient experience

Participants highlighted the crucial role of getting the right information, suggesting that this has the potential to impact one’s overall experience with an implanted medical device, either positively or negatively. When discussing their experience with implanted medical

devices overall, those who described their overall experience positively were satisfied with the information they received or were simply happy to have received their device and have improved health and quality of life as a result. On the other hand, those who described their experience negatively, felt that the information they received was insufficient or incorrect, or had negative experiences around the process of getting their device.

Receiving more information was identified by most participants as being important. Some mentioned that they felt more reassured and supported when they had more information, and, for some, this reassured them even more than actually receiving the device itself. This was especially the case for one participant who lived a 2–3-hour drive from their medical team. Another participant said that "information is power", saying that the more information patients are given about their treatment journey, the more control they have over their health.

When discussing whether they received information from their medical team before their procedure, for most responses there was a clear divide between positive and negative attitudes towards the amount and quality of information participants received, and it was clear that the level of information received had a significant impact on participant's experience. This is exemplified by one participant, who in their first hip operation, carried out in 2018, received a comprehensive amount of information about the device and the procedure and "was thankful for that because after my op I was out within two days. I was very happy with how things went". However, for their second hip replacement they were more anxious due to having less information. It is clear that many of the participants appreciated being informed and, thus, were able to have a say in their care. This was felt by most who received clear communication from their medical team about their procedure. For example, many had a choice between which devices they received, and, in some cases, could decide if they would go ahead with the procedure based on the pros and cons provided by the doctors.

Some patients described having little to no information before their procedures, however, were neutral in their responses.

For a small number of participants, receiving information was not a priority and didn't influence their experience. Two participants were just grateful to be receiving the device to maintain their health. One mentioned that "knowing what type of device wouldn't really matter to me" and the other patient thought that the "requirement of information is very different depending on the device" and that something like a pacemaker requires more monitoring by staff and awareness of what to do if something goes wrong.

Getting the right information

Information about the device and suitability: Some participants mentioned that it is important to receive specific information about the device, such as the device details, how it works, its longevity, and what to do if the device stops working or requires a replacement.

Two participants thought it was important to know beforehand whether they were suitable to receive the planned device, as an essential part of information relating to their health condition. One participant highlighted the need to have the device details to hand, in case they were required for future medical needs or an emergency. Someone else thought a "credit card-sized device card", as some already have mentioned, would be important to have, similar to the implant cards discussed in previous questions, though they were previously not aware of these.

Information about impact on life: Many mentioned the importance of knowing beforehand how the device will impact their daily life in order to make informed decisions about their health. They wanted to know, for example, what their future might look like, and whether the device would help with pain and discomfort they were experiencing. Participants also wanted to know if the device is safe and what risks are involved, and one mentioned wanting to specifically be aware of any contraindications that would impact on their safety and day-to-day life.

Information related to the procedure: Participants also wanted to know about the procedure, and what it would be like before, during, and after getting their device. Some felt it was important to know what to expect post-surgery and what could be done to aid recovery, such as physiotherapy exercises. One person, who had an anxious experience awaiting their procedure, noted that it would have been helpful to have been allowed to visit the hospital before being admitted. They suggested that information people are provided with beforehand should potentially allow an opportunity for familiarisation with premises, or other aspects as well.

Aftercare and support: Participants discussed the importance of receiving the appropriate level of aftercare, which one person felt was lacking based on their experience. One participant said that having follow-ups for one year post-procedure should be established. In relation to this, another participant said they wanted more signposting and support after receiving their device, and that the audiology department who dealt with their aftercare were less knowledgeable about it than the medical team who had done the procedure.

Up to date, correct, and joined-up information and support: Needing to have accurate and up to date information was a common factor in participants' views of what is important. For instance, one participant discussed their negative experience when they were given inaccurate information about what their physical restrictions were post-surgery. Participants also discussed that communication between multi-disciplinary medical teams should be joined-up, and one participant said that this would give them confidence about their care. Another participant highlighted the impact of services not being joined-up in their experience. They said that while waiting to get their device, an unknown to them member of staff said that they did not require a device, despite all other tests and discussions saying differently and the procedure being booked. The procedure was then cancelled, without the participant being informed about the reasons. They eventually did get the device, but this had been a negative experience for them.

Access to information and confidentiality: Some thought that, being given staff telephone numbers to contact for immediate support and reassurance, would be a more accessible way of communication. Two participants noted that they would benefit from a tracing system or database that would contain their device information. They suggested this would be helpful for those who "don't have everything they need on their doorstep", such as their medical teams or hospital located nearby. They also thought that a database would automatically alert staff and patients when their device needed replaced or if there was an issue. Two participants discussed wanting access to their personal details, for instance, their medical records. One participant highlighted the importance of confidentiality and data protection, describing how, in their case, patient confidentiality was breached by their medical team when personal details were discussed openly in front of a group of patients.

Section 5: Conclusions and recommendations

This section of the report brings together the main conclusions drawn from the findings of this Gathering Views exercise and outlines recommendations.

5.1 Conclusions

Information received from the medical team before the implanted medical device procedure

The findings show that, for a large proportion of participants' devices, participants got information from their medical team before the procedure, covering many important elements, which they were happy with. However, many didn't receive all the aspects of information, observed inconsistencies, and had further information needs.

For more than half of participants' devices, participants did receive information from their medical team before the procedure, and most received information on the type of proposed device, device longevity, and information about potential problems. Many had positive experiences around this and were satisfied with the information provided. Participants highlighted a wide range of ways in which they received this information, for example, having in person discussions, getting letters and leaflets, going to a "joint replacement school", or being given dummy devices to practice on. Participants highlighted further positive aspects, such as feeling that they could ask questions, getting satisfactory and helpful answers, being allowed to get help from a translator or a family member, and staff being supportive.

On the other hand, for nearly a third of participants' devices, participants said they did not receive information from their medical team beforehand. For most of these devices, participants did not receive information about the device manufacturer nor information about alternative devices. Many felt that they got minimal or no information and described the significant impact this had on their patient experience. Some recognised that there may not be any appropriate alternative devices or treatments. Some participants said that staff communication was insufficient and poor, and that staff did not have time to provide information appropriately according to their needs, describing significant challenges during their care due to communication issues. Some participants discussed issues and concerns about the way they received some of this information, for example, needing to access information online and this being a potential barrier for some. For a small number of participants, however, not receiving information was not an issue, as they did not feel they needed this.

Participants specifically discussed needing more information from their medical team before the procedure on:

- device type, number, and alternatives
- how long the device is expected to last (device longevity)
- the procedure, recovery, aftercare, and
- risks and potential problems.

The role of information from the medical team in setting expectations, understanding benefits and risks, and providing fully informed consent

For a significant proportion of participants' devices, participants said they had enough information to help set their expectations, understand benefits and risks, and provide fully informed consent, which participants were positive about. However, for some of their devices, this was not the case, and participants discussed inconsistencies and further information needs.

For over half of their devices, participants confirmed that the information was enough for them to understand what might happen and know what to expect after getting the device. Similarly, for most of their devices, participants said that the information was enough to clearly understand benefits and risks. For most of their devices, participants confirmed that the information they received was enough to provide their fully informed consent, though some explained that they felt consent did not really apply in their situation, as getting the device was their only option, and they trusted the medical team. Many said the information was clear and sufficient.

For some of their devices, however, the information provided by the medical team before the procedure was not enough for participants to understand what might happen next and know what to expect. Similarly, for some of their devices, participants felt that the information was not enough to clearly understand benefits and potential risks, and some said they didn't receive any information about benefits nor risks. Some participants felt that the onus was on them to ask the right questions and that staff were too busy to give them their full attention. For a small number of their devices, participants felt the information they were provided was not enough to give their fully informed consent, and some commented that, in hindsight, they would have benefitted from more information. They felt that more information would alleviate their anxiety and they would feel more supported. Participants also discussed that the timing and the way they receive information can influence how useful it is. At times, they felt overloaded with information. They would have preferred the information at a different time or in a different way, as well as being more supported to engage with the information and understand it.

Further information needs and sources before getting the device

The findings suggest that discussions between participants and their medical team on where to find further information were not widespread. Although, for more than half of their devices, participants did look for further information, with participants expressing some concern around this.

For over half of their devices, participants were not signposted to further information sources by their medical team and did not have a discussion about this. For over a third of their devices, participants said they did not look for further information, as they did not feel the need, or they were too unwell to do so.

On the other hand, for some of their devices, participants did have a discussion about where to find more information with their medical team, and most were signposted to the NHS Inform website, or their GP or specialist clinic.

For over half of their devices, participants confirmed that they did look for more information, from a range of sources and in different ways, such as through family and friends, peer groups, other relevant professionals, and doing their own "independent research". They discussed accessing information through online and digital sources, as well as offline sources.

Participants noted that, before getting the procedure, they wanted more information around the device, the process, and the expected impact on their lives. They also explained they wanted to receive the right information, both in terms of content as well as receiving the information in the right way for them. Participants also highlighted the importance of peer support and hearing from others with lived and living experience of their device.

When discussing sources of further information, participants expressed concerns around accessing information online, mainly focusing on concerns around quality of information, information overload, and potential access barriers.

Information received from the medical team after the implanted medical device procedure

The findings confirm that, for most of their devices, participants did receive post-procedure information from their medical team, which covered most of the elements of information discussed. Many participants were positive about this. However, for some of their devices, participants did not get any information after the procedure, and participants discussed issues around the information received and further information needs.

For most of their devices, participants confirmed they received information from their medical team after the procedure. For most of their devices, they got information on who to contact if there were issues, who to contact about recovery and next steps, and information about how the process went. For half of their devices, participants said they also got information about the actual device type. For over a third of their devices, participants also got an implant card, information about the actual device manufacturer and the device serial number. Participants discussed getting this information in a range of ways, many through follow-up appointments or printed sources, for example, letters or booklets. Some participants said they were satisfied with the information they were given, that it was comprehensive, and they were able to ask questions.

On the other hand, for some of their devices, participants said they did not get any information after the procedure. For over half of their devices, participants said they did not

get the actual device serial number, an implant card, nor information about the actual device manufacturer. For nearly half of their devices, participants said they did not get information about the device type. Some participants also discussed broader communication issues after the procedure, for example, not being able to fully remember information they were given right after the procedure due to their condition at the time, or issues with staff communication, such as their questions not being answered or having the wrong contact details.

Many discussed not getting an implant card. Those that did get an implant card further discussed that the implant card they received wasn't always a "credit-card-sized card" and wasn't as easy to store as hoped for. Some discussed having information about the actual device on the device packaging.

Participants confirmed the safekeeping of information for just under half of their devices, but, for over a third of their devices, participants said they do not have the details they were given, suggesting that this is an important aspect to consider when providing information. Participants discussed that the way information is provided and the timing of this may influence whether they are able to store this information safely for future.

For most of their devices, participants confirmed that they received clear and understandable information about the expected recovery process and how to take care of themselves and the device. However, some received more detailed information than others on this, and some participants say they would have liked to receive more in-depth information.

For over half of their devices, participants said they would have liked to receive further information from their medical team after getting the device. For many, their further information needs were around treatment, recovery and aftercare, and the medical device. On the other hand, for over a third of their devices, participants said they did not want any further information, and some participants recognised that what information they were given after the procedure could depend on the type of device.

Providing feedback around experiences with implanted medical devices

The findings show that, while participants had only been asked to provide feedback for around a third of their devices, most said they would be happy to provide feedback, including providing feedback routinely, and many said they knew how to do this if needed.

For half of their devices, participants said they had not been asked to provide feedback about their experience, and, for just under half of their devices, participants said they did not know how to provide feedback. Some participants said they did not know how to feed back but thought they could find out if they needed to.

On the other hand, for over a third of their devices, participants had been asked to provide feedback, and, for just over a third of their devices, they said they do know how to provide

feedback. Most said they would provide feedback through the service that carried out the procedure, and many said they feed back through their follow-up appointments.

For most of their devices, participants confirmed that they would like to be able to routinely feed back about their experience. Participants discussed wanting to provide feedback in a range of ways, including:

- in person
- online
- surveys and questionnaires
- over the phone
- over videocall, and
- at follow-up appointments.

For a small number of participants' devices, participants did not want to provide feedback routinely, mainly as they thought it would add pressure to the system, due to their personal circumstances, or due to the amount of time since their procedure.

An implanted medical device tracking system

The findings suggest that participants have positive views about a potential implanted medical device tracking system, and can see a range of benefits. However, participants also outlined what would be required of the system to ensure these benefits.

Participants discussed a range of benefits in having an implanted medical device tracking system, for both staff and patients, including enhanced communication and increased access to information for all. Participants also discussed what they would expect and need from such a system, such as the system being robust and secure, with increased confidentiality and privacy. The information they would expect to find on this system focused on:

- the device used in their care
- how long the device is expected to last (device longevity)
- device functionality
- recall, potential risks, or whether there are any problems with the device
- benefits of having this information, and
- information on how to provide feedback.

However, not all participants saw the need or benefit of having this system, or would access the information on it, so this would need to be made clear to patients.

Priorities and considerations around information about implanted medical devices, procedures and processes

Priorities and key considerations on this topic included:

- The importance of information in shaping the overall patient experience, with participants often linking their overall positive experience with having satisfactory information, and negative experiences with a lack of the desired information. However, this differed between participants and their information needs, and, for some participants, it was more important that their information needs were respected, for example, if they did not feel they needed extensive information.
- Getting the right information, the right way, with participants highlighting that it was not enough to get some information. They wanted particular information, for it to be provided in the way that suits their needs, and at the right time for them. They discussed wanting information about the device and its suitability, the procedure, the impact on their lives, and aftercare and support. They noted this information needs to be up to date, correct, and joined-up. They also highlighted the need for the information to be accessible and confidential.
- A person-centred approach to information around implanted medical devices, ensuring that patients who have, or are due to get, an implanted medical device, are given the information they need, in the way they wish, and at the time that facilitates their understanding and suits their needs. This requires patients to be consulted on their information needs, and these to be understood, recorded, and implemented appropriately.
- Ensuring information is provided and available through a range of methods and avenues, which suit individual information needs, preferences, and access requirements.
- The role of people's "independent research" and patient initiative, recognising that many patients will seek further information and supporting them to do so appropriately, addressing concerns discussed by participants, such as relating to finding information online and needing to assess quality and appropriateness.
- Differences and inconsistencies in information provided between different procedures, which have significant impact on the participant experience, as highlighted by these findings, and could lead to unequal outcomes for patients. The differences and inconsistencies discussed by participants included differences in levels of information provided:
    - between less and more commonplace procedures, or newer and more established procedures and devices
    - between less and more high-risk procedures and devices
    - between a first procedure and subsequent replacement procedures
    - between different devices the same patient has
    - depending on the person's demographic characteristics, such as age, or their medical situation, for example, if they have had a heart attack or not

    - depending on the staff's perception of the person's existing medical knowledge and understanding, for example, staff thinking that someone who is a medical professional may already have a good understanding so may not provide as much information
    - depending on the staff member and team delivering the information, with some participants saying that certain roles and teams were able to provide more in-depth information than others
    - depending on the person's access needs and preferences, with some needing support to fully understand information, for example, a translator, or alternative formats
    - depending on procedure timelines, with participants who had a shorter timescale between finding out about the procedure and getting it saying that they did not get as much information as those who waited longer for their procedure
    - depending on the person's health and medical condition, which may mean that they are less able to seek information themselves, so all their information needs should be addressed by their medical team
- The perceived impact of the COVID-19 pandemic, with participants discussing how the pandemic may have influenced what information they got, when and how, as well as its impact on implanted medical device procedures and processes.

The landscape of implanted medical devices

These findings suggest that patients who receive one implanted medical device as part of their care, may be more likely to receive further devices, whether replacement devices or different devices, which could be linked to the same health condition, or a separate issue. This highlights the need to consider this aspect when planning and delivering care and support for these patients, including when considering their information needs. In practice, this could mean that, for patients who have more than one medical device, it is even more important that their care is joined-up and that their medical team have a deep understanding and discuss with them how these multiple devices may interact or not, and what impact this may have on their lives.

While this Gathering Views exercise aimed to engage with a diverse group of participants in terms of demographic characteristics and medical devices, we note that this work has highlighted this further subgroup of patients, those with multiple devices, as important to consider in future relevant work, including their particular needs and experiences.

5.2 Recommendations

The recommendations below are for Scottish Government to take forward, working where appropriate with NHS Scotland, health boards and partner organisations. We recognise that some of the below recommendations and particular aspects contained in them may be wider in scope than the MDLU's remit, therefore are for consideration by the wider healthcare system and service providers. Therefore, it is made clear where recommendations are specific to the Scottish Government towards improving information processes or for wider consideration, with Scottish Government notifying health boards and networks and supporting them to consider these points.

For Scottish Government

Recommendation 1: Consider the findings in this report to guide the implementation of Scotland's first Medical Devices Policy Framework, and work towards addressing health inequalities and barriers which may be more prominent among certain groups of the population.

These findings should inform and enrich the Equality Impact Assessment (EQIA) developed by Scottish Government for this work. These findings should also be considered by Scottish Government when developing any national training and resource packages on this topic, to ensure that the different needs of groups and individuals are met, for example regarding access, language, cultural aspects, and representation.

Recommendation 2: Continue to work on the development and implementation of an electronic implanted medical device tracking system through the NHS Scotland Scan for Safety Programme.

This work should be informed by the perceived benefits discussed in these findings, as well as the concerns and requirements around it.

Recommendation 3: Consider how to support NHS boards on a national, 'Once for Scotland' basis to provide all patients receiving an implantable medical device with the right information, at the right time, in the right way, both before and after receiving their implant, based on their needs and preferences. Work towards improving consistency in the information provided to patients around their implanted medical devices and related procedures and processes.

Consider developing guidance around what information should be provided to patients. This should consider the following factors, which have been found through this work to be linked to inconsistencies in information processes:

- procedures being commonplace or more innovative/new
- procedures being less and more high-risk procedures and devices
- procedures being a first procedure or a replacement
- procedures being for a different device

- depending on the person's demographic characteristics, health context, and medical needs
- depending on staff perception of the patient's existing medical knowledge and understanding
- depending on the staff member and team delivering the information
- depending on the patient's access needs and preferences
- depending on procedure timelines and waiting times
- influence by the COVID-19 pandemic and response measures and processes

This may be supported by developing the following:

- a guidance document for those that create patient information resources that details what is key to include (BRAN questions[7], where to find more information, the Scottish adverse event reporting system).
- a clear resource that outlines minimum expectations around information, which would outline the content of the information, who it should be provided by, and at what point in the patient journey. This should be available to staff and patients, to support clarity and help set expectations. For example, this could be a generalised NHS Inform webpage or leaflet for patients to be signposted to that could be entitled "So you are receiving an implantable medical device: What you need to know", outlining what they should know in order to be able to give fully informed consent, so that they feel empowered to ask the right questions. This could be linked to in the guidance developed as part of the Framework implementation. This could also outline the range of ways available in which to receive this information, as well as potentially signposting to key sources of further information. This could also include considering relevant staff training and development, including the importance of staff discussing with patients what information they may receive and at what point of their patient journey.
- dedicated training materials for clinicians regarding the importance of fully informed consent before a patient receives an implantable device and what information is key to provide to patients to allow this (BRAN, what to do after the implantation, when to seek further treatment). This would ensure that the importance of addressing patients' information needs and the potential impact on their patient journey and health is appreciated and understood by staff involved.

This should support equity of information and service across people, devices, and locations.

[7] For more information on the BRAN questions see the NHS Inform webpage.

For wider consideration

Recommendation 4: Consider how NHS boards and local organisations can best address patient information needs and ensure that information processes around implanted medical devices are person-centred.

This should take into account medical aspects, as well as the current findings in relation to what aspects of information participants described as most important to them. When this is made clear, then this should be discussed with patients, and their information needs and preferences should be recorded and adhered to throughout their patient journey, with an accessible option to change their preferences when and if needed.

Consider particular gaps in addressing patient information needs, as highlighted by these findings, such as some participants' experiences around providing consent or understanding risks, and the issues or barriers discussed. This work should take into account the information aspects and needs discussed in these findings, as well as that some patients have broader information needs than others. This should include considering how to support patients when looking for further information on their own, for example, developing a resource on how to discern the quality and suitability of online information. Accessibility of format, medium, and language would be a key aspect of this work, potentially needing to provide this information in a range of ways and formats. The safekeeping of important information should also be considered, ensuring that information is also stored safely by the services or centrally. This should also look at how participants may be more likely to retain and store information longer term, including whether patients are likely to understand and retain information at the specific point in time, if verbally provided.

Recommendation 5: Consider how feedback processes can be improved within the patient journey of people with implanted medical devices, and how routine feedback may help ensure a person-centred approach in addressing patients' information needs.

Ensure that patients have equal and consistent opportunities to provide feedback and information around this, using a range of options, and that they are asked to provide feedback starting early in their patient journey and continuing throughout, if the patient is not opposed to this. This should also consider streamlining processes around patients sharing their lived/living experience, for example signposting patients on how to do so and where, as well as ensuring that patient stories are accessible and easy to find for others. This could also include potentially developing an archive of patient stories to provide a diversity of experiences for people to learn about different devices and the patient journey.

Recommendation 6: Consider further exploring the barriers to patients fulfilling their information needs around implanted medical devices.

This could seek to identify where there may be bottlenecks around this in services or potential lack of clarity in roles, as well as the potential role of health inequalities and disparities. This work may also wish to include explicit focus on the subgroup of patients who have multiple implanted medical devices.

Section 6: Next steps and acknowledgements

This report has been shared with the Scottish Government and has informed the Medical Device Policy Framework's initial Action Plan. This work is mentioned in the Framework under Theme 3: Improving the information available to patients about medical devices used, and these findings will contribute to the improvement of information available to patients and relevant processes, supporting the implementation of Scotland's first-ever Medical Devices Policy Framework. Further recommendations and findings in this report will also be considered as potential additional areas for action, for example the findings about patient attitudes will be taken into consideration during the development of all policies by the MDLU and the Scan for Safety Programme. Scottish Government will also consider the findings of this work alongside findings from ongoing work exploring staff views on this area.

Healthcare Improvement Scotland - Community Engagement & System Redesign will liaise with the Scottish Government to provide feedback to participants about how the views expressed in this report have been used.

Healthcare Improvement Scotland - Community Engagement & System Redesign will liaise with relevant stakeholders to collect information around the impact of these findings and recommendations 6, 12 and 18 months after this report's publication. A summary of this information on impact will be posted on our website.

We will use the learning and experience of this exercise including the equality monitoring information within our work to inform future methods of Gathering Views.

We thank everyone who took part and shared their experiences, thoughts, insights, comments, and suggestions. We are incredibly grateful to the organisations who supported us to link with groups and individuals and for the time they gave us to discuss the issues covered in this report.

Appendix 1 – The questions used in the Gathering Views

Gathering Views – Implanted medical devices

Question set

To confirm at the start of the interview

1. Inclusion criteria

- You have, or have recently had, one or more implanted medical devices
- Contraceptive devices are not included in this work
- You got this in the last 5 years, from 2018 onwards
- You got this through NHSScotland, not privately nor abroad
- You got this through planned care, not as part of urgent care

What we will ask you

In this interview we'll be asking you questions around information you may, or may not, have received before or after getting your implanted medical device. We will also ask you about what information you may have liked to receive or feel you needed, about feeding back on your experience, and lastly a couple of questions on the tracking system.

What we mean when we say "implanted medical device"

By "implanted medical device" we mean anything embedded into the body to be used in your diagnosis, treatment, or care. You may also know these as "implants", and these can include, for example, pacemakers, joint replacements, or transvaginal mesh implants.

Section 1. About your implanted medical device

1. Please tell us what implanted medical device you have as part of your care. If you have more than one device, tell us what all of them are.

- [ ] Joint replacement
- [ ] Lens replacement (cataract surgery replacing the cloudy lens within the eye with an artificial one)
- [ ] Breast implants
- [ ] Implant in a blood vessel e.g. stent put inside a vessel or replacement of vessel section with graft (stent graft)
- [ ] Heart valve
- [ ] Pacemaker
- [ ] Implantable defibrillator

- [ ] Cochlear implant
- [ ] Implantable stimulator as part of neurosurgery/neurology
- [ ] Gastric balloon
- [ ] Other (please specify):

2. Please tell us what year you got your implanted medical device

- [ ] 2023
- [ ] 2022
- [ ] 2021
- [ ] 2020
- [ ] 2019
- [ ] 2018
- [ ] Can't remember
- [ ] Other (please specify):

Section 2. Information you received BEFORE getting your implanted medical device

Information from the medical team

3. We are interested in finding out what information you received from your medical team before getting your implanted medical device.

3A. Do you remember getting any information from your medical team about your implanted medical device before receiving your implant? We are asking if you got information about the implanted medical device specifically, and not about general information, for example about coming into hospital.

- [ ] yes
- [ ] no
- [ ] not sure

Tell me more about this

3B. Before getting your implanted medical device did you receive any of these from your medical team?

	yes	no	not sure
Type of proposed device	☐	☐	☐
Manufacturer of proposed device	☐	☐	☐
Information about alternative devices	☐	☐	☐
Device longevity, which means when the device might need to be replaced	☐	☐	☐
Information specifically about potential problems if the device is not working properly	☐	☐	☐

Tell me more about this

3C. Can you remember any other information that you were given by your medical team before getting your medical device?

4A. Still thinking about the information you received from your medical team before getting your implanted medical device, was it enough for you to understand what might happen after getting your implanted medical device and to know what to expect?

- [ ] yes
- [ ] no

☐ not sure

Tell me more about this

4B. At the time, was this information enough for you to clearly understand the benefits and the potential risks around getting the implanted medical device?

	Yes	No	Not sure
Enough to understand benefits	☐	☐	☐
Enough to understand potential risks	☐	☐	☐

Tell me more about this

4C. At the time, did you feel that the information you received from your medical team before getting the implant was enough for you to give your fully informed consent to receive the implant?

☐ yes

☐ no

☐ not sure

Tell me more about this

4D. Thinking about your experience before getting the implant, what other information would have been useful at this stage to help you provide your consent?

5A. Information before getting the medical device from sources other than the medical team

- [ ] yes
- [ ] no
- [ ] not sure

Tell me more about this

5B. If so, did they suggest you find more information through any of these options?

	yes	no	not sure
NHS Inform website	☐	☐	☐
Your GP or local specialist clinic	☐	☐	☐
Charitable organisation, for example the British Heart Foundation	☐	☐	☐
Other health organisation, for example NHS England, private healthcare etc.	☐	☐	☐
Professional associations or Royal Colleges	☐	☐	☐

5C. Where else did they suggest you look for information? And what information did they suggest you look for there?

6A. Before getting your implanted medical device did you look for more information, in addition to what you got from your medical team?

- [ ] yes
- [ ] no
- [ ] not sure

6B. What other information did you look for before getting your implanted medical device and where? And how useful did you find that information?

Section 3. Information you got AFTER getting your implanted medical device

7. We are also interested in finding out what information you received from your medical team after getting your medical device.

7A. Did you get any information from your medical team after getting your medical device?

- ☐ yes
- ☐ no
- ☐ not sure

Tell me more about this

7B. After getting the device did you receive any of this information from your medical team?

	yes	no	not sure
An implant card. This is often a small credit-card-sized card which includes details of the specific device used in your care	☐	☐	☐
Information on the actual device type	☐	☐	☐
Information on the actual device manufacturer	☐	☐	☐
Information on the actual device serial number	☐	☐	☐
Details on how the process of getting the implanted medical device went	☐	☐	☐
Details on who to contact if you had any issues with your health that relate to your implanted medical device	☐	☐	☐
Details on who to contact about your recovery, rehabilitation, next steps	☐	☐	☐

Tell me more about this

7C. What other information did you get from your medical team after getting your medical device?

7D. If you were given details of the implanted device, do you still have them?

- [ ] yes
- [ ] no
- [ ] not sure

Tell me more about this

8. After getting your implanted medical device did you receive clear and understandable information and advice from your medical team about the expected recovery process and how to take care of yourself and, if needed, the implanted medical device?

Tell me more about this

9. After getting your implanted medical device, was there other information you would have wanted to get from your medical team? What more information did you want?

- [ ] yes
- [ ] no
- [ ] not sure

Tell me more about this

Section 4. Feeding back on your experience

10A. Were you asked to provide feedback? This could be about whether your health had improved after you got your implanted medical device and if you had experienced any complications or difficulties.

- [ ] yes
- [ ] no
- [ ] not sure

Tell me more about this

10B. If not, do you know how you can feedback on this?

- [ ] yes
- [ ] no
- [ ] not sure

Tell me more about this

11A. Would you like to be able to routinely feedback about your experience with your implanted medical device?

- [ ] yes
- [ ] no
- [ ] not sure

Tell me more about this

11B. How would you like to do this?

Section 5. The implanted medical device tracking system

Now I will ask you a couple of questions around what you think about the tracking system being developed by Scan for Safety Programme. You don't need to know much about this programme, we just want to know your initial thoughts.

National Services Scotland in partnership with Scottish Government and NHS Scotland are working to progress the NHS Scotland Scan for Safety Programme. This programme aims to develop and implement an electronic system to help track and trace implanted medical devices consistently across Scotland, starting with high risk implanted medical devices, for example pacemakers and heart valves. The system will include information on the patient, procedure, clinical staff, information about the device itself and where the procedure took place. Once completed, it is hoped that you would be able to access information about your personal implanted medical device online.

This work aims to improve patient safety through making sure that devices can be traceable, patients can be recalled quickly if any issues with an implanted device are identified, and device performance and clinical outcomes can be monitored.

12A. How do you think you could benefit from this?

12B. What information about your device would you want to find?

Section 6. What matters to you

13. What matters most to you about the information you get around your implanted medical device used in your care?

Appendix 2 – Materials circulated to participants before the Gathering Views discussions

Healthcare Improvement Scotland | Community Engagement

Participant Information Sheet
Gathering Views – Implanted medical devices

About this work

HIS-Community Engagement has been asked by the Medical Devices and Legislation Unit (MDLU), who are part of Scottish Government, to carry out a Gathering Views exercise by asking patients about their experiences of receiving an implanted medical device, sometimes known as an implant.

The MDLU are committed to developing policies to improve patient safety in Scotland around medical devices. Gathering patient views will help the MDLU to ensure that patient interests and experiences are built into the foundation of the Strategy as it is being developed.

The findings from this work will:

- guide the Medical Devices Strategy and wider medical devices policy as they develop, aiming to improve patient safety.
- inform the NHSScotland Scan for Safety Programme. This is a joint programme between NHSScotland and the Scottish Government to develop an approach to tracking and tracing high risk implanted devices across Scotland. The aim is for information around medical devices to be recorded digitally and in the same way across Scotland, at the point of care, to improve patient safety and help patients make informed choices about their treatment and care.

Engagement for this piece of work will be taking place from June until August 2023, and the report is anticipated to be published in November 2023, though this might change.

What we mean when we say "implanted medical device"

By "implanted medical device" we mean anything embedded into the body to be used in your diagnosis, treatment or care. You may also know these as "implants", and these can include, for example, pacemakers, joint replacements, or transvaginal mesh implants.

Gathering the views of people with Implanted Medical Devices

We are inviting people who have received an implanted medical device in the last five years, through planned care, to share their experiences with us.

We are looking to talk to you if you:

- Have one or more of the following implanted medical devices:
  - Heart valves
  - Pacemakers
  - Implantable defibrillators
  - Intravascular stents
  - Aortic aneurysm stent grafts
  - Vascular and non-vascular stents
  - Gastric balloons
  - Joint replacements
  - Lens replacement (cataract surgery replacing the cloudy lens inside the eye with an artificial one.)
  - Cochlear implants
  - Implantable stimulators
  - Breast implants

- Got the implanted medical device within the last 5 years, from 2018 onwards. This includes people who have had an implant for longer but got their implant replaced in the last 5 years.
- Got the implanted medical device through NHSScotland, not privately nor through another part of the NHS, for example NHS England, or in another country abroad.
- Got the implanted medical device through planned care, not as part of urgent care.
- We can also speak with you if you are a carer or guardian of someone with an implanted medical device matching the criteria above.
- We can also speak to you if you got an implant within the last 5 years, but you don't have it anymore.

How you can take part

For this work we will be doing individual interviews, and these can be done in person, online or via telephone. Please let the Engagement Officer know how you prefer to have this interview. During the interview we will take notes to ensure we capture what you've said accurately. We may also ask you if we can record the interview to help us take notes.

In the interview we'll be asking you questions on your experience of getting an implanted medical device. We will focus specifically on:

- Information that you may have received before and after getting their implanted medical device
- Feedback processes around this
- Your thoughts on the tracking system being developed for implanted medical devices.

Your participation is voluntary. You are free to withdraw your comments or views at any time without giving a reason and this will not affect you. If your comments or views have already been shared online or on social media, or included in wider pieces of work, for example in a published report, it may not be possible to remove them and stop their use completely. However, we will delete the images or recordings from our database and will go to all reasonable efforts to stop using them in future.

Your information and how we will use your comments

We may use direct quotes from you, but they will be made anonymous and will not include your name or any other identifying information. Anonymised quotes, summaries or analysis of your comments or views may be used in the following ways:

- Published reports
- Presentation materials for education or improvement workshops, conferences or events
- Information or promotion leaflets
- Healthcare Improvement Scotland's websites or social media, or the websites or social media of partners mentioned in the "Partners involved" box at the top of this document
- We may also use your contact details to get in touch with you after the work is completed, to find out about your experience and how we can improve.

To support our work, we will hold information relating to you, such as:

- Personal details. This may include contact details, health condition or diagnosis, and so on
- Written notes of the comments and views you have given us
- Audio or video recording of the interview

Equality monitoring information: As part of this work, we will also be collecting equality monitoring information, such as information regarding sex, sexual orientation, disability, age, religion and ethnic group. Providing this information is optional but important. This information is anonymous and will not be linked to your feedback. It helps us ensure we gather feedback from people from a range of backgrounds and contexts. When thinking of people's experiences around implanted medical devices, it is important for us to hear from people with different characteristics and from different backgrounds, to help us understand their needs and potential barriers, taking into consideration health inequalities. You can complete the equality monitoring form online at this link:
https://www.smartsurvey.co.uk/s/GVMedDevicesEM/
Or if you prefer you can ask an Engagement Officer to help you with this.

We will hold records of our engagement with you only for as long as necessary following the conclusion of the project. All information will be held in accordance with the General Data Protection Regulation and the Data Protection Act 2018.
You can find out more about how Healthcare Improvement Scotland use your personal information here: http://www.healthcareimprovementscotland.org/footernav/respecting_your_privacy.aspx
For our full privacy policy, please go to www.hisengage.scot/privacy.
For more information about how we process your personal data, or if you have a concern, contact our Data Protection Officer at his.informationgovernance@nhs.scot. Alternatively, you have the right to complain to the ICO https://ico.org.uk/concerns/.

Next steps and getting in touch

Please read this information sheet carefully and discuss with others if you wish to. If you have any questions, please get in touch as outlined below.
If you want to participate in this work, please complete the consent form or tell the Engagement Officer you are speaking with that you consent to take part.
You can also let the Engagement Officer know if you would like to receive a digital copy of the report from this work once it is published. They may also ask you whether you are happy for us to get in touch with you in the next months to ask you how you found your experience participating in this work.

If you have any questions, please get in touch with your local Healthcare Improvement Scotland:
Name:
Email:
Phone:

Or you can contact: Donald F Crichton, Area Manager (Community Engagement – North Region), Healthcare Improvement Scotland by telephone 01851 703292 or by email: donald.crichton@nhs.scot

Your rights

The Data Controller for this information is: Healthcare Improvement Scotland (HIS)
Under data protection laws you have the right to be informed of what your information will be used for; access to the information held about you; to rectification if there are any errors in the information held; of erasure; and to withdraw consent.

HIS Data Protection Officer: If you have questions or concerns about how we process your personal data, or if you wish to exercise your rights, email: his.informationgovernance@nhs.scot
If you would like to know more about how Health Care Improvement Scotland use and protect your personal information see our privacy notice here:
http://www.healthcareimprovementscotland.org/footernav/respecting_your_privacy.aspx

Participant Consent Form
Gathering Views – Implanted medical devices

By ticking the options below you are giving your consent to take part in a Gathering Views discussion.

If you wish to proceed, please confirm the following, verbally or in writing:

1	I have read and understood the information sheet.	☐
2	I have been able to ask questions about this work and am happy with the answers I got.	☐
3	I understand that I can choose whether or not I will take part in this discussion and that I can choose not to answer any question or stop taking part at any time, without having to give a reason.	☐
4	I agree for what I say to be used in reports and publications about this work, but that my name will not be used. I give permission for Healthcare Improvement Scotland to hold relevant personal data about me and I understand that my comments are anonymous.	☐
5	I agree to take part in this work.	☐

Name

Appendix 3 – Equality Monitoring form

About this Equality Monitoring form

We are capturing equality monitoring information, including data relating to sex, sexual orientation, disability, age, religion and ethnic group to ensure we gather feedback from people from a range of backgrounds and contexts. We want to understand how representative the people we talk to are. You are not required to answer any questions you do not wish to answer. The information you provide is not linked to your name or any other personal details and will be kept anonymous.

1. What is your sex?

- ☐ Female
- ☐ Male
- ☐ Prefer not to say

2. Do you consider yourself to be a trans person or have a trans history?

Trans is an umbrella term to describe people whose gender does not correspond with the sex they were registered at birth.

- ☐ Yes
- ☐ No
- ☐ Prefer not to say

If you answered yes, please tell us your preferred terms - e.g. non-binary, trans man, trans woman (optional).

3. Which age group do you belong to?

- ☐ Under 16
- ☐ 16-25
- ☐ 26-35
- ☐ 36-45
- ☐ 46-55
- ☐ 56-65
- ☐ 66 and over
- ☐ Prefer not to say

4. If you are under the age of 26, please can you tell us whether you have ever had any experience of being in care? This can include foster care/supported care, kinship care, residential care, looked after at home (supervision order).

- ☐ Yes, I have had experience of being in care
- ☐ No, I have not had experience of being in care
- ☐ Prefer not to say
- ☐ Not applicable

5. Do you consider yourself to be disabled?

(The Equality Act 2010 defines a disability as a physical or mental impairment that has a substantial and long-term adverse effect on a person's ability to carry out normal day-to-day activities. Substantial means the effect is more than minor or trivial and long-term means the condition has lasted or is likely to last 12 months or more).

- ☐ Yes
- ☐ No
- ☐ Prefer not to say

If yes, please include any more information you are happy to share:

6. Can you use British Sign Language (BSL)?
   - ☐ Yes
   - ☐ No
   - ☐ Prefer not to say

7. Do you look after, or give any help or support to family members, friends, neighbours or others because of either:
   - long-term physical/mental ill-health/disability; or
   - problems related to old age?
   - ☐ Yes
   - ☐ No
   - ☐ Prefer not to say

8. Which of the following best describes your sexual orientation?
   - ☐ Bi/Bisexual
   - ☐ Gay/Lesbian
   - ☐ Heterosexual/straight
   - ☐ Prefer not to say
   - ☐ Something else. Please write in:

9. How would you describe your religion, religious denomination or belief?
   - ☐ Buddhist
   - ☐ Christian - Church of Scotland
   - ☐ Christian - Roman Catholic
   - ☐ Christian - another denomination
   - ☐ Hindu
   - ☐ Jewish

- ☐ Muslim
- ☐ Sikh
- ☐ Pagan
- ☐ None
- ☐ Prefer not to say
- ☐ Other, please write in:

10. What is your ethnicity?

- ☐ African, African Scottish or African British
- ☐ Arab, Arab Scottish or Arab British
- ☐ Bangladeshi, Bangladeshi Scottish or Bangladeshi British
- ☐ Black, Black Scottish, Black British
- ☐ Caribbean, Caribbean Scottish or Caribbean British
- ☐ Chinese, Chinese Scottish or Chinese British
- ☐ Indian, Indian Scottish or Indian British
- ☐ Mixed or multiple ethnic groups
- ☐ Pakistani, Pakistani Scottish or Pakistani British
- ☐ Roma
- ☐ Showman/Showwoman
- ☐ White Gypsy/Traveller
- ☐ White Irish
- ☐ White British
- ☐ White Polish
- ☐ White Scottish
- ☐ Prefer not to say
- ☐ Other, please write in:

11. Do you usually have enough money each month to pay bills, buy the food, clothing and essentials you need and participate in your community?

- ☐ Yes
- ☐ No
- ☐ Prefer not to say

12. Please use this space to tell us anything else you would like us to know about how you identify in relation to any of the above questions.

Appendix 4 – Equality monitoring data

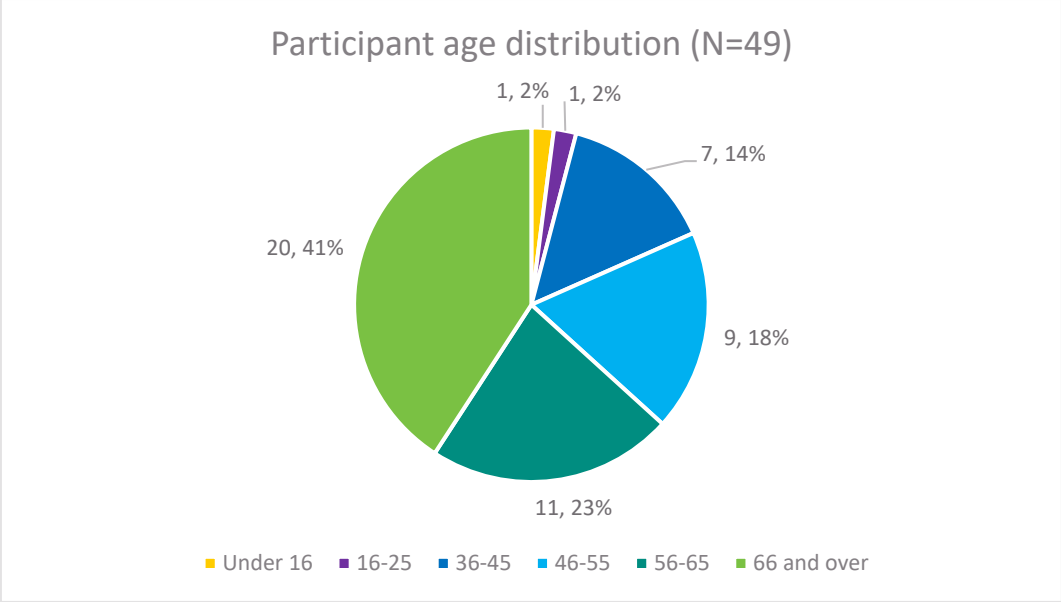
Response rate

Providing equality monitoring information is optional, and 49 out of the 65 participants completed this (75%).

Equality monitoring questions, in the form of an online survey, were shared with the participants, either before or during the interview. We also offered alternative ways to provide this information, via email, telephone, or through a paper copy.

Participant characteristics (N=49):

- Sex: 33 of the people we engaged with are female (67%) and sixteen male (33%).
- Gender reassignment and gender identity: 48 of those who answered this question do not consider themselves to be trans or have a trans history. 1 person said “prefer not to say”.
- Sexuality: 46 said they are heterosexual/straight (96%), 1 person said they were gay (2%) and 1 person said “prefer not to say” (2%).
- Age: The distribution of the participants’ age is showed in the chart below. No participants that completed the equality monitoring form were in the 26-35 category.



- Care experience: No participants who completed the equality monitoring form said that they have had any experience of being in care, such as foster care.
- Disability and long-term health conditions: 14 (29%) said their day-to-day activities are limited a lot due to a health problem or disability which has lasted, or is expected to last at least 12 months. 12 (24%) said they are limited a little due to this. 23 (47%) said they are not limited due a health problem or disability.
- Use of BSL: None said that they use British Sign Language (BSL).
- Carers: 13 (27%) said that they look after or support family members.

- Religion and beliefs: 17 (35%) said they are Christian – Church of Scotland. 5 (10%) said Christian – Roman Catholic, and 5 (10%) Christian – another denomination. One (2%) said they are Pagan, one (2%) Sikh. 16 (33%) said they have no religion and two (4%) said “prefer not to say”. Two (4%) said “other”, one of which is “born again Christian” and another “not particularly religious, more interested in Hinduism and Buddhism”.
- Ethnicity: 32 (65%) are White Scottish and twelve White British (25%). 1 (2%) said Indian, Indian Scottish or Indian British, 1 (2%) Chinese, Chinese Scottish or Chinese British, 1 (2%) White Gypsy/Traveller and 1 (2%) White Polish. 1 (2%) said “prefer not to say”.
- Deprivation: 44 (90%) said they usually have enough money each month for essentials and to participate in their community, 3 (6%) said they don’t and 2 (4%) preferred not to say.

You can read and download this document from our website.
We are happy to consider requests for other languages or formats.
Please contact our Equality, Inclusion and Human Rights team on 0141 225 6999
or email his.equality@nhs.scot.

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