Good Practice in Shared Decision-making and Consent

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ABBREVIATIONS

AMD	Associate Medical Director
AWI	Adults with Incapacity
CMO	Chief Medical Officer
EC4H	Effective Communication for Health
GMC	General Medical Council
IT	Information Technology
MD	Medical Director
NICE	National Institute for Health and Care Excellence
PREMs	Patient Reported Experience Measures
PROMs	Patient Reported Outcome Measures
RM	Realistic Medicine
SDM	Shared Decision-Making
SG	Scottish Government
SGSSS	Scottish Graduate School of Social Science
SPSO	Scottish Public Services Ombudsman
UK	United Kingdom
VBRP	Value Based Reflective Practice

1. INTRODUCTION

This research project forms part of a national strategy focused on a person-centred approach to ensure NHS Scotland Boards support people through informed, shared decision-making to better reflect their preferences and what matters most to them.

The project consists of three phases and sets out the findings from: a literature review on consent and shared decision-making; a summary of a group consultation held with the Person-Centred Stakeholder Group; an online survey based around the self-assessment questions drawn from the 2017 Scottish Public Services Ombudsman (SPSO) report Informed Consent, which was administered to 15 Health Boards; and 10 follow-up interviews conducted with the survey respondents. This stakeholder engagement and consultation work has been commissioned by the Scottish Government to increase the understanding of the systems and processes that are currently used in consent within the health services, to support evaluation of their effectiveness, and to inform future improvement in this area. By capturing multiple dimensions, we hope that this report will provide both the impetus and the direction for change across NHS Scotland services, where the aspirations for excellence are propelled by the vision of putting the individual at the centre of all decisions.

1.1 POLICY CONTEXT

The right to give or refuse consent to medical treatment is a cornerstone of modern medicine, protected by a range of human rights standards. This fundamental concept of involving and engaging people in decisions about their health and treatment can be tracked back to the roots of the NHS and has long been recognised in Scotland. The 2010 Healthcare Quality Strategy for NHSScotland contained a commitment to building 'mutually beneficial partnerships between patients, their families and those delivering healthcare' as one of three Quality Ambitions underpinning the strategy. Putting the person at the centre of all decisions was further emphasised by the Government in the 2020 vision. In 2016, the Scottish Government published a Health and Social Care Delivery Plan, which recognised that 'individuals and where appropriate, their families – should be at the centre of decisions that affect them'. This principle of patient involvement and shared or supported decision-making signifies a real shift in practice, placing people 'in the driving seat' of their own healthcare decisions.

There is an increasing acknowledgement that supported decision-making often leads to more effective healthcare. Shared decision-making is a key feature of the realistic approach to healthcare, which aims to support people through informed decisions that better reflect their preferences and what matters to them most. Scotland's Chief Medical Officer (CMO), Dr Catherine Calderwood, has championed the concept in her three annual reports. In her first annual report, she sets out a new clinical paradigm, based on a 'realistic medicine' approach that will support people through informed, shared decision-making to better reflect their preferences and what matters most to them. Practicing Realistic Medicine, published in April 2018, contains an important chapter on understanding and managing risk, which examines how the UK Supreme Court's decision in Montgomery v Lanarkshire Health Board (2015) and

learning from dissatisfaction could support the practice of realistic medicine. The shift away from the more paternalistic model of 'the doctor knows best' to the new clinical paradigm, in which informed patients have greater control over their own health, is also one of Scotland's National Clinical Strategy aspirations and a key element of Audit Scotland's NHS in Scotland 2016 report recommendations.

A key aspect of the work to improve supported decision-making is supporting people's skills, confidence, knowledge and understanding so that they can be fully involved in decisions about their care and treatment, to be active partners in their care, and to navigate health and social care systems. Health Literacy is being increasingly recognised as a significant public health concern around the world. The SG developed a national action plan, publishing Making it easy: a Health Literacy Action Plan for Scotland in 2014, Making it Easier in 2017 and a resource website, The Health Literacy Place.

Work towards patient engagement and better involvement in shared decision-making gained momentum following the landmark decision in the Montgomery case. When discussing the benefits and risks of various treatment options with patients, the new ruling requires clinicians to take into account the patient's individual circumstances and preferences and to ensure patients are aware of 'material risks' involved in a proposed treatment. It emphasises the importance of dialogue and a person-centred, rather than paternalistic, approach. Although the ruling placed the responsibility on healthcare professionals to ensure patients are fully engaged in decisions about their health and wellbeing, rather than leading to radical changes in practice, it has brought the law in line with current ethical guidance for healthcare professionals.

Despite this cultural shift towards giving patients a stronger voice in decisions about their health and care, the lawfulness of patients' consent to medical treatment has been a consistent feature of clinical negligence cases. The 2017 Scottish Public Services Ombudsman (SPSO) report on Informed Consent, published in February 2017, identified that inadequate medical consent was the most frequently recurring issue identified in its complaints investigations and recommendations to NHS Boards over the last five years. While this theme is not new, it is particularly important in light of the renewed focus and policy changes underpinning consent following the Montgomery case.

In terms of the guidance available on consent, there have been significant changes in response to the decision in the Montgomery ruling. In 2016, the Royal College of Surgeons published Consent: Supported decision-making, a guide to good practice which emphasised the need to move away from the more paternalistic traditional model of consent towards more patient-centred discussions. The same year, the Mental Welfare Commission released new guidance that sets out key principles of supported decision-making for individuals with mental disabilities, their families and those who support or work with them. The General Medical Council has also launched an extensive consultation and engagement exercise to inform the revision of its guidance for doctors on consent and shared decision making, which was last published in 2008. The 2016 Scottish Government's Health and Social Care Delivery Plan set out that people should be 'regularly involved in, and responsible for, their own health and wellbeing'. It contains a commitment to reviewing the consent

process for patients in Scotland, together with the General Medical Council (GMC) and Academy of Medical Royal Colleges, and this work is currently underway.

2. OVERALL AIMS OF THE PROJECT

The overarching aim of this research is to increase the understanding of, and evaluate the effectiveness and robustness of, the current consent systems and processes within NHS Boards and explore the challenges the Boards are facing whilst preparing to adapt to future changes in the guidance. More specifically, the Scottish Government wants to understand what would enable healthcare professionals to encourage, strengthen and facilitate shared decision-making.

2.1 RESEARCH SPECIFIC OBJECTIVES

The research objectives are:

1. To establish whether the current consent process forms part of a wider culture of person-centred care and supported decision-making with patients;
2. To identify how existing processes and tools support good practice (or not);
3. To identify support needs at an individual and organisational level;
4. To identify examples of good practice that could be shared across NHS Scotland;
5. To provide recommendations for future improvement.

The research project consists of three phases:

Phase 1: Carry out a literature review on consent and shared decision-making and provide a balanced overview of the existing policy and guidance on the topic.

Phase 2: Conduct a group consultation with the Person-Centred Stakeholder Group and gain a better understanding of the health service user experience around consenting process and shared decision-making (or lack of).

Phase 3: Drawing on the existing policy and guidance, more specifically, the 2017 SPSO report, carry out the following:

a) Design a questionnaire for the Health Board Medical Directors and Clinical Governance leads for their completion online.

b) Follow up all questionnaire respondents by inviting them for a short follow up face-to-face or telephone interview. This approach provided respondents with an opportunity for further deliberation.

Detailed information about the methodology of this project, including the design and analysis but also the ethical and governance considerations, is provided in Annex A.

2.2 POINTS TO CONSIDER WHEN READING THE REPORT

For meaningful analysis of the findings, it is important to consider the context in which this research project was carried out and the myriad factors that potentially influenced its outcomes.

This research was carried out at the time NHS Scotland celebrated its 70th birthday. Despite many successes achieved over the past decades, there have been significant changes in demographic and health trends, and the demand for healthcare services has increased dramatically. Challenges facing the NHS have been widely reported, including increasing costs, growing demand, and the continuing pressures on public budgets.

Lastly, qualitative research was used primarily for exploratory purposes, in order to uncover trends in thoughts and opinions and provide deeper insights into the problem. Due to a small sample however, the research findings are not intended to be generalised to reflect the views of the whole of population.

2.3 STRUCTURE OF THIS REPORT

As this project used a sequential design methodology, the three phases of the research are analysed and discussed in stages in order to aid the understanding of the findings. Chapter 3 discusses the extent to which the current consent process forms part of a wider culture of person-centred care and supported decision-making with patients in practice. This section begins by outlining the Person-Centred Stakeholder Group's understanding of and perspectives on good consenting process, and what it means to them. The findings are reported to align with the project's specific objectives. Chapter 4 provides findings from the survey questionnaire, which was distributed to 15 NHS Health Boards. Chapter 5 reports findings from the follow-up interviews carried out with the survey respondents and focuses on the three major themes that were commonly reported during the interview process: (1) Issues and Barriers; (2) Tools for change; and, (3) Processes for change. Finally, Chapter 6 outlines the conclusions and recommendations for policy and practice.

3. STAKEHOLDER GROUP CONSULTATION

This section details the findings from the consultation workshop held with eight members of the Person-Centred Stakeholder Group, in which the researcher asked for the participants' views and opinions on what a good person-centred consenting process should look like. The aim of this exercise was to capture ideas and suggestions, provide useful insights on how health service users feel about the process of consent and to explore what could be done to improve or prevent a poor experience. Shifting the focus on what the service users themselves identify to be important and illustrating people's unique perspectives allowed the researcher to gain a deeper insight into the complexities of shared decision-making and what really matters to patients during the consenting process.

Discussion focused around four areas: 1) the format or means of a good person-centred consent; 2) the type and amount of information that should be given; 3) by whom, where and when; and finally, 4) the importance of addressing individual circumstances, preferences and concerns during consent.

3.1 WHAT IS THE PERSON-CENTRED STAKEHOLDER GROUP?

The Person-Centred Stakeholder Group includes a range of people who have lived experiences of using healthcare services or caring for someone who does, who work in organisations providing health and social care services, and who represent third sector and statutory organisations with expertise in delivering person-centred care. The Group was established in 2014 and has actively engaged with the SG on a wide range of policy initiatives related to various aspects of person-centred care.

3.2 KEY FINDINGS

The workshop participants were well-informed around the key principles of the consent process and placed the emphasis on the need for a 'cultural shift' within the NHS and for healthcare professionals to adopt more personalised and individualised approaches within their practice. The need to provide patients with all the information by contextualising it into specific circumstances was seen as a key priority of true shared decision-making. The discussion revealed that whilst health service users recognise the challenges that healthcare professionals face in their everyday practice, they were also concerned that patients are not given adequate time to fully 'understand, digest and reflect' the information about their care and treatment. They also questioned the implications of declining or changing their mind about the treatment options without any judgement or repercussions. The identified themes were:

3.2.1 Consent is a process

In the first part of the group consultation the participants were asked about the appropriate forms that shared decision-making consenting process should take. The Group expressed that rather than 'forms', the questions should have been posed about the 'format, method or means' of taking consent. It was agreed that consent

should not be a tick box exercise; rather, it is a ‘process’ or a ‘person-centred dialogue’ that requires time. This dialogue or a ‘meaningful conversation’ should be interactive and evolve as the process of healthcare provision continues.

The Group described a good person-centred consenting process as ‘context-dependant’ and a ‘partnership contribution’ between the individual and the health professional. It was also suggested that this process ‘depends on the person’s capacity’ and that there needs to be ‘scope for rethinking all the options’ without any pressure from the healthcare professionals or the organisation. The type and amount of information given must also be adapted to the person’s level of understanding.

The perception was that the process of consent requires the healthcare professional to make room for the patient narrative to take place in order to promote a more person-centred and relationship-focused approach. Some participants suggested that although the paternalistic culture of the ‘doctor knows best’ is still dominant in the healthcare system, it is no longer consistent with the ethos of informed consent and true shared decision-making. Others expressed the view that the focus of consent needs to shift towards working together with the health service user and tailoring the discussions and interventions to the circumstances and preferences of the individual and what matters most to them. This is to ensure care is personalised and patients are enabled to make informed choices about how to manage their own health.

3.2.2 The right person, at the right time, in the right way

In the next question, the Group was asked to comment on who they felt was best placed to carry out a good person-centred consenting process, when was the most appropriate time to have a meaningful conversation and where these conversations should take place. The participants agreed that for true shared decision-making to take place, there first needs to be trust between the individual and healthcare professionals and the people involved need to feel that they can openly and honestly discuss different options and work in partnership towards the agreed goal. In order to achieve this, there needs to be ‘true collaboration’ between the professional and the patient, and the involvement of families, carers and significant persons needs to be encouraged.

There was a general perception that there is often a lack of time for good person-centred conversations to take place. This might be due to organisational constraints and a lack of resources, but also due to poor, or a lack of, forward planning. It was suggested that the consent process should begin ahead of time, for example during GP appointments, and the decisions could be documented using the electronic Key Information Summary (KIS)[1]. Although the KIS is currently used for patients with long-term or complex conditions, having the summary available for all patients could improve communication between the services. Some participants emphasised that these should be created with explicit patient consent and should ideally be written by a healthcare professional who has a unique knowledge and understanding of the

[1] The KIS is an electronic summary of medical history and patient wishes that allows GPs record sharing with other parts of the NHS. The level of detail contained on a KIS depends on the complexity of the patient’s clinical condition, and it is designed to be added to as the patient’s clinical condition changes over time.

patient and their circumstances in conjunction with the patient and, where appropriate, a family member or a carer. As the KIS contains up-to-date patient information, having information about patient capacity and/or personal preferences in relation to specific treatments or procedures could potentially save time for clinicians and reduce the risk of inappropriate care being given in emergency situations.

The group expressed that consent should be sought at the right time for the person not, for example: "when they are having breakfast, or when it suits the professional". The importance of having adequate time to ensure health professionals can meaningfully engage in conversations with patients about treatment options was thought to be the key of a good consenting process. Some participants raised the point that the consenting process should be initiated by, for example, sending patients a preparation pack or a booklet containing links to relevant information alongside their appointment letter.

The group felt that 'timing is a big issue' - patients should not only have 'the right to say no' and not feel 'punished' for it but there should be a 'cooling off' period and time to 'digest and reflect' on the information provided before making any decisions with regards to health. This is to ensure that consent is not merely a 'tick box exercise' without active engagement of the patient but a meaningful process where patients have the right to ask questions and exercise their autonomy. For instance:

"If I've got an issue with explaining what my problems are and I've only got 7 minutes with my GP, how do I explain everything, and they've got a waiting room full of people."

3.2.3 Information provision and understanding

There was a general consensus among the participants that the information provided to the patient should be contextual – based on the decision and the potential impact on the person. It should also be staged and evolve as the process of healthcare continues. Some pointed out that patients may receive information, but the wrong kind or at the wrong time: "can someone really refuse when asked to sign just prior to being operated on?". There was also a perception that there can be too little information about the impact of the treatment on someone's life. As one participant put it: "People may get told that of 100 people, here's what happens to 5".

It was suggested by the Group that maximising patient participation in shared decision-making can be achieved by first exploring the patient's preferences about the level and type of information they want. Some felt that provision of information is not enough, and support is needed to make use of that information. This could include both oral and written information available in a variety of formats, including communication aids such as pictures, symbols and information written in different languages.

The group pointed out that not all patients are able to understand numerical data and percentages as well as risks associated with a specific treatment. Therefore, the information should be tailored appropriately to the patient's age and ability, so those affected can take part in the decision affecting them, rather than having to leave it to someone else to make it or even help them make it on their behalf. Some

participants expressed concerns about the implications of consenting someone with communication difficulties.

Addressing accessibility issues was felt to be one of the key aspects of person-centred consent. The Group agreed that healthcare professionals need to consider 'individual patient requirements' and make sure healthcare services are 'inclusive and supportive of all people', including adults with disabilities, sight, speech or hearing problems and those who may have problems understanding or speaking English. Ensuring all patients are able to fully participate in shared decision-making about their treatment and care need to be a priority of NHS services.

The group also suggested that interpreters should be easily available within health services and that all patients should have the opportunity to be accompanied by a friend or family member during the decision-making process. The choice to take notes or audio record conversations should also be given. Ensuring that the patient understands the information and encouraging the person to clarify what is important to them is vital. To support individuals throughout this process, the information about patient preferences needs to be shared between healthcare professionals.

It was felt among the group that there needs to be a way of ensuring that professionals are absorbing the information patients are giving them. Patients need to feel confident that consent is an effective person-centred conversation, not one aimed at preventing litigation. Moreover, implicit consent may be seen as having been given, just by going to an appointment: "Once in progress, it's a conveyor belt to surgery".

Members of the Stakeholder Group highlighted the importance of using approved decision aids, such as leaflets to supplement information provided orally in discussion. It was also suggested that anticipated communication needs of the patient should be checked prior to the clinic appointment. For instance:

"So, some people, they don't need somebody to speak for them, they just need the support from that other person…but for other people they will need somebody to speak up for them and help them to understand what is going on. Sometimes the language that is used, for example, in health and social care is not the ordinary language we use outside or it could be that because I've got a learning disability, or I have problems with literacy."

Concerns were raised by members of the Stakeholders Group with regard to the information provided on paper, which may differ to what is being said during the consultation. Some felt that healthcare professionals need to ensure that patients understand the information that is given to them. This could be achieved by active listening and addressing any concerns, as well as checking that the patient has understood what they have been told. 'Staged reviewing' and using the 'teach-back' technique at times agreed with the patient were suggested as effective strategies that can promote patient engagement and check understanding of the information. It was also highlighted that healthcare professionals need adequate training and education in effective consenting techniques to equip them with a range of tools and techniques, including decision aids to use in consultations with patients.

As a follow up to this question, the Group was asked about the type and the amount of information that should be given during a person-centred consenting process. The Stakeholders felt that 'realistic discussions' staged over a period of time are key to a meaningful and person-centred consenting process. This means having sufficient time to discuss all the available options, but also being able to digest and consider all the available options, and then come back at a future date when the person is better informed and talk about the available treatments, side effect and alternatives. The group acknowledged the current organisational constraints including the lack of time and workload pressures that clinicians face on an everyday basis. These constraints may pose challenges in providing person-centred care. Extending GP visit times to enable the conversations about individual preferences and concerns was suggested as a likely solution. There was a perception that a signed consent form does not necessarily guarantee that an informed consent has taken place. Members of the Stakeholder Group raised the point that more emphasis should be placed on ensuring patient involvement in all aspects of the consent process, as well as patient understanding of the treatment or a procedure that they are agreeing to.

3.2.4 Recognising power dynamics

The Stakeholder Group suggested that more emphasis must be placed on shifting the balance of power towards the patient having a greater say in their care. It was felt that a fundamental cultural shift requires the paternalistic and unbalanced interactions to be replaced by a model of partnership where patients feel empowered and supported to express their individual needs, values and preferences and thus have influence over decisions about their health. Group members posed a question with regard to who 'holds' the consent process. Some raised the point that it can feel very service-led, as it is up to consultants to record how they came to a decision, not the patient. It was also suggested that service-led consent documents are not effective, and it is highly likely that conversations will be in the format of these documents. There was an agreement that a cultural shift is not only about doctors handing power over to patients:

"I think that the basis of […] poor communication is that it's not an equal relationship […] I can get away with not explaining everything because there's that imbalance of power. I think if we had a much more equal relationship between the people who are receiving the care and those people who are involved in the delivery of it. It's not a partnership, is it? I receive, and you give. So surely, I should be an equal partner in my own care and treatment?"

The 'power imbalance' between those providing and receiving treatment and care was felt to impact negatively on shared decision-making and prevent people from having honest and meaningful discussions. It was suggested that 'feeling empowered' is only reached by taking into account the person's preferences and perspectives. Being 'actively involved' and 'able to express what matters the most' was felt to be key to achieve this goal.

It was suggested that patients need to be informed and educated about their responsibility in shared decision-making. The paradigm shift is dependent on two experts working together, where the patient's personal expertise and knowledge of their preference is of equal value to medical expertise. There was agreement that

patients need to be assured that active participation and expressing their preferences or declining the treatment will not result in judgement or retribution. In order to enable shared decision-making and overcome the 'white-coat silence', patients need to be encouraged to ask questions about their care (Judson et al., 2013). One participant pointed out:

"I think that there are lots of people who really don't understand consent. There are some people who would be saying: but you're the doctor so you make the decision and wouldn't understand that actually, it's really important for me to make that decision".

One of the Group members spoke of a personal experience of being admitted to the hospital for a planned surgery and being told on the day that she might need an alternative procedure, which was then carried out later that day. She described how very little time was given to consider or discuss the options and how it left her feeling:

"By the time I was in the gown it felt a bit late…I'm in a paper frock and you're three doctors with suits on".

This clinical encounter clearly illustrates the power imbalance between the healthcare provider and service user and how it can hinder shared decision-making. Evidence suggests that despite being well-educated and well-informed, many patients find it difficult to use their knowledge to participate meaningfully in decisions about their healthcare and feel prohibited from speaking up or feel a pressure to be compliant and passive (Frosch, May, Rendle, Tietbohl, & Elwyn, 2012). Moreover, when confronted with unquestioned confidence, people may not feel able to express their individual preferences even when they are hugely concerned about safety or the quality of care they are receiving (Joseph-Williams, 2014).

3.2.5 Safeguarding capacity

The group felt that it may be relatively easy to determine whether the patient does and does not have capacity, but the difficulty arises from the cases in between where the capacity may fluctuate, and the capacity is presumed. One of the participants talked about her personal experience:

"In advance of the treatment, I was required to sign a consent form. Technically, I had given consent. Capacity was assumed, or not fully questioned. Capacity is both contextual and situational. I was confused, distressed, and with an impaired ability to process and retain information, yet capacity was assumed..."

Many different factors can influence someone's decision-making capacity. Also, judgement may be impaired due to external factors. It is widely recognised in health literature that people's capacity to make informed decisions may be diminished in a stressful state. Moreover, the unfamiliar surroundings, long waits, and feelings of anxiety and vulnerability may all contribute to a reluctance to voice questions to health professionals (Judson, Detsky, & Press, 2013). Family or carer's involvement in the conversation should therefore always be considered to ensure the patient is safeguarded during the consent process.

It was pointed out that making decisions about health can be overwhelming for some people and can cause serious stress. The shock of the diagnosis or being in a busy healthcare environment may diminish understanding and make the mind recoil against some treatment options. It was pointed out that people generally take their time when making decision that will impact their lives, such as buying a car or a house. In business situations for example, decisions can often fail because they are rushed, and the alternatives are not clear at the outset. Some group participants suggested that the same approach has to be taken when making decisions about treatment and care. It was felt that unless it is an emergency situation, clarifying patient understanding, allowing adequate time to ask questions and working through this process in partnership based on trust and openness will reduce the likelihood of overlooking important factors. Most importantly, patients need to be allowed to move through the process at their own pace.

The need for greater support from advocates was suggested by the stakeholders as an alternative approach to ensuring patients with learning disabilities receive appropriate help and support and that their wishes are respected. One participant representing a patient advocacy organisation commented:

"Advocacy is about people having as much information as they need to make the right decision for them and it's about making an informed decision. For some people it could be that they want lots and lots of information but for other people, for example, if I've got a learning disability then I might not be able to process all of that information so it's about the advocate working with me at my pace to make sure that I understand and I'm making the best decision under the circumstances".

3.2.6 Personalised approach and knowing the 'real me'

Knowing all of the relevant and necessary information, including the minor risks, was believed to be crucial in being able to make an informed decision. An individualised approach to health care provision, really knowing the patient and tailoring the information and services to each patient's unique needs and circumstances were agreed to be the cornerstones of a good person-centred consenting process. Participants highlighted that the person-centred consenting process should encourage patients to express their personal needs and preferences for treatment and care. When discussing various options with the patient, it was suggested that it is important to first understand their underlying value system and be prepared to discuss any sensitive issues and concerns. These discussions should be on-going, giving the individual the option to change their mind or allowing the patient to choose not to undergo a treatment or procedure in a non-judgemental and non-punitive manner.

Participants emphasised the importance of the person-centred view in the consent process and what that person would like to know, including all material information, such as alternative procedures, all risks, benefits and side effects. It was pointed out that more attention needs to be paid during consultations to what really matters to patients, in other words, to 'diagnosing patient preferences' (Mulley, Trimble, & Elwyn, 2012). This could be achieved by discussing the information from the patient's perspective and by placing it within the context of individual circumstances.

Explaining what the likely consequences of undergoing or not undergoing the procedure mean for that patient and discussing alternative options was felt to be fundamental to true shared decision-making.

There was a general consensus that developing an understanding of the patient as an individual means not only considering the patient's preferences but also their social and personal circumstances, including previous experiences of healthcare. Some of the group raised the point that healthcare professionals need to get a good sense of what is important to the particular patient and the likely significance they attach to the risks and side effects of a treatment or procedure. The group agreed that a good person-centred consent means not only listening to the individual preferences but also acknowledging and accepting that the patient may have different views from the healthcare professionals about their preferred treatment options or the consequences of no treatment. It was suggested that it is not up to the healthcare professional to determine what risks are material to the patient, but for the individual to make that decision and be able to discuss it in a supportive and non-judgemental environment.

The group were also in agreement about the importance of discussing the involvement of the family, carers or significant persons with the patient. It was suggested that the degree and nature of involvement of other people and information sharing should be clarified prior to discussing any key decisions about their care and should be reviewed regularly throughout the course of treatment.

3.2.7 The right to 'say no'

A number of participants recognised that the right to 'say no' is central to a person-centred consent, where the choice of not receiving a treatment is fully supported and guided by openness and honesty. The group agreed that the right to refuse treatment should be at the heart of every person-centred consenting process. Yet, it was felt that refusal to treatment can be perceived as an aggressive act. One participant expressed that:

"But it could be that actually I'm worried that if I say no then I'm not going to get any healthcare at all".

Participants expressed that as long as the individual has the capacity to make an informed decision and has been given sufficient information to make that decision, it is paramount to allow them to choose not to undergo a treatment, even if healthcare professionals do not agree with their decision. However, it was felt that more support is needed for patients who choose to decline the treatment.

3.3 SUMMARY

To summarise, the discussions with the Person-Centred Stakeholder Group highlighted a number of key points that should be taken into consideration for any follow-up work and policy recommendations. Three broad key findings were identified from this meeting. **Firstly**, the information given by clinicians needs to be effective and appropriate for the audience, keeping in mind that patients have differing levels of understanding and that many people understand less than usual

during stressful situations, as well as differing levels according to age and ability. **Secondly**, there was the issue of timing around consent, whereby consent processes should be carried out when it is appropriate for the patient rather than the clinician, and a suggestion that there is scope to begin the consenting processes earlier, i.e. during GP appointments to maximise the length of time for decision-making. Furthermore, patients should not feel pressured into a decision (one way or the other) due to lack of time or feel that they cannot change their mind over a treatment at a later date. **Thirdly**, and finally, patients need to be informed and educated about their responsibility in shared decision-making further. By this we mean the paradigm shift towards two people working together (patient with personal expertise and medical expert). This signals a shift from patients underestimating their ability to understand the information given to them by clinicians and as a result, tend to entrust the expert with the knowledge to make decisions for them (Joseph-Williams, Edwards, & Elwyn, 2014). Patients need to be reassured that active participation in their healthcare will not result in penalisation or poorer levels of care. Related to this, patients need to be reassured of the importance of discussing their healthcare needs and preferences with friends and family members as well as healthcare professionals.

4. GOOD PRACTICE IN SHARED DECISION MAKING & CONSENT SURVEY

This chapter of the report provides the results of a survey circulated to Health Board Medical Directors and Clinical Governance leads. The aim of this survey was to provide an overview, and thus gain a better understanding, of the systems and processes that are currently used in consent within NHS Scotland. The survey formed the core of this research project. Participants were invited for a follow-up interview in order to expand on particular aspects of their initial response; these interviews are discussed in Chapter 5.

4.1 NHS SCOTLAND HEALTH BOARDS

Delivery of frontline healthcare services in Scotland are the responsibility of 14 regional National Health Service (NHS) Boards that report to the Scottish Government. These regional NHS Boards are responsible for the protection and the improvement of their population's health and for the delivery of frontline healthcare services. Seven Special NHS Boards and one public health body support the regional NHS Boards by providing a range of important specialist and national services. Full details can be found on the Scottish Government website: www2.gov.scot/Topics/Health/NHS-Workforce/NHS-Boards

For the purpose of this project, all regional NHS Boards and the Golden Jubilee Foundation Special Board were invited by email between the 1st and 31st of May 2018 to take part in the survey.

All 15 Boards completed the survey. Five responses were received from Medical Directors, 4 from Associate Medical Directors, and 6 from Clinical Governance leads. The survey results are outlined and discussed below.

4.2 SURVEY RESULTS

4.2.1 Changes in policy and practice

First, Boards were asked whether there have been any changes in relation to consent since the Supreme Court's landmark decision in the Montgomery case (2015). Twelve out of 15 Boards stated that both policy and practice around consent and shared decision-making have changed; whilst the remaining 3 reported change in practice only. The main reason for the change in policy and/or practice around consent and shared decision-making was:

- The Montgomery ruling (11 Boards)
- The 2017 SPSO Informed Consent report (2 Boards)
- Specific complaints with the Health Board (1 Board)
- Other – 1 Board reported that the reason for change in policy and practice was the mixture of the above as well as the Realistic Medicine movement.

When asked to provide a brief summary of the existing policy and guidance on shared decision-making and consent, it was clear that there was some variation across the Boards in their approach to implementing changes. One third of Boards reported that they have updated their local policy on consent; others reported that they have developed and disseminated new consent guidelines, which will inform planned revision of the policy. Two Boards commented that they are awaiting the General Medical Council (GMC) guidance on consent before updating their policy, and the majority stated that they are in process of developing new consent forms. Some Boards provided links or copies to their existing policy or guidance on consent. Although the content and wording of the provided documents varied slightly, the analysis of specific sections revealed a recurring common theme: the consent guidelines described consent as a process over many stages, encouraged shared decision-making and person-centred information provision including an explicit discussion with the patient about different treatment options, specific risks and benefits as well as the option of doing nothing.

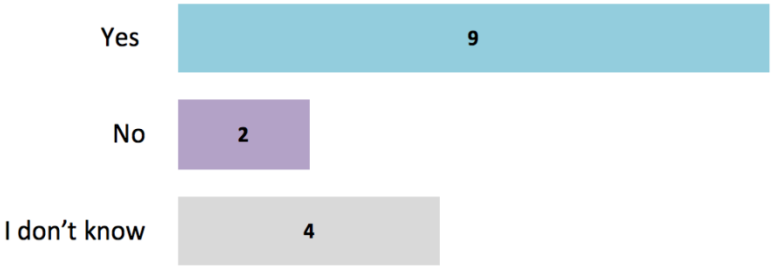
4.2.2 Readiness for adapting to future changes in GMC guidance

In light of the legal changes in the UK law following the Montgomery case, the GMC has launched an extensive consultation and engagement exercise to inform the revision of its guidance for doctors on consent and shared decision making, which was last published in 2008. The review will ensure that the guidance remains clear, helpful, relevant to clinicians' and patients' needs and compatible with laws throughout the UK. Boards were therefore asked about the extent to which they feel prepared for adapting to any future changes. The survey found that 6 Boards felt 'completely' prepared, whilst 9 Boards only felt prepared 'to some extent'.

4.2.3 Specific patient complaints in relation to consent

A great deal of work is currently underway to strengthen consent processes locally and nationally and thus increase people's involvement in making decisions about their health. However, the 2017 Scottish Public Services Ombudsman Report found that inadequate consent was the most recurring theme in the complaints they reviewed. Boards were asked whether they have received any complaints regarding informed consent and lack of shared decision-making since the Montgomery ruling (Figure 1). Only 2 Boards indicated that they have not had any complaints in this area, with 4 stating that they did not know.

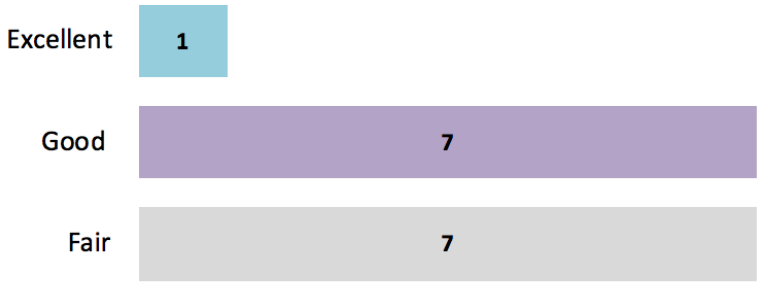
Figure 1. NHS Boards receiving patient complaints about consent and lack of shared decision-making since the Montgomery ruling in 2015



The survey then sought to determine whether Boards have received any recent recommendations from the Scottish Public Services Ombudsman as a result of an investigation of patient complaints focused on consent and/or lack of shared decision making. Seven Boards reported having received specific recommendations; although all agreed to share their responses to those recommendations with the SG researcher, only 1 Board provided the information.

Overall, the current practice regarding consent and shared decision-making was rated as either good (7 Boards) or fair (7 Boards). Although no Board rated their practice as poor, only NHS Lanarkshire indicated that their practice is excellent (Figure 2).

Figure 2. Overall rating of the current practice regarding consent and shared decision-making within NHSScotland Boards



4.2.4 SPSO self-assessment checklist

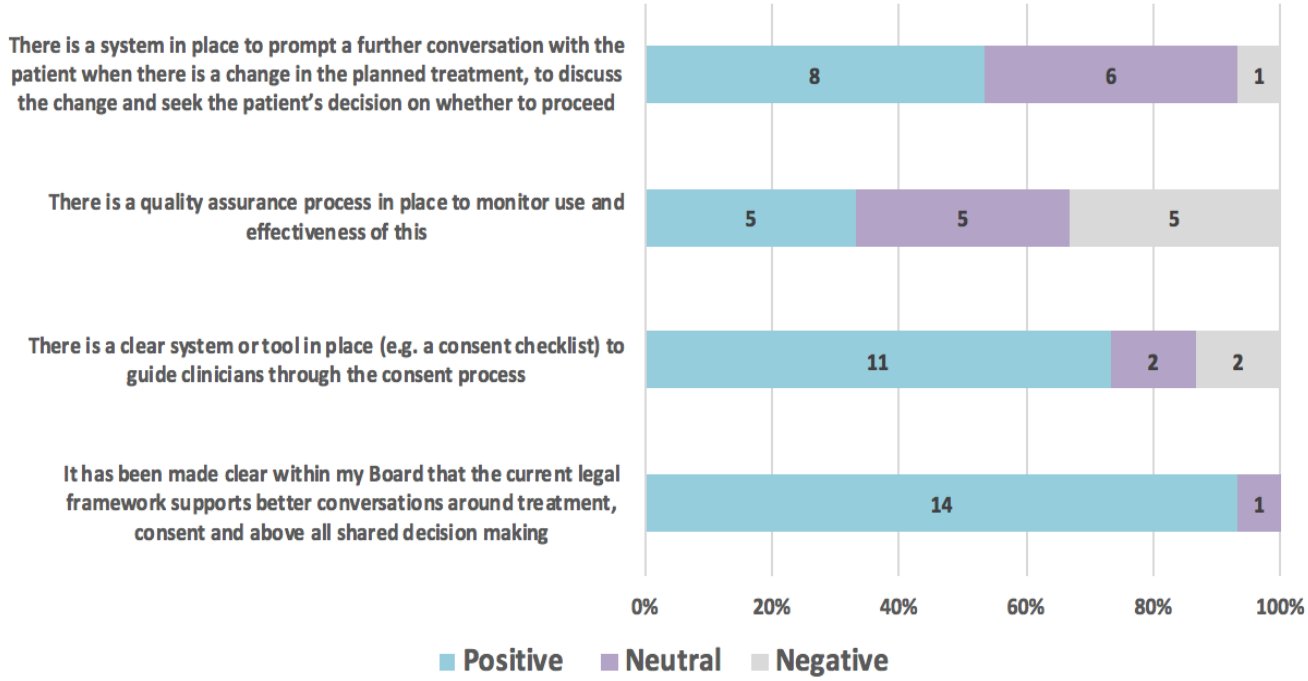
As a result of patient complaints, the Scottish Ombudsman produced a set of recommendations to evaluate the effectiveness of the current processes and develop improvements, including use of communication techniques, information provision and training. The report provides a self-assessment consent checklist for organisations and individuals to use to review their policy and practice. In her 2016-17 annual report, the Chief Medical Officer for Scotland, Dr Catherine Calderwood encouraged clinicians to consider how these questions can help to better understand how the local systems and processes can be improved to support shared decision-making during the consent process.

Boards were asked if they are currently applying the SPSO report (2017) consent checklist. Ten reported that they are applying it to some extent, 3 that they are not applying it at all, 2 Boards stated that they never heard of it and/or they did not know.

There was some variation in the results concerning local systems and processes (Figure 3). Although nearly all (14) respondents indicated that it has been made clear within their Health Board that the current legal framework supports better conversations around treatment, consent and shared decision-making, only 11 reported that there is a clear system or tool in place (e.g. consent checklist) to guide clinicians through the consent process. Moreover, only 8 respondents were confident that there is a system in place within their Board to prompt a further conversation with the patient when there is a change in the planned treatment, to discuss the change and seek the patient's decision on whether to proceed. Only 5 Boards

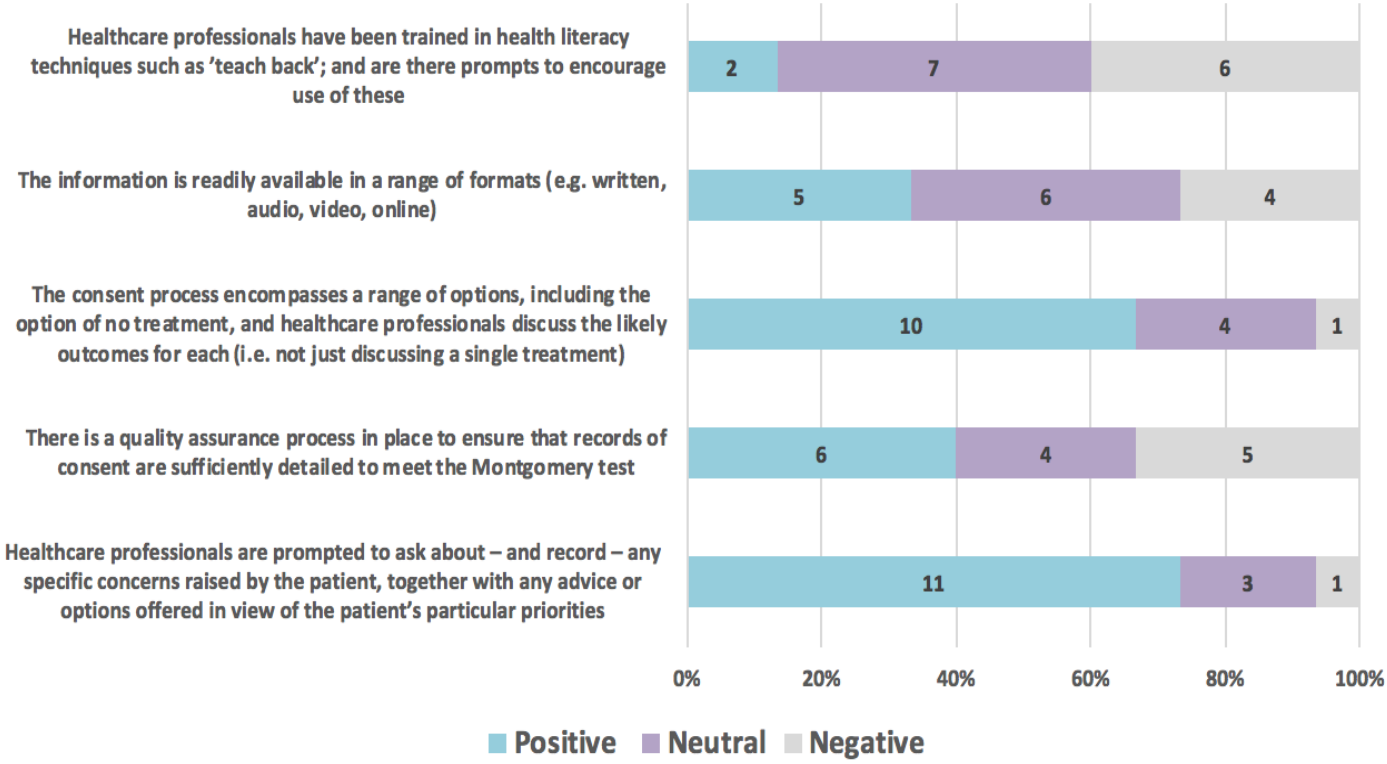
reported that there is a quality assurance process in place to monitor use and effectiveness of this. These results clearly suggest that there is scope for implementation of improvement actions in this area.

Figure 3. Summary of the SPSO self-assessment checklist for NHSScotland Boards (part a)



The responses were significantly less positive about information provision and the use of communication techniques (Figure 4). Only 2 Health Boards reported that healthcare professionals have been trained in health literacy techniques, such as 'Teach Back' and that there are prompts available to encourage the use of these. In response to the question as to whether the information is readily available in a range of formats, for example written, audio, video and/or online, only 5 Boards indicated that these are available in their area.

Figure 4. Summary of the SPSO self-assessment checklist for NHSScotland Boards (part b)



Work to improve supported decision-making involves strengthening health literacy so patients can fully understand the choices they are making and therefore be involved in making decisions about their health. The Scottish Government's Health Literacy Action Plan sets out how everyone involved in health and social care should see improved health literacy as a way to reduce health inequalities. It is clear from these survey responses that more work is required to develop more health literacy responsive organisations and produce supporting materials to guide healthcare professionals and patients to ask the right questions.

Good consent process allows patients to make an informed decision about the best course of action for themselves in the context of their own lives. The chances of successful treatment are also increased due to better communication and co-operation between doctors and patients (Shokrollahi, 2010). Good practice regarding asking about and recording any specific concerns raised by the patient, together with providing advice or offering options in view of the patient's particular priorities, was reported by 11 Boards.

Similarly, the survey found that in 10 Health Boards the consent process encompasses a range of options, including the option of no treatment, and healthcare professionals discuss the likely outcomes for each rather than discussing just one treatment.

These findings align with the 2018 Scottish Inpatient Experience Survey results, where 86 per cent of people said that the risks and benefits of their operation or procedure were explained to them beforehand and 80 per cent said that their questions were answered in a way that they could understand. Similarly, the 2017

Our Voice Citizen's Panel survey report found that although 92 per cent patients state they feel comfortable asking their doctor about their treatment or care options, only 67 per cent do so, often due to their doctor's attitude.

It is evident from the results that more training is needed to enable healthcare professionals to deliver accurate information to their patients in the most effective and appropriate way. Making sure that patients understand all the information they require to make an informed decision is key to carrying out a successful consent process. With appropriate training and helpful communication tools, clinicians may become more confident in delivering information, placing their patients at the centre of all conversations by giving them the opportunity to discuss any specific issues or areas of concern in a meaningful way.

4.3 GOOD PRACTICE – 'FREE TEXT' COMMENTS

The survey included open-ended questions eliciting 'free text comments' to capture deeper insights on the current consent and shared decision-making practice; also, to identify areas for improvement and further investigation. Key issues related to four overarching themes: tools, education, system/organisation and culture.

4.3.1 Tools

The key tool that facilitates good practice across the Boards was the implementation of a revised consent form within their Boards, which is clearer and more specific about shared decision-making. Other examples included:

- Reviewing all patient information leaflets to ensure there is information on risks and benefits;
- Ongoing work in some specialities to test other ways of giving information, e.g. using videos;
- New consent forms and policy, which are in early stages of use and development;
- Updating consent policy and forms to prompt and record necessary steps for effective shared decision-making;
- Sending postcards to patients prior to outpatient appointment to encourage them to ask the "Choosing Wisely 5 Questions" at their visit and to empower patients to engage in a more productive conversation;
- Exploring role of decision-making aids and SURPASS[2] consent forms;
- Procurement of the EIDO[3] leaflets on consent;
- Clear guidance and a variety of guides and sample forms, videos and best practice information from Colleges and other regulatory bodies available; and,
- Person-centred coaching tool supporting staff to ask questions when reviewing the quality of completion of consent forms.

[2] qualitysafety.bmj.com/content/18/2/121.short
[3] www.eidohealthcare.com/

4.3.2 Education

Views on the training available to clinicians were generally positive. These included awareness raising workshops, development of Effective Communication for Healthcare (EC4H) and 'Teach Back' sessions as part of the Realistic Medicine approach, continuing to update and enhance awareness and monitor process. Other examples were:

- A range of formal training on consent principles and Adults with Incapacity (AWI) as standalone, e-learning and blended within other training provision;
- Specific training provided to junior doctors;
- Realistic Medicine Continuing Medical Education (CME) sessions;
- Good conversations and Value Based Reflective Practice (VBRP) along with an adapted leadership tool called Aspire to Lead, which focuses heavily on the Patient/Doctor consultation/conversation;
- LearnPro e-learning module - Consent for Transfusion;
- Consent discussion at Morbidity and Mortality (M&M) meetings;
- Engagement with the General Medical Council (GMC) to provide local training and workshops for clinical staff; and,
- Support and training provided within departments specific to their needs and the needs of their patients.

Whilst only 2 Boards reported lack of any local training available on consent, there was a general consensus that there is lack of training provided on shared decision-making specifically.

4.3.3 System/Organisation

Respondents reported a range of good examples of practice around consent. These included conducting a well-established clinical process, whose main strength is its general robustness. Given the volume of interventions provided, these processes result in very few complaints about consent. Others commented on the pockets of excellent practice within specialties, for example, one respondent expressed:

"Our Orthopaedic Team were unfortunate to be involved in a case which went to the SPSO. This led to the team changing their processes to ensure that the appropriate clinician had time to discuss procedures, the patient had time to reflect and consider then discuss again with the same clinician. The same clinician would also do the operation. This created other issues around flow but significantly improved the consent process."

Some respondents pointed out that their Health Board has recognised the need to change practice and this has manifested in updating consent guidelines, which cover shared decision-making and importance of discussing issues relevant to the patient during consent, such as specific risks, concerns and the option of doing nothing. Others commented on carrying out audits within their organisation in order to capture the extent to which practice has changed and inform further work.

4.3.4 Culture

The majority of the respondents expressed that they are keen to develop principles of and practice Realistic Medicine. It was reported that the focus on shared decision-making is there. However, most agreed that to change cultures and habits is a very slow process. One respondent commented:

"We have a clear consent form, which prompts clinicians to do the right thing. However, strong policy and documentation are only part of the requirement - shifting the culture to shared decision-making is a longer challenge."

Some respondents mentioned good teamwork and consultants who are open to patient decisions as key factors to good practice in relation to consent. Others reported applying palliative care approaches, working with surgeons, anaesthetics and other teams. In general, the respondents stated that staff within their Boards seek to maintain a positive and inclusive culture, which is patient-centred. Staff expectations in this area were believed to be high.

4.4 BARRIERS TO GOOD PRACTICE

Respondents referred to a diverse range of issues that were felt to hinder healthcare professionals' ability to deliver good practice in relation to consent. These ranged from lack of evidence-based and consistent information for patients containing accessible and adequate information on all options (including the option of doing nothing), culture and habits around communication, health literacy, variation in practice, time constraints in terms of training and education, to a lack of consensus as to a standardised way of producing and providing patient information. One respondent commented that:

"The main barrier is the capacity to take on this important issue as well as the vast number of other important issues, such as Duty of Candour, Information Governance and GDPR, Records Management Plan, Health and Safety training requirements...."

Several respondents raised the point that there are no major barriers to the quality of shared decision-making; rather, it was noted, there are constraints to good practice. These included: lack of universal provision of high-quality written information to back up verbal communication and variation in clinician sense of risk threshold when deciding what factors to discuss with the patient. Additional areas of concern were the following:

- Lack of appropriate written patient information which has a standardised document control system in place;
- Lack of good quality tools to explain risk and benefit in a format that lay people can understand;
- A lack of consensus as to a standardised way of producing and providing patient information;
- Clinician time, both in individual consultations, and in the waiting times pathways;
- Common waiting lists - often consent is not done in clinic, rather left to pre-assessment or pre-op with another individual;

- Lack of communication skills and few decision-making aids to help;
- Lack of patient engagement and public readiness for these conversations with clinicians;
- Large geographical area can present challenges in consulting with colleagues, gaining consensus and establishing a standardised consent process;
- Fluid workforce and reliance upon locums. This adds strain to permanent staff who often find time is short to deliver true shared decision-making;
- Lack of clarity in law, for example, Montgomery states that patients should be given full information, but then that they should not be overburdened with information; and,
- Lack of quality assurance system to mitigate against poor individual practice.

4.5 ENABLERS OF GOOD PRACTICE

In response to the question about what would enable healthcare professionals to encourage, strengthen and facilitate shared decision-making, respondents highlighted the need for standardised policy on consent and a Scotland-wide repository of patient information to draw from. The majority also highlighted the need for a centralised training to support implementation of shared decision-making. There was a general agreement among respondents that the capacity to deliver high-quality shared decision-making is largely dependent on time. Therefore, it was pointed out that more time is needed in highly pressured clinical workflows to be fully responsive to patient needs. Others felt that technology needs to be better utilised to facilitate the process, for example, video or voice recording of the conversations. It was also pointed out that a standardised electronic informed consent system would help to reduce variations in practice. One respondent stated that in order to strengthen shared decision-making, there is a need to:

"…reinforce the message that it is not just about giving the information about risks and benefits, but about ensuring that patients have understood the information".

The enablers that were believed to be key to good practice were cultural factors, such as more role models within the organization, and courage and confidence to drive the change. Other reported enablers were:

- Better evidence-based models of communication and supportive decision tools when discussing risks;
- Availability of a wider range of health information, and access to resources to develop health information using different media;
- Public education to help people understand rights and responsibilities so they approach shared decision-making as a clinical partnership;
- Organisational focus;
- Steadier workforce;
- Greater flexibility of time during appointments to ensure full discussions take place;
- The '5 Questions' used more extensively;
- Ongoing teaching sessions or discussions involving the relevant clinical staff;
- Increased opportunities for learning; and,

- Supporting information about local data on meaningful outcome measures, i.e. patient reported outcome measures (PROMs) and patient reported experience measures (PREMs).

4.6 SUMMARY

In summary, NHS Scotland has a long and successful history of improvement actions, enhancing clinical effectiveness and aiming to provide high-quality care to patients. It appears clear however that NHS Boards' systems need to be better adapted to enabling and supporting people in making informed decisions about their health and wellbeing in a meaningful way. The survey results also indicate that more work is needed to support healthcare professionals to further develop the skills and knowledge necessary for true shared decision-making to take place, and to create a more open and trusting environment that will facilitate meaningful conversations with patients.

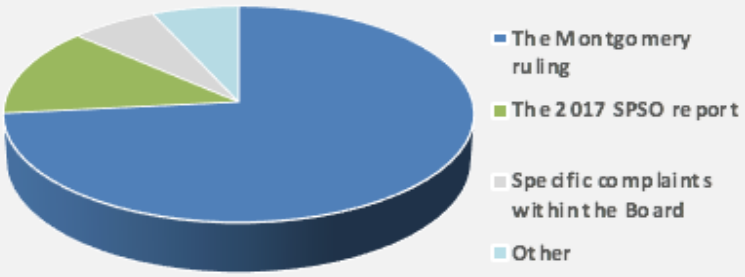
These preliminary research findings have not only helped to provide a basic understanding of the systems and processes currently used in consent but have also highlighted certain areas for further investigation and informed future improvement. These are explored in more detail in the next section.

Summary of changes around consent and shared decision-making within NHSScotland Health Boards since the Montgomery ruling 2015

12 out of 15 Boards stated that policy and practice have changed

3 out of 15 Boards stated that only practice has changed

Main reason for change in policy and/or practice



40% felt that their Board is well prepared for adapting to future changes in GMC guidance on consent & shared decision-making

60% felt they were only prepared to some extent

67% are to some extent applying the SPSO checklist within their Board

9 Boards have received complaints focused on informed consent and lack of shared decision-making since the Montgomery ruling

1 Board rated their current practice around consent and shared decision-making as **excellent**, 7 as good and the remaining 7 as fair

5. SEMI-STRUCTURED INTERVIEWS WITH NHS BOARD LEADS

Drawing on the responses provided in the online survey, it was possible to canvas more detailed views of those involved. Qualitative semi-structured interviews were used as they are one of the most effective and commonly used methods of data collection within the social sciences, which allows participants to express and discuss their views and perceptions freely (Bradford & Cullen, 2012), whilst still ensuring some uniformity across the interviews in terms of what is discussed.

Interviews (mainly face-to-face interviews) were conducted with the leads of ten of the fourteen NHSScotland Boards, namely: NHS Ayrshire and Arran; NHS Borders; NHS Dumfries and Galloway; NHS Fife; NHS Grampian: NHS Greater Glasgow and Clyde; NHS Highland; NHS Lanarkshire; NHS Lothian; and, NHS Shetland.

Analysis of the interview data highlighted a number of issues that currently act as barriers to improving the consent process as well as suggestions of several tools and processes for good practice around the consent process and shared decision-making. The interviewees envisaged a future of consent and shared decision-making in Scotland that was more standardised and enhanced perhaps by a national repository of patient information. They also spoke of more effective communication that allows the patient to discuss what matters to them, as well as shifting away from the idea that the doctor has all the answers:

"It's ok to say I don't know to a patient. […] you just open doors to have a much more meaningful conversation about what matters to the patient and what is shared decision-making"

It was felt that this will lead to more effective and efficient outcomes, simply through honesty between two partners working together.

This chapter will lay out the challenges to better consenting and shared decision-making, along with the suggestions that could be utilised to reduce identified barriers and create better outcomes for Scotland. First, some initial background will be provided on the reasons that the interviewees cited for the climate of increased desire for changes to consent and shared decision-making.

5.1 CATALYSTS FOR CHANGE?

The drive for better practices around consent and shared decision-making processes has risen from a series of recent events and shifts in society, which have acted as catalysts for change. There was a general agreement among the Board leads about the main drivers that have shifted the focus and re-defined the landscape of informed consent. These drivers have been described in the form of key cases and related reports.

5.1.1 Key Cases

A number of legal and medical cases have raised awareness of the inconsistencies and issues in the consent process, and have acted as vehicles for changing and improving processes. The Montgomery versus NHS Lanarkshire case was widely cited by interviewees as being influential in raising awareness of the consent process, in terms of its recommendations in regard of acceptable consent practice as well as focusing on individual material risk. In addition to raising awareness, the Montgomery case acted as a catalyst for change:

"So the key driver to our changes was the case against Lanarkshire and that was the thing that said to us: ok, we've looked at the document that came out and we thought we need to have a look at our process"

Furthermore, the Montgomery case enhanced the focus on shared decision making. One interviewee commented:

"I came at it from the view of trying to have fully informed consent; trying to move towards the concept of shared decision-making"

In addition, some cases have led to recommendations of better practices around consent and informed decision-making. One example is the improvements to consent procedures following the allegation that some women did not receive all the information to make an informed decision around having transvaginal mesh implants inserted:

"Our gynaecologists […] amended their consent forms and provided women with a helpful leaflet about the procedure and the process and what was involved and the benefits and sometimes the risks and that then helped us as a basis for amending our wider consent policy across the organisation"

This example highlights a system change that was made to consent and decision-making processes as a result of a specific case. In addition, a series of reports discussed below have had a broader impact on consent issues in Scotland.

5.1.2 Key reports

The Chief Medical Officer's Annual Report 2014-2015, Realistic Medicine, dedicates a chapter to describe a vision for shared decision-making and informed consent. The report places emphasis on building a personalised approach to care and moving away from the traditional 'doctor knows best' approach to consent. Although the majority of Board leads agreed that the Montgomery case was the main driver for policy changes, it was felt that the Realistic Medicine movement was much more fundamentally behind it. In addition, other reports mentioned by some of the Board leads were: the 2016 Inpatient Experience Survey (which one interviewee highlighted as leading to changes to their consent process), and the 2017 Scottish Public Services Ombudsman report called 'Informed consent: learning from complaints', where examples of complaints related to consent have been used to illustrate failures to adequately discuss, inform and agree an outcome of care with patients.

The combination of these cases and reports has brought the goals of better consent practices and shared decision-making to the forefront of health and social care decisions in Scotland. However, the interviewees raised some current issues and barriers to improving these practices which are discussed in more detail in the next section.

5.2 ISSUES AND BARRIERS

The main issues and barriers discussed by the interviewees can be categorised within five interlinked areas. Some of these barriers are more patient-related and others more health practitioner-related:

- Use of complex language;
- (Perceived) lack of time;
- Lack of consistency and clarity in consent procedures;
- Reluctance to change; and,
- Inefficient IT and technology use.

Due to their interlinked nature, solving even one of these issues should have a knock-on positive effect in reducing the negative impact of the others.

5.2.1 Use of complex language and low health literacy

Low health literacy levels can limit a person's understanding of complex health information and therefore impede their involvement in decision-making about their care and treatment. The interviewees felt that: "low health literacy is a big barrier to effective consent", and needs to be supported at a wider level by checking the level of understanding that is assumed in relevant leaflets. Furthermore, there was a widespread reference to the complex language used in the conversations with patients, which can lead to a lack of understanding and consequently a lack of patient engagement. The use of complex language could mean that "the patient might not understand why they're getting the procedure", which further necessitates the need for using straightforward language in various forms.

5.2.2 (Perceived) lack of time

Interviewees highlighted the pressure they felt battling a constant push on productivity within healthcare and a desire to 'do things well' (e.g. better consent processes). This can cause tension between how much time clinicians spend on their clinical responsibilities and how much time they can afford to spend talking to their patients. Nevertheless, time pressures in the busy clinical context was the most frequently cited barrier to having the true knowledge about that person's wishes and concerns. Yet, it is widely known that, when given an opportunity to tell their story, patients are commonly and quickly interrupted (Herstoff, 2017). An approach more in line with Realistic Medicine may therefore serve to reduce this time pressure:

"We know that if you do it [the consent process] well, it actually reduces the number of people who then go on to have surgery"

Some interviewees also spoke of pressures they felt from the patient wanting 'the perfect knowledge' and the frustrations of not being able to provide that knowledge and build effective patient-doctor relationships in a busy healthcare environment:

"I think you're going to find [...] that patients will often describe a desire for perfect knowledge – because every consumer does – the problem that we then have as a provider organisation is that the amount of energy and effort to provide that perfect knowledge is going to constrain our ability to do other things"

This issue was felt to be exacerbated by the waiting time pressures within the NHS. These are a series of standards that set the maximum amount of time a patient will wait at each stage from referral to receiving treatment. They are designed to help reduce patient anxiety, improve the quality of life of patients, improve the clinical outcomes and improve the timeliness of treatment. These standards relate to acute hospital care, such as for hip or knee surgery or cataract removal. Allowing patients a 'cooling off period' - more time during the process of consent - becomes a challenge in terms of the treatment time guarantee. This means that unless there is a mechanism for 'pausing the clock', then Boards will get penalised for not adhering to the national waiting time standards.

Patients who understand their health conditions, the risks and potential benefits of their treatment are likely to experience superior outcomes. Good communication is essential in helping patients reach those outcomes (Kyle & Shaw, 2014). It is only when communication is effective and balanced that healthcare professionals can establish caring relationships with patients and begin to gather information to facilitate the process of true shared decision-making. There needs to be a balance between job productivity (serving many patients) and as a service provider to individual patients. Interviews revealed that clinicians often have to juggle multiple tensions in their practice to meet legal expectations of consent, satisfy patient rights as a consumer and be able to deliver best quality care. The processes within health and social care need to be made more transparent so that patients understand the full time-cost of their healthcare needs. As one interviewee highlighted:

"…[if] we kind of give a more consumer rights perspective that burden is going to get bigger and bigger […] which means that we cannot actually deliver the care that they need"

However, some departments are already leading the way:

"Orthopaedics is a great example that I cited earlier in terms of their having good information available; seeing their patient and then bringing them back for a second appointment"

This is an effective method that others could learn from, to help ensure better outcomes for the patients. In fact, this lack of standardisation and clarity across departments was identified as an issue within consenting procedures, which is discussed below.

5.2.3 Lack of consistency and clarity in consent procedures

Board leads highlighted a huge disparity in the consent process within and between specialties, even between two hospitals within the same Board. The process was felt to be lacking consistency in terms of when the consent process is carried out, the conversations that take place within these processes and the level of documentation of these conversations.

Although, as Section 5.2.2 described, perceived lack of time may be a key factor in the inconsistent consent processes and may, to a certain extent, explain why consent often happens at inappropriate times without allowing patients more time to absorb and reflect on the information. The interviewees clearly recognised this problem:

"But we should not be consenting people just when they're lying on a trolley in a goony – definitely not"

A similar issue relates to inappropriate consenting procedures in which the full individual risks are not disclosed and explained to the patient, perhaps as some clinicians tend to avoid having 'difficult conversations':

"Some of them felt uncomfortable about talking about certain risks, like you might die"

Furthermore, the specific patient risks need to be explained better as they may be different for every individual. To illustrate:

"It is really about relative consent. […] if you're a pianist who's consented for hand treatment their consent is a different conversation because the risks and benefits of treatment to that person relative to them is going to be higher in terms of failure than if that patient's a footballer"

Relative consent, which involves a dynamic and robust process of information sharing around the specific risks, should become the standard practice. Health Board leads spoke of the need for better documentation around each individual consenting process. Currently clinicians do not always document what was discussed during conversations with the patient, which is fundamental in terms of adhering to guidance on the ethical consent procedures.

Furthermore, there is a current lack of consistency of consent processes over and above the physical form. By this we mean that it is the discussions around consent that need to be the greater focus of the process, rather than the mere signing of the form. It is these discussions that should form the basis of better consent practices through shared decision making and person-centred care. It was suggested that the perceived time and workload pressures compromise the documentation of these discussions:

"Whenever a consent form is required, the doctor's defence is always 'Well I didn't have time to do that but we did discuss it' or 'I didn't have time to document it all but we did discuss it' – but you have no proof"

The signed form for a procedure is only a small part of consent and there are specific legal requirements of what has to be disclosed to patients during the process. Many Board leads pointed out that they are awaiting upcoming GMC's review and renewal of the consent policy. Not wanting to waste precious resources on changing current procedures only to have them shortly superseded by new GMC guidelines was identified as the main reason for holding off with updating the existing forms and policies:

"We didn't really want to go through the whole process and come out with a sort of finalised document and then have the goalposts changed"

The new GMC guidelines were anticipated to provide a new framework for shared decision-making and aid better consistency of the process.

Finally, when asked about a quality assurance process to ensure that records of consent are sufficiently detailed to meet the Montgomery test, the majority agreed that there was no system for quality assurance in place. Some leads suggested using audits or writing to patients to obtain feedback, others pointed out that consent is embedded in the process of safety checks. One interviewee pointed out that rather than implementing a quality assurance, a continuous improvement approach would be more appropriate. This would ensure that patients have been given the right information, which in turn would enable them to partake in shared decision-making.

Each of the highlighted issues around consistency act as current barriers to more robust consent and shared decision-making. However, each can be improved through better guidance, and by making more efficient use of time (for example with the help of decision aids and tools). Changing peoples' attitudes is a bigger challenge for the NHS, as illustrated below.

5.2.4 Reluctance for change

Many practices are ingrained within the health and social care culture, which has produced a reluctance to change in some areas and by some (but by no means all) health and social care staff. The participants spoke about the pitfalls of 'defensive medicine', where one aims to prevent problems before they occur by developing a mind-set of doing things 'because it's routine'. Practices based on routine and habits were considered by the interviewees to prevent clinicians from developing an understanding of the patient as an individual and their healthcare needs. As one interviewee highlighted:

"When are we starting to make the right choices for individuals rather than have blanket policy that everyone that comes in gets a chest x-ray and an ECG as not everyone will need it"

Although reluctance to change is a normal human reaction that can occur in any system, this barrier can significantly impact on implementing efficient health and social care processes and the promotion of a more individually-tailored healthcare system.

5.2.5 Inefficient use of Information Technology

Similarly, poor use of Information Technology (IT) is also a barrier that can make informed consent more difficult. The NHS in Scotland is committed to the development and uptake of new technologies to enhance the delivery of healthcare interventions and thus improve health outcomes. Yet, despite the well-recognised benefits of technology, it is generally acknowledged that its adoption within healthcare has been slow and disparate. It was evident throughout the interviews that there are numerous challenges associated with poor IT infrastructure and patient information transfer. Being able to move patient information from different settings was viewed as essential in enabling clinicians to connect 'the bits of the jigsaw' and thus help patients make choices according to their wishes and preferences. For instance, one Board lead spoke of frustrations around:

"…[making] a connection between an acute care physician in a general hospital with a patient who's got a cancer diagnosis who's just been admitted. The cancer or the oncologist over here knows an awful lot about their prognosis and what might be reasonable and yet we've no way of connecting these two things"

Improving the IT infrastructure across the organisation would be an effective and efficient way to reduce wastage in the system and create more time for realistic approaches to medicine.

In summary, the Board leads highlighted a number of current issues and barriers to better consent processes. Although some require national level solutions (such as provision of guidance and ensuring relevant consent), others can be enacted at the Board or practice level (such as using more appropriate language). Tools for these solutions, as identified by the Board leads, are presented below.

5.3 TOOLS FOR CHANGE

Five pathways (two groups of 'tools', and three groups of 'processes'), to enhance good practice in shared decision-making and consent were suggested by the Health Board leads. Each pathway maps as a potential solution onto one or more of the barriers. These tools and processes are:

<u>Tools</u>

- Better usage of decision aids (in various forms)
- Better consent forms and procedures

<u>Processes</u>

- More training and support at all levels
- Changing the culture at a societal level
- Increase the use of digital technology for health

These tools (and processes) are interlinked and utilising a combination of them was believed to have more positive implications that a singular tool/process on its own. The first group of identified tools is a variety of forms of decision aids.

5.3.1 Better usage of decision aids (in various forms)

There was widespread discussion by the interviewees on the importance of using a variety of forms of decision aids to promote better consent and shared decision-making practices. They were reported to enable: more opportunities for clarifying information for the patient; address the differing health literacy levels of patients; and provide practitioners with aids to facilitate more meaningful conversations with their patients. These decision aids should however be used as a conversation 'opener' rather than any sort of substitute for a meaningful conversation. The identified forms of decision aids included information leaflets, knowledge exchange techniques to promote better understanding of procedures and the recording of conversations. These aids were believed by participants to facilitate a fuller conversation about a procedure and risks involved, allowing the patient more time to consider all the options.

Information leaflets

Research has shown that decision aids not only help to empower patients in making informed decisions but also bridge the wide gap between the theory and practice of informed consent (Pope, 2017). They facilitate a process of shared decision-making, combining clear documentation and consultation. It was clear during the interviews that some clinicians were in favour of using decision aids, such as knowledge exchange techniques, in their practice. Others were more sceptical, stating concerns around lack of detail that it is not clear from the literature whether decision aids are helpful or not. Some participants commented that although useful at times, they are drawn from research conducted in the general population and are not specific to the patient. It was also suggested that they may take the focus away from the human conversation, leading to a more mechanistic consent process.

Nevertheless, there was a general agreement that patient leaflets are useful tools or enablers to good practice. As one interviewee put it:

"You can put in things that are kind of prompts and pushes but you can also put in enablers. For example, our Board had been paying for EIDO [Experts in Informed Consent] leaflets and most of our clinicians didn't even know they existed and actually they like them"

Recent research has shown that on average, patients remember less than half of the recommendations made by their doctors (Laws, Lee, Taubin, Rogers, & Wilson, 2018). Patient recall could be enhanced by limiting the amount of information to be remembered in a single visit, also using information leaflets to encourage patient engagement. In other words:

"the patient would capture a couple of words, but you could see that they would focus on one word and they would miss half of the conversation, so they might not take it all on board and if they didn't have something to take away with them then they would have no way to recall or to think about that"

The use of leaflets was described as a useful tool to encourage better practices around informed consent, which enables the patient to have a better understanding

of potential benefits and risks of a procedure. However, some interviewees pointed out that in order to enable more effective conversations, there is a need for more personalised leaflets containing, for example, statistics referring to the published risk rates of local surgery.

However, other interviewees were less enthusiastic about the quality of the leaflets:

"For my taste, they're never adequately quantified for me personally but I'm a kind of numbers person, so I would want to know what the actual rate is or even a range and we just don't get that"

This perhaps reflects the complexity of different patient information needs. As good information helps patients to participate fully in shared decision-making, there is a requirement to review and develop these leaflets further to maximise their benefit.

Knowledge exchange techniques

In addition to leaflets techniques for knowledge exchange should, and in some cases are, being utilised to encourage better understanding of procedures. These act as a starting point for more meaningful dialogue between patient and practitioners and promote a two-way conversation. Some effective techniques suggested by interviewees are described below.

Choosing Wisely[4] is a national initiative that seeks to advance a dialogue between patients and healthcare providers on avoiding unnecessary medical tests. It was created to help patients engage in these conversations and empower them to ask questions about what tests and procedures are right for them. There was widespread enthusiasm among some interviewees about using the 5 Questions, devised as part of the Choosing Wisely initiative as a tool to help prompt better conversations, with plans of including the questions with patient appointment letters:

"One of our plans had been to have a little card with the 5 questions and send it out with the outpatient appointment"

Some Board leads highlighted initial reluctance within their Board around using the 5 Questions, feeling that encouraging patients to ask more questions would 'eat' into the already limited consultation time. However, they conceded that the questions should empower patients to engage in decisions about their health and thus lead to more effective consultations and inevitably healthcare over time.

There are many ways to convey information to patients in an effective manner. Posters have been shown to be useful tools that have the ability to increase knowledge, change attitudes, and alter behaviours (Ilic & Rowe, 2013). Displaying the 5 questions on a poster in surgeries and hospitals was considered to be an effective means of promoting the message:

"We were talking about putting them out in the clinician's eye-line in every clinic room and having posters and leaflets in the waiting areas for the patients because actually

[4] www.choosingwisely.co.uk/about-choosing-wisely-uk/

most of them are waiting for a fair amount of time. So, you do read the posters because you get bored"

The 'teach-back' technique is another knowledge exchange tool to check that the health professional has clearly explained information to the patient and that the patient has understood what has been discussed. However, there were varying levels of awareness of this technique. Some interviewees commented that they had never heard of it, whilst others considered it a useful method currently being introduced within their Board, whereby patients are expected to demonstrate to their clinician how they would explain their procedure to a friend or family member.

The Best Case/Worst Case communication tool is another tool designed to help patients facing difficult decisions regarding the choice of treatment, including surgical procedures. This tool helps healthcare professionals, patients and caregivers evaluate and discuss these decisions and make informed choices that reflect patients' values and preferences (Kruser et al., 2017). It supports this through the use of drawings and written diagrams to compare the best and worst outcomes of various potential treatments. According to one Board lead, the communication tool:

"has been shown to change the way clinicians are describing trajectories in a way that people understand"

ReSPECT (Recommended Emergency Summary of Care and Treatment) was also mentioned, as a process that creates personalised recommendations for a person's clinical care in a potential future emergency in which they are unable to make or express their choices:

"So what RESPECT does is that it is a document that highlights emergency care wishes"

In contrast to many advanced care and treatment escalation plans, which can be very lengthy, ReSPECT aspires to be concise, clear and in a format that is immediately recognisable in any care setting (Wolff & Whitehouse, 2017). In short, it provides healthcare professionals with a summary of information to help them decide in an emergency situation about that person's care and treatment. It is currently being piloted in several areas of the UK.

Recording conversations

In recent times, audio-video recording of consent process for patients entering a clinical trial has been made mandatory in some countries. There are many reasons why filming or tape-recording a consent process might be beneficial and it is becoming common for patients to ask to record a consultation on their mobile phones. One participant was in favour of this suggestion, stating:

"We should all be encouraging and welcome patients to make their own recordings, which they can choose to use or not, and not be put off by it and actually, you're far less likely to have any litigation if patients actually have all that information upfront. It's a bit of a no-brainer"

Although most interviewees were in favour of patients recording the consultations, they spoke about their colleagues being more resistant to the idea, even though it promotes transparency and better documentation of the consent process. As one interviewee put it:

"if someone wants to record it so that they are able to play it over later to their family and then if they've got any questions, I would much rather that they came back to me and had those questions answered than sit at home and worry about them"

This outlook is in line with the ideals of Realistic Medicine and person-centred care, for which better consent processes are an integral part.

In summary, there are a wide array of decision aids available and clinicians and patients should be flexible in their consideration and use of those as different aids will be valuable to different people in differing contexts and situations. However, these decision aids should be precisely that – aids to further discussions and actions, an idea which can be strengthened through additional training and support at all levels.

5.3.2 Better consent forms and procedures

To facilitate better processes around consent, updated consent forms are being introduced in some areas. However, some Board leads felt that the new consent forms are much more prescriptive than the old ones and therefore take the focus away from the patient and their preferences and specific circumstances. Others said that they act as useful prompts in capturing all the important information about the patient and facilitate good documentation of the consent process. There was also a widespread reference to the length of time that it takes to complete the new consent forms, which may act as a barrier during busy hours of the clinics:

"We rolled out the new consent form in March 2018. It used to be a one-page document but now it's 4 pages. It contains a lot of information on it. It fully documents the actual consent process. From what information has been given it states the possibility that you might need a blood transfusion as well. It's got possible, probably, and likely. The only thing that comes back from that is the length of time it takes to complete it because that's one of the stumbling blocks that we've […] encountered."

Participants also pointed out that although consent forms are only required in certain situations, such as prior to surgery for example, consent is a process by which a patient gives informed agreement for the treatment or intervention to go ahead. It is a legal requirement to seek patient consent in all situations to respect patient autonomy. As one senior clinician noted:

"We tried to design a consent form that prompted clinicians to basically do the right thing"

The new consent forms were felt to be useful prompts that facilitate effective conversations with the patient around specific risks and benefits of a treatment, alternatives or the option of no treatment:

"…it's acting as a prompt to talk about and to ask is there anything that you're particularly worried about; the benefits and risks of alternative treatments that might be offered including the option of no treatment"

The consent process should also enable a clinician (and a recent legal judgement has highlighted this) to consider the significance of a risk for that particular patient (with reference to their preferences) and what effect it would have on that patient's life, rather than generic risks or population level figures. This signifies a move away from a mere signature on the consent form to a robust process of information-sharing. This has had a significant impact on the consenting practice as the focus changed from giving patient information to addressing material risks.

However, although the new consent forms were felt to provide the opportunities for better information-sharing, concerns were also raised regarding using bespoke versions of consent forms with prepopulated information about the procedure. It was pointed out that this type of form may remove the capacity to have personalised patient conversations:

"I think the more you make something a pre-written tick box form the greater the risk you have of missing what's important to the patient"

This would suggest that the consent form needs to be completed after the patient is fully informed (through conversations, decision aids, knowledge exchange tools etc.) of the risks and benefits of each treatment option, including the option of no treatment. The processes for change discussed below should be considered in tandem with the tools.

5.4 PROCESSES FOR CHANGE

The processes for change will require a transformation on a larger scale. However, providing more training and support at all levels was identified as a starting point.

5.4.1 More training and support at all levels

Various forms of training were suggested by the Board leads to promote better practices around consent and shared decision-making. Training around effective communication was described as a cornerstone of medicine. Therefore, for true shared decision-making to take place, both healthcare professionals and patients must first commit to sharing information and respecting each other's point of view by active listening. As such, additional training on the principles of Realistic Medicine (including active listening) has been established is many Health Boards. According to one interviewee:

"I think we have some clinicians who really do not have the skills to listen. They are so driven by pressures to get their point of the operation across that they go in with that and it's how you get them to see that actually if you go in with a different mind-set and let them [the patient] do the talking that actually you will gain far more information"

Specifically, additional training on consent and shared decision-making was also explored during the interviews. Whilst some Board leads talked about an array of the available training within their Boards, including optional seminars, engagement with the GMC and a variety of workshops on good conversations as well as a mandatory e-learning module on consent; others pointed out the scarcity of available training:

"There's no specific training on consent. We're kind of in the watershed between the Lanarkshire case and the Ombudsman's guidance and we're waiting for the national UK work that ex-CMOs across the UK have set off"

With the exception of one Board, there was very little mention of any training available on shared decision-making.

Additionally, there was a perception that there is scarcity of training dedicated to consent and shared decision-making per se within the undergraduate medical curriculum. Some Board leads pointed out that medical students do not have any practical 'consenting' experience prior to leaving medical school and have to face 'outdated attitudes' of their senior colleagues when coming into the system. It was felt that that all healthcare professionals, regardless of grade or specialty, should be able to carry out a good consenting process. For instance, one suggestion was:

"What we need to do is […] when both undergraduates and post-graduate doctors are trained that this is the way they're taught to do it"

It was also pointed out that training should start early, during undergraduate programmes and continue throughout the career. On-the-job training and peer review were suggested as alternative approaches to improving practice around consent. Newly qualified doctors with a good ethos were perceived to have a positive influence on "a healthcare environment saturated with old habits and outdated attitudes"

Overall, training on better communication should be promoted further to enhance the outcomes for NHSScotland and subsequently its patients. More training may also provide a feasible solution to the reluctance to change, which is discussed elsewhere in this report. Simultaneous support mechanisms to foster a positive and collaborative atmosphere are already being promoted within various Boards.

Compassionate care and effective communication are key to the person-centred consent process. Throughout interviews, participants referred to the continuous stresses and dilemmas that they are faced with while caring for patients. Undoubtedly, enhanced communication, teamwork, and compassion shown by healthcare professionals can make all the difference to a patient's experience of care. However, there was a strong agreement among participants that in order to provide compassionate care to patients, clinicians must first feel supported in their work.

Some interviewees talked about having adopted Values Based Reflective Practice (VBRP) within their Boards. The model has been developed by NHS Scotland to help healthcare staff deliver high-quality compassionate care by promoting regular inter-disciplinary group reflection on practice. One participant mentioned

implementing Schwartz Rounds within their Board, which are run by the VBRP facilitators during multidisciplinary team meetings. In 2009, Schwartz Rounds were brought to the UK by the Point of Care programme at The King's Fund and continue to be supported by The Point of Care Foundation. Schwartz Rounds allow staff to get together regularly to reflect on and discuss the emotional and social aspects of working in healthcare. Evidence shows that staff who attend Rounds feel less stressed and isolated, with increased insight and appreciation for each other's roles (Goodrich, 2016). The Rounds can help clinicians feel more supported in their jobs, allowing them the time and space to reflect on their roles and therefore facilitate person-centred approaches to care.

Celebrating excellence and sharing and highlighting examples of good practice were described as an important part of improving shared decision-making processes. The NHS safety culture predominantly focuses on negative events. Staff are encouraged to report incidents using online tools, such as Datix. Although learning from errors and mistakes is important in healthcare, having this as the sole focus can lead to positive performance not being recognised (Sinton, Lewis, & Roland, 2016). Some participants raised the point that this can hinder transfer of good practice across the organisation. Interviews also revealed that a positive reporting system may produce moral and cultural benefits for NHS staff and add value in a system that is frequently under-resourced. One of the participants mentioned using positive feedback and reporting excellence via the online tool Greatix:

"When we hear that they're doing really good informed consent around procedures and things, then should feed that back to the individual, so we are looking at things like GREATIX – which is a thing used down south which is positive feedback"

There were a range of other improvement actions identified by the interviewees that have been implemented within Boards with a view to fostering better practice regarding consent and shared decision-making. These included: setting up a working group to establish core principles for the consent process to cover wide-ranging scenarios (such as emergency procedures, high risk procedures and high volume, low complex medical interventions). Others talked about creating new and more detailed information leaflets, a new consent process, changing procedures in outpatient clinics in terms of the consultation time in order to fully explain the potential implications of certain procedures, the benefits and the potential risks, and allow patients sufficient time to consider what it means for them. Other Board leads placed the emphasis on ensuring that the consent process is more individualised.

Changing an ingrained behaviour within an organisation is difficult. It is especially challenging in healthcare due to the complex relationships between a wide range of stakeholders, patients and carers. However, the discussions with the Board leads revealed that certain factors may help to promote an environment that is open to change. For example, a strong leadership was felt to be key in fostering a shift of the power dynamics. The interviewees reflected on the fact that embedding shared decision-making into healthcare requires 'courage, confidence and strong role models'. This cultural change could be facilitated through effective training and support mechanisms at all levels to make shared decision-making in health and social care more commonplace.

5.4.2 Changing the culture at a societal level

There was a strong sense during interviews that in order to accomplish the sought after 'cultural evolution' - where healthcare professionals work in close partnership with patients – it is crucial to create role models who are driven by a vision of Realistic Medicine. Empowering and encouraging senior clinicians to be the custodians of the professional agenda was felt to be essential to initiate the much-needed change and break outdated attitudes:

"The CMO's wishes for us all to practice Realistic Medicine by 2025 – and that timeline reflects the fact that it takes years to change culture. […] So, we need to create that critical mass of senior role models that practice Realistic Medicine and it will then happen but it's not going to happen overnight"

There was also a widespread reference to the shift away from the patriarchal model of practice towards supporting patients in self-managing their health:

"this kind of sense of what we've called the patriarchal model so the clinician's team knows best and will just tell you what's happening to you and we've began to shift from that"

It was felt that the change has to come at a societal level by creating conditions where people feel empowered to express their needs and make their own choices with support from the healthcare service. It is a well-established fact that clinicians will have a better medical knowledge than patients due to years of training, experience and access to the latest research. As most patients have little medical knowledge, they may believe that 'the doctor knows best' (Mulley et al.,2012). The interviewees spoke about the challenges of helping patients to build an informed choice that is right for them as an individual without unconsciously dominating conversations by their own opinion. It was felt that patients often want to abandon "their choice to the perspective of the expert"

However, not providing an opinion may aid that shift of power back to the patient. It was suggested that conversations could be initiated by saying:

"It's ok to say I don't know and there was a beautiful piece written the other day about its ok to say I don't know to a patient. … you just open doors to have a much more meaningful conversation about what matters to the patient and what is shared decision-making"

This highlights that health professionals need to recognise patients as experts with a unique knowledge of their own preferences for treatments and outcomes.

Several suggestions were given by the Board leads as examples of involving patients more in decisions about their own healthcare. The National Institute for Health and Care Excellence (NICE) continues to stress the importance of increasing patients' direct control over their health. Patients have the responsibility for managing their health and this needs to be recognised in the ways health care professionals interact with patients. Yet, patient engagement in decision-making remains a challenge. Health service users are often viewed as passive recipients of

care prescribed by the clinician. Interviews with the Board leads revealed some interesting reflections on the importance of patient education about their responsibilities of being actively involved in decision-making. Some participants raised the point that strategies to support patient education and engagement should be at the forefront of consent policy. There was a general agreement that patient roles must be recognised and supported in order to counter the issue of the lack of partnership between patients and healthcare providers:

"The issue with a lot of the public is that they are not going to challenge the doctor or ask if there are any alternatives"

The Board leads suggested that this could be altered by utilising the House of Care and Personal Outcomes Approach. This approach empowers patients to self-manage their conditions by supporting and enabling people to articulate their own needs and decide on their own priorities, through a process of joint decision making, goal setting and action planning. It was felt that using the model would ensure that the healthcare system is responsive to patients with various needs and conditions and encourage healthcare professionals to support people through shared decision-making and working in a partnership:

"The intent there is to create a different type of relationship where what you're really doing is you put the patient in a position where they self-manage, so our role becomes different […] and that different relationship has thrown up a different set of conversations and discussions"

The approach could also enable more conversations whereby the option of 'no treatment' is explored. However, the interviews revealed that people need to be supported in decisions they make about their care, and their right to refuse or choose the option of no treatment must be respected. As one Board lead put it:

"*O*ne girl said to me: *'*do you mean I have permission not to do this?*' A*nd actually, I was - oh my goodness, does she really think she *has to have permission?"*

Changing the culture at a societal level will mean that patients are not only fully informed of their healthcare options but feel more in control of the decisions they make about their health and wellbeing. The move towards the Personal Outcomes Approach was believed to engage and enable people to be active participants in shared decision-making:

"So it could be that actually the patient is inviting us to perform something for them […] I've got this and this is what I need and therefore, I'm commissioning you to deliver it for me"

Changing the concept of the patient as a passive recipient of care will require more a patient-centred approach. Supporting better shared decision-making through more active patient engagement will aid these changes and help to redesign the patient`s role. Additionally, better use of decision aids and digital technology discussed below will have a role to play in this cultural shift.

5.4.3 Increase the use of digital technology

Better use of digital technologies has the potential to transform how we deliver healthcare services. In services constrained by budgets, it is clear that making the most of technology is essential. Evidence shows that increased use of digital technology can drive efficiency and deliver value for money as well as benefiting the health and wellbeing of the public (Local Government Association, 2018). Moreover, technology allows us to gather and transfer information in new and more comprehensive ways. Interviewees suggested that better use of technology could start with audio-recording conversations with patients. They also pointed out that using technology to create short videos about risks and benefits of standard procedures would be beneficial for people with health literacy problems. Others mentioned having an electronic system that would allow consent forms to be pre-populated for specific procedures:

"I think if you had an electronic system that would be fantastic because you could load it and pre-populate it. So […] it would pre-populate exactly what the risks are, and they would add any that are pertinent just to that particular patient given their medical condition"

It was felt that this would reduce time pressures clinicians are constantly under and allow for more time to be spent having discussions with the patient.

Electronic versions of a hospital newsletter were suggested as another simple solution that can be used to connect with and update staff on what is going on in the organisation. It may act as an instrument for wider learning that could be useful to others and for sharing and encouraging good practice. It can help outline any barriers healthcare professionals face in their practice and the methods used to overcome these. One of the senior clinicians reflected that:

"We've set up a newsletter, which goes throughout the whole of hospital and we have a primary care newsletter and if anything's particularly pertinent then we'll pop it in there as well"

Another suggestion was to build a national repository of patient information. Building a national library of electronic up-to-date and well-controlled patient information was thought to be vital to improve the consent process. The bespoke version of a Scottish central library of public information would allow both healthcare professionals and patients to easily obtain the clinically valid evidence-based treatment information. Participants commented that being able to use the same source of nationally-held information would support and improve the care around consent:

"...so that everybody goes to clinically valid evidence-based treatment information and we've all got the same source"

Others raised the issue that although a national library would improve consistency of documentation, it would not necessarily guarantee a good delivery of information. Nevertheless, it was felt that it would provide a good starting point.

Finally, the discussions with the Board leads around tools and processes for change led to a conversation about what they envisaged as 'the ideal consenting process'.

5.5 IDEAL CONSENTING PROCESS

Throughout the interviews, participants referred to how they envisaged good consent would look like in an ideal world. The general consensus was that a good consent process is one that enables and empowers the patient to ask questions and to make informed decisions about the care and treatment that they would like to receive. This process must be person-centred, unhurried, individualised and visible to everyone. An emphasis was placed on the importance of continuity of care, spending more time with patients at critical therapeutic points of their lives and engaging in a rich dialogue. Overall, it was felt that it is a meaningful conversation with the patient that truly matters:

"although we spend hours and hours agonising over the precise wording of our consent form, actually, the form is irrelevant. It's just a symbol that we have talked about these things. It's the conversation that's the bit that really matters"

Research has shown that patients choose different or less treatment as they become better informed (Foot et al., 2014). The interviewees raised the issue about the differences between what healthcare professionals commonly assume patients want, compared to what they actually want when this discussion takes place. Therefore, taking the time to find out how the patient is truly feeling can go a long way in obtaining a wealth of information about what matters to them. For instance, as one Board lead described, shared decision-making can start with:

"What are your goals? What do you want? How are you today? What can I do to help you? […] They not only give you probably the relevant information that you need to know but they also will give you a lot more information"

The majority of interviewees agreed that having a standardised Scotland-wide approach to consent policy, such as the national approach to early warning scores for example, would lead to better consistency across the organisation. It was felt that having a single standard policy and consent form for the whole of Scotland would potentially reduce waste of resources at every individual Board level, eliminate unwanted variation in consent practice between and within Boards and provide a model to work from:

"I think the headline thing for the Board would be that if there were standardised consent forms for Scotland; standardised patient leaflets […] and a standardised consent policy […] that would then be slightly modified but on a board by board basis. I think those 3 things…would have saved a lot of work; a lot of hassle and would have really helped to move things forward more easily"

However, some recognised that a national approach would not necessarily aid effective communication or create trusting relationships with patients, which should be the fundamental part of true shared decision-making to ensure that patients get 'the care they need and no less, the care they want, and no more' (Coulter & Collins, 2011).

6. CONCLUSIONS AND RECOMMENDATIONS

This research project set out to explore: whether current consent processes form part of a wider culture of person-centred care and supported decision-making with patients within NHSScotland; to identify how existing processes and tools support good practice (or not); to identify examples of good practice that could be shared across the organisation; and finally, to provide recommendations for future improvement. It was undertaken by holding a group consultation with the Person-Centred Stakeholder Group, administering an online survey questionnaire to 15 NHS Health Boards and interviewing 10 Board leads.

This research found that while embedding shared decision-making into systems and processes and changing people's attitudes is an enormous challenge for NHSScotland, several improvement actions are already underway. Examples of these have been provided and discussed throughout this report.

The findings revealed a recognition that all healthcare professionals should adopt a more personalised and individualised approach within their practice. The need to provide patients with context-specific information was seen as a priority. The discussions showed that, whilst health service users recognise the challenges that healthcare professionals face in their everyday practice, they were also concerned that patients are not given adequate time to fully 'understand, digest and reflect' the information about their care and treatment. They also questioned the implications of declining or changing their mind about the treatment options without any judgement or repercussions. Therefore, patients need to be assured that active participation and expressing their preferences or declining the treatment will not be punitive. In order to enable true shared decision-making, patients need to be actively encouraged to ask questions about their care and feel able to discuss the options.

It was felt that changes need to happen at 'a societal level' and patients need to be informed and educated about their responsibility in shared decision-making. The paradigm shift away from the 'doctor knows best' is dependent on two experts working together, where the patient's personal expertise and knowledge of their preference is of equal value to medical expertise. However, for true shared decision-making to take place, there first needs to be trust between the individual and healthcare professionals so the people involved feel that they can openly and honestly discuss different options and work in partnership towards an agreed goal. In order to achieve this, there needs to be collaboration between the professional and the patient, and the involvement of families, carers and significant persons needs to be supported.

There was a general perception among participants that there is often a lack of time for good person-centred conversations to take place. This might be due to organisational constraints and a lack of resources, but also due to poor, or a lack of, forward planning. These constraints often prevent clinicians from practising Realistic Medicine and truly understanding the values, needs and preferences of individual patients. Participants offered valuable insights and suggestions on what could help to address these issues. They called for support, clear guidance on and better access to effective communication techniques, increased training on shared decision-making and more focus on patients' engagement in their own health and

care. These findings resonate with the recent report published by the GMC (2017) on doctors' attitudes to consent and shared decision-making.

The approach to designing and implementing consent policy was subject to continual debate. Whilst some Board leads suggested a standardised Scotland-wide approach, others pointed out that in order to improve practice of shared decision-making, the priority for the NHS is not a new consent policy but changing the ingrained attitudes and behaviours of healthcare professionals so that talking about the patients' preferences, values and needs becomes routine.

Reflecting on the narratives that have emerged from the interviews, it appears that an essential step in implementing shared decision-making is to improve the current systems and processes at each individual Health Board level in order to enable clinicians to do 'the right thing'. More emphasis needs to be placed on putting prompts in place to encourage healthcare staff to ask about and record specific concerns raised by the patient, together with any advice or options offered in view of the patient's particular priorities. Whilst records of consent need to be sufficiently detailed to meet the Montgomery test and measures should be taken to monitor the use and effectiveness of this, the consent process needs to encompass a range of options, including the option of 'no treatment'. There is a requirement for all NHS Boards to have access to and ensure that information is readily available in a range of formats (e.g. written, audio, video, online). Moreover, all healthcare professionals should be offered training in health literacy techniques such as 'teach-back'; and have appropriate prompts in place to encourage the use of these. There is also a requirement for a system that prompts a further conversation with the patient when there is a change in the planned treatment.

This research highlights a number of areas of future work related to involving and engaging the patient more in the conversations around their own healthcare and processes around consent and providing better support to health and social care practitioners. The associated recommendations highlighted below should help to create a more solid backdrop for better consent processes and shared decision making that underpin the current health and social care practices in NHSScotland. These recommendations range from the broad to the specific and will necessitate a range of actions from policymakers as well as other relevant stakeholders at a local and national level.

6.1 BRING THE CONVERSATION BACK TO THE ROOM

'Bring the conversation back to the room' means ensuring various mechanisms are in place to allow a rich and meaningful dialogue built on partnership to be placed at the heart of every interaction between those providing and receiving treatment and care. These mechanisms should equip healthcare professionals with the skills (openness, honesty, effective communication) that will enable patients and their families to talk about their preferences, values and needs. Healthcare professionals should appreciate the differing levels of health and language literature amongst their patients and use appropriate platforms and forms of decision aids to support their conversations and practices. To support effective conversation, it is recommended to:

- Provide more guidance on the effective ways of communication (including evidence-based methods and resources) to enable health professionals to clearly explain risks, benefits, outcomes and alternative treatments;
- Develop a national standardised repository of evidence-based information about treatments and procedures and the associated risks, in a range of formats;
- Provide clear guidance on the appropriate use of and better access to high-quality decision-making aids for both healthcare professionals and patients to guide shared decision-making;
- Provide staff with education and adequate skills to both communicate information clearly to the patient and to ensure the patient has understood the information (e.g. the 'teach-back' technique);
- Provide staff with training on how to build a more supportive relationship with the patient to enhance person-centred consultations in which the patient feels more actively involved in their own treatment plans.

6.2 PROMOTE CULTURAL TRANSFORMATION

This research has identified that transformation is needed within the healthcare system in Scotland to promote and subsequently accept a more personalised and less hierarchical model. The primary data collection highlighted the desire to build personalised approach to care and shift the current style of making decisions for patients to sharing decisions with patients. Furthermore, a more collaborative and positive healthcare system should be strived for in terms promoting opportunities for learning and sharing examples of good practice around shared decision-making and the consent procedure; as well as further research into moving from a paternalistic to a more person-centred culture of care delivery. The assumption of the superiority of clinical knowledge needs to be actively discouraged within the NHS. To rebalance the decision-making power, patients must be recognised as equal partners in their care and treatment and feel supported to express their own needs and priorities through a process of information-sharing, goal-setting and action-planning. Realisation of these ideals can be aided through several recommendations:

- Encourage NHS Boards to share examples of good practice in consent and shared decision-making across NHS Scotland;
- Increase training opportunities and embed shared decision-making into undergraduate education for all healthcare staff; and,
- Promote peer review of good consenting practice across NHSScotland.

6.3 ENGAGE THE PUBLIC

This research highlighted the importance of the changing role of the patient, as well as a transformation of the role of the healthcare professional. Changes in the consent process as well as shared decision-making necessitate a transformation in the role of the patient as a more active participant in their own healthcare where possible. Individuals need to be made aware of their responsibility in managing their health and wellbeing, and to feel more empowered to take an active role in their own healthcare decisions. This can be implemented through better engagement with the public over the importance of and growing trend towards better practices around

consent and shared decision-making. By undertaking measures to build patients' skills and knowledge of navigating and using health and social care systems, they may become more confident to take an active role in their own healthcare decisions. The following recommendations have been suggested to better engage the public in decisions about their health and social care decision-making:

- Create clear guidance for healthcare professionals on how to most effectively involve people in decisions about their health and care, with respect to individual needs and capabilities;
- Create patient/public campaigns to increase people's knowledge, understanding, skills and confidence to use health information and navigate health and social care systems;
- Make information and training on shared decision-making publicly available to encourage people to become actively involved in decisions about their health and care.

6.4 IMPROVE LOCAL SYSTEMS AND PROCESSES AROUND CONSENT AND SHARED DECISION-MAKING

To support implementation of the other groups of recommendations, it is important to improve the local systems and processes around consent and shared decision-making to enable more meaningful conversations around healthcare with the patient and to necessitate more collaborative and supportive ways of working between health and social care practitioners. A range of measures can be implemented to further this goal, such as improving consent documentation, so it supports a more personalised and meaningful consenting process for the patient. Improving consent documentation and processes in these ways can be made possible through availability of decision aids and training in health literacy techniques. There also needs to be measures in place to appropriately assist patients with specific needs, as well as when patients change their mind about a procedure. With this in mind the following recommendations are suggested:

- NHS Boards should encourage healthcare professionals to ask about (and record) any specific priorities and concerns raised by the patient;
- Consent discussions should encompass a range of options, including the option of no treatment;
- Create a system, across all NHS Boards, which enables a further conversation with the patient when there is a change in the planned treatment;
- Provide greater support from advocates to ensure patients with learning disabilities receive appropriate help and support. Provide support and guidance to help patients with low health literacy.

6.5 SUPPORT EFFECTIVE WAYS OF WORKING

Supporting and promoting effective ways of working for health and social care staff is key in enabling better processes of consent and shared decision-making with patients. This area was widely discussed by the interviewees, as they offered potential solutions and ways forward for better practices through more effective ways

of working. Greater and more efficient utilisation of technology was cited as a tool to improve consent processes and storing information to enable more personalised and valuable healthcare conversations with patients. Furthermore, a national approach to consent was suggested to eliminate unwarranted variation and resource waste in favour of a more effective and standardised form that could be Montgomery-proofed. To support these more effective ways of working, the following policy recommendations have been suggested:

- Improve the consent process by making better use of technology to record care-planning and shared decision-making conversations;
- Create a national set of principles of good consent practice;
- Consider an effective Scotland-wide approach to consent and standardised patient leaflets; and,
- Provide more electronic resources for healthcare staff on the benefits and risks of common treatments or procedures.

Overall, the key message is that although effective shared decision-making is not yet the norm and there is a requirement for greater patient engagement in decision-making about their health and care, examples of excellent practice do exist across NHSScotland. The challenge that NHSScotland currently faces is to devise effective ways for supporting shared decision-making and ensuring it is embedded in mainstream clinical practice. In summary, future improvement actions, where possible, can take note of the aforementioned suggestions and recommendations and develop a policy and a range of resources to further improve the practice of consent and shared decision-making within the NHS.

7. CONFLICT OF INTEREST

The author declares no conflict of interest. This PhD Internship was funded by the Scottish Graduate School of Social Science (SGSSS). The Office of the Chief Researcher (OCR) in the Scottish Government was responsible for central co-ordination of this internship scheme.

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ANNEX A: Full Methodology

1. OVERARCHING RESEARCH DESIGN

This is a sequential design mixed-methods exploratory study. It incorporates initial findings from a literature review on the topic, a group consultation with key stakeholders and a survey questionnaire component, followed by semi-structured interviews. The purpose of a sequential mixed-methods design is data complementarity. Whilst quantitative methods were used to achieve the research aims by providing 'factual' data, qualitative methods were deemed appropriate to supplement the answers with more meaning from the perspective of the participants. This pragmatic approach of applying a comprehensive set of strategies was adopted in order to minimise research waste and increase the value of the research.

1.1 POPULATION & SAMPLE

1.1.1 Survey Questionnaire & Interviews

As discussed in the full report, the selected survey population consists of 14 regional and 1 special NHS Boards. In order to produce a sample that is representative of the population being studied, purposive sampling of stakeholders was used, which involved identification and selection of informants that are especially knowledgeable about or experienced with a subject of interest (Palinkas et al., 2015). All survey respondents were offered the opportunity for a follow-up interview. Given the timescale of this research project, a pragmatic approach of recruiting a manageable sample was adopted. This strategy had been discussed and decided upon during regular meetings with the research team.

Although the sample size in qualitative research is generally sufficient when additional interviews do not result in identification of new concepts or when data saturation is reached (Sargeant, 2012), it had been decided at the start of the project that the researcher would interview all respondents that agreed to be contacted for a follow-up discussion. Given the aims and scale of this project, it was not possible to specifically include consideration of protected characteristics within the research.

1.1.2 Person-Centred Stakeholder Group

The rationale for conducting a group consultation with the Person-Centred Stakeholder Group is that group discussions can generate deeper insights through capturing diverse views and opinions and through shared feedback and interactions between the participants (Murray et al., 2016).

Active engagement with the Group was considered vital to this project in order to inform understanding of the good consenting process from health service users' point of view, which would in turn influence the future improvement actions and practice recommendations. This approach also ensured that the focus of the project is not excessively "medicalised" or purely driven by policy but has instead practical application based on the interaction and feedback with the public.

ANNEX A: Full Methodology

1.2 RECRUITMENT

Recruitment of participants for both phases of the project followed the same procedure. There was no direct contact with children, patients or adults with incapacity at any stage of the project. This project did not require an NHS Research Ethics Approval, which had been confirmed by using the HRA screening tool: http://www.hra-decisiontools.org.uk/ethics/

1.2.1 Survey questionnaire and interview

Medical Directors and Clinical Governance leads in NHS Boards were contacted via email and invited to complete the survey questionnaire. Using a standardised approach, an invitation email was sent on behalf of the Chief Medical Officer for Scotland (Annex B). All 15 Health Board leads completed the survey questionnaire. The respondents were then given an opportunity to take part in a follow-up interview. Ten survey respondents agreed to be interviewed. A list of the contacted Health Boards and those who agreed to be interviewed is provided in Section 6.

1.2.2. Group consultation

Person-Centred Stakeholder Group members were invited via email invitation to discuss issues around person-centred consenting process. Eight stakeholders participated in the group discussion.

1.3 CONSENT

All participants contacted to take part in this project were informed that their participation is voluntary and that they can withdraw at any time without giving a reason for doing so. All participants were encouraged to ask questions about the project, first by email or phone, and then at the time of the individual interviews and the group consultation.

1.3.1 Survey questionnaire & interviews

Participants were initially contacted via email (Annex B) and provided with a copy of the Privacy Notice explaining the purpose of the research and their rights.

A positive email response constituted first-stage written consent. The Health Board Medical Directors acted as gatekeepers prior to contacting Clinical Governance Leads. If they considered this approach inappropriate, they were asked to nominate the correct route or a person for sending the questionnaire to. It was clearly stated in the questionnaire that only those participants who give consent for a follow-up interview will be contacted by the researcher to arrange a follow-up meeting.

1.3.2 Group consultation

The Person-Centred Stakeholder Group was contacted via email with a summary of the research project and the Privacy Notice (Annex C) explaining their rights. Members of the group were asked to give up a maximum of 60 minutes of their time during one of their quarterly meetings to take part in a group consultation. In order to

ensure that the participants are fully and adequately informed about the project, they were provided with sufficient information about the purpose of the research, links to relevant documents and policies and were given an opportunity to ask questions. Those who did not respond to the email invitation but volunteered to participate on the day of the meeting were provided with verbal information and a hard copy of the Privacy Notice.

The group consultation was opened by the researcher by providing a short PowerPoint presentation on the current changes in the policy and practice around shared decision-making and consent. The discussion then followed an indicative topic guide in order to allow participants to elaborate on and discuss their views and opinions freely. The discussion was facilitated by Animate - an independent consulting organisation commissioned by the SG. Hand-written notes taken during the discussion were shared with the Stakeholders afterwards to check for accuracy of interpretations.

1.4 DATA COLLECTION

Data collection for different stages of the project was carried out using following methods:

1.4.1 Survey questionnaire

A copy of the survey questionnaire is provided at Annex D. Drawing on the SPSO self-assessment checklist, it was developed in close consultation with the Realistic Medicine Core Group in order to ensure the relevance of the questions and to minimise the overall length. The survey questions were reviewed by the Group to maximise engagement with respondents and to ensure compliance with General Data Protection Regulations.

The survey contains 18 multiple-choice questions that also gave the respondents an opportunity for further elaboration. Respondents had the option to skip questions that were not relevant to their Health Board. The researcher's contact details including her phone number were provided to handle questions about the survey and to offer assistance with the completion. Completion of the survey was voluntary, and all responses have been kept confidential at all times.

The survey data was collected by the researcher using Questback. Questback is an online questionnaire tool which can be used to carry out medium to large scale surveys. It is easy to use and has many additional features, such as easy creation of reports of survey results, routing of questions, and automated reminders to respondents who have not yet completed a survey. The Scottish Government's Questback license is managed by the Office of the Chief Researcher.

A follow-up email was sent to people who had not responded to this initial invitation after a couple of weeks in order to boost the response rate. This email included a reminder, information about the survey and a link to the questionnaire.

Once respondents had received the invitation email, they could complete the questionnaire online. Data from these responses was captured automatically on

Questback and held separately from their names and addresses to ensure confidentially. Following the reminder email, the responses were verified by the researcher to ensure that all data had been captured and transferred into Microsoft Excel. To ensure integrity, the data was then checked by the SG statistician.

1.4.2 Semi-structured interviews

Semi-structured interviews format was adopted for this stage. This approach allowed for core survey questions to be elaborated on, as well as allowing for other questions to emerge from the dialogue between the researcher and the interviewee. With participants' permission, the researcher recorded the interviews using a digital voice recorder and transcribed them verbatim (typed them out, word for word) for the purpose of analysis. Transcripts were entered onto NVivo v.11 Qualitative Software and were subject to analysis. All digital data captured during the interviews was password protected, encrypted and stored securely on the SG network drive only accessible to the researcher.

1.4.3 Group consultation

Data from the group consultation was captured by taking hand-written notes. The notes were kept anonymised in accordance with the Good Clinical Practice guidance on record keeping. All records were accurate, respectful of participants and protected from unauthorised disclosure. All written data was kept in a locked filing cabinet within the SG, to which only the main researcher had access. A summary of the discussion was then written up and circulated to the group to ensure that they are in agreement with the conclusions drawn.

1.5 DATA ANALYSIS

1.5.1 Free Text Survey Comments

The survey asked respondents if there was anything that they would like to tell us about the available training within their Health Board on informed consent, the barriers to good practice and also the facilitators that would encourage, strengthen and facilitate shared decision making. The survey also asked the respondents to share good examples of practice.

All 15 respondents left comments. Disclosive details that could be used to identify people were removed when the comments were analysed by the researcher. These details included personal names, addresses, job titles and links to specific Health Boards. Analysis on the free text comments was carried out and reported together with the interview data.

1.5.2 Qualitative data

Using computer-assisted data analysis tools, the qualitative data obtained from interviews and he group consultation was organised according to emerging categories and analysed using framework analysis. Framework analysis is a qualitative method that is suited to research that has specific questions, a limited time frame, a pre-designed sample (Ritchie & Lewis, 2003). In keeping with the aims and

objectives of the research project, codes were grouped into clusters focused around similar concepts and ideas. Repeated reading and comparison of responses allowed the researcher to become familiar with the transcripts, identify the emerging themes and issues, index, map, and finally, interpret the information (Gale, Heath, Cameron, Rashid, & Redwood, 2013).

Findings were analysed in close consultation with the SG policy experts. Rigour of qualitative data was ensured by transparency of the reporting process and congruence of the methodological approach, also by constant comparison across participants accounts. Themes derived from interviews were developed until the point of data saturation. Prior to writing the full report, the entire team met to discuss the themes and structure for reporting.

The clearly articulated rationale for and appropriate research design to meet the study aims helped reduce distortion of findings and reporting bias. The validity of the questionnaire was ensured by consulting relevant literature and the experts within the research team. The draft of the report was first circulated around the policy team for peer review and a chance to clarify any inaccuracies in reporting. Based on the reviewers' comments, the main researcher then wrote the full report, providing recommendations for future practice and improvement actions.

2. ETHICAL AND GOVERNANCE CONSIDERATIONS

The Scottish Government expects that its researchers and social research contractors will follow the highest practical ethical standards in delivering research that is vital to the interests of the people of Scotland. This is to ensure that all research (commissioned and internal) is conducted in line with a number of key ethical principles. Therefore, this project has undergone an internal ethical process, which incorporated the Government Social Research principles, along with local information and an integrated privacy impact assessment. This procedure has been designed to improve the governance and quality of social research within the SG and is similar to ethical procedures and clearance outlined in universities and in industry-standard ethics guidance such as that of the Social Research Association and the Market Research Society. The project was then reviewed for sensitivity by the Ethical Advisor and received a sign-off during the management process. To fully comply with the requirements of the General Data Protection Regulation, a Privacy Notice was compiled, a copy of which can be viewed at:
www2.gov.scot/Resource/0053/00534688.pdf

2.1 DATA PROTECTION

Confidentiality was ensured at all times by conducting the research activities in a quiet, private area, where the conversation could not be overheard or disturbed. All participants were interviewed at a time convenient to them. All data collected, processed and stored for the purposes of this project complied with the GCP guidelines and the principles of Data Protection legislation and remained confidential at all times. Access to collated participant data was restricted to the research team only.

ANNEX A: Full Methodology

2.2 DATA STORAGE & SECURE DISPOSAL

With participants' consent, a digital recording device was used for the purposes of transcription and data analysis. Participants were informed of its use, the anonymity of their data and of the destruction of voice files immediately following transcription. All quotations from participants' interviews were anonymised. Participants were informed of this arrangement prior to taking part in any research activities. Transcription was performed by the main researcher who is fully aware of the existing guidance on confidentiality and data protection. Electronic and written personal data was stored securely and confidentially under the terms of Data Protection legislation. The SG computers used to store and analyse the data have limited access measures via user names and passwords.

In the transcription of the audio recording, any identifiable details were removed. For example, names were replaced with a pseudonym. Direct quotes used to support the analysis were all anonymised. All data have been treated in the strictest of confidence, and in accordance with existing guidelines (i.e. ICH GCP and the Data Protection legislation). All personal data was destroyed once it was no longer needed for the research purposes.

ANNEX B: Survey Email Invitation

Scottish Government
Riaghaltas na h-Alba
gov.scot

Dear Colleague,

I am writing to invite you, as NHS Scotland Medical Directors, to ask for your help in securing your Board's participation in a short survey on good practice in shared decision-making and consent. The survey has been commissioned by the Scottish Government to increase our understanding of the systems and processes that are currently used in consent within NHS Scotland, to support evaluation of their effectiveness, and to inform future improvement in this area.

This is an important piece of work. The lawfulness of patients' consent to medical treatment has been a consistent feature of clinical negligence cases. The 2017 Scottish Public Services Ombudsman report on Informed Consent, published in February 2017, identified that inadequate medical consent was the most frequently recurring issue identified in its complaints investigations and recommendations to NHS Boards over the last five years. The Scottish Government's Health and Social Care Delivery Plan contains a commitment to reviewing the consent process for patients in Scotland with the General Medical Council and Academy of Medical Royal Colleges, and that work is now underway.

Shared decision-making is a key feature of the realistic approach to medicine I have championed in my three annual reports as Scotland's Chief Medical Officer. Practising Realistic Medicine, published last month, contains an important chapter on understanding and managing risk, which examines how the UK Supreme Court decision in Montgomery v Lanarkshire Health Board and learning from dissatisfaction could support the practice of realistic medicine. The Montgomery ruling requires healthcare professionals to take into account the person's individual circumstances and preferences when explaining a treatment to them. It emphasises the importance of dialogue and a person-centred approach, and a move away from a more paternalistic approach.

Your Board's participation is vital to the success of this research and I will shortly be contacting Patient Affairs Department leads to invite them to complete the survey. If you do not consider this approach appropriate, I would be grateful if you could nominate someone within your Board and advise our researcher, Gosha Wojcik, who is the most appropriate contact. Gosha can be contacted on: Malgorzata.Wojcik@gov.scot or 0131 244 4728. She will also be able to answer any further questions you have about the survey.

I would like to thank you, in advance, for your support.

Yours sincerely,

Catherine
Dr Catherine Calderwood MA Cantab FRCOG FRCP Edin

Chief Medical Officer for Scotland

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Scottish Government
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gov.scot

Good Practice in Shared Decision Making & Consent – workshop with the Person-Centred Stakeholder Group

Privacy Notice

The Scottish Government has recently commissioned a piece of research into Good Practice in Shared Decision-Making and Consent. As part of this project, the lead researcher, Gosha Wojcik would like to explore some of the key questions with the Person-Centred Stakeholder Group, through a workshop discussion.

This privacy notice explains how your personal data, that is, any identifiable information collected through the workshop, will be used.

Why is this research needed?

This research is a means for the Scottish Ministers to monitor how well they are fulfilling their duty, under Section 1 of the NHS (S) Act 1978, to continue to promote a comprehensive and integrated health service that is designed to secure:

1. improvement in the physical and mental health of the people of Scotland, and
2. the prevention, diagnosis and treatment of illness, and for that purpose to provide or secure the effective provision of services in accordance with the 1978 Act.

The Scottish Government's Health and Social Care Delivery Plan says that people should be regularly involved in, and responsible for, their own health and wellbeing. It contains a commitment that the process for obtaining people's consent to treatment will be reviewed by the Scottish Government, General Medical Council and the Academy of Medical Royal College. The Scottish Public Service Ombudsman (SPSO) report on Informed Consent, published in February 2017, identified that inadequate medical consent was the most frequently recurring issue identified in its complaints investigations and recommendations to NHS Boards over the last five years.

This research is focussing on better understanding the systems and processes that are currently used in consent, in order to share learning and best practice, as well as helping to inform consideration of targeted improvement actions by NHS Boards.

ANNEX C: Privacy Notice for Person-Centred Stakeholders Group

The information gathered through this workshop contributes to the research by providing a service user perspective on what a good, person-centred consenting process would look like.

How will your contribution at the workshop be captured and used?

Gosha will ask at the start of the workshop if participants are happy for her to take notes during the group discussion. This is strictly for data analysis purposes and will supplement the information captured by the event facilitators. Confidentiality and anonymity will be maintained at all times. All records will be accurate, respectful of participants and protected from unauthorised disclosure. The notes will be transcribed into a word document as soon as possible after the event and the original copy destroyed immediately afterwards.

Gosha will analyse the captured information and produce a summary of the main issues which people have raised. This summary, which will be part of a larger research report on medical consent practices, will be circulated to everyone who attended the workshop to ensure that it accurately reflects their contribution. Direct, anonymised quotes may be used to support the analysis, but no individuals will be identifiable in the summary or final report.

It is anticipated that the final research report will be published on the Scottish Government website www.gov.scot.

Who has access to information that identifies you?

Access to the recording of the workshop, and its transcript is very tightly controlled and is restricted to a small number of named individuals within the Scottish Government. No other personal information will be collected.

How long your information is stored for?

The transcript of the workshop session will be stored securely and confidentially under the terms of Data Protection legislation until the research report is finalised. All personal data will be destroyed once it is no longer needed for the research purposes.

Your rights

Taking part in this workshop gives you an opportunity to provide your views on the policy, guidance and processes that are currently used in consent. It is entirely voluntary and we are grateful to you for agreeing to take part.

Data Protection legislation gives rights to individuals in respect of the personal data that organisations hold about them. These include the right to:

- access a copy of the information an organisation holds about them;
- object to processing that is likely to cause or is causing damage or distress;
- prevent processing for direct marketing;

- object to decisions being taken by automated means;
- have inaccurate personal data rectified, blocked, erased or destroyed in certain circumstances; and
- claim compensation for damages caused by a breach of the Act.

The Information Commissioners Office provides information on your rights under Data Protection legislation at https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr

If you are concerned about our information rights practices, you should contact us directly. However, if you have engaged with us and are still dissatisfied, you have the right to lodge a complaint with the Information Commissioners Office. For more information see https://ico.org.uk/concerns/

How to contact us?

Please contact us if you have any concerns about our privacy policy or information we hold about you. You can contact us:

- by emailing us at: Joanna.Swanson@gov.scot
- or by writing to us at: Scottish Government, Person-Centred and Quality Team, Room GER, St Andrew's House, Regent Road, Edinburgh, EH1 3DG.

ANNEX D: Good Practice in Consent and Shared Decision-Making 2018 Survey

Healthcare Quality and Improvement Directorate
Planning and Quality Division
St Andrew's House, Regent Road, Edinburgh
EH13DG
www.gov.scot

Scottish Government
Riaghaltas na h-Alba
gov.scot

Good Practice in Shared Decision-Making & Consent Survey 2018

Q1. Please tell us your role / job title and the department you work in:

Role / job title	
Department	
Health Board	

Q2. Have there been any changes within your Health Board since the Supreme Court's landmark decision in the Montgomery case (2015)?

- ☐ Yes, policy and guidance on consent and shared decision making have changed – go to Q3
- ☐ Yes, practice has changed – go to Q3.
- ☐ I never heard of it – go to Q4
- ☐ I have heard of it but there has been no change in either policy or practice – go to Q4
- ☐ I don`t know – go to Q4

Q3. The main reason for the change in policy and/or practice around good practice in shared decision making and consent was:

- ☐ The 2015 Montgomery ruling
- ☐ The Scottish Public Services Ombudsman (SPSO) Informed Consent report (2017)
- ☐ Specific complaints within your Health Board
- ☐ Other – please specify

Q4. What is the existing policy and guidance on shared decision making and consent within your Health Board? Please provide a link or a brief summary.

ANNEX D: Good Practice in Consent and Shared Decision-Making 2018 Survey

Q5. Have you received any complaints within your Health Board focused around informed consent and lack of shared decision making since the Montgomery ruling?

- ☐ Yes - go to Q6
- ☐ No - go to Q7
- ☐ I don't know/can`t remember – go to Q7

Q6. Would you be willing to share some examples of those complaints with the Scottish Government researcher in a follow-up discussion?

- ☐ Yes
- ☐ No
- ☐ I don`t know/can`t remember any examples

Q7. Has the SPSO made any recent recommendations to your Health Board as a result of an investigation of patient complaints focused on consent and/or lack of shared decision making?

- ☐ Yes– go to Q8
- ☐ No – go to Q9
- ☐ I don`t know/can`t remember – go to Q9

Q8. If yes, would you be willing the share your response to the recommendations with the Scottish Government researcher?

- ☐ Yes
- ☐ No

Q9. Are you currently applying the SPSO Report (2017) consent checklist in your Health Board?

- ☐ Yes, completely
- ☐ Yes, to some extent
- ☐ No
- ☐ I never heard of it
- ☐ I don`t know/can`t remember

Q10. The General Medical Council is currently undertaking an extensive consultation and engagement exercise to inform the revision of its guidance for doctors on consent and shared decision making, which was last published in 2008. Is your Health Board well prepared for adapting to any changes in guidance?

- ☐ Yes, completely
- ☐ Yes, to some extent
- ☐ No
- ☐ I don`t know/can`t remember

Q11. What training on informed consent and shared decision making is currently available to clinicians within your Health Board?

Q12. What are the barriers (if any) to good practice in shared decision making and consent within your Health Board?

Q13. Overall, how would you rate the current practice around consent and shared decision making within your Health Board?

- ☐ Excellent
- ☐ Good
- ☐ Fair
- ☐ Poor
- ☐ Very poor

ANNEX D: Good Practice in Consent and Shared Decision-Making 2018 Survey

Q14. How much do you agree or disagree with each of the following statements? Please tick one box on each line. If a statement is not applicable, please leave that line blank.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Strongly disagree
It has been made clear within my Board that the current legal framework supports better conversations around treatment, consent and above all shared decision making	☐	☐	☐	☐	☐	☐
There is a clear system or tool in place (e.g. a consent checklist) to guide clinicians through the consent process	☐	☐	☐	☐	☐	☐
There is a quality assurance process in place to monitor use and effectiveness of this	☐	☐	☐	☐	☐	☐
There is a system in place to prompt a further conversation with the patient when there is a change in the planned treatment, to discuss the change and seek the patient's decision on whether to proceed	☐	☐	☐	☐	☐	☐
Healthcare professionals are prompted to ask about – and record – any specific concerns raised by the patient, together with any advice or options offered in view of the patient's particular priorities (as required post-Montgomery)	☐	☐	☐	☐	☐	☐
There is a quality assurance process in place to ensure that records of consent are sufficiently detailed to meet the Montgomery test	☐	☐	☐	☐	☐	☐
The consent process encompasses a range of options, including the option of no treatment, and healthcare professionals discuss the likely outcomes for each (i.e. not just discussing a single treatment)	☐	☐	☐	☐	☐	☐
The information is readily available in a range of formats (e.g. written, audio, video, online)	☐	☐	☐	☐	☐	☐
Healthcare professionals have been trained in health literacy techniques such as 'teach back'; and are there prompts to encourage use of the	☐	☐	☐	☐	☐	☐

ANNEX D: Good Practice in Consent and Shared Decision-Making 2018 Survey

ALMOST THERE, ONLY FEW QUESTIONS LEFT!

Q15. Is there anything particularly good within your Health Board in the practice of shared decision making and consent? Could you share some examples?

Q16. What would enable healthcare professionals within your Board to encourage, strengthen and facilitate shared decision making?

Q17. Is there anything else you would like to tell us?

Q18. Would you be happy for the Scottish Government researcher to contact you for a short follow-up discussion?

- ☐ Yes
- ☐ No