

# Informed consent

Learning from complaints

**SCOTTISH PUBLIC SERVICES OMBUDSMAN**

## Contents

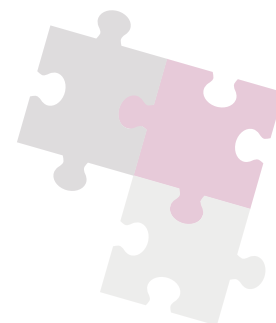
Introduction	6
Changing consent: the legal and policy context	7
Listening to people's experiences	10
SPSO's perspective	25
Consent checklist	26
Online references	30
Endnotes	32

## Who we are

The Scottish Public Services Ombudsman investigates complaints brought by members of the public about public services (including health). We are the final stage for complaints, which means we normally investigate complaints after the organisation complained about has had an opportunity to investigate and resolve the issues themselves. We are funded by the Scottish Parliament and are independent of the NHS.

To further the learning from SPSO complaints, we carried out an analysis of complaints we investigated and recommendations we made over the last five years to identify systemic themes. We found that inadequate medical consent was the most frequently recurring of the issues identified.<sup>1</sup> It continues to be a key theme in the complaints we see.

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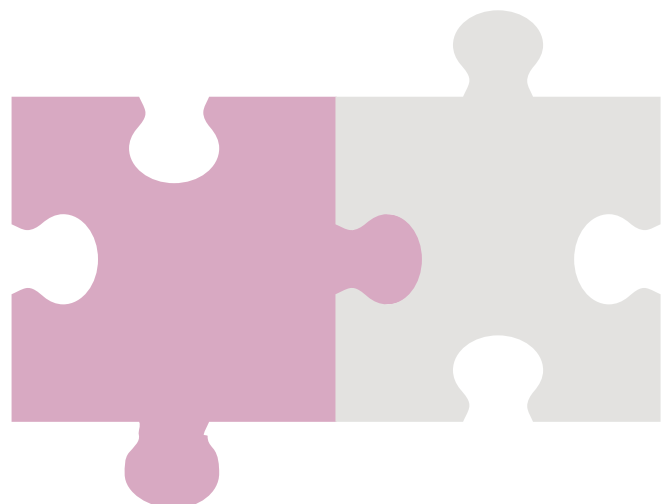
## Why we are publishing this report

**As well as putting things right for individuals, complaints can and should drive service improvement.**

In our work we routinely hear stories from people about how and when things go wrong. Complaints flow from the experience of service users, and should be an important part of the evidence that informs improvements.

As this report demonstrates, there is a great deal of work underway to strengthen consent processes and increase people's involvement in their health decisions. We think it is timely to add our own perspective, so that the real-life experiences of ordinary people can be taken into account in developing changes to policy and practice.

We have used our experience of consent complaints to develop a set of self-assessment questions, to help evaluate whether a consent process is sufficiently robust to avoid the common failings we see. These questions are drawn into a consent checklist at the end of this report.



## Who this report is for

This report is a contribution to a wider discussion about how consent processes in Scotland can be improved.

We urge all **healthcare organisations** to consider the case studies throughout the report and use the consent checklist to evaluate the effectiveness of their current processes and develop improvements. The checklist can also be used by **healthcare professionals** to reflect on their own professional practice and consider how existing processes and tools support good practice (or not).

**Policy makers** should consider the consent checklist when developing and evaluating improvements to the consent process to ensure that these take into account the unique perspective offered by complaints.

**Improvement and scrutiny organisations** may find the checklist useful in evaluating the effectiveness of consent processes as part of their suite of improvement tools.

**Board members** have a responsibility to ensure that complaints are considered as part of the organisation's overall governance and quality assurance arrangements. We draw board members' attention to our report and ask that you consider the following questions:

- Are you satisfied that your consent arrangements are in line with the post-*Montgomery* legal requirements?
- Are you satisfied that sufficient resources are available to enable health professionals to comply with the new legal requirements for obtaining consent?
- Does the consent process form part of a wider culture of person-centred care and supported decision-making with patients?
- Is your Board actively seeking to learn from its own experience and examples of good practice elsewhere?

# Introduction

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The principle that a person must give informed consent before any medical treatment is a fundamental cornerstone of medical practice, founded in the patient's right to decide what happens to their own body. It is also central to NHS Scotland's principles of person-centred care and supported decision-making. Yet failings in the way consent is obtained is a recurring theme in the cases we investigate. While this is not a new theme, it is particularly topical in light of significant and ongoing changes in the law and policy underpinning consent, including the Scottish Government's recent commitment to carry out a review of the consent process in 2017, together with the General Medical Council and Academy of Medical Royal Colleges.<sup>2</sup> In view of these recent and upcoming changes, we think it timely to add our own perspective – which is that of the ordinary citizen.

Each of the case studies in this report (and other similar examples that did not make it into this report) reflects the experience of someone who has taken the time and trouble to share their concerns. Together, our complaints provide a unique perspective of what is happening on the ground: how law, guidance, policies and processes translate into everyday experiences for patients and health professionals. While complaints show us a negative picture – where things have gone wrong or where people are unhappy – by focussing on how and why things go wrong, we can help to develop tools and systems to help get things right in future. To that end, we have set out in this report our common findings about where things have gone wrong in consent processes, illustrated with case studies, and we provide a resource for healthcare organisations, policy-makers and scrutiny and improvement organisations to use in improving consent processes for the future.

While we welcome the renewed focus and policy changes in the wake of the landmark case of *Montgomery* (2015),<sup>3</sup> the complaints we continue to see demonstrate that good policies and guidance are not enough. In each of our case studies, consent policies and processes were in place, with good practice guidance, training and tools available to staff. Despite this, failings still occurred. These complaints show us that more is needed on the ground to ensure healthcare professionals have the information and tools they need readily to hand, at the time they need them, and that they are prompted to use them. More is needed to ensure health professionals have the time to engage in meaningful conversations about treatment decisions. More is needed to ensure patients are properly informed about what the consent process involves, why it is important, and what their rights are.

# Changing consent: the legal and policy context

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Giving or refusing consent to medical treatment is an essential component of the right to autonomy, and is protected by a range of human rights standards.<sup>4</sup> The principle of including people in decisions about their health has long been recognised in Scotland. In 2010 the Scottish Government identified decision-making partnerships between patients, their families and healthcare services as one of three Quality Ambitions underpinning the **Healthcare Quality Strategy**, an emphasis which was reflected in the **2020 Vision** developed in 2011. In the Scottish Government's recent consultation on new **National Health and Social Care Standards**, the need for patients to 'be involved' has been agreed as one of the five overarching principles.<sup>5</sup> In December 2016, the Scottish Government published a **Health and Social Care Delivery Plan**, which recognises that people should be 'regularly involved in, and responsible for, their own health and wellbeing'.<sup>6</sup>

The shifting emphasis from the language of 'consent' to that of 'patient involvement' and 'shared decision-making' or 'supported decision-making'<sup>7</sup> reflects a move away from the traditional model of consent as a discrete requirement for invasive examinations or interventions (primarily surgery). Supported decision-making means that patients should have a voice in all aspects of their healthcare, including decisions about medication and overall management of their conditions. While informed consent for discrete interventions remains important, this aspect only forms *part* of a broader requirement for healthcare professionals to support patients to make their own decisions. People should be 'in the driving seat' of their own healthcare decisions.<sup>8</sup>

Work to increase supported decision-making has gained impetus following the Supreme Court's landmark decision in *Montgomery* (2015).<sup>9</sup> This ruling endorsed a new test for consent, which requires healthcare professionals to take into account a patient's individual circumstances and preferences when explaining a treatment, and to consider what risks this particular patient would be likely to attach significance to. The *Montgomery* ruling fundamentally changed the balance of power between patients and healthcare professionals, empowering patients to take an active role in their healthcare. In *Montgomery*, the Supreme Court identified:

social and legal developments which... point away from a model of the relationship between the doctor and the patient based upon medical paternalism. They also point away from a model based upon a view of the patient as being entirely dependent on information provided by the doctor. What they point towards is an approach to the law which, instead of treating patients as placing themselves in the hands of their doctors... treats them so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices.<sup>10</sup>

# Changing consent: the legal and policy context

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As *Montgomery* places responsibility on healthcare professionals to ensure patients are fully involved, the decision has clear implications for current ways of working and resourcing. Healthcare providers will need to consider whether their current consent arrangements meet the post-*Montgomery* legal requirements. For example, streamlined 'straight to procedure' models for high volume day case procedures (such as endoscopy) may not meet the *Montgomery* threshold, as they do not provide scope for discussions between patients and healthcare professionals prior to the day of procedure.

## Realistic Medicine

There is a growing recognition that supported decision-making can lead to more effective healthcare. In her first annual report (**Realistic Medicine**, 2016), Chief Medical Officer Dr Catherine Calderwood linked the concept of shared decision-making with 'reducing harm and waste', suggesting that more careful consideration of a patient's treatment options, taking into account their individual preferences and priorities, could help to minimise overtreatment.<sup>11</sup> This is echoed in Scotland's **National Clinical Strategy** (February 2016) and Audit Scotland's report **NHS in Scotland 2016**, both of which call for a new clinical paradigm in which informed patients take greater responsibility for managing their own health.

The Scottish Government's **Health and Social Care Delivery Plan** (December 2016) takes up the concept of realistic medicine, and specifically acknowledges the role of informed consent processes within this:

A new clinical paradigm, based on a 'realistic medicine' approach and backed by clinical leadership, will support people through informed, shared decision-making that better reflects their preferences and what matters most to them. There needs to be a greater focus on the discussions that medical practitioners have with people about their care, and what different types of medical intervention can entail. Relationships between individuals and practitioners should be based on helping people understand options about their care and choose treatment according to their preferences.<sup>12</sup>

The Health and Social Care Delivery Plan includes specific commitments for 2017 to refresh the Scottish Government's Health Literacy Plan, and to review the consent process with the General Medical Council and the Academy of Medical Royal Colleges.

Following the Realistic Medicine report, the Chief Medical Officer received feedback from around Scotland and internationally on the principles of Realistic Medicine, and details from this were published in a **Feedback Report** (November 2016). Shared decision-making was highlighted as one of the topics with the greatest number of responses from clinicians.<sup>13</sup> The Feedback Report also outlines recent and current projects within Scotland where consent and shared decision-making have been a focus. Together with the Feedback Report, the Chief Medical Officer set out four strategic initiatives for achieving her vision of Realistic Medicine, with the first of these being:

Moving the model of interaction with our patients to one where care is more personalised and the public are more fully supported to share decisions relating to their care.<sup>14</sup>

# Changing consent: the legal and policy context

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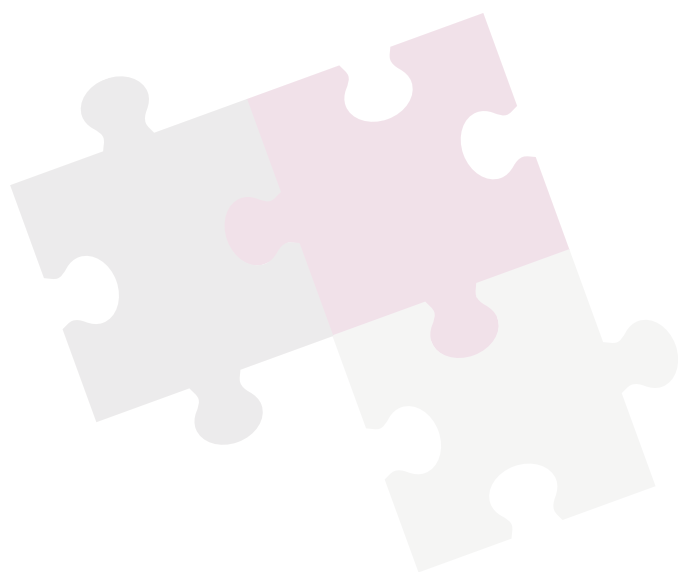
## Health literacy

A core aspect of the work to improve supported decision-making is strengthening health literacy, as patients can only be involved in decisions about care and treatment when they fully understand the choices they are making. The Scottish Government has developed a national action plan **Making it easy: a Health Literacy Action Plan for Scotland** and a resource website, **The Health Literacy Place**. In December 2016, the Scottish Government committed to refreshing the Health Literacy Plan in 2017.<sup>15</sup> NHS Education for Scotland is also undertaking work aimed at raising awareness and the capabilities of professionals to address health literacy.

## Recent and upcoming changes in consent guidance

The past few months have seen significant changes in relation to the guidance available on consent:

- In response to the decision in *Montgomery*, the Royal College of Surgeons released good practice guidance emphasising the new requirement for tailored individual consent discussions: **Consent: Supported decision-making – A guide to good practice** (November 2016).
- The Mental Welfare Commission released a new **Good Practice Guide: Supported Decision Making** (November 2016).
- The General Medical Council launched a **review of its 2008 guidance, Consent: Patients and doctors making decisions together**.
- The Scottish Government committed to reviewing the consent process for patients in Scotland, together with the General Medical Council and the Academy of Medical Royal Colleges, in 2017, with recommendations to be implemented from 2018.<sup>16</sup>





# Listening to people's experiences

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While every story we see is different, there are a number of common threads in the complaints we investigate involving consent. Our experience is mirrored in the findings of other quality and regulatory bodies, such as Healthcare Improvement Scotland inspection reports, which frequently note problems with consent processes (particularly in the context of adults with incapacity).<sup>17</sup>

The case studies in this report reflect stories from the past: as the final stage for complaints, our findings are published some time after the events complained about.<sup>18</sup> In most cases, the organisation concerned will have already taken the action we recommended to remedy the issue. However, analysis of our cases over the years shows that inadequate consent is not a simple or short-lived issue, but a recurring theme. In our view, these cases offer valuable insight into a persistent and widespread issue.

All of the case studies have been anonymised to protect the privacy of the people involved.<sup>19</sup>

This section sets out the common problems we find in relation to consent:

- In many cases, we see **a lack of time**: time for discussion, time for questions, and time for consideration.
- Patients and healthcare professionals can have **different understandings** of what has been agreed.
- In some cases, patients' involvement in their care was limited as their **individual communication** needs were not met.
- There is often **a lack of adequate record-keeping**, so it is not possible to tell what was discussed.
- In a few cases, health professionals have not respected the patient's **right to choose** what treatment or investigations to undergo, or their right to withdraw consent at any stage.
- A number of cases relate to consent involving **adults with incapacity**, including cases where welfare attorneys are not identified or involved, or where certificates of incapacity are put in place without a clear accompanying care plan.

In the following cases, we found there was a lack of time for consent conversations to take place, either due to inadequate planning and resourcing, or to unexpected changes in the planned treatment. Where the scope or extent of a planned treatment is changed at a late stage, there is a risk for consent processes to be 'ticked off' as done, without involving the patient in the change of plan. Problems can also arise where multiple clinicians are involved, as fully informed consent may require input from several different people (for example, in case 201406803 we found the patient should have been warned of the risks of the anaesthesia, as well as of the surgery itself).

### **Consent on the way to theatre (201402959)**

Mrs C was admitted to hospital to have a blockage in her bowel investigated. This was examined in the operating theatre and the blockage was resolved there and then. However, Mrs C experienced excruciating pain and complained that she was not given an anaesthetic for the procedure. She said the consultant ignored her requests to stop. She also complained that she was asked to sign a consent form on her way to theatre.

We found Mrs C could have been offered anaesthesia or sedation for the procedure, and we noted that Mrs C was already taking strong pain medication when she was admitted, potentially indicating that she may have wished something to control her pain during the procedure. We also found it was not appropriate for Mrs C's consent to have been obtained on her way to theatre, which the board had already acknowledged.

We identified inconsistencies in the board's account of what happened during the procedure. The board said both that the consultant had stopped when asked by Mrs C, and that they had proceeded, but with Mrs C's verbal consent. However, neither of these scenarios was documented in the operation note. We concluded that the consent process was not handled reasonably and we upheld this complaint.

# Taking time to consent

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## **Surgery changed on the day**

In one case (201508584), Mrs C complained on behalf of her son (Mr A), who had bilateral gynaecomastia (swelling of male breast tissue) and surgery was planned to remove the excess tissue from both breasts. Mrs C complained that on the day of the operation, staff changed the procedure her son was to have by operating on one breast instead of both, and they failed to communicate this to him appropriately. We found it was unreasonable that the decision to operate only on Mr A's right breast (not both) was made just before the operation. We were also concerned that staff did not obtain Mr A's signed consent for the revised procedure, and it did not appear that he was given written information about what was going to happen or shown photographs of other patients who had undergone the procedure, to help him understand the planned surgery.

In a similar case (201405369), a woman was admitted to hospital for a planned procedure (pelvic floor repair), but was only told on the morning of the surgery that she might need a vaginal hysterectomy (which was then carried out later that day). She complained to us about the action taken in relation to obtaining consent for the procedure. We upheld this aspect of her complaint, as we found it was unreasonable that she was only told about the possibility of such a significant procedure on the day of the surgery and that she was given little time to consider this.

## **Limited interaction with the patient before surgery (201406803)**

Mrs C underwent a modified Broström procedure (ligament repair) on her ankle. Following surgery, tests showed she had severe nerve damage, which was believed to have been caused by the nerve block anaesthesia that she received for the procedure. Mrs C complained that she was not informed the nerve block would be carried out, or about the risks this involved, and she said she did not see the consultant anaesthetist before the procedure. Mrs C told us the nerve damage has had an enormous impact on her life.

We found no documented evidence in Mrs C's medical records of a discussion about the surgical procedure and its possible side effects. We noted the General Medical Council guidance on consent was clear that patients must be told about recognised serious adverse outcomes, even if they are rare. Nerve damage was a recognised side effect of the nerve block so, even though the risk of permanent nerve damage was very rare, we considered Mrs C should have been warned about it. The limited interaction with Mrs C before her operation meant that staff did not obtain her informed consent and we upheld her complaint. We were concerned that these failings may have been caused by the pressures on the service, and we recommended the board conduct a review to ensure enough time is spent with patients, before procedures, to obtain consent properly.

# Taking time to consent

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## Self-assessment questions:

- Is there a **clear system or tool** in place (e.g. a consent checklist) to guide clinicians through the consent process? Is there a quality assurance process in place to monitor use and effectiveness of this?
- Does the consent process **allow time for the patient to reflect** and consider their options (including speaking to friends and family), and then to **ask any further questions**, before making significant decisions?
- Is there 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?
- Is there a clear requirement for **each healthcare professional involved in a treatment to document their own role in the consent discussion** (for example, where a procedure involves an anaesthetist as well as a surgeon)?

## Useful tools and references:

- General Medical Council, **Consent: patients and doctors making decisions together** (2008)
- Royal College of Surgeons, **Consent: Supported decision-making – A guide to good practice** (2016)
- Chief Medical Officer, **Realistic Medicine** (2016)



## Ensuring a shared understanding

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In the following cases, we found patients did not fully understand the treatment they were consenting to and the implications of giving their consent. This can arise where people are not fully informed about the risks of the treatment, the involvement of trainee staff or additional procedures that might be required. In some complaints we receive, patients question a decision that was made about treatment, without fully understanding their responsibility to make their own decision on the basis of their personal assessment of the risks involved.

### **No evidence that the doctor explained the proposed treatment (201202382)**

We received a complaint about the treatment of a man by his GP, including that the GP did not discuss his intended treatment during a home visit. The board said the GP gave assurances that, to the best of his recollection, he had provided a full explanation to Mr A before giving him an injection. However, we found no evidence of this in the papers the board sent us, and it was not clear when a statement by the doctor could have been made, as we could see no evidence that the board consulted the doctor after the complaint. We noted that the General Medical Council guidance on consent requires doctors to explain the proposed treatment and check that their explanation has been understood. We found no evidence to support the board's assertion that either of these things happened.

### **Ms C was denied the opportunity to make an informed decision about her surgery (201407899)**

Ms C had suffered from internal and peri-anal abscesses for a number of years and was referred to a surgeon to undergo a procedure on her buttocks. Ms C said she had been assured that she would not suffer from any issues with continence following the operation, as this was a significant concern for her. However, following the operation, Ms C found that she was incontinent. As a result she had to undergo a colostomy procedure, which had a significant impact on her personal life.

We obtained medical advice, which indicated that incontinence was a well-recognised side-effect of the procedure Ms C had. Ms C said she never would have consented to the procedure had she been made aware of this risk, and we found her medical notes documented that this was an area of great concern to her. We considered it was unreasonable that this risk was not discussed with her and documented prior to surgery, nor was it included on the consent form she signed.

While the board accepted that the consent form did not document incontinence as a risk of the surgery, they disputed whether Ms C was given an assurance that there was no risk of this complication from the procedure. We did not accept that this removed the responsibility of medical staff to ensure that Ms C was able to give informed consent, particularly as she had identified a specific concern before the operation. Ms C was therefore denied the opportunity to make an informed decision about the surgery she was to undergo.

## Self-assessment questions:

- Are patients routinely given **information about the consent process**, and their right and responsibility to make their own decision?
- Are healthcare professionals 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*)?
- Is information readily available in a **range of formats** (e.g. written, audio, video, online)?
- Have clinicians been **trained in health literacy techniques** such as 'teach back'; and are there prompts to encourage use of these?

## Useful tools and references:

- General Medical Council, **Consent: patients and doctors making decisions together** (2008)
- Royal College of Surgeons, **Consent: Supported decision-making – A guide to good practice** (2016)
- **The Health Literacy Place**
- NHS Inform, **patient information leaflets on consent**



## Meeting individuals' needs

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We receive a number of complaints about communication not meeting people's individual needs, including where reasonable adjustments are required for a disability. While only some of these relate specifically to consent (two case studies are given below), most raise issues which are applicable to all communication. For example, in one case (201305243), a woman who uses British Sign Language (BSL) was in hospital for three days without an interpreter. In another case (201401536), we found that the consultation booking process would not meet the needs of people with disabilities generally, as it did not enable the board to plan ahead and make reasonable adjustments once a patient's needs were known. In these cases, we found the organisations failed to meet patients' individual needs for communication.

### **No evidence that staff took account of Mr A's additional needs (201405825)**

Mr A, who suffered from anxiety and hearing loss, required an operation to fit a pacemaker in his heart. Mr A and his son complained that he was given inadequate information about possible complications of the surgery and received incorrect treatment during the surgery. They said that, as a result of errors in the surgery, Mr A's quality of life was adversely affected and he had to undergo another operation to repair the incorrectly positioned pacemaker. We found no evidence that sufficient information was given to Mr A about the procedure and risks, or that staff took account of his additional needs (given his anxiety and loss of hearing).

### **Mrs C should have been offered the information verbally (201500312)**

Mrs C was referred to hospital for a coronary angiogram and percutaneous coronary intervention (a procedure to examine the coronary arteries, and if narrowing or blockages are found, to stretch these to enable blood to flow properly). This is performed by inserting a tube into the heart via the femoral artery, where the leg meets the body. Following the procedure, Mrs C had bleeding from her femoral artery, and it was necessary to carry out emergency surgery to stop this. Mrs C was concerned there was a lack of due care during the procedure, and said she had been traumatised by the procedure and suffered from flashbacks and memory loss.

While we did not find failings with Mrs C's surgery, we noted that the consent documentation showed Mrs C was not keen to read the information about the procedure, and there was no record that this information was given to her verbally or the key risks of the procedure discussed. While we acknowledged that Mrs C also had responsibility to ensure she understood the risks of the procedure before agreeing to it, we found that staff should have offered Mrs C the relevant information verbally (and documented this) before continuing with the procedure.

## Meeting individuals' needs

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### Self-assessment questions:

- Are there processes in place for staff to **check and record any special needs or reasonable adjustments** before the consent process begins (e.g. when making appointments)?
- Is there a clear line of responsibility for **requesting and arranging communication support** (e.g. BSL or foreign language interpreter, or independent advocate)?
- Are **communication aids readily available** (such as visual aids, or allowing audio recording of the discussion for the patient to listen to later); and do clinicians make use of these in practice?

### Useful tools and references:

- Equality and Human Rights Commission website
- The Health Literacy Place
- Mental Welfare Commission, **Good practice guide: Supported Decision Making** (2016)



## Keeping a record

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In the following cases, we found inadequate record-keeping of consent conversations, which meant there was no evidence of what was discussed. While national policies and guidance emphasise that consent is about having a meaningful conversation, we still see an overreliance on generic consent forms and standardised patient leaflets, with no record of how the healthcare professional has engaged with their patient as an individual (the key message from *Montgomery*).

### **No evidence that all the risks and benefits had been discussed (201508192)**

Mrs A was told that she may need an operation to replace a heart valve but, before this could go ahead, she would need to undergo a cardiac angiogram (a test used to assess other parts of the heart structure, as well as the valve). Mrs A gave her consent and underwent the angiogram, which is an invasive procedure. Mrs A said she experienced pain during the procedure and asked for it to be stopped. However, staff continued the procedure. Mrs A did not recover well and, while no abnormality was obvious, her condition did not improve. Her level of consciousness declined and a few days later she was noted to have lost power in her legs. A scan of her spine showed evidence of a type of stroke (ischaemic event) within her spinal cord. Mrs A was transferred to a different hospital, where her scan was reviewed and found to show the appearance of a stroke on the surface of the brain. Mrs A did not recover the use of her legs, and she complained that she had not been warned of the risks associated with an angiogram. The board said their staff thought that Mrs A had given informed consent for the procedure. However, we found that the board's consent forms and printed information were inadequate, and there was no evidence that all the relevant risks and benefits of an angiogram had been discussed with Mrs A, including that bleeding and vascular damage (which could cause a stroke or heart attack) are a recognised complication.

### **A consent form was signed, but no evidence that staff explained the risks (201507563)**

Mr C, who suffered from a hereditary heart condition, had an operation to remove a device implanted in his chest to monitor his heart rhythm. The operation was carried out by a trainee doctor. When the trainee doctor encountered difficulties, he was assisted by a more senior trainee doctor. Mr C subsequently required a second operation to revise the scar the first procedure had left on his chest. Mr C complained about the first operation, including that the trainee doctor performing the surgery had not been competent to do so.

The board said the consultant responsible for supervising the trainee's work during the procedure was available, but had not been present throughout. They acknowledged that Mr C's experience fell short of what he could have expected.

The only evidence of consent on file was a signed consent form which contained minimal information other than the name of the procedure to be carried out and Mr C's signature. The board had no evidence that staff explained the risks and possible complications of the procedure to Mr C. While the board said that significant scarring was a recognised complication of the procedure, we found no evidence that this was explained to Mr C.

### Self-assessment questions:

- If a template is used for consent discussions (e.g. pro forma consent form), does this require the healthcare professional to **record specific details of the discussion**, including who will be carrying out the treatment, the particular risks discussed, possible additional treatment that may be required, and any concerns raised by the patient?
- Is there a **quality assurance process** in place to ensure that records of consent are sufficiently detailed to meet the *Montgomery* test?

### Useful tools and references:

- General Medical Council, **Consent: patients and doctors making decisions together** (2008)
- Royal College of Surgeons, **Consent: Supported decision-making – A guide to good practice** (2016)



## Respecting the patient's right to choose

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In the following cases, we found staff failed to respect the patient's right to make their own decision about treatment. In these cases, healthcare professionals made decisions about their patients, based on what the healthcare professional considered to be best, rather than supporting the patient to make their own decision. These cases reflect the 'old model' of the relationship between patient and doctor, based on medical paternalism, which the Supreme Court rejected in *Montgomery*.

### **Mrs C withdrew consent for the procedure (201403214)**

Mrs C was scheduled to have a colonoscopy procedure and it had been planned that this would be carried out under general anaesthetic. This was because a previous colonoscopy procedure using conscious sedation had been a painful experience for her. However, the operating theatre which she was meant to be treated in was unexpectedly unavailable, so the procedure was carried out in the endoscopy unit using conscious sedation instead. Mrs C said she experienced excessive pain and discomfort during the procedure, and continued to experience pain for more than a month afterwards. Mrs C said that, during the colonoscopy, she asked many times for it to be stopped and the nursing staff also asked for the procedure to be stopped. However, the doctors (a senior staff grade surgeon and a consultant colorectal surgeon) continued nonetheless. Mrs C said she had been left severely traumatised by what occurred.

Our investigation identified a number of serious failings including poor communication, poor record-keeping, poor understanding of the consent process, and a failure to stop the procedure when asked by Mrs C. As Mrs C had prepared for the procedure and waited a long time on the day, we found it was reasonable for it to be attempted using conscious sedation. However, it should have been clearly understood that if Mrs C experienced excessive discomfort, the procedure should be stopped immediately and rescheduled to be carried out using a general anaesthetic. We considered that the consultant had not complied with General Medical Council guidelines on obtaining informed consent and had communicated poorly with Mrs C. There was evidence in Mrs C's medical records that she and nursing staff asked the surgeon to stop and we found that, on arriving to find both patient and nursing staff requesting that the procedure should be stopped, it was unreasonable for the consultant to have taken over from the staff grade surgeon and continued. We considered that the evidence clearly demonstrated the withdrawal of Mrs C's consent for the procedure.

# Respecting the patient's right to choose

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## **Miss C should have been offered alternative options (201403459)**

Miss C had a cyst on one of her ovaries, and an operation was planned to drain and possibly remove the cyst. The day before the operation, the surgeon reviewed Miss C's notes and determined the procedure was inappropriate for her in the specific circumstances and that a more complex procedure, removal of both ovaries, was recommended in national guidelines. Miss C was unaware of this change in the thinking of her clinicians until she arrived at the hospital on the day of her surgery. After discussion with her, the operation went ahead with removal of both ovaries. Miss C subsequently complained that consent was not properly obtained for the procedure.

We upheld Miss C's complaint about this. We agreed the guidelines recommended removal of both ovaries in most cases, but said that this should also be determined by the wishes of the patient. In this case, as it was clear that Miss C had concerns, removal of just the affected ovary with the cyst should have been discussed as an option. We considered Miss C should have been offered this information as part of the consent process.

## **Mrs C said her concerns were ignored (201303973)**

Mrs C complained about the care and treatment she received for a blood disorder, autoimmune haemolytic anaemia (AHA). Mrs C's medical history included another condition for which she had been prescribed simvastatin. When Mrs C was diagnosed with AHA, she was treated by the haematology team and prescribed steroids to improve her blood count (haemoglobin levels), which is the accepted first-line treatment for AHA. An alternative treatment is removal of the spleen, and this was recommended to Mrs C. Mrs C agreed to this, but reluctantly, as she thought that the simvastatin tablets were causing the AHA symptoms.

We found problems in communication between the medical team and Mrs C, and in the way they sought her consent for the operation. Mrs C had agreed to the operation and signed a consent form. However, this was with some reluctance, as she was sure the simvastatin medication was the cause of her symptoms, which she then tried to discuss with hospital doctors. She felt that she was being ignored, and spoke to her GP who contacted the hospital to say that Mrs C had changed her mind about the operation. However, when Mrs C next went to the clinic, the doctor that Mrs C's GP had spoken to told her that she had to have the operation, which then went ahead. We were concerned that, although the consent form was signed, doctors did not review the issue of her consent in light of Mrs C's concerns. We were also unable to find a record in Mrs C's notes of the discussions about the pros and cons of the operation.

# Respecting the patient's right to choose

## The operation performed on Miss C was not the procedure she had consented to (201508020)

Miss C worked on a farm, where she suffered a crush injury to her left ring finger. She was taken to the hospital where she underwent surgery. Miss C said she had been told that her finger would undergo a partial amputation, which she had consented to. This procedure would have the specific benefit of allowing her to return to work in the shortest possible time period (and it was clear that returning to work quickly was a primary motivation for Miss C).

We found the procedure undertaken was not that listed on the consent form, which she expected to have. Instead, Miss C underwent a terminalisation of the finger, which led to additional hospital follow-up visits, a prolonged healing process and, therefore, a much longer absence from work than Miss C had anticipated when she consented to the partial amputation procedure.

Additionally, no record was made of any discussions with Miss C, despite the form containing clearly marked sections for this. We found that no treatment plan was recorded, nor was the rationale for performing surgery other than a partial amputation recorded. We considered the board's records of the consent process were inadequate, and the operation performed on Miss C was not the procedure she had consented to. The board were unable to explain this, instead maintaining that Miss C had undergone the appropriate surgery.

### Self-assessment questions:

- Are patients **routinely given information about their rights** to ask questions, to take time to consider their options, and to withdraw consent at any time? Is this information available in a range of formats?
- Does the consent process **encompass a range of options**, including the option of no treatment, and discuss the likely outcomes for each (i.e. not just discussing a single treatment)?

### Useful tools and references:

- NHS Inform, **patient information leaflets on consent**
- Scottish Human Rights Commission, **Health & Social Care** website
- Academy of Medical Royal Colleges, **Choosing Wisely** website
- Chief Medical Officer, **Realistic Medicine (2016)**

While we have chosen to focus this report on consent processes in a broad sense, a recurring theme within the complaints we see about consent is in the context of adults with incapacity. This has also been identified by Healthcare Improvement Scotland as an area requiring further improvement in relation to older people in acute hospitals.<sup>20</sup> Issues include failing to properly assess capacity, failing to identify or involve a patient's welfare attorney, and relying on adult with incapacity (AWI) certificates for the provision of all care (whereas AWI certificates should be linked to a specific treatment or care plan). The completion of a certificate of incapacity for a patient does not mean that the principles of the consent process are reduced in importance. The discussions with a person's welfare attorney or next of kin should be as meaningful as they would be with a patient who does have capacity, and potential alternatives to the treatment planned should also be discussed. While there is a range of good practice guidance and support available for this situation (referred to at the end of this section), the complaints we receive suggest work is still required to put this into practice. In the case below, we found staff did not correctly follow the process for obtaining informed consent in relation to an adult with incapacity.

### **A certificate of incapacity was in place, but it did not cover the procedure (201400643)**

Mrs C complained about the care and treatment provided to her late husband Mr A, who died in hospital aged 61. Mr A had been unwell for some time prior to admission and cared for by family members at home. We found that there were a number of significant failings by the board in Mr A's care, including a lack of any overall plan and confusion between staff about whether Mr A was being provided with active or end of life care. We were also critical that Mr A's family were not involved in decision-making about his care. On the day he died, Mr A had a gastroscopy to investigate some of his symptoms. We found that there had been no clear assessment of the risks of such a procedure and further, that, at the time, Mr A did not have the capacity to consent to such a procedure. A certificate of incapacity was in place, but this only allowed staff to provide general treatments which Mr A could not consent to. However, it did not provide consent or agreement for this specific procedure, which would normally require specific and additional consent, and we found that Mrs C and her family should have been involved in this decision. This meant that when the decision to go ahead with the gastroscopy was made, Mr A was denied safeguards put in place by legislation to protect patients such as him, who lack decision-making capacity.

## Self-assessment questions:

- Where a person may have limited capacity for making decisions relating to the consent process, is there an appropriate tool readily available to support a **proper functional capacity assessment**?
- Does this include **considering whether the patient may be able to make a supported decision**?
- Does this include **considering who to involve in the decision** (e.g. welfare attorney, independent advocate, family members)?
- If the individual cannot express their wishes, are healthcare professionals prompted to **consider what information is available about the individual's wishes and preferences** from other sources?
- Is there a **quality assurance** process in place, to ensure that adults with incapacity certificates are properly completed and linked to clear and specific care plans?

## Useful tools and references:

- Mental Welfare Commission, **Good practice guide: Consent to treatment** (2010)
- Mental Welfare Commission, **Good practice guide: Supported Decision Making** (2016)
- Mental Welfare Commission, **Right to Treat? Delivering physical healthcare to people who lack capacity and refuse or resist treatment** (2011)
- General Medical Council, **Mental Capacity Decision Support Tool** (2016)
- NHS Education for Scotland, **Think capacity, think consent** (2012)

# SPSO's perspective

It is clear from the complaints outlined in this report that change is needed. However, this is not solely about behaviour change at an individual clinician level. It is not just about providing training in how to obtain informed consent. It isn't even about having a policy that says that such conversations should take place. Human factors literature<sup>21</sup> tells us that, to effect real and lasting change, organisations need to look beyond the individuals carrying out tasks, or the policies setting out how they should be doing them. While these have their part to play, sustained attention must also focus on systems-based interventions: practical systems and tools to develop and prompt new behaviours, together with an organisational culture that supports its staff with the time and resources they need to fully involve patients in decision-making.

This doesn't diminish the importance of training and education tools which equip healthcare professionals to ensure that patients are giving informed consent to treatment; rather it highlights the need to adopt a combination of approaches. It's about having a robust system in place where those human interactions and conversations can take place, and be recorded adequately. It's about thinking how best to support healthcare professionals in this, whether through the use of standardised checklists, reserving appointments specifically for those discussions to take place, or handheld devices that allow easy access to electronic records.

In considering and designing improvements to consent processes it is also important to recognise, share and learn from the many areas of good practice which already exist. A wide range of tools have been developed to better inform and educate patients, and to support clear and effective communication (the **consent checklist** includes references to a number of these). The Chief Medical Officer's recent **Feedback Report** on Realistic Medicine included a 'snapshot' of current and planned Realistic Medicine activity across Scotland, including projects focussed on effective supported decision-making.<sup>22</sup> We encourage healthcare professionals to identify and capitalise on existing good practice, both within the organisation and across the sector.

As our case studies demonstrate, consent requires more than a 'box-checking' exercise, and it is not the case that 'one size fits all'. However, we also recognise that carefully developed documentation, informed by research and field testing, can form part of an effective system for prompting changes in behaviour and culture which can lead to lasting improvement. An example of this is the development of a standardised hospital prescription chart to reduce prescribing errors by the Behavioural Insights Team (**trialled in a London hospital**).<sup>23</sup> Crucially, whatever systems and processes are in place, they should be robustly quality assured to monitor their effectiveness and drive continuous improvement.

We consider that complaints from members of the public should form an important part of the evidence informing future improvements to consent processes.



# Consent checklist

The consent checklist, like the fundamental principle of consent, applies to all health professionals and settings: hospitals, GP practices, dental practices, allied health professionals and others. It provides, in a single document, the questions healthcare organisations and policy-makers need to ask to ensure consent processes are sufficiently robust to avoid the common failings we see. It also provides a very good indication of the questions we will ask an organisation, when investigating a complaint involving consent.

## Findings

### Taking time to consent

We found there was a lack of time for consent conversations to take place.

## Self-assessment questions

- Is there a **clear system or tool** in place (e.g. a consent checklist) to guide clinicians through the consent process? Is there a **quality assurance process** in place to monitor use and effectiveness of this?
- Does the consent process **allow time for the patient to reflect** and consider their options (including speaking to friends and family), and then to ask **any further questions**, before making significant decisions?
- Is there 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?
- Is there a clear requirement for **each healthcare professional involved in a treatment to document their own role in the consent discussion** (for example, where a procedure involves an anaesthetist as well as a surgeon)?

## Useful tools and references

General Medical Council, **Consent: patients and doctors making decisions together** (2008)

Royal College of Surgeons, **Consent: Supported decision-making – A guide to good practice** (2016)

Chief Medical Officer, **Realistic Medicine** (2016)

# Consent checklist

Findings	Self-assessment questions	Useful tools and references
<p><b>Ensuring a shared understanding</b></p> <p>We found patients did not fully understand the treatment they were consenting to and the implications of giving their consent.</p>	<ul style="list-style-type: none"><li>➤ Are patients routinely given <b>information about the consent process</b>, and their right and responsibility to make their own decision?</li><li>➤ Are healthcare professionals prompted to ask about – and record – <b>any specific concerns raised by the patient</b>, together with any advice or options offered in view of the patient’s particular priorities (as required post-<i>Montgomery</i>)?</li><li>➤ Is information readily available in a <b>range of formats</b> (e.g. written, audio, video, online)?</li><li>➤ Have clinicians been <b>trained in health literacy techniques</b> such as ‘teach back’; and are there prompts to encourage use of these?</li></ul>	<p>General Medical Council, <b>Consent: patients and doctors making decisions together</b> (2008)</p> <p>Royal College of Surgeons, <b>Consent: Supported decision-making – A guide to good practice</b> (2016)</p> <p>The Health Literacy Place</p> <p>NHS Inform, <b>patient information leaflets on consent</b></p>
<p><b>Meeting individuals’ needs</b></p> <p>We found organisations failed to meet patients’ individual needs for communication.</p>	<ul style="list-style-type: none"><li>➤ Are there processes in place for staff to <b>check and record any special needs or reasonable adjustments</b> before the consent process begins (e.g. when making appointments)?</li><li>➤ Is there a clear line of responsibility for <b>requesting and arranging communication support</b> (e.g. British Sign Language or foreign language interpreter, or independent advocate)?</li><li>➤ Are <b>communication aids readily available</b> (such as visual aids, or allowing audio recording of the discussion for the patient to listen to later); and do clinicians make use of these in practice?</li></ul>	<p>Equality and Human Rights Commission <b>website</b></p> <p>The Health Literacy Place</p> <p>Mental Welfare Commission, <b>Good practice guide: Supported Decision Making</b> (2016)</p>

# Consent checklist

## Findings

### Keeping a record

We found inadequate record-keeping of consent conversations meant there was no evidence of what was discussed.

## Self-assessment questions

- If a template is used for consent discussions (e.g. pro forma consent form), does this require the healthcare professional to **record specific details of the discussion**, including who will be carrying out the treatment, the particular risks discussed, possible additional treatment that may be required, and any concerns raised by the patient?
- Is there a **quality assurance process** in place to ensure that records of consent are sufficiently detailed to meet the *Montgomery* test?

## Useful tools and references

General Medical Council, **Consent: patients and doctors making decisions together** (2008)

Royal College of Surgeons, **Consent: Supported decision-making – A guide to good practice** (2016)

### Respecting the patient's right to choose

We found staff failed to respect the patient's right to make their own decision about treatment.

- Are patients **routinely given information about their rights** to ask questions, to take time to consider their options, and to withdraw consent at any time? Is this information available in a range of formats?
- Does the consent process **encompass a range of options**, including the option of no treatment, and discuss the likely outcomes for each (i.e. not just discussing a single treatment)?

NHS Inform, **patient information leaflets on consent**

Scottish Human Rights Commission, **Health & Social Care** website

Academy of Medical Royal Colleges, **Choosing Wisely** website

Chief Medical Officer, **Realistic Medicine** (2016)

# Consent checklist

Findings	Self-assessment questions	Useful tools and references
<p><b>Consent and incapacity</b></p> <p>We found staff did not correctly follow the process for obtaining informed consent in relation to an adult with incapacity.</p>	<ul style="list-style-type: none"><li>➤ Where a person may have limited capacity for making decisions relating to the consent process, is there an appropriate tool readily available to support a <b>proper functional capacity assessment</b>?</li><li>➤ Does this include <b>considering whether the patient may be able to make a supported decision</b>?</li><li>➤ Does this include <b>considering who to involve in the decision</b> (e.g. welfare attorney, independent advocate, family members)?</li><li>➤ If the individual cannot express their wishes, are healthcare professionals prompted to <b>consider what information is available about the individual's wishes and preferences</b> from other sources?</li><li>➤ Is there a <b>quality assurance</b> process in place, to ensure that adults with incapacity certificates are properly completed and linked to clear and specific care plans?</li></ul>	<p>Mental Welfare Commission, <b>Good practice guide: Consent to treatment</b> (2010)</p> <p>Mental Welfare Commission, <b>Good practice guide: Supported Decision Making</b> (2016)</p> <p>Mental Welfare Commission, <b>Right to Treat? Delivering physical healthcare to people who lack capacity and refuse or resist treatment</b> (2011)</p> <p>General Medical Council, <b>Mental Capacity Decision Support Tool</b> (2016)</p> <p>NHS Education for Scotland, <b>Think capacity, think consent</b> (2012)</p>

# Online references

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## Academy of Medical Royal Colleges

Choosing Wisely website: <http://www.choosingwisely.co.uk/about-choosing-wisely-uk/>

## Audit Scotland

NHS in Scotland 2016: <http://www.audit-scotland.gov.uk/report/nhs-in-scotland-2016>

## Chief Medical Officer

Realistic Medicine: Chief Medical Officer's Annual Report 2014-15:

<http://www.gov.scot/Resource/0049/00492520.pdf>

Realistic Medicine: Feedback Report (2016): <http://www.gov.scot/Resource/0051/00510939.pdf>

## Equality and Human Rights Commission

Website: <https://www.equalityhumanrights.com/en/commission-scotland>

## General Medical Council

Consent: patients and doctors making decisions together (2008):

[http://www.gmc-uk.org/guidance/ethical\\_guidance/consent\\_guidance\\_index.asp](http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp)

Review of the 2008 consent guidance: [http://www.gmc-uk.org/guidance/news\\_consultation/30001.asp](http://www.gmc-uk.org/guidance/news_consultation/30001.asp)

Mental Capacity Decision Support Tool (2016): [http://www.gmc-uk.org/Mental\\_Capacity\\_flowchart/](http://www.gmc-uk.org/Mental_Capacity_flowchart/)

## Mental Welfare Commission for Scotland

Good practice guide: Supported Decision Making (2016):

[http://www.mwscot.org.uk/media/348023/mwc\\_sdm\\_draft\\_gp\\_guide\\_10\\_\\_post\\_board\\_\\_jw\\_final.pdf](http://www.mwscot.org.uk/media/348023/mwc_sdm_draft_gp_guide_10__post_board__jw_final.pdf)

Good practice guide: Consent to treatment (2010):

<http://www.mwscot.org.uk/media/51774/Consent%20to%20Treatment.pdf>

Right to Treat? Delivering physical healthcare to people who lack capacity and refuse or resist treatment (2011):

<http://www.mwscot.org.uk/media/51822/Right%20to%20Treat.pdf>

## NHS Education for Scotland

Think capacity, think consent (2012):

[http://www.nes.scot.nhs.uk/media/1557644/capacity\\_and\\_consent-interactive.pdf](http://www.nes.scot.nhs.uk/media/1557644/capacity_and_consent-interactive.pdf)

## Royal College of Surgeons

Consent: Supported decision-making – A guide to good practice (2016):

<https://www.rcseng.ac.uk/library-and-publications/college-publications/docs/consent-good-practice-guide/>

## Scottish Government

The Healthcare Quality Strategy for NHS Scotland (2010):

<http://www.gov.scot/Resource/Doc/311667/0098354.pdf>

2020 Vision (2011): <http://www.gov.scot/Topics/Health/Policy/2020-Vision>

National Health and Social Care Standards Consultation, 2016-17: <http://www.newcarestandards.scot/>

Health and Social Care Delivery Plan (2016): <http://www.gov.scot/Resource/0051/00511950.pdf>

National Clinical Strategy (2016): <http://www.gov.scot/Resource/0049/00494144.pdf>

The Health Literacy Place: <http://www.healthliteracyplace.org.uk/>

NHS Inform patient information leaflets on consent: <https://www.nhsinform.scot/search?q=consent>

## Scottish Human Rights Commission

Health & Social Care website: <http://www.scottishhumanrights.com/health-social-care/>

# Acknowledgements

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Equality and Human Rights Commission

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General Medical Council

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Mental Welfare Commission for Scotland

NHS Education for Scotland

Patient Advice and Support Service

Patient Opinion Scotland

Dr Ian Reeves, Consultant Geriatrician

Royal College of Physicians and Surgeons of Glasgow

Scottish Government – Person-centred Health and Care Policy Team

Scottish Human Rights Commission

# Endnotes

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- 1 In particular, consent was a recurring theme in the recommendations we made to health boards and primary care providers at the conclusion of our investigation of a complaint. While specific complaints about consent were less common, the issue was (and continues to be) often identified as part of a broader complaint about care and treatment.
- 2 Scottish Government, 'Health and Social Care Delivery Plan', December 2016, p15  
<http://www.gov.scot/Resource/0051/00511950.pdf>
- 3 *Montgomery v Lanarkshire Health Board* 2015 SC (UKSC) 63; [2015] UKSC 11.
- 4 The Human Rights Act 1998 requires all public authorities, including the NHS, to comply with the European Convention on Human Rights (ECHR). Medical treatment without consent constitutes an interference with private and family life (Article 8 of the ECHR) and may also constitute inhuman or degrading treatment (Article 3 of the ECHR). The International Covenant on Economic, Social and Cultural Rights, the Convention of the Elimination of Discrimination against Women and the Convention of the Rights of the Child have also been authoritatively interpreted to place duties on states to support informed consent. International human rights standards, which the UK (including Scotland) has signed up to, also place importance on the need to respect autonomy. In particular, the UN Convention on the Rights of Persons with Disabilities (CRPD) places strong emphasis on the requirement to provide support for decision-making (to enable a person to form and express their own wishes about treatment). This crosses over with the requirement to make services and procedures accessible to disabled people and the need to make reasonable adjustments for individuals, which are provided for in the Equality Act 2010, Human Rights Act 1998, Article 9 CRPD and echoed across international human rights standards.
- 5 Consultation on the new standards closed on 22 January 2017:  
<http://www.gov.scot/Topics/Health/Support-Social-Care/Regulate/Standards/NCSreview>
- 6 Scottish Government, 'Health and Social Care Delivery Plan', December 2016, p4  
<http://www.gov.scot/Resource/0051/00511950.pdf>
- 7 'Shared decision-making' and 'supported decision-making': These terms are largely interchangeable, although 'supported decision-making' has traditionally (but not exclusively) been used in the context of patients requiring additional or specific support (for example, due to impaired capacity). In this report, the term 'supported decision-making' is preferred, as this emphasises the autonomy of the individual, with the input of the health professional being to help that person make an autonomous decision.
- 8 A key focus for this work has been in the context of promoting supported self-management for people living with long-term conditions (LTCs). This is outlined in the Scottish Government's national strategy: 'Gaun Yersel: Strategy for self-management', May 2013  
<http://www.gov.scot/Topics/Health/Support-Social-Care/Self-Management>
- 9 *Montgomery v Lanarkshire Health Board* 2015 SC (UKSC) 63; [2015] UKSC 11.
- 10 *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, paragraph 81.
- 11 Chief Medical Officer, 'Realistic Medicine: Chief Medical Officer's Annual Report 2014-15', p5  
<http://www.gov.scot/Resource/0049/00492520.pdf>

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- 12 Scottish Government, 'Health and Social Care Delivery Plan', December 2016, p15  
<http://www.gov.scot/Resource/0051/00511950.pdf>
- 13 Chief Medical Officer, 'Realistic Medicine: Feedback Report' November 2016, p5  
<http://www.gov.scot/Resource/0051/00510939.pdf>
- 14 Chief Medical Officer, 'Realising Realistic Medicine', November 2016  
<http://www.gov.scot/Resource/0051/00510943.pdf>
- 15 Scottish Government, 'Health and Social Care Delivery Plan', December 2016, p15  
<http://www.gov.scot/Resource/0051/00511950.pdf>
- 16 Scottish Government, 'Health and Social Care Delivery Plan', December 2016, p15  
<http://www.gov.scot/Resource/0051/00511950.pdf>
- 17 See, for example: Healthcare Improvement Scotland, 'Unannounced Inspection Report – Care for Older People in Acute Hospitals: Galloway Community Hospital (NHS Dumfries and Galloway) 19-20 January 2016'  
[http://www.healthcareimprovementscotland.org/our\\_work/inspecting\\_and\\_regulating\\_care/opah\\_dg/galloway\\_community\\_march\\_16.aspx](http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/opah_dg/galloway_community_march_16.aspx)  
and 'Unannounced Inspection Report – Care for Older People in Acute Hospitals: Royal Infirmary of Edinburgh (NHS Lothian) 30 August–1 September 2016'  
[http://www.healthcareimprovementscotland.org/our\\_work/inspecting\\_and\\_regulating\\_care/opah\\_lothian/rie\\_november\\_2016.aspx](http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/opah_lothian/rie_november_2016.aspx)
- 18 While many of these investigations were concluded pre-Montgomery, the Montgomery decision explicitly endorsed the 2008 General Medical Council guidance – the standard we normally use when determining cases involving consent issues.
- 19 All of our decisions are published in either short decision summaries or full investigation reports (for cases where we consider there is a wider public interest). These are available at <http://www.spsos.org.uk/our-findings>. The electronic version of this report includes hyperlinks to the full investigation report (where applicable). All investigation reports and decision summaries for the case studies in this report can be found by searching using the case reference number on the SPSO website. We do not name the person making the complaint, and usually refer to them as Mr / Ms / Mrs C or A.
- 20 Healthcare Improvement Scotland, 'Care for Older People in Acute Hospitals: Progress report (May 2013-July 2014)', November 2014  
[http://www.healthcareimprovementscotland.org/our\\_work/inspecting\\_and\\_regulating\\_care/opah\\_overview\\_reports/opah\\_overview\\_report.aspx](http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/opah_overview_reports/opah_overview_report.aspx)
- 21 See, for example: Reason, James, "Understanding adverse events: human factors", *Quality in Health Care*: 1995: 4 pp 80–89.
- 22 Chief Medical Officer, 'Realistic Medicine: Feedback Report' November 2016, Annex C  
<http://www.gov.scot/Resource/0051/00510939.pdf>
- 23 King D, Jabbar A, Charani E, et al, 'Redesigning the 'choice architecture' of hospital prescription charts: a mixed methods study incorporating in situ simulation testing', *BMJ Open* (Vol 4, Issue 12) 2014  
<http://bmjopen.bmj.com/content/4/12/e005473>  
More commentary about the project is also available from the Behavioural Insight Team's website:  
<http://www.behaviouralinsights.co.uk/trial-results/redesigning-hospital-prescription-charts-to-reduce-prescribing-errors/>







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