Shared Decision Making and Consent in Pain Medicine

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PAIN MEDICINE
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April 2023

Purpose

The purpose of this document is to frame the principles of decision making and consent (as described by the GMC, legislation and case law), within the context of the practice of Pain Medicine. Case examples are used to illustrate potential pitfalls as well as key features of best practice, with direct reference to the appropriate GMC guidance, legislation or case law.

Importantly, this document is not intended to be a replacement for written GMC guidance on decision making and consent, nor a substitute for independent up-to-date legal advice.

Introduction

The principle of shared decision making and consent to treatment is an important part of medical ethics, and fundamental to good medical practice. All doctors are required to practise in line with current GMC guidance, and government legislation. Laws can also be clarified by court decisions (case law) that set important precedents which other courts are bound to follow or apply in subsequent cases. In recent years, a number of important court judgments have resulted in updated guidance on decision-making and consent.

In the light of developments in case law, the General Medical Council (GMC) updated their guidance on decision making and consent in November 2020. This guidance outlines seven principles of decision making and consent:

- All patients have the right to be involved in decisions about their treatment and care and be supported to make informed decisions if they are able.
- Decision making is an ongoing process focused on meaningful dialogue: the exchange of relevant information specific to the individual patient.
- All patients have the right to be listened to, and to be given the information they need to make a decision and the time and support they need to understand it.
- Doctors must try to find out what matters to patients so they can share relevant information about the benefits and harms of proposed options and reasonable alternatives, including the option to take no action.
- Doctors must start from the presumption that all adult patients have capacity to make decisions about their treatment and care. A patient can only be judged to lack capacity to make a specific decision at a specific time, and only after assessment in line with legal requirements.
- The choice of treatment or care for patients who lack capacity must be of overall benefit to them, and decisions should be made in consultation with those who are close to them or advocating for them.
- Patients whose right to consent is affected by law should be supported to be involved in the decision-making process, and to exercise choice if possible.

Key Legal Decisions

The case law in this area is always evolving and some of the implications of the most relevant judgments are given at the end of each case.

All of these cases can be found at https://www.bailii.org/

Case 1 | Decision making and consent in sciatica: Exploring the principles of good consent

A 39 year old lady is referred to the pain clinic by a community physiotherapist. The referral states that the lady has been struggling with sciatica due to a localised disc prolapse in her lumbar spine. The physiotherapist requests that the patient be considered for a steroid nerve root block injection to help manage her symptoms.

The patient attends a new patient consultation in the pain clinic. She has symptoms, signs and imaging results that are concordant with a diagnosis of sciatica. During the consultation, the pain doctor explores with the patient more about her social circumstances, work and hobbies as well as her feelings and what matters to her about her health.

You should try to find out what matters to patients about their health – their wishes and fears, what activities are important to their quality of life, both personally and professionally – so you can support them to assess the likely impact of the potential outcomes for each option

The patient lives with her partner and their young son. She works part time in a job that involves a lot of driving. Her job is very important to her but she has found it difficult to drive with sciatica, and has had time off work. She is normally fit and active and regularly attends the gym, but has not been able to do so recently as her pain has been too difficult. She is worried that not exercising will mean she may put on weight. As a teenager she struggled with an eating disorder. Her son is two, and attends a local nursery when she is at work. She has no close family nearby.

You should ask questions to encourage patients to express what matters to them, so you can identify what information about the options might influence their choice. If you need more information to help you decide what options would serve the patient's needs, you must ask for it before recommending an option or proceeding with treatment.

The pain doctor asks the patient if she has had any thoughts about how she would prefer to manage her symptoms. The patient says that her GP offered her medication but she declined because of concerns about possible side effects. She has always tried to manage medical problems with 'natural' remedies in the past. She also mentions that she and her partner are thinking about trying for another baby.

You must give patients the information they want or need to make a decision. This will usually include:

a. diagnosis and prognosis

b. uncertainties about the diagnosis or prognosis, including options for further investigation

c. options for treating or managing the condition, including the option to take no action

d. the nature of each option, what would be involved, and the desired outcome.

The pain doctor explains the diagnosis and together they review her MRI scan. It is explained that for most people the problem will resolve in time. This may take months, or even a year or two. For some people sciatica and back pain persist, or they develop worrying signs and symptoms that may need referral to see a surgeon. The pain doctor explains that they may be able to help the patient manage her symptoms whilst hopefully the underlying problem improves. The options discussed include; doing nothing/carrying on as she is, trying medication to help reduce the pain and make her activities easier, trying a nerve root block injection, or further input from physiotherapy and learning techniques to help cope better with her symptoms (such as mindfulness).

You must give patients clear, accurate and up-to-date information, based on the best available evidence, about the potential benefits and risks of harm of each option, including the option to take no action.

The patient explains that she does her physiotherapy exercises regularly, and also practises meditation. She asks about the side effects of the common medications used to manage sciatica. The pain doctor talks about the common side effects of anti-neuropathic pain medication. They also discuss the likelihood that they will help, and the option to change medication if they do not. The doctor also mentions specific risks that are particularly relevant to this patient, namely the risks of taking medications were she to become pregnant, and the effects of some medications on driving and weight. The other options are also discussed in more detail. The nerve root block procedure is explained using a model spine. Common side effects and complications are discussed. Rare, but potentially serious side effects (including nerve damage and paralysis) are also mentioned. The likelihood of the injection helping, and temporary nature of the effects are also discussed.

You should usually include the following information when discussing benefits and harms.

a. Recognised risks of harm that you believe anyone in the patient's position would want to know. You'll know these already from your professional knowledge and experience.

b. The effect of the patient's individual clinical circumstances on the probability of a benefit or harm occurring. If you know the patient's medical history, you'll know some of what you need to share already, but the dialogue could reveal more.

c. Risks of harm and potential benefits that the patient would consider significant for any reason. These will be revealed during your discussion with the patient about what matters to them.

d. Any risk of serious harm, however unlikely it is to occur.

e. Expected harms, including common side effects and what to do if they occur.

The patient is undecided about which, if any, of the options open to her she would like to try. She would like to discuss things with her partner. The pain doctor checks that the patient is confident to access online information about the options discussed, then directs her to the pain service website which contains a number of patient information leaflets on medications and injections. The pain doctor also gives the patient a copy of the consent form that is used for nerve root block injections for her to take away and read.

Patients need relevant information to be shared in a way they can understand and retain, so they can use it to make a decision. To help patients understand and retain relevant information you should:

a. share it in a place and at a time when they are most likely to understand and retain it

b. anticipate whether they are likely to find any of it distressing and, if so, be considerate when sharing it

c. accommodate a patient's wishes if they would like to record the discussion

d. accommodate a patient's wishes if they would like anyone else – a relative, partner, friend, carer or advocate – to be involved in discussions and/or help them make decisions

e. use an interpreter or translation service if they have difficulty understanding spoken English

f. share it in a format they prefer - written, audio, translated, pictures or other media or methods

g. give them time and opportunity to consider it before and after making a decision.

The pain doctor and patient agree to talk again on the telephone in two weeks. In the meantime, the pain doctor will send the patient a copy of the letter outlining what they discussed in the consultation. The pain doctor asks the patient to write down any questions she might have ahead of the next consultation, so she will remember them more easily.

After two weeks, the patient and pain doctor speak again on the telephone. The patient asks for more information about rare but potentially serious complication of injections. Some of the questions the doctor is not able to answer, and he explains why there is some uncertainty, and why they cannot give the patient a precise answer.

You must answer patients' questions honestly and accurately, and as fully as is practical in the circumstances. You must be clear about the limits of your knowledge and, if you can't answer a question, explain whether it is something you are uncertain of or something that is inherently uncertain.

The patient decides she would like to go ahead with the nerve root block injection. The doctor explains the procedure and what to expect next. The doctor explains they will run through the risks and benefits again on the day, and they will ask the patient to sign a copy of the consent form they were given in the last consultation. If she has any further questions, or changes her mind, the patient should contact the pain clinic. A copy of the consultation letter is sent to the patient outlining what was discussed on the telephone.

The standard of care required in obtaining consent to treatment

Montgomery v Lanarkshire Health Board [2015] UKSC 1

In this judgment The UK Supreme Court decided that clinicians must take reasonable care to ensure patients are aware of any material risks involved in treatment. The judgment has impacted clinical care in a number of ways, in particular to provide information about the risks and benefits of reasonable alternative therapeutic options. There continues to be a tension between the objective clinical risks of procedures versus allowing patients' choice and also how much responsibility patients should bear for the outcome of any decisions they make. A passage from the judgment is given below:

> *¶87 "An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk"*

Case 2 | Decision making, consent and pain medications: Discussing harm and disagreeing with a patient's choice of option

A distressed young woman comes into the clinic having been referred by her General Practitioner. She is 27, has been a smoker since the age of 16 and both she and her husband work in low-paying jobs with uncertain security. There are domestic tensions.

She is complaining of back pain and an aching pelvis and has been requesting opioids to control this pain.

The GP has access to MRI services and has performed a scan which shows minor degenerative change in the spine. There are no other sinister features and the symptoms vary day to day.

Between the referral from the GP to when the patient attends clinic, she has started using a walking aid and has gone on sick leave. She is requesting something stronger to treat her pain and uses phrases such as "something must be done". She asks about morphine patches and morphine, and she also mentions that she wants to try gabapentin as she cannot sleep at night, and the pain radiates down her legs.

The pain doctor is concerned that the use of these drugs would not be in the clinical interests of the patient.

If a patient asks for treatment or care that you don't think would be in their clinical interests, you should explore their reasons for requesting it, their understanding of what it would involve, and their expectations about the likely outcome.

The pain doctor explores with the patient her understanding of the cause of the pain, and her reasons for requesting morphine and gabapentin.

The patient explains that she has a 'degenerating spine', and that she fears it is 'crumbling away'. She is afraid of movement and exercise in case her spine is damaged further. The pain is a result of the damage to her spine, and this is probably related to her job which involved a lot of bending and lifting.

The patient mentions that her neighbour has back problems and uses a "morphine patch" which she says is "marvellous", and her neighbour has also felt much better on gabapentin. She feels the GP is not taking her pain seriously by refusing to prescribe her the same medications.

If after discussion you still consider that the treatment or care would not serve the patient's needs, then you should not provide it. But you should explain your reasons to the patient and explore other options that might be available, including their right to seek a second opinion.

The pain doctor explains the likely cause of the patient's back pain and they look at her MRI scan together. The doctor seeks to reassure the patient that she has misunderstood some of the language used to describe her spine, and gives advice about movement, exercise and work. The doctor explains the evidence and recommendations around medications and chronic back pain, and explains that other treatments are likely to be more helpful, such as physiotherapy. They also discuss the side effects and complications of using morphine and gabapentin, and why they might cause harm.

The patient remains unsure about the information the pain doctor has given. She agrees to see a physiotherapist but feels she "needs a strong painkiller to take the pain away first".

You must respect your patient's right to decide. If their choice of option (or decision to take no action) seems out of character or inconsistent with their beliefs and values, it may be reasonable to check their understanding of the relevant information and their expectations about the likely outcome of this option and reasonable alternatives. If it's not clear whether a patient understands the consequences of their decision, you should offer more support to help them understand the relevant information.

The pain doctor is concerned the patient has not understood why they think drugs such as morphine and gabapentin are not appropriate, and risk causing harm. They ask the patient to look at some videos on the pain clinic website that help explain the role and problems of using opioids in chronic pain, and other video resources designed to help explain chronic pain. They agree to meet again in clinic at a later date to discuss things.

With the patient's consent, the pain doctor also refers the patient to a chronic pain physiotherapist who helps to deliver the local pain management programme. They ask the physiotherapist to help explain some of the concepts that were covered in their consultation, in the knowledge that this is an area they often deal with.

There may be members of your healthcare team who are expert in certain conditions and their treatment, who are skilled communicators, or who have developed a trusting relationship with the patient. You should consider the role these team members could play in contributing to the dialogue that leads to a decision.

The pain doctor reviews the patient back in clinic after she has started some sessions with the chronic pain physiotherapist. She seems to have a better understanding of chronic back pain, and is no longer asking for strong pain medication to manage this. The patient has enrolled on a pain management programme, and has started swimming at a local pool. You agree to leave follow-up with the pain management team running the pain management programme.

The need to provide information to enable a patient to make a decision

Pearce & Pearce v United Bristol Healthcare NHS Trust [1998] EWCA Civ 865

A mother was advised by her clinician to delay childbirth but that delay led to the child being stillborn. The Court agreed the clinician should have advised the mother of that risk and allowed her to decide when to deliver. This judgment emphasises that if there is a significant risk which would affect the judgment of a reasonable patient, then it is the responsibility of a doctor to inform the patient of that risk. The clinician must provide the information needed so that the patient themselves can determine what treatment course they should opt for.

Case 3 | Decision making, consent and pain injections: The information you give to patients and reviewing a decision

A 45 year old lady is seen in clinic by a pain consultant. She has a long history of lower back pain, and has noticed a gradual deterioration in her symptoms. She cannot garden anymore and her back has recently stiffened up. She has self-managed her back pain over the years by keeping her weight under (reasonable) control, exercising and taking occasional paracetamol and over the counter codeine when needed.

An MRI was performed by a spinal surgeon which showed age-related changes to the spine. The surgeon explained there were no surgical options, and so referred the patient to the pain clinic. The pain consultant felt that the signs and symptoms displayed by the patient were consistent with facet joint pain. The pain consultant talked glowingly about the results of injections for this.

You must try to make sure the information you share with patients about the options is objective. You should be aware of how your own preferences might influence the advice you give and the language you use. When recommending an option for treatment or care to a patient you must explain your reasons for doing so, and share information about reasonable alternatives, including the option to take no action. You must not put pressure on a patient to accept your advice.

After talking to the pain consultant, the patient was keen to undergo facet joint injections. The pain consultant explained the procedure, the risks and potential complications. They asked the patient to sign a consent form in clinic for 'facet joint blocks'.

Consent forms can be a helpful prompt to share key information, as well as a standard way to record a decision that can make regular review easier. They can be used to review decisions made at an earlier stage, and the relevant information they were based on.

But, filling in a consent form isn't a substitute for a meaningful dialogue tailored to the individual patient's needs.

After a two month wait, the patient attends a day-case injection list, where a pain fellow is performing the injections. The pain fellow has done these injections before but is relatively inexperienced, and on that day is working without direct consultant supervision.

The patient was not expecting a doctor in training, she was expecting "her consultant" and although she wants the injections, she is clearly hesitant. Although the pain fellow feels somewhat under pressure of time, they decide to spend some time reviewing the patient's decision.

You should review a patient's decision immediately before providing treatment or care and, if treatment is ongoing, make sure there are clear arrangements in place to review decisions regularly, allowing patients opportunity to ask questions and discuss any concerns. You should also consider regularly reviewing a decision to take no action.

Reviewing a decision is particularly important:

a. if you haven't personally had a discussion with the patient because they were initially seen by a colleague

b. if significant time has passed since the decision was made

c. if the patient's condition has changed

d. if you have reason to believe the patient might have changed their mind

e. if any aspect of the chosen treatment or care has changed

f. if new information has become available about the potential benefits or risks of harm of any of the options that might make the patient choose differently.

You must make sure that patients are kept informed about the progress of their treatment, and you should let patients know that they can change their mind at any time.

The pain fellow develops concerns about the patient's expectations of their proposed injection treatment. The patient is expecting to be 'cured' by the injections and does not remember any discussion about 'diagnostic' injections possibly leading to further treatment. The pain fellow cannot find any record of alternatives to injection treatment being discussed with the patient, nor does the patient remember this.

The pain fellow explains to the patient that they feel the patient has not had the opportunity to understand the procedure properly, nor discuss alternative treatments. They also explain that they are not as experienced as the consultant that the patient was expecting to do the injection, and they feel it is unfair on the patient for them to go ahead and do the injection instead.

The patient is furious that her injections are being postponed. The pain fellow apologises, but explains that they feel it is the right thing to do, and that the patient needs more time and information than they are able to give that day for them to make an informed decision. They arrange another clinic appointment for the patient and send them written information about the injection. The patient makes a formal complaint to the hospital at the delay to their treatment.

Information must be accurate and clear and in language which can be understood by the patient

Thefaut v Johnston [2017] EWHC 497

In this judgment the clinician was criticised for over estimating the possible success rate of the procedure quoting *at least* a 90% success when it was found the success rate was more likely to be 85%. The clinician also minimised the risk associated with the procedure by almost an order of magnitude by quoting to the patient a risk of complications of 0.1% when in fact the risk was nearer 1%. These differences in percentages were considered by the Court to constitute a 'material (i.e. significant or substantial) difference'.

The patient must be given adequate time and space in which to make a decision

Thefaut v Johnston [2017] EWHC 497

The clinician was also criticised for not providing adequate time and space for patient-clinician communication. In this case, a 5 minute phone call prior to surgery was considered inadequate.

The personal characteristics of the patient may not be obvious but are significant when providing information and obtaining consent

Thefaut v Johnston [2017] EWHC 497

At paragraph 55 of the judgment it was stated:

> *"Some characteristics of a patient are obvious: In particular that person's actual medical condition which would include its severity. Other personal factors may be less self-evident: such as the patient's tolerance for or stoicism towards pain, or the ability to manage pain. Other factors might be quite remote from the medical or physiological condition of the patient, such as the*

> *patients need to return to work, or the fact that the patient has suffered a recent event in his/her life (such as a bereavement or a divorce) which renders that person unusually fragile and (say) unwilling to take chances at that particular time."*

The paternalistic role of doctors deciding what treatment to offer the patient, which was unpinned by the decision in Bolam (where the skill of a doctor was judged by a reasonable group of their peers) is no longer acceptable in modern day clinical practice.

The emphasis now is on a patient's choice made after being informed of clinically appropriate options. The patient has the right to choose a therapeutic option and its possible impact on their health. The medical advice about treatment options has to consider medical factors but must also take into account patient value judgements. The implications are that we as clinicians are required to familiarise ourselves with our patients sufficiently well to understand their views and values and thereby support them in the decision-making process.

The acceptable standard patient clinician interaction in the consenting process is now much higher, as set by the Courts following the judgment in Montgomery and subsequent case law. Any standard of consent previously considered adequate by a group of peer clinicians (Bolam) will no longer be considered as decisive. The assessment of that standard now will combine factors important to both the clinician and patient. Clinicians should ensure there is enough space and time allowed for jargon free, meaningful, patient-centred dialogue. A short conversation, just prior to surgery, with an unfamiliar patient pulled from a group waiting list is unlikely to reach that standard.

Warning about the possible symptoms associated with potential complications

Spencer v Hillingdon Hospital NHS Trust [2015] EWHC 1058 (QB)

In this case the claimant underwent a procedure but they were not warned of the possibility of post-operative deep vein thrombosis and pulmonary embolism. They later presented at the hospital feeling unwell, but failed to mention calf pain as a symptom. Later they suffered bilateral pulmonary emboli. The Court decided the patient should have been warned about possible symptoms of a complication.

Patients must be warned about the possible consequences of a procedure. If they are not and if they suffer symptoms and fail to recognise the significance of the symptoms then the clinician may be liable.

Information must comprise information as to material risks

Montgomery v Lanarkshire Health Board [2015] UKSC 1 - and as to uncertainties – Webster v Burton Hospitals NHS Foundation Trust [2017] EWCA Civ 62

In the case of Webster v Burton a child was born with profound physical and cognitive problems which would have been avoided had the child been delivered electively 3 days earlier. There was already evidence that the child was small for dates and there were other significant findings. The clinician chose to allow the pregnancy to continue under the circumstances. The Court of Appeal found that if the mother been told of these problems and risks, she would have elected to undergo an earlier delivery and in that scenario the child would have avoided the brain injury. The Court accepted that if the Bolam test were applied, it would have been reasonable for the clinician to allow the pregnancy to continue despite the risks but since the decision of Montgomery, the mother's wishes should have been taken into account. The hospital was therefore liable in damages.

Credits

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Review

Usually within three years or sooner if important information becomes available.

Feedback

If you would like to provide feedback on this framework, email FPM at contact@fpm.ac.uk

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