

## *Informed Consent*

*With Paul Grant and Jo Redman*

### *About Paul Grant*

- *Combines careers as an Osteopath (currently non-practising) and a Solicitor for 44 years*
- *A senior dispute resolution partner in the niche two branch firm of BSG Solicitors LLP*
- *Utilises medical knowledge by representing medical/alternative therapists before their regulatory bodies (i.e. GMC, GDC, HCPC, GCC, or GOsC)*
- *Lectures on various medical subjects*
- *Has a Masters in Medical Ethics*
- *Obtained Law degree from London University and works part time as Judge*
- *Obtained Osteopathic diploma from the College of Osteopaths and is now its Chairman*

### *About Jo Redman*

- *3 times World Kickboxing Champion who won her third world title in Italy in 2013*
- *Has Asperger Syndrome and is young patron of the charity Anna Kennedy Online*
- *Has spoken in several events such as at the House of Commons and at Autism's "Got Talent" about her journey to achievement within her sport*

## Common complaints

Communication and consent are central to the majority of complaints filed by patients against osteopaths and chiropractors. Issues with non-consent often have to do with breakdown in communication.

## Notes

- The practitioner's notes are important pieces of evidence that can be used during hearings before a Professional Conduct Committee (PCC), since they are

- a) an aide memoire and
- b) contemporaneous

whenever there is a dissonance between what the practitioner says and what the patient claims, the notes can weigh heavily in the defence of the practitioner. They are accepted as true notes of the particular date.

- The issue with many practitioners is that they do not write down their notes immediately. They do them either at the end of the day or whenever they find the time. But in between patients, the clinician should always allot at least 10 to 15-minute gap to write down their notes to avoid missing or forgetting important information.

### Note

- Documents to be presented in court should include a glossary of common terms (including a list of medical abbreviations/acronyms) for easy referencing during cross examination in the hearing.
- If there is a need to amend any handwritten notes, the clinician should always affix his/her initials, indicate the date when the amendment was done, and the honest justifications for changing them.

- A clinician should never rely on other clinician's notes as basis for treatment prescription. Whenever a patient is referred to another clinician, the referring clinician can share his/her notes for reference purposes only.

- Whenever a patient returns after several months, the clinician should update the patient's case history (ask them all the screening questions) – keep the red flags very current.

- There is no standard requirement for handwritten notes. They just need to be legible (to the person who wrote them or to another practitioner who relies on them). The Council requires transcribed copies in cases when they cannot read the written manuscripts.

- A practitioner's notes are subject to the *Data Protection Act* - the regulation of the processing of information relating to individuals, including the obtaining, holding, use or disclosure of such information. (Note that the *GDPR* supersedes the *DPA* in May 2018)

- A practitioner can charge up to £10 for notes furnished to a Solicitor.

#### **The 2015 landmark case for informed consent in the UK**

Source: <http://www.bmj.com/content/357/bmj.j2224>

Nadine Montgomery, a woman with diabetes and of small stature, delivered her son vaginally; the baby experienced complications owing to shoulder dystocia, resulting in hypoxic insult with consequent cerebral palsy. Her obstetrician had not disclosed the increased risk of this complication in vaginal delivery, despite Montgomery asking if the baby's size was a potential problem.

Montgomery sued for negligence, arguing that, if she had known of the increased risk, she would have requested a caesarean section.

The Supreme Court of the UK announced judgment in her favour in March 2015. The ruling overturned a previous decision by the House of Lords, which had been law since at least the mid-1980s.

It established that, rather than being a matter for clinical judgment to be assessed by professional medical opinion, a patient should be told whatever

## Electronic notes

- Electronic notes are useful and reliable in that the creation and amendment dates can easily be audited.
- Legibility is much better than handwritten notes.
- Red flag warnings can also be seen easily.

## Informed consent

- Is the **voluntary** agreement of a **competent** individual to participate in a therapeutic procedure with an **adequate understanding** of its nature, purpose, benefits, and risks.
- Failure to record an informed consent may result in a hearing before the PCC.
- Audio recording a session with the patient can be done with the latter's consent. CCTVs are never allowed in treatment rooms.
- For gaining informed consent from patients electronically, tick-box confirmation is acceptable.
- Valid consent can be gained from patients
  - a) prior to attending the treatment sessions;
  - b) during new patient consultation and
  - c) when making follow up sessions.
- There are cases where patients have challenges understanding the things that the clinician has said and therefore could not have reliably given informed consent. It can be overridden by a person with parental responsibility or by the Court.

- Attending an appointment does not constitute informed consent by the patient to treatment.

- Consent can be written, but oral consent is acceptable. However, the clinician has to specify this in their notes. Written consent will be judged in court according to its value, but it is nonetheless evidence (including evidence of good intent).

- Consent can be implied. For example, the practitioner has explained all the risks and says, "I'd like to treat your arm" and the patient moves the arm towards the practitioner to facilitate this.

- Citing statistics (E.g. the risk of a serious adverse consequences with a cervical manipulation is less than 1:600,000) gives comfort to patients and makes it easier for them to process that there is a very minimal risk involve in the particular procedure, and therefore they give consent.

- Clinicians who spent sufficient time (i.e. 25 minutes or more) talking to patients are less likely to be sued because they are likely to have provided details as to the benefits, risks, and alternatives (BRA) options for the proposed treatment or procedure. The latter should ALWAYS be given.

### Standard Required

- The law and General Councils require a "reasonable standard" of decision making in practice. This is based on the Bolam case (*Bolam v Friern Hospital Management Committee* [1957]).

#### The Bolam test

As far as the law of negligence is concerned the medical profession is in a privileged position because it is recognised that medical opinion may differ. Accordingly it is sufficient if a doctor, surgeon, midwife or nurse follows a practice adopted by a recognised body of medical opinion. If there is such a body of medical opinion and it is followed then the medical practitioner will not be liable for any adverse outcome despite the existence of another medical practice that would have adopted a different course which could or would have produced a better outcome.

- Note that this was modified as a result of the Bolitho case (*Administratrix of the Estate of Patrick Nigel Bolitho (deceased) v City and Hackney Health Authority [1997]*)

### Complaints (GOsC Procedure)

- Complaints made to the General Council may come from the members of the general public including patients, fellow practitioners or other health professionals.

- If a complaint is filed against an osteopath, the document – “Fitness to Practise Complaints Procedure” will be furnished to him/her which provides guidance on what to do at each stage of the process.

- Once the General Council receives the complaint, an Investigating Committee will check its merits whether or not there is sufficient evidence (*prima facie* case) to take it forward to a hearing by the PCC.

The latter does not hear contractual cases (i.e. suing for money), only those which concerns the practice of osteopathy.

- The Investigating Committee uses the following documents as guide in deciding whether or not there is *prima facie* case– “The Investigating Committee Decision-making Guidance” and the “Guidance Threshold Criteria for Unacceptable Professional Conduct”.

#### **Bolitho**

A doctor could be liable for negligence in respect of diagnosis and treatment despite a body of professional opinion sanctioning his conduct where it had not been demonstrated that the body of opinion relied on was reasonable or responsible. In the vast majority of cases the fact that distinguished experts in the field were of a particular opinion would demonstrate the reasonableness of that opinion. However, *if it could be demonstrated that the professional opinion was not capable of withstanding logical analysis*, the judge would be entitled to hold that the body of opinion was not reasonable or responsible. The final arbiter as to whether there has been professional negligence is the court, which must decide whether the requisite logical basis for a defendant's expert medical opinion is absent.

The legal question is as to what features particularly characterise an expert medical opinion as one that is

- Screening the complaint: An independent osteopath known as a “screener” will study the complaint to make sure that it is worth dealing with by the General Council. The ‘threshold criteria’ for unacceptable professional conduct indicates the types of complaints that should generally be rejected because they do not qualify as unacceptable professional conduct.

- Investigating a complaint: If the screener decides that the Council has power to deal with the complaint, the case will be referred to the Investigating Committee.

- The screener will write a report indicating the allegation, the osteopathic practice standards that apply, and other relevant information needed.

- The caseworker will then inform the osteopath being complained about. The latter will be furnished with copies of the screener’s report and the complaint papers.

- The osteopath has 28 days to respond to the allegations before the Investigation Committee considers the complaint.

- The Investigating Committee is composed of osteopaths and lay members (non-osteopaths) and is chaired by a lay person.

- Legal advice: The osteopath being complained about should contact the professional indemnity insurer or if more preferred, an independent legal adviser about the complaint. They can help in writing the response as soon as possible.

**Hearings (at the GOsC – GCC procedures will be similar)**

- The PCC hears complaints against an osteopath if it concerns professional conduct or competence, or a criminal conviction that is relevant to his/her work.

- The Health Committee hears complaints if it concerns the osteopath’s mental or physical health.

The Health Committee is comprised of osteopaths and non-osteopaths and at least one registered medical practitioner. This committee can look at cases without having a hearing – a private meeting suffices in consideration of

- Hearing process: If the Investigating Committee decides that there is indeed a case to answer, a public hearing before the PCC will be arranged. The caseworker will inform the osteopath of the date, time, and place of the hearing.

### Communication, Consent, and Asperger Syndrome

Those affected have difficulty with social interactions and exhibit a restricted range of interests. Ability to give informed consent may be affected. Asperger's is considered to be on the high functioning end of the autism spectrum.

Areas of difficulty	Manifestations
Social interaction	<ul style="list-style-type: none"> <li>• Difficulty picking up the telephone to make a call</li> <li>• Difficulty dealing even with happy events</li> <li>• Difficulty picking up social cues</li> <li>• Unable to emotionally adjust to change especially when things did not go as planned, or when asked to go outside their comfort zone</li> <li>• Inability to see things from other person's perspective</li> </ul>
Communication	<ul style="list-style-type: none"> <li>• Difficulty expressing feelings and preferences to things they might like or dislike</li> <li>• Inability to react</li> <li>• Inability to give verbal feedback</li> <li>• Crowded rooms impair their communication</li> </ul>
Sensory	<ul style="list-style-type: none"> <li>• Bright lights and noises can be painful</li> <li>• Difficulties with touch and taste</li> <li>• Sensitive sense of smell</li> </ul>

Areas of difficulty	Manifestations
	<ul style="list-style-type: none"> <li>• Inability to tell whether it is hot or cold and to recognise pain or hunger</li> <li>• Hypo or hypersensitivity to proprioceptive input</li> </ul>
Executive function	<p>Inability to:</p> <ul style="list-style-type: none"> <li>• plan</li> <li>• judge and organise</li> <li>• put things in proper perspective</li> <li>• see the wider scope and bigger details (very much focused on small details)</li> </ul>

### Challenges in seeking informed consent from patients with Asperger's

- Patients with Asperger's get very stressed and anxious in situations that are unfamiliar or new to them. At such times their communication can be unreliable. They might give consent but may not actually have understood or processed any information that the clinician has communicated.
- Giving them options to choose from is important to help them arrive at a decision. For example, if offering a drink, name the options available. Note that on occasions, although they might want one of the options offered, they might reject it because they are not comfortable around the person making the offer.
- They can be very unpredictable. Their recall of events may not be accurate. Also, they do not have the capacity to filter and judge which information is relevant. They tend to give all the details at once.
- They tend to forget what they are told to do. A written note to remind them helps.

- They can listen better when they are not making eye contact. Do not force that 'gaze' as it will make them very uncomfortable.

### In practice – how to deal with patients with special needs

- It is always recommended for them to have a chaperone to help in the communication process.
- Try to ensure that the patient is warned what to expect (ring the door bell, you will be met by a receptionist...)
- Put on the clinic website all the details pertinent to the clinic processes that will give them a sense of what happens when they arrive for their first appointment.
  - Give step by step information of what they will expect to happen upon entering the building (whether or not a receptionist will meet them or they will have to find their own way into the waiting room) up to when they leave. This helps them a lot in conditioning themselves.
  - Provide as much visual information available in many different formats as possible.
- Remove elements which may cause anxiety if possible (bright lights, unnecessary noise, crowded waiting rooms, etc.). Let the patient know that it is OK to wait in their car, if that helps.
- Try not to change anything with which they are already familiar (eg faces/receptionists, treatment room, clinic processes, expectations from the clinic)

- Use visual techniques/pictures to impress messages on them because when they are anxious, their ability to read gets impaired -seeing a picture with the word helps them bind the association.



- Provide them visual cards as a communication aid that they can use to convey a message or feeling that they cannot express. There are several types of visual aid fans available for autism at [The Play Doctors](http://ThePlayDoctors1)<sup>1</sup>.

- Fidget toys can also help them cope with stressful appointments. There is no specific toy for this purpose – stress balls or other squashy toys would be suitable. Just don't expect to get the toy back afterwards.

- Knowing that they are permitted to do things differently gives them assurance and keeps them from being overly anxious and stressed.

- Some patients may find that chewing (gum or sweets) helps to reduce stress.

#### Purpose of fidget toy for people with Autism



- Helps them concentrate
- Reduces anxiety, allowing them to deal with stressful situations
- Helps them to listen (keeps them focused and not easily distracted)
- Calms them in situations that are uncomfortable or unfamiliar

<sup>1</sup> <https://www.theplaydoctors.co.uk/product/personal-communication-fans-3-pack-mixed-set/>