Academy of PHYSICAL MEDICINE

Broadcast Summary

Informed Consent

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Fear

- Fear of the law should not interfere with normal practice
- Incidence of litigation is not increasing
- Cannot avoid the occasional patient who will complain, however

Consent

- An integral part of treatment – not separate
- Generally it is done well
- Can be oral – no need for written/signed forms
- Forms can interfere with the patient relationship
- Osteopaths and chiropractors have set the bar vey high in terms of standards of communication with patients (but GPs have followed suit)
- Part of informed consent is allowing patients to make an informed decision – even if it's not the one you would have preferred

Legal Requirements are contained in various policy documents:

- NHS Choices: Consent for Treatment (http://www.nhs.uk/conditions/consent-to-treatment/pages/introduction.aspx
- Care Quality Commission - Supporting note - Consent to care and treatment (2011)
- PDO78 Consent and Physiotherapy Practice (2012)
- Osteopathic standards (2012)
- Osteopathic advice: Patient's capacity to consent (England 2013)/Northern Ireland/Scotland
- Chiropractic Code of Practice and Standard of proficiency (2010), B4
- Department of Health

Give patients the information they need in a way they can understand

Osteopathic Standard A3, Chiropractic B3

- Osteopaths: any material or significant risks associated with the treatment you are proposing
- Chiropractors: any foreseeable risks and likely benefits

- Likely outcomes, with or without care
- Explain any alternatives/options to the treatment.
- State people involved (a chiropractic requirement, but patients may like to know who's involved and who they may be talking to – no surprises)
- Focus on the patient's individual situation and risk to them
- Check that the patient has understood the information given to them
- Using models, diagrams and non-technical language may help

Emotional issues to consider in consenting

- Practitioners can be concerned that this disrupts the "softness" of the encounter – need not be the case – preparation may ease the process
- Practitioner familiarity with the process can also lead them to overlook the patient's need for information
- Managing patient's **anxiety** about their condition and about their treatment
- Perception of risk is personal, **emotional** and **hard to understand** and relate to
- Setting **realistic expectations** (from both perspectives) of
  - Benefits (always put benefits first)
  - Risks (or are they side-effects?)
- Small risks tend to be **over-amplified** by lay people
- **Comprehension and memory** related to
  - Timing of information – time to digest what is said
  - Vulnerability of lying down and/or being undressed
  - Way information is relayed (Trevena et al 2013)

Setting the scene

- Sitting
- Not too naked
- Had time to absorb diagnosis and ask questions – a pause for thought
- Patient calm
- "Now that we have identified the problem, it's time to think what to do next" (Elwyn et al)
- Consider if a shared decision making model helps eg (Elwyn et al, J Gen Intern Med 2012, 27: 1361-7)

Choice Talk - Elwyn stage 1

- Offer choice (and pre-empt suspicious patients who believe that choice = incompetency)
  "There is good information about how these treatments differ that I'd like to discuss with you."
- Justify personal choice
  "Treatments have different consequences … some will matter more to you than to other people…"
- Discuss uncertainty
  "Treatments are not always effective and the chances of experiencing side effects vary…"
- Check reaction. Some patients may be disconcerted or express concern:
  "Shall we go on" or 'Shall I tell you about the options?"

Explain any alternatives to the treatment

- Remember you are already the chosen one.
- Alternatives means the reasonable options – not an exhaustive list
- Balanced comparison should not drive patients away. Avoid jargon/convoluted terms, however:
  Eg. For pain, manipulation has a comparable risk to exercise or analgesic drugs and less risky than prolonged use of analgesics (info leaflet)
- Keep in straightforward language where possible (even written consent forms can be in lay persons language)
  Eg. The risks of increased pain are about the same if I do this treatment as if you did exercise… etc
- Admission that you may not be the best person for a particular problem, and referral elsewhere:
  - Increases credibility
  - Can result in future referrals from patient and other practitioner

What if patients don't want to make a decision?

- Defer decision if necessary
- Find out concerns if relevant
- Some patients ask clinicians to "tell me what to do …
  "I'm happy to share my views and help you get to a good decision. But before I do so, may I…

    - describe the options in more detail so that you understand what is involved?"
    - ask what's on your mind?"

Option Talk – Elwyn stage 2

- Check knowledge even for apparently well-informed patients:
  "What have you heard or read about the treatment of frozen shoulder?"
- List options. Write them down and say:
  "Let me list the options before we get into more detail"
- Phrase as positive, personalised options, eg:
    - Doing nothing better phrased as 'watchful waiting' or 'active observation'
    - "Both options are similar and will involve you doing exercise on a regular basis"
    - "These options will have different implications for you compared to other people, so I want to describe …"

Personalise, chunk, summarise

- Start with benefits and manage expectations
  - Cure?
  - Freedom from pain?
  - Return to full mobility?
- Chunk information (Elwyn)
- Use decision tools if helpful (Elwyn)
- Patients like written info (Leach et al 2011)
- Control how presentation biases perception (Trevena et al 2013)
- Summarise and check. Keep onus on self not patient

“May I check that I explained that clearly by asking you to tell me what ..

Benefits and Risks

“Before I start I should mention that common side effects are pain, discomfort, headache, tiredness/fatigue, radiating pain or discomfort, paraesthesia, dizziness, nausea, stiffness, hot skin, fainting, early or heavy menstruation, epigastric pain, tremor, palpitation and perspiration. Any questions?”

What patients want *(Leach et al 2011)*

- Most effective and cost-effective treatment
- Benefits of treatment - (ideally a complete cure) – reality check for both
- Risks/side effects of treatment, on all, but especially on first visit (including pain, mild stiffness, dizziness, etc)
- Practitioner to discuss how risks apply to personal situation
- Information that is quick to read, understand and discuss
- Brief and detailed information leaflets available
- Information tailored to the individual’s needs

Practical issues to consider in conveying risk (*Leach et al 2011, Trevena et al 2013, Bogardus et al 1999)*

- First appointment hardest
  - Maintaining rapport – competence, care, trust
  - No blanket consent before treatment
  - Personalising patients’ information and preference for involvement in decision
- Choosing which risks to discuss
- Conveying in words, numbers (if known), visuals
- Exploring understanding, reactions and opinions of information
- Giving and keeping record

Decision talk – Elwyn stage 3

- Guide the patient to form preferences. “What, from your point of view, matters most to you?”
- Elicit a preference. Offer more time or be willing to guide the patient, if they wish.
- Check for the need to either defer a decision or make a decision.
  “Are you ready to decide?” or
  “Do you want more time? Do you have more questions?”
  “Are there more things we should discuss?”
- Remind the patient that decisions may be reviewed.

Record of consent in notes

- Patient can give consent orally – ie does not have to sign legal looking forms
- Blanket form has little credibility – has to be tailored
- Blanket form for all patients before meetings have no credibility

- If info sheets or forms used, they need to be included in the notes
- Clinician has to record consent (or didn't happen)
- A couple of lines summary is usually sufficient – you need time to treat the patient

Using risk words

- Seems straightforward
- Vocabulary of risk can include: likely, possible, probable, unlikely, rarely, etc.
  What do "frequently" and "rarely" mean as a percentage

Understanding of vocabulary

- **Frequent**
  - Patients describe as 70% with a range of 30-90% *(Woloshin et al 1994)*

- **Rare**
  - Doctors describe as 5% (sd 6%),
  - Patients as 24% (sd 31%) *(Sutherland et al 1991)*

- Huge personal variation in interpretation
- People tend to think in terms of 3 levels of risk (e.g. high, moderate, low)
- Research definitions of risk separate from perception of risk
- Numbers needed alongside words

Emotional impact of numbers and wording

- 1 in 10 women get breast cancer (generally felt to be more likely)
- There is a 10% chance of getting breast cancer (percentages seem more remote)
- 9 out of 10 women do not get breast cancer (generally better received)
- There is a 1 in 10 chance that you will get breast cancer

What presentation do you prefer?

Perception of frequencies versus percentages

- **Frequencies**
  - More people-orientated
  - Brings message home
  - Using "you" brings closer still
  - Needs positive and negative pairing
- **Percentages**
  - More mathematical and looks scientific
  - More difficult to understand
  - Potential for confusion as to percentage of what
  - Helps some to see it as lower risk (anxiety-reducing)
  - Seen as relevant to others not to self (distancing)

Keeping percentages meaningful for target audience

- Who are you talking to?
- For what purpose?
- Percentage of what? Is it meaningful? Is it clear?

E.g. 1. Less than 1% of patients experience moderate adverse effects such as troublesome pain, numbness or tingling lasting weeks or months. 99% of patient do not have these adverse effects *(from a patient info leaflet)*
E.g. 2. 55% of patients achieved at least a 30% decrease in symptoms *(from an osteopathic journal paper)*
E.g. 3. In an American trial, osteopathic treatment reduced back pain by 30% on average *(patient info leaflet)*

Using absolute figures not relative

- Relative risks exaggerate
  - leave to pharmaceutical companies, advertising media, etc.
  - You are 5 times more likely to get …
- Relative benefits exaggerate
  - This treatment is 3 times more effective than….

Using averages and ranges

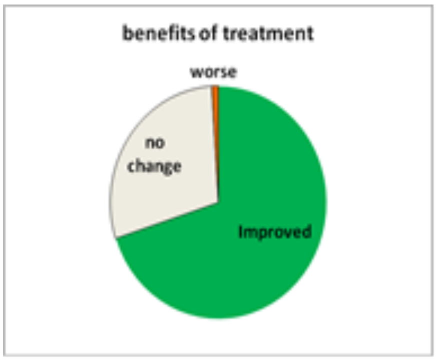
- Sets up realistic expectations
- Normalises experience
- Reduces anxiety

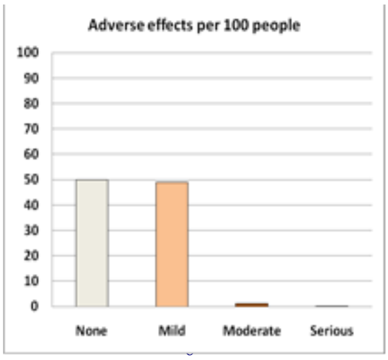
E.g 1. The average age for potty training is 2 ½ years. The normal time for potty training is 18 months to 8 years
E.g 2. Most patients get some increase in movement within 3 to 6 sessions. Some have reported an immediate difference and others said it took longer before they saw a real change

Visual representation: Graphs

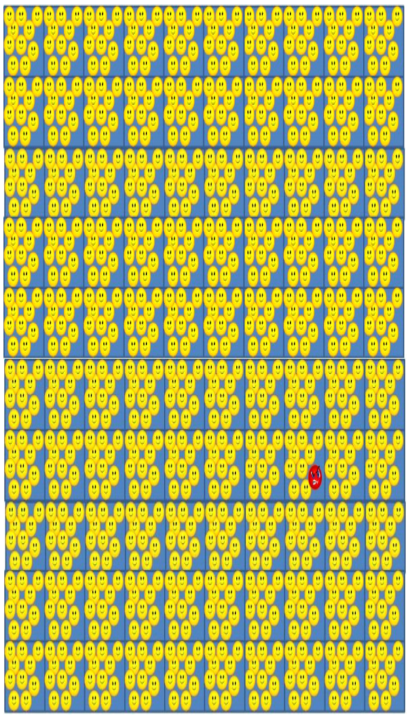
- Include benefits where possible
- Vertical bars useful for comparison between two options
- Vertical preferred to horizontal presentation
- Order of presentation of graphs may affect decision

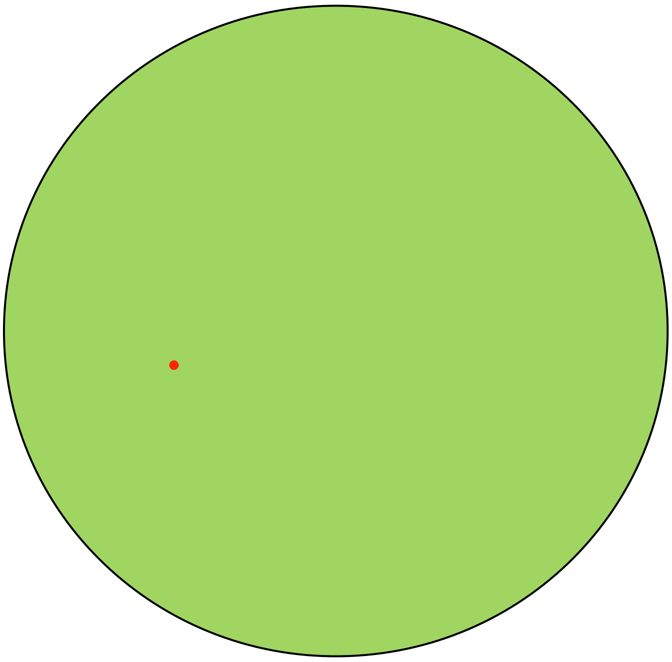
Lee et al 2009, Schapira et al 2001





Risk of 1 in 10,000





Risk of serious effects are rare but need to be mentioned if relevant to patient (e.g. damage to nerves or arteries occurs in less than 10-10,000)

What other visuals useful alongside explanation?

Stick figures or faces?

- Single probabilities
- More understandable, less clinical, easier to identify with
- Seen as representing higher risk in lower educated groups
- Needs low denominators to make real usually (1 /10 rather than 10/100)
- Grouping effects perception of risk
- Context can be seen as inappropriate (smiley faces) or patronising
- Grain of sand for large numbers (but distancing)
- Avoid jokes (you are more likely to be kicked by donkey variety)

Be aware of own resistance to discussing risks

- Explaining benefits and risks is patient expectation
- Research is available on risks and benefits

  - Further work will help
  - Information leaflets and more detailed guidance good way forward
- Time is well spent
- Takes less time than this talk
- No evidence that it is harming business
  - increases credibility
  - patients recommend others
- No evidence that litigation increasing

Example of Poor Communication

- “I wouldn’t have had this treatment if I’d known that the success rate was so low”

Suggested Procedure (a summary of above):

- Make the patient feel comfortable – in the right frame of mind to listen
- Give them thinking time
- Explain what they need to know and the decisions they need to make
- Encourage them to take an active part in the decision-making
- Ensure that if the decision is left to you, it is a deliberate decision, not one borne out of anxiety
- Check throughout that they continue to understand and consent