MEDICINES USE AND SAFETY WEBINAR

• Welcome to the MUS Webinar on **Informed Consent and the Law – Implications for medicines-related conversations** with Nina Barnett, Consultant Pharmacist Care of Older People and Claudia Carr, Senior Lecturer, Hertfordshire Law School.

• The webinar itself will start at 1pm – shortly before 1pm Jane Hough will be doing sound checks – bear with her if you hear this more than once!

• To join the audio call 0203 478 5289 access code 952 625 199.

• The webinar will be recorded and both recording and slide set will be available on the SPS website – under **Networks** (you need to be logged onto the SPS site to access the recording).

• If you want to make a comment or ask a question – please use the “chat” function (you need to choose to direct your question to “All Participants” from the drop down box).

• Nina and Claudia will answer questions at the end of the presentation.
Upcoming MUS Events

Webinars:

11th April – Top Tips for caring for patients with mental health and/or substance misuse issues in physical health settings with Ray Lyon and colleagues

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13th June – Administering medicines to patients with swallowing difficulties – Paresh Parmar

7th June – CHS Learning Event in London – programme being developed

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Medicines Use and Safety Update March 2018 - link

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Informed Consent And The Law: Implications for Medicines Related Conversations

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Informed consent and information disclosure

Aims and Objectives

• This webinar will:
  • Outline recent case law in relation to information disclosure and informed consent to health related treatment in the UK
  • Outline the requirements which support application of the new law within medicine related consultations
  • Discuss the implications for pharmacy consultations
Consent to treatment

The importance of informed consent

- Where the patient has capacity, the patient must consent to medical treatment
- Test for capacity – Mental Capacity Act 2005
- Where the patient lacks capacity, either temporarily or permanently, the need for capacity can be dispensed with and the patient is treated in their ‘best interest’
- Consent must be given free of undue influence and coercion and must be informed
Before 2015, the ‘Bolam’ test was applied to determine cases where it was questioned whether there had been adequate information disclosure and whether the patient was able to provide informed consent.

The Bolam test states ‘a medical professional is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a reasonable body of medical men skilled in that particular art’.

Since the decision in Montgomery v Lanarkshire Health Board (2015), Bolam no longer applies to information disclosure.

Bolam still applies to other areas of clinical negligence such as diagnosis and treatment.
Montgomery v Lanarkshire Health Board (Scotland) 2015

The facts

• Brief facts:
• Mrs M was of slight statute and a pregnant insulin dependent diabetic.
• Likely to have a larger than average baby.
• Increased risk of 9-10% of shoulder dystocia; ‘a major obstetric emergency associated with a short and long term neonatal and maternal morbidity’
• Associated risk in 0.1% of cases of hypoxia, cerebral palsy or death.
• Mrs M was advised of the risk of a larger than average baby but not of the risk of shoulder dystocia. She was not offered a caesarean section as an alternative.
• Had Mrs M been offered a caesarean section, she would have chosen this method of delivery.
• During labour, shoulder dystocia occurred, the baby suffered significant injury and Mrs M sued for damages.
• Successful – awarded £5.25m damages
Montgomery
Patient Autonomy

- ‘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’.

- Patient at the centre of the decision making process
- Shared decision making
- Final rejection of paternalism
The below applies to anyone who ‘treats’

‘The doctor is under a duty to take reasonable care to ensure that

• a) the patient is aware of any material risks involved in any recommended treatment and

• b) of any alternative or variant treatments.

The test of materiality is whether

• a) a reasonable person in the patient’s position would be likely to attach significance to the risk or,

• b) the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it’.
Montgomery
Emphasis on dialogue

• Whether a risk is material cannot be reduced to percentages alone
• There are a variety of factors to be taken into account for example:
  • -the nature of the risk
  • -the effect any materialising risk would have on the patient’s life
  • -the importance to the patient of the benefits of the treatment
  • -alternative available and those related risks.
The test in Montgomery
It’s not new!

• Patients are not incapable of understanding medical matters…

• Consent: patients and doctors making decision together 2008

• The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice. The patient weighs up the potential benefits, risks and burdens of the various options as well as any non-clinical issues that are relevant to them. The patient decides whether to accept any of the options and, is so, which one’ para 5

• GMC – Good Medical Practice 2013 – duties of a doctor
• Emphasis on patient centred care and:
  • obtain consent to provide care and pharmacy services
  • involve, support and enable every person when making decisions about their health, care and wellbeing
  • listen to the person and understand their needs and what matters to them
  • give the person all relevant information in a way they can understand, so they can make informed decisions and choices
Post Montgomery
Where are we today?

- The decision is Montgomery has been followed in a number of cases.
- **Webster v Burton Hospitals NHS Foundation Trust 2017**
  - Failure to advise the patient of anomalies in a scan or arranging follow up scans during her pregnancy denied the patient the opportunity to request an induced pregnancy. Had the baby been at the time the patient would have requested, injury to the baby would have been avoided.
- **Hassell v Hillingdon Hospitals NHS Foundation Trust 2018**
  - Mrs H was not advised of the risk of paralysis as a result of spinal cord injury as a result of spinal surgery. She was not advised of the possibility of conservative treatment and the surgeon had failed to take reasonable care and skill to ensure Mrs H was aware of the material risks and alternatives,
Information disclosure
The law as it is today

There is a duty of care on those who treat patients, to present their patients with options concerning their treatment and the risks associated with that treatment to allow them to make their own informed decisions and thus to provide informed consent.
Comments from Nina?
How does the Montgomery judgement apply to pharmacy consultations?
Mr A, 78yr, medication review
- Lives alone, 3rd floor, recently widowed
- Fallen x4 in 3 months, no injuries
- Has BPH, Rx tamsulosin
- Also prescribed furosemide 40mg om

No indication for diuretic in the notes
- No HF or hypertension noted
Case scenario continued

Medication review – stop furosemide
  • Patient became upset and anxious
  • Furosemide helps BPH symptoms
  • ???

What are the options for the prescriber?
No change to medication - prescriber considers the likelihood of furosemide contributing to the falls as low.
Option 2

Withhold furosemide for two weeks.

Agree with the patient to a trial of stopping furosemide, following an explanation that it is the tamsulosin helping the BPH and why the furosemide seems to confer a benefit.

Explain that the furosemide may increase risk of falls and agree to meet again in two weeks to feed back with regard to BPH symptoms.
Stop the furosemide

Tell the patient that there is no clinical indication for this medication.
The patient was admitted to hospital one week later following a fall.

What would a “reasonable” prescriber do?

What would a “reasonable person in the patient’s position expect?”
The patient had undocumented heart failure which was worsened by stopping the furosemide.

- Was the course of action taken not one that a reasonable prescriber would have taken?
- Can it be shown that no other prescriber acting reasonably would have deprescribed the furosemide?
- Did the lack of furosemide caused damage i.e. the worsening heart failure?
- What would a reasonable person in the patient’s position expect?
The patient had no further falls but presented to his GP one month later with shortness of breath.

- Potential for heart failure not discussed
  - Patient lives on the 3\textsuperscript{rd} floor (no lift) = material

- What about informed consent to deprescribing?
Option 3
Informed consent to medication review (deprescribing)

The patient did not give full informed consent
The adverse effect of stopping the medicine was material to the patient and he was not informed.

- the risk, which was not outlined, materialised (SOB)
- if the patient had known of this risk, they would have made a different decision (continue) despite the falls risk
- no reasonable alternatives were offered

The patient did not have enough information to weigh up the risk/benefits of stopping the medicine

In relation to informed consent, poor outcomes can happen. The key is that the patient agrees to a course of action in the full knowledge of all potential risks and benefits.

So how does this fit with a person-centred consultation?
Requires joint working between practitioner and patient to:

- **Prioritise** the issues based on the importance to the patient, risks, benefits, clinical experience and current evidence.
- **Focus** on one or a small number of relevant issues, rather than trying to “solve” the clinician-identified concerns.
- **Identify** and discuss options including reasonable alternatives.
- **Ensure** effective communication by practitioner and patient, family/carers and other practitioners to changes made, including follow up.

Aligns with GMC (2008) and GPhC (2017) guidance
Structure for a person-centred consultation

- Negotiate agenda
- Agree goals
- Identify options
- Co-create care plan

- "Need to know" - Use clinical expertise to inform safe & effective use of medicines.
- "Want to know" - Asking relevant questions as
  - they might not know they want to know
  - you need to find out what matters to them in order to offer reasonable alternatives

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A person-centred approach to consultations

1. Assess patient
2. Define context and overall goals
3. Identify medicines with potential risks
4. Assess risks and benefits in context of individual patient
5. Agree actions to stop, reduce dose continue or start
6. Communicate actions with all relevant parties
7. Monitor and adjust regularly

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Use Four E’s questions

- **Explore** what the patient wants to know and *follow their agenda*
- **Educate** them on what they want to know
- **Empower** patients to take responsibility for medicines taking
- **Enable** behavioural change by discussion of embedding into routine

Embed a person-centred approach into pharmacy activities

- Medicines reconciliation
- Medication review
- High risk medicines consultation
- Discharge consultation
- Medicines Use Review
- Dispensary Consultation
Informed consent through evidence based person-centred consultations requires:

- Best available research evidence
- Clinical expertise of the practitioner
- Patient's circumstances, goals, values & wishes

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http://www.bmj.com/content/312/7023/71
Comments from Claudia?
Further reading

- General Medical Council. 2013 Guidance on consent
  http://www.gmcuk.org/guidance/ethical_guidance/consent_guidance_index.asp

- Sokol D. Let’s raise a glass to the ordinary sensible patient *BMJ* 2015;351:h3956doi:10.1136/bmj.h3956 (Published 28 July 2015) http://www.bmj.com/content/351/bmj.h3956

- General Pharmaceutical Council Standards for Pharmacy Practice May 2017
  https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf

- Lee A ‘Bolam’ to ‘Montgomery’ is result of evolutionary change of medical practice towards ‘patient-centred care’ *Postgraduate Medical Journal* 2017;93:46-50. http://pmj.bmj.com/content/93/1095/46


- Barnett N and Sokol D. Why pharmacists need to re-evaluate what information they provide to patients 25 Jan 2017 http://pharmaceutical-journal.com/opinion/comment/why-pharmacists-need-to-re-evaluate-what-information-they-provide-to-patients/20202226.article


- Barnett N and Carr C. The Montgomery judgement and pharmacist consultations *Prescriber* Published 29th January 2018 http://www.prescriber.co.uk/article/montgomery-judgment-pharmacist-consultations/

Questions?
Poll Question Number 1

Overall I found the webinar content useful to me:

- Agree strongly
- Agree
- Disagree
- Disagree strongly
Poll Question Number 2

I would recommend this learning event to others:

- Agree strongly
- Agree
- Disagree
- Disagree strongly
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