Non-Medical Authorisation Course

Consent

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Learning Outcomes

- Understanding of what consent is
- An awareness of the latest recommendations regarding consent for blood transfusion
- How to obtain consent
- How to document the consent procedure
- What information to give to patients

General Principles

Every human being of adult years and sound mind has a right to determine what shall be done with his own body (Schloendorff case, 1914).

Consent is a general legal and ethical principle, that valid consent should be obtained from a patient (parent / guardian) before starting treatment or physical investigation, or providing personal care, for a person.

For the consent process to be valid, the patient must be competent (have capacity) and have received sufficient information to make an informed voluntary decision.

The law and consent/refusal Adults

A patient who is **16 years of age or over** and who you deem to **have mental capacity**, can consent, or refuse any treatment. If the patient refuses treatment, you must ensure they have received an explanation **in terms that they can understand** of the subsequent consequences. They must also understand the risks and benefits or any alternative options to the treatment advised.

The law and consent/refusal

If you have a patient of **16 years and over** who you think **lacks mental capacity**, you must treat that patient in accordance with his/her best interests.

Close relatives and friends may be able to give you information about the patients known views on transfusion related issues.

The law and consent/refusal Children

If the patient is **under 16** and is assessed as **being Fraser* competent**, you can obtain consent from the patient. You should however ensure that you take all reasonable steps to liaise with someone with parental responsibility to obtain their views (unless there are issues of confidentiality between the patient and the individual with parental responsibility).

* Fraser competent rather than Gillick competent

The law and consent/refusal

If your patient is **under 16** and assessed as **not being Fraser competent**, then anyone with parental responsibility (PR) can consent on behalf of the patient.

Parental responsibility

If the parents are married at the time of the birth or jointly adopted a child they both have PR even if divorced, non/resident

Unmarried parents

Before 01/12/2003 only the Mother automatically had PR. The Father now has to jointly register the birth, or have a PR agreement with the mother or a PR order made by a court

So what does that mean in practice?

Valid consent/refusal

- Voluntary — no coercion
- Information — clear, tailored to patients understanding and/or wishes, risks v benefits, none bias, alternatives, long term
- Written or verbal — verbal must be documented in the patients healthcare record
- Trained Practitioner — in the procedure for which consent being obtained

Capacity and Decision

A patient has capacity if they:-

- Understand
- Retain
- Use and weigh up the information needed to made a decision

AND

- Can communicate their wishes

Decision - a choice that you make about something after thinking about many possibilities

Patients that lack capacity

- Care of your patient is your first concern
- Treat individually and respect their dignity
- Support and encourage patient involvement

Children & young people

- Involve them as much as possible in discussions about their care, even if they are not able to make decisions on their own.
- A young person's ability to make decisions depends more on their ability to understand and weigh up options, than on their age.
- Any decision however, may be overruled by the courts if refusing treatment could lead to their death or severe permanent injury, by applying for a Specific Issue Order
- Clearly, this is a complex and controversial area - legal advise should be sought if needed.

Advanced decisions

- Patient who are ≥ 18 years of age may have made an Advance Decision to Refuse Treatment (‘living will’ or ‘advance directive’) in anticipation of future incapacity

- This is a well-established rule of common law, and the Mental Capacity Act (MCA) 2005 now puts advance decisions on a statutory basis.

- Healthcare Professionals must follow an advance decision if it is valid and applicable, even if it may result in the person’s death. If they do not, they could face criminal prosecution or civil liability.

Advanced decisions

- If an advance decision is not valid or applicable to current circumstances, Healthcare professionals must consider it as part of their assessment of the person's best interests. Advance decisions made before the MCA came into force may still be valid if they meet the provisions of the Act.

- If, after discussion, a patient refuses blood products, clearly document this in their case notes to be signed and witnessed by two medical professionals wherever possible.

- If the patient has already signed a consent form, but then changes their mind, you (and where possible the patient) should note this updated decision on the consent form, and case notes and ensure that all members of staff are aware of this update

Advanced decisions

- Where a patient has refused blood products, you must ensure that you continue to provide any other appropriate care to which they have consented.

- You should also ensure that the patient realises they are free to change their mind and accept blood products if they later wish to do so and you should continue to conduct in depth discussions with them (and make a record of the same) so as to ensure they are kept up to date with all possible risks at all times.

Jehovah's Witnesses

- Refusal of blood products by Jehovah's Witnesses is protected by the terms of the European Convention on Human Rights, which is incorporated into UK law by the Human Rights Act 1998 - freedom to act on religious beliefs.

- If you require further advice regarding any aspects of a Jehovah's Witness' treatment, contact your local Jehovah's Witness Hospital Liaison Committee or email info@hlcnottm.co.uk

- Remember - patients who refuse blood are not necessarily members of the Jehovah's Witness community

SaBTO

- *Advisory Committee on the Safety of Blood, Tissues & Organs SaBTO (DoH expert committee)*
- *Advises UK Ministers and Health Departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/transplantation*
- *Publishes advice and guidance, reports and statements*

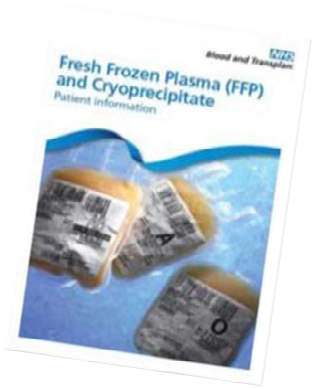
SaBTO

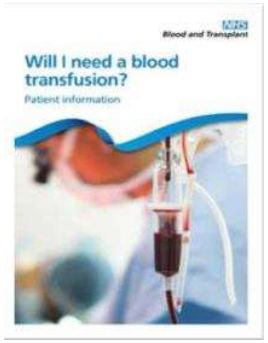
Advisory Committee on the
Safety of Blood, Tissues and Organs

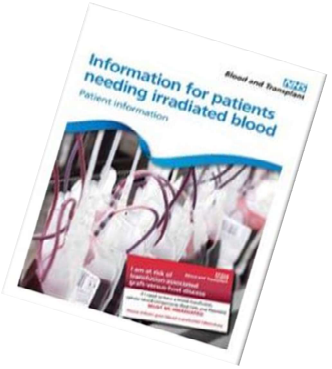
SaBTO Recommendations

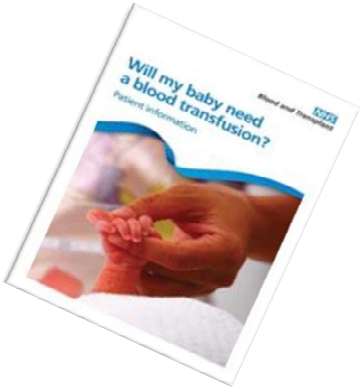
- Valid consent for blood transfusion should be obtained and documented in the patient's clinical record by the healthcare professional.
- There should be a modified form of consent for long term multi-transfused patients, details of which should be explicit in an organisation's consent policy.
- There should be standardised information for patients and HCP’s
- Patients who have received a blood transfusion and who were not able to give valid consent prior to the transfusion should be provided with information retrospectively.

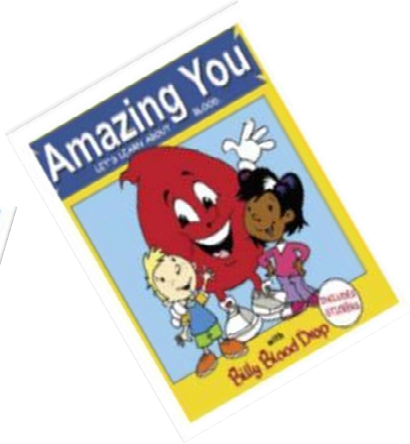
Information leaflets

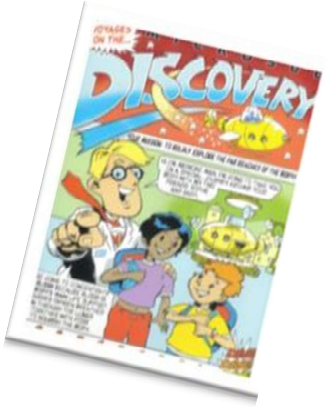












Consent.....explaining risk

Montgomery *v* Lanarkshire March 2015

The Case

- Nadine Montgomery, diabetic and pregnant
- Vaginal delivery with shoulder dystocia occurring - baby born with serious disabilities as a result
- 9-10% known risk of dystocia in women with diabetes
- Dr/Miss McLellan acknowledged she did not discuss this risk with such women as fearful they would opt for caesarean section (CS).
- The court held that McLellan should have informed Montgomery of the risks and discussed the option of CS

What does this mean?

- The Bolam test is no longer applicable ("If a doctor reaches the standard of a responsible body of medical opinion, he is not negligent“).
- The law now requires a Doctor to take

“reasonable care to ensure that the patient is aware of material risks involved in any recommended treatment and of any reasonable alternative or variant treatments.”

What should YOU do?

- Have I explained the “material” risks of the proposed treatment?
  - What risks would a person want to know about?
  - What other risks would this particular patient want to know about?

  Do I know the risks?

- Have I explained what alternatives to blood products are available?

  Do I know the alternatives?

- Have I tried to ensure the patient understands all the information?

  Do I know how I would do this?

- Have I documented the details of the consent process?

Exceptions!

- The patient requests not to be informed
  - document in notes !
- Clinical situation means consent cannot be obtained
  - inform patient post event
- There is a genuine and significant risk of harm associated with providing the patient the information at that time

Being too busy is not an adequate reason!!

Key to success

- Discuss – indications, risks, benefits, alternatives
- Provide – PIL, give time to decide, quiet/private environment non-bias discussion
- Document – what was discussed, leaflets given, any consultation with others e.g. interpreter/SALT/ LPA, Advance decision
- Respect – patients decision – just because their decision may seem irrational doesn't mean they lack capacity!
- Check-patient understands all the information provided

Web based resources

- www.transfusionguidelines.org.uk
- www.gov.uk/government/piblications/patient-consent-for-blood-transfusion
- www.jw.org
- www.bcshguidelines.com
- www.learnbloodtransfusion.org.uk
- www.nhsbt.nhs.uk

If it's not written down, it's rumour.

If it's not signed and dated, it's graffiti!

Dr Tetzlaff – FDA Inspector

Thanks for listening