Ethical implications of introducing new surgical biotechnologies

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Objectives

- Define the term “informed consent”
- Understand the patient persepctive with regard to the introduction of new surgical technologies
- Appreciate the role and place of clinical trials with respect to new surgical technologies

Content

- Medical Ethics
- History
  - Experimentation
  - Nuremberg Trials & Declaration
  - Tuskegee
  - Declaration of Helsinki
- Informed Consent
- Biotechnology

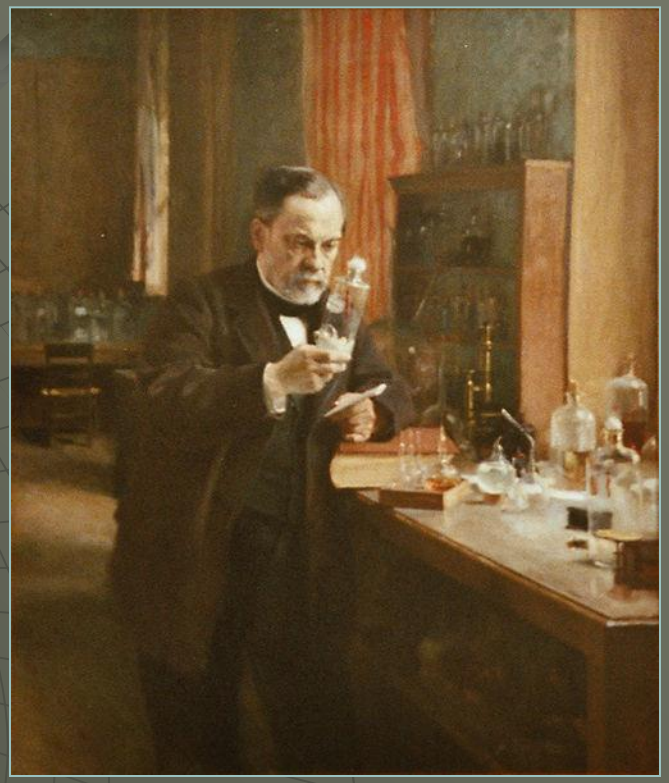
Medical Ethics

- Autonomy
- Beneficence
- Non-maleficence
- Justice
- (Veracity)

History

- Slaves or prisoners
- Jenner
- Walter Reed
- Pasteur

- No consent, No control



Nuremberg

- "Doctors Trial"
- Nazi human experimentation
- Mengele, Brandt etc.
- 20/23 were doctors
- 7 acquitted
- 7 sentenced to death
- Remainder 10 years to life

Nuremberg code (Alexander)

- Informed consent is essential.
- Research should be based on prior animal work.
- The risks should be justified by the anticipated benefits.
- Research must be conducted by qualified scientists.
- Physical and mental suffering must be avoided.
- Research in which death or disabling injury is expected should not be conducted

Nuremberg code (Trial judges)

- Fruitful results, unavailable by other means
- Adequate preparation for the protection of the subject
- Subject must be at liberty to withdraw
- The scientist in charge must stop the study if continuation will result in injury, disability or death

Tuskegee (1)

- "Tuskegee Study of Untreated Syphilis in the Negro Male"
- Tuskegee, Alabama 1932 – 1972
- 399 (plus 201 controls)
- "arguably the most infamous biomedical research study in U.S. history"

Tuskegee (2)

- Initially a 6 – 8 month incidence study, followed by a treatment phase
- Contemporary treatment questionable effective and toxic
- Wall Street Crash ended funding for treatment
- 1947 penicillin established as standard therapy

Tuskegee (3)

- Actively prevented subjects getting treatment
- Described investigations as “Special Free Treatment”
- Inducements to remain in the study
- Autopsy required for free funeral benefits

Tuskegee (4)

- 1972 Peter Buxtun “whistle blower”
- 74 test subjects still alive
- 28 had died directly of syphilis
- 100 died of related complications
- 40 wives infected
- 19 children born with congenital syphilis

Tuskegee (5)

- Belmont Report
- National Research Act
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

- Institutional Research Boards

Declaration of Helsinki

- World Medical Association June 1964
  - Combined Nuremberg with Declaration of Geneva
  - Consent "if at all possible"
- 1975 First Revision
  - Oversight by "independent committee"
  - Informed Consent developed further
- Subsequent revisions not accepted by EU or FDA

Informed consent

- No legal definition -developing concept
- Professionally based -> patient based
- Voluntary
- Significant Risks (Reasonable v. particular patient
- Alternatives

Biotechnology

- Overall/long-term efficacy
  - Carotid endarterectomy
- Underlying theory subject to criticism
  - Gastric ulcer surgery
  - Breast cancer surgery
- Technical improvement on accepted treatment

Biotechnology

- Is this a modification or a new alternative?
- Why is it being introduced?
- Are there (likely to be) significant new risks?
- Has the patient been told this is innovation and offered alternatives?

Biotechnology

- Prospective randomised double-blind controlled trial?
  - Blinding?
  - Placebo?
  - Surgical skill?
  - Case mix?
  - “Equipoise”

November 2009

Alert

Patient Safety Alert

NPSA/2009/PSA004A
24 November 2009

NHS
National Patient Safety Agency
National Reporting and Learning Service

Safer spinal (intrathecal), epidural and regional devices – Part A

From 1 April 2011 all spinal (intrathecal) bolus doses and lumbar puncture samples should be performed using syringes, needles and other devices with connectors that **will not** also connect with intravenous equipment.

NHS organisations will need to review and update their purchasing policies, procedures and clinical protocols to include the use of specified devices with safer connectors. NHS organisations should not request further orders for non-compliant devices six months before the 1 April 2011 implementation date.

These devices with safer connectors are not currently available. By issuing this Alert the NHS is stating clearly to the medical device and pharmaceutical industry that it will only buy products that facilitate safer practice. The 2011 deadline is intended to allow sufficient time for the industry to develop new devices.

Issue
There have been fatal cases where intravenous medicines have been administered by the spinal (intrathecal) route and epidural medicines that have been administered by the intravenous (vein) route. There is also the potential for medicines intended for regional anaesthesia to be administered by the intravenous route, with fatal outcomes.

These wrong route errors will always be possible as long as medical devices with standard (Luer) connectors are used. The introduction and use of medical devices which do not physically connect with intravenous equipment will further reduce the risk of wrong route errors.

Other safeguards
The introduction of devices with safer connectors does not replace previous safe practice guidance on intrathecal chemotherapy and epidural therapy, but rather is intended to further minimise risks to patients.

The National Patient Safety Agency (NPSA) has previously issued guidance in 2007 to minimise the risks of wrong route epidural incidents, and in 2008 on using minibags for intravenous doses of vinca alkaloids. The Department of Health in England has also issued guidance on intrathecal chemotherapy. However, wrong route incidents are still being reported.

Action by all organisations in the NHS and independent sector

An executive director, nominated by the chief executive, working with clinical and procurement staff should implement a 'Purchasing for Safety' initiative to ensure that:

by 1 April 2011

- all spinal (intrathecal) bolus doses and lumbar puncture samples are performed using syringes, needles and other devices with safer connectors that will not connect with intravenous Luer connectors;
- medical device and pharmaceutical manufacturers supply devices with safer connectors well before the required implementation date, to enable clinical evaluation and changes in the supply chain to occur;
- new orders for non-compliant devices should not be requested six months before the required implementation date to enable time for clinical evaluation and changes in the supply chain.

A recommended checklist for implementation is on the next page.

***NOTE:** Guidance in this Part A Alert should be read in conjunction with the Part B Alert detailing actions on safer connectors for epidural, spinal (intrathecal) and regional anaesthesia infusion and bolus devices. The alert is being issue in two parts in order to allow two separate timescales for implementation.*

Alert

Patient Safety Alert

NPSA/2009/PSA004B
24 November 2009

NHS
National Patient Safety Agency
National Reporting and Learning Service

Safer spinal (intrathecal), epidural and regional devices – Part B

From 1 April 2013 all epidural, spinal (intrathecal) and regional anaesthesia infusions and bolus doses should be performed with devices with connectors that **will not** also connect with intravenous equipment.

NHS organisations will need to review and update their purchasing policies, procedures and clinical protocols to include the use of specified devices with safer connectors. NHS organisations should not request further orders for non-compliant devices six months before the 1 April 2013 implementation date.

These devices with safer connectors are not currently available. By issuing this Alert the NHS is stating clearly to the medical device and pharmaceutical industry that it will only buy products that facilitate safer practice. The 2013 deadline is intended to allow sufficient time for the industry to develop new devices.

Issue
There have been fatal cases where intravenous medicines have been administered by the spinal (intrathecal) route and epidural medicines that have been administered by the intravenous (vein) route. There is also the potential for medicines intended for regional anaesthesia to be administered by the intravenous route, with fatal outcomes.

These wrong route errors will always be possible as long as medical devices with standard (Luer) connectors are used. The introduction and use of medical devices which do not physically connect with intravenous equipment will further reduce the risk of wrong route errors.

Other safeguards
The introduction of devices with safer connectors does not replace previous safe practice guidance on intrathecal chemotherapy and epidural therapy, but rather is intended to further minimise risks to patients.

The National Patient Safety Agency (NPSA) has previously issued guidance in 2007 to minimise the risks of wrong route epidural incidents, and in 2008 on using minibags for intravenous doses of vinca alkaloids. The Department of Health in England has also issued guidance on intrathecal chemotherapy. However, wrong route incidents are still being reported.

Action by all organisations in the NHS and independent sector

An executive director, nominated by the chief executive, working with clinical and procurement staff should implement a 'Purchasing for Safety' initiative to ensure that:

by 1 April 2013

- all epidural, spinal (intrathecal) and regional infusions and boluses are performed with devices that use safer connectors that will not connect with intravenous Luer connectors or intravenous infusion spikes;
- medical device and pharmaceutical manufacturers supply devices with safer connectors well before the required implementation date, to enable clinical evaluation and changes in the supply chain to occur;
- new orders for non-compliant devices should not be requested six months before the required implementation date to enable time for clinical evaluation and changes in the supply chain.

A recommended checklist for implementation is on the next page.

***NOTE:** Guidance in this Part B Alert should be read in conjunction with the Part A Alert detailing actions on safer connectors for spinal bolus doses and lumber puncture samples. The alert is being issued in two parts in order to allow two separate timescales for implementation.*

Devices Regulation

- [Neuraxial Connectors]
- PIP Implants
- TAVI
  - BMJ 2012;345:e4710
- "I think, at the end of the day, we will see everyone moving to increasing use of comparative trials,"
  - Guido Rasi, Executive Director, EMA

Wax philosophical!

- Cost
- Time
- Carbon footprint
- Translating
- Best v most good?

Biotechnology

- Innovation is inevitable
- Good research is necessary
- Independent ethical supervision is necessary
- Surgery is different to medicine!