Testing times for the Welsh NHS?
SMTL’s role in medical device assessments

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About SMTL

• Based in Princess of Wales Hospital, Bridgend.
• Funded by WAG through WHSSC (Welsh Health Specialised Services Committee).
• Provide testing and technical services on medical devices to the NHS in Wales, and to Industry and the UK Health Service on a commercial basis.
• 16 staff, including pharmacists, microbiologists, technicians, admin staff.
• UKAS accredited for testing
• Sit on numerous committees, including MHRA CSD, BSI/CEN committees (Chair of CH/205/1), Welsh Decontamination Committee, Chair of WNCRG, WHS groups ...
• Close working relationship with Welsh Health Supplies
SMTL’s Activity Breakdown

- All Wales Testing - WHS & Contracts
- WAG advice/support (WNCRG, NPSA alerts)
- CAGs/Sub groups (IV, urology, dressings, etc)
- Contract Monitoring
- Mid Glamorgan QA/COSH - POW, RGH, PCH
- All Wales defect/incident investigation.
- Commercial Testing
- Web sites (SMTL, dressings.org, World Wide Wounds)
- Grants
- Problem Solving - e.g., UHW cardiac instruments 2010
Testing - general principles.

- Why?
  - Product safety
  - Product functionality
  - Product equivalence
  - Price/Performance (CBA)

- How?
  - Official test methods
  - In house test methods

- What to test?
  - Commodity Advisory Groups, sub groups and users
  - Defect reviews
  - Literature searches
Case Study: Tonsillectomy Instruments

- 2000/2001- SEAC advice:
  - Tonsil/Adenoid surgery - performed with single-use instruments
- Rationale: possible long incubation periods for vCJD, young patient population
- PASA tender - 2 suppliers awarded national contracts
- Clinicians asked for their views on the ’sample’ instruments - generally favourable
- Wales opted for one specific supplier
Introduction of the instruments

- Instruments placed into practice in June 2001
- Clinical problems experienced immediately - esp. post-op bleeds
- Some clinicians felt this was due to inexperience with these new instruments
- SMTL received a number of complaints
  - Gags slipping
  - Eves snares jamming
- Lab investigation confirmed these problems
- WAG formed a steering group to look at the issues
UK Problems

- Reports of increased secondary haemorrhage rates
- DoH view - associated with single-use diathermy
- Device alert issued October 2001 - review practice
- December 2001 - revert to reusable devices
- Retrospective analysis of Welsh data:
  - Return to theatre rates - from 1.6% (pre 2001) to 4.4% (during 2001)
  - 20% of operations experienced an instrument malfunction
Welsh Strategy

- In Wales, continued to comply with SEAC advice
- Suspend tonsil and adenoid surgery except for emergency surgery
- For emergencies - use reusable instruments only once and quarantine
- Perform an investigation into instruments and suppliers
  - SMTL
  - WHS
  - Alun Tomkinson (ENT, UHW)
Welsh Procedure

1. WHS requested expressions of interest
2. Sample instruments sent to SMTL
3. Paper audit by SMTL
4. Benchtop lab. analysis performed - compared traditional reusables with single use- SMTL + AT
5. Suppliers audited - SMTL, AT & WHS
6. Welsh Assembly funded the “Single Use Instrument Surveillance Programme” (SISP) to ensure that the instruments selected resolved the problem
Results

- One supplier’s drawing was non-functional, and most of the rest had no drawings.
- Some manufacturers were misleading about their instruments and systems (e.g., drawings and change control).
- One manufacturer was on their 4th revision of instruments.
- Significant instrument design issues and systematic QA problems.
- Interactions between instrument failures likely to have accounted for some incidents.
Gwynne Evans Dissector

Original Gwynne Evans

Single Use Gwynne Evans
Slipping Gags

Original Gag

Single Use Gag
Slipping Draffin Rods

Original Rods

Single Use Rods
Tongue Plates Jamming

Original Plate

Single Use Plate
2002-2003 Surgical Drawing
2003-2004 Drawing
Results (cont)

- Only one manufacturer - BBraun - had no significant issues - 0% flawed instruments, 93% as good as original (AGAO)
- Closest competitor - 13% flawed, 60% AGAO
- Worst company - 40% flawed, 40% AGAO, no change since previous audit
- One supplier relied on 100% inspection to eliminate the defective 4-15% of their instruments (QC vs QA)
- BBraun awarded a 3+ contract
Clinical Outcomes

- Single use Instrument Surveillance Programme provided excellent evidence
- Primary and Secondary post-operative haemorrhage returned to previous rates (statistically indistinguishable):
  - Reusables - 1.3%
  - Single Use BBraun - 1.4% (was 4.4% during 2001)
- Some benign instrument failures experienced - annoying rather than clinically significant
Lessons Learnt

- CE Marking alone was insufficient to allow selection of safe and effective devices (all were CE marked)
- Single use devices must be at least as good as reusable
- Manufacturers with no insight into the key characteristics/functionality of their devices should be treated with caution
- The quality of the instrument delivered to the surgeon is highly dependent on the quality system of the manufacturer/supplier:
  - Same source, different suppliers -> sig. different quality of supplied instruments
Where are we now?

- Surveillance has continued:
  - Nov 2010 - SISP published showing Coblation (modern/innovative technique) associated with 7-13 fold increased odds ratio for post-op haemorrhage;

- Repeated exercise for new contract in 2008/2009:
  - diathermy testing - CEDAR - 3 brands, all failed the relevant ISO standard;
  - audits/testing for steel instruments:
    - uncontrolled technical files, inadequate drawings ...
    - 90 degree adenoid curettes instead of 45 to 75
    - J/L shaped tooth guards,
    - tongue plate slots too wide,
    - retractors with sharp edges,
    - guarded 14mm curette packaged as 10mm non-guarded,
    - negus knot pusher which cut/frayed sutures,
Outcomes...

- BBraun regained the business for steel instruments;
- Diathermy is being retendered;
- Monitoring exercise will be undertaken to check BBraun are still acceptable during the contract period;
Current Projects

- Non Luer Connectors / NPSA Neuraxial alert / WNCRG
  - 20-30 clinicians engaged from across Wales
  - includes lab testing & clinical assessments
  - WAG supported
  - surveillance expected to play a significant role
  - based on tonsillectomy model

- Safer Sharps
- Rinse water for SSD & endoscopy
- Silver Dressings
- Particulates in theatre trays
- Examination gloves
- Vaginal speculums
Questions?

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References

- Medical electrical equipment. Particular requirements for the safety of high frequency surgical equipment. BS EN 60601-2-2:2007