An update on water testing.

Pete Phillips
Director
Surgical Material Testing Lab.
Princess of Wales Hospital
Bridgend
About SMTL

- Provide testing and technical services on disposable medical devices to the NHS in Wales, UK NHS & Industry
- 16 staff, including pharmacists, microbiologists, technicians, admin staff
- UKAS accredited for testing
- All Wales dressing/medical device testing
- Pharmaceutical QA for 4 hospitals
- Incident/defect investigation
- Commercial testing
Why did we start the project?

- Welsh SSD departments were concerned:
- Washer Disinfectors failing regularly
- NBs don't like to see FAIL on reports
- Some elements of 2030 based on WfI
- How relevant are some 2030 requirements?
- Any evidence that the failures are related to increased risk for patients?
- Any evidence that failures cause problems with instruments?
Principles

- Is there evidence that the water characteristics being examined affect patient health, instrument quality, or reprocessing equipment efficiency?
- What is the evidence for setting the limits at the present level?
- Is there evidence that would allow us to:
  - Stop testing that parameter
  - Relax the limit to a more realistic one
  - Tighten the limit to reduce risks
  - Add other tests which may be more appropriate
- Accept that a 'one size fits all' may not be the best approach – scopes and SSIs may need different limits
Water Meetings

- Welsh Decontamination Group
  - Jo Ford and SMTL staff produced a document looking at the evidence base.
- SSD Managers Group
- Water sub group
- Consultation group (not just Wales)
- UK water meeting (Spring 2010)
Grades of Evidence

- From the EPIC project - adapted from CDC guidelines and modified
- **Category 1**: generally consistent findings in a range of evidence derived from a majority of acceptable studies.
- **Category 2**: evidence based on a single acceptable study, or a weak or inconsistent finding in multiple acceptable studies.
- **Category 3**: limited scientific evidence that does not meet all the criteria of ‘acceptable studies,’ or an absence of directly applicable studies of good quality. This includes published expert opinion derived from systematically retrieved and appraised professional, national and international guidelines.
Criticality of each parameter

- Some limits have no direct effect on patients
- Some are relevant to operational aspects of the decontamination equipment
- Others have no impact on either
- Consulting on usefulness of differentiating between:
  - **Critical** – compromise patient health
  - **Semi-critical** – no direct effect on patient health, may affect instrumentation/equipment - instrument corrosion/WD scaling
  - **Non-critical** – cosmetic (discolouration)
Critical Instruments

- The critical status of the instrument is also important.
- AAMI use the following classification:
  - **Critical** – introduced into the human body, either in direct contact with bloodstream or into normally sterile areas (surgical instruments)
  - **Semi-critical** – contact mucosal membranes or non-intact skin but do not usually penetrate blood barrier or other normally sterile areas (endoscopes, laryngoscopes)
  - **Non-critical** – usually only contact the skin of the patient
Analyses of historical data & proposed limits

- Summary of results found from SMTL water testing
- Compare to HTM 2030 limits
- Analyse potential risks
- Examine the level of evidence
- Discuss possible limit changes
Water Hardness

- HTM 2030 - <210mg/l
- Range seen: 20-180mg/l
- Effects: scaling of WDs and scope channels, increased chemical usage, deposition on instruments
- No reports that above range is causing clinical problems
- Semi-critical (no clin effects)
Water Hardness – Evidence

- Scope manufacturer: water hardness not an issue if manual cleaning and high level disinfection
- SMTL's test results clearly show that Welsh water remains within the hardness limits
- Shah - detergents have a protective effect
- The expert group do not think that the hardness levels currently seen are a problem for SSIs
- Overall grade: Category 2
Water Hardness – AAMI

- Most WDs can operate with water at a hardness of 1234 ppm CaCO3
- Tap water considered hard if > 150 ppm, therefore use <150 ppm limit for potable water
- Other limits (for softened and RO water) are based on the limits achievable by the process, not on evidence that these limits cause problems in practice.
Water Hardness – Proposal

- Evaluate local conditions
- Evaluate effect on equipment and instrumentation
- SSIs:
  - Remove limit or keep at <210mg/l
- Scopes:
  - Considering reduction to 50mg/l, keep at 210mg/l, or recommend water softener
- AAMI: limit is 150mg/l – could consider this, but danger of failing departments for no good reason?
Chloride levels

- HTM 2030: <10mg/l
- Range seen: 5.5-50mg/l
- Effects: Potential corrosion of s. steel instruments.
- No reports that the range found in Wales is causing problems
- Level of criticality: semi-critical (steel instruments)
Chloride levels - Evidence

- German Instrument document – risk of instrument damage low as long as chloride below 120mg/l
- AAMI:
  - chloride > 250mg/l → pitting
  - keep <120mg/ml to avoid corrosion
- SMTL test data – all below 50mg/l, and no reports of corrosion across Wales
- No published evidence that these levels cause instrument damage
- Overall grade: 2
Chloride levels - Proposal

- Relax the chloride limit from 10mg/l to 50mg/l
- Probably irrelevant to scopes
- To be confirmed.
- Rinse aid can reduce the risk of concentration of chlorides during drying.
pH

- HTM 2030: 5.5-8.0
- Range seen: 6.1-7.7
- Effects: Stainless steel can withstand a wide range of pH
- Extremes of pH are not an issue in mains water
- Level of criticality: non-critical (steel instruments & scopes)
pH - Evidence

- **Stainless Steel Advisory Service:**
  - SS unaffected by the usual range of pH of mains water
  - Role of pH is determined by the chemical species present (e.g., chloride ions)

- **AAMI:**
  - Water that is either too acidic (the pH is less than 6) or too alkaline (the pH is more than 9) can cause pitting and staining of instruments and shorten their useful lives

- **Overall Grade:** 1
pH - Proposal

- Leave pH limits at the HTM2030 levels
- Question: does pH actually tell us anything useful?
  - Could we consider dropping it in the future?
- Probably irrelevant to scopes
Endotoxin

- HTM 2030: <0.25EU/ml
- Range seen: SSI – 0.2-50EU/ml, scopes 0.7-30EU/ml
- Effects: pyrexia, inflammatory responses
- Most studies based on IV admin
- Level of criticality: Critical
Endotoxin – USP/EP

- Safe to receive 5EU/Kg/Hr IV (EP) - 350EU for 70Kg person
- Lowered to 200EU/person (safety margin)
- Estimate that you can only recover 10% per device
- Limit set at 20EU/device in USP
Endotoxin - Evidence

- Steeves' paper:
  - rinse water with 26.5 EU/ml -> 0.15 EU/instrument;
  - ET contamination occurs after the WD stage
  - HTM2030 levels 'unnecessarily stringent'

- German 2006 paper: similar conclusions

- Scopes: HIS working party (2002) – routine ET monitoring not necessary

- SMTL scope results – 0.7-30EU/ml. No reported effects

- AAMI: Rinse water with 100EU/ml unlikely to stimulate adverse patient reaction

- Overall grade: SSI – 1, Scopes - 2
Endotoxin – Proposal

- **SSIs:**
  - If potable water is used for final rinse, then remove the ET limit
  - Consider testing instruments ready for use (post sterilisation) instead

- **Scopes:**
  - Evidence tends to support relaxation/removal, esp. the AAMI statement
  - HTM 0106 – removed the requirement
Microbial contamination (TVCs)

- HTM 2030: <0cfu/100ml
- Range seen:
  - <1cfu/100ml: SSI=32% Scopes=37%
  - 1-9cfu/100ml: SSI=15% Scopes=26.5%
  - 10-100 cfu/100ml: SSI=6% Scopes=21%
  - >100 cfu/100ml: SSI=47%, Scopes=15.5%
- Effects: post op infection, false +ve
- Level of criticality:
  - SSI=non-critical – terminally sterilised
  - Scopes=critical
Microbial Contamination – Evidence (1)

- **AAMI:**
  - Potable water considered acceptable for pre/post cleaning and final rinse of many devices
  - Reasonable bacterial limits for potable water < 200cfu/ml
  - Recommend high purity or DI water for rinsing of 'critical devices'
  - High purity water: <10cfu/ml (i.e., 1000cfu/100ml)

- **BS EN ISO 15883:**
  - Final rinse water < 10cfu/100ml
  - Free of legionellae, Ps. Aeruginosa, and mycobacteria
Microbial Contamination – a diversion ...

- AAMI:
  - High-purity water should be bacteria-free if tested at the point of generation
  - However, because most facilities will transport water to the site of use through pipes and because collection may result in low levels of bacteria being detected, the bacterial level has been defined as 10 cfu/mL
Microbial Contamination – Evidence (2)

- SSI: terminal sterilisation, can eliminate high challenges of micro-organisms (Grade 1)

- Scopes:
  - all hinges around the 'criticality' issue
  - risks of false +ves (Grade 1 / 2)
  - documented outbreaks of multi-drug resistant Ps. aeruginosa cross infections – but don't know inoculation levels necessary or the risk from final rinse water (Grade 2)
  - Much agreement on the 'traffic light' approach (Grade 2)
Microbial Contamination – Willis (HPA)

- Proposed a series of action levels for endoscopy rinse water
  - 0/100ml – Satisfactory
  - 1-9/100ml on a regular basis - Acceptable - "reasonable level of Control"
  - 10-100/100ml - Unsatisfactory - investigate and super-chlorinate
  - >100/100ml - Unacceptable - remove from use until resolved
Microbial contamination - Proposal

- SSIs:
  - Due to terminal sterilisation step, relax to 1,000cfu/100ml

- Scopes:
  - Poor published evidence base for both sides of the argument
  - Pragmatically, good consensus for the Willis proposal
  - Draft HTM 0106 - use Willis system
  - Avoids unnecessary clinic cancellations
  - Undertake risk assessments
  - Question: could we consider the AAMI limit?
General Points

- General recommendation to use potable (drinking) water for reprocessing:
  - AAMI state that potable water can be used for precleaning, cleaning and rinsing of semicritical devices

- Recommend undertaking water analyses before installation of reprocessing equipment:
  - Check sources (eg: tanked water)
  - Consider any pipework replacement that may be necessary
  - Consider appropriate treatments
Next Steps

- Finalise the evidence sifting/grading
- Circulate to the expert group
- Complete the initial paper
- Produce a slimmed-down paper for publication
Any Questions?

- Pete Phillips
- pete@smtl.co.uk
- 01656-752820