The Central Sterilising Club Annual Scientific Meeting

Manchester, 1 – 2 April 2019

Wayne Spencer

This year's meeting was held at the Worsley Park Marriott Hotel & Country Club near Manchester. The conference was introduced by the chair of the club, Val O'Brien with the news that next year's conference dates had already been set and that it would be in Stratford-upon-Avon on the 30th to the 31st March 2020. As part of her opening address she relayed some interesting facts about Manchester although given the that it was April fool's day, some delegates seemed unsure as to which facts were true and which were made up. But indeed, it is true that William Cowherd from Salford near Manchester is credited with first advocating the theory of vegetarianism in the UK!

The Keynote opening presentation was delivered by Dr Robert Spencer. He began with some interesting quotes about science including a famous quote from Donald Rumsfeld "There are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns — the ones we don't know we don't know". This led to a discussion of null hypothesis and how it can catch the scientist out. He linked this to the UK BSE outbreak and its link to vCJD. He used the example of the early days of HIV as a known unknown and discussed future challenges such as robotic surgery, antimicrobial resistance and the future of the NHS. He saw protein detection as a continuing problem and stated that there were millions of viruses yet to be discovered and they were one of the great unknown unknowns! He formally declared the conference open and hoped that delegates enjoy the two days.

The Kelsey Lecture was delivered by Prof Dr Margreet C Vos, clinical microbiologist at Erasmus University Medical Centre. Professor Vos presented on the Failure of cleaning and disinfection of endoscopes. Her presentation mainly focused on duodenoscopes and the incidents around them. She stated that reported infections are the tip of a huge iceberg with risks around breaches in reprocessing and complex design. She presented work of Du et al showing post ERCP infections and reported that the organisms identified did not represent patients natural occurring flora. Although we now have better data, we still do not know whether most infections are related to a contaminated endoscope or not. Multi drug resistant organisms compounded the problems and she highlighted Carbapenem-Resistant Enterobacteriaceae as a particular issue. She discussed the 2016 senate report from the United States on multi-drug resistant organisms and endoscopy.

Vos highlighted the problem at her own hospital regarding issues with the Olympus TJF-Q180V duodenoscope and a pseudomonas aeruginosa outbreak. She discussed the changes in that particular endoscope design regarding the closed elevator wire channel and the fixed distal cap. The O-ring used to seal the elevator wire did not prevent contamination into the channel. As a result of issues identified they then undertook a nationwide study to see if other hospitals had a similar problem or if the problem was due to practices at their own hospital. The study found that 22% of endoscopes sampled had more than 20 CFU of contamination. 50% of endoscopes tested positive for gut flora. Swabs of elevator mechanisms and biospy channels were most contaminated and 53% of centres had a problem. Interestingly the survey data should no differences between new or old endoscopes.

She stated that comparing studies is difficult because they use different frequencies of sampling, different culture methods and different sampling procedures. She posed the question whether reprocessing was too complicated to ever be error free. Professor Vos then discussed biofilm and highlighted some papers that showed biofilm formation in endoscopes was quite common. In the second part of her presentation

she talked about possible solutions to the endoscope problem including:

- Microbial surveillance. She stated that this wasn't common practice in the Netherlands. All the published guidelines she reviewed from across the world had different indicator organisms and different sampling frequencies. In the Netherlands they decided frequency should be based upon prevalence and that first they should undertake a prevalence study. The actions to take would depend on the organisms found. She recommended forming a risk management team to decide on actions.
- Measurement of cleaning. She looked at ATP being used as a marker but warned it may not have a correlation to culture results. She highlighted the Sethi paper that used ATP testing to optimise reprocessing strategies. This paper concluded that education improved ATP results and that ATP testing may incentivise staff to adequately clean endoscopes. She also presented on-going work looking at whether using ATP as a threshold value for determining when to repeat manual cleaning led to fewer positive cultured scopes.
- Better inspection such as using a borescope. Vos discussed the Barakat paper from 2018 which looked at endoscopic evaluation of endoscope working channels with a high-resolution inspection endoscope.
- Double high level disinfection.
- Redesign of endoscopes/modification of endoscopes.
- Sterilization of endoscopes. However, for this point she warned that it was no substitute for good cleaning and that cleaning was still the most important step.
- Using only new or single use endoscopes. Vos however did report that papers show that even new endoscopes can be contaminated with organisms including gut organisms (Coton et al), and that this also comes with a high cost.

In discussing the above points, she compared papers looking at the success of these extra measures instigated in the US but stated that consensus as to which measures were most successful was difficult to arrive at. She summarised by saying that gastro-endoscopy had been associated with more HCA outbreaks than any other medical device. Prevention requires perfect reprocessing with a collective responsibility. Surveillance, teaching and monitoring was key.

After coffee there followed two corporate presentations. The first was delivered by Richard Bancroft of Steris. Richard's presentation discussed the use of test soils and surrogate devices to validate cleaning efficacy and considered the impact of changes to international standards in this area.

He stated that the changing regulatory landscape was a challenge for the future alongside new diseases and challenges such TSE's and that all this needed reflecting in changing international standards. He briefly discussed TSE death rates (including the sporadic forms as well as the more high profile vCJD cases) and how it impacted UK guidance with its 5μg per instrument side protein level. He posed the question as to how we could possibly measure instrument side on an endoscope with its complex lumens and geometry.

Bancroft outlined forthcoming revisions to the BS EN ISO 15883 series and the recent changes to Part 4 for endoscope washer-disinfectors. He also presented work being undertaken at ISO level to evaluate the performance of test soils so that test soils were determined on properties and not by their formulation. He stated that the future Part 5 would not necessarily contain lots of formulations for soils. There would be benchmarks for soil performance in terms of amount of analyte remaining after a standard wash process.

The second corporate presentation was delivered by Joy Markey of Clinipak. This presentation identified risk factor considerations for reusable wraps. Markey began by saying that we shouldn't lose sight of our primary aim which is preventing infection. She provided a packaging systems checklist, which stated that packaging should:

- Be appropriate for the items to be sterilized;
- Be appropriate to the method of sterilization;
- Provide adequate seal integrity;
- Provide an adequate barrier to particulate matter and fluids;
- Be able to withstand the physical conditions of the sterilization process;
- Allow both penetration and removal of the sterilant;
- Be able to maintain integrity of the pack after processing until used;
- Be resistant to punctures, tears and other damage that may break the barrier;
- Be resistant to penetration by microorganisms from the surrounding environment;
- Be free of holes;
- Be Non-liniting

She discussed the combinations of wraps types often used and stated that there was often lots of different combinations in the same department. There were also many different wrapping methodologies. She stressed that any fundamental change to the wrapping practice should be risk assessed and evaluated. The following process changes should lead to performance requalification:

- Changes to the number of layers of wrap;
- Changes to the wrap methodology (Markey later stated that these may also impact on end user aseptic presentation);
- A change in the strength/thickness of the wrap;
- A change of supplier/manufacturer;

She recommended conducting some trials of any new wrap solution before going live with a new product. This should include some sterility testing of processed product before the new method is rolled out widely. She concluded by warning against the presumption that wrapping materials can automatically be used as a suitable aseptic trolley cover to maintain the sterile field.

After lunch the conference continued with a debate. This year's debate was titled "This house believes that existing arrangements for external audit of decontamination quality management systems delivers critical assurance and value for money". Supporting the motion was David Pickard of the British Standards Institute and opposing the motion was Paul Jenkins of North Bristol NHS Trust. The motion was carried by a large majority despite some thought-provoking arguments offered by Mr Jenkins.

Paul Ceaesar continued the formal presentations with a talk titled "Sterilization of flexible endoscopes - take it or

leave it". Paul works at the Tjongerschans Regional Hospital in the Netherlands and offered a passionate and sometime controversial view. He discussed the accuracy of the data on reported incidents and said he was surprised that we should still be having problems so many years after these issues were first discovered. He argued that when the reprocessing instructions were 120 pages long, it was very difficult to comply with every step. The time required to manually wash an endoscope was shown to be 34 minutes in a paper by Ofstead et al but staff are never given this much time. He asked how many studies needed to be done before we act! He compared our willingness to keep using problematic endoscopes with the approach of the airline industry which recently grounded Boing 737 planes after two accidents. Ceaesar suggested that some low cost items such as buttons and valves can't be cleaned effectively and should be single use. He had introduced the use of single use disposable ERCP distal tips with a pentax scope within his hospital recently to try and reduce the risk and stated that it was time for a change in duodenoscope processing that involved sterilization.

Paul then presented some data from Dutch hospitals that showed good results with low temperature sterilization of some flexible scopes but said that cost often prevented adoption. He suggested todays reprocessing methods are based on cost and a willingness to live with the risk. It was argued that endoscopes should be routinely sterilized but concluded by saying that even with sterilization, the cleaning stage needs proper attention and there is never enough time allocated to the wash process.

This was followed by a two part presentation by Phillipe Destrez. The first part was about the forthcoming WFHSS guidelines and the second part about medical device manufactures evaluation programs for low temperature sterilization. Phillipe outlined the existing guidance and standards that will influence the new WFHSS document and stressed the importance of the revision to ISO 15883 Part 5. Phillipe also took the opportunity to highlight the development of the 3 new standards based around vaporized hydrogen peroxide sterilization (validation of the hydrogen peroxide process and a standard for biological indicators at ISO level and a sterilizer equipment specification at CEN level). He stated that the purpose of the WFHSS guideline was not to supersede the national documents already in existence but to find consensus across them and produce a document that set some minimum requirements whilst at the same time encouraging innovation. The document would review regulation and standards, review the Spaulding classification and encourage the improvement of IFU's.

In the second part of his presentation he discussed the medical device validation process when manufacturers of devices were proposing a low temperature process in their IFU's. This involved testing for both materials compatibility and device functionality in addition to sterility testing. He stated that manufacturers had a responsibility to develop sterilization systems for the future, but users had a responsibility to ensure that they followed the IFU's that were developed as a result.

The second day was commenced with a paper presented by Thomas Vanzieleghem from Onelife on biofilms and how to remove them. Thomas began by describing biofilms as a microbial community composed of multiple species developing on surfaces or at interfaces and encased in a self-produced matrix of polymers. He stated that 99% of bacteria live in biofilms. The biofilm matrix consists of DNA, polysaccharides, proteins and lipids of which the proportions vary and every biofilm is different. He described the four stages of biofilm development:

- Adhesion;
- Accumulation;
- Maturation;
- Dispersion;

He explained how resistance to antibiotics is stimulated by gene transfer between the bacteria in close proximity. Bacteria in biofilms are also more tolerant to biocides because of slow metabolism, limited diffusions of the biocide into the biofilm and absorption of the biocide into the polysaccharide walls. Biofilms were a major problem for endoscopes and he reported on several papers demonstrating biofilm issues with endoscopes as long ago as 2004. Ensuring endoscopes were cleaned as soon as possible was really important because as time goes on, biofilm formation and protein adhesion increases rapidly leading to a decrease in the ability to clean properly. Thomas reported that anecdotal evidence from France suggested that scopes returned from repair were often problematic due to the conditions in the workshop and use of oils etc. These may require additional cleaning.

Thomas concluded his presentation by describing some of the measures that can be used to either help limit or identify biofilms such as thorough drying of the endoscope, cleaning in a timely manner, regular inspection and sampling and culturing. He said that pressure to clean and turnaround endoscopes quickly was a major issue in Belgium that put additional pressure on staff and reduces the margin of safety. His final point was a reminder that killing (e.g. sterilization) is not a substitute for cleaning. This had also been a common theme from the speakers on day 1 and highlights the importance of the need for good cleaning regardless of the desire for sterilization.

The second presentation of the day was delivered by Professor Bill Keevil of Southampton University who discussed "Surfaces and surface disinfection: How clean is clean and how dead is dead".

Professor Keevil began where Thomas Vanzieleghem left off with the theme of biofilms but this time in respect of surface contamination. He showed images of biofilm on stainless steel endoscope components and others showing protein adherence to surgical instrument surfaces. These seemed to be linked to inorganic compounds present on the surfaces.

He then discussed how new technologies were redefining what we classed as "alive". Modern molecular or physiological methods like ATP and PCR testing were identifying microbial contamination that was not necessarily culturable or alive in the classic sense of the term. The question was asked did this mean it was not a hazard because we could not obtain a live culture on a plate? He described some of the new systems in use but stated there were still instances where culturing was more relevant than physiological methods. He showed a model system for helping with these concepts describing four states:

- Live (normal culture will show growth);
- Stressed (sub lethal damage capable of resuscitation);

- Viable but Not Culturable (dormant, incapable of normal lab resuscitation but showed evidence of high rRNA content, respiration); and
- Dead.

But the fundamental question was whether stressed or VBNC organisms present a risk to public health? Keevil reported some papers that showed these could be hazards. He reported on work by Giao et al in 2008 with chlorine stressed L pneumophila that showed non-culturable organisms that became culturable when exposed to favourable conditions. Examples were shown that demonstrated that disinfection performance could be overestimated if using culturable methods only. Work by Highmore et all used animal models to show that VBNC pathogens could still affect a host animal.

After coffee the subject matter changed away from biofilms with a presentation by Mike Ralph on the role of the principal engineer and plans to update the Health Technical Memoranda. Mike stated that he was originally employed by NHS Improvement but that today this was merging with NHS England. He discussed this transition and then offered a look back in time at the development of the Department of Health decontamination guidance. He said that although the future was still uncertain and subject to change because of the merger, NHS Improvement now had a dedicated guidance program lead with some resources and they had created a future standards working group. However, he stressed that funding was limited. Mike identified his role as principal engineer but stressed again that this was a time of change with the new organisation. He had a wide remit including decontamination, water, fire, ventilation and more. He discussed the arrangements for reporting estates "defects and failures" and "patient safety alerts" and said there was often overlap between them. As an example, the National Patient Safety Alert Committee would issue safety alerts but not necessarily all estates and facilities alerts. They were currently redesigning the Kahootz portal which would also issue estates alerts. He felt that duplicating alerts through NaPSA and Kahootz was better than the risk of professionals in the field missing them.

John Campbell gave a perfusionists perspective on cardiopulmonary bypass and mycobacterium chimaera endocarditis. John, from Nottingham University Hospitals NHS Trust, began by outlining the training and education requirements for perfusionists. He discussed the development of cardiac surgery in the UK and stated that heater coolers have almost been around as long as cardiac surgery itself. Heater-cooler devices are often necessary for use during surgery to warm or cool patients as part of their care and they are especially important for surgery involving the heart and lungs (cardiothoracic surgeries). The heater cooler is used to cool the blood and sometimes the patient by means of a heat exchanger system. This heat exchanger itself is stainless steel or polyurethane and has a heat range of 4 to 37.5°C. Mycobacterium chimaera is a slow growing non-tuberculosis mycobacterium and in 2015 an alert was issued by the UK Department of Health reporting infections in Europe linked to the use of heater coolers. Infections due to mycobacterium chimaera are extremely difficult to treat and the mortality rate is circa 50%. The original source of this problem may have been linked to water used to test the machines in the factory which meant that every machine sold could potentially be contaminated. After initially thinking they had avoided the problem, the hospital tested positive for mycobacterium chimaera after undertaking more strenuous tests. The measures to mitigate problem required weekly disinfection (taking 2 hours per machine) and daily water changes and this placed significant pressure on the cardiac team.

He then showed pictures of the contaminated tubing inside the machine. There were pipework dead-legs where optional circuits could be fitted which were reservoirs for stagnant water. These showed biofilm development. The hospital then invested in new machines but from day 1 started getting high microbial counts. In 2017 they issued a patient notification to over 3700 patients identified at risk. Manufacturers of the units issued a series of field safety notices identifying required updates in maintenance schedules and highlighting pipework failures. As part of these updated requirements from the manufacturer they were required to implement measurement of the hydrogen peroxide disinfection process to ensure a minimum of >100ppm concentration and this needs to be measured daily. This is supported by weekly alternate disinfection and water changes. He estimated the cost of compliance at nearly £30,000 per annum for three machines.

John stressed that in the future they need to work with companies to develop heater coolers that are water free and can be thermally disinfected. The machines need to be more robust as the manufacturers recommend disinfectant is destroying the machines in the long term. The latest field safety notice reports issues with leakage from sealing components and the need to resolve a nickel depletion issue by the fitting an internal water tank deflector plate.

The final presentation before lunch was titled "Sustaining the NHS" and was delivered by Rose Gallagher of the Royal College of Nursing. Rose expressed sustainability as an approach that allowed us to meet our own needs without compromising the ability of future generations to thrive and survive; but that this was only possible with support from nature. Yet many of the things we were doing were actually detrimental to nature and our world around us. This was shown with the example of global warming with a predicted increase in temperature of 1.5°C between 2030 and 2052. Climate change affects physical and mental health and therefore has a direct impact on healthcare. As part of this global system the UK NHS is committed to reducing its carbon emissions. Surprisingly use of anaesthetic gases represents 5% of acute hospital gas emissions and respiratory inhalers account for 4.3% of the health and social care sector's carbon footprint. We need to look at how we manage waste and focus on reducing plastic use.

Rose then discussed how this impacts upon decontamination services including areas such as management of waste, ethical procurement, reviews of single use versus multiple use items and local employment. Rose concluded with the example of glove use in the NHS. She relayed the sobering fact that over 4 billion gloves are used by the NHS annually and that this required 4 billion gloves to be disposed off. These are oil-based products and often there was unnecessary use of gloves.

Lunch was followed by the third corporate presentation from Damien Barrell of Advanced Sterilization Products who

discussed the new Sterrad ALLClear system. Damien began by discussing HAI rates in hospitals based on some data from the United States. He suggested that 28% of surgical site infections were down to ineffective decontamination and in particular, cleaning of endoscopes. He discussed the requirements of the sterile supply department, the surgeon and the hospital management. He stressed the importance of having processes available that were compatible with the new generations of medical devices and that sterilizer manufacturers should have programs for compatibility testing of new medical devices. He warned that compatibility of a medical device with one hydrogen peroxide process did not necessarily mean compatibility with another. Contact times, vacuum levels and sterilant concentrations in the chamber were all different. Damien concluded by outlining the new all clear technology fitted to their latest sterilizer that would prevent aborted cycles that needlessly used process consumables.

The fourth corporate presentation was about a solution for Trans-oesophageal probe disinfection and this was delivered by James Doherty of Wassenburg Medical. James gave an overview of a project that Wassenburg were undertaking to allow processing of a TOE probe in their endoscope washer-disinfector. He described the use of TOE probes in cardiology and cardiac surgery for providing ultrasound images. The challenge for decontamination was to be able to clean and disinfect the distal end while keeping the probe handle and connector area out of the process fluids in the machine. They designed a TOE probe case that encased the handle and connection area and would still fit inside their chamber.

After coffee Wayne Spencer presented results of a field trial of a new Process Challenge Device and discussed whether residual indicator amount reflected protein removal. The primary aim of the study was to look at cycle optimisation for new Washer-Disinfectors in order to get the best PCD results possible and to check whether this gave a correlation to better protein removal. The PCD used was a new type of device which gave a quantifiable residual level rather than the traditional type of PCD which only gives a pass/fail result. Four different detergents from three manufacturers were used during two separate trial stages. Detergent pH types ranged from neutral, neutral enzymatic, mild alkaline enzymatic and alkaline. He reported results that showed that changing the temperature had a far greater impact than changing wash time on the amount of residual indicator with the alkaline detergent and that increasing wash time never offset a decrease in temperature. He expressed surprise at the difference in remaining indicator for the three different makes of detergent with detergent A giving results in the region of 28% residual indicator at one end of the spectrum but detergent D at the other extreme giving results of 65%.

Part two of the trial used a residual protein measurement technique based upon Annex 3 of the German DGKH, DGSV and AKI Guideline from 2017 and compared residual protein with indicator result. Wayne reported that good indicator removal did not always correlate to lower protein results when comparing detergents. The difference in protein levels between detergent A with 28% residual indicator and detergent C with 65% residual indicator were minimal. However, he did stress that changes in indicator result for a given detergent once a baseline had been set, did indicate performance changes for the washer outcome. In his conclusions he stated that he thought that PCD's are useful, as changes in indicator removal performance do reflect changes in wash performance. However, as there is no standard for PCD performance which defines pass and fail endpoints (such as there is for BD packs), an indicator that gives you a baseline result may be more useful than an indicator that only shows a pass or fail. He ended with a warning that we should not chose a PCD just because it always shows a pass and that we should not chose our next detergent based only upon how well it cleans our process challenge device.

The final presentation of the meeting was provided by Fiona Kennedy of Applied Management Systems who discussed registration for decontamination units both now and in the future. Fiona began with a historical look at the varying standards and quality of sterile processing in the UK. She linked improvements to the particular UK requirement for NHS in-house reprocessing departments to meet the essential requirements of the European Medical Device Directive (whether those units were placing on the market or not). She reported that this became a Department of Health requirement in 2003. This led to centralisation of services, fewer units and improved standards. She explained that many SSD's previously utilised ISO 9001 as well as ISO 13485 but these standards have now diverged and the vast majority of sterile services departments will only continue with ISO 13485 systems. The 2016 version of ISO 13485 has introduced a more risk-based approach and as a result required SSD's to have additional purchasing controls, medical device files and validation of sterile barrier systems. The change to the Medical Device Regulations (MDR) from the previous directive were discussed and as part of the new regulatory framework, unannounced visits by notified bodies to UK SSD's were now included in audit regimes. Essential requirements have been replaced by safety and performance requirements.

Fiona discussed the impact of a no deal brexit and stated that the MHRA will take on responsibility for the UK market and the UK device regulations from 2002 will be amended to reflect the new European Medical Device Regulations and be implemented as the UK MDR 2019. She warned that certificates issued by UK Notified Bodies prior to brexit will continue to be valid but only for a not yet defined grace period! It is likely that UK Notified Bodies will continue to oversee these medical devices and their manufacturers to ensure on-going compliance. However, what happens when certificates need renewing is uncertain and whether UK units would need to still register when placing devices on a UK only market is still unclear. Fiona concluded with a discussion on whether hospitals needed to register with MDR as a manufacturer (as opposed to just ISO 13485 certification) and given the cost, should consider whether it is cost effective for small amounts of third-party work. There would be savings in just having an ISO 13485 audit rather than a full MDR audit.

Val O'Brien closed a very informative and well organised conference and invited delegates to the CSC study on September 16th, 2019 at the Belfry Hotel in Nottingham.