The desired outcome for the summit:

A list of priority issues that the healthcare community together can commit to address related to the reprocessing of reusable medical devices.

Keynote Presentation

Dr. Evelyn McKnight, HONOReform Foundation

- Mine is one of 130,000 stories
- She contracted hepatitis C during her treatment for breast cancer
- This wasn't discovered until she was at the hospital to undergo a second round of treatment for cancer.
- Ultimately she had the stem cell rescue treatment.
- They discovered there was an outbreak of hepatitis C infection in Nebraska
- Tested 4 cancer patients with elevated liver enzymes; all had hepatitis C. They had been treated for cancer.
- The state did an investigation and 680 patients were notified that they needed to be tested for the condition. 460 came forward to be tested. Of those, 99 patients were diagnosed with Hepatitis C.
- When they looked into the process being used, they learned that a syringe was being reused to access a multi-dose vial with solution that had been given to other patients.
- Housekeeping had found bloody needles on the floor. There were complaints from pharmacy, lab, nursing and patients.
- The complaints went to Dr. Javed, the Nebraska Excess Liability Foundation (NELF), and administration of the hospital where the clinic was located.
- The administration felt they didn't have jurisdiction because the doctor's practice was privately held and he rented space from the hospital.
- Ultimately, hepatitis C took the lives of 6 cancer patients who were in the care of the physician.
- Interferon was the worst treatment she had; even worse than her cancer treatment.
- There were 89 lawsuit, resulting from Dr. Javed's practice; $16m was paid from NELF.
- In past 12 years, there have been 40+ hepatitis C outbreaks in the U.S.
- Evelyn and her husband started a foundation to address this issue.
- This issue isn't exclusive to private practices.
- Over the past 12 years 130,000 people in the U.S. have received a letter, similar to what she had received, indicating they needed to be checked for hepatitis C.
The One and Only campaign [One needle, one syringe, only one time] has been designed by a coalition of mfg, professional orgs, and patient safety groups.

Outbreaks continue to affect many patients. I prefer to refer to patients as people.

If this can happen to a doctor's wife in the middle of the country, it can happen to anybody.

You are here to prevent a tragedy like the Nebraska outbreak to make sure it never happens again.

SESSION 1: Defining “Clean”
Ralph Basile, MBA, Healthmark
Victoria Hitchins, PhD, U.S. Food and Drug Administration
Chuck Hughes, SPSmedical Supply Corp.
Daniel Schwartz, MD, MBA, CMS/CMCS

Session goals:
Identify essential factors to be considered when defining “clean” for handling and further reprocessing.

1. Types of test soil being used; Test soil should mimic what is actually used in clinical practice.
2. I'm confused as an end-user as to how to define "clean."
3. Fact that many devices don't come apart; how do we ensure that lumens and crevices are clean?
4. We would like to have the instrument assembled and ready to go in surgery.
5. "Clean" is talking about measurement or verification. Issue is that generally manufacturers don't design the instruments to have negative controls to know what the baseline is. They get measurements off the instruments themselves and don't know what the numbers mean because baseline is higher than expected.
6. Sometimes you need something faster to save a life; you have to make a decision whether to use a dirty device.
7. Degrees of clean--clean, cleaner, cleanest.
8. Can we add disposable parts to the hard to clean areas of reusable items.
9. Timing of cleanings--In Europe any endoscope hung for more than 7 hours has to be recleaned.
10. Analytical endpoints and clinical relevance. At what level is soil going to compromise sterilization and disinfection.
11. Needs to have lack of toxicity associated with it.
12. We need levels--what soil, are we talking proteins; how much protein can we measure with analytical methods; it has to be balanced between easy to detect soil (e.g. protein or hemoglobin) or if we go with more complex soil.
13. How much protein or hemoglobin can we consider to be residual?

14. Clean is very visual to health care workers. The first inspection is what you can see; that's what constitutes clean until the instrument goes through various processes. We're having to rely on human factors.

15. Procedures are looking at what we can extract from the instrument, not what we can't extract; what's remaining after the extraction.

16. When you do validation for cleaning in the lab, it's fairly subjective. It may be better to validate devices that have been used in the field and returned and you go through reprocessing cycle to see if that works. 99% of time when you test in the labs, it ends up being cleaned.

17. Biocompatibility issue related to residual toxicity.

18. As patient, I want the device to be in same condition as new. Rendered in same state as new. We can struggle with measuring this, but the true measure is no possibility of adverse reaction.

Identify the greatest challenges to end user verification of the manufacturer-recommended device cleaning processes.

1) Make it simple
2) We don't have the facilities to clean; resources aren't there; sometimes cleaning area is small and other times huge. We expect same type of cleaning.
3) Cost is a challenge. Instructions need to be simple, cost-effective, and able to replicate by users with a wide variety of skills.
4) Mfg recommendations currently in place or do we need new recommendations? What we have now isn't working.
5) Some products we can't visually see if they're clean.
6) Wide range of medical devices to be cleaned on daily basis.
7) Lack of instructions on how to tell if the device is clean.
8) Standardized, simple process that is repeatable.
9) Different devices that look similar but have different readings. Users trying to interpret and compare readings from different mfg devices.
10) Multiple steps in the instructions are needed, but hard to follow. Need training and need to document that steps have been followed.
11) EU Medical Device Act says if you aren't able to follow the mfg instructions, you can't service the instrument.
12) Mfg only required to validate one methodology for cleaning or reprocessing. There may be one or more ways to clean or reprocess. If you don't validate for multiple methodologies, you might be limiting hospitals to use newer technologies that are more cost-effective.
13) Automated ways or simpler ways to clean/reprocess devices.
14) Pick one or two or three of most common practices used or preferred and have mfc
validate to all of those practices. Validate to current reprocessing modalities.
15) What do you do if you have instructions for use from mfc's that have been out for 20
years, limited instructions; and similar devices w/instructions that are very complicated?
16) Standardized, simple and realistic. It's not reasonable to repeat the process 3 times
when it is one of many, many steps.
17) Refine definitions.
18) Standards for the device and revalidation.
19) Marketplace reality that is a horizontal issue across the medical device arena; the people
using the devices have their favorite brands and models (today's or 20-year old); multiple
brands and sets of instructions. We can't change reality. Given that reality how do we
help the people in central sterilization cope better with the reality?
20) Marketplace needs to tell mfc's what is needed; e.g. make sure this is something I can
do in the hospital.
21) I haven't seen instructions that define how you are to determine whether something is
clean; they give you protocol, but no endpoint.
22) From mfc perspective, we need to work with customers. At same time, we have to scale
the bar set by FDA and create process that meets worst case challenges. We all have
to work together. The high bar that is set is very complicated.
23) If users choose to do a different process than mfc's, they need to validate it.
24) Mfc's are required to do worst case scenario (e.g. examples from presenters). This is not
how our devices are normally used. Users should not allow biomaterial to dry on a
device for hours before being cleaned. The requirement results in complex
steps/protocols that may not be necessary in a lot of cases.
25) Devices sit in OB for hours and hours, so matter does dry.
26) Physicians like certain instruments, but our job is to educate them to the outcome that
comes from using those instruments. Health care professionals own the process.
27) Reality is that it's not the majority of facilities that allow devices to sit for hours. Not
worst case scenario.
28) Outdated instructions. Push requirements to update old device instructions. Should be
updated on annual basis.
29) Endpoints would be a great benefit, but caution is when we say clinically or scientifically
relevant we are saying we have capabilities to reach those requirements.
30) We set defined structured cleaning regiments that mfc's have to validate. When one-off,
we say you have to qualify. I don't know how we address this in the states.
31) We don't do a lot of education at point of use. Most instructions don't focus on point of
use cleaning.
32) If pre-treatment is done, that could shorten the process.
33) We have to re-educate people constantly; we need to give respect and pay to the people
who are reprocessing; separate central supply from reprocessing. Elevate reprocessing
to the level we need it to be at.
Identify and prioritize the additional scientific evidence needed to assist in creating a uniform definition of “clean” for further reprocessing.

1) As mfc, one of the hardest things is that the existing literature is limited re: publication of acceptance criteria for an analytical test like TOC. Who is going to provide acceptance criteria for the rest of us?

2) We have lots of data on endoscopes. [Note: Audience doesn't assume this]

3) We lack data on surgical instruments, different components of them.

4) When we perform or write protocols, we need detail about levels of soiling. Do we need to include other parts of the device (e.g. handle of the device)? What is the best way to handle soiling?

5) U.S. standards vary in terms of level against Europe. We are working from financial point at much lower level.

6) How many cycles before a device is obsolete? How old is old? This definition should be established. How do you track cycles?

7) Scientific evidence is moving and dynamic.

8) We (mfc) are also asked (by FDA) to do prion testing. We don’t know how to do that.

9) Mfc's occasionally find that prion testing has been done. I discourage anyone from engaging in this kind of thing in terms of the waste stream. It’s extremely difficult to get rid of. Not everyone in the industry can engage in this. We need Prion activation studies.

10) We are not doing testing on single instrument. We are testing detergents and need to make sure the instructions are coming from the detergent manufacturer.

11) Show removable proteins rather than prion testing. This is way beyond mfc's capabilities.

Prioritize the top 3-5 challenges to be addressed in pursuing a definition of “clean” and identify corresponding goals to overcome these challenges.

<table>
<thead>
<tr>
<th>Prioritized Challenges</th>
<th>Goals to overcome the challenge</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Types of test soil being used; Ensure test soil mimics what is actually used.</td>
<td>Table until tomorrow's discussion on this topic</td>
</tr>
<tr>
<td>2. Fact that many devices don't come apart; how do we ensure that lumens and crevices are clean?</td>
<td>1. Make the design with fewer lumens</td>
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<td></td>
<td>2. Put disposable component on the device</td>
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<td>3. Right tool (brush size) to clean</td>
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<td></td>
<td>4. Design for it to be easy to disassembly and reassembly.</td>
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</table>
5. Identify parameters required to clean

6. Follow mfc's validated process instructions

3. Analytical endpoints and clinical relevance. At what level is soil going to compromise sterilization and disinfection.

1. Need data

2. Gather research to end up with goal of having consensus standard of compromise sterilization and compromising further process or "as is"
   - Needs to be safe and functional after being cleaned based on intended use
   - Clean enough for further effective processing--disinfecting or sterilization

4. As patient, I want a reprocessed device to be in same condition as new. We can struggle with measuring this, but the true measure is no increased probability of adverse reaction.

   - See #3
   - Determine how many times it can be used. (life cycle)
   - Need functional measurement of performance
   - Functionality is covered under reliability testing by mfc

5. Cost is a challenge. Instructions need to be simple, cost-effective, and able to replicate by users with a wide variety of skills.

6. Lack of instructions on how to tell if the device is clean.

7. Standardized, simple process that is repeatable.

8. Pick one or two or three of most common practices used or preferred and have mfc validate to all of those practices. Validate to current reprocessing modalities.

9. Outdated instructions. Push requirements to update old device instructions. Should be updated on annual basis.

10. We have to re-educate people constantly; we need to give respect and pay to the people who are reprocessing; separate
central supply away from reprocessing. Elevate reprocessing to the level we need it to be at (paying people).

11. As mfc, one of the hardest things is that the existing literature is limited re: publication of acceptance criteria for an analytical test like TOC.

12. When we perform or write protocols, we lack detail about acceptable levels of soiling. Question is do we need to include other parts of the device (e.g. handle of the device)? Best way to handle soiling

13. How many cycles before a device is obsolete? How old is old? This definition should be established. How do you track cycles?

SESSION 2: Design Issues with Reusable Medical Devices

Mark Duro, New England Baptist Hospital
Thomas Gilmore, Olympus America, Inc.
Mike Wiklund, PE, CHFP, Wiklund Research & Design

Session goals:

Identify the biggest design issues that need to be addressed.

1) Not able to disassemble/reassemble
   - Have to disassemble instrument to clean it. Much easier to clean if you don't have to disassemble it.
   - Users are going to disassemble devices that are not intended to be disassembled
   - Being able to reassemble and have it reassembled for surgery.
   - Something on the device that tells us it has to be disassembled.

2) Service life of product in the field; dynamics of evolving reprocessing so that the product remains validated. [material selection and chemistry of reprocessing]

3) Small and angled lumens [combine with 7]

4) Things that don't need to be washed by hand; clean by automated process

5) Complexity of the design; overdesigned

6) Devices aren't designed to be cleaned from the very beginning of the design process.
7) When device should be disassembled–before or after sterilization. [combine with 1]

8) Containers and trays come from mfc's--no rough protrusions and how they relate to sterility maintenance.

9) Rough surface finish of internal components [combine with 7]

List **what is impeding progress** in getting at these design issues.

**Biggest Impact and Shortest Time [highlighted]**

1) Money

2) Mfc's don't talk to each other or with those cleaning the products [combine with 9]

3) Technology advancements that make things more complicated and smaller.

4) Having at the cleaning done by those with the lowest level of education and training; doesn’t match to complexity of the devices.

5) Not knowing exactly what the FDA wants; lack of clear standards.

6) Newer materials may solve a lot of problems.

7) There has to be shared accountability. Health care providers have to adhere to processes or validate their own.

8) Long-term compatibility of device with standards and instructions.

9) Lack of data around what does/doesn't work (e.g. registry that collects info about best practices) in real clinical environment; needs to become part of feedback loop.

10) Devices don't look the same; patent issues.

11) Desire for standardization but no group that wants to create or govern the standards.

12) Environmental concerns--greening of our environment. Fewer disposables, green chemical compatibility issues.

13) New materials and solutions and accessories come about and receive FDA clearance, but aren't embraced in clinical guidelines that aren't updated often.

14) Total ownership cost of instruments and equipment, as well as employee salaries. Fully-loaded cost. Drive medical device industry to reduce overall cost.

**SESSION 3: Human Factors Considerations in Reprocessing Procedures and Instructions**

Sue Klacik, CCSMC, FCA, ACE, IACHSMM
Linda Condon, Johns Hopkins Hospital
Emily Hildebrand, Phoenix VA Healthcare System
R. Darin Ellis, PhD, Wayne State University
Session goals:

Identify human factors issues that manufacturers, design engineers, and end users must consider when establishing reprocessing procedures.

1) PPEs are very cumbersome; engineers need to take this into account.
2) Size of the brush--mfc's should identify what size of brush goes with each product.
3) Provide videos or photos showing assembly and disassembly.
4) If lots of parts to be assembled and disassembled, the parts need catalog numbers and be sold separately.
5) Provide a quick checklist of the key items in the instructions to put on the wall (don't need the warnings all the time).
6) Symbol that indicates if product needs to be disassembled.
7) Different levels of disinfectants needed, they can be switched inadvertently.
8) Implementation--Process that is phased in so we have all information coming to us in timely fashion, and all info comes at once. All changes at one time.
   - Terrified of 21CFR(11)--what are implications for electronic records and signatures?
9) Instructions should be simple to follow and standardized. Acknowledge that they must be detailed and are lengthy.
10) Instructions need to take into account who will be using them. Write them with input from the users and usability testing rather than for their employees.
   - 3 levels of human factors would have to be addressed [search, comprehend, apply]
   - We want them simpler, but need them to be more complex
   - Write for the lowest common denominator
   - Use symbols, but needs FDA approval and recognition
   - Instructions don't need to be written to 3 different levels of instruction
   - Place instructions into buckets [chunking them]; keep them clear, simple, standardized. Every mfc can follow the same template that is developed by a group.
   - When mfc writes IFU, it's to limit liability and fulfill FDA and Int'l requirements. Their purpose is not primarily to help the user.
     - If IFU aren't helping users, outbreaks will happen and consequences will go back to the mfc's.
   - Make sure we give the correct specifics with regard to brushes, for example.
   - Remember there are human decisions involved in the instructions.
   - Clear guidelines, standards and steps that everyone agrees to.
   - Caution of making instructions too simple and they will be ignored.
   - Keep the language simple.
11) Design different modes that would satisfy legal requirements (includes all cautions); beginner mode has more pictures; and expert mode that is more checklist.

12) Device mfc needs to build into the pricing the money it takes to train on disassembly and reassembly.

13) Symbols are good. Legal sign-off is required and then a lot of verbiage is added. Train lawyers!! Approach to lawyers: Inform them they are making it worse.


15) Ask FDA to clarify that when mfc makes significant changes, the IFU should be reevaluated for human factors (new problems created when trying to eliminate a problem).
   - IFU were developed with data of medical device and patient protocols. FDA then makes it a requirement.
   - You need the FDA to provide guidance on how to make your IFUs in the retrospective a little easier and not go through clearance process again.

16) There should be IFU written currently; quit listing all worst case scenarios. Need IFU that complies with regulatory standards and legal standards and instruction for the users. Two different documents! [e.g. Quick Start instructions for electronics]

17) Train people

18) Automate the system—Consistent results. [Benchmark the auto industry automation]
   - Economies of scale
   - Cost

19) Environment, skill set, time involved—If mfc's come together and decide it takes 60 minutes, you haven't addressed the issue that the users only have 16 minutes to do the process. Get back to the environment in which devices are being decontaminated. Hiring more people, providing more time, more sets of devices, etc.

**Identify the critical elements of feasible reprocessing processes** (e.g., number of steps, number of processes, etc.)

1)

**Identify the critical elements of clear instructional documents** for end users

1)

**Prioritize the top 3-5 human factors challenges** to be addressed

1) Time constraints
2) PPE
3) Resources
4) Training
5) Lack of automation
6) Environmental issues
7) Qualifications
8) Lack of pay
9) Information--related instructions for use
10) Literacy
11) Adult learner methods
12) Technology
13) Bad habits and sacred cows
14) Infection control
15) Implementation path
16) Ethnically diverse workforce
17) Physical incapacities (e.g. color-blindness)
18) Workflow inefficiencies from outdated facilities
19) Feedback for performance
20) Accountability of users, of employers and clarity of who is accountable

SESSION 4: Competency Requirements for Reprocessing Staff
Ramona Conner, Association of Perioperative Registered Nurses (AORN)
Marilyn Hanchett, RN MA CPHQ CIC, APIC
Sue Klacik, CCSMC, FCA, ACE, IACHSMM
Eileen Young, RN, CNOR, Olympus America, Inc.

Session goals:

Current challenges and barriers to implementing core competency requirements in
variety of settings.

1) Certification requirement
2) Root cause of lack of recognition of importance of infection control across the industry;
   Starts with education of top-level administration that they need to spend the money and
   support the efforts.
   • Infection prevention is everybody's business
   • Getting risk management involved
Create a business case for infection prevention.

3) Easy to say we need to require certification of CS professionals; obstacle is at state level it is a 3-5 year process. We need a requirement to come from FDA, CDC, Joint Commission or other regulatory agency.
   - Not just certification; ensuring they remain competent
   - Maybe require 2-year degree and minimum pay comparable to the competencies

4) Routine inspection of CS departments

5) Demand is higher than trained professionals; not a lot of training programs available. AST program provides very little CS training. CS training should be enhanced on AST side. [combine with 3]

Essential criteria to ensure proper reprocessing

1) Experience
2) Education
3) Physical abilities
4) Appropriate resources:
   - required equipment in each type of facility (ambulatory surgery center, hospital, etc). Adequate facilities (e.g. space)
   - Adequate staffing with appropriate pay
5) Performance based measurement/benchmarking
6) Clear, standardized, repeatable standards and processes.
7) Validated IFU
8) Adequately trained manufacturer's reps
9) Ability to obtain good training from manufacturers

Top 3-5 criteria to assist in developing standardized core competency requirement and continuing education program

1) Mandated certification
2) In-house educators
3) Cooperation/collaboration between different departments
4) Good training from and for the manufacturers
5) Standardized excellent educational materials

First Day Wrap-up
SESSION 5: Reprocessing Standards Activities
Joe Lewelling, VP Standards Development, AAMI

- A large knowledge base of different organizations works on the AAMI Standards Program.
- AAMI works domestically and also holds the secretariat of ISO/TC 198, Sterilization of health care products.
- Every time a problem is solved, new ones arise, primarily because technology is changing.
- As technology changes, it requires use of new materials; often those materials don't work well with old equipment.
- It is not only the processes but the practices that cause writing standards to be very difficult.
- Changes in technology lead to higher expectations from the health care industry.
- If instrument design doesn't consider the reprocessing needs, the instrument can be dangerous.
- There are ISO and AAMI standards for reprocessing that address how to validate instructions and provide clear instructions to users of devices.
- ST79 is the most notable guideline for sterilization and sterility assurance in health care facilities
- A lot of health systems are using steam sterilization incorrectly. Steam sterilization consists of a wide range of processes. The use of the term "flash" sterilization has been replaced with "immediate-use steam sterilization."
- We've heard a lot that bad practices can lead to serious conditions in patients. The community as a whole is working hard to prevent these infections. Hospital acquired infections from improperly reprocessed medical devices are rare.
- Standards catch the state-of-the-art; they aren't good at pushing the state-of-the-art.
- In addition to this Summit, AAMI has new working groups on various aspects of this problem-- namely, endoscope reprocessing and human factors for device reprocessing.
Standards don't solve problems; they help. It's not just up to us. People have to use the standards.

SESSION 6: Considerations for Selecting Test Soils and Evaluating Biomarkers
Trabue Bryans, WuXi App Tec, Inc.
Emily Mitzel, Nelson Laboratories, Inc.

Validation--If I clean the device this way, it will be acceptable for use
Verification--Did I clean the device in the appropriate way so it is acceptable for use?

Session goals:
Reach consensus on the necessary criteria for clinical relevance and worst case test soil (including use of worst case healthy vs. worst case diseased human secretions in guiding the choice of test soil for a validation study).

1) Continue to use microbial markers in conjunction with other markers.
   • Concern that it is too variable.
   • You can get approval without the biological markers.
   • If the marker adheres to the device, you can't measure it.
   • We don't want to look at microbial markers as the acceptance criteria, but keep them while we explore newer types of markers and measurements.

2) Ensure test soil mimics what the device is actually exposed to in clinical practice (i.e. bone, cement).
   • Internal channel of a 16 inch device was extremely difficult to clean. The test soil needs to mimic what the device is exposed to in clinical practice.
   • Consider use of worst case healthy vs. worst case diseased human secretions in guiding the choice of test soil for a validation study.

3) FDA is looking for something that is direct measurement of clinically relevant soil.
   • Sensitivity to detect the test soils based on extraction method.
   • Radioactive tag; short half-life

4) Do some of the testing at the hospital as part of the process for validation. [Pre-market testing]
   • We can't have hospitals involved because devices can't be used on patients before they are cleared by the FDA.
• Removing the worst-case condition--device in use for several months. Worst-case condition is different when the device is new and shiny. Adhesion is much different.

5) **Post-market testing of devices.**

• Do testing after the instrument has been in use for a while. "Confirmation"

• If it's not FDA cleared device, you can't use it in a patient.
  – You can get IRB approval.
  – Use instruments repetitive simulated use.
  – Simulated use of the device so it's not clean and you can deal with this issue.
  – You can't simulate that a device has been in use.

• This is about improving recommendations.

• Post-market testing similar to what we see in pharmaceuticals. After device is out there, need opportunity to report back issues. Period of time where FDA is collecting data about breaches or adverse events.

• Mfc's are responsible for post-market surveillance. Orgs should make improvements post-market.

• There are things going on in use that cannot be replicated in the mfc's lab.

Proposed Solution: We need a standard, scientific process for cleaning QA in the health care setting.

6) Spore reduction can be clinically relevant if you have evenly dispersed spores through the soil. [Spore loads]

7) Minimum load that can cause infection. Could there not be any soil, but enough microbial material for infection?

• Handle it with disinfection and sterilization

8) **Int'l effort within ISO for better definition of test soil. Standardization of test soil around the world.**

• May not be simple (e.g. devices used during spinal surgery depends where on spine the device is being used).

• ASTM workgroup looking at test soils, part of F04 medical device group.

9) It's impossible to define series of test soils for every possible scenario. Address worst-case scenario.

10) 3-tier approach--visual, general non-specific method (e.g. TOC); protein or carbohydrate analysis. Soil needs to contain these markers.

11) You don't have to remove soil completely from the surface; establish your recoveries and apply that to your analysis.

12) It's not just the marker issue, it's the design of the product. If mfc doesn't understand that you can't effectively clean it, it goes back to the design. **We need to define that the mfc is responsible to validate cleaning method to most difficult cleaning location.**
We are working in a free market. Users need to notify the mfc if there is a problem with cleaning the devices.

13) Communication feedback loop with the mfc--Is it working?

- Customer feedback and communication is very important in the mfc's processes. Is there a feedback loop in the CS to get info back to the mfc that occurs prior to a problem occurring?
  - Acceptable ways of reporting.
  - Ensuring the info gets to the mfc from the organization when it's reported.
  - Mechanism is in place to feed complaints back to the mfc. In my company, we train sales reps that when complaint is received, they report it to their internal regulatory affairs dept.

- Mfc's are responsible for ensuring that devices can be cleaned or reprocessed effectively. [e.g. seal the material on the surface of the device]

- Every company has a site that provides contact information to submit complaints.

- Mfc's say they train their sales reps and responders to complaints.

Proposed Solution: If customer complaints aren't resolved, we want them to call the President of the company or the FDA.

- Mfc's should build in the feedback loop that users say they want.

Process:
1. Sales rep
2. Customer service; say, "I need an answer by...."
3. Upper management or MedWatch

- Unless you have buy-in from top administrators in the organization, you cannot use the MedWatch loop to provide feedback.

- Address 510k issues re: mfc taking info from this Summit to make changes in design.

- If redesign is needed, or any change impacting safety and effectiveness, it would require approval.

- FDA role in breakdown of communication is MedWatch. Heard that MedWatch is too intimidating.
  - If user isn't getting action by mfc, they have opportunity to submit it to the FDA.
  - FDA can authorize changes, studies to validate methods, etc.
  - How can we develop a better communication mechanism through the FDA?
  - Don't have to use the entire Form 3500.
    - Write out detailed clinical description.
    - MedWatch can help the user fill out the forms.
The new AAMI benchmarking tool could be a real aide. If we could get hospitals of different sizes to input data, it would help mfc's understand the tools and how they are used. **Action:** Mary will take this back to the office for consideration.

14) Systems issue--deeply embedded cultures within industry and others are getting in the way with solving some of these issues.

- In hospitals, CS isn't buying the devices; physicians are; purchasing departments are purchasing based on cost, etc.
- Look at processes inside the hospitals where products are purchased, used, maintained and reprocessed. **[AAMI could coordinate different orgs coming together to address this.]**
- re: leaders in the CS who are here have this frustration, there are many other orgs out there that don't have CS leaders
- AORN has recommended purchasing decision guidelines.

**Identify greatest challenges test soils and validation endpoints present relative to worst-case simulated validation studies.**

1) Identifying the best types of tests for what is clean.
2) Why are different types of instruments out there; it causes a multitude of variability. Core question FDA is asking is, "What is clean?" Contaminant should be reduced so device is safe for subsequent patient use. It won't interfere with something during processing.

**Prioritize the top 3-5 challenges to be addressed regarding test soils and cleaning validation endpoints.**
SESSION 7: Standardized Reprocessing Requirements and Terminology

Rose Seavey, Seavey Healthcare Consulting, Inc.
Rod Parker, Stryker

Session goals:

1. Identify the requirements and terminology that can and should be standardized across all devices that are intended to be reprocessed.

Categories:

A. DECONTAMINATION

CLEANING--soil or microbial removal

1. Pre-cleaning point of use
2. Removal
3. Acceptance criteria for cleaning
4. Scrubbing
5. Visible
6. Brushing
7. Disassembly
8. Detergent
9. Flushing
10. Mechanical cleaning
11. Manual cleaning
12. Rinsing
13. Pre-processing
14. Soaking
15. Ultrasonic
16. Lubrication
17. Necessary tools
18. Identifying brush size
19. Drying process
20. Wiping
21. Water quality
22. Temperature
23. Solution
24. Concentration
25. Duration of time for cleaning
26. Agitation
27. Articulation
28. Immersion
29. Pressure
30. Suctioning
31. Enzymatic
32. Thoroughness or thoroughly
33. Alkaline
34. Routine
35. Hospital policy
36. Warm--provide specific temps or ranges
37. Manual
38. Mechanical
39. Immersed
40. Non-immersed

**Action:** AAMI will coordinate cross-representative group of stakeholders to meet to define these terms.

- Put the definitions in the standardized IFU document
  - May 1 guidance document from FDA
- We need the detail along with the descriptive word (e.g. scrub--how?)

**Process:**
1. Search for existing definitions and review those. Accountable: Joe
   - AAMI's existing documents
2. Define through Standards Working Groups.
3. Develop the grid that includes Methods/Conditions/Criteria
4. Publish the glossary; widely distribute and communicate about it

**B. DISINFECTION --removal of organic and microbial contaminants**

[1) from standpoint of making instrument safe to handle for further processing; 2) prepares instrument for next patient]

*Spalding's Classification* spells out the levels of disinfection and what to do.

- Low, intermediate and high
- Thermal disinfection
- Chemical disinfection
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- Environmental
- Pasteurization
- Safe to handle

C. STERILIZATION
- IUSS (immediate-use steam sterilization)
- flash, fractional, steam, gas
- Types
- Cycles [those validated for the U.S.]
- Time and temperature
- Sterility assurance levels
- Pressure
- Indicators
- Packaging
- Humidity
- Drying
- Wrapped
- Cool-down
- Aeration
- Container
- Positioning
- Unloading
- Loading
- Load limit
- Load types
- Density

Issue:
Lack of clarity of definitions we’re currently using. Need a glossary of standardized terminology and definitions.

2. Gain consensus on those requirements.

3. Discuss the importance of consistent terminology and use across all points of contact within a manufacturer.
   - Consider who is the intended user of the IFU
   - Certified, trained users of the devices
   - Follow standard format for IFU
     - consistent terminology
     - Section that defines the standard [e.g. ISO 17664; ISO 11139]
   - Lack of objective measurements for some terms (e.g. clean)
   - Consider the different settings in which the devices will be used, cleaned, etc.

ACCEPTANCE CRITERIA
1. If we identify the level of what is clean (e.g. how much protein can be left on the device after cleaning), we can come up with the specificity.
   
   Endpoints
   
   •

LEVEL OF SPECIFICITY [Things to consider]
1. When talking about detergents, temp ranges, certain pH levels, times, amounts--we need ranges.
2. Where there is an instruction that has high risk for interpretation or high risk of ambiguity, provide details
3. People need to follow IFU for detergents as well as devices

CLARITY ON TERMS [5th grade level]
1. Thorough

Actions:
1. Short-term, AAMI will take the outcomes to sterilization standards committee by end of the month.
2. Long-term, we will continue to work with all of the other organizations.

As Joe goes forward to develop this issue, I hope they consider __________.
SESSION 8: Establishing Action Plans and Deliverables from the Summit

Session Goals: See Master List of Priorities

1. Identify the top 5 priorities on the Master List according to importance and impact on patient safety.

2. Identify the potential timeframe of “addressing” or “fixing” each issue.

3. Identify stakeholders that should be involved in addressing the priorities.

WRAP UP

Have we gotten out in the open all of the obstacles?

- Scientific research is needed to determine some of the solutions; who is going to fund this?

- Lack of overall communication and urgency, not with the people (e.g. mfc's and health care providers) in this room, but those that aren't present.

- How do we get communication out to everyone that industry and health care providers need to work more closely together? This is high-level barrier.
  - New manufacturers
• Manufacturers have to figure out how to develop processes that are most efficient and less time-consuming. Health care professionals have to commit to following the processes.

• Kinds of research/data--level of soil, disinfection, amount of soil left on typically clean device, testing on new device vs. used device

• We need to stop pointing fingers. Everyone needs to take accountability.

• Technology hasn't been static for 20 years, so some of the problems are newly created.

• Certification of techs needs to be mandated.

• We don't have all of the stakeholders here. Those focused on cleaning the device, and those focused on designing the device for the medical professional. Innovation of medical devices and what physicians demand/need--what are the mfc's going to put their resources into.

• Who is going to enforce and ensure these things happen? Institutions agree to comply with standards, but base purchasing and organizational decisions on cost.

• Technology for reprocessing--some chemicals are highly toxic. We are looking to mfc's of detergents to provide better products and support our needs in terms of cleaning, better ways to clean, etc.

• Industry needs help from the FDA to be supportive in getting changes through the approval process quickly and painlessly as possible.
  – FDA can sometimes move rapidly if they have consensus on something.
  – What's doable:
    o Standard operating procedures to revise labeling to adequately clean devices based on real-world experience
    o Develop document that's agreeable to the users
  – We have to think about the entire universe of medical devices.
  – We have to keep public safety foremost in our vision.

• Getting the attention of senior management in hospitals that this is a priority. There is something that multiple orgs can do together to make a compelling case.

• Recommendations and guidelines don't have to be followed.