Reprocessing Guidelines for Basic Neonatal Resuscitation Equipment in Resource-Limited Settings

Introduction Workshop

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Reprocessing for Basic Neonatal Resuscitation Equipment Workshop Agenda

8:00–8:15am	Registration
8:15–8:45am	Welcome and introductions
8:45–9:00am	Pre-test
9:00–10:00am	Reprocessing theory
10:00–10:15am	Tea break
10:15am–12:30pm	Hands-on reprocessing stations
12:30–1:30pm	Lunch
1:30 – 1:40pm	Post-test
1:40–3:45pm	Small group discussion
3:45–4:00pm	Tea break
4:00 – 4:45pm	Report on small group discussion
4:45 – 5:00pm	Workshop evaluation
5:00–5:15pm	Distribution of certificates of participation

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Introduce facilitators

Objective and aims of the workshop

OBJECTIVE: To introduce the new reprocessing guidelines for basic neonatal resuscitation equipment. The workshop will develop the expertise of the attendees and equip them with tools to implement changes both nationally and at facility level.

SPECIFIC AIMS

At the end of the workshop, participants will be able to:

- Describe the new reprocessing guidelines and be familiar with all reprocessing steps.
- Understand the rationale for each step.
- Understand strategies to improve reprocessing of neonatal resuscitation equipment both nationally and at the facility level.
- Be able to use and improve upon templates for training content, flow, and materials.

Introduction

- **Reprocessing**: multistep process to clean, sterilize/high-level disinfect (HLD), and store reusable medical equipment to make it safe for use on next patient.
- Any object in health facility can serve as vehicle for transmission of hospital-acquired infections.
- Although resuscitation equipment may look clean, it can still harbor microorganisms (including the inside of the ventilation bag).
- Gram-negative bacteria thrive on **insufficiently reprocessed** or **improperly stored** medical equipment and are known to cause outbreaks.
- **Adequate reprocessing of medical equipment is essential to helping newborns survive.**

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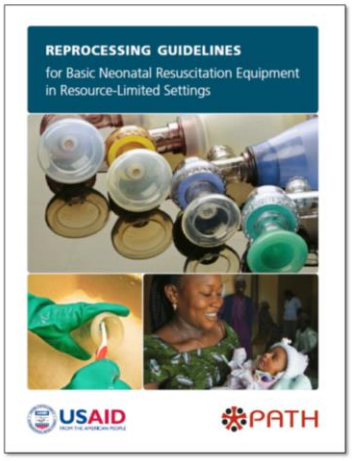
- The term “Reprocessing” may also be called “Processing” in some countries.
- Nearly 50% of early-onset neonatal bloodstream infections are due to gram-negative bacteria
- Microorganisms or chemicals remaining inside the ventilation bag can be ventilated into the infants lungs.

Content of guidelines

- Focus on basic neonatal resuscitation equipment to support Helping Babies Breathe implementation.
- Overview of reprocessing materials and equipment.
- Space planning and workflow.
- Detailed, step-by-step reprocessing instructions for each piece of equipment.
- Training and supervision considerations.
- Considerations for health facility administrators and ministry of health (MOH) officials.



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The development of new guidelines were first considered after anecdotal reports by HBB trainers and others involved in neonatal resuscitation activities about the level of reprocessing that was undertaken for this equipment and the infection risk that it posed to newborns. These reports came from a number of different countries.

PATH was tasked with leading this activity. An observational and qualitative reprocessing assessment was first conducted.

This assessment provided insight for the development of these guidelines.

Process to generate guidelines

- Recommendations based on the best available evidence as of November 2015.
- When no literature existed, a consensus process was used.
- Factors identified during a reprocessing assessment conducted by PATH were considered while developing recommendations.
- Guidelines underwent both internal and external review.

Members:

Process Leaders:
- **Manjari Quintanar Solares**, MD, MPH, PATH
- **Siobhan Brown**, MPH, CPH, PATH

- **Sherri Bucher**, PhD, MA, Indiana University School of Medicine
- **Annie Clark**, CNM, MPH, University Research Co., LLC
- **Pegeen Eslami**, MD, University of Massachusetts School of Medicine
- **Jennifer Gilbertson**, MSE, Laerdal Global Health
- **William Keenan**, MD, St. Louis University School of Medicine
- **Frode Liland**, MSc, MBA, Laerdal Global Health
- **Goldy Mazia**, MD, MPH, Maternal and Child Survival Program (MCSP)/PATH
- **Indira Narayanan**, MD, Independent Neonatology Consultant; Adjunct Professor, Georgetown University Medical Center
- **Susan Niermeyer**, MD, MPH, Helping Babies Breathe Editorial Committee/American Academy of Pediatrics; University of Colorado School of Medicine
- **Magdalena Serpa**, MD, MPH, MCSP/PATH
- **Michael Visick**, MD, MPH, Helping Babies Breathe Editorial Committee/American Academy of Pediatrics; Latter Day Saints Charities

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Spaulding Classification System

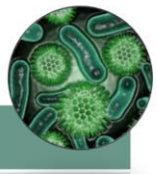
Critical Items: Objects that enter sterile tissue or the vascular system and pose a high risk for infection if they are contaminated with any microorganism. Includes: surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities, etc.

Semi-Critical Items: Objects that come into contact with **mucous membranes or nonintact skin**. Must be **free from all microorganisms, but a small numbers of bacterial spores are permissible**. Includes: respiratory therapy (including **resuscitation equipment**) and anesthesia equipment, some endoscopes, esophageal manometry probes, cystoscopes, and diaphragm fitting rings, etc.

Photo credit: PATH/Jillian Zemanek

Non-Critical Items: Objects that come in contact with intact skin but not mucous membranes. Intact skin acts as an effective barrier to most microorganisms. Includes: bedpans, blood pressure cuffs, crutches, bed rails, floors, and patient furniture, etc.

Levels of disinfection for medical equipment



Disinfection level	Spaulding Classification	Microorganisms killed
Low	Non-critical (depends on equipment purpose)	Vegetative bacteria (except *M. tuberculosis*), some fungi, and some viruses.
Intermediate	Non-critical (depends on equipment purpose)	*M. tuberculosis*, vegetative bacteria, most viruses, and most fungi, but does not always kill bacterial spores.
High	Semi-critical	All microorganisms except some bacterial spores, particularly if there is heavy contamination. HLD is the MINIMUM required for semi-critical items. Sterilization also appropriate for some semi-critical items.

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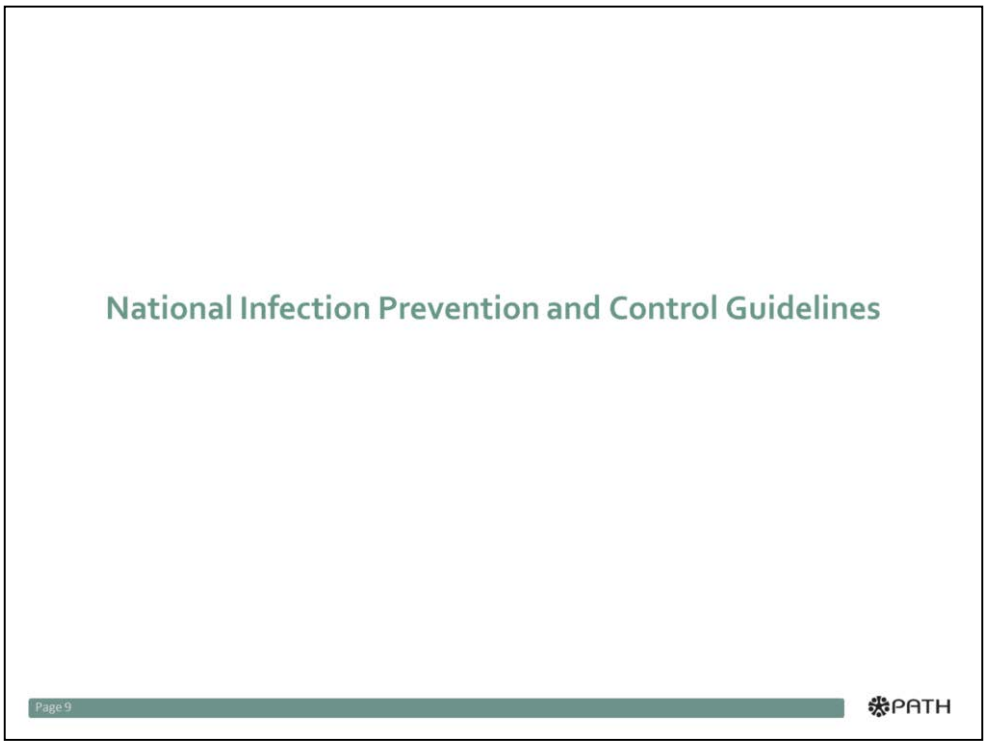
- Low-level kills: *Staphylococcus aureus, Salmonella typhi, Pseudomonas aeruginos*a, HIV, herpes simplex, and hepatitis B & C viruses.
- Intermediate-level kills: all killed by low-level disinfection plus *M. tuberculosis*, polio virus, rhinovirus, *Candida,* and *Aspergillus*.
- High-level: Achieved chemically by soaking equipment in the correct concentration of a disinfectant and during the correct time and temperature. It can also be achieved by boiling or steaming the equipment for 20 minutes.



- Describe/show your country's current infection prevention and control (IPC) guidelines that describe reprocessing of reusable equipment.
- Are participants aware of the existence of these IPC country guidelines?
- Compare country IPC guidelines with the new Reprocessing Guidelines: Which steps are described? Do they go into detail of how to conduct each step? Are recommendations aligned?
- Pay special attention to terminology used. "Decontamination" is sometimes confused with "Disinfection". " Point out to the change in terminology that was decided for the new Reprocessing Guidelines: the purpose of "decontamination" (now called "immediate

pre-cleaning” in the new Reprocessing Guidelines) is to protect the health worker from viruses while handling the equipment. However, it does not achieve “disinfection” which is the step needed to protect the baby. Since these terms get confused easily in different documents, the expert group who developed the new guidelines decided to not use the term “Decontamination”.

Reprocessing assessment

Conducted in Uganda in 2015 in urban and rural facilities.

- Nine facilities: Health Center III, Health Center IV, district hospital, regional hospital, national referral hospital.
- Thirteen units: labor wards and special newborn care units.
- Sixteen participants: nurses, midwives, nurse/midwives, student nurse. Included supervisory roles. Experience ranged

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- Availability of Guidelines: 23% of units (3 of 13) had posted guidelines, but only one participant was aware of them. One unit had posted reprocessing guidelines that described reprocessing with a chemical that was not available in the facility.
- Supervision of and training for reprocessing varied widely both at facility-level and within individual units. EXAMPLE: staff in same unit gave very different responses to questions about supervision and training.
- Available equipment and process: EXAMPLES:
  - one unit had Cidex (glutaraldehyde) while another in same hospital did not.
  - 69% of units had access to an autoclave, but only 27% of those used it for resuscitation equipment

(suction bulb only).

- Other commonly observed things include:
    - Single-use devices frequently reused.
    - Ventilation bag was wiped with chlorine, but no further cleaning or disinfection.
    - Mask was washed with soap and water
    - Suction bulb was generally the only piece that was fully disinfected/sterilized.
    - Bleach solutions were not always diluted properly.
    - Equipment stored in open containers.

- Top row: a “clean” mask with debris and spider, a mask without an air-filled cuff (will not seal around nose/mouth of infant), rusty storage container and metal instruments that could puncture silicone resuscitation equipment.
- Bottom row: JIK (bleach) bucket without a lid, reprocessing a single-use device, container with bloody equipment with water that was also used to scrub resuscitation equipment.

Equipment: Single-use vs. reusable

Single-use equipment is not designed to be disassembled or withstand disinfection. It should be discarded after one use. Reuse of single-use equipment poses an infection risk to infants. One way to identify single-use equipment is to look for text imprinted into the equipment such as "single-use" or ⊗ .

Photo credit: PATH/Manjari Quintanar

Photo credit: PATH/Siobhan Brown

Reusable resuscitators may state "autoclavable," "reusable," or "silicone."

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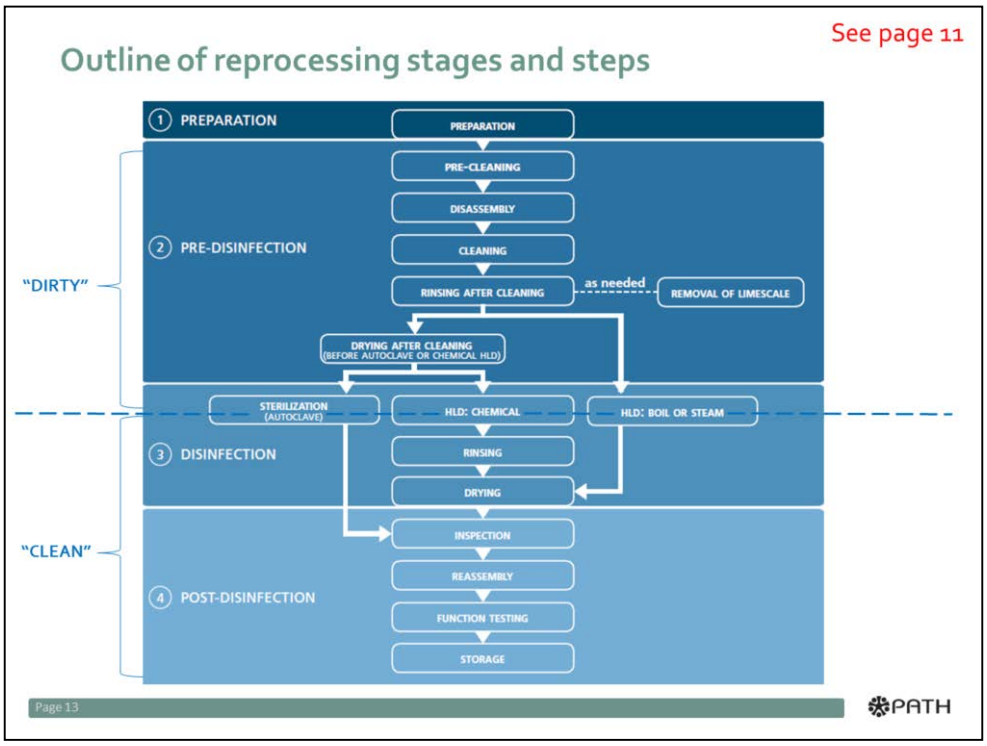
There are reusable suction bulbs too (you must be able to open them). Laerdal penguins are not the only reusable suction devices.

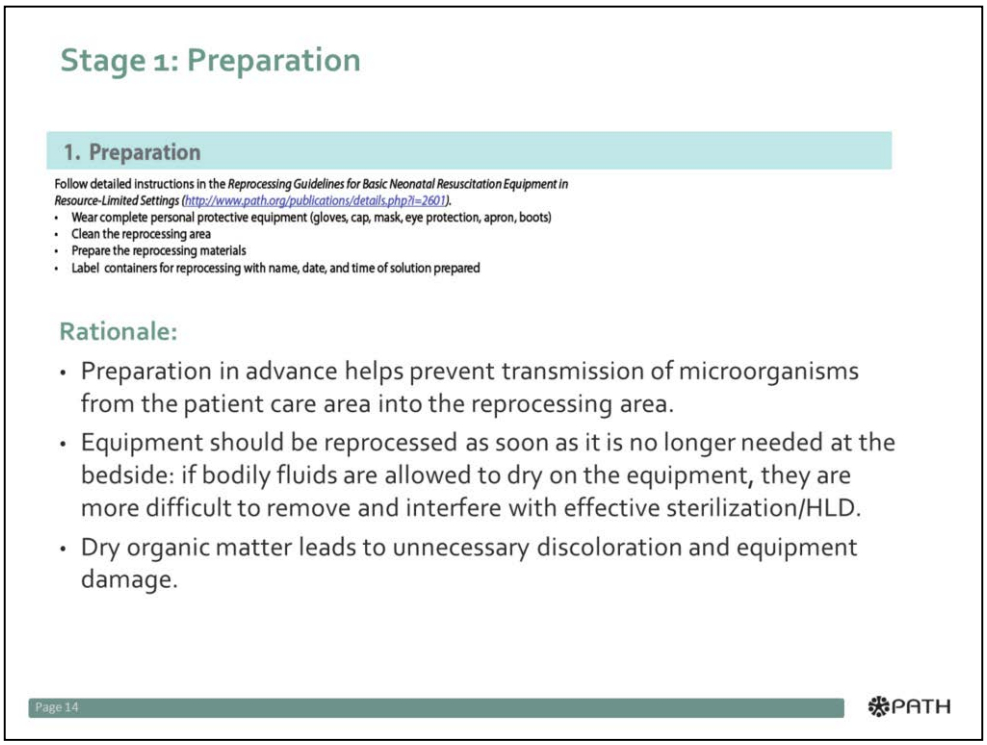


- Although reprocessing is comprised of a series of steps that must be followed to achieve equipment that is safe to use on newborns, these guidelines offer multiple options for disinfection of the equipment. The guidelines were designed this way to allow facilities to choose the method that works best with the resources they have available. For example, although the preferred method would be to autoclave the resuscitation equipment, not all facilities have an autoclave available for this purpose. Therefore, they can choose from another option such as boiling, steaming, or chemical disinfection based on the resources that they have.

- Point out to stages and briefly mention what is happening in each one (preparing everything; making item safe for

handling and ready for disinfection; disinfecting-actually making safe for reuse; checking proper function and storing safely).

- Describe more about disinfection methods. Two options for chemical disinfection have been described (chlorine or glutaraldehyde) and two options for thermal disinfection (boiling and steaming).
- Remind participants that equipment is not ready to be reused until it has gone through all steps (through function testing).
- Explain “Dirty” and “Clean”



Display the reprocessing general job aid, and point to the sections you are referring to as you go through this and the next slides.

Personal protective equipment

- Gloves (two types)
- Cap
- Mask
- Apron
- Eye protection
- Footwear

Utility or exam gloves

and

Sterile or HLD gloves

Photo credit (all): Creative Commons

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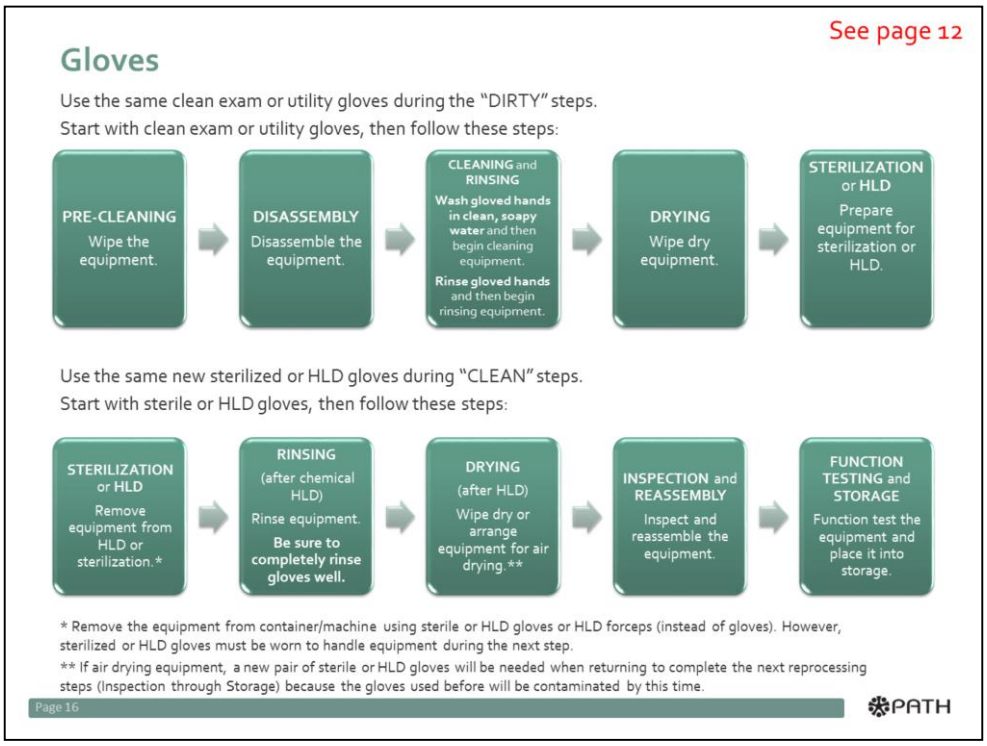

- Gloves are in short supply, so we considered ways that gloves could be used without wasting while preventing recontamination of the equipment.
- Clean utility or exam gloves can be worn for initial steps, but sterile or high-level disinfected gloves must be worn once equipment has been sterilized/disinfected.
- Never wear torn or punctured gloves. Never wear the same gloves that were used for patient care or to clean the delivery area.

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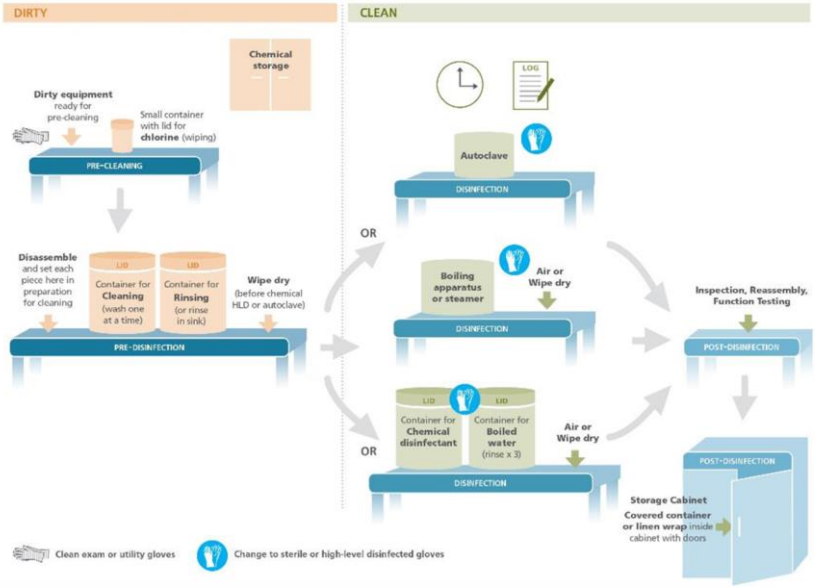
Reprocessing space layout



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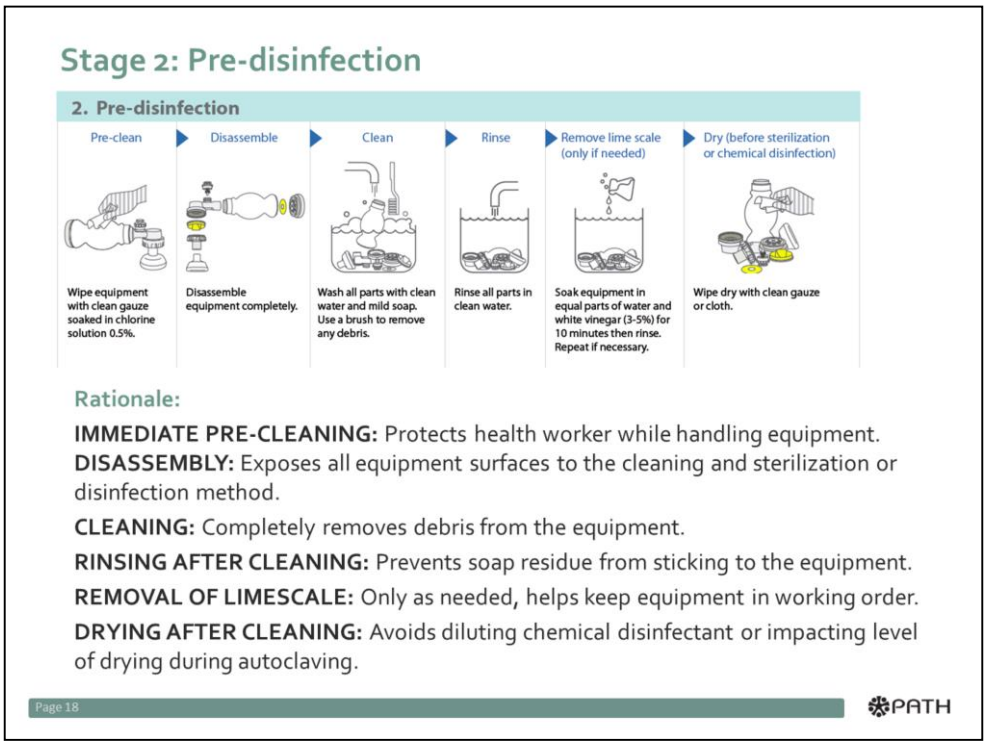
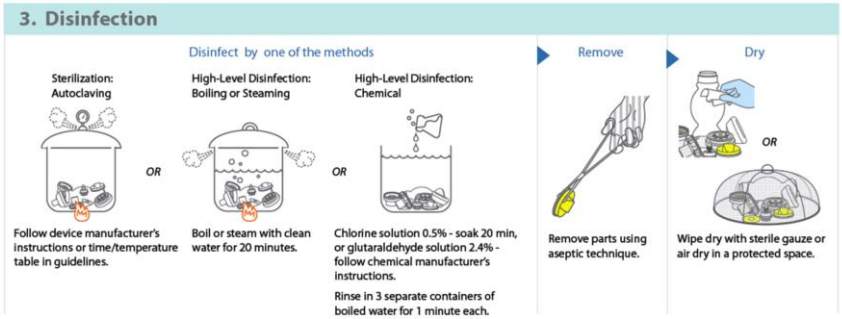


- Explain differences in terminology: Existing guidelines use the term “decontamination” for what we call here immediate pre-cleaning. Existing guidelines may recommend soaking in chlorine, which is correct, but the new guidelines recommend wiping to decrease total reprocessing time and still confer protection to the health worker.

Stage 3: Disinfection



Rationale:

STERILIZATION OR HLD: Eliminates all or most microorganisms from equipment surfaces.

RINSING AFTER CHEMICAL HLD: Removes all chemical residue from equipment after chemical HLD.

DRYING AFTER HLD: Avoids growth of new microorganisms and allows proper function testing.

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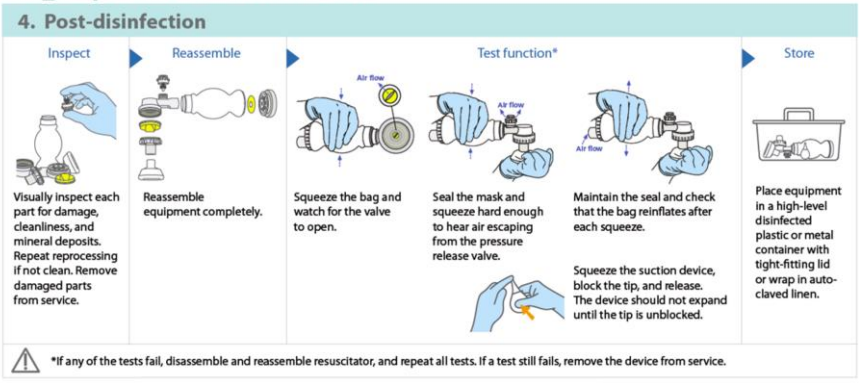
Stage 4: Post-disinfection



Rationale:

INSPECTION: Ensures all equipment parts are intact.

REASSEMBLY: Ensures equipment is ready for use when resuscitation is required.

FUNCTION TESTING: Ensures equipment is in working order and has been properly reassembled.

STORAGE: Keeps equipment free of microorganisms and dust until it is needed.

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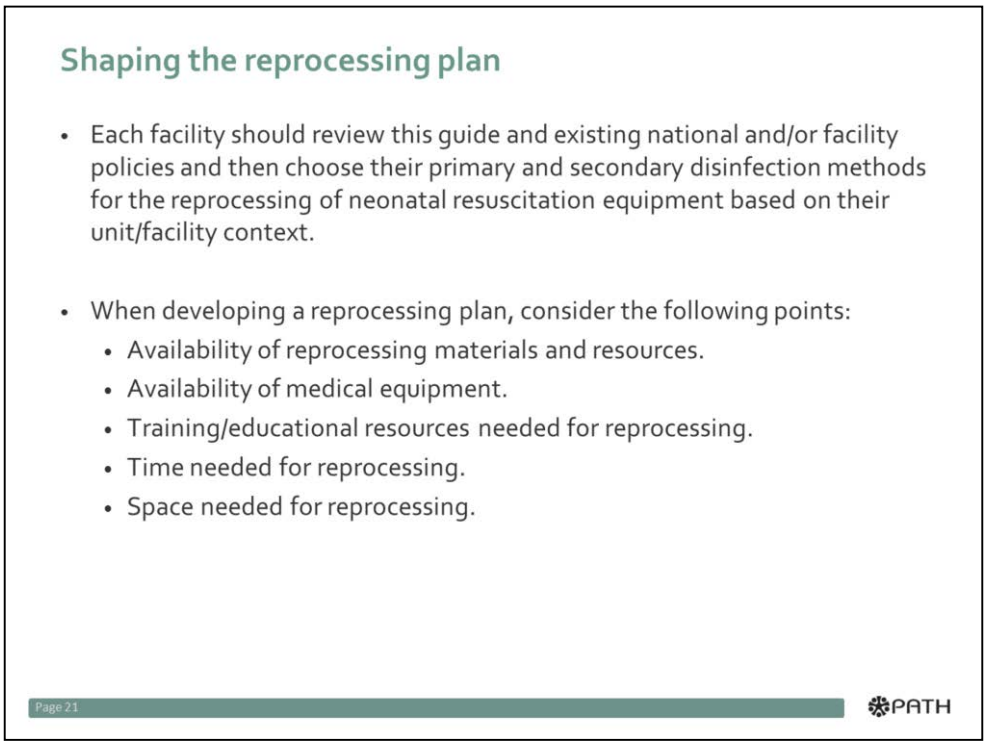
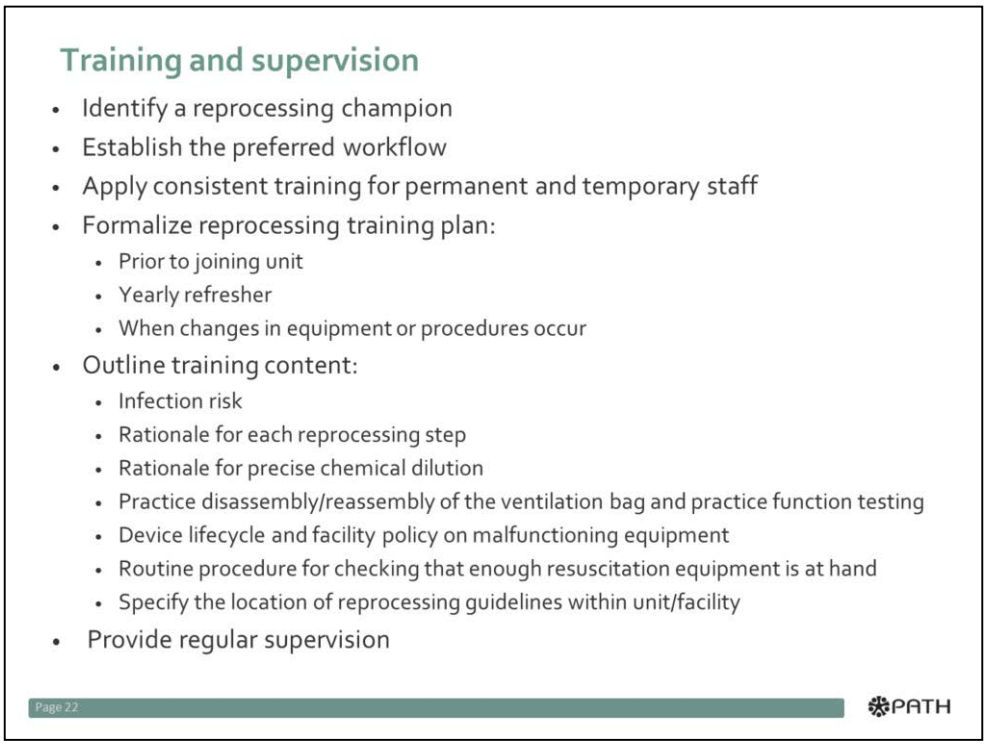


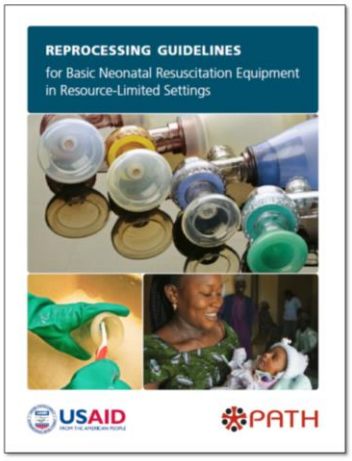
- Since reprocessing materials and equipment can vary within facilities or within the same district/county/province, the facility or unit guidelines should be facility- or unit-specific, taking into consideration the availability of reprocessing equipment/materials.
- A facility may decide that all units within the facility will select the same disinfection methods in order to (1) maintain training consistent among staff that rotates between units, (2) plan procurement of reprocessing materials efficiently.
- The primary method of sterilization/HLD and any secondary methods available (if the primary method cannot be undertaken) should be defined.

- Time: protecting the dedicated time of the person or people assigned to reprocessing is important to ensure that reprocessing occurs regularly. Reprocessing should be viewed as a planned and scheduled part of the workload rather than as an activity to be done in addition to regular duties. Further, time constraints which impact reprocessing also lead to equipment shortages, meaning that the equipment is not ready and available when needed. In facilities where there are not staff devoted exclusively to reprocessing, it is recommended that one person be assigned to reprocessing for each shift each day.
- Space: an area that is specifically intended for reprocessing must be designated within the unit or facility. In an ideal situation, there would be separate reprocessing rooms for “dirty” (contaminated) and “clean” (sterilized/high-level disinfected) equipment. When such expansive space is not available, separate areas of a reprocessing room must be designated for these processes to avoid recontamination of clean equipment. Although some facilities have made use of outdoor space for reprocessing, this is not recommended because it exposes medical equipment to further dust and debris, and compromises the effectiveness of chemicals in direct sunlight and heat.



Training content (rationale for chemical dilution): Chemicals must be diluted precisely, particularly chlorine. A solution that is too weak will not disinfect the equipment. A solution that is too strong will damage the equipment and shorten its lifespan.

Getting acquainted with the manual



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Walk through the guidelines section by section to familiarize the participants with the document and its usefulness. Remind them that the job aid summarizes the guidelines but many details that they will have questions on will be found described in the guidelines, so it's helpful to know where to find the information.

Point out some highlights by section, clearly identify appendices.

Other planning tools

It is necessary to have enough functional resuscitation equipment available in each unit that provides resuscitation to accommodate the number of patients that may need resuscitation. When planning, consider that equipment may be undergoing reprocessing and cannot be used for a period of time.

PATH has developed a variety of tools to aid in planning for the procurement of basic neonatal resuscitation equipment and its reprocessing:

- Quantification Tool for Basic Neonatal Resuscitation Commodities.
- A Toolkit for Procuring Quality-Assured Basic Neonatal Resuscitation Commodities.
- Reprocessing Guidelines for Basic Neonatal Resuscitation Equipment in Resource-Limited Settings (and associated job aids).
- Quality Improvement Road map.

These resources are available at www.path.org.

Acknowledgements

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Questions?