DIALYZER REPROCESSING
Training for
Non-Reprocessing Staff
Presented by Minntech Renal Systems
What is Dialyzer Reuse?

- Dialyzer **reuse** is the practice of using the same dialyzer for the same patient for multiple treatments.
What is Reprocessing?

• Dialyzers are not just reused, they are reprocessed

• The reprocessing procedure involves cleaning, testing, filling the dialyzer with a high-level disinfectant or sterilant (Renalin® Cold Sterilant), inspecting, labeling, storing and rinsing the dialyzer before it is reused for the next treatment
Who Does the Reprocessing?

- The dialyzer will be carefully reprocessed after each use by trained personnel.
- Many dialysis facilities have dedicated technicians whose main role is reprocessing dialyzers.
How Long Has Dialyzer Reuse Been Practiced?

• Dialyzer reuse is as old as chronic dialysis itself

• Dialyzer reuse has been practiced safely in the United States since the 1960’s, and continues to be a common practice in over 1,500 dialysis facilities

• Hundreds of millions of patient treatments have been safely and effectively performed using reprocessed dialyzers
Why Do Facilities Reuse Dialyzers?

- Dialyzer reuse can lower or eliminate the chance of having a “first-use” reaction
- A “first-use” reaction can occur when blood contacts new dialyzer membranes
- When the dialyzer is reused, the biocompatibility of the dialyzer membrane is enhanced
- Dialyzer reuse can lead to a decrease in the immune system activation
Why Do Facilities Reuse Dialyzers?

- Companies sometimes use ethylene oxide (ETO) to sterilize dialyzers.
- Ethylene oxide is a colorless, flammable, toxic gas that is used to sterilize medical supplies.
- Patients can have a reaction if the ETO in a new dialyzer is not rinsed out before the treatment is started.
- Unfortunately, there is not a test to ensure that a dialyzer has been rinsed free of ETO.
- Facilities that reuse dialyzers preprocess all new dialyzers before they are used for the first time.
- Preprocessing flushes out the ETO and other manufacturing residues, and tests and disinfects or re-sterilizes the dialyzer before it is used for the first time.
Why Do Facilities Reuse Dialyzers?

- Reuse helps the environment
- Reprocessing reduces the amount of raw materials necessary to manufacture all the dialyzers needed for treatments and dramatically decreases the number of discarded dialyzers that end up in community landfills.
Why Do Facilities Reuse Dialyzers?

• The most expensive disposable item of a treatment is the dialyzer

• The cost of treatment keeps going up, but the amount of money that the government pays the dialysis facility for each treatment is fixed

• This fixed rate is supposed to pay for all dialysis supplies, staffing and other services that are part of the treatment

• Savings from dialyzer reprocessing can be used to provide additional patient services
Is Dialyzer Reuse Safe?

• Yes

• Multiple studies have demonstrated that reprocessed dialyzers are as safe and effective as disposable dialyzers.

• Dialyzer reuse is safe when the process is done correctly. Facilities must follow RD47, AAMI Recommended Practice – Reuse of Hemodialyzers, created by patients, health and business experts, scientists and government officials.

• These guidelines cover:
  • Training
  • Water quality
  • Reprocessing the dialyzer
  • Dialyzer inspection
  • Dialyzer labeling
  • Storage
  • Testing the reprocessed dialyzer for the presence of sterilant or disinfectant
  • Testing the reprocessed dialyzer for residual sterilant or disinfectant
  • Monitoring patients during the treatment
  • Quality assurance activities
What Guidelines Are Followed During Reprocessing?

• Dialyzers should be reprocessed in accordance with:
  – AAMI Recommended Practice RD47 – Reuse of Hemodialyzers
    • CMS (Centers for Medicare and Medicaid Services) has incorporated RD47 into their dialysis facility survey process
  – Reprocessing equipment Directions For Use (DFU)
  – Multiple-use dialyzer DFU
  – Unit Policy and Procedures
How Are Reuse Staff Trained?

• All staff that reprocess dialyzers must participate in an in-depth training program

• The training program covers at least the following:
  – Principles of hemodialysis
  – Facility reprocessing policies and procedures
  – Reprocessing records and documentation
  – Operation and maintenance of the reprocessing equipment
  – Infection control practices
  – Emergency procedures

• Successful completion of the training will be documented

• Staff are tested annually to verify competency and are retrained if new procedures are instituted
What Is the Cycle of Dialyzer Reprocessing and Use?

1. Post treatment
2. Reprocessing
3. Inspection
4. Labeling
5. Storage
6. Treatment
7. Rinsing & residual testing before treatment
8. Inspection & presence testing
What Happens During Reprocessing?

• After the treatment is finished, the dialyzer is cleaned, tested and then filled with a sterilant or high-level disinfectant
  – During the **cleaning phase**, any blood that remains in the dialyzer at the end of treatment is flushed out of the fibers
  – Testing consists of measuring the total cell volume (**TCV test**) and a fiber integrity test (**pressure test**)
    • **A total cell volume (TCV)** is the measurement of the fluid volume of the blood compartment of the dialyzer
      – A TCV test is performed to ensure that the fibers are not clotted
      – AAMI RD47 requires a TCV of at least 80% of the original volume
      – The original TCV is established when the dialyzer is preprocessed
    • **A pressure test** is performed on the dialyzer to ensure that there are no broken fibers
    • If the dialyzer fails the volume or pressure test, it will be thrown away, and a new dialyzer will be preprocessed for the next treatment
      – The dialyzer is then **filled with a sterilant or high-level disinfectant**
• These steps can be done manually or with automated equipment
• Using automated equipment allows the process to be repeated over and over again without mistakes
How Is the Reprocessed Dialyzer Inspected?

- After the dialyzer is reprocessed, staff will visually inspect the dialyzer and check for the following:
  - Confirm that the level (volume) of sterilant or high-level disinfectant in the dialyzer is sufficient
  - Confirm that the blood and dialysate ports on the dialyzer are capped and not leaking
  - Check that the dialyzer is not damaged or leaking
  - Confirm that both the inside and outside of the dialyzer look clean
How Is the Reprocessed Dialyzer Labeled?

• After passing the visual inspection, staff will place a new information label on the dialyzer

• According to AAMI RD47, the label will show, at minimum:
  – The patient’s name
  – Number of times the dialyzer has been used
  – Date the dialyzer was last reprocessed

• Labels from the Renatron system will also include:
  – Patient number
  – Time of last reprocessing
  – Current and minimum TCV values
  – Dialyzer model type
  – Dialyzer/Patient specific barcode number
  – Space for initials of the person(s) who reprocessed, inspected and tested the dialyzer

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Beehive, Kary

Patient # 000040242  ID verify 1: _______  2: _______
Current vol. 109  Min vol. 88
Use # 4  Rep. # 5  Program. HF
Last reprocessed.  12:11:00  10/14/2004
Dialyzer # 957A9C94A  Model: Primus 1350
Reprocess & Inspect: __________  Inspect & Indicator: __________  Residual: __________

**PASS**
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How is the Reprocessed Dialyzer Stored?

• After the dialyzer is reprocessed, inspected and labeled, staff will store the dialyzer in a clean and safe area until it is time to use it again.

• Storage considerations:
  – Minimum & maximum storage time for sterilant or high-level disinfectant
  – Minimize deterioration, contamination and breakage
  – Segregate new, reprocessed and used dialyzers to clearly indicate status of the dialyzers
  – Environmental conditions (temperatures and light conditions)
How is the Dialyzer Prepared For the Next Treatment?

• Before the dialyzer is prepared for use, the dialysis staff must inspect the dialyzer **AGAIN** and test the dialyzer for the presence of sterilant or high-level disinfectant.

• After rinsing, the dialyzer must be tested to ensure that any residual sterilant or high-level disinfectant is within safe levels.
What Is Involved In Dialyzer Inspection?

• Staff confirms that the:
  – Sterilant or high-level disinfectant was in the dialyzer for the correct amount of time
    • Minimum contact time for Renalin is 11 hours
  – Level (volume) of sterilant or high-level disinfectant in the dialyzer is sufficient
    • Minntech recommends that headers be at least 2/3 full for Renalin-reprocessed dialyzers
  – Dialyzer is properly labeled
  – Dialysate and blood ports are capped
  – Exterior and interior of the dialyzer are clean
Why Is a Presence Test Performed?

- Staff performs a presence test to verify that the concentration of sterilant or high-level disinfectant in the dialyzer is effective.

Note: Do not insert test strip into the dialysate port as this may damage the fibers.
Why Is Rinsing & Residual Testing Performed?

• Before the treatment begins, the staff must rinse the sterilant or high-level disinfectant from the dialyzer and then perform a test to confirm that any residual sterilant or high-level disinfectant is within safe levels
  – Minntech recommends that the residual test be done immediately before patient initiation
  – Minntech recommends that this level be less than 3ppm for Renalin-reprocessed dialyzers
What Happens After Treatment is Done?

- When the treatment is completed, the dialyzer will be capped and sent to the reprocessing room.

- The dialyzer will be reprocessed and the cycle will be repeated.
How Are Dialyzers Transported &Handled?

• Dialyzers should be transported in a clean and safe manner:
  – Dialyzers should not be leaking on each other
  – Dialyzers should not be manhandled
  – Some facilities place used dialyzers in bags for transportation

• Many facilities refrigerate dialyzers if they can not be reprocessed within two hours
How Many Times Can a Dialyzer Be Reprocessed?

• The Medical Director will establish the maximum number of times a dialyzer can be used.

• Additionally, a dialyzer must pass all the required tests in order to be reused.
How Are Records Kept?

• Detailed records are kept for every reprocessed dialyzer

• These records are maintained electronically or can be recorded by hand
What is Central Reprocessing?

- Central reprocessing refers to a dialyzer reprocessing facility that receives and reprocesses dialyzers from more than one dialysis clinic and returns the dialyzers for subsequent use.

- Dialyzers are transported to the central facility in a controlled environment.
What Environmental Controls Apply to Reuse?

• Ensure that airborne levels of reprocessing chemicals are within OSHA guidelines
  – Formaldehyde - 0.75 ppm TWA (time weighted average)
  – Gluteraldehyde - 0.2 ppm
  – Peracetic acid (Renalin) - none developed
    • Monitor constituent components of Renalin:
      – Acetic Acid – 10 ppm
      – Hydrogen Peroxide – 1 ppm TWA

• Ensure that storage temperatures of sterilant or high-level disinfectant are within specification
  – Renalin Cold Sterilant stored between 32° - 75° F
  – Renalin reprocessed dialyzers stored between 59° - 75° F
What (PPE) Personal Protective Equipment Should Be Used?

• The PPE should be appropriate for the task
• Staff should use Standard Precautions
• Staff should follow the sterilant or disinfectant manufacturer’s recommendations
• PPE should be consistently worn
What About Patient Safety?

- All patients are monitored for:
  - Inadequate dialysis
  - Septicemia (infection of the blood)
  - Pyrogenic reactions
  - Acute reactions to residual germicide/sterilant

- Dialyzers should not be reprocessed from patients who have tested positive for hepatitis B surface antigen

- If a cluster of adverse patient reactions is associated with dialyzer reuse the facility must suspend reuse until the problem is corrected
What About Staff Safety?

• Staff safety is an important part of a dialyzer reprocessing program

• Staff safety issues include infection control and chemical exposure and are addressed by the following:
  – Personal protective equipment
  – Adequate ventilation
  – Hand washing
  – Eye-wash stations
  – Spill control procedures
  – Written procedures
  – Material Safety Data Sheets
Take Home Message

Reuse is as old as chronic dialysis itself and has proven to be a safe and effective method of maximizing dialysis resources.