I. Infection Prevention in Dialysis Patients  
   a. Alan Kliger, MD

II. Medical Leadership and Culture of Safety  
   a. Leslie Wong, MD  
   b. Renee Garrick, MD

III. Infection Prevention in a Quality Assessment & Performance Improvement (QAPI) Program  
   a. Jerry Jackson, MD  
   b. George Aronoff, MD

IV. Practical Steps for Detecting and Managing Patients with Bloodborne Pathogens  
   a. T. Alp Ikizler, MD

V. Antimicrobial Stewardship: Protecting Our Patients  
   a. Erika D’Agata, MD
The Dialysis Infection Crisis in the United States: A Call to Action

Alan S. Kliger, MD
Yale New Haven Health System

To enhance the quality of life for people with kidney failure by engaging nephrologists as team leaders in transformational change that continuously improves the safety of life sustaining dialysis.
Disclosures

• Alan S. Kliger, MD
  • Employer: Yale New Haven Health System
  • Consultancy: American Society of Nephrology, National Institutes of Digestive Disease and the Kidney
  • Honoraria: DCI (Dialysis Provider), ARA (Dialysis Provider)
  • Scientific Advisor/Membership: Qualidigm (Quality Improvement Organization)
Why is *infection* a critical issue for dialysis?
MORBIDITY:

*Infection* is second leading cause
Adjusted all-cause mortality is falling in HD and PD.
Cause of Death in Prevalent Dialysis Patients

Overall

- Sudden cardiac death (SCD): 27.5%
- Other cardiovascular death (OCVD): 13.6%
- Unknown (UNK): 21.1%
- Other (OTHER): 15.9%
- Withdrawal (WD): 14.4%
- Infection (INF): 9.5%

Age 18–44

- SCD: 31.9%
- OCVD: 11.8%
- UNK: 24.4%
- Other: 15.8%
- WD: 5.7%
- INF: 10.5%

Age 45–64

- SCD: 31.1%
- OCVD: 13.4%
- UNK: 22.3%
- Other: 13.6%
- WD: 9.3%
- INF: 10.4%

Age 65–79

- SCD: 26.9%
- OCVD: 14.1%
- UNK: 20.5%
- Other: 14.2%
- WD: 15.1%
- INF: 9.3%

Age 80+

- SCD: 22.8%
- OCVD: 13.4%
- UNK: 19.8%
- Other: 13.3%
- WD: 22.3%
- INF: 8.6%

PEER Report: Dialysis Care & Outcomes in the U.S., 2014 | Hospitalization |
Incident One Year STD* Death Rates by CVD vs Infection 1996-2014: Incident-based after 90 days

*Adjusted for age, sex, race, cause of ESRD and incident year; PEER Report
Prevalent One Year STD* Death Rates by CVD vs Infection 1996-2014: deaths/100 Pt Yrs

- CVD 51% decline since 1996
- Infection 40% decline since 1996

*Adjusted for age, sex, race, cause of ESRD and prevalent year; PEER Report
MORBIDITY:

Infection-Related Hospitalization
Adjusted all-cause & cause-specific hospitalization rates for ESRD patients 2005-2014

Hemodialysis all-cause hospitalization rates have been declining, but hospitalizations for infections have not kept pace, and are now as frequent as CVD hospitalizations.

Period prevalent ESRD patients; adjusted for age, sex, race, primary cause of kidney failure & their two-way interactions; reference group: ESRD patients, 2011. Abbreviation: ESRD, end-stage renal disease. 2016 Annual Data Report, Vol 2, ESRD, Ch 5
There are more hospital days for infection than for CVD.

Infection Hospital Days

- All dialysis
- Hemodialysis
- Peritoneal dialysis
- Transplant

CVD Hospital Days

- All dialysis
- Hemodialysis
- Peritoneal dialysis
- Transplant

Data Source: Special analyses, USRDS ESRD Database, 2016 Annual Data Report, Vol 2, ESRD, Ch 5. Period prevalent ESRD patients, adjusted for age, sex, race, primary cause of kidney failure & their two-way interactions; reference group: ESRD patients, 2011.

Abbreviation: ESRD, end-stage renal disease.
Incident Pt First year hospitalization rates for CVD and Infection: per 100 Pt Yrs

Incid Quarterly CVD Pri Dx Rate
Incid Quarterly Infect Pri Dx Rate
Prevalent Pts Trends in CVD and Infection Hospitalization Rates: per 100 Pt Yrs
C. Diff Admissions 1st years vs. Prevalent per 100 Pt Yrs

Incid C. Diff Pri Dx Rate
Preval C. Diff Pri Dx Rate

PEER Report

NTDS
Nephrologists Transforming Dialysis Safety
Transmission routes

• Physical contact
• Blood-borne transmission
• Respiratory
• Contaminated food, medication

Patient-to-patient or staff-to-patient transmission could occur through

• Contaminated devices, equipment, or supplies
• Environmental surfaces
• Hands of personnel
Principles to Prevent Infection Transmission in Hemodialysis Units

https://www.cdc.gov/dialysis/guidelines/index.html

- Infection control precautions for all patients: standard precautions
- Cleaning and disinfection
- Routine serologic testing for hepatitis B and C
- Hepatitis B vaccination
- Isolation of hepatitis B-infected patients
  - Other Infections, ex.: hepatitis C, human immunodeficiency virus (HIV): individualize by patient and facility
- Hand Hygiene
- Medication/Injection Safety
Staff should use gloves whenever caring for a patient or touching equipment

- Change gloves and clean hands between patients every time
- Use gloves when handling blood lines, blood specimens
- Use gloves when touching equipment and other surfaces

Anything taken to, or kept on, a patient’s machine should be considered contaminated

- Either throw it away or decontaminate it before the next patient’s use

Medications should be prepared in an area away from the patient’s machine and only one patient’s medications should be administered at a time

- No common trays or carts should be taken from one patient’s machine to another
- Do not puncture single-use vials more than once
• Staff members should wear protective gear (gowns, face shields, eye wear, and masks) when initiating or terminating hemodialysis (HD) treatment, cleaning dialyzers, and centrifuging blood.

• Staff members should not eat or drink in patient care areas or the laboratory.
  • There are no **CDC or federally mandated restrictions** on patients eating food during treatment.

Centers for Disease Control and Prevention. Recommendations for preventing transmission of infections among chronic hemodialysis patients. MMWR Recomm Rep 50(No. RR-5); 1–43, 2001
Careful mechanical cleaning to remove debris should always be done before disinfection.

<table>
<thead>
<tr>
<th>Category</th>
<th>Low-Level Disinfection</th>
<th>Intermediate-Level Disinfection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross blood spills or items contaminated with visible blood</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Hemodialyzer port caps</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Interior pathways of dialysis machine</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Water treatment and distribution system</td>
<td>X</td>
<td>X*</td>
</tr>
<tr>
<td>Scissors, hemostats, clamps, blood pressure cuffs, and stethoscopes</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Environmental surfaces, including exterior surfaces of HD machines</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

*Water treatment and fluid concentrate distribution systems require more extensive disinfection if significant biofilm is present within the system.

Principles to Prevent Transmission of Blood-borne Infections in HD Units

- Medication Safety
- Isolation of hepatitis B-infected patients
- Implementation and auditing of hand hygiene and environmental disinfection policies and procedures
- Monitoring for early detection of seroconversion
  - Routine monitoring of hepatitis B and C serologic status
- Hepatitis B vaccination
Requirements for admission to dialysis unit

- HepBsAg, hepatitis B core antibody (HepBcAb), and anti–hepatitis B surface antibody (HBsAb) status
- Hepatitis C virus (HCV) ([https://www.cdc.gov/mmwr/pdf/wk/mm62e0507a2.pdf](https://www.cdc.gov/mmwr/pdf/wk/mm62e0507a2.pdf)) and HIV status

Monthly monitoring

- Alanine transaminase (ALT) (serum glutamic pyruvic transaminase [SGPT])
- HepBsAg (in patients not immune to hepatitis B)

Semi-Annual monitoring (q 6 months)

- HCV

Annual Monitoring

- HepBsAb
Isolation Precautions for HepBsAg+ Patients

There should be a separate room/area, dedicated machines, equipment, and instruments for HepBsAg+ patients
• These cannot be shared with HepBsAg– patients

The separation of HepBsAg+ and HepBsAg– patients should be complete
• Staff who care for HepBsAg+ patients should only treat patients who are immune to hepatitis B (titers > 10 mIU/ml)

No dialyzer reuse
What Is The Responsibility of a Strong Infection Prevention Program?

TEACHING QUALITY IMPROVEMENT TECHNIQUES

• Root cause analysis

STRESSING INFECTION PREVENTION

• Standard precautions
• Handwashing
• Catheter elimination
• Vascular access care and cannulation
• Water system maintenance
• Dialyzer re-use issues
• Chair/HD machine cleaning
• Isolation

PERFORMING INFECTION SURVEILLANCE

• Identifying blood borne pathogen threats likely to impact dialysis and transplant patients, family members and staff
• Surveillance for Blood stream infections
What Is The Responsibility of a Strong Infection Prevention Program?

TREATING INFECTION ACCORDING TO GUIDELINES

- Adopting/developing an antibiotic stewardship program
- Addressing the need for standardized protocols to manage the spread/treatment of hepatitis B & C, HIV, multiple drug-resistant organisms (MDROs)

ADDRESSING THE POSSIBILITY OF EMERGING THREATS

- Developing educational programming to protect patients and staff from emerging threats
- Being aware of local and national resources to manage unanticipated emerging infections (Emory: Ebola; Zika)
What Is The Responsibility of a Strong Infection Prevention Program?

LEADERSHIP

- Address responsibility confusion:
  - Do nephrologists believe that infection prevention is their responsibility?

- Correct knowledge deficits
  - Environmental, technology, equipment challenges

- Replace complacency with activism
  - Dialysis has become “routine” and shortcuts have become “normal”
  - Rushed atmosphere, little time, little staff
Nephrologist Leadership and the Culture of Safety

Leslie P. Wong, MD, MBA, FASN
Vice Chairman, Cleveland Clinic Nephrology

Renee Garrick, MD, FACP
Vice Dean and Professor of Clinical Medicine, New York Medical College
Disclosures

• Leslie P. Wong, MD, MBA, FASN
  • Director of End-Stage Renal Disease, Cleveland Clinic

• Renee Garrick, MD, FACP
  • Medical director of DCI dialysis facility in Hawthorne, NY
  • Executive Medical Director, Westchester Health Network, and Westchester Medical Center
U.S. dialysis facilities do not reliably follow basic infection control.

The number of citations is increasing each year.

<table>
<thead>
<tr>
<th>#</th>
<th>V-Tag</th>
<th>Tag Description</th>
<th># Citations</th>
<th>% Surveys Cited</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>V113</td>
<td>IC-Wear Gloves/Hand Hygiene</td>
<td>648</td>
<td>33.6%</td>
</tr>
<tr>
<td>2</td>
<td>V122</td>
<td>IC-Clean, disinfect surfaces &amp; equipment/written protocols</td>
<td>581</td>
<td>30.1%</td>
</tr>
<tr>
<td>3</td>
<td>V543</td>
<td>POC-Manage volume status</td>
<td>323</td>
<td>16.8%</td>
</tr>
<tr>
<td>4</td>
<td>V403</td>
<td>PE-Equipment maintenance- manufacturer’s DFU</td>
<td>307</td>
<td>15.9%</td>
</tr>
<tr>
<td>5</td>
<td>V147</td>
<td>IC-Staff education re catheters/catheter care</td>
<td>269</td>
<td>14.0%</td>
</tr>
</tbody>
</table>
Traditional Approaches

- Policies and procedures
- Staff training and education
- Audit compliance
- Disciplinary action
- Plan of correction
- Employee termination
• “Nobody follows hand hygiene consistently.”
• “Dialysis staff have a “not my job” attitude.”
• “Leadership for infection control is lacking.”
• “The nurse manager should be in charge.”
• “Everyone needs to be more engaged and empowered.”
A system is not the sum of its parts
It is how these parts fit together

Russell Ackoff (1919-2009)
Professor Emeritus of Management Science
Wharton School
“Einstein of Problem Solving”
ESRD Care as a Macro-System

- External factors
- Corporate management
- Regulation and payments
- Nephrology professions
- Each facility is unique
- Culture is local

Change starts locally
Systems Thinking

**Event Oriented Thinking**
Thinks in straight lines

- Policies
- Training
- Compliance
- Infection Control

“Cause and Effect”
Looks at parts in isolation

**Systems Thinking**
Thinks in loop structure

- Infection Control
- Leaders
- Culture

“Dynamic Complexity”
Looks at the whole and relationships
Why Empowerment Fails

• People have to want more authority first
• Lack of clear hierarchy of authority causes confusion and uncertainty

Leadership in the Facility

§494.250 Condition: Responsibilities of the dialysis facility medical director
- Delivery of patient care
- Outcomes
- Quality of care

NTDS Webinar, May 23, 2017
Designated Leader and Situational Leaders

These roles are interconnected and interdependent.

While good leadership starts at the top, bad leadership at any level can undermine efforts to prevent infections.
“The way we do things around here”
= Culture
Culture

• Survival mechanism for groups of individuals facing problems
• Shared learning of solutions that have worked well enough to be considered valid
• Starts as a behavior, but becomes a way to think, a way to feel - drops from awareness
• Provides stability and a group identity

Edgar Schein
Professor Emeritus
MIT Sloan School of Management
Why Culture is So Powerful

• You are not just talking about behavior
• You are not talking about “spoken values”
• You are talking about unspoken beliefs and values that help preserve identity, esteem & survival
• Challenging culture provokes unconscious reactions by the group & individuals

Schein E, Organizational Culture and Leadership, 2017
Communication based on mutual trust  
Shared perception about importance of safety  
Confidence in the efficacy of preventive measures  
Shared commitment to reduce preventable harms and deaths in healthcare
Role of Leaders in Culture

• New organizations – founding leaders demand behaviors and create a new culture
• Established organizations – leaders must teach new behaviors & beliefs
• This can only occur if old (maladaptive) behavior & beliefs are unlearned

Schein E, Organizational Culture and Leadership, 2017
The Intersection of Quality and Safety

- Safety is one of the 6 domains of Health Care Quality* (safe, effective, patient centered, timely, efficient, equitable)
- Safe Care = patients should not be harmed by the care that is intended to help them. But, it is possible for a desired outcome to occur despite the use of processes that are risky or “unsafe”
- How much risk can a system “tolerate” before “failures” occur?
- Consider this in the context of the 2016 report that medical error remains the 3rd leading cause of death in the US**

**BMJ 2016;353:i2139
Which of the Following is the Most Common Cause of Serious Errors?

1. Inattentiveness
2. Lack of knowledge
3. Failure to clearly communicate
4. Errors related to the Electronic Record (EMR)
5. Lack of motivation
Which of the Following is the Most Common Cause of Serious Errors?

**Answer:** Failure to clearly communicate

- It is estimated that 80 percent of serious medical errors involve miscommunication between caregivers during patient transitions or hand-offs*

- Implement SBAR, I-PASS or other scripted tools encourage clarifying questions, and cross-checks and similar “crew resource management tools”

*The Joint commission, 2012, Center for Transforming Healthcare*
Which of the Following did Staff Indicate as the Major Reason for Medical Errors?

1. Not enough staff to handle work-load
2. Patients too hard to work with
3. Staff fail to follow policies and procedures
4. Staff lack knowledge
5. Staff work too many hours
Answer: Staff fail to follow policies and procedures*

- Work-arounds and other “short-cuts” bypass key policy and safety steps

*Garrick et al; CJASN 7:680, 2012
Why Dialysis Staff Breach Policies

- Many breaches are intentional violations
- Behavioral response to organizational pressures/stress
- Shortcuts to improve performance
- Absent of visible harm, the shortcuts become accepted
- CULTURE MIGRATES AWAY FROM SAFETY

Adopted from Amalberti, R. Qual Saf Health Care 2006
When dialysis patients were asked:
How often do you worry that someone might make a medical mistake during your treatment?

✓ 48.6% of patients said “sometimes to always”
• Freedom from accidental or preventable injuries produced by the care
• Trust us to do the right thing; say when we did not and correct it
• The goal is to create a system of care delivery that:
  ▪ Prevents errors
  ▪ Learns from the errors that do occur
  ▪ Identifies, trends, and learns from “good catches/ “near misses”
  ▪ Is built on a culture of safety that involves health care professionals, organizations, and patients

Modified from IOM and AHRQ
Establishing a Culture of Safety

A culture in which every individual feels comfortable/safe drawing attention to potential hazards or actual failures without fear of retaliation

---A JUST CULTURE

with 200% accountability and high reliability
Elements of a Culture of Safety

• Care systems must be trustworthy
  • Acknowledge the high-risk nature of dialysis
  • It must recognize that a safe environment is NOT error free
  • Report “near misses” as well as events
  • When errors occur (with or without harm) events are shared openly and honestly with both patients and staff
  • It must be non-punitive; system errors, not individual’s failures

• We must demand individual accountability
  • Unacceptable deviance from, or disregard, for policy and procedure prompts peer review and remediation
Developing a Culture of Safety

- Conduct patient safety leadership walk rounds
- Designate a patient safety officer
- Create an adverse event response team
- Perform Root Causes - implement and track effectiveness of improvements
- Re-enact real, and simulate possible, adverse events
- Share safety catches and events

Make it easy to do the right thing

http://www.ihi.org/resources/Pages/Changes/DevelopaCultureofSafety.aspx
High Reliability Organizations

• For a system to be trustworthy it must RELIABLE
• Goal: to achieve a persistently low rate of error despite operating in an environment that can be unpredictable and is consistently hazardous
• Examples: Nuclear power, airlines
• A relentless focus on safety

Klier, A : Yale Medical system
How is High Reliability Accomplished?

- **Sensitivity to operations**
  - “Situational awareness” how should/ how do our systems work, does that match current policy

- **Reluctance to accept simplistic solutions**
  - Be wary of simplistic solutions to complex problems; systems can fail in ways that have not previously considered

- **Preoccupation with failure/risk**
  - Think ahead to predict, mitigate, eliminate risk, track and share good catches

- **Deference to expertise**
  - Age and rank don't necessarily make you the “expert” The frontline staff are often the experts

- **Commitment to resilience**
  - Contain, mitigate, and recover form errors, improvise correctly when needed; remember, errors will occur
Dialysis Facilities Safety Risk: Contributing Factors

- **The environment of care of dialysis is complex**
  - Advanced technology, dynamic human physiology
  - Open interfaces between humans and machines (i.e. humans decide actions – no auto pilot or prefect “fail safes”)

- **Many chances for error**
  - Multiple policies and processes: often not well standardized
  - Treatments involve multiple steps each with separate risk point
    - Water treatment – multiple steps and checks
    - Equipment – staff interface: set up and intra-treatment
    - Infection control risk points – hand hygiene and access care
    - Communication risks – multiple staff – poor handoffs
      - Patient factors: may be frail; acutely changing physiology

In complex environments the design of the systems often permits or facilitates “human error” which can lead to safety breaches.
The Road to High Reliability

Human error is inevitable BUT we can reduces risks and rates

Applied Human Factors Engineering

• Error rates can be measured.
• Some tasks and situations are more prone to errors than others.
• Can we reduce errors by identifying and mitigating these factors?
Reliability of a Series Work Process
(following Infection control steps during HD initiation)

A Set Series of Tasks is done each time

Each task is performed at a reliability level “R” and so the Reliability of the system = R1 x R2 x R3 x R 4 x R5......

How can we move from system 1 to system 3
Or from system 2 to "perfection"
• Check lists can reduce error rate from 10/100 to 3/1000

• Larger fonts, more white space reduce error rate from 3/100 to 3/10,000

• Math should be PRE-calculated as much as possible (e.g. maximum allowable UFR rates etc) otherwise error rate/task can be 1-3/100

• Standardize and simplify as much as possible

• Design machines and systems with forcing functions, fail safes, double checks (reduces error rate from 1/10 to 5/10,000)
Focus on Safety: Human Factor Engineering

**Usability Testing**
- Can/will policy and procedure work in “real-world;” can staff implement and sustain?

**Standardization and Hard-Wired Safety Tools**
- Automate and remove options – reduces possibility of selecting unsafe care sequences

**Forcing Functions**
- Efforts to anticipate, detect, avoid, and mitigate unsafe actions before they occur

**Resiliency Efforts**
- Aids in situational awareness, team response, adherence to safety tools

**Simulation**
- Efforts to anticipate, detect, avoid, and mitigate unsafe actions before they occur
Safety Roadmap: Designing Highly Reliable Systems for Safety

- Reduce hand-offs
- Simplify and standardize processes and communication
- Improve physical features of the workplace
- Create redundant safety measures
- Reduce reliance on memory
- Utilize checklists and hard stops effectively
- Employ technology effectively
- Collaborate and improve communication among ALL staff
- Involve patients and their families
Forms of Resistance to Change

Denial

Blaming or evading

Maneuvering and bargaining
How Leaders Overcome Resistance

- Provide a compelling vision for change
- Provide formal training and support
- Role model behaviors and address barriers
- Create psychological safety
Nephrologists as Change Agents

Commitment to Ending Preventable Infections

Leadership creates Motivation

Motivation creates Learning

Learning creates Internalization

Rate Limiting Step

Create Sense of Urgency

Inspire with Vision

Teach and Role Model

Desired Culture

Commitment to Ending Preventable Infections
Safety Champs

Safety Starts with Me

C - Communicate Clearly
   • Repeat Backs / Read Backs with Clarifying Questions
   • Phonetic and Numerical Clarifications

H - Handoff Effectively
   • SBAR

A - Attention to Detail
   • Self-check using STAR

M - Mentor Each Other – 200% Accountability
   • Cross-Check and Coach teammates
   • Speak up for Safety: ARCC it up – “I have a Concern”

P - Practice and Accept a Questioning Attitude
   • Validate and Verify
   • Stop the Line – “I need clarity”

Be a safety “CHAMP” for our patients
Including Infection Prevention in a Quality Assessment & Performance Improvement (QAPI) Program – Tools and Resources

Jerry W. Jackson, MD, FACP
Chairman, FMC Patient Safety Council

George Aronoff, MD, MS, FACP, FASN
Vice President, Clinical Affairs, Office of the Chief Medical Officer, DaVita Kidney Care
Disclosures

• Jerry W. Jackson, MD, FACP
  • Chairman, FMC Patient Safety Council

• George Aronoff, MD, MS, FACP, FASN
  • DaVita Kidney Care—Employee
  • Qsource—Board of Directors
  • University of Louisville Research Foundation—Intellectual Property
  • Dosis, Inc.—Board of Directors, Owner
Elements Needed for Effective QAPI

Medical Director Leadership

Culture

Framework for Improvement

Subject Matter Knowledge
### Paradigm A: QAPI is Only a Meeting

<table>
<thead>
<tr>
<th><strong>Medical Director</strong></th>
<th>Well, just one more thing before we end the meeting. Were there any infections this month?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nurse Manager</strong></td>
<td>Yes, there were 2 BSI’s—but they were both in catheter patients. So, what can you do?</td>
</tr>
<tr>
<td><strong>Medical Director</strong></td>
<td>I suppose you are right. What is the current status of those 2 patients?</td>
</tr>
<tr>
<td><strong>Nurse Manager</strong></td>
<td>Both are OK for now. The Vascular Access Center exchanged their catheters, so neither had to be admitted. They are nearly finished with their Vancomycin.</td>
</tr>
<tr>
<td><strong>Medical Director</strong></td>
<td>Great—see you next month!</td>
</tr>
</tbody>
</table>
The following is a dialogue between the Medical Director and the Nurse Manager 10 days before the next QAPI meeting.

**Medical Director**

I reviewed the cases of the 2 patients with BSI this month and feel this might be a high risk situation. Let’s prioritize this for full QAPI review.

---

**Nurse Manager**

Certainly. What do we need to do?

---

**Medical Director**

Obtain the NHSN Run Charts over the past 4 quarters to see if there are any trends that stand out. Then, we need to look at the observational audits on the involved staff members to see how they are performing on all aspects of catheter care.
Also, I noticed that the culture results were called to me a couple of days late, so I would like to look at our communication process to see why that happened. And, go through the RCA Questionnaire with the involved staff members. Start the Flow Diagram based on things you spot in this information, then ahead of the meeting we can consider all the findings. We will need to brainstorm on the underlying causes and put together some preliminary action plan ideas to discuss with the full team.

I am writing all this down and will begin working on it right away. I realize how important it is to prevent infections in the facility, and I agree this should be given top priority.

Thanks! I will see you next week to go over all the information with you and exchange ideas. Call me if questions come up in the meantime.
§494.150 Condition: Responsibilities of the Medical Director

“Quality assessment and performance improvement program”

“Ensure that policies and procedures related to patient admissions, patient care, infection control and safety are adhered to by all individuals who treat patients…”

§494.110 Condition: QAPI

“The program must include…the following:

Infection control; with respect to this component the facility must—

A. analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence;

B. develop recommendations and action plans to minimize infection transmission, promote immunization; and

C. take actions to reduce future incidents.”
Components of QAPI — A Process View

Data or Information

• Which metrics should you follow?
• Which data are suitable for trending?

Analysis

• What patterns emerge from the data?
• How can analysis reveal system weaknesses?

Action Planning

• Analysis is pointless unless it leads to actions for improvement.
• The QAPI Program offers a platform for information sharing and learning among all facility staff.
• Communications from the QAPI Program can influence culture!

The QAPI Program offers a crossroad for information sharing and learning among all facility staff.
Data

Evidence from the medical literature is important to build knowledge, but improvement efforts should be built around your own facility data.

Dr. Edwards Deming

“In God we trust—
all others bring data.”
## Data for Infection Control in the Facility’s QAPI Program: Measuring the Process and the Outcome

### Process Type Data:

<table>
<thead>
<tr>
<th>Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHSN</td>
</tr>
<tr>
<td>• Outpatient dialysis center practice survey</td>
</tr>
<tr>
<td>Internal Audits (multiple types)</td>
</tr>
<tr>
<td>Antibiogram</td>
</tr>
<tr>
<td>Antibiotic Prescribing Practices by Practitioner</td>
</tr>
<tr>
<td>Root Cause Analysis Results</td>
</tr>
<tr>
<td>Near Miss Reports</td>
</tr>
<tr>
<td>Communication Data</td>
</tr>
<tr>
<td>Vaccination Data</td>
</tr>
</tbody>
</table>

### Outcome Type Data:

<table>
<thead>
<tr>
<th>Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHSN</td>
</tr>
<tr>
<td>• Facility Rate Tables</td>
</tr>
<tr>
<td>• Facility Run Charts</td>
</tr>
<tr>
<td>Self-generated BSI rates, trended</td>
</tr>
<tr>
<td>Non-NHSN infections</td>
</tr>
<tr>
<td>• Wound data</td>
</tr>
<tr>
<td>• Pneumonia</td>
</tr>
<tr>
<td>• Influenza</td>
</tr>
<tr>
<td>• Cellulitis</td>
</tr>
<tr>
<td>• Others</td>
</tr>
</tbody>
</table>
Here is an example of a **NHSN BSI Rate Table**. It shows:

- Facility’s overall BSI rate by access types in the blue box
- The national average for those categories in the yellow box; comparing the facility vs. the national rates using the p-value column
- This is only the mean rate for a quarter, not an actual trend
- The national rate is not “good enough”, it is simply the national average for the quarter.

### Bloodstream Infection (BSI) Rate Table

<table>
<thead>
<tr>
<th>Access Type</th>
<th>Summary Yr/Qtr</th>
<th>Months</th>
<th>Number Bloodstream Infections</th>
<th>Patient-Months</th>
<th>Bloodstream Infection Rate/100 patient-months</th>
<th>NHSN Bloodstream Infection Pooled Mean Rate/100 patient-months</th>
<th>Incidence Density p-value</th>
<th>Incidence Density Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>2016Q1</td>
<td>3</td>
<td>2</td>
<td>211</td>
<td>0.95</td>
<td>0.64</td>
<td>0.5513</td>
<td>.</td>
</tr>
<tr>
<td>Fistula</td>
<td>2016Q1</td>
<td>3</td>
<td>0</td>
<td>97</td>
<td>0.00</td>
<td>0.26</td>
<td>0.7743</td>
<td>10</td>
</tr>
<tr>
<td>Graft</td>
<td>2016Q1</td>
<td>3</td>
<td>0</td>
<td>63</td>
<td>0.00</td>
<td>0.39</td>
<td>0.7802</td>
<td>10</td>
</tr>
<tr>
<td>Other Access</td>
<td>2016Q1</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>0.00</td>
<td>0.51</td>
<td>0.9849</td>
<td>.</td>
</tr>
<tr>
<td>Tunnelled</td>
<td>2016Q1</td>
<td>3</td>
<td>1</td>
<td>45</td>
<td>2.22</td>
<td>2.17</td>
<td>0.8778</td>
<td>59</td>
</tr>
<tr>
<td>Nontunnelled</td>
<td>2016Q1</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>33.33</td>
<td>2.05</td>
<td>0.0615</td>
<td>100</td>
</tr>
<tr>
<td>Any CVC</td>
<td>2016Q1</td>
<td>3</td>
<td>2</td>
<td>48</td>
<td>4.17</td>
<td>2.16</td>
<td>0.3661</td>
<td>82</td>
</tr>
</tbody>
</table>

Non-shaded (white) area includes the facility data.

Shaded (yellow) area includes aggregate data from all of NHSN. Use this information to compare each facility to the rest of NHSN.
All Dialysis Rate Tables are Interpreted Similarly

- IV Antimicrobial Start
- IV Vancomycin Start
- Bloodstream Infection (BSI)
- Access Related Bloodstream Infection (ARBSI)
- Local Access Site Infection (LASI)
- Vascular Access Infection (VAI)

***ARBSI= a positive blood culture with the suspected source reported as the vascular access or uncertain

***LASI= Pus, redness, or increased swelling of the vascular access site and access-related bloodstream infection is not present.

***VAI= either a local access site infection or an access-related bloodstream infection
Data: Benefits of Trending

- Trending allows one to assess the stability of the system over time.
- Trending allows close-to-real-time detection of outbreaks at the facility.
- Trending allows one to judge the effectiveness of actions.
Data: Difficulties in Trending Infection Data

Some months have zero infections.
• For this reason, quarterly trends are easier to interpret.

Self-generated trended facility data could be sufficient for QI purposes, but this approach would possibly lack case-mix adjustment, standardization and/or stratification by vascular access type.
• NHSN offers a facility-specific Run Chart by infection type and VA type.
Available CDC Dialysis Infection Prevention Audit Tools

CDC Checklist Tools

**Checklist: Hemodialysis catheter exit site care**
- Wear mask (if required) and remove dressing
- Perform hand hygiene
- Put on clean gloves
- Apply sterile gown
- Allow to dry
- Do not touch
- Repeat as necessary
- Perform hand hygiene

**Checklist: Hemodialysis catheter connection**
- Wear mask (if required)
- Perform hand hygiene
- Put on new, clean gloves
- Apply skin antisepsic and allow it to dry
- Do not contact site (after antisepsis)
- Insert needles aseptically
- Connect to blood lines aseptically
- Remove gloves
- Perform hand hygiene

**Checklist: Arteriovenous fistula/graft cannulation**
- Clean site with soap and water
- Perform hand hygiene (staff)
- Put on clean gloves
- Apply skin antisepsic and allow it to dry
- Do not contact site (after antisepsis)
- Insert needles aseptically
- Connect to blood lines aseptically
- Remove gloves
- Perform hand hygiene

**Checklist: Hemodialysis injectable medication preparation**
- Ensure medication preparation area is clean
- Impact medication via, discard if necessary

**Checklist: Hemodialysis injectable medication administration**
- Perform hand hygiene
- Scrub hands
- Attach aseptically
- Do not touch
- Perform
- Remove
- Do not bring patient to chair

**Checklist: Dialysis Station Routine Disinfection**
- Use sterility before disinfecting
- Do not bring patient to chair after disinfection

Core Interventions for Dialysis Bloodstream Infection (BSI) Prevention

1. Surveillance and feedback using NHSN
   - Conduct monthly surveillance for BSI and other dialysis events using CDC's National Healthcare Safety Network (NHSN). Conduct facility and laboratory surveillance to detect and correct deficiencies in infection control and prevention practices.

2. Hand hygiene compliance
   - Implement and improve hand hygiene opportunities. Monthly and annual reports reflect compliance with hand hygiene practices.

3. Catheter access site care
   - Perform site care at each dialysis visit to prevent bloodstream infection.

4. Staff education and competency
   - Train staff in infection control, including proper alcohol-based hand hygiene methods and educating patients to report symptoms of infection.

5. Patient education and engagement
   - Educate patients and caregivers about infection prevention measures and the importance of hand hygiene.

6. Catheter reduction
   - Implement a policy that reduces the number of catheter access sites when feasible.

7. Chlorhexidine-resistant antibiotic
   - Use an effective skin preparation, such as chlorhexidine, to reduce the risk of infection.

8. Catheter hub disinfection
   - Clean catheter hubs with an appropriate alcohol at each access or disinfect catheter hubs daily.

9. Avoid infection transmission
   - Apply antimicrobial or barrier-coated catheters or perform catheter hub disinfection during changing.

• Analysis can be used to address 3 Questions of the Framework for Improvement:
  o What are we trying to accomplish?
  o What changes can we make that will lead to improvement?
  o How do we know that a change results in improvement?

• Analysis should move from the broad framework down to the detailed plan:
  o First establish what improvements are needed
  o Then prioritize the areas of need to be addressed immediately
  o Then develop the details of the action plan and its implementation and followup

• Each Step in this process requires the application of tools and methods
Examples of tools and methods used at different points along this path toward improvement:

- Pattern recognition using data review
- Failure mode and effects analysis
- Cause and effect diagramming
- Root Cause Analysis applied to:
  - Individual adverse events
  - Multiple similar adverse events
  - Unsafe conditions
  - Near miss events
- Plan-Do-Study-Act cycles
Communications—the Lifeblood of Teamwork and Learning

• If the data, analysis, and action planning of the QAPI Program is restricted to its Committee members, how would this information translate into improvements at the point of care?
  
  - Involvement of everyone who comes in contact with patients is especially critical for infection prevention.

• Communication can be formal or informal

  - Morning Briefs and afternoon Debriefs
  - Ad hoc Team Huddles
  - Medical Director led teaching sessions for staff
  - Staff member to staff member feedback, call outs
The “Days Since Infection” Poster can be used as a focal point for discussions around infection prevention in general and specifically the facility’s current actions (developed in the QAPI Program) needed for improvement.
Putting Quality Improvement Tools Into Action
Root Cause Analysis (RCA)

• Structured method used to examine major safety events
• More than “putting out fires”; finding a way to prevent the fire

<table>
<thead>
<tr>
<th>In-depth review of:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organization and management of policies/procedures</td>
</tr>
<tr>
<td>The environment of care</td>
</tr>
<tr>
<td>Staffing levels and staff competency</td>
</tr>
<tr>
<td>Interactions of the care team</td>
</tr>
<tr>
<td>Patient-specific factors</td>
</tr>
<tr>
<td>Institutional and regulatory factors</td>
</tr>
<tr>
<td>Specific task functions</td>
</tr>
</tbody>
</table>
Root Cause Analysis (RCA)

- Keep an open mind
- Avoid “diagnostic bias”
- Suspend personal biases
- Actively resist jumping to conclusions
  - “Reluctance to simplify”
  - Deference to expertise
- How to use a Fishbone Diagram for RCA
Root Cause Analysis Fishbone Diagram

Problem

Cause 1

Cause 2

Cause 3

Cause 4

Cause 5

Cause 6

Cause 7

Cause 8
What is an Action Plan?

A list of *tasks* specific to the next steps toward completion of an improvement aim; it is not a restatement of the goal.

The plan can be frequently modified as tasks are completed or if re-direction is needed.

It should include **timelines** and a list of **who is responsible** for each step.

Is part of the overall **Quality Improvement Work Plan**.
Quality Improvement Work Plan

• Guides QI performance activities

• Describes
  • QI program activities of performance indicator development and refinement
  • Ongoing and time-limited performance improvement projects
  • Focused studies
  • Other monitors to ensure quality care

• Helps to ensure that the entire team understands what is being monitored

• Allows for transparency and improves accountability
<table>
<thead>
<tr>
<th>Root Cause</th>
<th>Action</th>
<th>Personnel</th>
<th>Time Frame</th>
<th>Target</th>
<th>Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Too many catheters</td>
<td>Communicate with surgeon</td>
<td>Medical Director</td>
<td>2 weeks</td>
<td>Importance of fistulas, timely visits and follow up</td>
<td>Monthly</td>
</tr>
<tr>
<td>Poor patient hygiene</td>
<td>Patient education</td>
<td>Social worker</td>
<td>2-3 months</td>
<td>Education programs for clinic. Individual patient intervention</td>
<td>Monthly</td>
</tr>
<tr>
<td>Protocol adherence</td>
<td>Re-educate nurses and techs</td>
<td>Nurse educator</td>
<td>2 months</td>
<td>Observed adherence with protocols</td>
<td>Monthly</td>
</tr>
<tr>
<td>Physical prophylaxis</td>
<td>Contact dialysis provider regarding Tego/Curos, approval for antibiotic lock solution</td>
<td>Medical Director</td>
<td>2 weeks</td>
<td>Start using physical prophylaxis</td>
<td>Monthly</td>
</tr>
<tr>
<td>Surveillance</td>
<td>Observe adherence</td>
<td>Head Nurse</td>
<td>Now and recheck</td>
<td>Record adherence with protocols</td>
<td>Monthly</td>
</tr>
</tbody>
</table>
Pareto Chart

• Named after Vilfredo Pareto, contains both bars and a line graph
• Individual values are represented in descending order by bars and the cumulative total is represented by the line
• Uses the Pareto Principle (80/20 rule); 80% of the effect comes from 20% of the causes
• Pareto chart helps to identify the most frequent defects, complaints, or other factor you can count or categorize
The Quality Paradigm

See It
• Requires Courage

Own It
• Requires Character

Do It
• Requires Will

Solve It
• Requires Imagination and Knowledge
Plan, Do, Check, Act (PDCA) Cycle

- An iterative 4-step management method used to control and continually improve processes and products
- Made popular by W. Edwards Deming who is considered to be the father of modern quality control
- Based on the scientific method; hypothesis-experiment-evaluation
- Once evaluated, the cycle begins all over again
- Multiple iterations of the PDCA cycle are repeated until the problem is solved
Plan, Do, Check, Act (PDCA) Cycle

**Plan**
- Identify problem
- Gather data
- Review current policy and procedure
- Isolate causes
- Root cause evaluation
- Define actions

**Do**
- Prepare
- Apply (pilot)
- Verify the tools

**Check**
- Verify results of actions taken
- Compare with plan
- Adopt, adapt

**Act**
- Adopt, adapt
- Standardize
- Disseminate and implement across system

Control Charts

UCL

CL

LCL

Observation out of control

Variation due to assignable causes

Variation due to normal causes

Variation due to assignable causes

Sample Number
Normal (or Common) Cause Variation

Data points within upper (UCL) and lower (LCL) limits, above and below the mean (CL)
Data point outside Control limit = “special cause” variation requiring investigation
Trend: 6-7 data points increasing (decreasing) in succession

Requires investigation
References

- CDC Making Dialysis Safer For Patients Coalition Resources: www.cdc.gov/dialysis/coalition/resource.html
Practical Steps for Detecting and Managing Patients with Bloodborne Pathogens – Lessons Learned from the Ebola Epidemic
Disclosures

• T. Alp Ikizler, MD
  • None
### The Problem

<table>
<thead>
<tr>
<th>Widespread epidemic of Ebola virus in West Africa in 2014 and 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>As of June 10, 2016, total of confirmed, probable and suspected cases of Ebola virus disease (EVD) in West Africa was 28,616</td>
</tr>
<tr>
<td>Confirmed 11,310 deaths</td>
</tr>
<tr>
<td>Of 27 patients who received therapy in United States and Europe, five (19%) required renal replacement therapy (RRT)</td>
</tr>
<tr>
<td>A number of gaps in the level of preparedness of inpatient hemodialysis units were identified.</td>
</tr>
<tr>
<td>Although it is unlikely that a person who may have EVD will present to outpatient hemodialysis center, it is recommended that HD centers be prepared for such an occurrence.</td>
</tr>
</tbody>
</table>

This would set a precedent for any other potential emerging threat at the Outpatient Dialysis Unit setting.
March 2014, initial Ebola Cases reported in Guinea, spreads to Liberia, Sierra Leone, Nigeria and Mali.

By June 2014, 330 deaths officially recorded.

July 2014, 2 physicians, one of which is the CMO in charge of battling Ebola epidemic in Sierra Leone, are dead.

September 2014, 6 million people quarantined in SL, door to door search reveals 130 cases and 92 bodies.

December 2014, over 7,000 deaths recorded, due to EVD including 11 physicians in Sierra Leone.
August 2014, two patients arrive at Emory for treatment of EVD

September 2014, Mr. Duncan story begins in Liberia.
- Presents to ED in Texas, states he was hospitalized in Liberia but discharged.
- Admitted to Texas hospital in early October 2014, requires intensive treatment, dies on October 8th.

Nurses taking care of Mr. Duncan travel. Two present with symptoms and are diagnosed with Ebola.

November, 2014 three patients arrive at University of Nebraska for treatment of EVD
Within 1-2 weeks of the Ebola onset, a transient dialysis patient was traveling on the same plane as one of the Texas nurses exposed to EVD (patient saw report on TV and reported it to FMC); FMC attempted to transfer patient to an academic center for treatment and was refused. Pt had no physical contact with the nurse on the plane.

Problems identified:

- No guidance - first thought that patients would be able to dialyze in the unit after all the patients had left but decided not to do this due to fear within the unit.
- Used NxStage and used bags for effluent…
  - didn’t think to use bleach in the bags at the time - this was early in the process
- NxStage was able to accommodate set-up for this home patient very rapidly.
- FMC reported this event to the local health department and to the CDC; this was early in the process and they were still looking for guidance for PPE
This was a potential exposure (although remote); home, staff-assisted dialysis was a good option.

If there were a large number of patients involved, would consider re-arranging system and dedicate an entire center to treat potentially exposed patients.

Sending patients to the hospital was a problem as it seemed the hospital was confused.

Everyone that came into the facility-UPS, FedEx, mailman, visitors, etc. had their temperature taken during that time period…but how do you take that temperature, and if it is elevated, then what??
### Gap Analysis of Out-Patient Hemodialysis Units

<table>
<thead>
<tr>
<th><strong>No on-site written policies for possible infection with Ebola virus, Middle East Respiratory Syndrome (MERS), Severe Adult Respiratory Syndrome (SARS)</strong></th>
<th><strong>No written process and list of relevant telephone numbers for alerting key dialysis center personnel</strong></th>
<th><strong>No designated person responsible for monitoring news, public health alerts or appropriate (e.g., CDC) websites</strong></th>
</tr>
</thead>
</table>
| Lack of a policy and adequate resources for appropriate triage of patients with suspected infection | Failure to have trained a limited number of personnel regarding specific isolation precautions and procedures  
  - High staff turnover | Potential lack of appropriate space for immediately placing a patient who is being evaluated for possible Ebola virus infection. |

<table>
<thead>
<tr>
<th><strong>No dedicated supply of the types of personal protective equipment (PPE)</strong></th>
<th><strong>No on-site written policies for possible infection with Ebola virus, Middle East Respiratory Syndrome (MERS), Severe Adult Respiratory Syndrome (SARS)</strong></th>
<th><strong>No written process and list of relevant telephone numbers for alerting key dialysis center personnel</strong></th>
<th><strong>No designated person responsible for monitoring news, public health alerts or appropriate (e.g., CDC) websites</strong></th>
</tr>
</thead>
</table>
| No on-site written policies for possible infection with Ebola virus, Middle East Respiratory Syndrome (MERS), Severe Adult Respiratory Syndrome (SARS) | Lack of a policy and adequate resources for appropriate triage of patients with suspected infection | Failure to have trained a limited number of personnel regarding specific isolation precautions and procedures  
  - High staff turnover | Potential lack of appropriate space for immediately placing a patient who is being evaluated for possible Ebola virus infection. |
Measures for Closing the Gaps at Out-Patient Dialysis Centers

• Designate an individual who will be responsible for monitoring news/websites for evidence of ongoing Ebola virus transmission
  • Consider nurse manager
  • Individual with infection prevention experience

• Implement Ebola preparedness plan
  • Identify
  • Isolate
  • Inform
Ebola Preparedness Plan in Outpatient HD Units

Identify

- Place signs
- Send message to patients via telephone and social media
- Screen patients before they walk all the way through the facility
- Identify signs and symptoms in high risk patients
  - Surveillance for 21 days in high risk patients
Ebola Preparedness Plan In Outpatient HD Units

Isolate

• Place in private room or area
• Use PPE at all times when contacting the patient
• Use personnel with training and limit exposure with other staff
• Minimize exposure to blood (i.e., limited to no blood draws)
• Consult health department
Inform

- Contact the relevant health department immediately
- Prepare for transfer to a hospital identified by the health department
- Arrange for safe transfer
- Communication is essential
Ebola Preparedness Plan in Inpatient HD Units

- Make available a written emergency preparedness policy in the dialysis unit
- Train in advance a group of physicians and nurses who will care for the dialysis patient
- Train ICU staff where dialysis will be performed
  - CRRT is preferred
  - Regional citrate preferred
- Arrange dedicated testing material and storage place for effluent
- Disinfect machines with bleach and rest for 7-10 days
Successful Delivery of RRT in Ebola Virus Disease

Proposed clinical practice guidelines for RRT in the acute phase of EVD

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Clinical Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modality</td>
<td>CRRT recommended for initial treatment. Consider transition to PIRRT (using same CRRT equipment) for continued RRT until patient either (1) recovers renal function or (2) is capable of leaving biocontainment isolation (i.e., negative viral PCR studies in blood)</td>
</tr>
<tr>
<td>Staff</td>
<td>If possible at the institution, all patients should receive RRT using CRRT equipment by extensively trained ICU nurses as primary clinical nurses at bedside. Minimize additional staff entry in the biocontainment environment (i.e., specialty dialysis nurses)</td>
</tr>
<tr>
<td>Access</td>
<td>Temporary antecubital dialysis catheter placed at bedside under direct ultrasound visualization. Extra precautions should be taken to contain bloody waste from this procedure. The right internal jugular vein is the preferred access site (with the left internal jugular vein as the backup site), given that this presents the lowest bleeding risk because patients with EVD may experience bleeding diatheses. Recommend that subclavian insertion sites be avoided. Unless portable chest imaging after access insertion is unavailable, femoral access sites should be avoided secondary to bleeding risks (retroperitoneal bleeding). Consider use of nonreflux dialysis grade caps for dialysis vascular access.</td>
</tr>
<tr>
<td>CRRT dosing</td>
<td>No EVD-specific dosing needs. Consistent with Kidney Disease Improving Global Outcomes statements, support target CRRT dose to deliver a total effluent dose of 20–25 ml/kg per hour unless higher dosing is needed to augment small solute and electrolyte clearance or correction of acidemia.</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>RCA is preferred and recommended in all patients to extend filter life and reduce potential staff exposures with filter exchanges.</td>
</tr>
<tr>
<td>Effluent disposal</td>
<td>CRRT effluent has a low infectious risk; however, if it is handled in an EVD-positive area and a small dialyzer leak may be undetected, recommend that effluent be treated as hazardous and disposed of in a similar manner as individual institution/local guidelines require for disposal of other bodily fluids in EVD.</td>
</tr>
<tr>
<td>Nutrition support</td>
<td>Ensure that patients receive appropriate augmented nutrition support while receiving CRRT as recommended by clinical guidelines (total daily protein intake of approximately 2 g/kg per day).</td>
</tr>
</tbody>
</table>
Practical Steps for Detecting and Managing Patients with Bloodborne Pathogens

• Based on the efforts of multiple organizations, much has been learned regarding how to safely and effectively perform hemodialysis on patients with Ebola Virus Disease (EVD).

• Many of the general strategies developed for management of patients with EVD should also be applicable, with appropriate modifications, for handling patients with other severe transmissible diseases that may emerge in the future.

• Uncertainty exits regarding the level of funding. Formation of the network of 10 National Ebola Training and Education Centers should help in the future.

• A number of areas require further research and evaluation.
  • Improvements in infrastructure, processes for detection, triage and isolation of individuals with EVD, the design of PPE, new technologies for environmental cleaning and disinfection, and best infection control practices.
  • Securing future funding represents a challenge
Antimicrobial Stewardship in Dialysis
Disclosures

• Erika D’Agata, MD, MPH
  • None
Methicillin-Resistant Staphylococcus aureus
Global dissemination

Legend
- Healthcare-Associated MRSA
- Community-Associated MRSA
- Vancomycin-Intermediate S. aureus

Vancomycin-Resistant Enterococcus
Global dissemination


© The Author 2013. Published by Oxford University Press on behalf of the Infectious Diseases Society of America. All rights reserved. For Permissions, please e-mail: journals.permissions@oup.com.
GRAM-NEGATIVE BACTERIA RESISTANT TO \( \geq 3 \)

<table>
<thead>
<tr>
<th>Year</th>
<th>Paeruginosa</th>
<th>Entrobacter spp.</th>
<th>Proteus spp.</th>
<th>Klebsiella spp.</th>
<th>E.coli</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994-95</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1996-97</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1998-99</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2000-01</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

D’Agata ICHE 2004
Multidrug-resistant Gram-negative Bacteria

- Currently the most concerning multidrug-resistant organism—very limited antimicrobial options
- Extended-spectrum beta-lactamase-producing gram-negative bacteria
  - Resistant to cephalosporins and most other antimicrobials
  - Susceptible to carbapenems
- Carbapenemase-producing gram-negative bacteria
  - New Delhi metallo-beta-lactamase (NDM-1)
    - Emerged in 2008
    - Susceptible only to polymixins
Klebsiella pneumoniae carbapenemase–producing K. pneumoniae and New Delhi metallo-β-lactamase-1–producing Enterobacteriaceae Global dissemination

Timeline Of Antimicrobial Resistance

“Bad Bugs, No Drugs: As Antibiotic Discovery Stagnates, A Public Health Crisis Brews” – Infectious Disease Society of America report

Development of New Antibiotics

Diagram showing the stages of development:
- Discovery
- Preclinical studies
- IND Filing
- Phase I
- Phase II
- Phase III
- FDA Review
- NDA Filing
- Product launch

Development time (years):
- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10

Key:
- IND = investigational new drug
- NDA = new drug application
• Infections are the major cause of hospitalizations and death

• Rates of hospitalization due to infection are increasing
  - 43% higher in 2009 than in 1993

• Mortality rates due to infections caused by antimicrobial-resistant bacteria are 2-5 fold higher than infections caused by susceptible bacteria

• Antimicrobial resistance rates are among the highest in patients requiring chronic hemodialysis
Saely et al. Am J Infect Control 2011

Hemodialysis was associated with 13-fold higher risk of ESBL-producing *Klebsiella pneumoniae* infections

OR 13.60, 95% CI 4.3-43.2
• CHD patients contribute to MDRO spread in the hospital setting (USRDS 2009)
  • 2 admissions per year
  • LOS 12 days
  • 36% readmitted within 30 days

• CHD patients contribute to MDRO spread in the community setting (Lu 2008)
  • 7% of CHD family members colonized with same MRSA strain
1. Prevent emergence of resistance
   - judicious use of antimicrobials

2. Prevent spread of MDRO
   - limiting patient to patient transmission
   - judicious use of antimicrobials
# Recommendations For The Prevention Of MDRO Spread

<table>
<thead>
<tr>
<th></th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Wear gloves when in contact with patients</td>
</tr>
<tr>
<td>2</td>
<td>Remove gloves and wash hands in between patients or stations</td>
</tr>
<tr>
<td>3</td>
<td>Follow published guidelines for judicious use of antibiotics</td>
</tr>
<tr>
<td>4</td>
<td>Avoid multiuse items</td>
</tr>
<tr>
<td>5</td>
<td>Do not use common medication carts</td>
</tr>
</tbody>
</table>

CDC MMWR 2001
Recommendations For The Prevention Of MDRO Spread

<table>
<thead>
<tr>
<th>Patients at high risk of MDRO spread</th>
<th>Infected wounds</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Drainage not contained by dressing</td>
</tr>
<tr>
<td></td>
<td>Fecal incontinence or diarrhea</td>
</tr>
</tbody>
</table>

Wear both gloves and dedicated disposable gowns when providing care

Provide dialysis during sessions with the least amount of other patients OR at a station with as few adjacent stations as possible

CDC MMWR 2001
Antimicrobial Use In The Dialysis Population

• **Paucity of data**
  • Antimicrobial starts or claims data
  • Two studies addressing inappropriate prescribing of vancomycin in the hospital
  • Only one study addressing inappropriate prescribing of all antimicrobials in outpatient
<table>
<thead>
<tr>
<th>Type of antimicrobial</th>
<th>Unit A</th>
<th>Unit B</th>
<th>Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>All antimicrobials</td>
<td>28.4 (5.2–50.0)</td>
<td>37.3 (10.4–67.2)</td>
<td>32.9 (5.2–67.2)</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>18.5 (5.2–35.0)</td>
<td>26.1 (7.6–50.0)</td>
<td>22.3 (5.2–50.0)</td>
</tr>
<tr>
<td>Cefazolin</td>
<td>5.2 (0.0–22.1)</td>
<td>4.9 (0.0–25.9)</td>
<td>5.1 (0.0–25.9)</td>
</tr>
<tr>
<td>Third- or fourth-generation cephalosporins(^a)</td>
<td>2.1 (0.0–10.1)</td>
<td>3.9 (0.0–13.0)</td>
<td>3.0 (0.0–13.0)</td>
</tr>
<tr>
<td>Aminoglycosides(^b)</td>
<td>1.2 (0.0–12.1)</td>
<td>0.8 (0.0–7.1)</td>
<td>1.0 (0.0–12.1)</td>
</tr>
<tr>
<td>Daptomycin</td>
<td>1.1 (0.0–13.0)</td>
<td>1.6 (0.0–12.1)</td>
<td>1.3 (0.0–13.0)</td>
</tr>
<tr>
<td>Carbapenems(^c)</td>
<td>0.08 (0.0–2.9)</td>
<td>0.3 (0.0–5.5)</td>
<td>0.2 (0.0–5.5)</td>
</tr>
<tr>
<td>Piperacillin-tazobactam</td>
<td>0.07 (0.0–2.3)</td>
<td>0.0</td>
<td>0.03 (0.0–2.3)</td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>0.06 (0.0–1.1)</td>
<td>0.0</td>
<td>0.03 (0.0–1.1)</td>
</tr>
</tbody>
</table>

\(^a\) Third- or fourth-generation cephalosporins received include ceftriaxone, ceftazidime, and cefepime.

\(^b\) Aminoglycosides received include gentamicin, amikacin, and tobramycin.

\(^c\) Carbapenems received include ertapenem and meropenem.
### Table 1. Pooled Mean Rates of Outpatient Parenteral Antimicrobial Use over a 35-Month Period in 2 Hemodialysis Units

<table>
<thead>
<tr>
<th>Type of antimicrobial</th>
<th>Unit A</th>
<th>Unit B</th>
<th>Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>All antimicrobials</td>
<td>28.4 (5.2–50.0)</td>
<td>37.3 (10.4–67.2)</td>
<td>32.9 (5.2–67.2)</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>18.5 (5.2–35.0)</td>
<td>26.1 (7.6–50.0)</td>
<td>22.3 (5.2–50.0)</td>
</tr>
<tr>
<td>Cefazolin</td>
<td>5.2 (0.0–22.1)</td>
<td>4.9 (0.0–25.9)</td>
<td>5.1 (0.0–25.9)</td>
</tr>
<tr>
<td>Third- or fourth-generation cephalosporins&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2.1 (0.0–10.1)</td>
<td>3.9 (0.0–13.0)</td>
<td>3.0 (0.0–13.0)</td>
</tr>
<tr>
<td>Aminoglycosides&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1.2 (0.0–12.1)</td>
<td>0.8 (0.0–7.1)</td>
<td>1.0 (0.0–12.1)</td>
</tr>
<tr>
<td>Daptomycin</td>
<td>1.1 (0.0–13.0)</td>
<td>1.6 (0.0–12.1)</td>
<td>1.3 (0.0–13.0)</td>
</tr>
<tr>
<td>Carbapenems&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.08 (0.0–2.9)</td>
<td>0.3 (0.0–5.5)</td>
<td>0.2 (0.0–5.5)</td>
</tr>
<tr>
<td>Piperacillin-tazobactam</td>
<td>0.07 (0.0–2.3)</td>
<td>0.0</td>
<td>0.03 (0.0–2.3)</td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>0.06 (0.0–1.1)</td>
<td>0.0</td>
<td>0.03 (0.0–1.1)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Third- or fourth-generation cephalosporins received include ceftriaxone, ceftazidime, and cefepime.

<sup>b</sup> Aminoglycosides received include gentamicin, amikacin, and tobramycin.

<sup>c</sup> Carbapenems received include ertapenem and meropenem.
### Table 1: Pooled Mean Rates of Outpatient Parenteral Antimicrobial Use over a 35-Month Period in 2 Hemodialysis Units

<table>
<thead>
<tr>
<th>Type of antimicrobial</th>
<th>Antimicrobial use, doses/100 patient-months (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unit A</td>
</tr>
<tr>
<td>All antimicrobials</td>
<td>28.4 (5.2–50.0)</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>18.5 (5.2–35.0)</td>
</tr>
<tr>
<td><strong>Cefazolin</strong></td>
<td>5.2 (0.0–22.1)</td>
</tr>
<tr>
<td>Third- or fourth-generation cephalosporins⁴</td>
<td>2.1 (0.0–10.1)</td>
</tr>
<tr>
<td>Aminoglycosidesb</td>
<td>1.2 (0.0–12.1)</td>
</tr>
<tr>
<td>Daptomycin</td>
<td>1.1 (0.0–13.0)</td>
</tr>
<tr>
<td>Carbapenems³</td>
<td>0.08 (0.0–2.9)</td>
</tr>
<tr>
<td>Piperacillin-tazobactam</td>
<td>0.07 (0.0–2.3)</td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>0.06 (0.0–1.1)</td>
</tr>
</tbody>
</table>

---

⁴ Third- or fourth-generation cephalosporins received include ceftriaxone, ceftazidime, and cefepime.

b Aminoglycosides received include gentamicin, amikacin, and tobramycin.

³ Carbapenems received include ertapenem and meropenem.
### Table 1. Pooled Mean Rates of Outpatient Parenteral Antimicrobial Use over a 35-Month Period in 2 Hemodialysis Units

<table>
<thead>
<tr>
<th>Type of antimicrobial</th>
<th>Unit A (range)</th>
<th>Unit B (range)</th>
<th>Combined (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All antimicrobials</td>
<td>28.4 (5.2–50.0)</td>
<td>37.3 (10.4–67.2)</td>
<td>32.9 (5.2–67.2)</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>18.5 (5.2–35.0)</td>
<td>26.1 (7.6–50.0)</td>
<td>22.3 (5.2–50.0)</td>
</tr>
<tr>
<td>Cefazolin</td>
<td>5.2 (0.0–22.1)</td>
<td>4.9 (0.0–25.9)</td>
<td>5.1 (0.0–25.9)</td>
</tr>
<tr>
<td><strong>Third- or fourth-generation cephalosporins</strong></td>
<td><strong>2.1 (0.0–10.1)</strong></td>
<td><strong>3.9 (0.0–13.0)</strong></td>
<td><strong>3.0 (0.0–13.0)</strong></td>
</tr>
<tr>
<td>Aminoglycosides</td>
<td>1.2 (0.0–12.1)</td>
<td>0.8 (0.0–7.1)</td>
<td>1.0 (0.0–12.1)</td>
</tr>
<tr>
<td>Daptomycin</td>
<td>1.1 (0.0–13.0)</td>
<td>1.6 (0.0–12.1)</td>
<td>1.3 (0.0–13.0)</td>
</tr>
<tr>
<td>Carbapenems</td>
<td>0.08 (0.0–2.9)</td>
<td>0.3 (0.0–5.5)</td>
<td>0.2 (0.0–5.5)</td>
</tr>
<tr>
<td>Piperacillin-tazobactam</td>
<td>0.07 (0.0–2.3)</td>
<td>0.0</td>
<td>0.03 (0.0–2.3)</td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>0.06 (0.0–1.1)</td>
<td>0.0</td>
<td>0.03 (0.0–1.1)</td>
</tr>
</tbody>
</table>

---

*a Third- or fourth-generation cephalosporins received include ceftriaxone, ceftazidime, and cefepime.

*b Aminoglycosides received include gentamicin, amikacin, and tobramycin.

*c Carbapenems received include ertapenem and meropenem.
Table 2. Indications for Vancomycin Use Among Chronic Hemodialysis Patients

<table>
<thead>
<tr>
<th>Indications</th>
<th>No. of Doses (n = 164)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appropriate</strong></td>
<td></td>
</tr>
<tr>
<td>Empiric therapy for a febrile patient on hemodialysis pending</td>
<td>73 (45)</td>
</tr>
<tr>
<td>Culture/susceptibility data*</td>
<td></td>
</tr>
<tr>
<td>Treatment of β-lactam-resistant organisms</td>
<td>51 (31)</td>
</tr>
<tr>
<td>β-Lactam allergy</td>
<td>5 (3)</td>
</tr>
<tr>
<td>Surgical prophylaxis in patient with a prosthesis</td>
<td>2 (1)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>131 (80)</td>
</tr>
<tr>
<td><strong>Inappropriate</strong></td>
<td></td>
</tr>
<tr>
<td>Continued therapy despite negative cultures for β-lactam-resistant organisms</td>
<td>23 (14)</td>
</tr>
<tr>
<td>Routine surgical prophylaxis</td>
<td>4 (2)</td>
</tr>
<tr>
<td>Single positive blood culture for coagulase-negative staphylococci</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Prophylaxis for indwelling or peripheral intra-vascular catheters</td>
<td>5 (3)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>33 (20)</td>
</tr>
</tbody>
</table>

*Not included in HICPAC guideline
### Table 3. Breakdown of vancomycin orders by appropriateness

<table>
<thead>
<tr>
<th>Initial indication</th>
<th>Number (percent) of courses, $n=163$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriate</td>
<td>143 (88%)</td>
</tr>
<tr>
<td>Unable to assess</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>Inappropriate</td>
<td>17 (10%)</td>
</tr>
<tr>
<td>Treatment of (\beta)-lactam-sensitive organisms with no significant allergy</td>
<td>10</td>
</tr>
<tr>
<td>Infected AVF</td>
<td>3</td>
</tr>
<tr>
<td>Catheter site culture growing CoNS</td>
<td>3</td>
</tr>
<tr>
<td>Prophylaxis for graft insertion</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>After culture and susceptibility</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriate</td>
<td>92 (56%)</td>
</tr>
<tr>
<td>Unable to assess</td>
<td>18 (11%)</td>
</tr>
<tr>
<td>Inappropriate</td>
<td>53 (33%)</td>
</tr>
<tr>
<td>Infection due to (\beta)-lactam-sensitive organism and no significant allergy</td>
<td>40</td>
</tr>
<tr>
<td>Catheter site swab with CoNS (no or negative blood cultures)</td>
<td>9</td>
</tr>
<tr>
<td>Negative catheter site swab (no or negative blood cultures)</td>
<td>3</td>
</tr>
<tr>
<td>Other infection with GNB isolated</td>
<td>1</td>
</tr>
</tbody>
</table>
Nafcillin/Cefazolin Superior To Vancomycin In The Treatment Of MSSA Infections

- **Schweizer et al. BMC Infect Dis 2011**

  - nafcillin/cefazolin - 79% lower mortality hazards compared to vancomycin alone

  - Among patients who initially received vancomycin empirically, those switched to nafcillin/cefazolin had 69% lower mortality hazards compared to vancomycin
Nafcillin/Cefazolin Superior To Vancomycin In The Treatment Of MSSA Infections

• Stryjewski et al. Clin Infect Dis 2007

  • MSSA BSI among 123 CHD patients

  • Treatment failure more common among those receiving vancomycin (31%) c/t cefazolin (13%) P=0.02

  • Cefazolin dose: 2-3 grams after HD
Nafcillin/Cefazolin Superior To Vancomycin In The Treatment Of MSSA Infections

• Chan et al. JASN 2012

• 38% lower risk of hospitalization or death among CHD patients receiving cefazolin c/t vancomycin

• HR=0.62  95%CI 0.46-0.83
Indications For Antimicrobial Use In Two Dialysis Centers (CDC Collaboration)

• Prospective study from 2010-2011

• Indications for antimicrobial doses

• Inappropriate reasons for administration based on national guidelines

Snyder, D’Agata Infect Control Hosp Epidemiol 2013
Inappropriate Indications For Antimicrobial Administration

1. **Empiric start (in dialysis unit)**
   - no fever and/or criteria for infection not met

2. **Continuing doses**
   - criteria for infection not met
   - more narrow spectrum antimicrobial not chosen

3. **Surgical prophylaxis – indication or choice of antimicrobial inappropriate**

   ➔ 30% of antimicrobial doses were not indicated
FIGURE 3. Total antimicrobial doses and percentage classified as inappropriate, by type of antimicrobial.
Categories and appropriateness of antimicrobial doses administered over a 12-month study period in 2 outpatient hemodialysis units.

Snyder, D’Agata Infect Control Hosp Epidemiol 2013
Reasons For Inappropriate Administration Of Antimicrobial Doses

Inappropriate antimicrobial doses N=276/926 (29.8%)

Criteria for infection not met N=146 (52.9%)

Presumed site of infection

BSI N=71 (48.6%)
SSTI N=64 (43.8%)
UTI N=7 (4.8%)
PNA N=4 (2.7%)

More narrow spectrum antimicrobial not chosen N=74 (26.8%)

Inappropriate antimicrobial

vancomycin N=48 (64.9%)

3rd/4th generation cephalosporin N=26 (35.1%)

Criteria for surgical prophylaxis not met N=58 (20.3%)

Figure 2. Reasons for inappropriate antimicrobial administration in 2 outpatient hemodialysis units. BSI, bloodstream infection; SSTI, skin and soft-tissue infection; UTI, urinary tract infection; PNA, pneumonia.
• **Empiric doses**
  • no fever, negative blood cultures, “chills”

• **Continuing doses**
  • did not meet definition of BSI
  • One positive culture with either fever, hypotension or chills
  • contaminant
• **Definition of SSTI**
  * new or increasing drainage at the site *or*
  * 2+ of the following: fever, redness, tenderness, warmth, new/increasing swelling
  * only either redness, tenderness or swelling documented

• **Definition for vascular access site infection**
  * pus, redness or swelling
  * only tenderness documented
Antimicrobial Not Narrowed

• Given vancomycin but beta-lactam antibiotic appropriate- 48 doses (65%)

• Given 3\textsuperscript{rd}/4\textsuperscript{th} generation cephalosporin but first generation appropriate- 26 doses (35%)
  • Based on susceptibility data of positive cultures
Elements of an Acute Care/Hospital Antibiotic Stewardship Program

It is the opinion of Dr. D’Agata that these elements may be applied to a dialysis facility.
1. Leadership Support

Dedicating necessary resources

- Personnel
- Financial
- Information technology
### 2. Identifying Individuals Who Will Lead The ASP (Champions)

#### Appoint a single leader responsible for the ASP

- Responsible at an executive-level or patient quality-focused committee

#### Identify a team

- Medical director
- Clinical manager or other
- Person with drug expertise
3. Drug Expertise

- Pharmacist
- Infectious disease physician
- Dialysis units
4. Identify Areas for Improvement

Review prescribing patterns
- Most common antimicrobials

Review patterns of obtaining cultures
- How often are cultures being obtained in the absence of signs or symptoms

Identify why antimicrobials are being prescribed inappropriately
- Type of antimicrobial
- Duration of antimicrobial treatment
- De-escalation
- Surgical prophylaxis
5. Tracking

Monitor process measures

- Adherence to facility-specific guidelines
- Time to de-escalation
- Impact on patients
  - AB-related adverse effects
  - *Clostridium difficile* infections
  - Drug-drug interactions
6. Reporting/Feedback

Regular reporting of information to relevant staff and leadership

- Single unit results and comparison to other units

Effective in reducing surgical site infections
7. Education

**Optimal prescribing**
- Published guidelines and clinical pathways

**Infection management**

**Emergence of resistance**
8. Strategies

- Antimicrobial order forms/checklists
- Formulary restriction
- Review with verbal feedback
- Positive deviance strategy