

## Infection Control: New Challenges Under the New Conditions

Priti R. Patel, MD, MPH  
Division of Healthcare Quality Promotion  
Centers for Disease Control and Prevention

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The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the Centers for Disease Control and Prevention.

**SAFER • HEALTHIER • PEOPLE™**

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## Nothing to disclose

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## New Conditions

- April 2008 – CMS released new conditions for coverage for ESRD facilities
- First update since 1976
- Incorporates CDC infection control recommendations:
  - 2001 Dialysis Recommendations
  - 2002 Catheter Guidelines
- CDC had input into the interpretive guidance



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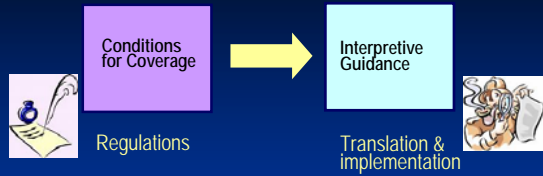
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## What's new in ESRD: CMS process



★ New conditions in effect as of October 14, 2008



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## Outline

- Medical Director Role
- What's new – items to be aware of
- Building an Infection Control Program

Background rationale

CMS requirement

Additional considerations



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## Role of the Medical Director

- Responsible for receiving all reports of infection control issues
- Familiar with the infection control program, be able to provide specifics
- Participate in QAPI meetings
- Review infection control issues (“continuously reported and discussed”), surveillance reports, identify problems
- Document action taken in response
- Report infections and adverse event clusters to public health -- **Transparency**

*Be aware & be involved*



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## New items

- Hepatitis B isolation
- Medication handling & use
- Environmental cleaning & disinfection
- Hand hygiene & glove use

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## New items (cont'd)

- Routine serologic testing
- Immunizations
- Training & education
- Surveillance

*"Comprehensive Infection Control Program" (p.6)*

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## Hepatitis B

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## HBV infection among dialysis patients

- Prevalence has declined dramatically due to:
  - Isolation practices
  - Vaccination
- Extra precautions
  - Infected persons can have high viral concentrations in blood
  - HBV can survive at room temperature on surfaces for at least 7 days
  - Surface antigen detected on clamps, scissors, machine control knobs
  - Can be transferred to patients via contaminated hands (gloved or ungloved), medications, equipment, and supplies



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## Prevention of HBV transmission in dialysis setting

### Recommendations

- Isolate HBsAg positive patients in separate room\*\*
  - Dedicated staff
  - Dedicated equipment
  - Dialyzers should not be re-used
- Conduct surveillance for HBV infection
- Supply tray to each patient (regardless of status)
- Cleaning/disinfection of non-disposable items
- Glove use
- Routine cleaning/disinfection of equipment and surfaces



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## New in the Conditions

- Hepatitis B isolation
  - New facilities must have a room
  - Existing facilities may have an area: must be separated by at least width of 1 dialysis station from adjacent stations
- No patient “buffer”
- Patients that require a booster dose of Hep B vaccine not eligible to be cared for by HCW treating HBsAg+ patient



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## Modified Contact Precautions

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### Criteria for Additional Precautions

- Additional precautions for patients at increased risk of transmitting pathogenic bacteria
- Criteria:
  - Infected skin wound with drainage not contained by dressings
  - Fecal incontinence or diarrhea uncontrolled with personal hygiene measures
  - Regardless of pathogen (need not be drug resistant)

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### Precautions to Prevent Bacterial Transmission

- Additional precautions for patients at increased risk of transmitting pathogenic bacteria
- Precautions:
  - Wear a separate gown over clothing and remove gown when finished caring for the patient
  - Dialyze the patient at a station with as few adjacent stations as possible (e.g., at end or corner of unit)

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## Precautions in outpatient dialysis



Contain drainage or use additional precautions

Separate gown anytime likely to come in contact with patient or equipment at their station



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## Hand hygiene

- Process
  - Hand hygiene should be performed frequently
  - Prior to contact with vascular access
  - Glove change in between tasks at the HD station
    - dialysate is not a sterile fluid
- Structure
  - Designate hand hygiene sinks distinct from utility sinks

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## Environmental Cleaning & Disinfection of the Station

- Separated from patient care processes
- Must be performed for adequate amount of time and with no patient at the station
- Process:
  - Patient# 1 completes treatment, leaves station
  - Station is cleaned & disinfected (no patient present)
  - Patient# 2 enters station
- Proper cleaning / disinfection of surfaces, priming buckets, etc.

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## Why?

- Lack of patient-free period between shifts associated with HCV outbreaks
- KDIGO: "Unit should ensure that there is enough time between shifts for effective decontamination of the exterior of the machine and other shared surfaces"<sup>1</sup>
- Patient privacy concerns
- Patient should not be exposed to bleach or other disinfectant solution

<sup>1</sup>KDIGO. Guideline 3: Preventing HCV transmission in hemodialysis units (2008)



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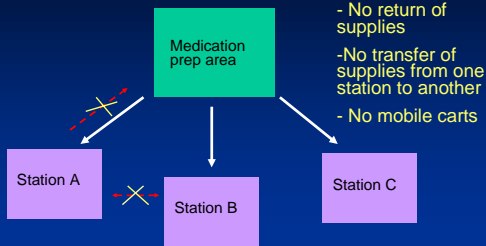
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## One-way flow of supplies

Clean

Dirty



- No return of supplies
- No transfer of supplies from one station to another
- No mobile carts



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## Supplies

Items taken into a station:

- Dedicated for use on only a single patient at that station
- Disposed of
- Cleaned and disinfected before taken to a common area or used on another patient



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## Medication vials



### Multi-dose vials

- Have preservative to prevent bacterial growth

preservative has no impact on HBV, HCV

### Single dose vials

- No preservative
- Pooling of medications caused outbreak of *Serratia* bloodstream infections



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## Req. What's new when it comes to single-dose medication vials?

- "Intravenous medication vials labeled for single use, including erythropoietin, should not be punctured more than once. Once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed."
- Multi-dose vials should be dedicated for one patient whenever possible
- No pooling meds
- Medications should be drawn at the time of use

### BEST PRACTICE

one vial, one patient; no re-entry or re-use



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## Where is this documented?



Infection Control Requirements for Dialysis Facilities and Clarification Regarding Guidance on Parenteral Medication Vials

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5732a3.htm>



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## Options

- Medications in prepackaged, pre-filled syringes
- Single dose vial for single patient
- Multidose vial for single patient
- Multidose vial for > 1 patient

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## Safety of medication strategies



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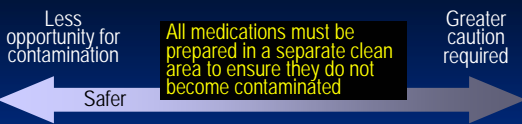
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## Safety of medication strategies



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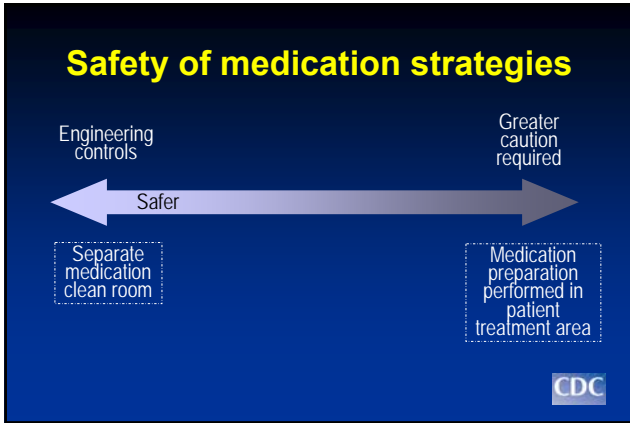
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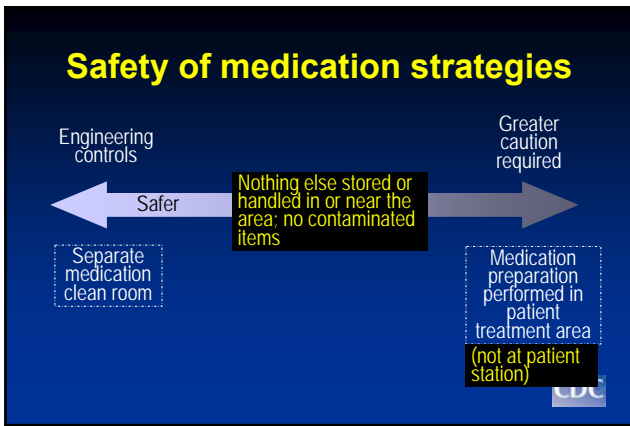
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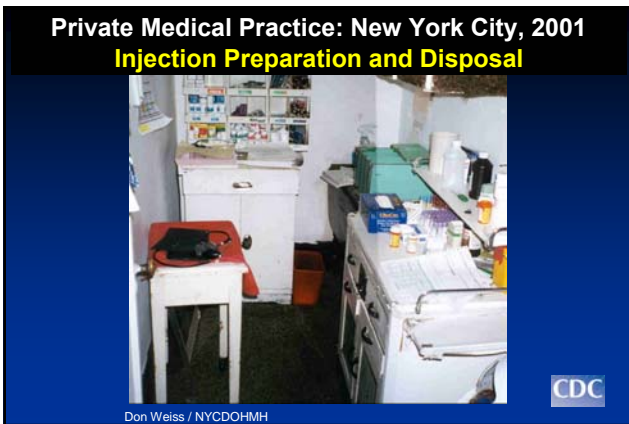
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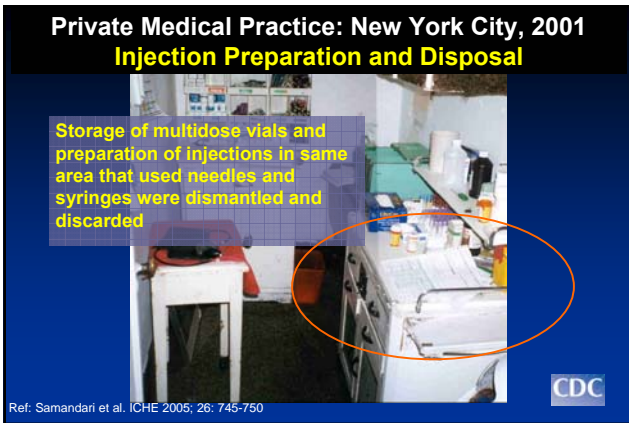
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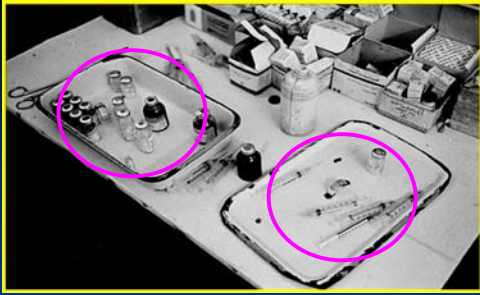
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### Injection Preparation Table, Pakistan



Joe Perz / CDC, Division of Viral Hepatitis



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### What else can be done to make medication administration safer?

- Reduce frequency of medication administration
- Utilize a standard dose, or standard set of patient doses
- Rational dose packaging
- Align cost structure / incentives with best practice



"Ug, this is okay, but what we really need is for you to start thinking outside the rocks."



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### The Facility must

- Implement a comprehensive infection control program:
  - Routine serologic testing
  - Immunization
  - Training & education
  - Surveillance



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## Hepatitis C Virus infections in dialysis

- Prevalence: 8-10%
  - (1.6% in general popn)
- Majority of infections are asymptomatic; majority develop chronic infection
- Isolation is not recommended, no vaccine
- Prevention requires strict attention to infection control practices




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## Schedule for Routine HBV & HCV Testing

	On admission	Monthly	Semi-annual	Annual
All patients	HBsAg Anti-HBs Total-anti-HBc Anti-HCV ALT			
HBV-susceptible		HBsAg		
Anti-HBs $\geq$ 10, anti-HBc (-)				Anti-HBs
Anti-HBs (+), anti-HBc (+)		No additional HBV testing needed		
HCV-susceptible		ALT	Anti-HCV	




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## HBV / HCV Testing

- HBV Testing
  - Required by CMS
  - Check total anti-HBc on admission
- HCV Testing
  - Not required or reimbursed by CMS
  - Only realistic way to identify transmission and rectify incorrect practices
  - Consider testing on admission, and annually (or with some frequency)

Must review and act upon results in a timely manner




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## HCV Outbreaks, 1998-2006

	% of patients with chronic HCV infection	% of susceptible patients that became newly infected
Maryland, 1998	22%	17.5%
Ohio, 2000	36%	8.2%
Wisconsin, 2000	4%	13%
Virginia, 2006	19%	13%

*N. Thompson, NKF Spring Meeting, Grapevine, Tx. April 3rd, 2008*



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## Immunization: Administration and Tracking

- Hepatitis B
  - All patients, all staff
- Influenza yearly
  - All patients, all staff
- Pneumococcal
  - All patients



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## Catheter Care Training & Education

- Most facilities (78%) required training only one time for staff who perform catheter care
- Facilities with low BSI rate had greater median # weeks of training required compared to facilities with high BSI rate (9.7 vs. 6.2 weeks)

*Patel P. Evaluation of Catheter Care Practices in Hemodialysis Centers. SHEA Annual Conference, April 2008, Orlando, FL*



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## Infection Control Training & Education

- Have an initial and ongoing training program
- Frequency: upon employment and at least annually thereafter
- Required content areas are specified
- Consider the depth & adequacy of training
- Periodic practice audits
- Patient education



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## Quality Improvement: Monitoring facility data

- Conduct surveillance to determine infection rates, monitor trends in those rates, and assist in identifying lapses in infection control practices
- A log or other tracking mechanism, such as the Dialysis Module of the National Healthcare Safety Network (NHSN) should be used
- Surveillance data
  - Bloodstream infection rates
  - Culture and susceptibility
  - Hepatitis B & C testing
  - Water testing
  - Immunization rates



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From CDC



Dialysis surveillance in the  
National Healthcare Safety  
Network (NHSN) is now  
open for enrollment.



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## What can surveillance do for outpatient dialysis centers?

- Identify areas for follow-up and prevention
- Compare data with other centers
- Report to stakeholders
  - Data available immediately following entry
  - Routine and custom reports



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## Dialysis Protocol Brief



Population	Chronic hemodialysis outpatients
Numerator	Complete form for each dialysis event <ul style="list-style-type: none"><li>–Hospitalization</li><li>–Outpatient IV antimicrobial start</li><li>–Positive blood culture</li></ul>
Denominator	<ul style="list-style-type: none"><li>•Number of dialysis outpatients on the first 2 working days of the month</li><li>•Stratified by 5 types of vascular access</li></ul>



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## NHSN uses the CDC Secure Data Network



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## Real-time analyses

- Line listings
- Rate tables
  - Infections stratified by vascular access type
  - Hospital incidents
  - Antibiotic starts
- Control charts



Analysis training available  
[http://www.cdc.gov/ncidod/dhqp/nhsn\\_training.html](http://www.cdc.gov/ncidod/dhqp/nhsn_training.html)




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## Standard Analysis Option Screen for Dialysis Event Surveillance

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## How event (numerator) and denominator come together

**TABLE 1. NUMBER OF EVENTS AND EVENT RATE BY TYPE OF VASCULAR ACCESS, DIALYSIS SURVEILLANCE, SEPTEMBER 1999 THROUGH MARCH 2005**

Event	Fistula No. (Rate*)	Graft No. (Rate*)	Cuffed Catheter No. (Rate*)	Non-cuffed Catheter No. (Rate*)	Port No. (Rate*)
Hospitalization	9,985 (8.7)	13,486 (12.0)	16,291 (18.6)	1,767 (26.6)	129 (17.7)
IV Antimicrobial start	2,601 (2.3)	3,605 (3.2)	8,255 (9.4)	616 (9.3)	92 (12.6)
Positive blood culture	656 (0.6)	1,241 (1.1)	4,855 (5.6)	559 (8.4)	90 (12.4)
Vascular access infection	675 (0.6)	1,760 (1.6)	6,681 (7.6)	674 (10.1)	100 (13.7)
Access related bacteremia	301 (0.3)	767 (0.7)	4,041 (4.6)	487 (7.3)	83 (11.4)
Outpatient vancomycin starts	1,404 (1.2)	2,133 (1.9)	5,609 (6.4)	445 (6.7)	73 (10.0)
Total incidents	12,134 (10.6)	16,301 (14.5)	22,925 (26.2)	2,239 (33.7)	205 (28.2)

\*The rate is the number of events per 100 patient-months

Klevens, Tokars, Andrus. Nephrology News and Issues June 2005




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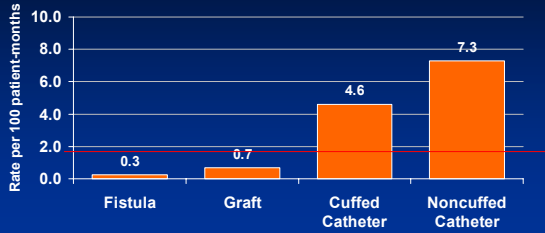
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### Rates of Bacteremia by Access Type - Dialysis Surveillance Network, Sep 1999 - Mar 2005



Klevens, Tokars, Andrus. Nephrology News & Issues 2005; June:37-43.



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### UK Experience

- Busy London dialysis unit: 112 patients
- Implemented CDC dialysis surveillance; described their experience over 18 months
- After initial set up, required 2 hours per month
- Maintained compliance with surveillance
- Outcomes: Reductions in
  - Access related bacteremia
  - Antibiotic usage
  - Hospital admissions

George A. Tokars JJ, Clutterbuck E.J. et al. Reducing dialysis associated bacteraemia, and recommendations for surveillance in the United Kingdom: prospective study. BMJ 2006; 332:1435-1439.



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### UK Experience

- “Surveillance raised awareness and provided a cornerstone for improved infection control and line care involving all staff of the dialysis unit.”
- “The data feedback generated unit led programmes of risk reduction and infection control.”
- “...should be part of quality care and risk management activity for all dialysis units.”

George A. Tokars JJ, Clutterbuck E.J. et al. Reducing dialysis associated bacteraemia, and recommendations for surveillance in the United Kingdom: prospective study. BMJ 2006; 332:1435-1439.



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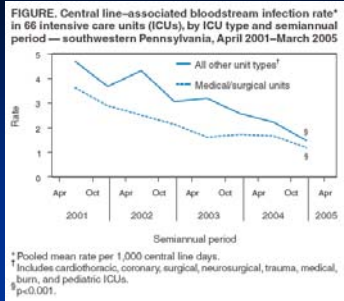
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## Reducing BSI rates in ICUs



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## NHSN Support

- Online help messages within NHSN
- Email: [nhsn@cdc.gov](mailto:nhsn@cdc.gov)
- Phone:
  - 800-893-0485
  - 404-639-4225
- [http://www.cdc.gov/ncidod/dhqp/nhsn\\_members.html](http://www.cdc.gov/ncidod/dhqp/nhsn_members.html)



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## Next steps for CDC

- Discuss surveillance requirements
- Address measures on the Measures Assessment Tool
  - Vascular access
  - Infection control
  - Vaccinations



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## The Medical Director should

- Promote a culture of patient safety and healthcare worker safety within the facility
  - Be a champion for positive change, enlist others
  - Do staff understand the importance of infection prevention?
  - Is it communicated as a facility priority?



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## The Medical Director should

- Consider ways to assess and improve practices & utilize available resources:
  - Partner with infection control professional (ICP) in affiliated healthcare system
  - Use the Network, engage independent consultants, and public health
  - Develop local infection control expertise: APIC meeting attendance, etc.
  - Assign a team to perform infection control audits
  - Provide feedback to the staff – surveillance data, immunization rates, audit results



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**PREVENTION  
IS PRIMARY!**

Visit CDC DHQP website -  
[http://www.cdc.gov/ncidod/dhqp/dpac\\_dialysis\\_pc.html](http://www.cdc.gov/ncidod/dhqp/dpac_dialysis_pc.html)

**Thank you!**  
[ppatel@cdc.gov](mailto:ppatel@cdc.gov)

\*The greatest challenge to any thinker is stating the problem in a way that will allow a solution\*  
– Bertrand Russell



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