

# **Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers**

## **Procedure Manual (Revised 7/20/00)**

**Hospital Infections Program  
Centers for Disease Control and Prevention  
Public Health Service, Department of Health and Human Services  
Atlanta, Georgia**

# Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers

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Dear Dialysis Center Personnel:

As you know, bacterial infections are major problems in hemodialysis patients. Therefore the Centers for Disease Control and Prevention (CDC) has established a voluntary surveillance system, "Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers." We would like to invite your dialysis center to participate in this project.

Each month, participating centers will report the number of chronic hemodialysis patients treated, and supply information on patients hospitalized or treated with an intravenous (IV) antimicrobial. Data will be forwarded to the CDC for analysis, and routine reports will be compiled and sent to participating centers. At their option, centers may enter and analyze their own data using programs supplied by CDC. We hope that these data will facilitate quality improvement measures.

This study is entirely voluntary. Dialysis center personnel decide whether to participate, and may elect to discontinue participation at any time.

In order to assure the confidentiality of the sources and the data it collects for this surveillance of bloodstream and vascular access infections in outpatient hemodialysis centers, the CDC Hospital Infections Program has obtained authorization to collect this data under the protection of Section 308(d) of the Public Health Service Act. The 308(d) confidentiality assurance affords this data the greatest protection against disclosure that CDC, as a Federal research agency, can provide under Federal law. The legislation stipulates that no information in a project protected by 308(d) can be used for any purpose other than the purpose for which it was supplied, nor be published or released in an identifiable format unless the establishment or person supplying the information or described in it has consented to such release.

As stated above, CDC will use the data for surveillance purposes only. However, a condition of participation is your agreement to report outbreaks or other problems of public health importance identified in this surveillance system, and for which you have been contacted by CDC, to the local or state public health authorities.

Thank you for considering participation in this surveillance system.

Yours truly,

Jerome I. Tokars, MD, MPH

Elaine R. Miller, RN, MPH

**Surveillance for Bloodstream and Vascular Access Infections  
in Outpatient Hemodialysis Centers**  
**How to Enroll**

1. Familiarize yourself with the protocol and example questionnaires. Discuss participation with your medical director and administrator.
2. Schedule and participate in a teleconference with Elaine Miller (404-639-6422). We will walk you through the process and answer any questions.
3. Complete and sign the Agreement to Participate (Section 2).
4. If your center has an IRB (Internal Review Board), and that IRB requires review of the protocol, then it is your responsibility to submit it to them and obtain approval before starting data collection.
5. Mail the completed Agreement to Participate to  
Elaine Miller  
Centers for Disease Control and Prevention  
1600 Clifton Rd Mailstop E-69  
Atlanta GA 30333
6. After we receive this, we will send you a supply of data collection forms, address labels, and envelopes, and you may begin data collection.
7. If you choose to use the Internet data entry system instead of mailing of paper forms, please see instructions that follow on pages 5-7.

**Surveillance for Bloodstream and Vascular Access Infections  
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### **Steps in Data Collection**

1. During the first week of the month, complete the CENSUS FORM.
2. During the month, as Hospitalizations and In-unit IV antimicrobial starts occur, record them on the LOG FORM.
3. For each row on the LOG FORM, complete one INCIDENT FORM.
4. For facilities using paper forms for data entry, when data collection is complete for a given month, photocopy the forms taking care not to copy the patients' names or identification numbers. Mail the photocopies without patient names or identification numbers to Elaine Miller at CDC using the envelopes and address labels supplied.
5. For facilities using the Internet data entry system, when data collection is complete for a given month, enter the data using the instructions on pages 5-7: Instructions for the Internet Data Entry System: How to Enter Data and Generate Data Reports.

## **Instructions for the Internet Data Entry System: How To Enter Data and Generate Data Reports**

If you use the Internet data entry system, you will send data and receive reports through the CDC Secure Data Network (SDN). This network was created for transmitting confidential information to and from government offices via the Internet. Before you can sign onto the system, you must first obtain a “digital certificate” for your computer. Request a copy of the instruction sheet: “Secure Data Network-How to Obtain a Digital Certificate” from Elaine Miller by phone or email. You can follow the remaining instructions in this section only after receiving the digital certificate.

### **Instructions for data entry and generation of data reports:**

A. Using the computer and web browser with the certificate installed, access <https://sdn.cdc.gov>. In doing this, you will get a series of screens that will alert you that you are entering a secure site. Continue to click “Next” or “finish” or “continue” as appropriate until your challenge phrase (password) is requested. When your challenge phrase is requested, type it in. Remember this is the case sensitive password (capitals are considered different than lower case letters) that you chose and wrote down when you were applying for your digital certificate. After the challenge phrase is accepted, click on “Dialysis Surveillance.”

B. After login, you see a Main Menu with a list of actions (listed below) that you may perform.

1. Enter Census data.

From Main Menu, click on “Census Summary.”

Click on the month and year desired.

Enter the data.

Click on “Save.” (Total census will be automatically computed for you)

Click on “Census Summary” to review the census data.

Click on “Main Menu” to return.

2. Enter a new patient. You must enter a patient on the Patient Form before you can enter an incident for that patient. You don’t need to enter all your patients, just the ones with incidents.

From the Main Menu, click on “Patient Form.”

Enter the data.

Click on “Save.”

Click on “Main Menu” to return.

3. Edit information on an existing patient. May use method a. or b.

a. From the Main Menu, click on “Patient Form.”

Enter the patient’s last name, first name, or medical record number, and click on

“Retrieve Patient.”

If there is only one such patient, the Patient Form for that patient will come up.

If there are multiple such patients, a list will come up. For the desired patient, click on “Patient,” and the Patient Form will come up.

Make the changes.

Click on “Save.”

Click on “Main Menu” to return.

b. Click on “List All Patients.”

For the desired patient, click on “Patient.” The Patient Form for that patient will come up.

Make the changes.

Click on “Save.”

Click on “Main Menu” to return.

4. Enter a new Incident. You must enter a patient on the Patient Form before you can enter an incident for that patient. You may use method a. or b.

a. From the Main Menu, click on “Patient Form.”

Enter the patient’s last name, first name, or medical record number, and click on “Retrieve Patient.”

If there is only one such patient, the Patient Form for that patient will come up.

If there are multiple such patients, a list will come up. For the desired patient, click on “Patient,” and the Patient Form will come up.

Click on “Enter New Incident.” A new incident form for that patient will come up.

Enter the data.

Click on “Save.”

May click on “Return to Incident Form” to check or edit it, or “Patient Form” or “List All Patients” to select a patient to enter a new incident, or “Main Menu” to return.

b. Click on “List All Patients.

For the desired patient, click on “Incident.” A new incident form for that patient will come up.

Enter the data.

Click on “Save.”

May click on “Return to Incident Form” to check or edit it, or “Enter another Incident” to enter a new incident, or “Main Menu” to return.

5. Edit existing incident.

From the Main Menu, click on “List Active Incidents.”

Click on the Incident you wish to edit.

Make the changes.

Click on “Save.”

Click on “Main Menu” to return.

6. Make a patient inactive.  
You would do this if the patient, for any reason, is no longer receiving chronic hemodialysis at your center. Follow instructions for “3. Edit an existing patient” to bring up the patient’s form. At the bottom of the Patient Form click on “Inactive.” Click on “Save” and “Main Menu” to return. The patient is kept in the database but is labeled “Inactive”. You may make the patient active again by bringing up the patient’s form (as per 3 above) and clicking on “Active.”
7. Delete an incident.  
You would do this if you find that you have entered an incident in error. Follow instructions for “4. Edit and existing incident” to bring up the incident form. At the bottom of the Incident Form, check “Delete Incident.” Click on “Save” and “Main Menu” to return. The incident is kept in the database but is labeled “deleted” and is not included in calculations. You may make the incident active again by bringing it up (as per 4 above) and clicking on the check by “Delete Incident” so that the check is removed.
8. Generating reports.  
From the “Main Menu,” click on “Tables” or “Graphs.”  
Place a check in the desired tables or graphs.  
Click on “Submit.”  
To print the reports, click on your Internet browser’s “Print” button.  
Click on your Internet browser’s “Back” button when you are finished generating the desired reports.  
Click on “Main Menu” to return.
9. Use the buttons on the screen such as “Main Menu” and “Patient Form” rather than “Back” or “Forward” buttons at the top of the screen which may cause problems. The only exception is that you should click the “Back” button after generating reports (see number 8 above).



**CENSUS FORM**

Provider number 999999

Month, year        03 / 1999

Record the number of chronic hemodialysis patients who received hemodialysis at your center at least once during the first week of the month.

Count each patient only once. If a patient has both an implanted access (graft or fistula) and a catheter, count this patient as having the catheter.

Vascular access type	Number of chronic hemodialysis patients
Graft	20
Fistula	10
Temporary catheter (noncuffed)	5
Permanent catheter (cuffed)	10
Total patients (= the sum of patients with grafts, fistulas, temporary catheters, and permanent catheters)	45

**Assurance of Confidentiality:** The information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.

**LOG.**

Form Approved OMB No. 0920-0442 Exp. date: 2/1/2002

Complete one row for each hospitalization or in-unit IV antimicrobial start. Complete an Incident Form for each row on this Log.

REMOVE THIS COLUMN BEFORE MAILING TO CDC	Provider number 999999 Year 1999				
Patient's name	Date mm / dd	Circle H and/or A H=hospitalization A=IV antimicrobial start	Problem	LOG Number	Incident Form Completed
John Smith	03/02	<input checked="" type="radio"/> H <input type="radio"/> A	Chest pain	1	<input checked="" type="radio"/> Y
Jane Doe	03/02	<input type="radio"/> H <input type="radio"/> A	Fever = 102/ F	2	<input checked="" type="radio"/> Y
Bill Miller	03/08	<input type="radio"/> H <input type="radio"/> A	Diabetic foot ulcer	3	<input checked="" type="radio"/> Y
Marie Rush	03/20	<input checked="" type="radio"/> H <input checked="" type="radio"/> A	Infected catheter	4	<input checked="" type="radio"/> Y
	/	<input type="radio"/> H <input type="radio"/> A		5	Y
	/	<input type="radio"/> H <input type="radio"/> A		6	Y
	/	<input type="radio"/> H <input type="radio"/> A		7	Y
	/	<input type="radio"/> H <input type="radio"/> A		8	Y
	/	<input type="radio"/> H <input type="radio"/> A		9	Y
	/	<input type="radio"/> H <input type="radio"/> A		10	Y
	/	<input type="radio"/> H <input type="radio"/> A		11	Y
	/	<input type="radio"/> H <input type="radio"/> A		12	Y
	/	<input type="radio"/> H <input type="radio"/> A		13	Y
	/	<input type="radio"/> H <input type="radio"/> A		14	Y
	/	<input type="radio"/> H <input type="radio"/> A		15	Y
	/	<input type="radio"/> H <input type="radio"/> A		16	Y
	/	<input type="radio"/> H <input type="radio"/> A		17	Y
	/	<input type="radio"/> H <input type="radio"/> A		18	Y
	/	<input type="radio"/> H <input type="radio"/> A		19	Y
	/	<input type="radio"/> H <input type="radio"/> A		20	Y

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Public reporting burden of this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.

**INCIDENT FORM**—complete one form for each hospitalization or in-unit IV antimicrobial start.

1. Name: First <b>John</b> MI <b>B.</b> Last <b>Smith</b>		2. Identification number: <b>123-45-6789</b>	
<b>REMOVE TOP BEFORE MAILING</b>			
3. Provider number 999999		4. Date <b>03 / 02 /1999</b>	
5. LOG Number <b>1</b>			
6. Incident type (circle H and/or A):			
<input checked="" type="radio"/> H = Hospitalization 6a. If this is a hospitalization, answer: After return to outpatient unit, was IV vancomycin given? <input type="radio"/> N <input type="radio"/> Y		A = In-unit IV antimicrobial start 6b. If this is an in-unit IV antimicrobial start, answer: Was IV vancomycin started? <input type="radio"/> N <input type="radio"/> Y	
7. Vascular accesses (circle all that the patient has): <input checked="" type="radio"/> 1 = graft    2 = fistula    3 = temporary catheter    4 = permanent catheter			
8. Problem(s) that led to hospitalization or IV antimicrobial start (circle at least one, may circle more than one):			
a. Pus, or redness, or increased swelling at vascular access site b. Vascular access problem <b>WITHOUT</b> infection (clotting, bleeding, etc) c. Fever (\$100F oral or \$101F rectal) d. Wound ( <b>NOT</b> related to vascular access) with pus or increased redness e. Pneumonia (a new infiltrate or pneumonia seen on chest X-ray) f. UTI (urine culture with >100,000 organisms/ml with not more than 2 species isolated) <input checked="" type="radio"/> g. Cardiovascular event (chest pain, heart attack, other heart problem, stroke, etc) h. Other, specify:			
9. Vascular access removed? <input checked="" type="radio"/> N <input type="radio"/> Y			
9a. If yes, circle the access that was removed: 1 = graft    2 = fistula    3 = temporary catheter    4 = permanent catheter			
10. Were <b>blood</b> cultures drawn in the unit before antimicrobial start, or within 1 day of hospital admission? <input checked="" type="radio"/> Y <input type="radio"/> N <input type="radio"/> U			
10a. If yes, result 1 = positive    2 = negative    3 = unknown			
10b. If <b>positive</b> , suspected source of positive blood culture:			
1 = vascular access    2 = a source other than the vascular access    3 = contamination    4 = uncertain			
10c. If <b>blood</b> cultures were positive, complete the following:			
		Antimicrobial susceptibility	
List organisms isolated from blood	Methicillin, Oxacillin, or Nafcillin	Vancocmycin	
List one code* or name per row	S   I   R   U	S   I   R   U	
_____	S   I   R   U	S   I   R   U	
11. Comments			
Fever: 100 F = 37.8 C    101 F = 38.3 C    N=no    Y=yes    U=unknown    S=susceptible    I=intermediate    R=resistant *SA= <i>S. aureus</i> SE= <i>S. epidermidis</i> CNS=coagulase-negative staphylococci    PA= <i>P. aeruginosa</i>			

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**INCIDENT FORM**—complete one form for each hospitalization or in-unit IV antimicrobial start.

1. Name: First **Jane** MI **E.** Last **Doe** 2. Identification number: **987-65-4321**  
**REMOVE TOP BEFORE MAILING**

3. Provider number 999999 4. Date **03 /02 / 1999** 5. LOG Number **2**

6. Incident type (circle H and/or A):  
 H = Hospitalization  A = In-unit IV antimicrobial start  
 6a. If this is a hospitalization, answer: After return to outpatient unit, was IV vancomycin given? N Y  
 6b. If this is an in-unit IV antimicrobial start, answer: Was IV vancomycin started? N  Y

7. Vascular accesses (circle all that the patient has): 1 = graft 2 = fistula 3 = temporary catheter 4 =  permanent catheter

8. Problem(s) that led to hospitalization or IV antimicrobial start (circle at least one, may circle more than one):  
 a. Pus, or redness, or increased swelling at vascular access site  
 b. Vascular access problem **WITHOUT** infection (clotting, bleeding, etc)  
 c. Fever (\$100F oral or \$101F rectal)  
 d. Wound (**NOT** related to vascular access) with pus or increased redness  
 e. Pneumonia (a new infiltrate or pneumonia seen on chest X-ray)  
 f. UTI (urine culture with >100,000 organisms/ml with not more than 2 species isolated)  
 g. Cardiovascular event (chest pain, heart attack, other heart problem, stroke, etc)  
 h. Other, specify:

9. Vascular access removed?  N Y  
 9a. If yes, circle the access that was removed: 1 = graft 2 = fistula 3 = temporary catheter 4 = permanent catheter

10. Were **blood** cultures drawn in the unit before antimicrobial start, or within 1 day of hospital admission? N Y  U  
 10a. If yes, result 1 = positive  2 = negative 3 = unknown  
 10b. If **positive**, suspected source of positive blood culture:  
 1 = vascular access 2 = a source other than the vascular access 3 = contamination 4 = uncertain  
 10c. If **blood** cultures were positive, complete the following:

List organisms isolated from blood List one code* or name per row	Antimicrobial susceptibility	
	Methicillin, Oxacillin, or Nafcillin	Vancoymcin
	S I R U	S I R U
	S I R U	S I R U

11. Comments

Fever: 100 F = 37.8 C 101 F = 38.3 C N=no Y=yes U=unknown S=susceptible I=intermediate R=resistant  
 \*SA=*S. aureus* SE= *S. epidermidis* CNS=coagulase-negative staphylococci PA=*P. aeruginosa*

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 Public reporting burden of this collection of information is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.

**INCIDENT FORM**—complete one form for each hospitalization or in-unit IV antimicrobial start.

1. Name: First **Bill** MI **W.** Last **Miller** 2. Identification number: **001-01-0001**  
**REMOVE TOP BEFORE MAILING**

3. Provider number 999999 4. Date **03 /08 /1999** 5. LOG Number **3**

6. Incident type (circle H and/or A):  
 Hospitalization A = In-unit IV antimicrobial start  
 6a. If this is a hospitalization, answer: 6b. If this is an in-unit IV antimicrobial start, answer:  
 After return to outpatient unit, was IV vancomycin given?  N  Y Was IV vancomycin started? N Y

7. Vascular accesses (circle all that the patient has):  graft 2 = fistula 3 = temporary catheter 4 = permanent catheter

8. Problem(s) that led to hospitalization or IV antimicrobial start (circle at least one, may circle more than one):  
 a. Pus, or redness, or increased swelling at vascular access site  
 b. Vascular access problem **WITHOUT** infection (clotting, bleeding, etc)  
 c. Fever (\$100F oral or \$101F rectal)  
 d. Wound (**NOT** related to vascular access) with pus or increased redness  
 e. Pneumonia (a new infiltrate or pneumonia seen on chest X-ray)  
 f. UTI (urine culture with >100,000 organisms/ml with not more than 2 species isolated)  
 g. Cardiovascular event (chest pain, heart attack, other heart problem, stroke, etc)  
 h. Other, specify:

9. Vascular access removed?  N  Y  
 9a. If yes, circle the access that was removed: 1 = graft 2 = fistula 3 = temporary catheter 4 = permanent catheter

10. Were **blood** cultures drawn in the unit before antimicrobial start, or within 1 day of hospital admission? N  Y  U  
 10a. If yes, result  1 = positive 2 = negative 3 = unknown  
 10b. If **positive**, suspected source of positive blood culture:  
 1 = vascular access  2 = a source other than the vascular access 3 = contamination 4 = uncertain

10c. If **blood** cultures were positive, complete the following:

List organisms isolated from blood List one code* or name per row	Antimicrobial susceptibility							
	Methicillin, Oxacillin, or Nafcillin		Vancoymcin					
<b>SA</b>	<input checked="" type="radio"/> S	I	R	U	<input checked="" type="radio"/> S	I	R	U
	S	I	R	U	S	I	R	U

11. Comments

Fever: 100 F = 37.8 C 101 F = 38.3 C N=no Y=yes U=unknown S=susceptible I=intermediate R=resistant  
 \*SA=*S. aureus* SE= *S. epidermidis* CNS=coagulase-negative staphylococci PA=*P. aeruginosa*

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**INCIDENT FORM**—complete one form for each hospitalization or in-unit IV antimicrobial start.

1. Name: First **Marie** MI H. Last **Rush** 2. Identification number: **444-44-4444**  
**REMOVE TOP BEFORE MAILING**

3. Provider number 999999 4. Date **03 / 20 /1999** 5. LOG Number **4**

6. Incident type (circle H and/or A):

H = Hospitalization

A = In-unit IV antimicrobial start

6a. If this is a hospitalization, answer:

After return to outpatient unit, was IV vancomycin given?  N  Y

6b. If this is an in-unit IV antimicrobial start, answer:

Was IV vancomycin started?  N  Y

7. Vascular accesses (circle all that the patient has): 1 = graft 2 =  fistula 3 =  temporary catheter 4 = permanent catheter

8. Problem(s) that led to hospitalization or IV antimicrobial start (circle at least one, may circle more than one):

- a. Pus, or redness, or increased swelling at vascular access site
- b. Vascular access problem **WITHOUT** infection (clotting, bleeding, etc)
- c. Fever (\$100F oral or \$101F rectal)
- d. Wound (**NOT** related to vascular access) with pus or increased redness
- e. Pneumonia (a new infiltrate or pneumonia seen on chest X-ray)
- f. UTI (urine culture with >100,000 organisms/ml with not more than 2 species isolated)
- g. Cardiovascular event (chest pain, heart attack, other heart problem, stroke, etc)
- h. Other, specify:

9. Vascular access removed?  N  Y

9a. If yes, circle the access that was removed: 1 = graft 2 = fistula  3 = temporary catheter 4 = permanent catheter

10. Were **blood** cultures drawn in the unit before antimicrobial start, or within 1 day of hospital admission?  N  Y  U

10a. If yes, result  1 = positive 2 = negative 3 = unknown

10b. If **positive**, suspected source of positive blood culture:

1 = vascular access 2 = a source other than the vascular access 3 = contamination 4 = uncertain

10c. If **blood** cultures were positive, complete the following:

Antimicrobial susceptibility

List organisms isolated from blood List one code* or name per row	Methicillin, Oxacillin, or Nafcillin	Vancomycin
<b>S. epidermidis</b>	S I <input checked="" type="radio"/> R U	<input checked="" type="radio"/> S I R U
	S I R U	S I R U

11. Comments **temporary catheter infected**

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 \*SA=*S. aureus* SE=*S. epidermidis* CNS=coagulase-negative staphylococci PA=*P. aeruginosa*

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# **Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers**

## **Section 2**

### **Agreement to Participate**

Agreement to participate Form Approved OMB No. 0920-0442 Exp. date: 2/1/2002  
Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers

Name of dialysis center: \_\_\_\_\_

Address \_\_\_\_\_

\_\_\_\_\_

Phone \_\_\_\_\_

Fax \_\_\_\_\_

Email address \_\_\_\_\_

HCFA provider number \_\_\_\_\_

As described in the introductory invitation letter, CDC will use the data for surveillance purposes only, and has obtained an assurance of confidentiality to protect the data. However, a condition of participation is your agreement to report outbreaks or other problems of public health importance identified in this surveillance system, and for which you have been contacted by CDC, to the local or state public health authorities.

We agree to participate in “Surveillance for Bloodstream Infection and Vascular Access Infections in Outpatient Hemodialysis Centers.” We understand that participation is voluntary and we can discontinue our participation at any time.

The primary contact person listed below agrees that data collected and transmitted to Centers for Disease Control and Prevention (CDC) will be complete and accurate, to the best of his or her knowledge.

Primary contact person:

Name (printed) \_\_\_\_\_ Title \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

Medical Director or Administrator

Name (printed) \_\_\_\_\_ Title \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

**Assurance of Confidentiality:** The information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).



Agreement to Participate, page 2

Name of dialysis center: \_\_\_\_\_

HCFA Provider number \_\_\_\_\_

Answer the following questions based on your dialysis center's policy. If your center has no policy, answer based on the most commonly followed procedure.

For puncture of a graft or fistula, answer:

- N Y This dialysis center has a written policy for puncture of graft/fistula  
 N Y Area washed with antibacterial soap  
 N Y Area washed with other, specify: \_\_\_\_\_  
 N Y Puncture site wiped with povidone-iodine (betadine, iodophor)  
     If yes,  
     Number of pads/swabs used: \_\_\_\_\_  
     Is the povidone-iodine left on \$3 minutes or allowed to dry? N Y  
 N Y Puncture site wiped with other, specify: \_\_\_\_\_

For dressing change of central catheters, answer:

- Y N This dialysis center has a written policy for catheter dressing changes.  
 Y N Staff person is required to wear a mask during dressing change.  
 Y N Patient is required to wear a mask during dressing change.  
 Y N Staff are required to wear clean nonsterile gloves to remove old dressing  
 Y N Staff are required to wear sterile gloves to clean the area and apply new dressing.  
 Y N If drainage is found at the exit site (i.e., the place where the catheter enters the skin),  
     drainage is removed with (specify): \_\_\_\_\_  
 Y N Exit site wiped with povidone-iodine (betadine, iodophor).  
 Y N Antibacterial ointment applied to exit site during dressing change.  
 Y N Dressing applied over exit site at least once weekly.

Specify type of dressing used over catheter:

\_none \_gauze \_band-aid \_transparent \_other (specify) \_\_\_\_\_

For access of central catheters, answer:

- Y N This dialysis center has a written policy for access of catheter.  
 Y N Staff person is required to wear a mask during access.  
 Y N Patient is required to wear a mask during access  
 Y N Staff are required to wear sterile gloves to clean the area and do access.  
 Y N Catheter port site (usually a rubber diaphragm)  
     wiped with povidone-iodine (betadine, iodophor).  
     If yes,  
     Number of pads/swabs used: \_\_\_\_\_  
     Is the povidone-iodine left on \$ 3 minutes or allowed to dry? Y N  
 Y N Catheter port site wiped with other (specify) \_\_\_\_\_

Specify type of dressing used over catheter:

\_none \_gauze \_band-aid \_transparent \_other (specify) \_\_\_\_\_

Regarding antimicrobial use, answer

- Y N This center has a written policy regarding antimicrobial use  
 Y N This center has access to a computerized listing of antimicrobials received by patients

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Public reporting burden of this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600

Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.

## **Institutional Review Board**

The CDC IRB has approved the study and this is all this is required by us. If your center has an IRB, and that IRB requires that they review the protocol, then it is your responsibility to submit it to them and obtain approval before starting data collection.

Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis  
Centers

Surv29.wpd 07/20/2000

## **PURPOSES**

1. To provide a method for individual hemodialysis centers to record and track rates of bloodstream and vascular access infections, hospitalizations, and intravenous (IV) antimicrobial starts.
2. To provide a method for Centers for Disease Control and Prevention (CDC) to aggregate, compare, and distribute these data to cooperating dialysis centers and the public health and medical communities.
3. To use these data to prevent infections and slow the spread of antimicrobial resistance.

## **SUMMARY**

Bloodstream and vascular access infections are a threat to hemodialysis patients. However, there are few studies of rates of such infections, and there are no standardized methods for ongoing data collection. Because of frequent hospitalizations and receipt of antimicrobials, hemodialysis patients are at high risk for infection with drug-resistant bacteria. This protocol outlines creation of a voluntary national surveillance system. Each month, dialysis center personnel will record the number of chronic hemodialysis patients that they treat (broken down into four types of vascular access). A one-page form will be completed for each hospitalization or in-unit intravenous (IV) antimicrobial start among these patients. These

data will allow calculation, stratified by type of vascular access, of rates of access-related bloodstream infection, vascular access infections, hospitalizations, in-unit IV antimicrobial starts, and uses of vancomycin. For individual dialysis centers, this surveillance system will provide a simple and standardized method to record data, calculate rates, and compare rates over time. It is hoped that collection and examination of these data will lead to quality improvement measures. For government and the medical and public health communities, aggregation of these data from many dialysis centers will provide a wealth of information which is not currently available.

## **INTRODUCTION**

At the end of 1996, 183,022 patients were being treated with chronic hemodialysis at 3,015 dialysis centers in the United States. Hemodialysis patients require a vascular access, a large blood vessel or catheter that can be punctured to remove blood. The blood is passed through a dialyzer to remove wastes and finally returned to the patient through the vascular access. Bacteremias and localized infections of the vascular access site are thought to be common in hemodialysis patients (1).

The only large recent studies of infections in hemodialysis patients have been conducted in France (1) and Canada (2). Although sophisticated surveillance systems for nosocomial infections in hospitalized patients in the United States exist (3), there are no standardized methods for surveillance for infections in outpatient hemodialysis centers. An important strategy for preventing infections, or any other complication, is to count them in a systematic manner, calculate appropriate rates of occurrence, and compare the rates over time.

This proposed surveillance system is intended to assist dialysis centers in using this approach.

Reported local signs of vascular access infection include erythema, warmth, induration, swelling, tenderness, breakdown of skin, loculated fluid, or purulent exudate (4-6). Among vascular access types, arteriovenous fistulas created from the patient's own blood vessels have the lowest rates of infection; grafts constructed from synthetic materials have intermediate risk; and central catheters have the highest risk (2,7,8). Because type of vascular access is the strongest known predictor of infection, this surveillance system will collect data on the population of hemodialysis patients at risk stratified by type of vascular access. This will allow calculation of rates separately for the different types of vascular access.

The rapid increase in vancomycin-resistant enterococci (VRE) in the United States is linked to use of antimicrobials, including vancomycin (9,10). Vancomycin is thought to be used commonly in dialysis patients because it can be administered once a week and is effective against two common pathogens, coagulase-negative staphylococci and *Staphylococcus aureus*. Strains of *S. aureus* with intermediate susceptibility to vancomycin have been isolated from only four patients worldwide. Of these four, one was receiving temporary dialysis and two were receiving chronic dialysis; all had received prolonged courses of vancomycin (11)(Centers for Disease Control and Prevention [CDC], unpublished data). Therefore, a secondary purpose of this surveillance system is to record rates of and syndromes prompting use of intravenous (IV) antimicrobials in hemodialysis centers.

Participation in this project is voluntary and centers may discontinue participation at any time. Only chronic hemodialysis patients, will be studied. For these patients, an "Incident Form" is completed for each hospitalization or in-unit IV antimicrobial start. It is assumed that

if a patient has a significant bacterial infection, he/she will be either hospitalized or started on an IV antimicrobial in the dialysis unit. Therefore, the Incident Forms will have data on all patients likely to have an infection.

Among infections, this project focuses on bacteremias and vascular access infections. Information on other infections is collected in a simplified manner to help define the indications for antimicrobial use and determine whether bacteremia is access-related, caused by an infection elsewhere, or of no identifiable origin. The distinction is important, because measures to prevent access-related bacteremia are different from those to prevent other bacteremias.

Dialysis center personnel may collect data on paper forms and send the forms to CDC, where the data will be entered into a computer and reports generated. However, if desired, individual center personnel may find it beneficial to enter their own data into a computer, perform analysis, and generate reports on-site that can be used for quality control efforts. For such centers, CDC will develop and supply simple computer programs to facilitate data entry and analysis. All data, regardless of whether collected on paper forms or in computer databases, will be sent to CDC, where it can be aggregated and summary reports prepared. These data will provide a wealth of information currently lacking about infectious complications suffered by chronic hemodialysis patients.

## **STUDY DESIGN**

### **Participation**

CDC will solicit dialysis centers to participate in this project through a letter to dialysis

centers (Attachment 1a). Centers treating primarily children may participate; data from these pediatric units will be analyzed and presented separately from the majority of units that treat primarily adults. Participation in this project is voluntary on the part of dialysis centers. The medical director, physicians, administrator, head nurse, and other key personnel should be familiar with the project and agree to participate. Centers may collect data for as little as one month or for an indefinite period, as desired. Collection of data for a longer period will result in information that is of more benefit to the dialysis center.

Centers wishing to participate should complete and submit Attachment 1, Agreement to Participate. This form requests information on infection control precautions and on policies for antimicrobial use. Centers may discontinue participation at any time. For centers that continue to participate, the Agreement to Participate will be filled out once per year to update information. The three forms for ongoing data collection include information on:

For hospitalizations:

1. that patients have been hospitalized.
2. the problem or diagnoses prompting hospital admission, especially whether the patient had signs and symptoms of access infection.
3. the results of blood cultures done in the hospital soon after admission.

For in-unit IV antimicrobial starts:

4. that patients were started on an IV antimicrobial in-unit.
5. the problem or diagnosis prompting use of the IV antimicrobial, especially whether patients had signs and symptoms of access infection.
6. the results of blood cultures done in the unit.

These steps will be easily accomplished at some centers through use of computerized databases or billing records, but will be a major challenge at other centers. Before participating, centers should, at a minimum, be sure that they can perform 1 and 4-6 from the list above. Data will be most useful to dialysis centers if they can perform all six.

Only chronic hemodialysis patients will be studied.

### **Data collection**

Ongoing data collection will use three forms (Attachments 2, 3, and 4). Center personnel may record data on paper forms and forward the forms to CDC after removing patients' names. Center personnel alternately could enter the data into a computer database.

**CENSUS FORM.** The Census Form (Attachment 2) is used to record the number of chronic hemodialysis patients with each access type who received hemodialysis at your center at least once during the first week of the month.

Count each patient only once; if the patient has both a implanted access (fistula or graft) and a catheter, count the patient as having a catheter.

- Provider number: the center's provider number as assigned by the health care financing administration (HCFA).
- Current month and year, in mm/yyyy format (e.g., 07/1998)
- Grafts: the number of patients having AV grafts
- Fistulas: the number of patients having AV fistulas
- Temporary catheters: the number of patients having temporary (noncuffed) catheters
- Permanent catheters: the number of patients having permanent (cuffed) catheters
- Total patients: the total number of chronic hemodialysis patients as of the first of the



month, equals the sum of patients who receive dialysis via grafts + fistulas + permanent catheters + temporary catheters.

LOG. One row of the Log (Attachment 3) is completed for each Incident (hospital admission or in-unit IV antimicrobial start). Include only chronic hemodialysis patients. There is room for 20 incidents on each form. Start a new log form each month. Information written on the Log will not be used in data analysis. This is used only to help insure that an Incident Form (see below) is completed whenever necessary.

- Provider number. The center's provider number as assigned by HCFA.
- Year. Use 4 digits, e.g., 1998.
- Patient name. Remove this column before sending the form to CDC.
- Date. The month and day of the hospitalization or IV antimicrobial start.
- Circle H or A. Circle H if this is a hospitalization, A if it is an in-unit IV antimicrobial start, or both if the IV antimicrobials were started in the unit and the patient was subsequently admitted to the hospital.
- Problem. Write in a brief description of the primary problem.
- Incident form completed. An Incident Form should be completed for each row on the Log. When the Incident Form is complete, circle Y on the Log Form.

INCIDENT FORM. One Incident Form (Attachment 4) is completed for each hospital admission or in-unit IV antimicrobial start. Include only chronic hemodialysis patients. Information recorded on this form will be used for analysis purposes.

1. Name: First MI Last. Refers to the patient's name. If data are transmitted to CDC on paper forms, remove this section of the form before sending it to CDC. If

reporting data by computer, name is optional.

2. Identification number. May use hospital number, social security number, or any unique identification number. If data are transmitted to CDC on paper forms, remove this section of the form before sending it to CDC.

3. Provider number. The center's provider number as assigned by HCFA.

4. Date: the month, day, and year (mm/dd/yyyy, i.e., 07/23/1998) of the hospitalization or IV antimicrobial start.

5. Number: Number the incident forms consecutively starting with 1. Each new month will start with 1.

6. Incident type. Circle "H" if this is a hospitalization, "A" if it is an in-unit IV antimicrobial start, or both if the IV antimicrobials were started in the unit and the patient was subsequently admitted to the hospital.

6a. If a hospital admission, answer: After return to the unit, IV vancomycin given?

This refers to IV vancomycin given in the dialysis unit after the patient has been discharged from the hospital and returns to the dialysis unit.

6b. If an in-unit IV antimicrobial start, answer: IV vancomycin started? This question is completed only if IV antimicrobials were started in the dialysis unit.

If the antimicrobial regimen included vancomycin, circle Y. Otherwise, circle N.

7. Vascular accesses (circle all that the patient has): Circle one or more numbers to indicate the patient's current vascular access: fistula, graft, temporary (noncuffed) catheter, or permanent (cuffed) catheter.

8. Problem(s) that led to hospitalization or IV antimicrobial start (circle at least one, may circle more than one).

If the patient was hospitalized, this question refers to problems causing the admission.

If this is an in-unit IV antimicrobial start, this question refers to problems causing the antimicrobial to be started.

- a. Pus, or redness, or increased swelling at vascular access site. Do not circle “a” if the patient merely has fever of unknown source (circle “c” instead). If the patient is felt to have an access infection, but does not have pus, redness, or increased swelling, do not circle “a” (circle “h” instead). If the patient has more than one access, indicate under “11. Comments” (at the bottom of the form) which access had the pus, redness, or increased swelling.
- b. Vascular access problem WITHOUT infection (bleeding, clotting, etc).
- c. Fever (\$100F oral or \$101F rectal). Circle this category if the patient has a fever with or without other symptoms or signs of infection.
- d. Wound (NOT related to vascular access) with pus or increased redness. This could be the site of a former surgical procedure NOT related to the access, a decubitus ulcer, a diabetic foot ulcer, etc. Do not circle “d” if the patient has a wound problem, but does not have pus or increased redness (circle “h” instead).
- e. Pneumonia (a new infiltrate or pneumonia seen on chest X-ray). Do not circle this choice if the patient is considered to have bronchitis or pneumonia, but does not have an infiltrate seen on chest X-ray (circle “h” instead).
- f. Urinary tract infection (UTI) (urine culture with >100,000 organisms/ml with

not more than two species isolated). If more than two species are isolated, it is likely the specimen was contaminated during collection, and the organisms are actually not causing an infection. Do not circle this choice if the patient is felt to have a UTI, but does not meet the criteria for this category (circle “h” instead).

g. Cardiovascular event (chest pain, heart attack, other heart problem, stroke, etc). Include arrhythmias, congestive heart failure, noninfective pericarditis, suspected or confirmed myocardial infarction (heart attack), cerebrovascular accident, stroke, etc.

h. Other, specify: If the primary reason for hospitalization or IV antimicrobial start is not listed under a-g above, print it neatly and concisely here. Use the physician’s assessment, if available; otherwise use the nurse’s assessment.

Examples are abdominal pain (specify etiology if known), bronchitis, cholecystitis, confusion, diverticulitis, electrolyte imbalance (calcium, potassium, etc), fluid overload, peritoneal dialysis catheter infection, prostatitis, sinusitis, surgery, or tooth extraction. If the diagnosis is unknown, write in “Unknown.”

9. Vascular access removed. Circle N or Y to indicate whether the vascular access was removed as part of this incident.

9a. If yes, circle the access that was removed:

Circle the appropriate number of the access removed. If more than one access was removed, circle more than one number.

10. Were any blood cultures drawn in the unit, or within 1 day of hospital admission?

Circle N, Y, or U. If the patient was hospitalized, we are looking for blood cultures taken within 1 day before to 1 day after hospital admission—do not record the many blood cultures a patient may have during a hospital admission. If the patient was hospitalized and you don't know if blood cultures were done, circle U.

10a. If yes, result 1=positive 2=negative 3=unknown. You would circle U only if the patient had been hospitalized and blood culture results are not available.

10b. If positive, suspected source of positive blood culture:

1=vascular access 2=a source other than the vascular access  
3=contamination 4=uncertain.

More than one of the above may be circled.

Circle "1=vascular access" only if there is some objective evidence of vascular access infection (i.e., drainage, pus, redness, swelling, pain, an open area, or a positive culture from the access showing the same organism found in the blood)—do not circle this category if the patient has a positive blood culture of no known etiology (instead, circle 4=uncertain).

Circle 2 if the patient has an infection at another site that could have caused the positive blood culture. Circle this option if either (a) or (b) is true: (a) a culture from another site (e.g, leg wound, urine) shows the same organism found in the blood; (b) there is clinical evidence of infection at another site, but a culture was not taken from it.

Circle 3 if the organism is thought to be a contaminant. Circle this

option if either the laboratory or the attending physician states that the positive blood culture is suspected to be a contaminant. Blood cultures positive for the following organisms may represent contamination: coagulase-negative staphylococcus (e.g., *S. epidermidis*, CNS), diphtheroids, *Propionibacterium* species, or *Bacillus* species. Coagulase-negative staphylococci (CNS) include *S. epidermidis* and several other species of *Staphylococcus* but NOT *S. aureus*. Diphtheroids may be reported by the laboratory simply as “diphtheroids” or as a name starting with “*Corynebacterium*” such as “*C. ulcerans*.”

Contamination is more likely if only one blood culture “set” is positive for the organism. Each blood culture “set” usually consists of 20 ml of blood inoculated into two blood culture bottles (10 ml into each bottle); more than 2 bottles filled from a single venipuncture should be interpreted as only one set.

Circle 4 = uncertain if there is insufficient evidence to decide among the three previous categories.

10c. If blood cultures were positive, complete the following:

List organisms isolated from blood. List one code or organism per row.

If the blood cultures were positive, indicate which organism or organisms grew.

On paper forms: Write in SA for *S. aureus*, SE for *S. epidermidis*, CNS for coagulase-negative staphylococci or PA or *Pseudomonas aeruginosa*.

Otherwise, neatly print the first letter of the genus and the entire species name (e.g., *K. pneumoniae*, *B. cepacia*, *C. diversus*, *S. marcescens*). If you do not know the organism, write in “Unknown.”

On the computer data entry screen: highlight the appropriate organism name or category in the drop-down list.

There is room for two organisms found in blood cultures; if more than two organisms were isolated from blood, list these under “Comment” (see below).

- Methicillin, oxacillin, or nafcillin. Answer R if the organism was reported to be resistant to oxacillin, methicillin, or nafcillin. If it is susceptible to one of these, circle S. If reported to be intermediate, circle I. If the organism was not tested, or if you do not have the result, circle U (unknown). Note that if a *S. aureus* isolate is resistant to oxacillin, it is also resistant to methicillin and is called a methicillin-resistant *S. aureus* (MRSA).

- Vancomycin. Circle S if the organism was susceptible to vancomycin, I if intermediate, or R if resistant. If the organism was not tested, or if you do not have the result, circle U (unknown). Note that if an enterococcus (e.g., *E. faecium* or *E. faecalis*) is resistant to vancomycin, it is a vancomycin-resistant enterococcus (VRE).

11. Comment(s). Use this to record any comment, additional explanation, other infection, or information that is not recorded elsewhere.

The answers to some questions about hospitalizations may not be known, especially initially. In such instances, only available information should be completed. When the patient is discharged from the hospital and returns to the dialysis center, update any information available. Circle or write in “Unknown” as appropriate if information is still not available; center personnel are not expected to go to

extraordinary lengths to obtain information from hospitalizations.

To obtain data from hospital admissions, center personnel could request that physicians record the following in the patient's dialysis unit chart as soon as possible after the hospital admission: the reason for hospital admission, whether signs of access infection (pus, redness or increased swelling) were present at the time of admission, and whether the patient had a positive blood culture within 1 day after hospital admission. Recording these data in the dialysis unit chart would be consistent with good record-keeping and will facilitate general quality control measures. Other data needed to complete the Incident Form could be ascertained after the patient is discharged from the hospital and returns to the unit.

Each time a patient is hospitalized (no matter how soon after the last hospitalization), a new entry should be made on the Log and a new Incident Form filled out. If the patient was hospitalized and returns to the dialysis unit on IV antimicrobials, do NOT make a new entry on the Log and do NOT complete a second Incident Form.

If IV antimicrobials are stopped for less than 21 days and then restarted, this is NOT considered a new incident (therefore do not make an entry on the Log and do NOT complete a new Incident Form). However, if IV antimicrobials are stopped for 21 days or more and then restarted, this is considered a new incident. Make an entry on the Log and complete a new Incident Form.

### **Data validation**

Dialysis center personnel should strive for day-to-day accuracy in data collection. Although not a formal part of the surveillance system, several methods to spot-check or



validate the data are possible. If a computerized laboratory database is available, dialysis center personnel could print out a list of all blood culture results for a given month and compare the list with the Log and Incident Forms to insure that all positive blood cultures have been reported. If pharmacy records are computerized, a list of medications dispensed could be printed to insure that all IV antimicrobial starts were recorded. If computerized lists of hospital admissions or diagnoses are available, these could be examined and compared to the Log and Incident Forms. Similar procedures could be used for handwritten records, if available.

Dialysis center personnel may be asked to allow CDC personnel or their representatives to examine dialysis center records for the purpose of validating one or more months of data. Such validation would be done only with the written permission of the medical or administrative director of the dialysis unit.

### **Data analysis**

If data are recorded on paper forms and forwarded to CDC, the data will be entered into a computer database at CDC. If the data is entered into a computer database at the center, data analysis can be done by personnel at the center using a program supplied by CDC.

The number of various types of bacterial infections, hospitalizations, and IV antimicrobial starts per month will be tabulated, and rates of these events per 100 patient-months will be calculated. An example of the calculation of patient-months is: if a center treated 50 patients during the first week in January and 52 during the first week in February, and 48 during the first week in March, this center would have 150 patient-months in the first three months of the year. If 2 bloodstream infections occurred during this time, the overall bloodstream rate would be  $(2/150)*100=1.33$  bloodstream infections per 100 patient-months.

Infections will be categorized as per the table below. Rates will be calculated separately for the four types of vascular access (fistulas, grafts, and temporary or permanent catheters). This table is for data analysis and interpretation, and personnel do NOT have to use it while collecting data. Clinical signs of infection of the access site include pus, redness, or increased swelling.

Category	IV antimicrobial therapy or hospitalization	Blood culture	Clinical signs of infection	Suspected source of positive blood culture
Vascular access-related BSI	Yes	Positive	Access or none	Access or uncertain
Vascular access infection without BSI	Yes	Not done or negative	Access	Not applicable
Other bacteremia	Yes	Positive	Nonaccess, or none	Nonaccess
Infections other than access	Yes	Not done or negative	Nonaccess	Not applicable

BSI denotes bloodstream infection

Nonaccess denotes a site other than the vascular access

Certain data (e.g., race/ethnicity distribution, age distribution, cause of renal failure, standardized mortality and hospitalization ratios, lists of hospitalizations) will be obtained as possible from HCFA and the US Renal Data Systems (USRDS). These data will be used to assess representativeness by comparing centers that do with those that do not participate in the surveillance system, and possibly to control for differences among participating centers in

patient populations. These data will be kept confidential, and any data user agreements that are needed to obtain the data will be followed.

### **Data release and publication**

Data that are forwarded to CDC will be aggregated and analyzed at CDC. Periodically, data will be released to participating dialysis centers. If appropriate, publications will be prepared and authored by CDC.

### **Records Management and Protection of Confidentiality**

This protocol has been approved by the CDC Institutional Review Board (IRB) (Protocol 2213). Participating centers can rely on the CDC IRB, or they can submit the protocol to their own IRB, as appropriate. This surveillance project involves collection of data from existing clinical records and does not include any intervention(s). Therefore, a waiver of informed consent has been requested and received from the CDC IRB.

Participating dialysis centers should take appropriate steps to maintain the confidentiality of any information collected as part of this project. Data may be transmitted from participating facilities to CDC (a) on paper forms, (b) by entering the data into an Internet-based data entry screen provided by CDC, or (c) by collecting data in a computer database created and maintained by the facility, and sending a summary file to CDC in a format specified by CDC. If method (a) is used, the paper forms should be photocopied, and then the top of the form containing personnel identifiers should be removed, prior to transmittal to CDC. If method (b) or (c) is used, data will be transmitted to CDC in encrypted form via the Internet using the CDC/ATSDR Secure Data Network (SDN), a secure transmission mechanism which meets the requirements of CDC's Internet security policy. At

CDC, all data, including personal identifiers, will be stored unencrypted in password-protected data files in a locked file or room, with access restricted to study personnel.

**PERSONNEL AND RESPONSIBILITIES**

At each participating dialysis center, one person should be identified as the primary contact person who has responsibility for data collection and transmittal to CDC. At CDC, the following personnel will be responsible for coordination, answering questions, aggregating data, analyzing data, and preparing reports:

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**TIMETABLE**

Completion of protocol: September 1998

Approval of the CDC IRB: November 1998

Submission for Office of Management and Budget (OMB) approval: December 1998

General availability of the system: March 1999

**LIST OF ATTACHMENTS**

1. Agreement to participate
  - 1a. Letter to dialysis centers
2. Census
3. Log
4. Incident Form

## REFERENCES

1. Kessler M, Hoen B, Mayeux D, Hestin D, Fontenaille C. Bacteremia in patients on chronic hemodialysis. *Nephron*. 1993;64:95-100.
2. Churchill DN, Taylor DW, Cook RJ, LePlante P, Barre P, Cartier P, et al. Canadian hemodialysis morbidity study. *Am J Kidney Dis*. 1992;19:214-234.
3. Gaynes RP, Culver DH, Emori TG, Horan TC, Banerjee SN, Edwards JE, et al. The National Nosocomial Infections Surveillance System: Plans for the 1990's and Beyond. *Am J Med*. 1991;91 (suppl 3B):116S-120S.
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## Attachment 1. Agreement to participate.

Form Approved OMB No. 0920-0442 Exp. date: 2/1/2002

## Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers

Name of dialysis center: \_\_\_\_\_

Address \_\_\_\_\_

\_\_\_\_\_

Phone \_\_\_\_\_

Fax \_\_\_\_\_

Email address \_\_\_\_\_

HCFA provider number \_\_\_\_\_

As described in the introductory invitation letter, CDC will use the data for surveillance purposes only, and has obtained an assurance of confidentiality to protect the data. However, a condition of participation is your agreement to report outbreaks or other problems of public health importance identified in this surveillance system, and for which you have been contacted by CDC, to the local or state public health authorities.

We agree to participate in “Surveillance for Bloodstream Infection and Vascular Access Infections in Outpatient Hemodialysis Centers.” We understand that participation is voluntary and we can discontinue our participation at any time.

The primary contact person listed below agrees that data collected and transmitted to Centers for Disease Control and Prevention (CDC) will be complete and accurate, to the best of his or her knowledge.

Primary contact person:

Name (printed) \_\_\_\_\_ Title \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

Medical Director or Administrator

Name (printed) \_\_\_\_\_ Title \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

**Assurance of Confidentiality:** The information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).



Attachment 1. Agreement to Participate, page 2.

Name of dialysis center: \_\_\_\_\_

HCFA Provider number \_\_\_\_\_

Answer the following questions based on your dialysis center's policy. If your center has no policy, answer based on the most commonly followed procedure.

For puncture of a graft or fistula, answer:

- N Y This dialysis center has a written policy for puncture of graft/fistula  
 N Y Area washed with antibacterial soap  
 N Y Area washed with other, specify: \_\_\_\_\_  
 N Y Puncture site wiped with povidone-iodine (betadine, iodophor)  
     If yes,  
     Number of pads/swabs used: \_\_\_\_\_  
     Is the povidone-iodine left on \$3 minutes or allowed to dry? N Y  
 N Y Puncture site wiped with other, specify: \_\_\_\_\_

For dressing change of central catheters, answer:

- Y N This dialysis center has a written policy for catheter dressing changes.  
 Y N Staff person is required to wear a mask during dressing change.  
 Y N Patient is required to wear a mask during dressing change.  
 Y N Staff are required to wear clean nonsterile gloves to remove old dressing  
 Y N Staff are required to wear sterile gloves to clean the area and apply new dressing.  
 Y N If drainage is found at the exit site (i.e., the place where the catheter enters the skin),  
     drainage is removed with (specify): \_\_\_\_\_  
 Y N Exit site wiped with povidone-iodine (betadine, iodophor).  
 Y N Antibacterial ointment applied to exit site during dressing change.  
 Y N Dressing applied over exit site at least once weekly.

Specify type of dressing used over catheter:

\_none \_gauze \_band-aid \_transparent \_other (specify) \_\_\_\_\_

For access of central catheters, answer:

- Y N This dialysis center has a written policy for access of catheter.  
 Y N Staff person is required to wear a mask during access.  
 Y N Patient is required to wear a mask during access.  
 Y N Staff are required to wear sterile gloves to clean the area and do access.  
 Y N Catheter port site (usually a rubber diaphragm) wiped with povidone-iodine (betadine, iodophor).  
     If yes,  
     Number of pads/swabs used: \_\_\_\_\_  
     Is the povidone-iodine left on \$ 3 minutes or allowed to dry? Y N  
 Y N Catheter port site wiped with other (specify) \_\_\_\_\_

Specify type of dressing used over catheter:

\_none \_gauze \_band-aid \_transparent \_other (specify) \_\_\_\_\_

Regarding antimicrobial use, answer

- Y N This center has a written policy regarding antimicrobial use  
 Y N This center has access to a computerized listing of antimicrobials received by patients

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Public reporting burden of this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.

Attachment 1a. Letter to Dialysis Centers.

Dear Dialysis Center Personnel:

As you know, bacterial infections are major problems in hemodialysis patients. Therefore the Centers for Disease Control and Prevention (CDC) has established a voluntary surveillance system, "Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers." We would like to invite your dialysis center to participate in this project.

Each month, participating centers will report the number of chronic hemodialysis patients treated, and supply information on patients hospitalized or treated with an intravenous (IV) antimicrobial. Data will be forwarded to the CDC for analysis, and routine reports will be compiled and sent to participating centers. At their option, centers may enter and analyze their own data using programs supplied by CDC. We hope that these data will facilitate quality improvement measures.

This study is entirely voluntary. Dialysis center personnel decide whether to participate, and may elect to discontinue participation at any time.

In order to assure the confidentiality of the sources and the data it collects for this surveillance of bloodstream and vascular access infections in outpatient hemodialysis centers, the CDC Hospital Infections Program has obtained authorization to collect this data under the protection of Section 308(d) of the Public Health Service Act. The 308(d) confidentiality assurance affords this data the greatest protection against disclosure that CDC, as a Federal research agency, can provide under Federal law. The legislation stipulates that no information in a project protected by 308(d) can be used for any purpose other than the purpose for which it was supplied, nor be published or released in an identifiable format unless the establishment or person supplying the information or described in it has consented to such release.

As stated above, CDC will use the data for surveillance purposes only. However, a condition of participation is your agreement to report outbreaks or other problems of public health importance identified in this surveillance system, and for which you have been contacted by CDC, to the local or state public health authorities.

Thank you for considering participation in this surveillance system.

Yours truly,

Jerome I. Tokars, MD, MPH

Elaine R. Miller, RN, MPH

Attachment 2  
**CENSUS FORM**

Form Approved OMB No. 0920-0442 Exp. date: 2/1/2002

Provider number     \_ \_ \_ \_ \_

Month, year         \_ \_ / \_ \_ \_ \_

Record the number of chronic hemodialysis patients who received hemodialysis at your center at least once during the first week of the month.

Count each patient only once. If a patient has both an implanted access (graft or fistula) and a catheter, count this patient as having the catheter.

Vascular access type	Number of chronic hemodialysis patients
Graft	
Fistula	
Temporary catheter (noncuffed)	
Permanent catheter (cuffed)	
Total patients (= the sum of patients with grafts, fistulas, temporary catheters, and permanent catheters)	

**Assurance of Confidentiality:** The information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.

Attachment 3. **LOG.**

Form Approved OMB No. 0920-0442 Exp. date: 2/1/2002

Complete one row for each hospitalization or in-unit IV antimicrobial start. Complete an Incident Form for each row on this Log.

<b>REMOVE THIS COLUMN BEFORE MAILING TO CDC</b>	Provider number _ _ _ _ _ Year _ _ _ _ _				
Patient's name	Date mm / dd	Circle H and/or A H=hospitalization A=IV antimicrobial start	Problem	LOG Number	Incident Form Completed
	/	H A		1	Y
	/	H A		2	Y
	/	H A		3	Y
	/	H A		4	Y
	/	H A		5	Y
	/	H A		6	Y
	/	H A		7	Y
	/	H A		8	Y
	/	H A		9	Y
	/	H A		10	Y
	/	H A		11	Y
	/	H A		12	Y
	/	H A		13	Y
	/	H A		14	Y
	/	H A		15	Y
	/	H A		16	Y
	/	H A		17	Y
	/	H A		18	Y
	/	H A		19	Y
	/	H A		20	Y

**Assurance of Confidentiality:** The information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

Public reporting burden of this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.

## Attachment 4

Form Approved OMB No. 0920-0442 Exp. date: 2/1/2002

**INCIDENT FORM**—complete one form for each hospitalization or in-unit IV antimicrobial start.

1. Name: First _____ MI _____ Last _____ <p style="text-align: center;"><b>REMOVE TOP BEFORE MAILING</b></p>	2. Identification number: _____																
3. Provider number _____	4. Date ____ / ____ / ____																
5. LOG Number ____																	
6. Incident type (circle H and/or A): <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;">                     H = Hospitalization                       6a. If this is a hospitalization, answer:                      After return to outpatient unit, was IV vancomycin given?    N    Y                 </div> <div style="width: 45%; border-left: 1px dashed black; padding-left: 10px;">                     A = In-unit IV antimicrobial start                       6b. If this is an in-unit IV antimicrobial start, answer:                      Was IV vancomycin started?    N    Y                 </div> </div>																	
7. Vascular accesses (circle all that the patient has):    1 = graft    2 = fistula    3 = temporary catheter    4 = permanent catheter																	
8. Problem(s) that led to hospitalization or IV antimicrobial start (circle at least one, may circle more than one): a. Pus, or redness, or increased swelling at vascular access site b. Vascular access problem <b>WITHOUT</b> infection (clotting, bleeding, etc) c. Fever (\$100F oral or \$101F rectal) d. Wound ( <b>NOT</b> related to vascular access) with pus or increased redness e. Pneumonia (a new infiltrate or pneumonia seen on chest X-ray) f. UTI (urine culture with >100,000 organisms/ml with not more than 2 species isolated) g. Cardiovascular event (chest pain, heart attack, other heart problem, stroke, etc) h. Other, specify: _____																	
9. Vascular access removed?    N    Y 9a. If yes, circle the access that was removed:    1 = graft    2 = fistula    3 = temporary catheter    4 = permanent catheter																	
10. Were <b>blood</b> cultures drawn in the unit before antimicrobial start, or within 1 day of hospital admission?    N    Y    U 10a. If yes, result    1 = positive    2 = negative    3 = unknown 10b. If <b>positive</b> , suspected source of positive blood culture: 1 = vascular access    2 = a source other than the vascular access    3 = contamination    4 = uncertain 10c. If <b>blood</b> cultures were positive, complete the following:																	
List organisms isolated from blood List one code* or name per row _____ _____	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th colspan="4" style="text-align: center;">Antimicrobial susceptibility</th> </tr> <tr> <th colspan="2" style="text-align: center;">Methicillin, Oxacillin, or Nafcillin</th> <th colspan="2" style="text-align: center;">Vancomycin</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">S</td> <td style="text-align: center;">I</td> <td style="text-align: center;">R</td> <td style="text-align: center;">U</td> </tr> <tr> <td style="text-align: center;">S</td> <td style="text-align: center;">I</td> <td style="text-align: center;">R</td> <td style="text-align: center;">U</td> </tr> </tbody> </table>	Antimicrobial susceptibility				Methicillin, Oxacillin, or Nafcillin		Vancomycin		S	I	R	U	S	I	R	U
Antimicrobial susceptibility																	
Methicillin, Oxacillin, or Nafcillin		Vancomycin															
S	I	R	U														
S	I	R	U														
11. Comments																	
Fever: 100 F = 37.8 C    101 F = 38.3 C    N=no    Y=yes    U=unknown    S=susceptible    I=intermediate    R=resistant *SA= <i>S. aureus</i> SE= <i>S. epidermidis</i> CNS=coagulase-negative staphylococci    PA= <i>P. aeruginosa</i>																	

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