External/On-Site Dialysis Data Validation

Tamara Hoxworth, M.S., Ph.D.

Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases
Division of Health Quality Promotion
Surveillance Branch

July 2024

External Validation - What is it?

What is it?

- Method to check NHSN data accuracy & make corrections as needed
- Compares info in patient charts/medical records to what was reported to NHSN
- External = typically done by entity outside facility, on-site at facility, sometimes remotely

Who does it and why?

- Facilities, Health Depts, LDOs, ESRDs use data to track infections, and evaluate and improve infection prevention practices
- CMS uses data to calculate QIP scores and reimbursement amounts
- Public use data to select where to receive care/make informed healthcare decisions

NHSN data are critical to ensure patient safety and improve healthcare for our citizens!!

Objectives - Dialysis Data Validation

- Investigate and improve NHSN data accuracy and completeness
- Identify surveillance gaps and make appropriate recommendations
- Assess facility staff understanding/knowledge of Dialysis Event Protocol
- Educate staff about common reporting errors and potential causes to ensure consistency and accuracy in monitoring/reporting events
- Provide staff with helpful resources
- Provide feedback to CDC on implementation guidance

How’s it done: Process Overview

- Select facilities
- Select patient charts within facility
- Personal visit to dialysis clinic (when on-site)
- Assess staff knowledge and reporting practices by survey
- Review data from patient charts/medical records (electronic or hard copy)
- Identify dialysis events in the patient records
- Compare what’s found in charts to data submitted to NHSN
- Educate staff on errors and how to correct them
- Provide summary report of findings & recommendations for data correction & surveillance program improvements & provide support/resources as appropriate

Colorado Dialysis Data Validations (2012, 2018) – Facility Selection

- 2012: 25 facilities in Denver metro area (chair size range 8-27, avg = 19)
- 2018: 20 facilities in Denver metro area

- Selected based on location, facility size, patient volume

- Visited facilities in Denver metro area including inner-city, suburban, and semi-rural facilities with diverse clientele

- Cities included Aurora, Broomfield, Castle Rock, Commerce City, Denver, Lakewood, Littleton, Lonetree, Longmont, Thornton, Westminster

Methods (1) - Site Visit Preparation

Emailed selected facilities general informational letter, explaining purpose, rationale, process, needed info. and requesting date for site visit; ***emphasizing visit is educational, not regulatory***

Once facility scheduled, 2nd email sent (call too), confirming date, requesting documents for review

Facilities asked to provide 5 alphabetized lists incl. name, DOB, PIDs for all patients that:

1. Were treated during 2 mos. before visit (e.g., if visit Jul 2012=list of patients treated Apr- May 2012)
2. Received any intravenous antimicrobial starts (IVAMS) during 2 mos. before visit
3. Had any positive blood cultures (PBC) during 2 mos. before visit
4. Had any vascular access complications during 2 mos. before visit
5. Were hospitalized for any reason during 2 mos. before visit

Methods (2) - Site Visit Preparation

Printed facility NHSN events for 2 month period (Jul visit = Apr-May events). Current NHSN Validation Protocol recommends going back 6 months

Prepared facility file to include printed copies of facility reported NHSN events, Survey, DE Protocol, 25 copies of DE Abstraction Worksheets, any other source data submitted

Requested space/room and presence of involved staff for entry, set up, survey, debriefing

1-2 CDPHE staff made on-site visit to facility to conduct medical record reviews

Methods (3) – Site Visit Survey, Chart Review

- Visit began with introductions, explaining project purpose/process, requesting docs, providing copy of Dialysis Event Protocol

- Survey/interview Facility Admin (FA) – surveillance & NHSN reporting practices
  - Example questions: Who enters data? Who ensures accuracy? Are you familiar with DE Protocol? Do you have a copy of it? For which days of the month are pts counted for denominator data? Which patients are included in denominator data? What data sources are used?

- Reviewed medical records of all patients on lists 2-5 above and a random selection from list 1 above to identify potential missed events, going back 6 mos. each chart

- Records reviewed included electronic or hard-copy patient charts and facility reports/lists of hospitalizations, antimicrobial utilization, lab results

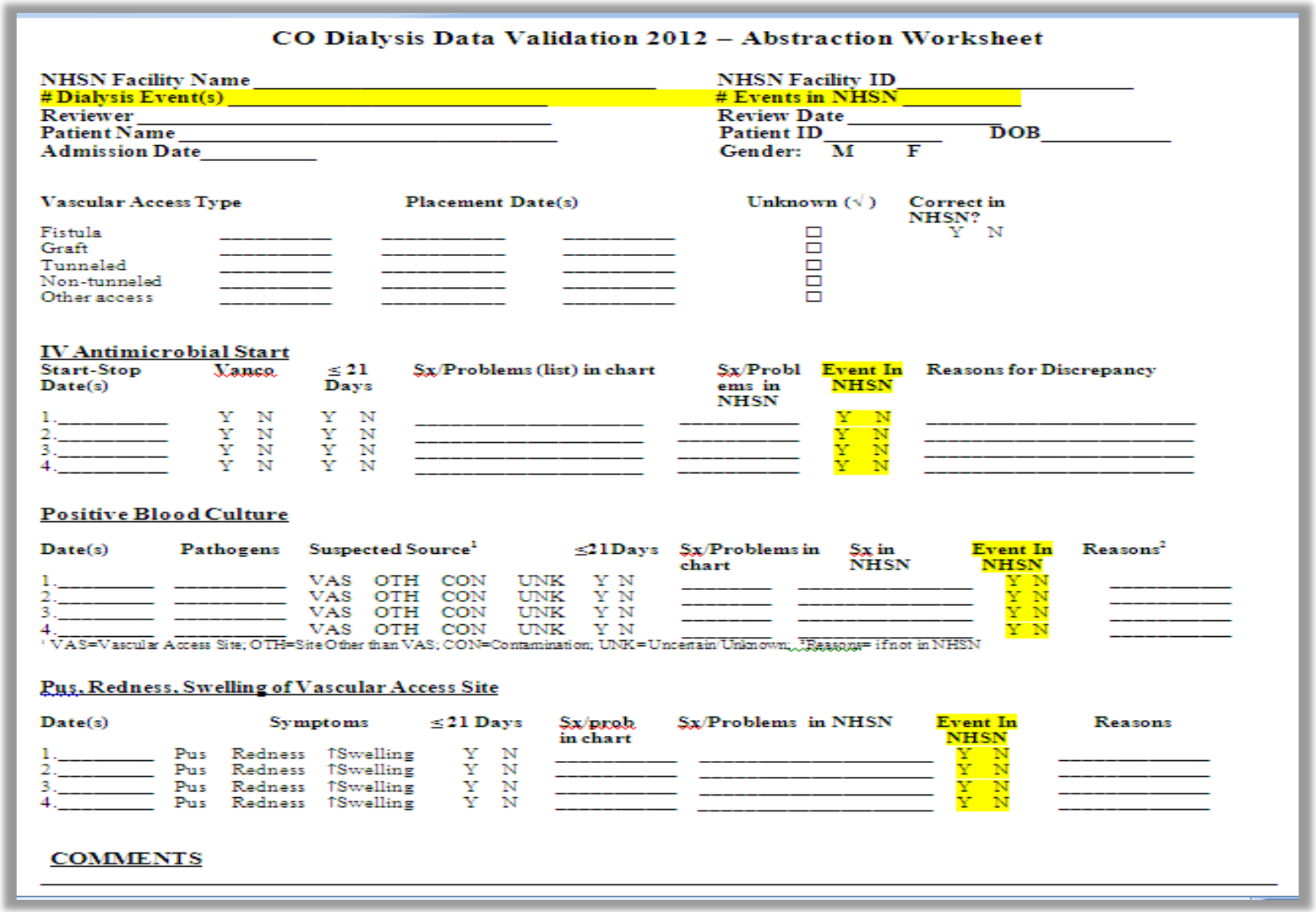
Methods (3.1) – Chart Review Detail

- Completed DE Abstraction Worksheet (see example) for each patient chart reviewed, identifying reportable DE based on NHSN criteria, definitions

- Compared events recorded on Abstraction Worksheet to those found in NHSN, identifying which were correctly reported, under-reported, over-reported

- Denoted discrepancies/errors incl following expected data issues:
  - Is event date correct, esp. with multiple events?
  - Are access dates correct?
  - Are there duplicate cases, esp. with 21-day rule?

DE Abstraction Worksheet (2012)



CO Dialysis Data Validation 2012 – Abstraction Worksheet

NHSN Facility Name _____ NHSN Facility ID _____
Dialysis Event(s) _____ # Events in NHSN _____
Reviewer _____ Review Date _____
Patient Name _____ Patient ID _____ DOB _____
Admission Date _____ Gender: M F

Vascular Access Type				Unknown (√)	Correct in NHSN? Y N
Fistula	_____	_____	_____	☐	
Graft	_____	_____	_____	☐	
Tunneled	_____	_____	_____	☐	
Non-tunneled	_____	_____	_____	☐	
Other access	_____	_____	_____	☐	

IV Antimicrobial Start

Start-Stop Date(s)	Vanco	≤ 21 Days	Sx/Problems (list) in chart	Sx/Problems in NHSN	Event In NHSN	Reasons for Discrepancy
1._____	Y N	Y N	_____	_____	Y N	_____
2._____	Y N	Y N	_____	_____	Y N	_____
3._____	Y N	Y N	_____	_____	Y N	_____
4._____	Y N	Y N	_____	_____	Y N	_____

Positive Blood Culture

Date(s)	Pathogens	Suspected Source[1]				≤21Days	Sx/Problems in chart	Sx in NHSN	Event In NHSN	Reasons[2]
1._____	_____	VAS	OTH	CON	UNK	Y N	_____	_____	Y N	_____
2._____	_____	VAS	OTH	CON	UNK	Y N	_____	_____	Y N	_____
3._____	_____	VAS	OTH	CON	UNK	Y N	_____	_____	Y N	_____
4._____	_____	VAS	OTH	CON	UNK	Y N	_____	_____	Y N	_____

[1] VAS=Vascular Access Site; OTH=Site Other than VAS; CON=Contamination; UNK=Uncertain/Unknown; [2]Reasons= if not in NHSN

Pus, Redness, Swelling of Vascular Access Site

Date(s)	Symptoms			≤21 Days	Sx/prob in chart	Sx/Problems in NHSN	Event In NHSN	Reasons
1._____	Pus	Redness	↑Swelling	Y N	_____	_____	Y N	_____
2._____	Pus	Redness	↑Swelling	Y N	_____	_____	Y N	_____
3._____	Pus	Redness	↑Swelling	Y N	_____	_____	Y N	_____
4._____	Pus	Redness	↑Swelling	Y N	_____	_____	Y N	_____

COMMENTS

_____

Medical Record Abstraction Tool - Current NHSN Protocol

Section 2

Identify all instances of the following events, as defined by the NHSN Dialysis Event Protocol. Arrange events of the same type chronologically. Refer to a calendar to help you apply the 21-day rule to determine which events should have been reported during the validation time period.

- Section 2a: Note all IV antimicrobial starts (IVAM)
- Section 2b: Note all positive blood cultures (PBC)
- Section 2c: Note all instances of pus, redness or increased swelling (PRS) at the vascular access (VA) site

2a. IVAM – All IV Antimicrobial Courses

For each IVAM course, starting with the earliest, enter the start and end dates and drug name. Select all documented problems and VA types that were present. Determine and enter if the event should have been reported to NHSN, and then select if it was reported. If it was reported to NHSN, enter the reported event date, and select the type(s) of VA reported as being present. If no VA types were present or reported, select "n/a" for that column. If the event was not reported correctly, select the most applicable misclassification reason from Table 2.

☐Chart review for this patient completed and no IVAM found during the validation time period

Drug Name; Start & End Date	Problems documented*	Type(s) of VA present (per chart)	Should event be reported to NHSN?	Was event reported to NHSN?	Type(s) of VA reported present (per NHSN)	Reported Event Date (per NHSN)	Reporting Misclassification Reason
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		

*Problems include: Fever, chills/rigors, drop in blood pressure, wound infection, urinary tract infection, cellulitis, pneumonia, other, or none

Methods (4) – Site Visit Debriefing/Education

- Conducted debriefing w/ FA, relevant staff invited by FA (typically nurse managers, NHSN users)
  - Verbal report of findings & discussion data discrepancies & potential causes
  - Opportunity to get more info about identified events & reach mutual agreement on appropriate DE status
  - Opportunity to further educate staff by referring to DE Protocol, reviewing NHSN DE definitions, criteria, common reporting errors and importance of accurate reporting
- Provided instructions for adding, correcting & deleting NHSN records

Methods (5) - Post Visit Activities

- Completed Facility Results Matrix (see example)
  - List all patient charts reviewed, denoting # reportable events found
    - correctly reported, under-reported or over-reported

- Tabulated total numbers of:
  - charts reviewed
  - reportable events found in source data (logs, reports, patient medical records)
  - events reported to NHSN
  - under- and over-reported events

- Prepared Facility Feedback Report of findings to share with facility (see example)

Facility Results Matrix (2012)

Charts reviewed NHSN Reports # Events Facility: Date Reviewed: 9/6/2012

Number – Reviewer	Charts Reviewed	Charts with no Events	Charts with Events	# Events Found in Charts	# NHSN Reports/ Events	Non-Reported Events	Over-Reported Events	Reason for Over/Under Report & Other Discrepancies
1-RAA		√						
2-RAA		√						
3-RAA		√						
4-RAA		√						
5-RAA		√						
6-RAA		√						
7-RAA		√						
8-RAA		√						
9-RAA		√						
10-RAA			√	1	1	0	0	Event in NHSN
11-RAA			√	5	5	0	0	All events in NHSN
12-RAA			√	2	2	0	0	Both events in NHSN, but event date needs to be changed from 7/26/12 to 3/26/12
13-RAA			√	1	1	0	0	Event in NHSN
14-RAA			√	2	1	1	0	PBC(7/27/12) not in NHSN
Total	14	9	5	11	10	1	0	

Other discrepancies found:

1- All available accesses reported but some with no placement date
2- Incorrect event date reported in NHSN
3- Unable to find admission date in chart due to most patients being transferred from other facility and ESRD

Dialysis Event Validation Summary (Current)

<<Facility Name>> - PBC Line List

OrgID	Patient ID	Symptom Onset Date	VA Affected^	Reportable to NHSN	Reported by Facility	Report Date	VA Present^	VA Reported^	Misclassification Reason(s)*

Add rows as needed

*** I) Misinterpretation of PRS identification or reporting criteria**
- a) Not reported because antimicrobials were not started
- b) Infection suspected but not confirmed and/or doctor says PRS is cellulitis
- c) Facility lacks process to track PRS events
- d) Misapplication of 21-day rule; event was within 21 days of previous PRS event
- e) Not reported for deceased patients or patients transferred out of facility

*** II) Missing data elements or incorrect information reported**
- a) Did not report all event elements (e.g., reported IVAM but not PRS)
- b) Event Date incorrect
- c) Vascular Access type incorrect
- d) Other, specify

*** III) Other, specify**

^ Vascular Access (VA) types: F=Fistula, G=Graft, T=Tunneled central line, NT=Non-tunneled central line, O=Other access device, N/A=None or not applicable

Facility Feedback Letter (2012)

Dialysis NHSN Data Validation - Project Report of Findings

Facility Name: XXXXXX Date of visit: September 18, 2012

Dear XXXX,

Thank you for allowing us to review patient medical records at your facility as part of the Colorado Dialysis Data Validation Project. We appreciate you taking time from your busy schedule to work with us and answer our questions. It was valuable for us to hear about challenges you encounter with surveillance, identification, and reporting of dialysis into NHSN. The valuable information you provided will enable us to provide clarity for other NHSN users and recommendations to CDC to improve the reporting process.

During our visit, 24 patient charts were reviewed. Of those 24 charts, 21 charts had a total of 52 reportable events, 43 of which had been entered into NHSN. Of the 51 total events you entered, 8 events were either over-reported or had no evidence found in the patients' medical records. These require confirmation to ascertain them as reportable events.

Of the 52 total events found in charts:

- 43 were reportable and had been entered into NHSN and
- 9 were reportable, but had not been entered into NHSN (called "non-reported events")

Of the 51 events entered into NHSN:

- 43 were reportable and had been entered into NHSN and
- 6 were over-reported either based on the 21-day rule or because reported symptoms did not meet the definition for the Pus, Redness or Swelling (PRS) event.
- 2 may have been over-reported because no evidence was found in the patient information we reviewed, and the FA needs to confirm these.

The summary of findings can be found in Table 1 below with additional details. The following steps are required to correct data discrepancies:

1. **Enter the 9 non-reported events listed in Table 1 below.**
2. **Delete the 6 over-reported events listed in Table 1 below.**
3. **Investigate and confirm the 2 possibly over-reported events listed in Table 1 below.**

Also, please review the NHSN Dialysis Event Protocol, noting the following common reporting issues found:

- DEs not reported in NHSN - *All IV antimicrobial starts should be entered into NHSN regardless of reason. The IV start can be based on a UTI, pneumonia, or other problems unrelated to an access infection. Also, multiple events can and should be entered on a single record or at a later time when information becomes available; records can be edited at any time (e.g., if a blood culture is drawn the day IV antibiotics are started, the IV start should be entered and later, if blood culture results show growth, it should be entered into the original record).*

- Symptoms or problems related to the event not reported in NHSN - *When possible, review patient treatment records, progress notes or consult with clinical staff to get more details on symptoms leading to the reported event and denote symptoms on the NHSN record.*

- Access Placement Date reported as unknown when it was found in patient's chart - *When possible, review documents under the "Access" tab in patients' charts to obtain placement date.*

- Entering monthly patient census for denominator data in NHSN - *Only the number of patients who received treatment on the first two working days of the month should be entered for the denominator data. You do not need to go back and change any past denominator forms, but please use the 1st two working days from here forward.*

We noted your excellent documentation, including your organized binders and use of the NHSN event "Comments" field. We appreciate your welcoming attitude and generosity with your time and helpfulness. We commend your conscientiousness in reporting required data and commitment to patient care. Your work is critical and makes patients safer!

Sincerely,
Tamara Hoxworth, Ph.D.

Facility Feedback Report (Current)

Appendix 4: Letter Template – Post-Validation Activities Summary

<<Insert Date >>
<<Facility Name>>
<<Facility Street Address>>
<<Facility City, State, Zip>>
Date of site visit:_____/_____/_____

Dear *<<Name of Facility Manager>>*:

Thank you for participating in the validation of facility surveillance practices and the Dialysis Event data reported to the National Healthcare Safety Network (NHSN). We appreciate you taking time from your schedule to work with us. The valuable information you provided will enable us to improve the quality of the data reported to NHSN and identify focus areas for education and training of NHSN users.

During our validation efforts, *<<number>>* patient charts were reviewed. The documentation from these charts was used to identify Dialysis Events that should have been reported to NHSN. Here is a summary of our findings, by event type:

IV antimicrobial starts:

- *<<Number>>* of IV antimicrobial start events found in charts by our staff
  - *<<Number>>* of these events found in charts that were reported to NHSN
  - *<<Number>>* of these events found in charts that were not reported to NHSN
  - *<<Number>>* of these events reported to NHSN, but were not found in charts

Positive blood cultures:

- *<<Number>>* of positive blood culture events found in charts by our staff
  - *<<Number>>* of these events found in charts that were reported to NHSN
  - *<<Number>>* of these events found in charts that were not reported to NHSN
  - *<<Number>>* of these events reported to NHSN, but were not found in charts

Pus, redness, or increased swelling at the vascular access site:

- *<<Number>>* of pus, redness, or increased swelling events found in charts by our staff
  - *<<Number>>* of these events found in charts that were reported to NHSN
  - *<<Number>>* of these events found in charts that were not reported to NHSN
  - *<<Number>>* of these events reported to NHSN, but were not found in charts

Colorado Findings – Discrepancies/Issues Found

- Lack of awareness or incorrect application of 21-day rule
- Confusion in reporting multiple, related events (e.g., IVAMS & PBC in same patient)
- Not subsequently editing record to add event (e.g., reported IVAMs, not PBC)
- Reporting positive wound cultures as PBC
- Not entering IVAMS or PBC if not related to vascular access
- Not entering IVAMS administered at other outpatient sites (e.g., ER, prison, LTC)
- Inconsistent tracking of patients after transfer from facility
- Inconsistent communication between facilities & hospitals, LTC facilities

Colorado Findings – Discrepancies/Issues Found (con't)

- Lack of information to objectively determine PRS events
- Lack of documentation in medical record of PRS events
- Not entering PBC if taken within 24 hours of hospital admission
- Lack of detail (date of collection, results) re PBCs taken in hospital
- Incorrect identification of antimicrobial (tendency to report Vanco when other AMX)
- FAs thought that infections need not be reported for deceased patients
- Incorrect calculation of denominator (entering entire month, including hospitalizations & missed treatments or excluding transients)

Lessons Learned

- On-site visits improved understanding workflow processes, strengthened relationship with dialysis facilities
- Enabled staff education by identifying misunderstandings re NHSN reporting
- Identified the need to ensure facility staff have/know NHSN DE Protocol through training, communication
- Identified the need to be more proactive, communicative w/ facilities about reporting rules & common errors
- Validation efforts needed!

Subsequent Steps

- Shared findings, recommendations with CDC, dialysis facilities statewide, dialysis community
- Restarted quarterly trainings to dialysis facilities
- Recommended ongoing validation function w dedicated staff (additional validations 2015, 2018)
- Implemented Dialysis Infection Prevention Collaborative (partnered w our regional ESRD Network, NET15)
- Developed Patient Education toolkit (also partnered with NET15)
- Hired NHSN Liaison (dialysis nurse) to maintain regular contact w/facilities, ensure accurate surveillance, reporting
- Presented findings at a CDC Work in Progress Seminar in 2013 and 2014 CSTE annual conference
- CDC published a dialysis data validation toolkit in 2014, recently updated

Colorado Validation Results

						% Under Reported				% Over Reported			
State	Year	# of Facilities	# Charts	#Events in Charts	#Events in NHSN	IVAMS	PRS	PBC	Total	IVAMS	PRS	PBC	Total
Colorado	2012	25	484	505	415	27%	25%	37%	29%	13%	14%	8%	13%
Colorado	2018	20	605	247	217	14%	16%	22%	16%	3%	11%	0%	9%

Other Key Findings from Colorado and other States

21% - 50% unaware/had not read DE Protocol

20% - had a copy

35% - 96% of FAs did NOT correctly report denominator data

59% - 78% did NOT know how to correctly assign vascular access categories

Incorrectly defined Dialysis Events:

- Positive Blood Culture (PBC) 7%
- Intravenous Antimicrobial Starts (IVAMS) 21%
- Pus Redness Swelling (PRS) 29%

14% had ever used Analysis/Report function to generate reports

CO (2018) Knowledge Improvements and Effective Surveillance Practices

Knowledge	Count (%)
21-day rule	18 (90)
Reporting of PBC within 1st day of hospital admission	17 (85)
Denominator data collection for 1st 2 working days	20 (100)
Not counting patients twice	20 (100)

Practices	Count (%)
Standardized process for requesting hospital records	17 (85)
Performed NHSN data quality check	19 (95)

Key Take-Aways

- ✓ NHSN data are critical to help assess patient care and ensure patient safety
- ✓ Crucial that we ensure NHSN data are valid and reliable
- ✓ Obtain valuable information about facility practices and knowledge
- ✓ Can get "free" data quality checks without penalty and education to help address issues before being selected by CMS for validation
- ✓ CO - follow-up Validation showed improved data quality, staff knowledge & surveillance practices!
- ✓ Ideally, validation would be an ongoing function
- ✓ Only 6 states to date & 1 county (we know of) have done external validations of dialysis data

START / KEEP VALIDATING!!

Thank you for your time!!

Dialysis Event External Validation Toolkit and Appendices (cdc.gov)

Questions?

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov