Validation of data

Evaluating quality & integrity of HAI surveillance data

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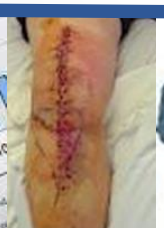
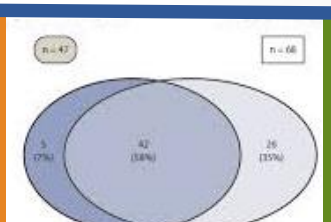
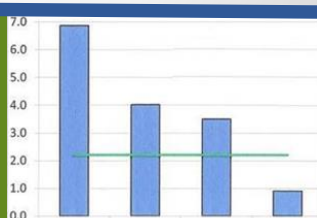


Conflict of interest

- Nil to declare

Affiliations & membership:

- Victorian Healthcare Associated Infection Surveillance System (VICNISS)
- Australian Infection Surveillance (AIS)
- Alfred Health
- Peter MacCallum Cancer Centre
- National Health Performance Authority (prev.)
- Australian Commission on Safety and Quality in Healthcare

Introduction

- HAI surveillance reliant upon self-reporting of data.
- Data used increasingly for:
  - longitudinal analysis
  - benchmarking
  - public reporting
- Recognised need to ensure quality, accuracy & reliability of HAI surveillance efforts.
- Maturation of surveillance programs:
  - 1970s-1980s: establishment of surveillance networks
  - 1990s-2000s: refinement of surveillance systems, including automation, risk adjustment & validation

Arnold EA & Thompson ND. Infect Control Hosp Epidemiol. 2012

Outline

- What is 'valid' HAI surveillance data?
- Why validate HAI surveillance data?
- Public reporting & funding
- NHSN framework for CLABSI validation
- International experience of validation
- Australian experience of validation

What is validation?

(of HAI surveillance data)

What is validation?

Definition: '*the act of confirming a product or service meets the requirements for which it was intended*'

'product or service'≡ HAI surveillance *methods*

'intended purpose' ≡ *objectives* of surveillance strategy

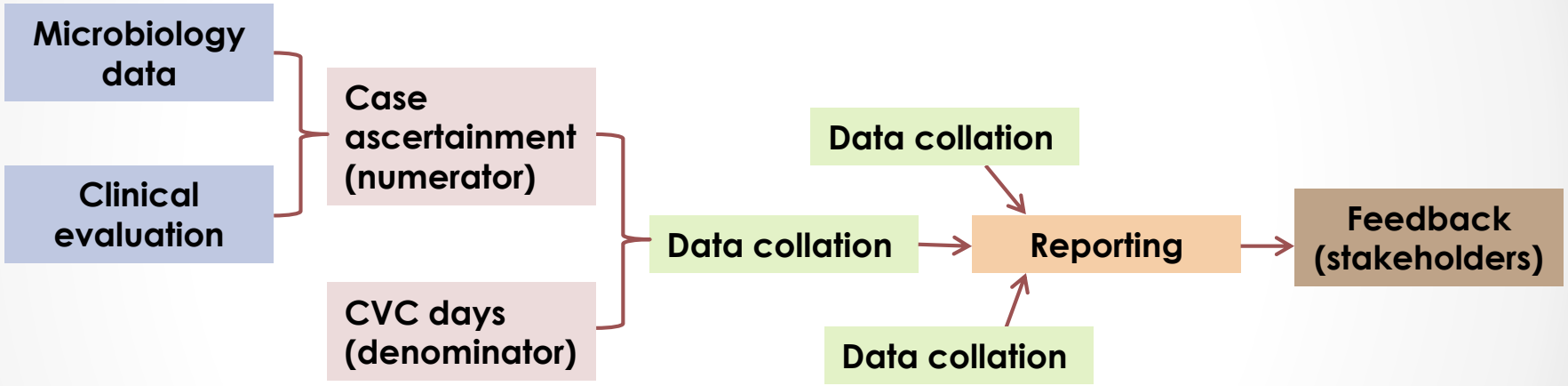
- Standardised HAI surveillance methods must be used to ensure quality and reliability of data.
- Independent means to determine the accuracy of HAI surveillance data.
- Essential for determining reliability of a surveillance network aggregating multiple data inputs.

Chernetsky Tejedor SC, *et al*. Electronic documentation of central line-days; validation is essential. Presented at SHEA 2011 Annual Scientific Meeting, Abstract 308.


Fail
Pass
DID YOU VALIDATE ?
INDEPENDENTLY VALIDATED
Focus on Quality
VALIDATED
Validation
How confident are you this data is accurate?
CEO
VALIDATION AHEAD

Where to start?

a CLABSI surveillance network



- Quality & timeliness of data feed (hospital)

- Knowledge & education of surveillance staff (reproducibility of methods)
- Sensitivity & specificity

- Data quality & error checks

- Time trends
- Peer-grouping
- Analytic methods (confidence intervals)

Validity vs. reliability

Validity

a multi-faceted construct

Validity construct	Features
Face validity	'on face value'; subjective; weakest measure of validity
Content validity	Comparison of ideal system with actual (e.g. checklist)
Predictive validity	Ability of a system to predict something it should theoretically be able to predict
Concurrent validity	Ability of a system to distinguish between groups that it should theoretically be able to distinguish between.
Convergent validity	The degree to which a system is similar to other systems that it theoretically should be similar to.
Discriminant validity	The degree to a system is not similar to other systems that it theoretically should be not be similar to.

Why validate HAI surveillance data?

HAI public reporting

HICPAC guidelines

AJIC special article

Guidance on Public Reporting of Healthcare-Associated Infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee

Linda McKibben, MD,[a] Teresa Horan, MPH,[b] Jerome I. Tokars, MD, MPH,[b] Gabrielle Fowler, MPH,[b] Denise M. Cardo, MD,[a] Michele L. Pearson, MD,[c] Patrick J. Brennan, MD,[d] and the Healthcare Infection Control Practices Advisory Committee*

McKibben L, *et al*. Am J Infect Control. 2005

Public reporting of HAIs

HICPAC recommendations

- Identify appropriate measures of healthcare performance
- Identify patient population for monitoring
- Standardised case-finding
- **Validation of Data**
- Supporting resources and infrastructure
- Reporting of HAI rates & risk adjustment
- Producing useful reports & feedback

Annals of Internal Medicine | MEDICINE AND PUBLIC ISSUES

Public Reporting of Health Care–Associated Surveillance Data: Recommendations From the Healthcare Infection Control Practices Advisory Committee

Thomas R. Talbot, MD, MPH; Dale W. Bratzler, DO, MPH; Ruth M. Carrico, PhD, RN; Daniel J. Diekema, MD; Mary K. Hayden, MD; Susan S. Huang, MD, MPH; Deborah S. Yokoe, MD, MPH; and Neil O. Fishman, MD, for the Healthcare Infection Control Practices Advisory Committee

Health care–associated infection (HAI) rates are used as measures of a health care facility's quality of patient care. Recently, these outcomes have been used to publicly rank quality efforts and determine facility reimbursement. The value of comparing HAI rates among health care facilities is limited by many factors inherent to HAI surveillance, and incentives that reward low HAI rates can lead to unintended consequences that can compromise medical care surveillance efforts, such as the use of clinical adjudication panels to veto events that meet HAI surveillance definitions.

The Healthcare Infection Control Practices Advisory Committee, a federal advisory committee that provides advice and guidance to the Centers for Disease Control and Prevention (CDC) and the Secretary of the Department of Health and Human Services about strategies for surveillance, prevention, and control of HAIs, assessed the challenges associated with using HAI surveillance data for external quality reporting, including the unintended consequences of clinician veto and clinical adjudication panels. Discussions with stakeholder liaisons and committee members were then used to formulate recommended standards for the use of HAI surveillance data for external facility assessment to ensure valid comparisons and to provide as level a playing field as possible.

The final recommendations advocate for consistent, objective, and independent application of CDC HAI definitions with concomitant validation of HAIs and surveillance processes. The use of clinician veto and adjudication is discouraged.

Ann Intern Med. 2013;159:631-635. www.annals.org

For author affiliations, see end of text.

J Antimicrob Chemother 2012; **67** Suppl 1: i23–i28
doi:10.1093/jac/dks198

Journal of Antimicrobial Chemotherapy

Recommendations for surveillance priorities for healthcare-associated infections and criteria for their conduct

A. P. R. Wilson[1]* and M. Kiernan[2]

[1]Department of Clinical Microbiology, University College London Hospitals, 46 Cleveland Street, London W1T 4JF, UK; [2]Infection Control, Southport and Ormskirk NHS Trust, Pathology Laboratory, Southport and Formby DGH, Town Lane, Southport PR8 6NJ, UK

'Local definitions of infection should be unequivocal and in line with those agreed nationally… Surveillance systems should be *validated* to ensure data collection is robust.'

Laying down the law on healthcare-associated infections

US Congress enacted legislation providing hospitals with financial incentives to improve patient care.

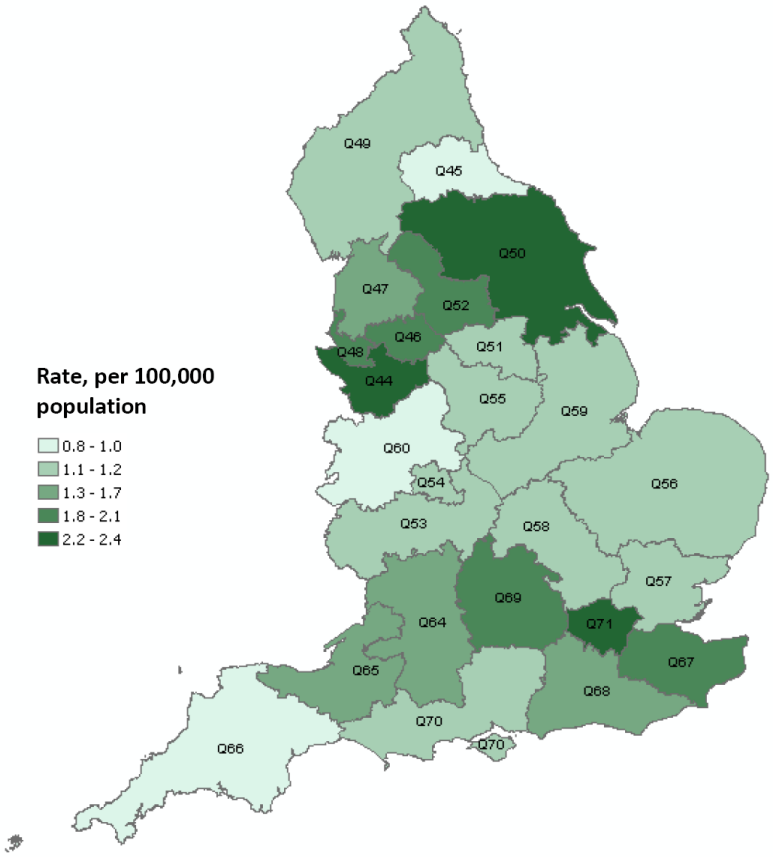
Comment:

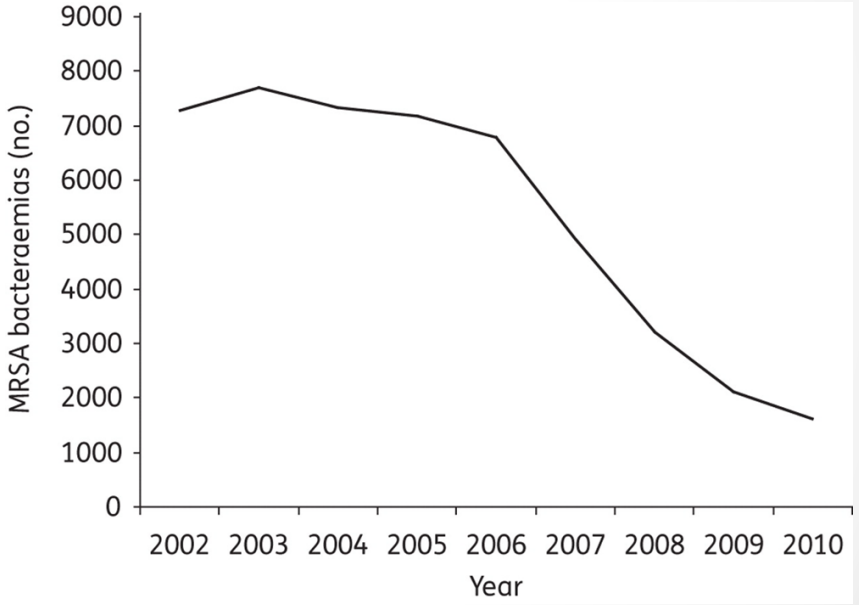
'For mandatory reporting of HAIs to be useful there need to be *uniform surveillance procedures* at local, national, and—ideally—international levels.'

Lancet Infect Dis. 2008

UK experience: MRSA

mandatory surveillance





Johnson AP, *et al*. J Antimicrob Chemother. 2012;67:802-809
Annual Epidemiological Commentary: Mandatory MRSA, MSSA and *E. coli* bacteraemia and *C. difficile* infection data, 2013/14. Public Health England, July 2014

UK experience

establishing MRSA surveillance

- **Peer grouping:**
  - initially 3 Trust categories, later refined to 6
  - small acute Trusts, medium acute Trusts, large acute Trusts, acute teaching Trusts, acute specialist Trusts and acute specialist Children's Trusts

- **Denominator:**
  - per 10,000 OBDs; same-day admissions excluded (e.g. dialysis)
  - per 100,000 population

- **Enhanced surveillance:**
  - web-based collection; clinical & epidemiological data
  - demographics, date of admission, date of bacteraemia, location at time of blood culture, consultant specialty, type of clinical care (2005)
  - additional data required for MSSA bacteraemia (2011)

Pearson A, *et al.* J Antimicrob Chemotherap 2009

UK experience

refining MRSA surveillance

- **Target:** '50% reduction by 2008' target set by Health Secretary in 2004.

- **Validation:** Cross-checking of microbiology isolates with submitted data.
  - inconsistencies reported to executive staff
  - review and re-submission of data

- **Accountability:** Chief Executive of each Trust assumed personal responsibility for accuracy of data and meeting of set target/s.
  - penalties if erroneous data

Validation: the NHSN experience

Validation of CLABSI data

NHSN guidelines

National Healthcare Safety Network (NHSN)
Validation Guidance and Toolkit 2012

Validation for Central Line-Associated Bloodstream Infection (CLABSI) in ICUs

Types of validation

Validation type	Scope	Common examples
Intrinsic	An automated process controlling the values and types of data that are entered into a surveillance system.	Point-of-entry validation routinely checks if data are reasonable, complete, consistent, and formatted in accordance with system requirements.
Internal	A systematic process used by a facility to assess whether sound surveillance methods, optimal healthcare data sources, and the highest calibre data abstraction and entry are in use for numerator and denominator records.	Investigations of surveillance practices; analysis and follow-up of aberrant or outlying results.
External	An audit process conducted by an agency outside the reporting facility (e.g. health department), in which a facility's surveillance determinations and methods are assessed.	Healthcare facility and medical record sampling to test proficiency in surveillance methods and accuracy in case-classification.

Intrinsic validation

- Detection & prevention of input errors.
- Does not assure the quality & completeness of HAI case ascertainment or the calibre of numerator & denominator data acquisition.
- Data cross-checks and rules built into a web interface for data entry are designed to reduce keystroke errors and provide an internal mechanism for assuring valid data are entered.

Internal validation

- Assessment of potential errors in case-ascertainment, case-classification (primary vs. secondary) location of attribution, denominator reporting, & risk adjustment variables.

- Education & training of staff responsible for surveillance.

External validation

- CDC recommendation regarding external validation of CLABSI data:
  - 'At least some external validation should be done *annually* to encourage accountability for accurate reporting, and what is done should be quantified to allow reliability of reported data to be assessed.'

- Requirements:
  - auditor expertise
  - secure data transfer mechanism between facilities & health department
  - pre-determined sampling methodology
  - targeted approach (e.g. pathogens)

		Final Determination	
	CLABSI Present	YES	NO
Hospital	YES	A True Positive	B False Positive "Overreport"
	NO	C False Negative "Underreport"	D True Negative

Requirement for **gold standard** assessment

Kelly H. *et al*. J Hosp Infect 2008

Accountability & resources

Validation type	Potential responsible agency	Resources
Intrinsic	Surveillance staff, IT departments Healthcare facility or service	+ automated continual
Internal	Surveillance unit within healthcare facility Healthcare facility or service	++ periodic
External	Jurisdictional/Departments of Health Network or national body responsible for surveillance	+++ ongoing

?

Assessing validity of HAI surveillance systems

International experience

Case vignettes to evaluate the accuracy of identifying healthcare-associated infections by surveillance persons

C. Schröder [a, b, *], M. Behnke [a, b], P. Gastmeier [a, b], F. Schwab [a, b], C. Geffers [a, b]

[a] *Institute of Hygiene and Environmental Medicine, Charité Berlin, Berlin, Germany*
[b] *German National Reference Center for the Surveillance of Nosocomial Infections, Berlin, Germany*

- German national healthcare-associated infections surveillance system (KISS)
- 10 case vignettes provided to surveillance personnel annually (2010-2012)
- Gold standard assessment by panel of epidemiologists & infection prevention staff
  - HAIs and cases not fulfilling HAI definitions
  - Multivariate regression analysis of factors associated with HAI rates

Schroder C. *et al*. J Hosp Infect 2015

Table I

Sensitivity and specificity of surveillance persons participating in validation from 2010 to 2012 ($N = 189$)

Parameter	Median sensitivity (IQR)	Median specificity (IQR)
Total HCAI	85.7 (75.0, 92.9)	94.6 (90.2, 95.7)
Lower respiratory tract infection	88.9 (77.8, 88.9)	82.9 (81.1, 84.7)
Urinary tract infection	90.0 (70.0, 100.0)	85.5 (83.6, 87.3)
Bloodstream infection	85.7 (71.4, 100.0)	81.4 (78.8, 83.2)

Table V

Multivariate regression analysis for the frequency of healthcare-associated urinary tract infections (UTIs), lower respiratory tract infections (LRTIs) and bloodstream infections (BSIs) ($N = 218$)

Parameter	Category	*P*-value	IRR (95% CI)
Regression model for healthcare-associated UTIs			
Sensitivity	>50% quantile (90.0)	0.03	1.33 (1.02, 1.75)
Specificity	>50% quantile (85.5)	0.40	0.89 (0.69, 1.16)
ICU type	Surgical	0.30	1.20 (0.85, 1.69)
	Internal	<0.01	0.54 (0.37, 0.79)
	Other	0.19	0.77 (0.53, 1.14)
	Interdisciplinary		1.00 = reference
Hospital type	Academic teaching	0.20	0.77 (0.52, 1.15)
	Other	<0.01	0.44 (0.28, 0.70)
	University		1.00 = reference
Length of stay	>75% quantile (5.7)	<0.01	2.37 (1.79, 3.14)
Regression model for healthcare-associated LRTIs			
Sensitivity	>50% quantile (88.9)	0.92	0.97 (0.57, 1.66)
Specificity	>50% quantile (82.9)	0.72	0.96 (0.78, 1.19)
ICU type	Surgical	0.15	1.24 (0.92, 1.66)
	Internal	<0.01	0.58 (0.42, 0.79)
	Other	0.62	0.92 (0.65, 1.29)
	Interdisciplinary		1.00 = reference
Hospital type	Academic teaching	0.79	1.05 (0.75, 1.47)
	Other	0.09	0.73 (0.50, 1.05)
	University		1.00 = reference
Ventilator utilization rate	>75% quantile (53.3)	<0.01	1.80 (1.42, 2.29)
Regression model for healthcare-associated BSIs			
Sensitivity	>50% quantile (85.7)	0.01	1.33 (1.06, 1.68)
Specificity	>50% quantile (81.4)	0.14	0.84 (0.66, 1.06)
Hospital type	Academic teaching	0.09	0.74 (0.53, 1.05)
	Other	<0.01	0.54 (0.37, 0.78)
	University		1.00 = reference
Length of stay	>75% quantile (5.7)	<0.01	1.73 (1.32, 2.26)

Major article

Assessment of the quality of publicly reported central line-associated bloodstream infection data in Colorado, 2010

Karen L. Rich MEd, BSN, RN, CIC [a,*], Sara M. Reese PhD [a], Kirk A. Bol MSPH [a], Heather M. Gilmartin MSN, RN, FNP-BC, CIC [b], Tara Janosz MPH [a]

[a] *Health Facilities and Emergency Medical Services Division, Colorado Department of Public Health and Environment, Denver, CO*
[b] *University of Colorado, College of Nursing, Aurora, CO*

	Stratified sample		
	Reported CLABSI (%)	Non-reported CLABSI	Total
Actual CLABSI	37 (67.3)*	18 (32.7)	55 (100)
Actual non-CLABSI	1 (0.2)	465 (99.8)	466 (100)
Total	38 (7.3)	483 (92.3)	521 (100)

Rich KL. *et al*. Am J Infect Control 2013

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY MAY 2012, VOL. 33, NO. 5

ORIGINAL ARTICLE

Statewide Validation of Hospital-Reported Central Line–Associated Bloodstream Infections: Oregon, 2009

John Y. Oh, MD, MPH;[1,2] Margaret C. Cunningham, MPH;[1] Zintars G. Beldavs, MS;[1] Jennifer Tujo, MSN, MPA, CIC;[3] Stephen W. Moore, RN, MS;[1] Ann R. Thomas, MD, MPH;[1] Paul R. Cieslak, MD[1]

TABLE 1. *Hospital Report, Health Department Review, and Final Determination of ICU CLABSIs from Sampled Records: Oregon, 2009*

Hospital report	Health department review	Final determination	No. (%) of patients	Agreement between hospital and health department
Yes	Yes	Yes	68 (8.3)	Concordant[a]
No	No	No	714 (87.4)	Concordant[a]
Yes	No	Yes	2 (0.2)	Discordant
Yes	No	No	6 (0.7)	Discordant
No	Yes	Yes	16 (2.0)	Discordant
No	Yes	No	11 (1.3)	Discordant
Total			817 (100.0)	

NOTE. CLABSI, central line–associated bloodstream infection; ICU, intensive care unit.
[a] Agreement, 96%; $\kappa = 0.77$ (95% confidence interval, 0.70–0.84).

Oh JY. *et al.* Infect Control Hosp Epidemiol 2012

TABLE 5. Effect of Validation on Hospital-Specific Incidence of ICU CLABSIs: Oregon, 2009

Change in CLABSI incidence after validation	No. (%)[a] of hospitals
Decreased by 0.70	1 (2)
No change	33 (75)[b]
Increased by 0.01–0.50	2 (5)
Increased by 0.51–1.00	2 (5)
Increased by more than 1.00	6 (14)[c]
Total	44 (100)

NOTE. Incidence is measured in infections per 1,000 central line–days. CLABSI, central line–associated bloodstream infection; ICU, intensive care unit.

[a] Percentages do not add to 100% because of rounding.

[b] 23 of 33 had no CLABSIs identified either before or after the validation.

[c] 3 of 6 had no CLABSIs before the validation.

Assessing validity of HAI surveillance systems

Australian experience

Validating SSI data

Validation of surgical site infection surveillance in Perth, Western Australia

Goggin LS, van Gessel H, McCann RL, Peterson AM, Van Buynder PG

Healthcare Infection 2009; 14:101-107

Method:

- Retrospective review at 10 WA hospitals
- Hip/knee surgeries (*n*=444) and structured ICP interview

Results:

- Sens 83%, spec 99%, PPV 94%, NPV 97%
- Comparable surveillance methods at 9/10 hospitals

Implications:

- Hospitals with lowest SSI rates had highest sensitivity to detect an SSI
- Difference in quality of surveillance and reporting by hospitals not responsible for variation in SSI rates.

Validating CLABSI data

Validation of statewide surveillance system data on central line-associated bloodstream infection in intensive care units in Australia

McBryde ES, Brett J, Russo PL, Worth LJ, Bull AL, Richards MJ

Infect Control Hosp Epidemiol 2009; 30:1045-9

Method:

- Retrospective review of medical records (*n*=108) at 6 Victorian hospitals.
- Reported CLABSI data compared with CDC/NHSN gold standard.

Results:

- Agreement with gold standard in 67.6% (k = 0.31).
- Sens 35%, spec 87%, PPV 59%, NPV 73%

Implications:

- Agreement unacceptably low.
- False-negative results problematic

Validating CLABSI data

Impact of revising the National Nosocomial Infection Surveillance System definition for catheter-related bloodstream infection in ICU: reproducibility of the National Healthcare Safety Network case definition in an Australian cohort of infection control professionals

Worth LJ, Brett J, Bull AL, McBryde ES, Russo PL, Richards MJ

Am J Infect Control 2009; 37:643-8

Method:

- Clinical case vignettes provided to surveillance staff participating in VICNISS program.
- NHSN assessment of cases used as gold standard.

Results:

- Overall concordance 57.1%
- By NNIS criteria: criterion 1- 52.8%; criterion 2a- 83.3%; criterion 2b- 58.3%; non-CLABSI cases- 51.4%.
- Updated NHSN definition concordance increased to 62.5%

Implications:

- Poor reproducibility of CLABSI case definition, but adoption of revised NHSN definition for CLABSI likely to improve concordance.

Validating CABGS SSI data

Validation of coronary artery bypass graft surgical site infection surveillance data from a statewide surveillance system in Australia

Friedman ND, Russo PL, Bull AL, Richards MJ, Kelly H

Infect Control Hosp Epidemiol 2007; 28:812-7

Method:

- Retrospective review of medical records (*n*=169) in Victorian hospitals
- Reported SSI data compared with CDC/NHSN gold standard.
- Random sample of ~10% of patients reported not to have an SSI.

Results:

- Agreement with gold standard in 96%
- Depth of SSI discordant in 1/3
- Frequent disagreement re: donor site SSI
- PPV 96%, NPV 97%

Implications:

- Broad agreement on number of patients with sternal SSI.
- Discordance regarding depth of sternal SSI and identification of donor site SSI.

Conclusions

Conclusions

- Validation a *diverse* and *broad* construct
- *Be specific* with reference to validation:
  - intrinsic vs. internal vs. external
  - sensitivity vs. specificity vs. both
- *Objectives* of HAI surveillance must be considered when evaluating validity of a surveillance strategy
- *Formal process for validation* of HAI surveillance systems required if:
  - public reporting
  - link with funding
- Evaluating validity of HAI data requires *resources*:
  - automated vs. periodic vs. continual
  - standardised methods for longitudinal comparison

Acknowledgements

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- VICNISS staff
  - A. Bull
  - J. Brett
  - S. Johnson
  - T. Spelman
  - M. Richards

Mandatory public reporting

potential consequences

- **Additional information** for consumers/stakeholders to make informed choices.
- May **reduce HAI rates**.
- May **divert resources** to reporting & collecting data and away from patient care/prevention.

- **Caveat:** current HAI surveillance methods were developed for voluntary use.
  - Publicly reported HAI rates may mislead stakeholders.
  - Limitations must be communicated within any publicly released report.
  - Consider modification of methods for purpose of mandatory reporting.

McKibben L, *et al*. Am J Infect Control. 2005

UK experience: MRSA

- MRSA bacteraemia reporting, April 2001
- Implemented by Public Health Laboratory Service

Public Health England

- Minimum dataset:
  i. total no. of blood culture sets taken,
  ii. total no. of positive blood cultures,
  iii. total no. of blood cultures positive for *S. aureus*,
  iv. MRSA-positive blood cultures expressed as proportion of all *S. aureus*-positive blood cultures.
- Data submitted quarterly by acute hospital Trusts, released in public domain.

Johnson AP, *et al*. Mandatory surveillance of methicillin-resistant *Staphylococcus aureus* (MRSA) bacteraemia in England: the first 10 years. J Antimicrob Chemother 2012