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Development of case vignettes for assessment of the inter-rater variability of national validation teams for the point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals

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SUMMARY

Background: In 2016–17 the European Centre for Disease Prevention and Control (ECDC) organized the second point prevalence survey (PPS) of healthcare-associated infections (HCAIs) and antimicrobial use in European acute care hospitals. This survey included a validation study to maximize the accuracy of case identification and classification.
Aim: ECDC developed case vignettes to assess the performance of the national validation teams.
Methods: Case vignettes were developed by two medical doctors with experience in the management of HCAIs and antimicrobial stewardship. The case vignettes were based on actual clinical cases. The distribution of HCAIs among the case vignettes reflected the distribution of HCAIs in the previous PPS. All case vignettes were pilot-tested by three expert raters. Agreement among the expert raters was measured using kappa statistics.
Findings: Sixty case vignettes were developed. Twenty-nine of them were HCAI cases and 31 were cases without an HCAI. The inter-rater reliability using kappa statistics was 0.78 for the presence of HCAI and 0.89 for the antimicrobial use, respectively.
Conclusion: The agreement between the expert raters was very good for antimicrobial use and good for the presence of HCAI. Case vignettes can be a tool to support standardization of surveillance, improving the validity and comparability of the data.

Introduction

The first European point prevalence survey (PPS) of healthcare-associated infections (HCAIs) and antimicrobial use was developed and performed in 2011–2012 by the European

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Centre for Disease Prevention and Control (ECDC) [1]. Before this PPS, there were no standardized definitions and methodology for PPS of HCAIs and antimicrobial use in European acute care hospitals. In 2016–2017, ECDC organized a second PPS aiming to collect data from a representative sample of hospitals from all European Union (EU) Member States and European Economic Area (EEA) countries [2,3].

To maximize accuracy in the detection and classification of HCAIs and the comparability of the results among EU/EEA countries, all countries participating in 2016–2017 were required to perform a national validation study supported by ECDC [4]. The overall protocol for the validation study was based on a pilot validation protocol used during the ECDC PPS 2011–2012 [5]. These validation studies were performed by national validation teams, each team consisting of at least one senior expert with experience in HCAI surveillance and especially in the use of the European case definitions [2].

However, as the validation teams were different in each country, it remained important to assess the reliability of the validation teams since their assessment served as the 'reference standard' for each country. For this purpose, the validation process included assessment of the performance of the members of the national validation teams with the use of clinical case vignettes. Case vignettes have been used earlier to evaluate clinical judgement [6]. The German national healthcare-associated infections surveillance system (KISS) has used case vignettes as part of the validation process and to facilitate calculation of the sensitivity and specificity for each member of the surveillance network, and recommends the case vignette validation methods for validation of other surveillance systems [7].

In this study, we report on the development of case vignettes for assessment of the inter-rater reliability of validation teams.

Methods

Development of the case vignettes

Two medical doctors, including one infectious disease specialist, both with experience in antimicrobial stewardship, management of healthcare-associated infections, and multidrug-resistant bacteria, developed the case vignettes based on real clinical cases (Figure 1).

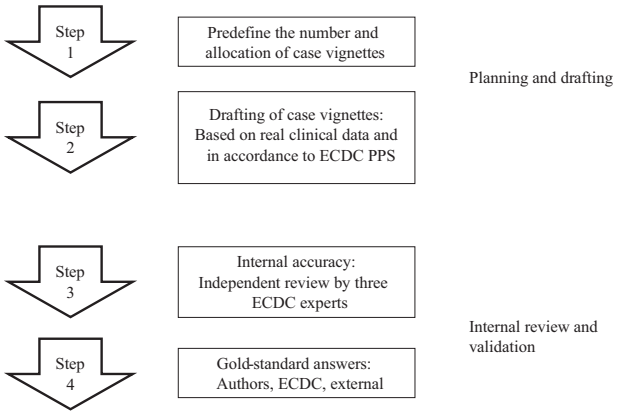

Figure 1. Development of the case vignettes.

The case vignettes included elements of real-life medical records and data that were necessary to fill in the mandatory fields as requested by the ECDC PPS protocol [2]. All case vignettes were similarly structured with a brief medical history and the reason for hospital admission. Each case vignette also included a description of clinical signs and symptoms of the patient, possible antimicrobial therapy, and laboratory and radiological results, if any, obtained during the hospitalization, as well as the course of hospitalization.

A total of 60 case vignettes was developed to guarantee a diversity in the case vignettes sent to each country. Twenty-nine case vignettes were HCAI cases. The distribution of different types of HCAI reflected the proportions of HCAIs found in the ECDC PPS 2011–2012 [1]. Examples of case vignettes are given in the Supplementary Appendix online.

Internal accuracy

All case vignettes were pilot-tested by three ECDC expert raters, from Belgium, Greece, and Finland, who worked at the Antimicrobial Resistance and Healthcare-associated Infections Disease Programme at ECDC. Two of them were medical doctors (one epidemiologist and one infectious diseases specialist) and the third was an infection control nurse. They all had experience in the ECDC PPS and in epidemiology, infection prevention and control, and surveillance of HCAIs and antimicrobial use. The expert raters were asked to answer the same questions for each of the case vignettes (Figure 2), as per the ECDC PPS protocol version 5.2 [2].

To avoid bias, all three expert raters were asked to independently review the cases, and to answer the aforementioned questions. The case vignettes were then discussed in a group together with the authors. The validity of the case vignettes was reviewed also by testing the answers of the three expert raters for agreement. After the review, the case vignettes were revised and missing data were added, where necessary.

Reference standard answers for case vignettes

The three expert raters and the authors of the case vignettes agreed on the intended correct answer for each of the questions and this was considered as the reference standard. When the expert raters and the authors of the case vignettes could not reach agreement, the cases were discussed in a teleconference with external experts who had contributed to the development of the ECDC surveillance protocol and the ECDC PPS validation protocol. When appropriate, frequently asked questions (FAQs) were developed to clarify the definitions in the ECDC PPS protocol that had resulted in difficulties with interpretation.

Statistical analysis

The main variables considered were the presence of HCAI (yes/no) and receiving antimicrobial therapy (yes/no). Sensitivity and specificity for both of the main variables were calculated for each expert individually. Reproducibility between the three expert raters was analysed using kappa statistics with the following categorization: 0.81–1.00 (very good), 0.61–0.80 (good), 0.41–0.60 (moderate), 0.21–0.40 (fair/marginal), <0.2 (poor). Negative values were possible and denoted 'poor' agreement [8,9].

Antimicrobial (AM)			Yes / No
If Yes, indicate:	Name		Generic or brand name
	Route		Parenteral (P), oral (O), rectal (R), inhalation (I)
	Indication		Treatment intention for community (CI), long-term care (LI), acute hospital infection (HI), surgical prophylaxis: SP1: single dose, SP2: one day, SP3 >1 day, medical prophylaxis (MP), other (O), unknown indication (U)
	Diagnosis (site)		According to site list
	Reason in notes		Yes / No
	Date start AM		
	Changed? (+ reason)		No change (N), escalation (E), de-escalation (D), switch iv to oral (S), adverse effects (A), other (O), unknown (U)
	If changed: Date start 1st AM		*Given for the indication*
	Dosage per day	Number of doses	E.g., 3 × 1 g
		Strength of 1 dose	
		Mg /g /IU	
Healthcare-associated infection (HAI)			Yes / No
If Yes, indicate:	Case definition code		
	Relevant device		Yes / No / Unknown (relevant device use before onset infection)
	Present on admission		Yes / No
	If not present in admission: Date of onset		
	Origin of infection		Current hospital / other hospital / other origin – unknown
	HAI associated to current ward		Yes / No / unknown
	If BSI: source		
	Microorganism	MO code	According to site list
	(MO)	Antimicrobial resistance	According to site list
		Pandrug-resistant	No (N) / possible (P) / confirmed (C) / unknown (U)

BSI, bloodstream infection

Figure 2. Form for the assessment of internal accuracy through independent review of the case vignettes.

Table I
Expert rater sensitivity and specificity for the presence of healthcare-associated infection (HCAI) and of antimicrobial use

Variable	Sensitivity (%)	Specificity (%)
Presence of HCAI		
Rater 1	89.7	96.8
Rater 2	89.7	90.3
Rater 3	86.2	93.5
Presence of antimicrobial use		
Rater 1	98.0	90.9
Rater 2	100	90.9
Rater 3	95.9	90.9

For other variables, such as type of HCAI or type of antimicrobial, a frequency analysis was performed and agreement with the reference standard was assessed.

Results

Development of the case vignettes

Sixty case vignettes were developed according to the described methodology. There were eight bloodstream or cardiovascular systemic infection cases (bloodstream infection, catheter-related infections, clinical sepsis and cardiovascular system infection), four lower respiratory tract infections including pneumonia, four urinary tract infections, three surgical site infections, and 10 other HCAIs such as *Clostridioides* (*Clostridium*) *difficile* infections or soft tissue infections. The remaining 31 case vignettes were cases without HCAI. These consisted of 11 community-acquired infections (CAIs) for which patients were receiving an antimicrobial for CAI, 10 cases without CAI or HCAI but with antimicrobials for other indications (e.g. surgical prophylaxis, medical prophylaxis), and 10 cases without CAI or HCAI and without antimicrobial use.

Two examples of case vignettes are reported in the Supplementary Appendix.

Internal accuracy

The sensitivities and specificities of the three expert raters are presented in Table I. The inter-rater reliability using kappa statistics was 0.78 for the presence of HCAI and 0.89 for presence of antimicrobial use.

Discrepancies in the inter-rater assessment of the case vignettes

In total, there were 10 case vignettes for which the expert raters found an HCAI, but this did not correspond with the reference standard reply. In one case vignette, two HCAIs were present at the same time according to the reference standard assessment, but all three expert raters only identified one HCAI.

Regarding case vignettes with healthcare-associated pneumonia, four different types of pneumonia were included. All expert raters correctly identified the presence of pneumonia, but they correctly identified the subtypes of pneumonia (PN1–PN5; Table II) in only seven of 12 assessments. None of the expert raters correctly identified the case of cardiovascular system infection – arterial or venous infection (CVS-VASC) or the case of central nervous system infection – meningitis or ventriculitis (CNS-MEN).

When an HCAI was identified, the field 'relevant devices' was answered correctly by the expert raters in 75% of the answers (in 25% of the cases the answer was incorrect or there was no answer). For all the HCAIs identified as urinary tract infections, 100% of the answers regarding 'relevant devices' were correct. For lower respiratory tract infections 81% of the answers were correct, and for bloodstream and cardiovascular system infections only 67% of the answers were correct.

For presence of antimicrobial use, the expert raters' replies to 177 (98%) of the 180 questions were correct. For 51 case vignettes, the patient received at least one antimicrobial. The 'reason for change' was 'escalation' in nine cases (70% correct answers from the expert raters), 'no change' in 33 cases (75% correct answers), 'de-escalation' in eight cases (67% correct answers), and 'switch i.v. to oral' in two cases (92% correct answers).

Discussion

Sixty case vignettes were developed to support testing, training, and self-assessment of the national validation team members for the ECDC PPS 2016–2017. They were envisaged as a standardized tool for the assessment of the performance of the members of the national validation teams. Case vignettes are a useful tool that has been used to assess clinical judgement and, in the field of HCAI surveillance, for assessing the validity of case definitions and of the accuracy of detection and classification of HCAIs by surveillance teams [6,7,10].

The 60 case vignettes included cases corresponding to the most common categories of HCAIs as defined in the ECDC PPS protocol and followed a distribution similar to that of the results of the ECDC PPS 2011–2012. They were based on actual clinical cases and were pilot-tested with a group of three expert raters to agree on the reference standard answers. Discrepancies in the assessment of the cases were discussed and the case vignettes were revised when clarification was deemed necessary.

All three expert raters reached >80% sensitivity and >90% specificity for both the presence of HCAIs and of antimicrobial use, similar to those reported overall in the ECDC PPS pilot validation study in 10 countries [5]. The sensitivity was also higher than in four national validation surveys carried out in 2012 during the second phase of the ECDC PPS 2011–2012 [1].

The agreement between the expert raters was very good for the presence of antimicrobial use and good for the presence of HCAI, reflecting the complexity of assessing HCAI cases, which is relevant for both prevalence studies such as the ECDC PPS and continuous surveillance of HCAIs. Despite agreed case definitions, assessment of the presence of HCAI by clinical or surveillance judgement may be influenced by personal experience, training, and abilities. For antimicrobial use, disagreement could be partly explained by misunderstanding of the case vignettes. The cases for which full agreement was not attained mostly concerned rare types of HCAI, e.g. a case of ventriculitis, or criteria that remained at least partially open for interpretation, e.g. some of the criteria for subcategorization of pneumonia.

Table II
Overview of expert rater assessment of each case vignette of healthcare-associated infection

Type of HCAI[a]	Correctly identified presence of HCAI				Correctly identified type of HCAI			
	Rater 1	Rater 2	Rater 3	Total	Rater 1	Rater 2	Rater 3	Total
Pneumonia, positive quantitative culture from minimally contaminated lower respiratory tract (LRT) specimen (PN 1)	Yes	Yes	Yes	3	Yes	Yes	Yes	3
Pneumonia, positive quantitative culture from possibly contaminated LRT specimen (PN 3)	Yes	Yes	Yes	3	No	Yes	No	2
Pneumonia, positive sputum culture or non-quantitative LRT specimen culture (PN 4)	Yes	Yes	Yes	3	No	No	Yes	1
Pneumonia, no positive microbiology (PN 5)	Yes	Yes	Yes	3	Yes	No	No	1
Neonatal case definitions — clinical sepsis (NEO-CSEP)	Yes	Yes	Yes	3	Yes	Yes	Yes	3
Systemic infections — treated unidentified severe infection (SYS-CSEP)	Yes	Yes	Yes	3	No	No	Yes	1
Cardiovascular system infection — arterial or venous infection (CVS-VASC)	No	No	No	0	NA	NA	NA	NA
Catheter-related infection-central venous line infection, microbiologically confirmed bloodstream infection (CRI3-CVC)	Yes	Yes	Yes	3	Yes	Yes	No	2
Catheter-related infection — central venous line infection, microbiologically confirmed bloodstream infection (CRI3-CVC)	Yes	Yes	Yes	3	No	Yes	Yes	2
Catheter-related infection — central venous line infection, no positive blood culture (CRI2-CVC)	Yes	Yes	Yes	3	No	Yes	No	1
Bloodstream infection (BSI)	Yes	Yes	Yes	3	Yes	Yes	Yes	3
Bloodstream infection (BSI)	Yes	Yes	Yes	3	Yes	Yes	Yes	3
Urinary tract infection, microbiologically confirmed symptomatic (UTI A)	Yes	Yes	Yes	3	Yes	Yes	Yes	3
Urinary tract infection, microbiologically confirmed symptomatic (UTI A)	Yes	Yes	Yes	3	Yes	Yes	Yes	3
Urinary tract infection, microbiologically confirmed symptomatic (UTI A)	Yes	Yes	Yes	3	Yes	Yes	Yes	3
Urinary tract infection, not microbiologically confirmed symptomatic (UTI B)	Yes	No	No	1	No	No	Yes	1
Surgical site infection, deep incisional (SSI-D)	Yes	Yes	Yes	3	Yes	Yes	Yes	3
Surgical site infection, organ/space (SSI-O)	Yes	Yes	No	2	No	Yes	Yes	2
Surgical site infection, organ/space (SSI-O)	Yes	Yes	Yes	3	No	Yes	No	2
Skin and soft tissue infection — decubitus ulcer (SST-DECU)	Yes	Yes	Yes	3	Yes	Yes	Yes	3
Gastrointestinal system infection — *Clostridium difficile* infection (GI-CD)	Yes	Yes	Yes	3	Yes	Yes	Yes	3
Gastrointestinal system infection — *Clostridium difficile* infection (GI-CD)	Yes	Yes	Yes	3	Yes	Yes	Yes	3
Gastrointestinal system infection — gastroenteritis (GI-GE)	Yes	Yes	No	2	No	Yes	Yes	2
Neonatal case definitions — laboratory-confirmed bloodstream infection with coagulase-negative staphylococci (NEO-CNSB)	Yes	Yes	Yes	3	No	Yes	Yes	2
Neonatal case definitions — necrotizing enterocolitis (NEO-NEC)	Yes	Yes	No	2	Yes	No	No	1
Bone and joint infection — disc space infection (BJ-DISC)	Yes	Yes	No	2	No	Yes	Yes	2
Central nervous system infection — meningitis or ventriculitis (CNS-MEN)	No	No	No	0	N.a.	N.a.	N.a.	-
Reproductive tract infection — other infections (REPR-OREP)	Yes	Yes	Yes	3	Yes	Yes	Yes	3
Reproductive tract infection — episiotomy (REPR-EPIS)	Yes	Yes	Yes	3	Yes	Yes	Yes	3

HCAI, healthcare-associated infection; NA, not applicable.
[a] Point prevalence survey of HCAIs and antimicrobial use in European acute care hospitals — Protocol version 5.3 [2].

The agreement reached for antimicrobial use was similar to the results of the ECDC PPS pilot validation study, but agreement was lower for the presence of HCAI [5]. This may be explained by the inclusion of challenging cases among the case vignettes. On the other hand, in comparison with another study on agreement on case vignettes of surgical site infections, the agreement reached among the three expert raters assessing the 60 case vignettes in our study was remarkably high, possibly reflecting similar training and previous experience [11]. The case vignettes were also useful for assessing challenges in the case definitions of the ECDC PPS protocol, thus helping to select topics for FAQs to be clarified for the national PPS teams and national validation teams.

Although case vignettes simulate reviews of patient records, they have limitations. First, they are necessarily a concise summary of all relevant information, thus eliminating the possibility of missing difficult-to-locate data when reviewing actual medical records. Second, depending on whether the case vignettes are constructed for training or validation, they tend to include a higher proportion of complicated cases than what is encountered in day-to-day surveillance. Therefore, the results of case vignette assessments are not expected to accurately reflect sensitivity and specificity of routine surveillance.

Differences in the incidences of HCAIs between countries have been attributed, among other factors, to different interpretations of case definitions and differences in the sensitivity of case-finding [12]. A standardized set of case vignettes may be useful to assess the variability of case-finding sensitivity between countries and between national teams. For the ECDC PPS 2016—2017, individual tests were created by a random algorithm for each member of each national validation team. Each test contained 10 case vignettes, including at least five different types of HCAI, at least four infections that were not HCAIs, and at least one case without HCAI or antimicrobial use. The tests were sent to the national validation teams prior to the ECDC PPS 2016—2017.

The case vignettes developed for this study may serve as a database of case studies for testing and training of the members of networks for continuous surveillance of HCAIs either at the national, European or other multi-country level.

In conclusion, surveillance of HCAIs requires common case definitions, surveillance procedures and indicators, but also reliable case-finding to ensure that the reported HCAI rates are robust and comparable. The use of case vignettes for capacity assessment and training of the surveillance teams is envisaged as an additional tool to support standardization of surveillance, therefore enhancing the validity and comparability of HCAI surveillance results and increasing their usefulness to inform policy-making.

Conflict of interest statement
None declared.

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None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jhin.2019.01.018.

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