Laboratory data as a quality indicator of health-care-associated infections in England

ABSTRACT

Routine diagnostic laboratory results, e.g. numbers of meticillin-resistant *Staphylococcus aureus* (MRSA) bacteraemias, have been used as health-care-associated infection quality indicators for decades. The English health-care-associated infection quality indicator system was one of the earliest in the world to mandate the collection and public reporting of such data and has been associated with a reduction of MRSA bacteraemias and *Clostridium difficile* infections but has shown mixed results for other infections.

Diagnostic laboratory data vary greatly between hospitals depending not only on the underlying frequency of the infection of interest, but on the case mix, numbers of samples processed and laboratory factors, which limits benchmarking. Further, over-reliance on laboratory reports has led to unintended negative consequences in England. So, while acknowledging the successes of the English system, the authors believe that it should be appraised in light of the goals of quality of care, patient safety, fairness and providing meaningful data, and alternative health-care-associated infection quality indicator measurements considered.

The NHS has an established history of nationwide quality improvement schemes; in England these include improving staff health and wellbeing, preventing public ill health by reducing risky behaviours, improving compliance with venous thromboembolism prophylaxis, and friends and family surveys of hospital care. These schemes change and develop over time with new focuses for better care being introduced annually.

For more than a decade there have been quality improvement schemes to reduce health-care-associated infections in the NHS. Health-care-associated infections are a common cause of patient harm worldwide and have a large associated economic burden. The prevalence of health-care-associated infections in England is around 6.6% (Public Health England, 2017e).

The impact of health-care-associated infections on patients and health-care systems has long been recognized. As meticillin-resistant *Staphylococcus aureus* (MRSA) infections increased at the end of the last century, initiatives to reduce health-care-associated infections were shared globally. Several nations took steps to control health-care-associated infection which included the measurement of quality indicators designed to improve patient safety by reducing morbidity and mortality caused by health-care-associated infection. These quality indicator systems, which are still used, differ between countries including the devolved administrations of England, Wales, Scotland and Northern Ireland. The differences apply to the measurements, definitions and protocols for diagnosing the infections, definitions of inpatient episodes *vs* hospital-assigned episodes, whether or not the data collection is mandatory or voluntary, if it is reported publicly, if it is risk adjusted and the way in which the data are presented (Public Health England, 2017b).

In the UK, there is an increasing reliance on laboratory results as the quality indicator measure of health-care-associated infection and antibiotic resistance, almost to the exclusion of other methods. There are many problems with the data generated by the routine diagnostic laboratory in this context; it may be incomplete or at worst misleading. Although there is nothing to stop hospitals from developing their own health-care-associated infection quality indicator initiatives, resource is usually diverted to nationally reported quality indicator schemes.

With the global rise of antimicrobial resistance, it is tempting to expand existing health-care-associated infection quality indicator systems to incorporate the reporting of a greater variety of antimicrobial-resistant organisms. However, this article focuses on and addresses some of the limitations of the laboratory-based health-care-associated infection quality indicator system used in England and suggests a different emphasis for such systems going forward.

Health-care-associated infection quality indicators

Structures, processes and outcomes can be measured as health-care-associated infection quality indicators. The number of side rooms available for isolation is a structure health-care-associated infection quality indicator. Process quality indicators include compliance with hand hygiene or antibiotic stewardship. Outcome measurements may incorporate laboratory-based data such as MRSA bloodstream infections or non-laboratory data such as patient satisfaction surveys or clinical infections identified by examination of the patient.

The most commonly used health-care-associated infection quality indicators in England have been laboratory-based outcome measures, such as *Clostridium difficile* diagnoses and MRSA bloodstream infection. These counts of organisms detected by the laboratory have many advantages,

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for example they are relatively simple and cheap to collect, they are patient-centred and they are simple to understand by health-care professionals and patients alike. However, there are several disadvantages of these measurements, particularly if they form the main basis of benchmarking of hospitals. Comparisons of hospitals by benchmarking has been an important part of the health-care-associated infection quality indicator process in England by both encouraging 'poorly performing' hospitals to improve their health-care-associated infection rates and sharing best practice from the best performing hospitals. It is important that this monitoring and benchmarking should accurately inform the predictable press interest and patient concern generated by it and provide appropriate reassurance.

History of health-care-associated infection reporting in England

The public mandatory surveillance of MRSA bloodstream infection (MRSA isolates identified from blood cultures) by all NHS hospitals in England was introduced in 2001 after a rise in numbers of MRSA bloodstream infections reported through a voluntary system. This was closely followed by public mandatory reporting of glycopeptide-resistant enterococcus (often referred to as vancomycin-resistant enterococcus) bloodstream infection and *C. difficile* infection reporting (positive *C. difficile* tests).

After mounting public and press concern, ambitious national targets for the reduction of MRSA bloodstream infection and *C. difficile* infections were set in 2004 and 2007 respectively (Duerden et al, 2015). A number of hospital chief executives lost their jobs as a result of problems with health-care-associated infection control in their institutions and hospitals were fined when the targets were breached. Health-care-associated infection rates and outbreaks became a leading item in the national press. Some of that may now seem inappropriate such as calling some hospitals 'dirty' and the publication of misleading MRSA league tables. Owing to rising numbers, mandatory reporting of meticillin-susceptible *S. aureus* (MSSA) and *Escherichia coli* bloodstream infections were added in 2011 (Department of Health, 2011a,b). Most recently, following concerns about Gram-negative infections and antibiotic resistance, mandatory reporting has been expanded to include *Pseudomonas aeruginosa* and *Klebsiella* spp bloodstream infections (Public Health England, 2017a).

Mandatory reporting in England improved MRSA bloodstream infection case ascertainment over the pre-existing voluntary scheme by 40% (Pearson et al, 2009). In spite of much scepticism about the potential for success, MRSA and *C. difficile* rates have fallen significantly (by 81.5% and 76.9% respectively between 2007–8 and 2016–17) (Public Health England, 2017b), the targets were more than met and all-cause 30-day mortality associated with these health-care-associated infections has also fallen (Public Health England, 2017d). However, countries without public reporting of health-care-associated infection have also seen improvements (Fitzpatrick and Riordan, 2016) similar to those observed in England. Further, MSSA and *E. coli* bloodstream infection (including antibiotic-resistant *E. coli*) have increased even with this reporting scheme (Public Health England, 2017b). A target has been set of a 50% reduction in health-care-associated Gram-negative bloodstreams infection by 2021 (Public Health England, 2017c).

As MRSA bloodstream infection and *C. difficile* infection rates fell, root cause analysis was introduced and latterly a system called post-infection review for MRSA, both of which emphasize learning and response to the issues giving rise to each individual case of MRSA bloodstream infection and *C. difficile* infection by those in the health-care facility responsible for the case. There is a 'zero tolerance' approach to MRSA bloodstream infection, meaning that zero cases are permissible. However, a hospital is only held culpable and thus penalised if the root cause analysis or post-infection review process (a detailed discussion, sometimes among peers from outside the facility) concludes that there was a lapse in the patient's care provided by the hospital that resulted in the health-care-associated infection. 'Third party' assignation is now possible in the post-infection review process and the case may even be attributed to the patient (depending upon specific evident behaviours, e.g. intravenous drug use resulting in MRSA bloodstream infection) or another trust.

The problem with using laboratory-based data as a health-care-associated infection quality indicator

Just as you could use ice-cream sales as a proxy measure of ambient temperature in different cities across the country, with all its obvious problems, there are issues with using reported laboratory data for measuring clinical infection rates.

For reasons here divided into pre-analytic, analytic and post-analytic, the numbers and species of bacteria isolated and reported can vary considerably between laboratories. Consequently, unless there is standardization, laboratory results are a very unreliable measurement with which to compare hospitals, e.g. *C. difficile* rates may vary by more than 50% simply depending on the diagnostic technique used (Planche et al, 2008) and variation may be more than 300% across Europe where different hospitals test more or fewer specimens for *C. difficile* (Davies et al, 2014). This could lead to a more than six-fold difference in reported rates of *C. difficile*. After the introduction of the public reporting system in England, it was necessary to standardize laboratory methodologies and sample collection protocols across laboratories nationwide to allow *C. difficile* infection to be used as a quality indicator of health-care-associated infection.

Pre-analytic: sample selection

Sampling algorithms can cause a skew, e.g. hospitals caring for complex orthopaedic cases mandate extra sampling to discern the presence of bone and joint infection, meaning that they may appear to have a higher rate of infection than other hospitals simply because they are looking for it better. They may also appear to have a higher rate as they are managing more complex cases at greatest risk of infection. Multiresistant Gram-negative bacteria are still relatively infrequent in England. Thus a hospital that serves a population with a large cohort of people from high-risk countries is more likely to have a multiresistant Gram-negative bacteria screening programme in place, testing strategies to ensure the detection of multiresistant Gram-negative bacteria and to detect higher numbers of these organisms than one serving a different population.

A hospital caring for patients with gastrointestinal diseases might send more specimens for *C. difficile* testing than other types of hospitals because of the higher incidence of loose stool. Further, to redress this potential imbalance, bias might also be introduced if an algorithm for the rejection of specimens is developed. 'Gaming' is the altering of behaviour to gain strategic advantage (Marshall et al, 2004), e.g. empirically treating patients who develop diarrhoea in hospital for *C. difficile* infection without laboratory testing for it, thus keeping the number of reportable laboratory-diagnosed cases low. A hospital caring for dermatology patients, who are at greater risk of colonization with *S. aureus*, might also appear to have a higher *S. aureus* bacteraemia rate, and a hospital caring for patients with neutropenic sepsis might have a high Gram-negative bacteraemia rate as a result of gut translocation. If all of these inequities are not adjusted for, the face-value laboratory data are misleading.

Analytic: laboratory methodology

Humans carry trillions of bacteria, the majority of which do not cause infection but are colonizing without causing harm. In fact there is an increasing acknowledgement of the active roles of these bacteria in maintaining human health. Colonization means that a laboratory can frequently detect a bacterium, even potentially pathogenic bacteria such as *E. coli*, MRSA or *C. difficile*, in healthy individuals who are infection free. Health-care-associated infections usually arise once an individual is debilitated in hospital, when this balance between human host and bacterial colonizer changes, and health-care-associated infections are frequently caused by a person's own bacteria. Therefore in order to diagnose health-care-associated infection, the clinical correlation of laboratory results is essential. As a corollary the use of laboratory data with no clinical information may have little meaning.

Specimens taken from sterile sites, such as blood, are easier to interpret clinically as these samples should not contain any bacteria. This simplicity, along with the fact that bloodstream infections are usually severe and therefore important, explains their popularity as a laboratory outcome measure. Thus MRSA bloodstream infections were used as a health-care-associated infection quality indicator at the time of the 'MRSA epidemic' of all types of MRSA infection at the turn of this century in England. However, contamination of blood cultures with skin-colonizing bacteria is common as a result of poor blood drawing technique. This contributed up to 12.4% of apparent MRSA bloodstream infections in one centre (Jeyaratnam et al, 2006). However, and probably in order to avoid gaming, contamination is not reflected in the reporting of MRSA bloodstream infection as all laboratory results must be reported without clinical interpretation, i.e. reported whether there is infection or not. A consequence of this is that even if it were possible to eliminate all MRSA bloodstream infection, there would still be laboratory reports recording MRSA bloodstream infection as a result of contamination.

Detecting and reporting relevant bacteria and associated antibiotic sensitivities from specimens submitted for examination can be challenging. Routine diagnostic laboratories receive hundreds of thousands of specimens each year potentially growing several different (usually commensal) micro-organisms. Identifying all of these organisms is too expensive, impractical and unnecessary for many specimen types. Different methodologies, including selective or chromogenic agars or the use of enrichment cultures, are used to aid this process, thus greatly affecting the results, as does choosing which bacterial colonies to fully identify, name and report, which can vary considerably between laboratories. The same specimen submitted to different laboratories could be reported as 'colonising flora', 'staphylocci, streptocci and coliforms' or even '*Staphylococcus aureus*, *Klebsiella oxytoca*, extended spectrum beta-lactamase *E. coli* and group B Streptococcus' (*Figure 1*). Thus many organisms will not be identified or reported by laboratories. Diagnostic laboratories often find much more of what they decide to look for, which is particularly true during outbreaks or where a conscious decision is made to look for a micro-organism. For example, a vancomycin-resistant enterococcus must be actively searched for otherwise it may be dismissed as

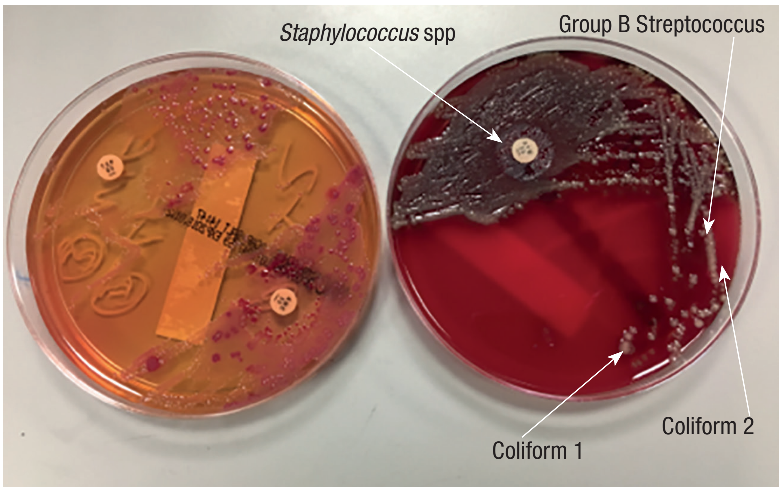

Figure 1. The bacterial growth from a single swab from a diabetic foot ulcer on two different agar plates to highlight the four different colony types: two different types of coliform bacteria, a beta haemolytic group B Streptococcus and a Staphylococcus spp. The plate on the left demonstrates the two different types of coliform.

Table 1. Prevalence of health-care associated infections by year

Prevalence study	Reference	Total patients surveyed (*n*)	Total number with health-care-associated infection (*n*)	Prevalence (%)	95% confidence interval (%)
2016 England	Public Health England (2017e)	48 312	3314	6.6	6.4–6.8
2011 England	Health Protection Agency (2012)	52 443	3360	6.4	6.2–6.6
2006 England	Hospital Infection Society and Infection Control Nurses Association (2007)	58 775	4812	8.2	8.0–8.4
UK 1993–4	Emmerson et al (1996)	37 111	3353	9.0	8.7–9.3
UK 1980	Meers et al (1981)	18 163	1671	9.2	8.8–9.6

Enterococcus spp commensal flora. The variation between laboratories is even more pronounced where antibiotic sensitivities are reported, particularly if resistant bacteria are found in colonizing normal bacterial flora.

It is significant that bloodstream infections only represent a small number of health-care-associated infections and do not monitor other important health-care-associated infections such as urinary tract infections or hospital-acquired pneumonia. Point prevalence surveys report that 4–19% of patients develop a health-care-associated infection depending on the country studied (Allegranzi et al, 2011). The most recent published point prevalence survey in England was undertaken in 2016 (Public Health England, 2017e) (*Tables 1* and *2*). Of the 3314 health-care-associated infections, 37.4% had micro-organisms identified: approximately 0.7% of all health-care-associated infections were caused by MRSA, 117 (3.5%) were caused by *C. difficile*, 0.8% were caused by vancomycin-resistant enterococcus, and *E. coli* and *S. aureus* bloodstream infection accounted for 39 (1.2%) and 45 (1.4%) infections respectively. *Pseudomonas aeruginosa* and *Klebsiella* spp bloodstream infections combined accounted for 1% of health-care-associated infections. Thus the organisms of interest in English hospitals form a fraction of all health-care-associated infections. Indeed, the top six clinical categories of health-care-associated infection, e.g. hospital-acquired pneumonia and urinary tract infection, account for over 80% of all health-care-associated infections. Changes in the prevalence of most of these top six will not be reflected by the current laboratory outcome measurements that are used in England. Thus laboratory-based data alone may oversimplify the situation and result in only a partial view of the overall problem.

Post-analytic: data output

The type of hospital and the case mix will affect the laboratory results and thus cause variation between hospitals. In order to make meaningful comparisons between institutions there should be adjustment of quality indicator measurements for confounding factors and case mix (O'Neill and Humphreys, 2009).

For the reasons described earlier, whether or not the hospital is a tertiary or quaternary centre for a particular speciality, private *vs* NHS or serving a large local immigrant population will affect the results. A children's hospital will have different results to a 'general' hospital or one looking after an elderly population. The age, socioeconomic background of patients and type of services provided by a hospital and the hospital workload should also be adjusted for. Currently, there is minimal risk adjustment in the English system; infections are reported as a rate per 1000 occupied bed-days with hospitals categorised according to size and teaching status. Thus inter-hospital comparison is limited and not that informative. It is only possible for a trust to monitor trends over time in its own data. The inevitable unofficial league tables which use unadjusted data may be misleading and cause patients to

Table 2. Prevalence of types of health-care-associated infections (HCAI)

Type of HCAI group	Number of HCAI (n)	HCAI prevalence % (95% confidence interval)	Relative per cent of HCAI (%)
Pneumonia or lower respiratory tract infection	969	2.0 (1.9–2.1)	29.2
Urinary tract infections	576	1.2 (1.1–1.3)	17.4
Surgical site infections	496	1.0 (0.9–1.1)	15.0
Systemic infections	417	0.9 (0.8–0.9)	12.6
Gastrointestinal infections	244	0.5 (0.4–0.6)	7.4
Bloodstream infections	220	0.5 (0.4–0.5)	6.6
Skin and soft tissue infection	164	0.3 (0.3–0.4)	4.9
Eye, ear, nose or mouth infection	95	0.2 (0.2–0.2)	2.9
Bone and joint infections	40	0.1 (0.1–0.1)	1.2
Cardiovascular system infection	29	0.1 (0.0–0.1)	0.9
CNS infection	28	0.1 (0.0–0.1)	0.8
Catheter-related infections without bloodstream infections	23	0.0 (0.0–0.1)	0.7
Reproductive tract infection	13	0.0 (0.0–0.1)	0.4
Total	3314		100

From Public Health England (2017e)

make decisions that are inconsistent with their goals (Fung et al, 2008; O'Neill and Humphreys, 2009).

There is often a failure to fund the staff required to collect, clean and report the data. Inadequate staffing locally and centrally may also be the reason for inadequate risk adjustment. However, one of the advantages of structure and process data is that they require minimal, if any, risk adjustment (Haustein et al, 2011). Although the reporting of clinically identified infections has its own limitations, e.g. subjectivity of definitions, biases as a result of physician reporting and data capture, it is felt that investment can ensure a 'level playing field' (Talbot et al, 2013). It has also been noted that evidence-based improvement strategies might require additional resources as opposed to quality indicator-based strategies which may be easier to implement with existing resources (Muller and Detsky, 2010), making the latter a favourable option but for the wrong reasons.

Unintended negative consequences

Focussing on a particular outcome can distract from other areas of patient care (Edmond and Bearman, 2007). Indeed, public reporting of quality data has been associated with unintended consequences (Fung et al, 2008) which is worrying, particularly as public reporting of health-care-associated infection rates is not always associated with improved processes or outcomes (Linkin et al, 2013).

It has been suggested that concentrating on the MRSA target (Commission for Healthcare Audit and Inspection, 2006) and on the mandated 4-hour wait in English emergency departments (Commission for Healthcare Audit and Inspection, 2006, 2007) were contributory factors in two large hospital-wide *C. difficile* outbreaks in England which resulted directly in several deaths. The inquiries into these outbreaks reported poor levels of patient care which were a consequence of that target-driven culture (Commission for Healthcare Audit and Inspection, 2006, 2007).

The government body responsible for introducing health-care-associated infection quality indicators, Public Health England, report that targeting MRSA bloodstream infection has been associated with a subsequent rise in other infections including MSSA bloodstream infection (Public Health England, 2017b). To quote:

> **'While the incidence of MRSA bacteraemia has fallen, the incidence of MSSA bacteraemia continues to increase. The high priority that MRSA receives, currently and historically, is likely to have focused clinical attention to this infection over MSSA' (Public Health England, 2017b).**

At the turn of this century, a quality indicator linked to financial reimbursement was introduced in the USA such that patients diagnosed with community-acquired pneumonia should receive antibiotics within 4 hours of presentation. Consequently, some hospitals produced algorithms to meet the target including administering antibiotics before reviewing the chest X-ray. This resulted in some patients who did not have community-acquired pneumonia or any infection receiving unnecessary antibiotics (Wachter et al, 2008).

Two financial reimbursement quality indicator schemes, called Commissioning for Quality and Innovation, were introduced in England in 2016 (NHS England, 2016). One scheme, 'Timely identification and treatment of sepsis', concerns the early identification and treatment of sepsis with antibiotics and the other, entitled 'Antimicrobial resistance and antimicrobial stewardship', requires the reduction of all antibiotics as well as two broad-spectrum antibiotics (carbapenems and piperacillin-tazobactam), the use of which has increased over recent years in England (Public Health England, 2016) coinciding with rising antimicrobial resistance in Gram-negative organisms, e.g. *E. coli*. However, it is clear that these two schemes are potentially at odds with each other. Further, it appears that the increasing consumption of carbapenems and piperacillin-tazobactam occurred after they replaced cephalosporin and fluoroquinolone antibiotics when the latter two were removed from many hospitals' formularies in a bid to meet the MRSA and *C. difficile* targets. Thus, if systems are not reviewed and revised, there is a risk of travelling around in circles.

A new emphasis

The aim of quality indicator monitoring is to improve quality of care and patient safety, thus an overarching view of health-care-associated infection and antimicrobial resistance should be adopted and alternative quality indicator measurements considered which have a clear, precise benefit to both. Although the root cause analysis, post-infection review and lapse in care assessment for MRSA and *C. difficile* infection now address some of the issues related to using non-risk-adjusted laboratory-based data, they are insufficient in addressing the shortcomings of the system. This is because, as with the original MRSA bloodstream infection and *C. difficile* infection health-care-associated infection quality indicators, *E. coli* and other Gram-negative bloodstream infections are new additional health-care-associated infection quality indicators but they do not undergo such case by case scrutiny. Further, the rigour of the entire root cause analysis and/or post-infection review process is not guaranteed. Therefore, it is time to reconsider the inclusion of structure and process quality indicators and clinically identified infections. A broader view of the risks, benefits, demand on resources and negative consequences for patients and beyond, e.g. rising antimicrobial resistance, should be anticipated, monitored and addressed in real time as part of the system, not unearthed as an unintended consequence. Field testing a quality indicator for these considerations is therefore required, as is a regular review of the system, especially as new priorities emerge. Risk adjustment should be included. There must be meticulous standardization of methodology and data validation to identify bias and gaming.

Conclusions

Despite the attraction of using the laboratory detection of bacterial isolates as a simple and cheap quality indicator measure of hospital infection rates, variations in sampling and methodologies make these reports unreliable as a comparator between hospitals. Lack of standardization and risk adjustment, as well as reporting bias, render the data limited for bench-marking. At best these organisms only represent a limited part of the overall burden of health-care-associated infection. We must recognize that over-reliance on laboratory reports may be misleading and paradoxically hamper the control of health-care-associated infections by giving only a partial or skewed view of the situation. Indeed the English health-care-associated infection quality indicator system, designed to improve patient outcomes, has scored some 'own goals' through a target-driven culture. Thus expanding it in its current form without modification, without taking stock of the good and the bad, is flawed. Other measurements may better serve our goals. We now need a joined-up view of health-care-associated infection and antimicrobial resistance in order to improve the meaning, safety, balance, fairness and accessibility of the English health-care-associated infection quality indicator system. **BJHM**

Figure 1 *is reproduced courtesy of Dr D Jeyaratnam. Some of the data included in this article were presented at the All-Party Parliamentary Group on Patient Safety - Inquiry into Infection Prevention.*
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KEY POINTS

- Laboratory-based health-care-associated infection quality indicator data can be misleading, particularly if used for benchmarking, leading to large differences in reported rates.
- Laboratory-based data gives only a partial view of the burden of health-care-associated infection as it overlaps with <40% of all clinically diagnosed health-care-associated infection.
- Mandatory public reporting of laboratory-based health-care-associated infection quality indicator data has been established in England for more than a decade.
- Since this quality indicator system was introduced rates of meticillin-resistant *Staphylococcus aureus* bloodstream infection and *Clostridium difficile* infection have fallen, as has all-cause mortality associated with them, but rates of *Escherichia coli* and meticillin-sensitive *S. aureus* bloodstream infections have increased.
- The target-driven culture associated with the laboratory-based health-care-associated infection quality indicator system may have had some unintended negative consequences.
- Review and revision of health-care-associated infection quality indicator systems is required. Consideration should be given to measuring clinically-diagnosed infections, structures and processes.
- The health-care-associated infection system must be balanced, fair and accessible in order to keep quality of care and patient safety at its core.

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