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Laboratory data as a quality indicator of healthcare associated infections in England: a review

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Corresponding Author:	Dakshika Jeyaratnam King's College Hospital NHS Foundation Trust London, UNITED KINGDOM
Corresponding Author Secondary Information:	
Corresponding Author's Institution:	King's College Hospital NHS Foundation Trust
Corresponding Author's Secondary Institution:	
First Author:	Dakshika Jeyaratnam
First Author Secondary Information:	
Order of Authors:	Dakshika Jeyaratnam
	Timothy Planche
Order of Authors Secondary Information:	
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Title page

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Picture 1 – The bacterial growth from a single swab from a diabetic foot ulcer on two different agar plates to highlight the 4 different colony types -2 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. ©DJeyaratnam

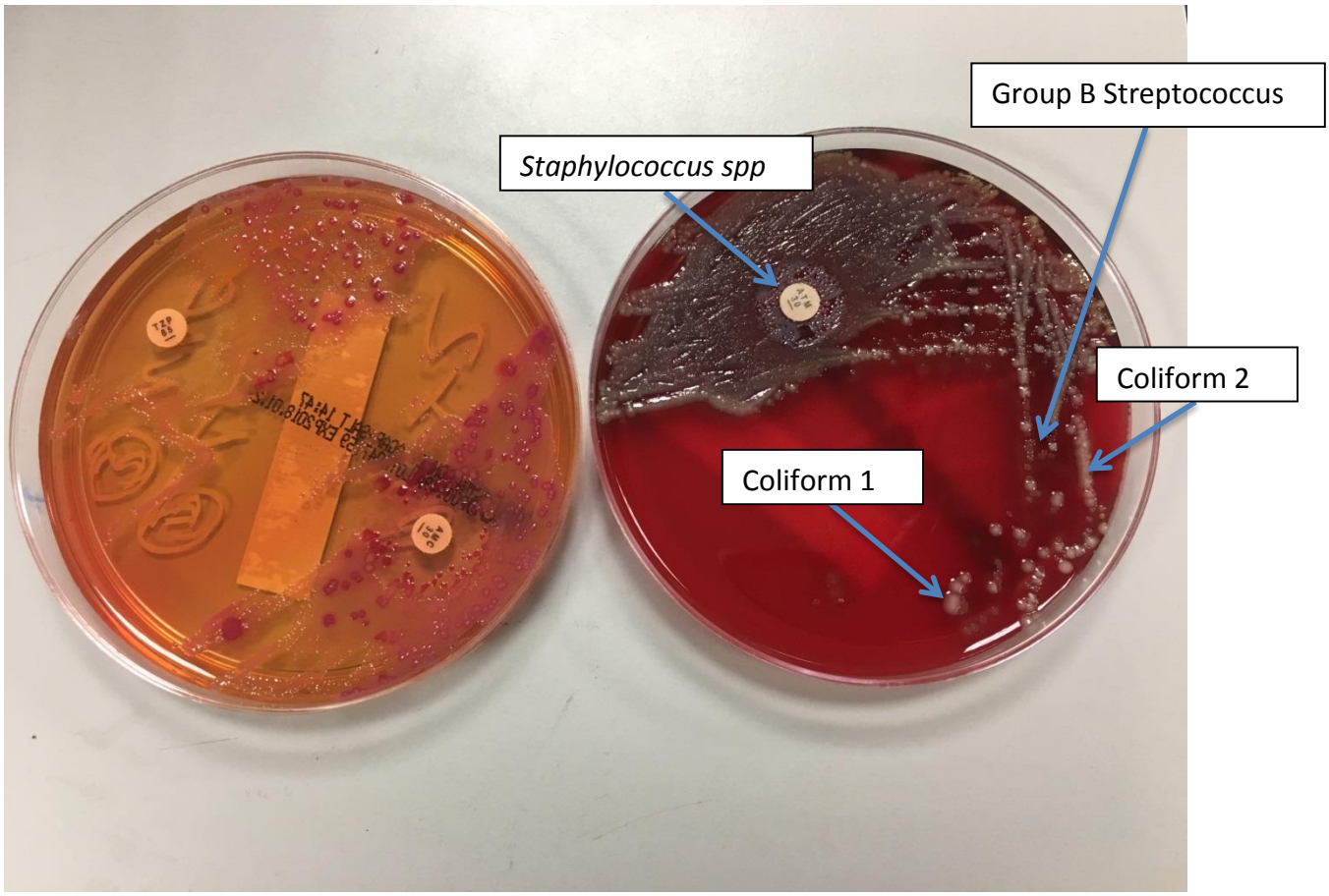


Table 1 - English National Point Prevalence Survey on Healthcare-associated Infections and Antimicrobial Use, 2016

Prevalence study	Total patients surveyed	Total number with HCAI	Prevalence	95% confidence interval (CI)
	N	N	%	%
2016 England	48,312	3,314	6.6	6.4-6.8
2011 England	52,443	3,360	6.4	6.2-6.6
2006 England	58,775	4,812	8.2	8.0-8.4
UK 1993/4	37,111	3,353	9.0	8.7-9.3
UK 1980	18,163	1,671	9.2	8.8-9.6

	Type of HCAI Group	Number of HCAI N	HCAI Prevalence % (95% CI)	Relative percent of HCAI %
1	Pneumonia/LRTI	969	2.0 (1.9 – 2.1)	29.2
2	Urinary tract infections	576	1.2 (1.1 - 1.3)	17.4
3	Surgical site infections	496	1.0 (0.9 - 1.1)	15.0
4	Systemic Infections	417	0.9 (0.8 - 0.9)	12.6
5	Gastrointestinal infections	244	0.5 (0.4 - 0.6)	7.4
6	Bloodstream infections	220	0.5 (0.4 - 0.5)	6.6
7	Skin and soft tissue inf.	164	0.3 (0.3 - 0.4)	4.9
8	Eye, ear, nose or mouth inf.	95	0.2 (0.2 - 0.2)	2.9
9	Bone and joint infections	40	0.1 (0.1 - 0.1)	1.2
10	Cardiovascular system inf.	29	0.1 (0.0 - 0.1)	0.9
11	Central nervous system inf.	28	0.1 (0.0 - 0.1)	0.8
12	Catheter-related infections without bloodstream infections	23	0.0 (0.0 - 0.1)	0.7
13	Reproductive tract inf.	13	0.0 (0.0 - 0.1)	0.4
	Total	3314		100

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/656611/ESPAUR_report_2017.pdf

Laboratory data as a quality indicator of healthcare associated infections in England: a review.

Abstract

Routine diagnostic laboratory results e.g. numbers of MRSA bacteraemias have been used as healthcare associated infection (HCAI) quality indicators (QI) for decades. The English HCAI QI 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 with mixed results for other infections.

Diagnostic laboratory data varies 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, whilst acknowledging the successes of the English system, we urge that we now appraise it in light of our goals of quality of care, patient safety, fairness and providing meaningful data, and thus consider alternative HCAI QI measurements.

Short introduction

The English HCAI QI system was associated with important successes. But with recent mixed results, some harmful 'own goals' and recognizing the partial view that it provides, which isn't always patient or hospital friendly, rather than expand it, it's time to reform it.

Main introduction

The National Health Service (NHS) has an established history of nation-wide quality improvement schemes; in England these range from improving staff health and well-being, 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 focusses for better care being introduced annually.

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

The impact of HCAI on patients and healthcare systems has long been recognised. As methicillin resistant *Staphylococcus aureus* (MRSA) infections increased at the end of the last century, initiatives to reduce HCAI were shared globally. Several nations took steps to control HCAI which included the measurement of quality indicators (QI) designed to improve patient safety by reducing morbidity and mortality due to HCAI. These QI systems, which are still employed, 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 in-patient episodes versus hospital-assigned episodes, whether or not the data collection is mandatory or voluntary, if it is reported publically, if it is risk-adjusted and the way in which the data are presented (Public Health England, July 2017).

In the United Kingdom (UK), there is an increasing reliance on laboratory results as the QI measure of HCAI 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. Though there is nothing to stop hospitals from developing their own HCAI QI initiatives, resource is usually diverted to nationally reported QI schemes.

With the global rise of antimicrobial resistance (AMR), it is tempting to expand existing HCAI QI systems to incorporate the reporting of a greater variety of antimicrobial resistant organisms. However here we focus on and address some of the limitations of the *laboratory-based* HCAI QI system used in England and suggest a different emphasis for such systems going forward.

HCAI Quality Indicators

Structures, processes and outcomes can be measured as HCAI QI. The number of side-rooms available for isolation is a structure HCAI QI. Process QIs include compliance with hand hygiene or antibiotic stewardship. Outcome measurements may incorporate laboratory-based data such as MRSA blood stream infections (BSI) or non-laboratory data such as patient satisfaction surveys or clinical infections identified by examination of the patient.

The most commonly used HCAI QIs in England have been laboratory-based outcome measures, such as *C. difficile* diagnoses and MRSA BSI. These counts of organisms detected by the laboratory have many advantages, for example they are relatively simple and cheap to collect, they are patient-centred and they are simple to understand by healthcare professionals and patients alike. There are however, 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 HCAI QI process in England by both encouraging 'poorly performing' hospitals to improve their HCAI 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 HCAI Reporting in England

The public, mandatory surveillance of MRSA BSI (MRSA isolates identified from blood cultures) by all NHS hospitals in England was introduced in 2001 after a rise in numbers of MRSA BSIs reported through a voluntary system. This was closely followed by public, mandatory reporting of glycopeptide resistant enterococcus (GRE) (often referred to as VRE) BSI and *Clostridium difficile* infection reporting (positive *C difficile* tests). After mounting public and press concern, ambitious national targets for the reduction of MRSA BSI and *C. difficile* infections were set in 2004 and 2007 respectively (Duerden B et al., 2015). A number of hospital chief executives lost their jobs as a result of problems with HCAI control in their institutions and hospitals were fined when the targets were breached. HCAI 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. Due to rising numbers, meticillin-susceptible *Staphylococcus aureus* (MSSA) and *Escherichia coli* (*E. coli*) BSI mandatory reporting were added in 2011 [Figure1] (Public Health England, March 2016). Most recently, due to concerns about Gram-negative infections and antibiotic resistance, mandatory reporting has been expanded to include *Pseudomonas aeruginosa* and *Klebsiella spp* BSI reporting (Public Health England, March 2017).

Mandatory reporting in England improved MRSA BSI case ascertainment over the pre-existing voluntary scheme by 40% (Pearson, A, Chronias A, Murray M, 2009) and 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, July 2017), the targets were more than met and all-cause 30 day mortality associated with these HCAIs has also fallen (Public Health England, 2015). However, countries without public reporting of HCAI have also seen improvements (Fitzpatrick F. and Riordan M.O, 2016) similar to those observed in England. Further, MSSA and *E. coli* BSI (including antibiotic resistant *E. coli*) have increased even with this reporting scheme (Public Health England, 2015, Public Health England, July 2017). A 50% reduction target for

healthcare associated Gram-negative BSI by 2021 has been set (Public Health England, August 2017).

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

The problem with using laboratory-based data as a HCAI QI

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 in to pre-analytic, analytic and post-analytic (Figure 2), the numbers and species of bacteria isolated and reported can vary considerably between laboratories. Consequently, unless there is standardisation, 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 T et al., 2008) and variation may be more than 300% across Europe where different hospitals test more or less specimens for *C. difficile* (Davies KA 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 standardise laboratory methodologies and sample collection protocols across laboratories nationwide to allow *C. difficile* infection to be used as a QI of HCAI.

a) 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. Multi-resistant gram negative bacteria (MRGNB) are still relatively infrequent in England. Thus a hospital that serves a population with a large cohort of people from the high-risk countries is more likely to have a MRGNB screening programme in place, testing strategies to ensure the detection of MRGNB 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 due to 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 MN, Romano PS, Davies HT 2004) e.g. empirically treating patients who develop diarrhoea in hospital for *C. difficile* infection without laboratory testing for it, thus keeping the reportable laboratory diagnosed cases low. A hospital caring for dermatology patients, who are at greater risk of colonisation with *Staphylococcus aureus,* might also appear to have a higher *Staphylococcus aureus* bacteraemia rate as might a hospital caring for patients with neutropenic sepsis have a high gram-negative bacteraemia rate due to gut translocation. If all of these inequities are not adjusted for, the face-value laboratory data is misleading.

b) Analytic: Laboratory methodology

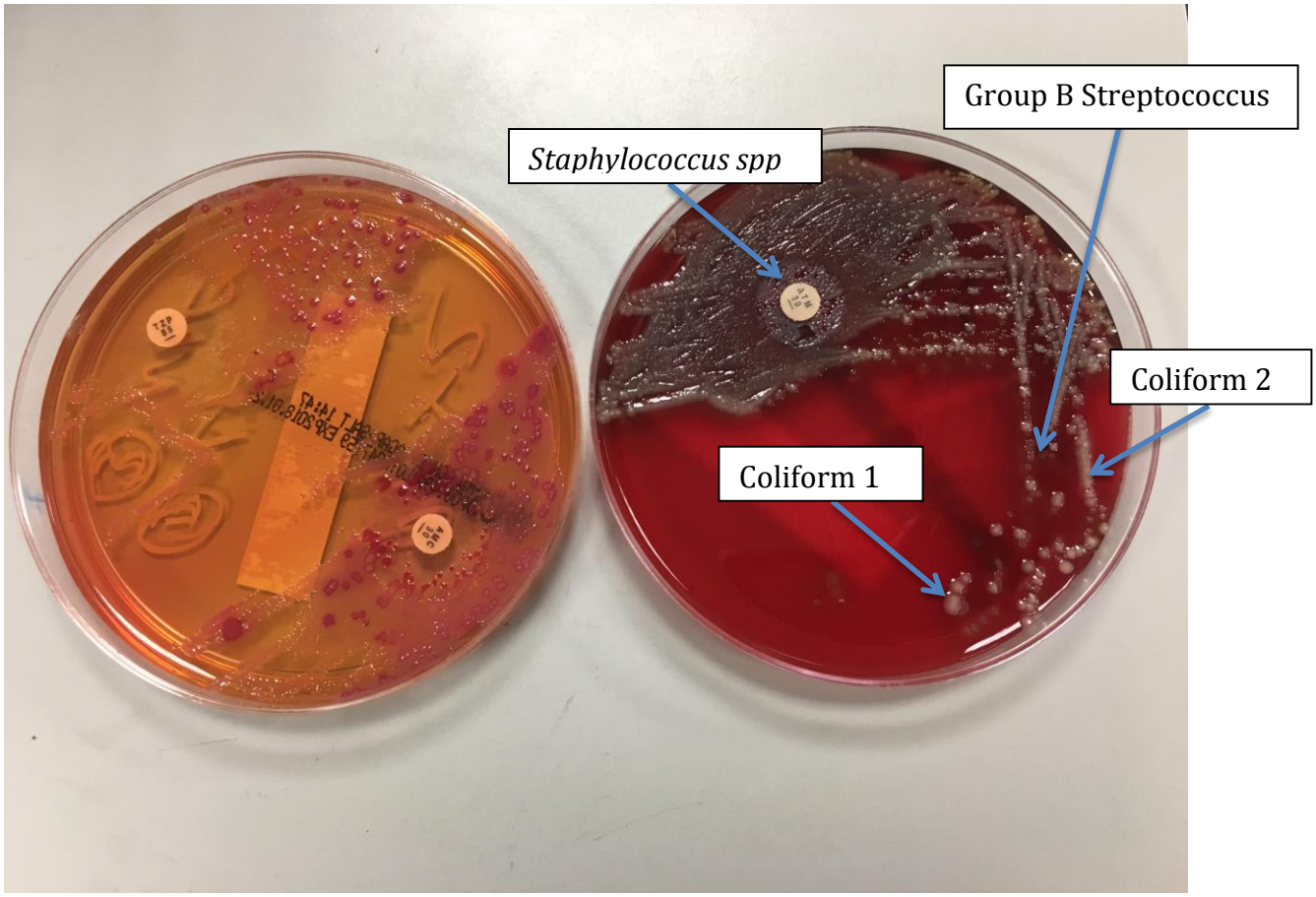
Humans carry trillions of bacteria, the majority of which do not cause infection but are colonising without causing harm. In fact there is an increasing acknowledgement of the active roles of these bacteria in maintaining human health. Colonization means that the detection of a bacterium by a laboratory, even potentially pathogenic bacteria such as *E. Coli,* MRSA or *C. difficile* can be frequently found in healthy individuals who are infection free. HCAIs usually arise once an individual is debilitated in hospital, when this balance

between human-host and bacterial coloniser changes and HCAIs are frequently caused by a person's own bacteria. Therefore in order to diagnose HCAI, 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 BSIs are usually severe and therefore important explains their popularity as a laboratory outcome measure. Thus MRSA BSIs were used as a HCAI QI 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-colonising bacteria is common due to poor blood drawing technique. This contributed up to 12.4% of apparent MRSA BSIs in one centre (Jeyaratnam, D, Edgeworth JD, French GL 2006). However, and probably in order to avoid gaming, contamination is not reflected in the reporting of MRSA BSI 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 BSI, there would still be laboratory reports recording MRSA BSI due to 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,* ESBL *E. col* and Group B Streptococcus" (Picture 1). Thus there are many organisms that 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 VRE must be actively searched for otherwise it may be dismissed as *Enterococcus spp* commensal flora. The variation between laboratories is even more pronounced where antibiotic sensitivities are reported, particularly if resistant bacteria are found in colonising normal bacterial flora.



Picture 1 – The bacterial growth from a single swab from a diabetic foot ulcer on two different agar plates to highlight the 4 different colony types -2 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. ©DJeyaratnam

It is significant that BSIs only represent a small number of HCAIs and do not monitor other important HCAIs such as urinary tract infections (UTI) or hospital-acquired pneumonia (HAP). Point prevalence surveys report that 4-19% of patients develop a HCAI depending on the country studied (Allegranzi B et al., 2011). The most recent published point prevalence survey in England was undertaken in 2016 (Public Health England, November 2017) [Table 1]. Of the 3,314 HCAI, 37.4% had micro-organisms identified: approximately 0.69% of all HCAI

were due to MRSA, 117 (3.5%) were due to *C. difficile* and 0.79% were due to VRE. Thus the organisms of interest in English hospitals form a fraction of all HCAIs. Indeed, the top six clinical categories of HCAI e.g. HAP and UTI and account for over 80% of all HCAI. Changes in the prevalence of most of these top 6 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.

c) Post-analytic: Data output

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

For the reasons described earlier, whether or not the hospital is a tertiary or quaternary centre for a particular speciality, private versus 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, socio-economic background of patients, 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 make decisions that are inconsistent with their goals (O'Neill E and Humphreys H, 2009, Fung CH et al., 2008).

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 behind inadequate risk-adjustment. However one of the advantages of structure and process data is that they require minimal, if any, risk-adjustment (Haustein T et al., 2011). Though the reporting of clinically identified infections has its own limitations e.g. subjectivity of definitions, biases

due to physician reporting and data capture, it is felt that investment can ensure a 'level playing field' (Talbot TR 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 MP and Detsky AS, 2010) making the latter a favourable option but for the wrong reasons.

d) Unintended negative consequences

Focussing on a particular outcome can distract from other areas of patient care (Edmond MB and Bearman GM, 2007). Indeed, public reporting of quality data has been associated with unintended consequences (Fung CH et al., 2008) which is worrying particularly as public reporting of HCAI rates are not always associated with improved processes or outcomes (Linkin DR et al., 2013). It has been suggested that concentrating on the MRSA target (Healthcare Commission, 2006) and on the mandated 4 hour wait in English Emergency Departments (Healthcare Commission, 2006, Healthcare Commission, 2007), were contributory factors in two, large hospital-wide *C. difficile* outbreaks in England which resulted directly in several deaths. The inquiries of these outbreaks reported poor levels of patient care which were a consequence of that target driven culture (Healthcare Commission, 2006, Healthcare Commission, 2007). The government body responsible for introducing HCAI QI, Public Health England, report that targeting MRSA BSI has been associated with a subsequent rise in other infections including MSSA BSI (Public Health England, July 2017). 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, July 2017).

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

called ‘Commissioning for Quality and Innovation’ (CQUIN), were introduced in England in 2016 (National CQUIN Templates 2016/17 Version number: 3.0, 2016). One CQUIN, ‘Timely identification and treatment of Sepsis’ concerns the early identification and treatment of sepsis with antibiotics and the other CQUIN, 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 have increased over recent years in England (Public Health England, November 2016) coinciding with rising AMR in gram-negative organisms e.g. *E.coli*. However it is clear that these two CQUINs 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 we do not review and revise our system, it seems that we are at risk of travelling around in circles.

A New Emphasis

The aim of QI monitoring is to improve quality of care and patient safety thus we should adopt an over-arching view of HCAI and AMR and consider alternative QI measurements which have a clear, precise benefit to both. Though the RCA, PIR and lapse in care assessment for MRSA and CDI 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 BSI and CDI HCAI QI, *E.coli* and other gram-negative BSI are new additional HCAI QI but they do not undergo such case by case scrutiny. Further, the rigour of the entire RCA/PIR process is not guaranteed. Therefore, it is time to reconsider the inclusion of structure and process QIs and clinically identified infections. A broader view of the risks, benefits, demand on resources and negative consequences for patients and beyond e.g. rising AMR should be anticipated, monitored and addressed in real-time as part of the system, not unearthed as an unintended consequence. Field-testing a QI for these considerations is therefore required as is a regular review of the system and all of these factors, especially as new priorities emerge. Risk-

adjustment should be included. There must be meticulous standardisation 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 QI measure of hospital infection rates, variations in sampling and methodologies make these reports unreliable as a comparator between hospitals. Lack of standardisation and risk-adjustment, as well as reporting bias render the data limited for bench-marking. These organisms, at best, only represent a limited part of the overall burden of HCAI. We must recognise that over-reliance on laboratory reports may be misleading and paradoxically hamper the control of HCAI by giving only a partial or skewed view of the situation. Indeed the English HCAI QI system, designed to improve patient outcomes has scored some 'own goals' through a target driven culture. Thus expanding it in its current form, without taking stock of the good and the bad, without modification, is flawed. Other measurements may better serve our goals. We now need a joined-up view of HCAI and AMR in order to improve the meaning, safety, balance, fairness and accessibility of the English HCAI QI system.

Key words/phrases

Quality Indicator

Healthcare Associated Infection

Mandatory Reporting

Benchmarking

Meticillin resistant Staphylococcus aureus

Clostridium difficile

Key Points

1. **Laboratory-based HCAI QI data can be misleading particularly if used for benchmarking, leading to large differences in reported rates. The reasons for this can be :**

    - **Pre-analytical e.g. differences in sampling strategies,**
    - **Analytical e.g. different testing algorithms**
    - **Post-analytical e.g. failing to adequately risk-adjust the data, all of which can be subject to gaming.**

2. **Laboratory-based data gives only a partial view of the burden of HCAI as it overlaps with <40% of all clinically diagnosed HCAI. The organisms of interest to the English HCAI QI system were responsible for only 7.1% of clinically diagnosed HCAI.**

3. **Mandatory, public reporting of laboratory-based healthcare associated infection (HCAI) quality indicator (QI) data has been established in England for more than a decade. These are methicillin-resistant *Staphylococcus aureus* (MRSA) bloodstream infections (BSI), *Clostridium difficile* infections (CDI), *E coli* BSI and meticillin sensitive *Staphylococcus aureus* (MSSA) BSI.**

4. **Since this HCAI QI system was introduced rates of MRSA BSI and CDI have fallen by 81.5% and 76.9% respectively, as has all-cause mortality associated with them. However rates of *E coli* BSI and MSSA BSI have both increased.**

5. **The target-driven culture associated with the laboratory-based HCAI QI system has been postulated to be responsible for some unintended negative consequences, associated with patient harm such as MSSA BSI and *Clostridium difficile* infection, the very things that the system is intended to reduce.**

6. **Review and revision of HCAI QI systems is required. Consideration should be given to measuring clinically-diagnosed infections, structures and processes. The HCAI system must be balanced, fair and accessible in order to keep quality of care and patient-safety at its core.**

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