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ORIGINAL ARTICLE

Clinical evaluation of the national hospital-acquired complication programme

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Key words
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Abstract

Background: The national hospital-acquired complication programme captures complications arising from patient-related and hospital-related factors, but the proportion of the two is unclear.

Aim: Health services are encouraged to evaluate data from the national hospital-acquired complications (HAC) programme and identify strategies to mitigate them.

Methods: A retrospective chart review compared HAC extracted from administrative data. The setting was a 430-bed university-affiliated metropolitan hospital. Records from 260 participants with, and 462 without, reported HAC from 2619 multi-day stay adults were reviewed. The main outcome measures were prevalence and positive predictive value (PPV) of HAC methodology.

Results: No errors of HAC coding or classification were identified. Four hundred and twenty-three HAC events were reported in 260 records; most commonly delirium (n = 57; 13.4%), pneumonia (n = 46; 10.9%), blood stream infection (n = 39; 9.2%), hypoglycaemia (n = 33; 7.8%) and cardiac arrhythmias (n = 33; 7.8%). One hundred and eight (25.5%) 'HAC' events in 69 separations (95% confidence interval (CI) = 2.05–3.33 per 100 separations) were false positive, and 43 of 462 (95% CI = 6.72–12.22 per 100 separations) were false negative. Prevalence of total (reported plus missing) HAC was 16.06 (95% CI = 14.02–19.52), reported HAC was 9.93 (95% CI = 8.76–11.21), potentially preventable HAC was 1.68 (95% CI = 1.22–2.26) and healthcare errors was 0.31 (95% CI = 0.13–1.30) per 100 separations. PPV of HAC for true clinical events was 0.74 (0.68–0.79), preventable events 0.18 (0.13–0.23) and healthcare error 0.03 (0.01–0.06).

Conclusions: Prevalence of HAC events was higher than expected, but PPV for healthcare errors was low, suggesting provision of care is a less common cause of HAC events than patient factors. HAC may be an indicator of hospital admission complexity rather than HAC.

Introduction

Clinicians make mistakes and patients suffer complications. The juxtaposition of these two facts naturally leads to an assumption that the former often precedes the latter, and that hospitals with higher complication rates are likely to have a lower standard of care than hospitals with lower rates.[1–5] To assist healthcare providers mitigate complications and improve patient safety, the national hospital-acquired complications (HAC) programme[6,7] has been developed by the Australian Commission on Safety and Quality in Healthcare (ACSQHC), endorsed by major health and safety institutions[8–10] and adopted by all Departments of Health[11–13] across Australia.

HAC are clinical complications for which mitigation strategies may reduce, but not necessarily eliminate, a future occurrence.[1–3] The HAC methodology has many attractive features. It addresses serious patient-related

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complications[10] and has support from clinical,[14] jurisdictional[8–13] and international[15] healthcare providers. Source data are common to all Australian hospitals,[6,16] coded by health information managers and guided by national coding rules.[17] The HAC algorithm[18] is open source, permitting hospitals to generate internal reports[14] or receive external reports with state[11] and national[19] benchmarks. The ACSQHC,[10] and jurisdictional[11–13] and health policy,[2,4,5] organisations urge health services to evaluate local data.

Implementation of the HAC programme requires clinicians who appreciate its analytic insights, analysts who appreciate its clinical limitations and healthcare managers who recognise its clinical implications. Clinical validation of the HAC methodology is therefore conspicuous by its absence. This may reflect confidence in the prevailing interpretation[5,8,11,14] based on historical data[20] or genuine concerns regarding medico-legal risks[7,10] of public reporting.[1] We sought to address this knowledge gap.

Our primary objectives were to assess the efficacy of the HAC methodology to identify adverse clinical events, its potential to identify risk mitigation strategies, and thus encourage hospitals and clinicians to evaluate their data.[5,19]

Methods

This research was undertaken in a 430-bed university-affiliated metropolitan public hospital with 55000-day procedure, and 25 000 multi-day, separations *per annum*, and the Millenium™ (Cerner Corp., Kansas City, MI, USA) electronic medical records (eMR) system. It required four stages: literature review and development of an audit tool, selection of assessors and power calculations, followed by chart review, analysis and reporting.

Given the paucity of contemporary audit tools,[21–23] we drew heavily on clinical expertise and one published historical audit.[4] The final survey tool (Supporting Information p9-13) was designed to be objective and comprehensive, based on categorical questions addressed to the medical record. Its primary purpose was to identify: (i) patient demographic and clinical characteristics; (ii) timing of the HAC event; and (iii) clinical management preceding the event compared with national guidelines.[10] Finally, the assessor was asked to apply clinical judgement to categorise each HAC event (Table 1).

All assessors were medical staff with a minimum of 3 years clinical experience, detailed knowledge of the eMR and no direct involvement in care of study patients. Each was required to audit a minimum of 30 records, and source data were limited to the medical records. Where uncertainty existed, access to a senior clinician was available.

Case identification was extracted from the Health Roundtable™ report[19] for the month of July 2018. Like all subscribers, the study hospital submits administrative data to the Health Roundtable™ quarterly, where data quality is checked and the HAC grouper (version 1.0[18]) applied. The confidential identified report is returned to the subscriber hospital. Accuracy of HAC classification was confirmed using published algorithms.[18]

Power calculations considered four distinct end-points and the limited historical data.[4,21] With 25 ,000 annual separations, a random sample of 400 was required to estimate the hospital frequency within ±5%; including a minimum of 240 HAC events to estimate the prevalence within ±6%; and 30 false-negative HAC events to estimate missed events within ±20%. After the required number was reached, the sample size was rounded up by including all separations from the last study day to

Table 1 Classification of reported HAC events

Category	HAC description	Separations *n* (rate†)	HAC events *n* (rate‡)
Category 1	Clinical event was likely and all appropriate management preceding the event was undertaken.	175 (6.68)	271 (1.48)
Category 2	Clinical event was likely and all appropriate management preceding the event may NOT have been undertaken.	3 (0.11)	5 (0.03)
Category 3	Clinical event was unlikely and all appropriate management preceding the event was undertaken.	58 (2.21)	105 (0.57)
Category 4	Clinical event was unlikely and all appropriate management preceding the event may NOT have been undertaken.	5 (0.19)	8 (0.04)
Category 5	Documentary evidence that this coded diagnosis was not a clinical event.	19 (0.73)	31 (0.17)

†Rate = subjects with HAC events per 100 separations; ‡rate = HAC events per 100 bed-days.

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furnish a reliable (bed-day) denominator for prevalence rates. The database was then locked, records de-identified and analysis performed.

Statistical analysis

Identified data were entered, encrypted and stored using REDCap™ software,[24] then de-identified, extracted and analysed using StataMP™ V16.1 (2019, College Station, TX, USA) statistical software. Grouped data are reported as median (interquartile range) or mean and 95% confidence intervals (CI) for Poisson-distributed events, with the user written Stata command 'xcipoibin'.[25] Rates per 100 separations or 100 hospital bed-days were derived from total separations or length of hospital stay (LOS) data, respectively. Positive and negative predictive indices were calculated with the user written Stata command 'diagt'.[26] Extrapolation of rates beyond the study population was based on cumulative bed-days (rather than the number of separations). The Eastern Health Human Research Ethics Committee (LNR2020-199585) approved this research. The need for patient consent was waived.

Results

A sample of 2619 adult multi-day separations from 45 consecutive calendar days (1 July to 14 August 2018) and 18 349 cumulative hospital bed-days was required to meet all power calculations. Out of this sample, the Health Roundtable™ report identified 260 separations with 423 HAC events, and 2359 separations without (Fig. 1). From the later subgroup, we reviewed 462 (19.6%) consecutive records for unreported HAC events. Thus, a total of 722 (27.6%) of the total sample were audited.

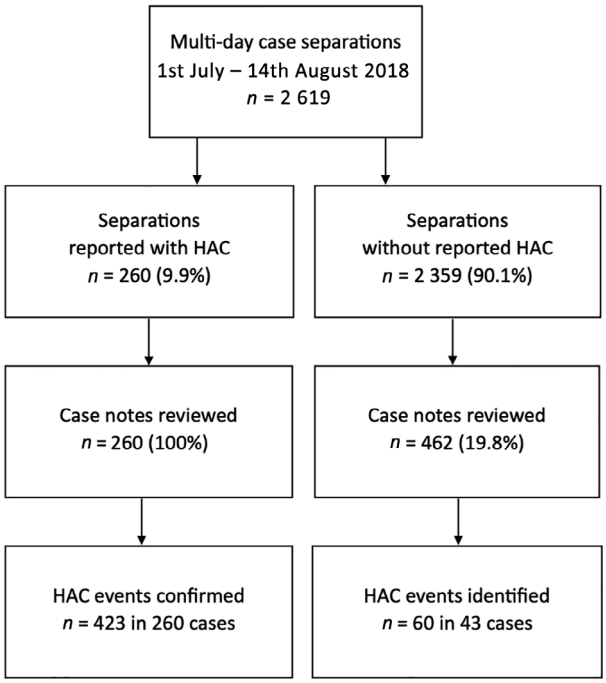

Figure 1 STROBE diagram of study population.

Medical records were accessible and complete for all separations except one (0.2%) missing a hospital discharge summary. There were no readmissions. We did not identify any HAC-related coding or classification errors – all reported HAC events were matched to clinical documentation. Inter-rater reliability was satisfactory (weighted kappa concordance 0.81; Supporting Information p5).

All HAC subclasses (except #16-Neonatal birth injury) were identified. The most frequent were delirium (n = 57; 13.4%), pneumonia (n = 46; 10.9%), 'blood stream infection' (n = 39; 9.2%), hypoglycaemia (n = 33; 7.8%) and cardiac arrhythmias (n = 33; 7.8%). The frequency of each HAC class is available in Supporting Information Table S1. All hospital wards and clinical services were associated with HAC events (Supporting Information Tables S2,S3).

A comparison of separations reported with and without HAC events is provided in Table 2. Those reported with (one or more) HAC events were older, carried a greater burden of comorbid disease, experienced a longer LOS and had a higher mortality risk compared with those without reported HAC events (P-value <0.001 for all comparisons). The estimated prevalence of separations with reported HAC events was 9.93 (95% CI = 8.76–11.21) per 100 separations, or 2.31 (95% CI = 2.09–2.54) HAC events per 100 bed days. Of those separations with reported HAC events, 164 (63.1%) experienced multiple events, at an average of 1.63 (95% CI = 1.48–1.79) events per episode.

Table 2 Demographics for separations coded with HAC events and those not coded with any HAC event

Group	Coded HAC	No coded HAC
Separations, *n*	260	2359
HAC events (95% CI)	423 (384–465)	230 (176–320)†
Age, mean (IQR) (years)	72 (63–84)	58 (41–76)
Male, *n* (%)	130 (50)	1042 (44)
Comorbidity, *n* (%)	173 (66.5)	349 (14.9)
LOS, mean (IQR) (days)	14 (6–18)	4 (2–7)
Death, *n* (%)	27 (10.4)	39 (1.7)

†Estimated, see text. All comparisons significant, P-value < 0.001. CI, confidence interval; HAC, hospital-acquired complication.

Classification of reported HAC events

Unequivocal healthcare errors were identified in eight separations at a mean rate of 0.31 (95% CI = 0.13–1.30) per 100 separations, and 3.07 (95% CI = 1.33—6.06) per 100 reported HAC events (Table 1, Categories 2 and 4). Examples include catastrophic bleeding from anticoagulants, pulmonary embolism, urinary tract infection and thrombophlebitis.

There were 54 HAC events in 44 separations associated with equivocal clinical management, and categorised as 'potentially preventable' clinical events, at a mean rate of 1.68 (95% CI = 1.22–2.26) per 100 separations, and 12.74 (95% CI = 9.57–16.62) per 100 HAC events. Although all these subjects were managed within accepted clinical practice guidelines[10] and no healthcare error could be identified (Table 1, Categories 1 and 3), the assessor judged that an alternative management strategy may have prevented its occurrence. Examples included hospital acquired infection ($n = 18$), hypoglycaemia ($n = 16$), cardiac complications ($n = 5$) and transfusion-associated pulmonary oedema ($n = 2$).

Of note, the majority of HAC events ($n = 331$; 78.3%) were judged more likely to be the direct consequence of patient-related factors despite clinical care that was consistent with local and national[10] guidelines (Table 1, Categories 1 and 3). Most were recognised complications of an (acute) admission diagnosis ($n = 236$; 55.8%), or a pre-existing comorbidity ($n = 158$; 37.4%) or prior medications ($n = 28$; 6.6%). These proportions were similar for all HAC classes and subclasses.

False-positive/negative HAC events

A total of 108 (25.5%) reported HAC events in 69 (26.5%) separations were classified as false positive (Table 1, Category 5). Most were associated with ambiguous or incomplete clinical documentation. Thirty-four (8.0%) suspected HAC events in 17 (7.3%) separations were confirmed as absent, based on available clinical data prior to hospital discharge. These included suspected infections ($n = 19$), malnutrition ($n = 4$), hypoglycaemia ($n = 3$) and aspiration pneumonitis ($n = 3$). A further 44 (16.9%) separations were coded with 55 (13.0%) HAC events that were already present on arrival but not documented until sometime after. A small number ($n = 13$; 2.7%) were due to terminal disease after redirection to symptom relief (palliative) care.

From the 462 consecutive chart reviews of records without (coded or reported) HAC events, the assessors identified 60 clinical events in 43 (9.31%; 95% CI = 6.74–12.34%) records that were consistent with the clinical definition of a HAC (subclass) event.[18] All were associated with insufficient documentation – such as a missing diagnosis – that precluded it being coded. These events included delirium ($n = 6$), incontinence ($n = 6$), medication errors ($n = 5$) and hypoglycaemia ($n = 4$). One (1.67%) was classified as a healthcare error and 11 (18.33%) as 'potentially preventable' adverse events, as previously defined.

We extrapolated from the number of observed false-negative cases (43 (95% CI = 31–60) of 462 separations over 2773 bed days) that an estimated 230 (95% CI = 176–320) separations in the study population (mean 8.78 per 100 separations; 95% CI = 6.72–12.22) may have experienced an adverse event that was not (coded or) reported.

Based on these data, we estimated the positive and negative predictive power of the HAC method to identify three clinical groups: (i) clinical HAC events; (ii) 'potentially preventable' HAC events; and (iii) HAC events due to healthcare error. The results are displayed in Figure 2 and summarised in Tables 3 and Supporting Information Table S4.

Combining the true-positive and (estimated) false-negative case numbers, we estimated the true prevalence of HAC events in the multi-day stay hospital population at a mean of 16.06 (95% CI = 14.02–19.52) per 100 separations and 3.46 (95% CI = 3.06–3.96) events per 100 bed-days.

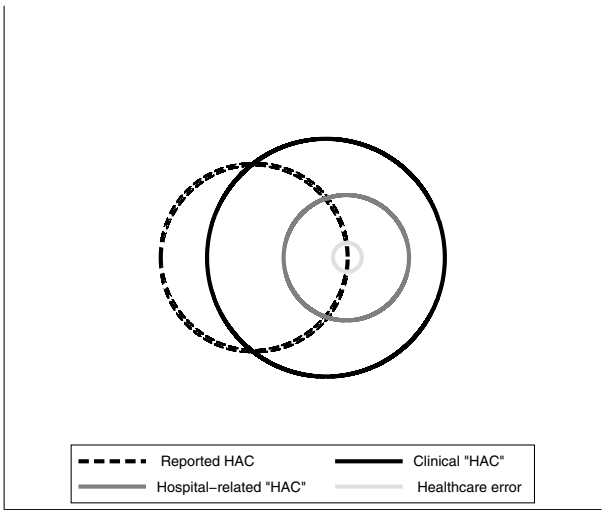

Figure 2 Venn diagram of relationship between reported (dashed black circle), clinical (solid black circle), and hospital-related (solid grey circle) "HAC" events; and healthcare errors (light-grey circle) within the study population (white square; n = 2,619); size of circles proportional to number of subjects and overlap represents degree of concordance.

Table 3 HAC prediction metrics (with 95% CI)

HAC subgroup	Total	Potentially preventable	Healthcare error
Prevalence†	16 (14–20)	3.9 (2.9–5.8)	0.05 (0.03–1.5)
Positive predictive value	0.74 (0.68–0.79)	0.18 (0.13–0.23)	0.03 (0.01–0.06)
Negative predictive value	0.90 (0.86–0.93)	0.98 (0.95–0.99)	0.90 (0.89–0.92)
Sensitivity	0.45 (0.37–0.52)	0.43 (0.29–0.58)	0.62 (0.20–0.89)
Specificity	0.97 (0.95–0.98)	0.92 (0.91–0.93)	0.90 (0.89–0.92)

†Prevalence per 100 separations estimated from positive and negative predictive values. Preventable = potentially preventable despite optimal care. CI, confidence interval; HAC, hospital-acquired complication.

Discussion

We reviewed 722 medical records from a single health service and estimate that 1 in 6 (multi-day stay) separations experienced a significant new adverse event during their hospital stay. Approximately 1 in 10 was coded with (one or more) HAC events, while gaps in clinical documentation may have led to under-reporting in 1 in 14 separations. No errors of HAC coding or classification[19] were identified. The estimated prevalence rates for each HAC class (Table S1) were similar to those reported elsewhere.[5–10]

These observations furnish several important insights. First, the HAC screening tool identifies a hospital cohort more likely to be associated with a serious adverse event, prolonged LOS, and increased costs[1,2,6,7,9,11] (Table 2). This cohort is likely to include healthcare errors; a subgroup that warrants further attention even if audit resources are limited. Surprisingly, the rate of healthcare errors was low, which is consistent with contemporary data derived from clinical audit.[21–23]

Second, reported HAC underestimated the true prevalence.[21,22] This is not unexpected since coding rules do not mandate reporting of all clinical events, and missing documentation precludes it. We estimated 1 in 14 separations was false negative for HAC events, and 1 in 4 reported HAC events as false-positive (Fig. 2).

Third, high rates of HAC events may not necessarily indicate a poor standard of healthcare, since the HAC definition[1–3,18] is agnostic to aetiology and captures complications arising from patient-related factors as well as hospital-related complications. Over 90% of reported HAC events lacked evidence of suboptimal care and carried strong circumstantial evidence of association with patient-related factors: comorbidities, illness severity or recognised treatment side-effects.

These results are at odds with the prevailing concept that HAC events are more likely in health services with lower standards than better-performing health services with lower rates.[1–3,5] This concept does not explain the high frequency of HAC events during optimal care, and in specialty services[5,19] (Supporting Information Tables S2,S3) and tertiary-referral hospitals[5,10,19,20,22] designed to improve outcomes and reduce adverse events.

Current evidence appears to indicate an alternative explanation. The majority of HAC events appear to be expected, albeit unwanted, complications arising in patients with complex disease requiring complex therapy, and the consequence of patient-related factors rather than suboptimal care. Under this model of healthcare, triage is guided by patient complexity and risk assessment, and management plans are tailored to detect and treat (and document) clinical deterioration[27] and optimise patient outcomes.

Correct classification of HAC events (Table 1) has immediate practical benefits. Mitigation of HAC arising from hospital-related factors or healthcare deficiencies requires education and training,[10] or the provision of additional staff and resources.[2,3] Mitigation of patient-related HAC events is unlikely to benefit from such interventions and more likely to respond to better risk assessment, attention to patient selection,[28] novel treatment pathways with less risks and fewer side-effects and timely response to clinical deterioration.

Fourth, we encourage each health service to investigate local HAC data.[10,18,19] Our findings may not apply everywhere. Our methodology is but one option (Supporting Information p8−12). Clinical review of as few as 30 HAC events should furnish insight. If our findings are confirmed, then it is unlikely that the current HAC methodology will distinguish hospital-related factors from patient-related factors, nor will the HAC programme identify better-performing health services, as intended.[1–5]

It should not be inferred from this report that the HAC programme has no clinical validity. Nor should we conclude that healthcare errors are insignificant and hospital standards cannot improve. We have demonstrated that the HAC methodology captures adverse events including healthcare errors. Moreover, HAC rates may furnish a comparative measure of patient complexity and disease burden. Even if most HAC events are expected it is important to know if and

when hospital-related complications exceed a minimum level.

Last, this investigation supports the need for clinical evaluation of clinical indicators by clinicians, prior to their adoption into clinical practice. This requires access to source data and methodology. Implementation of novel indicators without clinical validation may lead to costly outcomes for the communities they seek to serve.

Our methodology profited from access to detailed clinical information, engagement with senior clinicians and access to health information managers. However, our methodology was limited to an unblinded, retrospective, chart review of a small proportion of total healthcare records from a single centre over a brief period, by health professionals within the same health service. Any of these factors may have resulted in sampling error, or subjective bias, despite our power calculations.

In summary, we identified a higher than expected prevalence of adverse clinical events. The predictive value of the current HAC methodology for these adverse events was reasonable, but poor at identifying hospital-related or healthcare errors. Patient factors appear to be a more common cause of HAC events than the provision of care. HAC rates appear to be an indicator of hospital admission complexity rather than HAC, and may represent a measure of healthcare success rather than an indicator of healthcare deficiency.

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Supporting Information

Additional supporting information may be found in the online version of this article at the publisher's web-site:

Appendix S1: Supporting information.
Table S1 Frequency of observed HAC subclasses.
Table S2 Clinical ward associated with reported HAC events.
Table S3 Clinical specialty associated with reported HAC events.
Table S4 HAC Sensitivity and Specificity.
Table S5 Classification system used to categorise Hospital Associated Complications.