

Care Bundles for Acute Kidney Injury: Do They Work?

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Key Words

Acute renal failure · Acute renal injury · Quality assessment

Abstract

Acute kidney injury (AKI) is common and is associated with poor patient outcomes, which in some cases appear associated with deficiencies in the provision of care. Care bundles (CBs) are a structured set of practices designed to improve the processes of care delivery and ultimately patient outcomes, and there have been some demonstrations of their utility in areas such as ventilator-associated pneumonia and in sepsis management. While there is a strong rationale for their use, the evidence base around AKI CBs is small but growing. Here, we review the existing data on the effectiveness of AKI CB and discuss optimal approaches to their future study.

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Introduction

The scale of the challenge posed by acute kidney injury (AKI) is apparent from its high incidence and very poor patient outcomes. In the absence of specific pharmacotherapies to treat AKI, current international guidelines including those from the National Institute for Health and Care Excellence [1] suggest that management is based around supportive care: correction and avoidance of hypovolaemia; prompt treatment of sepsis and shock; avoidance of medications that may cause or worsen AKI; appropriate investigation to determine aetiology; and prompt referral of patients with a need of specialist input. However, despite this approach being supported by expert opinion and in line with current best practice, a number of studies encompassing a variety of healthcare systems have demonstrated that this does not reliably happen in routine clinical care [2–7]. In particular, the 2009 UK National Confidential Enquiry into Patient Outcome and Death report described poor standards of care in more than half of the 976 cases of AKI that were reviewed (defined as a standard of care below that the expert advisors would expect from themselves, their trainees and

their institution) [2]. These findings continue to be replicated in more recent studies [7, 8] and are implicated in worse outcomes reported in patients who sustain AKI at weekends [3]. It is therefore easy to understand the interest in care bundles (CBs) to address these variable standards of care delivery. One of the attractions of a CB is that it can encompass the wider multi-disciplinary team as opposed to exclusively focussing on physicians, and anecdotally we have found this to be a significant enabler to CB usage. The principles that underpin CB usage in AKI have been summarised in a recent review article [9], so here we undertake a more focussed review of recent evidence around their effectiveness.

What Is a CB and How Should We Evaluate Effectiveness?

A CB is defined as ‘a structured method of improving processes of care and patient outcomes; a small, straightforward set of evidence-based practices, treatments and/or interventions for a defined patient segment or population and care setting that, when implemented collectively, significantly improves the reliability of care and patient outcomes beyond that expected when implemented individually’ [10].

There are obvious differences in focus, scope and purpose between a CB designed in this way and clinical guidelines, which aim to provide comprehensive management advice over the entire patient pathway (although it is not uncommon to see CBs that more resemble guidelines). Compliance is measured with an ‘all or none’ approach; partial completion of a CBs counts as ‘none’ [9]. It is also apparent that a CB is not a single intervention but rather a number of independent elements (usually between 3 and 6) that are delivered together as a complex intervention. A CB is therefore not analogous to a treatment administered directly to the patient, but aims to change clinician behaviours with the ultimate aim of improving delivery of patient care. These factors therefore raise the question as to how best to study the effectiveness of CBs.

In reality, the success of a CB depends on the combined effects of the design and content of the bundle, the context in which it is being used, and the application/uptake of the bundle in the chosen clinical arena [11]. Simply producing a CB is unlikely to effect change and it may also be that bundles need to be tailored for different locations. Traditional experimental study design that answers a specific question (e.g. a randomised controlled trial with

fixed protocols to address whether an intervention works or not) is less suited to investigating and understanding complex social interventions [11]. This is highly relevant when considering that a CB is not a therapy that is directly administered to a patient, but it is rather a tool to change delivery of care. In addition, the considerable heterogeneity that exists within the syndrome of AKI needs to be accounted for (e.g. effect of differing underlying aetiologies, how AKI differs across various clinical situations and patient phenotypes) as does the variation that may arise during the process of CB development and implementation. Therefore, to assess whether a CB is effective, data are required on a number of different levels: acceptability and usage, measuring effect on process of care, determining which elements work and in which settings, impact on patient outcomes and sustainability. Data capture also needs to account for the iterative nature of the process, moving from an early innovation or development stage, through initial testing and refinement, application across different contexts and finally scaling up and spreading [12]. In summary, quality-improvement methodologies may be required to support optimal CB adoption, but additionally a quality improvement approach to their evaluation may be best placed to capture the complexity, the heterogeneity and context-sensitive nature of the intervention, alongside the assessment of effect [11, 12].

Review of Current Evidence

The published literature concerning AKI CB is small and currently originates from the United Kingdom; there are 5 studies that describe the introduction of AKI CBs, all of which include complete descriptions of the content of the bundle used. While bundle content is broadly similar and aligned to current guidelines, there is some variation in the number of elements (between 5 and 11) and the detail of specified actions. Implementation in all studies was accompanied with some degree of education and publicity; 3 report effect on process of care and 2 report patient outcomes. Details of these studies are included in table 1.

The first report of an AKI CB was by Forde et al. [13], who introduced a 5-step ‘checklist’ into a 30-bedded surgical ward. Introduction was supported by a number of quality-improvement methodologies, including a 4-week teaching programme, formative learning in response to feedback and the use of run-charts to measure uptake. A time-series analysis was performed, comparing a baseline

Table 1. A summary of the published studies examining effect of AKI CBs

Study	Setting	Study size, duration and design	CB content	Implementation approach	Outcomes
Forde et al. [13], 2012	30 bed surgical ward, followed by roll-out to surgical wards and MAU	Initial 6 weeks implementation followed by 2 × 2-month roll-out periods. Before and after implementation comparison. Sample size not reported	5 elements: medication review; manage hypotension; fluid balance; urinalysis; exclude obstruction	Education across the MDT, adapting approach to feedback, measurement of CB usage	In the post-implementation phase, 100% AKI recognition, 80% CB completion in 67% of AKI cases. No process measures or patient outcomes were reported.
Tsui et al. [14], 2014	MAU	100 patients, before and after implementation comparison (6 weeks and four week periods respectively)	11 elements: record baseline creatinine, assess fluid status, urinalysis, medication review (2 elements); urine protein-creatinine ratio; monitor urine output; renal US; 3 referral elements	Education to junior doctors and at divisional meetings. Advertising posters in MAU	Improvements in the following: documentation of baseline creatinine (52.7–83%, $p < 0.001$), assessment of fluid status (58.2–81%, $p < 0.001$), urinalysis (41.8–92%, $p < 0.001$), nephrotoxic drugs stopped (18.5–85.7%, $p < 0.001$), renal dose adjustment (18.5–83.3%, $p < 0.001$), fluid balance monitoring (10.9–67.9%, $p < 0.001$), urinary protein: creatinine ratio (0–62%, $p < 0.001$), and renal US (7.27–75%, $p < 0.001$). Possible reductions in HDU utilisation and RRT in ICU but event rates in this sample size were small
Joslin et al. [15], 2015	Hospital wide	192 patients, before (2011) and after (2013) comparison, data collection periods were 7 days	8 elements: patient assessment; fluid therapy; manage hyperkalaemia; urinalysis; medication review; repeat serum creatinine; renal US; fluid balance charting	Hospital-wide publicity campaign; AKI audit results presented at educational and induction meetings	Between 2011 and 2013, there were significant improvements in: AKI recognition (59 vs. 75%, $p < 0.001$); assessment of fluid status (37 vs. 65%, $p < 0.001$); completion of fluid balance chart (32 vs. 45%, $p = 0.002$); discontinuation of nephrotoxic medications (27 vs. 61%, $p < 0.001$); AKI inclusion in discharge summary (38 vs. 55%, p value not presented). No significant improvement in 3 other measures was observed. Mortality rates were between 12 and 10% pre- and post-CB.
Kolhe et al. [17], 2015	Hospital wide	2,297 patients; 306 had CB completion within 24 h of AKI. Retrospective observational study	6 elements: fluid assessment; urinalysis; diagnose cause of AKI; order investigations; initiate treatment; referral	CB linked to electronic alert. Education to junior doctors and at divisional meetings. Advertising posters in wards	Lower mortality with CB completion (18 vs. 23.1%, $p = 0.046$), lower progression to higher AKI stages (3.9 vs. 8.1%, $p = 0.01$). Differences maintained in logistic regression analysis. Process measures not collected, although data on proportions of patients who received individual elements of CB are presented
Kolhe [18], 2016	Hospital wide	3,518 patients; analysis of 939 with CB and 1,823 without. Retrospective propensity score case-control analysis	As above	As above	Mortality lower (20.4 vs. 24.4%, $p = 0.017$) and AKI progression lower (4.2 vs. 6.7%, $p = 0.02$) in those with CB completion. Differences maintained in logistic regression analysis. Process measures not collected

CB = Care bundle; HDU = high dependency unit; ICU = intensive care unit; MAU = medical admissions unit; MDT = multi-disciplinary team; RRT = renal replacement therapy; US = ultrasound.

audit of all cases of AKI as per KDIGO criteria from a 1-week period ($n = 50$) with a second cohort post-implementation. Improvements were seen in AKI recognition (31 vs. 100%) and CB completion (80% completion increasing from 20 to 67%). Spread to other areas within the hospital was described, but patient outcomes were not measured. In a similar study, Tsui et al. [14] introduced an 11-element CB into a London hospital's medical assessment unit, supported by education and publicity. Again, a before–after audit was performed for each of 50 sequential AKI cases. Processes of care were reported to improve, with improvements in AKI recognition, assessment of fluid status, appropriate investigation and cessation of medications contributing to AKI, the latter increasing from 18.5 to 85.7% ($p < 0.001$). Notably, there was a clear difference between patients who did and did not have a CB completed, with significantly higher standards of care in those who did. In a third study, also of similar design, Joslin et al. [15] described a hospital-wide approach to CB introduction, especially because AKI occurs across all acute medical and surgical specialties [16]. Following a baseline audit in all AKI patients over a 1-week period in 2011 ($n = 100$), a CB was developed and made available via the electronic medical record (EMR); implementation was supported by an improvement team, media launch and an education programme. A repeat audit in 92 patients using identical methods was performed in 2013. There were some differences between the 2 cohorts, with higher stages of AKI and more risk factors (that may imply greater co-morbidity) in the post-implementation cohort. The authors reported improvements in the delivery of AKI care in half of the 10 metrics assessed; these included AKI recognition (increasing from 59 to 79%), assessment of fluid status, completion of fluid balance chart and discontinuation of nephrotoxic medications. A number of these improvements were achieved within the first 24 h after AKI recognition. Although process measures were reported, it was not clear what proportion of patients had the CB completed, which makes assessment of direct effects difficult. Taken together, these results suggest that CBs can potentially improve process of care, although there are some obvious weaknesses in these studies' design: these include the single-centre uncontrolled nature of the comparison groups, the before–after design (which cannot control for independent temporal changes) and the limited scope of data collection that prevents any conclusion about effect on patient outcomes. However, feasibility and sustainability, the latter up to 12 months in the study of Joslin et al. [15], are demonstrated.

We have also reported our experience with a hospital-wide CB, although with a slightly different approach [17]. After developing a CB within the EMR, we studied uptake and impact before and after the introduction of an interruptive alert, which directed clinicians towards CB completion at onset of AKI. Again, launch of the CB and the alert was supported by education and publicity. In the baseline period (6 months), there were 1,209 episodes of AKI and 1,291 in the 5-month post-implementation period. Prior to the alert, CB completion within the first 24 h of AKI was very low (2.2%) but increased tenfold afterwards to 21.6% in the post-interruptive period (a further 10.2% of patients had CB completed after 24 h). Significantly, in-hospital mortality was lower in patients who had the CB completed within 24 h (18 vs. 23.1%, $p = 0.046$) and progression to higher AKI stages was lower. These associations were preserved on multivariable analysis and persisted despite a higher proportion of emergency admissions and higher AKI stages in the early completion group. However, there were some weaknesses with this initial study, in particular, the possibility of residual confounding; so to address these, we have recently performed a second analysis using propensity score matching [18].

Considering a larger number of patients (3,717 AKI episodes from 3,518 patients over an 18-month period, CB completion rate 25.6%), we matched 939 AKI events in whom the CB had been completed within 24 h to 1,823 events when it was not. One-to-many matching was based on propensity score using logistic regression. CB completion maintained its strong association with improved survival and lower risk of AKI progression (unadjusted in-hospital mortality was 20.4 vs. 24.4%, $p = 0.017$) and this was maintained on logistic regression and sensitivity analyses. While these results are also from a single-centre and unmeasured confounders cannot be completely excluded; they are the first to suggest that CBs can have an impact on patient outcomes which is of greater potential significance in the absence of other current proven interventions for AKI.

Conclusions

There is a strong rationale behind CB usage in AKI. Currently available data support the premise that they can improve both process of care and patient outcomes, but the limited nature of the evidence base at present precludes definite conclusions. As we move forward to address these evidence gaps, it is critical that study design

takes account of the complex nature of CB development, tailoring to context and implementation. The case that traditional study design may not be suited this type of evaluation is increasingly made [11, 12]; a more evolved approach may be to move away from asking 'do CBs work, yes or no?' to which the answer is likely to be 'yes, at least sometimes' and attempt to answer the more important question of 'how, and in what contexts, can AKI

CBs be adapted to work?' [12]. By doing so, we can aim to take AKI CBs forward in a way that maximises the chances of building successfully on current promises.

Disclosure Statement

The authors have no conflicts of interest to declare.

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