A Multicentre, Stepped-Wedge Cluster Randomised Trial of a Complex Intervention to Reduce Harm Associated with Acute Kidney Injury


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Introduction
Acute kidney injury (AKI) is common and associated with poor outcomes. AKI management requires methodological delivery of basic elements of care but variations in standards of AKI care are commonplace. It has been suggested that strategies to address these gaps in care may translate into improved patient outcomes. We sought to test this hypothesis by evaluating the effectiveness, at the hospital level, of a package of measures to reduce harm associated with AKI.

Methods

- **Study design:** Multi-centre, pragmatic, stepped-wedge cluster randomised trial (SWCRT), summarised in figure 1.
- **Study setting:** Five UK hospitals, including teaching and non-teaching centres. Differences between centres included size (range 593 to 2061 beds), number of emergency admissions (23k to 83k per annum); and pre-existing quality improvement infrastructure.
- **Intervention:** AKI alerts, a care bundle and an educational program, introduced sequentially at an organisation-level across fixed three month periods until all hospitals were exposed to the intervention.
- **Randonmisation:** Hospitals were randomly allocated to the order in which they introduced the intervention.
- **Patients:** All patients with AKI aged ≥18 years hospitalised for ≥3 days. Chronic dialysis was the only exclusion criterion.
- **Data collection:** In 3 month periods, with a minimum of two pre-exposure (control), one transition and at least one post-implementation (intervention) periods per site. AKI episodes were identified as per a modified KDIGO definition using the NHS England AKI detection algorithm. Patient demographics, comorbidity and outcome data were collected from hospital episode statistics. A nested evaluation of the effect on processes of care was by case-note audit.
- **Outcome measures:** The primary outcome was 30-day mortality associated with AKI. Secondary endpoints included AKI incidence, AKI progression, hospital length of stay (LoS) and effects of the intervention on process of care.
- **Sample size:** With a trial duration of two years, 10,850 AKI episodes would be required to detect a decrease in mortality from 16% to 12.8% with 80% power

Results

24,059 AKI episodes were studied (incidence 7.6 cases/100 admissions) in 20,719 patients. Details patient control and intervention periods are shown in table 1

![Figure 1](https://example.com/figure1.png)

**Table 1. Characteristics of patients in control and intervention periods.** Note that hospitals contributed different proportions of patients to control/intervention periods due to SWCRT design, so any site and outcomes analyses were fully adjusted for patient characteristics, time, centre and necassity.

**Primary outcome**

Overall 30d mortality was 24.5%, with no difference between control and intervention periods (OR 1.07, 95% CI 0.93-1.24).

**Secondary outcomes**

Hospital length of stay (LoS) was reduced in the intervention period. Results from quantile regression analysis are shown in figure 2A.

Conclusions

A complex, hospital-wide intervention to reduce harm associated with AKI resulted in improved AKI detection, shorter duration of AKI and a modest reduction in LoS, but did not alter 30-day AKI mortality.

- **Duration of the intervention on LoS:** The quantile regression showed that the effect was seen in 80-90th percentiles i.e. those patients with a longer AKI duration (>5 days). These results are shown in figure 2B.
- **The incidence of AKI increased in the intervention period:** (crude incidence 7.3/100 admissions vs 8.0/100 admissions). After adjustment for age, gender, time, season and centre the rate of AKI was 11.6% higher in the intervention period (p<0.001). There was also an increase of 32% in the proportion of patients with a censored diagnosis of AKI (n=17x) during the intervention period (p<0.001).
- **There was no difference in the rate of AKI progression between control and intervention periods after adjustment for age, gender, comorbidity and time (OR 0.97, 95% CI 0.83 to 1.14).
- **Process measures were assessed:** In 1042 patients. In the intervention period, improvements were seen in several metrics including AKI recognition, medication optimization, fluid assessment and urinalysis; care bundle usage was 40% with variation between centres (range 15-68%). These data are shown in figure 3.

![Figure 2](https://example.com/figure2.png)

**Figure 2.** Comparison of process of care elements control and intervention periods. For each audit measure, results are compared using Chi-squared analysis. Confirmed participation for reasons other than relief of obstruction was included in a balancing measure to survey uncomfortable complications.

**Figure 3.** Differences in length of stay during the intervention. Results show significant reduction in AKI duration at 68% percentile with an effect size of 0.7 days (95% CI 1.2 to 0.1), and a trend to reduction in LoS at higher percentiles.

**Figure 4.** Quantile regression analysis of AKI duration. Results show significiant reduction in AKI duration at 68% percentile with an effect size of 0.7 days (95% CI 1.2 to 0.1) and a trend to reduction in LoS at higher percentiles.