Supplementary material

PILOT STUDY

The pilot was a single-ward retrospective interrupted time series study to explore the effect of the policy intervention on the monthly proportion of inappropriately omitted medication.

Study design, setting and time period

This pilot study collected all medication data of all available eligible patients at a single surgical ward at Austin Health, a tertiary-referral hospital in Melbourne, Australia during 8-months pre-intervention (June 2011 to January 2012) and 8-months post-intervention (May 2013 to December 2013). The intervention period spanned February 2012 through to April 2013. Data extraction, medical record review and allocation of appropriateness took place between December 2013 and February 2014.

The hospital's Human Research and Ethics Committee approved the study (H2011/04470).

Intervention

The intervention centred around a draft version of the Medications and Oral Restrictions policy and included bedside signs, education sessions, opinion leaders and clinical champions. The implementation strategies and processes employed are detailed in Table 1, below:

Table 1. Implementation strategies and processes for draft policy pilot

Strategies	Tool used	Description
Decision support	Bedside signs	Traffic light colour-coded with: • Green *Fasting* – give all oral medications. • Red *Nil by mouth* – do not give anything orally. Seek alternative route. • Amber Restricted oral intake – check orders/clinical notes before giving.
	Badge cards	Includes logo with project message and table of medications to consider withholding.
	Flow chart	Flowchart guiding decisions for each of the 3 medication scenarios – *fasting*, *nil by mouth* and restricted oral intake.
Education/ Information provision	Education sessions	Brief discussion at handovers two times per day on week of rollout. New policy emailed to ward staff and made available on ward.
Audit/feedback		Audit of 60 consecutive orthopaedic surgery (elective and non-elective) patients over a month. Fed back to Nurse Unit Manager and Clinical Nurse Educator. Independent of the project team, the Nurse Unit Manager and Nurse Educator followed through with ward rounds with a focus on medication administration in *fasting/nil by mouth* patients.

Opinion leaders	Medical Director of Orthopaedics, Nurse Unit Manager, Nurse Educator, Associate Nurse Unit Manager.
Focus group	Focus group held with senior nurses from study ward to discuss the practicalities of policy and tools.
Clinical champions	Six senior nurses from the target ward were selected by the Nurse Unit Manager and detailed to carry out the changes on the floor.
Electronic prescribing	• Independent of the project. Hospital-wide changeover to electronic prescribing occurred during the project timeframe. The study ward changed over end of November 2012 • Instigated by the project. *Fasting* and 'pre/post procedure' as standard acceptable reasons for not giving medications removed from the electronic prescribing menu.

Data sources and measurements

Patients were retrospectively identified from the hospital admissions list. Consecutive, non-elective orthopaedic surgery patients admitted to the orthopaedic ward who were on the ward for at least eight hours prior to their surgery and who were prescribed at least one regular medication were included. 'At least eight hours' was stipulated to ensure adequate time for regular medications to be charted. Approximately 20 patients met these inclusion criteria each month; therefore consecutive patients were included rather than a randomly selected sample. The orthopaedic unit/ward was selected because patients on orthopaedic/spinal units have been reported to be at increased risk of medication errors compared to other units.[1,2] Patients who did not have regular medications prescribed were excluded.

The time interval for whether a medication dose was withheld or given was assessed from when the patient commenced their fasting for theatre to the time the patient left the ward to go to surgery. The medication record was manually checked to determine whether doses were administered or withheld. For doses that were not given, the reason (if any) was determined from the medication record (paper based pre- and electronic post-implementation) or the patient's clinical notes. Valid reasons for a nurse omitting a medication dose included 'as per doctor' or 'low blood pressure'. Inappropriate comments to explain why doses were omitted were fasting (unless it related to oral hypoglycaemics), nil by mouth, withhold, clinically inappropriate, 'going to theatre', OT, OR, 'theatre today' or any other variants if there was not another appropriate or apparent clinical reason (e.g. omission of oral hypoglycaemics were considered appropriate, even if there were no documentation for why they were withheld). 'Blanks', where the administration box for a dose of a medication was left empty/unaccounted, were considered inappropriate unless a valid clinical reason was documented elsewhere or on

a previous entry. Question marks, dashes, and any other unrecognisable marks were considered blanks. One of the investigators (TT) assessed the doses for appropriateness. Doses that were assessed as inappropriate were then checked by another investigator (DS). Any disagreement was resolved by consensus between the two investigators.

The primary endpoint was proportion of medications that were omitted inappropriately (as a proportion of all medications to be administered over the preoperative fasting period).

Statistical methods

In order to minimise bias due to variations in patient activity and junior medical and nursing staff experience, consecutive patients were included. This resulted in a total of about 20 eligible patients per month. With an average of five regular medications per patient this led to a total of about 800 medications in the pre- and post-intervention period or an average of 100 medications at each month.

A segmented linear regression model was used to assess the effect of the quality improvement intervention on the monthly proportion of inappropriately omitted medication. The regression was based on two periods of 8 consecutive months each with linear segments defined as the pre-intervention time period and the post-intervention time period. The intervention time period was not chosen as a third segment as the intervention was introduced gradually over time. The following underlying assumptions were checked: independence of residuals via a plot of the residuals over time and testing first-order autocorrelation using the generalised Durbin-Watson statistic, normality assumption of residuals via a QQ-plot of the residuals, and homogeneity of variance via a plot of the residuals versus predicted values. The latter plot was also used to examine the linearity assumption. No seasonal autocorrelation was investigated for this pilot study because less than 12 consecutive monthly data points were available in each segment. Likewise non-stationarity was not assessed due to the limited number of time points in this pilot study. The change in level and change in trend after the intervention were obtained to estimate the intervention effect. A two-sided 5% level of significance was used. Statistical analyses were performed using SAS (version 9.4, SAS Institute, Cary, NC) for Windows.

Results

There were 748 pre- and 817 post-intervention medication records. A total of 260 (35%) medications were withheld inappropriately pre- and 73 (9%) post-intervention.

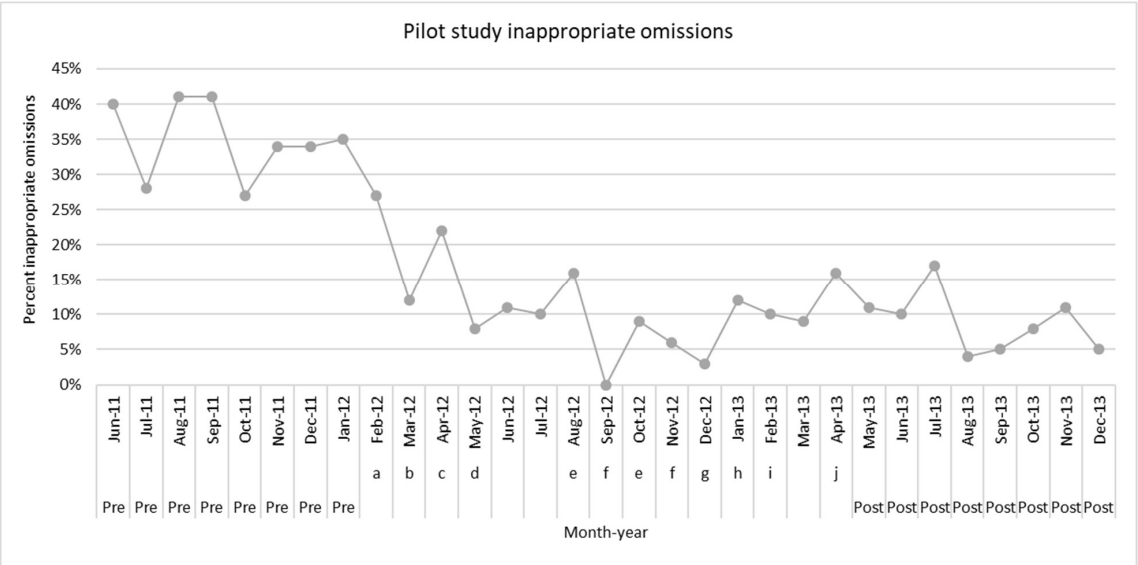
The mean patient age was 69 years, with no differences across the study periods. There were more females (59%) to males (41%); however, there were no differences in the proportion seen across the study periods.

There were no differences in the number of medication doses charted per patient throughout the three study periods. The mean (standard deviation) number of medication doses omitted inappropriately per patient decreased from 2(2) pre-intervention to 1(2) during implementation and 1(2) post-intervention.

Examination of time series

The proportion of medications doses omitted by month are shown in Figure 1, including those during the intervention period. Visual inspection suggests a trend over time whereby the monthly proportion of inappropriately omitted doses decreased from start of the pre-intervention period until the implementation period.

Figure 1. Percentage of medications omitted inappropriate preoperatively



Legend

a Consultation with Nurse Unit Manager and Associate Nurse Unit Manager
b Hospital-wide Medication Administration Survey. Results discussed elsewhere.[3]
c Focus group to discuss the appropriateness and format of the project tools (e.g. bedside signs, badge cards etc)

d Rollout on ward
e Audit/feedback
f Nurse Unit Manager/Clinical Nurse Educator rounds (which occurred independent of the investigators following audit/feedback)
g Electronic prescribing commenced
h Removal of fasting as a reason for not giving medications from electronic prescribing catalogue
i Removal of 'pre/post procedure' as a reason for not giving medications from the electronic prescribing catalogue
j Refresher campaign (posters/signs, quizzes, Clinical Nurse Educator questions)

Inappropriate omissions

The policy intervention was associated with an intervention effect in the monthly proportion of medication doses omitted inappropriately from pre- to post-intervention. The results indicate that an estimated 36.1% (95% CI [25.1, 47.1]) of medication doses per month were omitted inappropriately at the start of the study period. Immediately after the end of the implementation period, the monthly proportion of doses omitted inappropriately decreased by 21.7% (95% CI [10.0, 33.5], P-value = 0.002). Refer to Table 2.

Table 2. Segmented linear regression analysis of monthly proportion of inappropriately omitted medications with inappropriately omitted medication

	Medications omitted inappropriately	
	Coefficient [95% CI] (%)	P-value
Baseline level *	36.1 [25.1, 47.1]	<0.001
Baseline trend **	-0.4 [-2.7, 1.8]	0.70
Level change ***	-21.7 [-33.5, -10.0]	0.002
Trend change ****	-0.4 [-2.9, 2.1]	0.73

CI = Confidence Interval
* Baseline level: monthly proportion at the start of the pre-intervention period
** Baseline trend: change in the monthly proportion during the pre-intervention period
*** Level change: change in the monthly proportion at the start of the post-intervention period
**** Trend change: change in the monthly proportion in the post-intervention period compared to the baseline trend
Visual inspection of the residual plot did not suggest serious violations of the underlying model assumptions. In addition, there was no evidence of auto-correlation (Durbin-Watson statistic: 2.5 with P-value >0.05).

REFERENCES

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3. To TP, Story DA, Booth J, Nielsen F, Heland M, Hardidge A. Oral medication administration in patients with restrictions on oral intake - a snapshot survey. *JPPR.* 2013;43:177-181.