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Impact of a policy to improve the management of oral medications when patients are fasting before a procedure: an interrupted time series analysis

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ABSTRACT

Background Managing medications inappropriately when patients have oral intake restrictions can cause patient harm. This study evaluated the impact of a medication policy separating fasting from nil by mouth with respect to giving oral medications in patients fasting before a diagnostic or interventional procedure.

Methods The policy stipulated that 'fasting' means oral medications should be given with a sip of water up to 1 hour before a procedure, unless there is a clinical reason to withhold, while 'nil by mouth' means nothing to be given orally, including medications.

The policy was implemented in Surgical areas in February 2015 and Medical areas in March 2015 at a tertiary referral hospital in Melbourne, Australia, and included bedside signs, clinical champions and education sessions.

The study was conducted in 2020. Admission and medication records were matched for non-elective procedure patients from January 2014 to May 2016. The monthly proportion of doses omitted inappropriately and overall omissions pre/post-policy implementation were compared using segmented regression.

Results Pre-implementation, the proportion of doses withheld inappropriately and total omissions in medical areas were 18.1% and 28.0%, respectively. Post-implementation, an absolute reduction of 13.4% (95% CI 9.0% to 17.7%) and 11.1% (95% CI 2.6% to 19.6%), respectively, was seen. Post-implementation linear trend showed a 0.3% (95% CI 0.0% to 0.6%) increase in inappropriate omissions but not overall omissions.

In Surgical areas, pre-implementation proportions for inappropriate and overall omissions were lower than Medical areas'. Post-implementation, there was an absolute decrease in doses withheld inappropriately (8.3%, 95% CI 0.8% to 15.7%, from 11.9% pre-implementation) but not total omissions.

Conclusions Distinguishing fasting from nil by mouth appeared to provide clarity for some staff: a reduction in inappropriate omissions was seen post-implementation. Although the small increase in post-implementation linear trend for inappropriate omissions in Medical areas suggests sustainability issues, total omissions were sustained. The policy's concepts require verification beyond our institution.

WHAT IS ALREADY KNOWN ON THIS TOPIC?

⇒ Uncertainty about what fasting and/or nil by mouth means for giving oral medications may cause inappropriate medication management.

WHAT THIS STUDY ADDS?

⇒ This study suggests that a policy separating the terms fasting from nil by mouth in the context of oral medication administration instructions appeared to provide clarity for staff and resulted in a reduction in medication omissions in patients fasting before a procedure.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY?

⇒ Practice and policy to improve medication management in patients fasting before a procedure should consider separating fasting from nil by mouth in terms of oral medication administration instructions.

INTRODUCTION

Many patients presenting for a diagnostic or interventional procedure take long-term oral medications. Studies show up to half of these medications are omitted inappropriately during the perioperative period, which can place patients at risk of undesirable complications.[1–7]

To improve pre-procedural medication management, organisations have advocated continuation of oral medications unless advised to the contrary,[8 9] and evidence-based guidelines recommending which medications to continue or withhold have been produced.[10 11] Other strategies such as targeted education of nursing staff about perioperative medication guidelines and pharmacist intervention have also been instigated.[12–14] However, alongside lingering concerns about risk of anaesthesia-associated aspiration of gastric contents, it is possible that medications are withheld inappropriately because of uncertainty regarding what

the expression nil by mouth and/or fasting means with respect to giving oral medications.[1 2 13 15–17] The use of nil by mouth (or fasting) to confer different meanings in different contexts is problematic; for example, signifying absolutely nothing is allowed orally in one setting but that sips of water and/or oral medications are exempt in another. The potential for confusion makes this practice unsafe, such as when a nil by mouth, unsafe-to-swallow patient who had a stroke is given oral medications and a patient attending surgery has all their long-term oral medications withheld because of 'nil by mouth' (or fasting) status. Several local medication and oral restriction-related patient incidents that resulted in adverse patient outcomes, including the fasting/nil by mouth scenarios mentioned, compelled the development of the Medications and Oral Restrictions Policy (the Policy) at our institution. The Policy separated and clarified terminology around oral intake restrictions and medication administration, particularly 'fasting' and 'nil by mouth'.

The purpose of this study was to evaluate the Policy's impact on medication doses omitted inappropriately and overall doses omitted in patients fasting before a procedure in Medical and Surgical Clinical Service Units of the hospital.

METHODS

Study design, setting and time period

This retrospective interrupted time series (ITS) study was conducted at a tertiary referral hospital in Melbourne, Australia, with over 900 beds. Data, medical record review and allocation of appropriateness took place between November 2019 and April 2020, using information recorded between January 2014 and May 2016.

Patients in the Medical Clinical Service Unit (Medical areas) and Surgical Clinical Service Unit (Surgical areas) were targeted, as these areas were most likely to be impacted by the Policy. Medical areas consisted of acute medical wards, with specialties such as renal, respiratory and infectious diseases. In addition to a surgical focus, Surgical areas also had cardiology and gastroenterology patients. There were five wards in Medical and three in Surgical areas. A fourth surgical ward was excluded because it piloted the Policy (in 2012).

The Standards for Quality Improvement Reporting Excellence[18] guidelines and 'Methodological and reporting recommendations for interrupted time series studies'[19] were used to guide reporting of this study.

Intervention

The Policy endorses three categories for giving medications in the context of oral restrictions and is supported by traffic light colour-coded tools, including bedside signs:

- Fasting (green) means give oral medications with a small sip of water, up to 1 hour before a procedure unless advised/there is a clinical reason to withhold, such as risk of bleeding, low blood glucose or low blood pressure.
- Restricted oral intake (amber) means that oral intake is conditional, such as 'sips only' immediately post-surgery or when a patient with swallowing difficulties requires texture modifications to enable safe swallowing. Medical orders should be checked before administering.
- Nil by mouth (red) means do not give anything orally, including medications and sips of water—a different route of administration should be sought.

The Policy was implemented in Surgical and Medical areas in February and March 2015, respectively. The month-long rollout included bedside signs that display the categories at the point of care, a badge card attachment with a table of medications to consider withholding, opinion leaders, clinical champions, six interactive education sessions per area and emails explaining the Policy (see online supplemental file 1). The interactive education sessions targeted nursing staff; however, medical, pharmacy, speech pathology and other staff members such as patient services assistants were invited to attend. Emails were sent to all staff members, including food services and dietitians.

The project lead was a senior pharmacist. The project team included the head of orthopaedics, anaesthetist, nurse executive, clinical nurse educator, quality coordinator, medicines information pharmacist, and two consumer representatives who were involved in the development and pilot of the Policy.

Patient and public involvement

Two consumer representatives were involved in the development and pilot of the Policy. Patients were consulted about the Policy and bedside signs during the development phase. As this study involved retrospective record review, patients were not involved in the recruitment to and conduct of the study and were not involved in plans to disseminate the study results.

Data sources and measurements

Inpatient admissions and medication administration records—process measures—were used to study the outcome of the intervention. Process measures provide quantitative data and enable monitoring of changes over time on the influence or effectiveness of policies or systems, and are an accepted measure of medication practice.[20]

Inpatient admissions and medication administration records from the electronic prescribing platform (Cerner, Missouri, USA) were matched for episodes between January 2014 and May 2016 in which patients underwent non-elective procedures and their medication administration in the 12 hours before their procedure. Consequently, Surgical areas had 13 months of data pre-rollout and post-rollout month, and Medical areas had 14 months data pre-rollout and post-rollout month (see online supplemental files 2 and 3). The data were

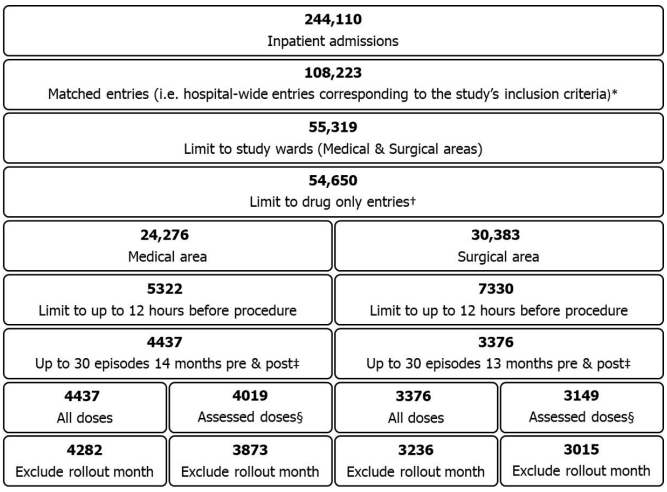

Figure 1 Data acquisition. *We were unable to access the total number of doses/Cerner entries covering the study period. †Some entries were reminders or drug level checks, for example, gentamicin level check, warfarin check. ‡Total entries (doses) when up to 30 episodes were randomly selected per month. Some months had less than 30 admission episodes to the area. §Some medications were excluded from assessment of appropriateness, for example, anticoagulants, antiplatelet agents, non-steroidal anti-inflammatory drugs, most laxative agents except lactulose for liver disease.

compiled in an Excel spreadsheet (Microsoft Corporation, Redmond, Washington, USA).

The primary outcome was proportion of doses omitted inappropriately. The secondary outcome was the proportion of total doses omitted.

Some medications involve a multiplicity of factors to determine whether they are appropriate in the pre-procedural period, which would be difficult to clarify retrospectively in a definitive and resource-efficient manner. As such, these medications were excluded from the study (figure 1). As needed ('prn'), medications were also excluded.

A codebook was developed a priori to facilitate a systematic approach to determining appropriateness of dose omissions: the assumption was that omissions were inappropriate unless an acceptable reason was documented. Valid reasons included: 'medication (or patient) not available'; 'duplicate task' or 'patient has IV (intravenous)'; low or high blood pressure, low blood sugar or other valid clinical reasons; 'as instructed by doctor'; and 'patient refused'.

Non-valid reasons for omissions found in the Cerner data download required a review of the patients' medical records. An omission was inappropriate if no further reason was documented or if the reason provided was deemed invalid, for example, 'patient for procedure' without further clarification.

Medical record review and determination of appropriateness were conducted by T-PT. This was piloted in 20 randomly selected patients before study commencement.

An inter-rater reliability analysis was performed to assess the degree to which the primary researcher (T-PT) and second rater (AL) consistently assigned medications omitted inappropriately after independently reviewing the patient's clinical notes. A 10% random sample of patient episodes from each area pre-implementation and post-implementation was selected. Cohen's kappa coefficient[21] and corresponding two-sided 95% CI were determined. A kappa of 0.6 or greater was recommended.[22] Eighty-one medication records from Medical areas and 45 from Surgical areas were reviewed by the second rater. The kappa coefficient was 0.83 (95% CI 0.71 to 0.96) and 0.85 (95% CI 0.68 to 1.00), respectively.

All doses requiring medical record review were subjected to resolving differences. Another researcher (AL) independently determined the appropriateness of the omissions. Differences were discussed with a third researcher (DS). Resolving differences was conducted for 1021 entries. The majority were resolved with immediate agreement between two researchers (Medical, 628/666, 94%; Surgical, 329/355, 93%). Some entries (25/666, 4%, Medical; 22/355, 6%, Surgical) required discussion with the third researcher.

Statistical methods

ITS analysis was employed because it is considered the most robust design to assess the effects of interventions in which randomisation and control groups are infeasible.[19]

Pilot study results (see online supplemental file 4) were used to conduct a sample size calculation. Segmented linear regression analysis showed a 21.7% (95% CI 10.0% to 33.5%) absolute decrease in the monthly proportion of doses omitted inappropriately post-implementation, with approximately 6% variability. A minimum of 12 time points (months) pre-implementation and 12 time points post-implementation, and 100 observations per time point[23] per area were needed to have at least 80% power to detect a level change of at least 12% (F-test of change in level regression parameter in a segmented linear regression, two-sided alpha=0.05). Calculations were preformed using SAS (V.9.4, SAS Institute) for Windows. Up to 30 patient episodes from the matched dataset were randomly selected per area per month using Excel (Microsoft Corporation, Redmond, Washington, USA) on the estimate that each episode generated approximately four medication records to aim for a sample size of 100 observations per month.

All available data were included in the analysis. Patient and medication characteristics were summarised using descriptive statistics. A segmented linear regression ITS model[24] was used to assess the Policy implementation effect. The regression was based on two periods of consecutive months, each with segments defined as pre-implementation and post-implementation. The implementation month was excluded. The following underlying assumptions were examined: linearity assumption by exploring alternative shapes using fractional polynomials, autocorrelation including the Cumby-Huizinga test along

Table 1 Demographic characteristics

	Medical areas			Surgical areas		
	Pre-implementation	Post-implementation	Total	Pre-implementation	Post-implementation	Total
Number of unique episodes*, n	394	353	747	376	373	749
Sex, n (%)						
Female	189 (48.0)	162 (45.9)	351 (47.0)	167 (44.4)	172 (46.1)	341 (45.3)
Male	205 (52.0)	191 (54.1)	396 (53.0)	209 (55.6)	201 (53.9)	410 (54.7)
Age (years)	73 (57–83)	73 (59–81)	73 (58–82)	60 (46–74)	59 (41–73)	59 (43–74)
Doses per episode†	4 (2–7)	5 (2–7)	4 (2–7)	3 (2–6)	3 (2–5)	3 (2–6)
Unique medications per episode†	4 (2–6)	4 (2–7)	4 (2–7)	2 (1–5)	3 (1–5)	3 (1–5)
Number of unique patients*, n	386	338	724	363	366	729
Sex, n (%)						
Female	184 (47.7)	157 (46.4)	341 (47.1)	167 (46.0)	170 (46.4)	334 (45.8)
Male	202 (52.3)	181 (53.6)	383 (52.9)	199 (54.8)	196 (53.6)	395 (54.2)
Age (years)	73 (57–83)	73 (59–81)	73 (57–82)	60 (45–74)	59 (41–74)	59 (43–74)
Doses per patient†	5 (2–7)	4 (2–7)	5 (2–7)	3 (2–6)	3 (2–5)	3 (2–6)
Unique medications per patient†	4 (2–7)	4 (2–7)	4 (2–7)	3 (1–5)	3 (1–5)	3 (1–5)
Unique episodes per patient	1 (1–1)	1 (1–1)	1 (1–1)	1 (1–1)	1 (1–1)	1 (1–1)
Number of months, n	14	14	28	13	13	26
Doses per month†	146 (132–154)	138 (121–142)	142 (123.5–148)	107 (95–131)	123 (101–131)	116 (99–131)
Unique medications per month†	63 (60–65)	63 (54–66)	63 (59–66)	53 (49–57)	53 (51–58)	53 (50–58)
Episodes per month	28 (28–29)	25 (23–28)	28 (25–29)	29 (28–29)	29 (28–29)	29 (28–29)
Patients per month	28 (28–29)	25 (23–28)	28 (25–29)	29 (28–29)	29 (28–29)	29 (28–29)

Statistics are median and IQR (25th–75th) percentile unless stated otherwise.
Data are based on up to 30 episodes (with a non-elective procedure) randomly selected per area per month.
*Some patients had more than one admission, hence there were more episodes than number of patients.
†Captured in the 12-hour pre-procedural time frame.

with the Durban-Watson statistic, non-stationary using the Dickey Fuller test, cyclic patterns/seasonality and outliers. If linearity was considered violated, an appropriate power transformation was determined and this non-linear term was added to the model. An autoregressive error term was incorporated if autocorrection was considered present. The absolute change in level and absolute change in trend after the implementation (linear model only) were obtained to estimate the implementation effect, along with Newey-West SEs. Additionally, the post-implementation linear trend over time was estimated. No covariates were included in the models. Statistical analyses were performed using Stata (StataCorp 2019. Stata Statistical Software: Release 15.1. College Station, Texas, USA: StataCorp) for Windows.

RESULTS

There were 3873 (2026 pre, 1847 post) and 3015 (1470 pre, 1545 post) medication records/doses for Medical and Surgical areas, respectively (figure 1). Medical areas had less admissions post-implementation and the median dose per episode was higher. The majority of the Surgical areas' demographics were similar pre-implementation and post-implementation (table 1).

In Medical areas, 446 (22%) doses required medical record review pre-implementation compared with 208 (11.3%) post-implementation. This figure was 198 (13.5%) and 144 (9.3%), respectively, for Surgical areas. Overall, 358 (17.7%) doses were withheld inappropriately pre-implementation and 105 (5.7%) post-implementation for Medical areas compared with 152 (10.3%) doses pre-implementation and 94 (6.1%) post-implementation for Surgical areas (monthly data are shown in online supplemental files 1 and 2).

The medication most prescribed and most likely to be withheld inappropriately was paracetamol. Other omitted medications included pantoprazole, furosemide, thyroxine (levothyroxine sodium), 'statins' (eg, atorvastatin), dexamethasone and anti-infective agents such as amoxycillin–clavulanate, doxycycline and metronidazole.

Examination of time series

The proportion of doses omitted by month is shown in figure 2. This visual output supports the linearity assumption pre-implementation and post-implementation for Medical areas. The pre-implementation period of inappropriate omissions for Surgical areas suggested a quadratic trend (parabola) violating the linearity assumption of the segmented linear regression model. The data were

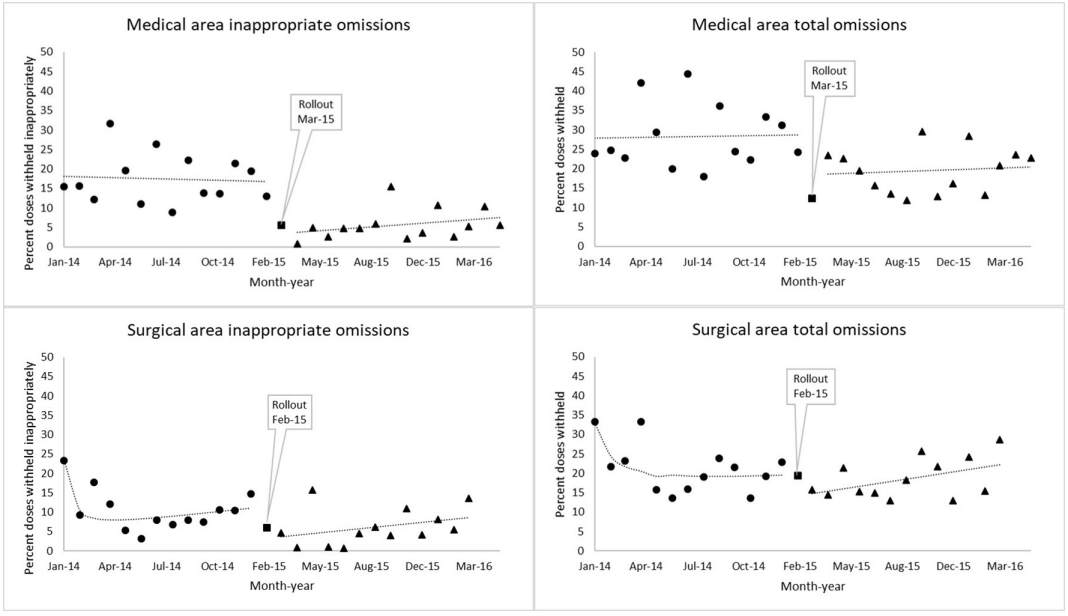

Figure 2 Time series of dose omissions. Legend: ● Pre-implementation, ■ Rollout month, ▲Post-implementation.

checked to rule out erroneous data. The visual output also suggested a pattern of 3–6 months per calendar year in Surgical areas pre-implementation and all areas post-implementation.

Inappropriate omissions

For Medical areas, the ITS of inappropriate omissions was assessed as stationary and incorporated an autocorrelation with lag 1, hereby assuming that adjacent months are correlated. There was a statistically significant absolute reduction in the proportion of doses withheld inappropriately post-implementation in Medical areas (13.4%, 95% CI 9.0% to 17.7%, p<0.001) from 18.1% pre-implementation (table 2). The post-implementation linear trend showed a monthly increase of 0.3% in the proportion of doses withheld inappropriately (95% CI 0.0% to 0.6%, p=0.03, table 3). No autocorrelation was assumed for Surgical areas. In Surgical areas, after accounting for the non-linear shape of the pre-implementation phase, a statistically significant absolute reduction in doses omitted inappropriately (8.3%, 95% CI 0.8% to 15.7%, p=0.03) was observed post-implementation from 11.9% pre-policy (table 2). The post-implementation trend was insignificant (0.5%, 95% CI −0.3% to 1.2%, table 3). The proportion of doses withheld inappropriately before implementation was lower than for Medical areas.

Total omissions

For total omissions, an autocorrelation with lag 1 was assumed for Medical areas and no autocorrelation for Surgical areas while both were assumed as stationary. In addition, in Surgical areas, similar to inappropriate omissions, the non-linear shape of the pre-implementation period was accounted for. A statistically significant reduction of 11.1% (95% CI 2.6% to 19.6%) was seen post-implementation from 28.0% pre-policy in Medical areas, but not for Surgical areas (5.5%, 95% CI −1.7% to 12.8%, from 24.8% pre-implementation) (table 2). The post-implementation trend was not significant for both areas (0.2%, 95% CI −0.5% to 0.8% and 0.7%, 95% CI −0.1% to 1.4%, respectively, table 3).

DISCUSSION

In a large tertiary care hospital in Melbourne, Australia, a policy implementation for giving medications in the context of oral restrictions was associated with an absolute reduction of 13.4% and 8.3% in the proportion of doses withheld inappropriately for Medical and Surgical areas, respectively. A decrease in total omissions was seen for Medical (11.1%) but not Surgical areas. The results suggest the Policy provided clarity and context for staff with respect to giving oral medications in the setting of fasting before a procedure, especially in Medical areas. This is supported by the findings of a focus group study of 36 surgical nurses, which indicated those who understood the context of the Policy found it valuable to their practice and helped with decision-making about medications when patients have oral intake restrictions.[25] Although a monthly increase of 0.3% in the proportion of doses withheld inappropriately in Medical areas post-implementation suggests sustainability issues, total omissions for the area were sustained (0.2%; 95% CI −0.5% to 0.8%, p=0.62) (table 3).

Our study determined the appropriateness of medication omissions in patients fasting before an unplanned procedure, which made it difficult to directly compare our results with published studies. A retrospective ITS analysis of missed medication doses in hospitalised patients by Coleman *et al* in the UK spanning 239 weeks reported the rate of missed antibiotic and non-antibiotic doses halved (10.3% to 4.4% and 16.4% to 8.2%, respectively) upon introducing clinical dashboards, executive-led root cause analysis meetings and publication

Table 2 Segmented regression analysis of primary and secondary outcomes

	Level before implementation			Monthly slope before implementation*			Level change after implementation			Change in slope after implementation†		
	Estimate	95% CI	P value	Estimate	95% CI	P value	Estimate	95% CI	P value	Estimate	95% CI	P value
Inappropriate omissions												
Medical	18.08	12.31 to 23.85	<0.001	−0.07	−0.69 to 0.56	0.83	−13.38	−17.73 to −9.02	<0.001	0.37	−0.35 to 1.08	0.30
Surgical	11.92	4.47 to 19.36	0.003	−0.24	−1.18 to 0.69	0.60	−5.50	−13.89 to 2.89	0.19	0.72	−0.48 to 1.93	0.23
Surgical non-linear‡							−8.28	−15.73 to −0.83	0.031			
Total omissions												
Medical	28.00	21.42 to 34.60	<0.001	0.11	−0.62 to 0.84	0.77	−11.07	−19.56 to −2.57	0.013	0.05	−0.88 to 0.98	0.91
Surgical	24.83	17.58 to 32.07	<0.001	−0.60	−1.49 to 0.28	0.17	−2.71	−9.76 to 4.34	0.43	1.28	0.12 to 2.45	0.03
Surgical non-linear‡							−5.54	−12.77 to 1.69	0.13			

*The monthly slope before implementation determines the baseline trend.
†The change in slope after implementation compares the difference between the pre-implementation and post-implementation slopes.
‡The level change after implementation after accounting for the non-linear shape of the pre-implementation period.

of a rapid response alert.[6] Furthermore, there was an ongoing implementation effect. In our study, the reduction in inappropriate omissions was approximately two-thirds for both Medical and Surgical areas; however, the decrease in total omissions was lower than that achieved in the Coleman study. A possible explanation for their continued effect may be the implementation strategies used, namely the dashboard eliciting ongoing, timely, relevant, electronic, information to staff, as well as the prolonged hospital-wide staged approach. In contrast, our strategies largely relied on use of the Policy's (static) bedside signs and local area championship after policy rollout.

Another UK study investigated the impact of introducing guidelines for managing medications before surgery.[13] The guidelines stipulated the continuation of regular oral medications perioperatively unless advice to the contrary and that up to 30 mL of water may be given to help patients take medications. Data were collected 6 months pre-guideline and post-guideline distribution. A two-thirds reduction (25.7% pre vs 6.9% post, p<0.001, Student's t-test) in the proportion of medications omitted was seen post-intervention. Key differences between this study and ours include: the study design, their data being collected retrospectively pre-intervention but prospectively post-intervention, and the study conducted in only one ward.

The pattern of 3–6 months per calendar year in Surgical areas pre-implementation and all areas post-implementation (figure 2) suggests staffing influences, such as nursing and medical staff rotations, commencement of new staff and school holiday periods whereby regular staff may have been temporarily replaced by those unfamiliar with the Policy. The post-implementation linear trend increase of 0.3% per month for Medical areas (table 3) suggested issues with sustainability. This is likely related to staff turnover, movement and/or competing workloads of the clinical champions or others involved in the implementation process.[25] However, overall omissions for this area remained constant post-implementation, which suggests a sustained effect and it is possible that the increase in inappropriate omissions was due to a relapse with documentation regarding omissions.

The presence of leadership and ongoing championship are instrumental to the successful implementation and sustainment of initiatives.[26 27] Coleman *et al* demonstrated that manipulating drug administration data from electronic prescribing systems for real-time reporting on 'clinical dashboards' alongside executive-level endorsement resulted in a significant decrease in missed doses.[6] In our situation, it may be simpler and less resource-intensive to harness structural systems, such as the electronic prescribing platform and clinical dashboards, to provide staff with timely Policy decision support and contextual information 'on the ground'. An advantage of this approach is that it will likely require less ongoing resources to implement and maintain.

Table 3 Post-implementation trend of primary and secondary outcomes

	Inappropriate omissions			Total omissions		
	Estimate	95% CI	P value	Estimate	95% CI	P value
Medical	0.30	0.02 to 0.58	0.03	0.16	−0.50 to 0.81	0.62
Surgical	0.48	−0.28 to 1.24	0.20	0.69	−0.07 to 1.45	0.07

Although the reduction in doses withheld inappropriately and total doses withheld were greater in Medical compared with Surgical areas post-implementation, the latter had a lower proportion of both these parameters pre-implementation. This was unusual and contrasted with reports in the literature, which suggest patients in surgical wards more likely to have medication omissions than those in medical wards.[28–32] It is feasible the difference stems from the impetus for the Policy being driven by key leaders in Surgical areas and the Policy being piloted on a surgical ward (excluded from this study). The pilot ward is located on the same floor as two of the Surgical area wards and has continued to operate the Policy since piloting it in 2012. Additionally, there is a shared nursing education structure within each area and a system of 'pool' nurses whereby nurses in a specific (eg, surgical) pool could be allocated to any ward in that pool. The proximity of the surgical wards, the shared education structure and surgical pool nurses already familiar with the Policy could have resulted in some of the Surgical cohort practising the Policy prior to hospital-wide implementation. A flow-on effect does not appear to have occurred in Medical areas, as reductions in inappropriate and overall omissions occurred following the Policy rollout in 2015.

Alternatively, Surgical area staff were likely more adept with managing medications during the fasting period as the surgical setting was their area of expertise. Wards in Medical areas were likely to be exposed to a wider variety of oral restriction conditions and the larger reduction seen post-implementation may be attributed to clinical context being provided by the separation of fasting from nil by mouth in terms of managing oral medications.

The 'ceiling effect' has been described as an intervention having limited effect because the population is already at/near pinnacle point, or the limitation of an assessment to capture the extent and variance of an accomplishment because the assessment is too simplistic or a maximum achievable score given the background of the group being investigated and the available information.[33] Alignment with a 'ceiling effect' lies with the post-implementation proportions of inappropriate omissions being similar between Medical and Surgical areas (table 2 and figure 2). Moreover, a review of guideline dissemination and implementation strategies found that in 86% of studies that observed improvements in process-of-care indicators, the median absolute improvement was only about 10%.[34]

The practice of weighting the decision of whether to give oral medications during the fasting period in favour of perceived 'critical or important' medications over 'non-essential' medications was suggested in the types of medications omitted. Paracetamol, due to its availability and widespread use, was the most omitted medication despite being prescribed as a regular dose. Sometimes, other oral analgesics (eg, opioids) were given where paracetamol was omitted. Paracetamol provides important baseline analgesia; it is the agent of first choice for long-term use in a variety of mild to moderate chronic pain states.[35] A randomised controlled study found no additional benefit with the addition of opioids or a non-steroidal anti-inflammatory agent over oral paracetamol alone[36] in acute pain situations. Consequently, paracetamol should not be omitted, especially in patients about to undergo an invasive procedure and, even more so, in those prescribed this agent to manage long-term pain. Other omitted agents that should have been continued perioperatively include pantoprazole,[37] 'statins'[38 39] (atorvastatin, simvastatin), anti-infective agents (amoxycillin–clavulanate, doxycycline and metronidazole) and steroids (dexamethasone, prednisolone).

Strengths and limitations

This study examined data spanning 29 months, and systematic approaches, including a coding manual, inter-rater checking and resolving differences, were used to improve rigour. The record reviews and assessment of appropriateness were conducted within a relatively short time frame (6 months) and, with a priori determined criteria for deciding appropriateness, likely minimised inadvertent coding differences over time. Nonetheless, limitations inherently exist.

Medical record reviews are susceptible to bias[40–42] and may affect estimate of the implementation effects in terms of inappropriate omissions. The researchers were also data collectors/reviewers and the study was not blinded. Medication omission without documented reasoning was considered inappropriate, but valid reasons may not have been documented. Total omissions were independent of researcher influence: it would have been less susceptible to bias had the study focused only on these rather than medications omitted inappropriately; however, this disregards that oral medications may have been omitted for valid reasons.

Coleman *et al* argued that, given the large tertiary care hospital setting from which their data were extracted, it was unlikely that variability caused by

factors other than the intervention confounded their results.[6] Our study was also based at a large tertiary care hospital setting, and other than potential flow-on effect in Surgical areas from piloting the Policy, it is unlikely that factors other than the Policy implementation confounded our results.

Up to 30 patient episodes per area per month were randomly selected to achieve as close to 100 records per month (surgical areas had more admissions but less medications per patient and Medical areas had less admissions but more medications per patient). Despite this, 1 of the 28 months in Medical and 8 of the 26 months in Surgical areas had under 100 records.

The Policy's fasting bedside sign advises 'give oral medications unless advised by a doctor or pharmacist'. This arose from substantive stakeholder consultation during the Policy development, as it seemed that oral medications were sometimes withheld despite no directive from the doctor to do so. It is conceivable medications may be given inappropriately if instructions to withhold are not provided. The complexity of the medication administration process, the nuances of the various oral intake statuses, patients' clinical circumstances and individual clinician factors/stance make it difficult to prepare any simple, brief, static sign to capture all oral medication administration scenarios.

Comparative analyses with a non-treatment group could not be undertaken because the Policy was implemented hospital-wide and this potentially limits the strength of the results. Our study focused on patients with non-elective procedures in Medical and Surgical areas, effectively a good representation of non-elective patients requiring fasting instructions pre-procedurally. Moreover, the difference in results for the two areas provides an interesting spectrum of the Policy's impact and is important for considering our next steps. It is likely a reflection of general differences that may exist between areas in other institutions, especially since medication management issues in the context of oral restrictions such as fasting before a procedure have been reported as problematic elsewhere. From these perspectives, the results may resonate with a wider audience despite the study being conducted in only one hospital.

The study focused on medication administration; however, it is possible that inappropriate omissions may have arisen from improper ordering by the doctor. It was not possible to reliably assess this in a retrospective study but should be considered in future work. Also needed in future work is assessment of the implications of the implementation from patient satisfaction and financial perspectives.

CONCLUSION

Separating fasting from nil by mouth in terms of oral medication administration appeared to provide clarity and context for some staff when managing medications in patients fasting before a procedure. This translated into a moderate reduction in medication doses omitted inappropriately, as well as overall omissions, especially in Medical areas; however, wider uptake of the Policy is still needed. While the small increase in post-implementation linear trend for inappropriate omissions in Medical areas suggests sustainability issues, total omissions were sustained. Structural system options, such as the electronic medication management system and clinical dashboards that are independent of staff movement and turnover, are being pursued to improve policy uptake. The Policy's concepts need to be investigated beyond our institution, with a comparison group unexposed to the Policy.

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