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Barriers to managing medications appropriately when patients have restrictions on oral intake

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Barriers to managing medications appropriately when patients have restrictions on oral intake

Running title:

Medications and oral restrictions barriers

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Criteria	Author
Made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;	All authors
Involved in drafting the manuscript or revising it critically for important intellectual content;	All authors
Given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content;	All authors
Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.	All authors

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SUMMARY

RATIONALE, AIMS AND OBJECTIVES:

Investigation of several serious adverse events in our organization highlighted that medications were managed inappropriately when patients have oral intake restrictions. The aim of this work was to identify the barriers to optimal medication management when patients have restrictions on their oral intake.

METHOD:

Data were feedback and comments obtained between 2010 and 2014 from a hospital-wide quality assurance project. Data had not been purposefully collected and were in response to a general request for feedback regarding managing oral medications when patients have oral intake restrictions. Data came from a range of clinical staff and from various forums associated with the quality assurance project including; 37 presentations, 34 group meetings and over 50 one-on-one meetings, as well as emails and other sources.

Data were analyzed using the Thematic Analysis approach. Data were coded inductively, and the domains of the Theoretical Domains Framework were used to categorize the data. Subthemes and themes were then developed.

RESULTS:

Barriers could be broadly grouped into systems level issues (organizational guidance, work environment) and the individual person level issues (staff knowledge, beliefs). These barriers highlight the complexity of the medication management task. The lack of standardized guidance and consistent terminology regarding medication administration when patients have restrictions on oral intake, particularly when *fasting* or *nil by mouth*, were important systems factors, as were workflow issues and the 'culture' of the environment in which staff practiced. Lack of knowledge about medication administration, social influences and role interpretation were important individual person factors.

CONCLUSION:

Systems and individual person level issues were significant contributors to inappropriate medication management when patients have oral intake restrictions. Many of the barriers may be addressed with systems approaches such as hospital-wide guidance that simplifies and standardize oral medication administration instructions, particularly regarding *fasting* and *nil by mouth* terminology.

MAIN TEXT FILE

INTRODUCTION

Patients sometimes have restrictions on what may be administered orally for a number of reasons. These restrictions may include the need to limit food and fluids prior to a procedure or surgery, the need to seek an alternative route for oral administration because of swallowing difficulties and gut dysfunction and the necessity of modifying the texture of what is administered orally to aid swallowing.

There are indications that oral medications may be managed inappropriately and inconsistently when patients have restrictions on their oral intake; for example, medications withheld when they ought to be given, given when they ought to have been withheld or manipulated (crushed) inappropriately. All of these actions have the potential to adversely affect the patient.[1-8] Some examples of reported incidents from our organization illustrate these issues:

- All of a patient's long term regular oral medications were withheld over several days because the patient was *fasting* (for surgery). Not receiving these medications may have contributed to the patient's post-surgical respiratory failure;
- Administration of oral medications to a patient designated as *nil by mouth* due to swallowing difficulties resulted in the patient aspirating;
- Crushing a controlled-release medication and administering this to a patient with swallowing difficulties may have led to a significant drop in blood pressure with subsequent sequelae.

We were unable to ascertain the total number of incidents at our organization due to the way in which the incidents were reported. However, it seems these issues are not unique to our organization as similar incidents have been described in the literature.[1-8] It is imperative there is an understanding of how and why these scenarios occur so that strategies may be instigated to minimize the risk to patients.

The purpose of this work was to identify barriers to the appropriate management of medications when patients have oral intake restrictions.

METHODS

Design, setting and time period

This was a qualitative analysis of feedback and comments that had been provided by clinical staff between 2010 and 2014 in response to a general request for feedback and comments to an organization-wide quality assurance project. The quality assurance project had been set up to investigate the issues and to develop strategies to improve the management of oral medications when patients have restrictions on their oral intake. The project was conducted at a tertiary-referral, metropolitan teaching hospital in Melbourne, Victoria, with in excess of 500 acute-care beds. The organization provides a broad range of generalist acute, subacute and rehabilitation care, in addition to being the statewide referral centre for liver transplantation, spinal medicine and toxicology.

The hospital's Human Research and Ethics Committee provided approval for the use of the data for this qualitative analysis (LNR/13/Austin/306).

Participants and data collection

Data had not been purposefully collected and were feedback and comments about the management of oral medications during periods of restrictions on patients' oral intake received from clinical staff by the first author as part of clinical quality assurance processes.

The feedback and comments came from clinical stakeholders such as nursing, medical, pharmacy and speech language pathology and ranged from senior management to those at the frontline. The verbal data came from various forums directly related to the quality assurance project in which discussions about the issues surrounding the management of oral medications during periods of restrictions on patients' oral intake took place and included; approximately 37 presentations, 34 group meetings and over 50 one-on-one meetings. Some

of the presentations and group meetings were multidisciplinary; the number of staff present or type of professions had not been noted. Of the 50 one-on-one meetings, there were 23 with nurses, nine with medical staff, 13 with pharmacists and five with speech language pathologists.

The first author took notes during and/or immediately after the presentations or meetings to record feedback or comments that were of relevance to the quality assurance project. None of the verbal feedback and comments had been audio-recorded.

Written feedback or comments were from emails from over 100 staff, with at least 50 from nursing, 20 from medical, 30 from pharmacy and 15 from other staff including speech language pathologists. Written feedback or comments were also taken from an in-house survey (unpublished) of intravenous paracetamol use and a medication administration survey[9] because these responses related to the management of oral medications when patients had restrictions on their oral intake. Data were also drawn from an in-house snapshot audit (unpublished) of medication administration during the period of restriction on patients' oral intake before a surgical procedure.

Data analysis

Data were analyzed using a Thematic Analysis approach.[10-12] Data were coded (NVIVO 11, QSR International, Melbourne) inductively, and the domains of the Theoretical Domains Framework [13,14] were then used to categorize the data. Subthemes and themes were then developed. The process was iterative, with data, subthemes and themes sorted and resorted before the final themes were reached. The coding was conducted by the first author in consultation with the other authors and data analysis was discussed by all authors.

Researcher experience and potential influence on findings

All authors have prior experience with qualitative research.

The first author was the project officer for the quality assurance project and therefore the findings may have been influenced by this involvement. The third author was also involved in the quality assurance project.

RESULTS

The identified barriers could be broadly grouped into two overall themes – those stemming from the systems level and those arising at the individual person level; although many of the issues were co-dependent and interrelate. (Please refer to table 1 for the coding tree.)

The Systems Level

Lack of standardized, organization-wide guidelines or policy

Staff from all disciplines highlighted that there was no unified hospital-sanctioned reference that staff could use to guide their decisions about whether to give or withhold medications when patients have restrictions on oral intake. Nursing and pharmacy staff were required to check with their patient's medical or surgical unit on an individual basis to determine whether to give or withhold oral medications. Many staff, particularly junior staff, indicated this individualized approach was impractical, frustrating and time consuming.

Junior doctors were often reliant on their superiors (either registrars or consultants) or other specialist units for direction but the recommendations provided by this range of sources were inconsistent. There was often a lack of standardization about oral medications administration between specialties. A junior doctor reported there was a "difference of opinion between surgical and anaesthetics" and, according to nursing staff from one ward, there were "different opinions from different medical teams". Other staff also indicated that anaesthetists vary with when they allow tablets and sips of water. One senior medical consultant wrote, "It is my experience that ...advice about the limit of any oral intake [including water intake for tablets] varies considerably between anaesthetists/proceduralists and we have had people cancelled from having ... [a procedure]...because medications were given with a small amount of water within four hours. This has been a recurring frustration over the years when people think they are doing what is acceptable only to encounter a different opinion".

The lack of hospital-sanctioned guidance coupled with the lack of agreement between staff created complexity and uncertainty with managing oral medications in patients with restrictions on oral intake.

Lack of clarity around roles and key decision makers

Where an individual patient was under the care of several medical teams (e.g., general medical, surgical and anaesthetics) it was often unclear to nursing and pharmacy staff which doctor was responsible for decisions around medication administration. A common cause of frustration for nursing and pharmacy staff was that often several units needed to be contacted before a decision was made. One pharmacist lamented, “Units say call someone else”.

Some units/doctors did not feel it was their responsibility to make medication-related decisions for their patients and thought these decisions should be deferred to another unit or specialty. This point was emphasized during a discussion at a surgical unit meeting where surgeons in that unit felt it was “up to medical units or anaesthetists to decide” about patients’ oral medications. However, this concept was not universal.

Workflow issues

Many staff found it challenging to follow up on medications in a timely manner, especially in dynamic clinical situations and changeable surgical timeframes. This was a particular issue with doctors charting/ordering or withholding patients’ oral medications perioperatively. Some doctors felt they were too busy to follow up medications; one surgical doctor stated he is “too busy, don’t have the time and therefore don’t write it [the medications] down or withhold the medications perioperatively”. A junior surgical doctor explained, “It’s impractical for doctors to withhold [medications] on [the] drug chart for every patient due to work load, especially during the bottleneck at 8am”. For nursing staff much time was spent clarifying the decisions made by the various medical teams and attempting to “chase up individual doctors or units” about whether to give or withhold oral medications. For many reasons, it was often difficult to establish the exact timeframes for patients going to surgery.

Therefore, as one of the pharmacists pointed out, “Medications are not given because there is uncertainty about whether the patient’s procedure is going ahead”.

A workflow issue impacting on oral medication administration related to patients admitted on the day of surgery. As identified by a senior pharmacist, “The problem with some pre-admission clinics is they sometimes occur months in advance and medications may change”. The medication therefore needed to be verified at the time of admission and prior to surgery. A further source of uncertainty that took time and resources to clarify related to whether the patient had taken their oral medications prior to admission for surgery, which may in turn be dependent on what they had been advised by their specialist, general practitioner, and/or others (e.g., nurse liaison, pharmacist).

Other workplace considerations also affected patients having their medications managed in a timely manner when they have restrictions on oral intake: for example, the time needed for medications to be reviewed by the doctor and for a suitable route of administration to be found, and during periods of reduced staff such as on weekends and after hours.

Workplace ‘culture’ and ‘rules of thumb’

The culture of the workplace contributed to inappropriate management of oral medications when patients had restrictions on their oral intake. There were often ‘rules of thumb’ – either specific to the local area (ward) or across the hospital – that were considered accepted practice and generally applied, but which were not always best practice for the patient.

Fasting and nil by mouth terminology

The terms *fasting* and *nil by mouth* were being used in a number of different contexts and there was a culture of using these terms to mean the same thing. One surgical registrar said her training was to “use *fasting* and *nil by mouth* interchangeably”. When conversations or questions were posed with one of the terms, some staff would respond using the other – for example, a question specifically stating *nil by mouth* elicited the response of, “[It] depends on [the] reason for *fasting*…” The fact that official documents such as the ‘National Inpatient

Medication Chart' define *fasting* and *nil by mouth* as the same entity,[15] particularly in the surgical context, lent support to this culture. One of the nurses used this reference to reinforce the view that *fasting* can be used in different contexts – "*Fasting* can mean anything and may not relate to pre-surgery. It was taken from the National Inpatient Medication Chart". However, the culture of using *fasting* and *nil by mouth* interchangeably has the potential to cause confusion in different clinical settings, particularly where oral medication administration may be involved and may lead to oral medications being managed inappropriately and adversely affect patient care.

Rules of thumb

There were a number of 'rules of thumb' in use. One such rule was that all oral medications were withheld if patients were categorized as '*fasting*' regardless of the setting, such as whether patients were having surgery or have difficulty swallowing, or the type of medication. A different rule was to only give oral medications that were considered 'important/urgent/critical': where this rule was used it was sometimes applied to all patients, regardless of the context. This was further complicated by the fact that there was no consensus as to which medications were considered 'important/urgent/critical'; for example, during meetings to ascertain a list of 'must give' medications an agreement could not be reached on which medications must be included. Other 'rules of thumb' examples included:

- Oral medications (tablets) were routinely crushed and given via the nasogastric tube if the patient was unable to take medications orally, regardless of whether the medication should be crushed or not;
- Some speech language pathologists provided the generic recommendation of 'crush tablets if possible' for patients with swallowing difficulties;
- If patients' long term morning medications were charted/ordered after 8am some nurses would assign the task to the following day and there was a risk that the morning medications would be missed, especially if nurses do not check whether patients have already taken/received those medications;

- It was routine practice for some doctors not to chart/order medications for patients prior to surgery.

Consequences of these rules may include:

- Patients having their medications inappropriately withheld because;
    - All oral medications, including patients' long term medications, were not charted/ordered by the doctor.
    - Only some medications were charted/ordered for patients by the doctor.
    - All or some medications were not given by the nurse prior to surgery.
- Medications were given orally to a patient who should not be receiving anything orally;
- Some oral medications were manipulated (e.g., crushed) inappropriately.

The Individual Person Level

Lack of knowledge

There appeared to be a lack of knowledge about medications in the context of restrictions on oral intake. Knowledge deficits were also implicated with the face-value acceptance and ongoing practice of certain 'rules of thumb'. There was not only uncertainty about whether medications in general should be given or withheld in a particular oral restriction context but also a lack of understanding about the medications themselves and which medication should be given or withheld. The clinical context and the individual medications were not consistently considered by nurses when withholding all of their patient's medications. An incident that illustrates this issue occurred when a patient with acute appendicitis was made *nil by mouth* by the doctor and although the patient had a number of oral medications charted/ordered the nurse did not give these because of the *nil by mouth* status. However, when the pharmacist clarified the order with the doctor it was discovered that it was not the doctor's intent for the medications to be withheld. The doctor expected oral medications to be given by the nurse when a patient was categorized as *nil by mouth* (and was not aware *nil by mouth* may be interpreted differently). Other examples of lack of knowledge included;

nurses crushing medications without checking whether this affects the medications' integrity, and the provision of the generic advice to 'crush tablets if possible' by some speech language pathologists as this may be misinterpreted as crush if it is manually possible for the tablets to be crushed as opposed to whether the tablet's formulation/integrity will be affected if crushed.

Fasting and nil by mouth confusion and oral medication administration

Relating to the systems level issue of using *fasting* and *nil by mouth* interchangeably is how these terms were interpreted with respect to oral medication administration. In one example, a pharmacist recounted an incident where a surgical intern changed all the patient's medications to a different route because she was told by her registrar that the patient was *nil by mouth*. However, the registrar did not mean medications cannot be given orally. An in-house survey (unpublished) exploring use of intravenous paracetamol highlighted the breadth of interpretation of the *nil by mouth* terminology and oral medication administration by nurses. Responses to the question of 'what form of paracetamol should be given to a patient who is *nil by mouth*', included:

- "Depends on how strictly *nil by mouth* [the] patient is. If strict, [give via] NG/IV/PR"
- "The patient can take medication [orally] with sips [of water]"
- "Depends on how severe her swallowing is..."
- "Depends on [the] reason for *fasting*, if for procedure [give] oral, otherwise [give] IV"

Although the term *nil by mouth* was often used to describe patients' oral intake status around the time of surgery, many such patients could safely take medications orally; as one surgical consultant pointed out, "very few surgical patients fit the category of *nil by mouth* where this meant total restriction from giving anything orally".

There was uncertainty with the use of *fasting* too; for example, a senior nurse wrote, "Consideration also needs to be for the surgical patients who are *fasting* for theatre as they do require their medications and can swallow and should have medications administered – [but]

this is sometimes not attended to as nursing staff may be reluctant to administer meds due to the *fasting* provision". Similarly, one of the consultants expressed, "My personal issues have been staff identifying if a patient is *fasting* pre-procedure – able to take meds, or true nil orally need UV/IM/PC substitutes".

The *fasting* and *nil by mouth* terminology use in different clinical contexts affected how medications were managed. This has the potential to place patients at risk of harm; for example, if patients' long term medications are unnecessarily withheld or if oral medications are given to patients who are unable to swallow.

Important/urgent/critical medications

Some staff strongly believed 'important/urgent/critical' medications such as 'cardiac' medications should be given but these and other medications that staff may deem 'important/urgent/critical' may not be the only important medications on the patient's regime. An in-house snapshot audit (unpublished) found that medications that many would consider 'important/urgent/critical' such as oral antibiotics, neuromuscular systems and central nervous systems medications were withheld (without being administered via an alternative route) when patients were categorized as *fasting* or *nil by mouth*.

Other than 'cardiac' medications there did not appear to be consistency with the interpretation of which other medications were considered 'important/urgent/critical'. Some staff were unaware stopping some medications abruptly may lead to adverse outcomes for the patient; the default for some was to withhold all oral medications without consideration of the 'importance' of the medications. As one of the ward pharmacists related, "Surgical units don't chart/order [medications] if [patient is] NBM (*nil by mouth*) including important meds…"

Social influences

Whether oral medications were given or withheld in a patient with restrictions on oral intake often depended on local influences and/or staff prior experiences. Staff working in an area

specializing in patients with swallowing difficulties tended to be reluctant to give medications orally in any patients categorized as *nil by mouth* or *fasting*. Peers or mentors also influenced practice; several nurses reported they were, "taught to withhold everything" or as one nurse understood, "[I would] withhold [medications] unless otherwise instructed". Other staff were swayed towards only giving 'important' medications or had been led to interpret that 'important' medications must be given when the patient is classified as *fasting* or *nil by mouth* – sometimes without considering the clinical context.

Past experiences also impacted on medication administration practice; one senior nurse revealed, "I was told off once by a surgeon for giving meds pre-surgery and once was enough for me not to do it again".

Beliefs

Staff strongly believed that they were acting in the patient's best interest. Senior doctors needed evidence supporting the necessity of continuing certain medications perioperatively; for instance, a senior anaesthetist questioned, "What is the evidence that missing just one dose is harmful?" There was also the belief that medications considered 'important/urgent/critical' must be given but that others could be withheld; for example, one nurse wrote, "Give only important meds, things that can be missed [are] not needed". Other staff held the firm belief that all oral medications should be withheld when a patient was *fasting* for a procedure to prevent the risk of aspiration; one anaesthetist remarked that some surgeons routinely advised their patients to withhold all oral medications. Adding to the complexity, anaesthetists themselves had a range of individual beliefs as highlighted by this comment, "I personally prefer my patients to have all their normal medications prior to anaesthesia, with the exception of... Anaesthetists, however, have widely ranging views on this and my view is not a universal one".

Role interpretation

Staff interpretation of their role and the opportunity (or lack of) to carry this out sometimes impacted on the administration of oral medications when patients have restrictions on oral intake.

There was widespread expectation that it was the doctors' role to make decisions about medications; for example, "Nurses should not be withholding any medications without discussing with the doctor" (senior consultant) and, "It is the doctors' decision what has to be withheld, not mine" (nurse). However, for various reasons, doctors did not always initiate medication-related decisions when patients had restrictions on oral intake, particularly when patients were going for surgery. In the absence of a decision, some nurses took the initiative as shown by this feedback from a senior pharmacist, "Nurses generally withhold [certain medications as], there is no written protocol". However, there was some uneasiness with nurses initiating medication decisions without consultation with medical staff as shown from this question and comment from the same pharmacist, "Does the doctor need to document which meds are to be withheld? I think currently this is done by nursing staff, therefore if the doctor is unable to review the meds, could there be a risk of nurses inadvertently administering meds which are to be withheld?"

An added layer of complexity with role perception was the wide range of opinions among doctors about whose role and/or which specialty/unit it was to make decisions about the patients' oral medications.

DISCUSSION

Medications were managed inappropriately when patients have restrictions on their oral intake due to a myriad of barriers. While the overarching factors were those arising at the systems level and the individual person level these were often co-dependent and interrelated. This is likely a result of the complexity of the hospital system and the medication administration process; a multitude of tasks and decisions impact on whether patients receive their medications or not.

Lack of guidance

In our setting, contributing to the complexity of the hospital system was a lack of hospital-wide unified guidance for the management of oral medications when patients have some form of restrictions on their oral intake. The process to discovering whether medications were to be administered or withheld was time consuming, frustrating and riddled with too many levels of uncertainty. Staff were uncertain as to which clinician was responsible for making the final decision. This uncertainty was compounded by differences in opinions amongst medical staff and a lack of knowledge and awareness about the medications and oral restrictions in a variety of clinical contexts. The inconsistencies affected workflow leading some staff to resort to, or rely on, local 'rules of thumb' and other workarounds that were not necessarily appropriate and which had potential to place patients at risk.

Our findings support a 2014 Australian qualitative study of nine nurses focusing on factors influencing nurses to withhold surgical patients' oral medications pre- and postoperatively.[16] The study found that the ward culture or environment was characterized by a lack of direction and leadership, which led to inconsistent practices and decisions surrounding the withholding of medications.[16] The authors reported that forming part of the ward culture were factors such as lack of guidelines, decisions based on 'a rule of thumb' and diversity in experience and levels of knowledge of staff.[16] Our findings also concurred with other aspects of the paper, such as issues around staff role perception and medication knowledge.[16] The similarities suggest that the barriers to managing medications appropriately in patients with restrictions on oral intake are not confined to our institution.

Fasting and *nil by mouth* context confusion and medication administration

The culture of using the terms *fasting* and *nil by mouth* interchangeably and employing them in an inconsistent manner seems to be a significant basis for some of the confusion with managing oral medications. *Fasting* and *nil by mouth* may be interpreted as absolutely nothing orally on a stroke ward because it is unsafe to give anything orally to those patients but on a surgical ward it may be understood that oral medications and/or sips of water are allowed. In the wrong context, a stroke/swallowing difficulty patient may be administered

oral medications and a surgical patient may be withheld medications needlessly. The use of terminology that potentially confers different meanings in different contexts within the same institution is concerning for its potential to contribute to patient harm.

There is a paucity of literature addressing the *fasting* and *nil by mouth* terminology confusion; however, there is substantial literature on the mismanagement of medications when patients are *fasting* or *nil by mouth*. Publications about the inappropriate omission of oral medications and the potential for harm from this when patients were *fasting* or *nil by mouth* for surgery have existed for a number of years.[1,17-21] Two of these studies suggest that the *nil by mouth* terminology is misleading and needs defining.[18,19] There have also been a number of case reports discussing adverse patient outcomes, such as 'pill aspiration', resulting from the inappropriate administration of oral medications or other oral intake to patients who were designated *nil by mouth*.[7,22,23] Many of the studies highlighted, as well as official documents such as the Australian 'National Inpatient Medication Chart'[24] and the New South Wales Agency for Clinical Innovation's 'Preoperative fasting in NSW public hospitals'[25] use *fasting* and *nil by mouth* interchangeably. However, as discussed, the interchangeable use of these terms has the potential to adversely impact patient care. Therefore, it is imperative the meaning of these terms is clarified, particularly with regards to the clinical context and oral medication administration.

Relating to *nil by mouth* and medication administration is the issue of inappropriate manipulation of oral medications, particularly when patients are unable to swallow medications and/or require their medications administered via a feeding tube. There is numerous literature regarding inappropriate manipulation of oral medications and the potential adverse implications of this for patients.[6,8,26-29] Some oral medications are formulated in such a manner that its reliability, and even safety to the patient, cannot be guaranteed if the medication is manipulated, such as when certain tablets are crushed or split. This medication administration context needs to be considered, along with the *fasting* and *nil by mouth* context confusion. Generic advice such as 'crush tablets if possible' should not be given and 'rules of thumb' such as crushing tablets for administration when a patient has a

swallowing difficulty should not be followed without understanding the implications and/or consulting a pharmacist or a suitable reference such as the 'Australian Don't Rush to Crush Handbook'.[30]

Systems versus individual person level barriers

Addressing both the systems and the person level considerations is important to minimizing the barriers to managing medications appropriately in patients with restrictions on oral intake. The nurse who admitted, 'I was told off once by a surgeon for giving meds pre-surgery and once was enough for me not to do it again', may have subsequently advocated and/or perpetuated the 'withhold all oral medications when *fasting*' stance and played a part in that 'culture'. The surgeon responsible may have firmly believed he was providing optimal care and in doing so may have contributed to a chain of events that led to the culture of the hospital. So although these situations began as 'individual person' consideration, the experience eventually contributed to the 'system' issues. In contrast, it could be argued that the system did not provide the capacity and/or means for both the nurse and the surgeon to be apprised of the most recent evidence regarding best practice for their patients. Nevertheless, at its core, the problem appears to be a lack of standardized guidance, resulting in the observed inconsistency and uncertainty, which would appear more systemic in origin. Therefore, strategies for improvement should initially focus on the systems perspective. It may be possible that improvements to some of the individual person level barriers to managing medications appropriately, such as lack of knowledge and social influences, may follow with the introduction of systems level strategies. Once the systems approaches are imbedded, individual person level issues such as perception of role and responsibility could be further explored and addressed.

The systems approach

The medication administration process is highly complicated and has been labeled as a 'complex system' by organizations such as the Institute of Medicine in the United States and the Australian Council for Safety and Quality in Healthcare.[31,32] One description of complex systems is 'any collection of a large number of technological and human parts, which are free

to interact in a proportionately larger number of ways, such that determining their long-term safety is difficult.[33] The 'complexity' of such a system has been defined as the 'interrelatedness of components of a system' that increases with the number of components in a system, number of relations between them and uniqueness of those relations'.[34] These definitions are highly relevant to our findings and the interrelatedness of the key barriers to optimal medication management identified. A 'systems approach'[31,32,35] is recommended for complex systems. This approach maintains that the overall effectiveness and efficiency in achieving objectives depends on identification, understanding and management of interrelated processes as a collective system.[36] Proven systems-based medication safety practices such as simplification, standardization and reducing reliance on memory[31,32,35] were needed to address the barriers to appropriate medication management identified in our setting.

Strategies instigated at our institution

This exploration of barriers to the appropriate management of medication when patients have restrictions on oral intake informed the design of our subsequent systems focused quality improvement interventions. A number of systems level strategies have been developed to address the unwanted practice variations, the *fasting* and *nil by mouth* confusion and improve oral medication administration when patients have restrictions on oral intake at our organization. We now have a hospital-wide standardized policy that specifically distinguishes *fasting* from *nil by mouth.* This policy provides oral medication administration instructions in the context of oral restriction categories. The Policy states:

1. The term *fasting* is only to be used before a procedure or surgery and means that all oral medications may be administered with a small sip of water up to one hour prior to the procedure unless there is a clinical reason to withhold, such as oral hypoglycaemics/risk of hypoglycaemia;
2. The term *nil by mouth* means absolutely nothing by mouth, including sips of water and oral medications. A different route of administration should be sought where possible;
3. *Restricted oral intake* means there are special conditions for giving oral intake; for example, 'sips only' immediately after surgery or texture modifications are required for

oral administration. Therefore, medical orders need to be checked and/or the relevant clinical staff need to be consulted before giving anything orally.

The Policy is supported by a Procedure Manual and colour-coded bedside signs that represent each oral restriction category. We are working on incorporating this Policy into our electronic medication management system.

Limitations

A limitation of this study was that data had not been collected purposefully for the study or in a controlled and standardized manner. The data were mainly derived from interrelated settings and investigations done in response to real-world, sometimes urgent clinical scenarios that required prompt attention. It was after most of the data became available and the complexity of the problem became apparent that a review of the available findings, to provide context, seemed warranted. This meant that validation of data via investigator and respondent triangulation could not be undertaken. A strength of this outcome is that the barriers identified were derived from a wide range of perspectives. Despite data being in different formats, there was consistency with much of the findings across formats, suggesting the issues identified were highly relevant to our setting.

CONCLUSION

Medications were managed inappropriately when patients have restrictions on oral intake and this had the potential to adversely affect patient care. This qualitative study found that many factors contributed to the medication management issue, including lack of standardized guidance, workflow issues and the culture of the system or the environment in which staff practiced. Lack of awareness, confusion over context and terminology, particularly *fasting* and *nil by mouth*, social influences and role interpretation of the individuals also contributed. Our findings suggest the core issues were systemic in origin and systems level strategies were needed to address the barriers. We have subsequently instituted a number of systems approaches to manage the barriers at our organization, including; development of a standardized, organization-wide policy to reduce unwanted variations, simplifying and

standardizing medication administration instructions in the context of oral intake restrictions and clarifying the *fasting* and *nil by mouth* terminology. The Policy is in use at our institution and plans are underway to assess its impact on oral medication administration.

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Table 1. Coding Tree for Barriers to Managing Medications When Orally Restricted

Inductive Coding Examples	Categories Using Theoretical Domains Framework	Subtheme	Theme
Clarity; communication; confusion; environment; experience; important medications; inter-professional relationships; knowing what to do; professional role; risk to patients; understanding;	Knowledge; social professional role; beliefs about consequences; memory, attention and decision process; environmental context and resources;	Lack of standardized, organization-wide guidelines or policy	Systems Level
Clarity; communication; environment; inter-professional relationships; knowing what to do; professional role; risk to patients;	Social professional role; beliefs about consequences; memory, attention and decision process; environmental context and resources;	Lack of clarity around roles and key decision makers	
Communication; environment; inter-professional relationships; understanding;	Social professional role; beliefs about consequences; environmental context and resources;	Workflow issues	
Environment; important medications; professional role; risk to patients; understanding;	Knowledge; social professional role; memory, attention and decision process; environmental context and resources; social influences;	Workplace 'culture' and 'rules of thumb'	
Clarity; communication; confusion; environment; important medications; knowing what to do; risk to patients; understanding;	Knowledge; beliefs about consequences; memory, attention and decision process; environmental context and resources; social influences;	Fasting and nil by mouth terminology	
Clarity; confusion; experience; important medications; knowing what to do; risk to patients; understanding;	Knowledge; social professional role; beliefs about consequences; social influences;	Lack of knowledge	Individual Person Level
Clarity; confusion; communication; environment; important medications; knowing what to do; risk to patients; understanding;	Knowledge; beliefs about consequences; memory, attention and decision process; environmental context and resources; social influences;	Fasting and nil by mouth context confusion and medication administration	
Communication; confidence; environment; experience; inter-professional relationships; professional role; understanding;	Social influences; social professional role; environmental context and resources	Social influences	
Environment; important medications; knowing what to do; professional role; risk to patients; understanding;	Knowledge; beliefs about consequences; environmental context and resources; social influences;	Beliefs	
Communication; environment; inter-professional relationships; knowing what to do; professional role; understanding;	Social professional role; environmental context and resources; social influences;	Role interpretation	