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Decreasing Pre-Procedural Fasting Times: A Benchmark Study

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Executive Summary

On a busy Surgical Trauma unit, scheduled procedures and operations are often delayed for priority emergent cases. Patients admitted to the unit with delayed procedures often endure extended fasting times beyond the six-hour intention of standard nothing by mouth (NPO) after midnight fasting order. With prolonged fasting times, patients inquire about pending surgery times and dietary options. Some providers may allow ice chips, but most doctors prefer patients to remain NPO in case Operating Room availability opens for surgery, leaving already anxious and uncomfortable patients more frustrated as prolonged fasting affects patients' physical and psychological well-being (Anderson & Comrie, 2009). Patient complaints reveal an opportunity to improve patient perceptions of hunger, thirst, comfort, and satisfaction. With the goal to increase patient satisfaction, the following PICOT was examined: In preoperative adults and children (P), how does allowing clear fluids pre-operatively (I) compared to remaining NPO (C) affect aspiration risk (O) during surgery (T)?

Research reveals strong evidence that supports shortened fasting times prior to procedures. Since 1999, current evidence allows clear fluids up to two hours prior to surgery for healthy children and adult patients that are not at high risk for aspiration undergoing anesthesia (American Society of Anesthesiologists Committee [ASAC], 2011). Evidence shows there is no need to keep low-risk preoperative patients NPO for extended periods; however, adoption of these updated fasting guidelines has been slow to be ingrained into organizational culture with most prescribers adhering to the long-held standard NPO after midnight fasting practice in both inpatient and outpatient settings. Because changes to clinical practice have been slow, it is important to disseminate findings that increase compliance with evidence-based practice and increase patient satisfaction with low implementation costs.

Decreasing Pre-Procedural Fasting Times Benchmark Study

Background and Rationale

While many hospitals do not claim strict NPO fasting policies, studies show that few hospitals adhere to full preoperative fasting guidelines of two hours for clear liquids and six hours for solid food prior to procedure (Green et al., 2020; Merchant et al, 2020). Prescribers worry about effects of excessive fasting but are reluctant to relax the policy due to concerns of aspiration and appropriate amount of volume though post-1984 studies show no aspiration related morbidity in children and no reports of death in health adults (Green et al., 2020). Nurses want the best for their patients, but many are not aware of modern fasting guidelines, so they are not able to effectively act as patient advocates due to a lack of knowledge (Millard et al., 2018). The lack of knowledge and lack of change indicates healthcare professionals lack competency and standard fasting practice is substandard.

Changing pre-procedural fasting guidelines from a long-held standard practice with complex barriers to implementation is a challenge with no easy solution. However, changing local practice to comply with national guidelines will improve known adverse consequences of extended fasting like irritability, dehydration, hypoglycemia, poor nutrition, electrolyte imbalance, poor wound healing, increased risk of developing pressure sores, and depressed immune system (Green et al., 2020; Millar, 2009). These adverse physical effects may contribute to preoperative complications and can lead to negative emotional and psychological effects such as an uncomfortable preoperative period (Anderson & Comrie, 2009). To tackle this issue, creativity and innovation are necessary to change outdated fasting practices that will improve the patient experience with a low risk of harm.

Project Goals

The goal of this benchmark study is to implement a pilot project to reduce pre-procedural fasting times in accordance with current guidelines and evidence. Liberal fasting guidelines have been long updated; yet clinical practice implementation has been slow. Therefore, it is important to bring awareness of prolonged fasting times, knowledge gaps, and current clinical practice. The project's aim is to utilize quality improvement methodology to reduce excess fasting times with a goal of achieving experienced clear liquid fasting times (CLFT) less than or equal two hours in over 60% of eligible patients within one year of pilot interventions. Secondary aims include measuring adoption rates, patient satisfaction, and monitoring balancing measures.

This project will evaluate healthcare professional's current knowledge of professional standards and assess patient preferences and how professionals view their team relationships. In compliance with the QSEN competencies, patient centered care will be achieved by recognizing patient's preferences and allowing for integration of best evidenced-based practice for low-risk aspiration patients. Utilizing evidence-based practice ensures risk of harm to patients and providers is minimized, especially when information and technology can enhance communication and quality improvement. The QSEN competencies will be supported by developing teamwork and collaboration.

Setting. With standard fasting orders being common in the United States, any surgical unit or facility may be considered for this change project. However, this project was formulated for a large 882-bed academic teaching hospital servicing adults and some pediatrics. The facility is the primary trauma center for the county with diverse surgical population. A pilot project will be implemented in inpatient surgical units including the Surgical Intensive Care Unit, Progressive Care Unit, and Medical Surgical Unit. The final goal is to spread the scale to all units in the hospital system as a sign of adoption and institutionalization.

Steler Model Timetable

Since this change project relies on individual practitioner practices, the Stetler model is optimal to guide this change project it focuses on the use of “critical thinking, reasoned variation, and individualization by each practitioner” (Dang et al., 2015) to facilitate safe and effective nursing practice change on the surgery units. The Stetler Model was utilized to guide implementation through a series of five progressive phases that includes (I) preparation, (II) validation, (III) comparative evaluation/decision making, (IV) translation/application, and (V) evaluation. The table below provides an overview of phase goals and tasks that are completed or pending. Each phase was allotted four months to achieve task aims; however, many phase tasks overlap and occur concurrently. When coronavirus has subsided and the organization is ready to proceed with the change project, the Stetler Model will begin at phase III with four months allocated for each remaining phase. However, other phase tasks my start concurrently.

Phase I: Preparation	**Phase II: Validation**	**Phase III: Comparative Evaluation/Decision Making Goals**	**Phase IV: Translation/Application Timeframe: 4 months**	**Phase V: Evaluation Timeframe: 4 months**
Tasks Completed: - Purpose confirmed: catalyst explored; affirmed perceived problems with infernal evidence (current practice). - Context confirmed: internal and external factors considered. - Sources of evidenced confirmed: type of research evidence determined: systematic reviews/guidelines.	Tasks Completed: - Credibility of evidence confirmed: critical appraisal of evidence that includes system reviews and guidelines; level and quality of evidence are specified.	Tasks Completed: - Cumulative findings synthesized and decision to use findings per strength of overall evidence shows best EBP practice. - Criteria evaluated with detailed qualifiers of application selected including inclusion/exclusion data. - Detailed EBP implementation plan formed including methods, levels, and direct instrumental use.	Tasks Completed: - Key stakeholders identified. - Change/implementation strategies planned per relevant research and local barriers. - Anticipate hurdles regarding no change in practice (physicians do not update orders) and implement processes (like education and open forums with physicians and hospital leaders to process this research evidence) to overcome challenges.	Tasks Completed: - Goals for formal design confirmed. - Consider cost/benefit and various evaluation efforts
Tasks Pending: - None: Purpose, context, and sources of evidenced confirmed.	Tasks Pending: - None: there is clearly sufficient, credible external evidence that meets project needs.	Tasks Pending: - Collection of baseline data to determine magnitude of problem. Access to electronic health record. Access patient satisfaction and staff surveys or determine how to create surveys.	Tasks Pending: - Per operational details and qualifiers, formal design of EBP change project complete. Pending package for dissemination and evaluation for sustainability. Incorporate evidence into action: - Team formation and approvals necessary for project implementation with system leadership, unit leadership, and ethic board pending. Identify leaders of key stakeholder groups. May include EBP mentor or champions/allies. - Apply interventions and PDSA review cycles.	Tasks Pending: Alternative Evaluations - Obtain results/outcomes evidence by implementing interventions. Evaluation utilizing PDSA cycles to ensure primary, secondary, and balancing measures achieved. - QI Team to frequently update stakeholders about initiative and results with dashboard that can be viewed by stakeholders and monthly meeting to discuss results. - Use evidence within and across units to achieve goals. - Evaluate as part of routine practice.

Phase I: Preparation

Preparation for evidence-based change project is complete with purpose, context, and sources of evidence confirmed.

Phase II: Literature Synthesis and Validation

Guided by the PICOT question, a systematic literature search was conducted in January 2020 and repeated in October 2020 and September 2021 to acquire the best evidence. The databases searched included the Cumulative Index to Nursing and Allied Health Literature

(CINAHL) and PubMed in both English and non-English language. Keyword and controlled vocabulary searches included the following terms: *NPO; NPO before surgery; NPO after midnight; preoperative fasting; aspiration; aspiration risk; limited to preprocedural fasting; aspiration; and "NPO after midnight."* Several articles and studies found in the search were reviewed again for specificity to the PICOT question, and 12 articles were selected for critical appraisal.

Aspiration was not noted as an adverse effect with zero incidences reported in healthy children and adults (ASAC, 2011; Brady et al., 2003; Lin et al., 2017; Noba & Wakefield, 2019; Green et al., 2020; Yip et al., 2021). Compared to the standard nothing after midnight standard fasting policy, studies show that allowing fluids up to two hours prior to surgery resulted in no significant increase in gastric volume and had no effect on gastric pH (ASAC, 2011; Brady et al., 2003; Brady et al., 2009; Lin et al., 2017; Green et al., 2020; Yip et al., 2021). In fact, fasting does not guarantee an empty stomach or reduce gastric pH, so there is no association of aspiration and fasting times (Green et al., 2020; Yip et al., 2021). Studies measured perceived emotional and psychological notions with an improvement on these secondary variables (Brady et al., 2003; Brady et al., 2009; Noba & Wakefield, 2019).

Evidence shows the potential for harm is low to moderate if the patient is low risk for aspiration. The level of evidence (4 Level I studies) combined with the strength (moderate with clinically meaningful improvement) and quality (moderate quality) of the evidence suggests that implementation should be undertaken with clinical expertise and consideration for patients' preferences and their values for best practices.

Since evidence-based practice (EBP) has been established and updated, further research explores current clinical practice regarding fasting times and surveys indicate gaps in practice

and knowledge of the updated fasting guidelines with 54% of anesthesiologists reporting allowing clear fluids two to three hours prior to procedure while only 42% of nurses being aware of updated fasting guidelines (Merchant et al., 2020; Millard et al., 2018). These studies reveal complex barriers to implementation including cultural concerns, unclear structures, unpredictable and inflexible systems, and lack of communication and knowledge (Millard et al., 2018; Merchant et al., 2020; Carey & Hogan, 2021).

With best practices and knowledge of perceived barriers established, several hospitals have published pilot studies that report their experience in reducing fasting times in both inpatient and outpatient settings. These studies successfully show the ability to reduce fasting times utilizing quality improvement methodologies without increased incidences of aspiration and improvements in emotional and psychological states (Newton et al., 2017; Isserman et al., 2019; Nye et al., 2019). These quality improvement projects provide a basis for organizations that wish to reduce fasting times and serve as models for quality improvement projects that facilities may implement and adjust as needed. Phase II is complete as critical appraisal of literature shows there is sufficient evidence that meets the project needs.

Phase III: Comparative Evaluation/Decision Making Goals

Stetler's Model is introduced in phase III with a detailed EBP implementation plan on how to reduce pre-procedural fasting times in the selected pilot group. Phase III also specifies how to collect baseline data to evaluate historical aspiration rates and fasting times (current practice), staff knowledge gaps, and patient satisfaction. The four-month timeline will begin with phase III tasks.

Method. A one-year project timeline was selected but may be adjusted based on availability of facility resources like personnel. Inclusion criteria includes inpatients undergoing

anesthesia procedures. Exclusion criteria includes any patient with disease specific fasting instructions, with prescribed standard fasting instructions for other reasons, with history of delayed gastric emptying, with severe reflux, with achalasia, etc.

The Plan Do Study Act (PDSA) quality improvement process cycles will monitor primary, secondary, and balancing measures. The primary measure is fasting times less than or equal to two hours. The secondary measure is patient satisfaction survey scores and adoption rates by staff. Balancing measures that will be tracked include occurrence of regurgitation/emesis, occurrence of procedural complications, case delays and cancellations due to fasting guideline violations.

Collection of Baseline Data. Updated fasting guidelines have been in place for over a decade without implementation (Andrew-Romit & Van de Mortel, 2011), so further need for external data will be determined by stakeholders and gatekeepers. Internal data that may help change current clinical practice should focus on understanding the facility or unit's current standards and practices. To review internal data, the facility should determine if electronic health record (EHR) can provide baseline fasting times and aspiration rates.

If the EHR is unable to provide a baseline, EHR updates may be considered for future tracking while patient surveys may provide average times in conjunction with EHR data that will show times of diet order changes with a food note documented by the nurse or patient care technician. The unit or facility can identify past incidences of aspiration and the associated fasting order retrieved from the electronic health record (EHR) to determine incidence rates.

Patient surveys conducted before and after surgery assess the patient's fasting preferences and satisfaction as well as subjective emotional and psychological variables. A data collection tool completed at the end of each shift will track patient complaints. Surveys will be completed

with prescribers, nurses, and leadership to identify any knowledge gaps and identify concerns regarding barriers to implementation. The Standards and Measures hospital-wide council has been identified as a potential source of baseline data.

Surveys in the planning stage are important for the organization realize potential to increase patient satisfaction as evidenced by survey scores that may increase reimbursement. A low survey score impacts a hospital's bottom line with a bad reputation and limiting funding received by Medicare. With many organizations moving towards value-based care that improves quality of care as defined by the Affordable Care Act, compliance with patient preference for fasting guidelines will decrease discomfort and anxiety without increasing risk for pulmonary aspiration. Before implementation, the facility should build a key driver program, process map, conduct a failure mode, and effects analysis.

Phase IV: Implementation – Linking Evidence to Action

Phase IV will move the evidence into action with several necessary steps in a well-planned and executed implementation of the evidence-based change. All interprofessional team members including EBP mentors to support sustainable change should be sought out and approvals obtained for the project. Key checkpoints in the PDSA processes will be completed to assess results and adjust for failures.

Stakeholders. In selecting inter-professional collaborators, the roles that should be represented on the multidisciplinary stakeholder team include patients, patient family liaisons, nurses, patient care technicians, and physicians, surgeons, and anesthesiologists because "effective interpersonal collaborative practice involves a partnership between a team of health professionals and client in a participatory, collaborative and coordinated approach to shared decision-making around health and social issues" (Orchard et. al, 2017, p. 22). It is important

that these roles are represented on the team because the development of relationships between these parties will improve communication.

Educating providers and improving team communication should improve patient advocacy. Therefore, inclusion of food services, dieticians and nutritionists is important for success as these team members play an important role in implementing inpatient diet orders and providing education to patients. Operations, operations managers, and quality data analysts as project management team members should also be included to ensure successful implementation.

The project leader will keep the project on track, keep stakeholders informed, ensure that the new fasting guidelines have fidelity, and evaluate outcomes for validity and accuracy. EBP projects must be owned by all stakeholders to improve patient satisfaction and move the project forward. Developing relationships and improving communication between these key stakeholders may lead to improved patient advocacy and satisfaction.

Since individual and systemic interventions are needed implement evidence-based guidelines (Dang et al., 2015), informal and formal medical and administrative leaders are other stakeholders that are essential in assessing organization readiness and must allow or grant permissions by creating a culture that allows change. Review of several successful quality improvement projects implementing updated fasting policies reveals that successful pilot projects had dedicated action from health system leaders in promoting the scale and spread of effective innovation as this can generate interest, excitement, and commitment from stakeholders with conceptual clarity and a well-defined strategy (Shaw et al., 2018). Unit or organizational specific allies and champions should be identified and may include best practice champions or EBP mentors, professional associations, networks, and administrative leadership (Dang et al.,

2015). The key to quality improvement success involves leadership promoting innovation, spread and scale.

Interventions. Several interventions have been identified to ensure success of the project and have been summarized in the chart below. Inventions specific to inpatients undergoing anesthesia include improving preoperative instruction points, creating a pre-anesthesia diet order, and educating staff. Since inpatients are given instructions by a multidisciplinary team, there is a need to identify all possible written and verbal sources of pre-op instructions and update all outdated sources including but not limited to hospital website, EHR, pre-recorded phone messages, and handouts. Patient family liaisons will review documents for clarity. These steps ensure patient understanding of updated fasting guidelines. Additionally, a pre-anesthesia diet order differentiated from standard clear liquid diet will allow for approved preoperative fasting foods to be delivered automatically at 0600 with breakfast. This new diet is integrated into the EHR as an order set that will cancel other diet order if applied. If NPO is searched, order to be titled "NPO at 0800 for operating room (OR)" or "case after 10AM." Finally, education will be provided to improve staff understanding of updated guidelines and interventions such as updating providers on EHR changes.

Anticipated Barriers to Standardizing Implementation. Unit specific barriers to implementation such as knowledge gaps, lack of protocols, and lack of buy-in is addressed through previously mentioned interventions. Large turnover of medical students has been identified as a barrier to institutionalizing guidelines (Nye et al., 2019), so preventative interventions will be implemented. Due to large turnover of medical students, education focused on nurses to be effective advocates for patients will be key to this plan as nurses educate medical students. Additionally, knowledge

level and occurrences will be reassessed ongoing until a system is in place that can be addressed by individual units. Educational efforts include on-boarding lectures, visual aid reminders, tip sheets in team workrooms, prospective reminder pages, patient satisfaction surveys, and email updates.

Phase V: Outcomes Evaluation

Phase V of Stetler's Model will merge with PDSA timelines as the final data collection for the project evaluation is conducted including a review of the project processes and if project goals were achieved. The primary outcome is the percentage of inpatients with reduced fasting times ideally less than four hours (Isserman et al., 2019; Newton et al., 2017; Nye et al., 2019) and statistical measures will show the impact of interventions and differentiate special cause variation from common cause variation. The secondary outcomes include review of aspiration rates to ensure there is not a spike in adverse procedural events attributable to a more liberal fasting regimen, tracking delays and cancellations rate due to violations in fasting guidelines, and percentage of patients that receive the pre-anesthesia diet compared to those that received the traditional nothing by mouth (NPO) after midnight diet order (Nye et al., 2019).
Balancing measures of patient emotional and psychological perceptions of fasting times, comfort, hunger, thirst, etc. will be tracked with Press Ganey patient surveys. Secondary outcomes and balancing measure data will be reviewed by Quality Improvement team and stakeholders monthly.

To evaluate effectiveness of an intervention, a statistical control chart will be utilized as a graphical representation of the descriptive statistics for the specific quantitative measurements selected for the change process. Primary outcome data will be collected weekly but charted monthly. The control chart will measure the impact of interventions and differentiate variation

by tracking the following data points: time on the horizontal axis, the process measured on the horizontal axis, and the mean is the center line representing average fasting times with upper and lower control limits shown. Proportions will be used to describe diet order secondary measure (Nye et al., 2019). A specific cause is considered when any of the following are true: a trend of six consecutive increasing/decreasing data points, a shift of eight consecutive data points in one direction (this would establish a baseline), alternating points, or data points are outside the limits (Issmerman et al., 2019; Newton et al., 2017).

Malloch and Porter-O'Grady (2015) state that assessment and evaluation review the process innovation and effectiveness of evidence. The value outcomes for the project should include increased Press Ganey scores, decreased patient complaints, and no reported increase incidents of aspiration after the evidence-based intervention. Numbers before and after implementation will be compared. The effective and seamless interface of knowledge creation, practice expertise, clinical values, care culture, clinical dynamics, and provider practices are important for the change process implementation phases especially the outcome, impact and evaluation (Malloch & Porter-O'Grady, 2015). If these elements do not allow for enacting this change process, education geared towards care providers (hospital leaders, physicians, anesthesiology, and nurses) will be the focus in the organization to facilitate some positive impact on this topic.

Costs/Benefits. Existing personnel will be the key resource needed to conduct surveys, educate staff, and perform data analysis from the EHR. Utilizing current staff to assume these responsibilities will save on costs. If practitioners implement updated fasting guidelines, a risk/cost analysis may be performed over the longer term to determine if reported incidences of aspiration increased hospital care and length of stay costs.

Recommendations

Involvement of the multidisciplinary team makes the implementation of this project a success to achieve the quality improvement goal of experienced clear liquid fasting times (CLFT) less than or equal two hours in over 60% of eligible patients within one year of pilot interventions. While convincing every physician to make changes to standard practice may be a difficult task, secondary aims will show improved adoption rates by staff and increased patient satisfaction. Balancing measures will not show increased occurrences of regurgitation/emesis, occurrences of procedural complications, case delays and cancellations due to fasting guideline violations.

Dissemination

The success of the project within the pilot group through interdisciplinary collaboration will allow leadership that wants organizational culture to promote innovation, scale and spread to choose taking the evidence-based intervention system-wide. The well-defined quality improvement strategy may be successfully implemented by other units taking into consideration differences in unit needs. Key departmental differences that must be accounted for knowledge of guidelines, perceptions of barriers to implementation, and various interventions that can be implemented. For example, inpatient units receive a new diet order and outpatient units offer fluids on arrival. The focus of the initiative was aligning local clinical practice with national guidelines, improving patient-center care, and accelerating change within the Magnet environment that helps the organization maintain requirement to remain Magnet-recognized organization.

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