Official title: Optimization of opioid discharge prescriptions following thyroid and parathyroid surgeries

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PROTOCOL TITLE:

Optimization of opioid discharge prescriptions following thyroid and parathyroid surgeries

Short title: Opioid use after thyroid and parathyroid surgeries

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SPONSOR / FUNDING AGENCY

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VERSION NUMBER/DATE

Protocol Version 2 / October 19, 2020

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change (Yes/No)
1	October 19, 2020	1. Increase the sample size of the post-implementation group from 75 to 80 patients 2. Update the study timeline	Not applicable

1. Study Summary

NA

2. Purpose of the Study / Objectives

Objective

The overall objectives of this study are to build, implement, and measure the impact of a quality improvement bundle to increase the proportion of thyroidectomy and parathyroidectomy postoperative patients who are discharged without new opioid prescriptions.

Research aims

Aim 1. Build the quality improvement bundle
Through cooperation of the Opioid Stewardship Program, information technology department, and surgical medical team, our research team will deploy a quality improvement bundle that will include (1) patient education, (2) provider education, and (3) electronic health record (EHR) configuration.

Aim 1a. Educate patients
Educational material will be adapted or newly developed and provided to patients prior to surgery (e.g., 1-page educational flyer) to set realistic pain and function goals and to discuss the role of opioids in the postoperative pain management plan. Additional education material will be prepared and given to patients at hospital discharge to counsel them on their pain management regimen and to emphasize the importance of non-opioid analgesia and non-pharmacological pain management strategies following hospital discharge. Patient educational materials will be delivered as part of routine medical care.

Aim 1b. Educate providers
Since most discharge opioid prescriptions are written by surgical residents or advanced practice practitioners, the research team will provide education to establish best practices for opioid discharge prescribing. Using a collaborative approach, the research team will provide in-service presentations and design and deploy pocket guides and wall flyers that remind providers of best practices during discharge planning activities.

Aim 1c. Enhance EHR support via new thyroid/parathyroid surgery perioperative and discharge order sets
Non-opioid analgesia options will be displayed to providers through perioperative order sets.
Example of a perioperative multimodal analgesia (MMA) regimen [1,2]

1. Approximately one hour before procedure initiation: acetaminophen 1000 mg PO, gabapentin 100-300 mg PO, and meloxicam 7.5 mg PO

2. Standard of care intraoperative anesthesia: intravenous propofol, midazolam, and fentanyl + inhaled anesthetics + antiemetics (intravenous dexamethasone and ondansetron) + subcutaneous infiltration with 1% lidocaine, with 1:100000 epinephrine solution, or 0.25% bupivacaine with 1:200 000 epinephrine solution
3. Following resumption of oral intake after the procedure: ibuprofen 600 mg PO and acetaminophen 500 mg PO every 6 hours, on an alternate staggered schedule (1 agent every 3 hours) for the initial 48 hours and subsequently as needed for discomfort.

To help providers identify opportunities to discharge patients without opioid prescriptions, the study team will collaborate with key provider stakeholders to design medical record alerts or guidance text that will appear to the provider during discharge medication reconciliation to identify patients who are candidates for being discharged without opioid prescriptions. A thyroid and parathyroid surgery discharge pathway/order set will be developed with defaults to non-opioid analgesics first. If opioids are selected as a second-line option, the medical record will default to short durations and low doses.

Examples of first line non-opioid analgesic orders include (order set defaults):

- Acetaminophen (TYLENOL) 325 mg PO Q4H-6H PRN for mild pain for up to 7 days
- Acetaminophen (TYLENOL) 500 mg PO Q6H PRN for moderate pain for up to 7 days
- Ibuprofen 200 to 600 mg PO Q6H PRN for moderate pain for up to 7 days
- Naproxen sodium (ALEVE) 220 mg PO Q24H PRN for moderate pain for up to 7 days

Examples of second line opioid analgesics include:

- Tramadol 50 mg PO Q6H PRN for moderate pain for up to 5 days (#10)
- Acetaminophen-codeine (TYLENOL WITH CODEINE #3) 300-30 mg Q6H PRN for moderate pain for up to 5 days (#10)

Aim 2. Implement the quality improvement bundle

The team will secure necessary hospital committee approvals that are routinely used to clinically validate and approve EHR enhancements and educational materials. Perioperative EHR order sets will be built by Houston Methodist information technology analysts and will be validated by the team of clinical experts supporting this project prior to implementation. The team will carefully select a go-live date using strategies that are customary for quality improvement implementations at Houston Methodist Hospital. The educational materials for patients will be implemented on a single date in all surgeon clinics and within the discharge process workflow. Provider educational material will be handed out and displayed in surgery floors, and multiple educational lectures will be held for different teams and shifts within a 1-month period.

Aim 3. Measure impact of the bundle

Following complete implementation of all components of the bundle from Aim 2 (planned for quarter 4 of 2020 and quarter 1 of 2021), investigators will start to collect post-implementation data and will measure the proportion of thyroidectomy and parathyroidectomy postoperative patients who do not receive new opioid prescriptions at discharge. The post implementation data (quarters 2 and 3 of 2021) will be compared to the historical (baseline) data obtained from January 2018 to December 2019.

Endpoints

Primary endpoint
The primary endpoint will be the proportion of thyroidectomy and parathyroidectomy postoperative patients who do not receive new opioid prescriptions at discharge. This outcome excludes continuation of previous, chronic opioid therapy.

Secondary endpoints
• Proportion of thyroidectomy and parathyroidectomy patients with opioid discharge prescriptions exceeding the recommended dose of 112.5 oral MMEs[3]
• Proportion of postoperative patients with opioid discharge prescriptions exceeding 5 days
• Proportion of thyroidectomy and parathyroidectomy postoperative patients who do not receive new opioid prescriptions from the surgeon's office within 7 days of surgery including discharge prescriptions. This outcome excludes continuation of previous, chronic opioid therapy
• Proportion of postoperative patients with opioid prescriptions exceeding 50 oral MMEs/day when new postoperative discharge prescriptions are added to existing opioid therapy

Research question
Does the implementation of a quality improvement bundle including patient education, provider education, and EHR support increase the proportion of thyroidectomy and parathyroidectomy postoperative patients who are discharged without new opioid prescriptions?

3. Background

Opioid discharge prescriptions predict long-term opioid use
Approximately 99% of postoperative patients receive opioid analgesics, and 14% experience opioid-related adverse effects, which increase hospitalization costs, length of stay, and 30-day hospital readmission.[4-6] Acute pain management with opioids following discharge from the hospital or emergency department is a determinant for chronic opioid use, dependence, and overdose.[7,8] Approximately 6% of patients persistently use new opioid therapy at 90 to 180 days after major or minor surgery. The incidence of new, persistent opioid use was 5% after thyroidectomy and 6% after parathyroidectomy procedures.[9]

Optimal opioid discharge prescriptions after surgery
For general surgery, the optimal duration of initial opioid discharge prescriptions is 4 to 9 days.[10] Patients undergoing thyroid and parathyroid surgeries can be discharged from the hospital with prescriptions as low as 20 to 70 oral morphine milligram equivalents (MMEs), and approximately 93% of patients will consume less than 100 oral MMEs within 2 weeks following hospital discharge.[11,12] Recently, a multidisciplinary expert panel with patient engagement published surgery specific recommendations suggesting less than 112.5 oral MMEs for opioid discharge prescriptions following thyroidectomy procedures.[3] However, up to 33% to 58% of patients undergoing thyroid and parathyroid surgeries do not need any opioid discharge prescriptions following surgery.[11] Quality programs that optimized perioperative MMA regimens, provider education, shared decision making, and patient education and empowerment have successfully reduced the proportion of patients discharged with opioid prescriptions to less than 5%.[1,13]
In 2018, our team developed a list of quality indicators for the Houston Methodist Opioid Stewardship Program.[14] Six quality indicators focused on appropriate patient discharge on an adequate acute pain management regimen:

- Proportion of opioid discharge prescriptions with a duration greater than 7 days
- Proportion of discharged patients with opioid discharge prescriptions ≥ 50 MME per day

- Proportion of patients discharged on opioids who received education on opioid purpose, adverse effects, monitoring, secure storage and disposal, and alternatives
- Proportion of patients discharged from the hospital with opioid discharge prescriptions
- Proportion of patients with opioid discharge prescriptions given in the emergency department that exceed 3 to 5 days
- Proportion of patients discharged from the emergency department with opioid discharge prescriptions

This quality improvement study directly addresses these quality indicators and aims to optimize opioid discharge prescriptions after thyroid and parathyroid surgery.

4. Study Design

Overview

This quality improvement, quasi-experimental study will be conducted in Houston Methodist Hospital to compare opioid discharge prescribing practices before and after the implementation of the quality improvement bundle that is expected to occur in quarter 4 of 2020 and quarter 1 of 2021. The pre-implementation (baseline) data on patients treated in 2018 and 2019 will be collected by the study team.

Patient population

The historical control data will include 160 patients who underwent a thyroidectomy or a parathyroidectomy procedure from January 2018 to December 2019. Twenty patients will be randomly sampled from each of the 8 quarters during the baseline period to provide historical trend leading up to the implementation. The post-implementation group will consist of the first 80 qualifying patients accrued over a 4- to 6-month period following the deployed bundle. Patients who underwent a thyroidectomy or parathyroidectomy procedure will be retrospectively identified using the ACS National Surgical Quality Improvement Program (ACS NSQIP®) data base and data reports from the Houston Methodist information technology department.

Study procedure

Table 1. Study procedure

Development	• Team recruitment • Protocol development • EHR enhancements development • Educational documents development
Approval	• IRB approval • Relevant patient care and quality committees
Implementation	• EPIC information technology team engagement • Resident, nurse practitioner, and physician assistants education • Testing the EHR enhancements
Evaluation	• Data collection • Data analysis
Results report	• Manuscript preparation • Report data back to HM committees for stakeholder engagement and follow-up to optimize appropriate perioperative pain management regimens

Study timeline

This study will start on January 1, 2020 and will end on Dec 31, 2021. Historical data collection will occur during quarters 1 to 2. Historical data will be analyzed and used to inform development of study interventions. Interventions will be developed and deployed during quarter 4 of 2020 and quarter 1 of 2021. Preliminary data estimates that approximately 300 thyroidectomy and parathyroidectomy surgeries are performed annually at Houston Methodist Hospital, which is approximately 25 per month. Following deployment, data on 80 post-implementation patients will be accrued over a 4- to 6-month period (quarters 2 and 3 of 2021). The analysis and final report will be completed and submitted to the University of Houston prior to December 31, 2021.

Table 2. Estimated project timeline

Activity	2020				2021			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Historical data collection	X	X						
Develop bundle		X	X					
Implement bundle				X	X			
Post-implementation patient accrual						X	X	
Analysis							X	X
Submit final report to University of Houston								X

Statistical analysis plan

Primary analysis

The primary outcome of this study is binary. The primary analysis will be a multiple variable logistic regression on this binary outcome that will be adjusted for candidate covariates. The list of candidate covariates includes: (1) pre-hospital opioid use (opioid naïve vs. non-naïve), (2) ASA score, (3) age, (4) surgery complexity, (5) surgery duration, (6) cancer diagnosis, (7) AUC of postoperative pain scores documented up to 12 hours prior to discharge, and (8) postoperative oral opioid MMEs (or number of opioid doses) administered up to 12 hours prior to hospital discharge.

Sample size estimates

The historical control data will include 160 patients who underwent a thyroidectomy or a parathyroidectomy procedure from January 2018 to December 2019. Twenty patients will be randomly sampled from each of the 8 quarters during the baseline period to provide historical trend leading up to the implementation. Using preliminary data, investigators estimate that 35% of thyroidectomy and parathyroidectomy patients were discharged without new opioid prescriptions in 2018 and 2019.

The quality improvement bundle is expected to result in an absolute risk increase of 20% in the primary outcome. Table 3 shows estimated sample sizes that were calculated before pre-implementation (baseline) data was collected and that were not adjusted for potential confounders.

Table 3. Estimated samples sizes for post-implementation cohort to achieve 80% power

Estimated historical control proportion	Absolute risk increase	Estimated post-implementation proportion	Estimated post-implementation sample size
35%	20%	55%	68
40%	20%	60%	70
45%	20%	65%	69

The estimates provided in the table above assumed a historical control sample size of 160 patients and estimated samples sizes needed to obtain 80% power using a 2-sided alpha of 0.05

After obtaining pre-implementation (baseline) data, investigators determined that the historical control proportion was 20%. Preliminary models were built to evaluate the effect of potential confounders on the proportion of patients who do not receive new opioid prescriptions at discharge. It was determined that 19% to 25% of the variability in the outcome was explained by the model (R^2 of 0.19 to 0.25). To ensure adequate sample size, a conservative approach was used, and sample size was adjusted by the variance inflation factor ($1/1-R^2$).[15,16] For a historical group with a sample size of 160 and a baseline proportion of 20%, a post-implementation sample size of 80 patients would provide 80% power to detect an absolute risk increase of 20%.

Statistical analyses will be conducted using STATA version 15 (StataCorp LP, College Station, Texas). All patient demographics and baseline characteristics will be summarized using descriptive statistics. Continuous variables will be reported using mean (and standard deviation) or median (and interquartile range). Categorical variables will be reported with counts and percentages. Confidence intervals at the 95% level will be calculated for proportions of patients with primary and secondary outcomes.

Secondary analysis

Trends of the primary outcome will be described over each quarter of the pre-implementation, control cohort starting January 2018 until December 2019. Monthly trends will also be described for the post-implementation cohort in quarters 2 and 3 of 2021.

Primary endpoint

The primary endpoint will be the proportion of thyroidectomy and parathyroidectomy postoperative patients who do not receive new opioid prescriptions at discharge. This outcome excludes continuation of previous, chronic opioid therapy.

Secondary endpoints

• Proportion of thyroidectomy and parathyroidectomy patients with opioid discharge prescriptions exceeding the recommended dose of 112.5 oral MMEs[3]
• Proportion of postoperative patients with opioid discharge prescriptions exceeding 5 days
• Proportion of thyroidectomy and parathyroidectomy postoperative patients who do not receive new opioid prescriptions from the surgeon's office within 7 days of surgery including discharge prescriptions. This outcome excludes continuation of previous, chronic opioid therapy
• Proportion of postoperative patients with opioid prescriptions exceeding 50 oral MMEs/day when new postoperative discharge prescriptions are added to existing opioid therapy

Data management

Data sources and collection

This study will rely on secondary data collection from the medical record. Investigators will request a NSQIP data report from the department of surgery and a report from the Houston Methodist information technology department containing a list of patients who had a thyroidectomy or parathyroidectomy procedure within the study time frame. Investigators will also request data reports for some data elements from the Information Technology department. Supplemental data elements will be collected from the Houston Methodist electronic medical record (EPIC) through manual chart review. In addition to data collection from EPIC, investigators ask for permission to collect data on opioid medications filled by patients after discharge. This data would be collected from the Texas Prescription Monitoring Program (PMP) that collects and monitors prescription data for all Schedule II, III, IV, and V Controlled Substances dispensed by a pharmacy in Texas or to a Texas resident from a pharmacy located in another state.
In addition to securely storing study data on the HM secure intranet, investigators ask for permission for study data capture, storage, and retrieval on Houston Methodist's secure and password protected REDCap instance (Holly Hall Datacenter). Data collection forms may also be built in Microsoft Excel® or Microsoft Access® to collect and record data.

Data elements

Data elements that will be collected for this study are described in table 4.

Table 4. Study data scope

Variables	Description	Source
Demographics		
Age in years	[0 to 115] Age at surgery encounter	IT data report
Gender	Male Female	IT data report
Height in inches	[0 to 100]	IT data report
Weight in kg	[0 to 500]	IT data report
Allergies		EPIC chart review
Race	White/Caucasian Black/African American Asian Other	IT data report
Baseline assessments		
Surgery date		IT data report NSQIP data base
Surgery type	Thyroid lobectomy Total thyroidectomy Unilateral parathyroidectomy Bilateral parathyroidectomy Both thyroidectomy and parathyroidectomy	NSQIP data base EPIC chart review
Surgery indication		EPIC chart review
Admission/discharge/transfer events (ADT)	Dates and hospital locations	IT data report EPIC chart review
Encounter type	Inpatient, outpatient, observation	IT data report EPIC chart review

Variables	Description	Source
ICD10 diagnosis and procedure codes		IT data report
Other surgeries performed during the same encounter		IT data report EPIC chart review
Comorbidities	e.g., kidney disease, liver disease, cancer, chronic pan …	IT data report EPIC chart review
Home/prior to admission medications		IT data report EPIC chart review
ASA score		IT data report EPIC chart review
Patient protected health information		
Name		IT data report
MRN		IT data report
VisitID/EncounterID		IT data report
Date of birth		IT data report
Date/time of admission		
Surgery data variables		
Anesthesia events	Induction, intubation, post-anesthesia assessments	IT data report EPIC chart review
Surgery duration		IT data report EPIC chart review
Surgery-related data	Surgery variables (techniques, complexity, incision length, intraoperative complications…) from OP notes and brief OP notes	IT data report EPIC chart review
Vitals and pain assessments throughout the hospital encounter (including OR)		
Vital signs	Blood pressure, heart rate, respiratory rate…	IT data report EPIC chart review
Pain scores	All scales documented: Numerical pain rating scale, FACES, CPOT, Wong-Baker…	IT data report EPIC chart review
Pain descriptors in flowsheets	Location, onset, type, frequency, orientation…	IT data report EPIC chart review
Function assessments in flowsheets	Effect of pain on daily activities	IT data report EPIC chart review
POSS scores		IT data report EPIC chart review
Medication data variables throughout the hospital encounter (including OR)		
All medication orders and administrations throughout the hospital encounter	Medication name, dose, route, frequency, order start/end time, administration time, rate changes, order set/order panel (for IV medications, PO medications, continuous infusions, PCA, PCEA, inhaled medications, patches)	IT data report EPIC chart review
Discharge data elements		
Discharge medications	New prescriptions and previous medications resumed on discharge (medication name,	IT data report EPIC chart review

Variables	Description	Source
	dose, route, frequency, quantity, refills, duration of use)	
Authorizing provider type	MD, DO, NP, PA	IT data report EPIC chart review
Discharge order set use		IT data report EPIC chart review
Medical team's follow up plan	Discharge summary notes	IT data report EPIC chart review
Patient communications with medical team via EPIC (emails, phone calls text…)	Medication inquiries and other patient questions	EPIC chart review
Pain assessments and opioid use after surgery	Follow up clinic visits documented in EPIC (1-3 weeks after surgery)	EPIC chart review PMP

5. Study Intervention

No experimental intervention is being deployed by this study.

This quality improvement bundle will be developed and deployed in accordance with standard practices for quality improvement at Houston Methodist. The bundle will provide education to providers and patients and will enhance the electronic health record to provide clinical decision support. After implementation, this quality improvement bundle will become the new standard of care.

6. Drugs, Biologics, Devices

N/A. This study is not intended to evaluate any FDA regulated drug, biologic, or device.

7. Collaborative / Multi-site Research

This study will be conducted at HMH only. All patients will receive care at HMH, and all patient data will be stored at HMH. Collaborators from the University of Houston will provide guidance on study design and analysis, but will not have access to patient-level data.

8. Data Privacy / Confidentiality

Houston Methodist policies for Protected Health Information will be followed, including all requirements for physical and electronic data security, use of encrypted devices, and HM password protected servers.

Throughout the conduct of this study, all required data will be recorded on approved electronic data collection forms that have been specifically designed to record all data pertinent to this clinical investigation. Data will include one or more of the 18 PHI identifiers. All electronic data will be stored within the corporate network on a secure server. Only Houston Methodist Research Institute credentialed investigators listed under this IRB submission will have access to identifiable patient data. Any paper records generated from this study will be stored in a locked HM office of an HM investigator.

PHI of medical record number (MRN), hospital encounter number (visitID), and date of admission or surgery will be used by the investigators to locate the charts of eligible patients in the EHR system to conduct manual chart review. The unique identifiers of MRN and visitID will be used to link data sheets in the study database and conduct relational database analyses.

The clinical investigator is responsible for maintaining adequate and accurate records as specified in Essential Documents for the Conduct of a Clinical Trial (section 8 of the ICH Guideline for Good Clinical Practice) to enable the conduct of the study data collection to be fully documented, and the study data to be subsequently verified. Upon study termination and after all analyses are complete, all records and data sets will be archived and destroyed in accordance with HM research policies.

During the course of this study, Houston Methodist investigators will collaborate with external investigators from the funding agency (University of Houston, College of Pharmacy):

1. J. Douglas Thornton, PhD, PharmD, BCPS, Assistant Professor of Pharmaceutical Health Outcomes and Policy
2. Matthew Wanat, PharmD, BCPS, BCCCP, FCCM, Clinical Associate Professor of Pharmacy Practice

When necessary, only de-identified and aggregated data reports will be shared with these external collaborators and with the funding agency to protect patients' confidentiality.
The funding agency will not have access to the study database, patient-level economic data, or protected health information.

No audio/video recordings or photographs will be used during the course of this study.

A list of all patients who underwent a thyroid or parathyroid surgery during the study time frame will be extracted from EPIC by HM Health Information Technology. Protected health information of name, MRN, CSN, date of birth, admission/discharge/surgery dates, and relevant drug administration dates will be collected. The PHI will be used by investigators to locate patient records in the EHR system to conduct manual chart review. The unique identifiers such as MRN, CSN and DOB will be used to link data sheets in the study database and conduct random chart audits for data quality assurance.

Identifier (or parts of)	Recorded	Disclosed	Comment
Names	Yes	No	Investigators use name during chart review to confirm that the correct patient's chart was opened for data collection.
All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and elements of dates (including year) indicative of such age	Yes	No	
Medical record numbers	Yes	No	

Data for all patients who underwent a thyroid or parathyroid surgery during the study time frame will be extracted from EPIC by HM Health Information Technology. PHI of name, MRN, CSN, date of birth, admission/discharge/surgery dates, and relevant drug administration dates will be collected.

Houston Methodist policies for Protected Health Information will be followed, including all requirements for physical and electronic data security, use of encrypted devices, and HM password protected servers.

Throughout the conduct of this study, all required data will be recorded on approved electronic data collection forms that have been specifically designed to record all data pertinent to this clinical investigation. Data will include one or more of the 18 PHI identifiers. All electronic data will be stored within the corporate network on a secure server. Only Houston Methodist Research Institute credentialed investigators listed under this IRB submission will have access to identifiable patient data. Any paper records generated from this study will be stored in a locked HM office of an HM investigator.

The clinical investigator is responsible for maintaining adequate and accurate records as specified in Essential Documents for the Conduct of a Clinical Trial (section 8 of the ICH Guideline for Good Clinical Practice) to enable the conduct of the study data collection to be fully documented, and the study data to be subsequently verified. Upon study termination and after all analyses are complete, all records and data sets will be archived and destroyed in accordance with HM research policies.

When necessary, only de-identified and aggregated data reports will be shared with external collaborators and with the funding agency to protect patients' confidentiality. The funding agency will not have access to the study database, patient-level economic data, or protected health information.

9. Data and Specimen Banking

This retrospective study does not involve any specimen banking.

10. Study Population

N/A. This study only involves secondary data collection from the medical record.

11. Screening and Recruitment

N/A. This study only involves secondary data collection from the medical record.

12. Withdrawal of Subjects

N/A. This is a retrospective study will collect information from the medical record for patients who have been already treated.

13. Provisions to Protect the Privacy Interests of Subjects

Houston Methodist policies for Protected Health Information will be followed, including all requirements for physical and electronic data security, use of encrypted devices, and HM password protected servers.

Throughout the conduct of this study, all required data will be recorded on approved electronic data collection forms that have been specifically designed to record all data pertinent to this clinical investigation. Data will include one or more of the 18 PHI identifiers. All electronic data will be stored within the corporate network on a secure server. Only Houston Methodist Research Institute credentialed investigators listed under this IRB submission will have access to identifiable

patient data. Any paper records generated from this study will be stored in a locked HM office of an HM investigator.

14. Risks to Subjects

The only risk to patients of this study is potential, unintended disclosure of protected health information.

To prevent potential, unintended disclosure, investigators will secure health information and study data on password protected HM computers, on the password protected HM intranet servers, and in locked investigator offices at HMH. Only Houston Methodist Research Institute credentialed investigators listed in this IRB submission will have access to the data and records. De-identified, aggregated data reports may be shared with external investigators (faculty from the University of Houston, College of Pharmacy), if needed.

15. Potential Benefits

This retrospective study does not have any direct benefits as patients were treated with standard of care. However, this study is evaluating the impact of a quality improvement bundle that is expected to improve the safety of pain management after thyroid and parathyroid surgery and reduce opioids in the community, while maintaining optimal pain management.

16. Financial and Economic Issues

N/A

17. Data Safety Plan

This research involves secondary use of data only.

18. Informed Consent Documentation and Process

Investigators request a waiver of informed consent for this retrospective research that uses existing records.

19. Waiver of Informed Consent and /or Authorization

Investigators are requesting a waiver of informed consent for this project.

1. **The study is no more than minimal risk to the participants**
   The only risk to patients of this study is potential, unintended disclosure of protected health information.
   To prevent potential, unintended disclosure, investigators will secure health information and study data on password protected HM computers, on the password protected HM intranet servers, and in locked investigator offices at HMH. Only Houston Methodist Research Institute credentialed investigators listed in this IRB submission will have access to the data and records. De-identified, aggregated data reports may be shared with external investigators (faculty from the University of Houston, College of Pharmacy), if needed.

2. **The research could not practicably be carried out without the requested waiver of consent**

Investigators will collect data retrospectively. Patients would have been treated and left the hospital after surgery. Due to the retrospective nature, it may not feasible for investigators to contact patients to obtain consent.

3. **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format**
   PHI will be used by the investigators to locate the charts of eligible patients in the EHR system to conduct manual chart review. The unique identifiers of MRN and VisitID will be used to link data sheets in the study database.

4. **The waiver will not adversely affect the rights and welfare of the participants**

   At the time of data collection for this study, patients would have been already discharged after receiving standard of care perioperative pain management.

5. **Whether participants will be provided with additional pertinent information after participation (i.e, whether debriefing will occur).**

   Patients will not be informed that their data is being collected for this retrospective study. Debriefing is not applicable to this study.

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