Automated Data Pipelines for Rapid Response to MHRA Alerts:

A Case Study of Peri-operative Modified-Release Opioids

Dylan Whitaker

8th May 2026, CDT training week



The problem



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022272 **NDA APPROVAL**

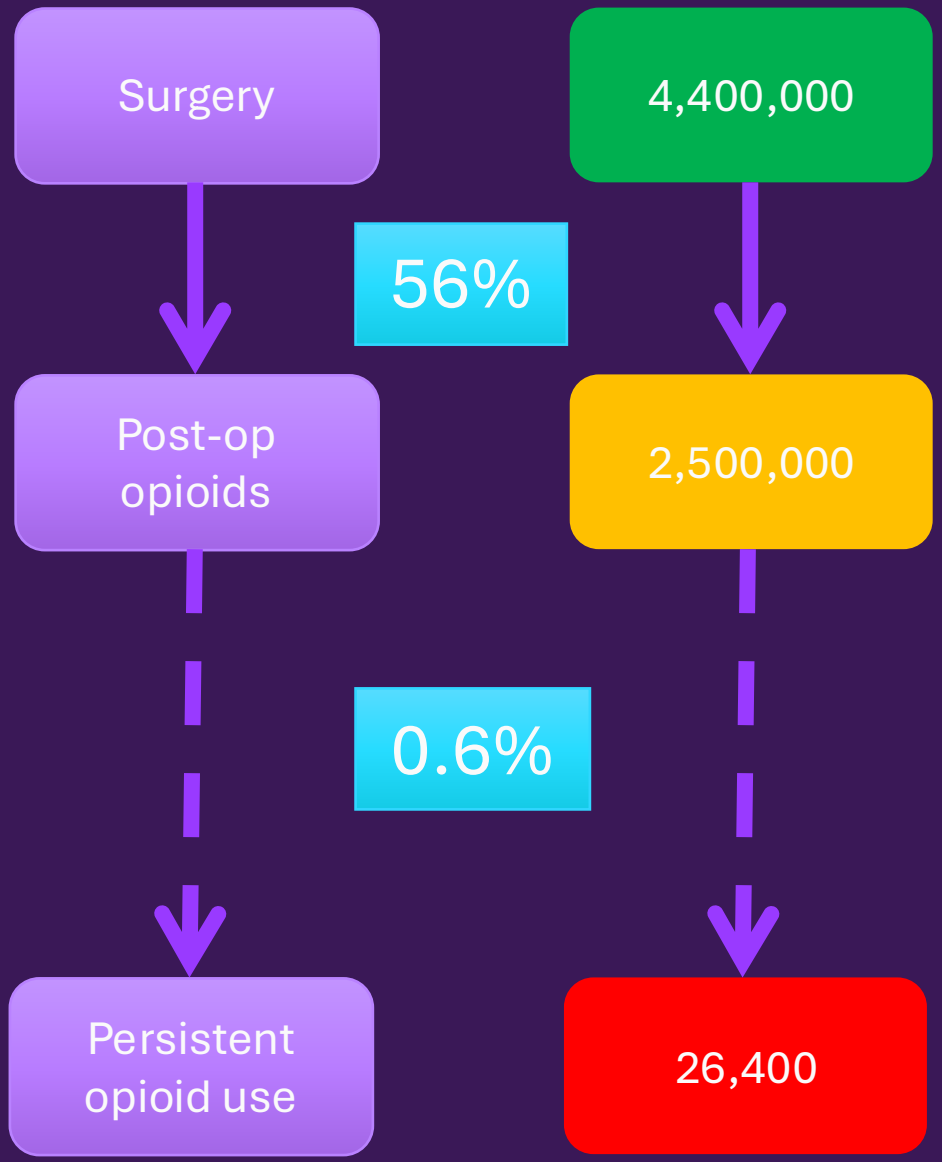
Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901-3431

Attention: Craig Landau, M.D.
CMO & VP Clinical, Medical & Regulatory Affairs

Dear Dr. Landau:

Please refer to your new drug application (NDA) dated, received November 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OxyContin (Oxycodone Hydrochloride Controlled-Release) Tablets.

Post-operative use



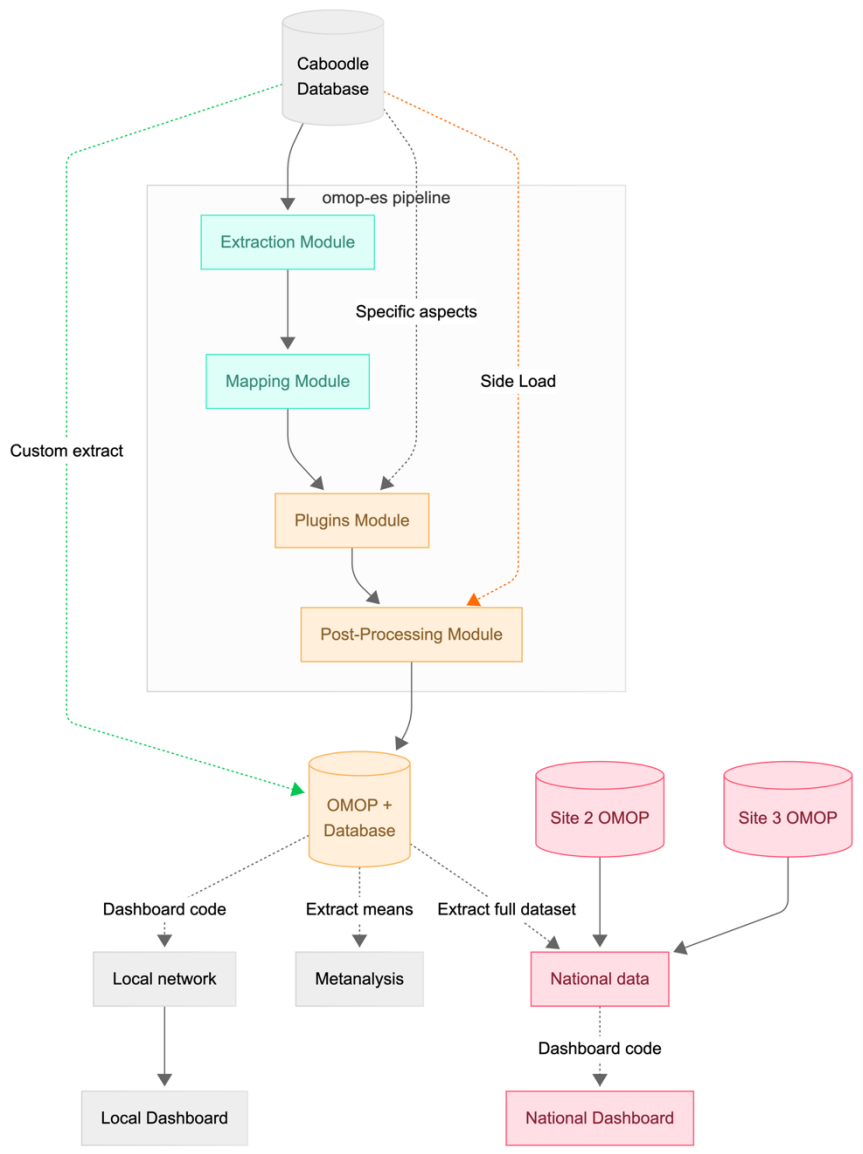
Medicines & Healthcare products Regulatory Agency

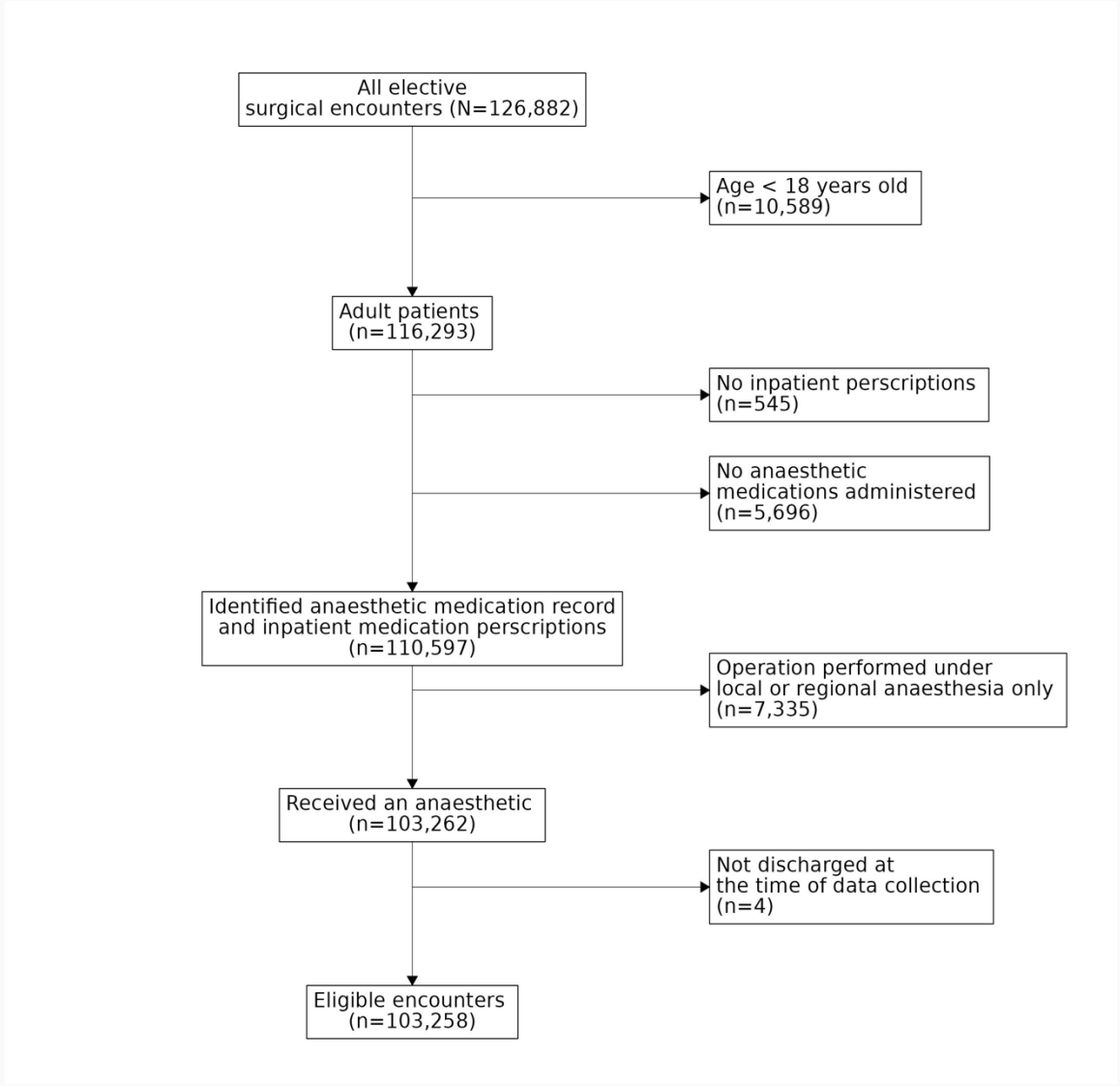
Modified Release Opioids and Treatment of Post-operative Pain

Public Assessment Report

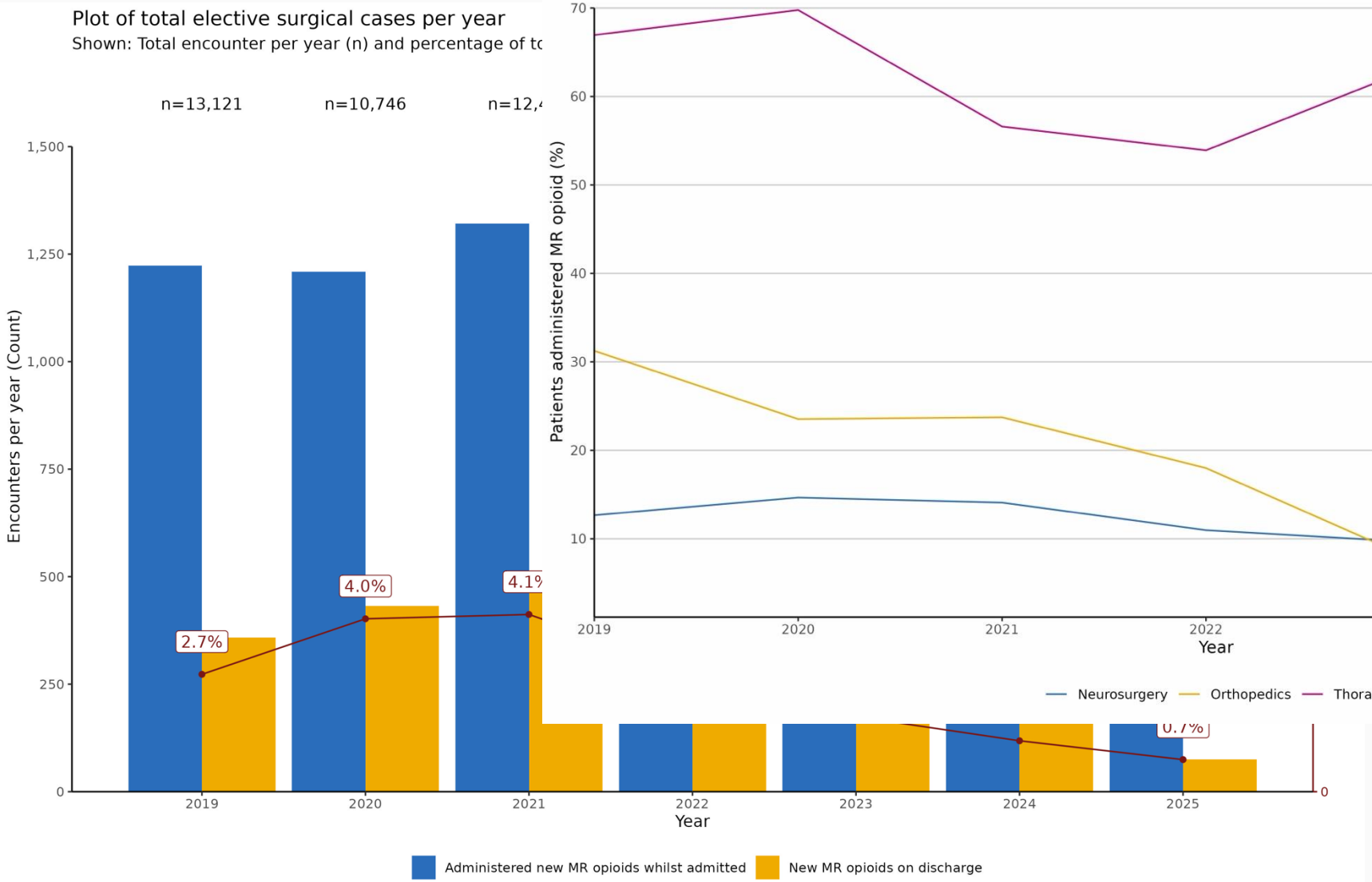
Published 12 March 2025

Infrastructure

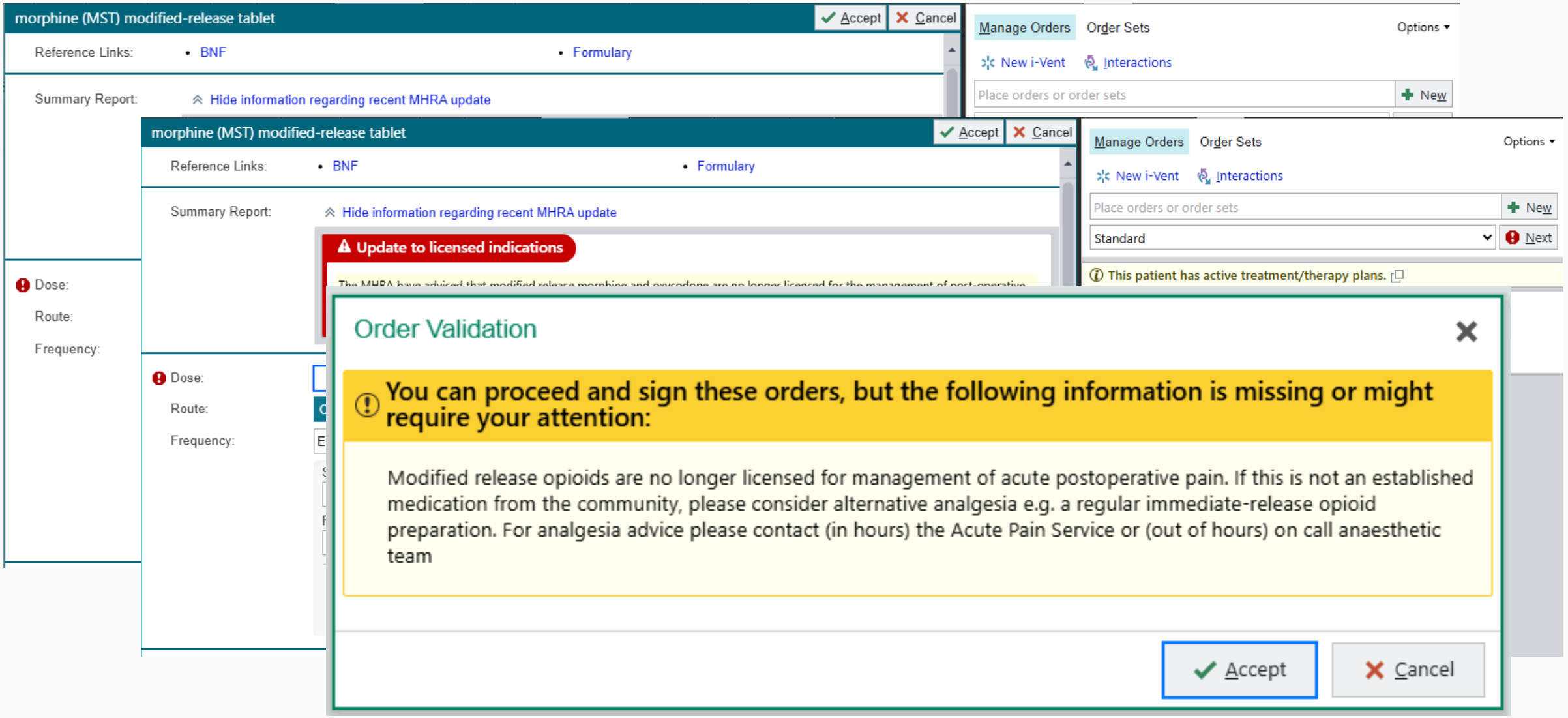




Results


Plot of total elective surgical cases per year
Shown: Total encounter per year (n) and percentage of tc
n=13,121
n=10,746
n=12,
Encounters per year (Count)
1,500
1,250
1,000
750
500
250
0
2.7%
4.0%
4.1%
0.7%
2019
2020
2021
2022
2023
2024
2025
Year
Administered new MR opioids whilst admitted
New MR opioids on discharge

Plot of modified release opioid new administration during admission by speciality per year
Top 3 specialities shown
Patients administered MR opioid (%)
70
60
50
40
30
20
10
2019
2020
2021
2022
2023
2024
2025
Year
Neurosurgery
Orthopedics
Thoracics


morphine (MST) modified-release tablet
Accept
Cancel
Reference Links:
BNF
Formulary
Summary Report:
Hide information regarding recent MHRA update
Manage Orders
Order Sets
Options
New i-Vent
Interactions
Place orders or order sets
New
Dose:
Route:
Frequency:
Update to licensed indications
Standard
Next
This patient has active treatment/therapy plans.
Order Validation
You can proceed and sign these orders, but the following information is missing or might require your attention:
Modified release opioids are no longer licensed for management of acute postoperative pain. If this is not an established medication from the community, please consider alternative analgesia e.g. a regular immediate-release opioid preparation. For analgesia advice please contact (in hours) the Acute Pain Service or (out of hours) on call anaesthetic team
Accept
Cancel

Onwards

Future work

- Working with clinical teams teams
- Missing data
- Ongoing data quality and engineering




```{sql, connection=conn}

SELECT TOP 10
*
FROM MedicationDim
WHERE Name = 'FENTANYL 100MICROGRAMS/10ML FOR RECOVERY SYRINGE'

```

MedicationKey <S3: integer64>	MedicationEpicId <dbl>	Name <chr>	GenericName <chr>	SimpleGenericName <chr>
169602	4084582	FENTANYL 100MICROGRAMS/10ML FOR RECOVERY SYRINGE	morphine sulfate 100mg/100ml infusion bag	morphine sulfate

Questions?

Supported with thanks by

NIHR | Central London Patient Safety Research Collaboration

NHS
University College London Hospitals
NHS Foundation Trust

SAFEHR
Secure | Anonymised | Fair Electronic Health Records

Funded by

UKRI Engineering and Physical Sciences Research Council

NIHR | University College London Hospitals Biomedical Research Centre

UCL

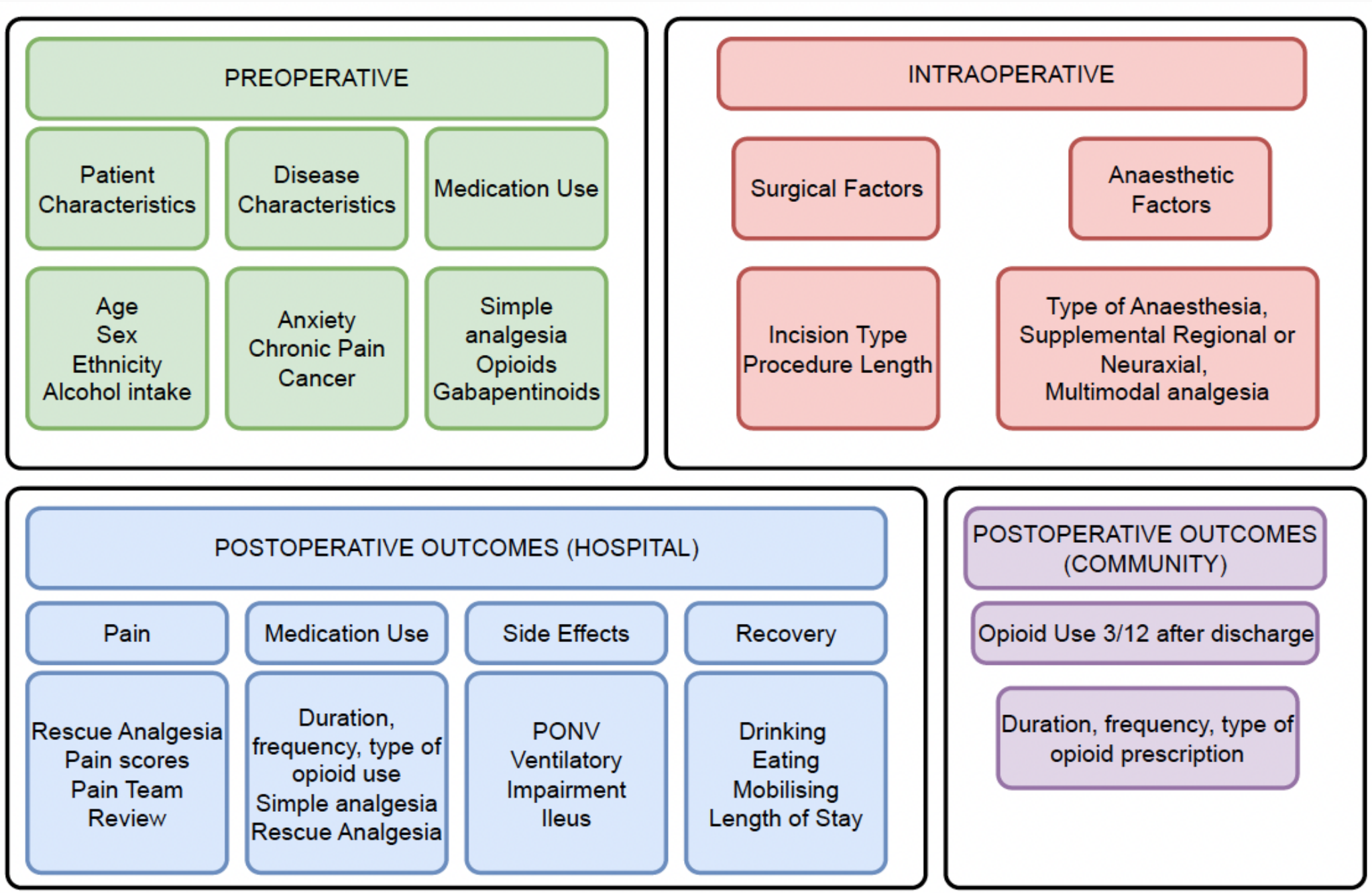
References

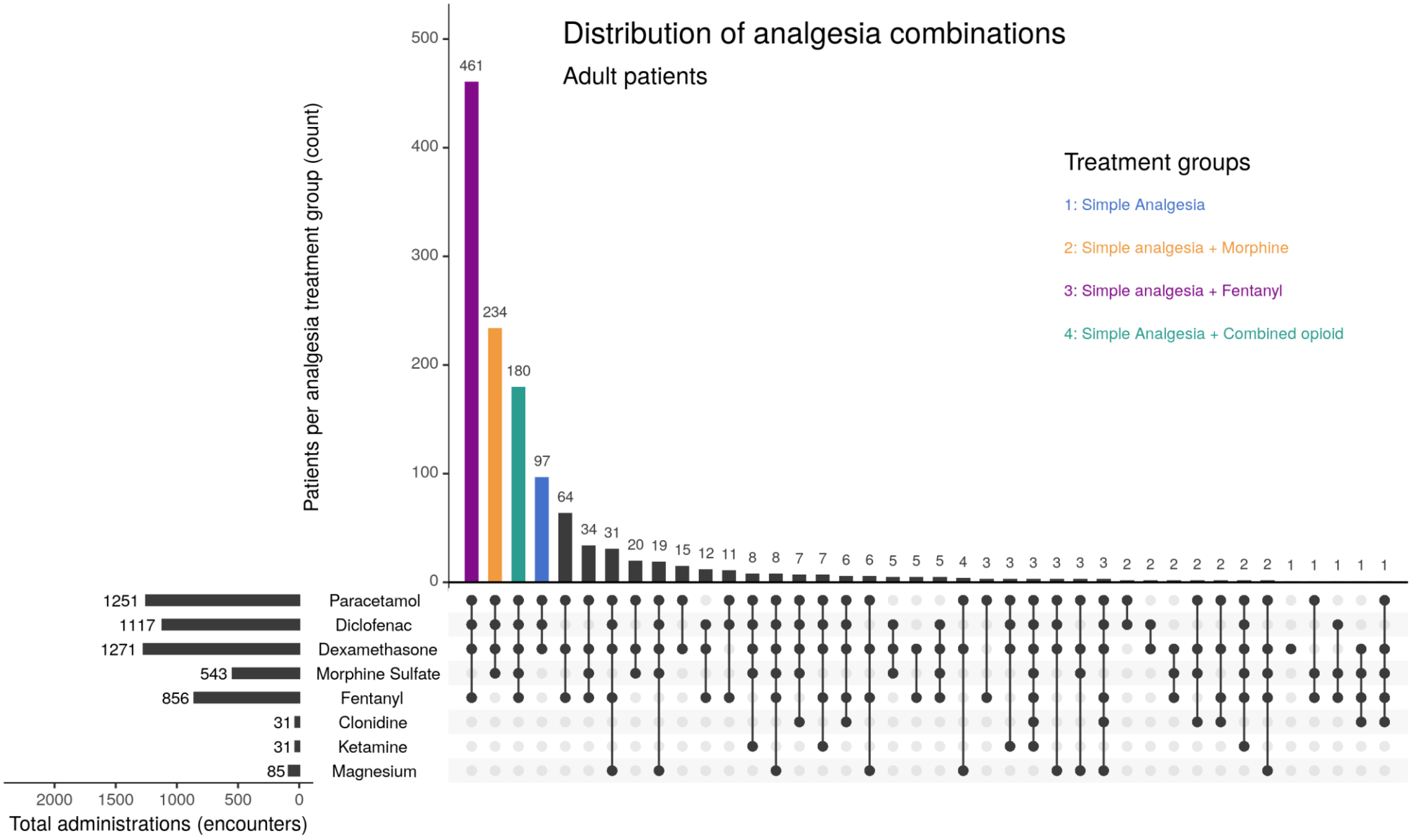
[1] – Time newspaper, online article https://time.com/4634809/photo-opioid-addiction/

[2] – Roberts et al, Bj Pain, Is England facing an opioid epidemic?, https://pmc.ncbi.nlm.nih.gov/articles/PMC10278447/

[3] - Norn S, Kruse PR, Kruse E. Opiumsvalmuen og morfin gennem tiderne [History of opium poppy and morphine]. Dan Medicinhist Arbog. 2005;33:171-84. Danish. PMID: 17152761.

[4] - Brat GA, Agniel D, Beam A, et al. Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study. *BMJ (Online)* 2018;360:j5790 doi:10.1136/bmj.j5790.


PREOPERATIVE
Patient Characteristics
Disease Characteristics
Medication Use
Age
Sex
Ethnicity
Alcohol intake
Anxiety
Chronic Pain
Cancer
Simple analgesia
Opioids
Gabapentinoids
INTRAOPERATIVE
Surgical Factors
Anaesthetic Factors
Incision Type
Procedure Length
Type of Anaesthesia, Supplemental Regional or Neuraxial, Multimodal analgesia
POSTOPERATIVE OUTCOMES (HOSPITAL)
Pain
Medication Use
Side Effects
Recovery
Rescue Analgesia
Pain scores
Pain Team Review
Duration, frequency, type of opioid use
Simple analgesia
Rescue Analgesia
PONV
Ventilatory Impairment
Ileus
Drinking
Eating
Mobilising
Length of Stay
POSTOPERATIVE OUTCOMES (COMMUNITY)
Opioid Use 3/12 after discharge
Duration, frequency, type of opioid prescription


Distribution of analgesia combinations
Adult patients
Patients per analgesia treatment group (count)
500
400
300
200
100
0
461
234
180
97
64
34
31
20
19
15
12
11
8
8
7
7
6
6
5
5
5
4
3
3
3
3
3
3
2
2
2
2
2
2
2
1
1
1
1
1
Treatment groups
1: Simple Analgesia
2: Simple analgesia + Morphine
3: Simple analgesia + Fentanyl
4: Simple Analgesia + Combined opioid
1251
Paracetamol
1117
Diclofenac
1271
Dexamethasone
543
Morphine Sulfate
856
Fentanyl
31
Clonidine
31
Ketamine
85
Magnesium
2000
1500
1000
500
0
Total administrations (encounters)