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BACKGROUND

Using RWD for long-term outcomes, costs and healthcare resources utilization research is increasingly popular and valuable because of:

- 👉 large scale, broad population;
- 👉 longitudinal nature tracking of healthcare utilization over time;
- 👉 broad range of healthcare services (primary, secondary, A&E, inpatient and outpatient);

However:

- 👉 lack clinical detailed information;
- 👉 require the integration and standardization of coding;
- 👉 lost to follow-up due to insurer change.

Evaluating the feasibility of RWD is crucial for ensuring its suitability in addressing specific research questions.

OBJECTIVE

Assess the feasibility of using a claims database representative sample for studying surgical outcomes in Germany from the statutory health insurance perspective.

METHODS

Data Sources: *InGef* representative sample for scientific purposes, which covers approx. 4.7% of the German population. Benchmark using peer-reviewed literature and national hospital database (*InEK* data browser).

Eligible population:

⌚ Jan 2016 - Dec 2022;

Adults with colorectal cancer diagnosis and no other primary tumors;

Colorectal open surgery, laparoscopic or robot-assisted (combination of OPS codes

LAP + (5-987)) and excluding codes for combined open-laparoscopic, peranal and conversions;

📅 Observability 1 year pre- and post-surgery (2015-2023).

Research question

To what extent is the *InGef* representative sample suitable for comparing postoperative long-term health outcomes, healthcare resource utilization, and costs between patients with colorectal cancer undergoing Robotic-Assisted Surgery (RAS), laparoscopic, and open colorectal surgery?

Feasibility study best practices:

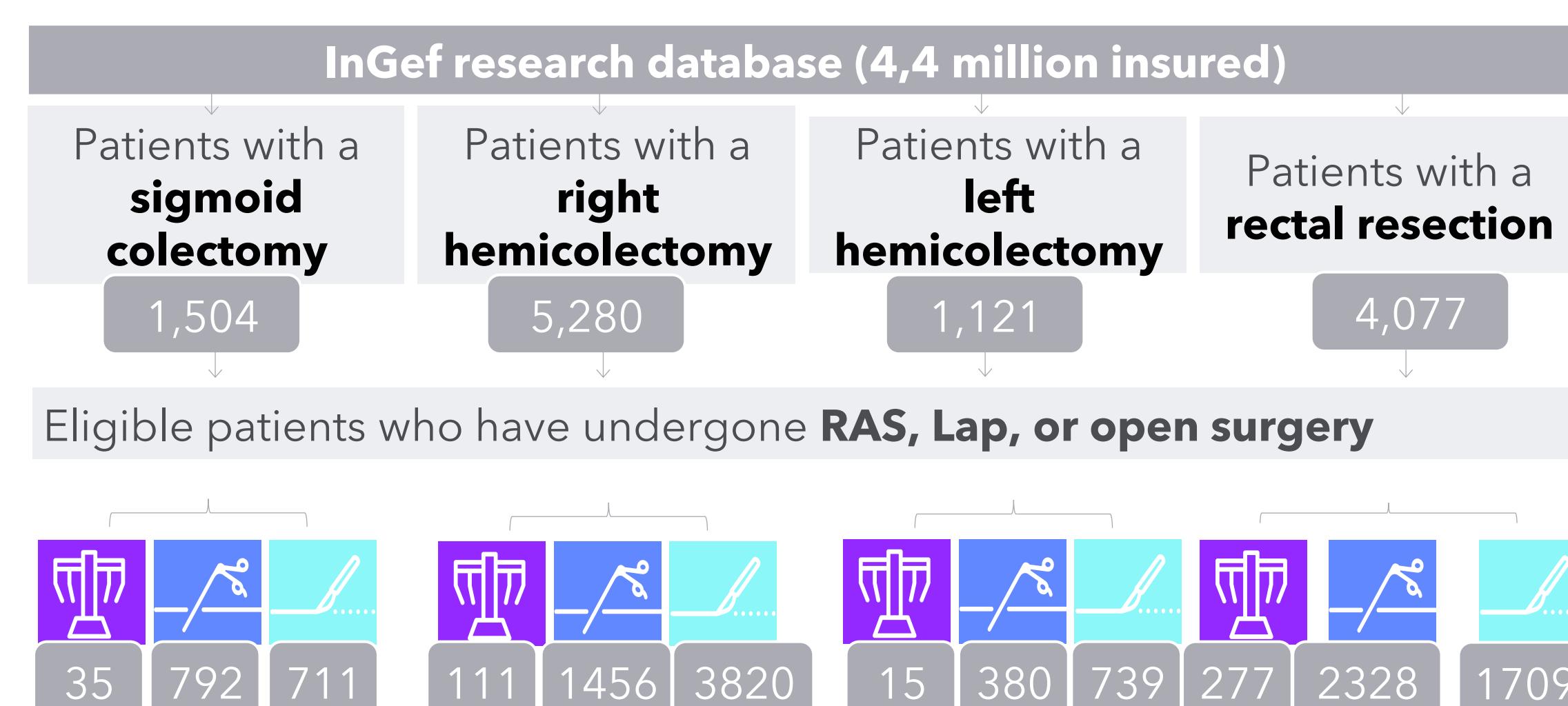
- STEP 1 - Define a **specific research question** to test the feasibility of the database
- STEP 2 - Identify the potential **sources of bias** and **verify** using internal & external validation
- STEP 3 - Define ways to **mitigate** the data issues

RESULTS

Volumes:

The distribution of procedures in the study sample—**63%** colonic resections and **37%** rectal resections, of which 85% involved sphincter preservation—was consistent with reported incidence rates and surgical volumes in recent German studies (Waldmann et al., 2023 [national registry]; Haug et al., 2014 [claims data]; Ghadban et al., 2019 [national DRG data]; Bogner et al., 2023 [federal registry]; Hunger et al., 2024 [hospital sample data]). Across these studies, **61-66%** of patients underwent colonic resections, while **28-38%** underwent rectal resections.

Population of interest flowchart

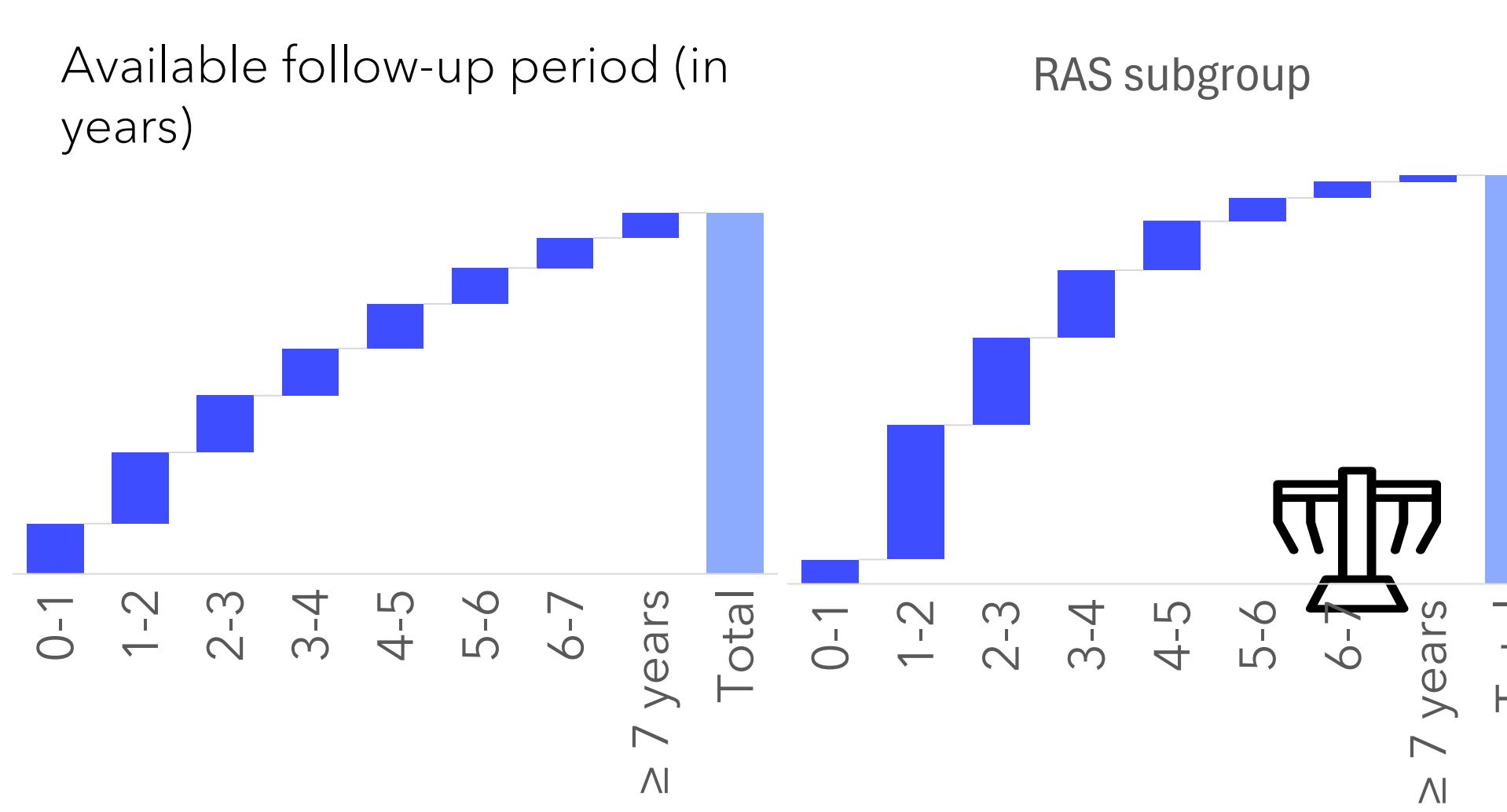


The rate of minimally invasive surgery (MIS) was **31%** for colonic resections and **48%** for rectal resections (2016–2022). In comparison, literature reports MIS rates of 20% for colon and 38% for rectal resections in 2015 (Ghadban et al., 2019 [national DRG data]) and 35% for colon and 46% for rectal resections in data from 2019–2023 (Krieg et al., 2024 [hospital sample data]). Among the MIS cases, the rate of RAS was **2%** for colon and **7%** for rectal resections – slightly below the ~9.8% colorectal RAS rate reported (Krieg et al., 2024). This provides reasonable representation of the national trends.

Longitudinal length:

Most patients across all types of colorectal procedures had available follow-up periods of at least one year (78–100.0%), on average 2.5–3 years for RAS and extends from 3.1–3.7 years for other procedures, providing a reasonable window for observation.

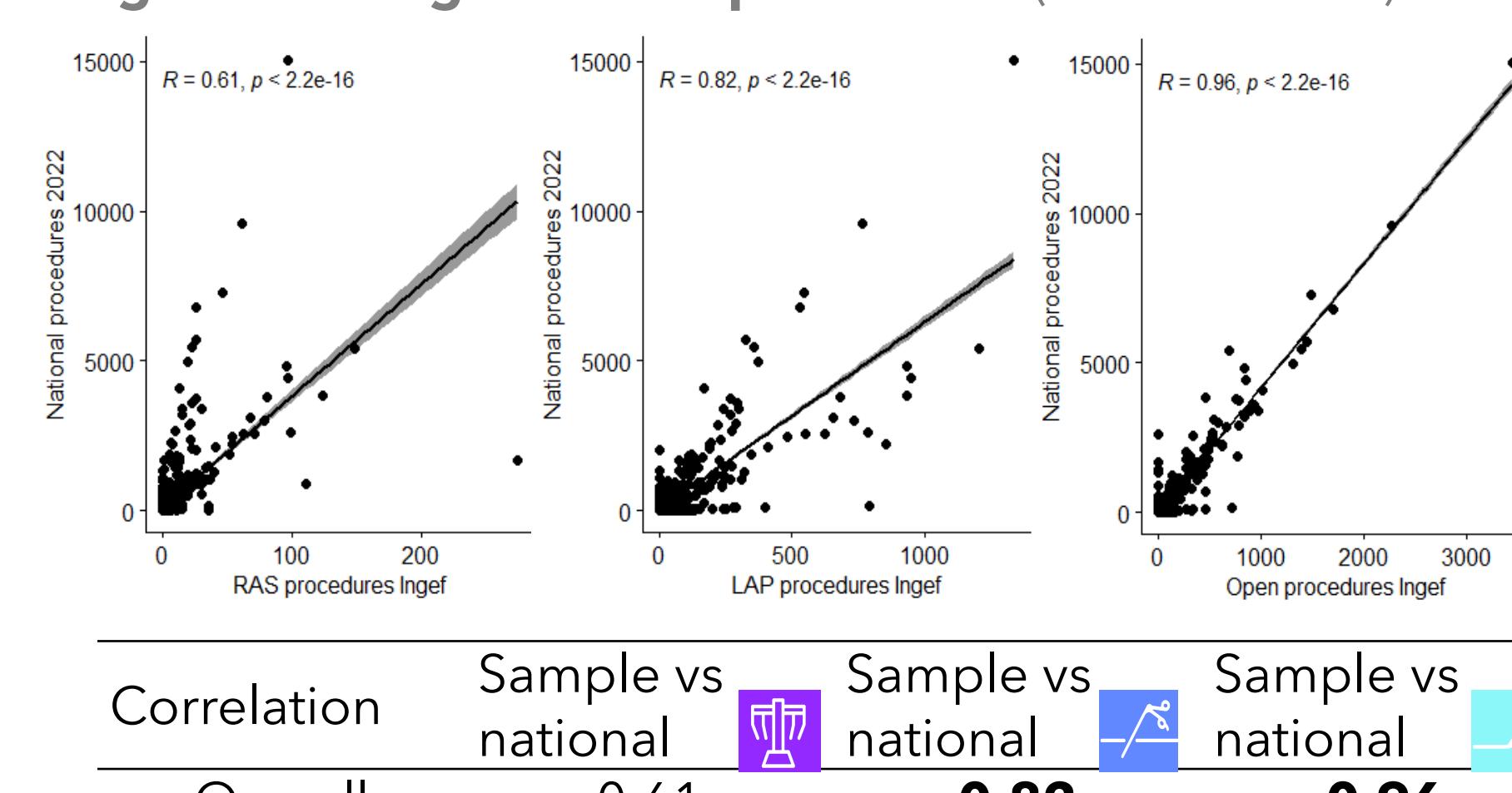
Waterfall of the volume of observations per follow-up window



Coding:

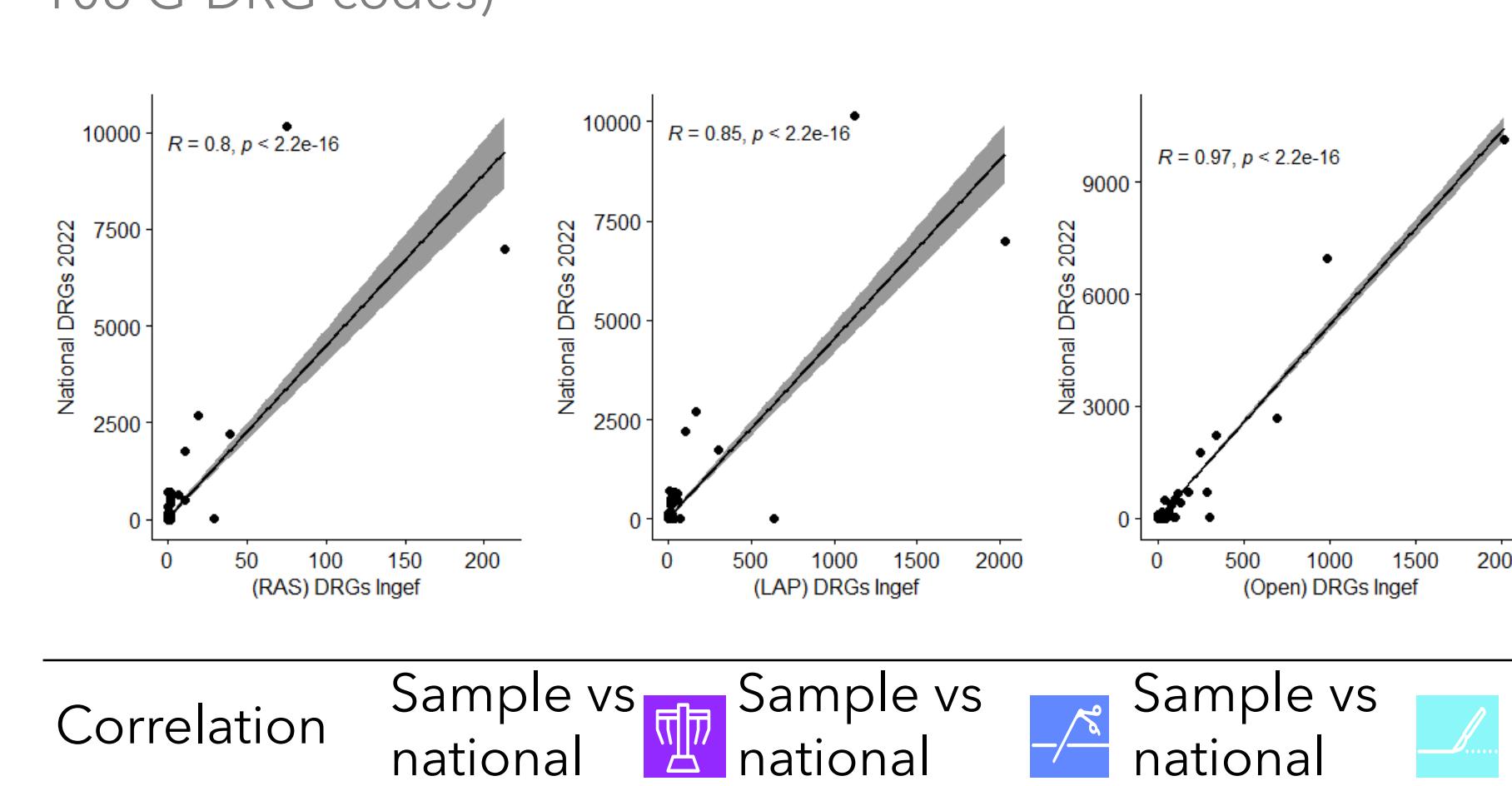
The hospitals in the sample have coding practices that aligned with national benchmark, as evidenced by the strong correlation between procedure OPS and G-DRG coding in the *InGef* claims sample and the national *InEK* database for patients sharing identical diagnoses*.

Correlations of OPS codes of performed procedures and surgeries during index hospitalization (n= 259 codes)



Correlation	Sample vs national	Sample vs national	Sample vs national
Overall	0.61	0.82	0.96
RH	0.78	0.98	0.99
LH	0.61	0.94	0.98
RR	0.81	0.96	0.93
Sig	0.71	0.94	0.96

Correlation of G-DRG coded in index hospitalization (n= 106 G-DRG codes)



Correlation	Sample vs national	Sample vs national	Sample vs national
Overall	0.80	0.85	0.97
RH	0.99	0.99	0.99
LH	0.94	0.96	0.96
RR	0.99	0.97	0.99
Sig	0.42	0.46	0.58

Patient characteristics:

Pre-surgical comorbidity patterns diagnosed were comparable across MIS techniques, whereas some differences were observed between patients who underwent open vs RAS procedures. Post-surgical complications diagnosed follow a similar pattern.

Correlation of ICD-10 codes at baseline (N=221 codes)

Correlation	RAS vs LAP	RAS vs Open	Open vs LAP
Overall	0.90	0.50	0.69
RH	0.90	0.86	0.93
LH	0.69	0.64	0.90
RR	0.91	0.82	0.90
Sig	0.81	0.68	0.88

Correlation of ICD-10 codes at follow-up (N=221 codes)

Correlation	RAS vs LAP	RAS vs Open	Open vs LAP
Overall	0.91	0.49	0.66
RH	0.89	0.79	0.88
LH	0.77	0.72	0.84
RR	0.93	0.74	0.84
Sig	0.84	0.60	0.77

CONCLUSIONS

The representative sample is adequate for the research purposes. Further exploration of data quality is recommended.

* Comparisons with the national benchmark (*InEK*) should be interpreted with caution, as patient selection in the benchmark is based only on diagnosis and surgical procedure, without excluding patients with additional primary tumors or those treated for recurrent disease.

References:

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