Guidance for improving the transparency of studies re-using health data

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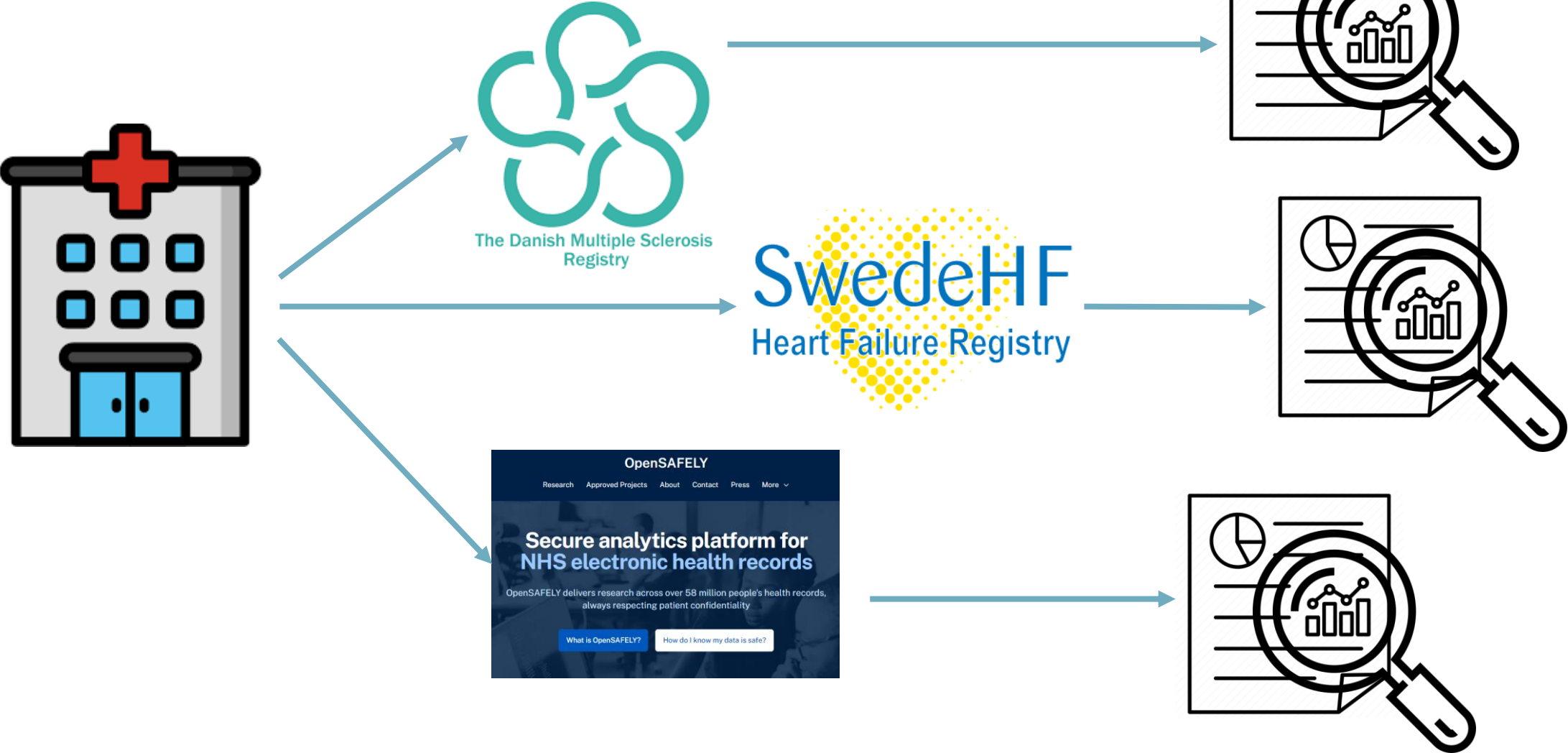BIH Berlin Institute of Health @Charité

GOAL OF THE STUDY

Mapping the available **guidance** for improving the **transparency** of studies that make **secondary use of health data**

1. What is the secondary use of health data?
2. What is transparency?
3. What is guidance?

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What is the secondary use of health data?

19.06.2024   Improving transparency in Studies that Re-use Health Data

What is transparency?

Three pillars:

- Registration

- Reporting (Methods + Results)

- Sharing (Data + Code)

What is guidance?

Types of guidance:

- Calls
- Justifications
- Recommendations

Analysis of guidance:
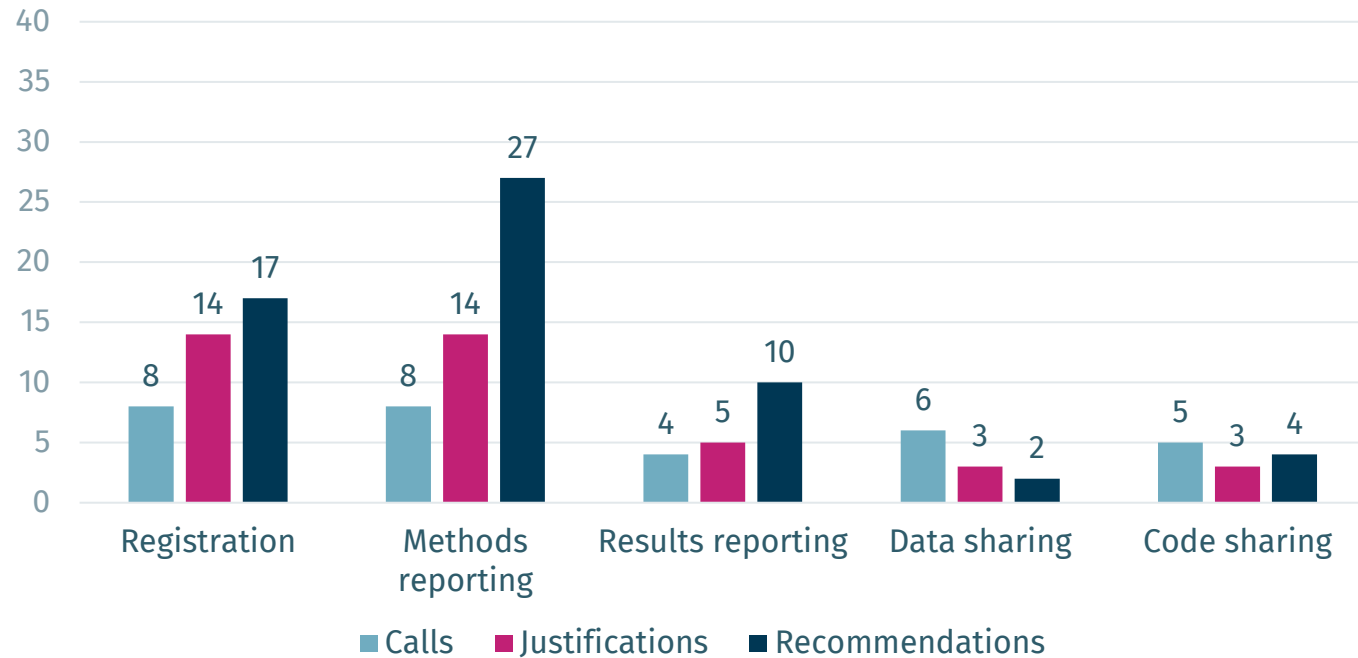
- Quantitative
- Qualitative

Types of documents:

- 114 peer-reviewed papers
- 23 Institutional documents

Sharing and reuse of health-related data for research purposes: WHO policy and implementation guidance

World Health Organization

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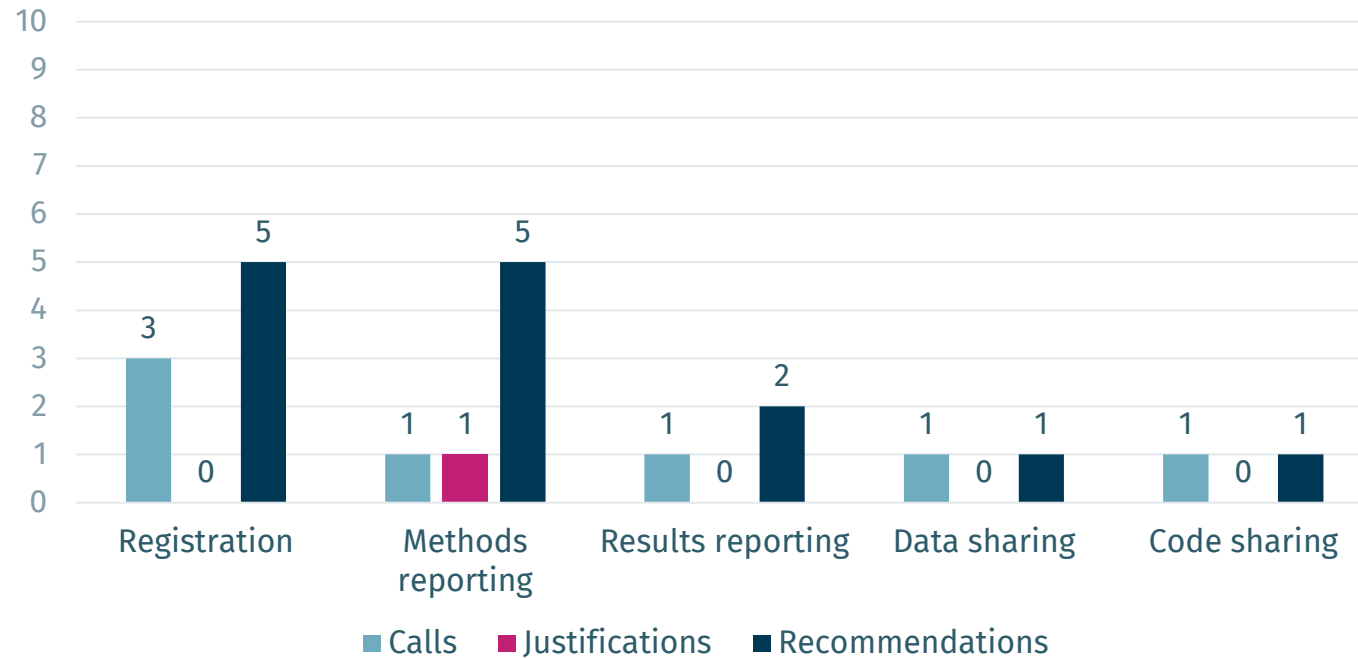
Quantitative results

Peer-reviewed literature (n = 114)

Total recommendations:
- 97 for registration
- 71 for methods reporting
- 14 for results reporting
- 2 for data sharing
- 4 for code sharing

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Quantitative results

Institutional documents (n = 23)

Total recommendations:
- 50 for registration
- 15 for methods reporting
- 2 for results reporting
- 1 for data sharing
- 1 for code sharing

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Qualitative results

- **Justifications** typically mimic justifications for more transparency in clinical trials
  - "there may be elevated concerns about financial and other incentives contributing to <u>reporting of cherry-picked results</u> when making secondary use of existing data" (Patorno et al., 2019)

- **Recommendations** are mainly found in more formal <u>reporting</u> guidelines and <u>registration</u> templates

TABLE 3. HARPER table of contents

7.4. Variables

    7.4.1 Context and rationale for exposure(s) of interest

        Table 6. Operational Definitions of Exposure

    7.4.2 Context and rationale for outcome(s) of interest

        Table 7. Operational Definitions of Outcome

    7.4.3 Context and rationale for follow up

        Table 8. Operational Definitions of Follow Up

    7.4.4 Context and rationale for covariates (confounding variables and effect modifiers, e.g. risk factors, comorbidities, comedications)

        Table 9. Operational Definitions of Covariates

7.5. Data analysis

    7.5.1 Context and rationale for analysis plan

        Table 10. Primary, secondary, and subgroup analysis specification

        Table 11. Sensitivity analyses – rationale, strengths and limitations

7.6. Data sources

    7.6.1 Context and rationale for data sources

        Table 12. Metadata about data sources and software

the**bmj**   covid-19   Research ˅   Education ˅   News & Views ˅   Campaigns ˅   Jobs ˅

Research Methods & Reporting

The reporting of studies conducted using observational routinely collected health data statement for pharmacoepidemiology (RECORD-PE)

BMJ 2018 ; 363   doi: https://doi.org/10.1136/bmj.k3532 (Published 14 November 2018)
Cite this as: *BMJ* 2018;363:k3532

Article | Related content | Metrics | Responses | Peer review

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Qualitative results

Other types of recommendations:

- **Meta-recommendations** (about the structure surrounding registration/reporting/sharing)
  - E.g. facilitating registration embargoes to prevent scooping (Zarin et al. 2020)
- **Cautionary statements** (about risks of misuse or challenges to implementation)
 - E.g. Registration only works if it is enforced (Dhruva et al. 2020)

What is lacking?

- Recommendations about **procedures**
- Recommendations about **sharing**

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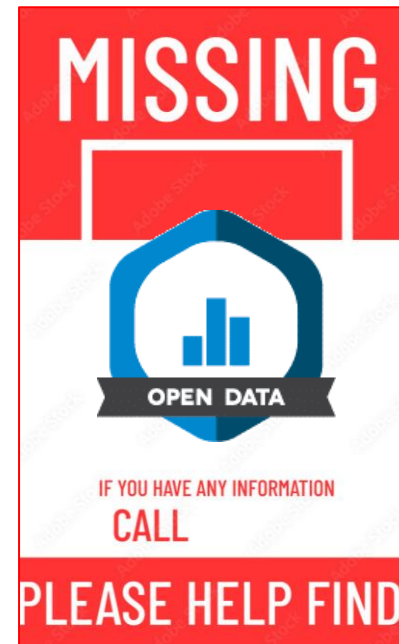
Conclusions

- Guidance exists in peer-reviewed papers but not so much in institutional documents
- Guidance exists for registration and reporting but not for sharing
- Guidance could be more procedural

- Limitations of improving transparency should be discussed more, both on the individual level as well as the structural level

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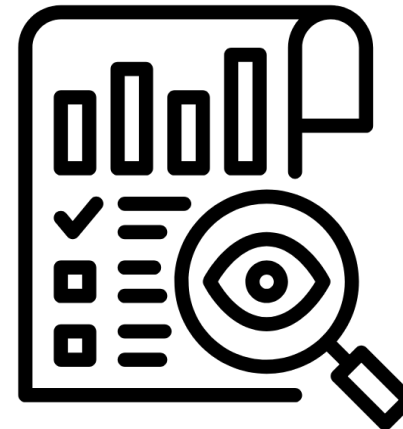
The road to transparency

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Thank you!

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