

Ongoing Swedish Initiatives To Improve The Potential For Real World Data Assessment Of Medical Devices

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Introduction & aim

- Medical devices (MDs) induce specific challenges related to health technology assessment (HTA) and health economics and outcomes research (HEOR).
- In Sweden, national initiatives to address some of these challenges are in progress.
- This study aims to understand the potential to generate value evidence for MDs using Swedish patient data registers. 1-5

Background

Market access and HTA pathways for medical devices in Sweden are depicted in Figure 1

- The majority of MD purchases is the responsibility of the individual regions, usually through procurement.
- The Dental and Pharmaceutical Benefits Agency (**TLV**) determines prices and reimbursement for MD consumables that are prescribed and dispensed in pharmacies. Such devices are subsidised under the national cost threshold scheme.
- As of 2020, all regions collaborate in a national managed introduction project for MDs. TLV supports the project by performing HTAs to inform the decision whether to recommend the MD.

Methods

- A review of Swedish national health registers was undertaken, focusing on available data, and the potential to study MDs.
- Ongoing RWE initiatives were analysed, focusing on their impact on the potential to follow-up MDs.⁶

References

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Disclosure

AHH is an employee of Coreva Scientific.RS is the owner of Coreva Scientific.

MDs procured by the regions National or regional procurement Decision whether to Horizon assess MD for national HTA based recommendation managed introduction National surveillance Prescription/pharmacy Discussion and negotiations: risk-sharing and other consumable MDs agreements between company, regions and TLV. Decision whether to Company submits TLV application HTA by TLV reimburse Figure 1 Pathways to HTA and market

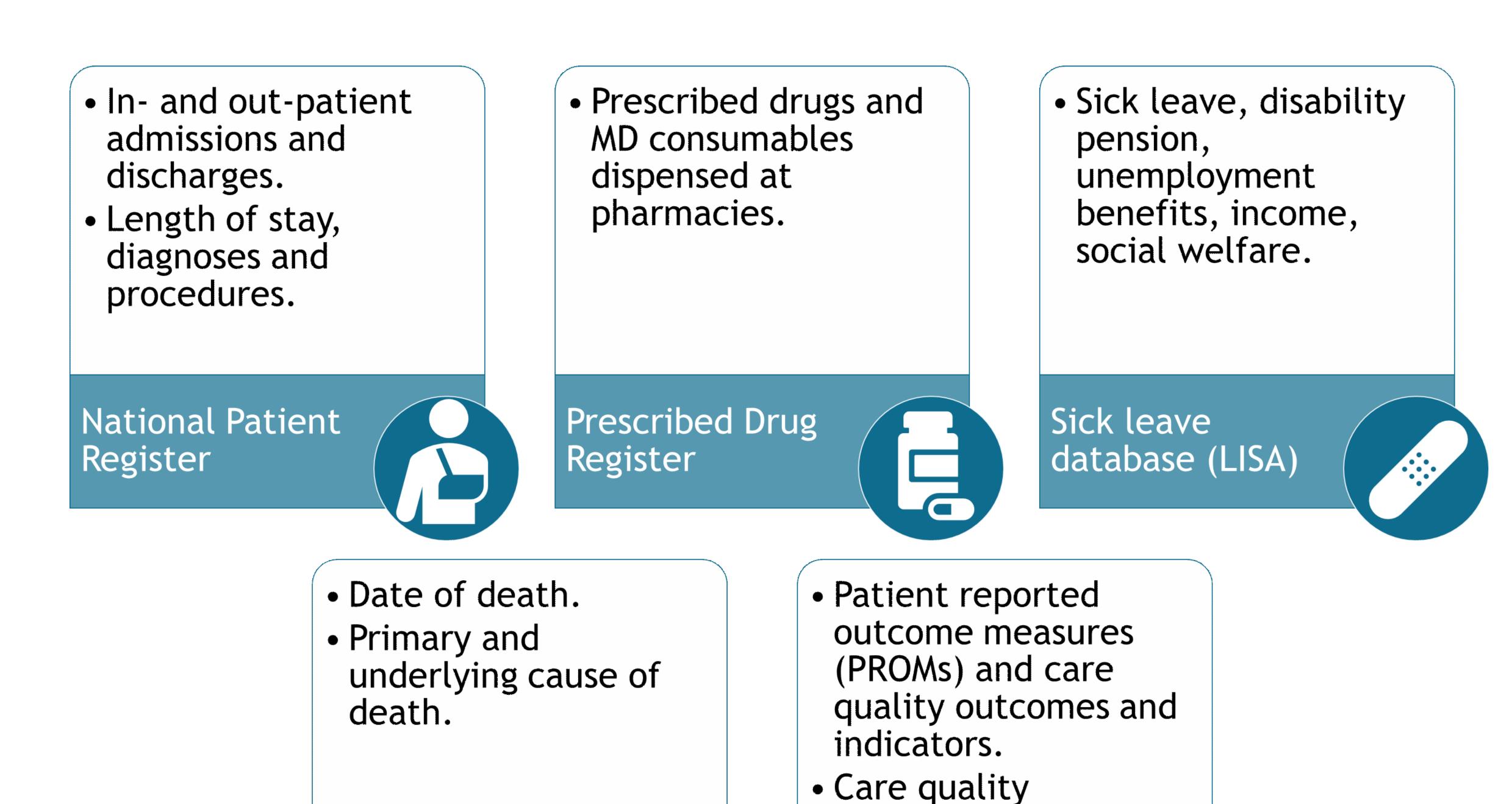


Figure 2 National health data registers LISA: The longitudinal integrated database for health insurance and labour market studies

Cause of Death

indicators.

National Quality

Results

Five data sources were deemed the most relevant national health registers for MD research (Figure 2). All data sources can be linked on a per patient basis.

Limitations of health data registers

The main limitations in using these registers for MD HTA and HEOR studies are:

- Specific devices used cannot be identified
- Limited specialized outpatient care data
- Long time lags in updating (some) registers
- Lack of laboratory data

Ongoing initiatives and their potential to improve the potential for MD assessment

- TLV has addressed the lack of laboratory data in pilot studies and are investigating the opportunity of extracting such data from regional systems.
- Other initiatives include patient-reported health data through an app, and automated reporting of data from regions.
- With the new EU Medical Device Regulation (MDR), Unique Device Identification (UDI) is required, creating potential for improved MD data collection and followup.

Discussion

- Swedish registers comprise comprehensive sources for HEOR studies, but limitations related to the assessment of medical device impact remain.
- As is common with register data reporting grouped diagnoses and interventions, specific devices are not directly identifiable in the national health registers.
- For some devices, this might be addressable through linkage with other data-sources.

Conclusion

Swedish authorities are undertaking several initiatives that will likely improve the potential for HTA and follow-up of medical devices using national health register data.