

Aggregated registry data from the Nordics

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Background

- ▶ Real-world evidence (RWE) is becoming increasingly more relevant throughout the life-cycle of a pharmaceutical product.
- ▶ Healthcare registers in the Nordics can provide data sources with complete coverage and follow-up.
- ▶ Extracting patient-level data requires ethical approval and suffers from long processing times.
- ▶ An alternative, faster option could be to request aggregated data.
- ▶ The project objectives was to derive real world evidence (RWE) on a specific rare genetic disease in the Nordics (Sweden, Norway, Denmark, and Finland).
- ▶ Project kicked off in September 2018 with all data applications finalised and submitted in October 2018 to January 2019. Final report delivered in October 2019.



The disease and relevant patient populations

- ▶ Family of rare genetic diseases characterized by potentially life-threatening attacks and, for some people, chronic pain and other symptoms that interfere in their ability to live normal lives.
- ▶ The study was performed on three overlapping patient populations.

Patient population	Diagnosis required	Age	Comorbidity diagnosis required	Health care visits analysed
Total	Yes	No requirement	No	All visits related to diagnosis
Symptomatic	Yes	At least 12 years	Yes, at least once (+/-45 days)	All visits related to diagnosis
Actively symptomatic	Yes	At least 12 years	Yes (+/-45 days)	Only visits related to diagnosis <u>with</u> a comorbidity diagnosis +/- 45 days



● Data objectives – for each country

- ▶ Prevalence – estimated from the number of unique patients with inpatient or outpatient visits in specialised care
 - Separately by patient population
 - National level, over a five-year time horizon
 - Regional and hospital level, during one year
- ▶ Incidence – estimated from the number of unique patients with a first inpatient or outpatient visits in specialised care
 - Separately by patient population
 - National level, over a five-year time horizon
- ▶ Patient characteristics (age, gender, age at diagnosis, etc)
 - Separately by symptomatic and actively symptomatic patients
- ▶ Health care resource use (inpatient/outpatient visits, LOS, type of ward, pharmaceutical treatments, etc)
 - Separately by symptomatic and actively symptomatic patients



Process

- Sweden was chosen as the first country and the required documentation was developed and submitted.
- Initial questions from the register holders were used to clarify and improve the application for the remaining countries.
- With minor adaptations, the application documents could be used in all four countries. Denmark and Finland required a separate project plan.
- In Sweden and Denmark, complete ICD-10 codes are available in the register but due to uncertainty as to how coding was actually performed, and the risk of getting a too small patient population, a truncated, higher level code (4 digits) was used.
- For Norway and Finland, only 4-digit codes were available.
- In all four countries it was possible to link the patients to the registers on purchased pharmaceuticals, but pharmaceutical treatments provided in a hospital setting was not reliably available from the registers in any of the countries.
- Due to confidentiality issues, numbers smaller than five were reported as <5.
- Due to the long processing time, Norwegian data for 2018 became available and was also included.



Summary of requirements and results

	Sweden	Denmark	Finland	Norway
Research plan required	No	Yes	Yes	No
Complete ICD-10 codes available	Yes	Yes	No, 4 digit	No, 4 digit
Prevalence data on national level	Yes	Yes	Yes	Yes
Prevalence data on regional and hospital level	Yes, but limited by confidentiality	Yes, but limited by confidentiality	Yes, but limited by confidentiality	Yes, but limited by confidentiality
Incidence data on national level	Yes	Yes	Yes	Yes
Patient characteristics	Yes	Yes	Yes	Yes
Health care resource use	Yes	Yes	Yes	Yes
Details on ward	Yes	No	No	No
Linking to prescribed drug register	Yes	Yes	Yes	Yes
Linking to inpatient administered drugs	No	No	No	No
Interaction during process	Medium	High	Very low	Low
Processing time (months, adjusted for summer vacations)	3	5	6	6
Cost (€)	1,200	6,700	2,000	3,200

● Aggregated data in HEOR - summary

- ▶ Aggregated data from the Nordics can provide valuable RWE but extended processing times remains an issue.
- ▶ Recently, processing times have been reduced, especially for cases concerning Covid-19.
- ▶ The required material for the different Nordic register holders is fairly similar and synergies can be expected if several countries are investigated in parallel.
- ▶ Good practice is to focus on one country initially to identify any confusing or unclear definitions or calculations.
- ▶ Uncertainties in coding and restricted data detail may limit the usefulness of data but findings from aggregated data studies can serve as starting points for more detailed studies.
- ▶ Inclusion of inpatient pharmaceutical treatments and primary care data would greatly improve the possibilities.
- ▶ Other interesting aspects to include in aggregated data analysis from the register holders would be time-to-event analyses.

