Real-time monitoring of Multiple Sclerosis care guidelines with clinical endpoints and computer-supported PROs: The Swedish MS registry

Jan Hillert[1,4], Karin Lycke[1,4], Lillemor Egertz[4], Eva Hagel[2], Håkan Eriksson[3], Leszek Stawiarz[1,4] and Swedish Neuroregistries - Multiple sclerosis[4]

[1] Department of Clinical Neuroscience (CNS) and [2] Department of Learning, Informatics, Management and Ethics (LIME), Karolinska Institutet, Stockholm, Sweden
[3] Carmona AB, Halmstad, Sweden
[4] Swedish Neuroregistries, National Quality Registries, Sweden (http://www.kvalitetsregister.se)

Context

The Swedish Neuroregistries (NEUROreg) is a national quality of care registry and a decision support tool where information on patients with 8 groups of diseases within the field of neurology is collected. The part-registry on multiple sclerosis (MS) - the MS registry (MSreg), is the most developed and covers over 80% of the prevalent MS patient populations. All neurology units in Sweden use NEUROreg/MSreg by its web-based interface.

The Swedish National Board of Health Welfare (Socialstyrelsen) are currently in the process of establishing National Guidelines for MS. In this work information from the MSreg has been instrumental. More importantly, once guidelines have been established, the MSreg will be used for monitoring the extent to which the guidelines are met by units, counties and regions within Sweden. This will be done by assessing quality indicators, i.e. statistics from the MSreg.

Problem

How can the MSreg provide MS care units and decision makers with relevant, reliable and patient relevant information on the quality of care and fulfilment of the coming national MS guidelines in a timely and robust fashion?

Assessment of problem and analysis of its causes

The Swedish Board of Health and Welfare (Socialstyrelsen) develops National Guidelines for MS by a standardized methodology, which has as its starting point the identification of a large number of matching “conditions” and “interventions” pairs. Such pairs are then scrutinized from an evidence point of view as well as for a cost-benefit point of view. Pairs are then ranked and indicators chosen to muse in the monitoring of fulfilment of the guidelines.

Intervention

The MSreg is engaged in the work in three different ways. First, it has provided statistics to describe the current practices in MS care, thus defining the problem. Second, it will be adapted to provide indicator statistics. This may include a change in what data to collect, but more typically, to develop out-data functions of the MSreg to enable easy access to statistics. Third, the SMSreg will develop an updated format and collection service for patient reported outcomes.

Strategy for change

There is a close collaboration between the project managers at the Board, its experts and the MSreg. Detailed statistics, most importantly on the use of disease modifying treatment (DMT) for MS has already been obtained and submitted for analysis including a cost-benefit approach to be used once guidelines are in place. We are in the process of jointly defining specific indicators for the various guideline elements.

A more ambitious component is the development of improved patient reported outcomes (PROs) by developing and item-bank based computer-assisted questionnaire to be distributed via the patient portal of SMSreg, to which patients log securely in from home.

Measurement of improvement

The MSreg has a unique, versatile and robust out-data function called the Visualization and Analysis Platform (VAP) (with a public component that can be visited on *www.neuroreg.se*). The VAP is the key element to the process of adapting new indicators and of improving already implemented ones.

Assessing guideline fulfilment with the MSreg is likely to provide a good coverage of the target population.

Providing a modern questionnaire PRO format based on modern test theory is likely to provide measurements with a high degree of validity as well as reliability.

Effects of changes

The project is in progress, and the first deliverable will be base-line information during the first half of 2016 for comparison prospectively with later statistics.

Lessons learnt

So far, we believe that the properties of the VAP will enable the development of indicators with a high degree of acceptance and therefore usefulness due to high coverage.

Messages for others

A clinical MS registry can reach a high degree of acceptance as an internet-based decision support tool and achieve high coverage even in a voluntary situation. We hope to show that a well-designed out-patient functionality can assist in fulfilling treatment guidelines based on physician and patient reported parameters.

Involvment of patients, cares or family members in the project

NEUROreg and MSreg both have patient representatives both in the respective boards as well as engaged in the development of new functionalities. In the development of new PROs patient participation is of course vital. We believe, that PROs will be increasingly important as outcome measures. The MSreg Patient Portal is designed with the hope of patients becoming increasingly important active partners in the health care process.

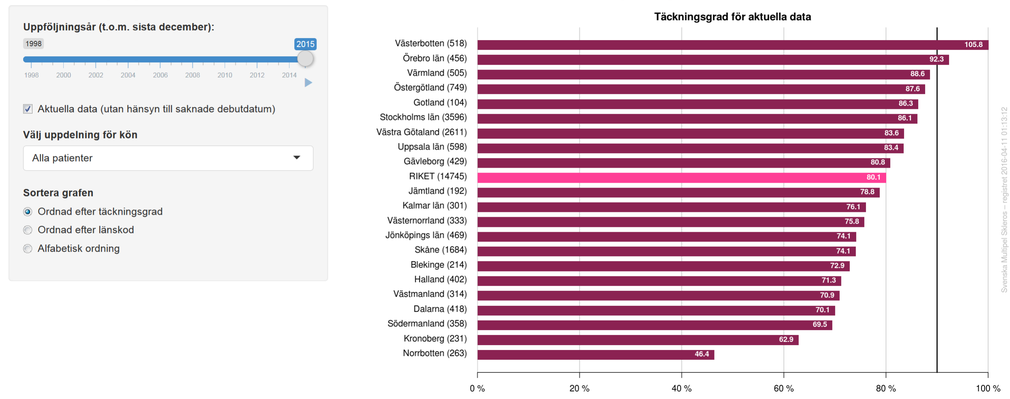
Conflict of interests

The development of the NEUROreg and MSreg is based on federal support only. The current efforts are likewise based on public funding only. In other research projects, JH has been a recipient of unrestricted research grants from Biogen Idec, Merck Serono, Genzyme and Novartis and served on advisory boards or as a speaker for the same companies as well as for Sanofi and Teva. LS, EH and HE do not declare any conflicts of interests.

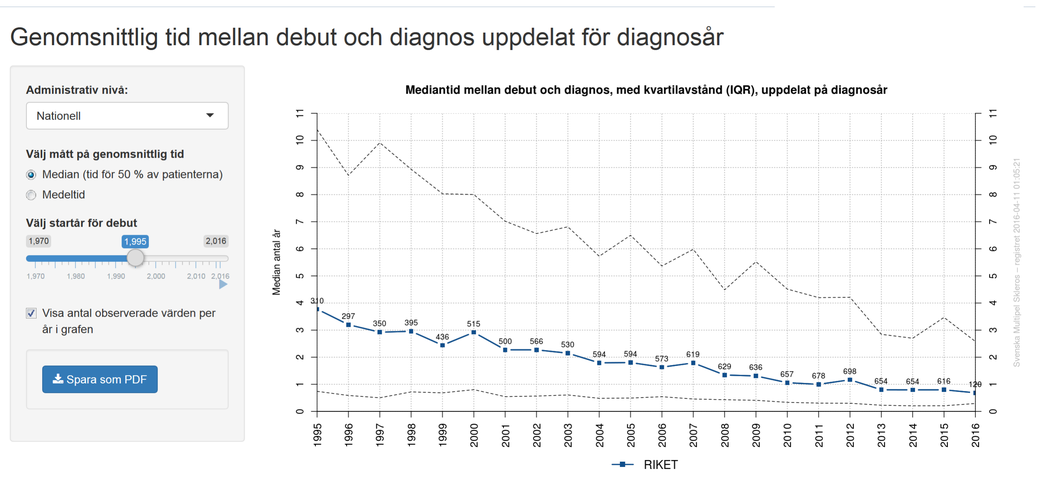
Ethics Approval

NEUROreg and MSreg are quality registries and as such are not subjected to ethical review.

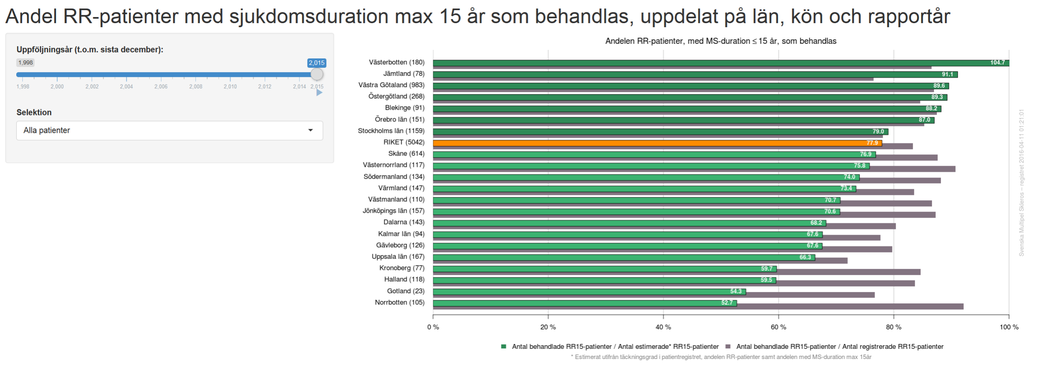
National MS care guidelines indicator, example 1: Coverage for MSreg Proportion and number of registered patients in MSreg compared with estimated number of prevalent MS patientes by county and gender, annually.



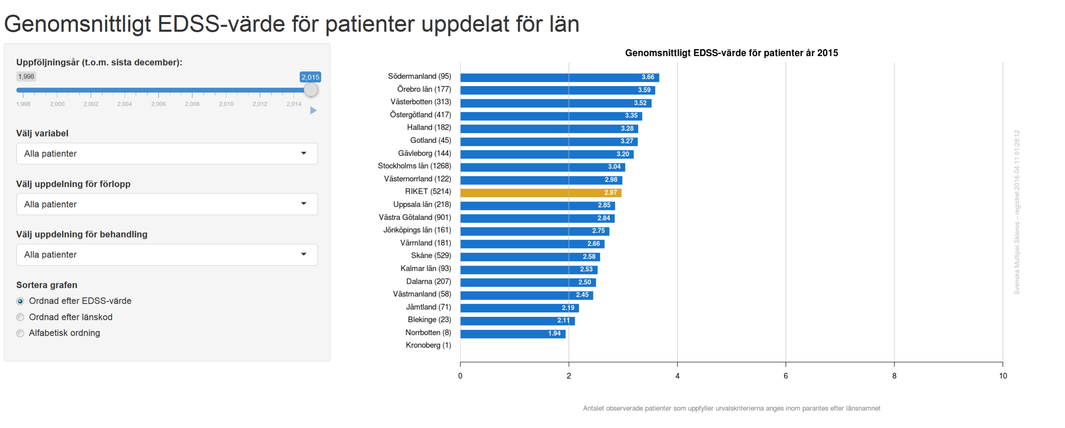
National MS care guidelines indicator, example 2: Time between MS onset and MS diagnosis Median (IQR) and mean time (95% CI) between onset and diagnosis was highly shortened from 4 years to 9 mths during 20 years thanks to the new diagnostic critera, access to MRI, increasing knowledge about MS and access to MS registry.



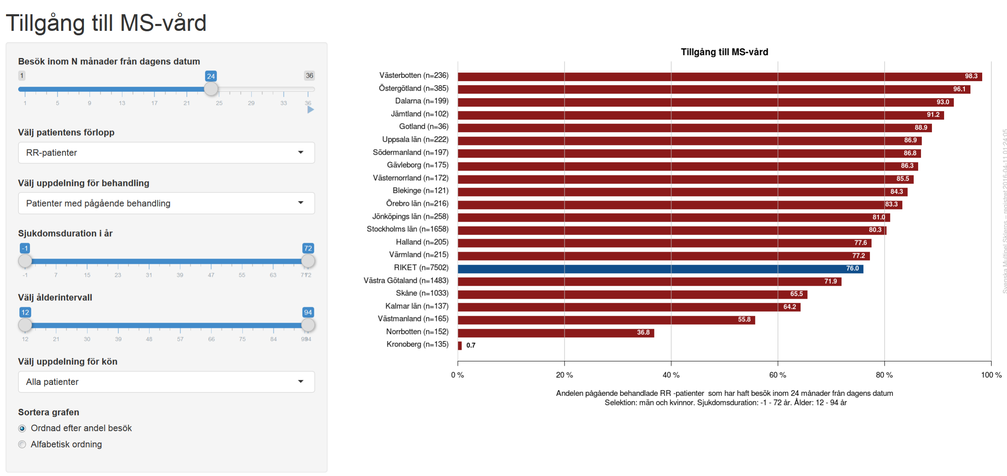
National MS care guidelines indicator, example 3: Do we treat correct subgroups MS-patienter? Proportion of MS patients with RR course and disease duration ≤15 years, treated with DMT, registered in MSreg (RR15-group) vs estimated number of MS patients in Swedish population (green bars). Grey bars show proportion of treated patients in RR15-group versus number of registered MS-patients in RR15-gruppen in MS-registry.



National MS care guidelines indicator, example 4: Expanded Disability Status Scale (EDSS) Comparison of MS related disability measured with EDSS-scale by county, gender, MS course and treatment strategy, annually.



National MS care guidelines indicator, example 5: Access to MS care Proportion od MS patients which could meet the neurologist during last N-months by county, MS course, treatment strategy, MS duration, age and gender.



Kontaktperson:
Leszek Stawiarz
Swedish Neuroregistry Development Coordinator
Karolinska Institutet
Department of Clinical Neuroscience (CNS)
Widerströmska huset, Tomtebodavägen 18A
171 77 Stockholm, Sweden
leszek.stawiarz@ki.se
tel: +46 765 562 503

http://www.neuroreg.se
tel: +46 8 524 845 00

http://ki.se
tel: +46 8 524 800 00

http://carmona.se
tel: +46 35 187 250