efpia

LIF *The research-based pharmaceutical industry*

DEFINE, TRACK, MEASURE AND IMPROVE

How health data and registries can help improve health outcomes for people with diabetes

1. A MULTI-STAKEHOLDER ROUNDTABLE

Measuring health outcomes is an essential tool in understanding their variation; identifying areas for improvement and assessing the benefits and impacts of clinical practice and care pathways; guiding public health policies and interventions and facilitating integrated care pathways. Registries play a significant role in collecting, measuring and reporting the health data that can inform these processes. Given the complex nature of managing chronic diseases such as diabetes, registries and health data can play an essential role in catalysing an evidence-based approach to disease management.

A roundtable meeting was convened in Stockholm, Sweden, on 14th June 2019. This was organised by EFPIA Diabetes Platform and LIF Sweden, and the purpose was to focus on the use of health data and registries, in particular the Swedish National Diabetes Register (NDR). The event was part of a wider effort by the EFPIA Diabetes Platform to accelerate the shift towards outcome-based care in diabetes. It was the first of three events in the coming months, which aim at informing a policy paper to be published in 2019. Given the fundamental role that registries and health data could play in shaping the future of diabetes care and management, the Stockholm roundtable was a fitting place to start.

The roundtable aimed to address three fundamental questions, via keynote speeches from Swedish and international experts, a multi-stakeholder roundtable discussion and three ensuing workshops. The scope of these questions was:

◊   Barriers and challenges: What are the key barriers to establishing and implementing a diabetes registry and health data, including defining what is the right data to collect?

◊   Clinical use: How can health data collected in a diabetes registry be used to improve outcomes in clinical practice?

◊   Policy use: How can health data collected in a diabetes registry be used to inform public health policy?

2. BARRIERS AND CHALLENGES: WHAT ARE THE KEY BARRIERS TO ESTABLISHING AND IMPLEMENTING A DIABETES REGISTRY AND HEALTH DATA, INCLUDING DEFINING WHAT IS THE RIGHT DATA TO COLLECT?

2.1 Addressing silos in funding and prioritisation in health care management

◊   Siloed budgeting was identified as a barrier to the financing and prioritisation of health data and registries in health care management. The cost for the basic infrastructure needed is here and now, and in a specific budget. However, the benefits for patients and society arrive only later, and are spread out over several budget and political cycles, which makes them difficult to factor in. However, examples were presented where short-term improvements in outcomes (such as avoided lower limp amputations) demonstrated data collection programmes can have measurable impacts that lower costs in the short term (see example below from the Steno Diabetes Center).

◊   To overcome the challenge of a lack of funding, there was discussion of the need for stakeholders such as health care professionals and patients to become better at making the case for investing in using data and registries. Various examples were shared, amongst others in Bulgaria, where a data project had to be shut down for lack of funding. In Poland, the general lack of useful and accessible data was seen as a significant challenge.

2.2 Ensuring complete datasets

◊   Another barrier was the issue of how to ensure that the captured data is complete. An interesting method tried in Bulgaria is the harvesting of data through automated word searches, "text mining", combined with a standardised way of structuring the input. A generational shift was also highlighted, where the new generation of health care professionals see the usage of data as something natural, whereas the current professionals can perceive this as an administrative burden.

◊   Data input should be made as simple as possible, to encourage use of the system. Time, effort, investment, and trust to build a successful registry is also required. Starting small, focusing on essential data elements based on what would be required to successfully monitor national (or European) guidelines were seen as essential success criteria.

◊   In Belgium, some sections of the health system are active in the collection of health data, whereas others parts are less, thus the interoperability of systems and datasets made the implementation and interpretation of health data a challenge.

2.3 Barriers to an EU wide registry

◊ For action at European level, the possibility of an EU-wide diabetes registry was debated. Here, barriers exist in the shape of different methods and practices, in different levels of trust and quality of data, and in the General Data Protection Regulation (GDPR) and its varied interpretation and implementation between countries.

2.4 Public trust

◊ Public trust in how and why data is collected and used was also seen as a potential barrier. In contrast, in the field of cancer it was highlighted that a perception ruled whereby the public and policy makers were more willing to allow the use of their data.

3. CLINICAL: HOW CAN HEALTH DATA COLLECTED IN A DIABETES REGISTRY BE USED TO IMPROVE OUTCOMES IN CLINICAL PRACTICE?

3.1 Greater patient engagement

◊ Giving the opportunity to patients to suggest the types of data they find valuable is the next step to increase the value of registries. Patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) are valuable tools that can help inform clinical practice to support achieving patient-centric outcomes.

3.2 Growing potential sources of data increase concerns over privacy

◊ Increasing uptake of continuous glucose monitoring tools will mean that patients will be able to share a growing amount of data. However, the correct systems and rules (including in relation to GDPR) need to be in place in order to leverage the value of this data.

3.3 Consensus on the need for wider use of data

◊ A wider usage of data to inform clinical decision making was endorsed by all stakeholders, and in this context the phrase was used: "Knowledge is sharing" – meaning that as the data is being collected and analysed, that it should be more effectively used to improve outcomes for patients. In this context, the Steno Diabetes Center in Denmark was mentioned as a great practise which could show the effectiveness of certain intervention to health care professionals and policy makers, based on concrete outcomes.

4. POLICY: HOW CAN HEALTH DATA COLLECTED IN A DIABETES REGISTRY BE USED TO INFORM PUBLIC HEALTH POLICY?

4.1 Focus on outcomes and not just outputs

◊ There was consensus amongst the participants that policy makers should increase their focus on achieving better outcomes and not only looking at outputs. The role health data can play in this process was seen as fundamental and should be supported by the case studies that can show policy makers the positive effects that health data and registries can play.

4.2 What role for industry?

◊ It was highlighted that the pharmaceutical industry should be involved in the ecosystem around the data collection and interpretation to better assess which kinds of new therapies were needed.

4.3 Cross border comparisons

◊ The value of a European-wide registry was widely supported, and the European Diabetes Forum was encouraged to look into this possibility. However, the challenge of developing such as system should not be underestimated and pilot projects, facilitated at a European level, could be a useful first step.

5. SHARING INSIGHTS AND EXPERIENCES

5.1 Swedish National Diabetes Register (NDR)

◊ The Swedish NDR was seen as an example of how the collection and analysis of health data is put into everyday use in clinical care, as well as in research. It was established in 1996 and has been available online since 2002. The indicators that can be followed via its online platform include HbA1c, blood pressure, blood lipids, statin treatment, use of glucose sensors and insulin pumps.

◊ The Swedish system of a personalised identifying number ("personnummer") makes both data input and cross-searches easier. It also enables cross linkage of quality registries to other official Swedish statistical platforms, adding great value and deepening the level of analysis achievable.

◊ The use of a simple and clear feature – known as "the button" – makes it easy to access data for all interested stakeholders, including clinicians and patients. This made it easy for clinicians to easily follow up on targets, follow up over time and to compare with peers.

5.2 Steno Diabetes Center, Copenhagen, Denmark

◊ The Steno Diabetes Center has demonstrated significant improvements in patient outcomes from the effective use of health data. Incidence of all lower-extremity amputations decreased by 87.5% among men and 47.4% among women with type 1 diabetes and by 83.3% among men and 79.1% among women with type 2 diabetes between 2000 and 2011. These results were achieved by careful and targeted monitoring and follow-up on patient data by a multi-disciplinary team of health care professionals.

5.3 Bulgarian National Diabetes Register

◊ A pseudonymised register of diabetic patients was generated in 2015 from outpatient records collected by the Bulgarian National Health Insurance Fund (NHIF). It is based on an existing system of patient registration in order to avoid putting additional burden on health care professionals.

◊ It captures epidemiological and complications data from across Bulgaria. It supports the study of diabetes and cardiovascular complications as well as life expectancy. It is also used as a way for the Bulgarian Ministry of Health to reward general practitioners as diabetes compensation is an important indicator in their assessment.

5.4 Establishing the first comprehensive description of diabetes related costs, Poland

◊ Currently, Poland lacks medical and epidemiological data to support evidence-based decision making for reimbursement, financing and organisation of care. There is also no system of medical registries in Poland for most common conditions, including diabetes.

◊ In order to address this challenge, a non-intervention, large-scale, epidemiological study has been commissioned that aims to combine existing data from the NFZ (the Polish National Health Fund) and epidemiological, medical and non-medical cost data to establish the true impact of diabetes in Poland.

◊ This project was initiated by the National Institute of Public Health (NIZP) and the Polish Academy of Science (PAN) and aims to inform public payors, patients and public health insurers of the estimated direct and indirect cost of diabetes and the cost borne by patients in Poland. This data can then assist in shaping policy and treatment decision.

5.5 Diabetes registries, data and outcomes in Belgium

◊ Health data related to diabetes treatment, management and outcomes is collected from a variety of different sources in Belgium. A lack of a national diabetes plan means there is a lack of a mandate to bring the different data sources together, and although data linkage is possible, it requires overcoming a lot of red tape. Health data is used for local evaluation and quality improvement initiatives, and national monitoring, reporting and bench marking.

◊ Barriers to be overcome in Belgium were seen as the lack of a clear vision on the data needed to guide diabetes policy, overcoming "islands of data" and complex IT infrastructure and having the right incentives to support data providers. However, care providers willingness to use health data to inform quality improvements, improved trust in the use of data by the public and the interest of the pharmaceuticals industry to re-use data is a potential lever for more meaningful use at all level of the health system.

Annex 1: Programme

9.00 – 9.10	Welcome and introduction	Lisa Kirsebom, moderator
		Dag Larsson, Senior Policy Manager, LIF Sweden
		Troels Rye-Andersen, Co-chair of the EFPIA Diabetes Platform; Head of Government Affairs, Novo Nordisk
9:10 – 9:20	Improving health outcomes for people with diabetes: the role of data and registries	Prof. John Nolan, Executive Director, European Diabetes Forum
9:20 – 9:35	How diabetes registries and health data are improving clinical care in Sweden?	Dr. David Nathanson, Senior Physician, Karolinska Institute; President, Swedish Society for Diabetology
9:35 – 10:00	Wider experience of diabetes registries, data and outcomes	Prof. Dimitar Tcharaktchiev, Head of Department, Medical University, Sofia
		Joanna Gła ewska, Research Director in PEX Sequence, Public institute for Health, Poland
		Dr. Kris Doggen, Scientific Institute of Public Health, Belgium
10.00 – 11.00	Roundtable: Understanding the barriers and opportunities of health data and diabetes registries	
11.00 – 11.25	Break	
11.25 – 12.10	Workshop session – Diabetes Circles	All participants led by a moderator for each session
12.10 – 12.30	Plenary – provide feedback and outcomes from workshops	Moderators from each of the workshops
12.30 – 12.35	Concluding remarks	Moderator and representatives from EFPIA Diabetes Platform and LIF Sweden

Annex 2: Participant list

Name	Job Title	Organisation
Dr. Alexandra Berry	Engagement Lead for the National Diabetes Audit	Diabetes UK
Anders Ekholm	Chairman	Stockholm Diabetes Association
Anna Mannervik	National Partnerships Lead	MSD
Dag Larsson	Senior Policy Manager	LIF
Dr. David Nathanson	President	Swedish Society for Diabetology
Prof. Dimitar Tcharaktiev	Head of Department	Medical University Sofia
Elvera Laanen	Government Affairs Manager	Novo Nordisk
Prof. Emmanuel Cosson	General Secretary	Société Francophone de Diabétologie
Erik Samuelsson	Brand Manager Diabetes	Boehringer Ingelheim
Prof. Francesco Cosentino	Professor of Cardiovascular Medicine	Karolinska University Hospital
Håkan Jonsson	Senior Director	Fipra Sweden
Joanna Głażewska	Research Director in PEX Sequence	Public Institute for Health
Dr. Johan Sundström	Professor of Epidemiology	Uppsala University
Prof. John Nolan	Executive Director	European Diabetes Forum
Klas Gränsbo	Medical Advisor	Sanofi
Dr. Kris Doggen	Head of the Health Services Research Service	Sciensano
Dr. Lina Nordquist	Member of Parliament	Riksdag
Lisa Kirsebom	Moderator	
Prof. Marit Eika Jørgensen	Research Manager	Steno Diabetes Center
Dr. Mats Bojestig	Director of Healthcare	Jönköping region
Neil Causey	Account Director	Fipra International
Niels Bonde	General Manager	Novo Nordisk
Roberta Savli	Senior Manager Healthcare Systems	EFPIA
Prof. Sarah Wild	Professor of Epidemiology	University of Edinburgh
Thomas Allvin	Executive Director Healthcare Systems and Strategy	EFPIA
Troels Rye-Andersen	Head of Government Affairs & Patient Relations	EFPIA Diabetes Platform, Novo Nordisk

"For the chance to approach meals without apprehension."

Jen, living with type 1 diabetes

#WeWontRest

"For the chance to find a cure for my daughter."

Jacob, diabetes research scientist

#WeWontRest

The **EFPIA Diabetes Platform** brings together six companies whose aim is improving the lives of everyone affected by diabetes. Together with various stakeholders across the research and health community, we look at how to improve diabetes management and to reduce complications.

Läkemedelsindustriföreningen is the trade association for the research-based pharmaceutical industry in Sweden with about 90 members and associate companies who represent approximately 80 percent of the total sales of pharmaceuticals in Sweden. LIF Service AB (LIF) represents its members in issues of common concern, assisting and informing them on questions vital to the industry. We are members of the European trade association EFPIA and the international trade association IFPMA as well as of the European associations AESGP.

We remain ambitious about the future for people living with diabetes. Through research, better management and collaboration, #WeWontRest until diabetes is defeated.