

From Real World Evidence to Real World Impact

Dr. Joris van Dijk, MSc & Job Eijsink, PharmD - Isala

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Real-world evidence (RWE) is, instead of evidence from classical randomized controlled trials (RCTs), collected through everyday practices by nurses and doctors and the resulting patient-reported outcomes (PROs). Although there is consensus that using RWE can tremendously improve outcomes in the healthcare sector, examples of implementation remain scarce. To get an idea of how technology can be used to gather, use and implement this type of evidence, we spoke to Joris van Dijk and Job Eijsink, both working at Isala Hospital. This hospital is a frontrunner when it comes to VBHC implementation in which real-world data collection plays a significant role. The culture in this hospital has led to several experiments among which the implementation of CTcue; a data and information software that enables the collection of both structured and unstructured data.

Real-world evidence can drastically change the future of healthcare

RCTs are (still) the gold standard when it comes to testing the efficacy of medical treatments. However, RCTs are very time-consuming and expensive. Additionally, the evaluated efficacy in an RCT may not be reflected in the 'real world', for example, due to strict enrolment criteria of the included test population. Therefore, there is an increasing interest in RWE for a wide range of medicines and therapies in the medical field. Job reveals from his experience:

Donia, M., Kimper-Karl, M. L., Høyer, K. L., Bastholt, L., Schmidt, H., & Svane, I. M. (2017). The majority of patients with metastatic melanoma are not represented in pivotal phase III immunotherapy trials. *European Journal of Cancer*, 74, 89-95.
Donia, M., Hansen, S. W., & Svane, I. M. (2019). Real-world evidence to guide healthcare policies in oncology. *Oncotarget*, 10(44), 4513.
Miksad, R. A., & Abernethy, A. P. (2018). Harnessing the power of real-world evidence (RWE): a checklist to ensure regulatory-grade data quality. *Clinical Pharmacology & Therapeutics*, 103(2), 202-205.



Joris van Dijk is a project innovator and postdoctoral researcher at Isala, with the vision to improve patient care. He does this on a patient level by optimizing clinical protocols while finding scientific knowledge gaps, filling them and translate it into hospital level by introducing and facilitating technical healthcare innovations.

Job Eijsink is a pharmacist in the hospital and is – through leading a VBHC team - very engaged in the implementation of VBHC. He is active in the development, building and implementation phases of VBHC patient pathways. In this way he stratifies the value of certain therapies for patients and is a useful sparring when it comes to medical decision-making for the health

“...from a research perspective we do not only see that the inclusion criteria for RCTs are stricter, but also that some complications or adverse events in the patients’ population, from the evaluated treatments are not considered in these studies. Although not observed, these complications can impact the survival rate in such a research group and turn the number of quality-adjusted life-years of a patient.”

Using real-world data reflects the heterogeneous populations with, for example, co-morbidities and since it can observe larger populations based on their overlapping characteristics”. RWE data is gathered from patients that are treated in a real-world setting, rather than a trial. To do so, most often a hospital’s (or institute’s) electronic health record (EHR) is consulted to enable research of certain patient pathways and medical conditions. It is believed that using this real-world data in the right way can drastically change the future of healthcare, due to improved and more so-called dynamic patient pathways.

Job states that *“ultimately, by really diving deeper and including a patient’s quality of life, these real-world patient outcomes will improve the development towards pay for performance models, with integrated PROs”*.

Collection and usage of the ‘right’ data

Joris and Job are both actively engaged in facilitating this data collection at Isala. This does not only include making sure that the right information is filled out at the right place in the EHR, but also that this is translated in dashboards which makes outcomes more vivid for medical specialists.

Joris explains that at Isala these dashboards showcasing the findings from the data are discussed regularly. Based on this, decisions are made in multidisciplinary teams. Think for example about the reduction of infections after a certain surgery or complications due to medicines prescribed from different medical disciplines. Besides, he underlines that *“A proper structure is crucial to use such a system the best way. The right information must be collected in the designated place in the system”*. This shows that with data collection alone, it is not easy to convince medical specialists to be involved in these projects. However, once the data is collected, outcomes can be presented in these

dashboards to medical experts concisely and clearly. In that way, they are incentivized to cooperate in these projects by using, for example, the right terminology and techniques to fill out certain patient-related outcomes. Based on Job’s expertise in research, he adds: *“Using RWE is also very interesting from a scientific perspective. Besides, it allows us to compare real-world data versus trials and potentially look further than we do so far in RCTs or the available data. Likewise, it is important to translate the data analyses that we do into clear dashboards. Data on its own will not improve patient outcomes, but improved shared decision-making based on our analyses will sure do”*.

“ A proper structure is crucial to use an RWE system in the best way ”

Practical implementation; where to start?

Isala has a great focus on integrating VBHC initiatives within several specializations. In these patient pathways, they integrate

data actively to monitor and analyze, for example, the time that one is hospitalized or the type of diagnosis. During the process of creating such a pathway, a dashboard is established that measures live the effect using standard indicators.

Across the whole patient pathway, data is then presented to medical experts. Joris emphasizes: *“Especially when one is working in a multidisciplinary team this is very important. Many people have a certain gut feeling of how well they are performing, but the data can show something different. Providing this feedback can improve the patient pathway and consequently the patient-outcomes”*.

Experience stories

An example of a system that is able to generate the data required for dashboards with data from the EHR is CTcue. CTcue is a tool that allows to systematically collect data that is registered in an EHR. This feature can make data matrices – also those that are unstructured – visible. In that way, clinical data can be linked to each other and can consecutively be visualized in dashboards to bring it back to the consultation room or adjust protocols.

“At Isala we have our own advanced BI department that can retrieve all structured data from the data warehouse itself. We can therefore do most of the jobs ourselves. As soon as we want to combine structured and unstructured data in a dashboard, we use CTcue to retrieve the unstructured data from the EHR, and then export this data to Power BI for visualization to create dashboards. An example of this is an infection that arises after pelvic surgery. The operation itself is stored in structured data, but often the occurrence of an infection after the operation is only registered in open text fields. By combining this data in a dashboard, valuable information emerges that can be

actively responded to, for example through preventive antibiotics or hygiene measures. – Said Joris”. When asked what dashboards are currently being kept, Joris answers; “At the moment, we have ‘outcome’ dashboards that are refreshed and discussed monthly or once a quarter, and we have ‘steering’ (clinical) dashboards that are refreshed nightly with lead times and numbers. Examples on steering dashboards are the time between referral and outpatient appointment, time between diagnostics and OR, time between OR and chemo, etc. These dashboards run entirely on our own data warehouse because you want it refreshed at night. For the

outcomes, we make use of CTcue, as the unstructured data is also very important here in order to be able to add value to healthcare.” Job adds to this: “outcomes visualized by CTcue (e.g. found by aetiological exploratory search) sometimes lead to further research with a publication as a result. However, this is not always necessary since it can also be used to make intuitive decisions, both at a management and clinical level. Implementing a well-established data system also improves the payment system behind it. In this way, we can pinpoint how much certain therapy costs as a whole.”

“... it is crucial to focus on a good connection between those with IT knowledge and those with medical expertise”

What's next?

There are several problems and challenges related to the collection and usage of RWE. One of the major obstacles, according to Joris, is the lack of cross-sectional understanding between different units in the hospital. He states: “I believe that it is crucial to focus on a good connection between those with IT knowledge and those with medical expertise. Very useful data is often already available for analysis but is not used in the right way. In our hospital, my team bridges the gap between the business intelligence team and medical professionals, since they sometimes speak a different language when it comes to the usage and interpretation of data. Bridging that gap is essential”. The usage of RWE can be very useful outside the walls of a hospital. Job accentuates: “If a hospital wants to connect well with other parties, the focus should also shift to the different healthcare levels, which should include primary care. When creating such a pathway, we have a much clearer outlook on what happens to the patient and can improve the decision-making. To make this possible, many parties have to come to the table. A good example of this is an initiative by Bas Nij Bijvank (Gynaecologist) at our hospital. This project is worth mentioning since it was able to make those connections through the barriers of primary care, secondary care, and maternity care.”. With the belief that VBHC in combination with RWE can improve healthcare in the long run, we hope that such initiatives keep increasing, to make sure that healthcare becomes more affordable and at the same time provide more value to the patients.

The Collision of Two Worlds: Value vs. Money in Maternity Care

Dr. Bas Nij Bijvank – Isala

Creating an integrated practice unit for Maternity Care, while improving quality and reducing costs. Read the full interview with Dr. Bas Nij Bijvank in the VBHC Thinkers Summer edition 2020.