INTRODUCTION

If we ask people who work in market access about what they think has most attention today, many will name real-world evidence (RWE) or real-world data (RWD). This is illustrated by the popularity of RWE subjects at conferences and the increasing number of RWE publications on PubMed (Figure 1). According to the recently published Second Annual Real-World Evidence Benchmarking Survey (2018) with executives of 20 top pharmaceutical corporations, almost all respondents (90%) reported they have either established or are currently investing in building RWE capability for use across the entire product life cycle. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) lists RWE as third place in the top ten health economics and outcomes research (HEOR) trends for 2019.

Figure 1: Number of PubMed citations per year with the subject ‘randomised controlled trial’ (RCT) or ‘observational study’ in the title

As somebody who had been leading experts in observational data analysis for over 20 years and delved deep into the subject when Johnson & Johnson was considering its position regarding comparative effectiveness research (2010), I have enough reasons to perform a reality check.
The following excerpt from this publication summarises the problems:

‘Effectiveness in the community depends not only on efficacy but also on diagnostic accuracy, provider compliance, patient adherence, and the coverage of health services.\textsuperscript{10} Misdiagnosis can result in the wrong people getting or not getting the treatment. Providers often fail to prescribe or administer the treatment properly. Patients typically take less than half of prescribed treatments. High tech, expensive, or new interventions are usually not available in all communities in the developed countries or to most communities in the rest of the world. To paraphrase Gray, what works well at the Sloan Kettering (a high-tech cancer center) may not work very well in Kettering (a small UK community).\textsuperscript{11}

Case studies on discrepancies between RCTs and real-world utilisation

With the increased availability of RWD came studies that looked at the differences between drug utilisation in RCTs and in daily practice.

A 2015 literature review found 52 studies that either compared the characteristics of RCT-enrolled patients with a real-world population or assessed how many real-world patients would have been eligible for RCT inclusion following the application of the actual RCT recruitment criteria. In 37 of the 52 studies (71\%) the authors concluded that RCT samples were not representative of patients in clinical practice and/or that population differences may have a relevant impact on the validity of the RCT findings in clinical practice.\textsuperscript{11}

Herland et al. looked at whether 870 out-patients with asthma and/or chronic obstructive pulmonary disease (COPD) met the typical recruitment criteria for asthma or COPD RCTs. Only 5.4\% of asthma patients met the asthma recruitment criteria, whereas 17\% of COPD patients met the COPD recruitment criteria. The authors concluded it is ‘questionable to extrapolate RCT results to larger, “real life” populations of patients with obstructive lung disease’.\textsuperscript{12}
Another study found that of 1446 non-valvular atrial fibrillation (AF) patients in a real-world registry taking warfarin, approximately 40–60% would meet the selection criteria used in comparative studies versus rivaroxaban (RE-LY trial, 54.5%), dabigatran (ROCKET-AF trial, 39.1%), and apixaban (ARISTOTLE trial, 59.9%). The authors concluded the expected stroke risk reduction and bleeding risk among real-world AF patients on warfarin may not match up with the clinical trial data.\(^\text{13}\)

Kilcher et al. performed two systematic reviews on rheumatoid arthritis (RA): one for observational studies, the other one for RCTs. This resulted in a meta-analysis of 51 RCTs and 76 observational studies, covering over 20,000 and over 30,000 patients respectively. Patients from observational studies were on average 3.0 years older (P<0.001), had suffered from RA for 3.1 years longer (P<0.001) and had 1.6 more prior disease-modifying anti-rheumatic drugs (DMARDs) (P=0.001). However, patients in RCTs had higher disease activity as shown by 0.6 points higher score in the disease activity score calculator for RA, DAS-28 (P<0.001). The authors concluded: ‘There are substantial systematic differences in patient characteristics between RCTs and registries in RA. The efficacy seen in RCTs may not reflect real-world effectiveness’.\(^\text{14}\)

van Staa presented details on findings from the large UK registry General Practice Research Database (GPRD) in the 3rd Annual Pharmacovigilance & Risk Management Congress, 2008, London. Mean daily doses, indications, and length of treatment with rofecoxib and celecoxib were very different from that reported in the clinical trials (Table 1). Part of these data were reported in peer-reviewed journals.\(^\text{15-17}\)

Carls et al. studied the role of adherence when comparing real-world and RCT clinical outcomes in type 2 diabetes patients. Patients who did not acquire enough drugs to cover at least 80% of their needs were classified as non-adherent. Only 64/221 (29%) of patients on GLP-1 RA products and 242/652 (37%) patients on DPP-4 products were adherent. In contrast, adherence in the RCTs was estimated at 95%. A regression analysis on the efficacy of GLP-1 RA and DPP-4 products in real-world settings showed that, for either drug class, poor medication adherence accounted for over 70% of the gap in HbA1c reduction.\(^\text{18}\)

Mason et al. found that, in the BADBIR observational study of 7136 patients with psoriasis, patients not meeting the recruitment criteria for clinical trials had lower effectiveness and higher rates of serious adverse events from biologic therapy compared with patients identified as eligible for clinical trials recruitment. Depending on treatment drug, 46–56% of patients were classified as eligible for the clinical trials; the main reason for failing recruitment criteria was concomitant diabetes (9–12% of sample).\(^\text{19}\)

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### Table 1: Discrepancies regarding indications, daily doses, and lengths of treatment on rofecoxib and celecoxib in RCTs and observational (GPRD) data

<table>
<thead>
<tr>
<th>Indication</th>
<th>RCT Rofecoxib</th>
<th>GPRD Rofecoxib</th>
<th>RCT Celecoxib</th>
<th>GPRD Celecoxib</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoarthritis</td>
<td>0%</td>
<td>35%</td>
<td>73%</td>
<td>36%</td>
</tr>
<tr>
<td>RA</td>
<td>100%</td>
<td>5%</td>
<td>27%</td>
<td>5%</td>
</tr>
<tr>
<td>Other</td>
<td>0%</td>
<td>60%</td>
<td>0%</td>
<td>59%</td>
</tr>
<tr>
<td>Daily dose (mean)</td>
<td>50 mg</td>
<td>22 mg</td>
<td>800 mg</td>
<td>224 mg</td>
</tr>
<tr>
<td>Patients with continuous Cox-2 use (months)</td>
<td>71% (11)</td>
<td>17% (11)</td>
<td>57% (6)</td>
<td>24% (6)</td>
</tr>
</tbody>
</table>
Ioannidis et al. compared the main outcomes of meta-analyses of RCTs with meta-analyses of non-randomised studies for 45 different indications. Only 11 indications had discrepancies in clinical outcomes that were statistically valid. The discrepancy was in favour of RCTs for six of these, so in five cases the non-randomised studies showed a better result.

Some examples of publications showing an advantage for real-world outcomes when compared with RCTs are listed below:

- Holden (2018) found greater improvement of key clinical outcomes in patients with diabetic macular oedema from a real-world study compared with the results of the FAME RCTs. This could be explained by patients in the real world having more severe visual morbidity at baseline.

- A meta-analysis of real-world studies showed that omalizumab treatment of chronic idiopathic urticaria met or improved on both efficacy and safety predictions from the RCTs.

- Real-world patients treated with abiraterone for post-chemotherapy metastatic castration-resistant prostate cancer had non-significantly longer overall survival and significantly shorter treatment duration compared with patients in the clinical trials.

Other recent publications found comparable or worse effectiveness/safety outcomes versus RCTs.

Payers use real-world data cautiously

Payers use concerns regarding real-world therapeutic value as an argument to draw conclusions on ‘unquantifiable benefit’ at the time of market entry. There are practical (product availability and distribution, follow-up of patients) and ethical (not-well-controlled utilisation before definite proof of therapeutic value) barriers to real-world utilisation before marketing authorisation. These make the RWE argument difficult to overcome, potentially leading to restricted reimbursement until generated RWD become available. Solutions such as conditional reimbursement – reimbursement pending positive RWE in the future – are not yet widely implemented.

The ISPOR Real-World Data Task Force Report on the use of RWD for reimbursement (coverage) and pricing (payment) decisions offers a good review of the utilisation and importance of RWD for patient access around ten years ago. While the study had a US focus, the authors claimed the conclusions had a global reach. RCTs were positioned as the gold standard for demonstrating clinical efficacy in restricted trial settings. There was, however, recognition that RWD can contribute to the evidence base needed for coverage and payment decisions.

A recent report from the 2017 ICER Membership Policy Summit revisited the same topic. For initial HTA assessments and payer coverage decisions, both HTA organisations and payers still rely largely on RCT or other controlled trial evidence generated for regulatory submission. There was significant use of RWE however, for re-assessments (safety signals; adherence; effectiveness and value for money; effectiveness within sub-populations), and sporadic use in outcomes-based contracting.

A COMMON MISCONCEPTION

There is ample scientific proof that the use of products in the real world is different to that in clinical studies. However, this does not mean that efficacy will always trump effectiveness.
In 2013 focus group discussions, US pharmacy and therapeutics (P&T) committee members confirmed RWE was too late to impact the initial decisions. A 2017 review of use of RWE in 27 P&T monographs, and therapeutic class reviews from six different payer organisations, found 21 references to published RWE versus 155 to published RCTs in therapeutic class reviews. There were no references to published RWE in the monographs. The authors concluded:

'\textit{Efficacy information (e.g., clinical trials, product labels) was the most cited source of evidence in P&T materials. "Effectiveness information", even among therapeutic class reviews where RWE is more available, was infrequently used.}'

Considerations about effectiveness is one of the elements in the current reimbursement decision-making process of the French Transparency Commission. Statements that illustrate the concerns regarding application of the new therapy in the French context are included in Table 2.

Table 2: Real-world related statements in French Transparency Commission appraisal documents taken randomly from the period 2008–2016

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>It is questionable that the experimental data can be transposed into real life as…</td>
</tr>
<tr>
<td>• …there are uncertainties about the criteria to identify the population of patients most likely to benefit from the product in clinical practice</td>
</tr>
<tr>
<td>• …age and risk distribution of selected patients, dose of comparator, additional measures, are not in line with daily practice</td>
</tr>
<tr>
<td>• …only few patients were pre-treated with the standard of care normally used in the previous line</td>
</tr>
<tr>
<td>• …it is unlikely the complicated therapeutic strategy would work in daily practice</td>
</tr>
<tr>
<td>• …the proposed treatment has not been studied on top of the current normal educational and psychological treatment</td>
</tr>
<tr>
<td>• …the product has not been studied in the normal combination</td>
</tr>
<tr>
<td>• …selected patients did not include the frail ones, so the benefit/risk ratio could be very different</td>
</tr>
</tbody>
</table>

Product names were kept confidential, quotes have been adapted from the original French texts.

Many people in the pharmaceutical industry will be aware of National Institute for Health and Care Excellence (NICE) using health technology assessment in funding decisions. Health economists know that this goes beyond the concept of cost per quality life year (QALY) because an important part of the assessment is about clinical effectiveness. However, although the NICE guidelines state that the appraisal committee’s judgements on clinical effectiveness must take account of ‘uncertainty generated by the evidence and differences between the evidence submitted for licensing and that relating to effectiveness in clinical practice’, they also highlight the importance of ‘evidence derived from high-quality studies with methodology designed to minimise bias’.

According to a 2017 publication, RWE is used extensively in the decision-making processes on public funding of drugs in Poland, contributing to nearly half (45%) of all the evidence considered. However it is important to point out that – according to the latest W.A.I.T. publication – the average time between marketing authorisation and patient access is 612 days for Poland, compared with 209 for the UK, so there is more opportunity to generate RWD in Poland.

Hence payers are using RWD, especially for re-assessments, or in case of late market entry.
With the rapidly growing availability of RWD, and the increasing demand for information on effectiveness, there is a strong push for creating and using RWD. Payers should wish to see RWE as it adds to deeper understanding about what the product does in a relevant environment. Companies hope to cope with the arguments that payers love to use on lack of predictability of product value in the real world. Therefore, RWE is hailed by many as the solution that will confirm or deny the therapeutic value of the product for public health.

We categorised recent (2017–2019) review publications about RWE in three main classes based upon our impression of their purpose:

- papers where the main message is in favour of using RWE (proponents)
- those that review benefits and shortcomings of both RWE and RCTs (balanced)
- and those calling for caution or are outspoken negative when discussing RWE (opponents)

Publications of proponents describe the benefits of RWE studies without much criticism. Reviews specific to a therapeutic area, e.g. gynaecology, ophthalmology or rheumatology, describe RWE findings and contrast these with RCT predictions. They highlight the additional information that can be gained from studying RWD e.g. effectiveness in vulnerable patient populations, healthcare resource use, long-term safety, safety in special groups such as pregnant women, long-term real-life outcomes, etc. and give examples of practical consequences such as service improvements.

We read with special interest publications that are funded or authored by large pharmaceutical companies as these offer some insight on the dominant feelings about RWE in the industry. RWE is positioned as a complement to RCT results so that payers and regulatory authorities achieve better understanding about the performance of medications in practice. There are calls for better sharing – i.e., making available to the industry – of existing RWD. This is a sensitive issue as we have seen authorities using RWD in negotiations on pricing and reimbursement. As always ‘knowledge is power’ hence they are not willing to lose this advantage. Moreover, there are political (offering access from a publicly funded database to private companies) and privacy (would a patient agree with the use of RWD by the industry) issues. Overall the industry sourced publications defend the position that RWE should be part of decision making, provided there are adequate measures taken to ensure quality.

Some publications are outspokenly negative on the use of RWD. The American Society of Clinical Oncology (ASCO) March 2019 publication detailed how RWE could lead to false claims regarding effectiveness, and concluded ‘Journal editors and clinicians should be critical of studies that report effectiveness in the absence of efficacy and should question the plausibility of such findings’. A publication by Professor Jingling Tang, who heads up the Hong Kong Branch of the Chinese Cochrane Centre, carries the title ‘Real world study cannot replace randomized controlled trial’. A publication ‘Proceed with caution when using real world data and real world evidence’ by Korean professors that specialise in medical informatics, reviews all weaknesses and technical issues and their consequences. Professors in law from the UNC Gillings School of Global Public Health believe that RWD carries legal risks e.g. implications for off-label fraud enforcement.
Most non-industry sponsored publications offer a balanced view. They recognise the weaknesses of RCTs, while cautioning for the use of RWD (Table 3).  

Table 3: Comments from reviews that cover both positive and negative aspects of RWE and RCTs

| Positive comments on RCTs | • RCTs are universally recognised as the most robust ‘evidence generators’  
|                         | • RCTs are conducted in real settings: patients visit hospitals at regular intervals; the medical institution performs inspections, physical examinations, and blood tests at regular intervals, and there is a high rate of compliance with these tests |
| Negative comments on RCTs | • Unsuit for to capture the impact of treatments in routine clinical practice  
|                           | • Not fully representative of an unselected real-world population |
| Positive comments on RWE | • More relaxed inclusion and exclusion criteria  
|                           | • Reflects the actual clinical aspects  
|                           | • Large samples are advantageous for studies of rare adverse drug reactions  
|                           | • RWE can have very large sample sizes  
|                           | • Provide information on treatments in patient groups that are usually excluded from RCTs  
|                           | • Are generally less expensive and quicker than RCTs  
|                           | • Can assess a broad range of outcomes |
| Negative comments on RWE | • Due to lack of randomisation: risk for bias  
|                           | • Do not provide a robust basis for comparing treatment strategies  
|                           | • Data sources have different objectives and are subject to specific limitations with respect to the disease and therapy-relevant analytical options  
|                           | • Extracted electronic medical data records can still be unstable and contain serious errors  
|                           | • Large amount of missing data; consequence of large sample size  
|                           | • It is difficult to confirm whether the drug was taken appropriately  
|                           | • Diagnosis can be very unreliable, especially for those based upon clinical symptoms only |
| Recommendations for RWE | • The combination of different sources into an integrative approach might improve the validity of RWE in MS  
|                           | • Standardisation of data collection and processing  
|                           | • The definition of uniform and transnational quality standards  
|                           | • Agree on and use criteria to define robustness of RWE |
Several authors offer their opinion on how RWE could be made more robust and add to the knowledge that is derived from RCTs (Table 3). The GRACE (Good Research for Comparative Effectiveness) checklist was developed especially for observational studies that compare active therapies, and was tested on a series of 48 publications. Of these 48 articles, experts considered 21 ‘good’ and 27 ‘not good enough’. The correlation with the checklist outcomes was however not good enough and the authors concluded the checklist could only serve as a ‘first pass’, urging further development of adequate tools to check the quality of observational studies.

In conclusion, whereas several review publications hail the importance and future role of RWE, numerous publications are highlighting the shortcomings of RWE. They call for caution when using RWE in healthcare decision making, and demand better quality and global quality standards. However, even if data gathering and analysis would be impeccable there are still reasons to be cautious with the interpretation of RWE: bias (systematic error) and multiplicity issues.

Understanding bias

Two elements of bias complicate all observational studies: confounding (when reasons for products choice e.g. diagnosis and clinical features, correlate with clinical outcomes) and channelling (type of selection bias, e.g. when a product is claimed to be safe it will be used in high risk patients).

A well documented textbook example of selection bias was the use of coxibs in patients with gastrointestinal (GI) risk factors. Whereas coxibs had shown lower rates of GI side effects and hospitalisation than other non-steroidal anti-inflammatory drugs (NSAIDs), an analysis of the real-world experience in the UK (using GPRD) showed comparable side effects rates and higher hospitalisation rates. This was resulting from a selection bias towards patients with higher GI risk profiles (Table 4).

Table 4: Channelling example for coxibs versus non-steroidal anti-inflammatory drugs (NSAIDs)

<table>
<thead>
<tr>
<th>Number of major GI risk factors</th>
<th>Prescriptions (%)</th>
<th>GI events rate (% of patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NSAIDs</td>
<td>Coxibs</td>
</tr>
<tr>
<td>0</td>
<td>31.1</td>
<td>20.8</td>
</tr>
<tr>
<td>1</td>
<td>31.3</td>
<td>29.3</td>
</tr>
<tr>
<td>2+</td>
<td>37.8</td>
<td>49.7</td>
</tr>
</tbody>
</table>

Role and risks of statistics

Health economists are used to statistical tests and corrections. They therefore may assume that the statement that an outcome is ‘statistically significant’ will automatically lead to agreement with other parties such as regulators and payers about the studied outcomes. However, the often-used phrase – often contributed to 19th century Prime Minister Benjamin Disraeli – ‘There are three kinds of lies: lies, damned lies, and statistics,’ – may be more prominent in the thoughts of these regulators and payers. This is especially true when techniques are difficult to understand for the non-expert in statistics.

There are statistical techniques to correct for bias, assuming the information to correct is available (which is not mostly the case). An excellent example proving this point is a study on osteoporosis drugs, where the authors used several statistical techniques to reduce confounding (see Figure 3).
In this example, confounder adjustments reduce the gap between the older and the newer product, and the rate of adjustment is dependent on the method of confounder adjustment.

The example of the Prasugrel versus ticagrelor in the previous section is a demonstration of another technique: propensity matching or matched pairs. It reminds me of a cynical remark from Robert J. Temple, the Food and Drug Administration Center for Drug Evaluation and Research’s Deputy Center Director for Clinical Science and Acting Deputy Director of the Office of Drug Evaluation. At a meeting around comparative effectiveness where another observational study using matched pairs was presented, Temple said: ‘if you do all this you end up with something that you could have done by a simple RCT’.

Other publications add to the scepticism about the validity of statistics when using RWD. A recent publication exposes ten common errors in statistical analysis of RWD from cancer registries: convenience, dichotomisation, stratification, regression to the mean, impact of sample size, competing risks, immortal time and survivor bias, management of missing values, and data dredging. This last point introduces the multiplicity issues.

Statistical errors caused by multiplicity refer to the simple fact that if you accept a 95% error range, this implies you have a 5% chance of finding a false positive. If you perform many statistical tests that are not based upon any medical assumption about causality of the outcome, you will have false positives, e.g. if you perform five tests, there is a 23% chance to obtain at least one significant result when indeed the null hypothesis is true.

This makes the concept of ‘data dredging’ of RWD something horrifying for payers and regulators. Of course, there are some statistical tests to correct for multiplicity, but these do not change anything on the sound logic of the multiplicity issue i.e. hardly convince anyone.
Customers are becoming smarter and conclusions based upon RWD are greeted with more scepticism than a few years ago. There is growing understanding about the opportunities and risks that RWD offers to both payers and industry. Observational studies provide an important source of information not given by RCTs, if the data are gathered, analysed, and interpreted with special attention to bias and data quality. Effectiveness in daily practice, long-term safety and clinical outcomes data, data on utilisation in vulnerable patient groups, use of economic resources etc, can be examples of valid RWE. However, for comparing effectiveness of a new entrant to older or competitive drugs there are strong concerns and calls for caution.

**THE PLACE OF REAL-WORLD EVIDENCE IN YOUR MARKET ACCESS STRATEGY**

What are the practical consequences for market access and commercial functions when they plan on developing and using RWE?

A few conclusions from all the above may help in your planning:

- There is strong drive to capture and analyse RWD on the effectiveness and safety of your product. Post-launch data capturing may even be mandatory as it is frequently requested by the regulatory authorities.
- For markets with ‘normal’ timelines for marketing authorisation, RWE is too late to be considered during initial pricing and reimbursement discussions. An early access program may deliver some early RWE, but these patients may not be representative for later utilisation.
- One may wonder if it was in favour of the industry to push for the need of RWEE, as this is now becoming expected and hence will need to be delivered, which is not without risk as outcomes may differ from clinical trials, both in bad and good directions.
- Studies that are comparing effectiveness between your product and competitors will be scrutinised more and more by payers with growing awareness of possible selection bias and confounding, so RWE may not be the best approach to demonstrate superiority. If performed there should be adequate attention to demonstrate – if possible – that the patients in both cohorts are fully comparable. A pure statistical correction is less likely to be accepted by the payer audience.
- Phrases like ‘real-world evidence’ and ‘data dredging’ may harm your case more than helping when the payer audience is sceptical and aware about statistical and quality issues.

We recommend careful study to see if there is a fair chance that your product will perform better or worse in the real-world before doing anything. In this exercise you should bring experts that may be able to predict channelling and other confounding factors when your product enters the market. You will need to communicate early when channelling risks to bring fewer positive data about the reasons and confounding factors. When you expect niching in high-risk patient groups you should ensure capturing data to explain the outcomes of your product in the utilisation framework.

In conclusion – a plan for RWE is needed to support market access and pricing, but it should not only consider benefits but should also take possible risks of real-world utilisation into account and have plans to mitigate the impact of potentially biased outcomes.
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Raf De Wilde is Senior Executive Advisor at Valid Insight. He is a global expert in life science market access, having over 39 years’ experience in the pharmaceutical industry and over 29 years in global market access.


In 1997, he joined Peter Lauper’s team that pioneered the ‘biosimilars’ concept and the first patient access schemes. Raf led a specialist oncology, real-world evidence and virology group between 2002 and 2004, where he created a centre of excellence for oncology pricing and specialised in biologics while leading the HEOR function at CENTOCOR. Raf was VP of Market Access at J&J leading teams working on oncology, cardiovascular and biotech products from 2004 to 2010.

Raf joined United Biosource Corporation (UBC) as Associate VP in early 2011 and stayed with Evidera until 2015, prior to joining Valid Insight in 2016. In his consulting career he has led nearly 200 global market access projects, including value strategies, price finding research, patient access schemes, negotiation tactics, tendering and contracting, WHO classification and naming strategies. He has moderated over 150 training workshops in Asia, Asia-Pacific, Europe, North America and Middle-East, and led the life sciences pricing training of the European Pricing Platform from 2011 to 2014.

Raf continues to teach the sessions on PROs and evidence-based medicine at the Master of Science in Pharmaceutical Medicine course of the University of Duisburg-Essen in Germany.

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With a team that includes some of the world’s leading market access and pricing experts, clients across the globe turn to us for innovative pricing, market access and value communication strategies through the full product development cycle.

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