INTRODUCTION:

Disinvestment – stopping the use of health technologies with little or no clinical benefits – can reduce health system costs and change practice towards effective innovations. In England, efforts to support disinvestment have included the National Institute of Health and Care Excellence (NICE's) list of 900+ "Do Not Do (DND) technologies". However, recent studies show ongoing, varying rates of DND technology, suggesting limited influence. In response, we propose a shift in perspective and reframing of the concept of 'disinvestment' to focus on 'appropriateness'.

METHODS:

We have developed a two-pronged approach to 'appropriateness'. The first develops local clinician agreements on specific, appropriate indications for a technology. The "RAND/UCLA Appropriateness Method" is being extended in this stage. This knowledge management process enables incorporation of local knowledge and practice via consensus development amongst local experts alongside scientific evidence. The second, and more novel, element is to specify and routinely collect data on technology use associated with these agreed indications. Shifting from cross-sectional clinical audits to real-time monitoring will highlight variation from the agreed indications, which can inform reimbursement policy and decisions. Evaluating the feasibility and sustainability of this approach will provide important lessons for scaling up.

RESULTS:

For clinicians, the reframing from disinvestment to appropriateness has important implications. The approach recognizes that there are very few technologies with absolutely no benefit. Framing the management of technology diffusion in terms of appropriateness emphasises benefits and maximises value for public health. Furthermore, combining local agreements on indications with real-time data capture facilitates intelligent, flexible commissioning and informs real-life evaluation.

CONCLUSIONS:

Shifting the perspective from disinvestment to appropriateness overcomes negative associations of stopping healthcare technologies. Linking clinically driven decisions on technology indications with routine data capture on use can transform clinical audit and healthcare commissioning. The combination of these approaches is, we believe, a novel approach on which more reflection and research will be valuable.

VP115 Practical Issues Of Using Real-World Data In Effectiveness Research

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INTRODUCTION:

The Innovative Medicines Initiative, IMI-GetReal project aimed to explore incorporation of robust methods for real-world data (RWD) collection and synthesis earlier in the medicines development process, both by pharmaceutical companies and healthcare decision makers. The focus was on the potential use of RWD, alone or in combination with randomized controlled trials (RCTs), to demonstrate effectiveness of new interventions. Four case studies were conducted in multiple disease areas to examine methods for predicting drug effectiveness and the perspectives of different stakeholders on these methods. This study aimed to identify practical obstacles in accessing and using RWD and RCT data for effectiveness research conducted as part of these case studies.

METHODS:

Qualitative content analysis was conducted to identify and characterize key issues relating to accessing and analysing study data from external sources, both RWD and RCTs.

https://doi.org/10.1017/S0266462317003725 Published online by Cambridge University Press

RESULTS:

Accessing RWD from registries proved difficult due to multiple reasons, including: complex and non-transparent application procedures, resistance from registry owners to discuss applications and datasets not being research-ready within project timeframes. There were also issues with the RWD eventually accessed, including a lack of individual participant data (IPD) and incomplete data. Where access to IPD from RCTs was obtainable, there were restrictions imposed on how it could be used. For example, it could not be used to target analysis on an individual product, but rather explore methodologies for data synthesis in a product-anonymised setting. This condition encouraged additional data sharing by other stakeholders.

CONCLUSIONS:

Despite the collaborative, multi-stakeholder nature of IMI-GetReal and proper disclosures with data owners, access to data proved challenging. Such barriers to data accessibility can delay effectiveness research, restrict opportunities for the development of methods incorporating RWD and diminish the potential use of RWD in decision making. Where data is intended to be used for this purpose, sufficient attention should be paid to these potential barriers.

VP116 Comparison Between Time To Off Treatment And Italian Medicines Agency Registries Treatment Duration

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INTRODUCTION:

The Italian Medicines Agency Registry represents a tool that could be a precious source of information regarding the mean treatment duration of a drug in a real world context. Monitoring registries are applied at the national level after market authorization and are designed not only to apply the Managed Entry Agreements (MEAs) but also to collect Real World Data on drugs safety, effectiveness and real life utilization. The purpose of this analysis was to compare the treatment duration from clinical trials and the mean treatment duration calculated using data from monitoring registries (1).

METHODS:

For each drug included in the analysis it was collected the treatment duration from Time To Off Treatment curves for the experimental drug (eTTOT) from Phase III clinical trials and the mean treatment duration data calculated by using the number of cycles (converted in months of treatment) of all treated patients extracted from AIFA registries (TTAR). The mean ratios between the Time of Treatment of Italian Medicines Agency and Experimental arm time to off treatment were calculated to identify potential correlations. High level of correlation was expected if Time to Payment By Result /Time To Off Treatment ratio was close to 1 (±.2).

RESULTS:

Six Roche products or different indications of the same product were identified as candidates for the analysis from 2013 to 2016. The mean TTAR/eTTOT ratio observed in patients treated from 2013 to 2016 was .97 (±.10), meaning that the mean treatment duration calculated from AIFA Registries is strongly comparable with the treatment duration observed in clinical trials. In one case the TTAR is even more major than eTTOT.

CONCLUSIONS:

A high level of correlation between TTAR and eTTOT was found. Additional analyses considering different cohorts of patients over time could be useful to have a more precise estimate of real world drug utilization. Even though RCTs remain the gold standard for demonstrating clinical efficacy in restricted trial setting, Real World Evidence from AIFA registries can contribute to the evidence base needed for healthcare decisions.

https://doi.org/10.1017/S0266462317003725 Published online by Cambridge University Press