INNOVATIONS in pharmacy 10th Anniversary Celebration
Special 'Call for Papers' in the Formulary Evaluations Section of the Journal

Post QALY: Scientific Approaches to Real World Formulary Decision Making

Guest Editors

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Objectives

The purpose of this anniversary supplement for *Innovations in Pharmacy* is to consider and / or propose modern, scientific methods for determining the evidence base for the fair pricing and accessibility of pharmaceutical products and medical devices. At present, such decisions are based on the construction of imaginary value assessment models that fail to meet the standards of normal science. Such a business model has been adopted by the Institute for Clinical and Economic Review (ICER) in the US, NICE in the UK and in a number of other countries.

For 30 years health technology assessment has been preoccupied with modeling cost-effectiveness claims based on incremental cost-per-QALY models. This has been, and continues to be, an irrational approach. Rather than recognizing the limitations of available evidence for product impact, notably in respect of the "quality" element of the QALY, leaders in the field have insisted on the relevance of approximate information. This puts to one side the role of real world evidence to support product assessment and the potential for future feedback of claims assessment to support ongoing formulary listing. Real world evidence may be limited at product launch, but this does not justify creating imaginary evidence to support formulary review.

The centerpiece of the value assessment framework is the QALY; constructed by discounting time spent in a disease state by a utility score. This is a mathematically impossible construct. It requires the application of a generic utility score. Unfortunately, this denies the limitations imposed by the axioms of fundamental measurement.

Utility measures such as the EQ-5D-3L and EQ-5D-5L instruments produce ordinal scores that cannot be used to create mathematically valid QALYs. It is mathematically impossible to multiply time spent in a disease state by an ordinal utility to create a QALY. Despite this being pointed out for 30 years, this problem has been ignored. Rather than generate real world data, technology assessment claims and recommendations for pricing and access rest on a series of assumptions that are patently false. It is time to put imaginary constructs and their claim as a cornerstone for value assessment, pricing and access behind us.

The key question is one of real world evidence:

- What real world evidence standards should be in place for formulary committee decision making for new products and devices?
- What evidence, including prospective claims assessment, should formulary committees require of a manufacturer to support product listing and pricing?
- What standards of measurement are required to determine whether claims are provisionally accepted or rejected?
- Should manufacturers be required to submit protocols to a formulary committee detailing how claims for clinical effectiveness and resource utilization in target populations are to be assessed?
- What claims assessment feedback criteria should be in place to assist formulary committees to determine product effectiveness?
- Should formulary committees insist on an ongoing commitment by the manufacturer to the disease area and therapeutic class for claims assessment when revisiting decisions about product placement, pricing, and access?
- What should be the minimum standards for monitoring claims in an observational tracking environment?

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Publication

This Special Supplement for Formulary Evaluations will be followed by calls for papers for each of the other subject sections in the Journal. The Special Supplement will publish papers from Q3/2020 to end Q2/2021.

All papers should be submitted for preliminary assessment to Professor Jon Schommer, Ph.D., Editor, Innovations in Pharmacy. Please follow the submission procedures detailed on the journal website and designate 'Formulary Evaluations' as the section.

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