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Complexities in pharmaceutical health services research

For over two decades, pharmaceutical manufacturers, health insurers, other payers and consultants among others have been conducting pharmaceutical health services research studies, sometimes called outcomes studies. These studies generally compare a new drug product with an existing therapy already on the market and widely used. And most of the time, such studies do inform us as to whether one or the other has superior therapeutic effects. The addition of pharmacoeconomic considerations, next, allowed us to determine whether the superiority of one product was worthwhile or not. If the two drugs offer about the same effectiveness and one has 5% more adverse events associated with its use, we can calculate the cost of repairing those adverse drug effects (ADEs) and determine a lower priced product is a bargain or not.

But, today we are faced with a multifaceted situation where a drug may be tested against that same drug combined with radiation, or we might be faced with a question as to whether a drug product may be more effective if used (a) alone; or (b) with drug X; or (c) with drug Y; or (d) combined with both drugs X and Y. This example represents a most complicated situation. The F.D.A. requires a single product be tested against a placebo, while the European Medicines Agency (EMA) would evaluate a candidate product versus a typical therapy in current use. So, if we want to know about the addition of drugs X, Y or X and Y, that would have to be supported by the drug's manufacturer after the drug is licensed and widely available. A study of this type would require four arms and would be most costly and lengthy. The number of clinical trial participants necessitates huge recruiting fees and study costs.

And if we find that the drug along with both drugs X and Y improves outcomes by 20 per cent over solo drug therapy, but the costs increase 400% by using all three drugs together, we will have created a new dilemma, especially when considering that there can now be ADEs from any or all of the three-drug therapy, which adds further expense to the equation. Other examples could be even more complex, but life today in pharmaceutical health services research will be increasingly complex.

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