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Review Article

Need of fostering academic research for bridging the gap of "science-commerce disconnect" in 'non-profitable' therapy areas

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ABSTRACT

Pharmaceutical companies share the goal of patient benefit with healthcare professionals. However, they are commercial organizations and hence, sometimes, commercial interest may take over science, resulting in "science-commercial disconnect". This can result in innovation-deficit and financial burden on the patients. Finding new indications for existing drugs and promoting academic research in 'non-profitable areas' are some measures to curtail pharmaceutical innovation-deficit. Greater involvement of academicians and non-government organizations in clinical research with government support/funding will help in providing best treatment options to the patients for better outcomes.

Keywords: Academic research, Financial profit, Patient centricity, Science-commercial disconnect

INTRODUCTION

Pharmaceutical companies continue to deliver therapeutic options to improve patients' health, quality of life and life expectancy. However, in some cases, "science-commercial disconnect" is visible possibly because of the commercial interests overweighing the real scientific needs. This reflects discrepancy between 'financial profits' and 'patient centricity'. As a result of this, the patient might suffer financially because of the high cost of treatment, deprived of better treatment option or both. The disconnect is a result of either unwillingness to invest in clinical research in certain disease domains which are not profitable for company's future revenue generation or make the product available to masses due to commercial implications. Secondly, drug-pricing regulations and increasingly competitive environment especially in generic segment result in diversion of budgets towards marketing of existing costly products and compromising clinical research activities by the pharmaceutical companies.

Following section describes few examples of "science-commercial disconnect" and possible measures to avoid it.

The research on antimicrobials does not seem to be proportionate to the rise in wide spread resistance to antimicrobial compounds. There are several reasons for this, one of which is "return on investment". Antibiotics may provide low 'return on investment' compared to other drugs used in the management of chronic diseases.

Generally antibiotics are used for short duration and approval is usually given for reserved indications to avoid or slow the development of drug resistance to new products.[1] The risk-adjusted net present value of for antibiotics is much lesser compared to drugs used for treatment of cancer, neurological disorder or a musculoskeletal disorder.[2] These reasons may result in reduced interest in development of newer and novel antimicrobial compounds. Therefore, the focus is diverted more towards chronic diseases, diseases of affluence or longevity for long term revenue generation.

Childhood absence seizures is another classical example of this disconnect. A double-blind, randomized controlled trial in newly diagnosed childhood absence epilepsy has shown ethosuximide and valproic acid to be more effective as initial monotherapy than lamotrigine in controlling seizures without major adverse events.[3] As ethosuximide is not available in India doctors have to rely on sodium valproate. In case of contraindications for using sodium valproate, clinicians face a challenge because of the unavailability of ethosuximide.

One more example is the use of bevacizumab intra-vitrieal use. Bevacizumab, a vascular endothelial growth factor-specific angiogenesis inhibitor is indicated for the treatment of various cancers.[4] Intravitreal bevacizumab is also used off-label by ophthalmologists because of its efficacy in various ophthalmological disorders such as choroidal neovascularization, proliferative diabetic retinopathy, and macular edema due to diabetic retinopathy or vascular occlusion.[5] Ranibizumab, another vascular endothelial growth factor A inhibitor is indicated for the treatment of neovascular age-related macular degeneration is not commonly used due to its high cost leading to unaffordability by patients from the low-income status.[5,6]

As, bevacizumab has been found to be well tolerated without significant retinal toxicity, ideally should be applied for regulatory approval in ophthalmological indications after conducting necessary clinical trials. In the absence of it, patients are at the receiving end in both cases; suffer financially if they are treated with ranibizumab and subjected to unapproved drug for ophthalmological indicated if treated with bevacizumab. Reports of loss of vision in few patients after intra-vitrieal use of bevacizumab injection, led the regulatory authority of India to release an alert notice that bevacizumab injection is not approved for intra-vitrieal use for ophthalmology purpose.[7]

Bevacizumab is available as 100 and 400 mg vials. The ABC trial has shown that intravitreous bevacizumab 1.25 mg injections as part of a six weekly variable retreatment regimen to be effective in the treatment of neovascular age related macular degeneration with low rates of serious ocular adverse events. [8] As single dose injections of 1.25 mg are not available; multiple doses from available vial is the only option, if bevacizumab is selected for use after discussion with patient. Multiple use of bevacizumab from single-use vials may not be a problem because an in-vitro study did not show microbial contamination. [9] However, these results need to be carefully extrapolated because of limited number of samples tested. If the drug is officially studied and approved for ophthalmological indication and supplied in suitable strength ampoules, such problems could possibly be avoided.

Similarly, a large body of experimental data indicates towards an association between aspirin consumption and decreased cancer incidence at several anatomic sites. Incidence of several cancers was lower among persons who reported aspirin use: the incidence rate ratios (and 95% confidence intervals) for all sites combined were 0.83 (0.74-0.93), lung cancer 0.68 (0.49-0.94), breast cancer in women 0.70 (0.50-0.96), and colorectal cancer in younger men 0.35 (0.17-0.73). Having said that, it is a low-cost alternative having minimal profit potential, thus does not attract enough attention compared to new blockbuster cancer drugs that cost billions to develop and can be sold for thousands of dollars a dose.[10]

These few examples unfortunately indicate that commerce runs the science and not vice versa. If reverse happens, patients would benefit more than today.

The changing trends in pharmaceutical industry can also be explained by an interesting observation of paradoxical self-reported illness- low in Bihar (India), and significantly high in the United States noted in British Medical Journal.[11] These observations indicate that industrialization of health can make more money from preventive healthcare interventions for the healthy and wealthy community compared to unwell poor minority community. Fear and anxiety among affluent class lead to purchase of more preventative health interventions, profiting pharmaceutical organizations.

If such trend continues, if not increased, the fear of needy patients getting deprived of essential treatment cannot be ruled out.

Measures to reduce "science-commercial disconnect"

There should be coordinated efforts to bridge the gap between commercial interest and clinical needs.

A few approaches to tackle the situation are:

1. Research pipeline must be proportionate to disease epidemiology, availability of less therapeutic options or rate of occurrence of resistance.

2. Government advisory bodies and pharmaceutical industries collaboratively should set targets for research and innovation.

3. Government incentives and award recognitions should be given for bringing breakthrough therapies in important but unaddressed diseases.

4. Mandatory proportionate investments on all four phases of research

5. Fostering pre-clinical and clinical research in academic institutes with government funding with rewards/recognitions.

6. As each new indication promises increased profits, companies should conduct more research on new indications for older drugs.

While it is difficult to always match the science with commercial interest, researchers and government should actively promote awareness and academic research to help patients get the best treatment.

CONCLUSION

Clinically significant superiority to existing alternatives is the need of the hour and medical innovation is the key to achieve it. Pharmaceutical companies in close association with clinicians significantly contribute to the progressive betterment of patient's health. However, sometimes commercial interests overweigh the clinical needs. A balance is required between pharmaceutical profits, availability of medicines and affordability – all in the interest of patient population. Researchers, academicians, and government should work together to bridge the gap of science-commercial disconnect and help patients to get the best treatment options.

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