

TDM in India

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Abstract

Introduction

TDM in India is delivered mostly in the health care facilities those are teaching and research Institutes. They exist in two types of frameworks (1) Public sector tertiary care hospitals (2) Private owned health care Institutions. There are other diagnostic laboratories conducting the drug assays, to support the health care systems. However, these essentially may not be regarded as TDM, because the circle of communication that is integral to TDM is missing there. There is no suggestion for dose modifications, as the patient clinical condition and interpretation of drug assay results in the light of the available information may not possible in these settings. TDM is a multi-disciplinary activity and therefore, primarily fosters in academic research organizations in India.

Contents

This talk aims to highlight upon

- (1) The importance of TDM in the context of India (with special reference to the specific diseases and health conditions)
- (2) Scope of research in TDM and implementation in patient care
- (3) The issues and challenges (Infrastructure and funding , cost-effectiveness, standardization of laboratory and methods)
- (4) The Road ahead to strengthen TDM in India

Body of the Talk

India is a developing country with regard to the health care services and delivery. TDM has a sparse presence and the research into the utility of TDM to Indian context is a work in progress. TDM has made a justified presence in centers where the facilities exist. This is evident from the contribution to the scientific literature from these centers. The therapeutic management of patients where TDM has proven to be of great value is antiepileptic drugs (as the older generation drugs are still frequently used), immunosuppressant drugs (organ transplantations are on the rise), Lithium and some of the chemotherapeutic drugs like methotrexate. The emerging evidence suggests that TDM can add value in other therapeutic areas like, antitubercular drugs, antimicrobial drugs, anti retroviral drugs, antifungal drugs. The research into these area and implementation of TDM has the potential to combat difficult challenges in therapeutics like emergence of MDR/XDR tuberculosis, antimicrobial resistance etc. TDM has proven to be immense utility to detect the drug interactions arising due to the use of complementary and alternative medications (Ayurveda, Unani and others) which are commonly used concomitantly by the patients. Generic drugs are commonly used in India and many critical drugs like

antiepileptics, immunosuppressants may have different extent of bioavailability than the innovator affecting the therapeutic outcomes due to generic substitutions. In this setting, TDM empowers the clinicians to switch between different commercially available generic preparations and hence allow to make an evidence based choice for the drugs that are less expensive.

There are several challenges for TDM in India, some are related to “TDM per se” and some are not related to TDM and are rather logistic. The notable ones related to TDM per se are (1) The main challenge faced in India for wide spread applicability of TDM based therapeutic decision is to prove the cost-effectiveness and cost-utility of such service. The cost of establishing a facility and providing quality service must be justified by the benefits obtained in terms of optimizing treatment and benefits thereof i.e. to prevent therapeutic failures, adverse events, improving outcomes and adding a positive pharmacoeconomic value. TDM in India need a substantial amount of in-house research to generate such evidence. (2) The other challenge is to establish the population (ethnicity) specific therapeutic ranges for various drugs. Majority of the reference ranges are derived from International therapeutic guidelines/consensus statements and studies conducted on other population. The unique combination of poor nutritional status, co-existing tropical diseases, special racial constitution necessitate research in this area. The other challenges are largely related to the logistics (3) Infrastructure and trained manpower. Like any other developing country, it is a challenge. Hence there is need for generating the data to justify such investments by the administrators as there is an opportunity cost associated with it in a resource poor setting. (4) Minimal turnaround time is a challenge when the workforce is limited. The purpose of the TDM may be lost with a high TOT, hence capacity building is the need of the hour (5) Need for standardization of the laboratories (accreditation) providing TDM services. As of now this is not a mandatory requirement by the regulatory bodies and practiced on a voluntary basis. Reinforcing standards would improve the quality of reporting and the physician’s confidence in the accuracy of the laboratory results. (6) Need for National Proficiency Testing Programs to ensure external quality assurance. The international PT programs are prohibitively expensive and hence impose a substantial financial burden on the TDM labs.

Therefore, there is a need for a forum or formal society to bring together all the stake holders viz. the pharmacologists, the clinicians and the hospital pharmacists, expert professionals in pharmacometrics and pharmacoeconomics to a common platform. The brain storming sessions in this forum may help devising strategies to strengthen TDM in India. These could include (1) A draft national list of priority drugs for TDM based on their utility to the Indian context, (2) Designate a few nodal centers to take the lead in research to generate population specific data and in addition these centers may also initiate capacity building (train young pharmacy graduates and pharmacologists) to establish other centers (3) Centers already experienced in delivering the TDM services could help the upcoming centers to maintain the required laboratory standards as per the national and international accreditation agencies. These centers could also be instrumental in initiating National Quality Assurance Programs. Finally, the government may be approached with a well drafted plan to initiate a National Program to strengthen TDM in India.