

# Challenges in management of prescriptions for patient-centric care

## Abstract

The paradigm changes from the product-centric market to patient centric care are a revolutionary change in health care delivery. The Federation of International Pharmacy (FIP), WHO, and all most all drug regulatory authorities of the developed countries are emphasizing on the importance of patient centric care and outcome research to measure quality of life of the patients. The governments are encouraging the health care providers for focusing on the patient care by providing the direct incentivizes on the other hand, health insurance companies are also putting pressure on health care providers to minimize the cost on medication by adapting to generic prescribing. In developing<sup>2</sup> countries, although the government has realized the importance of patient centric care, they are also emphasizing to set the house in order by bringing various laws and regulations for example Pharmacy Practice Regulations 2015. In this manner they are bringing out fundamental changes in implementing the existing laws and enacting the new laws in regulations to improve the quality of life of patients. In this article we discuss the trends and their impact on clinical, humanistic and economic outcomes.

**Keywords:** federation of international pharmacy, patients, humanistic, guideline

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**Abbreviations:** FIP, federation of international pharmacy; R&D, research and development; CROs, contract research organizations

## Introduction

Prescriptions are the primary instruments written by the healthcare<sup>3</sup> professionals to a Pharmacist in order to dispense the medications. A guideline for prescription writing includes the rough estimate of risk benefit analysis while prescribing the drugs. In case benefits over the weigh the risks, then the drug can be prescribed not in case risk if endangers patient<sup>4</sup> safety benefits. The patients are of prime importance while writing the prescription.<sup>5</sup> This is because all most all drugs carry a burden of adverse drug reactions and cause a potential injury to the patients if not carefully monitored. Further, the patients respond differently to the same drug and dose. Allergic manifestations of some drugs are varied and are bothersome. In this context recently the Pharmacovigilance program has been made mandatory for the Pharma industries<sup>6</sup> who are supposed to carry out Pharmacovigilance of their products in the market and submit the report periodically to the regulatory<sup>7</sup> authorities (Table 1). This paradigm shift from efficacy to safety has its origin in the shift from the product centric marketing to patient centric care. In most of the developed countries rather than medicines, how to use them safely is the emphasis which is achieved through patient education, care and outcomes of the treatment. The pharmaceutical marketing focuses on the prescribing habits and exerts pressure on the prescribers and the pharmacist to sell more drugs to meet the sales targets. This has led to unethical practices in health care delivery. The medicines are prescribed irrationally and sold to the patients who are indulging in unsafe consumption of the medicines. On the top of it, there is also practice of self medication. It is very unfortunate to consider money is more important than health. There are problems arising due to lack of scrutiny of prescriptions in the

health care delivery system. For examples, prescribers are free and are left out free of regulations regarding the prescribing. In the developed country, prescriptions are monitored and looked for any irrationality in prescriptions.

The teams of health care providers are supposed to look after the patients to ensure a patient safety along with outcomes. Despite of a system, the medication errors and adverse drug reactions in patients are alarmingly high. There is a myth among patients and health consumers that every ill has a pill and they haunt the prescribers and pharmacist provide medicines which act as quick magic remedies. Over reliance on modern medicines has led to the widespread belief that modern medicines are good and safe. This is because many patients and health consumers believe that modern medicines have a scientific back ground and are adequately tested for safety hence cannot cause harm severely. One has to realize the importance of health rules like a balanced diet, adequate exercise and good lifestyle practices in maintaining good health. The medications may be able to give satisfactory clinical outcomes, but may not be able to ensure good quality of life for patients. The over reliance on medicine may affect the quality of life by causing drug induced diseases. There is a need for the patients to understand that medications have a limitation on quality of life and management of health on long term health outcomes. There is an urgent need to burst the myth of medicine's ability to control the disease provides a good quality of life. The stake holder of the health care system involving Government, Drug Regulators, Industry, Prescribers, Pharmacists and health consumer should exercise constraint in over indulgence and reliance on modern medicines.

The Governments in developed countries have adapted a patient centric care and are engaged in strengthening the health care system, ensuring health care for patients and health consumers with

improved quality of life. Generally, in developed countries public spending and investment in the health care is sufficient enough to run satisfactory no nonsense health care delivery. They adopt stringent quality standards and also established service standard for health care providers. On the contrary the governments of the developing economies don't have political will and does not want to invest more money in the health care delivery system. Due to poor standards of public health facilities majority of the citizens are haunted by a variety of communicable and non-communicable disease. For example, Tuberculosis, AIDS, Diabetes mellitus and Hypertension are major threats of morbidity and mortality in developing countries. Most of the public suffers from malnutrition along with poor quality of life. Due to inadequate funding what so ever the resources are there are utilized in providing drugs to the patients in primary health care. The private pharmaceutical industry is playing havoc for example, over drug utilization of the antibiotics, proton pump inhibitors and many me too drugs. It has reverted back which is leading to the development of highly resistant microbes, unsafe self medication of Proton Pump inhibitors leading to infection by Clostridium difficile and kidney damage. The self medication of Proton pump inhibitors is leading to anemia and osteoporosis.

**Table1** Major regulatory agencies world wide

Country	Name of regulatory authority
USA	Food and Drug Administration (FDA)
UK	Medicines and Healthcare Products Regulatory Agency (MHRA)
Australia	Therapeutic Goods Administration (TGA)
India	Central Drug Standard Control Organization (CDSCO)
Canada	Health Canada
Europe	European Medicines Agency (EMA)
Denmark	Danish Medicines Agency
Costa Rica	Ministry of Health
New Zealand	Medsafe - Medicines and Medical Devices Safety Authority
Sweden	Medical Products Agency (MPA)
Netherlands	Medicines Evaluation Board
Ireland	Irish Medicines Board
Italy	Italian Pharmaceutical Agency
Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)
Ukraine	Ministry of Health
Singapore	Centre for Pharmaceutical Administration Health Sciences Authority
Hong Kong	Department of Health: Pharmaceutical Services
Paraguay	Ministry of Health
Sweden	Medical Products Agency (MPA)
Thailand	Ministry of Public Health
China	State Food and Drug Administration

Table continued....

Country	Name of regulatory authority
Germany	Federal Institute for Drugs and Medical Devices
Malaysia	National Pharmaceutical Control Bureau, Ministry of Health
Pakistan	Drugs Control Organization, Ministry of Health
South Africa	Medicines Control Council
Sri Lanka	SPC, Ministry of Health
Switzerland	Swissmedic, Swiss Agency for Therapeutic Products
Uganda	Uganda National Council for Science and Technology (UNCST)
Brazil	Agencia Nacional de Vigilancia Sanitaria (ANVISA)
Japan	Ministry of Health, Labour & Welfare (MHLW)

#### INTERNATIONAL ORGANIZATIONS

World Health Organization (WHO)

Pan American Health Organization (PAHO)

World Trade Organization (WTO)

International Conference on Harmonization (ICH)

World Intellectual Property Organization (WIPO)

Drug Regulators of developed countries are well equipped to administer the drug laws, regulations. They are able to identify the wrong doings by the Pharmaceutical industry and control and do not allow to interfere with the public health. They have become proactive and are visiting the industries to find out any deviation from the standards leading to the poor quality of care. However, regulators in developing countries are ill equipped with infrastructure and are usually over burdened by the huge amount of workload. The quality assurance and marketing management are mostly left with the manufacturer without supervision by regulators.

The pharmaceutical industry is based on the corporate model which very much popular. Industry is engaged from the point of drug discovery, drug development, manufacture, distribution, marketing and generation of prescriptions. Public sector Pharmaceutical industries are having a social perspective are not able to thrive like private pharmaceutical industries. The private Pharmaceutical industry has to manage themselves with their own resources or by public investments. Private industry, unlike public sector has to work hard in order to survive in competition with other private industries and public sectors. Globally in the developed market in the Pharmaceutical industries has faced tougher regulatory environment and kept the standards as per the regulations. They have invested huge money in Research and Development (R&D) endeavors.<sup>8</sup> To invent a new drug and bring it to market is a mammoth task involving at least decade of time with huge money. In recent times, many big pharma industries have been forced to close down the R&D activities and lay off thousands of scientists unable to sustain economically. Now they have started outsourcing R&D activities to the developing countries, leading to surge of contract research organizations (CROs) in Developing countries. Pharmaceutical industries in developing countries are engaged in manufacture of basic chemical drugs and finished formulations. They have acquired a niche position of exporting

the finished products globally. For example, the developing countries Pharma industry is making generic drugs for the developed world. The regulators of the developed countries have been actively engaged in monitoring the manufacturing facility, process, human resource and other details as per their regulations. In this process, several industries from developing countries have been found violating regulations leading to punitive action against the defaulter. The pharma industries in the developing countries is not adequately regulated and monitored. As a result of this the manufactured products from developing country have looked with suspicion. The industry is also infamous for its unethical promotion of drugs leading to irrational prescribing and dispensing of prescription medicines without the prescription.

Prescribers in a developing nation have to work in an environment where patient centric practice is prevalent.<sup>9</sup> There are many examples where in a health care provider found guilty was punished by the court of law for lapses in services provided. Service providers and the pharma industry are closely watched for any unethical practices leading to abuse of prescription medicines.<sup>10</sup> On the contrary, in the developing economy, although regulations have been enacted but its enforcement seems to be totally absent. The rampant abuse of prescription medicines by health care providers and patients are wide spread, leading to damage of the health for the patients and health consumers. The examples of drug induced injuries have not come to the notice in the public as many of the cases do not get media exposure. The quality of life of the patients and health consumers are a neglected issue as the market in the developing country is a product centric.

Quality use of medicines is the responsibility of pharmacist. Community pharmacists are engaged in assisting the patients and health consumer in ensuring quality outcomes. The community pharmacists are issued licenses to practice after they clear the professional examination. If the pharmacist is interested to continue after the license date, he has to appear again and prove his competency for providing services. On the contrary, in a developing country to register as pharmacist one should have a prescribed qualification and apply to authorities to get licenses and open a pharmacy retail outlet. Pharmacist with poor orientation towards profession prefers to sell more drugs<sup>11</sup> than to practice patient safety. Pharmacists in drug stores are simply trading the prescription drugs against the money. Health consumers and patients have no idea that they should ask the pharmacist for their doubts while using the medicines. Hence, patients and health consumers don't get the instructions and information for safe use of medicines. For example, diphenhydramine is dispensed for cold and cough, cause drowsiness, may lead to an accident if the driver was not instructed not to drive, while using diphenhydramine. Every medicine is unique and different in its side effect profile. It is fundamental to educate the patients how to use the medicines prescribed, for e.g., Antibiotics like Erythromycin bioavailability increases in the presence of a fatty meal. However, Azithromycin should not be consumed along with the food as bioavailability gets reduced in the presence of food. There is a professional engagement of the pharmacist to provide pharmaceutical care services for every patient who uses the prescription medicines dispensed by the pharmacist. Such facilities are always encouraged by the government and usually motivates by paying special incentives. In developed countries, the patients are instructed in detail about how to handle the medicines by the pharmacist, in case of any strange adverse drug reactions while using the medicines. Such practices are totally absent

in the developing countries. In developing countries Patients and Health consumers have to face the risk due to the absence of services.

## Common types of pharmaceutical fraud

### Compromises in manufacturing processes

The deviations from the GMP are usually observed from manufacturing facilities from a developing country. The compromise of the standards by manufacturers is a major cause for the concern for the developed countries who import the finished formulations. The regulatory agencies of the developed countries, although take all measures and meticulous inspections, there are several cases where these regulatory agencies slapped heavy penalties for deviation from the GMP leading to poor quality of the finished products.

### Off-label marketing

The post-marketing surveillance and pharmacovigilance gives in-depth knowledge of drug effects of the products in the market. There are experts in the industry in house R&D who are quick to identify the new indication for the drug. For example, sildenafil was found to be useful in the pulmonary arterial hypertension and exercise capacity in men and women. However, the drug was approved for treatment of erectile dysfunction in men. The off-label promotion of sildenafil which was ill-legal and irrational. There was no proper clinical data or evidence of its efficacy and safety for the off-label uses.

### Best price Fraud

The differential pricing of the pharmaceutical price is observed worldwide. Every government is keeping an eye the medicine prices. For example, irrational pricing with profiting motto is unethical and illegal. In India there is a drug price control order which gives guidelines to industry for the pricing of medicine.

### Kickbacks

The Pharmacy marketing is having the unfair liaison with the prescribers and retail pharmacy outlets. The modus of operand involves giving expensive gifts, cash, foreign trips, cash incentives and bonus schemes to push the products which are exorbitantly priced to the patients and health consumers.

## Pharmaceutical career- a patient care

Pharmacy practice had a beginning in the USA nearly 50 years ago in that time pharmacist mainly engaged in manufacture and dispensing the prescription medicines. As more medicine were introduced, several challenges and issues which popped out leading to innovation of new technology and skills were evolved for safe and effective use of medicine. There were also issues arising out of drug-food interactions, me-too drugs, leading to duplication of medicine in therapy, for e.g., the dose related issues and adverse drug reactions, poly pharmacy. The therapy was more focused on product on the product due to promotional practices by Pharma industry. Too much hype was created about drugs and was promoted as blockbuster drugs. However, it didn't take much to realize that, no drug is safe and indiscriminate use will definitely leads to drug induced injuries for e.g., alupurinol and paracetamol causes liver toxicity, most of the anticancer drug like doxorubicin causes cardiotoxicity.

Gentamycin and Cox 2 inhibitors causes nephrotoxicity,<sup>12,13</sup> no steroidal anti inflammatory drugs can cause gastric bleeding

The system of health care delivery has become more dubious and the rational use of the medicines obscure. The organization, like WHO, USFDA and Drug regulators of the developed countries were first to realize and react wide spread abuse of allopathic medicines. There were several regulations enacted and scrutiny of prescription was made mandatory. In this process, it became clear that the objective of the health care delivery should be focused on the patients' quality of life and well being rather than the clinical orientated medicine usage among patients. This led to the transformation of pharmacist to take a lead in the identification, evaluation, checking of the dose along with the appropriateness of using the medicines in patients. The importance of checking and ensuring of safety and efficacy of the treatment was extended further to focus on the quality of life of patients. Pharmaceutical care has an inbuilt capacity to delivery patients orientated holistic care engaging the patients themselves to participate in self care of their condition. The pharmacist involved directly communicates with the patients and prepares a customized the pharmaceutical care plan. The review of the patient's status of health periodically ensures continues monitoring and identifying the issues patient is facing. After identification if the problem falls in the domain of Doctor/Nurse a referral to respective health care professional is done by the pharmacist. If the problem is due to drug, disease, or life style, it is resolved by the pharmacist himself. Hand book of Pharmaceutical Care by WHO-FIP is advocating the implementation of pharmaceutical<sup>14-16</sup> care as a system of health care delivery.

## Limitations of pharmaceutical care

The idea of pharmaceutical care in the health care delivery is opposed by the stakeholders for the sake of conflict of interest or lack of information. For example, Pharma industry fears loss and reduction in sale of drugs due to the changed business model. The prescribers do not feel comfortable if any other professional looks at their prescription and tries to analyze and suggest the lacuna in prescription. The pharmacists who were engaged in merchandize of medicines also have a fear of loss of prescription medicines leading to erosion of revenues.<sup>17,18</sup>

## Conclusion

The health care delivery should be efficient to provide patients and health consumers' good quality of life at an affordable price supported by clinical evidence. On this journey new concepts like RCT, Meta-analysis and Systematic reviews are the new tools to measure, identify, and correct the deviations in health care delivery. Integration in IT with health care delivery is assuring the revolutionary changes in the quality of the life. The Pharmacoeconomics has been utilized identify the worth of treatment and identify the best choice of treatment in terms of economics. The documentation of healthcare delivery is one of the new initiatives to converse and negotiate the implementation of best treatments for the patients.<sup>19</sup>

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## Conflict of interest

The author declares there is no conflict of interest.

## References

1. Plessis DD, Sake JK, Halling K, et al. Patient centricity and pharmaceutical companies: Is It Feasible. *Ther Innov Regul Sci*. 2017;51(4):460–467.
2. Bernhard G, Mahler C, Seidling HM, et al. Developing a shared patient-centered, web-based medication platform for type 2 diabetes patients and their health care providers: qualitative study on user requirements. *J Med Internet Res*. 2018;20(3):105.
3. Delaney LJ. Patient-centred care as an approach to improving health care in Australia. *Collegian*. 2018;25(1):119–123.
4. <https://www.medcom.dk/media/8560/the-practice-of-patient-centered-care.pdf> accessed on 21/07/2018.
5. [https://www03.ibm.com/industries/ca/en/healthcare/files/060516\\_PatientCentric\\_Briefing.pdf](https://www03.ibm.com/industries/ca/en/healthcare/files/060516_PatientCentric_Briefing.pdf) accessed on 21/07/2018.
6. Geetanjali Sengar, Prana, Tripathy. Pharmaceutical regulatory agencies and organizations around the world: scope and challenges in drug development. Pharma review; 2018.
7. <https://www.pharmatutor.org/articles/pharmaceutical-regulatory-agencies-and-organizations-around-world-scope-challenges-in-drug-development> accessed on 26/05/2018.
8. Jayadevappa R. Patient-centered outcomes research and patient-centered care for older adults: A Perspective. *Gerontol Geriatr Med*. 2017;3:1–4.
9. Clarke S, Ellis C, Thombs BD, et al. Defining elements of patient-centered care for therapeutic relationship: a literature review of common themes. *Eur J Pers Cent Healthc*. 2017;5(3):362–372.
10. Hudon C, Fortin M, Haggerty JL, et al. Measuring patients' perceptions of patient-centered care: A systematic review of tools for family medicine. *Ann Fam Med*. 2011;9(2):155–164.
11. Bjornsson ES. Hepatotoxicity by drugs: The most common implicated agents. *Int J Mol Sci*. 2016;17(2):224.
12. Naughton Ca. Drug induced nephrotoxicity. *Am Fam Physician*. 2008;15;78(6):743–750.
13. <https://en.wikipedia.org/wiki/Ototoxicity> accessed on 20/07/2018.
14. Steven Fox. Report details fraud and abuse by pharmaceutical companies. Medscape Medical News© 2011 WebMD, LLC; 2018.
15. P Kumar AS, Tripathi H, Singh SP, et al. Pharmacological application of barium containing bioactive glass in gastro-duodenal ulcers. *Materials Science and Engineering: C*. 2018;92(1):424–434.
16. Arepalli SK, Tripathi H, Manna PP, et al. Enhanced in vivo biocompatibility of magnesia-contained bioactive glasses. *Journal of the Australian Ceramic Society*. 2018. p. 1–6.
17. Shakya M, Paliwal P, Patil S, et al. Cardioprotective effect of 'qolest'a polyherbal formulation against doxorubicin induced cardiotoxicity in wistar rats. *International Journal of Research in Pharmacy & Science*. 2011;1(3):86.
18. Paliwal P. Cardioprotective effect of 'Stresx'A polyherbal formulation against doxorubicin induced cardiotoxicity in wistar Rats (Doctoral dissertation, KLE University, Belgaum, Karnataka).
19. Arepalli SK, Tripathi H, Manna PP, et al. Preparation and in vitro investigation on bioactivity of magnesia-contained bioactive glasses. *Journal of the Australian Ceramic Society*. 2018:1–11.