

Code of ethics for the national pharmaceutical system: Codifying and compilation

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Pharmacists as one of health-care providers face ethical issues in terms of pharmaceutical care, relationship with patients and cooperation with the health-care team. Other than pharmacy, there are pharmaceutical companies in various fields of manufacturing, importing or distributing that have their own ethical issues. Therefore, pharmacy practice is vulnerable to ethical challenges and needs special code of conducts. On feeling the need, based on a shared project between experts of the ethics from relevant research centers, all the needs were fully recognized and then specified code of conduct for each was written. The code of conduct was subject to comments of all experts involved in the pharmaceutical sector and thus criticized in several meetings. The prepared code of conduct is comprised of professional code of ethics for pharmacists, ethics guideline for pharmaceutical manufacturers, ethics guideline for pharmaceutical importers, ethics guideline for pharmaceutical distributors, and ethics guideline for policy makers. The document was compiled based on the principles of bioethics and professionalism. The compiling the code of ethics for the national pharmaceutical system is the first step in implementing ethics in pharmacy practice and further attempts into teaching the professionalism and the ethical code as the necessary and complementary effort are highly recommended.

Key words: Pharmaceuticals, pharmacy ethics, pharmacy professionalism

INTRODUCTION

Science development and intricacy of health-care management and health-care services necessitate more involvement of pharmacists in the patient care. Previously, the pharmacists were the sole holders of the knowledge of pharmacy with special skills in compounding and dispensing medications, but industrialization changed their role and they now retreat themselves by dispensing despite “over-qualification.” In fact, pharmacists are supposed to be medicine experts, but mostly in the community pharmacy work as a drug dispenser. Of course, this is the viewpoint of authors based on what is happening at the time of writing this paper.

Although pharmacy is a science based and value based profession, its practice values are rarely defined. This means that those credits that show the pharmacy as a worthwhile profession are lacking. The conflict between different practice values is important. The interface between invisible values and interests is sometimes the origin of ethical dilemmas, which mostly is not sensible by pharmacy practitioners. Hence, not only the raised conflict is not fully understood, but also it remains unresolved and therefore providing a guideline as

well as teaching those professional values is of special importance.

In Iran, pharmacists are trained in an almost 6-years education program (Doctorate of Pharmacy) with emphasis on applied therapeutics and patient centered care. The graduated pharmacists mostly go to common pharmacies or pharmaceutical companies and all must complete continuous medical education (CME) courses to take annual score and allowance to work. The feedbacks coming from Iranian associations, regulatory organizations or common sources confirm the major need to have a national pharmaceutical code of conduct.^[1]

Health-care in Iran is governed by both private and public sector, but the predominant model in pharmacy is private. Unfortunately, community pharmacy ownership is not limited to pharmacists and stakeholders sometimes hire pharmacists for their community pharmacy. At the moment, the high amount of money exchange in especially community pharmacies has converted the profession of pharmacy to a business. Although this is not limited to pharmacies, the matter raises special ethical challenges in dealing with patients or other health professionals.

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It is believed that the essence of health-care is changing, and patients are more actively participating in their own care.^[2] Therefore, more ethical concerns raise^[3] and necessitates having guidelines for pharmacists to deal with such cases.

In some developed countries, there is a better understanding of the role of pharmacists in the health-care management and use of their knowledge and skill. In those countries, especially the US and UK, community pharmacies are increasingly involved in the primary care service sector and some pharmacists have some special prescription rights. Thus, they are faced with new concerns and responsibilities, which need technical skills as well as consideration of values and relationships.

Our former investigations in Iran showed that pharmacists have no big attitude toward professionalism as well as ethical issues and confirmed the necessity of teaching the principles of professionalism in addition to providing an ethical guideline.

Therefore, the experts from Medical Ethics and History of Medicine Research Center (MEHMRC) and the Pharmaceutical Sciences Research Center from Tehran University of Medical Sciences (TUMS) aimed to provide the code of ethics for national pharmaceutical system containing different workplaces where pharmacists play their role as a health-care professional. To provide that aim, firstly a working group consisted of experts in the field of pharmacy, medicine, medical ethics, and the law was formed. A thorough search into finding codes and guidelines of developed countries using keywords such as pharmacy, ethics, ethical issues, code of conduct, etc., or their combination was carried out. The resulted codes and guidelines were reviewed and the most useful points were extracted, compiled, and compared to local rules and context. The draft was submitted to review of pharmaceutical experts in various workplaces and then comments were gathered and discussed in several meetings to reach a consensus. The final code of ethics consists of five code and ethical guidelines useful for pharmacy practitioners working in different fields including pharmacy, pharmaceutical manufacturers, pharmaceutical importing companies, pharmaceutical distributor companies, and policy making or regulatory organizations. The food and drug organization (FDO) of Iranian Ministry of Health and Medical Education is almost the only policy maker in the pharmaceutical system. The document is centered at patients' interests and patients oriented pharmaceutical care and the pharmacists' responsibilities were directed toward.

PROFESSIONAL CODE OF ETHICS FOR PHARMACISTS

The code consists of 8 articles originated from principles of bioethics and professionalism in pharmacy; each

one containing special notes. Those articles included respect for patient's dignity and autonomy, beneficence, non-maleficence, justice, empathy, honesty, cooperation, and excellence. In addition, the proper ethical relationship between pharmacists and patients, pharmacists and physicians, and other health-care providers were considered. The main themes of the provided code of conduct are brought in the next sections.

Respect for patient's dignity and autonomy

Although patients get much of their information about the disease and medications from their physicians, but still physicians do not meet all patient's needs. Patients need more information about their medications and prefer to discuss drug-related issues with physicians as primary health-care provider, but lack of enough time and in some occasion knowledge about medications provide a good chance for pharmacists to show their abilities and expertise. Fairly, it is a pharmacist's responsibility to fulfill the information gap, but often patients are not aware of pharmacist's capacities. A study in the US confirmed that realization of pharmacist's role in providing drug information results in lowering the cost of treatment.^[4] Pharmacists should try on renovating their relationship with patients to attract their trust to the pharmacy system.

Patient consultation has been mentioned as the most important ethical issue in the pharmacy practice on the way to help better treatment of patients with lower costs. The patients' privacy and exceptions, desire, and their rights for refusing treatment have been considered.

Providing drug information for patients not only includes drug usage, dosage, and indication, but also it should contain information on adverse drug reactions, (ADR) warnings, interactions, contraindications, and drug storage.^[5] Community pharmacies in less developed countries do not pay enough attention to provide sufficient drug information for patients, which has a detrimental effect on the scientific position of community pharmacies.^[6,7] Counseling take times and it may not be possible for pharmacists to counsel all patients. In addition, counseling is considered as the temptation factor of the conflict between the financial income and patients interests. In order to overcome this obstacle in the US, the congress passed the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) as a standard of pharmacy care in 1993. According to OBRA 90, pharmacists have to offer drug counseling to patients, which may be declined by patients. Most studies reported an increase in counseling frequency after OBRA 90 in USA.^[8] Hussain and Ibrahim reported unpleasant process of patient counseling in Pakistan where mostly unqualified salespersons dispense the medications and wish legislative support for providing patient-oriented services in the community pharmacies.^[9]

Beneficence

The second article of this code has been provided regarding beneficence to the patients at the aim of optimizing drug therapy according to the patient's interests. Providing the best health-care services needs efficient pharmacist-patient relationships, confirming the accuracy of the prescription and documentation of every professional function carried out in the pharmacy. One of the most important issues in this code is the pharmacists' responsibilities for selling every drug including supplements, herbal products, over the counter medications, etc., The second article emphasizes on the pharmacists duty and accountability.

The patient's best interests and respect for medicines have been defined as the two core values in a study consisting qualitative interviews with 38 selected practitioners.^[10] Another study in Canada demonstrated that 71% of Canadians take natural health products and supplements on a routine basis.^[11] Their availability and high demand should not mean they are safe as even these products may cause serious side-effects in special populations.^[12] Furthermore, their potential interaction with other medications should not be neglected. Therefore, pharmacists are recognized as the most eligible healthcare professionals to advise patients on health products and to provide evidence-based drug information.^[13] The potential responsibility of pharmacists in counseling consumers about the harms/benefits of natural products and their interactions was stated previously.^[14] It is believed that pharmacists are obliged to get the ability of counseling patients about the natural health products.^[15] In accordance with some codes, the Iranian code emphasizes that a pharmacist cannot refuse drug delivery unless offering an alternative although in the pharmacy code of ethics of France, refusal of delivering oral emergency contraceptives is forbidden.^[16] In term of informed objection, our code states that if there is no possibility to fill a prescription, the pharmacist should redirect patient to substituted sources.

Non-maleficence

In the third article, it has been emphasized that a pharmacist should not harm the patient. This article describes the situation in which a pharmacist is not able to do his/her tasks and guides the pharmacist how to assign his/her duty to the technician. Furthermore, quality of the drugs, drug dispensing in the pharmacy were mentioned as the pharmacists' responsibility. Furthermore, the way in which a pharmacist faces medical error, serious ADR, and drug abuse was described.

In order to prevent quackery, providing sufficient and efficient drug information to patients regardless of financial benefits is highly recommended in this code. American Pharmacists Association (APhA) in its early codes of ethics

stated passive agreement of prevention from quackery then urges the discontinuance of quackery and later put an obligation on discouraging objectionable nostrums for the sake of profit. Patient safeguarding and drug safety is of the most important issues in health-care which principally decrease morbidity, mortality, and health-care costs.^[17] The development of new technologies complicated drug delivery process more than before and accordingly medication error is inevitable.^[18] A study determined that prescription and administration account for about 80% of the errors.^[19] Therefore, the way we approach medication error is an essential element in preventing harms and assuring patients safety. Therefore, in this code, direct supervision of a registered pharmacist on every function in the pharmacy has been considered obligatory.

Justice

Justice was stated as the fourth article that mandates fair resource allocation in pharmacies and guides the pharmacists at the condition of drug shortage. Furthermore, this article took a brief look at the conflict of interests of pharmacists.

Gouveia and Shane believed that regardless of market forces and financial problems, pharmacists ought to play a critical role in reducing the cost of treatment and improving the quality of health-care.^[20] They proposed a model of pharmacy practice consisting of 3 elements including the pharmacy practice across the continuum of care, the major elements of pharmacy practice, and evolution of pharmacy.^[20] Sporrang *et al.* evaluated moral distress in all staffs of 3 pharmacies and found some distressing issues such as prioritizing between customers as very stressful issue in pharmacy. They concluded that ethical codes are not enough for alleviating moral distress and supportive measures should be provided by management and work organization.^[21]

Empathy and excellence

Showing empathy with patients in cooperation with physicians and other health-care providers are of major concerns, which were indicated in the fifth and sixth articles.

Fostering a shared responsibility and better therapeutic consequences needs empathy, kindness and compassion in service to build up a proper relationship with patients.^[22,23] Updating knowledge, pharmacists can develop their professional patients oriented services based on patients interests and develop better cooperation with physicians and other health-care providers, which lessen the confusion in patients mind. Well-organized pharmaceutical care programs were shown to amend therapeutic outcomes especially in chronic diseases such as diabetes.^[24] Public confidence and the pharmacy reputation were regarded as

two considerable goals, which need to be supported. Both topics have been regarded in our code as well as the code of UK. Faults including dispensing controlled drugs, drug trafficking, and inappropriate self-medication may cause loss of public confidence to pharmacists.

Honesty

The next article emphasizes on honesty that describes the situation in which gifts are given to the pharmacists. In this part, much stress has been put on a pharmacist's attendance in work days, banning buy and selling of special products which threatens the profession, body piercing, etc.

APhA in its pharmacist's code of ethics states that a pharmacist should not allow his name to be used in connection with advertisements for promotion of unworthy products. Later in 1969 and 1981, APhA indicated absolute banning of dispensing, promoting or distributing non-therapeutic products although the last updated code insists on telling the truth to the patient and lacks any reference to this type of medications; however, it indicates honesty, integrity, and ethical and transparent manner of pharmacists.^[25] Some pharmacies in the world sell tobacco and alcohol that is not a good message to consumers, but this has never happened in Iran. In the recent decades, pharmacy profession showed its opposition against selling non-medications harmful products such as cigarette and alcohol.^[26,27] In spite of apparent opposition of pharmacy to selling tobacco, some pharmacies do not pay enough attention to this fact. A study has shown that 93% of non-clinically affiliated pharmacies in San Francisco sell cigarettes,^[28] which are in agreement with the other studies.^[29-31] Although Corelli *et al.* reported lower contributions, they state that if pharmacists have a choice, they choose not to sell cigarette or alcohol.^[32]

Cooperation

In the last article, pharmacists are encouraged to respect his/her colleagues and other health-care providers. It is believed that pharmacists challenge to increase their visibility in the health-care team as well as providing rational high level care and modifying their relationship with other health-care providers.^[24] In the last decade, developed countries like Canada revised the relationships between pharmaceutical companies and health-care providers and exposed some special issues in this regard including conflict of interest between pharmaceutical companies and health-care professionals.^[16]

ETHICS GUIDELINE FOR PHARMACEUTICAL MANUFACTURERS, IMPORTERS AND DISTRIBUTORS

In these three guidelines, the responsibility of pharmaceutical companies for clients, patients, healthcare

providers (physicians), community and environment, national interests, and advertisement has been described.

Pharmaceutical companies spend high amount of money for promotion and marketing and consider a large share for physicians. Financial conflict of interest between industry representatives and physicians, drug distributors and pharmacists/physicians distorts the value of altruism in pharmacy practice because it introduces bias in decision making and compromises public trust. Although there is little compliance with a proper intermediate basis, which concerns the rights of industry, patient, physician, pharmacist, and the public and we tried to codify the way pharmacists manage their conflict of interest by evaluating the value of the proposed gift. If the gift is considerable, the pharmacist should disclose his/her relationship with the company; however, industry-physicians/pharmacists relationship is necessary for medical innovation and development. The controversy over the issue was previously reviewed and demonstrated that the relationship between physicians and pharmaceutical representatives initiates in medical school and continues at high rates. Their meetings cause the physicians request for including drugs in the formulary, and alterations in their prescription practices. Furthermore, traveling for educational congresses or attending CME programs by support of pharmaceutical companies affects their prescription practices and increases non-rational prescribing.^[33] Of course in Iran, there is a center located in FDO that audits all prescriptions of physicians to prevent irrational use of drugs^[34] and this partly controls such unethical relations between pharmaceutical companies and physicians, but it is not enough as there are still lots of problems in irrational use of drugs in Iran such as antibiotics or analgesics.^[35-37] It has to be added that world pharmaceutical market is full of such bad behaviors and Iran is not an exception as most of the famous pharmaceutical companies have representatives in Iran and as a matter of fact they have invested and focused on Iranian market.^[38] Therefore, competition ethics was considered as an important factor, which should be regarded in the drug industry although confidentiality and privacy should be respected. In our code, any deceptive behavior has been forbidden. Furthermore, manufacturers ought to consider ethics, honesty, and accuracy in publishing the results of their investigations. Most importantly, drug companies should observe rules, and standards governing their work environment. The final goal of each drug importer company has been described as developing pharmaceuticals and related technologies by observing justice in resource allocation. Advertising is one of the key elements of drug companies regardless of its type, which should be unbiased, frankly, and accurate. Only after permission of ministry of health, the companies are allowed to advertise their products.

ETHICAL GUIDELINE OF DRUG POLICY MAKER

Today the FDO of Iranian ministry of Health regulates whole pharmaceutical products from production to consumption. The FDO should ensure safety and effectiveness of all medications. As providing regulations and making decisions in a system with high financial turnover makes it vulnerable to different types of violations, the FDO should have a code of conduct drawing an ethical frame-work on the way to solve several ethical challenges. In the year 2004, Nikfar *et al.*^[39] monitored the national drug policy (NDP) and its standardized indicators and conformity to decisions of the national IDSC in Iran. According to that study, to help save lives and improve health, it is important to be sure about equity to access to drugs, drug efficacy, quality and safety, and rational use of drugs, which are standardized NDP objectives and useful to evaluate the pharmaceutical system performance in a country. To identify strengths and weaknesses of pharmaceutical policy formation and implementation in Iran, four standard questionnaires of the World Health Organization (WHO) were used. To assess the agreement between decisions of Iran IDSC and standardized NDP indicators in the years (1998-2002), a weighted questionnaire by nominal group technique based on the questions that should be answered during discussion about one drug in IDSC was designed and used. They found out that the system, structures, and mechanisms were in place; however, they did not function properly in some topics. Assessment of 59 dossiers of approved drugs for adding to NDL during last 5 years showed that IDSC's members pay more attention to efficacy, safety, and rationality in use rather than accessibility and affordability that is an ethical concern as well.^[39] The term inequity has a moral and ethical dimension. It refers to differences, which are unnecessary and avoidable, but are also considered unfair and unjust. Hence, in order to describe a certain situation as being inequitable, the cause has to be examined and judged to be unfair in the context of what is going on in the rest of the community.^[40] They pointed that clarification of NDP's objectives and their impact for IDSC's members will result in improvement of the equity in access to pharmaceuticals.^[39] This means that there are many ethical concerns just in making a decision on what drug should be added to country's drug list. Our ethical code describes the responsibility of the staffs of FDO in terms of community and defines its susceptibility to violations. Furthermore, it emphasizes on updating the staffs knowledge and ethical awareness as well as government obligations. Our code indicates the staffs' behavior as justifiable and far from discrimination and conflicts. The responsibility of FDO about drug companies was defined as accountability, predictability, and providing unbiased and justified services and legal obligations. The staffs are banned from accepting gifts or any type of accreditation from companies.

The responsibility of the FDO about consumers is to ensure the standard quality of drugs and controlling the quantity and quality of drug production, packaging and importation as well as trying to facilitate drug availability. In case of revealing any issue about drug safety, the FDO should inform the company at least 24 h before public awareness. In this code, a substantial role for a supervisory board has been proposed. The code states conflicts of interests as the most challenging issue between FDO staffs and employees and the way in which the disclosure should be provided. Most importantly, it might provide special regulations for advertisements and any supportive efforts of drug companies for scientific congresses.

In a study, it was determined that most medical students have a negative attitude about accepting a \$50 gift by a public official although less than half of the students had a negative attitude about accepting a gift from pharmaceutical companies by their own.^[41]

CONCLUSION

The imbalance between pharmacist's knowledge and expertise and their role in health-care as well as lack of pharmacist's involvement in providing special health-care services necessitates this profession to get revolutionized.^[1] In a systematic review, it was found that in low and middle income countries, lack of standards influence professional services and hence effective contribution of pharmacists in health-care should be revolutionized.^[42] The same though exists among Iranian experts who have experience working in Iranian FDO and has participated in national policy decisions in part. The alteration of pharmacy practice from drug dispensing to pharmaceutical care obliges pharmacists to be informed of ethical challenges faced by other health-care providers as well as ethical challenges of their profession. Of course, it should not be forgotten that the science of pharmacy and pharmaceutical sciences has been extensively innovated in the world and now nobody can say that all to know by pharmacists is how to work in the pharmacy. Nowadays, many pharmacists work in pharmaceutical companies or even governmental organizations or insurance companies and etc., Wingfield *et al.* deem advisable that pharmacy ethics should be systematized and integrated into the wider scheme of general health-care ethics.^[43] In order to guide pharmacists in providing patients oriented health-care services; firstly the pharmacists should get aware of their responsibilities, which are defined as pharmacist's professionalism. From the other hand, pharmacists face ethical challenges in their daily work as much as physicians and need to have a special ethical frame-work to make decisions. Therefore, we provided the code of ethics for the national pharmaceutical system in order to inform

the pharmacists about their role and responsibilities and helping them solving the ethical issues in a different field of pharmacy practice. However, researchers indicated that ethical codes could never substituted personal moral responsibilities and a complicated correlation between an individual's moral standards and professional ethics codes exists.^[21] In addition, there may be obstacles to fulfill the requirements of professional code of ethics originated by organizations, stakeholders, etc., Therefore, teaching ethics is a fundamental way of implementing applied ethics in professions in association with ethical guidelines. It is thought that health professional students moral reasoning can be augmented by education,^[44] but another study suggests teaching, measuring and case discussion as enhancements of moral reasoning.^[45] Bayrami, and Abdollahi believe that a continuous program for informing students about ethical codes is mandatory and have positive effects on their future profession.^[46] Of course, the most effective time of teaching ethics to pharmacy students, which may affect the outcome is under debate. Scharr *et al.* believe that higher exposure to ethics and training may influence higher level of awareness about ethical issues,^[16] but the proper term time for teaching ethics is not well-known. Bumgarner *et al.* indicate teaching ethics at early stages although Latif suggests second year as the proper time of ethics education and ethical dilemma exposure.^[44,47] Taken together compiling the code of ethics for the national pharmaceutical system is the first step in implementing ethics in pharmacy practice and further attempts into teaching the professionalism and the ethical code as the necessary and complementary effort is highly recommended.

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