



Compliance with National Standards for Purchasing Medical Devices After Health Transformation Plan (HTP): A Multiple-Case Studies of Isfahan's Hospitals

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Abstract

Background: Given the importance of compliance with quality and price standards in purchasing medical devices and regarding that one of the interventions of Iran's health transportation plan (HTP) is monitoring the process of purchasing medical devices, this study aimed at determining if the given standards of purchasing medical devices has been complied.

Methods: A retrospective cross-sectional descriptive study was conducted during year 2016. The study covered a sample of 4 university hospitals in the cities of Isfahan, Najaf Abad, and Shahreza. Data, including name, number, price and brands of medical devices purchased by these hospitals were gathered for a period of 3 months (June 21 to September 21, 2014). These data were available in selected hospitals as well as Medical equipment offices in the University and were compared with standards set by the ministry of health (accessible in the database of IMED). Analysis was performed using the SPSS software.

Results: The average percentage of compliance with prices and brand standards of medical devices in the studied hospitals were 77.89 and 76.04, respectively. Non-teaching hospitals and those located outside of the capital city (Isfahan), complied with the mentioned standards better than those were teaching hospitals and located in Isfahan city.

Conclusions: Although the compliance with price and brand standards of purchasing medical devices were good, yet regarding the need to achieve the desired level, more periodic inspections in the area of medical devices purchasing and also greater awareness about the benefits of compliance with defined standards are recommended.

Keywords: Hospital, Consumable Medical Equipment, Standard, Health Transformation

1. Background

Nowadays, many countries around the world are facing many challenges to finance their health system (1). The problem of increasing shortage of financial resources of the health sector from one side and inefficiency of the health system from other side, has led health policy makers and planners towards better and effective management of financial resources through innovation in financing, taking efforts for minimizing the costs, and design and implementation of strategies for coping with inefficiency (2). The importance of better management of financial resources is increased when this subject is raised about hospitals, because hospitals play a crucial role in providing health services and also training medical students (3). Furthermore, based on the extensive study of the World Bank, 50% to 80% of health sector resources in developing coun-

tries are allocated to these centers (4). Therefore, optimal and proper use of financial resources is very important and ought to be focused by the hospital managers and officials.

One of the major cost items in hospitals is related to medical devices (5). This is because high demand for receiving costly services, such as surgery in the hospital, has increasingly affected the hospital costs. Medical devices, include all medical supplies that have been manufactured to be used, alone or in combination for one or more specific medical purposes (6). Among different types of medical devices, those that are designed and made only for single use are named consumable medical devices (CMD) (e.g. prostheses, implements etc.). Consumable medical devices are widely used in hospital settings. The high volume of CMD use makes it necessary to consider their quality and price during the purchasing process because any

mistake in purchasing could threaten the quality and safety of care and also can result in waste of resources (7). A review of evidence shows that in Iran, lack of regulatory and supervision of medical devices purchasing has resulted in low quality and high price of these devices (8), and has led to problems in increasing financial protection as well as public access to the required equipment, particularly in the time of sanctions against the country (9). These problems have led to consideration of some interventions in the area of medical devices in the new health transformation plan (HTP). In these interventions, a list of the best brands of the world medical devices was prepared by the Iranian food and drug organization (FDO), and approved and provided to the state public hospitals, for grading and pricing of the CMD. Also, the hospitals were announced to purchase the CMD based on this list and any purchase out of the approved list of FDO was deemed as breaching of the regulations. Following this action, an intervention was assigned to the Ministry of health and medical education (MOHME) for pricing the medical devices, by virtue of approval No. 50603T/33206, dated May 24th, 2014. As set forth in this approval, the given prices shall be executed as approved and applicable prices for all health facilities, including public and private sectors. In addition, it was anticipated to make the prices online and accessible to the public, and all listed companies shall be bound to the approved prices.

After three years of implementation of the aforementioned intervention, it is the time to determine the extent of compliance with these national standards for purchasing of CMD, which have been considered by the hospitals. The present study was an attempt to address the level of compliance.

2. Methods

The present multiple-case study was a retrospective cross-sectional research, which was conducted during year 2015 in Isfahan province, Iran. This approach helped greater analysis and comparison between cases (10). The study population consisted of 35 teaching and non-teaching hospitals of Isfahan University of Medical Sciences (IUMS). Four hospitals were purposefully selected as the study sample. These hospitals included 2 teaching hospitals of Isfahan city. One of them with 800 active beds (hospital A) was the main center for referring patients from different zones of the province and neighboring provinces, and hospital B with 330 active beds was assumed as the largest trauma emergency center of the province. Two other hospitals (hospitals C and D) were non-teaching, with 133 and 108 active beds, and were located within counties outside of the province capital, and

both were assumed as main hospitals to provide health services. These hospitals were selected based on the opinions of experts and persons involved in the HTP implementation and curative deputy of IUMS, mentioning that these hospitals widely used the CMD. Furthermore, based on the consultation with medical equipment officers, the likelihood of purchasing faults in the selected hospitals was higher. Moreover, upon this selection, the requirement for comparison of the province capital status to other cities was provided. It is important to mention that, considering these criteria to select the cases limited the issue of generalization. The data of the study, included name, quantity, price and brand of CMD purchased by these hospitals, which was collected within three months (June 21 to September 21, 2014), upon obtaining data collection permit from the authorized body. Comparison of these data to the standards designated by MOHME was done using the SPSS software.

3. Results

Analysis of data in relation to the percentage of compliance with the standard price of CMD purchased in the selected hospitals after HTP indicated that hospitals D and A, respectively, obtained 88.57% and 65.45% as the least and most compliant with the standard price. Analysis of data with respect to the compliance of brand standard of CMD purchased in the selected hospitals after HTP also demonstrated that hospitals D and C, respectively, obtained 65.71% and 87.95% as the least and most compliant with standard brands.

Altogether, analysis of data in relation to determination of compliance with the standards of MOHME, for purchasing of CMD of selected hospitals HTP indicated that the mean compliance with price and brand standards for purchase of CMD of studied hospitals was 77.89% and 76.04%, respectively.

Comparison of the mean percentage of compliance with the CMD purchase standards in different types of hospitals also showed that the compliance percentage of price and brand standards in non-teaching hospitals located outside of the province capital was higher (Table 1).

4. Discussion

Hospitals always try to consider quality, safety, ease of use and economic considerations when they want to buy CMD. Doubtless, compliance with the defined standards results in the growth and improvement of performance and increases the efficiency. The standards defined by MOHME for purchasing CMD have been designed and declared to

Table 1. Compliance with the Price and Brand Standard in Studied Hospitals (= 4)

| Hospital | Number of CMD Item Purchased by Hospital | Compliance with | |
|--|--|-----------------|-------|
| | | Price | Brand |
| A | 158 | 65.45 | 72.22 |
| B | 75 | 80.85 | 78.26 |
| C | 157 | 76.67 | 87.95 |
| D | 54 | 88.57 | 65.71 |
| Total | | 77.89 | 76.04 |
| Teaching located in Isfahan city | | 73.15 | 75.24 |
| Non- Teaching located out of Isfahan city | | 82.62 | 76.83 |

Abbreviation: CMD, Consumable Medical Devices.

hospitals along with this direction. This study intended to determine the percentage of compliance with MOHME standards for purchase of CMD of hospitals after HTP implementation.

The findings indicated that the compliance with SMD standards in all four hospitals was not at the desired level. More investigations to find the reasons of this gap showed that one of reasons was offering the CMD in IMED with different names or not-matching the routine and common names known to the officials. This made difficulties for the officials to choose each case for purchase. Moreover, access of the users to IMED requires a long time for finding each one of the equipment, and since the consumable items have been classified in different fields, it makes it difficult to search for finding respective equipment in the system. Furthermore, one of the most important activities in the HTP intervention in the area of medical equipment price and quality control is providing online and updated information about the price and quality of CMD via a declared website, in this regard it is recommended to prioritize the organization and usability of this website. Furthermore, it is suggested to meet the system end-user requirements, which are advanced search and retrieval of structured and up-to-date information and friendly and informative ways of presentations of CMD (11).

The second reason for the gap between current and desired level is unawareness or low awareness of the use and usefulness of compliance with the CMD standards. The importance of training and empowering health workforce as a means to control risk associated with medical devices and improve safety and quality of services is completely approved by evidence (12, 13). Therefore, for further compliance with standards determined by MOHME, it is recommended to define the usefulness of compliance with these standards and illustrate the consequences of using nonstandard items for hospital managers and officials by MOHME through well-designed training courses.

The third reason for status quo of compliance with standards is referred to the inadequacy of supervision and continuous controls on the performance of equipment purchase. The importance of monitoring and its effect on the successful execution process is clear to all. Therefore, one of the other solutions for reaching the ideal status in compliance with purchase standards is periodic inspection by hospital managers on purchasing process based on the standard by medical equipment suppliers and officers of hospital and submission of report on compliance with these standards to MOHME.

Another finding of the study indicated that non-teaching hospitals outside of Isfahan have higher level of compliance with standards with respect to the brand as well as the price, compared to teaching hospitals inside Isfahan. It seems that smaller size of the hospital, not being a teaching hospital and lower patient visits are some variables of the extent of compliance with standards. These variables decrease the need to purchase daily CMD and purchases with lower volume are made better, in compliance with the standards and higher quality. Given the increase of fault probability in high volume purchases, further supervision on procurements and medical equipment department of large and teaching hospitals and attention to the compliance with skilled and specialist human resources are recommended for reduction of fault and increasing of the compliance with standards.

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