

Management of material resources with a focus on technical complaints

Gerenciamento de recursos materiais com enfoque na queixa técnica

Roseli Broggi Gil¹, Lucieli Dias Pedreschi Chaves², Ana Maria Laus³

¹ Nurse, Master of Fundamental Nursing. University Hospital, State University of Londrina. Londrina, Paraná, Brazil. E-mail: roseligil@gmail.com.

² Nurse, Doctor of Nursing. Associate Professor, Ribeirão Preto College of Nursing, University of São Paulo (EERP/USP). Ribeirão Preto, São Paulo, Brazil. E-mail: dpchaves@eerp.usp.br.

³ Nurse, Doctor of Fundamental Nursing. Associate Professor, EERP/USP. Ribeirão Preto, São Paulo, Brazil. E-mail: analaus@eerp.usp.br.

ABSTRACT

Descriptive study aimed to characterize the process of notification of the technical complaint of consumables in a public teaching hospital, a member of Sentinela Hospital Network of the National Health Surveillance Agency. The data obtained was from the printed notices that resulted in 260 notifications analyzed from 2007 to 2009. The results showed a predominance of non-conformities in the group of medical-hospital material (80.4%) and the main complaints referred to the structure of the products used (79%). Of the total amount of notifications, 7.7% were referred to the National System of Notifications in Sanitary Surveillance. The nurses were the professionals who mostly (81.2%) made the notifications. The findings of this research revealed the importance of implementing and using systems for making systematic records of material evaluations as a basis for efficient management regarding the maximization of economic resources.

Descriptors: Materials Management, Hospital; Previous Analysis of Products; Health Care Economics and Organizations; Health Surveillance.

RESUMO

Estudo descritivo cujo objetivo foi caracterizar o processo de notificação da queixa técnica de material de consumo em hospital de ensino público e integrante da Rede Hospital Sentinela da Agência Nacional de Vigilância Sanitária. Os dados obtidos dos Impressos de Notificações resultaram em 260 notificações analisadas, relativas ao período 2007 a 2009. Os resultados apontaram predominância de não conformidades no grupo de material médico-hospitalar (80,4%) e as queixas principais se referiram à estrutura dos produtos utilizados (79%). Do montante das notificações, 7,7% foram encaminhados ao Sistema Nacional de Notificações em Vigilância Sanitária. Os enfermeiros foram os profissionais que majoritariamente (81,2%) realizaram as notificações. Os achados desta investigação revelaram a relevância da implantação e uso de sistemas de registros sistemáticos de avaliações de materiais, enquanto subsídio para uma gestão eficiente no que concerne à maximização de recursos econômicos.

Descritores: Administração de Materiais no Hospital; Análise Prévia de Produtos; Economia e Organizações de Saúde; Enfermagem; Vigilância Sanitária.

INTRODUCTION

The current national scene shows a continued growth in health expenses, not only related to the universalization of access resulting from the creation of the Unified Health System (SUS, as per its acronym in Portuguese) and the technological incorporation of the last few decades, but also due to management issues⁽¹⁾. In this sense, public service managers have experienced difficulties in managing their institutions with the scarce financial resources granted by the government, due to “[...] the federal healthcare spending reduction, facing the popular demands for health services.”⁽²⁾

Hospitals, from an organizational point of view, have different characteristics from any other organization. Among them is the complexity of operating uninterruptedly and interacting with people in fragile moments, when they need special assistance and, in many cases, sophisticated features. The incorporation of new technology refers to the responsibility of offering greater safety for both the patient and professional care providers; however, work processes also need to be reviewed, with ongoing training related to both direct care and material resources management systems.

The sum of expenditures on human and material resources contributes to increased hospital costs⁽³⁾, a fact experienced in both public and private institutions. The value of the sum of direct and indirect costs ranges from “[...] 35% to 45% of the hospital’s total budget, and increases due to the degree of the material system disorganization.”⁽⁴⁾ Material resources are responsible for a significant portion of expenditures in health institutions, given that the direct acquisition costs “[...] are between 23% and 29%, depending on the complexity and organization of the institution”⁽⁴⁾. These data scale the relevance of adopting tools for the management of these resources from an economic point of view as well as the results arising from their use, in addition to showing that the quest for knowledge about cost in this area is fundamental to the survival of the healthcare-providing institutions. Thus, issues such as the efficiency and

effectiveness of activities must be worked on together with quality and safety aspects, as well as the rational use of resources to avoid waste⁽⁵⁾. At no point should the financial and cultural issues overlap with the assistance aspects of quality and safety.

In Brazil, “[...] the products’ health surveillance, including all life cycle phases, from manufacturing to marketing [...] is a competence of the National Health Surveillance Agency (ANVISA)”⁽⁶⁾. The Agency is responsible for the legislation and regulation of products as a way to promote health surveillance and subsidize institutions regarding the control of marketed products. Therefore, the commercialization of healthcare products is linked to specific laws and grouped into five categories: *in vitro* diagnostics products; health products (materials and equipment); sanitizing products; personal hygiene products, cosmetics, and perfumes; and medicines.

ANVISA⁽⁷⁾ defines health products as “[...] products used in medical, dental and physiotherapy procedures, as well as in the diagnosis, treatment, rehabilitation or patient monitoring.”

With increased large-scale incorporation of different technologies in the healthcare work process came the need for the implementation of monitoring systems that would enable the early identification of technical problems, that is, quality deviation/technical complaints (TC), in order to minimize the occurrence of adverse events.

In the context of Health Surveillance⁽⁸⁾, “[an] adverse event is considered any undesired effect, in humans, due to the use of products under health surveillance,” and “[a] technical complaint understood as any notification of product or company alteration suspicion or irregularity, related to technical or legal aspects, which may or may not cause damages to individual or collective health.”

Reports on the occurrence of TC and AE is not only limited to our country and the present time. Developed countries such as the United States and European Union members have adopted stricter measures since the 1980s⁽⁶⁾.

The national literature has pointed out the commercialization of hospital consumables with unsatisfactory and questionable quality, requiring the competent bodies to adopt some compliance measures⁽⁹⁻¹¹⁾. One way to avoid this is to introduce a pre-qualification process as a strategy for checking product compliance before purchase. This is a tool for risk management, as it acts as a barrier against the entry of dubious quality products but, importantly, it should be systematic and accurate^(10,12).

The current legislation, however, does not guarantee, in its entirety, that safety is maintained after obtaining registration⁽⁶⁾. In this scenario, control measures in the post-marketing stage of these healthcare products turn out to have great relevance. Post-marketing surveillance (Vigipos) of health products is defined as a “Notification and Research System in Health Surveillance for monitoring, analysis and investigation of adverse events and technical complaints regarding the services and products under surveillance in the post-marketing/post-use stage”⁽⁸⁾.

Thus, the technical defect notification has become an important management tool, supporting ANVISA in the adoption of its measures because it allows the identification of irregularities in the product and/or the manufacturer regarding deviations in quality, and guides health institutions toward the analysis and monitoring processes of the new technologies and resources available. However, it has been challenging to obtain reliable information that enables the systematic quality monitoring of hospital consumables in the post-marketing stage. From this perspective, this research was developed in order to characterize the technical defect notification process of hospital consumables in the material resources management context of a large public hospital.

METHODOLOGY

This is a descriptive, retrospective study with a quantitative approach. Data collection was conducted by

the Nursing Assistance in Material Resources Control with the nursing board of a teaching hospital in the state of Paraná. This institution provides outpatient and hospital care of high complexity, has 316 beds—all in compliance with SUS—and has been integrated with ANVISA’s Brazilian Network of Sentinel Hospitals since 2002.

Before the data collection, the study was authorized by the hospital and later approved by the bioethics and ethics committee in the investigated hospital research (CAAE No 0197.0.268.153-09).

Data were obtained by the main investigator of this study, who operates in AECRM, and extracted from the notification forms established by risk management for the formalization of technical complaints and/or adverse events of hospital consumables, for the period from January 2007 to December 2009. For research inclusion purposes, the criteria were defined as the registration of a complaint to be documented in specific forms and available in the unit’s documentary file.

The variables of interest in this investigation referred to the type of product; the material group in which it was included; the type of occurrence reported; the problem category; the month and year of occurrence; the sector that registered the problem; the professional category of the notifier; and the notifications reported to the National System of Notifications in Health Surveillance (NOTIVISA) system.

Hospital consumables referred to any product used to provide direct patient care in treatment or internment, of single use, standardized, and acquired in the institution following the current law. The research was categorized into three groups: medical-hospital materials; personal hygiene materials; and materials for use in the sterilization process.

The variable “problem category” was analyzed in terms of packaging, structure, and/or changes in appearance, based on criteria adopted by ANVISA⁽⁸⁾.

Regarding the packaging, noncompliance issues were considered to be in the identification of different amounts of the units described on the packaging, sealing failure,

inadequate size for the product, and/or difficulty in opening the material without violating aseptic technique. Structural noncompliance included the presence of cracks, breakdown of the product or part of it, fitting, obstruction, leaks, size, absorption, shear loss, and/or the presence of foreign bodies. Altered aspect of noncompliance included color, odor, and stains. Facing the possibility of concurrent categories, two other types of framing were also adopted: packaging and structure, and altered aspect and structure. When the noncompliance did not fit into any of the frameworks in the established categories, a so-called “does not apply” category was defined.

The data, released in a specific collection instrument for this research, were coded for transcription purposes into Epi Info, version 3.3.2, and analyzed using descriptive statistics.

RESULTS

In the period investigated 409 technical defect notifications were received, and 260 met the inclusion criteria. Among the 149 excluded, 72 (48.32%) were not found in the document file.

As for the number of hospital consumables categorized, it was found that, in the three groups created, medical-hospital supplies covered 33 reported items, corresponding to 80.4% of the complaints; material for personal hygiene, five items, corresponding to 15.8%; and equipment for use in the sterilization process, consisting of only one type of material, representing 3.8%.

Chart 1 highlights only the materials reported with higher percentages, following the classification by group material and year.

Chart 1: Distribution of the most reported products, according to the material group and year. Paraná, Brazil, 2007/2009.

Group Material	2007		2008		2009		Total	
	N	%	N	%	N	%	N	%
Medical-Hospital Material								
1. Three-way connector	6	13.05	6	8.33	0	-	12	5.74
2. Device for peripheral and central venous access	6	13.05	6	8.33	12	13.19	24	11.48
3. Performance tests	4	8.70	5	6.94	10	10.99	19	9.09
4. Surgical suture thread	3	6.53	4	5.55	5	5.49	12	5.74
5. Surgical gloves	1	2.17	18	25.00	18	19.78	37	17.70
6. Sterile and non-sterile procedure gloves	2	4.35	3	4.17	5	5.49	10	4.78
7. Syringe	6	13.05	5	6.94	6	6.59	17	8.13
8. Aspiration, enteral, <i>Foley</i> and urethral probe	6	13.05	4	5.55	5	5.49	15	7.18
9. Other products	12	26.05	21	29.19	30	32.98	63	30.16
Subtotal	46	100.00	72	100.00	91	100.00	209	100.00
Personal Hygiene Material								
1. Disposable diaper	1	14.29	3	33.33	6	24.00	10	24.39
2. Interfold paper towel	4	57.13	6	66.67	18	72.00	28	68.29
3. Other products	2	28.58	0	-	1	4.00	3	7.32
Subtotal	7	100.00	9	100.00	25	100.00	41	100.00
Material for Use in the Sterilization Process								
1. Packaging for material to be sterilized	0	-	3	100.00	7	100.00	10	100.00
Subtotal	0	-	3	100.00	7	100.00	10	100.00
Total	53	100.00	84	100.00	123	100.00	260	100.00

The total percentage obtained for each of the other medical-hospital products reported is shown below in descending order: diuresis collector closed systems and crepe bandages (4.31%); needles (2.87%); thoracic drainage systems (1.91%); bags for blood collection, endotracheal tubes, gauze pads, performance test

extensors, and bacteriological filters (1.44%); waterproof surgical fields, bone wax, arteriovenous lines, and adhesive paste for examination (0.96%); disposable aprons, tracheostomy cannulas, epidural catheters, nasal continuous positive airway pressure circuits (CPAP), operative field compresses, drains (Penrose and Kher),

urinary devices, flexible rods for examination collection, scalpel blades, duckbill masks, closed systems for aspiration, and latex tubes (0.48%). For the personal hygiene group 2.44% were for razors, toilet paper, and antiseptic alcohol gel.

Aspects concerning the structure of the material obtained the highest percentage of

noncompliance/quality deviation (76.15%), according to the technical defect category.

Regarding the product, problems concerning the structure of the three groups of material were found, with a special highlight on medical-hospital equipment (78.95%), as shown in Chart 2.

Chart 2: Problem category distribution and relation to the material group. Paraná, Brazil, 2007/2009.

Problem Category Material Group	Problem Category							
	Medical-Hospital Material		Personal Hygiene Material		Material for Use in the Sterilization Process		Total	
	N	%	N	%	N	%	N	%
Packaging	20	9.57	-	-	-	-	20	7.69
Structure	165	78.95	24	58.54	9	90.00	198	76.15
Altered aspect	9	4.30	3	7.32	-	-	12	4.62
Packaging and structure	10	4.79	1	2.44	-	-	11	4.23
Structure and altered aspect	1	0.48	13	31.70	-	-	14	5.39
Does not apply	4	1.91	-	-	1	10.00	5	1.92
Total	209	100.00	41	100.00	10	100.00	260	100.00

The Surgical Center Division; the Neonatal Intensive Care Unit, representing a section in the Mother and Infant Division; and the Service Division, comprising the units of Endoscopy, Hemodialysis, Hemodynamics, and Radiology, were the sites of the institution that forwarded the greatest number of notifications.

Another relevant fact refers to the identification of nurses as the professional category that most (81.2%) elaborated and forwarded information on the noncompliance of medical-hospital material.

It was also found that 7.7% of the technical complaints received, because they fit in the technical surveillance area, were sent to the NOTIVISA.

DISCUSSION

Material resources management in health constitutes a subject of increasing importance, as not only a result of technological advances and inputs in the pharmaceutical industry in terms of materials and equipment, but also in issues related to the administrative process of

organizations, lack of a control system; consumption, waste, and costs; as well as fundamental aspects of care, such as quality and safety⁽¹³⁾.

Given the significant percentage of operating expenses of health institutions, the magnitude and complexity of expense management is clear, comprising the programming processes (standardization, technical data, forecasting), acquisition, storage, distribution and control, and use and monitoring.

The challenge is to balance revenue and expenditure and, as such, the implantation of operating systems in the administrative structure is required, enabling management guided by efficient results. Among these, the hospital consumables' technical defect notification process can be considered a material management auxiliary tool, because it produces information as input for decision making.

Given its value and importance to systematize the actions and behaviors relevant to occurrences with the products, the notification form established can be

compared to documents that comprise the medical records of a patient. This would allow the investigation of the reported facts and their consequences, including notification via the NOTIVISA system. It would help to underscore the product's technical aspects during the bidding process and allow for database construction and statistical analysis, among other things⁽¹⁴⁾.

The number of technical complaints obtained by the hospital studied with the adoption of this system can be considered an institutional quality indicator. The information provided is important, and significant for the support of internal investigations, including tracking the product. However, the large number of complaints not located when collecting data shows a significant gap regarding the documentation system. This highlights the need for reevaluation of this stage of the work process. The hospital opted for provision of the printed material included on its intranet with short-term web deployment project, making it easier for the notifier to follow the course of his account. It was hoped that this would stimulate the deployment of new notifications upon the occurrence/observation of irregularities in the products. This measure also aims to accelerate the conduct by the AECRM and the hospital risk management staff.

A noteworthy aspect is that, because this is a teaching hospital, it is essential to maintain a smooth flow of consumables, so that their shortage does not compromise either the care processes or the teaching-learning processes⁽³⁾. But in order to accomplish this, the professionals' participation is fundamental to guarantee the quality and safety of the healthcare provided. For those institutions that are part of the Hospital Sentinel Project, it is risk management's competence to adopt the necessary measures according to each case, that is, "[...] controlling or eliminating the risk of patients and workers' exposure to these products, while further investigations are carried forward by the competent bodies"⁽¹⁵⁾. Hospitals that have not yet introduced this service can and should report technical complaints or adverse events

to ANVISA by means of the appropriate communication (telephone/email/website).

Some authors⁽¹⁶⁾ claim that success in managing materials depends largely on the involvement of professionals directly linked to areas where the actual consumption occurs, particularly in aspects related to the control and proper use, in order to reduce waste and improve efficiency.

Whatever the course, healthcare educational institutions play an important role in the education and awareness of providers regarding the rational use of material resources for the different practices in service, which suggests the inclusion in the curriculum of issues related to the management of material resources⁽¹⁷⁾ and costs, emphatically addressing awareness and the ethical and legal responsibility that each provider represents in the healthcare risk management process. Therefore, it is believed that the new professionals are multipliers for the awareness of managers and can promote the implementation of structured services, seeking the acquisition of quality products that provide safety and fair market prices.

The success of any system crucially depends on the commitment of professionals, both for supply and for the use of the information. They subsidize many decisions aimed at continuous quality improvement when purchasing products. In order for that to happen, everyone's participation in careful evaluation is needed, especially in terms of materials subject to sanitary surveillance, with the patient's and care providers' safety in mind.

Despite the incentive to formalize the reporting of technical defects in the investigated institution, we can infer that there is underreporting, since many products commonly used in assistance areas did not have a formalized notification process for their various sectors. Unfortunately, underreporting is a fact in the Brazilian reality.⁽⁶⁾ Some authors attribute the causes to a "[...] shortage and overload of staff in health facilities and time to notify the identified problems"⁽⁹⁾.

The care units rated as critical (Surgical Center and the NICU) were the ones that stood out in the number of notifications sent. These are traditionally sectors that have the most sophisticated material resources; that is, the latest technology is inherent to the work process and is considered vital for developing activities. Having that in mind, as well as the volume of materials used in the different care processes, it is possible to infer that providers in these areas have developed greater skills of observation and evaluation of these items. The process of care in specialized units depends largely on the rational and safe use of materials and life support equipment, among other procedures, which also requires efficient maintenance of effective policies⁽¹⁸⁾.

In this investigation, the results have indicated, with a special highlight, the medical-hospital material group items represented by basic products (gloves, venous access devices, performance tests, syringes, etc.) among the materials that present noncompliance, which shows that this segment needs closer attention from a health surveillance point of view, especially in the post-marketing stage. Certainly there is need to consider that this group comprises the set of materials that represent a high risk to users because of their large-scale use.

The technical complaints regarding surgical and procedure gloves match with reports from other hospitals around the country. These facts subsidized ANVISA to publish Board Resolution–RDC 5/2008⁽¹⁹⁾, which establishes minimum identity and quality requirements for the types of gloves under a sanitary surveillance system.

The notifications regarding performance tests were also detected by ANVISA, through the NOTIVISA system, as being the product with the highest number of notifications in terms of structure, especially drip and leak failures⁽⁹⁾. A multicenter study was conducted in several Brazilian hospitals and coordinated by the Technical Surveillance Unit/Nuvig/ANVISA, in order to pre-qualify performance tests⁽¹⁰⁾. This establishes minimum identity and quality requirements for single-use transfusions,

gravitational infusions, and infusion performance tests for use with an infusion pump. RDC⁽²¹⁾ was also published on 03/2011 in relation to hypodermic syringes, to improve quality in the manufacturing process of these products and, consequently, ensure patient safety.

Another finding from this research relates to the identification of the notifier, especially nurses, indicating their involvement in the material resources evaluation in this institution. The literature reports the significant participation of nursing in the process of material management, based on the fact that this team is the largest solicitor and user of the products, especially those classified as medical-hospital⁽²²⁾.

In the managerial dimension of the nurses' work process, the relevant issues regarding material resources and equipment expressed concern with nursing care assistance as it configures their purpose, in addition to cost management for the institution^(17,23). Thereby, it is believed that, due to their care experience, nurses are the main actors in the hospital's consumables management, ensuring the efficiency and effectiveness of nursing care with the use of products that provide safety for the patient and the care provider. Additionally, nurses are able to more objectively articulate their needs in terms of administrative areas and hospital support⁽²⁴⁾.

The nature of work in patient care enables the development of critical sensitivity on the part of professionals. This allows them to become more aware of the relevant details of a product's quality, under the perspective of providing patients with the best material at the lowest cost.

The advances and the incorporation of new technologies characterize the importance and responsibility of the institutions before the Brazilian Sentinel Hospital Network–ANVISA, in the context of monitoring the technical defects/adverse events of the products under health surveillance (technical surveillance, pharmacovigilance, blood safety, disinfectants, and cosmetics) in the post-marketing stage⁽²⁵⁾.

Monitoring the necessary requirements for the acquisition of hospital materials implies not only a waste of resources, but constitutes a health violation that involves aspects of the legislation and the Criminal Code⁽¹⁰⁾.

One of the post-market monitoring goals is to provide ANVISA with information as a way to promote health surveillance and support institutions with regard to the control of products sold. Thus, the notification form allows evaluation/feedback on the performance of different materials in the post-acquisition phase, subsidizing research and the formalization of reporting technical defects and/or adverse events to the NOTIVISA. In addition, the notification form endorses the technical advice area so as to declassify bidders' proposal in future acquisitions. In addition, this instrument strengthens the activities of materials management, as it approaches the user responsible for technical advice, strengthening the commitment to issues related to risk management.

CONCLUSION

Emphasis in the health sector is being dictated by resource constraints facing a growing demand that is ever more encompassing and exigent. Increased spending on health is directly related to increases in service costs. Reducing costs in hospitals is a delicate task by the very nature of the services provided. Despite these difficulties, the management of hospital costs, in order to optimize resources, is necessary and an important factor in the long sought-for financial balance and for increasing the quality of care provided.

Due to this complexity, hospitals need qualified and prepared administrators to address the problems concerning their resource management.

The notification process guides to adverse advents and technical defects result in analysis, which enables noncompliance investigations present in the material and necessary for the technical surveillance area. This should be in the direction of always offering the patient and the

professional care provider products with the specific characteristics/requirements for each procedure.

This research's findings revealed the relevance of the implementation and use of systematic record systems of material evaluations, with subsidies for efficient management with regard to the maximization of economic resources.

The monitoring of products in the post-marketing stage, through IN, must be continuous in order to identify early intervention needs, as well as the systematization of actions and approaches adopted.

This also enables the implementation of a traceability system for all materials, which allows for the adoption of early measures to minimize the impact of a lack of material resources. This lack can be due to poorly judgment in programming items, loss of inventory control, total ignorance of consumption due to lack of reliable data, and control and material waste due to poor quality, all of which can lead the professionals involved to intense distress. Risk management must be part of the health professionals' routine, as it becomes everyone's responsibility and not only the managers', reflects directly in the care process, and should be performed under ethical and moral principles.

ACKNOWLEDGMENT AND FINANCING

Article extracted from the dissertation "The notification process of technical complaints about consumption material for hospital use in the context of material resources management in a public university hospital"; Post-Graduation Program in Fundamental Nursing of the School of Nursing of Ribeirão Preto, University of São Paulo, 2011. Fellow of the National Council of Science Development (CNPq) – 2009-2011.

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Received: 12/02/2013.

Accepted: 07/01/2014.

Published: 12/31/2015.