An Analytical Framework for Assessing Drug and Therapeutics Committee Structure and Work Processes in Tertiary Brazilian Hospitals

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Abstract: University teaching hospitals usually provide tertiary care and are subject to early adoption of new technologies, which may compromise healthcare systems when uncritically adopted. Knowledge on the decision-making process – drug selection by drug selection committees or DTCs – is crucial to improve the quality of care. There are no models for studying the selection of drugs in Brazilian healthcare services. This study aims to discuss DTC structure and the processes regarding adoption of medicines in tertiary university hospitals in Brazil and to propose an analytical structure for providing direction for the future. State of the art content regarding drug selection processes and DTC procedures was reviewed in three databases. Information on the medicine selection process in a Brazilian gold standard teaching hospital was collected through observations and a review of existing procedures. A structured discussion on medicine selection and DTC procedures in tertiary hospitals ensued. This discussion resulted in findings that were organized in three dimensions, composing an analytical framework for the application in tertiary Brazilian hospitals (i) motivations for the adoption of drugs; (ii) necessary structural and organizational aspects for decision-making; and (iii) criteria and methods employed by the decision-making process. We believe that the suggested framework is compatible with tertiary Brazilian hospitals, because a gold standard in the country was able to conduct all its procedures in the light of WHO and international recommendations. We hope to contribute in producing knowledge which may hopefully be adopted in tertiary hospitals across Brazil.

Timely and evidence-based adoption of medical technologies and medicines is critical for improving patient care [1–3]. Researchers, physicians and patient groups tend to welcome new technologies [4] that may pose risks to patients and might compromise the effectiveness of healthcare systems. Also, lack of evidence-based procedures and clear policies for handling conflict of interests may challenge the provision of equitable services and therapy to all in need [1–5].

Possible advances of novel pharmaceuticals may be limited. A study in France perceived that only 17 of 984 (1.7%) medicines launched were real advances in pharmacotherapy studied during the period of 2001 to 2010 [6,7]. Unfortunately, the intense marketing practices to health professionals and the public by manufacturers generate undue expectations and induce demand for innovations if not critically balanced in technique-oriented healthcare facilities [8–11]. This is not in the best interest of physicians, patients or health authorities.

Brazil is a middle-income country that in July 2013 had an estimated population size of 200.1 million inhabitants [12]. The Brazilian Public Health System (Sistema Único de Saúde – SUS) was initiated in 1990 and adopts comprehensive universal care as a principle. Over the years, a trend to establish parallel subsystems (reimbursed private and direct public providers) in the scope of SUS was developed to meet demand for specific needs. Parallel subsystems lead to difficulties in system management and continuity of care [13]. Failures in resolving simpler clinical needs in primary and secondary settings burden structure and processes pertaining to tertiary care [14].

In SUS, expensive and technically advanced health services and care are predominantly delivered by private outpatient clinics and hospitals and by public university hospitals [13], usually early adopters of new technologies [8,15]. The Brazilian Association of University and Teaching Hospitals cites around 100 such institutions in the country, of which 70% are public facilities [16]. Innovative drugs account for a large percentage of formulary additions in Brazilian university hospitals. Related expenditures with these medicines are high [17]. The financing of high-cost medicines is the responsibility of Brazilian federal and state governments, and expenditures have increased in the last decade. From 2003 to 2008, a 347% increase in total cost of these medicines for the system was observed. In absolute values, from 2005 to 2008, federal public expenditures in medicines amounted to nearly 1.15 billion

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USD per year, while in the entire four-year period, federal and state public spending with high-cost medicines totalled approximately 13.4 billion USD [18,19].

In the light of this, it is especially important for tertiary Brazilian university hospitals to acknowledge and build on the perspectives of health professionals and managers to assure correct information as a basis for decisions on the adoption of new drugs. The process of recommending drugs must be performed in a critical, evidence-based manner, ideally by a drug and therapeutics committee (DTC) formed by respected independent pharmacotherapeutic drug experts, including clinical pharmacologists, pharmacists and general practitioners [3,9,20–22]. This is the only way to assure the inclusion of true pharmaceutical innovations in formularies because their actual prescription and use are subject to the influence of a myriad of medical, economic and social factors involving researchers, pharmaceutical companies, governments, mass media, health professionals, individual patients and patient organizations [10,11,23]. Few studies shed light either on triggers for adoption, or on structure and organization of complex health facilities and the selection process for new therapeutic alternatives by DTCs [24–26].

Despite the importance of the selection process, few Brazilian hospitals presently have a functioning DTC and little is known about how the adoption of medicines takes place [27,28]. This study aims to discuss DTC structure and the processes regarding adoption of medicines in tertiary hospitals in Brazil and to propose an analytical structure for providing direction for the future.

Methods

State of the art content regarding drug selection processes and DTC procedures was reviewed in MEDLINE and in the most consulted databases in the Brazilian context: LILACS and SCIELO. The core search included publications in Portuguese, English and Spanish. No further limits were applied. The following search terms were used, in English, Spanish and Portuguese, individually or combined: ‘drug selection’, ‘drug committee’, ‘pharmacy and therapeutics committee’, ‘drug and therapeutics committee’, ‘priority settings’, ‘hospitals’ and ‘new medicines’. The World Health Organization (WHO) policy recommendations were also consulted [29].

Also, DTC procedures at a gold standard tertiary Brazilian university hospital, the Porto Alegre General Hospital (Hospital de Clínicas de Porto Alegre – HCPA), were examined. This hospital is classified as a large general hospital, part of SUS, with approximately 700 clinical and surgical beds including highly complex care as well as services in neurology, neonatology, oncology and transplantation [30]. HCPA has been continuously conducting a consolidated drug selection process since 1986 with allocated staff and medical experts [31]. Activities of the drug committee (Comissão de Medicamentos – Comedi) were studied. Sources of information included documents, interviews and observation of committee meetings. During meetings, hospital administrative support to the committee, member involvement and responsibilities, evidence-based discussions and decisions, activities regarding development and dissemination of DTC publications, policies and guidelines were observed. Information collection was authorized by Comedi’s coordinator. A review of normative and procedure documentation and the summary of Comedi’s observed procedures and decision-making from 2006 onwards were subsequently undertaken.

Theoretical information of DTC activities and structure and practical aspects regarding structure and the selection process at the gold standard Brazilian hospital permitted the drafting of a structured discussion regarding the adoption of drugs by tertiary hospitals and the workings of DTCs. A resulting analytical framework for assessing drug and therapeutics committee structure and processes in tertiary Brazilian hospitals was subsequently proposed.

This research was approved by the Ethics in Research Committee of the Sergio Arouca National School of Public Health. Oswaldo Cruz Foundation, in Rio de Janeiro, Brazil (Review Number 142/10 CAAE 0148.0.031.000-10).

Results and Discussion

Motivation for adoption of new medicines.

Characteristics of new technologies have shown to be directly related to demand and adoption [11,23]. As a consequence, the nature of these technologies and the sources of information regarding them are important analytical categories to consider.

In addition to information on efficacy of innovative drugs disseminated in scientific journals [32–34], other elements give rise to requests for formulary inclusion. They involve the simple interest for what is new; this might be reinforced by rare clinical situations for which there are no established pharmacological therapies.

As such, evaluation and selection of essential medicines should be based on priority therapeutic needs of the population, according to the WHO [29]. Therefore, the epidemiological profile of patients should guide decision-making, an explicit recommendation by the WHO.

Other important elements are prescriber contact and involvement with new drugs in controlled clinical trials conducted at university hospitals and the direct influence and relationship of power brokers – professors and researchers – with the pharmaceutical industry [10,11,35–37].

During the selection process, at institutional or at country level, comparative assessment is a mandatory procedure when deciding on the adoption of any new technology considered essential for the health facility or system. In countries such as Australia, Scotland, Spain (Catalonia) and Sweden [9,21,38], drugs are evaluated to allow market authorization and on the benefits for healthcare and patients, usually in two separate processes. This will depend on where budgetary responsibilities lie, for example, new drugs may be reimbursed or recommended by national bodies (such as the Scottish Medicines Consortium or the reimbursement agency in Sweden – TLV). However, recommended drugs are significantly reduced in formularies and guidance such as the Wise List in Stockholm Healthcare Region [9,21].

In Brazil, the drug registration process, although requiring that many relevant aspects of the technology be evaluated (efficacy, safety and, for instance, cost-effectiveness), does not in fact compare it with already available technologies [29].

In HCPA, the epidemiological profile is a first motivation for adoption of medicines. An addition to the formulary is recommended if the drug to be evaluated: (a) offers advantages that justify replacing the first choice for treatment; or when (b) is indicated for any new therapeutic procedure in the insti-
tution. In both cases, a crucial, strict criteria-based comparison of available options is made when a request for formulary inclusion is received through proper committee channels and procedures.

It is worth noting that teaching hospitals in Brazil and elsewhere are traditional targets for pharmaceutical companies, because those institutions gather professors (who wish to pass on what is perceived as the best and most up to date knowledge to their students) and students (who are eager for everything that is new and thus regarded as the best) [15,39]. Gertner [40] studied the use of evidence to subsidize adoption of health technologies in Brazil. He found that pharmaceutical companies create markets in the public system, by exploring what he named as ‘uncertainty’ – the use of foreign data as favourable approximations in the clinical setting, when no Brazilian data are available – and the resulting vulnerability of decision-makers in making clinical choices. In Brazil, uncritical adoption of medicines and treatments in university hospitals has been linked to health litigation throughout the health system [41].

Structure and organization for medicine selection.

Structure and organization for medicine selection refers to the necessary resources for the selection process to effectively take place. The DTC structure seems to be directly related to the organization of the decision-making process. DTCs show diverse organizational features and support from either pharmacy, pharmacology, clinical pharmacology or clinical departments [3,20,32–34,42–45].

A list of essential medicines, or a medicine formulary, is considered helpful in assisting prescribers with assessing the value of medicines based on critical evaluation of the evidence and cost-effectiveness as compared to current alternatives [3,21]. Drafting a list of essential medicines involves interdisciplinary aspects and different types of knowledge. The procedure must be decentralized and participatory but conducted by a single entity; its institution must be ratified by an internal norm or equivalent [29]. According to the WHO, some aspects are essential. These include technical support, trained human resources and access to databases and bibliographies. Administrative aspects, such as office space, weekly workload for members, keeping of official decision records, policies and guidelines and the monitoring of activities by the board of directors, are also essential [29]. A very relevant aspect must be highlighted – the training of health professionals for their roles in the DTC. This specifically means enabling health professionals, such as pharmacists and clinicians, to work collaboratively with clinical pharmacologists to foster pharmacotherapeutic exchange and debate in healthcare settings [3,20,46].

The member structure of DTCs varies according to the characteristics of those in charge of decision-making. Overall, pharmacists, nurses and the main medical specialties are represented in DTCs [32–34,47,48]. Members’ insufficient knowledge to evaluate drugs [49–51] and activity overload [48] are pointed out as problems preventing smooth committee operations.

Defining DTC functions and activities and members’ roles are part of the structuring process. The main DTC-reported roles are perceived as drug evaluation and the maintenance of an institutional formulary [33,34,47,51]. The WHO [29] adopts an additional number of functions: drug information provided to staff, drafting of institutional policies and therapeutic guidelines and monitoring use.

Members’ impressions and feelings with respect to their own participation in decision-making and the relevance of interpersonal relationships in DTC performance are highlighted by Bagozzi et al. [44]. The authors analysed the behaviour of members of 222 DTCs in teaching hospitals with more than 300 beds in the USA. Their conclusion was that negative and positive feelings such as frustration, envy, embarrassment, persuasion ability, cooperation and open-mindedness varied between physicians, nurses and pharmacists involved in the process, but mainly in respect of the roles they played inside the committee. Overall, personal interaction was positive but not prominent. In hierarchical settings (such as a DTC), personal relationship effects are less apparent and the official standing of the healthcare professional seems to prevail and leads to collaboration. This speaks for the importance in keeping DTCs on the formal side.

Adopting transparency and avoiding conflict of interest are important conditions for DTC decisions to be respected in clinical practice. This is especially important in hospitals that deal with innovation and tertiary care. Members should preferably not be connected with the pharmaceutical industry. In case some kind of relationship exists, this connection must be clearly stated in conflict of interest statements [29].

Dutch and Australian studies have reported situations in which the adoption process did not seem to be entirely regulated in the scope of the DTC. In the Netherlands, responsibilities of some hospital DTCs were transferred to the pharmacy department. Routine prescription of non-formulary drugs, as well as the use of samples donated by manufacturers, are both examples of circumstances that resulted in uncritical adoption, because they bypassed the formal evaluation process that preceded adoption in some hospitals in those countries [34,51].

In the United States, DTCs are reported as working in a formal manner, with an agenda, meeting minutes and outcome, for example, the publication of institutional policies, formularies and therapeutic protocols. If compared to that level of organization, in other countries, DTC operations often appear less formal and effective [32]. Inadequate DTC structures and organizations were considered barriers to their implementation in Dutch and Australian hospitals [34,51] and affected the formularies [50]. These problems were due mainly to a lack of clinical pharmacologists and medical specialists as committee members or to a lack of resources for comprehensive drug evaluation.

Physicians and DTC members are prone to involvement with the pharmaceutical industry. Funding for educational meetings and training courses and funding for clinical research received from manufacturers are some of the frequent opportunities the pharmaceutical industry is using to influence members [23]. The Wise List process shows a comprehensive
policy on conflict of interest. Members share values and manifest conflict when existing [3]. The WHO [29] goes a step further and suggests that members with potential conflict should abstain from such relationships or not be part of the medicine selection process.

Studies describing DTC experiences in countries did not always mention conflict of interest precautions with the exception of Scotland and Sweden [3,9]. Farmer and Nelson [52] reported that most (76%) individuals interviewed from 38 DTCs in American university hospitals were not formally instructed on potential conflict of interest.

An important aspect of DTC success, and resulting quality of formularies, lies in the recruitment of physicians knowledgeable in clinical pharmacology with research and teaching experience, as well as in the adherence to clear criteria and procedures [3,9,20,21,53]. Similarly, formularies encompassing primary and secondary care are well accepted in Scotland with clear principles of drug selection enhanced by including professionals knowledgeable in the disease areas and in clinical pharmacology [9].

University hospitals in Brazil present heterogeneity. Size, type of management, legal nature, facilities, staff requirements and training are very different. Adjustments are somewhat accomplished within the level of care. An additional cause of lack of uniformity is the fact that university hospitals are regulated by the Ministry of Education and not by the Ministry of Health [25], which drafts clinical guidelines and enforces sanitary regulations and policies.

Although recommended in teaching hospitals by the Ministry of Education, DTCs are by law not mandatory in Brazil [27]. A study conducted with a sample of 250 hospitals in Brazil in 2003 found that only 29 had a DTC, and of these, only nine were active [28]. Most of the hospitals that presented a DTC were complex university facilities. However, data also showed that the adoption of new high-cost medicines was frequently conducted outside the DTC and suggest that adoption of new medicines in these settings may occur uncritically and informally by management. Hospital procurement lists were frequently and inadequately accepted as a therapeutic formulary in major university hospitals. Inclusion in this procurement list is not subject to evidence-based selection, but the result of managerial choices or pressures from prescribers and industry [16,17].

However, processes, organization and documentation of HCPA’s Comedi were similar to the model recommended by the WHO [29]. The committee possessed an independent structure with adequate facilities. It was administratively linked to the Unit of Clinical Pharmacology. Since 1991, there have been eight published versions of the hospital formulary (the last version was published in 2008 and a new one is in development). DTC regulations are constantly updated and available to hospital staff. Newsletters and bulletins on medicines and drug utilization are published periodically. Executive members monitored drug prescribing on a daily basis. Observation of Comedi’s structure and functions and of formulary management at HCPA indicated the feasibility of application of international recommendations in Brazil.

In HCPA, consultative members include two full professors from the Pharmacology Department with experience in clinical pharmacology, as well as one full professor from the School of Nursing and the Head of the Pharmacy Service. Four other members had executive functions: three physicians (general practitioners) and a pharmacist officially designated by the hospital director. Clinical specialists contributed as ad hoc consultants. The committee convenes weekly.

Aspects regarding conflict of interest are especially important in Brazilian university hospitals. Close involvement of the pharmaceutical industry with students and staff at these hospitals is common. Marketing is intense and invasive. Manufacturer representatives are usually seen inside facilities, promoting innovations and providing simple novelties to reinforce the message and drug name as well as distributing samples [55]. However, many physicians that recognize their involvement with the pharmaceutical industry hesitate in admitting its influence on their daily practice. More than 98% of university hospital physicians admit receiving pharmaceutical company representatives; 86% receive gifts and 14% actually admit prescribing medicines in return for prizes and other amenities [55,56]. Moreover, the influence on medical students may also be pervasive, because it favours the habit of accepting not only compensations but biased information which may pose a risk to their future patients [55].

At the HCPA, according to WHO recommendations, all Comedi members must declare in writing any connections with the pharmaceutical industry. Members involved in any drug promotion or marketing activities are not allowed on the committee. No extra monetary compensation for Committee members is allowed. Comedi’s experience shows that there is a way to guarantee availability and involvement of key health professionals in Brazilian settings, keeping a safe distance from potential conflict.

Criteria and methods for medicine selection: review on how Brazilian experience accords with international reports.

Efficacy, safety and cost-effectiveness are identified by the WHO as essential criteria for selecting new drugs [29].

Search for quality evidence must be centred on systematic reviews of the literature and meta-analysis and on treatment guidelines published by governments or medical societies [33,34,43,49]. This must be highlighted as a best practice for DTCs. Lower ranking information (in the hierarchy of evidence) includes oral communications given by specialists at meetings and conferences or published in case reports or made available by the pharmaceutical industry [33,34,43].

Competence in the critical assessment of drugs is essential to DTC membership, when considering the pressures to adopt new medicines especially in a tertiary care environment. Consequently, training in clinical pharmacology is a crucial aspect for successful DTCs [3,20]. Joint involvement of primary care physicians and hospital specialists in DTCs is also a key aspect as they complement each other and give scope to formulary decisions and balance narrow super-specialist aspects role of new drug option [3,9,29,33,34,46,57].
Dissemination of information on products by DTC members also appears to be a key aspect that makes all the difference in the implementation of drug recommendations from DTCs in hospitals and ambulatory care. Adequate communication, exchange and follow-up with all physicians and other health professionals will help with implementation of formulary guidance [3,9,58].

The context in which this paper specifically intends to examine DTCs is the teaching hospital. In spite of the fact that DTCs should have the same central role wherever they exist, that is, selection of essential medicines in healthcare facilities and systems, extra care must be taken to ensure compliance with best practice in tertiary care facilities. This does not always happen because the pressures for adoption of new medicines are much higher and comparative evaluation not always forthcoming. These medicines have typically had only a short market history and basically more, if any, data on efficacy than on safety.

In addition, there are concerns that the patient population in clinical trials may be different to that seen in clinical practice with greater co-morbidities [1]. Typically Phase III clinical trials are conducted under ideal and highly controlled conditions to seek high internal validity to enhance the potential of demonstrating clinical benefit [1]. However, this may lead to substantial differences from their subsequent use in clinical practice with generally Phase III clinical trials not including treatment preferences and/or multi-modal treatment programmes [1]. These points are particularly important in teaching hospital environments with complex co-morbid patients. Without such guidance, new drugs may be withdrawn due to unacceptable risk/benefit ratios in routine clinical practice [1].

In Dutch and Australian hospitals, information pertaining to risks of use was considered decisive for selection [34,45] while pharmacological data on drug efficacy were crucial domain in the USA, Sweden and the United Kingdom [36,43,59]. In a number of countries, it was considered that the medicine selection process is potentially influenced by political, social and ethical issues, such as drug financing, pressures from patient groups, specialists’ opinions (peers, university professors and members of medical societies) and marketing. These issues should be balanced by the independent expert opinion in the DTC [33–35,39,47,53].

Surprisingly, ranking the level of evidence and stringency as to the use of the best evidence available [21] were issues not typically mentioned or discussed in country experiences, although this procedure is part of the selection criteria for the Wise List in Stockholm County [3].

The Wise List experience in Stockholm shows that personal contact (visits) with ambulatory care physicians by physicians and pharmacists employed by the County Council to disseminate materials and exchange information enhances prescriber adherence to the list [3,9], being founded on evidence-based academic detailing [59] and comprehensive communication strategies adapted to the needs of various prescriber and patient groups [3]. Similarly, adherence to formularies in Scotland is enhanced by joint development of formularies involving different professionals and pharmacotherapeutic experts as well as health board monitoring of physician behaviour [7,58].

Brazil started organizing health technology assessment processes beginning in 2003. The federal government began fostering research and binding use of best evidence and rational use to clinical, managerial and political decisions in the health system. For this purpose, one initiative under implementation is the Health Technology Assessment Centers (Núcleo de Avaliação de Tecnologias – NATS). Since 2009, 29 NATSs have been set up in university hospitals throughout the country [16].

In spite of this effort, in Brazilian hospitals, the importance given to specialists commonly subverts organizational procedures. The power and authority conferred to specialized physicians mark them as independent agents which govern independent departments. In certain cases, the fragmentation brought by senior professors’ behaviours leads to multiple ‘institutes’ within departments. It also results in a certain detachment and lack of institutional commitment, making uniform procedures and adoption of protocols impossible to establish, hospital-wise [61]. Facing and changing this situation is essential to improve rational adoption and use of new technologies and legitimize the decision-making process.

At the HCPA, efficacy and safety were understood as the first essential conditions in the process of adopting a new drug. When confronting two equally safe and efficacious options, the focus shifts to comparative cost-effectiveness [31]. The use of high-ranking evidence is also common practice at HCPA.

HCPA maintains all information on requests, assessments and decisions regarding the adoption of new drugs on the institutional web page, which warrants transparency of the selection process. This may, however, if not directly guaranteeing involvement of hospital staff, promote sharing and dissemination of drug information and adherence to drug formulary [29].

In countries such as Brazil, where oftentimes research data produced in loco are not available [40], DTC work in evaluating evidence is essential to guide better clinical decisions.

A theoretical model for assessing the selection process by DTCs in tertiary Brazilian hospitals.

According to the WHO, a crucial condition to achieve efficient management of new technologies – such as drugs – in healthcare services is the institution of a forum that gathers physicians, clinical pharmacologists, pharmacists and managers, to achieve a balance between meeting the needs of quality health care and resource constraints [24]. The responsibility of DTCs is thus clearly defined: electing the best therapeutic options through a systematic, multidisciplinary and transparent process, based on independent information and objective evaluation with the contribution of the best available experts [29].

Overall, the state of the art on drug selection in hospitals presented elements related to the structure, activity and roles of multidisciplinary committees, that is, DTCs. Selection criteria and use of evidence, as well as factors that influenced decision-making, were highlighted. Aspects pertaining to the demand for adoption of new technologies by healthcare services, such as the
lack of available treatments for a wide range of health problems, marketing strategies for the promotion of new pharmaceuticals and the relationship between prescribers and the pharmaceutical industry were widely discussed in the literature.

The USA and Canada [32,34,42–44,47,49,60,62–64], as well as European countries [3,21,23,33–35,38,50,65–68], Australia and Asian countries describe the evaluation of new drugs by DTCs and experiences gathered with the implementation of multidisciplinary forums in hospitals [38,45,46,48,51,54,57,69]. One Brazilian study [27] that discussed the selection of drugs by a DTC was found. No publications from other Latin American countries on DTCs were forthcoming.

Results that emerged from this discussion led to three main dimensions: (i) what motivates the adoption of new drugs on the essential medicines list; (ii) what structural and organizational aspects are necessary for decision-making; and (iii) what criteria and methods the decision-making process employs. This may be organized in a simple framework (Table 1).

Table 1.

Analytical framework for assessing drug and therapeutics committee structure and processes in Brazilian hospitals.

<table>
<thead>
<tr>
<th>Motivation for adoption of new drugs</th>
<th>Defining needs</th>
<th>Defining nature and source of initial information about the new drug</th>
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<tbody>
<tr>
<td></td>
<td>Publication of new data about the drug in scientific journals</td>
<td>Medical staff contact with the drug through involvement in clinical research</td>
</tr>
<tr>
<td></td>
<td>Drug promotion at academic events, such as seminars and meetings or visits from pharmaceutical sales representatives, donations and free samples</td>
<td></td>
</tr>
<tr>
<td>Structure and organization for selection</td>
<td>Characterization of the decision-making process (mandate)</td>
<td>Technical-administrative support for committee (office space, human resources, access to databases)</td>
</tr>
<tr>
<td>Defining structure</td>
<td>Documenting decisions, policies and guidelines as permanent hospital records</td>
<td>Support and monitoring of activities by hospital board or clinical director</td>
</tr>
<tr>
<td>Defining committee membership and participation criteria</td>
<td>Proposals and alternatives to distance committee members from potential conflict of interest</td>
<td>Multidisciplinary membership; physicians (representing major specialties, including surgery, obstetrics and gynaecology, internal medicine, paediatrics, infectious diseases), clinical pharmacologists, pharmacists, nurses and managers (representing the hospital’s board of directors)</td>
</tr>
<tr>
<td>Defining committee roles and responsibilities</td>
<td>Criteria for member participation and detailing member role</td>
<td>Formal designation of membership, workload and term</td>
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<tr>
<td></td>
<td>Presence of ad hoc consultants</td>
<td></td>
</tr>
<tr>
<td>Criteria and methods for selection</td>
<td>Evaluation of new drugs</td>
<td>Drafting list as final product of selection (formulary)</td>
</tr>
<tr>
<td>Defining selection criteria</td>
<td>Developing drug use policies (non-selected drugs, research with new drugs, free samples, limited use for certain patients, etc.)</td>
<td>Developing and monitoring therapeutic guidelines</td>
</tr>
<tr>
<td>Defining methods used throughout the drug evaluation and selection process</td>
<td>Advice on drugs to the hospital’s entire board of directors</td>
<td>Modus operandi: Organization and forwarding of requests for evaluation; frequency of committee meetings; existence and type of information included in request for a new drug; policies for prescription of non-selected drugs</td>
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<td></td>
<td>Comparative analysis of best evidence available, considering the study design and quality and study outcome</td>
<td>Drafting of evidence-based expert reviews</td>
</tr>
<tr>
<td></td>
<td>Other alternative methodologies used in drug adoption</td>
<td>Process transparency and dissemination</td>
</tr>
</tbody>
</table>

Perspectives for application of this framework are under way, in four major university hospitals in Rio de Janeiro as a recommended tool for assessing adoption of new drugs in these healthcare settings. We will report on their utility and acceptance in future publications.

Final Comments

We believe this discussion gives insight into the role of DTCs in the drug selection process and opens perspectives for their implementation in tertiary Brazilian hospitals. We found very few publications in Brazil regarding DTCs as well as the criteria and methodology for including new medicines in formularies. However, the country has a large public health system which is committed to comprehensive universal care, thus bringing forth the need to strengthen effective and safe selection of new drugs for the system as a public health priority. University hospitals are environments that foster the adoption
of new technologies and considered as a gateway to the entire system for these technologies.

WHO recommendations, the experiences of other countries, as well as of the Brazilian HCPA gold standard, especially descriptions of the Brazilian context, provide information as to whether WHO and other recommendations can be adopted by committees in diverse scenarios.

The discussion brought forth information with respect to structure, membership, functions and DTC criteria as well as providing a great number of examples, especially regarding difficulties experienced by DTCs. Important differences in how those multidisciplinary forums were organized and in how they achieved their goals were observed. In this respect, descriptions of North American and Australian committees stand out, because of the number and quality of published experiences.

This study has limitations. We acknowledge that the state of the art was limited to three large-scale databases. We did not aim to produce a systematic review. However, because we intended to bring the discussion to Brazilian hospitals and to the Brazilian healthcare setting, these databases represent the most consulted ones with respect to collective and public health in Brazil. We also highlight that most of the aspects that were discussed found corroboration in the WHO DTC guidelines and were addressed by guidelines of the Brazilian gold standard.

There were also limitations with regard to language – consulted experiences were limited to publications in English, Spanish and Portuguese. Again, we believe that this is acceptable because most sites concentrate on English language publications which are retrieved by the health professionals in Brazil. A single gold standard was also chosen for examination of drug selection in a tertiary hospital. We also believe that this is acceptable because the experience of the HCPA is unique in the country.

In Brazil, the assessment of drugs by multidisciplinary committees in healthcare services has not been frequently described or discussed. We believe that this is an important finding and adds weight to the rationale behind this paper. However, despite the potential for application in scenarios where selection of medicines is under way, this analytical framework should be researched and challenged in other facilities to investigate whether the processes need refining in wider and more diverse settings. In regard to the level of care, different interests and players involved in formulary decision-making, we estimate that the framework, developed according to the state of the art and grounded in real and current experience in Brazil, may contribute to knowledge on drug selection in tertiary hospitals and perhaps other health facilities that present a drug selection process. Consequently, we hope that other hospitals will review the suggested approach and adopt it to their settings.

We emphasize that the scope of this discussion may be addressed by all tertiary hospitals reviewing selection processes. A national gold standard DTC, compliant to all WHO recommendations, subject to the same influences and shortcomings that are encountered elsewhere in Brazil was able to surmount difficulties and adhere to best practices. This paper aims to show that reproducing this experience may be possible, given necessary attention to each aspect discussed, ultimately leading to the improvement of the quality and efficiency of prescribing, given increasing resource pressures.

Competing interests.

The authors declare that they have no competing interests.

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References

14 O’Dwyer GO, Oliveira SP, Seta MH. Evaluation of emergency services of the hospitals from the QualiSUS program. Ciência Saúde Colet 2009;14:1881–90.


Fischer MA, Avorn J. Academic detailing can play a key role in assessing and implementing comparative effectiveness research findings. Health Aff 2012;31:2206–12.


