A bibliometric study of access to medicines research in developing countries

Community pharmacy based research activity in India

Medicines information in medical journal advertising in Australia, Malaysia and the United States

Antimicrobial use in Ulaanbaatar, Mongolia

Value of pharmaceutical innovation
Southern Med Review
An International Journal to Promote Medicine Use and Access Research

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**Context:** In developing countries where health systems and health policy are constantly evolving, there is a great need to publish informative research. However, there are few avenues to do so due to, also inexperienced or untrained researchers, topics out of the scope of current mainstream journals and limited funding are some of the other challenges.

**Aims and Objectives:** Southern Med Review provides a platform for researchers to disseminate commentary and empirical research findings, with a view to improving the rational use of and access to essential medicines.

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**Indexing and Abstracting:** The journal is indexed in Directory of Open Access Journals (DOAJ), EBSCO Host, Open J Link, Gale, Global Health, CAB Abstract Databases, Ulrich’s Periodical Directory and in New Zealand’s National Library. Articles are also deposited in the WHO’s Essential Medicines Documentation Database.
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Evidence based pharmaceutical policy research: Is it all talk or does it contribute to improving health in developing countries?

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It is always said that the foundation to improving “medicines use” and developing a “health system” is to create reliable data - the hard core evidence to explore and solve problems. The process of data gathering also has some other advantages; it provides an accurate picture of a country’s pharmaceutical needs, serves as a training tool for researchers, and it increases the country’s scientific output. However, naturally the main question we would be asking is, whether the data has managed to serve its primary aim – to bring a positive change to people’s lives. The answer to this question in many cases could be a ‘no’ as policy implementation requires action, transparency and commitment.

The problem with data gained from pharmaceutical policy research is, that if not properly used, its relevance diminishes rapidly. Also, however credible the evidence is, implementing policies requires political commitment. One such case study is World Health Organization/Health Action International research on medicine prices, availability and affordability. Examples from many developing countries show that no matter how robust the data is, stakeholders with vested interests are always willing to lay counter arguments. Most often, the aim is to question the authenticity of data. There is no problem in a scientific debate; however very often during this disagreement process, the truth is lost and the public become confused with who is right and who is wrong. As a result, the opportunity to inform and build public opinion around a genuine public health issue vanishes.

The question then arises, what are developing countries gaining from this hard core pharmaceutical evidence? In this scenario, would it not be more logical for them to focus on “hands on clinical pharmacy activities” or “individualized pharmaceutical care” rather than investing on policy based work? These hands on activities could be better inhaler techniques, improving corticosteroid usage, monitoring adverse effects, medicines interaction reporting and managing medicines compliance. Would concentrating on these patient related activities produce better “value for money” or even “value for time” in these countries? This is a rather provocative question, the answer to which is not an easy one, however it certainly merits investigation. Either way, as a journal we advocate that there is a need to build a database which narrates the aims, objectives and most importantly outcomes of pharmaceutical policy based projects – what is achieved and what is lost, whether the research has transformed into action or not.

Nevertheless, the Southern Med Review is a journal with a mission to support evidence based pharmaceutical policy research and in the current issue two bibliometric reviews focusing on “policy & practice” have been published. Ritz et al provides us with a bibliometric study of publication patterns in access to medicines research within the developing world. The paper provides an understanding of the extent to which medicines policy research is being undertaken and helps to set a future research agenda. A letter to the Editor by a pharmacy student published in the current issue also shows that our work is stimulating comparative thought and making a difference which is the primary objective of this journal.

With all of the above in mind, we welcome your contributions and look forward to a challenging yet rewarding 2010.

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References
A bibliometric study of publication patterns in access to medicines research in developing countries

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Abstract

Objectives: Developing countries face considerable problems in both accessing and properly utilizing essential medicines. One challenge to achieving these goals in resource-poor settings is a limited knowledge base as to what works to improve the selection, access and use of essential medicines including; ways to ensure affordable prices, increase sustainable financing, and strengthen reliable supply systems that are relevant to these settings. The objective of this study was to search the existing evidence base on access to medicine issues in developing countries and to assess publication patterns regarding the nature of topics studied, areas where gaps of information exist and the general trends in publications in this area.

Methods: A PubMed search was conducted to retrieve publications on access to medicines in developing countries between 1999 -2008. Our search strategy builds and expands on a search strategy developed for a Cochrane review to include a wider range of topics related to access to medicines and pharmaceutical policy. Retrieved articles were categorized by research topics, year of publication, study area, and country of residence of corresponding author to establish patterns in publications with respect to these categories over the past 10 years.

Results: Medicine selection, intellectual property rights, and monitoring and quality assurance were among the top topics studied over the last 10 years. Corresponding authors residing in high-income countries represented around 50% of all publications relative to low-income (18%) and middle-income countries (32%). Although an increasing trend in the number of publications per year was found, the increase was relatively small and variable over a 10-year period.

Conclusions: There are few peer-reviewed publications on access to medicines in developing countries with an average of only 76 publications per year over the past 10 years. Increasing the local evidence base as to what works to improve access to medicines in resource poor countries, particularly to the poor, is of the utmost priority to accelerating the achievement of global medicine goals.

Keywords: Bibliometrics, Access to Medicines, Essential Medicines, Drug Utilization

Background

Thirty-two years have passed since the World Health Organization (WHO) created the first Model Essential Medicines List (EML) in 1977 as a standard for countries to select medicines and to create their own lists of essential medicines. Increasing access to these essential medicines is crucial to preventing millions of deaths a year. As of 2008, at least four out of every five countries in the world had a national EML in place. Medicines account for 20 – 60% of health spending in developing countries, and up to 90% of people in developing countries have to pay for their medicines out-of-pocket. Individuals affected by these high payments are disproportionately poor and medicines remain unaffordable for many.

In 1978, the Declaration of Alma Ata identified the quality, rational use and provision of essential medicines as one of the eight key components of primary health care. During the 1985 Conference of Experts on Rational Use of Drugs in Nairobi, the modern definition of rational use of medicines was promulgated. This definition states, “rational use of
A bibliometric study of publication patterns in access to medicines research

The objective of this study was to perform a bibliometric analysis of publications related to access to medicines policies in the published literature to assess the state of access to medicines research in developing countries. Bibliometrics look at publication patterns in research areas using quantitative analysis and statistics to analyze citation data. An examination of the nature of existing evidence through analysis of the data by topic and study region occurred. Publication patterns were examined to explore changes in the output of and capacity for research in developing countries over the past 10 years. These findings will serve as evidence based guide for the proposed ATM Research Network and in setting priorities and building capacity for research related to pharmaceutical policy in developing countries in the future.

Methodology

A bibliometric search was performed in PubMed, building on a search strategy developed in a Cochrane review on pharmaceutical policy and expanded to include a wider range of topics related to this area. The targeted search included studies published between 1999-2008. However in examining trends we also explored any recent change in trends, i.e., between 2005 and 2008 that may be linked to the various initiatives to improve research for health around this period, e.g., the Mexico Summit for Health Research and efforts to accelerate progress towards achieving the millennium development goals for health.

Articles were selected if they met the following criteria:

1. Focus on one or more of the following themes:
   - Medicines regulation and classification (licensing) policies
   - Drug monitoring
   - Medicines selection
   - Medicines pricing policies
   - Medicines intellectual property/patent policies
   - Medicines marketing policies
   - Medicines information
   - Prescribing policies
   - Medicines utilization or medicines use
   - Medicines insurance policy and medicines financing
   - Medicine reform/policy
   - Access to Medicines
   - Medicines supply management

2. Publications concerning developing countries

3. Publication date: 1999 to 2008

4. Limited to human subjects

5. All languages were included

Studies on substance abuse or poisoning were excluded.

Retrieved articles and methods for analysis

A total of 761 publications were retrieved for the period between 1999-2008; 350 were published between 2005-2008. The retrieved citations were downloaded from the PubMed database and analysed using Reference Manager and Excel software. Extracted data included author names, publication title and abstract, publication date, affiliation and country of residence of corresponding author, study area, main theme with respect to the categories listed above, and journal.

Three publications from 1999-2008 were eliminated because they were published in 2009, this occurred because they were published electronically in 2008. Only 535 publications had data on country of residence of corresponding author.

The retrieved articles were further analyzed to categorize the country of residence of corresponding author according to World Bank country income classification and the World Bank and the geographical regions. A more detailed report including the search strategy is available from the WHO.
A bibliometric study of publication patterns in access to medicines research

We also analyzed the frequency of publications by topic for the retrieved articles. This was done in two stages. The first following the detailed topics listed above for the selection criteria and the second using a more general categorization involving fewer overarching content areas. The aggregated categories included procurement, quality assurance and references to pharmacists. It should be noted that the proportion of articles published by theme does not add up to 100% as some articles are classified under more than one theme.

Results

Table 1 shows the distribution of articles per year. Although there was a general increasing trend in the number of publications per year, there was some fluctuation between years.

Table 1. Number of publications per year, 1999-2008

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Publications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>40</td>
</tr>
<tr>
<td>2000</td>
<td>48</td>
</tr>
<tr>
<td>2001</td>
<td>83</td>
</tr>
<tr>
<td>2002</td>
<td>75</td>
</tr>
<tr>
<td>2003</td>
<td>81</td>
</tr>
<tr>
<td>2004</td>
<td>84</td>
</tr>
<tr>
<td>2005</td>
<td>78</td>
</tr>
<tr>
<td>2006</td>
<td>59</td>
</tr>
<tr>
<td>2007</td>
<td>114</td>
</tr>
<tr>
<td>2008</td>
<td>96</td>
</tr>
</tbody>
</table>

The overall correlation reflecting the association between the number of publications and year was $0.715 \ p < 0.05$. The R-squared value 0.51 suggests a steady and significant increase over the 10 years.

The top aggregated themes for both time periods were selection, intellectual property, monitoring, regulation and quality assurance, access, and insurance and financing. Monitoring moved from fourth most common theme in 1999-2004 to the most important theme from 2004-2008. Since several themes might have been addressed in the same paper, this analysis only gives a general description of the distribution and does not add up to 100%, see Table 2.

Despite a limited increase in studies related to pharmaceutical policy and reform, these papers ranked 7th for themes studied in 2005-2008. The bottom four themes of pharmacists, prescribing/utilization, information and marketing remained the same for both time periods.

On average, 50% of corresponding authors resided in high-income countries both during the whole 10-year period (1999-2008) and the last four years (2005-2008). Corresponding authors residing in low-income countries represented 18% and 19%, on average, of the total number of papers over the past 10 years and four years respectively, see Figure 2.

Table 2. Publication topics and numbers per year grouping

<table>
<thead>
<tr>
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<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Selection</td>
<td>135</td>
<td>Monitoring</td>
<td>106</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>88</td>
<td>Selection</td>
<td>98</td>
</tr>
<tr>
<td>Regulation &amp; Quality Assurance</td>
<td>84</td>
<td>Regulation &amp; Quality Assurance</td>
<td>62</td>
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<tr>
<td>Monitoring</td>
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<td>Access</td>
<td>35</td>
</tr>
<tr>
<td>Access</td>
<td>24</td>
<td>Procurement &amp; Distribution</td>
<td>25</td>
</tr>
<tr>
<td>Procurement &amp; Distribution</td>
<td>21</td>
<td>Policy/Reform</td>
<td>17</td>
</tr>
<tr>
<td>Medicine Supply</td>
<td>13</td>
<td>Insurance and Financing</td>
<td>16</td>
</tr>
<tr>
<td>Policy/Reform</td>
<td>9</td>
<td>Medicine Supply</td>
<td>12</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>8</td>
<td>Pharmacists</td>
<td>11</td>
</tr>
<tr>
<td>Prescribing &amp; Utilization</td>
<td>8</td>
<td>Prescribing &amp; Utilization</td>
<td>11</td>
</tr>
<tr>
<td>Information</td>
<td>4</td>
<td>Information</td>
<td>6</td>
</tr>
<tr>
<td>Marketing</td>
<td>3</td>
<td>Marketing</td>
<td>2</td>
</tr>
</tbody>
</table>

We cannot explain the increase in publications between 2006 and 2007. Further analysis revealed that authors residing in Brazil tripled their previous contribution of four papers in 2002 to 12 in 2007, which may explain some of this difference. However this was not sustained in 2008, when a total of 96 papers were published.
Figure 2. Country of residence of corresponding authors by World Bank region

Figure 3 shows the contribution of the EURO and AMRO WHO regions, who combined represent on average around 50% of the total publications per year during the analysis period. The next biggest contributors were authors residing in the Western Pacific region with around 14% of publications per year on average. EMRO country authors only contributed a total of 45 articles (8.5%) for the entire time period of 1999-2008, the lowest of all WHO regions.

The top eight countries of residence of corresponding authors in 2008 were the United States, the United Kingdom, Brazil, China, India, the Republic of Korea, Nigeria and Japan, (Table 3). The following six countries all contributed two publications in 2008 (Australia, Egypt, Malaysia, the Netherlands, Sweden and Switzerland). Out of the 46 total publications representing the top eight countries in 2008, 35% were from corresponding authors residing in developing countries (China, India and Nigeria). Korea went from 1 to 2 articles a year for only four of the previous nine years to six articles in 2008.

Table 3. Top eight countries of residence of corresponding author, 2008

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of Publications</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States of America</td>
<td>8</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>7</td>
</tr>
<tr>
<td>Brazil</td>
<td>6</td>
</tr>
<tr>
<td>China</td>
<td>6</td>
</tr>
<tr>
<td>India</td>
<td>6</td>
</tr>
<tr>
<td>Republic of Korea</td>
<td>6</td>
</tr>
<tr>
<td>Nigeria</td>
<td>4</td>
</tr>
<tr>
<td>Japan</td>
<td>3</td>
</tr>
</tbody>
</table>

Discussion

Publications over time

While the number of publications has increased over the period of review, there is considerable variation over the last decade. These findings highlight the importance of examining the content and geographical origin of publications over a series of years rather than assuming that a cross-sectional examination at a point in time is generalizable over a number of years.

Topics

Insurance and financing has dropped off in terms of relative interest in recent years. This is concerning when one considers that in developing countries, medicines account for 20-60% of overall health care spending compared with less than 15% in most high-income countries. The increased focus on drug monitoring including adverse drug reaction and pharmacovigilance in the developing world are heartening since there seems to be a greater interest in whether or not the medicines are working effectively.

Publications related to Intellectual property (IP) were high in both time periods, since IP continues to create interest and further policy debate. Publications on prescribing and utilization remained low over the 10-year period. There is a need for greater attention to the patterns of prescribing and utilization of drugs to provide important data sources if policy planning is to take place in the future. Such data will contribute to a better understanding of how to best prioritize medications in low and moderate-income countries.

Country of Origin of Corresponding Author

As predicted, high-income countries contributed most to research on access to medicines relative to middle and low-income countries. The EURO and AMRO regions were the
highest contributors to the literature on access to medicines. Developing country authors have recently contributed to a higher share of publications related to access to medicines in their respective countries, which shows increased interest and capacity to undertake this type of research from developing country researchers.

Limitations

One of the main limitations of this study was limiting our search to only the PubMed search engine and the journals covered by this database. In addition this search does not include studies published in the grey literature, sometimes the most common form of publication in the developing world, but which is often difficult to access. However, since the objective of this study was to search for the nature of the evidence and its distribution among topics and study areas, we believe that this analysis provides a fair representation of the general trends regarding the evidence. This study also provides a baseline with which to compare future studies.

Conclusion

Access to essential affordable medicines is a Millennium Development Goal. There is a need for increased capacity of developing country researchers to perform research and take the lead in choosing questions relevant to them, study the issues and publish to share their knowledge. The evidence base on medicines pricing, quality, affordability and the impact of policies in developing countries should be strengthened to better inform policy.

The recent initiative to create an ATM research network with a particular focus on developing countries and other similar initiatives will hopefully address some of these knowledge gaps. The ATM Research Network could catalyse collaborative opportunities for and investments in more relevant research for the developing world, as well as increase the capacity to undertake and use evidence from this research to improve access to essential medicines in developing countries. Creating and fostering cooperation and future integration between developing and developed world institutions is an important strategy to build this capacity and to achieve a sustainable solution for improving access to medicines in developing countries through informed policy-making.

This study provides the first bibliometric analysis of publications in the access to medicines field. The findings presented in this paper provide a solid basis for setting priorities for research on access to medicines in developing countries and for monitoring the progress in the knowledge base over time. In addition, the search strategy developed for this analysis will assist policy makers in identifying evaluations for different pharmaceutical policy options and will inform future studies interested in both the development of the field as well as in gathering the latest evidence on available interventions.

Acknowledgments

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References

Community pharmacy based research activity in India: A bibliometric study of the past ten years

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Citation: Basak SC, Sathyanarayana D. Community pharmacy based research activity in India: A bibliometric study of the past ten years. Southern Med Review (2010) 3; 1:7-10

Abstract

Objectives: The objective of this study was to analyze and record the published evidence regarding community pharmacy practice in India during the past decade (1998-2008).

Methods: A bibliometric review analysis of the original papers was undertaken to assess the different aspects of community pharmacy practice in India. The MEDLINE, Index Copernicus, IndMed, DOAJ databases and the journals such as Indian Journal of Pharmaceutical Sciences and Indian Journal of Hospital Pharmacy were used as data sources. Type of papers, type of journals, category of papers, production indicators and impact factor of the journals were analyzed.

Results: Thirty papers were included in the study. The papers were published in 13 different journals, 33.3% of them being in the Indian Journal of Hospital Pharmacy. The average number of authors per paper was 2.73 (SD=1.41). Impact factor was available for only three journals.

Conclusions: There are limited studies being published in India which cover the community pharmacy related activities in India. The key indicators which emerge from the literature review present some fundamental challenges to the development of the role of the community pharmacist in India.

Keywords: Community pharmacy, India, Community pharmacy practice, Bibliometric review

Introduction

The expansion of the role of community pharmacists was given an important boost in 1990, when Hepler and Strand coined the term ‘pharmaceutical care’. However, community pharmacy is not considered a well established healthcare profession in India. Community pharmacies are managed by less qualified (as compared to many countries) diploma trained pharmacists. Recently many pharmacists, institutions and professional organizations have indicated a clear strategy for pharmacist’s involvement in management of modern medicines including their selection, optimization, safe and cost effective therapy. Though for sometime the World Health Organization has had a vision for the pharmacists’ role in health promotion and in safe and effective use of medicines. To date the involvement of Indian community pharmacists in such activities are not known. Recently revised and new journals such as Indian Journal of Hospital Pharmacy, Indian Journal of Pharmacy Practice and International Journal of Community Pharmacy are focusing on community based pharmacy activities. Also, in the recent decade or so, there has been a noteworthy increase in the number of presentations at national conferences focusing activities in community pharmacies necessitating the need to record the full extent of community pharmacy based publication.

Study of publication patterns, known as bibliometric study is a useful tool for obtaining information and trends in a certain subject area. There are reviews of the scientific literature concerning community pharmacies in various countries but there is no bibliometric analysis focusing on Indian community pharmacy publications. The aim of this study was to undertake a bibliometric analysis of the published literature regarding community pharmacy practice in India.

Methods

A bibliometric review of articles or papers that described the community, retail or private pharmacy practice in India was undertaken. The search covered the period 1998 to December
Community pharmacy based activity in India

2008 using Medline/Pubmed, Index Copernicus, IndMed and DOAJ databases. A direct search was made in primary sources, specifically in the journals Indian Journal of Pharmaceutical Sciences (online) and Indian Journal of Hospital Pharmacy (offline). Google, Google Scholar and Scirus search engines were also used.

Search strategies included the terms: community (or retail, private) pharmacy in India, community pharmacy practice in India and community (or retail) pharmacist in India. For the PubMed/medline search, the term community pharmacy and India was used. The search strategy for the review included all the permutations of each term, including plurals as well as associated words: pharmacy, pharmacies, pharmacist, pharmacists, pharmacists’, drug retailer(s) among others. Reference lists of retrieved papers were also scanned for other relevant papers.

Papers or articles were included in the review if they met the following criteria: English language, publication dates between 1998 to December 2008, relevant to community pharmacy, and research (or review) based on Indian scenario. The study restricted to English language as the language for pharmacy teaching, administration, management and practice is English in India. Papers were excluded if they were hospital and clinical studies. Editorials, letters, and articles available in pharmacy news weeks or periodicals were also excluded.

The search strategies were refined after conducting pilot searches. All terms were searched for in title, abstract and main body text. We reviewed the outcome of each search. The title and the abstract of the articles retrieved were analyzed to identify original papers. Identification of relevant papers was based on strict predetermined criteria. All original papers (research and review) which provided an aspect of community pharmacy based activity were included in our study. The articles restricted to opinions and studies that did not involve community pharmacists/ pharmacies were excluded. Also excluded were papers relying on anecdotal evidence to provide a general overview or statement.

The variables recorded for each paper were: main author, number of authors, year of publication, journal type, area of study, origin of bibliographic references. The change in the number of publications in the period studied, the number of authors per publication, authors’ affiliation, the citation index, the impact factor of the journals in which the articles were published, were all recorded and analyzed.

Results

One hundred fifty four papers were identified, of which 109 were journal based, and 45 non journal articles. After excluding non journal articles and duplicated papers, only 24 complied with the inclusion criteria. A further 6 relevant papers were identified from cross reference lists, a total of 30 papers were therefore included in the review and analysis.

Discussion

A total of 30 papers on Indian community pharmacy aspects (3 papers per annum) represent a very low rate of publication in this area of study. There could be many reasons for this including the non availability of appropriate pharmacy practice journals in India and also may be long time required for publication in the leading Indian journals such as Indian Journal of Pharmaceutical Sciences. More than 50% of the papers were published in 3 Indian journals; Indian Journal of Hospital Pharmacy, Indian Journal of Pharmaceutical Education and Research, and Indian Journal of Pharmaceutical Sciences. None of these journals are included in the Science Citation Index (SCI) of the Journal Citation Reports (JCR) database managed by the Institute for Scientific Information (ISI) and therefore is not considered for the impact.

The papers included for consideration were published in 13 journals (Table 1), and 33.33% of the papers were published in Indian Journal of Hospital Pharmacy. A total of 22 papers were published in Indian journals, whereas the remaining 8 papers were published in the Pharmaceutical Historian, Social Science and Medicine, The Pharmaceutical Journal, Research in Social, Administrative Pharmacy, American Journal of Health-System Pharmacist, International Pharmacy Journal and in International Journal of Tuberculosis and Lung Diseases.

Of all the papers, 36.66% were surveillance studies, 26.6% case (or research) studies, and remaining reviews, reports or commentaries. Figure 1 shows number of papers published during 1998-2008. Four papers published in impact factor (IF) or indexed journals were contributed by non-pharmacy researchers.

The total number of authors was 82, which corresponded to 68 different individuals. Seven papers were written by a single author and the average number of authors per paper was 2.73 (SD=1.41). Sixty three authors from a total of 68 published one paper (92.6%). The number of authors listed according to number of paper published is shown in Table 2. The Impact factors (IF) of the journals in which the papers were published are depicted in Table 1.
Table 1. Distribution of papers and journals impact factor (IF)

<table>
<thead>
<tr>
<th>Journal</th>
<th>ISSN</th>
<th>Articles published</th>
<th>IF (year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indian Journal of Hospital Pharmacy</td>
<td>0019-526X</td>
<td>10</td>
<td>No</td>
</tr>
<tr>
<td>Indian Journal of Pharmaceutical Education and Research*</td>
<td>0019-5464</td>
<td>4</td>
<td>No</td>
</tr>
<tr>
<td>Indian Journal of Pharmaceutical Sciences</td>
<td>0250-474X</td>
<td>3</td>
<td>No</td>
</tr>
<tr>
<td>Eastern Pharmacist</td>
<td>0012-8872</td>
<td>3</td>
<td>No</td>
</tr>
<tr>
<td>Research in Social and Administrative Pharmacy</td>
<td>1551-7411</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Pharma Review</td>
<td>0973-399X</td>
<td>1</td>
<td>No</td>
</tr>
<tr>
<td>American Journal of Health-System Pharmacist</td>
<td>1079-2082</td>
<td>1</td>
<td>1.71 (2007)</td>
</tr>
<tr>
<td>International Pharmacy Journal</td>
<td>1010-0423</td>
<td>1</td>
<td>No</td>
</tr>
<tr>
<td>Pharmaceutical Historian (London)</td>
<td>0079-1393</td>
<td>1</td>
<td>No</td>
</tr>
<tr>
<td>Social Science and Medicine</td>
<td>0277-9536</td>
<td>1</td>
<td>2.45 (2007)</td>
</tr>
<tr>
<td>The Pharmaceutical Journal</td>
<td>0031-6873</td>
<td>1</td>
<td>No</td>
</tr>
<tr>
<td>International Journal of Community Pharmacy</td>
<td>NA</td>
<td>1</td>
<td>No</td>
</tr>
</tbody>
</table>

NA- Not available; *-Previous name- Indian Journal of Pharmaceutical Education

factor (IF) calculation. The absence of IF and non-indexation in those databases prevents wide publicity or further citation of the work. However, recently the latter two journals are included in Science Citation Index Expanded database, which will boost citation index of the papers published in these journals. Many of the studies carried out are descriptive studies of community pharmacy practice primarily concerned with a limited number of specific issues and a few are speculative opinion. Also, there is no study involving controlled randomized experimental designs. The results may, however, serve as an indictment of pharmacy policy and decision makers for failing to encourage researchers about the discipline.

To our knowledge this is the first bibliometric study of the literature in the community pharmacy based research in India.

The community pharmacy practice aspects in India are neglected field in terms of scientific publication output as compared with the publication of papers in other fields of pharmaceutical sciences. There is a need to undertake research into community pharmacists’ activities and to systematically assess their education and training needs.

Table 2. Number of authors according to the number of papers published

<table>
<thead>
<tr>
<th>No. of papers</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>5</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authors</td>
<td>63</td>
<td>02</td>
<td>01</td>
<td>01</td>
<td>01</td>
</tr>
<tr>
<td>Percent</td>
<td>92.6</td>
<td>1.47</td>
<td>1.47</td>
<td>1.47</td>
<td>1.47</td>
</tr>
</tbody>
</table>

Conclusion

We conclude that only a small number of research or review articles on community pharmacy activity were available. This is perhaps indicative that less emphasis has been placed on the community pharmacy research necessitating the need to focus on the areas such as medicine utilization and appropriate use of medicines.

Acknowledgements

The authors thank Prof V. Srinath of Department of Pharmacy, Annamalai University for his invaluable advice and encouragement.

References

17. FIP Meetings Report. How pharmaceutical services are provided to patients around the world. The Pharmaceutical Journal 2004;273:359.
Medicines information in medical journal advertising in Australia, Malaysia and the United States: A comparative cross-sectional study

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Abstract

Objective: The aim of this study was to compare the provision of medicines information in medical journal advertising in Australia, Malaysia and the United States.

Methods: A consecutive sample of 85 unique advertisements from each country was selected from the advertisements published between January 2004 to December 2006 in three widely circulated medical journals and one prescribing reference manual. The availability of brand name and generic name, indication, contraindications, dosage, side-effects, warnings, interactions and precautions was compared between the three countries.

Results: We examined 255 distinct advertisements for 136 pharmaceutical products. Journal advertising in Australia, Malaysia and the US usually provided brand names and generic names (range 96 -100%). Information on dosage was significantly less likely to be mentioned (32%) in the US than in Australia (92%) and Malaysia (48%) (P < 0.001). Warning information was significantly less likely to be provided in Australia (5%) than in the US (81%) and Malaysia (9%) (P < 0.001). Apart from information on brand name, generic name, warnings and dosage, other product information significantly less likely to be provided in journal advertising in Malaysia than in Australia and the US (P < 0.001). Similar trends in the provision of product information for the same medicines published in these countries were noted. Brand name and generic name were always provided in the three countries (100%). However, information on the negative effects of medicines was less frequently provided in Malaysia than in Australia and the US.

Conclusions: Journal advertising in Australia, Malaysia and the US failed to provide complete product information. Low quality of information provided in Malaysia indicates the need for effective regulation of provision of medicines information in journal advertising. Different standards of medicines information provided in these three countries suggest that pharmaceutical promotion needs to be better controlled at the international level.

Keywords: Pharmaceutical advertisements, promotion, regulation, Malaysia, Australia.

Introduction

Journal advertising is used by pharmaceutical companies as a marketing strategy to promote pharmaceutical products to health professionals. In 2004, pharmaceutical companies in the United States (US) spent $0.5 billion on journal advertising ¹. The companies have been criticised for providing poor quality information²⁴ that may negatively influence doctors' prescribing behaviour⁵, ⁶.

Following the World Health Organization (WHO) Conference of Experts on the Rational Use of Drugs in1985, the WHO has introduced a set of Ethical Criteria for Medicinal Drug Promotion⁷. The Ethical Criteria for Medicinal Drug Promotion was established to support and encourage the improvement of health care through the rational use of medicinal drugs⁸. It sets out the general standards for ethical promotion of pharmaceutical products that can be used as a model by governments⁹.
Medicines information in journal advertising in Australia, Malaysia and the United States

The International Federation of Pharmaceutical Manufacturers Association (IFPMA) code of conduct sets standards for the ethical promotion of medicines by pharmaceutical companies. The IFPMA code generally is based on the WHO Ethical Criteria for Medicinal Drug Promotion. However, the IFPMA code allows less medicines information to be presented in advertisements than the WHO Ethical criteria. Contrary to the WHO Ethical Criteria, the IFPMA code does not require information on warnings, major interactions, and content of active ingredient per dosage form or regimen and name of other ingredients known to cause problems to be provided in advertisements. The IFPMA code requires that all promotional material should be consistent with locally approved product information.

In addition to the IFPMA, in most countries pharmaceutical promotion is controlled by governmental agencies and/or by the pharmaceutical companies through voluntary codes of conduct, most often underpinned by legislation. The US is a country with a long-established control system by governmental agencies. Australia and Malaysia are examples of developed and emerging countries, respectively, where pharmaceutical companies self-regulate their promotional activities by implementing voluntary codes of conduct which complement the requirements set by government legislation. The codes, regulations and legislation provide standards for all types of promotional materials for prescription medicines including all printed and audiovisual promotional materials.

In Australia, pharmaceutical advertising is regulated by government legislation through the Therapeutic Goods Act 1989. Medicines Australia, which represents research-based pharmaceutical companies, administers a code of conduct for promotional practice. Similarly, in Malaysia pharmaceutical advertising for prescription medicines is regulated by government legislation through the Medicine (Advertisement and Sale) Act 1956. The Pharmaceutical Association of Malaysia (PhAMA), which represents pharmaceutical companies, administers a code of conduct as a guide for the advertising of prescription medicines. Adherence to the codes is a condition of Medicines Australia and PhAMA membership. Failure to comply with the codes will result in sanctions including discontinuation or modification of any practice that is determined to breach the code, the issuance of retraction statements, fines, suspension or expulsion from Medicines Australia or the PhAMA.

In the US, pharmaceutical promotion is regulated by the Food and Drug Administration (FDA). The FDA’s Division of Drug Marketing and Communication (DDMAC) is responsible for ensuring that promotion of medicines is in compliance with the FDA’s rules and regulations. The laws require that pharmaceutical advertising provide accurate and balanced information relating to the medicine’s risks and benefits. FDA may issue regulatory letters to any pharmaceutical company that is found to be in breach of the laws. The letters may serve as a basis for additional regulatory action including recalls or seizures of promotional materials or activities, and criminal prosecution.

Most pharmaceutical companies are international companies. Generally, every pharmaceutical company has their own set of ethical standards based on the standards set forth in the IFPMA code of conduct. According to the codes that are publicly available, promotional materials should support the appropriate use of medicines by presenting information accurately, without exaggeration and must follow all relevant local laws and company policies and procedures.

Despite the existence of regulations and control of medicine promotion, the quality of medicines information in journal advertising has been questioned. A systematic review identified nine studies that evaluated provision of medicines information. Three were multinational comparative studies and seven were single country studies. The multinational comparative studies revealed that the provision of balanced medicines information in journal advertising was a problem both in developed and developing countries. The negative effects of a medicine, which may discourage use of that medicine, less commonly appeared in advertisements. All of the multinational comparative studies were published before 1998. Similar to multinational studies, single country studies suggested that medicines information was poorly presented in journal advertising. In 1992, a content analysis of 109 pharmaceutical advertisements in ten leading American medical journals found that in 40% of the cases, information on efficacy was not balanced with that on contraindications and side effects. In Australia, only one study examined the availability of medicines information in journal advertising. In 1994, in a review of 12 advertisements in four medical journals, 9% failed to mention approved names of the medicines. The provision of information on the negative aspects of medicines, which is essential for appropriate use of medicines, was not further explored in this study.

To our knowledge, no study has assessed the quality of medicines information in journal advertising in Malaysia and the most recent studies in Australia and the US were published in 1994 and 1992 respectively. No comparative study has been conducted on the quality of medicines information in journal advertising among these three countries. Moreover, no comparative data is available on the presentation of medicines information for the same products in different countries. This study provides the first data on the standards of journal advertising in Malaysia, recent data on the quality of information in journal advertising in Australia and the US, and also comparative data on the quality of information in journal advertising in Australia, Malaysia and the US.

We aimed to compare the provision of medicines information in medical journal advertising in Australia, Malaysia and the United States. The specific objectives were:

– to compare the availability of medicine information (brand name, generic name, indications, contraindications, dosages, side-effects, warnings, interactions and precautions) in pharmaceutical advertisements.
To assess whether specific aspects of Medicines Australia’s and Pharmaceutical Association of Malaysia’s (PhAMA) codes of conduct were implemented in practice.

To compare the availability of medicines information in pharmaceutical advertisements for the same medicines promoted in Australia, Malaysia and the US.

**Methods**

This research was specifically designed as an exploratory and descriptive analysis of the availability of medicines information in medical journal advertising in Australia, Malaysia and the United States.

**Selection of advertisements**

We used a convenience sample of one major national family practice journal in Australia and the US. As there was no such journal in Malaysia, we chose the Medical Journal of Malaysia and the Monthly Index of Medical Specialties (MIMS), the latter because it is widely used by general practitioners as a reference.

The journals selected to cover primary care practitioners’ publications were:

- Australian Family Physician, which is the official journal of the Royal Australian College of General Practitioners (readership = 38,608 with about 28,000 of these being general practitioners) (Jonathon Tremain, personal communication 2009 Feb 02).
- American Family Physician, which is the official clinical journal of the American Academy of Family Physicians (readership = over 188,200, no data are available on the general practitioners’ readership)23. MIMS, which is regarded as an official drug reference of the Malaysian Medical Association (MMA) (readership = 7000, with about 4200 of these being general practitioners) (Eileen Khoo, personal communication 2009 Feb 03),
- Medical Journal of Malaysia (MJM), which is the only Malaysian medical journal that is subscribed by the three established medical schools in Malaysia, University of Science Malaysia, National University of Malaysia and University Malaya (readership = over 3500, no data are available on the general practitioners’ readership) (Matilda Cruz, personal communication 2009 Feb 03).

We estimated that the majority of general practitioners in Australia subscribed to the Australian Family Physician. However, we were unable to accurately estimate the percentages of general practitioners subscribed to the journals and prescribing index in Malaysia and the US because the information on the total number of general practitioners for each country was not available in the public domain.

A consecutive sample of 85 unique advertisements from each country was chosen from the selected publications. The publications were published between January 2004 to December 2006. An abstraction form was developed to record the availability of product information.

All prescription medicine advertisements were extracted. A product advertisement different from other advertisements for the same product in terms of graphic presentation or written content was considered to be one unique advertisement. All unique advertisements of the same product that appeared in separate issues of a publication were counted as one advertisement.

The availability of brand name and generic name, indication, contraindications, dosage, side-effects, warnings, interactions and precautions in the main body of advertisements and separate fine print product information was recorded. The separate fine print product information that appeared on different page of advertisement but in the in the same publication was considered as part of the advertisement if there was a statement provided to readers to refer to it.

The presence or absence of information on Pharmaceutical Benefit Scheme (PBS) listings and restrictions (a requirement of Medicine Australia’s code of conduct) and the provision of minimum abbreviated product information which must include approved indication, dosage, contraindications, precautions and side effects (a requirement of the Pharmaceutical Association of Malaysia’s (PhAMA) code of conduct) was also recorded.

**Data analysis**

Data entry was undertaken using SPSS database version 14.0. Chi-square analysis was used to assess differences between countries. The Bonferroni correction for multiple comparisons was applied in dividing our significance level (0.05) by the number of tests that were conducted, and applied the value as our new cut off level for statistical significance.

**Results**

**Inter-rater reliability**

All data were extracted by one researcher. Three other researchers, a researcher from Australia, a pharmacist and a family medicine specialist from Malaysia, independently determined the availability of product information in a randomly selected sample of 30 advertisements from each country. The availability of product information was defined as the presence or absence of any information on brand name, generic name, indications, contraindications, dosages, side-effects, warnings, interactions and precautions. We did not assess the completeness or accuracy of product information. Kappa tests were conducted with STATA version 10 to assess the consistency between observers. Kappa (κ) for inter-rater reliability for the presence or absence of product information between the researchers was 0.91 (almost perfect agreement) (z = 63.3, p < 0.001)24.

A total of 255 distinct advertisements for 136 pharmaceutical products were included in the analysis. All advertisements in the US (n=85) and none in Australia and Malaysia referred readers to separate fine print product information. All advertisements were published over a two-year period (Table 1).
### Medicines information in journal advertising in Australia, Malaysia and the United States

#### Table 1. Circulation list of advertisements

<table>
<thead>
<tr>
<th>Country</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>15</td>
<td>32</td>
<td>38</td>
<td>85</td>
</tr>
<tr>
<td>Malaysia</td>
<td>33</td>
<td>31</td>
<td>21</td>
<td>85</td>
</tr>
<tr>
<td>US</td>
<td>24</td>
<td>25</td>
<td>36</td>
<td>85</td>
</tr>
</tbody>
</table>

#### Availability of product information

The availability of product information varied between countries (Figure 1 and 2). In the US, most information was frequently found in advertisements (range 81-100%). However, information on dosage was significantly less likely to be mentioned (32%) than in Australia (92%) and Malaysia (48%) ($\chi^2 = 66.8; \text{df}=2, P < 0.001$). Similar to the US, in Australia, most information was always provided (92-100%) but warning information was significantly less likely to be provided (5%) than in the US (81%) and Malaysia (9%) ($\chi^2 = 144.1; \text{df}=2, P < 0.001$).

In Malaysia, information on side effects, contraindications, warnings, interactions and precautions appeared in less than half of advertisements (range 9-41%). Apart from information on brand name and generic name, warnings and dosage, other product information was significantly less likely to be provided in advertisements published in Malaysian journals than in Australian and US journals ($P < 0.001$).

Nearly all advertisements (98%) appearing in the Australian medical journals provided information on Pharmaceutical Benefit Scheme (PBS) listings and restrictions. In Malaysia, 31% of advertisements provided the minimum abbreviated product information including approved indication, dosage,

#### Figure 1. Comparative availability of information on benefits of medicines in advertisements (n/85 x 100%)

![Figure 1](image)

#### Figure 2. Comparative availability of information on harmful effects of medicines in advertisements (n/85 x 100%)

![Figure 2](image)

contraindications, precautions and side effects as required by the Pharmaceutical Association of Malaysia (PhAMA) code of conduct.

#### Availability of product information for the same medicines by country

Four medicines were advertised in all the three countries in 32 unique advertisements (Table 2). One company promoted two medicines and three companies promoted one medicine respectively. Product information for all categories except for brand name, generic name, dosage and warnings was significantly less likely to be provided in advertisements published in Malaysia compared with Australia and the US (Figure 3 and 4). Our analysis of availability of product information for the same medicines found that brand name and generic name were always provided by all the pharmaceutical companies in the three countries. However, information on the negative effects of medicines was less frequently provided in Malaysia than in Australia and the US (Table 3).

#### Discussion

Pharmaceutical advertisements in medical journals in Australia, Malaysia and the US usually provided brand names and generic names. Information on indications, side effects, contraindications and precautions was more commonly provided in Australia and the US than in Malaysia. Information on dosage was less commonly mentioned in the US and information on
Medicines information in journal advertising in Australia, Malaysia and the United States

Table 2. Number of the same products advertised in Australia, Malaysia and in the United States

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Brand name</th>
<th>Company</th>
<th>Australia n</th>
<th>Malaysia n</th>
<th>US n</th>
<th>Total n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candesartan</td>
<td>Atacand®</td>
<td>AstraZeneca</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Ezetimibe/simvastatin</td>
<td>Vytorin®</td>
<td>MSD and Schering-Plough</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Esomeprazole</td>
<td>Nexium®</td>
<td>AstraZeneca</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Atorvastatin</td>
<td>Lipitor®</td>
<td>Pfizer</td>
<td>4</td>
<td>8</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td>13</td>
<td>12</td>
<td>7</td>
<td>32</td>
</tr>
</tbody>
</table>

warnings less likely to be provided in Australia. Similar trends in the provision of product information were noted for the four products advertised in these three countries. Pharmaceutical companies in Australia nearly always provide information on the Pharmaceutical Benefit Scheme (PBS) listings and restrictions. Two-thirds of advertisements in Malaysia failed to provide the minimum abbreviated product information as required by Pharmaceutical Association of Malaysia (PhAMA) code of conduct.

Complete information on benefits and risks of medicines provided in pharmaceutical promotion is crucial to doctors in order to determine the most appropriate treatment for patients. However, we found that essential information on negative effects of medicines was frequently missing in Malaysia compared with Australia and the US. Similar findings have been observed in two comparative multi-country studies, where more balanced information was provided in developed countries than in an emerging country. Even the minimum abbreviated prescribing information required by the Malaysian PhAMA code of conduct was not commonly provided in our study. The failure of pharmaceutical companies in Malaysia to provide balanced and complete information as required by their marketing code is even more a concern as Malaysia has no comprehensive independent source of prescribing information unlike Australia and the US. Malaysian doctors may be more likely to rely on commercial sources of information.

The quality of medicines information in journal advertising is lower in Malaysia than in Australia despite apparent similarities in the type of advertising control via the industry code of conducts. There may be several reasons which could explain the differences observed. Firstly, the administration of the code

Figure 3. Comparative availability of information on benefits for the same medicines advertised in the three countries (n/85 x 100%)

Figure 4. Comparative availability of information on harmful effects for the same medicines advertised in the three countries (n/85 x 100%)

Product information: * for p < 0.05 after adjustment for multiple comparisons for Australia/Malaysia, ** for p < 0.001 for comparison Australia/US, other results assumed to be non-significant if no symbol.

Figure content is not transcribed into a text format due to its graphical nature.
Medicines information in journal advertising in Australia, Malaysia and the United States

Table 3. Availability of product information for the same medicines by each company

<table>
<thead>
<tr>
<th>Company</th>
<th>Australia (n=7)</th>
<th>Malaysia (n=3)</th>
<th>US (n=2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AstraZeneca</td>
<td>Brand name, generic name, indications, dosage, side effects, contraindications and interactions were provided in all advertisements. Precautions were missing in two advertisements and warnings were missing in all advertisements.</td>
<td>Brand name, generic name, indications, dosage, side effects, contraindications, interactions and precautions were provided in all advertisements. Warnings and precautions were missing in one advertisement.</td>
<td>Brand name, generic name, indications, dosage, side effects, contraindications, interactions and precaution were provided in all advertisements. Warnings were missing in one advertisement.</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Only information on warnings was not provided in all advertisements.</td>
<td>Only brand name and generic name were provided in all advertisements</td>
<td>Only information on dosage was not provided in all advertisements.</td>
</tr>
<tr>
<td>Schering-Plough and Merck Sharp and Dohme</td>
<td>Brand name, generic name, indications, dosage, side effects, contraindications and interactions were provided in all advertisements. Warnings and interactions were missing in all advertisements.</td>
<td>Only brand name and generic name were provided in the advertisement.</td>
<td>Only information on dosage was not provided in the advertisement.</td>
</tr>
</tbody>
</table>

of conduct in Australia is a transparent process. Medicines Australia publishes on its website comprehensive reports on all code breaches and sanctions imposed28. In Malaysia, no similar information is available in the public domain. The PhAMA ethics committee discloses information about its rulings and the names of companies involved in complaints only to its members12. Public reporting of violations of the code is a strong incentive for pharmaceutical companies to comply with the code in order to avoid negative publicity and deterioration of their public image29. The availability of information on complaints, code breaches and sanctions may discourage repeated breaches and support a more careful approach to future promotional activities29.

Secondly, the range of financial sanction imposed is lower in Malaysia than in Australia. PhAMA code of conduct states that a company that is found to be in breach could be fined up to US $ 13,917.00, much less than in Australia (up to US $ 135,280.00)12. This level of financial sanction is still small compared to the amount of money invested by pharmaceutical companies on promotion28. Increasing the amount of fines may deter pharmaceutical companies from breaching the code29.

Efforts to improve the quality of medicines information provided in advertisements published in Malaysian medical journals are needed. A range of policy options need to be considered including the improvement of the PhAMA code of conduct by requiring public reporting of all code violations and increasing the financial sanctions when advertisements are found in breach of the code. Other policy options include proactive screening of all advertisements by an independent body before they are published in medical journals. This may prevent the dissemination of incomplete information to doctors which may lead to irrational prescribing. The Malaysian Advertisements Board (MAB) 14 is a unit of Ministry of Health Malaysia which oversees medicines advertisements in Malaysia. To date, the MAB has only provided a guideline on the promotion of non-prescription medicines to the public 14. It scrutinises all publications from the print and electronic media concerning the use of medicines by the public. Although the MAB is empowered by law to set policies, directives and guidelines for all advertisements related to medicines that have medical and/ or health claims, its activities do not focus on direct-to-doctors advertising 16. The role of the MAB needs to be expanded to oversee direct-to-doctors advertising.

Most advertisements (95%) published in Australia failed to provide information on warnings. In contrast with Malaysia and the US, the Australian minimum product information 11 only requires provision of information on boxed warnings and not on all warnings included in the product information. Further analysis of the Australian advertisements found that only one advertisement did not provide the required box warning as included in the product information. Our results suggest that there is a need for Medicines Australia to strengthen its code of
conduc to include the requirement for warnings in the minimum product information. Australian health professionals may be missing important safety information in journal advertising.

Unlike in Australia and Malaysia, information on dosages is not required in the American advertisements 35. Only a minority of pharmaceutical companies in the US voluntarily provided information on dosages in advertisements (32%). These findings suggest that most pharmaceutical companies will only provide the medicines information when they are required to do so. The FDA should be proactive in updating the requirements for the provision of medicine information in advertisements; given dosage information is essential for correct prescribing as well as for the appropriate use of medicines.

Our analysis on the provision of product information for the same medicines marketed in the three countries is limited by the small sample size (<32 advertisements for four products). The medicines were promoted for cardiovascular and gastrointestinal diseases. At the time the advertisements appeared in journal advertising, the medicines were new and no generic options were available. The medicines provided no incremental benefit and in some countries they were more expensive than existing treatments. Moreover, the market for these medications was huge with global sales estimated at US$ 59 billion in 200631.

However, essential information required for appropriate prescribing was often missing in advertisements of the same medicines published in Malaysia compared with Australia and the US. All companies that had a product included in our analysis have their own guideline or code of conduct on pharmaceutical promotion32-35. All guidelines and codes of conduct state that companies have to comply with relevant international and local regulations. However, the different standard of information provided in these three countries suggests that the companies apply their marketing standards differently in different countries. Our findings lend support to earlier observations that some pharmaceutical companies employ different standards in their promotional activities in countries with different types of controls and resources to control promotional activities36. Collaboration between regulating bodies in different countries would be beneficial in controlling multi-country pharmaceutical promotion activities.

Our study showed that medicines information in journal advertising across these three countries was often incomplete and the problem was not limited to a developing country. These results are consistent with the findings of a recent systematic review that showed that the low quality of information in journal advertising was a global issue39. Effective control over incomplete medicines information in journal advertising would appear necessary not only in developing countries where regulation of pharmaceutical promotion might be weak but also in developed countries which have stricter regulations12.

Our study was limited by the sample size. The results may not be generalisable to other countries and other medicines. Our study was designed to assess the presence or absence of product information. We did not attempt to examine the accuracy or completeness of information.

Conclusion

Pharmaceutical companies provide different standards of medicines information in Australia, Malaysia and the US. Less medicine information was provided in journal advertising in Malaysia than in Australia and the US. Warnings and dosage information was less likely to be presented in advertisements in Australia and the US respectively. As information on medicines in pharmaceutical promotion may influence doctors’ prescribing practices, regulation of promotional practices in Australia, Malaysia and the US need to be strengthened, both by the government and pharmaceutical companies. Effective regulatory systems to control pharmaceutical promotional activities in countries with different local standards is crucial.

Competing Interests: Two of the authors Noordin Othman and Agnes Vitry and one of the reviewers Robyn Clothier are members of Healthy Skepticism, an international non-profit organisation aiming to improve health by reducing harm from misleading drug promotion. Azidah Abdul Kadir has been funded by several pharmaceutical companies to perform research, attend conferences and has received speaking honorariums.

Acknowledgements: We thank Robyn Clothier (Healthy Skepticism, Adelaide, Australia), Dr Azidah Abdul Kadir (Department of Family Medicine, School of Medical Sciences, Universiti Sains Malaysia, Health Campus, Kelantan, Malaysia) and Rohana Hassan (Department of Pharmacy, Seberang Jaya Hospital, Penang, Malaysia) for their help in reviewing advertisements for the inter-rater reliability test.

References

Medicines information in journal advertising in Australia, Malaysia and the United States


Antimicrobial use in a country with insufficient enforcement of pharmaceutical regulations: A survey of consumption and retail sales in Ulaanbaatar, Mongolia

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Abstract

Objective: To examine the inappropriate use of antimicrobials by investigating (1) actual utilization pattern and retail sales and (2) antimicrobial resistant information provided by health professionals in Ulaanbaatar, Mongolia.

Methods: We investigated antimicrobial use in Ulaanbaatar, Mongolia by surveying 619 consenting customers who attended 250 randomly chosen pharmacies in December 2006. Pharmacy staff were also interviewed about antimicrobials purchased. In January 2007, we surveyed 117 consenting Ulaanbaatar medical doctors from seven local hospitals about their perceptions of treatment failure due to antimicrobial resistance.

Results: Among 619 pharmacy customers, 48% of them had bought at least one type of antimicrobial medicine and, of these, 42% had a prescription to purchase antimicrobials. On average, 67% of the customers reported that a pharmacy worker had given them information regarding the dose and timing at which the medicine should be used but only 9% reported that they had been given information regarding possible adverse effects. The survey of medical doctors suggested that some antibiotics had become less effective clinically between 2001 and 2006.

Conclusion: The study shows that less than half of all customers who purchased an antibiotic at a pharmacy had a prescription. This shows that antimicrobials can be readily purchased without a prescription despite the existence of laws making such practices illegal. There is a need to establish a vigilant drug regulatory authority to promote enforcement and regulation of medicines in Mongolia. To create awareness regarding the dangers of antimicrobial resistance, educational campaigns for consumers are also necessary.

Keywords: antimicrobial utilization, antimicrobial resistance, developing country, Mongolia.

Introduction

During the past few decades, the number of antimicrobial-resistant pathogens has increased rapidly in many parts of the world1. Of note, the rate of increase of antimicrobial-resistant pathogens in Asia is the highest in the world2-4. One of the major reasons for the increase in antimicrobial-resistant pathogens in many developing countries is that antimicrobials can be purchased without a prescription5. The World Health Organization (WHO) warns that the purchase of antimicrobials without a prescription leads to the misuse and overuse of antimicrobials, resulting in the emergence of antimicrobial-resistant pathogens1.

Many developing countries have a limited ability to manufacture antimicrobial medicines; therefore, they must obtain antimicrobial medicines from other countries. Numerous commercial dealers of pharmaceutical products compete with
one another to extend sales in developing countries, providing imported medicines to meet the demand for antimicrobials in these countries. However, the control and regulation measures for the sale of pharmaceuticals in developing countries are often insufficient. Mongolia is one such country where antimicrobials can be widely purchased without a prescription, despite the existence of laws prohibiting this act. Penalties imposed on offenders guilty of such acts include closure of a store where such a trade has been conducted. Despite this, the measures to control and regulate the sale and purchase of antimicrobials in Mongolia are insufficient. This is a problem that not only affects Mongolia, but also impacts many developing countries throughout the world. In this context, the objectives of the present study were to explore the antimicrobial utilization pattern and retail sales; another objective was to explore the perceptions of clinicians regarding antimicrobial resistance.

Methods

We conducted three surveys using structured questionnaires: one for pharmacy workers, one for pharmacy customers, and one for practicing medical doctors. The study protocol was approved by the ethical review boards of the Tokyo Medical and Dental University and the Ministry of Health, Mongolia.

Study area

The study was carried out in Ulaanbaatar, the capital city of Mongolia, where the general public’s accessibility to antimicrobials has been rapidly increasing in recent years as a result of the rapid economic development. Mongolia is a landlocked central Asian country, with a total area of 1.6 million square kilometers. Among the total 2.7 million populations, 32% are living in Ulaanbaatar, the capital of Mongolia. On the financial side, the Mongolian economy has experienced positive GDP growth averaging 8.7 percent from 2004 to 2006. Mongolia’s current health system has been evolving for more than 70 years and is characterized by three levels of care: primary, secondary and tertiary care. Although these health facilities still do not meet the current needs of the country, it is reported that for every 1000 Mongolians 2.7 physicians are available. Health insurance was introduced in 1994 and it is estimated that about 78% of the population is covered. However, it is still common that patients have to pay out of pocket in private pharmacies to obtain the necessary medications.

Subjects, sampling and questionnaire procedures

The pharmacies surveyed in the present study (both pharmacy workers and customers) were selected from a list provided by the Mongolian Ministry of Health. A total of two hundred and fifty pharmacies were randomly selected from amongst the five hundred pharmacies registered in Ulaanbaatar. Interviewers of the pharmacy and customer survey were clinical pharmacology professionals with sufficient knowledge of antimicrobials and pharmaceutical practice. A three day training workshop was conducted to train the interviewers, providing them with knowledge and interviewing skills. Two interviewers visited each of the pharmacies and interviewed the pharmacy staff. Following individual interviews with the pharmacy workers, the study team spent one hour outside of the pharmacy and asked for their cooperation in completing a short interview. A total of 619 pharmacy customers agreed to participate in the study.

The survey for practicing medical doctors was a self-administered report based on a structured questionnaire form: the reports were collected after a complete explanation of the purpose of the survey and a step-by-step explanation of the questions had been made by specially trained doctors. All queries were collected and answers and clarifications were given to the participating medical doctors before they submitted their completed questionnaire forms. The self-administered survey of the medical doctors was completed by 117 medical doctors who agreed to participate in the study. These doctors were selected from amongst 7 leading hospitals in Ulaanbaatar.

Face to face in depth interview of ten medical doctors were conducted. These doctors were randomly selected from participants of the medical doctor’s survey. These doctors answered questions regarding antimicrobial therapy. The questions were also asked regarding doctors’ knowledge on Centre for Disease Control guidelines.

Questionnaire items

The interview questionnaire for the pharmacy workers included the following items: the names of all the antimicrobial medicines sold at the pharmacy (regardless of strength), the average number of customers who bought medicine per day, and the average number of customers who bought antimicrobial medicine per day during the two week period prior to the study. The interview questionnaire for the pharmacy customers included the following items: customer’s age, sex, educational background, purchase of antimicrobial and non antimicrobial medicines, types and whether it was the oral or injectable form. The other questions were age, symptoms of the expected user of the medicine, presentation of the prescription (to purchase antimicrobial medicines), and instructions given by the pharmacy staff regarding the use of the medicines.

The self-administered questionnaire for the medical doctors asked for their professional estimates as to the current prevalence of antimicrobial resistance, their clinical experiences with antibiotics and the expected number of ineffective treatments encountered during the application of each of the antimicrobial agents.

Period of the survey

The pharmacy staff and customer interviews were conducted in December 2006, while the survey of medical doctors was performed in January 2007. The study was performed during
the winter season because the prevalence of acute respiratory infection is typically high during this time and thus a large number of antimicrobials are prescribed.

**Analysis**

All data were entered and analyzed using SPSS software (version 14.0). The average numbers of pharmacy customers who bought specific antimicrobial medicines per fifty customers (who bought both antimicrobial and non-antimicrobial medicines) from that pharmacy were calculated for each type of antimicrobial. This indicator was used to represent the retail sales of antimicrobials.

**Results**

Results and knowledge from pharmacy workers reveal the types of antimicrobials which has been sold to customers at pharmacies during the two weeks prior to the study (Table 1).

**Table 1. Types of antimicrobials sold to customers at community pharmacies in Ulaanbaatar, Mongolia**

<table>
<thead>
<tr>
<th>Group</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penicillins</td>
<td>Benzylpenicillin</td>
</tr>
<tr>
<td></td>
<td>Phenoxymethylpenicillin</td>
</tr>
<tr>
<td></td>
<td>Oxacillin</td>
</tr>
<tr>
<td></td>
<td>Ampicillin</td>
</tr>
<tr>
<td></td>
<td>Amoxicillin</td>
</tr>
<tr>
<td>Cephalosporins</td>
<td>Cefazolin</td>
</tr>
<tr>
<td></td>
<td>Ceftriaxone</td>
</tr>
<tr>
<td></td>
<td>Cephalexin</td>
</tr>
<tr>
<td>Aminoglycosides</td>
<td>Gentamycin</td>
</tr>
<tr>
<td>Tetracyclines</td>
<td>Tetracycline</td>
</tr>
<tr>
<td></td>
<td>Doxycycline</td>
</tr>
<tr>
<td>Macrolides</td>
<td>Erythromycin</td>
</tr>
<tr>
<td></td>
<td>Clarithromycin</td>
</tr>
<tr>
<td></td>
<td>Azithromycin</td>
</tr>
<tr>
<td>Others</td>
<td>Chloramphenicol</td>
</tr>
<tr>
<td></td>
<td>Vancomycin</td>
</tr>
<tr>
<td>Synthetic antibacterial medicines</td>
<td>Sulfamethoxazole-trimethoprim</td>
</tr>
<tr>
<td>Sulfonamide</td>
<td>Sulfamethoxazole-trimethoprim</td>
</tr>
<tr>
<td>Quinolones</td>
<td>Ofloxacin</td>
</tr>
<tr>
<td></td>
<td>Ciprofloxacin</td>
</tr>
<tr>
<td>Others</td>
<td>Metronidazole</td>
</tr>
</tbody>
</table>

Table 2 shows the number of customers who bought each type of antimicrobial medicine per 50 customers who visited pharmacies to buy medicine.

Among the 619 pharmacy customers who agreed to participate in this study, 48.0% of them (297 customers) had bought at least one type of antimicrobial medicine. Among those who bought antimicrobials, 42.1% of them (125 customers) had a prescription for the antimicrobial medicine that was purchased. Antimicrobials commonly used by injection were benzylpenicillin (used by 90% of customers who bought antimicrobials), cefazolin (80%) and gentamicin (90%).

The most common reasons for purchasing antimicrobials were acute respiratory disease (54.8%), genitourinary disease (15.5%), and gastrointestinal disease (10.7%). Among the pharmacy customers who suffered from acute respiratory disease, 45.1% of them bought oral penicillin, either amoxicillin (24.6%) or ampicillin (20.5%). The most common strength of these two antimicrobials was 500 mg (selected by 70% of customers who bought amoxicillin or ampicillin), and rest of them (30%) bought 250 mg which mainly used for children.
Table 3 shows the summary of instructions given by pharmacy workers to pharmacy customers. On average, 67.3% of the customers reported that a pharmacy worker had given them information regarding the dose and timing at which the medicine should be used; 8.9% of them reported that they had also been given information regarding adverse effects.

The study reveals that the doctors feel that the medicines such as benzyl penicillin, gentamicin, metronidazole, ampicillin, phenoxymethyl penicillin, and ciprofloxacin are no longer very effective in treatment as they may have a problem of antibiotic resistance.

Discussion

The results of the pharmacy worker and pharmacy customer surveys were consistent, with about half of the pharmacy customers purchasing antimicrobial medicines: the pharmacy worker survey indicated that an average of 4.6 (SD = 1.8) out of 10 customers purchased antimicrobial medicines, while the pharmacy customer survey showed that 40.0% of the pharmacy customers purchased antimicrobial medicines. The results of the pharmacy worker and pharmacy customer surveys also consistently showed that 40% of the customers who purchased antimicrobials had a prescription: the pharmacy worker survey reported that 4.0 (SD = 2.3) out of 10 customers who purchased antimicrobials had a prescription, while the pharmacy customer survey showed that 42.1% of the customers who purchased antimicrobials had a prescription. These results are based on customers who visited community pharmacies in Ulaanbaatar.

The pharmacy worker survey indicated that, amoxicillin and ampicillin, sulfamethoxazole-trimethoprim, and metronidazole were the most frequently sold antimicrobials in Ulaanbaatar pharmacies. The frequent sale of amoxicillin and ampicillin, both of which are oral penicillins, as over-the-counter drugs has also been reported in Vietnam and Mexico16, 17. The frequent use of these medications is most likely explained by their cost and availability; amoxicillin and ampicillin are generally less expensive than other antimicrobials, and over 70% of all pharmacies throughout the world sell amoxicillin18. All pharmacies in the present study sold both amoxicillin and ampicillin. Generally, variations in the types, frequency, and methods in which antimicrobials are used by the general public vary in countries according to disease patterns, patient characteristics, and the quantity and quality of care services at health facilities19. Variations in the general characteristics of antimicrobial use in developing counties also arise from the ability to purchase antimicrobials inexpensively and without a prescription.

Among the pharmacy customers who bought over-the-counter medicines, more than half of the customers were seeking treatment for acute respiratory diseases; amoxicillin and ampicillin were sold to more than half of these customers. Antimicrobials were also frequently sold to patients suffering from genitourinary or gastrointestinal diseases. Antimicrobials sold to these patients included not only penicillins, but also a wide range of other antimicrobials including chloramphenicol and gentamicin. There is a concern that the amount of antimicrobial use is related to the increase in drug-resistant pathogens20. In fact, our survey of perception of medical doctors showed that the antimicrobials which were frequently sold in community pharmacies were losing their effectiveness for the treatment of patients.

High consumption of antimicrobials among patients with common diseases such as acute respiratory disease and gastrointestinal disease were frequently reported in several countries16, 17 and the same has been observed in Mongolia. Especially the patients who are suffering from genitourinary disease are on rise in Mongolia and these patients frequently visit community pharmacies.

There is a tendency in developing countries to take antimicrobials even when their symptoms are not serious or even when there are no signs of infection21. One such medicine is chloramphenicol, which is widely used in developing countries, primarily because it is cheap and broad spectrum. However, this medicine is now rarely used in developed countries because of its serious adverse effects, such as the development of aplastic anemia22. The present survey shows that chloramphenicol is commonly used in Mongolia, especially for the treatment of gastrointestinal disease. However, the present study shows that...
only 4% of the customers, who purchased chloramphenicol, received information regarding side effects.

To date, there have been limited laboratory studies conducted on antimicrobial sensitivity in Mongolia and it is difficult to establish whether antimicrobial resistance has increased or not. Hence, promoting the use of an antimicrobial sensitivity test before prescribing antimicrobials is an important approach to monitor and to control the further emergence of antimicrobial resistance.

Although it is a crude measure of changes in resistance, this survey of experienced medical doctors in Ulaanbaatar also suggested that based on their clinical experience some antimicrobials are losing their effectiveness for the treatment of patients with infectious disease.

There are no specific antibiotic guidelines in Mongolia and it is necessary to promote and establish best practice clinical guidelines. These guidelines should not be limited to medical doctors, but should also target and include pharmacists and pharmacy workers. The knowledge of pharmacy workers about antimicrobials play a key role in promoting the rational use of antimicrobials, considering the fact that many consumers purchase directly in Ulaanbaatar. Hence, the education of prescribers and dispensers (including drug sellers) is important for appropriate antimicrobial use and for the containment of antimicrobial resistance.

This study provides an understanding of the sale and use of antimicrobials by a sample of the general public in Ulaanbaatar, Mongolia. At present, the public can purchase antimicrobials for the treatment of common diseases, such as acute respiratory infection, without requiring a prescription and without receiving proper instructions regarding the use of such medicines. The development of comprehensive and consistent control measures at national level to regulate the medicine quality and distribution is urgently needed in Mongolia. Also, antimicrobials should not be available as over-the-counter drugs.

Conclusion

The present study is first of its kind and it explores the use of antimicrobials in Mongolia. The study reveals that antibiotics are commonly available in Mongolia and the consumers have easy access to these medicines. Establishing a drug regulatory authority could improve the enforcement and also can aid to improve the quality use of antimicrobials. Mass educational campaigns could also create awareness regarding the use of antimicrobial in Mongolia.

Conflict of interests

The authors report no conflicts of interest.

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Assessing different perspectives on the value of a pharmaceutical innovation

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Abstract
Numerous pharmaceutical products are launched each year for the treatment of various medical conditions. The prescriber is in a difficult position to determine which the optimal product is for a specific patient, when he has available immediate release as well as sustained action capsules and tablets, chewable tablets and liquid dosage forms. Some have activity within 15 minutes while others take longer. Some are more costly but have never been implicated with gastric distress; some are very widely prescribed and others are not well known. Some are promoted as enhancing compliance and others for schedule simplicity.

In order to make sense of the array of diverse product attributes and to determine the value associated with different dosage form features, separate panels of practicing physicians, practicing pharmacists and patients were asked to ascribe value to a list of 10 drug product features that were mentioned in drug product advertisements in medical journals, by indicating what percentage price increase that feature might merit over a basic product without that feature. In addition, the respondents were asked to rank order the mentioned product features.

In all three panels, efficacy and safety were accorded the highest status. Pharmacists and patients appeared to be most welcoming of some of the listed features. This pilot study demonstrates that there appears to be a recognized value assigned to some product features and it may differ by audience.

Introduction
Pharmaceutical products can often ameliorate disease symptoms, control and stabilize chronic conditions, reduce risk factors and even cure some conditions. Some new drugs frequently reach a market where existing drugs treat the same conditions, often providing some improvement over the older therapy – e.g., perhaps doing so more rapidly, or more safely or with fewer adverse events or treatment failures. Since new drugs reaching the market are often not tested “head-to-head”, against current therapies, but rather are evaluated against placebos in Phase III registration trials, it is difficult for a pharmacist or prescriber to assess the relative value of two therapeutic options for the same condition.

Today, if a physician wants to know which the best product in a category is, or which drug demonstrates the greatest efficiency, there are only a limited number of resources to turn to. The Physician’s Desk Reference (PDR) or MIMS describe individual drugs but the prospective prescriber will have to study multiple monographs, if they even exist, since they are paid for by their manufacturers and not all drugs are included. No one has the time to undertake that effort.

Services such as the Medical Letter makes comparisons of therapeutic areas from time to time, but often these are not frequent enough to be definitive and they are rather brief. Other reference works, such as Facts and Comparisons list the most significant features of the drugs comprising a category but do not offer recommendations.

And on top of this uncertainty, one can never tell what features or characteristics are important to an individual prescriber. The determination of value has been little studied in the serious professional and scientific literature. In 1993, Coyle and Drummond published a paper: “Does Expenditure on Pharmaceuticals Give Good Value for Money: Current Evidence and Policy Implications,” in Health Policy1 that asked some of these questions. A few years later in 1996, Grund published
an article, “The Societal Value of Pharmaceuticals: Balancing Industrial and Healthcare Policy,” in PharmacoEconomics, but the focus was societal. More recently, there have been further efforts to discern value, such as the article by Berndt, “Pharmaceuticals in U.S. HealthCare: Determinants of Quantity and Price,” in the Journal of Economic Perspectives.

Moreover, the pharmacist or physician faces a second hurdle in that the newer, sometimes improved product may often have a higher price than the older product. In essence, the prescriber is caught in the dilemma of having to determine the new drug’s value. Value can be difficult to define, and is often quite subjective. This question is faced by consumers of all manner of goods and services on an everyday basis. Is the self cleaning oven worth the $100 greater price versus a manually cleaned oven? Is the video camera with six hours capacity worth the higher price, compared with a four hour capacity camera?

The assessment of value sometimes becomes so complex that consumers and potential buyers give up the quest of independently determining value and turn to professional resources. In consumer goods, that might be a report in “Consumer Reports” or in another journal for lay persons. In health care, for example, a prescriber can review journal reports about new health technologies, or wait for assessments from organizations such as the Emergency Care Research Institute (ECRI), the National Institute for Health and Clinical Excellence (NICE) or other health technology assessment organizations, or from respected neutral publications such as “The Medical Letter” or “Facts and Comparisons”.

Unfortunately though, such product evaluation bodies rarely conduct or have head-to-head comparisons. They often must resort to comparing results from different placebo controlled trials. In addition, the goal of selecting the product(s) of greatest value is made quite difficult by the wide array of diverse product features such as differing efficacy claims, tolerability profiles, formulations, dosage forms and indications.

There are continuing calls for a more efficient and improved, and less costly health care system in the United States and in most countries around the globe. Pharmaceuticals account for more than 10 percent of total healthcare expenditures in many developed countries, and a higher percentage in lesser developed countries. Pharmaceuticals are only evaluated for safety and efficacy in clinical trials, but increasingly they must demonstrate economic value when compared to other treatments or no treatment at all. Data on costs and treatment outcomes (e.g., morbidity, mortality, quality of life) are collected either prospectively or retrospectively, and economic analysis such as cost-effectiveness or cost-benefit can be conducted to ascertain relative value. Pharmacoeconomic studies along with clinical trial data can often provide a better measurement of treatment value than clinical trials alone, but unfortunately, the outcomes data used in pharmaco-economic analysis is not available until after a product has been on the market for an extended period of time, such as a year or longer, when there are a sufficient number of users.

To understand the true value of pharmaceuticals it may be prudent to go beyond the commonly used outcomes of morbidity, mortality and quality of life. Indeed other attributes such as ease of compliance, fewer side effects, doctor familiarity with the product, patient understanding of the disease treatment, can also influence how a drug is perceived, valued, used by patients and ultimately even the outcomes. For the last twenty years, pharmacoeconomic studies have demonstrated that certain medications can reduce emergency room visits and hospital admissions even though they may be expensive on a first look; the use of statin therapy to treat people with high cholesterol, for example, reduces hospital admissions and cardiac surgeries; also the use of anti-retroviral drugs reduces mortality and morbidity for HIV/AIDS patients. In summary, drugs can be a viable economic alternative to patients being hospitalized with catastrophic illnesses.

Some medicines, when taken as prescribed, can reduce costs in health care and increase productivity. People with depression often report related ailments such as back pain, headaches, lack of focus, and even heart disease. While depression treatment may not directly act upon these other disorders, often it is associated with more successful treatment, improved worker productivity and decreased hospitalizations.

New drugs in a therapeutic class may have fewer side effects, and improved safety records and effectiveness which encourage compliance with the prescribed regimens. Improved compliance can ultimately lead to better patient outcomes. So, we are left with a quandary for health care professionals in their evaluation of competing drug products.

Objective

The objective of this study was to more fully characterize the determinants of pharmaceutical product value and to develop a simplified value assessment methodology to aid in formulary decision making.

Since today, even without comparative risk/benefit and other quantitative data, some products within a therapeutic category become very popular with healthcare providers and others languish on pharmacy shelves and in warehouses with minimal sales activity. There must be some features or variables about these drug products that drive this differentiation.

This study was conducted in an effort to ascertain the perceived value of selected drug product features.

Methods

Several pharmacy students were recruited in 2007 to review pharmaceutical product advertisements in twelve leading American medical journals from issues published in 2005 and 2006. From these twelve journals, which comprised general medical and several medical specialties, drug advertisements were individually analyzed and the principal message determined.
Assessing different perspectives on the value of a pharmaceutical innovation

and recorded. Messages included claims such as, for example, “more potent than existing products”, or “new levels of safety”.

The messages from those advertisements (N=200) were condensed into 10 categories, by the investigators, which are shown in Table 1. There were, of course, many more messages in the 200 advertisements that were reviewed, but duplicates were eliminated as were messages that appeared as only to inform readers of the availability of a product, without featuring any advantages or reasons why that specific product should be prescribed. The investigators reduced the number of message categories by a continuous chain of refinement to eliminate duplicate categories by referring, where necessary to the original advertisement to gauge the thematic and athematic message components.

Table 1. Key product features from medical journal drug advertisements*

<table>
<thead>
<tr>
<th>Feature</th>
<th>M.D.s (%)</th>
<th>Pharmacists (%)</th>
<th>Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid Relief</td>
<td>0</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>Ease of Use</td>
<td>0</td>
<td>15</td>
<td>5</td>
</tr>
<tr>
<td>Facilitate Compliance</td>
<td>0</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Schedule Simplicity</td>
<td>0</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>Highly Effective/Superior</td>
<td>10</td>
<td>15</td>
<td>20</td>
</tr>
<tr>
<td>Once Daily dosing</td>
<td>0</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>Safety</td>
<td>10</td>
<td>50</td>
<td>30</td>
</tr>
<tr>
<td>Combination Product</td>
<td>0</td>
<td>15</td>
<td>20</td>
</tr>
<tr>
<td>No Addiction Risk</td>
<td>0</td>
<td>20</td>
<td>30</td>
</tr>
<tr>
<td>Full Range of Strengths</td>
<td>0</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

For example a firm could promote its antacid as “the woman’s antacid” even if clinical results do not demonstrate any special advantage for women using that product versus any other antacid on the market.

Results

The findings differed as evaluated by the three cohorts. In terms of willingness to pay an increased price for innovative features, patients and pharmacists were the most welcoming of improved features (price increase ranged from 5-30% and 10-50%, respectively, and for all product features), and physicians the least (price increase ranged from 0-10%, and only for two product features). Across all three study groups the greatest price increases were consistently for efficacy and safety.

When asked specifically to rank order the ten product features (Table 3), improved efficacy or safety were the number one choice for all three study groups. However, after efficacy and safety, there were subtle yet noteworthy differences in ranking for other product features. For example, where compliance was noted as relatively unimportant to patients and pharmacists, it was considered much more important by physicians. And, where rapid symptom relief was less important to physicians, it was clearly more meaningful to pharmacists and patients.
Table 3. Ranking of importance of drug product features by Physicians, Pharmacists, and Patients
(1=highest, 10=lowest)

<table>
<thead>
<tr>
<th>Feature</th>
<th>M.D.s</th>
<th>Pharmacists</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid Relief</td>
<td>7</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Ease of Use</td>
<td>6</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Facilitates Compliance</td>
<td>2</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Schedule Simplicity</td>
<td>5</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>High Effective/ Superior</td>
<td>3</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Once Daily Dosing</td>
<td>4</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Safety</td>
<td>1</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Combination</td>
<td>8</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>No addiction</td>
<td>10</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Full Range of Strengths</td>
<td>9</td>
<td>8</td>
<td>10</td>
</tr>
</tbody>
</table>

Discussion & Conclusion

The results obtained from this pilot study cannot be generalized because of a very small sample size, as well as the use of a convenience sample of respondents. Nevertheless, our study provides proof of concept that there are measurable differences in perceived value of pharmaceuticals based on product characteristics and upon whom one asks, and that in order to fully assess value it is necessary to include a broad perspective comprising providers and patients. Although we did not include payers or payer advisors in our study, clearly this group should be included as well in future research.

In addition, our method and findings can be useful in drug development decision making, where pharmaceutical manufacturers can perhaps guide research and development efforts along the lines of characteristics most highly valued by patients, providers and payers. This preliminary study suggests that a more robust follow-up investigation using an increased sampling frame with greater geographic dispersion, along with randomization of respondents, could be highly informative.

A more complete treatment of this subject would include the assessments of feature value by consumers/patients, the very persons who must endure the effects of these medications. In addition, it could be useful to add a willingness to pay evaluation in an effort to appreciate real monetary numbers instead of theoretical percentage increases supplied by the respondents to this study. Also, more detail could be provided on the product features – especially regarding relative efficacy, safety and tolerability. Perhaps greater price increases would be acceptable with greater improvements in efficacy and/or lower risks of side-effects. One commonly heard dilemma from personnel at health authorities and managed care organizations is: How does one differentiate products where there may be very little difference among products in a class and between the original molecules? Here, we might find that while the clinical effectiveness is quite similar, that different metabolic pathway may lead to fewer interactions, or one may cause less gastritis, or be more greatly tolerated and therefore be taken close to the prescribed regimen, and may lead to superior outcomes. And this may be expected to influence patient preference for certain products because of their unique features.

Traditionally, product pricing decisions by pharmaceutical companies consider the avoided cost of care without drug treatment such as surgery or hospitalization, and a further consideration of other therapies; competing drugs or medical procedures, but they normally do not consider patient opinion. Yet, if patients report to their physician that one drug was responsible for unpleasant diarrhea, that physician will most likely veer toward the use of a different product in the future.

Finally, studies like this hold the possibility of demonstrating to health plans, Ministry of Health or Social Security personnel that while they might not place a high value on certain product characteristics or features, that the persons who must endure the disease and the use of the product – the patient, may feel differently about the importance or worth of some aspects of the product. As members of, and contributors to, health plans and/or national health care systems, patient perspectives and preferences are critical to consider.

The authors urge investigators to explore this area further using randomly selected and larger sample sizes (to allow for statistical tests and modeling), diverse populations of patients, providers and payers, and more comprehensive and detailed value assessment techniques.

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Assessing different perspectives on the value of a pharmaceutical innovation


A student reflects on the rest of the world through Southern Med Review

Nearing completion of my four year Pharmacy degree in New Zealand I recall learning plenty about Pharmaceutical Management Agency Ltd (PHARMAC), the government-operated agency responsible for purchasing all of the medicines used by New Zealanders. I learned that the PHARMAC system has advantages and disadvantages and is unique to New Zealand. No other place in the world has a system like this, i.e. the ‘New Zealand system’ is unique, and different to ‘Everywhere Else’.

Reading the Southern Med Review teaches me something about ‘Everywhere Else’ and in the bigger picture of the world-wide pharmaceutical market it seems that the situation in every other country is just as unique and different as in my own country. It is interesting to learn how differently the rest of the world approaches the medications side of healthcare. That, in countries such as Vietnam, price and even the availability of medicines varies from city to city. Drug companies are free to distribute any informative material they wish in Nepal without interference from the government. Issues over things like counterfeit medicines never arise in New Zealand but seem to be a problem in countries like Thailand. The role of community pharmacists in India is very different to the way pharmacy is practiced in New Zealand. I also find it interesting to compare the affordability of drug therapies between other countries and my own.

As a full time student I earn an income working during the weekends, and when making purchases I compare the prices of goods relative to the time I spent working to pay for them. A full tank of petrol costs me six hours of my time at work, and lunch costs me what I earn in thirty minutes. A similar technique was applied in the article titled ‘Medicine prices, availability, and affordability in Vietnam’ (Vol 2 Issue 2 Sep 2009) where it was reported that an average, unskilled government worker in Vietnam would have to commit twenty one days worth of his wages to cover the cost of one course of innovator brand ranitidine. The lowest price generic brand only costs 1.3 days worth of wages when treatment is sought from the private sector.

Amount of time spent working to pay for medical treatment is an easily understandable unit of measure, far more relevant than the usual method of comparing $ with $, which is usually only reported in US$ and does not take into account affordability, the cost relative to the average wage.

Each article I have read outlines important and challenging issues faced by countries, which are interesting to me because each situation is very different to New Zealand. There are lessons to be learned from the unique solutions which follow, and I look forward to reading future issues while practicing as a pharmacist.

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