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Brazilian Journal of Health Economics

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Edição Suplementar, estudos apresentados no

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Disseminação da ATS para a tomada de decisão

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Faculdade de Farmácia UFMG

Apoio:

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UFMG Universidade Federal de Minas Gerais

FUNED Fundação Ezequiel Dias

PNAUM

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NORMAS PARA PUBLICAÇÃO

Informações gerais

1. O Jornal Brasileiro de Economia da Saúde (***J Bras Econ Saúde***) é uma publicação com a chancela acadêmica do Departamento de Clínica Médica da Faculdade de Ciências Médicas da Universidade do Estado do Rio de Janeiro para conteúdos científicos, com periodicidade quadrimestral. É dirigido a pesquisadores e formuladores de políticas de saúde, gestores e avaliadores do processo de incorporação de tecnologias em saúde. Tem como missão, a divulgação do conhecimento produzido pela Economia da Saúde como forma de contribuir para a diminuição dos impactos negativos que podem estar associados aos processos decisórios relativos à incorporação de novas tecnologias, tratamentos e medicamentos. São aceitos para avaliação: estudos de custo da doença, análise econômica em saúde, análise de impacto orçamentário, estudo observacional, ensaio farmacoeconômico, inquérito epidemiológico, avaliação de tecnologias em saúde, formulação de políticas de saúde, planejamento e gerenciamento econômico de serviços de saúde, inovação metodológica e revisão da literatura, sob a forma de artigos originais, artigos de revisão, artigos de atualização e editorias (conforme detalhamento a seguir). Os artigos podem ser submetidos nos idiomas português, espanhol ou inglês. Autores interessados em traduzir seu artigo para inglês podem solicitar um orçamento de tradução ao J Bras Econ Saúde. O Jornal Brasileiro de Economia da Saúde não recebe subsídios financeiros de nenhuma sociedade, instituição governamental ou associação. Trata-se de iniciativa privada e independente. Os recursos responsáveis por seu mantenimento provêm da comercialização do espaço editorial destinado à publicação de artigos cujo desenvolvimento tenha recebido suporte financeiro de empresas privadas. Também são comercializadas cotas de patrocínio institucional. As submissões de artigos não são passíveis de cobrança. A tabela de custos para publicação deve ser consultada junto à Editora.

2. Artigos submetidos ao ***J Bras Econ Saúde*** devem ser inéditos, isto é, não devem ter sido publicados nem submetidos para análise por outras revistas, no todo ou parcialmente. Em casos de figuras já publicadas, autorização deve ser obtida e a fonte deve ser citada. Uma vez publicados, os Direitos Autorais dos artigos passam a ser de propriedade da Doctor Press Editora responsável pelo J Bras Econ Saúde.

3. As Instruções para Autores do ***J Bras Econ Saúde*** incorporam as recomendações dos *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*. A versão completa do texto está disponível em www.icmje.org. Manuscritos que estiverem em desacordo com as instruções aqui apresentadas serão devolvidos para a incorporação de ajustes antes da avaliação pelo Conselho Editorial.

4. Todo artigo publicado no ***J Bras Econ Saúde*** passa pelo processo de revisão por especialistas (*peer review*). Os artigos submetidos são primeiramente encaminhados aos editores para uma avaliação inicial quanto ao escopo do trabalho e às exigências editoriais do Jornal. Se a avaliação é positiva, o artigo é enviado a dois revisores especialistas na área pertinente. Todo o processo é anônimo, ou seja, os revisores são cegos quanto à identidade dos autores e seu local de origem e vice-versa. Após a avaliação do artigo pelos revisores, os artigos podem ser aceitos sem modificações, recusados ou devolvidos aos autores com sugestões de modificações, sendo que cada artigo pode retornar várias vezes aos autores para esclarecimentos e modificações, sem que isso implique necessariamente a aceitação futura do trabalho.

5. O número de autores de cada manuscrito fica limitado a seis. O conceito de co-autoria implica contribuição substancial na concepção e planejamento do trabalho, análise e interpretação dos dados e redação ou revisão crítica do texto. Contribuições significativas feitas ao estudo, mas que não se enquadram nesses critérios, podem ser citadas na seção de agradecimentos. Os nomes dos autores devem ser descritos de maneira completa, sendo o primeiro deles o do autor principal. Ao submeter um artigo ao processo de avaliação do ***J Bras Econ Saúde***, os autores se responsabilizam integralmente pelas opiniões e por todo o conteúdo nele contido.

6. Ao submeterem seus manuscritos ao J Bras Econ Saúde, os autores assumem total responsabilidade sobre as opiniões e conteúdos descritos em seus artigos.

7. Artigos de pesquisas clínicas (*clinical trials*) devem ser registrados em um dos Registros de Ensaios Clínicos validados pelos critérios estabelecidos pela Organização Mundial da Saúde e pelo International Committee of Medical Journal Editors (por exemplo, www.actr.org.au, www.clinicaltrials.gov, www.ISRCTN.org, www.umin.ac.jp/ctr/index/htm e www.trialregister.nl). O número de identificação do estudo deverá ser apresentado ao final do resumo.

8. Para textos que forem aceitos para publicação, uma declaração, assinada por todos os autores deverá ser enviada à revista, contendo as seguintes informações: a) o manuscrito é original; b) o manuscrito não foi publicado nem submetido a outra revista, nem o será se vier a ser publicado no ***J Bras Econ Saúde***; c) todos os autores participaram ativamente na elaboração do estudo e aprovaram a versão final do texto; d) situações de potencial conflito de interesse (financeiro ou de outra natureza) estão sendo informadas; e) foi obtida aprovação do estudo pelo comitê de ética da instituição à qual o trabalho está vinculado (para artigos que relatam dados de pesquisa experimental; f) foi obtido consentimento informado dos pacientes incluídos no estudo (quando aplicável). As informações sobre a aprovação do estudo por comitê de ética e a obtenção de consentimento informado também devem constar na seção Métodos do artigo.

9. Antes da publicação dos artigos aceitos, os autores correspondentes receberão, via e-mail, em arquivo PDF, o artigo editorado para aprovação. Nessa fase, as correções devem limitar-se a erros tipográficos, sem alteração do conteúdo do estudo. Os autores deverão devolver as provas aprovadas via e-mail ou fax até 48 horas após o recebimento da mensagem.

Tipos de artigos publicados

Artigos originais. Trabalhos resultantes de pesquisa científica que apresentam dados originais sobre Economia da Saúde e incluem análise estatística descritiva e/ou inferências de dados próprios. Esses artigos têm prioridade para publicação. Devem ser compostos de: página de rosto, resumo e palavras-chave, ***abstract*** e ***keywords***, texto (dividido nas seções Introdução, Métodos, Resultados, Discussão ou equivalentes, Conclusões), agradecimentos (se aplicável), lista de referências (máximo de 40), tabelas (se houver), legendas de figuras (se houver) e figuras (se houver).

Artigos de revisão. Trabalhos que têm por objetivo resumir, analisar, avaliar ou sintetizar trabalhos de investigação já publicados em revistas científicas. Devem incluir síntese e análise crítica da literatura levantada e não ser confundidos com artigos de atualização. Devem ser compostos de: página de rosto, resumo e palavras-chave, ***abstract*** e ***keywords***, texto, lista de referências, tabelas (se houver), legendas de figuras (se houver) e figuras (se houver).

Artigos de atualização ou opinião. Trabalhos que relatam informações geralmente atuais sobre tema de interesse para determinadas especialidades (por exemplo, uma nova técnica de modelagem ou método). Têm características distintas de um artigo de revisão, visto que não apresentam análise crítica da literatura. Devem ser compostos de: página de rosto, resumo e palavras-chave, ***abstract*** e ***keywords***, texto, lista de referências, tabelas (se houver), legendas de figuras (se houver) e figuras (se houver).

Cartas ao leitor. Cartas ao editor comentando, discutindo ou criticando os artigos publicados no ***J Bras Econ Saúde*** serão bem recebidas e publicadas desde que aceitas pelo Conselho Editorial. Devem ser compostas de: título, nome do autor, identificação da publicação que está sendo comentada e lista de referências (se houver). Recomenda-se um máximo de 500 palavras, incluindo referências. Sempre que possível, uma resposta dos autores será publicada juntamente com a carta.

Preparação dos originais

Utilize preferencialmente o processador de texto Microsoft Word". Os trabalhos devem ser digitados em fonte Times New Roman tamanho 12, espaço simples, alinhados à esquerda, iniciando cada seção em página nova, na seguinte ordem: página de rosto, resumo e palavras-chave, abstract e keywords, texto, agradecimentos, lista de referências, tabelas, legendas de figuras e figuras. Todas as páginas devem ser numeradas.

Siglas devem ser definidas por extenso na primeira ocorrência no texto; após a primeira ocorrência, somente a sigla deverá ser utilizada. No resumo, o uso de siglas deve ser evitado.

Substâncias devem ser apresentadas utilizando seu nome genérico. Se relevante, o nome comercial da substância e o fabricante podem ser informados entre parênteses.

A apresentação de unidades de medida deve seguir o sistema internacional (SI).

Genes de animais devem ser apresentados em itálico com inicial maiúscula (exemplo: *Sox2*); genes de seres humanos também devem ser apresentados em itálico, porém com todas as letras maiúsculas (exemplo: *SOX2*). Proteínas devem seguir o mesmo padrão de maiúsculas/minúsculas, porém sem itálico.

Página de rosto

A página de rosto deve conter:

- Título conciso e explicativo, representando o conteúdo do trabalho, em português e inglês
- Título resumido (máximo de 150 caracteres)
- Nomes dos autores
- Afiliação dos autores, indicando departamento/unidade, instituição e região geográfica
- Nome da instituição onde o trabalho foi executado
- Informações sobre auxílios recebidos sob a forma de financiamento, equipamentos ou medicamentos
- Congressos onde o estudo foi apresentado
- Nome, endereço, telefone, fax e e.mail do autor correspondente

Resumo e abstract

Todos os trabalhos devem apresentar um resumo em português e um ***abstract*** em inglês. Trabalhos escritos em espanhol devem apresentar, além do resumo no idioma original, também um resumo em português e um ***abstract*** em inglês. O conteúdo dos textos deve ser idêntico, e não deve ultrapassar 250 palavras. Para artigos originais, o resumo deve ser estruturado como segue: Objetivo, Métodos, Resultados e Conclusões. Para relatos de caso, artigos de revisão e artigos de atualização, o resumo não deve ser estruturado. Deve-se evitar o uso de abreviações no resumo, e não devem ser citadas referências.

Logo após o resumo/***abstract***/***resumen***, deverão ser apresentadas de três a seis palavras-chave que sejam integrantes da lista de Descritores em Ciências da Saúde (http://decs.bvs.br).

Agradecimentos

Esta seção é dedicada a reconhecer o trabalho de pessoas que tenham colaborado intelectualmente, mas cuja contribuição não justifica co-autoria, ou de pessoas ou instituições que tenham dado apoio material.

Referências bibliográficas

No texto, as citações serão identificadas entre parênteses, pelo sobrenome do autor seguido do ano de publicação. Exemplos: um autor (Steptoe, 1978), dois autores (Edwards & Steptoe, 1980), mais de dois autores (Van Steirteghem *et al.*, 1988).

A lista de referências deve ser apresentada em ordem alfabética (último sobrenome de cada autor seguido das duas primeiras iniciais), e não deve ser numerada. Trabalhos do mesmo autor devem ser ordenados cronologicamente; trabalhos de mesmo autor e ano devem ser identificados com letras após o ano (2000a, 2000b, etc.). A apresentação das referências seguirá os modelos propostos nos *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* (ver exemplos a seguir). Todas as referências citadas na lista devem ser mencionadas no texto e vice-versa.

1. Artigo de periódico: Edwards RG, Steptoe PC, Purdy JM. Establishing full-term human pregnancies using cleaving embryos grown in vitro. Br J Obstet Gynaecol. 1980;87:737-56.

2. Livro: Wolf DP, Quigley MM, eds. Human in vitro fertilization and embryo transfer. New York: Plenum Press; 1984.

3. Capítulo de livro: Simpson JL. Gonadal dysgenesial and sex abnormalities: phenotypic-karyotypic correlations. In: Vallet HL, Porter IH, eds. Genetic mechanisms of sexual development. New York: Academic Press; 1979. p. 365-77.

4. Artigo de revista eletrônica: Abood S. Quality improvement initiative in nursing homes: the ANA acts in an advisory role. Am J Nurs [revista eletrônica]. 2002 Jun [citado 2002 ago 12];102(6):[aproximadamente 3 p.]. Disponível em: http://www.nursingworld.org/AJN/2002/june/Wawatch.htm.

5. Artigo publicado na Internet: Wantland DJ, Portillo CJ, Holzemer WL, Slaughter R, McGhee EM. The effectiveness of web-based vs. non-web-based interventions: a meta-analysis of behavioral change outcomes. J Med Internet Res. 2004;6(4):e40. Disponível em: http://www.jmir.org/2004/4/e40/. Acessado: 29/11/2004.

6. Site: OncoLink [site na Internet]. Philadelphia: University of Pennsylvania; c1994-2006. [atualizado 2004 set 24; citado 2006 mar 14]. Disponível em: http://cancer.med.upenn.edu/.

7. Software: Smallwaters Corporation. Analysis of moment structures: AMOS [software]. Version 5.0.1. Chicago: Smallwaters; 2003.

Tabelas e figuras

Tabelas e figuras (gráficos, fotografias, etc.) devem ser numeradas em algarismos arábicos conforme a ordem de aparecimento no texto e devem ter legendas individuais, apresentadas ao final do trabalho. Cada tabela e figura deve ser submetida em folha separada.

Nas tabelas, deverão ser utilizadas apenas linhas horizontais, e cada dado deverá constar em uma célula independente. Explicações sobre itens das tabelas devem ser apresentadas em notas de rodapé identificadas pelos seguintes símbolos, nesta sequência: *,†, ‡, §, ||,¶,**,††,‡‡.

Figuras em geral (gráficos, fotografias, etc.) serão publicadas em preto e branco. Despesas com a eventual reprodução de fotografias em cor serão de responsabilidade do autor.

Figuras podem ser submetidas eletronicamente, nas extensões .jpg, .gif ou .tif, com resolução mínima de 300 dpi (para possibilitar uma impressão nítida), ou por correio (ver instruções de envio mais adiante). Todas as figuras enviadas pelo correio devem ser identificadas no verso com o uso de etiqueta colante contendo o nome do primeiro autor, o número da figura e uma seta indicando o lado para cima.

Fotografias escaneadas não serão aceitas; fotografias em papel devem ser encaminhadas pelo correio. Fotografias de pacientes não devem permitir sua identificação.

Gráficos devem ser apresentados somente em duas dimensões.

Figuras já publicadas e incluídas em artigos submetidos devem indicar a fonte original na legenda e devem ser acompanhadas por uma carta de permissão do detentor dos direitos (editora ou revista).

Envio/submissão de artigos

Os artigos devem ser submetidos preferencialmente por e.mail (jbes@jbes.com.br) ou pelo site: www.jbes.com.br. Texto e figuras devem ser enviadas como um anexo à mensagem. Figuras (exclusivamente gráficos e fotografias digitais) podem ser enviadas nas extensões .jpg, .gif ou .tif, com resolução mínima de 300 dpi e tamanho máximo total (do conjunto de figuras) de 3 MB.

INSTRUCTIONS FOR AUTHORS

General information

1. The Jornal Brasileiro de Economia da Saúde (Brazilian Journal of Health Economics - ***J Bras Econ Saúde***) is edited every four months and academically supported by the Medical Practice Department of the School of Medical Sciences at Universidade do Estado do Rio de Janeiro. The journal is directed to researchers and health policy planners, as well as managers and evaluators of health technology incorporation. Its mission is to disseminate the knowledge produced by Health Economics as a way to contribute to diminish the negative impacts that may be associated to decision-making processes related to health technologies incorporation, treatments and medicines. The following categories of articles may be submitted for consideration of publication: Disease cost studies, health economics analysis, budget impact analysis, observational studies, pharmacoeconomic essays, epidemiological surveys, health technology assessment, health policies formulation, economic planning and health services management, methodological innovations and review of the literature. These articles may be presented as original articles, review articles, updates and editorials (details on each format are presented below). Manuscripts may be submitted in Portuguese, Spanish or English. Authors who are interested in translating their articles into English may request a translation estimate to the J Bras Econ Saúde. The Jornal Brasileiro de Economia da Saúde does not receive financial support from any society, governmental institution or association. It is a private, independent initiative. Financial resources of the publication come from commercialization of publishing space to manuscripts that received financial support from private companies. Some institutional sponsorship quotas are also commercialized. Submission of the manuscripts is free of charge. A table of publication costs may be requested to the publishing house.

2. The manuscripts submitted to the ***J Bras Econ Saúde*** should be unpublished, that is, partial or complete versions of them should not have been submitted for consideration of publication in other journals. In the case of figures that have already been published, the authorization for reprint should be provided, and the source, cited. Once published, the article's Copyrights are transfered to Doctor Press, the publishing company responsible by JBES.

3. The ***J Bras Econ Saúde*** instructions for authors incorporate the recommendations of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. The complete version of these requirements is available in www.icmje.org. Manuscripts that do not comply with the instructions presented here will be sent back to the authors for review before they are evaluated by the Editorial Board.

4. Every article published in the ***J Bras Econ Saúde*** is sent to expert consultants for peer review. Manuscripts are initially analyzed by the editors to be evaluated in terms study objectives and editorial requirements of the Journal. When accepted by the editor, the manuscript is sent to two expert reviewers in the area of study. The whole process is confidential. The reviewer is blind to the identity and affiliation of the authors, and vice-versa. After the manuscript is evaluated by the reviewers, it may be either accepted unaltered, or rejected, or returned to the authors with suggestions for changes. Any manuscript may be returned to the authors several times for clarification or changes, but this is not a guarantee of future publication.

5. The maximum number of authors per manuscript is six. Co-authorship implies in substantial contribution to conceiving and planning the study; data analysis and interpretation; writing and critical review of the text. Significant contributions to the study that do not fit these categories may be cited in the acknowledgements section. Authors' names must be written in a complete way, being the main one the first name. By submitting an article, the authors are fully liable for their opinions and for all contents contained therein.

6. To submit their manuscripts to the J Bras Econ Saúde, the authors take full responsibility for the opinions and contents described in their articles.

7. Clinical trials should be registered in one of the in a public trials registries acceptable to the World Health Organization and the International Committee of Medical Journal Editors (for example, www.actr.org.au, www.clinicaltrials.gov, www.ISRCTN.org, www.umin.ac.jp/ctr/index/htm and www.trialregister.nl). The trial registration identification number should be presented at the end of the abstract.

8. When the manuscript is accepted for publication, a declaration signed by all the authors should be sent to the Journal, stating that: a) the manuscript is original; b) it was not published or submitted for appreciation in other journal, and will not be, if published by the ***J Bras Econ Saúde***; c) all the authors actively participated in the elaboration of the study and approved of the final version; d) any potential conflict of interest (financial or of other nature) is disclosed; e) the study was approved by the ethics committee of the institution where it was carried out (for manuscripts based on experimental trials); f) an informed consent forms were signed by all patients included in the study (when applicable). Information on approval by the ethics committee and informed consent should also be presented in the Methods section of the manuscript.

9. Before accepted manuscripts are published, the final proofs in PDF format will be sent to the corresponding authors, by e-mail, for final approval. Changes at this stage should be limited to typographical errors, without any alterations in the contents of the study. Authors should return corrected proofs by e-mail or fax within 48 hours of receipt.

Categories of articles

Original articles. Studies that are result of scientific research and present original data on Health Economics, and that include descriptive statistical analysis and/or inferences drawn on these data. These articles have priority for publication. They should have the following sections: cover sheet, abstract and keywords in Portuguese, abstract and keywords in English, main text (divided into Introduction, Methods, Results, Discussion or similar section, Conclusions), acknowledgements (if applicable), references (no more than 40), tables (if any), legends to the figures (if any) and figures (if any).

Review articles. Studies whose objective is to summarize, analyze, evaluate or resume investigation trials that have already been published in scientific journals. These articles should include a summary and critical analysis of the literature, and they should not be confused with update articles. Review articles should have the following sections: cover sheet, abstract and keywords in Portuguese, abstract and keywords in English, main text, references, tables (if any), legends to the figures (if any) and figures (if any).

Update or opinion articles. Studies that report updated information on some subject of interest of given specialties (for example, a new modeling technique or method). They have characteristics that are different from the review article, once they do not present any critical analysis of the literature. They should have the following sections: cover sheet, abstract and keywords in Portuguese, abstract and keywords in English, main text, references, tables (if any), legends to the figures (if any) and figures (if any).

Letters to the reader. Letters to the editors commenting, discussing or criticizing articles published in the ***J Bras Econ Saúde*** are welcomed and published, provided they are accepted by the Editorial Board. They should have the following sections: title, name of the author, identification of the article the author is commenting, and list of references (if any). It is recommended that letters to the editor should not should not exceed 500 words in text, including the references. Whenever possible, the author's reply will be published together with the letter.

Manuscript preparation

Manuscripts should be preferentially sent as a Microsoft Word® file. Use Times New Roman, 12-point font; double-spaced text, aligned to the left. Start each section on a new page, in the following order: cover sheet, abstract and keywords in Portuguese, abstract and keywords in English, main text, references, tables (if any), legends to the figures (if any) and figures (if any). All pages should be numbered.

Abbreviations should be expanded when they are first mentioned in the text; after that, use only the abbreviation. Avoid the use of abbreviations in the abstract.

Substances should be presented by their generic names. If relevant, the commercial name of the substance and the manufacturer may be presented between parentheses.

All units of measure should conform to the International System of Units (SI).

Animal genes should be written in italics with only the first letter capitalized (for example: *Sox2*); human genes should also be written in italics, but all letters should be capitalized (for example: *SOX2*). Protein products should follow the same standard of animal / human genes for capital letters, but should not be italicized.

Cover sheet

The cover sheet should have:

- A concise and clear title, both in Portuguese and in English, representing the content of the study.
- Summarized title (no more than 150 characters)
- Name of the authors
- Affiliations of the authors, indicating the department / unit, institution and geographical region.
- Name of the institution where the study was carried out.
- Information on support received in the form of grants, equipment or drugs.
- Congresses where this study was presented.
- Name, address, telephone and fax numbers, and e-mail of the corresponding author.

Abstract in Portuguese and in English

All manuscripts should have an ***abstract*** in Portuguese and one in English. Manuscripts that are written in Spanish should also have ***abstracts*** in Portuguese and in English, besides the one in Spanish. The content of these abstracts should be identical and they should not exceed 250 words each. Abstracts of original articles should have the following structure: Objective, Methods, Results and Conclusions. Case reports, review and update articles should not have structured abstracts. Abbreviations should be avoided in the abstract, and it should have no references.

Three to six keywords chosen from those available in the Health Science Descriptors (http://decs.bvs.br) should be presented after the abstracts in Portuguese, English and Spanish.

Acknowledgments

This section should be used to recognize the work of people who had collaborated intellectually with the study but do not fulfill the requirements of co-authorship, or people or institutions that have provided material support.

References

Throughout the text, citations should be identified between parentheses using the last name of the authors and the year of publication. Examples: one author (Steptoe, 1978), two authors (Edwards & Steptoe, 1980), more than two authors (Van Steirteghem *et al*., 1988).

The list of references should be presented in alphabetical order (using the last name of each authors followed by the two first initials). This list should not be numbered. Reports of the same author should be presented chronologically; reports of the same author in the same years should be identified with letters after the year (2000a, 2000b, etc.). References will be presented according to the models proposed in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (see examples below). All references listed should be mentioned in the text and vice-versa.

1. Journal article: Edwards RG, Steptoe PC, Purdy JM. Establishing full-term human pregnancies using cleaving embryos grown in vitro. Br J Obstet Gynaecol. 1980;87:737-56.

2. Book: Wolf DP, Quigley MM, eds. Human in vitro fertilization and embryo transfer. New York: Plenum Press; 1984.

3. Book chapter: Simpson JL. Gonadal dysgenesial and sex abnormalities: phenotypic-karyotypic correlations. In: Vallet HL, Porter IH, eds. Genetic mechanisms of sexual development. New York: Academic Press; 1979. p. 365-77.

4. Electronic journal article: Abood S. Quality improvement initiative in nursing homes: the ANA acts in an advisory role. Am J Nurs [electronic journal]. 2002 Jun [cited on 2002 ago 12];102(6): [approximately 3 p.]. Available in: http://www.nursingworld.org/AJN/2002/june/Wawatch.htm.

5. Internet article: Wantland DJ, Portillo CJ, Holzemer WL, Slaughter R, McGhee EM. The effectiveness of web-based vs. non-web-based interventions: a meta-analysis of behavioral change outcomes. J Med Internet Res. 2004;6(4):e40. Available in: http://www.jmir.org/2004/4/e40/. Accessed on: 11/29/2004.

6. Site: OncoLink [Internet site]. Philadelphia: University of Pennsylvania; c1994-2006. [updated on 2004 set 24; cited on 2006 mar 14]. Available in: http://cancer.med.upenn.edu/.

7. Software: Smallwaters Corporation. Analysis of moment structures: AMOS [software]. Version 5.0.1. Chicago: Smallwaters; 2003.

Tables and figures

Tables and figures (graphs, pictures, etc.) should be numbered in Arabic numerals in the order they appear in the text, and their individual legends should be presented in the end of the manuscript. Each table and figure should be submitted on a separate sheet.

Tables should have only the horizontal lines, and each result should be placed in one independent cell. Explanations on the items in the tables should be presented in footnotes identified by the following symbols, in this order: *,†, ‡, §, ||,¶,**,††,‡‡.

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SUMÁRIO
SUMMARY

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Research on economic evaluations in health

A disseminação da ATS para a tomada de decisão

Dissemination of HTA for decision-making

A Avaliação de Tecnologias de Saúde (ATS) fortificou-se nos últimos anos, tornando-se foco de grandes debates. É uma ferramenta essencial na garantia do acesso da população a medicamentos, dispositivos médicos e procedimentos de saúde que sejam efetivos, seguros e comercializados a um preço aceitável para o Poder Público e para a sociedade. Entretanto, diversos desafios surgem após a conclusão de um estudo de ATS. Como fazer com que os resultados obtidos sejam implantados na prática? Ou ainda, como traduzir este conhecimento à sociedade, aos médicos, gestores dos sistemas de saúde, ao Poder Judiciário e aos demais interessados?

Neste sentido o Centro Colaborador do SUS para Avaliação de Tecnologias e Excelência em Saúde (CCATES), em parceria com o Ministério da Saúde, promoveu o II Simpósio Internacional de Farmacoeconomia no SUS entre os dias 10 e 12 de novembro de 2014, na Faculdade de Farmácia da UFMG. O Simpósio teve como objetivo fomentar a discussão no campo da ATS, em especial, sobre as estratégias de disseminação de evidências na tomada de decisão.

A incorporação de tecnologias e a elaboração de Protocolos Clínicos e Diretrizes Terapêuticas foram temas que permearam as discursões entre os representantes do Brasil, Argentina, Portugal, Escócia, Estados Unidos, Suécia, Austrália e do Banco Mundial, que na oportunidade traçaram o panorama internacional destas práticas. Outro ponto importante foi o debate acerca de tecnologias em saúde que se apresentam obsoletas ou que já não se apresentam mais vantajosas frente às alternativas terapêuticas. O desinvestimento, que pretende possibilitar realocação de recursos destas tecnologias para outras consideradas mais custo-efetivas, foi abordado pelo pesquisador do Karolinska Institutet da Escócia. Os conflitos e as sinergias entre o mercado e as políticas de saúde e o acesso a novas tecnologias na visão da Justiça também compuseram a pauta de discussões, incluindo aspectos como o gerenciamento de pacientes de alto custo e a medicina personalizada.

Representantes do National Prescribing Service (NPS) apresentaram as estratégias desta organização australiana sem fins lucrativos dedicadas à promoção do uso com qualidade de medicamentos. Como exemplo de uma destas estratégias foi apresentado o detalhamento acadêmico, que se constitui de visita face-a-face realizada por um profissional de saúde ao prescritor, objetivando a intervenção eficaz para melhorar os padrões de prescrição. Outra estratégia bem sucedida apresentada foi a campanha Resistance Fighter, estratégia direcionada à sociedade. Esta campanha conta com a participação de celebridades australianas na conscientização da população sobre o risco do uso indiscriminado de antibióticos.

O II Simpósio Internacional de Farmacoeconomia no SUS permitiu a difusão dos avanços do conhecimento científico no âmbito da ATS e sua aplicação e a articulação em rede internacional para realização e disseminação de avaliações de tecnologias. Aproximadamente 200 ouvintes participaram do evento, que contou com a presença de 11 convidados internacionais e 23 nacionais, três minicursos e apresentação de 34 trabalhos aqui publicados. Os diapositivos e as fotos do evento estão disponíveis no site do Centro Colaborador do SUS (www.ccates.org.br).

Boa leitura!

Juliana de Oliveira Costa
Daniel Resende Faleiros
Augusto Afonso Guerra Júnior
Comissão Organizadora
II Simpósio Internacional de Farmacoeconomia no SUS

OPINIÃO
OPINION ARTICLE

NPS MedicineWise: a national approach to improving the quality of use of medicines

Jonathan Dartnell[1] , Aine Heaney[2], Karen Kaye[3], Yeqin Zuo[4]

Keywords:
Quality of health care,
Quality use of medicines,
National medicines policy.

ABSTRACT

The investments made by governments to provide affordable access to effective health technologies are significant. To ensure this investment delivers optimal health outcomes, policies, strategies and programs to ensure appropriate use of technologies and avoidance of waste are also required. In Australia, NPS MedicineWise has been funded by the Australian Federal Government since 1998 to design, develop, implement and evaluate national programs to improve the quality use of medicines and medical tests. The investment in these programs has consistently achieved demonstrable improvements in the use of medicines and medical tests. Moreover, it has resulted in improved health outcomes and savings in government expenditure far in excess of the cost of the programs. This model has been important in supporting and sustaining Australia's universal health care system.

Introduction

The promise of universal health care in providing improved access to health services, improved health outcomes and financial risk protection, creates expectations that health professionals and consumers will have ready access to an increasing range of medicines. In this context, Australia's National Medicines Policy has provided a strong framework to support and address some of the tensions that arise with the introduction of new technologies (especially medicines) and changes in health care delivery (Australian Government Department of Health and Ageing, 2000). The policy is based on 4 pillars. Firstly, medicines should meet appropriate standards of quality, safety and efficacy—in Australia this is addressed by the national regulator, the Therapeutic Goods Administration. Secondly, consumers should have timely access to medicines, at a cost individuals and the community can afford—this is addressed by the Pharmaceutical Benefits Scheme which facilitates subsidised access to approved medicines for all Australians. Thirdly, the pharmaceutical industry should be viable and should act responsibly with respect to its activities to support research and market access. Fourthly, there should be mechanisms to ensure quality use of medicines (ie rational and responsible use of medicines) once access has been enabled. These four pillars are inter-dependent and all four are necessary if the health needs of our community are to be consistently and cost-effectively safeguarded.

NPS Medicinewise

NPS MedicineWise (previously known as the National Prescribing Service) was established to provide a nationally coordinated approach to improving the quality use of medicines (Weekes et al, 2005). NPS MedicineWise is an independent, not-for-profit organisation with a mission to enable both health professionals and consumers to make better decisions about medicines and medical tests, and thereby achieve better health and economic outcomes. Since 1998, the Australian Federal Government has funded NPS MedicineWise to

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design, develop, implement and evaluate national programs to improve the quality use of medicines, and more recently medical tests. Since inception, the investment in these programs has consistently achieved demonstrable improvements in the use of medicines and medical tests. Moreover, it has resulted in improved health outcomes and savings in government expenditure far in excess of the cost of the programs. This model plays an important role in supporting Medicare, Australia's universal health care system.

Australia has been well served by national formularies and clinical practice guidelines (Therapeutic Guidelines, 2015; Australian Medicines Handbook, 2015). Yet while these resources are well disseminated and provide essential repositories of guidance for practitioners, on their own they don't ensure appropriate use of medicines and related technologies. The translation of evidence into practice is complex and often challenging. Providing timely access to evidence--based information is not enough because, for example, the evidence may be contested, may not be readily applied in the local setting, or may require significant changes in health professional and/or consumer behaviour. Understanding this complexity and designing and delivering programs that enable and sustain changes in behaviour is critical to positively influencing quality use of medicines.

The NPS MedicineWise approach is to identify problems with medicines and medical tests where: (1) there is an identified gap between best practice and current practice; (2) closing that gap will make a significant improvement in health and economic outcomes; and (3) the problem is likely to be responsive to awareness raising, educational and quality improvement activities. Each year NPS MedicineWise delivers at least three national educational programs focussed on carefully selected therapeutic issues. Program design takes into account the many individual and environmental factors that affect the use of medicines or medical tests. Programs employ a range of tactics and strategies with multiple products and services delivered through multiple channels, which are designed to positively influence prescribing decisions and promote evidence based care.

Quality use of medicines stresses the importance of patient-professional communication along with patient knowledge and understanding their medicines; thus along with our consumer education programs and campaigns, general medical practitioners (GPs) in primary care (ie primary care physicians) being the main prescribers for government subsidised medicines are an important audience for our programs. To achieve impact, we use strategies that achieve active rather than passive participation. The chosen strategies use a mix of interventions with a sound theoretical basis, informed by insights into the barriers and enablers for achievement of desired behaviour change. Interventions include educational materials, educational meetings, educational visiting (ie academic detailing), audit and feedback, strategic use of opinion leaders, reminder systems and patient mediated strategies.

National educational visiting services using academic detailing techniques and facilitated peer group discussions are cornerstone activities for NPS MedicineWise programs. Academic detailing entails one-on-one practice-based visits involving a peer-to-peer interaction between two professionals (O'Brien, 2007). It applies behaviour change principles to provide education and information in an objective, service based approach (rather than a sales focus), that can be directly related to a health professional's clinical practice. This assists them in overcoming barriers to change and addresses not only knowledge and skills, but also beliefs and attitudes. NPS MedicineWise uses a skilled and highly trained health professional workforce to discuss key topics in a focused (approximately 30 minute) interaction in the general practitioner's clinic. The discussions centre on areas of clinical interest where there are known variations in practice, and provide a collegiate environment in which to address clinical controversy, decision dilemmas and opportunities for practice improvement.

Examples of programs

NPS MedicineWise has implemented four national programs in primary care to improve type 2 diabetes since 2001. For the 2008 diabetes program, over a third of all Australian GPs actively participated in activities including educational visits (academic detailing or peer group discussions), self-directed clinical audits and/or case studies (NPS MedicineWise, 2015). Key messages focused on encouraging lifestyle interventions, management of risk factors, first-line use of metformin and early initiation of insulin. Interrupted time series analysis was used to assess the association between GP participation in NPS MedicineWise programs and the prescribing of targeted medicines, using Pharmaceutical Benefit Scheme data on national prescribing rates. The program led to an estimated 7% relative increase in the modelled rate of prescribing of metformin (by defined daily doses per 1000 population per day). GP participation in the program was associated with a relative decrease of 19% in the modelled prescription volume of glitazones in the year following the program with consequent net savings from avoided government expenditure of AUD$46 million on glitazones. . An economic evaluation was conducted to model the economic impact of the program as a result of improved glycemic control through the increased use of metformin. The model estimated an impact on patient health outcomes over a ten year period, by preventing cases of lower extremity amputations, cataract extractions, major cardiovascular events, retinopathy and nephropathy. The model also demonstrated fewer cases of heart failure avoided attributable to the reduced use of glitazones. The

model predicted the 2008 diabetes program was estimated to have saved the health system $7 per $1 invested in the NPS MedicineWise program.

NPS MedicineWise has also delivered several programs on stroke and antithrombotics over the last decade. In 2009, NPS MedicineWise delivered a stroke prevention program targeting GP prescribing of antiplatelet and anticoagulant medications (NPS MedicineWise, 2015). The key messages for GPs were to systematically assess and re-assess the risk benefit of warfarin and antiplatelet agents, prescribe aspirin as the antithrombotic of choice in primary stroke prevention when cardiovascular risk is high, however most patients with atrial fibrillation require warfarin. About a third of GPs in Australia actively participated in NPS MedicineWise activities. In addition to the interventions previously described, individualised reports of recent prescribing history were distributed to all GPs in the country. Feedback reports focused on prescribing patterns for anti-thrombotic medications together with provision of program materials incorporating the key messages. An epidemiological study using linked data relating to people aged 45 years and above in New South Wales was used to evaluate the health outcomes associated with this program (Banks, 2011). The evaluation found that the 2009 program was associated with an increased initiation rate of prescribing of aspirin and associated with a decreased rate of hospitalisation for primary ischaemic stroke in people at a high risk of cardiovascular disease. In addition, based upon the program's key messages and an understanding of current prescribing practice, it was expected that inappropriate prescribing of clopidogrel would decrease. The results of the interrupted time series regression model demonstrated that GP participation in the program was associated with a relative decrease of 10% in prescribing of clopidogrel (defined daily doses per 1,000 population per day) with consequent savings from avoided government expenditure of AUD$46 million for the three years after the program on the Pharmaceutical Benefits Scheme.

Conclusion

The investments made by governments to provide affordable access to effective health technologies also need to be supported by policies, strategies and programs to ensure appropriate use of those technologies. Investing in nationally coordinated quality use of medicines programs can yield significant improvements in medicine use, better health outcomes and overall savings for the health system..

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TEMAS | TOPICS

RESUMO DE ARTIGO
ABSTRACT ARTICLE

Efficacy and safety of medicines based on Cannabis Sativa extract for the treatment of epilepsy in Rett Syndrome

Felipe Ferré[1], Orozimbo Henriques Campos Neto[2], Lívia Lovato Pires de Lemos[3], Juliana de Oliveira Costa[4], Augusto Afonso Guerra Júnior[5], Francisco de Assis Acurcio[5]

Keywords:
cannabidiol, cannabis sativa, rett syndrome, epilepsy

INTRODUCTION: Rett syndrome is a rare inherited neurodevelopmental disorder associated with the X chromosome that affects one in every 10,000 girls. Epilepsy happens in about nine out of 10 children with Rett syndrome. **OBJECTIVES**: We aimed to evaluate the effectiveness and safety of medications based on Cannabis sativa for the treatment of epilepsy in patients with Rett syndrome compared with anticonvulsants available in the Brazilian National Health System. **METHODS**: We searched The Cochrane Library (via BIREME), Medline (via Pubmed), Lilacs, Centre for Reviews and Dissemination (CRD) and Trip database databases aiming to find studies of Cannabis sativa treatment for Rett syndrome. We also selected Health Technology Assessments (HTA) on sites of international agencies and REBRATS. We also performed an additional search of clinical trials for the treatment of epilepsy with drugs containing known concentrations of cannabinoids extracted from Cannabis sativa. **RESULTS**: Summary of results of selected studies: no studies met the criteria for participant (patients diagnosed with Rett syndrome with episodes of epilepsy), intervention (medications based on Cannabis sativa), comparison (placebo drugs for epilepsy in Rett syndrome were identified -valproic acid, carbamazepine, clobazam, clonazepam, ethosuximide, phenytoin, phenobarbital, gabapentin, lamotrigine, primidone, topiramate, vigabatrin) and outcome (psychomotor improvement, reduction of seizures and adverse events). The four studies found in the supplementary search on the plant extract usage in the treatment of epilepsy had small sample, were of poor quality and inconclusive: two presented results in favor of the use of cannabidiol and two showed no differences among the groups. **CONCLUSION**: There is a lack of scientific evidence of efficacy and safety of plant extracts with high concentration of cannabidiol and low concentrations of delta-9-tetrahidrocanabinol.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Judicial requests of drug treatment cancer, Minas Gerais, 1999-2009: descriptive study

Karina Alves Ramos[1], Juliana Alvares[2], Francisco de Assis Acurcio[2], Mariangela Leal Cherchiglia[3], Eli Iola Gurgel Andrade[3]

Keywords:
judicial decisions, pharmaceutical care, off-label use, oncology, health system

INTRODUCTION: Although the existence of a Brazilian public policy of integral care of patients with cancer, which includes the supply of drugs, judicial demand for oncology drugs has been cited in some studies as being significant. The drugs used in cancer treatment are responsible for much of the resources expended in compliance with court orders, which is justified, probably due to the high cost and technological sophistication of oncology drugs. **OBJECTIVES**: To analyze the profile of lawsuits by medicine to treatment of cancer filed against the Secretary of State Health of Minas Gerais in the years 1999-2009. **METHODS**: Retrospective descriptive study conducted from data obtained from lawsuits against the Secretary of State Health of Minas Gerais in which drugs were ordered for use in treatment of cancer, in the analyzed period. Data were collected at lawsuit, the recipient patient, health care that originated prescription medication and sued in court. Medicines were ranked ordered according to the Anatomical Therapeutic code Chemical - ATC. Possible requests for antineoplastic medication were checked for use in display not included on the product label (off-label) approved by health regulatory agencies in Brazil and the United States. **RESULTS**: 8.05% of all lawsuits containing claims for drugs to treat cancer, being mostly conducted by private attorneys. Most medical care related to the study patients (46.9%) was performed on health facilities located in the macro-region of Minas Gerais center, especially in the city of Belo Horizonte, and private hospitals (37.0%). The most frequent diseases were reported by the beneficiaries as malignant neoplasm of brain (15.4%) and malignant neoplasm of the breast (12.2%). Among the most requested drugs, highlights the temozolomide (17.23%) and rituximab (11.41%). The products belonging to the class of monoclonal antibodies (32.0%) and protein kinase inhibitors (31.6%) were the most defendants. Among the drugs that do not fall into the category of antineoplastic agents and immunomodulators, 62% did not belong to some public drug programs at the time of request judicial assistance, and the majority was painkillers. 8.0% were found to court orders of medicaments for off-label use, both according to the Brazilian regulation, as in accordance with US regulation. There was a predominance of requests for deferrals and injunction in favor of the beneficiary. **CONCLUSION**: The judicial requests of drugs for the treatment of cancer has contributed to the deepening of existing inequalities in health care, in that it was used by the private sector to fund high-cost beneficiaries with public resources treatments. On the other hand, it showed a deficit of incorporating technologies in Health System in oncology, which requires improving the model of care provided. It is necessary, therefore, improvements in public health care, the regulatory mechanisms, the additional assistance and criteria for evaluation of judicial proceedings, in order to promote greater equity in access to health services.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Health litigation - profile of demand medicines and influence of intellectual property rights protection in Minas Gerais state/Brazil

Renata Cristina Rezende Macedo do Nascimento[1],
Augusto Afonso Guerra Júnior[2], Roberto Luiz da Silva[3]

Keywords:
pharmaceutical services, right to health, health litigation, intellectual property, rational use of medicines

INTRODUCTION: The right to Pharmaceutical Service (PS) in Brazil is guaranteed as part of the right to health. The government should formulate and implement policies in order to guarantee people's access to essential medicines. Such normative advance, recognized as a fundamental right, led to recourse to judicial review and gave rise to increased litigation for the enforcement of this right to give the PS status of a fundamental right. This phenomenon is called litigation of PS. Appropriate use of medicines is an essential component of better cost-effectiveness of modern health care. In this regard it is essential to evaluate which technologies represent therapeutic innovations in order to qualify public funding in the Unified Health System (SUS). **OBJECTIVES**: To analyze the influence of intellectual property rights protection on the profile of drug request by litigation in the Health Department of Minas Gerais state (SES-MG), public spending and its interfaces with the rational use of drugs and the incorporation of new technologies in the SUS. **METHODS**: This is a descriptive observational study of litigation by drugs attended by SES-MG. There were analyzed 4,140 records of lawsuits in 2010 attended by SES-MG and 1,065 rulings and published in the website of the Court of the State of Minas Gerais in the period from 2007 to 2009. **RESULTS**: In 2010, SES-MG attended 28,104 prescriptions requirement of legalization, the average being 2.2 medications per patient. The prevalence of polypharmacy was 10.6%. In addition to individual lawsuits, the SES-MG attended 19 civil suits which included 135 medicines. The ten most demanded drugs were protected by patents. Of these, only three were standardized in SUS-MG. For all products there were prescription of brand name, an average of 50% of the requests had required supply trademark. The survey indicated a prevalence of jurisprudential injunction and the use of prescription drugs cited as evidence without making expertise. Ensuring the constitutional right to health was the speech used in more shares. It was observed that the lawsuits are at odds with the rational use of medicines recommended by World Health Organization (WHO). **CONCLUSION**: The annual expense to ensure access to medicines for litigation is growing and represents a major challenge for the public manager. The high prevalence of new medicines prescribed by trademark and the biological products show the need to review and strengthen the policy of generic drugs in Brazil.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Analysis of the efficacy, safety and cost-effectiveness of duloxetine and trazodone to treat neuropathic diabetic pain

Wânia Cristina da Silva[1], Kennedy Crepalde Ribeiro[2],
Augusto Afonso Guerra Júnior[3], Francisco de Assis Acurcio[3]

Keywords:
neuropathic pain, diabetic neuropathy, duloxetine, trazodone

INTRODUCTION: Neuropathic pain is an important complication of diabetes mellitus (DM) type 1 or type 2. In Brazil, it is necessary detailed analysis of these drugs on efficacy, safety and costs of treatment due to the increase of litigation for the supply of new technologies in the public health system (SUS). **OBJECTIVE**: The aim of this study is to analyze the scientific evidence on the use of duloxetine and trazodone in the treatment of diabetic neuropathic pain, and present the comparative costs of existing alternatives in the Brazilian public health system. **METHODS**: We researched and selected publications with the highest level of evidence in The Cochrane Library, Medline (via PubMed), LILACS and Centre for Reviews and Dissemination (CRD). Likewise, sought for health technology evaluations in foreign agencies websites and evaluated the evidence quality and strength of the recommendation according to the Grade system. To evaluate the data of the comparative costs, we used the list prices regulated by the Brazilian government. **RESULTS**: The revisions included showed results in favor of duloxetine; but in most cases, the drug is compared to placebo. Direct comparisons with other drugs have not been conclusive. International agencies indicate duloxetine, amitriptyline, gabapentin and pregabalin for neuropathic pain. The publication that evaluated the efficacy and safety of trazodone showed results in favor of this drug, but this was just a cases series. Studies of cost-effectiveness of duloxetine have been the only ones found, which, although good results, was not the most cost-effective option. **CONCLUSIONS**: Although the pharmacoeconomic studies have shown favorable the new technology, duloxetine, there is a lack of scientific evidence to support the nationwide use of duloxetine and trazodone to replace tricyclic antidepressants and gabapentin, indicated by the public health system in Brazil.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Análise do perfil dos pacientes que realizam a oxigenoterapia no atendimento domiciliar do SUS, no município de Sobral-Ceará

Francisco Regis Araújo Ferreira Gomes[1], Maíra Barroso Pereira[2]

Palavras-chave:
oxigenoterapia domiciliar prolongada, doença obstrutiva pulmonar crônica, perfil dos pacientes

INTRODUÇÃO: A Secretaria de Saúde e Ação Social do município de Sobral oferece o serviço de oxigenoterapia domiciliar prolongada (ODP), considerada atualmente o principal tratamento não farmacológico para portadores de doença pulmonar obstrutiva crônica (DPOC) e hipoxemia crônica, aumentando a sobrevida e a qualidade de vida desse grupo de pacientes, possibilitando a diminuição das internações hospitalares. **OBJETIVOS**: O objetivo desse estudo foi analisar o perfil dos pacientes que realizam a oxigenoterapia no atendimento domiciliar do SUS, no município de Sobral-Ceará. **MÉTODOS**: Trata-se de um estudo descritivo, retrospectivo, com abordagem quantintativa baseado em análise documental dos dados do serviço de Assistência Farmacêutica e dos 39 pacientes que realizaram oxigenoterapia domiciliar, no período de abril a dezembro de 2009. **RESULTADOS**: Em relação ao perfil do paciente e do tratamento, observou-se que 41,03% destes eram do sexo masculino e 58,97% do sexo feminino; 69,00% possuíam a idade maior ou igual a 60 anos; 84,72% eram provenientes da zona urbana; a patologia mais frequente foi a DPOC (66,68%); o pneumologista foi o médico especialista que mais solicitou o tratamento (48,74%); 87,18% dos pacientes utilizavam cilindros de oxigênio e 12,82% o concentrador de oxigênio; os gastos com os cilindros de oxigênio foram de R$ 91.112,00, e de R$ 26.840,00 com os concentradores de oxigênio, totalizando em R$ 117.952,55 o gasto total com a oxigenoterapia, sendo que este gasto representou 2,77% do gasto total com a assistência farmacêutica. **CONCLUSÃO**: Após a análise dos resultados desta pesquisa, propõe-se a otimização dos recursos disponíveis através da elaboração de protocolos, elencando critérios que possam assegurar o uso adequado da oxigenoterapia tanto para os médicos, pacientes e cuidadores, como também para a reorientação das politicas do cuidado domiciliar no âmbito do SUS do município de Sobral, com o objetivo de garantir a integralidade da atenção.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Avaliação do perfil e do gasto público com o tratamento dos pacientes portadores de alergia à proteína do leite de vaca atendidos pelo estado do Ceará

Lívia Valérya da Cruz Paiva[1], Maíra Barroso Pereira[2]

Palavras-chave:
alergia à proteína do leite de vaca, fórmulas nutricionais especiais, gastos públicos

INTRODUÇÃO: A alergia alimentar tem se tornado um grande problema de saúde pública, afetando não só a qualidade de vida do paciente, como causando um grande impacto financeiro, social e médico para as pessoas acometidas e seus familiares. A alergia à proteína do leite de vaca (APLV) constitui uma das formas de manifestação de alergia alimentar mais comuns em crianças e ocorre principalmente nos três primeiros anos de vida. O tratamento da APLV fundamenta-se na exclusão dos alérgenos alimentares e utilização de fórmulas nutricionais especiais (FNE), para atender as necessidades nutricionais das crianças e assim permitir o crescimento e desenvolvimento normal. Essas fórmulas apresentam alto custo e se tornam muitas vezes inacessíveis a população. **OBJETIVOS**: A pesquisa avaliou o perfil dos pacientes portadores de APLV no Ceará e os gastos públicos do Estado com a distribuição de FNE no ano de 2009. **MÉTODOS**: O estudo foi do tipo descritivo, retrospectivo, com abordagem quantitativa, realizado através de um formulário pré-elaborado em que constavam informações como: idade da criança, sexo, município de origem, solicitante da FNE, renda média familiar, tipo de FNE prescrita, presença de doença associada à APLV, uso de aleitamento materno, antecedente familiar de alergia, entre outras. O projeto de pesquisa foi aprovado pelo Comitê de Ética do Hospital de Messejana. Os dados foram analisados através do Microsoft Office Excel 2007, sendo apresentados em forma de gráficos e tabelas. A amostra foi constituída por 439 processos que correspondem a todas as solicitações de FNE ao Estado do Ceará em 2009. **RESULTADOS**: Observou-se que as crianças na faixa etária de 0 a 11 meses foram as que mais solicitaram FNE ao Estado. Não houve diferença significativa entre os sexos. A maior parte dos solicitantes era proveniente da capital Fortaleza. As mães foram as que mais solicitaram FNE para o tratamento de seus filhos. A renda média familiar que mais predominou foi a de menor que 3 salários mínimos. A maior parte das crianças fez uso de leite materno durante os primeiros meses de vida e não possuía antecedente familiar de alergia. O Estado do Ceará gastou com essas fórmulas, no ano de 2009, R$ 7.009.351,00. **CONCLUSÃO**: Com base nos resultados percebeu-se que não foi possível caracterizar os pacientes com APLV no Ceará, pois o perfil encontrado foi bastante diversificado, e que o gasto público com as fórmulas nutricionais especiais foi bastante significativo.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Evaluation of technologies for the treatment of major depression: a review of the efficacy of sertraline and citalopram compared to fluoxetine

Sarah Nascimento Silva[1], Júlia de Paula Penna Palhares[1], Augusto Afonso Guerra Júnior[2], Francisco de Assis Acurcio[2]

Keywords:
depression, technology assessment, sertraline, citalopram

INTRODUCTION: The World Health Organization (WHO) classifies depression as a major cause of disability worldwide and is associated with high rates of medical comorbidity and premature mortality. Spending on treatment implications on quality of life and productivity arouse the interest of researchers of health and economy, since the disease involves high social and economic cost to society. Selective Serotonin Reuptake Inhibitor (SSRI) antidepressants offer improvements in depression disorder by increasing the amount of serotonin in the synaptic cleft, thus increasing synaptic stimulation and serotonergic activity in the body. The SSRI are indicated as first choice in the treatment of depression in many guidelines, since they show have fewer adverse events than other classes of antidepressants. It is also observed that SSRI drugs are very similar in their clinical profile, however, evidence suggests differences between speed of response and the incidence of some adverse events, in addition to providing the difference in treatment costs. **OBJECTIVES**: To review the existence of scientific evidence about the effectiveness of drugs citalopram and sertraline compared to fluoxetine for treatment of major depression in adults. **METHODS**: A systematic search was performed in Medline (via PubMed), Centre for Reviews and Dissemination (CRD), The Cochrane Library, and LILACS. We searched for systematic reviews (SR) of clinical trials that compared the efficacy and safety of drugs sertraline and citalopram front the fluoxetine for the treatment of moderate or severe depression. The quality of evidence was assessed by the GRADE system. **RESULTS**: Seven SR, six with meta-analysis were included. Assessing the effectiveness, the results of SR showed a slight superiority of sertraline to fluoxetine front, and no significant differences were found between fluoxetine and citalopram. As for security, most studies proved inconclusive or slightly favorable to fluoxetine. Compared to rates of noncompliance, the results were not statistically significant, which leads us to conclude that there is no difference between the drugs. Most SR showed evidence of poor quality and it was possible to recognize all weak superiority of sertraline and fluoxetine on citalopram. **CONCLUSIONS**: Considering that most of the results had limitations and inconclusive data, there is evidence to support the use of fluoxetine as SSRI drug of first choice for the treatment of moderate or severe depression, once your profile is similar to the evaluated technologies, and this availability in the Health System in Brazil. In inadequate response to treatment with fluoxetine and still which it is desired to maintain the use of a SSRI, sertraline can be used.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Efficacy and safety of antidepressants citalopram, sertraline and venlafaxine in treatment of anxiety disorders patients

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Keywords:
anxiety disorders, systematic review, antidepressants, Brazilian Public Health System

INTRODUCTION: Anxiety disorders are composed by Generalized Anxiety Disorder (GAD), Obsessive-Compulsive Disorder (OCD), Post-traumatic Stress Disorder (PTSD), Panic Disorder (PD), Social Anxiety Disorder (SAD) and Specific Phobias. They are caused by the interaction of neurobiological vulnerability (such as genetic characteristics), adversity during childhood (fear, abuse, disease) and environmental factors such as stress and trauma. Selective Serotonin Reuptake Inhibitors (SSRI) and Serotonin and Norepinephrine Reuptake Inhibitors (SNRI) are recommended as first-line drug treatment, due to its cost-effectiveness. **OBJECTIVES**: To evaluate whether venlafaxine, citalopram and sertraline are safer and more effective to treat patients with anxiety disorders than the technologies available in the Brazilian Public Health System (SUS) - clomipramine, diazepam, clonazepam, clobazam and fluoxetine. **METHODS**: We conducted an overview of systematic reviews. The databases The Cochrane Library, Medline, LILACS, APA PsycNET and Centre for Reviews and Dissemination were searched. We searched for systematic reviews of clinical trials that compared each drug with placebo, with each other or with other therapeutic options available in the SUS for the treatment of anxiety disorders. Additionally we searched for health technology assessments (HTA) on websites of international agencies and in the Brazilian Network for Health Technology Assessment. We selected studies published in English, Portuguese or Spanish. **RESULTS**: We included 14 systematic reviews. None of the reviews found scientific studies comparing these drugs directly with each other or between the alternatives incorporated into the SUS, and, in general, drugs showed statistically significant efficacy when compared against placebo. Nine Health Technology Assessments (HTA) were also considered. In none of these HTA pharmacological therapy was appointed as first choice treatment, and these studies advocated psychological interventions. The studies do not recommend therapy with benzodiazepines (BZD) and antipsychotics. **CONCLUSION**: The pharmacological treatment is considered as second line in anxiety disorders, however there is still no clinical protocol defined in the SUS for the management of these diseases. Venlafaxine, citalopram and sertraline showed efficacy and safety profiles similar to clomipramine and fluoxetine, which are available in the SUS. It is indicated the use of clomipramine for PD and fluoxetine or clomipramine for OCD. In the current therapeutic indications listed in the SUS´s National Therapeutic Form or in Clinical and Therapeutic Guidelines, there is no pharmacological treatment option for patients with PTSD, SAD and GAD in SUS. Considering the approved indications in labels for use in Brazil, as well as the estimated costs of treatment, it is indicated the use of sertraline for PTSD and SAD and the use of venlafaxine for the treatment of GAD.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Revisão sistemática e comparação indireta de medicamentos biológicos para espondilite anquilosante

Tatiana Sanjuan[1,2], Bernardo Tura[2], Marcelo Goulart[3], Marisa Santos[4]

Palavras-chave:
revisão sistemática, comparação indireta, medicamentos biológicos

INTRODUÇÃO: Espondilite anquilosante (EA) é uma doença reumática inflamatória de evolução crônica que acomete preferencialmente o esqueleto axial. Atinge adultos jovens, com forte impacto socioeconômico e na qualidade de vida dos pacientes. **OBJETIVOS**: O objetivo deste estudo foi comparar a eficácia dos medicamentos biológicos antifator de necrose tumoral alfa, aprovados pela Agência Nacional de Vigilância Sanitária brasileira, para o tratamento da espondilite anquilosante, incluindo adalimumabe, etanercepte, golimumabe e infliximabe. **MÉTODOS**: Foi realizada uma revisão sistemática da literatura com busca nas bases bibliográficas Medline, Cochrane e LILACS, até maio de 2014, a fim de identificar ensaios clínicos randomizados relevantes. O método Bayesiano de comparação mista dos tratamentos foi aplicado para análise pareada, que permite combinar evidências diretas e indiretas para realização de comparações de tratamentos. Dado que todas as tecnologias são comparadas ao mesmo tempo, é possível ordená-las de acordo com a probabilidade de cada uma ser a melhor escolha. Utilizou-se como desfecho para critério de eficácia, o índice de atividade de Bath para a espondilite anquilosante de 50% nas semanas 12 a 24. Ao final, foram selecionados 6 ensaios clínicos randomizados que compararam os resultados do desfecho definido, nas semanas 12, 18 e 24, para estes medicamentos biológicos em pacientes refratários ao tratamento padrão. **RESULTADOS**: O estudo envolveu, na totalidade, 1.532 pacientes com espondilite anquilosante oriundos de diferentes ensaios clínicos. Todos os agentes biológicos provaram ser superiores ao placebo, com exceção do etanercepte que não foi significantemente diferente. Avaliou-se o desfecho incluindo acompanhamentos entre 12 e 24 semanas. O infliximabe apresentou a maior razão de chances (odds ratio) em comparação com o placebo, OR 6,65 (IC 2,27 - 19,50); seguido pelo golimumabe OR 5,10 (IC 1,68 – 15,50); adalimumabe OR 4,33 (1,48 – 12,70); e etanercepte OR 2,94 (IC 0,54 – 16,10). Os intervalos de credibilidade foram largos, sem superioridade entre os medicamentos biológicos. Após a realização das simulações, o infliximabe foi o medicamento biológico com o melhor desempenho na maioria das simulações (56,34%), seguido dos medicamentos: golimumabe (20,50%), adalimumabe (14,09%), e etanercepte (9,07%). **CONCLUSÕES**: Nosso estudo, de acordo com os resultados da comparação indireta, foi conclusivo em demonstrar a não superioridade de eficácia de nenhum tratamento biológico na avaliação pareada. O ranqueamento mostrou que o infliximabe apresentou maior probabilidade de sucesso nas simulações. O resultado sugere que são necessários mais estudos para que se comprove, de fato, a superioridade dos medicamentos biológicos no tratamento da EA. Dada a incerteza de superioridade de eficácia entre os medicamentos biológicos, sugere-se que o escalonamento de utilização dos mesmos seja realizado em função do menor custo, da comodidade posológica e da possibilidade de eventos adversos. O infliximabe é o único dentre os biológicos estudados que necessita de infusão em ambiente hospitalar e, portanto, com riscos e custos adicionais em seu uso. Propõe-se que seja utilizado em pacientes mais graves, ou em casos de falha com outro medicamento biológico. O método de comparações indiretas pode ser utilizado para tomada de decisão de incorporação ou desincorporação, e elaboração de protocolos clínicos, subsidiando o gestor nesta avaliação.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Compliance with clinical protocol and therapeutic guidelines on prescribing acetylcholinesterase inhibitors for treatment of Alzheimer's disease in Minas Gerais, Brazil

Celline Cardoso Almeida-Brasil[1], Juliana de Oliveira Costa[2], Augusto Afonso Guerra Júnior[3], Francisco de Assis Acurcio[3], Edgar Nunes de Moraes[4], Juliana Alvares[3]

Keywords:
Alzheimer's disease, compliance, Clinical Protocol and Therapeutic Guidelines

INTRODUCTION: Acetylcholinesterase inhibitors (AChEI) are commonly used in the treatment of mild and moderate Alzheimer's disease (AD) and it is provided by the Brazilian National Health System (SUS). The treatment is available free of charge to eligible patients, according to criteria and norms established by the Clinical Protocol and Therapeutic Guidelines (CPTG), through the opening of an administrative request. The non-observance of the CPTG leads to delays in the process of drug dispensation, which may harm the patient in need for the treatment. **OBJECTIVES**: To describe prescriber's non-compliance to CPTG for Alzheimer's disease, assessing the frequency of AChEI requests not approved, as well as the reasons for that. **METHODS**: A cross-sectional study was conducted using 165 AChEI requests from Minas Gerais state, prescribed between October 2012 and May 2013 and selected randomly. The drug requests were available from the SUS/MG, which receives the request from the physician and sends it to an analyst to approve or deny the request. We estimated the frequency of not approved-requests and assessed patient's medical records included in the requests (i.e., differential diagnosis of dementia and cognitive tests, such as Mini-mental State Examination – MMSE and Clinical Dementia Rating – CDR) in order to investigate the reasons for non-compliance that led to non-approval of AChEI release. **RESULTS**: From the 165 AChEI requests included in this study, 38% were not approved and returned to the prescribers. The main reasons included: incongruence between cognitive tests (22%); high degree of dependence in basic activities of daily living, suggestive of score 3 at the CDR test (12%); cognitive tests applied wrongly (8%); and presence of untreated depression (7%). According to the CPTG for Alzheimer's disease, patients classified as CDR-3 are not eligible to AChEI treatment. Furthermore, the CPTG preconizes that depression should be treated in order to confirm the diagnosis of AD. **CONCLUSIONS**: The reasons presented suggest non-observance of the CPTG inclusion criteria and lack of knowledge in how to perform cognitive tests. Failure to comply with the CPTG generates an unnecessary cost to the State, regarding the analysis and reanalysis of requests by referees, expendable clinical examinations and ineffective treatment. Dissemination and clarification of clinical protocols and guidelines through educational interventions for prescribers, such as academic detailing, is important to ensure patient access to effective medication, in the corresponding stage of the disease.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Treatment of diabetic neuropathic pain: efficacy, safety and cost-effectiveness of pregabalin and the association of vitamin B12, uridine and cytidine (ETNA®)

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Keywords:
diabetic neuropathic pain, pregabalin

INTRODUCTION: Pregabalin is an anticonvulsant indicated for the treatment of neuropathic pain in adults. Its mechanism of action is the reduction of calcium influx to regulate transmission of excitatory messages between nerve cells. ETNA® is a combination of vitamin B12, uridine and cytidine nucleotides and it is indicated for the treatment of peripheral nerves diseases. **OBJECTIVES**: To evaluate if pregabalin and ETNA® are safer, more effective and more cost-effective than gabapentin and amitriptyline (available in SUS) to treat diabetic neuropathic pain. **METHODS**: a search for systematic reviews and economic studies was performed in the databases The Cochrane Library (via Bireme), Medline (via PubMed), LILACS and Centre for Reviews and Dissemination (CRD). Manual search was also conducted on the internet and in the references of the studies found. Health Technology Assessments (HTA) have been selected in international agencies and in Brazilian Network for Health Technology Assessment (REBRATS). Studies published in English, Portuguese or Spanish were selected. **RESULTS**: Nine studies were included, four systematic reviews, one clinical trial and four economic studies. Systematic reviews considering efficacy and safety of pregabalin evaluated the following outcomes: reduction in pain intensity, treatment response rate (≥50% on pain reduction), the Patient Global Impression of Change and adverse events. These reviews showed results in favor of pregabalin compared to placebo. The ETNA® clinical trial showed results in favor of the intervention but compared to vitamin B12 alone. The results of cost-effectiveness for pregabalin considered as a measure of effectiveness the number of days with no pain or mild pain, the number of days with 30% and 50% reduction in pain and QALY gains. Only one cost-effectiveness study has not favored pregabalin. **CONCLUSION**: The treatment for neuropathic pain is contemplated in the therapeutic guideline for chronic disease, which recommends the use of amitriptyline in monotherapy as first choice or its association with gabapentin in cases of therapeutic failure with the monotherapy. The evidences appraised here allow indicate the use of pregabalin in replacement of gabapentin only in cases of therapeutic failure of the schemes mentioned above, since no study included direct comparisons between pregabalin and amitriptyline or gabapentin, making it impossible to support the therapeutic superiority of pregabalin compared to other drugs already used in Brazil. The evidence does not support ETNA® use due to lack of studies with sufficient evidence of quality to ensure the efficacy and safety of this intervention and justify the expense.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Efficacy and safety of dutasteride and abiraterone for prevention and treatment of prostate cancer

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Keywords:
prostate cancer, dutasteride, abiraterone, CRPCm

INTRODUCTION: Prostate cancer is one of the most common prostatic diseases in adults and can compromise the longevity and quality of life of these individuals. The drug dutasteride and abiraterone, according to the literature, could be used as alternative therapies for prevention and treatment of prostate cancer. Dutasteride inhibits the production of an androgen that is directly involved in the development of benign prostatic hyperplasia, while abiraterone is an inhibitor of the biosynthesis of hormones that stimulate the growth of prostate cancer cells. However, these drugs are not available in the Brazilian's Unified Health System (SUS). **OBJECTIVES**: Assess the available scientific evidence on the efficacy and safety of dutasteride and abiraterone for prevention and treatment of prostate cancer. **METHODS**: We searched Medline (via Pubmed), The Cochrane Library and LILACS databases for systematic reviews (SR) of randomized clinical trials (RCTs) that assessed the use of abiraterone and dutasteride for the treatment of prostate cancer. We searched Health Technology Assessments (HTA) in sites of international agencies and the Brazilian Network for Health Technology Assessment. Quality of the evidence and strength of recommendation were evaluated using the GRADE system. **RESULTS**: We identified 110 publications and included in the evaluation four complete studies, including two RCTs and two SR. The RCT showed that dutasteride reduced by 38-66% cancer progression compared to placebo, with a similar safety profile. Both RCTs have important limitations, such as funding by the manufacturer of dutasteride, considerable loss of follow up and no evaluation of survival. No HTA recommendations of dutasteride use in the treatment of prostate cancer were found. Regarding the prevention of prostate cancer, dutasteride was evaluated in a SR of moderate quality, which showed favorable efficacy results, but with possible increase of disease progression. This fact resulted in the withdrawal of the license by the manufacturer of this therapeutic indication. High quality SR showed that the use of abiraterone and prednisone promotes 26% higher survival and 45% lower disease progression compared to placebo combined with prednisone in the treatment of metastatic castration-resistant prostate cancer (CRPCm). However, abiraterone presented unfavorable safety profile. HTA recommend abiraterone for the treatment of CRPCm with disease progression during or after failed therapy with docetaxel. **CONCLUSION**: For the initial stages of prostate cancer, surgery, radiation therapy, brachytherapy, and in some cases, vigilant observation are indicated. The evidence evaluated is not sufficient to ensure a positive balance between the benefits and harms related in the use of dutasteride. For patients with symptomatic CRPCm, docetaxel generally is used as a first choice and in the case of failure of therapy, the abiraterone is a possible alternative. However, as recommended by HTA other drugs such as cabazitaxel and mitoxantrone could be used after failure with docetaxel, and it is difficult to choose one therapy over another, being necessary to conduct studies considering the impact of these drugs on patient's quality of life.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Profile of renal transplantation in Brazil according to demographic and clinical characteristics of recipients and donors

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Keywords:
renal transplantation, profile, Brazilian National Health System

INTRODUCTION: Renal transplantation is recognized as the best option for patients with end-stage renal disease, both in clinical and economic perspectives. Brazil has one of the largest public programs of organs and tissues transplantation of the world. The Brazilian National Health System (SUS) is responsible since the search for the donor until the post-transplant treatment. The success of transplantation is related to characteristics of the recipients and donors, among them the age and the type of donor (dead, living related, or living not related). It is necessary to know the profile of these individuals and their geographical distribution to guide the planning of specific actions for this population. **OBJECTIVES**: To describe the profile of kidney transplantation in Brazil according to demographic and clinical characteristics of recipients and donors. **METHODS**: Cohort from kidney transplanted (Jan/2000 to Dec/2009) developed from the deterministic-probabilistic linkage of Authorization for Hospital Hospitalization database -AIH/SUS. Information about donors was obtained for 106 patients transplanted in Belo Horizonte in the period of 2006-2009. **RESULTS**: In the 10 years of analysis, we identified 26.282 kidney transplants, an increase of 49.0% in the number of procedures, and decrease between 2003 and 2005, followed by a significant increase. The Brazilian Society of Nephrology saw a rise of 103.8% in the number of dialysis patients in these 10 years. Most of the recipients were male (59.6%), in which the most common type of transplant was living donor. In women the opposite was observed ($p < 0.01$). The average age was 40 years. Kidney transplantation was more frequent in the 18-42 years old group (48.8%) and less in the ≥67 years old group (1.6%). The age of the living donors recipients was lower than that of the cadaver transplant recipients ($p < 0.01$). 51.0% of the transplants were from living donors. It was observed that by the year 2006 most of the provided organs were from living donors (55.2%) and by 2009 most were from cadaveric donor (55.9%). From the 106 transplants with donor's information, 70.7% were cadaver, aged 32.95±13.87, and 50.6% were female. Among the living donors the average age was of 41.76±8.30 and 51.6% were men. Most were brothers (63.0%), followed by parents (16.6%). Transplant between individuals of different sex occurred in 64.5% of living donors and 51.3% in transplantation with cadaver organ. Overall, the highest number of transplants performed was in São Paulo State (38.6%), followed by Minas Gerais (10.7%) and Rio Grande do Sul (9.5%). **CONCLUSION**: Renal transplantation in Brazil occurs predominantly among men, aged between 18-42 years old, with organ from cadaver donors. The living donor transplant recipients were younger and major donors were siblings. In absolute numbers, São Paulo, Minas Gerais and Rio Grande do Sul are presented as major transplanters states. Over this period there was an increase in the number of kidney transplants, which did not follow the increase in the number of dialysis patients. This indicates that despite the recent advances and efforts in the area the number of kidney transplants is still insufficient.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Overview of the Specialized Component of Pharmaceutical Assistance in Minas Gerais: flux and time of processing of requests

Rosângela Maria Gomes[1], Lívia Lovato Pires de Lemos[2], Juliana de Oliveira Costa[3], Grazielle Dias da Silva[4], Francisco de Assis Acurcio[5], Augusto Afonso Guerra Júnior[5]

Keywords:
Specialized Component of Pharmaceutical Assistance, compliance, requests, process

INTRODUCTION: Access to medicines of the Specialized Component of Pharmaceutical Assistance (CEAF) is carried out through opening of administrative proceedings in accordance with detailed rules and Clinical Protocols and Therapeutic Guidelines. The compliance of the medicines requests in Minas Gerais are evaluated by the Health Department of Minas Gerais State in partnership with the SUS Collaborating Centre (CCATES)/Federal University of Minas Gerais. Public information allows knowing the number of deferred requests. However, it is also necessary to understand the flow, the time to process the requests and the profile of the rejected and returned ones to provide a better service. **OBJECTIVES**: To assess the demand for medicines of the CEAF and the time spent to conduct the proceedings in Minas Gerais. **METHODS**: Analysis of all requests of CEAF medicines held in Minas Gerais, in 2013, by consultation to the Integrated Management System of the Pharmaceutical Assistance (SiGAF) and records of the CCATES. **RESULTS**: In the year 2013 we evaluated 85 thousand processes, of which 79% were granted, 13% returned and 5% refused. According to the 10th International Classification of Disease, most of the demands was for endocrine, nutritional and metabolic diseases (21.2%), followed by diseases of the skin and subcutaneous tissue (13.6%). Isotretinoin (26.0%) and the analog of insulin glargine (21.0%) were the most requested medicines. Insulin glargine is provided in Minas Gerais for the treatment of Diabetes Mellitus type 1. Isotretinoin is provided for Severe Acne Treatment, which occurs in 15% of patients with acne - skin disease. In the 2006 dermatological census 65% of the patients had acne - skin disease. The total average processing time was of 57.98 (± 30.89) days, and the average time spent on the compliance analysis was of 8.4 days (14.5%). The rest of time was spent on bureaucracy (49.5 days). **CONCLUSION**: Most of the requests came from patients with endocrine, nutritional and metabolic diseases, with emphasis on the request of insulin glargine, provided by State decision. The demand for isotretinoin was higher than the prevalence of severe acne reported in the literature. The total time of the conduct of proceedings decreased if compared to 2008, coinciding with the implementation of the SiGAF and the CCATES. It should be noted that analysis of compliance, key stage of the process, corresponded only to 14.5% (8.4 days) of the total time, and that can be further reduced with the electronic analysis and use of digital certification, such as already occurs with the federal revenue. It is recommended to optimize the processing time and transportation steps, as it represented more than 85% of the flow time.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Safety and effectiveness analysis of sunitinib in the treatment of patients with unresectable Pancreatic Neuroendocrine Tumor

Stephanie Ferreira Botelho[1], Gustavo Laine Araújo de Oliveira[2], Francisco de Assis Acurcio[3], Augusto Afonso Guerra Júnior[3]

Keywords:
sunitinib, everolimus, neuroendocrine tumors, pancreatic neoplasms

INTRODUCTION: Sunitinib is an antineoplastic, protein kinase inhibitor, inducing apoptosis and reducing proliferation to malignant cell. It is indicated for the treatment of renal cell carcinoma, gastrointestinal stromal tumors after disease progression, imatinib contraindication, and unresectable Pancreatic Neuroendocrine Tumor (PNET). **OBJECTIVES**: To review the available scientific evidence on sunitinibe use in the treatment of unresectable PNET and evaluate its safety and effectiveness for treating of this tumor type. **METHODS**: The databases The Cochrane Library (via BIREME), Medline (via PubMed), LILACS and Centre for Reviews and Dissemination (CRD) were searched. Manual search of references in the studies found was performed. Health Technology Assessments (HTA) was searched in the Brazilian Network for Technology Assessment and Health (REBRATS) and international agencies as Agencias y Unidades de Evaluación de Tecnologías Sanitarias (AUnETS/Spain), Canadian Agency for Drugs sites and Technologies in Health (CADTH/Canada), National Institute for Health and Clinical Excellence (NICE/UK), Health Technology Assessment Programme (NIHR/UK) and Pharmaceutical Benefits Advisory Committee (PBAC/Australia). Cohort studies and clinical trials, systematic reviews and economic evaluations conducted in any geographic region, with patients of either sex, older than 18 years, with unresectable PNET were eligible. Studies comparing the use of sunitinib any other therapeutic intervention, placebo or no treatment intervention groups were selected. Progression-free survival, overall survival, time to response, objective response rate, duration of response and adverse events were evaluated. **RESULTS**: The search returned 665 studies and five were selected: a phase III clinical trial, two phase II clinical trials, a matching-adjusted indirect comparison of two phase III clinical trials and a cost-effectiveness analysis. Compared with placebo, sunitinib provided improved overall survival (11.4 months vs. 5.5 months), progression-free survival (71.3% vs. 43.2% in six months of treatment) and response to treatment (9.3% vs. 0.0%, p-value = 0.007). Compared to everolimus, no significant differences were observed in overall survival (HR = 0.81, IC95% = 0.49-1.31; p-value = 0.383). However, neutropenia (OR = 0.15; p-value = 0.049) and hypertension (OR = 0.19, p-value = 0.021) were significantly associated with sunitinib compared with the everolimus. Furthermore, the Incremental Cost-Effectiveness Ratio tends to discourage sunitinib compared with the everolimus (ICER = US$ 41.702,00 per QALY with everolimus). **CONCLUSION**: Considering the evaluation of the safety and cost-effectiveness, sunitinib is recommended only in everolimus contraindication. Considering the methodological quality and the available scientific evidence, this recommendation is weak. Other clinical trials are needed to strengthen the evidence.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Insulin glargine in a Brazilian State: an assessment of drug utilization, effectiveness and value to provide future direction

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Francisco de Assis Acurcio[3], Augusto Afonso Guerra Júnior[3]

Keywords:
insulin glargine, systematic review, Brazil, law suits

INTRODUCTION AND OBJECTIVE: The cost and utilization of the insulin analogue (Insulin glargine) has grown appreciably in the State of Minas Gerais in Brazil in recent years, with costs growing on average by 291% per year. This growth has been driven by an increasing number of successful law suits and a 536% price differential between insulin glargine and neutral protamine Hagedorn (NPH) insulin. One way forward to address concerns with its growing utilisation is to undertake a systematic review assessing the efficacy and safety of insulin glargine compared with NPH insulin in patients with Type I diabetes. As a result, provide published data to support future recommended activities by the State to limit its use. **METHODS**: A systematic review of published studies between January 1970 and July 2009 using established methods documenting the effectiveness of insulin glargine in patients with Type 1 diabetes. Only randomised controlled clinical trials included. **RESULTS**: Out of 803 studies, only 8 met the inclusion criteria. Most were of poor methodological quality or had a high risk of bias. No study could be classified as double-blind, and only one study documented increased efficacy of insulin glargine in relation to both glycaemic control and hypoglycaemic episodes. Typically, there was no significant difference between insulin glargine and NPH insulins in terms of their effectiveness (Souza et al., 2014a). **CONCLUSION**: This systematic review showed no therapeutic benefit with insulin glargine over other insulin formulations although considerable cost differences. This was similar to the findings from other world-renowned organizations and other published studies, which showed at best only minor health gain from long-acting insulins vs. standard (NPH) insulins (Souza et al., 2014a, 2014b). We therefore recommend to the State Authorities to delist insulin glargine or renegotiate a price reduction for continued listing. This is in line with activities undertaken by authorities in other countries (Souza et al., 2014a). This systematic review provides support for this decision as well as documentation to combat potential law suits if there cannot be satisfactory discussions. Consequently, we recommend this approach to other health authorities.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Comparative analysis of antiretroviral drugs purchases of public and private pharmaceutical companies from 2008 to 2013

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Keywords:
government purchasing, pharmaceutical services, anti-retroviral agents, Strategic Pharmaceutical Services Component

INTRODUCTION: The purchases of medicines by the Brazilian Unified Health System (SUS) are guided by the Brazilian Federal Law n° 8666, June 21, 1993, which stablishes rules for bids and contracts for the public administration. According to the Law n° 9313/1996, the provision of antiretroviral (ARV) is a federal responsibility. The National Medicines Policy (PNM) states as priority the production of essential medicines by public laboratories. The final report of the First National Pharmaceutical Services Conference held in 2003 had 648 referrals. From these, 119 were approved in the Axis II - Research and Technological Development for the National Drug Production. Among these proposals, we highlight 21 related to the development and use of public laboratories for drugs strategic supply to SUS. As a product of this conference, the National Board of Health approved the National Pharmaceutical Services Policy (PNAF) in 2004. **OBJECTIVES**: Comparing the purchase of ARV from public and private laboratories between 2008 and 2013. **METHODS**: Retrospective analysis of ARV purchases data by the Brazilian Ministry of Health between 2008 and 2013. It was stratified the comparison of quantities and expenditures according to the provider type. In order to assess the progression during the study period, it was calculated trend lines and straight equations. Through the equations, it was determined the average annual growth for the purchased quantities and for the investments. **RESULTS**: 41 medicines of 21 active ingredients in seven pharmaceutical forms were purchased from twenty different suppliers, from which six were public and fourteen private laboratories. The SUS purchased 2,487,693,460 pharmaceutical units and invested around R$ 4.6 billion in drug treatment for people living with HIV/AIDS. The relative participation of public and private laboratories was, respectively, 58.0% and 42.0%. There was incremental variation of 127,953,944 pharmaceutical units purchased, corresponding to an increase of 40.9%. From this amount, 96.5% were purchased from public laboratories. Considering the amount invested in ARV purchases during the period, the predominance was of private laboratories in relation to the public. The proportional investment was 63.1% for private and 36.9% for public laboratories. However, there was an annual average increase of R$ 53.9 million for public laboratories and an annual average reduction of R$ 20.9 million for private laboratories. **CONCLUSION**: Large amount of resources is applied by the SUS to ARV purchases, in accordance with the Law n° 9313/1996. These purchases from public laboratories meet the PNM and contribute to the execution of PNAF, strengthening the SUS and reducing its technological dependence.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Innovation combined with the public purchasing power: the case of strategic pharmaceutical services component

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Keywords:
pharmaceutical services, Strategic Pharmaceutical Services Component, public production

INTRODUCTION: The Brazilian Public Health System (SUS) considers strategic the medicines used to treat endemic diseases or diseases with socioeconomic impacts. These medicines, provided by the Strategic Pharmaceutical Services Component (CESAF), are often overlooked by private pharmaceutical companies, being crucial the investment in its public production. **OBJECTIVES**: The aim of this study was to identify innovative strategies of CESAF that contributes to the development of public purchasing power. **METHODS**: A retrospective study, based on drug acquisition records of the CESAF, between 2006 and 2012, was performed. In a descriptive fashion, data were stratified by public health programs and percentual of public laboratory production. **RESULTS**: The results show a gradual increase of public laboratory participation: 17% in 2006 to 38% in 2012. Some items, like the STD/AIDS antiretrovirals program, represented a large budget demand with a continuous increase of the public laboratory production: 25% of all acquisitions in 2006 to 52% in 2012. Financial savings were obtained with the public production. For instance, the public production of zidovudine + lamivudine combination (a standard antiretroviral therapy) reflected a reduction of 20% in the costs for the health system (current unit values of R$ 1.37 in 2006 to R$ 1.10 in 2012). Adjusted by the IPCA (Broad Consumer Price Index), the unit value in 2006 corresponds to R$ 1.85 in 2012, reflected a reduction of 40.5%. The major contribution of public production was to provide people the access to medications to prevent or greatly minimize the impact of neglected diseases, which corresponded to 36% of drug acquisitions in 2006 and 60.4% in 2012. **CONCLUSION**: Several factors contribute to the public purchasing power, like the centralized strategic acquisition by the CESAF and the strengthening of public laboratory production through Product Development Partnerships.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Inibidores da enzima dipeptil peptidase tipo 4: análise de custo-efetividade em pacientes atendidos pelo Sistema Único de Saúde em um município de médio porte mineiro

Ingrid Almeida Silva[1], Jésus Augusto Damasceno[1], Alexandra Rodrigues Alves[1], Roberta Niriam Reis Rodrigues[1], Paula Gonçalves de Souza[1], Carolina Mirtes Melo[1], Alda Cristina Franco Correa Maia[2], André Oliveira Baldoni[3], Cristina Sanches Giraud[4]

Palavras-chave:
judicialização, inibidores da enzima dipeptidil peptidase do tipo 4, custo-efetividade

INTRODUÇÃO: Recentemente, os Inibidores da enzima dipeptidil peptidase tipo 4 (DPP-4) surgiram como um tratamento alternativo para os pacientes que não conseguem obter resultados satisfatórios com os fármacos de primeira escolha para tratamento do Diabetes Mellitus tipo 2 (DM2). Uma vez que estes medicamentos não fazem parte da lista de medicamentos essenciais disponíveis à população atendida pelo Sistema Único de Saúde (SUS), o alto número de processos judiciais para a sua aquisição tem exercido forte pressão nas discussões para a inclusão de um representante desta classe na Relação Municipal de Medicamentos Essenciais (REMUME). **OBJETIVOS**: Realizar estudo de custo-efetividade, da perspectiva do setor público, para seleção de um representante dos inibidores da DPP-4 para atender os pacientes provenientes do SUS atendidos pelo componente básico da Assistência Farmacêutica em um município de Médio Porte do estado de Minas Gerais. **MÉTODOS**: As variáveis de interesse do estudo foram custo direto de aquisição do medicamento, custo do tratamento das reações adversas (RAM) e porcentagem de redução de hemoglobina glicada (Hb1c) de cada inibidor da DPP-4 comercializado no Brasil em monoterapia ou em associação com metformina. Diferentes fontes foram consultadas para obtenção dos dados de interesse: revisão sistemática em três bancos de dado para avaliação da efetividade e perfil de reação adversa a medicamento (RAM); consulta de preço médio ao consumidor dos Inibidores da DPP4 incluídos no estudo; consulta ao DataSus para avaliação dos custos diretos do tratamento das possíveis RAMs. O custo direto (aquisição do medicamento e o valor total gasto em reações adversas) foi estimado visando atender a uma demanda de 100 pacientes anualmente. O parâmetro de efetividade considerado foi a porcentagem de redução da hemoglobina glicada. Finalmente, a razão de custo-efetividade foi calculada pela diferença entre o custo das opções terapêuticas, dividida pela diferença entre os valores reduzidos de HB1c. **RESULTADOS**: Verificou-se que o tratamento de 100 indivíduos por um período de 12 meses implicará em um acréscimo orçamentário para aquisição variando entre R$ 166.440,00 (Linagliptina + Metformina) e R$ 414.640,00 (Saxagliptina). Adicionalmente, prevê-se a utilização de R$ 21.767,00 (Vildagliptina) a R$ 55.260,08 (Linagliptina + Metformina) em recursos da saúde para o tratamento das RAM previstas. Verificou-se que a sitagliptina apresentou melhor relação custo-efetividade, enquanto, a saxagliptina apresentou menor desempenho nesta relação. **CONCLUSÃO**: Os estudos econômicos de intervenção em saúde são ferramentas importantes para a tomada de decisão. No presente estudo demonstrou-se que a linagliptina em associação com a metformina apresenta menor custo, porém, a sitagliptina apresenta a melhor relação custo-efetividade. Finalmente, as discussões em torno da judicialização do SUS devem caminhar para que a inclusão de medicamentos nas Relações de Medicamentos Essenciais se dê pela comprovada eficácia, e não pela pressão exercida pelos processos judiciais.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Simplified budget impact estimation of the Minas Gerais state treasure: state bill 4,508/2013

Juliana de Oliveira Costa[1], Lívia Lovato Pires de Lemos[2], Daniel Resende Faleiros[3], Augusto Afonso Guerra Júnior[4], Leonardo Maurício Diniz[5], Francisco de Assis Acurcio[4]

Keywords:
budgets, diabetes mellitus, jurisprudence

INTRODUCTION: The draft Law 4,508/2013 of the Legislative Assembly of the State of Minas Gerais proposes the obligation of the State to ensure patients with diabetes mellitus (DM), through the State Department of Health, access to all the technologies available on the market, such as laboratorial exams, medicines, equipment and supplies for the application of insulin as well as the reimbursement by SUS to citizens who purchase these in the private market. **OBJECTIVES**: To estimate the budget impact for the State Treasury if the draft Law 4,508/2013 is approved in the Legislative Assembly of the State of Minas Gerais. **METHODS**: The estimated budget impact was calculated considering four scenarios for each type of DM, according to the prevalence of DM1 (477,407) and DM2 (4,057,961) in the population of Minas Gerais in 2013. We considered that 100% of patients with DM1 would use combined insulin therapy: intermediate-acting insulin and rapid-acting insulin, or insulin analog ultra-fast. Among patients with DM2 we considered that 40.7% were taking oral hypoglycemic and 7.9% were in use of combined insulin therapy. For each scenario we considered the minor and major values of each technology. We obtained the price of medicines and supplies in the Pharmaceutical Market Regulation Chamber and on the Minas Gerais or São Paulo banks prices and the annual cost of each therapy was calculated according to the Daily Defined Dose (DDD) of the World Organization Health. The health budget for the years 2013 and 2014 were consulted in the Secretariat of State for Planning and Management of Minas Gerais (SEPLAG/MG). **RESULTS**: The estimated budget impact on the Treasury of the State of Minas Gerais ranged from 895 million to 10 billion Reais per year for DM1, according to the scenarios (i) NPH and regular insulin + syringes, (ii) NPH and regular insulin + pen applicator, (iii) insulin analogues + pen applicator, and (iv) infusion pump and regular insulin. Regarding DM2, values ranged from 251 million to 2.1 billion Reais per year, according to the scenarios (i) monotherapy biguanide (metformin), (ii) biguanida in combination to sulphonylurea or dipeptidyl peptidase 4 (DPP-4), (iii) biguanide and sulphonylurea combination or DPP-4 and nocturnal insulin NPH, and (iv) insulin analogs therapy. The total estimate ranged, therefore, from 1.1 to 11.7 billion Reais per year. Data from SEPLAG/MG indicated that the total expenditure on health in Minas Gerais for the year 2014 will be of about 7.5 billion Reais. The most optimistic scenario in terms of forecast spending with the possible approval of the bill 4,508/2013 would result in an expense of 14.7% of the total health budget of Minas Gerais. **CONCLUSION**: It is estimated that with the possible adoption of the bill 4,508 of 2013, of the Legislative Assembly of the State of Minas Gerais, the impact on the budget of the Treasury of Minas Gerais State may vary from 1.1 to 11.7 billion Reais per year.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Comparison of antipsychotic drugs prices for the treatment of schizophrenia between Brazil and Canada: a public health system perspective

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Keywords:
schizofrenia, cost and cost analysis, antipsychotic agents

INTRODUCTION: Schizophrenia spectrum disorders produce significant impact on quality of life of patients and are associated with high costs of treatment. Considering that budget is the main limiting factor for coverage and development of health systems, the comparison of the costs of drugs used to treat schizophrenia between countries proves important. **OBJECTIVES**: The objective of this study is to compare the costs of antipsychotics acquired by the public health system of Canada and Brazil in 2012. **METHODS**: The unitary costs of the antipsychotic drugs used to treat schizophrenia were compared. The data about public medication acquisitions of Brazil, in 2012, was acquired from the Health Prices Bank (BPS, from Portuguese "Banco de Preços em Saúde"). To estimate the public medication acquisitions of Canada, in 2012, the publication Régie de l'assurance maladie du Québec by the Public Health Agency of Quebec was used. Prices were adjusted by Purchasing Power Parity (PPP) and were described by average unit cost for each drug. **RESULTS**: The average unit price was found to be US$ 0.04 and US$ 0.41 for risperidone 1 mg, US$ 0.05 and US$ 0.83 for risperidone 2 mg, US$ 0.06 US$ 1.42 for risperidone 3mg, US$ 2.34 and US$ 1.51 for quetiapine 200 mg, US$ 8.22 and US$ 3.11 for quetiapine 300 mg extended release, US$ 4.90 and US$ 1.56 for ziprasidona 80 mg, US$ 3.75 and US$ 3.98 for olanzapine 10 mg, US$ 0.30 and US$ 0.64 for clozapine 25 mg, US$ 1.12 and US$ 2.60, for clozapine 100 mg, US$ 0,07 and US$ 0,25 for chlorpromazine, US$ 0.04 and US$ 0.05 for haloperidol 1 mg, US$ 0.03 and US$ 0.12 for haloperidol 5 mg, US$ 2.00 and US$ 4.52 for haloperidol decanoate, in Brazil and Canada, respectively. The biggest difference was observed in the quetiapine 300 mg extended release, as the price paid by the Brazilian government was 164.3% higher than the price paid by the Canadian government. Olanzapine 10 mg showed the closest unity cost between Brazil and Canada with a price only 5.8% higher in Canada. The costs of 77% of the drugs were found to be higher in Canada. **CONCLUSIONS**: Socio-economic issues may define the prices of the products in the market, varying the willingness-to-pay of the population for a particular product or service. The price regulation and public production of medications can also contribute to the reduction of the prices practiced in pharmaceutical markets in several countries.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Proposed Brazilian guideline for disinvestment

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Keywords:
disinvestment, resources reallocation, health technology, Public Health Systems

INTRODUCTION: New technologies have been developed and brought to market at a speed never seen before. Pressure on Public Health Systems to make available to the public new technologies resulted in clear and structured processes of incorporation, which, however, have "non substitutionary"/cumulative feature. Additionally, technologies already offered may have become obsolete, present safety issues or may not be cost-effective. These technologies are candidates for disinvestment, which is the reallocation of resources from the funding of technology for other purposes. Methods for divestment - since identification technologies until implementation of the decision - have not yet been defined. **OBJECTIVES**: Propose a guideline for divestment suitable for universal health care systems. **METHODS**: Integrative literature review and expert panel composed of managers and researchers in the fields of Public Health and Law. **RESULTS**: After consulting the international literature, we found that most publications on the subject did not address the implementation of the divestment decision. This may be due to the fact that in most countries, medicines, one of the most evaluated technologies, are financed through co-payment or reimbursement. In Brazil medicines are purchased and distributed by public entities or financed by co-payment, so the Guideline should address the implementation of the divestment in the aspects of logistics and distribution. With this in mind and based on the incorporation process adopted by the National Commission on Technology Incorporation in SUS (CONITEC), a flow that involves five steps was proposed: (1st) the identification, resulting of request by health professionals, industry, government entities or society; (2nd) prioritization to rank the priority requests for analysis; (3rd) evaluation according to the guidelines of Technology Assessment (HTA) of the Brazilian Network of HTA (REBRATS); (4th) disinvestment decision considering the existence of alternative/substitute technology and the epidemiological assessment of the risk-benefit; (5th) development of an Action Plan to be agreed between the entities with the participation of the Health Councils and Committees. This plan should consider the time required for the consumption of stocks and to purchase the replacement technology and the spread of decision for managers, prescribers, judiciary and patients. **CONCLUSION**: Adopting a guideline of disinvestment after extensive debate in society may lead to the improvement of processes and steps. Disinvestment presents itself as an important tool for the reallocation of scarce public health resources, thus it is imperative to define a guideline that addresses the fundamental aspects of this process.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Avaliação dos medicamentos básicos fornecidos pelo Programa Farmácia Popular do Brasil no Estado de Minas Gerais

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Palavras-chave:
assistência farmacêutica, medicamentos básicos, Farmácia Popular do Brasil, atenção primária a saúde

INTRODUÇÃO: Conforme a Constituição Federal de 1988, acesso à saúde é um direito fundamental e deve ser assegurado a todos os cidadãos. Além disso, é dever do Estado organizar o Sistema Único de Saúde (SUS) por meio da formulação e implementação de ações que assegurem o acesso da população aos serviços de promoção, proteção e recuperação da saúde. A Assistência Farmacêutica só se concretiza mediante o acesso aos medicamentos pelos pacientes, nas quantidades adequadas e no momento oportuno. Nesse sentido, diferentes programas vêm sendo implantados em todo território nacional com o objetivo de garantir e ampliar o acesso da população aos medicamentos. Dentre eles, o Programa Rede Farmácia de Minas (RFM) e o Programa Farmácia Popular do Brasil (PFPB). **OBJETIVOS**: Avaliar a influência na demanda e nos custos dos medicamentos atualmente fornecidos no Estado de Minas Gerais, de forma concomitante na RFM e no PFPB. A RFM visa garantir o acesso aos medicamentos pela população por meio da organização da Assistência Farmacêutica para atenção primária à saúde, otimizando os recursos financeiros e aprimorando as atividades técnico-gerenciais. **MÉTODOS**: Foram consultados documentos (leis, portarias e legislações) e coletados dados de fontes primárias e secundárias dos programas. Para a avaliação da cobertura do PFPB nos municípios mineiros, comparou-se o número de farmácias conveniadas com o programa em cada município com o número total de municípios. Para análise do elenco, foi considerada a evolução da demanda dos medicamentos comuns aos dois programas, no Estado de Minas Gerais, conforme pactuação do Componente Básico da Assistência Farmacêutica (CBAF). **RESULTADOS**: Em relação ao elenco, dos 22 medicamentos comuns aos dois programas avaliados, 17 são adquiridos pela SES-MG. Ao realizar o levantamento do número de unidades farmacêuticas solicitadas à SES-MG pelos municípios, observou-se que cinco medicamentos sofreram diminuição ao longo dos anos de 2010 a 2013, o que pode estar associado à implantação do PFPB, intensificada no mesmo período avaliado. No que tange aos recursos financeiros, o gasto médio total da SES-MG nos últimos quatro anos com os medicamentos comuns aos dois programas foi de cerca de R$ 22 milhões. No contexto atual, pode-se dizer que há duplo financiamento dos medicamentos comuns aos dois programas, o que aprovisiona aproximadamente, 10% do recurso total destinado a Assistência Farmacêutica na atenção primária à saúde, no estado de Minas Gerais. **CONCLUSÕES**: Tendo em vista a crescente discussão acerca da dificuldade de aquisição de medicamentos pelos Estados e Municípios, bem como a falta de correção dos valores pactuados para o CBAF, torna-se importante discutir a utilização deste recurso aprovisionado para aquisição de outros medicamentos importantes para a atenção primária à saúde, deixando a cargo do PFPB o atendimento às prescrições dos medicamentos coincidentes.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Spending on primary care drugs distributed in the city of Morada Nova - Ceará

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Keywords:
pharmaceutical assistance, expenditures on drugs, primary care, rational use of drugs

INTRODUCTION: In recent years, spending on drugs has become a threat to the sustainability of public health systems of many countries. This work was based on the need to develop a profile analysis of distributed medicines and related public spending in Primary Health Care in the city of Morada Nova – Ceará, to contribute to the rationalization of spending and drug use. **OBJECTIVES**: Analyze spending on drugs distributed in Health Basic Units of the Primary Health Care System in the city of Morada Nova - Ceará. **METHODS**: It is characterized as a retrospective study, with descriptive approach, quantitative character, making a temporal cut in 2009. To this end, characterize the financing of Pharmaceutical Assistance in Primary Health Care System, drug distribution scaled in Number of Units Distributed System (NUD), according to Anatomical Therapeutic Chemical Classification System (ATC), correlating spending. **RESULTS**: The city of Morada Nova joined the centralized purchasing by the State and had a cast of 121 pharmaceutical products, where the NUD was 3,334,489 (tablets, vials, caps, tubes, etc.). This quantity generated a total cost of R$ 145,798.00. The average price of a unit was R$ 1.00, with a maximum value of R$ 21.00 and a minimum of R$ 0.01. Among dosage forms, the tablet had the highest cost (R$ 67,795.67), as well as the largest volume distribution (NUD = 3,171,900), followed by the bottle (R$ 53,267.38) and the tube (R$ 7,839.87). The therapeutic group that represented the biggest expense was the antibacterials for systemic use with 17.6% of total expenditure; therapeutic subgroup ACE inhibitors (9.7%) and Captopril 25mg was the product involving the largest expenditure (9%). **CONCLUSION**: we conclude that there is a need to follow Health Basic Units for proper management of pharmaceutical assistance, targeting the Rational Use of Drugs and thus the optimization of public spending on health.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Perfil e gastos dos indivíduos com diabetes mellitus em municípios de Minas Gerais

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Palavras-chave:
medicamentos, insumos, gastos, perfil, diabetes mellitus

INTRODUÇÃO: O diabetes mellitus (DM) é uma das doenças crônicas não transmissíveis mais prevalentes no mundo, e tem assumido proporções epidêmicas nos últimos anos. Isso a torna um problema de saúde pública mundial ao comprometer a produtividade, a qualidade e a duração da vida dos indivíduos acometidos. A prevalência, os custos e a morbimortalidade associados à doença são aspectos importantes na análise situacional do DM. **OBJETIVOS**: Descrever as características sociodemográficas, de saúde e os gastos mensais com medicamentos e insumos de pacientes com diabetes mellitus em Minas Gerais. **MÉTODOS**: Realizou-se um estudo epidemiológico com delineamento seccional, por meio de inquérito domiciliar, em 61 municípios do interior participantes da Rede Farmácia de Minas, em Belo Horizonte e Contagem, em janeiro de 2014. Foi realizada análise descritiva, utilizando-se a distribuição de frequências para variáveis categóricas e medidas de tendência central para variáveis contínuas. **RESULTADOS**: Foram entrevistados 2.618 indivíduos. Observou-se que 84% relataram ter DM tipo 2 e 10% DM tipo 1, 69% era do sexo feminino, 44% brancos, cerca de 50% casados, com idade média de 61 anos. Em Belo Horizonte e Contagem, 23% e 20% declararam ter ensino médio completo, respectivamente, enquanto no interior, 25% primário incompleto. Em relação à classificação econômica (ABEP), houve predomínio de pessoas de categoria C1, 29% em Belo Horizonte e 35% em Contagem, contra 29% da categoria D nos municípios do interior. De forma geral, 31% relataram ter plano de saúde particular, sendo 47% em Belo Horizonte. As comorbidades mais prevalentes foram hipertensão (76%), problemas de visão (68%), dislipidemia (44%), obesidade (32%) e depressão (31%). Verificou-se que 47% apresentam autopercepção de saúde regular, 13% fumam, 18% consomem bebida alcoólica e 40% foram mais de cinco vezes ao médico no último ano. Foi observado que 97,6% utilizavam medicamentos. Destes, 81,5% não têm dificuldades para adquiri-los e 59,3 adquirem diretamente no Sistema Único de Saúde (SUS). O número médio de medicamentos em uso foi de 5,3, com variação de 0 a 17. A maior parte dos indivíduos gasta entre R$ 25,00 e R$ 50,00, mas houve relatos de gastos superiores a R$ 600,00. Verificou-se que 43% usaram algum insumo para o tratamento do diabetes. Destes, 67% adquiriram no SUS. Entre os indivíduos que gastaram com insumos, observa-se que a maior frequência dos gastos estava entre R$ 1,00 e R$ 100,00. **CONCLUSÃO**: A escolaridade e a classificação econômica foram maiores nas cidades da região metropolitana em relação às do interior. O gasto mensal com medicamentos foi semelhante em Belo Horizonte, Contagem e municípios do interior, sendo que 41% afirmaram não ter gastos com medicamentos no último mês, 70% com insumos e a maioria não tem problemas para adquiri-los. Isso indica participação importante do SUS no acesso a medicamentos e insumos para o DM em Minas Gerais, com diminuição dos gastos para os indivíduos.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Custo do tratamento da esquizofrenia sob a perspectiva do paciente

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Palavras-chave:
antipsicótico, custo, esquizofrenia

INTRODUÇÃO: A esquizofrenia é um problema de saúde pública de relevância mundial, tanto em países desenvolvidos quanto em países subdesenvolvidos. Na população geral, 4,6 em cada 1.000 pessoas têm a doença em um ponto de tempo específico da vida. A doença crônica caracteriza-se pela recorrência de surtos (em 75% dos indivíduos acometidos), intervalados por variados períodos de tempo. O tratamento convencional é feito com antipsicóticos, tais como clorpromazina (mais adequada em fase aguda por seus efeitos sedativos) e haloperidol (no tratamento de manutenção), e representam alto impacto nos custos do tratamento. **OBJETIVOS**: Estimar o custo mensal dos medicamentos para o tratamento da esquizofrenia, sob a perspectiva do paciente. **MÉTODOS**: Estimou-se o custo máximo mensal e anual do tratamento da esquizofrenia a partir da média do Preço Máximo ao Consumidor (PMC) definido pela Câmara de Regulação do Mercado de Medicamentos (CMED) de 2014. O PMC é o preço máximo permitido para venda ao consumidor e inclui os impostos incidentes por Estado. Os preços máximos de cada medicamento foram calculados segundo a média dos preços máximos individuais; os custos máximos mensais e anuais foram calculados com base na dosagem de manutenção recomendadas pelos Protocolos Clínicos e Diretrizes Terapêuticas do Ministério da Saúde (Portaria Nº 364 de 2013). **RESULTADOS**: O haloperidol é o fármaco mais usado na manutenção do tratamento, é o antipsicótico de primeira geração que apresenta o menor custo para o paciente, podendo chegar ao valor máximo de R$ 28,02 ao mês. Em contrapartida, o decanoato haloperidol injetável de depósito, que é indicado em casos de não adesão ao tratamento, tem custo máximo de R$ 2.020,80/mês/paciente. A risperidona é um antipsicótico de segunda geração e se revela muito eficaz no tratamento de manutenção, além de permitir dose única diária; entretanto, merece destaque para o custo mensal do tratamento, alçando um custo máximo de R$ 345,24 ao mês, apresentando um aumento de 1.224,25% em relação ao tratamento mensal com haloperidol. A clozapina é indicada em pacientes não responsivos ou intolerantes a antipsicóticos de primeira geração, alçando custo mensal e anual máximos de R$ 1.231,44 e R$ 14.277,28, respectivamente. Em relação à clorpromazina, utilizada na fase aguda da doença, seu custo máximo mensal pode chegar a R$ 744,30 e anual a R$ 8.931,60. Quetiapina, antipsicótico de segunda geração, mostra-se eficaz também na fase aguda e apresenta boa tolerabilidade com um custo mensal máximo de R$ 1.609,69 e anual de R$ 19.316,16. **CONCLUSÃO**: Os valores discrepantes dos custos dos tratamentos com diferentes antipsicóticos, seja de primeira ou segunda geração, merecem destaque no que tange a realização de estudos posteriores sobre a efetividade dos tratamentos em relação ao custo.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Evolution of spending on judicial demand for medicines, supplies and health services at the Minas Gerais Department of Health (SES/MG) 2003-2014

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Keywords:
judicialization, health services, health economics

INTRODUCTION: The perception of the concept of right to health shows distinct between the different areas in which permeates, like the user's vision, health professionals, public administrators or legal professionals. In general, health professionals converge on the ideals individualistic ethic, according to which health is priceless and any effort in trying to save a life is valid and justifiable. Based on this premise and building upon the constitutional precept that "health is a right and duty of the State", in recent years the number of lawsuits for medicines, health products and services is increasing. However the fact that health has a cost and the available resources are finite cannot be ignored, even when the investment is made by government or by the supplemental health services. The field of Health Economics lies on the precept of the ethic of the common health economics, prioritizing actions that aim the collective welfare, which promotes space for discussion on the most appropriate for the efficient management of health services form. The phenomenon of judicialization of health prejudices the public budget available for social programs. **OBJECTIVES**: To describe the evolution of the judicial demand for medicines, health products and services costs on SES/MG in the 2003-2014 period. **METHODS**: An evolutionary and quantitative analysis of the numbers of lawsuits with deferred injunctions against the state of Minas Gerais which pleaded medicines, supplies and health services spent their spending was made. These data were obtained from the Assessoria Técnica da SES/MG. **RESULTS**: In 2003, 2004, 2005, 2006, 2007 and 2008 the total annual actions recorded were, respectively (with their total cost to the State) of: 249 (R$ 2,007,477.00), 390 (R$ 2,808,252.00), 629 (R$ 8,469,378.00), 986 (R$ 18,179,467), 1464 (R$ 22,848,689.00) and 1850 (R$ 42,552,696.00). From the year 2009, average number of shares and spending increased dramatically, and from 2009, 2010, 2011, 2012, 2013 and 2014 (until September), the respective values were: 2960 (R$ 32,456,797.00), 4137 (R$ 53,167,094.00), 4403 (R$ 93,893,237.00), 7243 (R$ 142,999,785.48), 9121 (R$ 204,932,778.69) and 4450 shares (R$ 50,506,976.99). **CONCLUSION**: The number of lawsuits in MG has grown unchecked, resulting in more robust spending in its care. This phenomenon, while pointing care gaps, upsets the constitutional principles of fairness and equality in the SUS, since they benefit individually only a small portion of the population that has knowledge and access to the legal instruments. The mobilization of public resources for lawsuits care harms the development of new shares in public health. The use of health economics as a way to rationalize the use of resources figure as a guiding instrument in making decision in public health management.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Gastos com antipsicóticos atípicos para pacientes com esquizofrenia em Minas Gerais no ano de 2013

Wallace Breno Barbosa[1], Rosângela Maria Gomes[2], Juliana de Oliveira Costa[3], Lívia Lovato Pires de Lemos[4], Cristina Mariano Ruas Brandão[5], Helian Nunes de Oliveira[6], Maria Heliodora de Souza Lui[7], Grazielle Dias da Silva[8], Francisco de Assis Acurcio[5], Augusto Afonso Guerra Júnior[5]

Palavras-chave:
esquizofrenia, gastos, antipsicóticos, componente especializado da assistência farmacêutica, sistema único de saúde

INTRODUÇÃO: A esquizofrenia é uma doença crônica que acomete cerca de 1% da população. Apresenta taxas elevadas de mortalidade e significativa redução na expectativa de vida do paciente, ocasionando elevado impacto em termos financeiros e sociais. No Brasil, os antipsicóticos atípicos para tratamento da esquizofrenia são disponibilizados aos pacientes por meio do Componente Especializado da Assistência Farmacêutica (CEAF). O acesso aos medicamentos do CEAF ocorre mediante abertura de um processo administrativo, que é analisado de acordo com os critérios definidos pelos Protocolos Clínicos e Diretrizes Terapêuticas (PCDT). Em Minas Gerais, a avaliação dos processos é realizada em parceria com o Centro Colaborador do SUS (CCATES/UFMG). O gasto total do Ministério da Saúde com o CEAF foi de R$ 1,41 bilhão em 2007 e a esquizofrenia representou 14,8% deste valor. **OBJETIVOS**: Descrever o perfil dos usuários, a demanda e os gastos relacionados com os antipsicóticos para o tratamento da esquizofrenia no Sistema Único de Saúde (SUS) em Minas Gerais no ano de 2013, por meio do CEAF. **MÉTODOS**: O gasto total foi estratificado por medicamento segundo consulta ao Sistema Integrado de Gerenciamento da Assistência Farmacêutica. As variáveis categóricas foram descritas a partir da distribuição de frequências e as variáveis contínuas segundo medidas de tendência central. **RESULTADOS**: O gasto com os antipsicóticos atípicos foi de R$ 46.799.531,71 em 2013. A olanzapina representou 53,18% deste gasto, seguido pela quetiapina (23,60%), ziprasidona (11,97%), clozapina (10,96%) e risperidona (0,30%). No mesmo período, foram avaliados 6.367 processos, representando 7,6% de todas as solicitações do CEAF em Minas Gerais. Desses, 73% foram deferidos, 23% devolvidos e 1% indeferido; 51,2% corresponderam a pacientes do sexo masculino com uma média da idade de 36,6±18,7 anos vs. 41,4±20,7 anos para o sexo feminino ($p<0,001$). As principais Gerências Regionais de Saúde (GRS) onde ocorreram as solicitações dos antipsicóticos foram Belo Horizonte (1.308; 20,5%), Governador Valadares (1.095; 17,2%) e Divinópolis (508; 7,9%). O município de Belo Horizonte foi responsável por 12% (766) das solicitações, Governador Valadares por 9% (573) e Uberlândia por 3,3% (211). A olanzapina foi o medicamento mais solicitado (40,3%), seguido pela risperidona (23,8%), quetiapina (18,6%), clozapina (10,5%) e ziprazidona (6,8%). **CONCLUSÃO**: A maioria das solicitações foi deferida (73%) e representou 0,3% da população do Estado. Destaque para as GRS onde ocorreram as maiores demandas, que se encontram na região com maior densidade populacional de Minas Gerais. O perfil dos usuários indicou uma distribuição equitativa entre sexos, como previsto na literatura. A idade média encontrada demonstra que a esquizofrenia é mais precoce nos homens que em mulheres, conforme literatura. Segundo o PCDT para esquizofrenia, todos os antipsicóticos, com exceção da clozapina, podem ser utilizados no tratamento, sem ordem de preferência. Apesar disso, a olanzapina foi prescrita para cerca de metade dos pacientes e correspondeu a mais da metade (53,18%) dos gastos com os antipsicóticos do CEAF, enquanto a risperidona obteve a segunda maior demanda e foi responsável por 0,30% destes gastos. Nossos achados sugerem a necessidade de estudos mais específicos quanto à preferência pela olanzapina, já que acarreta maiores gastos ao SUS.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Stent farmacológico: vale quanto custa? Uma análise de custo-efetividade dos stents no tratamento da doença arterial coronariana

Juliana Alvares[1], Alessandra Maciel Almeida[2], Daniel Resende Faleiros[3], Augusto Afonso Guerra Júnior[1], Francisco de Assis Acurcio[1]

Palavras-chave:
stents farmacológicos, doença da artéria coronariana, análise custo-benefício

INTRODUÇÃO: A doença arterial coronariana (DAC) é em 90% dos casos resultante da oclusão ou do estreitamento das artérias coronarianas por aterosclerose. Apesar de seu longo processo de desenvolvimento, a DAC pode acarretar, no curso de minutos, complicações graves ou mesmo fatais. Dentre as opções terapêuticas disponíveis, a angioplastia coronária transluminal percutânea (PTCA) com implante de stent tem sido cada vez mais utilizada, cerca de três vezes mais que a Cirurgia de Revascularização Miocárdica (CRVM), por apresentar menor morbidade e reduzido tempo de recuperação. Os stents são próteses endoluminais tubulares metálicas em forma de malha que são inseridas no lúmen vascular com a função de mantê-lo aberto e evitar a reestenose decorrente da hiperplasia neointimal ou do espasmo resultante da ICP. Podem ser metálicos (Bare Metal Stents - BMS) ou revestidos com fármaco (Drug Eluting Stents - DES). Este estudo tem o objetivo de realizar análise de custo-efetividade do stent farmacológico (DES), comparado ao stent convencional (BMS) no tratamento da doença arterial coronariana na perspectiva do Sistema Único de Saúde (SUS). Tem ainda a finalidade de avaliar o preço baseado no valor terapêutico do DES. **MÉTODOS**: Foi realizada uma análise de custo-efetividade na perspectiva do Sistema Único de Saúde (SUS) utilizando o modelo de Markov. Os ciclos foram anuais e os horizontes temporais adotados foram de cinco e de dez anos. Comparou-se BMS com DES (eluído com sirolimus). Foi utilizada uma coorte hipotética com idade média de 50 anos. As probabilidades de transição foram obtidas da literatura e painel de especialistas. Os custos foram obtidos do Banco de Preços do Ministério da Saúde e Tabela do SUS. Utilizou-se taxa de desconto de 5%. Realizou-se análise de sensibilidade variando os custos dos stents metálico e farmacológico com o objetivo de se estabelecer o preço de equilíbrio entre os stents, considerando sua diferença de efetividade. **RESULTADOS**: Para o horizonte temporal de 5 anos, observou-se que o stent convencional representa um gasto médio anual de R$ 4.645,33 e o farmacológico de R$ 6.424,54. O stent convencional se mostrou mais efetivo e menos custoso, sendo, portanto, a estratégia dominante. Para o horizonte temporal de 10 anos, observou-se que o stent convencional representa um gasto médio anual de R$ 4.948,11, e o farmacológico de R$ 6.504,99. O stent farmacológico mostrou efetividade incremental de 0,03 Anos de Vida Ganhos (AVG) em relação ao BMS. A razão de custo-efetividade incremental foi de R$ 60.171,27 por AVG. A análise de sensibilidade demonstrou que, dada a diferença de efetividade, o custo máximo do DES para se obter o mesmo resultado deveria ser de R$ 2.536,99. **CONCLUSÃO**: Observou-se que a efetividade incremental obtida com o uso do DES não é suficiente, em relação ao seu custo, para que ele seja considerado custo-efetivo. A análise do custo baseado no valor terapêutico, obtido em análise de sensibilidade, mostrou que o valor máximo que se deve pagar pelo stent farmacológico, dada a diferença de efetividade em relação ao stent metálico, é de R$ 2.536,99.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Enzyme replacement therapy in the treatment of Pompe disease

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Keywords:
enzyme replacement therapy, Glycogen Storage Disease Type II, efficacy, safety

INTRODUCTION: Pompe disease is a rare, inherited disease characterized by the deficiency of the production of acid alpha glucosidase. It manifests clinically in two forms: Infantile or late-onset Pompe disease. The enzyme replacement therapy (ERT) is the only available treatment for the disease, but is not currently provided by the Brazilian National Health System (SUS). **OBJECTIVES**: The aim this study was to evaluate the efficacy, safety and the cost of alglucosidase-alfa (Myozyme®) for ERT for Infantile and late-onset Pompe disease. **METHODS**: We searched for scientific studies in the electronic database PubMed, MICROMEDEX and in the website of the Brazilian National Health Surveillance Agency (ANVISA). The price of alglucosidase-alfa was obtained at the Regulatory Chamber of the Pharmaceutical Market (CMED) with 0% of Interstate Tribute for Services and Goods. Treatment costs were calculated considering every other week dose of 20 mg/kg for children (weight 10 kg) and adults (weight 70 kg). **RESULTS**: We included a clinical trial about Pompe disease in infants and three studies of Pompe disease in children or adults. The proportion of patients alive at 18 months of age was 100% in the group using ERT vs. 1.6% in the control group for Pompe disease in infants. Considering the live ones with non-invasive ventilation the ratio was of 72.2% vs. 0%, respectively. Regarding late-onset Pompe disease, a systematic review funded by the product manufacturer showed that 2/3 of patients had improvement or stabilization of their disease for most of the evaluated outcomes. However, the classification/presentation of outcomes did not allow evaluating if there was a significant clinical improvement. After two years of ERT there was a deterioration of the clinical status and patients developed antibodies against the enzyme, whose effects on the effectiveness of ERT still need to be further elucidated. The clinical trial included showed results in 78 weeks in favor of the use of ERT to the outcomes of distance walked during a 6-minute walk test; predicted forced vital capacity and maximal expiratory pressure. However, the authors considered the results modest. Only the observational study included evaluated the survival of patients with late-onset Pompe disease, and showed that up to nine years of follow-up patients treated with ERT have chances 59% lower to die. In further analysis the authors stated that eight years would be needed in ERT to obtain an extra year of life. The annual cost of treatment with ERT for infantile and late-onset forms were R$ 117,371.52 and R$ 821,600.64, respectively. Thus, eight years of ETR would correspond to a cost of more than R$ 6.5 million per patient with late-onset Pompe disease to obtain an extra year of life. **CONCLUSION**: ERT seems to have less effect in patients with late-onset Pompe disease than in infantile patients and results in high cost of treatment. Thus, further studies are needed to state on its efficacy and safety in patients with the late-onset form.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Interchangeability between innovative, similar and generic pramipexole in the treatment of Parkinson's disease

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Keywords:
Parkinson's disease, pramipexole, Interchangeability

INTRODUCTION: Parkinson's disease (PD) is a chronic and progressive neurodegenerative disorder caused by the death of brain neurons and consequent decreased production of a neurotransmitter, dopamine. Pramipexole is a dopamine agonist that acts "replacing" dopamine. In Brazil, pramipexole is provided to the population by the Specialized Component of Pharmaceutical Assistance. In the market are available: reference medicine (Sifrol®); pramipexole immediate release generic; and similar medicine (brand-name non innovative). There are considerable differences in price. **OBJECTIVES**: Evaluate the interchangeability between pramipexole generic, innovative and similar medicines, according to parameters of safety and efficacy. **METHODS**: A search was performed for Brazilian and other countries official documents and reports that addressed the standards for registration of generic and similar medicines on the websites of National Health Surveillance Agency (ANVISA), Food and Drug Administration (FDA), European Medicines Agency (EMA) and World Health Organization. Search for scientific studies was conducted in Medline (via PubMed), Centre for Reviews and Dissemination, The Cochrane Library, and LILACS. **RESULTS**: According to the Law and resolutions of ANVISA the interchangeability between reference and generic, or similar medicines, is expected as they have to demonstrate bioequivalence for the registration of the medicine in the Ministry of Health. ANVISA resolutions regulated waiver from traditional bioequivalence studies for drugs considered to present high solubility and high permeability according to the Biopharmaceutics Classification System. In August 2014 pramipexole was included in the list of drugs eligible for biowaiver, as it is considered to present high absorption (greater than or equal to 85%) and wide therapeutic index, i.e., the therapeutic dose is far from the toxic dose. Furthermore, this drug has not been reported in human bioequivalence. In the United States of America, pramipexole is eligible for biowaiver since 2010. The European agency has not released the list of drugs, but as the World Health Organization considers drugs with high solubility and high permeability eligible for biowaiver. After applying the eligibility criteria one scientific study was included. This is a narrative review that concludes that patients with Parkinson's disease should be treated with brand name medicines. This study has important limitations regarding the fact that the authors can choose the ones that support their opinion. The peculiarities of patients with Parkinson's disease are presented as an argument, such as reduced gastric motility, affect the effectiveness of generic drugs, similar and reference in the same way. **CONCLUSION**: There is no normative support that point out to differences in safety and efficacy between brand name and generic drugs of pramipexole, and the Brazilian and foreign regulations showed no evidence of bioinequivalence between different formulations of pramipexole dihydrochloride. In addition, scientific evidence of quality was not found, as precepts the evidence-based medicine, that pointed to differences in clinical effect between the presentations studied.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Assessment of new technologies in Brazil: advances of CONITEC in the last three years

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Keywords:
Brazil, CONITEC, health technology assessment, transparency and access

INTRODUCTION: In 2011, Federal Law 12.401 established the National Committee for Health Technology Incorporation in SUS (CONITEC), defining criteria and deadline (180 days) for evaluation of new technologies and development of clinical guidelines. According to the law, CONITEC's assessment must consider evidences about efficacy, accuracy, effectiveness, safety, economic evaluation and budget impact analysis. The following institutions participate in the CONITEC's recommendations: Secretariats of MoH; CNS (National Health Council); CFM (Federal Council of Medicine); ANVISA (Brazilian Health Surveillance Agency); ANS (National Regulatory Agency for Private Health Insurance and Plans); CONASS (National Council of States Health Secretaries); and CONASEMS (National Council of Municipal Health Secretaries). **OBJECTIVES**: Evaluate CONITEC's performance in the improvement of access to new technologies in the Brazilian Public Health System (SUS). **METHODS**: This is a retrospective descriptive study, based on information from database of CITEC, the previous Commission of MoH, (period 2006-2011) and CONITEC (period 2012-2014). **RESULTS**: In CITEC, the evaluation of 340 technologies was submitted. However 44% were not evaluated; 57% of the technologies evaluated were incorporated into the SUS. In CONITEC, until October 2014, 353 technologies were submitted, 190 evaluated, 25% not evaluated because of non-accordance with the law and the others are still under evaluation. Among evaluated technologies by CONITEC, 61% (116) were incorporated, 30% were not adopted and 9% had disinvestment recommendation. In both scenarios the most of the technologies submitted were medicines (64%). 90% of submissions were assessed during the established deadline. Moreover, CONITEC has already done 97 public consultations, receiving 5.105 contributions. The new technologies available in the SUS after CONITEC's creation have already benefited more than 21 million Brazilians, reflecting more than US$ 1 billion public spending on medicines, devices and procedures, such as: trastuzumab in breast cancer treatment, five biologics for rheumatoid arthritis, palivizumab for RSV infection, HPV vaccine and drug-eluting stents. All the HTA reports are public and available on the internet (www.conitec.gov.br). Other important action developed by CONITEC in 2014 was the First Experts Panel to Prioritize Clinical Guidelines for Rare Diseases. **CONCLUSION**: In just three years, CONITEC has evaluated more than the total evaluated by the former CITEC in its six years of activity. It is important to emphasize that 116 technologies were adopted in this period, increasing at three times the annual average before 2011. The successful experience of CONITEC is based on the creation of the Department of Management and Incorporation of Health Technology (DGITS) in the Secretariat for Science, Technology and Strategic Inputs (SCTIE) of MoH, responsible to give technical and administrative supports to CONITEC; on partnerships developed with 20 universities and teaching hospitals in Brazil; and on international collaboration with institutions and networks such as NICE (National Institute for Health and Care Excellence) and RedETSA (HTA Network of the Americas). As a consequence, in 2014, CONITEC was awarded as one of the main initiatives in the 18th Award for Innovation in Public Management of National School of Public Administration (ENAP), where social participation and transparency were recognized as strengths of CONITEC's initiative.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

Direct cost-benefit analysis to the pharmacotherapeutic monitoring of hypertensive patients in District Basic Health Unit in Ribeirão Preto-SP

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Keywords:
pharmaceutical care, hypertension, cost-benefit analysis

INTRODUCTION: The chronic diseases represent the highest morbidity and mortality rates in Brazil and a large expenditure on outpatient and hospital care. Among them, the World Health Organization highlighted in 2010, the systemic arterial hypertension (SAH) as a risk factor for 9.4 million deaths worldwide annually. In the same year in Brazil, hypertension was responsible for assigning a cost to the Unified Health System (SUS) of approximately R$ 969.231.436,00. However, studies have shown some health technologies as effective in improving blood pressure parameters and control of its complications, among which stands out the Pharmaceutical Care (PC). **OBJECTIVES**: This study aimed at comparing the directly costs related to the therapeutic monitoring of PC to hypertensive patients and analyze the cost-benefit. **METHODS**: This paper is a study of mixed model composed of part retrospective cohort, experimental and pharmacoeconomic. The database comes from a cohort of 104 hypertensive patients in treatment. This population comprises SUS users of a District Basic Health Unit in Ribeirão Preto-SP. Patients were followed for 84 months (2006-2012) with an intervention period (2009), and dedicated a year of PC. We assessed the clinical parameters of systolic and diastolic blood pressure, triglycerides, cholesterol and its fractions, number of appointments (basic, specialized and emergency care) and antihypertensive drugs used. The study considered three periods to analyze the results, before-PC, in PC and post-PC, and the data analyzed by ANOVA1, considering the significance level of 5%. **RESULTS**: There was significant reduction ($p < 0.0001$) in mean systolic and diastolic pressure, before-PC 134 mmHg (130; 139) and 84 mmHg (81; 86); PC 118 mmHg (116; 120) and 75 mmHg (74; 77) and Post-PC 125 mmHg (122; 128) and 79 mmHg (77; 81). The same was observed for overall cholesterol ($p = 0.0188$), with averages of 212 mg/dL (202; 222); 199 mg/dL (184, 215); 199 mg/dL (185; 213), respectively to the three periods. The direct cost analysis reveals an increase of R$ 298.99 to realization of exams and R$ 265.20 on the use of antihypertensive drugs, but this increase was offset by a reduction of R$ 1,651.10 in appointments. This represents a final -R$ 1,086.90 with PC and -R$ 4,445.60 accumulated in three years after discharge of patients (mean -R$ 10.56/patient per year). However, when we include the cost of the pharmacist, it was obtained a cost-benefit ratio, CBR> 1. **CONCLUSION**: The model of PC for hypertensive patients was effective in lowering blood pressure and overall cholesterol, with the trend of maintaining these parameters maintained for 3 years after discharge of patient. However, there is a need to compare the CBR to the respective rate found for other health technologies for the treatment of hypertension or to make a more complex analysis costs, including complications of the disease. Therefore, an economic justification to presence of the pharmacist in the monitoring of hypertensive patients is possible.

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RESUMO DE ARTIGO
ABSTRACT ARTICLE

NPS MedicineWise experience with HTA evidence dissemination

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Keywords:
quality use of medicines, national behaviour change programs, academic detailing

INTRODUCTION: In Australia, proven health technologies are subsidised by Government and available through the Pharmaceutical Benefits Scheme (PBS) for medicines and the Medicare Benefits Schedule (MBS) for medical tests and services. NPS MedicineWise is a not-for-profit organisation that develops national programs that synthesise, contextualise and disseminate health technology assessment (HTA) evidence, aiming to enable the best possible decisions about medicines and medical tests by health professionals and consumers, and thereby improve health technology implementation and consequent health and economic outcomes. **OBJECTIVES**: To assess the benefits of a nationally coordinated approach to HTA evidence dissemination. **METHODS**: For each NPS MedicineWise program, a range of activities were implemented to deliver program messages to health professionals and consumers. Educational facilitators based in local areas conducted face-to-face visits (academic detailing) with general practitioners (GPs) and small group case study discussions. Clinical audits with feedback were available to help GPs reflect on their practice. Information resources on health management and decision aid tools were distributed to support good decisions by health professionals and consumers. Awareness, skills and knowledge change of consumers and health professionals were measured in national surveys. Interrupted time series analysis was used to assess the association between GP participation in NPS programs and PBS and MBS utilisation and expenditures, controlled for underlying trends, seasonality, autocorrelation, and medicine price changes. Cost consequence analysis was undertaken to articulate downstream benefits from programs. **RESULTS**: In the last 4 years NPS MedicineWise implemented several national programs each year to improve medicine and medical test use including, for example, for the management of diabetes, cardiovascular risk, stroke, dementia, low back pain and vitamin D testing. Each year about 50% of GPs in Australia actively participated in at least one NPS program. In 2014, 98% of GPs were aware of NPS MedicineWise and 94% trusted it as a source of information about medicines. In 2014, 26% of consumers who used regular medicines were aware of NPS MedicineWise and of those who were aware, 65% rated it as a good or very good source of information. Active GP participation in NPS MedicineWise programs was significantly associated with positive changes in prescribing and medical test referral rates in accord with program objectives. For example, national level changes were achieved for metformin (7% increase), high dose statins (6% decrease), clopidogrel (12% decrease), cholinesterase inhibitors (10% decrease), low back CT scan (15% decrease), and vitamin D testing (12% decrease). Over the last 4 years, programs have demonstrated savings to PBS over US$ 60 million per year, easily outweighing the cost of the programs. Cost consequence analysis for the 2008 diabetes program modelled that over 10 years 477 cases of lower extremity amputations, 950 cases of cataract extraction, 2,602 cases of major cardiovascular events and 1,529 cases of retinopathy or nephropathy will be avoided due to improved glucose control as evidenced by HbA1c improvements. **CONCLUSION**: National programs improve evidence-based health technology use and yield significant health and economic returns on investment for the funders of health technology.

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