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**MINISTRY OF HEALTH**

# Health technology assessment: A selection of studies supported by Decit

**BRASÍLIA - DF**

2011



**MINISTRY OF HEALTH**  
**Secretariat of Science, Technology and Strategic Inputs**  
**Department of Science and Technology**

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# Preface

This publication's aim is to offer, to those interested in the growth of Health Technology Assessment (HTA) in Brazil, a sample of the studies supported by the Ministry of Health since 2005. It also complements existing information systems - Pesquisa Saúde and the REBRATS Information System (SIS-REBRATS), which are regularly updated and improved and are available for consultation on the Internet: ([www.saude.gov.br/pesquisasaude](http://www.saude.gov.br/pesquisasaude); [www.saude.gov.br/rebrats](http://www.saude.gov.br/rebrats)).

This publication is a product of the Brazilian Network for Health Technology Assessment (Rebrats), an initiative of the Ministry of Health that is carried out through the Department of Science and Technology. Rebrats is a network of institutions that act with the goal of promoting and spreading HTA throughout Brazil. Its guiding principles are quality and excellence in the relationships between research, policy and management during the diverse phases of assessing technologies (incorporation, dissemination, relinquishment), in the appropriate time and context for which the care is given.

The publication begins with an introductory chapter that explains the process adopted by the Ministry of Health in recent years in order to support HTA studies through public calls. Further on, a selection of concluded studies are presented, in addition to projects that are in development. Making use of the process that has been adopted, the document presents a series of analyses done on various grievances, considering different types of technologies and the most varied methods. The project coordinators were invited to collaborate on the present edition. Therefore, the opinions expressed in this document are entirely those of the authors.

Due to the diversity of this subject and the dynamics of the health area, the content is frequently updated on the SIS-Rebrats website, which should be consulted frequently. It is hoped that this publication be used in management processes involving health technologies. The Department of Science and Technology invites Unified Health System managers, as well as others who are interested in this area, to contribute to its constant improvement.



# Introduction

In recent years, a continuous rise in health costs has been observed in parallel to an ever greater production of new technologies. However, this increase in supply has not necessarily increased the benefits to society, benefits which society still might enjoy if there were a rational use of these technologies.

Health technology assessment (HTA) is a continuous process of analyzing and summarizing the potential health benefits and the economic and social consequences inherent in employing certain technologies, while considering the following aspects: safety, accuracy, efficacy, effectiveness, costs, cost-effectiveness, aspects of equity, and the ethical and cultural and environmental impacts involved in their utilization. These dimensions require a multidisciplinary perspective when making analyses, involving diverse disciplines such as epidemiology, statistics, economy, engineering, medicine, among others.

Due to this diversity of analysis and the specificity demanded in some cases, the Ministry of Health, through the Department of Science and Technology (Decit), adopted a model that allows for a separation of HTA production into two main areas: (1) internal production elaborated by Decit and (2) external production, by promoting priority projects with teaching and research institutions.

In summary, internal production consists of elaborating rapid response reports (created in one to two weeks) and of rapid reviews (created in up to three months). This production aims to synthesize the best possible evidence available on the use of a specific technology for a specific condition, in such a way as to assist Ministry of Health managers in any decision-making process that needs to be more brief.

Whereas external production, to be presented in detail further on, consists of supporting the development of studies that have HTA themes, such as systematic reviews, economic evaluations, analyses of health technology management, among others. On average, these studies are conducted in up to two years, they involve more complex analyses and require data collection from the services routine, and they can also assist in the future internal production of rapid reviews.

In a more operational way, external production conducted by Decit in the HTA area has become consolidated in recent years through five stages: (i) identification; (ii) prioritization; (iii) promotion; (iv) monitoring; and (v) dissemination). As described in the following, these activities were guided by the approximation of the Unified Health System's (SUS) managerial needs with the studies supported by Decit.

Particularly in Brazil, managers have indicated difficulties in adopting research results from studies conducted in other contexts since they are based on health system realities that are different from Brazil's. Additionally, managers do not have a skilled technical teams at their disposal that are able to identify potential publication biases and critically evaluate the published scientific information.

Literature shows that managers are interested in defining assessment priorities, and in participating in some phases of developing research projects in order to be able to use results in a timely manner and in an a way that is appropriate to the real health policy context.<sup>2 3</sup>

The promotion stages adopted by Decit were created based on the premise that interactive processes favor appropriation and cooperation among managers and researchers in order to formulate health policies and studies.

In this way, a lot of measures to promote HTA studies exist. The present text presents the strategy of thematic bids on health technology assessment, carried out in partnership with the National Council for Scientific and Technological Development (CNPq) of the Ministry of Science and Technology (MST).

## Identifying HTA topics

Identifying the need for studies is the beginning of the process for supporting HTA research. This stage is heavily influenced by the SUS's constitutional bases, mainly by the State's duty to offer universal and equity access to health services. Considering the dynamism of the system and the innumerable research possibilities that can be developed involving health technologies, it is important that HTA studies be directed towards specific questions that involve decision-making processes in the SUS.

In recent years, Decit has adopted two processes for identifying HTA topics: one active and another passive. The active process consists of conducting meetings with the strategic areas of the Ministry of Health that are involved in the decision-making process regarding the offer of technologies in the SUS. Standing out among them is the Commission for Health Technology Incorporation and health care sectors (such as primary care, middle and high complexity and pharmaceutical care). In these meetings, taking into account the planned budget for the period and subsequent stages, certain information is considered: the technology to be evaluated, the population covered, the importance of research to the SUS, the evidence available, the type of study necessary and other information, when available.

The passive process of identification consists of receiving research requests through administrative lines coming from diverse agents, internal and external to the Ministry of Health and also coming from society. From this process, an electronic request form was created to solicit HTA studies where any citizen can submit a proposal by accessing the HTA page on the Ministry of Health website or on the Brazilian Network for Health Technology Assessment website (Rebrats), for more information: [www.saude.gov.br/rebrats](http://www.saude.gov.br/rebrats)). Upon indicating a bid directed at HTA, the passive process is stimulated by disseminating the possibility of undertaking a study.

Although it is not ideal, the identification process permits that the studies to be prioritized possess different contexts and that they attend to different levels of SUS management (from the federal to the hospital perspective). Approximately 30% of the studies supported come from the passive process. From a future perspective and in harmony with growth in the Rebrats Information System, it is expected that an information system be developed so that this process may be transparent and supervised by society.

## Prioritization of HTA topics

When available, resources for supporting HTA studies are finite and often far beneath what is needed for the analysis of health technologies. For this reason, determining priority studies is essential for an optimized administration of the available research funds.

Based on a survey of the processes and criteria adopted in other countries, and as agreed upon by the agents involved in the identification process, five criteria are considered when determining priority topics:

1. Epidemiological relevance: estimate the magnitude of the problem or disease burden, by employing previously standardized methods. Analysis of the risk factors responsible for the persistence of diseases, injuries or problems.
2. Relevance for services/policies – probability of cost reduction and increased access: refers to the possible alterations, increases or decreases, in the costs generated by procedures/interventions and an increase of access to services.
3. Knowledge phase – a sufficient availability of scientific evidence: refers to the analysis of the availability of quality studies in the area and the need to conduct new studies.
4. Operational viability: calculates and identifies the amount of resources (financial, human and infrastructure) currently available for a group of diseases and injuries, for a specific disease, or for risk factors.
5. Social/judicial claims – State pressure: refers to analyzing the existence of political pressure (associations of disease carriers, researchers, Public Ministry, Judiciary, international organizations, Mercosur countries, etc.) and judicial actions so that a given technology be evaluated or quickly incorporated. It is also related to analyzing the need to make regulatory decisions regarding the incorporation or exclusion of the technology, in addition to its consonance with the National Priority Agenda in Health Research.

These criteria and the topics identified in the previous phase are worked through a matrix, in order to identify previously attended topics and duplicate requests. This information is synthesized and presented in annual prioritization workshops that include the participation of managers and researchers from different regions of Brazil.

The prioritization results, which are submitted to the later stage (of promotion), reveal the transversality of HTA. Considering the International Statistical Classification of Diseases and Related Health Problems, the topics given priority go from the use of technologies for managing infectious and parasitic diseases to the evaluation of factors that influence the state of health and contact with health services.

As it also occurs in other contexts, the prioritization of HTA topics is aligned with the epidemiological profile of the population attended by the SUS, such as the injuries related to aging (cardiovascular diseases), infectious diseases, mental health and external causes (violence, accidents and traumas).

### **HTA promotion**

Decit supports HTA-related research that is carried out by Research & Development institutions, in accordance with SUS management priorities, taking into account the available resources. HTA research promotion is conducted through public calls (to be described below) and through the direct contracting of strategic projects.

At the moment, the Ministry of Health enjoys a partnership with the MST in order to support research projects. This partnership consists of an articulation with MST promotion mechanisms – the National Council on Scientific and Technological Development (CNPq/MST) and the Financing Institution for Studies and Projects (FINEP/MST) – in the operationalization of resources destined to health research that was approved the previous year. In the past few years, in the specific case of HTA, thematic bids were organized in partnership with the CNPq.

Taking advantage of the consolidated experience of the CNPq's promotion mechanisms provides transparency and reliability in the transfer of resources to research groups. The public competition of projects allows for, when properly communicated, the strengthening of emerging academic initiatives and a greater dissemination of resources. This strategy also provided, in 2009, the involvement of resources from the health science and technology sectorial fund.

The necessary administrative procedures for passing resources between executive powers takes time – in order to follow the legal requirements – thus impairing the stages of submitting, evaluating and contracting projects take, on average, a year to be finalized.

The submission stage is relatively short, hampering the elaboration of quality proposals, except for cases of research groups that have a portfolio of well-defined projects. The period provided for the evaluation creates a situation where projects are evaluated by a judging committee which meets for two to three days.

The need to use the resources within the same year does not allow for projects to be adjusted before their contracting. At the same time, the obstacle of using the resource of a specific fund to cover defrayal items or capital (for example, the fact that MoH resources are not destined to pay personal grants), requires additional articulation within promotion institutions in order to guarantee engagement of the resources.

The procedures described above and monitoring conducted by DECIT's technical team and the CNPq minimize the time between receiving research results and the managers' decision-making process.

## Monitoring in HTA

With the goal of uniting the health manager with the research that might guide future decision-making, Decit lists strategic HTA projects that need methodological adjustments, together with the health care areas at the Ministry of Health. The criteria utilized in selecting these projects includes those with a larger budget and those with a greater response pressure by the SUS manager. Normally, monitoring occurs in three moments during the project: the initial phase (adequation of the expected results); intermediary phase (presentation of preliminary results); and the final phase (presentation of final results).

Making the manager aware of research needs, like the liberation of inputs and/or the availability of information, creates the possibility of unanticipated complementary activities by project coordinators, such as changing the way of measuring the results and the form of adherence to parameters for constructing more realistic scenarios. With the involvement of different research groups working on the same topic, it is possible to share experiences and create a certain harmonization between the planned research methods.

Operationally, the activity starts with the detailed analysis and monitoring of these projects by external consultants, by Decit's technical body, by the health care area manager of the Ministry of Health, by the promotion agency (CNPq) and by the coordinators of the research proposals themselves. The analytical process begins with the presentation of the research proposal by the project coordinators, followed by commentaries and suggestions by the MoH's health care area and by the external consultants. Apart from mediating the debate, Decit, in partnership with the CNPq, intercedes in administrative and legal matters.

Concurrently, an administrative survey is done regarding the current state of the projects, such as the clearance of resources, the signing of agreements, institutional pendencies, etc. This propitious activity improves political articulation among the agents involved, once any gaps that are necessary fill before beginning and to carry out the projects are identified.

Through presential meetings, a reduction in the distance between managerial needs and academic interests has been perceived. All the projects that are involved in this activity are altered (to a greater or lesser extent) according to the interests of the health decision-makers, just as the managers release the information and inputs that are necessary to better conduct the study.

To fortify the initial strategy of identifying HTA topics, the participation of the same people in the monitoring and assessment of supported projects creates a better rationalization and guidance of the HTA promotion measures supported by Decit. This way, there is a lesser risk of the research response diverging due to a SUS management need.

## Dissemination of HTA findings and recommendations

In order to minimize a duplication of efforts when producing HTA studies for the SUS, the Ministry of Health disposes of two consultation tools on the Internet: Pesquisa Saúde ([www.saude.gov.br/pesquisasaude](http://www.saude.gov.br/pesquisasaude)); and the SIS-Rebrats ([www.saude.gov.br/rebrats](http://www.saude.gov.br/rebrats)). Pesquisa Saúde contains all the studies supported by Decit, regardless of whether they are related to HTA or not. However, the SIS-Rebrats is exclusively related to HTA. The content available on the SIS-Rebrats site is undergoing permanent evaluation in order to rationally guide the decision-making process involving health technologies.

Additionally, in recent years, a model was adopted for presenting the results of promotion bids, based on the experiences of the International Network of Agencies for Health Technology Assessment. It is expected that the entirety of these reports be systematically organized in a publishing format and by email. Aiming for an international insertion of Brazilian HTA studies, Decit is hopeful regarding the inclusion of concluded studies in the Centre for Reviews and Dissemination's database of University of York.

It is worth mentioning that these initiatives do not substitute the conventional strategies of scientific dissemination, such as publishing in national and international periodicals.

## Final comments

Support for conducting Health Technology Assessment research at the Ministry of Health is guided by the constitutional principles of the Unified Health System, is directed by the National Policy of Science, Technology and Innovation in Health and by the National Policy of Health Technology Management as well as being influenced by the health research promotion model adopted in Brazil in recent years.

Challenges for improving the process are fundamental. It has become apparent that the available information systems need improving in order to better guarantee transparency and agility in the promotion process. Valid prioritization processes should be continued, as well as the participation of SUS users. The implementation of mechanisms is suggested regarding new possibilities for fund raising and for improving administrative processes. Arranging for additional media, such as radio and television, is recommended in order to attain a greater dissemination of information.

Finally, the strategy of MoH support for conducting HTA research, together with other initiatives, will promote the safe and effective use of health technologies, under conditions that are both fair and aligned with the SUS's principles of universality and integrality.

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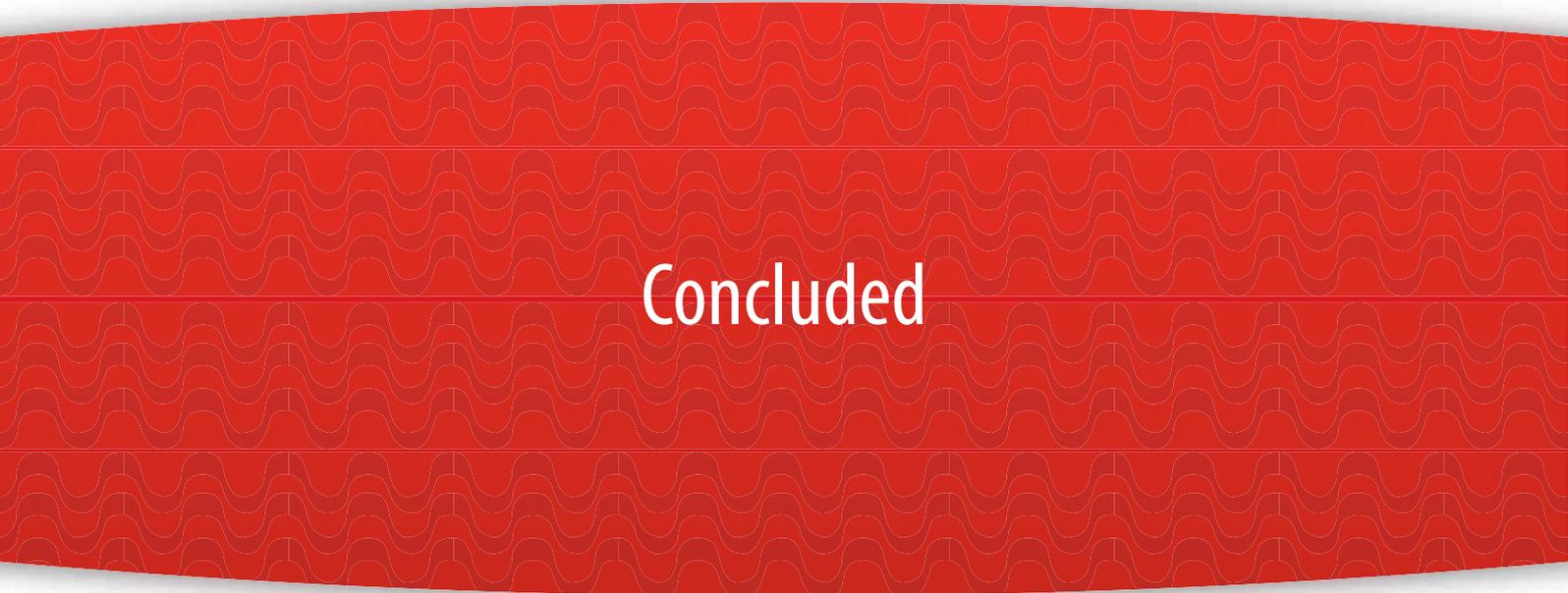
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Concluded

### Access to medicines through the Judiciary Power and its impact on the National Pharmaceutical Care Policy

Maria Célia Delduque (coordinator) e Silvia Badim Marques  
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Fundação Oswaldo Cruz

#### AIM

The overall objective of this study was to assess the political impact of judgments in cases that focus the demand for medicines against the Brazilian State, facing the national drug policy.

#### Methods

This analysis was undertaken in national level, through the survey, data organization and analyses of the judgments, applications and defenses process, of the following Brazilian Courts: Distrito Federal, São Paulo, Rio de Janeiro, Rio Grande do Sul, Pernambuco and Minas Gerais. To draw the panorama of these processes, we sought quantitative results, consistent in describing the profile of the actions and pleadings collected, the medications required, and qualitative results that shows how the actors of these processes - authors, defendants and judges - interpret and defend the right to pharmaceutical assistance in the six Brazilian states here selected. To obtain the qualitative results the Software Statistical Package for the Social Sciences – SPSS was used. It is noteworthy that the team chose to use this Software because it allows a good organization and systematization of the data, in addition to enable finest crossovers between the selected variables. The qualitative results were obtained from the use of the methodology “Collective Subject Discourse”, able to demonstrate all the speeches presents in the court cases. This methodology allows us to identify the central ideas and key phrases that exist in each process for, lately, build unique speeches for each main idea identified, capable of grouping together the entire group of processes.

#### Conclusions and results

It was observed that the panorama of judicialization of the drug policy in Brazil is complex, with different characteristics in each state of the Brazilian federation.

For example, while in Sao Paulo and Pernambuco predominate actions proposed by private lawyers, in Rio de Janeiro and Distrito Federal predominate, mostly, actions represented by the Public Defender of those States. The central idea more frequent on the discourse of the judges was that the “Constitutional right to health must be guaranteed comprehensively for all Brazilian citizens, through positive benefits of the State, despite of the policy, administrative and budgetary issues. This demonstrates that the jurisprudence needs to advance to understand public policy as fundamental part of the right to health. We conclude that there was impact on public policy of drugs, because the medicines mostly demanded on the processes (Humira, Enbrel, Insulina Lantus, Remicade, AAS, Mabthera e Sinvastatina), 78,3% were not included in the rol of drugs available on the public health system, through clinical protocols. And among these drugs, 79,3% were not included also in the rol of essential drugs – RENAME. However, it is emphasized that 47,4% of the medicals prescription that support the judicial applications of these drugs were from doctors of the Public Health System. This demonstrates that, in almost half of the requests of the drug demanded by the Judicial Power, the author of the action was attended by the Public System, that prescribed a drug that wasn't included on the public politics.

#### Recommendations

It is recommended, from this study, the creation of permanent spaces of dialogue between public managers, prosecutors, public defenders, judges and civil society organizations, so all those involved in this conflict can join efforts to guarantee the right to health harmonically. And, also, those public managers can hear, through other channels, society's demands for drugs, update their official lists of drugs more regularly, and exchanging information that enable them to act before a lawsuit is filed. The study highlights the importance of creating judicial branches that are specialized in health, as well as training of judges in health law. That it is necessary so that judges can respond the judicial demand for drugs in a more consistent way with the policies established, and with the issues involving the Brazilian public health. And we stress the importance of the awareness of medical professionals regarding their prescribing practice, in an effort to know the alternatives of public health before prescribe a drug to a patient.

## Diagnostic Accuracy of Positron Emission Tomography (PET): results of a systematic review on melanoma, Hodgkin's disease and pulmonary carcinoma

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### AIM

Review the current state of knowledge about the clinical applications of Positron Emission Tomography (PET-scan) in oncology; draft a cost-effectiveness study on the technology in specific clinical indication, to be financed by the Brazilian Ministry of Health; systematize the findings of a panel of experts, in order to aid the decisions of the Ministry on the incorporation of PET-scan tables for reimbursement of the Unified Health System (SUS).

### Methods

We conducted a survey and synthesis on technology assessment in the public domain already implemented by Health Technology Assessment international agencies belonging to INAHTA. There were four systematic reviews on the accuracy and impact of clinical management of PET in therapeutics for the following neoplasm and applications: (1) staging, assessment of therapeutic response and assessment of recurrence in non-small cell lung carcinoma; (2) staging, assessment of therapeutic response and monitoring of recurrence in Hodgkin lymphomas; (3) detection of local and distant metastases in melanoma. We searched Medline, HealthSTAR, BIOSIS, and CancerLit databases until August 2004. Inclusion criteria were: experimental or observational studies using dedicated PET systems and with radiopharmaceutical  $^{18}\text{F}$  fluoro-2-D-glucose ( $^{18}\text{F}$ FDG); with 12 or more patients, where the results observed with PET and other imaging methods under comparison were confronted with the results of

the gold standard; publications in Portuguese, English, Spanish, and French. The selection of abstracts, full text assessment and data collection were conducted by two independent reviewers, with disagreements resolved by a third reviewer. The methodological quality assessment was based on the criteria proposed by the Cochrane Methods Working Group on Systematic Review of Screening and Diagnostic Tests. For data analysis, the papers were classified according to the hierarchical model of diagnostic effectiveness by Fryback and Thornbury: diagnostic accuracy, efficiency in handling the diagnosis and treatment; impact on health outcomes and societal efficiency.

### Conclusions and results

The evidence showed that PET-scan was helpful in the evaluation of distant metastases in melanoma, but presented low sensitivity to detect microscopic and premature metastatic disease. In Hodgkin lymphomas, it was accurate for the initial staging, evaluation of treatment response and detection of preclinical relapse. In lung carcinoma, evidence was enough to suggest the PET as a recommended test for tumor staging and at a distance; in the evaluation of mediastinal extension, however, data were less conclusive, although its accuracy is consistently considered superior to conventional image methods. Studies evaluating the impact on health outcomes from the use of PET-scan were extremely scarce in all neoplasms examined. Review of cost-effectiveness studies on the use of PET-scan in lung cancer pointed to its potential to produce resource savings due to the reduction of unnecessary or avoidable surgical procedures, and may result in reduced morbidity and improved quality of life for patients.

### Recommendations

Local economic assessments were recommended, in order to support the processes and decisions concerning the incorporation of technologies in the country, especially in the public health system.

## The treatment of rheumatoid arthritis with biological agents in the Brazilian Unified Health System (SUS)

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### AIM

To present clinical evidence and economic information about the treatment of rheumatoid arthritis with adalimumab, etanercept and infliximab in a University Hospital of the Brazilian public health system (SUS).

### Methods

Systematic review of randomized trials and meta-analysis of effectiveness by measuring the absolute risk. A systematic review of cohort studies assistencial registry to complement the decision making model. To estimate the annual spend on acquisition of anti-TNFs. To start the data mining of Datasus from São Paulo State, in the last decade, for a retrospective cohort of patients with the disease in the use of anti-TNF to get information on clinical events and associated costs.

### Conclusions and results

Twenty-three randomized trials met the eligibility criteria, including six on infliximab, nine on adalimumab and eight on etanercept. Adalimumab and etanercept show benefit only when combined with methotrexate. The ACR50 response had similar results with NNT = 6 (95% CI 5 to 8) to infliximab, and NNT = 5 (95% CI 4 to 6) for adalimumab and etanercept. The ACR70 response was seen more favorably with adalimumab NNT = 8 (95% CI 6 to 10), followed by infliximab 10mg/kg with NNT = 9 (95% CI 7 to 13), etanercept, NNT = 10 (95% CI 7 to 16) and with infliximab 3mg/kg NNT = 12 (95% CI 9 to 20). The annual cost was estimated from the average value of the acquisition of anti-TNFs in the last three years by the Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, considering that spending on the acquisition

of biological agents corresponds to the main costs over one year of patients follow-up. To get a response of 50% improvement in a single patient is necessary to treat six patients with annual cost of infliximab R\$ 272,154.24, five patients with adalimumab for R\$ 280,486.25 or five patients with etanercept for R\$ 365,107.60. The more favorable clinical response evaluated by ACR70 showed that infliximab with the largest annual expense, only the dosage of 10mg/kg showed similar results with the other two anti-TNF in the amount of R\$ 1,224,694.08. Adalimumab was the anti-TNF with the most favorable response, being necessary to treat 8 patients with expenditure of R\$ 448,778.00 to get the response in one patient, and 10 patients with etanercept in the amount of R\$ 730,215.20. The study of spending on intervention and assistance care related to the frequency of clinical complications and comorbidities of patients with RA will be done in the data warehouse Minersus, loaded with DATASUS data of São Paulo State, through the retrospective cohort of 31,358 patients with RA identified, of which 3,275 treated with anti-TNF. Developed in parallel an study to assess the methodological quality of the original articles retrieved in the systematic review that presented their conclusions based on clinical outcome, compared with the quality of which are based on surrogate outcomes. It was developed a review of patient preferences and shared decision making with the objective of implementing the patients' compliance to anti-TNF, to support the development of an specific tool. The expected product is the value attributed to health status by patients with RA based on their preferences and cultural values.

### Recommendations

Information obtained by the measure of absolute risk allows someone to compare and estimate directly the annual spending with the 3 anti-TNF available in the SUS.

### Further research/review required

Data mining of health care information from SUS to generate retrospective cohorts for the study of benefits and costs of identified patients with rheumatoid arthritis, treated with anti-TNF.

### Impact of lawsuits on the National Pharmaceutical Care Policy: clinical management and the medicalization of justice

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#### AIM

Investigate the phenomenon of judicialization in pharmaceutical care as an instrument for ensuring access to public health system in Brazil linking it to events observed in the Unique Health System (SUS) in the state of Minas Gerais in the period 1999 to 2009. Specific goals: a literature review, identify evolution, nature, values and spending trends of lawsuits and possible technological innovations incorporated through the courts.

#### Methods

The literature review for developing the conceptual framework was done through a systematic search on the internet in search of specialized sites. All the same happened to review the regulatory framework of pharmaceutical care in Brazil on the websites of Ministry of Health and the State Bureau of Health of Minas Gerais. Case study was based on data contained in administrative files of judicial actions and demands for health services under the State Bureau of Health of Minas Gerais (SES/MG). The search was performed by applying a specific form developed by the team of researchers from GPES/UFMG and subsequent multivariate analysis.

#### Conclusions and results

The database identified 6,184 administrative files containing 14,220 applications, of which 11,296

are for medicines, and 2,924 for materials and procedures, with 6,967 beneficiaries. 60.7% of court orders were delivered, 11.7% had suspended its delivery, 3.1% were dismissed and 4.8% had no final court decision. 67.9% of cases were filed in State Court of first instance, 16.5% in the Superior Court of Minas Gerais, 15.6% assigned to federal authorities. 65.7% of the lawsuits are ordinary; 25.4% writ of mandamus. 48.0% were filed in the State Capital. 18.8% are retired, 53.2% are women. 55.4% have lawyers. 6.4% of the diseases relate to rheumatoid arthritis and diabetes mellitus. The amount spent on litigation in 2002 was 250 thousand reais and 44.4 million reais in 2008 (value upgraded by the Consumer Price Index Broad - IPCA).

#### Recommendations

The analysis of the database allowed the construction of beacons for evaluating a set of variables related to judicial orders. It is hoped that the continued partnership between SES/MG and Minas Gerais Federal University expand the use of records of lawsuits as a resource for research on actors and actions involved in the phenomenon of legalization of health.

#### Further research/review required

New discoveries will happen through study with the purpose of evaluating access, coverage and quality of pharmaceutical services, from court decisions in the face of state management of the SUS/MG, which was selected in the Public Notice 09/2009-PPSUS, Foundation for Research Support of Minas Gerais - FAPEMIG.

#### Reference

ANDRADE, E. I. G. et al. A judicialização da saúde e a política nacional de assistência farmacêutica no Brasil: gestão da clínica e medicalização da justiça. **Revista Médica de Minas Gerais**, Belo Horizonte, v. 18, p. 46-50, 2008.

## Cost-effectiveness analysis comparing different therapeutic interventions for urinary incontinence among elderly women

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### AIM

The general objective of this study was to comparatively evaluate the cost-effectiveness of two different therapeutic interventions for women aged 60 years or over with urinary incontinence due to bladder hyperactivity: drug therapy using tolterodine LA (4 mg) versus physiotherapy for urological dysfunction (intravaginal electrostimulation).

Specifically, the intention was to estimate the comparative effectiveness of these interventions in a group of Brazilian elderly women, in terms of the number of weeks for which these elderly women remained continent and any adverse effects from the interventions under comparison, and to assess the efficiency of the most cost-effective intervention for Brazilian realities.

### Method

The group that was studied was composed of all the women aged 60 years and over with a diagnosis of urinary incontinence due to bladder hyperactivity, who were followed up at the geriatric urology outpatient clinic of the Geriatrics Service, Pedro Ernesto University Hospital (HUPE), State University of Rio de Janeiro (UERJ). To answer the research question, the study was composed of three modules: an analysis on the effectiveness of the interventions, an assessment on the costs involved in each intervention and a comparative cost-effectiveness analysis (decision analysis) between the interventions. All the women with a complaint of involuntary loss of urine were evaluated and underwent a urodynamic examination. The women who received a diagnosis of urinary incontinence due to bladder hyperactivity were assessed with a view to providing treatment. Two randomly groups

were created by means of random division: a group to be treated with drugs and a group to be treated with physiotherapy. The exclusion criteria used in the study were that women presenting the following were excluded: dementia; acute-angle glaucoma; gastric or urinary retention; or hypersensitivity to medications.

### Conclusions and Results

The cost-effectiveness relationship was assessed comparatively for two different therapeutic interventions among women with a diagnosis of urinary incontinence due to bladder hyperactivity: drug therapy using tolterodine LA (46 patients) and physiotherapy for urological dysfunction (33 patients). The women were all aged 60 years or over and were followed up at the outpatient clinic of the Geriatrics Service, Pedro Ernesto University Hospital, UERJ, taking into consideration any adverse effects from the interventions and the number of weeks for which the elderly women remained continent. After data gathering and analysis, the physiotherapeutic intervention was found to have a lower cost than shown by the drug intervention, with better effectiveness, thus suggesting that the physiotherapeutic intervention presented better performance.

### Recommendations

It is important to continue with this project, with a view to carrying out other studies and developing control and rehabilitation programs for urinary incontinence among elderly women attended within the National Health System (SUS), starting from skills training for human resources.

## Economic analysis and influence on cardiovascular morbimortality of statins and fibrates used to treat patients with dyslipidemia in Ribeirao Preto-SP

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### AIM

The objectives of this study were to perform an economic analysis and the influence of atorvastatin, simvastatin, bezafibrate or ciprofibrate on the cardiovascular morbimortality in individuals who used these drugs during the year of 2007, dispensed by the Outpatient Pharmacy of Clinical Hospital of FMRP-USP.

### Methods

This is an observational and descriptive study of transversal character. The sample was composed of 332 (31,11%) individuals, randomly selected among 1067 patients (standard error of 5%), of both sexes, living in Ribeirão Preto-SP conveyed by the Single System of Health (SUS) and private clinics. Individuals were submitted to an interview and had their medical records examined.

### Conclusions and results

Among the 310 patients interviewed, 157 (51%) were males with ages ranging from 15 to 63 years old ( $X = 62,0 \pm 12,23$ ). Five deaths were reported in 2007, and of those patients, 100% were males, with ages ranging from 57 to 74 years old ( $X = 68,2 \pm 6,95$ ). 227 (73,22%) patients were using statins, 54 (17,42%) fibrates and 31 (10%) controls (no use of drugs). The average of body mass index (BMI) of 246 (79,35%) patients evaluated was above 28,7 Kg/m<sup>2</sup>; 121 (39%) patients were using simvastatin, 104 (34%) atorvastatin, 25 (8%) ciprofibrate and 29 (9%) bezafibrate. The lipid profile was more elevated in

atorvastatin and bezafibrate groups. A total of 253 events and/or procedures were found. 132 (52,17%) patients had atherosclerosis documented, 60 (23,71%) angina pectoris, 28 (11,47%) heart failure, 6 (2,44%) acute myocardial infarction, 6 (2,44%) arterial aneurysm, 4 (1,62%) vascular brain accident. Regarding the procedures, 11 cardiac catheterism and 7 angioplasties were verified. Regarding the economic analysis, atorvastatin treatment group showed to be the most expensive one (R\$ 994,69 patient/year). For the simvastatin group (R\$337,61 patient/year), there were increased costs for lab and complementary tests, while among the group of fibrates there were no substantial differences in the cost of treatments. It is concluded that among the evaluated individuals, there was a prevalence of elderly people, deaths of male patients and overweight (BMI > 25kg/m<sup>2</sup>). The presence of atherosclerosis and angina pectoris were the predominant cardiovascular events and the cardiac catheterism procedure was the most performed. Although treatment with atorvastatin was the most expensive, patients in that treatment had a lower incidence of cardiovascular events and procedures, and lower costs with lab and complementary tests.

### Recommendations

The lipid-lowering drugs have an important impact both in relation to clinical and therapeutic aspects for the health of patients with dyslipidemia and financial resources of the health system that offers. Determining the efficacy of treatments and procedures is of fundamental importance, because the economic resources are limited and thus, the social priorities should be established. Pharmacoeconomics studies provide information for better choice of technology available, helping institutions to direct their efficient financial resources in a fair manner without harm to society.

### Reference

SOCIEDADE BRASILEIRA DE CARDIOLOGIA. Departamento de Aterosclerose. IV Diretriz Brasileira sobre Dislipidemias e Prevenção da Aterosclerose. **Arquivos brasileiros de cardiologia**, São Paulo, v. 88, supl. 1, p. 2-19, 2007.

## Evaluation of the effectiveness of tuberculosis control actions, comparing the care model of the Family Health Program, basic health units and a renowned tuberculosis clinic in the city of Campina Grande/PB

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### AIM

Evaluating the Effectiveness of Actions to Control Tuberculosis, Comparing the Care Model of the Family Health Program, Basic Health Units and Reference Tuberculosis Clinic in the city of Campina Grande / PB.

### Methods

Descriptive study, survey, for evaluation of health services with a quantitative approach. The evaluation of the effectiveness of the actions to control TB was based indicators of Health Services: Structure - Process - Result. The primary data were obtained through interviews with TB patients. We administered a questionnaire adapted from the validated instrument to assess attention to tuberculosis proposed by Villa and Ruffino-Neto (2009). The secondary endpoints were obtained through SINAN-NET/PB.

### Conclusions and results

Comparing the health services, Clinics of Reference (AmbRef), Family Basic Health Units (UBSFs) and Basic Health Units (BHU), found that among 81 patients interviewed 40.1% were seen in AmbRef; 56, 8% in UBSFs and 3.1% at UBS. In AmbRef 90.9% did not perform supervised treatment (ST). 6.1% had co-infection TB-HIV and were undergoing MDR treatment. 96.8% managed to answer certain questions with the professionals who attended. In UBSF, 56.5% performed TS, none had co-infection TB / HIV and 8.7% did MDR. 91.3% managed to answer certain questions with the professionals who attended.

## Assessment of the effectiveness of health services providers' management models in tuberculosis (TB) control in cities in the Southern, Southeastern and Northeastern regions of Brazil

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### AIM

To assess the effectiveness of health services providers in diagnosing TB in cities in the southern, southeastern, and northeastern regions of Brazil.

### Methods

A geographical cohort conducted in the cities of Ribeirão Preto, São José do Rio Preto, Feira de Santana, João Pessoa, Foz do Iguaçu, Pelotas, Natal e Rio de Janeiro. Data were collected from primary sources (interviews) and secondary sources (Information systems), using a questionnaire based on The Primary Care Assessment Tool (MACINKO; ALMEIDA, 2006) which was adapted for TB care assessment in Brazil (VILLA; RUFFINO NETTO, 2009). Indicators of structure – process – outcome for health services evaluation, proposed by Donabedian (1996), Starfield (2002), Tanaka & Melo (2001; 2004) and Hartz (2006), have been constructed.

### Conclusions and results

The study has found that the first health care provider sought for TB diagnosis was an emergency service (PA-Brazil). However, both the PA's and primary care service providers have been found not to be effective to suspect or require the proper exams for TB diagnosis and most of them referred the patients to specialized services providers (TCP's- Tuberculosis Control Programs) and hospitals, where most diagnosis were made. Such result may have contributed to the high number of times the patients have had to visit a health care facility, which has resulted in a longer time for diagnosis. It is noteworthy that seeking stages and formally ingressing the primary care service system does not necessarily represent a condition to use it. Although decentralization of TB suspects screening to Primary care level has been recommended, the actions are concentrated at levels where technology is higher and there is a greater offer of diagnostic exams. The traditional model (TCP) remains as the major diagnostic service and is responsible for continuing treatment. Its greater effectiveness may be associated to the quality of reception, availability of exams, and qualification and commitment of professionals.

### Recommendations

The results found in this study have allowed us to show how incorporation of TB diagnostic actions has been occurring at several health care facilities in the studied cities. Although the health system management model (based on traditional health care facilities or on the Family Health strategy) and TB control actions provision (centralized or decentralized) are different, it is necessary to invest in permanent education of health staff and in the improvement of conditions of health care services and TB diagnosis access.

### Further research/review required

To deepen studies on the specific care technologies of TB diagnosis and treatment, by integrating them it other attributions and abilities of the Primary Health Care (PHC) and promoting co-responsabilization of the different services of health care for the diagnosis and accompaniment of cases, as well as guaranteeing laboratorial support in the service that takes care of TB suspects and cases. Moreover, at a first moment it is necessary a specialized approach integrated to the PHC services as solution to reach and to promote the opportune diagnosis and treatment of the disease.

## Evaluation of quality of life, anxiety and depression in women with breast cancer during chemotherapy treatment

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### AIM

To evaluate the quality of life, anxiety and depression in women with breast cancer during chemotherapy treatment.

### Method

The study included women diagnosed with breast cancer undergoing first chemotherapy treatment. The European Organization for Research and Treatment of Cancer EORTC QLQ-C30 questionnaire and the specific module BR-23 for women with breast cancer were used to evaluate the quality of life. The Hospital Anxiety and Depression Scale (HADS) was used to assess anxiety and depression.

### Conclusions and results

79 women diagnosed with breast cancer were included, assisted at the Outpatient Mastology of the Department of Gynecology and Obstetrics, located at the Clinical Hospital of the Ribeirão Preto Medicine School, University of São Paulo (HCFMRP-USP). The age of them ranged from 29 to 69 years and the average was 49.3 years, most were married (60.8%), Caucasian (79.7%), and 40.5% had elementary education. Among 39 women submitted to the adjuvant treatment, 59% of them were undergone to lumpectomy. Regardless of whether adjuvant or neoadjuvant

treatment was adopted, it was observed that the Functional Body Image Scale, Symptom Scale Arm and Breast present results which show important compromises with events that continue throughout the treatment. Regarding to quality of life, there was a reduction in indicators of global measure of health, physical function and role performance during treatment, indicating deterioration in quality of life. Anxiety was present in 63.3% and depression in 54.4% of the studied women.

### Recommendations

Results indicate the need for elaboration and implementation of protocols and nursing care, with the purpose of assessment of adverse events and proper management of them.

### Recommendations for research

Proposition of clinical research for validation of proposed protocols.

## Evaluation of the regularity of the information feed in the Public Health Budget Information System (SIOPS) in municipalities of Pernambuco, from 2000 to 2006

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### AIM

The aim of this article was to assess the influence of regional integration of the municipality, its management condition and population size on the regularity of Siops information feeding through the use of Generalized Linear Models, in municipalities of Pernambuco, from 2000 to 2006.

### Methods

The presence or absence of correct transmissions was the variable considered in the evaluation of regularity. The calculation of correct transmissions considered the number of zero transmissions ("failure") and positive transmissions ("success") to the level of intersection of the factors involved.

### Conclusions and results

The population size and Regional Health Management factors were considered significant in regarding municipality correct transmission ratio. There were significant differences between the average delay time of the various Regional Health Managements and municipal administration

conditions, but the final model was not the ideal, not able to fully explain the total variation. Population size and regional integration have an influence on overall percentage of defaults.

### Recommendations

The results indicate that allocation of commitments and management entitlements favors the strengthening of the administration capacity and, consequently, of the information systems. Management conditions and location of the municipalities are not the only factors of influence on the delay.

### Further research/review required

Other factors should be analyzed to obtain a more complete model to explain the variability of the delay on Siops feeding time intervals.

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BEZERRA, Adriana F. B. et.al. Avaliação da Regularidade na Alimentação do Sistema de Informações sobre Orçamentos Públicos em Saúde (Siops) em Municípios de Pernambuco, de 2000 a 2006. **Cadernos de Saúde Pública**, Rio de Janeiro, v. 18, n. 1, p. 45 – 53, jan./mar. 2010.

### Evaluation measurement technology used by the hemoglobinometer Hb-010 (Agabê™) and its possible utilization in the Unified Health System

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#### AIM

To validate portable, low cost, point-of-care hemoglobinometer of Brazilian technology, and evaluate the feasibility of direct hemoglobinometry on different scenarios covered by the Unified Health System.

#### Methods

Validation methodology was based on to compare measurements gathered by the Agabê™ with similar equipment (Hemocue™) and venous lab equipment (CELM-530/550™), in peripheral and venous blood, respectively. It was performed 10h pipette-training focused on to 5 nurses and 11 nurses auxiliars, to standardization of the collecting technique. Afterwards, the Agabê™ was incorporated in the attendance routine of two primary care units (CACM and Family Health Unit Milton Santos), in São Paulo, and in community campaigns of anemia diagnosis, treatment and monitoring in Ilhabela-SP, Santa Luzia do Itanhi-SE and river basin communities over mouth of Amazon River, in Afuá-PA and Macapá-AP. It was performed three measurements: baseline for diagnosis; 6th week, for monitoring; 12th week, at the end of treatment. To whom diagnosis as anemic at baseline, was prescribed iron salt (ferrous sulphate 3 to 5 mg/kg/day for 12 weeks). Moreover, was performed investigation about eating habits in those communities, by quali and quantitative approaches, and healthy eating counseling to health professionals and subjects who participated in the research project. The research project was approved by the ethical committee of the Federal University of São Paulo (nº536/07).

#### Conclusions and results

In the validation phase, the Agabê™ has been presented comparable precision and accuracy

with the Hemocue™ and CELM-530/550™ in both, peripheral and venous blood. The pipette collecting training had been showed volume accuracy and precision variations non superior to 2% and 8%, respectively. It was performed about 3,000 fingerprick collected samples in community campaigns. Anemia prevalences were: 26,4%, in Ilhabela; 22,4%, in Santa Luzia do Itanhi; e 54%, in the Amazon region. The recovery rates were 78,9%, 79% e 60%, respectively. Median hemoglobin evolution pattern during the treatment was positive and similar in all communities despite of regional, economic and cultural differences, suggesting that this strategy could be replicated in different regions of the country. It was estimated anemia prevalence reduction after treatment, by mean recovery rates, assuming that the anemia incidence rate was null in that timeframe. Thus, anemia prevalences were reduced to 5.6% in Ilhabela, 4.6% in Santa Luzia do Itanhi, and 28.4% in the Amazon region.

#### Recommendations

Consciousness about anemia consequences in the communities, seemed crucial to involve them in the campaigns. Also, the monitoring work performed by the community health agents related to improve eating habits and medication use, was very important as treatment adherence, as well as the results showing hemoglobin improvement of each patient.

#### Futher research/review required

The most obstacle was the 10h pipette technique that is necessary to collect 10µL of the blood sample after fingerpricking. It is necessary an intimacy of nurse professionals with this technique demanding a minimal number of collection to provide trustable results. Next steps to apply this technology, should be focused on training and simplification of collecting technique to be used in the primary care attention, in Brazil.

#### Reference

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COSTA, J.T. et al. Prevalência de anemia em pré-escolares e resposta ao tratamento com suplementação de ferro. **Jornal de pediatria**, Rio de Janeiro, v. 87, p. 76-79, 2011.

## First public Brazilian multi-slices computed tomography (MDCT-CA) compared to invasive coronary angiography (ICA): systematic appraisal, one year utilization review and health care system impact analysis

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### AIM

To assess the cost-effectiveness of the examination of coronary arteries with multi-slice computed tomography, MDCT, compared to invasive coronary angiography in adult patients with suspected myocardial ischemia and uncertain risk of coronary artery disease, CAD, and the economic impact that the adoption of this practice will have, from the Brazilian public healthcare system, SUS, perspective.

### Methods

(1) Systematic review, meta-analysis of sensitivity and specificity, predictive values, accuracy and correlation between the MDCT predictive values compared to invasive c coronary angiography, (2) micro-costing of activities related to coronary angiotomography and conventional angiography and (3) estimate the potential impact of new technology for the SUS. (4) Evaluation of events during follow-up of patients after one year post-indexed diagnostic activities (5) sensitivity analysis.

### Conclusions and results

A noninvasive 64 layers of detectors MDCT coronary angiotomography with can correctly predict 96% of segments without stenosis observed in 628 invasive procedures and correctly identifies 93% of the results obtained by invasive coronary angiography (with higher accuracy than the meta-analysis synthesis: 90 %, with 95% confidence interval from 87% to 93%). In one third of patients with atypical angina with low probability of stenosis, both diagnostic tests correctly identified the

absence of coronary artery abnormalities requiring therapy. The average radiation dose rate was  $19 \pm 6$  milli-Siverts, similar to the sum of mean doses of radiation in routine invasive coronary angiography plus control scintigraphy. During the study, the average direct cost for the operation of MDCT coronary angiotomography was R \$ 420.00 versus R \$ 1,338.00 for invasive coronary angiography (Group a), R \$ 7,000.00 in angioplasty (Group b) and R \$ 23,000 , 00 in coronary artery bypass surgery (group C) and only 20% of women and 35% of men needed to be submitted to myocardial revascularization by angioplasty or surgery within one year of observation. In cases of atypical chest pain with low likelihood of coronary stenosis, the emergency sector could use the MDCT coronary angiotomography and avoid triggering a complex differential diagnosis algorithm to ascertain cardiac ischemic event probability, associated with intense use of resources.

### Recommendations

The optimization of the healthcare process, using a prior noninvasive MDCT coronary angiotomography can avoid to invade > 15% of these cases, about 19,000, "white catheterizations" within the SUS limited installed capacity in order to prevent health risks associated with invasive techniques and to concentrate the use of the Hemodynamic Division for cases with high likelihood of coronary stenosis, leading to increased resolving ratios. With such increment in the therapeutic procedures within the same installations, the direct cost per resolved case decreases of more than 10%, it may prevent waiting times and approximately 2,000 deaths. Under efficient planning, it could open space for increased access to SUS healthcare.

### Further research/review required

Multicenter economic studies of algorithms and diagnostic and therapeutic itineraries can help improve the SUS planning.

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## New therapeutic approaches in brain ischemic injury

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### AIM

Brain stroke is the leading cause of adult disability worldwide. To date there is no satisfactory treatment for stroke once neuronal damage has occurred. Bone marrow-derived mesenchymal stem cells (MSCs) has been useful for functional recovery. This leads to new approach in treatment of brain damage.

### Methods

MSCs were obtained from term human placenta were isolated and analyzed by flow cytometry for presence of mesenchymal and hematopoietic markers. Cell plasticity was evaluated by its ability to in vitro and in vivo differentiation. In vivo plasticity was analyzed in mice by middle cerebral artery occlusion.

### Conclusions and results

Mice treated with MSC had enhancement of structural neuroplasticity from uninjured brain leading to leads to functional recovery after stroke.

### Reference

MARTINI, M. M. et al. A influência do microambiente na diferenciação de células tronco mesenquimais de placenta humana. In: CONGRESSO BRASILEIRO DE CÉLULAS-TRONCO E TERAPIA CELULAR, 5., 2010, Gramado. **Anais de congresso**. Gramado, 2010. 160 p.

## Cariostatic effect and retention of three materials used as occlusal sealants – a two-year evaluation

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### AIM

The aim of this study was to evaluate the cariostatic effect and retention of a resin sealant (FluroShield), a glass-ionomer cement (Vitro-Fil) and a hybrid material (Vitremer), used as occlusal sealants.

### Methods

Eight-six students (6-10 years old) were selected in a public school in Fortaleza/Brazil, whose the four first non-carious molars permanent were erupted. For each child was realized a random distribution to define which tooth would receive which of the four treatments of this study. The control group received no treatment and the others were sealed with the one of the above mentioned materials. Teeth were evaluated using a tactile and visual exam after 6, 12, 18 and 24 months. Data were analyzed using a non-parametric test of Friedman with a significance level of 5%.

### Conclusions and results

After two years there was no difference in carious lesions presence between the four groups tested ( $p=0,528$  in the last evaluation). Carious lesions were detected in 6, 7, 6 and 10 permanent teeth, respectively to FluroShield, Vitremer, Vitro-Fil and control group. Statistical difference was found in retention between the groups ( $p= 0,0001$  in two years) and a high rate of total losses of

sealants (44.6% FluroShield; 98.3% Vitremer and Vitro-Fil). None of the tested materials nor the control group demonstrated a better clinical performance in caries control and the ionomeric materials (Vitremer and Vitro-Fil) presented a lower retention rate than the resin material (FluroShield) after two years.

### Recommendations

Hybrid materials should not be used as occlusal sealants because its low efficacy, high cost and technique sensitiveness.

### Further research

Evaluations still need to be conducted to reveal the longer-term clinical performance of low-cost materials.

### Reference

LIMA, E. M. C. Efeito anticariogênico e de retentividade de três materiais usados como selantes oclusais: avaliação de dois anos. In: REUNIÃO ANUAL DA SOCIEDADE BRASILEIRA DE PESQUISA ODONTOLÓGICA, 23., 2006. **Brazilian oral research**, 2006. v. 20, p. 178.

## Screening program evaluation of uterine cervical cancer in Goiás, biennium 2006 and 2007

Rita Goreti Amaral, Tatyana X. A. Matteucci Ferreira, Luciana Vieira Araújo, César Augusto Rezende, Iraci R. Rezende, Edna J.C. Manrique, Suelene B. N.Tavares, Jeane C. Lopes, Ângela C.N. Lima, Luiz Carlos Zeferino.

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### AIM

Estimate the coverage rate and check the periodicity of its realization, calculate the prevalence of cervical cancer precursor lesions and verify the sample adequacy of the Pap smears.

### Methods

Study based on data from the Uterine Cervical Cancer Information System-SISCOLO in 2006-2007 in the state of Goiás, divided into five geographical regions. The coverage was evaluated by examining the ratio of cervical screening indicator and target population, represented by the total number of cervical screening in the female population 25 to 59 years on the female population 25-59 years. Were also analyzed the variables previous cytology and cytology previous time. The prevalence of lesions was calculated by age group and by regions. The quality of the method was analyzed by the variable sample adequacy.

### Conclusions and results

The coverage of exams in the State of Goiás during 2006-2007 was 0.12, less than half the minimum parameter of 0.3, recommended by the Ministry of Health. The North Central macro-region had the highest ratio (0.15) half the minimum parameter of 0.3, when compared with other macro regions. In some macro regions observed values too low, suggesting the existence of problems in sending information. Regarding timing, it was noticed that in the prior age bracket of 25 to 59 years, the majority was the one year interval, followed by two years, in all macro regions.

The analysis of the frequency in which women had taken the tests was limited by the high percentage of "no information" and "do not knows", reinforcing the need to discuss the quality of information. Regarding the prevalence of injuries, it was observed that in the age group of 25 to 59 years, there was a predominance of atypia of undetermined significance (ASC-US) and low-grade squamous intraepithelial lesion (LSIL) in all macro regions. The percentage of unsatisfactory samples in the state of Goiás remained around 1%. The Midwest and Southwest macro regions have higher rates of unsatisfactoriness approximately 1.3% and in all macro regions the main reason was due to desiccation (inappropriate fixation). A coverage rate below the estimated need and a shorter interval than recommended, problems in data quality, higher prevalence of LSIL and ASC-US and a percentage of unsatisfactory samples could be corrected.

### Recommendations

The results of this research will enable the planning and implementation of corrective strategies, aimed at increasing the coverage of cervical screening, and ensuring quality care for women and promote the training of professionals in the women health care at all stages of screening.

### Further research/review required

To evaluate the effectiveness of using SISCOLO investing in the quality of the information entered into the system to optimize the actions of cervical cancer screening.

## Economic analysis of drug therapy for benign prostatic hyperplasia in the Brazilian public health care system

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### AIM

To perform an economic analysis of drug therapy for benign prostatic hyperplasia (BPH) from the perspective of the Brazilian Public Healthcare System.

### Method

Clinical trials and systematic reviews on drug therapy of BPH with  $\alpha$ -blockers,  $\alpha$ -reductase inhibitors and combination were reviewed. Epidemiological data on incidence, prevalence and natural history were also evaluated. A specialist's panel was carried out with the objective of identifying health resource utilization during acute urinary retention (AUR) episodes and shows an overview of treatment and outcomes of these patients in public hospitals. A Markov model was elaborated using a hypothetical cohort of men over 55 years with BPH and the evaluated outcomes were AUR and surgeries (open and transurethral prostatectomy). Finasteride 5mg/day and finasteride 5mg/day+doxazosin 2mg/day were compared to placebo with time-horizon and adherence rate of the clinical trials. The populations were different within clinical trials used for the two comparisons. Only direct costs were included. The costs of procedures and tests were obtained from reimbursement database of SUS (SIGTAB). Drug prices came from public government database (banco de preços do SUS). The incremental cost-effectiveness ratios (ICER) were calculated for an episode of AUR and surgery avoided. Costs and benefits were discounted at 5% a year and expressed in Brazilian currency (Reais 2010). Sensitivity analysis was conducted to test the strength of the model.

### Conclusion and Results

Finasteride reduced 59.6% of AUR episodes and 57.9% of surgeries compared to placebo in 6 years time-horizon and discontinuation rate of 34%. Average treatment costs were R\$764.11 and R\$579.57 per patient in finasteride and placebo groups, respectively. The ICER were R\$4,130 per AUR avoided and R\$2,735 per surgery avoided. The combination of finasteride+doxazosin reduced 75,7% of AUR episodes and 66,8% of surgeries in 4 years time horizon with a average cost of R\$670.50 and R\$349.58 per patient in combination therapy and placebo, respectively. The ICER were R\$21,961 for AUR avoided and R\$11,980 per surgery avoided. Sensitivity analysis demonstrated that adherence rate and finasteride price influenced the results significantly. The study results suggest that finasteride treatment for BPH is cost-effective over placebo in the Brazilian public healthcare system reality. The combination therapy, although controlled better and faster the urinary symptoms, increased the costs and ICER ratios. The prostatic volume and PSA levels influenced the finasteride's ability to prevent outcomes, with higher efficacy in larger glands. The budget impact of this drug incorporation would depend on the adherence rate, which is low in real world possibly due to adverse effects and drug cost.

### Recommendation

The study results show that drug therapy of BPH can reduce the occurrence of adverse clinical outcomes (AUR and surgery) at a reasonable cost, with clear improvement in quality of life of these individuals.

### Recommendation for research

The lack of data on prevalence, incidence and natural history of BPH decreases the accuracy of economic studies and budget impact analysis results, as well as local data on drug effectiveness in the real world.

## Economic assessment of nucleosides/nucleotides analogous drugs - adefovir dipivoxil, entecavir and telbivudine - in treating chronic viral hepatitis B

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### AIM

Economic and epidemiological assessment in adults with chronic infection by Hepatitis B virus, users of the Ministry of Health's Exceptional Medicines Program.

### Methods

The research included as components: 1. Systematic review of random clinical trials published between 1970 and 2008 in the Medline (Pubmed) databases, in the Latin American and Caribbean Literature on Health Sciences (Lilacs), Cochrane Controlled Trials Databases and NHS Centre for Reviews and Dissemination, to assess the effectiveness of nucleos(t)ides analogous drugs used in treating CHB (ADV, ETV and TBV); 2. cost-effectiveness analysis, from SUS's perspective, of the treatment with ADV, ETV and TBV in relation to the treatment established so far (LAM) for CHB patients, HBeAg positive and negative. Markov's Model was developed with time horizon of 40 years. Costs and benefits were discounted in 5%. Annual rates of disease progression and efficacy of medicine were obtained from the literature. The price of medicines was based on the price list of medicines of the Câmara de Regulação do Mercado de Medicamentos (Board of Regulation of the Medicines Market) and the costs of the stages of the disease were based on the literature.

### Conclusions and results

All nucleos(t)ides analogous drugs presented effectiveness superior or similar to Lamivudine (LAM). Entecavir (ETV) may be indicated to treat chronic hepatitis B (CHB) as an alternative to LAM in

treatment-naive patients HBeAg positive and negative considering its low potential for viral resistance. The addition of adefovir (ADV) to LAM presented good results in patients resistant to LAM. The use of ETV and telbivudine (TBV) in such patients presents low risk of cross-resistance. TBV is one of the most recent antiviral available, but antiviral resistance poses a limitation to its use as a therapeutic option to LAM. Adverse events related to nucleos(t)ides analogous drugs were similar in characteristics, severity and incidence when compared to LAM and placebo. In the economic assessment, when 5.0% discount was applied in costs and effects for HBeAg positive patients, 14.31 AVG was obtained when starting with ETV, which presented cost-effectiveness of R\$3.230,51. For HBeAg negative patients, beginning with ETV resulted in more AVG (12.42), with a difference of 0.35 AVG when compared to patients who started with LAM. ICER was R\$19.882,12 per AVG. Beginning with ADV or TBV proved to be more costly and less effective than with ETV. Starting with ETV when compared to LAM showed ICER within the cost-effectiveness level acceptable in Brazil. For all scenarios suggested, arbitrary selection of the discount rate did not alter the study.

### Recommendations

The eradication of hepatitis B is rarely accomplished, but the benefits of early treatment to suppress the viral load and the resulting reduction of the risk of compensated cirrhosis and hepatocellular carcinoma have consensus in the literature. Therefore, the availability of ETV as part of a strategy of early treatment is economically attractive for CHB patients. The importance of treatment availability is emphasized to improve the patients' quality of life and reduce this disease's economic impact on SUS (National health system), mainly in its more advanced phases.

### Further research/reviews required

The results obtained and future developments of this investigation may contribute towards a decision-making process on the permanence of medicines or the incorporation of new therapeutic alternatives at SUS. The investigation on effectiveness and cost-effectiveness must also include longitudinal observational studies.

## Economic budget impact analysis of simvastatin and atorvastatin versus placebo in the secondary prevention of cardiovascular events within the Brazilian Unified Health System

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### AIM

The objective of this study is to perform an economic evaluation analyzing the treatment with atorvastatin and simvastatin in comparison to placebo treatment, within the Brazilian Public Healthcare System (SUS) scenario, for patients with high risk of cardiovascular disease; analyzing if the additional cost related to statin treatment is justified by the clinical benefits expected, in terms of cardiovascular event and mortality reduction.

### Method

Cardiovascular event risk and mortality risk were used as outcomes. Statin efficacy at LDL-c and cardiovascular events levels lowering data was obtained from a systematic review with meta-analysis. A decision analytic model was developed to perform a cost-effectiveness analysis comparing atorvastatin 10mg/day and simvastatin 40mg/day to placebo treatment in patients with dyslipidemia in Brazil. The target population of this study was a hypothetical cohort of men and women with a mean age of 50 years old and high risk of cardiovascular disease. The model includes only direct costs obtained from Ambulatory and Hospital Information System and Price Database of Brazilian Ministry of Health. The comparative cost-effectiveness analysis itself was done through Excel spreadsheets covering a 5 or 30-years time horizon.

### Conclusion and Results

The result shows that atorvastatin 10mg/day in comparison to placebo has higher cost with

higher effectiveness in the time horizon of 5 and 30 years. The simvastatin 40mg/day appears to be a strategy with lower cost and higher effectiveness in comparison to placebo, in both times horizon analyzed. The budget impact analysis shows that the use of simvastatin 40mg/day, in patients with high risk of cardiovascular disease, leads to a cost minimization in comparison to the use of atorvastatin 10mg/day.

### Recommendation

The treatment with simvastatin is responsible for saving of, approximately, BRL1.1 billion in comparison to treatment with placebo. Otherwise, the treatment with atorvastatin leads to an additional cost of, approximately, BRL118.6 billions in comparison to the treatment with placebo.

### Recommendation for research

It could be useful to compare the results to others studies that performed similar analyses in other countries and how this could be translated into policy implications for others Latin American.

### References

ARAUJO, et al. Cost-effectiveness and budget impact analysis of rosuvastatin and atorvastatin for LDL-cholesterol and cardiovascular events lowering within the SUS scenario. **Int. Atheroscler**, [S.l.], v. 2, n. 3, p. 189-194, 2007.

## Economic evaluation and budget impact of anticytokines adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis in the state of Parana, Brazil.

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### AIM

This study aims contribute to answer the following questions: Have the anticytokines adalimumabe (ADA), etanercept (ETA) and infliximab (IFX) different cost-effectiveness in the treatment of rheumatoid arthritis (RA) in the SUS-Brazil perspective? Are some of these alternative therapies most cost-effective? What is the budget impact to the health system by using these drugs?

### Method

A systematic review was performed for evaluate efficacy and safety of anticytokines for RA, comparing them with methotrexate (MTX). The cost of each drug was calculated based on prices from medicines center of Parana (CEMEPAR) in 2008. For other direct costs involved in treatment, we used the table values of the SIA / SUS MS (Ministry of Heath / Brazil). A Markov model was used relating the effectiveness of each drug to its cost, taking MTX as a control drug. The utility in each stage of treatment was calculated from the values of HAQ (Health Assessment Questionnaire) before and after treatment. We considered a 10 years' time horizon, using cycles of six months. The budget impact of anticytokines in Parana (about 10 million inhabitants) was calculated by creating different scenarios, considering the rate of RA patients receiving anticytokines included in the program of exceptional drugs.

### Results and conclusions

In assessing the cost-effectiveness between MTX and anticytokines the following values were found (R\$ /

QALY): 511,633 for ADA, 437,486 and 657,593 for ETA and IFX. In the analysis of incremental cost (ICER), the ICER (R\$/QALY) of ADA was 628,124 , for ETA 509.974 and 965,927 for IFX. Sensitivity analysis showed that ETA in some situations, had better values of cost-effectiveness than ADA. In budget impact analysis was observed that in 2008 the costs of anticytokine for RA in PR was R\$ 7,502,574, which represents 2.84% of total drugs spending and 5.02% of exceptional drugs spending. Projecting the number of new patients for 2009, we found that would generate an additional cost of approximately R \$ 8,500,000. This information should be evaluated by clinicians and managers to allocation of resources. The incremental cost of each anticytokine to MTX is only one criterion that must be taken into consideration when choosing therapy.

### Recommendations

The three anticytokines are effective in the treatment of RA, but with different efficacy and safety. Therefore, each patient must be evaluated individually. The unfavorable ratio R \$ / QALY and incremental cost found for anticytokines is due to the use of MTX, a drug with substantially less cost than the anticytokines, as an alternative therapy. It is important that the three anticytokines continue to be available to patients, because depending on the response to treatment, there is necessity to change to another anticytokine therapy. There are no direct comparative clinical trials of anticytokine each other. Analysis is needed for cost-effectiveness and incremental cost with reference to the comparison of anticytokine. Others studies focusing on the calculation of costs under a social perspective and including other biologic drugs for RA, expanding the range of possible interventions and comparable, can be achieved.

### References

WIENS, A. et al. Meta-analysis of the efficacy and safety of adalimumab, etanercept, and infliximab for the treatment of rheumatoid arthritis. **Pharmacotherapy**, Carlisle, v. 30, p. 339-353, 2010.

## Economic evaluation and budgetary impact of the treatment of hematological complications of cancer treatment

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### AIM

To evaluate, from a clinical and economic perspective, the effectiveness and cost-effectiveness of the use of CSF and EPO for: 1) CSF in addition to antibiotics for the treatment of febrile neutropenia 2) CSF, antibiotics or observation for the treatment of afebrile neutropenia 3) CSF, dose reduction or dose maintenance for the secondary prevention of febrile neutropenia (i.e. in patients that have developed neutropenia in a previous cycle of chemotherapy) 4) EPO for the treatment of the patients with cancer and anemia.

### Methods

We performed a broad systematic review of the medical literature in many different databases. We searched for randomized controlled trials and systematic reviews that had studied the proposed questions. When adequate, we performed a meta-analysis of the studies. Whenever possible, we performed a cost-effectiveness analysis of each treatment alternative under the perspective of the Brazilian public health system (SUS).

### Results

The use of CSF for the treatment of febrile neutropenia is not linked to a reduction in the mortality rates, according to the performed meta-analysis, that included 12 studies (RR = 0,75; IC95% 0,49 a 1,14;  $p=0,18$ ;  $I^2=0\%$ ). There are no studies that support the use of CSF for the treatment of afebrile neutropenia. For this situation, the use

of antibiotics is associated to a reduction in the rates of hospitalization, according to a published meta-analysis (RR= 0,66; IC95% 0,54 a 0,81). From an economic perspective, oral antibiotics are a cost-saving strategy and should be preferred over observation or CSF. There are no studies to support the use of CSF for the secondary prevention of neutropenia, therefore, the current medical practice (reduction of the chemotherapy dosis of 20%) should remain as the preferencial one. EPO use is not linked to increase or reduction of deaths, when used in patients with  $Hb < 11g/Dl$  and can reduce the rates of transfusion in 36%. From an economic perspective, EPO is a more expensive treatment in SUS. If the price of EPO 10.000UI is set in R\$ 8,03, it can become a cost-saving strategy.

### Conclusion

There is no recommendation for the use of CSF in the treatment of febrile neutropenia, due to the lack of efficacy of it. There is no recommendation for the use of CSF to treat afebrile neutropenia or for the secondary prophylaxis of neutropenia due to the lack of studies. The use of antibiotics to treat afebrile neutropenia is recommended from a clinical as well as an economic point of view. For the secondary prophylaxis of neutropenia, the current medical practice of dosis reduction should continue as the preferred one. EPO use can reduce the transfusion rate, but has no influence in mortality. If the EPO 10.000 UI price is reduced to R\$ 8,03, it can become a cost-saving strategy.

## Interferons alfa pegylated (2a and 2b) and ribavirina for treatment chronic hepatitis C, genotype 1: a cost-effectiveness analysis

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### AIM

A cost-effectiveness analysis and also a budget impact analyses were conducted for treatments indicated to adults infected with type 1 genotype of hepatitis C virus. The use of alfapeguinterferon 2a plus ribavirina was compared with alfapeguinterferon 2b plus ribavirina having non-treatment as baseline

### Methods

A Markov model projected hepatitis C development in a group of 1000 patients for a 30 year period, and for the several states of the disease development

### Conclusions and results

The ribavirina therapies combined with 2a/2b alfapeguinterferon have presented effectiveness statistically identical when evaluated in a 30 year period of the disease development. The treatment strategy with 2a alfapeguinterferon plus ribavirina has been more cost-effective and dominated the alternative treatment. Although, there aren't significant differences of effectiveness between the 2 types of alfapeguinterferon, the price difference between them makes the alternative with 2a alfapeguinterferon plus ribavirina be more efficient. The budget impact for the 2008/2017 period, the use of 2a alfapeguinterferon plus ribavirina results in expense reduction of approximately 19%, if all the patients were treated with all the therapeutic schemes mentioned above. Alfapeguinterferon 2a plus ribavirina has been more cost-effective.

### Recommendations

As there were no significant differences between the effectiveness of the two Alfapeguinterferons, this conclusion is due solely to the price of the drug incorporated into the model. This means that the decision between one drug or another depends on the price being charged. Consequently, the recommendation of the study is that choosing the most cost effective use of Alfapeguinterferon 2a or 2b depends on the price that can be achieved in the acquisition of each of these drugs.

### Further research/review required

The demand for economic evaluations focused on the treatment of hepatitis C is evident in the work undertaken by international agencies of health technology assessment. Interest in the topic is associated with significant rates of prevalence of the disease, which develops from chronic and may progress to severe or fatal, and the high cost of treatment protocols used, which are developing and whose effectiveness and cost can assume a wide variation. Considering the role of the Sistema Único de Saúde (SUS) as the main source of supply of health services, which assumes the universality and comprehensiveness of care, the discussion becomes relevant, in that it is necessary to provide wide range of services for millions of people with diverse needs, with finite resources.

## Cost-effectiveness of treatment of combination therapy of chronic hepatitis C for genotype 1

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### AIM

To estimate a cost-effectiveness analysis of antiviral treatment of combination therapy with interferon or peginterferon plus ribavirin which are indicated to adult patients with chronic hepatitis C for genotype 1, without a previous use of specific medication, in the perspective of Health Public System (SUS).

### Methods

A decision analytical Markov model was used to simulate disease progress in a hypothetical cohort of patients with chronic hepatitis C, genotype 1. The cost-effectiveness was expressed in cost per quality-adjusted year of life saved. Clinical data were obtained from available publish reports.

### Conclusions and results

The therapy using ribavirina with peginterferon vis a vis . interferon, showed an increase of 36% of the patients with sustained virological response, and, at the same time, there was a reduction of 17% in patients with " compensated cirrhosis. Moreover, there was also 15% decrease in deaths

because of hepatocellular carcinoma and other problems associated with the development of this disease. Based on the development of the natural disease, the treatment strategy with interferon plus ribavirin has shown a smaller cost-effectiveness ratio (R\$ 1.925,78 per quality adjusted life year) than the one with peginterferon plus ribavirin. The sensitivity analysis has shown that this result depends directly on the relative price of the conventional interferon and peginterferon. From perspective of SUS, the model simulation has suggested that the treatment of genotype 1 hepatitis C with interferon plus ribavirin is the most probable choice to be cost-effective.

### Recommendations

The result obtained shows the need for a more accurate reflection of the choice of treatment. considering the evolution of hepatitis C in thirty years to a cohort of 1000 patients using the combination of Ribavirin with pegylated interferon provides an estimated gain of 1% (0.33 life years) life years over the use with conventional interferon at a cost 94% higher.

## Life cycle of medical equipment in health care establishment

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Santa Catarina Federal University

### AIM

To develop methodology for evaluating the life cycle of medical equipment of the establishment of health cares.

### Methods

The method define the life cycle of medical equipment through the indicator of life index, which proposes the use of a numerical result for prioritizing and recommending the replacement of equipment, obtained from the weighted sum of attribute values and using the multiparametric methodology.

### Conclusions and results

Based on the methodology developed to determine the life cycle and the data collected in hospitals of Santa Catarina, it was found that 45% of medical equipment is in the stage of beginning Life, 38.71% at the End of Life and 16.13% at the Half-Life. The determination the index life of the medical equipment and stages of life, enabled developed a program the management of technology in accordance with the functional status of medical equipment and relation cost-benefit.

### Recommendations

Health managers to make decisions according to the need for medical equipment in hospital and clinical engineers in order to develop programs for managing the lifecycle of health technologies.

Further research/review required

Health technology assessment; Clinical Engineering; Incorporation of health technologies

### Reference

ALBORNOZ, I. et al. Aplicação do fator MEL como metodologia para avaliação econômica durante a vida útil de equipamentos médico-hospitalares. In: CONGRESSO INTERNACIONAL DE INVESTIGACIONES BIOMÉDICAS DEL CARIBE COLOMBIANO, 2. 2006. [Anais...]. Barranquilla, 2006.

JANNER, I. et al. Fator MEL como metodologia para avaliação econômica durante a vida útil de equipamentos eletromédicos. In: CONGRESO DE LA ASOCIACIÓN CHILENA DE CONTROL AUTOMÁTICO, 17., 2007. **Anales ACCA**. Temuco, 2007. v. 1, p. 187-191.

**Patients' cost and the health system cost-effectiveness of different directly observed treatment strategies of tuberculosis control in Brazil**

Anete Trajman, Ricardo Steffen, Marcia Ferreira Teixeira Pinto, Caroline Silveira Santos Cyriaco, Ninarosa Cardoso, Margareth Moita Sá, Andrea Rossoni, Betina Mendez Alcântara Gabardo, Monica Façanha  
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**AIM**

To evaluate costs for patients and their families and estimate, under the health system perspective, the incremental cost-effectiveness rate (ICER) per completed treatment (CT) of the directly observed treatment (DOT) compared to the self-administered treatment (SAT) for increasing tuberculosis (TB) treatment adherence.

**Methods**

We interviewed 479 patients on the second month of bacteriologically proofed pulmonary TB. Direct and indirect costs were computed, as well as additional costs with help for daily tasks. The number of hours lost were multiplied by the hourly wage in Brazil. The estimated hourly wage was 1.31 American dollars (US\$), based on the Brazilian annual minimum wage in 2008, divided by the assumed number of annual hours of work based on a 44 weekly hours of work contract. Average costs were extrapolated to the projected total informed number of DOT and follow-up visits throughout the entire duration of the patient's TB treatment, which was assumed to be 6 months. Healthcare system additional costs for DOT were calculated based on salary of staff responsible for direct observation of treatment, since the same facilities are used for both strategies, during regular working hours, with no additional service costs. Salary information was gathered at the Municipal Health Departments, and doubled, to include Brazilian regulatory costs. The cost of each DOT (pill collection) visit was estimated to be a third of the cost of a patient visit, based on the relative times reported by patients for DOT and medical follow-up visits. The measure of effectiveness was treatment completion rate, since not all patients completing treatment have a bacteriological confirmation of cure. Sensitivity analyses were

performed to explore the degree of uncertainty of the treatment outcomes, the costs of follow-up and pill-collection visits, and the frequency of weekly pill-collection visits.

**Conclusions and results**

Although TB diagnostic tests, consultations and drugs are free of charge in Brazil, costs for patients are high, considering their low income. Higher costs were in Belém, and lowest in Paraná (in Paranaguá, DOT is community-based, which reduces costs with travel and waiting time). DOT costs doubled in Paraná and increased by 4-fold in Belém and Ceará. Most patients' costs were due to lost hours. These high costs for patients may be hampering the targeted 85% cure rate recommended by WHO. Supervision strategies and type of healthcare worker were different: from daily in Paranaguá to 3 times weekly (first two months) followed by twice weekly (4 last months), done by healthcare agents, nurse aids or nurses. DOT increase significantly the rate of treatment completion, with exception to Rio de Janeiro, where it was modest (8% increase). In Belém it was 11%, in Paraná, 23%. The high ICER (US\$ 6616/CT) in Rio de Janeiro, when compared to other states, is due to the modest outcome improvement. The high effectiveness rates in Paraná resulted in the lowest ICER (US\$ 2599/CT). Sensitivity analyses showed robustness of DOT cost-effectiveness, and that the highest impact on ICER was the reduction of frequency of supervision.

**Recommendations**

We suggest other supervision strategies, such as domiciliary supervision by family or a healthcare agent to reduce patients' cost with TB treatment. Further research/review required  
 The cost-effectiveness of domiciliary or home-based treatment by family should be evaluated, as well as monetary incentives to increase adherence to TB treatment.

**Reference**

STEFFEN, R. et al. Patient's costs and cost-effectiveness of tuberculosis treatment in DOTS and non-DOTS facilities in Rio de Janeiro, Brazil. **PlosOne**, [S.l.], v. 5, n. 11, p. e14014, nov. 2010.

## Construction and establishment of a system for data integration and management on percutaneous coronary intervention (PCI) procedures performed in Brazil: a pilot project

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### AIM

Construction and establishment of an integrated multi-center national report system with prospective data capture on coronary angioplasty practice for immediate and long-term clinical evaluation of patients treated with percutaneous coronary interventions (PCI) in Brazil.

### Conclusions and Results

In order to attend to the demand of management, evaluation, and strategies around the practice of Interventional Cardiology under the Unified Health System (Sistema Único de Saúde - SUS) this pilot project, which is part of the Brazilian federal public health target "Monitoring High Complexity Cardiology Interventions", comprised the basic technical construction of an integrated multi-center report system for prospective data capture of patients treated with percutaneous coronary interventions (PCI) procedures performed in Brazil. As of today, this parameterized platform could determine in a preliminary manner, although wide enough, the risk profile and in-hospital outcomes of the 1.249 coronary patients treated by PCI in 8

national centers. In total, 60% were clients from the Unified Health System (SUS), 38% from health insurances and 2% were private clients. Average age was  $63.7 \pm 11.3$  and 65.1% were men. Diabetes was present in 6.1%, 2.0% had prior coronary surgery, and 27% prior angioplasty. Upon admission, 39% were stable and 18% had ST elevation myocardial infarction. At least one coronary stent was used in 93% and one or more drug-eluting stents in 16.2% of the patients. By the official end of this pilot project, patients included in this report system had a mean clinical follow-up of 92.7 days. Total mortality during the first 90 days was 2.5%, without differences between SUS or health insurance patients ( $p=0.5$ ). Specifically, mortality was 0.2% in stable patients, 2.4% in patients with acute coronary syndromes without ST elevation, 6.1% with ST elevation myocardial infarction, and 3.6% in those with angina equivalent.

### Recommendations

The Brazilian report system for national data integration and management of Percutaneous Coronary Interventions (PCI) performed in the country, is compatible to others existing database and may be made available to others potential users (High Complexity Services Assistance enabled in Procedures of Interventional Cardiology of the Unified Health System) and/or to strategic studies of the interest of Brazilian Health Industrial Complex: coronary stents.

### Reference

PAULA, Leonardo J. C. de. Construção e Validação de um Sistema Integrado de Dados de Intervenção Coronária Percutânea no Brasil (Registro ICP-BR): Perfil Clínico dos Primeiros 1.249 Pacientes Incluídos. **Revista Brasileira de Cardiologia Invasiva**, São Paulo, v. 18, n. 3, p. 256-262, set. 2010.

## Conception, Validation and Standardization of the Quality of Life Scale for Patients with Work-related Musculoskeletal Disorders (QoL-WMSD Scale)

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 Federal University of Bahia

### AIM

Develop, validate, and standardize the Quality of Life Scale for Patients with Work-related Musculoskeletal Disorders (QoL-WMSD) to the Brazilian context.

### Methods

Initially, we conducted a systematic literature review using medical and psychological journals, which supported the construction of the theoretical dimensions and descriptors for the construct measurement. Secondly, we accomplished semi-structured interviews with 14 patients affected by WMSD, by seeking to find the descriptors associated with the individual meaning of quality of life. Descriptors and dimensions pertaining to other quality of life measures were also investigated with the goal of finding specific and general characteristics that could contribute to developing the QoL-WMSD Scale. From these investigations, items of the QoL-WMSD scale will be developed and applied in 600 subjects, 100 subjects to North (Manaus), Midwest (Brasilia), Southeast (Rio de Janeiro) and South (Porto Alegre) regions, and 200 subjects to Northeast region (Salvador and Aracaju). As a sample criterion inclusion we selected workers who were away from their work activities according to Brazilian Decree nº 6.042 of February 12, 2007. These workers were diagnosed as belonging to the Group XIII of ICD-10 by the medical expertise of National Institute of Social Insurance. Different techniques of data analysis will be used by combining the procedures of Classical Test Theory (CTT) and Item Response Theory (IRT). By using CTT we will employ procedures of factor analysis to test the construct validity as well as the calculation of Cronbach's alpha to the internal consistency. By using IRT we will do a statistical analysis of item residuals (infit and outfit), differential item functioning (DIF),

structural equation modeling (SEM) and reliability study (item information function - IIF). Finally we will do the scale standardization by geographic regions just as by gender.

### Conclusions and results

As partial results from the content analysis, the descriptors emerging from the interviews were combined with the theoretical descriptors. From a set of 72 descriptors, four dimensions were constituted as follows: 1) Physical Aspects, which includes mobility and locomotion (e.g. edema, pain in specifics locations of the body, mobility pain, intensive pain, lack of energy and fatigue, alteration in sleeping and resting pattern etc.); independency (e.g. relying on others to make activities, have the self-care compromised etc.); 2) Occupational Aspects, which includes possibility of disability (e.g. fear of not being considered capable, fear of being fired because of disability etc.); financial difficulties (e.g. loss or reduction of income, change in pattern of life, need the money of others etc.); stability and safety (e.g. do not interrupt projects, preservation of remuneration and position in company, fear of unemployment, guarantee of the benefits, change the area of expertise etc); 3) Psychological Aspects (e.g. anxiety, depression, feelings of guilt, constant feeling of frustration etc.); 4) Social Aspects, which includes leisure and recreation (e.g. diminution of exits to the street, do not attend to parties etc.), social support (e.g. family support, support of patients with WMSD, spirituality support etc.). An additional sub-scale will be developed to evaluate general aspects of quality of life that were potentially affected by the specific WMSD.

QoL-WMSD is expected to be the first constructed and validated scale that measures of quality of life for patients with WMSD in Brazil.

### Reference

CUMMINS, R. A. Assessing quality of life. In: BROWN, R. I. (Ed.). **Quality of life for people with disabilities**. London: Stanley Thornes, 1997.

## Cost-effectiveness of Interferon- gamma release assays for the diagnosis of latent TB infection: a review

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### AIM

To review studies on the cost-effectiveness of the use of Interferon-gamma release assays (IGRAs) for the diagnosis of latent tuberculosis infection (LTBI).

### Methods

We searched MEDLINE and Scielo databases for studies on the cost-effectiveness of IGRAs. The terms (costs OR cost-effectiveness) AND ("interferon-gamma release assay" OR IGRA) AND "latent tuberculosis" were used on March 9, 2010. Search on list of references of found articles were also carried out.

### Conclusions and results

Fifteen articles were found, 9 were on the cost-effectiveness of the use of IGRAs, one from the list of references was added. None was performed considering high-burden country costs or outcomes, 9 out of 10 were performed in high-income countries. Studied populations (contacts, high-risk for HIV, immigrants from high- to low-incidence countries), screening strategies (IGRA alone, or compared to TST or sequential TST/IGRA), IGRA tests (QFT-G, QFT-GIT and T-SPOT-TB) and effectiveness measures (QALY, number of TB cases averted, number of LTBI cases identified, life-years gained) were heterogeneous.

Overall, IGRA with or without TST was considered cost-effective, although some studies showed advantage in specific situations: BCG vaccinated, high-risk populations for LTBI or HIV, immigrants from high to low-incidence countries.

### Recommendations

There are still few studies on cost-effectiveness of IGRAs, mostly in high-income low-incidence countries. Methods are heterogeneous, which makes generalization of findings difficult, especially for high burden tropical countries, where BCG vaccination is universal and atypical mycobacteria are found, reducing TST specificity.

### Further research/review required

Studies taking into account national parameters and costs are necessary before the use of IGRAs in low and middle income countries can be recommended.

### Reference

STEFFEN, R. et al. A cost-effectiveness of IGRA for the diagnosis of latent TB infection: a review. **Int. J. Tuberc. Lung. Dis.**, Paris, v. 14, n. 11, supl. 2, S126, 2010.

## Patients' cost and health system cost-effectiveness of different observed treatment strategies for tuberculosis control in Brazil

Anete Trajman, Ricardo Steffen, Marcia Ferreira Teixeira Pinto, Caroline Silveira Santos Cyriaco, Ninarosa Cardoso, Margareth Moita Sá, Andrea Rossoni, Betina Mendez Alcântara Gabardo, Monica Façanha  
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 Gama Filho University

### AIM

To evaluate costs for patients and their families and estimate, under the health system perspective, the incremental cost-effectiveness rate (ICER) per completed treatment (CT) of the directly observed treatment (DOT) compared to the self-administered treatment (SAT) for increasing tuberculosis (TB) treatment adherence.

### Methods

We interviewed 479 patients on the second month of bacteriologically proofed pulmonary TB. Direct and indirect costs were computed, as well as additional costs with help for daily tasks. The number of hours lost were multiplied by the hourly wage in Brazil. The estimated hourly wage was 1.31 American dollars (US\$), based on the Brazilian annual minimum wage in 2008, divided by the assumed number of annual hours of work based on a 44 weekly hours of work contract. Average costs were extrapolated to the projected total informed number of DOT and follow-up visits throughout the entire duration of the patient's TB treatment, which was assumed to be 6 months. Healthcare system additional costs for DOT were calculated based on salary of staff responsible for direct observation of treatment, since the same facilities are used for both strategies, during regular working hours, with no additional service costs. Salary information was gathered at the Municipal Health Departments, and doubled, to include Brazilian regulatory costs. The cost of each DOT (pill collection) visit was estimated to be a third of the cost of a patient visit, based on the relative times reported by patients for DOT and medical follow-up visits. The measure of effectiveness was treatment completion rate, since not all patients completing treatment have a bacteriological confirmation of cure. Sensitivity analyses were performed to explore the degree of

uncertainty of the treatment outcomes, the costs of follow-up and pill-collection visits, and the frequency of weekly pill-collection visits.

### Conclusions and results

Although TB diagnostic tests, consultations and drugs are free of charge in Brazil, costs for patients are high, considering their low income. Higher costs were in Belém, and lowest in Paraná (in Paranaguá, DOT is community-based, which reduces costs with travel and waiting time). DOT costs doubled in Paraná and increased by 4-fold in Belém and Ceará. Most patients' costs were due to lost hours. These high costs for patients may be hampering the targeted 85% cure rate recommended by WHO. Supervision strategies and type of healthcare worker were different: from daily in Paranaguá to 3 times weekly (first two months) followed by twice weekly (4 last months), done by healthcare agents, nurse aids or nurses. DOT increase significantly the rate of treatment completion, with exception to Rio de Janeiro, where it was modest (8% increase). In Belém it was 11%, in Paraná, 23%. The high ICER (US\$ 6616/CT) in Rio de Janeiro, when compared to other states, is due to the modest outcome improvement. The high effectiveness rates in Paraná resulted in the lowest ICER (US\$ 2599/CT). Sensitivity analyses showed robustness of DOT cost-effectiveness, and that the highest impact on ICER was the reduction of frequency of supervision.

### Recommendations

We suggest other supervision strategies, such as domiciliary supervision by family or a healthcare agent to reduce patients' cost with TB treatment.

### Further research/review required

The cost-effectiveness of domiciliary or home-based treatment by family should be evaluated, as well as monetary incentives to increase adherence to TB treatment.

### Reference

STEFFEN, R. et al. Patient's costs and cost-effectiveness of tuberculosis treatment in DOTS and non-DOTS facilities in Rio de Janeiro, Brazil. **PlosOne**, [S.l.], v. 5, n. 11, p. e14014, nov. 2010.

## Evidence-based listing decisions in the public health care system in Brazil: cost-effectiveness of the centrifugal pumping compared to roller pump during extra-corporeal circulation in open heart valve surgery

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University of São Paulo

### AIM

To evaluate the Centrifugal Pumps (CP) for the Health Ministry's listing decision. CP is intended to improved blood and air handling and to eliminate over pressurization risk. The arterial pump, coupled to the oxygenator and the cardiectomy suction system, is one of the most critical items of an extracorporeal circuit (ECC). Multimorbid cardiac patients may fail to compensate mechanical blood damage and complications reported with a conventional roller pump use (RP). Complications result in significant impact on hospital budget, subsequent economic burden on society and reduce patients' quality of life.

### Methods

Literature review and two studies were performed in patients undergoing cardiac valve surgery using ECC. Patient's clinical diagnosis, preoperative variables and EuroSCORE risk strata were matched CP 1:2 RP retrospectively or 1:1 in the prospective study; aiming to ascertain hematological and coagulation profile before, during, immediately after ECC and at day 1 and 2 postoperative; use of heparin and protamine, total prime volume, average flow pump, diuresis and blood pressure, complications, hospital resources used, real costs and outcomes.

### Conclusions and results

Retrospectively, there were 83 CP (aged  $53.1 \pm 16$ , 95% CI: 52.3 a 53.8) and 153 RP (aged  $55.6 \pm 14$ , 95% CI: 52.6-58.7) patients analyzed. Mean age, weight and body surface area were similar in both groups; preoperative hypertension ( $\text{Chi}^2 = 0.207$ ), smoking ( $\text{Chi}^2 = 2.115$ ), anticoagulation with aspirin ( $\text{Chi}^2 = 0.913$ ) and UFH with warfarin

( $\text{Chi}^2 = 0.207$ ). The average additive EuroSCORE observed was 6.34 CP group [95% CI: 4.7-7.8] and 5.14 at RP [95% CI: 4.4-5.9], resulting logistic 9.17 EuroSCORE for the CP group and 6.54 in RP group ( $p < 0.03$ ). The prospective validation study included 10 consecutive patients same age range and matched strata with those retrospectively studied, 5 CP and 5 RP undergoing same surgery. There was no difference in the hematological, clotting changes or complications between the groups regardless of the anatomical valve operated or biological or mechanical implants; except for the significantly lower platelet count 1 day after ECC in patients using RP, mostly observed at the highest risk patients and who recovered by the 2nd post-operative day. 90% of all patients were discharged well and improved ( $p > 0.10$ ). There were no adverse events after average 17 months patients' follow-up. In both studies, the aggregate costs were similar excluding the additional cost of the disposable CP device. There was no significant difference in postoperative morbidity or lethality, but high risk patients demonstrated outcomes comparable to those being defined for medium risk patients. Based on these evidences, the Brazilian Health Ministry has listed CP conditional coverage for expected 10% of the surgeries, occurring for high risk patients, e.g. having surgery plan requiring prolonged ECC or having depressed left ventricular ejection fraction.

### Recommendations

Follow-up CP utilization review in tertiary cardiology hospitals and specific indications listings were recommended.

### Further research/review required

Further field economic studies, CP utilization review and indications appropriateness studies are required.

### Reference

MAZZETTO, M. et al. Resultados preliminares da utilização de bombas centrífugas em cirurgias com circulação extracorpórea. In: CONGRESSO BRASILEIRO DE ENGENHARIA BIOMÉDICA. 20., 2006. [Anais...]. São Pedro, SP, 2006. p. 75-76.

## Performance of health services in tuberculosis control

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### AIM

To evaluate the impact of the implementation of DOTS in an indigenous population in the city of Dourados.

### Methods

Retrospective cohort study was performed to compare the treatment default and mortality rate after 9 years of DOTS implementation in indigenous populations compared with non-indigenous population in Dourados. Multivariate analysis was performed using multiple imputations to identify predictive factors of treatment default.

### Conclusions and results

With the implementation of DOTS in this community, we observed a 90% reduction in treatment default and a 64% reduction in the incidence of tuberculosis. In multivariate analysis, HIV positive status (OR 2.47; 95% CI 1.01-6.08) and race-non-indigenous (OR 3.05; 95% CI 1.63-5.69) were associated with treatment default. Despite the success achieved

with the implementation of DOTS, the incidence of tuberculosis in the indigenous population is still more than 10 times higher than in the non-indigenous population; additionally, there have been new cases in children and young adults as well as occurrence of geographically related cases, which indicates continued transmission and maintenance of the epidemic in this community

### Recommendations

To improve the effectiveness of TB control, the NCTP has prioritized the reduction of treatment default rates by increasing adherence to treatment through DOTS. The implementation of DOTS in socially and economically disadvantaged populations, such as the indigenous population in Dourados, showed a significant reduction in treatment default and TB incidence.

### Further research/review required

Future studies should be necessary to verify the impact of DOTS in others indigenous communities.

## Performance and Costs of Virtual Histology by Coronary Intravascular Ultrasound and Multi-Slice Computed Tomography: Comparative Study of Coronary Artery Atherosclerotic Plaque Characteristics

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 São Paulo University Medical School

### AIM

We aim to compare the overall accuracy and cost profiles of Intravascular Ultrasound, IVUS, with Virtual Histology (VH) and noninvasive 320-slice MultiDetector Computed Tomography, 320MDCT, in a per-patient analysis protocol. The IVUS-VH is a new technique with the potential to quantify coronary plaque characteristics. 320MDCT is emerging as an alternative non-invasive method for plaque characterization.

### Methods

Prospective study including established diagnosed coronary disease, CAD, consecutive cases referred for IVUS, MDCT previously evaluated, with minimum two-year follow-up. Endpoints included lumen & plaque parameters, death or major cardiovascular events occurrence. Index procedure and follow-up resources used were estimated through records review. Micro-costing estimate annualized 2008 costs (\$1 US= R\$1.00) are presented excluding honoraria fees. Bland-Altman paired differences and SPSS 10.0 were used for the statistical analysis.

### Conclusions and results

The 68 patients (45 males, mean 59.6 (95% CI: 57.4 – 61.8) years of age) were included from December 2006 to December 2008 and had MDCT before the VH-IVUS examination. Measurements for luminal area, vessel area, arterial wall area (plaque plus media area) and percent plaque burden were significantly correlated (r-Spearman: 0.81; 0.78; 0.55 e 0.49; respectively -  $p < 0,001$  for all correlations). MDCT slightly underestimated VH-IVUS measurements for luminal area (median: 0.4mm<sup>2</sup>, range: -5.6 mm<sup>2</sup> to 10.2 mm<sup>2</sup>), but overestimated vessel area, arterial wall area, and plaque burden (median: 3.0 mm<sup>2</sup>; 3.2 mm<sup>2</sup> e 13.9%, respectively). Increasing plaque density at MDCT

was significantly associated with VH-IVUS high dense calcium and necrotic core relative composition; as well as, VH-IVUS low fibrofatty relative composition and low necrosis-to-calcium ratio. Compared to IVUS, MDCT presented 97.4% sensitivity, 90.1% specificity and all coefficients were significantly correlated. At the index-hospital-admission, one patient died, 9.5% presented one MACE and two required surgical revascularization, CABG. There was 2.7 days average length of stay (95%CI: 2.4 to 3 days LOS). Only 7.5% of the patients required ICU stay (average 1.2 days, 95%CI: 0.9 to 1.4). Interventionist-index admissions average hospital operational costs were US\$ 6.008,09 (95%CI:\$ 5,088.15 to \$ 6,928.03); where devices and materials summed 57%, drugs 5%, tests 10% (including MDCT) and LOS 28%. The surgical admissions average costs were \$ 24,357.66 (95%CI: \$ 15,120.29 to \$ 33,595.03); where devices and drugs, tests (including MDCT) or LOS represented 35%, 23% and 42%, respectively. During 2,369 patient-months of follow-up (average 36 months, 95% CI: 32 to 38), one patient died, one patient required CABG and another underwent coronary angioplasty. There was 0.002 hospital admissions incidence density per patient-month and there were no infarctions. In conclusion, detailed diagnosis with IVUS and MDCT was associated with a low event rate outcome after 36 months in a population with established coronary disease; and, MDCT has similar performance to IVUS for diagnosis coronary assessment.

### Recommendations

Ongoing 320MDCT PPSUS/MS-FAPESP sponsored comparative study warrants further detailed evaluation.

### Further research/review required

Extend clinical trial and economic assessment to multiple centers.

### Reference

FALCÃO, João Luiz de Alencar Araripe; LEMOS NETO, Pedro Alves; ROCHITTE, Carlos Eduardo. **Comparison of coronary artery dimensions and atherosclerotic plaque composition between coronary angiography by 64-slice computed tomography and virtual histology intravascular ultrasound technique.** São Paulo, 2010. 99 p. Tese (Doutorado) - Universidade de São Paulo, Faculdade de Medicina, São Paulo, 2010.

## A new methodology for polyvalent intravenous immunoglobulin solution production

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### AIM

Due to the evidence found in the literature and the need to establish new technologies for the production of blood derivatives in Brazil, the aim of the present work was to develop an alternative methodology to the classic method of cold ethanol for the production of a solution containing immunoglobulin G concentrate. In order to achieve this goal, a combination of two non-denaturing chemical agents (caprylic acid and polyethylene glycol) was tested in the precipitation of protein fractions. Detergent action of caprylic acid, was also assessed in the inactivation of enveloped viruses.

### Methods

Highly purified intravenous immunoglobulin G concentrate (IV IgG) was produced with the use of polyethylene glycol associated to a single-stage precipitation by ethanol, instead of the classic Cohn-Oncley process, which employs cold alcohol as the precipitating agent, in a three-stage process. Precipitation of crude fraction containing more than 95% of immunoglobulin G was performed by liquid chromatography with a cation exchanger, CM-Sepharose, as stationary phase. During the process, the product was subjected to two-stage viral inactivation. The first stage was performed by the action of sodium caprylate, 30 mM at pH 5.1 +/- 0.1, and the second stage was performed by the action of a solvent-detergent mixture. The finished product was formulated at 5% with 10% sucralose as stabilizing agent.

### Conclusions and results

The process yields 3.3g of IgG/liter of plasma. The finished product analysis showed an anti-complementary activity lower than 1CH50. Polymer and aggregate percent levels were lower than 3% in the five batches studied. The analysis of neutralizing

capacity showed the presence of antibacterial and antiviral antibodies in at least three times higher concentrations than the levels found in source plasma. The finished product fulfilled all purity requirements stated in the 4th edition of the European pharmacopeia.

### Recommendations

The method described can help fractionation centers to develop, or improve, their techniques of the production of IV IgG concentrates, with intact molecules and preserved subclasses, increasing the range of indications, and also enhancing the chances of therapeutic success. The technology developed showed high yield levels in the production of intact IgG – 3.3g/liter of plasma. The method has potential to show higher productivity than the Cohn-Oncley method, because the precipitation time of the fractions obtained by ethanol is higher than in the fractions obtained by polyethylene glycol.

### Further research/review required

It makes it possible to introduce several parallel technologies in order to improve finished product purification process, and it also allows linking of this method to other plasma fractionation methodologies. It is important to emphasize that thermal stability at 57°C for 54 hours allows the development of another viral inactivation step.

### Reference

LUCENA, A. E. S. et al. A new methodology for polyvalent intravenous immunoglobulin solution production with a two-stage process of viral inactivation. **Journal of pharmaceutical sciences**, Washington, US, v. 46, n. 4, 2010.

## Diagnosing the current situation of using carboxymethyl cellulose dressings. Systematic review and epidemiological study at Antonio Pedro University Hospital

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### AIM

Make a diagnosis of current situation of using carboxymethylcellulose dressing compared with other alternatives for the treatment of wounds and burns, as to the efficacy / effectiveness, safety and current practices adopted in the Unified Health System (SUS), in order to develop recommendations to the Ministry of Health for the rational use of these technologies.

### Methods

Systematic review of randomized controlled trials on the efficacy / effectiveness and safety of carboxymethylcellulose dressing compared to other alternatives for the treatment of wounds and burns was conducted in August 2010. Epidemiological study over the period 2009-2010 in patients with chronic wounds.

### Conclusions and results

The studies retrieved from the application of specific search strategies led to the selection of 31 studies for inclusion in the systematic review. Carboxymethylcellulose dressings were compared with several alternatives in the studies included, and the saline gauze was the most frequent (26%). According to the Oxford scale, 18 studies were classified as 1b and level of recommendation A. The remaining studies were classified as 2b, with a level of recommendation B. Were reported treatment-related deaths in only four studies

(13%). Recurrence of ulcers were uncommon, being reported in only two studies (6%). Moreover, reports of effects or adverse reactions were done in 45% of studies. Only one study evaluated the quality of life of patients. Fourteen studies were related to the treatment of venous leg ulcers, eleven for pressure ulcers or decubitus ulcers, five for burns, and one study was related to the treatment of diabetic foot ulcers. In general, there was no consensus in the studies regarding the superior efficacy of the carboxymethylcellulose dressings in relation to the different alternatives evaluated for treatment of wounds and burns. Epidemiological study evaluated 186 patients in 2 years with a total number of 2500 appointments. Socio demographic data showed 54% female, 55 % aging from 57 to 82 years old; 53 % with incomplete middle school, being 54% married and living in Niteroi/Brazil. All of them present cardiovascular diseases and/or mellitus diabetes. Among them, 65% have chronic venous ulcers, 25% diabetic ulcers and 2% arterial ulcers. The ulcers were 15 cm in average, located in the lower part of the leg, with little exudate, no fetid smell and being treated for over five years. The evolution of the wound was of at least 2 months and maximum of 20 years, having initiated the treatment with the minimum of 1 week and maximum of 4 years. Macerated borders; periwound skin with moisture or redness. The products used for dressing were essential fatty acid, collagenase, alginate, hydrogel, and Unna's boot.

### Recommendations

Despite the potential benefits of a carboxymethylcellulose based dressings in treating burns and wounds, the published studies are still controversial in relation to the effectiveness of these technologies in these cases.

### Futher research/review required

In face of the highly heterogeneous clinical outcomes assessed in the included studies for different indications is necessary to conduct clinical trials with standardized clinical outcomes, addressing the same technologies, aiming more conclusive results regarding the efficacy of alternative treatments.

## Diagnosis and protocol assistance to patients with venous ulcers treated at a Hospital in Rio Grande do Norte

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### AIM

Identify relevant aspects of the scientific literature covered in the protocol for assisting patients with venous ulcers (VU); to identify issues to be proposed by the judges study to the protocol for assisting patients with VU and present the structure of the protocol proposed by the judges study to assist patients with VU treated at a referral hospital of Rio Grande do Norte

### Methods

Descriptive study, with quantitative approach, performed at the outpatient surgical clinic of the Hospital Universitário Onofre Lopes (HUOL), located in Natal-RN upon approval by the Ethics Committee (No 081/07). The sample consisted of 39 professionals, 30 nurses, seven doctors and two physical therapists, members of the surgical clinic HUOL and other institutions of Rio Grande do Norte and Jequié/Bahia, were the judges responsible for reviewing and selecting the guidelines already proposed in the literature on protocols about VU. After a literature review of relevant aspects of the protocol for assisting patients with VU (patient assessment and injury, and record documentation, care of injured and perilesional skin, an indication of coverage, use of antibiotics, pain treatment, surgical and medical, improved venous return, relapse prevention, job training and referral and counter-referral), a proposed protocol was structured to judges. Following examination, was held to validate the content with the application of Kappa (K), accepting scores  $\geq 0.81$  and Likert scale, whereas rates from 4.0 to 5.0. The data collected were organized in Microsoft Excel and exported to SPSS 15.0.

### Conclusions and results

The literature review included national and international scientific articles, thesis, dissertation and institutional protocols. The aspects that have obtained very good agreement ( $K \geq 0.81$ ), remained in the protocol. In the analysis of the aspects proposed, the items had very important evaluation, ranging from 4.1 (drug treatment) to 4.9 (Evaluation of patient and lesion and care of the injured and perilesional skin). The proposition of the protocol is arranged in eleven items: A) Evaluation of patient and lesion, B) Registration and documentation, C) Care of the injured and perilesional skin, D) Indication of coverage, E) Use of antibiotic and pain treatment, F) Surgical treatment of CVI, G) Drug treatment, H) Improving venous return and relapse prevention, I) Referral of patients, J) job Training K) reference and counter reference. It is concluded that this study brought a scientific contribution to health professionals, supporting improvements in quality of care people with venous ulcers.

### Recommendations

It is vital that the professionals who care for people with UV at various levels – primary, secondary and tertiary – to take ownership of the knowledge of the aspects of composition of protocol found in the literature and in this study so that they can base their actions scientifically, cause changes with the managers to improve the quality of care and life of patients with UV and their families.

### Further research/review required

The next step is a new submission of the protocol to the same judges, aiming at adapting and suggestions, then it will implement the protocol in assisting people with the UV at HUOL for one year, with assessment based on the outcome of patients.

### Reference

DANTAS, D.V. et al. Assistance to patients with venous ulcers based on protocols: literature review in electronic databases. **Rev. enferm. UFPE** [on line], v. 4, n. esp., p. 2001-2007, nov./dez., 2010.

## Effect of temperature and storage conditions on the stability of insulin marketed in the SUS and its relationship with the variation of blood glucose in vivo

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### AIM

To evaluate the stability of insulin sold in Brazil after the vial open and correlate with the variation of glycemia.

### Methods

The raw materials were used vials of NPH and regular (Lily and NovoNordisk), with the criterion of choice for prescription drugs and insulin supplied by SUS Caçador - SC. For assessment of thermostability, the samples were stored for a period of 28 days at a temperature of 6 and 25 ° C during these period aliquots at 0, 1, 7, 14 and 28 days. The data were evaluated kinetically by calculating the average life of so active in medicine. The tests were validated by insulin spectroscopy in the UV region, through the determination of linearity, precision, accuracy, robustness and specificity. For the in vivo blood was collected from 80 patients at home at 0, 15 and 30 days after opening the bottle of insulin, causing the concentration of fasting plasma glucose and glycosylated hemoglobin A1C fraction.

### Conclusions and results

The testing method showed a precision and accuracy with CV 0.4%, recovery rate of 99.99%, while the strength was not influenced by pH and solvents tested. To validate the refrigerated conditions was obtained from a zero-order reaction, while for the ambient temperature conditions of the first order,

obtaining values of stability of insulin at 42.3 and 27.1 days respectively. These results show that temperature influences directly the stability of insulin. In vivo tests was observed glucose levels at 0, 15 and 30 days after opening the bottle of insulin ( $115 \pm 18$  mg / dl,  $173.5 \pm 23$  mg / dl and  $160 \pm 15$  mg / dl respectively). The glycosylated hemoglobin values remained stable for all patients (7%) consider themselves so a good control for diabetic patients. Changes in blood glucose levels may be related to reduced stability of insulin or due to incorrect use of the same, since insulin given in the SUS is presented as a suspension. Dosage forms that are presented as a suspension can be misleading at the time of administration if the patient has not been properly oriented.

### Recommendations

Need to conduct an effective job of pharmaceutical care in the SUS in the city since the majority of patients followed are elderly and have difficulties at the time of insulin administration, as well as hypoglycemic medications administered. They end up taking the medication at the wrong times and doses makes it difficult to obtain satisfactory results in the treatment of diabetes.

### Further research/review required

Development of a pharmaceutical care home along with the Family Health Program (PSF).

## Effectiveness of antimuscarinic drugs in the treatment of neurogenic detrusor overactivity: a pharmacoeconomic evaluation

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### AIM

To compare the costs and the effectiveness of two antimuscarinic drugs commonly used in the clinical practice – oxybutynin and tolterodine – in two different formulations, extended (ER) and immediate-release (IR), for the treatment of neurogenic detrusor overactivity (NDO), based on Brazilian maximal consumer price index and from a patient's perspective.

### Methods

A systematic review of literature was conducted in order to obtain clinical and urodynamic data which are important in the urological practice (based on expert opinion), concerning the effects of these antimuscarinic agents in the neurogenic population. Furthermore, a pharmacoeconomic evaluation was performed to compare the costs of these drugs in terms of their effectiveness in increasing cystometric capacity, reducing detrusor pressure and increasing the volume of urine voided in 24 hours. For each antimuscarinic formulation, it was calculated the costs involved with each percentual of effectiveness obtained, in a time horizon of one month.

### Conclusions and results

Oxybutynin IR was the most cost-effective antimuscarinic, based on its dominance in all the three key urological parameters analyzed. The most cost-effectiveness ratio (CER) observed was oxybutynin IR in pediatric (\$0.46) and adult

patients (\$0.48) for each increased percentage in the cystometric capacity to a level more than 30%, compared to the baseline capacity. With regard to the reduction of detrusor pressure to a level less than 40cmH<sub>2</sub>O, oxybutynin IR had the best CER (\$0.30 for each percentage of pressure reduced), data only calculated for pediatric population, given the absence of data published for adult patients. Finally, for each increased percentage in the volume voided/24h was found \$1.03 for pediatric and 1.78 for adult patients, both CER referring to oxybutynin IR.

### Further research/review required

No health economic study was found in the area of antimuscarinic therapy and neurogenic detrusor overactivity which addresses the necessity of conducting this kind of study. Moreover, additional research is recommended such as randomized controlled trials in order to evaluate the treatment effects on short and long-term, as well as population-based cohort studies may add valuable information about the impact of treatment not only on health-related quality of life, but also on the budget of the healthcare system.

### Reference

No paper was published yet.  
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 \* currency exchange quote for US Dollar = 1.68 (January, 28th, 2011)

## Effectiveness of chronic hepatitis C treatment in Santa Catarina, 2003 to 2007: the need of data record in health services

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### AIM

To verify the effectiveness of chronic hepatitis C (CHC) treatment, with interferon (INF) or alpha interferon (PEG) combined with ribavirin between 2003 and 2007 in Santa Catarina.

### Methods

We performed a retrospective cohort study of patients registered for HCC treatment in the cities Florianópolis, Joinville, Blumenau, Tubarão, Criciúma and Itajaí, who started treatment with PEG or INF associated with ribavirin, during the period January 2003 to July 2006. Data collection was performed in three steps: A) in the database of Diaf-SES-SC, B) in the processes at the patient care locals; C) through contact with patients. The information collected concerning the number of patients who underwent treatment, municipality of residence, percentage of patients who completed treatment, percentages of patients who achieved sustained viral response (SVR), access to treatment according to the protocol via Brazilian Specialized Component Pharmaceutical Assistance (CMDE) or through judicial processes.

### Conclusions and results

During the analyzed period, 2085 requests for HCV treatment were registered in Santa Catarina. 1,232 (59.1%) of these were approved. The study sample consisted of 716 requests, 472 (PEG) and 244 (INF), corresponding to 681 patients (35 patients received retreatment). Among the requests, 179 were lawsuits

and 537 through CMDE. The overall percentage of completed treatments was 75.7%, being lower in the group receiving PEG (69.1%) compared to INF (88.5%). The number of treatments with SVR was 45 (PEG) and 39 (INF) and no response (non-responders plus relapsed) was 78 (PEG) and 91 (INF). Among the 542 completed treatments, the response data of 289 were considered unknown, 87 (64.4%) from the lawsuits and 202 (49.6%) from the CMDE. The analysis by municipality showed significant differences in the percentage of unknown results and SVR. The data indicate that the local infrastructure can have an effect on the treatment effectiveness. Moreover, treatments performed by lawsuits increase the lack of information on the treatment outcomes.

### Recommendations

The local structure for patient care showed fragilities in the patients monitoring and recording of essential information for treatment outcome analysis and for the health planning. The high percentages of unknown results indicate little interaction between clinical services, pharmaceutical care and epidemiological surveillance. Considering that Hepatitis C is a reportable disease, subject to surveillance, these services need a structure that enables the monitoring of patients and data recording.

### Further research/review required

Considering the relevance of adverse effects, the high cost of treatment as well as the consequences of the non-response to treatment, both in terms of patients quality of life and epidemiological surveillance, we recommend a study about the effectiveness of hepatitis C treatment in association with the services organization in Brazil.

## Creation of an information system on elderly health from a Health Prevention Card for the Elderly: Tools for the diagnosis and follow-up of the elderly at risk of needing hospital admission

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### AIM

The System for the Health Information of the Elderly (SI) was developed with the aim of turning possible the planning of the health promotion activities and of the prevention of chronic diseases and their complications. The target-population is the elderly (both healthy and frail) cared by the Family Health Strategy Program (ESF) of the Brazilian public health system Unique System of the Health do Brasil (SUS). The electronic tools of the SI able the identification of the frail elderly in the community, the elaboration of a Health Promotion Program and the individual care protocols.

### Methods

The SI was developed from three research projects. The first was a population based study where the efficacy of an instrument to predict the risk for repeated hospital admissions (PRA) was evaluated in the identification of the frail elderly, from the use of PRA by the Community Health Agents (ACS) in the community and compared with the real hospital admissions of those elderly evaluated by the ACS. In the second Project, a web based software for the SI was developed. For operational purposes, the electronic tools of the SI for the management of the care of the elderly were structured in four modules: (I) Registry of the Elderly Population; (II) Health Status Diagnosis of the Elderly Population; (III) Program for the Health Promotion, individual report of the health indexes, Notebook for the Health Promotion of the Elderly, and Individualized Therapeutic Project; (IV) Support System for the Decision Making and Planning. In the third Project, the effects of Health Promotion Program for the Frail Elderly in the ESF

were evaluated using a randomized community clinical trial in which the intervention group was subjected to the individualized care protocol applied by the ACS.

### Results and Conclusions

In the first Project, 7% of the elderly population attended by the ESF (from the Progreso County, RS) presented high risk for the hospital admissions in six months. During the follow-up period, this group had 6,5 times more hospital admissions than the group classified as low risk. In the third project, the intervention group showed a reduction in the functional decline in the performance of the basic activities of daily living. After adjustment for confounders, the intervention Group (OR 0.24) and the male elderly (OR 0.42) kept the reduced chance of the functional decline. There were no differences in the hospital admissions between the groups when comparing the year before and after the randomization and after the end of follow-up period ( $p=0.682$ ;  $p=0.374$ ). The results of the projects showed the efficacy of the tools for the management of the care of the elderly brought by SI for the use by the ESF team. In the same way, these tools could be used by the county and state managers of the SUS to build the local actions to face the difficulties that come with the complexity of the health care of the elderly.

### Recommendations

To develop a scientific investigation to define which are the health professionals that are capable to perform activities for the health promotion and chronic diseases prevention and their complications in the frail elderly population attended by basic attention team of SUS.

### References

MACHADO, D. M. et al. Validade preditiva de instrumento para identificação do idoso em risco de hospitalização. **Rev. Saúde Pública**, São Paulo, v. 45, n. 1, p. 106-112, 2011.

## Equity in access and use of procedures of high complexity / cost in SUS - Brazil: evaluation of kidney transplants

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### AIM

To analyze individual and context factors associated with the access to kidney transplant in Brazil and in Belo Horizonte / MG.

### Methods

To achieve the proposed objectives we used two separate studies that comprise the Research "Economic and epidemiological evaluation of renal replacement therapies (RRT) in Brazil" – Project RRT. The 1st study, observational, prospective non-concurrent, used data from the National Base in RRT to study factors related to the probability of being transplanted in Brazil from 2000 to 2004. The National Base in TRS is a result of the relationship deterministic-probabilistic technique based on the following Public Health System databases: High Complexity/Cost Procedures Authorization System (APAC) from the Ambulatory Information System (SIA); Hospital Information System (SIH) and Mortality System Database (SIM). The 2nd study, longitudinal follow-up aims to incidents patients between and jan./2006 dez./2008 in Belo Horizonte / MG. This study was a component of non-concurrent two years and a concurrent of one year. Data were obtained by conducting two interviews: 1st collected retrospective data for the two years and collecting patient's records and 2nd corresponded to 1-year prospective follow-up, which found the outcome of patient follow-up.

### Conclusions and results

In the 1st study found that patients less likely to receive kidney transplants were female (RR 0.81), aged > 65 years (RR 0.06), had diabetes mellitus (RR 0.55), residents in Northeast (RR 0.52), North (RR 0.56)

and Midwest (RR 0.69) region. In the 2nd study found that individuals most likely to be transplanted (0.821) had health insurance, white skin and the doctor said he was able to perform transplants. The increase of 1 at age decreased by 0.010 the probability of this individual be transplanted. It was concluded that demographic, clinical, social, access to health services and economic are associated with differences in access to renal transplantation in the country.

### Recommendations

This study contributed information for decision making of managers in the SUS and formulating a policy to ensure equity in access to kidney transplantation, preventing other conditions, other than health needs, generate disparities in the opportunities for such treatment to thousands of Brazilians.

### Further research/review required

Developing research using primary data and nationwide to monitor the care provided to patients in renal replacement therapy, since its entry into TRS, to the inscription on the transplant list and then to the effectuation of a kidney transplant. Apart from socio-economic, demographic and clinical services usage and characteristics of services provided (dialysis centers, transplant etc).

### Reference

CHERCHIGLIA, M. L. et al. Perfil epidemiológico dos pacientes em terapia renal substitutiva no Brasil, 2000-2004. **Rev. Saúde Pública**, São Paulo, v. 44, p. 639-649, 2010.

MACHADO, Elaine Leandro et al. Iniquities in the access to renal transplant for patients with end-stage chronic renal disease in Brazil. **Cad. Saúde Pública**, [S.l.], 2010. ahead of print.

### Funding strategies for organizing and strengthening primary health care in large cities in the state of Sao Paulo

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#### AIM

To identify and analyze the strategies for financing public health care services in cities with over 100,000 inhabitants in the state of São Paulo, relating them to the models of organizing primary health care (PHC) in these cities.

#### Methods

Execution of three articulated modules: a) review of the literature on the subject of financing and organization of the primary health care; b) secondary data research for all municipalities with more than 100,000 inhabitants; and c) case studies with municipalities that present different conditions of development and outpatient services.

#### Conclusion and results

The funding of local health care systems is related to the characteristics of PHC in the municipalities studied. Greater ability to collect tax revenues, higher total health expenditures and a higher percentage of own resources invested in health care are associated with municipalities that have a PHC model delivered in public units, higher levels of organization and/or evaluation, and access to a broader range of health care services. On the other hand, lower ability to collect local taxes, increased reliance on federal resources and a lesser percentage of own resources are associated with the preeminence of the health family program, lower levels of organization and/or evaluation and limited access to health care services. Interviews with local health care managers revealed the existence of the following challenges: difficulty to recruit and retain qualified professionals, resistance of the population and health professionals to the family health strategy, and limited availability of

financial resources for investment in primary health care activities at the local level. In order to face those challenges, some important initiatives were adopted, including transfer of specialized services to the state government, greater involvement of local health care managers in PHC activities, and investment in training and qualification of health care professionals. Health care managers recognize that the money transferred from the MoH is important to fund their local health care systems. However, they consider that the transferred amount is not enough. At the same time, they point out the low level of support of the state government in developing PHC activities. They also admit that there is little room for municipalities to increase the share of own resources invested in health care because their ability to collect tax revenues is limited. With respect to the minimum level of resources to fund health care services, they understand that the new legislation (EC29) was able to force municipalities to allocate more resources to health care, yet the lack of regulation is one factor that has allowed its non-compliance in practice.

#### Recommendations

It is recommended to review the current criteria for determining the amount of money to be transferred from the federal government to municipalities as part of PHC. They should include not only the size of the population and the implementation of strategic programs, but also health care needs of the population, the availability of financial resources in these cities and the degree of compliance with pre-defined goals.

#### Further research/review required

It is recommended further research to identify: 1) the adoption of different funding models that seek equity in distribution of health resources at the international level, and 2) successful experiences in the context of PHC activities at the local level.

#### Reference

VIANA, Ana Luiza d'Ávila. Financiamento da saúde: impasses ainda não resolvidos. **Trab. Educ. Saúde**, [S.l.], v. 6, n. 3, p. 599-612, nov.2008/ fev.2009.

Cost-utility study of antipsychotics haloperidol, risperidone and olanzapine for schizophrenia treatment under the perspective of the Brazilian Unified Health System, Santa Catarina State, 2006

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### AIM

To assess cost-utility relationships of first and second-generation antipsychotics for treatment of schizophrenia outpatients.

### Methods

A five-year Markov model was constructed based on a survey of the records of patients seen in 2006 at a psychosocial care center in the municipality of Florianopolis, Southern Brazil. Costs were evaluated from the perspective of the Sistema Único de Saúde (SUS – Unified Healthcare System). Utility was measured in quality-adjusted life years obtained in the literature.

### Conclusions and results

The Markov model indicated risperidone and haloperidol utilization before olanzapine as the most cost-effective alternatives. Antipsychotic agents haloperidol and risperidone are more cost-effective than olanzapine. Strategies prioritizing the use of antipsychotics with better cost-effectiveness could optimize resource allocation without necessarily compromising the health of patients treated through the Sistema Único de Saúde.

### Recommendations

The establishment and fulfillment of strategies involving more cost-effective treatment flow-charts or guidelines, in which patients begin treatment with risperidone and haloperidol before olanzapine may optimize resource allocation without affecting patient's health.

### Further research/review required

Future economic evaluation models will be useful for reaching more precise definitions as to the efficiency of allocation of public resources for pharmacological treatment of schizophrenia, which shall include clinical trials carried out among SUS patients, with longer follow up periods, and including other antipsychotic drugs, both first and second-generation.

### Reference

LINDNER, L. M. et al. Avaliação econômica do tratamento da esquizofrenia com antipsicóticos no Sistema Único de Saúde. **Rev. Saúde Pública**, São Paulo, v. 43, supl. 1, p. 62-69, 2009.

**Cost-effectiveness studies of vaccines against rotavirus, varicella, pneumococcal conjugate, meningococcal C conjugate and hepatitis A for the National Immunization Program/PNI of the Ministry of Health.**

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**AIM**

Conduct cost-effectiveness studies of vaccines against rotavirus, varicella, pneumococcal conjugate, meningococcal C conjugate and hepatitis A for the National Immunization Program/PNI of the Ministry of Health.

**Methods**

Epidemiological estimates and of health care utilization direct and indirect costs of diseases to be prevented and their introduction in the PNI were developed as well as models appropriate to each case, and calculated the incremental ratios of outcomes and sensitivity analysis.

**Results and Conclusions**

The study of rotavirus vaccine CE was based on a decision tree type model and the incremental ratios for the outcomes studied suggested it to be very cost-effective in the Brazilian context, reinforcing the decision of its introduction in universal immunization schedule that occurred during the period the study was being developed. The study of varicella vaccine CE was based on a dynamic model and the incremental ratios obtained for the outcomes studied suggested its introduction would be moderately cost-effective. The study of pneumococcal 7-valent vaccine and 10 valent vaccine CE, based on a decision tree model, indicated the important epidemiological impact of pneumococcal disease in Brazil and the need for significant reduction in the initial price of the vaccine. The study helped to identify the value of the vaccine and the decision to establish its introduction led to a trading price to that obtained in the study. The study meningitis C

conjugate vaccine CE, based on decision tree model, indicated that the introduction of the vaccine, considering the price of the vaccine at the time, could be considered cost-effective. During the study period there were localized outbreaks of meningococcal C meningitis the public health authorities decided to introduce the vaccine in the PNI. The study of CE hepatitis A vaccine is underway. A dynamic model is being developed based on recently obtained serum epidemiological data. CE studies of vaccines selected by the managers of PNI in 2005 as potential vaccine candidates for introduction into immunization programs, allowed the production of structured information on the epidemiology of the diseases and costs of the utilization of health services and estimates of the potential impact of the introduction of new vaccines and cost-effectiveness of their introduction into the national program. The studies allowed the development of expertise in the area and diffusion of knowledge among managers on economic evaluations of vaccines and their use as support in decision-making.

**Recommendations**

Economic evaluation studies of vaccine CE should be complemented with assessments of budget impact and epidemiological post-introduction

**Further research/review required**

Health information systems must be strengthened, as a basis for the routine development of CE studies and expertise in economic evaluation as part of public health activities should be stimulated.

**Reference**

SARTORI, Ana Marli Christovam; SOÁREZ, Patricia Coelho de.; NOVAES, Hillegonda Maria Dutilh. Cost-effectiveness of introducing the 10-valent pneumococcal conjugate vaccine into the universal immunisation of infants in Brazil. **Journal of epidemiology and community health**, doi: 10.1136/jech.2010.111880.

## The treatment of rheumatoid arthritis with biological agents in the Brazilian Unified Health System (SUS)

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### AIM

To present clinical evidence and economic information about the treatment of rheumatoid arthritis with adalimumab, etanercept and infliximab in a University Hospital of the Brazilian public health system (SUS).

### Methods

Systematic review of randomized trials and meta-analysis of effectiveness by measuring the absolute risk. A systematic review of cohort studies assistencial registry to complement the decision making model. To estimate the annual spend on acquisition of anti-TNFs. To start data mining of Datasus from São Paulo State, in the last decade, for a retrospective cohort of patients with RA in the use of anti-TNF to get information on clinical events and associated costs.

### Conclusions and results

Twenty-three randomized trials met the eligibility criteria, including six on infliximab, nine on adalimumab and eight on etanercept. Adalimumab and etanercept show benefit only when combined with methotrexate. The ACR50 response had similar results with NNT = 6 (95% CI 5 to 8) to infliximab, and NNT = 5 (95% CI 4 to 6) for adalimumab and etanercept. The ACR70 response was seen more favorably with adalimumab NNT = 8 (95% CI 6 to 10), followed by infliximab 10mg/kg with NNT = 9 (95% CI 7 to 13), etanercept, NNT = 10 (95% CI 7 to 16) and with infliximab 3mg/kg NNT = 12 (95% CI 9 to 20). The annual cost was estimated from the average value of the acquisition of anti-TNFs in the last three years by the Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, considering that spending on the acquisition of biological agents corresponds to the main costs over one year of patients follow-up. To get a response of 50% improvement in a single patient is necessary to treat six patients with annual cost of infliximab R\$ 272,154.24, five patients

with adalimumab for R\$ 280,486.25 or five patients with etanercept for R\$ 365,107.60. The more favorable clinical response evaluated by ACR70 showed that infliximab with the largest annual expense, only the dosage of 10mg/kg showed similar results with the other two anti-TNF in the amount of R\$ 1,224,694.08. Adalimumab was the anti-TNF with the most favorable response, being necessary to treat 8 patients with expenditure of R\$ 448,778.00 to get the response in one patient, and 10 patients with etanercept in the amount of R\$ 730,215.20. The study of spending on intervention and assistance care related to the frequency of clinical complications and comorbidities of patients with RA will be done in the data warehouse Minersus, loaded with DATASUS data of São Paulo State, through the retrospective cohort of 31,358 patients with RA identified, of which 3,275 treated with anti-TNF. Developed in parallel an study to assess the methodological quality of the original articles retrieved in the systematic review that presented their conclusions based on clinical outcome, compared with the quality of which are based on surrogate outcomes. It was developed a review of patient preferences and shared decision making with the objective of implementing the patients' compliance to anti-TNF, to support the development of an specific tool. The expected product is the value attributed to health status by patients with RA based on their preferences and cultural values.

### Recommendations

Information obtained by measure absolute risk allows someone to compare and estimate directly the annual spending with the 3 anti-TNF available in the SUS.

### Further research/review required

Data mining of health care information from SUS to generate retrospective cohorts for the study of benefits and costs of identified patients with rheumatoid arthritis, treated with anti-TNF.

### Reference

To be published in EBM (BMJ Group): Surrogate endpoint is associated with worse methodological quality of studies in RA treated with anti-TNF: a systematic review applied in health technology assessment for the Ministry of Health of Brazil. Nobre M, Costa FM.

## Risk factors and interventions for the reduction of maternal and child morbidity and mortality in pregnant teens

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### AIM

Identify risk factors for maternal and child morbidity and mortality in pregnant teenagers; show teenage pregnancy as a risk factor for neonatal and newborns and assess the effectiveness of interventions used to reduce maternal and child morbidity and mortality in pregnant teenagers.

### Method

Systematic Review of Literature (LSR) with meta-analysis was used. Data base was consulted on MEDLINE via PubMed, Scientific Electronic Library Online (SciELO) and Latin American and Caribbean Center on Health Sciences (LILACS). This work covers studies published from 2000 to 2010 whose inclusion and exclusion criteria were: original study with statistical data, while excluding review studies, qualitative research, case reports, editorial and communications and was confined to the selected theme, which led to the exclusion of items that did not cover teen pregnancy and its consequences for morbidity and mortality of mother and/or fetus. Publications in which consensus was reached among researchers resulted in lower qualifications to the study design, including quantitative research with insufficient data or unfit for the purpose of research. The LSR was used with seven studies: a case-control and six cohorts. Meta-analysis of five studies was included. For data analysis software Stata version 11.0 was used and forest plot graphs were made from the odds ratios and their confidence intervals. The Q test was used to evaluate the heterogeneity between studies.

### Conclusions and results

The LSR highlights prevalent risk factors for maternal and child mortality and morbidity among pregnant adolescents: social, cultural, educational and economic indicators. Dystocia deliveries were seen as an important risk factor for maternal mortality. Prematurity and low birth weight are risk factors for early mortality in children of adolescents. As to intervention strategies against maternal and child mortality in teenage pregnancy, follow-up during prenatal, childbirth and postpartum proved to be the strongest preventive measure. The reduction in length of stay; the increase of services to assist pregnant women were also shown to be important intervention strategies, as well as the need for further actions aimed at sex education among adolescents. The parental support was seen as a protective effect. The results of the meta-analysis showed the association of teenage pregnancy with neonatal mortality from the combined effect of 1.28 (95% CI 1.13 to 1.44,  $p < 0.001$ ). A meta-analysis also confirms the association between mortality and teenage pregnancy postpartum as the combined effect of 1.64 (95% CI 1.08 to 2.50,  $p < 0.001$ ).

### Recommendations

More straightforward implementation of public policies for groups of adolescents, both within the basic health and educational systems (schools, youth groups and others), with the prospect of reducing teenage pregnancy and recurrence.

### Recommendations for research

Develop studies to assess the effectiveness of strategies in health education aimed at teenagers.

## FDG-PET is cost-effective in preoperative staging of non-small cell lung cancer in Brazil

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### AIM

Previous studies have shown that positron emission tomography (PET) is more accurate than computed tomography (CT) for the staging of non-small cell lung carcinoma (NSCLC). In the present study the cost-effectiveness metabolic staging (MS) with FDG-PET is compared to conventional clinical staging (CCS) strategy for preoperative staging of NSCLC.

### Methods

Two decision strategies were compared CCS and CCS coupled with FDG-PET in all 83 patients before the beginning of treatment. A standard of reference was determined with CT, FDG-PET, histology and follow-up exams. The results of the CCS were compared to the MS with FDG-PET results. Local unit costs of procedures and tests were evaluated.

### Conclusions and results

The incorporation of FDG-PET coupled with CCS in the staging procedure upstaged 72.3% (60/83) and downstaged 2.4% (2/83) of the patients. As a result of these changes in staging, 45.0% (38/83) of the patients would have received a different therapeutic regimen. Local Average CCS costs without PET were \$ 3,037 compared to \$ 4,161 with PET. However, due to treatment

modifications, average treatment cost per patient with CCS was \$12,089 and with PET staging was \$10,591, with a 12.3% decrease in costs. **CONCLUSION:** FDG-PET is more accurate than CT in NSCLC staging. Given observed probabilities, FDG-PET is highly cost-effective and would reduce costs for the public healthcare program in Brazil.

### Recommendations

Include FDG-PET/CT in public health care system in Brazil for the evaluation of NSCLC patients.

Further research/review required

Perform randomized clinical trials for the evaluation if these results are reproducible.

### Reference

- FERREIRA, R. M. et. al. Estudo de custo efetividade para o SUS do FDG-PET em câncer de pulmão. **Radiologia Brasileira**. São Paulo, n.41 (suplemento 1), 2008, p. 94-95.
- MUSSOLINO, R. et. al. PET-FDG no câncer de pulmão-custo efetividade para o sistema único de saúde. In: XXXIV CONGRESSO BRASILEIRO DE PNEUMOLOGIA E TISIOLOGIA, 34., 2008, Brasília. **Anais ...** Brasília: Sociedade Brasileira de Pneumologia E Tisiologia, v. 34, p. R4, 2008.

## Consistency of FDG-PET accuracy and cost-effectiveness in initial staging of Hodgkin's lymphoma patients across jurisdictions

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### AIM

To evaluate the cost-effectiveness of 18-F-fluoro-2-deoxy-D-glucose positron emission tomography (FDG-PET) scan in initial staging of HL patients.

### Methods

All 210 patients were staged with conventional clinical staging (CCS) methods, including computed tomography (CT), bone marrow biopsy (BMB) and laboratory. Patients were also submitted to metabolic staging (MS) with whole-body PET scan before the beginning of treatment. A standard of reference for staging was determined with all staging procedures, histology and follow-up exams. The accuracy of the CCS was compared to MS. Local unit costs of procedures and tests were evaluated. Incremental cost-effectiveness ratio (ICER) was calculated for both strategies.

### Conclusions and results

In the 210 HL patients, the sensitivity of FDG-PET was higher than CT and BMB in initial staging (97.9% vs. 87.3%,  $P < 0.001$  and 94.2% vs. 71.4%,  $P = 0.003$  respectively). The incorporation of FDG-PET in the staging procedure upstaged 50 (24%) and downstaged 17 (8%) patients. Changing in treatment would be seen in 32 (15%) patients. Local CCS costs strategy was \$3,751 compared to \$4,588 with PET/CT. The ICER of PET/CT strategy was \$162

per modified treatment patient. PET/CT costs in initial and at the end of treatment would increase only 2% of total costs of HL staging and first line treatment. The results of our study indicate that FDG-PET is highly accurate in the initial staging of HL patients. For HL patients staging PET + CT and PET/CT are highly cost-effective and increase only 2% of total public HL healthcare program if performed in both initial and at end of first line treatment.

### Recommendations

Include FDG-PET/CT in public health care system in Brazil for the evaluation of HL patients.

### Further research/review required

Perform clinical trials for the evaluation if these results are reproducible in non-Hodgkin lymphoma patients.

### Reference

CERCI, J. J. et al. Consistency of FDG-PET accuracy and cost-effectiveness in initial staging of Hodgkin lymphoma patients across jurisdictions. **Journal of clinical lymphoma and myeloma**, [S.l.], 2011.

## Drug distribution expenses in primary health care in Fortaleza-CE and qualities of pharmaceutical services in 2006 and 2007 biennium

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### AIM

The main objective was to understand the distribution of spending on PHC Fortaleza-Ce between the Regional Health (RH) and among its Health Units (H.U.) and analyze the factors associated with the Quality of Pharmaceutical Care (QPC).

### Method

Ecological study, cross-sectional descriptive study of primary and secondary data acquisition and distribution of medicines for Primary Health Care (PHC) in Fortaleza-Ce, in the biennium 2006 and 2007 as well as development and implementation of indicators of Quality Pharmaceutical Care (QAF) established by informal consensus among pharmacists in the municipal.

### Conclusions and results

Total expenditure on basic drugs was estimated at H.U. R\$ 9.29 million and the per capita expenditure of R\$ 3.82 per patient and the expense of R\$ 2.41. The Being who had the highest spending was the RHII (R\$ 2,216,886.94) which has a high Human Development Index (HDI). The average expenditure per patient was higher in RH V (R\$ 2.82) which is concentrated the population with lower income and low HDI. The therapeutic classes with higher spending were: systemic antibiotics (18.8% of the total, mainly beta-lactams, followed by antidiabetics (9.4% oral hypoglycemic agents) and antihypertensive drugs acting on the renin-angiotensin system (8.6% and

8,2% only with captopril). Medicines consumed more DDD/ 1,000 patients seen per day): Captopril, Hydrochlorothiazide and acetylsalicylic acid. The Antiasthmatic had the highest unit price, the higher expenditure / DDD were with: Fenoterol, 600.000UI benzathine penicillin and 0.35 mg norethindrone. The QPC management was classified as poor (67.91% of care indicators). The U.S. also has the QPC as poor. The QPC showed an inverse correlation ( $r = -0.110$ ) with drug expenditures, but without statistical significance. The presence of the Pharmacist in the H.U. had a positive association with QPC ( $p$ -value = 0.014) and reduction of drug spending (savings of R\$ 0.32 in average per patient). The per capita spending on medicines in the PHC of Fortaleza (R\$ 3.82) and expenditure per patient (R\$ 2.41) were lower than those agreed upon by management spheres (R\$ 6.20) revealing difficulties in management. A greater allocation of resources in the area with the highest HDI in relation to poorer areas and more populated suggests the existence of distortions that lead to inequity in the Health Care System. The contribution of the professional Pharmacist in the H.U. reduced spending but did not affect the QPC, whose insecurity was determined by deficiencies in the item structure, among them shortage of pharmacists in the H.U.

### Research recommendations

The results indicate that needs are met partially. It is recommended to the reapplication of the indicators for systematic evaluation of the QPC, hiring and training of pharmacists for the units, improve infrastructure pharmaceutical services and upgrade of Municipal Value of Essencial Drugs.

### References

CORREIA, Ana R. F. Definição de indicadores para avaliação da assistência farmacêutica na rede pública de Fortaleza/CE (Brasil) baseada em métodos de consenso. **Lat. Am. J. Pharm.**, [S.l.], v. 28, n. 3, p. 366-374, 2009.

### Process management: protocol as a tool for improving quality and reducing costs in university hospitals

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#### AIM

The aim of this study is ascertain the extent to which the use of medical care protocols can bring about improvement in the quality of services, by standardizing processes, and, at the same time, reduce costs directly related to the implantation of knee prostheses.

#### Methods

The research strategy used was to carry out a quasi-experiment. The experimental subjects were the patients undergoing knee replacement surgery at the Federal University of Pernambuco's teaching hospital. The experimental variable tested was the introduction of medical care protocols. The quasi-experiment was carried out at the Federal University Hospital's Orthopedics and Traumatology Inpatients Unit. The time series was divided into two distinct periods. During the 1st period, all the patients were attended to according to the hospital's existing routines. During the 2nd period, all the procedures were carried out according to the medical protocols established for the study. At the end of the 2nd period, the data collected before and after adoption of the protocols were compared. Data collection involved recording quality indicators and direct costs of knee replacement surgery and the direct costs associated with the time spent in hospital while undergoing the procedure.

#### Conclusions and results

The results of the study show that the use of care protocols at the Federal University Hospital's

Orthopedics and Traumatology Inpatients Unit led to an improvement in all the quality indicators selected. As for costs directly related to the surgery, it was found that there was a reduction when the results were taken as a whole. Costs related to medical and auxiliary staff, gas therapy and the depreciation in the value of medication were lower after the introduction of the protocols, while the direct cost of inpatient care fell not only overall, but for each item analyzed.

#### Recommendations

It is recommended that the introduction of protocols be carried out with the participation and assent of the whole team involved. Various interviews and meetings should be held to explain the system to the professionals involved and to draw attention to points that need to be worked on. Above all, the results should be published as they are achieved. The integration of the team is a decisive factor in assuring the success of the introduction of this system.

#### Further research/review required

It is recommended that research should be conducted into other factors that might impact the introduction of protocols, such as sociological, organizational, behavioral and motivational factors. A multidisciplinary approach greatly improves the conclusions reached on this subject, as each specialist is able to consider the problem and identify factors related to their own area of specialization and provide a complementary explanation that will contribute to overall understanding of the process.

## ABO blood group and pre-eclampsia – a systematic review

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### AIM

Preeclampsia (PE) is associated with fibrin deposition in the placenta and kidney microcirculation. It is known that non-O blood groups (A, B or AB) subjects have increased risk for thrombus formation, as compared to those of group O. Since 1953, when Pike and Dickins related an association between O blood group and PE, several other studies were performed with the same objective, but there is no consensus until now relating to this association. In order to investigate the association between ABO blood groups and PE, a systematic review of studies published in this context was performed.

### Methods

It was conducted a computerized search of the databases Medline, Embase, LILACS, Medline and Web of Science up to July 2010. Optimized search strategies were used with a combination of terms such as pre-eclampsia, eclampsia, pregnancy induced hypertension, toxemia, HELLP syndrome and ABO(H) blood group system. Cohort, case-control and sectional studies were included if compared pre-eclamptic woman with a controlled group constituted of health pregnancy woman regarding the typed blood group, the risk factor of interest.

## Conclusions and results

Overall, 46 full text articles were identified. Twenty-three studies were considered potentially relevant, of which only three were included. These studies included 507 cases of preeclampsia and severe preeclampsia among 1761 pregnant women. The studies were generally of good methodological quality although one study considered only the severe form of PE (13) and was very small (number of cases=55). Generally, no overall effect was found when all the study's findings were pooled comparing blood group A versus non-A for the risk of PE [odds ratio of 0.88 (95% CI 0.71 to 1.10) with no substantial heterogeneity (P=0.34, I<sup>2</sup>=7.0%)]. A similar result was observed when comparing group B with non-B pregnant [odds ratio of 1.08 (95% CI 0.75 to 1.56), with low heterogeneity (P=0.25, I<sup>2</sup>=28.0%)]. Once more, no overall effect was found when all the study findings were pooled as regards non-O versus O blood group [odds ratio 0.86; 95% CI 0.69 to 1.08] and no substantial heterogeneity was observed (P=0.69, I<sup>2</sup>=0.0%). It was observed a significant overall effect when comparing blood group AB versus non-AB pregnant [odds ratio of 2.37 (95% CI 1.62 to 3.47) with no evidence of heterogeneity (P=0.63, I<sup>2</sup>=0.0%)].

### Recommendations

Further research/review required  
The limitation of this systematic review was to include only articles in English, Spanish and Portuguese and should be conducted a new review including papers in other languages.

### Reference

ALPOIM, P. N. et al. ABO blood group and pre-eclampsia: a systematic review. In: INTERNATIONAL SYMPOSIUM ON WOMEN'S HEALTH ISSUES IN THROMBOSIS AND HAEMOSTASIS, 4., 2011, Berlim. [Annal...]. Berlim: Elsevier, 2011. (Thrombosis reserch 127: S123-S150)

## Impact of FDG-PET in preoperative staging and clinical management of patients with esophageal cancer – experience of a single center in Brazil

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### AIM

This study aims to evaluate the role of FDG-PET on preoperative staging and therapeutic management of patients with esophageal cancer in a single center in Brazil.

### Methods

98 patients (mean age of  $59.8 \pm 9.7$  years, 79.7% male) with biopsy proven esophageal cancer were included. All patients were prospectively evaluated between September 2006 and March 2008 and underwent FDG-PET whole body scans in addition to conventional staging methods (computed tomography – CT and gastro-esophageal endoscopy). After evaluating the findings of both methods, therapy was defined.

### Conclusions and results

FDG-PET was positive at the primary sites in 92% of the cases. Only 8 patients didn't have positive PET findings at the primary site, 3 of which were limited to the submucosa and 2 were in situ adenocarcinomas. There were no statistically significant differences in the degree of metabolism measured by SUV between adenocarcinomas and spinocellular carcinomas. PET

showed no difference in initial staging in only 37.6% of the patients, with 25.8% of the patients being upstaged and 36.6% downstaged. This translated into a change in management decision for 26% of the patients.

### Conclusions

FDG-PET showed high sensitivity in the detection of esophageal cancer and proved to be effective in preoperative staging of the disease, changing management in 26% of the patients.>

### Recommendations

FDG-PET should be strongly recommended as the gold standard staging methodology for esophageal cancer, especially in those patients without previously proven distant metastasis. The technology also proved to be cost-effective in a complementary study from the same group, by reducing the number of unnecessary surgical procedures.

### Further research/review required

Further research should focus the role of FDG-PET in the evaluation of neoadjuvant chemo and radiotherapy in esophageal cancer.

### Impact of lawsuits on national pharmaceutical care policy: clinical management and the medicalization of justice

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#### AIM

Investigate the phenomenon of judicialization in pharmaceutical care as an instrument for ensuring access to public health system in Brazil linking it to events observed in the Unique Health System (SUS) in the state of Minas Gerais in the period 1999 to 2009. Specific goals: a literature review, identify evolution, nature, values and spending trends of lawsuits and possible technological innovations incorporated through the courts.

#### Methods

The literature review for developing the conceptual framework was done through a systematic search on the internet in search of specialized sites. All the same happened to review the regulatory framework of pharmaceutical care in Brazil on the websites of Ministry of Health and the State Bureau of Health of Minas Gerais. Case study was based on data contained in administrative files of judicial actions and demands for health services under the State Bureau of Health of Minas Gerais (SES/MG). The search was performed by applying a specific form developed by the team of researchers from GPES/UFMG and subsequent multivariate analysis.

#### Conclusions and results

The database identified 6,184 administrative files containing 14,220 applications, of which 11,296 are for medicines, and 2,924 for materials and procedures, with 6,967 beneficiaries. 60.7% of court orders were delivered, 11.7% had suspended

its delivery, 3.1% were dismissed and 4.8% had no final court decision. 67.9% of cases were filed in State Court of first instance, 16.5% in the Superior Court of Minas Gerais, 15.6% assigned to federal authorities. 65.7% of the lawsuits are ordinary; 25.4% writ of mandamus. 48.0% were filed in the State Capital. 18.8% are retired, 53.2% are women. 55.4% have lawyers. 6.4% of the diseases relate to rheumatoid arthritis and diabetes mellitus. The amount spent on litigation in 2002 was 250 thousand reais and 44.4 million reais in 2008 (value upgraded by the Consumer Price Index Broad - IPCA).

#### Recommendations

The analysis of the database allowed the construction of beacons for evaluating a set of variables related to judicial orders. It is hoped that the continued partnership between SES/MG and Minas Gerais Federal University expand the use of records of lawsuits as a resource for research on actors and actions involved in the phenomenon of legalization of health.

#### Further research/review required

New discoveries will happen through study with the purpose of evaluating access, coverage and quality of pharmaceutical services, from court decisions in the face of state management of the SUS/MG, which was selected in the Public Notice 09 /2009 -PPSUS, Foundation for Research Support of Minas Gerais - FAPEMIG.

#### Reference

ANDRADE, E. I. G. et al. A judicialização da saúde e a Política Nacional de Assistência Farmacêutica no Brasil: gestão da clínica e medicalização da justiça. **Revista médica de Minas Gerais**, Belo Horizonte, v. 18, p. 46-50, 2008.

### The impact of a program for asthma control in a low-income setting

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#### AIM

The prevalence of asthma is increasing in developing countries and the burden of uncontrolled asthma affects patients, families and the health system. This is to evaluate and report the impact of a targeted and comprehensive approach to the most severe cases of asthma in a low-income setting.

#### Methods

The Program for Control of Asthma (ProAR) was developed from 2003 in Salvador, Bahia – Brazil, prioritizing the control of severe asthma. By facilitating referrals from the public health system and providing proper multidisciplinary but simple management including education and medication, for free, the Program enrolled 2,385 patients in 4 reference clinics until 2008. They were offered regular follow up and discharged back to primary health care only when asthma control could be maintained without requirement of a combination of an inhaled corticosteroid and a long acting beta 2 agonist, which is not available in primary care.

#### Conclusions and results

ProAR has markedly reduced health resource utilization and decreased the rate of hospital admissions due to asthma in the entire 2.8 million inhabitants City by 74% in 3 years. Moderate to severe rhinitis was associated with lack of control of asthma. The average income of the families of patients of ProAR was US\$2,955 a year, and they spent 29% of all their income attempting to control

the severe asthma of one member – a unbearable expenditure for a low-income family. The Program was shown to be cost-effective, it reduced costs to the public health system (by US\$387/patient/year) and to the families (by US\$789/patient/year). In conclusion, an intervention prioritizing the control of severe asthma was feasible, effective and reduced costs in a low-income setting of Brazil.

#### Recommendations

Asthma is highly prevalent in Brazil, where it is the third cause of hospital admissions other than those related to birth and delivery. Severe asthma brings an enormous burden to families and health systems and constitutes a barrier to development. It requires greater priority in public health. While building capacity of primary health care for the management of mild to moderate cases, it is important to develop reference centers for the most severe patients, which can markedly reduce morbidity and costs to the families and the public health system.

#### Further research/review required

It is important to investigate risk factors for deaths due to asma in Brazil and the impact of citywide interventions on asthma mortality.

#### Reference

SOUZA-MACHADO, C. et al. Rapid reduction in hospitalisations after an intervention to manage severe asthma. **Eur. Respir. J.**, [S.l.], v. 35, n. 3, p. 515-521, mar. 2010.

## COMT inhibitors for the treatment of Parkinson's disease: a systematic review and metanalysis

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### AIM

COMT inhibitors available for use in clinical practice, tolcapone and entacapone, are utilized as adjunctive therapy for patients with Parkinson's disease (PD) mainly in patients with motor fluctuations. The aim of COMT inhibitor therapy is to increase the duration of effect of each levodopa dose and thus reduce the time patients spend in "off" phase. Recently, trials with patients in early stage of disease have been published. Objectives are to evaluate the efficacy and safety of COMT inhibitors (tolcapone and entacapone) therapy, in patients with different stages of PD.

### Methods

A systematic literature search was performed between 1990 and August 2009. Only randomized, controlled trials in articles that included original, non duplicated descriptions of patients with PD treated with COMT inhibitors (tolcapone or entacapone) were selected for analysis.

### Conclusions and results

Twenty trials fulfilled the inclusion criteria (7 with tolcapone and 13 with entacapone). In this review 1190 patients were enrolled in trials with tolcapone (795 patients with motor fluctuations and 395 without motor fluctuations). In the entacapone trials 3974 patients were included (2408 with motor fluctuations and 1526 without motor fluctuations). The trials ranged in duration from 6 weeks to 6 months. As compared to placebo, tolcapone and entacapone resulted in

greater increase in "on" time and reduction in "off" time in patients with motor fluctuations. Treated patients also showed greater motor UPDRS scores in patients with motor fluctuations. The mean difference for entacapone was of 1.01 hours on per day in relation to placebo ( $p < 0.0001$  with 95% coefficient interval of 0.63 -1.39). The results were not consistent across all endpoints. The trials that evaluated patients with non motor fluctuations failed to show significant improvement in motor measures. Patients receiving COMT inhibitors had greater decrease in the dose of levodopa compared to placebo. Incidences of dyskinesia were significantly higher with the COMT inhibitors compared to placebo. Withdrawals due to adverse events were higher in patients on tolcapone (9.7%) and entacapone (12%) than patients on placebo (9.1% and 8.1%, respectively in tolcapone and entacapone trials). The mean difference for entacapone was of -96.06 mg ( $p < 0.001$ ) and -178,04 mg for tolcapone ( $p < 0.0001$ ) versus placebo. Tolcapone and entacapone were associated with significantly higher rate of dyskinesia than placebo. Dyskinesia was observed in 48.9% of patients that had received tolcapone, versus 19.8% on placebo, and entacapone (19.2%) versus 11.1% of placebo group. In conclusion, both tolcapone and entacapone reduced "off" time, reduced levodopa dose and improved motor impairments and disability. This was at the expense of increased risk of dyskinesias and adverse events.

### Recommendations

In the management of the motor complications seen in PD, tolcapone and entacapone can be used to treat motor fluctuation. However, there is no enough evidence to justify its utilization in patients without fluctuation.

## Innovation and health: public/private regulatory capacity in two technological processes

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### AIM

To identify and analyze the factors that influence decision making in the uptake of two selected technologies in the Brazilian health care system - an organizational technology (health social organizations - OSS) and a medical equipment (positron emission tomography – PET / CT).

### Methods

Case study involving the uptake and use of two selected technologies in the Brazilian health care system. Data collection was performed by means of access to management contracts for a sample of 13 hospitals in the State of São Paulo and interviews with representatives of the public system, health care organizations, manufacturers of the technology and health care professionals.

### Conclusion and results

The OSS model is, in practice, the transfer of the management of public health care facilities to private organizations (public non-state), through a legal instrument (management contract or agreement) which establishes a set of goals with respect to a range of health care services to be provided. Results showed that administrators of the public health care system at the state level have not been able to create instruments to monitor financial results, which should be part of a strategy that remove from the state the responsibility for the provision of health care services and transfer it to the private sector, which has greater flexibility of operation. Moreover, the establishment of financial ceilings can also generate cuts of unclear nature, which makes sense from the standpoint of most primary logic of the budget constraint, but may also cause undesirable effects in other dimensions of care. In

the case of PET/CT, the decisions to acquire the technology are made by managers of hospitals and clinics that adopt a differentiation strategy based on technological leadership. The factors influencing this decision are: the institution's history of pioneering the uptake of new health technologies, pressure of clinical staff, the prestige of the doctor or area that calls for the acquisition of technology, availability of financial resources, facilitating access to technology, competition between providers of health care services, availability of scientific evidence, return on investment, and availability of inputs required for operation of the technology. Paying agents in the public and private health systems have little influence in the process. This situation affects the distribution of benefits and costs among different social groups and tends to perpetuate existing inequalities in Brazilian society. From a health care perspective, public authorities have not adopted appropriate instruments to monitor and evaluate results for both technologies.

### Recommendations

It is recommended to strengthen the role of public health administrators in two dimensions: 1) improving the financial monitoring system of OSS model, and 2) adopting policy instruments to influence the spending decisions of private health care agents regarding the uptake and use of new health technologies.

### Further research/review required

It is recommended further research 1) to examine the different models of public-private partnership in the provision of health care services, and 2) to identify successful international experiences with regard to the administration of health technologies.

### Reference

VIANA, Ana Luiza d'Ávila; SILVA, Hudson Pacifico. Avaliando a difusão de tecnologias médicas no sistema de saúde privado no Brasil: o caso da tomografia por emissão de pósitrons (PET). **Revista brasileira de saúde materno-infantil**, Recife, v. 10, supl. 1, p. s59-s72, 2010.

## Artificial Intelligence in Medicine: Application of Case Based Reasoning in Diagnostic Radiology Pneumonia in Children

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### AIM

This work aims to develop a decision support system using the case-based reasoning (CBR) and content-based image retrieval (CBIR) as a method of processing images for radiological diagnosis of pneumonia in childhood, to build an intelligent monitoring system of radiological pattern of pneumonia in children, contributing to the detection of (i) variations in the endemicity of pneumonia, (ii) emergence of new radiological patterns, (iii) Georeferencing cases of pneumonia in aid for Public Management. It contributes to evaluation of health, detecting cases referred to hospital with radiological diagnosis of pneumonia by the health system and, however, "rejected" by a diagnostic system proposed here

### Methods

The CBR methodology is based on individual knowledge processing that aims to solve new problems based on previously solved problems and together with the content-based image retrieval guided by evaluation of the characteristics contained in the images. In the city of Goiania, the Department of Health began in July 1999 and vaccination against Hib in local health services, and concurrently was implemented a surveillance system population community acquired pneumonia admitted to pediatric hospitals in the city. Currently we have a database with about 25,000 images from the chest radiographs of children with the clinical diagnosis of pneumonia and provided by two trained

radiologists to read and interpret the images. This database is an excellent digital collection to build an expert system that can generate RBC evidence and contribute to decision making in clinical practice.

### Conclusions and results

The results achieved with this methodology show that it is possible to build a platform that will assist health professionals to make best diagnosis, and contribute in a different health areas to use information technology to aid in clinical practice.

### Recommendations

The first prototype (pilot project) will become operational in 2011 where we can track the performance of the system when compared with traditional models of care and decision making.

### Further research/review required

After the outcome of the pilot project will be necessary to evaluate the effectiveness, safety and cost-effectiveness of information technology applied.

### Reference

OLIVEIRA, L. L. G., et al. Computer-aided diagnosis in chest radiography for detection of childhood pneumonia. **International journal of medical informatics**, [S.l.], v. 77, p. 555-564, 2008.

## Behavioral interventions to promote condom use among women living with HIV/Aids

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### AIM

To investigate the effects of behavioral interventions to promote condom use among women living with HIV/AIDS.

### Methods

Systematic review of interventions and meta-analysis were conducted according to the Cochrane Collaboration methods. Randomized clinical trials (RCTs) and Controlled clinical trial (CCTs) that investigated behavioral interventions designed for people living with HIV were included based on the follow criteria: 1) to have women living with HIV/AIDS among participants, 2) to aim to promote protected sex, 3) to have protected sexual intercourse (anal or vaginal) or biological markers of STD (chlamydia, gonorrhoea, trichomonas) as outcomes assessed three months or more after intervention. We searched electronic scientific databases, clinical trials databases, conference proceedings and conference websites in order to identify studies from 1980 to May 2010. Among more than 3,000 abstracts screened, we selected six studies whose results were included in a meta-analysis involving a total of 756 women living with HIV/AIDS.

### Conclusions and results

Meta-analysis showed no effect of behavioral interventions on consistent condom use among women living with HIV/Aids immediately post-intervention ( $p = 0.6$ ), and three ( $p = 0.21$ ), six ( $p = 0.46$ ) and twelve months post-intervention ( $p = 0.49$ ). Previous meta-analysis studies show that behavioral interventions are effective in reducing sexual risk behaviors among adults living with HIV/Aids, especially when most of the sample is men. However, our study did not find the same

result among HIV+ women. Condom use in women involves a specific dynamics, including reproductive desires, serology and type of partner relationship. Considering that, achieving success in promote condom use among women living with HIV/Aids tends to be associated with the quality of attention on these specific dynamics.

### Recommendations

Although condom use is an effective strategy for reducing HIV and STD transmission, its promotion has been a challenge, especially among women. Gender-tailored behavioral interventions target to promote condom use among women are recommended as part of strategies to reduce HIV transmission. However, additional strategies must also be emphasized, as viral load reduction, couple and reproductive counseling.

### Further research/review required

There are gaps regarding the development of randomized clinical trials on behavioral interventions for women living with HIV/AIDS, particularly in Brazil. It pointed out the urgent need for Brazilian studies involving interventions to promote condom use based on a strong scientific and methodological rigor. Such interventions must include strategies that respond to the women's specific difficulties in using condoms. Thus, it is expected to expand and qualify the scientific production in Brazil. Therefore, more Brazilian researchers will be able to offer training in this area.

### Reference

CARVALHO, F. T., et al. Behavioral interventions for increasing the use of condoms in women with HIV (protocol). **Cochrane database of systematic reviews [online]**, v. 2, 2009.

## Educational and behavioral interventions in childhood obesity: a systematic review with metaanalysis of randomized clinical trials

Graciele Sbruzzi, Bruna Eibel, Claudia Ciceri Cesa, Rodrigo Antonini Ribeiro, Sandra Mari Barbiero, Rosemary Petkowicz, Willian Brasil de Souza, Carla Martin, Beatriz D'Agord Schaan, Lucia Campos Pellanda

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### AIM

To assess the effectiveness of educational and behavioral interventions to prevent or treat childhood obesity by a systematic review and metaanalysis of randomized clinical trials (RCTs).

### Methods

Data Sources: PubMed, EMBASE and Cochrane CENTRAL and references from studies and reviews included (from inception until March 2010) without language restriction. Study Selection: Eligible studies were RCTs enrolling children 6- 12 years-old which assessed the impact of educational and behavioral interventions longer than 6 months on body mass index (BMI), waist circumference, blood pressure, total cholesterol (TC) and high-density lipoprotein cholesterol (HDL). Data Extraction: Two reviewers independently carried out data extraction and quality assessment. Data Analysis: Calculations were performed using a random-effect model. Pooled-effect estimates were obtained using the final values.

### Conclusions and results

Results: Of 18.014 articles retrieved, 24 RCTs (22.444 patients) were included. Educational and behavioral interventions vs. no intervention altered: A) waist circumference (3 comparisons;

n:535) by -3.33cm (95%CI -6.19, -0.47; I2 58%), B) BMI (17 comparisons; n:17.285) by -0.11kg/m<sup>2</sup>(95%CI -0.34, 0.12; I2 89%), C) systolic blood pressure (5 comparisons; n:6065) by -1.01mmHg (95%CI -2.47, 0.46; I2 79%), D) diastolic blood pressure by -1.10mmHg (95% CI -3.36, 1.16; I2 93%), E) TC (4 comparisons; n:6763) by -1.4mg/dL (95%CI -5.7, 2.9; I2 85%) and F) HDL by 1.06mg/dL (95%CI -0.48, 2.6; I2 78%).

### Conclusion

Educational and behavioral interventions programs longer than 6 months caused significant effect on waist circumference, but no significant effect on BMI, blood pressure, TC and HDL compared with control. Financial support: MCT/CNPq/CT-Saúde/MS/SCTIE/DECIT, FAPICC.

Recommendations

### Further research/review required

New approaches, including trials with more comprehensive strategies are needed to improve these results.

### Reference

Manuscript is currently being written

## Judicialization and public health: a proposal for analysis and monitoring of individual judicial demands for access to medicines

Vera Lúcia Edais Pepe (coordination), Miriam Ventura (co-coordination), Claudia Garcia Serpa Osorio-de-Castro, Tatiana Aragão Figueiredo, João Maurício Brambati Sant'Ana, José Gilberto Pereira, Grazielle Silva de Lima, Ricardo Ribeiro Alves Fernandes, Rafael da Silva Cota, Letícia Figueira Freitas, Luciana Simas Chaves de Moraes, Michelly Ribeiro Baptista, Denise Gomes, Nara da Rocha Saraiva, Jacilene Geaquinto Leão Adriano

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Oswaldo Cruz Foundation

### AIM

To develop a methodology for monitoring and evaluation of judicial demands for medicines, aiming to contribute to better pharmaceutical services and to reduction of the number of suits.

### Methods

During the first stage, three databases of the State of Rio de Janeiro were analyzed to depict information quality and flow, from sentencing to supply of medicines, and content of lawsuits. In the second stage a thorough search of the literature – original papers, theses and dissertations - was achieved. In the third stage descriptive studies were analyzed, in order to build the variable dimensions for the indicator framework. The fourth stage led to formulation of 40 indicators which were submitted to a specialist consensus, resulting in a group of 30 indicators adjusted to the Brazilian context. In the fifth and last stage indicators were detailed with respect to definition, calculation method, use, limits, sources and analytical categories.

### Conclusions and results

The Monitoring and Evaluation Indicators for Judicial Demands for Medicines Manual presents four dimensions: 1. Socio-demographic characteristics of the suitor - per capita monthly income of family; % of population in age category; % of population according to occupation; % of population according to municipality of origin. 2. Procedural characteristics of suits - % of suits according to representation; median time period for injunction ruling; median time period for

subpoena of health authority; median time period for supply of medicine; % of injunction rulings; % of suits with judicial requirement for injunction ruling; % of rulings favorable to suitor; % of appellate rulings favorable to suitor; extra-judicial demand ratio; collective suits ratio; % of suits according to defendant category. 3. Clinical and regulatory characteristics of suits - % of medicines according to therapeutic/pharmacological/chemical sub-group; % of medicines prescribed by non-proprietary (generic) name; % of prescriptions by non-proprietary (generic) name only; % of demanded medicines included in the official essential medicines lists; % of suits containing additional documents to the prescription; % of medicines categorized by strength of recommendation of evidence as having grades I or IIa; % of principal diagnoses, by diagnostic category; % of patients registered at supply levels, previous to suit date; usage of demanded medicines ratio; % of demanded medicines with therapeutic alternative available in the Brazilian Health System. 4. Political and administrative characteristics of suits - % of marked approved medicines; % of medicines according to each medicines-financing segment; % of suits with at least one medicine prescribed according to an off-label indication; % of suits that demand at least one medicine not covered by a medicines-financing segment; % of suits that demand at least one medicine belonging to the 'Specialized Component' financing segment.

### Recommendations

The indicator framework is important to characterize the country situation. We suggest that the health and justice establishments better their information systems and that they follow up on the plaintiffs post-medicines-use outcomes.

### Recommendations for research

We recommend the validation of the indicator framework by means of a multicenter study involving all levels of government and interdisciplinary teams.

### References

PEPE, V. L. E. A judicialização da saúde e os novos desafios da gestão da assistência farmacêutica. **Ciência coletiva e saúde**, São Paulo, v. 15, p. 2405-2414, 2010.

## Educational and behavioral interventions in childhood obesity: a systematic review with metaanalysis of randomized clinical trials

Graciele Sbruzzi, Bruna Eibel, Claudia Ciceri Cesa, Rodrigo Antonini Ribeiro, Sandra Mari Barbiero, Rosemary Petkowicz, Willian Brasil de Souza, Carla Martin, Beatriz D'Agord Schaan, Lucia Campos Pellanda

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### AIM

To assess the effectiveness of educational and behavioral interventions to prevent or treat childhood obesity by a systematic review and metaanalysis of randomized clinical trials (RCTs).

### Methods

Data Sources: PubMed, EMBASE and Cochrane CENTRAL and references from studies and reviews included (from inception until March 2010) without language restriction. Study Selection: Eligible studies were RCTs enrolling children 6- 12 years-old which assessed the impact of educational and behavioral interventions longer than 6 months on body mass index (BMI), waist circumference, blood pressure, total cholesterol (TC) and high-density lipoprotein cholesterol (HDL). Data Extraction: Two reviewers independently carried out data extraction and quality assessment. Data Analysis: Calculations were performed using a random-effect model. Pooled-effect estimates were obtained using the final values.

### Conclusions and results

Results: Of 18.014 articles retrieved, 24 RCTs (22.444 patients) were included. Educational and behavioral interventions vs. no intervention altered: A) waist circumference (3 comparisons;

n:535) by -3.33cm (95%CI -6.19, -0.47; I2 58%), B) BMI (17 comparisons; n:17.285) by -0.11kg/m<sup>2</sup>(95%CI -0.34, 0.12; I2 89%), C) systolic blood pressure (5 comparisons; n:6065) by -1.01mmHg (95%CI -2.47, 0.46; I2 79%), D) diastolic blood pressure by -1.10mmHg (95% CI -3.36, 1.16; I2 93%), E) TC (4 comparisons; n:6763) by -1.4mg/dL (95%CI -5.7, 2.9; I2 85%) and F) HDL by 1.06mg/dL (95%CI -0.48, 2.6; I2 78%).

### Conclusion

Educational and behavioral interventions programs longer than 6 months caused significant effect on waist circumference, but no significant effect on BMI, blood pressure, TC and HDL compared with control. Financial support: MCT/CNPq/CT-Saúde/MS/SCTIE/DECIT, FAPICC.

Recommendations

### Further research/review required

New approaches, including trials with more comprehensive strategies are needed to improve these results.

### Reference

Manuscript is currently being written

### Brief neuropsychological assessment model for health centers.

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### AIM

Due to the fact that a neuropsychological assessment is fundamental for the definition of several diagnoses in childhood, as it involves more than the simple application of tests for intellectual abilities, and that the traditional model for neuropsychological assessment is highly costly, the aim of this study was to analyze the applicability of a brief neuropsychological assessment model for children with possible developmental disorders, which could be useful for health centers in several regions of Brazil.

### Methods

The model was based on a Brief Neuropsychological Assessment – Instrumento de Avaliação Neuropsicológica Breve: versão para crianças (NEUPSILIN-INF), which is being standardized for the Brazilian population, in two Brazilian cities – Porto Alegre and São Paulo. The efficiency of such instrument in the detection of potential cases of developmental disorders, combined with tests for intellectual abilities and behavior scales which composed the brief assessment model, was tested in a sample of 86 children who sought assistance at an Assistance Center (Child Neuropsychological Assistance Center - NANI). The clinical group was compared to the normative group from the city of São Paulo through statistical measures (General Linear Model- GLM).

### Conclusions and results

The mean age of the children was 9.8 years  $\pm$  2,0 (varying from 5 to 14 years), 69.8% male. The majority

of the reasons for referral were related to learning difficulties at school (53.5%) and hyperactivity or inattention problems (32.6%). The remainder was related to specific difficulties (5%), such as psychomotor difficulties, speech delay, anxiety/depression (2%); developmental delay (3%). From the 86 children seen, 31% (n=27) presented a lower percentile (<20) in non-verbal tests for intellectual abilities. With regard to the results for NEUPSILIN-INF, a significant positive correlation was found between the scores obtained in the test for intellectual abilities and in the visuo-constructive and arithmetic abilities subtests, only. With regard to the mean score for NEUPSILIN-INF, patients had significantly lower scores when compared to the normative group in the attention, visual perception, memory, executive functions, visuo-constructive and arithmetic abilities subtests, with no differences being found only in the language tasks. Thus, NEUPSILIN-INF proved useful in the detection of cognitive alterations in complaints related to learning difficulties, inattention, specific difficulties during child development. It was also observed that the utilization of the tests for intellectual abilities alone may not be efficient in order to identify such difficulties.

### Recommendations

In view of the considerable shortage of public services for complaints regarding developmental disorders, the use of this brief assessment model can be an economically efficient model, which has been a challenge for the health centers in Brazil.

### Further research/review required

We recommend the continuity of studies into the use of NEUPSILIN-INF, with the identification of those tasks which are more sensitive for certain clinical profiles such as, for instance, global developmental delay, dyslexia, Attention deficit hyperactivity disorder, among others, which could be the basis for appropriate intervention programs for each case.

### Reference

CAREY, P. F.; KONKOL, R. J. Neuropsychology: adaptation for a busy pediatric neurology clinic in a managed care setting. **The permanente journal**, [S.l.], v. 6, n. 3, summer, 2002.

## Management of asthma in a Brazilian city after a structured action plan in the primary care: data after four years

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### AIM

Asthma is a chronic high prevalence disease. In Brazil most cases are managed at exacerbations and neglected at primary care. All guidelines recommend the use of inhaled steroids (IS) associated or not with bronchodilators as the primary treatment for asthma. Despite this recommendation, IS are poorly used by the physicians. Coordinated interventions for asthma management, education of patients and healthcare providers are the most efficient solution to improve diagnosis and treatment. Thus, a Brazilian city created an structured program to solve those issues (PRL). The aim of PRL was to training healthcare providers for better diagnosis, economic and social cost reduction and changing the practice throughout local health system organization and by using primary care strategy in a context of reference and contra reference. The goal of this project was to evaluate the global impact of those actions due the high professional and patients compliance in a strong permanent education process environment.

### Methods

Physicians and nurses from Primary Care Units (PCU) were trained from November 2003 to May 2004. Inhaled Steroids was given to all PCU, education programs for patients were created, active search of respiratory patients and the creation of a reference with a respiratory physician, were the strategies. Epidemiologic secondary data were collected during the 4 years of PRL.

### Conclusions and results

It was analyzed 5510 patients in 39 PCU after training. Those patients were majority females (56,3%) with median age of 27,4 years, most of

them were adults (48,3%). After PRL, was observed reduction in the inhaler use at units per habitant. The absolute number of admissions between 2000 to 2007 was reduced progressively. Those who were admitted the median hospital time was 3,3 days (SD 3,55). Elderly had their admission time extended for 5,6 days ( $p < 0,001$ ). The admission time thought the years 2000 to 2006 were the same with significant difference. When compared the time before PRL (2000-2003) and after PRL (2004-2007) was observed a significant decrease in the admissions from 104/100.00 hab. to 53/100.000 hab. ( $p < 0,01$ ). We conclude that PRL was a success because it was able to change the treatment of Asthma (use of IS, admissions and nebulized procedures reduction at PCU) and organized the health system with emphasis at primary care. The investment and training at PC improve the whole system.

### Recommendations

A bigger investment in training of primary care professionals and access to IS.

### Further research/review required

Its necessary more studies in compliance of patients en PRL.

### Reference

CERCI NETO, A.; FERREIRA FILHO, O. F.; BUENO, T. Redução de internação hospitalar por crise asmática após a implantação de programa multiprofissional de controle de asma na cidade de Londrina. **J. Bras. Pneumol.** [S.l.], v. 34, n. 9, p. 639-645, 2008.

## D-dimer plasma levels and pre-eclampsia – A systematic review

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### AIM

Pre-eclampsia (PE) is associated with fibrin deposition in placental and renal microcirculation. D-dimer (D-Di) is the smallest fragment of the breaking of fibrin clot. The plasma level of this fragment has been used as a marker of production / degradation of fibrin in vivo. It is well established that plasma levels of D-Di have a negative predictive value for the diagnosis of deep vein thrombosis. Several studies show an increase of D-Di plasma levels in PE. The aim of this study was to review publications that assessed the D-Di plasma levels in pregnant women with PE and normotensive pregnant, by the most sensitive technique used (Enzyme-linked immunosorbent assay-ELISA), to define the diagnostic value of this marker for this disease.

### Methods

We performed a systematic review following the methodology recommended by the Cochrane Collaboration. The electronic search included the Medline / Pubmed, EMBASE, LILACS and Web of Science (updated through August 2010) using sensitive search strategies, including a combination of free terms and controlled vocabulary from the relevant keywords. Additional studies were manually searched on the lists of references of potentially relevant articles. Only publications in English, Spanish and Portuguese were considered.

We included observational studies evaluating D-Di plasma levels in pregnant women with PE and normotensive pregnant. Among the 194 titles in the literature, 47 were considered potentially eligible and 10 were selected for this review.

### Conclusions and results

Among the 10 relevant studies to answer the question proposed in this systematic review, five had sufficient data and appropriately, allowing the combination of their results through a meta-analysis. These studies evaluated 347 cases of PE and 604 normotensive pregnant women. The results of the studies included in this meta-analysis showed high variability, some showed elevated D-Di plasma levels in pregnant women with PE and others in normotensive pregnant women. Analysis of the results showed no significant differences between D-Di plasma levels, measured by ELISA, in patients with PE compared to normotensive pregnant women.

### Recommendations

Further research/review required

The limitation of this systematic review was to include only articles in English, Spanish and Portuguese and should be conducted a new review including papers in other languages.

### Reference

Manuscript under review.

## Improving Medication Adherence After Hospitalization in Chronic Cardiovascular Disease: Preliminary Results of a Randomized Controlled Trial

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### AIM

To assess a brief intervention in post-discharge patients with cardiovascular diseases taking prescribed drugs with the aim of improving medication adherence

### Methods

A randomized controlled study of post-discharge patients with cardiovascular diseases was conducted at a hospital in Maceió, Brazil. 61 patients were recruited between October 2009 and January 2010 and were randomized to intervention (n = 30) and control (n = 31) groups. The intervention were performed by ward-based pharmacists, control group received usual care. The primary outcome measure was medication adherence assessed using the Morisky Medication Adherence Scale (MMAS-8) at 1 month after hospital discharge hospital discharge by phone call.

### Results

The mean age of the patients was 61 years (SD 12.73), 52.5% were male, and 57.4% were married or living as if married. Mean number of prescribed medications per patient was 4.5 (SD 3.3). Medication adherence was 48.4% and 83.3% in the usual care and intervention groups, respectively (Cohen's d = 0.741) during the intervention period. Taking adherence was significantly greater (P=.004) in the intervention group than the usual care group. Potential factors that may affect medication adherence (e.g. sex, age, marital status, number of prescribed medications,

to undergo surgery during hospitalization and main diagnosis) were not related to medication adherence after 1 month. In logistic regression having receiving intervention was the only significant risk factor for medication adherence. This effect may be due to several causes. First, although 12 different classes of drugs were used by the patients' physicians, a narrow variety of drugs inside these classes were prescribed (mostly aspirin, enalapril, losartan, clopidogrel and rosuvastatin). Such rigid adherence to medical guidelines, while may lead to excessive costs, permitted us to focus our efforts on a restricted number of therapies. Second, our intervention was centered on subjects considered critical to success of treatment and it may be related to a MMAS-8 question commonly answered incorrectly between non-adherent patients: "Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?" In our study, physicians reported that some patients came back or contacted them by phone call after an adverse drug event for which they were warned during counselling session, instead stop taking medicines. Based on these findings, we conclude that a brief intervention based on MMAS-4 is an effective method to improve adherent behaviour in post-discharge patients with cardiovascular diseases taking prescribed drugs.

### Recommendations

The evidence suggests that a simple, inexpensive and safe counselling protocol based on validated MMAS-4 could increase medication adherence in post-discharge patients with CDV.

### Further research/review required

Despite the encouraging results, we need to examine other behavioural determinants that may influence medication adherence and clinical outcomes. These results need to be replicated using a multicentre, longer, randomized strategy, and such a study is already being carried out in patients with chronic cardiovascular diseases.

## Consumers' preferences and demands for medicines

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### AIM

The aim of this study was to identify the determinants of the demand for medicines used to control high blood pressure amongst patients covered by a private health insurance

### Methods

We used a mixed logit model that incorporated a set of latent variables (attitudes and perceptions toward medicines choice) to explain how individuals' demographic factors influenced choice. A simultaneous estimation was performed to assess together the latent model and the discrete choice model. The dummy variable, generic or not generic medicine was the dependent variable. The independent variables were the socio-economic and demographic characteristics of individuals and the perception and attitudes, what included perceived quality of medicines, price, influence of doctors or pharmaceutical professionals, beliefs etc.

### Conclusions and results

Branded medicines were preferred to generic drugs for all socio-economic and demographic groups. Individuals perceived branded medicines as better quality ones rather generic drugs. They were willing to pay more for those class of drugs because they believed they were superior. Individuals were not only influenced by the doctors and pharmaceutical professionals but also by their own beliefs these drugs were consumed by rich people, and so they had a better performance to cure/improve their health conditions. Option for the generic drugs

was only in case of the branded medicines were too expensive. Our findings seem to contrast with other studies where generic drugs were perceived as cheaper and with similar quality as branded medicines. However, in spite of these studies have pointed out for different perceptions of generic drugs, they have also stressed that individuals usually score generic drugs similarly, but do not use to consume them very much. According with some authors, only 12% of their study population have stated they actually consume generic drugs. This contrast result may indicate that the methods used to capture individuals' perceptions and attitudes toward medicines' use are unable to identify individuals drives for drugs. The joint model here proposed seems to be able to associate the socio-economic and demographic characteristics of individuals and their psychometrics indicators (perceptions and attitudes) to explain their behaviour towards drugs.

### Recommendations

We recommended that models jointly incorporate psychometric measurements and socio-economic and demographic characteristics of individuals to explain their behavior toward different choices analysis.

### Further research/review required

CAREY, Peter F.; KONKOL, Richard J. Neuropsychology: Adaptation for a busy pediatric neurology clinic in a managed care setting. In: THIRTIETH NATIONAL MEETING OF THE CHILD NEUROLOGY SOCIETY, 30., 2001, Victoria. **Annal of the Thirtieth National Meeting of the Child Neurology Society**. Victoria: Child Neurology Society, Oct 17-20, 2001.

## PET Project - Technology Assessment of Positron Emission Tomography

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### AIM

The study assessed the evidence of accuracy, impact on clinical management and therapeutic health outcomes in the use of Positron Emission Tomography (PET-scan) for diagnosis, staging and re-staging of the following cancers: head and neck cancers, esophagus, colon and rectum, breast, lung, melanoma and malignant lymphoma.

### Methods

The methodology used was a rapid review of health technology assessment (HTA), bringing together three complementary strategies: (1) survey ratings produced by HTA agencies of from the INAHTA database; (2) survey of clinical practice protocols regarding the use of PET-scan in the cancers under study, from international (National Guideline Clearinghouse and National Library of Guidelines) and national sources (Projeto Diretrizes of Brazilian Medical Association and websites of specialty societies); and (3) literature search for systematic reviews (SR) and meta-analysis in the MEDLINE, COCHRANE, LILACS and SciELO databases.

### Conclusions and results

The study resulted in seven technical-scientific reports that sought to assist decision-making processes of the Ministry of Health regarding the incorporation of PET-scan to the national reimbursement tables. Considering the evidence of accuracy and impact on clinical management and treatment, the PET-scan was particularly useful in lung cancers (diagnosis of solitary

pulmonary nodule, staging of non-small cell lung cancer, differentiation between residual lesion and recurrence, when anatomical image was non-explanatory) and lymphomas (evaluation of response to treatment and examination of residual masses, to differentiate between scar tissue and viable tumor). It also presents potential clinical utility in the following cancers and directions: (a) head and neck cancers (diagnosis of hidden primary tumor, discovered from the presence of cervical lymph node metastases; differentiation between recurrence and residual disease); (b) colon and rectum cancer (staging of potentially resectable liver metastases, cases with elevated CEA enrolled, with anatomical imaging techniques with negative or equivocal results; assessment of hepatic and extra-hepatic recurrence); and (c) melanoma (evaluation of systemic metastases in staging and evaluation of recurrence). In these two groups of neoplasias, the use of PET-scan can avoid surgery and other unnecessary diagnostic procedures, as well as induce changes in the type of planned therapeutic procedure. We found no evidence to recommend routine use of technology in esophageal and breast cancers. The impact of technology on final health outcomes is sparsely studied in the literature and no conclusive evidence was found

### Recommendations

It is recommended that the possible incorporation of the PET-scan rates to reimbursement tables for Unified Health System's medical procedures preferentially consider those situations where the technology is accurate and shows the potential for change in clinical management therapy, to ensure its rational use and effective cost. It is also suggested monitoring the use, that should be guided by clinical practice protocols.

### Further research/review required

We recommend the development of local cost-effectiveness studies, because differences in cost structures, clinical practices for diagnosis and treatment, and distribution and availability of health resources prevent that external economic evaluation results are fully translated to the Brazilian reality.

## Can C-reactive protein be used as a predictor in diagnosing pre-eclampsia? Results of a systematic literature review

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### AIM

To evaluate if elevated serum concentrations of c-reactive protein (CRP) in the first and second trimesters of pregnancy are associated with the occurrence of pre-eclampsia (PE) and thus the potentiality of this inflammatory marker to be used as a health technology in the routine of health services for prenatal care.

### Methods

This is a systematic literature review. The identification of references was made through MEDLINE search using the following keywords: ("C-reactive protein" OR CRP) AND (preeclampsia OR pre-eclampsia OR "gestational hypertension"). Only studies in which the relationship between CRP and PE were studied prospectively were included in the review.

### Conclusions and results

Twelve studies in which CRP levels were measured before the diagnosis of PE were included. Eight studies found a positive association between

higher CRP serum concentration at the beginning and middle of pregnancy and the subsequent occurrence of PE. Of the six studies that evaluated the PCR in the first trimester, only three found a positive association between serum levels of this inflammatory marker with the occurrence of PE. Among the six studies that evaluated CRP levels in the second trimester, four found a positive association. However, there is great heterogeneity in relation to some important methodological issues of the reviewed studies, as the moment of the serum CRP evaluation and variety in sample size and characteristics that must be taken into account when interpreting these results. The evidence on the relationship between elevated serum concentration of CRP in early pregnancy and the increased risk of PE are scarce and insufficient.

### Recommendations

There is still no scientific support to justify the use of serum concentration of CRP as a technology in prenatal health care routine to identify women at risk of developing PE.

## Quality of life and its relation to the diagnostic technologies in swallowing disorders in total laryngectomized: applicability of the Swal-QOL questionnaire

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### AIM

To present the Swallowing Quality of Life Questionnaire (SWAL-QOL) to evaluate the quality of life in swallowing and its relation to the use of diagnostic technologies in total laryngectomized.

### Methods

An analysis of the questions and the applicability of SWAL-QOL questionnaire in total laryngectomized were performed. With this, were attempted to analyze the practicality of the questionnaire, clarity of questions, the questionnaire response options and convenience in the data analysis for statistical purposes.

### Conclusions and results

QOL-SWAL questionnaire has comprehensive, clear and objective questions. It facilitates the computation of data for statistical analysis,

and evaluates and relates the quality of life in swallowing of total laryngectomized and the use of diagnostic technologies in these cases. QOL-SWAL questionnaire is an instrument to evaluate the quality of life in swallowing and its relation to the use of diagnostic technologies in total laryngectomized. This Questionnaire contributes to a better rehabilitation of the swallowing process.

### Reference

MONTONI, N. P., et al. Cross-cultural adaptation of the SWAL-QOL and Swal-care questionnaires into brazilian portuguese. **Applied cancer research**, [S.l.], v. 29, n. 3, p.129-134, 2008.

## The relationship between electrocardiographic findings and the left atrial volume index in patients with positive serology for Chagas disease

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### AIM

Relate the electrocardiogram (ECG) with Doppler echocardiogram (ECHO) focusing on the Left Atrial Volume Index (LAVI) indexed by body surface.

### Method

Seventy three patients with Chagas disease were submitted to anamnesis, electrocardiogram (ECG) and Doppler echocardiogram (ECHO). Data from 24 patients were considered after excluding all those with diseases that interfere with the ECHO parameters. Details: <http://www.periodicos.uem.br/ojs/index.php/CienCuidSaude/issue/view/291>

### Conclusions and results

The data show that there is no significant difference among the different ECG alterations between participants without co-morbidities which interfere with ECO (24) and those with co-morbidities (73). This means that the group of 24 subjects represents the real tendency of the electrocardiographic findings of the total participants in the study. Table 1 shows that the proportions of ECHO findings follow the same tendencies in the groups of 24 and 73 participants/subjects.

In the group consisting of 24, 3 out of 12 participants with normal ECG presented altered ratio E/A ou E'/A', 4 presented increased LAVI and

normal ejection fraction (LVEF), but close to the limit. Six from 12 chagasic patients with normal ECG and without co-morbidity presented at least one marker for altered cardiac dysfunction. The prevalence of participants with altered LAVI, increased LAV and ratio E/A e E'/A' lower than 1, did not differ significantly between the group of 24 and 73. However, were significant only the differences between the averages of the ratio E/A and E'/A' among the patients with normal and altered ECG in the group of 73, which reassures the importance of these markers as predictors of cardiac function alteration. The average for LAVI and LAV in patients with altered ECG in the group of 73 signals cardiac compromising, although the difference between patients with normal or altered ECG is not significant. The same tendency is verified comparing both groups.

### Recomendations

The study provides perspective to evaluate the evolution of these parameters. It is suggested that the Doppler echocardiographic assessment is routinely used in patients with pathologies that evolve with diastolic dysfunction.

### Further research/review required

Corroboration of these data by other groups with amplified casuistic will allow rethinking the concept of cardiac compromising in individuals with positive serology for Chagas disease, with regular ECO evaluation, with LAVI calculation as a routine, even in individuals with normal ECG.

### References

CASSAROTTI, D. J. et al. Alterações do ecodopplercardiograma em pacientes com doença de chagas e eletrocardiograma normal: dados preliminares. **Rev. da soc. bras. de med. tropical**, Rio de Janeiro, v. 41, supl. 3, p. 194-197, 2008.

## Positron Emission Tomography with 2-[18F]-fluoro-2-desoxy-D-glucose after two cycles of ABVD predicts event free survival in early and advanced Hodgkin Lymphoma

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### AIM

To assess the prognostic value of FDG-PET after two cycles of chemotherapy using ABVD in overall patients with Hodgkin lymphoma (HL) and in the subgroups of early and advanced stage, and low and high risk according to International Prognostic Score (IPS).

### Methods

One hundred fifteen patients with newly diagnosed HL were prospectively included in the study. All submitted to standard ABVD therapy followed by consolidation radiotherapy in case of bulky disease. After two cycles of ABVD, patients were evaluated with PET (PET2). PET2-negative was defined as no pathologic FDG uptake at any site, including all sites of previously increased pathologic uptake. A study was considered PET2-positive in the presence of a focal FDG uptake that could not be attributed to physiological biodistribution. PET2 minimal residual uptake (MRU) was defined as low-grade FDG uptake with avidity smaller than, equal to or only slightly higher than the uptake in mediastinal blood pool structures. Prognostic analysis compared three-year event free survival (EFS) rate to PET2 results, clinical data (age, sex, initial staging, presence of B symptoms, bulky disease, erythrocyte sedimentation rate - ESR, albumin, hemoglobin, lymphocytes and IPS).

### Conclusions and results

Of the 104 evaluated patients, 93 achieved complete remission after first-line therapy. In a median follow-up of 36 months, relapse or disease progression was seen in 22 patients. Treatment failure was seen in 16 of the 30 PET2-positive patients and in only six of the 74 PET2-negative patients. PET2 was the only significant prognostic factor. The three-year EFS for PET2-positive patients was 53.4% and was 90.5% for PET2-negative ones ( $p < 0.001$ ). When patients were divided in low and high IPS risk and early and advanced stage disease, PET2 was also significantly associated with treatment outcome. PET2 appears to be the most important prognostic factor in HL and provides valuable prognostic information in patients with HL treated with ABVD with 3-year. A negative interim FDG-PET is highly predictive of treatment success in overall HL patients as well as in subgroups of early or advanced-stage disease, independent of the risk according to IPS. However clinical trials are needed to define the best way to use this important new prognostic factor in designing response-adapted therapies.

### Recommendations

To include FDG-PET/CT in public health care system in Brazil for prognostic evaluation of HL patients.

### Further research/review required

Evaluate if the prognostic value of PET is the same in other subtypes of lymphoma and most important perform prospective clinical trials to evaluate if changes based on PET2 results in clinical better outcome, with less intensive and/or toxic regimens in PET2-negative patients, and with more aggressive treatment strategies in PET2-positive patients.

### Reference

CERCI, J. J. et al. 18F-FDG PET after 2 cycles of ABVD predicts event-free survival in early and advanced hodgkin lymphoma. **J. nucl. med.**, [S.l.], v. 51, n. 9, p. 1337-1343, sep. 2010.

## Cost-effectiveness of positrons emission tomography in Hodgkin lymphoma patients in unconfirmed complete response or partial remission after line therapy

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University of São Paulo

### AIM

Assess the cost-effectiveness of fluorine-18-fluorodeoxyglucose positron emission tomography (FDG-PET) in patients with Hodgkin lymphoma (HL) with unconfirmed complete response (CRu) or partial remission (PR) after first-line treatment.

### Methods

130 patients with HL were prospectively studied. After treatment, all CRu/PR patients were evaluated with FDG-PET. PET-negative patients were compared with standard follow-up and PET-positive with biopsies results. Local unit costs of procedures and tests were evaluated. Cost-effectiveness relation was projected to estimate annual economic impact of strategies without and with FDG-PET on HL management.

### Conclusions and results

After treatment CRu/PR was observed in 50 (40.0%) of the 127 patients; FDG-PET sensitivity, specificity, positive and negative predictive values were 100%, 92.0%, 92.3% and 100% (accuracy of 95.9%). Local restaging costs strategy without PET was \$ 350,050 compared to \$ 283,235 with PET, a 19% decrease. The incremental cost-effectiveness ratio is of less \$3,342 to detect one true case. PET costs represented 1% of total costs of HL treatment. Simulated costs in the 974 patients registered in the

2008 Brazilian public healthcare database, showed that the strategy including restaging PET would have a total program costs of \$ 55,500,902 which is \$ 516,765 less than without restaging PET, resulting in a 1% cost saving. FDG-PET demonstrated 95.9% accuracy for HL patients with CRu/PR after first-line therapy. Given observed probabilities, FDG-PET is highly cost-effective and would reduce costs for the public healthcare program in Brazil.

### Recommendations

Include FDG-PET/CT in public health care system in Brazil.

### Further research/review required

To assess if results are reproducible in non-Hodgkin lymphoma patients.

### Reference

CERCI, J. J. et al. Cost effectiveness of positron emission tomography in patients with hodgkin's lymphoma in unconfirmed complete remission or partial remission after first-line therapy. **J. clin. oncol.**, [S.l.], v. 28, n. 8, p. 1415-1421, mar. 2010.

## Protocols of quality of life and its relations with human communication in rural workers underwent total laryngectomy

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Federal University of Pernambuco

### AIM

To survey protocols of quality of life related to human communication disorders that can be applied to rural workers underwent total laryngectomy.

### Methods

A systematic review of studies using protocols of quality of life in human communication in patients with laryngeal cancer was done. The databases like: Medline, Medline OLD, LILACS, SciELO Brazil, Pub Med and The Cochrane Lybrary were widely used.

### Conclusions and results

The protocols more appropriate for the evaluation of quality of life and communication in total laryngectomized are: HHIE-S, a self-assessment questionnaire, in Portuguese for obtaining auditory Handicap; VHI (Voice Handicap Index

with 30 questions about functional, emotional and physical aspects related to voice disorders; the SWAL-QOL (Quality of Life Disorders), a questionnaire with 44 questions that evaluate 10 areas of quality of life and deglutition; and the evaluation protocol of the communication satisfaction in patients after total laryngectomy (Bertoncello, 2004). The data resulting from the use of these quality of life protocols can give support to researchers for expansion and comprehension of clinical reasoning in the study of quality of life and its relation with language, hearing, voice, mastication and deglutition in laryngectomy rural workers.

### Reference

PAULA, F. C., GAMA, R. R. Quality of life evaluation after total laryngectomy. **Rev. bras. cir. cabeça pescoço**, São Paulo, v. 38, n. 3, p. 177-182, 2009.



Developing

## The Brazilian experimental algorithms for the treatment of mood disorders in the public health system

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### AIM

Algorithms for the treatment of mood disorders using only medications provided by the Brazilian Public Health System are being proposed in a Mood Disorders Outpatient Program at the São Pedro Psychiatric Hospital in Porto Alegre, Brazil. The main objective of the study is to evaluate interventions based on the best cost-effectiveness relation to manage mood disorders in the public health system.

### Methods

Algorithms for mood disorders were developed through a critical review based on the available literature. The sample is composed of adults with current mood disorders (Bipolar or Major Depression), according to Diagnostic Statistics Mental (DSM-IV). Individuals are accompanied every two weeks and the outcomes evaluated are: quality of life, assessed by the World Health Organization Quality Of Life (WHOQOL-BREF) and Medical Outcomes Study Short Form (SF-36) and response to treatment by the Young Mania Rating Scale (YMRS) and the Hamilton Rating Scale for Depression (HAM-D).

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## Analysis of available evidence and the effects of educational intervention in changing lifestyle habits in children in order to reduce childhood obesity

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### AIM

Conduct a systematic review of the available evidence on interventions in food consumption, nutrition and physical activity based on the Social Cognitive Theory in order to promote a change in lifestyle habits in schoolchildren leading to a reduction in obesity. To analyze the effects of educational intervention in food consumption, nutrition and physical activity in schoolchildren in the public and private schools in Viçosa, MG, based on the Social Cognitive Theory, for promoting healthy life habits in children to reduce overweight and obesity.

### Cost-effectiveness analysis of enzymatic replacement therapy in the treatment of mucopolysaccharidosis

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Bahia Federal University

#### AIM

To evaluate the cost-effectiveness of enzyme replacement therapy (ERT) used for treating patients with MPS I, II and VI.

#### Methods

Patients in the North and Northeast of Brazil are analyzed before and after the ERT and, prospectively, the cohort submitted to therapy compared with those without ERT. Simultaneously, clinical data collection and institutional and family costs will be refined and quality of life measured by the SF36 and CHQ-PF50 CHAQ questionnaires. The variables are expressed as percentages, average and standard deviations and compared with Chi-square, T-test and Mann-Whitney. The ratio between the difference of the cost of interventions and the difference of the health outcomes obtained will give the incremental cost-effectiveness.

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### Assessment of the demand for referrals from hypertension and diabetes for medium complexity health care in the São Paulo region

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#### AIM

To evaluate the profile of the demand for referrals for medium complexity health care in the Sao Paulo region. Specific Objectives: To analyze the referrals for consultations and exams for Outpatient Medical Specialties (OMS) according to clinical protocols and to analyze the solvability of Primary Care and OMS.

#### Method

A case study, with its outlining conditions for the evaluation of health care being hypertension and diabetes mellitus. The research will be conducted in three stages: 1) characterization of the health regions of the state; 2) interviews with health managers and professionals and 3) interviews with patients referred to the OMS and analysis of medical records.

## Assessment of the incorporation of new information and communication technology for information and knowledge management in health services of the Federal District.

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### AIM

Despite the numerous digital inclusion initiatives in Brazil, the number of people excluded from socio-technological factors remains high. This is particularly true amongst professionals who make up the Family Health Strategy (FHS) teams, especially the 1,162 Community Health Agents (CHAs) working within the health regions under the Health Secretariat of the Federal District. Since December of 2007, these agents have been in a process of digital inclusion that has centered on: intersecting Information, Education and Communication in Health (IEC) practices; including new information and communication technologies; and producing content for knowledge and information management within basic health networks. Therefore, the project seeks to: a) describe the training process for CHAs in health information and communication with a focus on content production, reception, mediation, and social applicability in knowledge production; b) analyze how Information, Education and Communication in Health inclusion strategies are applied in the daily practices of CHAs using palmtops; and c) assess the perception of subjects that directly or indirectly use ICTHs, based on a sample of CHAs, communities, and managers and on results of knowledge and information management.

### Methods

This is a qualitative study based on action-research that covers the administrative health regions of the Federal District. The study will last 20 months and will be based on a sample of 1,162 CHAs, representatives of regional health councils, communities aided by the CHAs, and managers directly or indirectly involved in projects. Community representatives will be chosen using a casual approach (random) during CHA visits to families under their care.

## Evaluation of depression treatment by the primary health care teams at area 2.2 of the Unified Health System in Rio de Janeiro, Brazil

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### AIM

To study how patients with depression are treated in primary health care units at the Area 2.2 of the City of Rio de Janeiro. The following aspects will be evaluated: prevalence, detection, access to treatment, effectiveness of the treatment interventions in primary care and of the two different models of integration with specialized care (reference X matrix support)

### Methods

A longitudinal, quantitative and qualitative prospective study evaluating the type of support and treatment patients with depression receive from primary care teams. Information will be assessed through questionnaires, scales, focus groups with patients and medical records review with a ten months interval between the two assessments.

## Evaluation of the therapeutic management of mood disorders: evidence and practice

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University of Brasilia

### AIM

To assess the efficacy, effectiveness, safety and use of pharmacological alternatives for treating bipolar and depressive disorders.

### Methods

A systematic review will be elaborated, with the following method: (1) locate existing systematic reviews, (2) evaluate the quality of the reviews and identify any need for updating the evidence, (3) identification and prioritization of the interventions employed for mood disorders with a lack of evidence, (4) elaboration of a systematic review of prioritized interventions and (5) summary of available therapeutic alternatives. In parallel, a cross-sectional study will be performed in Federal District health care units to assess the therapeutic management of these disorders.

## Economic evaluation of protocol implementation on human albumin in patients with nephrotic syndrome in Salvador, Bahia

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Bahia Federal University

### AIM

To evaluate the cost-effectiveness and cost-utility for the implementation of human albumin protocol in patients in Salvador.

### Methods

A prospective analysis of two cohorts of patients with nephrotic syndrome will be compared to those of the albumin following the clinical protocol with those who do not follow the protocol or use other expanders. Clinical data will be collected in the medical files, institutional costs will be verified and the quality of life obtained through questionnaires SF36 and CHQ-PF50. The variables are expressed by averages that will be compared with the Student's t-test. The cost-effectiveness incremental will result on division of the difference of strategy costs by the difference in health results and QALY indexes obtained.

## Bone tissue bioengineering using biomaterials

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Federal University of Bahia

### AIM

The biological behavior of biomaterials agglutinated with fibrin (FI) and associated with enteral administration of Strontium doped hydroxyapatite (HA) will be analyzed on bone repair

### Methods

With 120 rats-16 groups: Sample A: 60 rats receiving Strontium doped (HA) a) 60 calvaria critical-sized bone defects will be filled with blood coagulum (group GI), HA microspheres (GII), FI (GIII), HA microspheres and FI (GIV) b) 60 femoral bone non-critical defects will be filled with blood coagulum (GV), HA microspheres (GVI), FI (GVII), HA microspheres and FI (GVIII) Blood quantification of Calcium, Strontium, Calcitonin and Parathormone will be done Sample B: 60 rats, without drugs administration will be submitted to functional locomotion analysis and kinesiotherapy

## Cost-effectiveness of positron emission tomography using 2[18 F]fluoro2deoxyDglucose (FDGPET) in non-small cell lung carcinoma, thyroid cancer, and colorectal cancer

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### AIM

To evaluate the cost-effectiveness of positron emission tomography using 2[18 F]fluoro2deoxyD-glucose (FDGPET) compared to conventional methods for the diagnosis and treatment of non-small cell lung carcinoma, thyroid cancer, and colorectal cancer.

### Methods

The analysis will be performed from the perspective of the Brazilian Unified Health System. A decision tree model will be constructed, considering three additional components: (1) a cost estimate of diagnostic procedure (FDG-PET), based on micro-cost analysis; (2) a systematic review of diagnostic accuracy and clinical impact of FDG-PET in thyroid cancer; and (3) an upgrade of diagnostic accuracy and clinical impact data of FDG-PET for non-small cell lung carcinoma and colorectal cancer, based on technology appraisals produced for the Ministry of Health in 2009.

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## Performance of the Family Health Program compared with the Basic Health Units in controlling systemic hypertension and associated factors in the municipalities of the state of Paraíba: a cohort study

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### AIM

To evaluate the performance of the Ministry of Health programs - ESF and UBS, in the control of systemic hypertension and to identify conditions associated to risk factors in the municipalities of Paraíba, Brazil, in 2010/11.

### Methods

A comparative study: quantitative and qualitative approaches to health professionals, managers and users, with the formation of a representative double-cohort of patients followed and not followed by programs from the municipalities. The evaluation uses the theoretical and methodological strategy of the basic categories of health quality: structure-process-outcome. Decision analysis will be employed through descriptive and multivariate statistical techniques and discourse analysis.

## Treating children with inhaled steroids to prevent asthma exacerbations

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Federal University of Minas Gerais

### AIM

To verify the efficacy of the intermittent treatment using beclomethasone and salbutamol to control and prevent mild persistent asthma

### Methods

Randomized control trial that will initiate with a four-week run-in period, in which patients will receive up to 250mcg of beclomethasone, once a day. Then those fulfilling the inclusion criteria will be included in the 44-week treatment phase. A total of 300 of these children will be randomized into two treatment groups, namely: 1) continuous use and 2) intermittent use of beclomethasone.

### Outcomes

Frequency of exacerbations, emergency room visits and hospitalizations in both groups; quality of life assessment; impact on pulmonary function and control of the inflammatory process through fractional exhaled nitric oxide monitoring.

## Non-invasive brain stimulation: a proposal for diagnosis and treatment of adults with attention deficit/hyperactivity disorder

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Federal University of Pernambuco

### AIM

Attention deficit hyperactivity disorder (ADHD) in adults is a disorder characterized by difficulties in diagnosis and treatment. This study proposes to examine a new strategy for the diagnosis of ADHD by paired-pulse transcranial magnetic stimulation (ppTMS) and to evaluate the clinical applicability of repetitive TMS and transcranial direct current stimulation (tDCS) and noninvasive and painless therapeutic tools on ADHD symptoms.

### Methods

Intracortical motor inhibition and facilitation will be tested with ppTMS in 20 ADHD adults and 20 healthy, age and gender-matched volunteers. Patients diagnosed as having adult ADHD will be divided into two crossover double-blind randomized, sham-controlled studies. On separate days, each volunteer will receive either (i) a single session of 10Hz rTMS (80% rest motor threshold, 1500 pulses; Study A) or anodal tDCS (10min, 1mA; Study B) over the left prefrontal cortex or (ii) a single session of sham rTMS or tDCS.

## Epidemiological evidences on the effectiveness of school-based interventions for obesity reduction in children and adolescents: a systematic review

Francisco de Assis Guedes de Vasconcelos (Coordinator); Bethsáida de Abreu Soares Schmitz; Caroline Franz Broering de Menezes ; David Alejandro Gonzalez Chica; Geovana Floriano Pereira; Greyce Luci Bernardo; Janaina das Neves; Manuella de Souza Machado; Maria Gabriela Matias de Pinho; Melina Valério dos Santos; Natali Carol Fritzen; Paulo Luiz Viteritte; Patrícia Tibúrcio Meura; Silvia Giselle Ibarra Ozcariz.

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Federal University of Santa Catarina

### AIM

To describe, through a systematic review, the current literature on school-based interventions to prevent or reduce overweight/obesity in children and adolescents.

### Methods

Four independent bibliographic reviews were performed at MEDLINE/PubMed; CAPES Theses Database; SciELO and LILACS. Inclusion criteria: school-based interventions aiming to reduce overweight/obesity, promote healthy nutrition consumption and/or nutrition knowledge, with  $\geq 4$  weeks of intervention and  $\geq 6$  months of follow-up for outcome assessment; studies published in English, Portuguese or Spanish and focusing on individuals aged 0-19 years of age. Exclusion criteria: studies including only girls or boys or only overweight children; interventions not involving children directly.

### Risk factors and interventions to reduce maternal and child mortality: a support for intervention in the Brazilian Unified Health System (SUS) in Ceilândia - DF

Patrícia Maria Fonseca Escalda; Olga Maria Ramalho de Albuquerque; Roberto do Nascimento Rodrigues ; Maria do Carmo da Fonseca; Geovane Máximo ; Celina Módena; Carmen Livia Faria da Silva Martins; Helena Maria Campos; Alberto Mesaque Martins; Luiza de Marilac Barbosa; Andrea Branco Simões.

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#### AIM

To identify the available evidence of risk factors and interventions for the reduction of maternal and child mortality; To analyze the profile of maternal and child deaths that occurred within the Regional Health Center in Ceilândia – DF; To investigate all the maternal and child deaths that occurred within the Regional Health Center in Ceilândia - DF; To conduct workshops with women from social movements and health professionals of the Regional Health Center in Ceilândia - DF in order to raise issues to be addressed in a training course for multipliers in gender and health; To develop a training course for multipliers in gender, health, sexual and reproductive rights for health.

#### Methods

We conducted a systematic literature review in which the following databases were consulted: Medical Literature Analysis and Retrieval System (MEDLINE), PUBMED and LILACS. In the existing databases of the Health Virtual Library, the choice of the Health Sciences Descriptors (DeCS) was based on the DeCS categories. These numerical representations follow a hierarchy within the controlled vocabulary in the health area. Its use enables the search of more specific terms related to the study's area of knowledge and enables an approximation to the focus of key concepts applicable to the study developed. For the analysis of the mortality profile, the GoM method will be used. This method allows for the describing of the causes of death for each individual either as a function of its degree of similarity or its fit to the vulnerability profiles found. The investigation of maternal and child deaths by the committees, already established in the Regional Health Center in Ceilândia – DF, was enhanced and speeded up by the participation of students from the Program of Education for Work, Health Surveillance – SEGETS – MS - UnB / FCE. In order to raise issues for the development of the training course for multipliers in gender and health, we adopted the qualitative research as a methodological approach and a workshop with a group dynamic was conducted. Participants were female members of social movements in Ceilândia - DF and undergraduate students of extension projects and from the Program of Education by Work / Health Surveillance in the context of maternal and child health.

## Global Initiative for Asthma (GINA) - Fostering implementation of good practices in Brazil

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Global Initiative for Asthma

### AIM

The Global Initiative against Asthma (GINA) is a NGO member of the Global Alliance against Chronic Respiratory Diseases (GARD) led by the WHO. It provides support for the implementation of its action plan, linked to the 2008-2013 Action Plan for the Global Strategy against Non-communicable Diseases. The main objective of GINA in Brazil is to establish a network of individuals and organizations committed to asthma control and to the improvement of: RECOGNITION OF ASTHMA, PREVENTION, DIAGNOSIS AND CONTROL, RESEARCH and EDUCATIONAL MATERIAL.

### Methods

A network of 109 experts is developing an action plan with benchmarks to assess process and impact. The main contribution of GINA is to collaborate with the Brazilian Unified Health System (SUS) in its effort to create primary care training.

## Intervention in attention deficit and hyperactivity disorder

Monica C. Miranda, Nayara Argollo, José Neander Abreu, Mauro Muszkat, Sueli Rizzuti, Luzia Flavia Coelho Scaramuzza, Deise F L Barbosa, Rita Lucena, Orlando F Amodeo Bueno  
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Federal University of São Paulo

### AIM

The aim of this study is to identify the benefits of a multimodal treatment of Attention Deficit Hyperactivity Disorder (ADHD), so: a) analyzes the effects of isolated treatments (use of methylphenidate) and combined treatments on the use of medication as cognitive-behavioral therapy (CBT), family intervention and cognitive training in cognitive and behavioral symptoms of children with ADHD; b) develops/adapts intervention techniques to our socioeconomic reality, i.e., translation and adaptation of the Attention Process Training Program; development of a computerized program to train working memory as well as the CBT group (important method of health centers). The study will be useful for the acquisition of new methods of intervention for ADHD in our culture.

### Methods

Participating in this study are 80 children from two institutions, 40 children from each. The children are assessed by neuropsychological and clinical criteria for ADHD and then exclusion criteria are randomized into four treatment groups: group 1 - children only make use of methylphenidate long-acting medication; group 2 - methylphenidate and training of attention; group 3 - methylphenidate and working memory training, group 4 - methylphenidate and cognitive-behavioral group. Children are re-evaluated after treatment to examine the effects of treatments for symptoms in children with ADHD.

## Maternal mortality and maternal near miss related to quality of childbirth care provided in hospitals: a systematic review of risk factors and methods used for their identification

Vera Pepe, Rosângela Caetano, Lenice Reis, Tatiana Figueiredo, Clarisse Fortes, Rondineli Mendes da Silva, Cláudia Regina Bastos, Ione Ayala de Oliveira, Cesar Favoreto, Rafael Cota  
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### AIM

The aim of this paper is to raise and synthesize the evidence on risk factors for maternal death and severe morbidity and adverse events related to labor and delivery, as well as on methods for the identification of maternal near miss and other adverse events in obstetric services.

### Methods

There are two ongoing systematic reviews guided by the following questions: 1. What are the risk factors for maternal death, maternal near miss and adverse events related to delivery care in maternity services? 2. What methods are used for to identify maternal near miss morbidity and adverse events in maternity services? To search for the articles, the following biomedical bibliographic databases were used: MEDLINE, EMBASE, WEB OF SCIENCE, SCOPUS and LILACS. For dissertations and theses, the following bases were investigated: CAPES thesis database; Digital Library of Theses and Dissertations, the Brazilian Institute of Information Science and Technology, and the Portal of Thesis of Public Health. The reference lists of retrieved articles and other academic products were reviewed to locate additional articles. The search strategy was based on research in selected fields, key and generic terms of descriptors that consider different areas (outcomes, type of care, place of occurrence and risk factors). The references obtained at each base were exported to software in order to manage references (EndNote<sup>®</sup> X version) and duplicates were excluded. In the initial phase of selection, two independent investigators reviewed studies based on title and abstract and excluded studies that did not meet the inclusion criteria. In a second step, the full text of the articles is analyzed regarding the eligibility criteria. Discrepancies between the reviewers are resolved by consensus.

## Standardization and validation of diagnostic procedures involving rapid tests for screening for hepatitis B and C

Livia Melo Villar, Biomédica, Doutora em Ciências, Lia Laura Lewis Ximenez, Elisabeth Lampe, Adilson José de Almeida, Gaffree Guinle, Clara Fumiko Tachibana Yoshida, Cristiane Alves Villela Nogueira, Ana Rita Coimbra Motta Castro.  
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Oswaldo Cruz Foundation

### AIM

The aim of this study is to validate diagnostic procedures involving rapid tests for hepatitis B and C for purposes of epidemiological studies in the field. Reference panels consisting of blood, serum and saliva samples positive or negative for HBsAg and anti-HCV according serological tests will be fabricated and used to determine the sensitivity, specificity, and positive and negative predictive values, repeatability and intermediate reproducibility. The cross reaction will be evaluated using reactive samples for syphilis, malaria, dengue or HIV. Finally, the efficiency of the rapid tests will be determined in remote areas such as indigenous, African and wetland populations.

### Systematic reviews on interventions to reduce mother-child mortality: (Catirina Project)

Maurício Gomes Pereira, Adriana Magalhães Ribeiro, Alberto Moreno Zaconeta, Eneida Fernandes Bernardo, Everton Nunes da Silva, Fabiane de Castro Vaz, Lucilia Domingues Casulari da Motta, Luiz Antonio Bueno Lopes, Maria Elizete de Almeida Araújo, Maria Fernanda Reis e Silva Thees, Nelson Diniz de Oliveira, Rogério Hoefler, Rossana Michelli Ferreira de Pontes, Taís Freire Galvão, Danyelle Mayara Silva, Teila Carvalho Oliveira, Mariana Correia Marques

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University of Brasilia

#### AIM

(1) To evaluate the effectiveness of interventions to reduce infant mortality from perinatal causes, diarrhea and poisoning; and (2) to evaluate the effectiveness of interventions to reduce maternal mortality caused by infections, hemorrhage and eclampsia.

#### Methods

Systematic reviews are being prepared following the same method: (1) mapping and prioritization of interventions; (2) database search; (3) peer study selection; (4) peer data extraction; (5) data synthesis; (6) results analysis and (7) results interpretation and final writing for publication.

### INATA project – infection and disease by tuberculosis in health professionals at primary health clinics, Brazil

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#### AIM

To investigate the risk of latent tuberculosis infection and disease for health professionals at primary health clinics in priority cities for tuberculosis control in Brazil using PPD-RT23 and QuantiFERON - (QFT)TB Gold.

#### Methods

This study will be conducted in two stages: the first step is a multicenter study in eight capitals of the five geographical regions to assess the prevalence of infection among the primary care team. The second stage will be a cohort of professionals who are negative to the tuberculin skin test (TST), and discordant tests (TST + and QuantiFERON-TB Gold - or QuantiFERON-TB Gold + and TST -) that will be followed one year after the first test to assess the security measures implemented by the study. In addition to conventional statistical techniques the following will also be used: a model of economic evaluation –An analysis of cost-effectiveness will be conducted in order to compare the costs and effectiveness of two diagnostic strategies for the Brazil health system, using a decision analysis model through the construction of a decision tree with probabilities of events considering the time horizons of the study. And an impact model will be developed considering the cost impact of the QuantiFERON-TB Gold test and will have as its assumptions: i) the epidemiological indicators of the disease, and ii) the cost of incorporating the test for Brazilian health system.

## Quality of life and its relationship to the use of diagnostic technology in human communication disorders in totally laryngectomized rural workers

Hilton Justino, Cleide Teixeira, Adriana Di Donato, Patrícia Balata, Daniele Cunha, Gerlane Nascimento, Leandro Pernambuco, Gutemberg Moura, Elthon Fernandes, Renata Andrade da Cunha, Klyvia Moraes, Lilian Muniz

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### AIM

To identify the degree of hearing handicap in post-laryngectomized patients through a reduced version of the self-assessment questionnaire HHIE-S in Portuguese and to identify the hearing thresholds of post-laryngectomized patients with a hearing handicap.

### Methods

It is an observational, cross-sectional and descriptive study. Until now, 15 post-laryngectomy volunteers 40 to 70 years of age were included. Data collection to assess the degree of hearing handicap was realized by a Portuguese self-assessment questionnaire HHIE-S. It consists of ten objective questions about social and emotional aspects and hearing difficulty. The audiometry test was performed on a clinical audiometer, Maico 4I with TDH-39P headphones, calibrated according to ANSI, S3. 6, 1989. The pure tone audiometry was applied at frequencies from 0.5 to 8 kHz in airways and frequencies from 0.5 to 4 kHz in bone. Normal threshold with values less than or equal to 25dBHL; slight loss for thresholds between 26-40dBHL; moderate hearing loss for thresholds between 41-70dBHL, and severe loss for thresholds between 71-90dBHL was considered. The standard of review for the test and prescription of individual sound amplification was to permanent hearing loss, unilaterally or bilaterally, with CIDE H90.3 (bilateral sensorineural hearing loss) and H90.6 (mixed hearing loss) or those that met the criteria of Resolution N° 17 of Decree 3.298/99 of the hearing impaired: a) arithmetic average of hearing thresholds for 500Hz, 1kHz, 2kHz and 3kHz frequencies is worse than or equivalent to 30dBHL (decibels hearing level); b) maximal hearing loss of 70dBHL for frequencies of 500Hz, 1kHz, 2kHz and 3kHz frequencies. To check the values of sound amplification as well as tracking user (annual) will be accomplished through objective measurements with probe microphone FONIX FP35 equipment. These measurements with the prosthesis in the external auditory canal of the volunteer measure the amplification gain of the prosthesis in everyday conditions with the schedule and volume of this prosthesis.

## Quality of life of patients with Chronic Myeloid Leukemia (CML)

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### AIM

To recognize the demographic and socio-economic status of patients with chronic myeloid leukemia assisted in the Hematology service of Napoleao Laureano and Lauro Wanderley Hospital; To identify the impairment level of the quality of life of patients with chronic myeloid leukemia; To highlight the valuable role of assessing the quality of life in clinical decisions during follow-up of patients with leukemia; The study aims to demonstrate the impact of chronic myeloid leukemia, a hematological malignancy, on the quality of life related to health and identify measures that could attenuate these aspects of a patient's life.

### Methods

Prospective observational study; Patients with a confirmed diagnosis of chronic myeloid leukemia will be selected and followed at the Hematology Service, Napoleão Laureano and Lauro Wanderley Hospitals; Patients with problems understanding and/or verbal communication, memory impairment or other reasons that compromise the accuracy of the information, other associated malignancies and those less than 16 (sixteen) years of age shall be excluded.

Application of the quality of life questionnaire EORTC QLQ C-30 version 3 to study in CML; Prospectively evaluate the responsiveness of the instrument EORTC QLQ C-30.

## Integrated health networks oriented by family health teams: guidelines for referrals to specialized health centers

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University of Pernambuco and Aggeu Magalhães Research Center / Fiocruz

### AIM

This project aims to evaluate the demand for referrals to specialized health care and diagnostic procedures in cardiology, endocrinology, ophthalmology and vascular surgery areas in integrated health networks conducted by the family health teams, in the three capitals of the Brazilian Northeast.

Based on the analysis of the health care model for diabetes mellitus, it will be possible to describe the current methods for setting quotas by the municipalities to the family health teams (FHT) for referrals to specialized care and diagnostic procedures; to identify the demand for specialized care and complementary exams from the family health teams; and to compare the provision of specialist consultations and complementary tests with the identified demand.

### Methods

This is an evaluative study, based on a triangulation of methods that will be held in the primary health care networks of three cities in the Northeast, from February 2011 to February 2013. Interviews will be conducted with health regulation managers of the municipalities in order to identify the methods used to define quotas for health care networks in the PHC services; a documental analysis of the records of referrals to specialists in cardiology, endocrinology, ophthalmology and surgery vascular; a database analysis of the municipalities' referral center; nominal groups with medical experts to generate consensus on parameters for RIS-oriented health care FHT.

### Systematic review on the effectiveness of educational interventions with students to reduce child obesity as an interventional aid at school from the regional school district of Ceilândia-DF

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University of Brasília

#### AIM

To summarize the evidence on the effectiveness of interventions to reduce child obesity with students through nutritional education and physical activity.

#### Methods

Systematic method of literature searching and selection using bibliographic databases: MEDLINE, LILACS, PSYCINFO, WEB of SCIENCE. Medical Subject Headings employed in this review: obesity; overweight; food and nutritional education; intervention studies; weight .

### Safety and effectiveness of immunobiologicals in rheumatic diseases: an experience from a network of university centers (CEDMACs)

Eloisa Dutra Silva de Oliveira Bonfa (Coordinator ); Carla Gonçalves Schain Saad; Clovis Artur A. da Silva; Jozélio Freire de Carvalho; Ana Cristina M Ribeiro; Julio Cesar Morales B; Ana Luisa Garcia Calich; Nadia Emi Aikawa; Vilma Santos ; Viana T; Maria Ieda Laurindo ; Ivan Silva and Leonardo F ; Ana Cristina Endo; Cleide Oliveira da Silva; Manoel Bértolo; Bruno Silva Ferreira de Araujo; Ana Luisa Ferrari Vanalle ; Juliana Yuri Sekiyama ; Oswaldo da Rocha Melo ; Sergio Arone Son; Paul Junior Louzada ; Rene D Ribeiro de Oliveira; Rodrigo de Oliveira ; Sergio Luna Almeida Couto; Roberto Toledo ; Ricardo Toledo Acayaba; Angélica de Carvalho.

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#### AIM

To strengthen the Brazilian Network of Health Technology Assessment (REBRATS) through an electronic database and serum samples that may provide subsidies for health policy through the safety assessment and response (clinical, serological and inflammatory) of treatment patients with rheumatic diseases with anti-TNF agents (adalimumab, etanercept, infliximab) and rituximab.

#### Methods

To assess patients with rheumatoid arthritis (RA), ankylosing spondylitis (AS) and psoriatic arthritis (PsA) treated with anti-TNF drugs (adalimumab, etanercept or infliximab) and anti-CD20 (rituximab). To evaluate the effectiveness, the criteria used will be predefined clinical responses to RA, EA, AP and incorporated into an electronic medical record already established at the Centers for Dispensing the High Cost Medicines (CEDMACS) and its association with genetic and serological markers. Safety will be assessed by the identification and monitoring of early and late complications.

## Light-emitting diode therapy in ulcer treatment for individuals with venous insufficiency

Claudia Patrícia Cardoso Martins Siqueira; Camila Mayumi Beresoski; Daniela Cristina Lopes Rujan; Dari de Oliveira Toginho Filho; Emerson José Venâncio; Francisco Pereira; Gabriela Coradi Garcia; Isabela Andrelino de Almeida; Ivan Frederico Lupiano Dia; José Leonil Duarte; Solange de Paula Ramos; Valdenea Aparecida Bordinassi de Castro; Ennio Mendes Ruiz; Francelaine Bruna Campana de Souza; Franciele Mendes de Lima; Karla Guivernau Gaudens Serafim; Maiara Santos Nogueira; Matheus Elmer Finatti; Mayara Caroline Ventura; Vinicius Monte Lima; Nilda Mara Munaretto do Vale; Solange Aparecida dos Santos;

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Londrina State University

### AIM

The objective of the study is to evaluate the efficiency of phototherapy (LED) in the treatment of chronic ulcers, evaluating scarring parameters and reduction in the inflammatory process as well as the viability of implementing this therapeutic resource in the clinical environment.

### Methods

Participants will include patients with chronic lower-limb ulcers (CLLUs) treated at UEL's University Hospital and Clinical Hospital. The application of phototherapy will be carried out with 625 nanometer (+/- 5 nm) wavelength LEDs in five different areas of the ulcer. Six months of weekly follow up will include assessment of pain (visual analogical scale), scarring (wound area), inflammatory markers (TNF-alpha and TGF-beta) and quality of life (WHOQOL-Bref questionnaire). Normality distribution will be evaluated with Bartlett tests, and intergroup comparisons will be made using ANOVA or Kruskal-Wallis.

### Treatment of wounds and burns with carboxymethylcellulose dressings: a systematic review of randomized controlled trials with meta-analysis

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Federal University of Rio Grande do Norte

#### AIM

To evaluate the available clinical evidence on the effect and safety of carboxymethylcellulose dressings, hydrogel and hydrocolloid, for the treatment of venous leg ulcers and burns. The project was divided into three reviews, two of them are systematic reviews regarding the effectiveness and safety of hydrogel and hydrocolloid for the treatment of venous leg ulcers and the protocols are in the registration process at the Cochrane Wounds Group. A third ongoing review is about the use of those dressings for the treatment of burns.

#### Methods

The methodology is based on the recommendations of systematic reviews by the Cochrane Collaboration. Randomized controlled trials demonstrating the efficacy and safety in the use of carboxymethylcellulose dressings in the treatment of venous ulcers will be included in the review. Studies are being searched for in electronic databases recommended by Cochrane, including MEDLINE, EMBASE, EBSCO CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL) and the Cochrane Wounds Register. Two independent reviewers are evaluating the titles and abstracts of all trials identified by electronic search and making the selection of studies that meet the criteria for inclusion for these systematic reviews. The primary outcomes for the review will be: time for ulcer healing or proportion of fully healed venous ulcers at the end point of the study; objective measurements of change in ulcer size, measured by a reduction in the original wound area, at the end point of the study; adverse events including pain, as defined by the authors (measured using survey/questionnaire/data capture process or a visual analogue scale). The secondary outcomes will be: signs and/or symptoms of clinical infection; incidence of bacterial flora; length of stay in the hospital; costs (including measurements of resource use such as number of dressing changes and nurse time); necessity of surgical procedure for venous insufficiency for the treatment of the ulcer, as venous transposition; health related quality of life (measured using a standardized generic questionnaire such as EQ-5D, SF-36, SF-12 or SF-6 or disease-specific questionnaire). Data analysis will be performed according to the guidelines of the Cochrane Collaboration.

## Validation and cost-effectiveness of an in-house quantitative method of real-time PCR in patients with chronic hepatitis B

Daniel Simon ; André Castagna Wortmann; Guilherme Becker Sander; Luiz Edmundo Mazzoleni; Nilo Ikuta; Paulo Dornelles Picon; Vagner Ricardo Lunge

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### AIM

To validate and study the cost-effectiveness of an in-house quantitative method of real-time PCR in comparison with commercial tests in Brazilian patients with chronic hepatitis B.

### Method

The viral load of hepatitis B virus (HBV) will be measured in blood samples of 100 patients with chronic hepatitis B by an in-house quantitative method of real-time PCR and by a commercial kit. The cost-effectiveness analysis will be conducted in a hypothetical cohort of 1,000 patients. The clinical consequences and the cost associated with to-treat or not-to-treat will be compared, considering the proportion found with the different methodologies of patients detected as being above the cohort points defined by the Ministry of Health for indication of treatment.

## Validation of test for rapid detection of HBsAg and anti-HCV in patients with viral hepatitis and an evaluation of its performance in the screening of elderly

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### AIM

Validation of rapid tests for HBsAg and Anti-HCV detection in patients with viral hepatitis and assessment of its performance in the screening of elderly.

### Methods

A cross-sectional study that will be conducted in two stages: 1) an evaluation of rapid tests for detection of HBsAg and HCV in patients with confirmed HBV or HCV chronic infection; and 2) an assessment of the performance of rapid tests in the serological screening of elderly citizens of Tubarão/SC. All subjects will be submitted to HBsAg, anti-HBc and anti-HCV (by amplified chemiluminescence). The accuracy of rapid tests will be evaluated by calculating the sensitivity, specificity, positive and negative predictive values.



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