

MINISTRY OF HEALTH OF BRAZIL

# Health Technology Assessment: a selection of studies supported by Decit

2<sup>nd</sup> Edition

BRASÍLIA - DF

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

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2011 Ministry of Health.



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BRAZILIAN MINISTRY OF HEALTH  
Secretariat of Science, Technology and Strategic Inputs  
Department of Science and Technology  
SCN, Quadra 02, Projeção C, térreo, sala 04  
ZIP code: 70712-902 – Brasília/DF  
Phone: (61) 3315-6248  
Site: [www.saude.gov.br/sctie](http://www.saude.gov.br/sctie)  
E-mail: [ats.decit@saude.gov.br](mailto:ats.decit@saude.gov.br)

*Organization*

Christine de Nazaré Silva Koury (LLC/CO/USA)

*Technical Review*

Christine de Nazaré Silva Koury (LLC/CO/USA)  
Flávia Tavares Silva Elias (Fiocruz)  
Marcus Tolentino Silva (FM/UFA)  
Jorge Otávio Maia Barreto (Decit/SCTIE/MS)

*Publication*

Eliana Carlan (Decit/SCTIE/MS)  
Jessica Alves Rippel (Decit/SCTIE/MS)

*Grafic Design*

Gustavo Veiga e Lins (Decit/SCTIE/MS)

*Normalization*

Delano de Aquino Silva (Editora MS/CGDI)

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# Presentation

In 2011, the Science and Technology Department of the Secretariat of Science, Technology and Strategic Inputs of the Ministry of Health took the initiative to publish the first issue of the document “*Avaliação de tecnologias em saúde: seleção de estudos apoiados pelo Decit*” (free translation: “Health technology assessment: a selection of studies supported by Decit”). This publication was aimed at disseminating studies supported by the Ministry of Health since 2005.

In its first sold out issue, the dissemination strategy consisted in publishing 1,500 copies in English and Portuguese. This publication is available on the Brazilian Health Technology Assessment Network (Rebrats) website and at the Virtual Health Library of the Ministry of Health.

Together, both editions provide the reader access to 102 abstracts of studies on Health Technology Assessment (HTA) that were selected and approved within a universe of 152 studies fostered through five public calls in partnership with the CNPq. Total funds invested from 2005 to 2010 amount to 12 million Brazilian Reals.

This second edition includes an introductory text aimed at the dissemination of the activities performed in the past five years by the Rebrats Professional Training Working Group created during the first meeting of the network’s Executive Committee. At that time, there was a need to educate and train experts in health technology assessment. This edition also includes a list of 14 HTA institutions offering training/refresher courses with their name and their respective web access links.

This publication used the summary format proposed by the *International Network of Agencies for Health Technology Assessment* (INAHTA).

**It is worth highlighting that summaries reflect authors opinions and those are not necessarily aligned with the Ministry of Health’s points of view. Due to the diversity of subjects covered and health dynamics, contents are frequently updated in the Rebrats Information System, which should always be consulted.**



# Introduction

The strong influence of an increased spending and resource constraints scenario in health has been observed in the last decades in the Brazilian and other foreign countries' health systems. There is equally a need to restructure health services aiming at greater effectiveness and better use of government financial resources. Thus, managers find themselves pressured and require consistent information about the benefits of technology and its impact on health services in order to support decision-making.

Health Technology Assessment (HTA) is one of the tools used to support decisions on the coverage of technologies and procedures in health systems. It is an ongoing assessment process targeting the systematic study of short and long-term consequences of using a specific technology or group of technologies, or even a technology-related topic (PANERAI; MOHR, 1989). Health technologies are defined as drugs, equipment, technical procedures, organizational, educational and support systems, healthcare programs and protocols, whereby health care and assistance are provided to the population (BRASIL, 2005).

HTA is also defined as a form of multidisciplinary research that examines the consequences of technology use, such as equipment, drugs, diagnostic tests, immunobiological products, procedures and service organization, aiming to assist system's decision-makers as to the incorporation and use of health technologies based on safety, effectiveness, economic and social impact, public health priorities, regional features, resource optimization and the principle of equity (GOODMAN, 1998; HUNNINK; GLASZIOU, 2001).

Two components stress the importance of research and continuing education in the field of HTA: changes in the epidemiological profile of populations and issues in the use of technologies in real-life health services, for example, the lack of scientific evidence on the effectiveness of widely-used technologies, the low use of established technologies, or the use of technology proven ineffective or with harmful effects (PANERAI; MOHR, 1989; OTA, 1994).

As from the 1990s, the scenario of continued growth in health spending, coupled with the increasing production of new health technologies led to the need of developing coordination mechanisms among sectors involved in the production, incorporation and use of technologies in health systems.

Brazil has seen the implementation of HTA education and research in universities, a fact that has contributed to the training of professionals and research groups since the early 1990s. Noteworthy is the work of the Brazilian Cochrane Collaboration Centre who is truly engaged in large-scale training as well as in epidemiology, health planning, quality and patient safety disciplines, lectures in public health schools in Rio de Janeiro, Salvador and São Paulo centres (BRASIL, 2004, p. 187).

In public health policies, the Secretariat of Science, Technology and Strategic Inputs (SCTIE) and the Science and Technology Department (Decit), established in 2001, are responsible for the implementation of the National Policy on Science, Technology and Innovation in Health, whose purpose is to promote the production and dissemination of scientific and technological knowledge in health focusing its adoption by health institutions and services.

Following the creation of the SCTIE, the Council for Science, Technology and Innovation of the Ministry of Health (CCTI) was established and, among other things, was in charge of setting guidelines and promoting technology assessment to incorporate new products and processes by decision-makers, providers and professionals of the Unified Health System

(SUS) (Ordinance MS N° 1418, of July 24, 2003). The Permanent Working Group on Health Technology Assessment (GT/ATS) was created within the Council with the purpose to promote SUS-relevant HTA studies.

The strategy of enhancing State regulatory capacity was a landmark that enabled scientific and technological research actions as an important tool for decision-making. The National HTA Network was established within this strategy, as well as countrywide human resources education, training and absorption, with incentives for scientific and technological production (BRASIL, 2004 b).

In order to expand the supply of HR educational and training courses, there was a recommendation the educational process should be tailored to regional needs and incorporated into development institutions. In addition, certain needs were assessed, such as creating professional MBAs for SUS Service Network technicians aiming to enhance professional qualification and research training to improve professional practice and quality of care; promoting continuing education; using the distance learning methodology; integrating university and service; and raising the awareness of managers to develop an ongoing education program.

Another structural HTA-development action was the promotion of health research and the increased dialogue between managers and researchers in priority workshops since 2006. At the time, prioritization criteria were identified for the selection of HTA topics with an agreement to support structuring HTA activities in Brazil, establish the Brazilian Network for Health Technology Assessment (Rebrats) as the strategy to disseminate HTA expertise and develop methodological guidelines to provide quality standards for HTA studies.

Thus, both the Ministry of Health, through the Department of Science and Technology of the Secretariat of Science, Technology and Strategic Inputs, and members institutions of Rebrats have promoted human resources education and training programs through Specialization and Professional MBA course in Health Technology Management with the aim of improving the ability to contribute to decision-making in health technology assessment and incorporation within the SUS.

Rebrats' Professional Training Working Group develops and conducts various courses. The first specialization and professional MBA course graduates completed their training in 2010. Of the 173 students enrolled in the two specializations courses and five professional MBAs, 151 completed the courses. In 2011, 674 professionals participated in continuing education through workshops, postgraduate and refresher courses. Noteworthy are the training activities within Mercosur, such as the workshops for the Economic Assessment of Technologies in partnership with Argentina, Paraguay and Uruguay.

The partnership with three hospitals of excellence in the Brazilian Public Health System Development Program (Proadi-SUS) enabled the increased supply of training programs which involves large-scale introductory courses, specialization and master-level post-graduation.

Between 2013 and 2014, some Rebrats institutions upheld the structure of earlier training courses, whereas others had their own professional MBA courses approved or had created specialization courses in health economics and health technology assessment.

All these actions are aimed at enhancing the capacity to contribute to decision-making in the assessment and adoption of technologies in the SUS. This publication presents structured summaries of studies as part of the outcomes of public calls and specialization courses.

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## Brazilian Institutions whose offering HTA training

Institutions	Courses 1	Site
Hospital Alemão Oswaldo Cruz	MBA in Economics and Health Technology Assessment	<a href="http://www.hospitalalemao.org.br/Educacao_Ciencia/Paginas/Instituto/MBAEconomiaAvaliacaoTecnologiasSaude.aspx">http://www.hospitalalemao.org.br/Educacao_Ciencia/Paginas/Instituto/MBAEconomiaAvaliacaoTecnologiasSaude.aspx</a>
IATS	Specialization in Health Technology Assessment	<a href="http://www.iats.com.br">http://www.iats.com.br</a>
Universidade Federal do Rio Grande do Sul	Master in Epidemiology: Health Technology Management	<a href="http://www.ufrgs.br/ppgepi/mp_gts">http://www.ufrgs.br/ppgepi/mp_gts</a>
Universidade Federal de Pelotas	Master in Public Health Evidence-Based	<a href="http://www.epidemiologia-ufpel.org.br/site/content/mestrado_profissional/index.php">http://www.epidemiologia-ufpel.org.br/site/content/mestrado_profissional/index.php</a>
Centro Cochrane do Brasil	Systematic review Workshops & Evidence-Based Health Course	<a href="http://www.centrocochranedobrasil.org.br">http://www.centrocochranedobrasil.org.br</a>
Universidade de São Paulo	Master in Management of Health Organization	<a href="http://www.hcrp.fmrp.usp.br/sitehc/informacao-galeria.aspx?id=413&amp;ref=1&amp;refV=12">http://www.hcrp.fmrp.usp.br/sitehc/informacao-galeria.aspx?id=413&amp;ref=1&amp;refV=12</a>
Instituto Nacional de Cardiologia	Master in Health Technology Assessment	<a href="http://fundacor.com.br/novosite/pg3/mestrado-profissional/mestrado-profissional-em-avaliacao-de-tecnologias-em-saude/">http://fundacor.com.br/novosite/pg3/mestrado-profissional/mestrado-profissional-em-avaliacao-de-tecnologias-em-saude/</a>
Instituto de Medicina Integral Prof. Fernando Figueira	Master in Health Evaluation	<a href="http://www.informazione3.com.br/cms/opencms/imip/pt/arquivos/Ensino/02.08.2013editalprocessoseletivo.pdf">http://www.informazione3.com.br/cms/opencms/imip/pt/arquivos/Ensino/02.08.2013editalprocessoseletivo.pdf</a>
Universidade Federal da Bahia	Master in Health Technology Assessment	<a href="http://www.isc.ufba.br/">http://www.isc.ufba.br/</a>
Hospital Sírio Libanês	Master Innovation and Management and in Health Technology	<a href="http://iep.hsl.org.br/cursos/Paginas/default.aspx">http://iep.hsl.org.br/cursos/Paginas/default.aspx</a>
Universidade Federal de Minas Gerais	Public Health Specialization: Epidemiology, Evaluation and Health Information Services	<a href="http://www.enf.ufmg.br/saudecoletiva/index.htm">http://www.enf.ufmg.br/saudecoletiva/index.htm</a>
Universidade Federal de Pernambuco	Master in Management and Health Economics	<a href="https://sites.google.com/site/ppgges/">https://sites.google.com/site/ppgges/</a>
Instituto Paulista de Estudos Bioéticos e Jurídicos	Postgraduate Sensu Lato in Economics and Health Technology Assessment	<a href="http://www.ipebj.com.br/curso/economia-avaliacao-tecnologias">http://www.ipebj.com.br/curso/economia-avaliacao-tecnologias</a>
Universidade Federal do Rio de Janeiro	Master and PhD in Public Policy, Strategic and Development.	<a href="http://www.ie.ufrj.br/index.php/index-pos-graduacao/index-stricto-sensu/politicas-publicas-estrategias-e-desenvolvimento">http://www.ie.ufrj.br/index.php/index-pos-graduacao/index-stricto-sensu/politicas-publicas-estrategias-e-desenvolvimento</a>

1- Free translation by the author



# Nutritional and metabolic changes associated with consumption of cocaine/crack: systematic review

Claudete Ferreira de Souza Monteiro, Fernando José Guedes da Silva Júnior, Adriana da Cunha Menezes Parente, Alexandre Castelo Branco Vaz Parente, Daniel Galeno Machado, Larissa Alves de Araújo Lima, Francisco Alberto de Brito Monteiro Júnior

claudetefmonteiro@hotmail.com

Universidade Federal do Piauí

## Objective

O consumo de crack leva a um padrão intenso, contínuo e repetitivo e suas consequências atingem tanto o usuário quanto a família e sua rede social. Dentre as consequências para o usuário são comuns as alterações nutricionais e metabólicas. O objetivo deste trabalho foi realizar um levantamento sistemático da evidência disponível sobre as alterações metabólicas e nutricionais em usuários/dependentes de crack.

## Método

The consumption of crack leads to a pattern intense, continuous and repetitive and its consequences affect both the user and their family and social network. Among the consequences for the user are the common nutritional and metabolic changes. The aim of this study was to survey systematically the available evidence on the nutritional and metabolic disorders in users/crack addicts.

## Method

We performed a systematic review of the literature in MEDLINE via PubMed, Scientific Electronic Library Online (SciELO) and the Latin American and Caribbean Health Sciences (LILACS), identified by descriptors in health sciences: "nutritional changes", "crack cocaine", "metabolic disorders". Were located 19 potentially eligible studies and five were selected for this review. Only the original studies, published between 2005-2010 in English, Portuguese, Spanish were included.

## Result and Conclusion

The studies obtained from the application of specific search strategies led to the following evidence: a crack addiction by contributing to a process of degradation multisystem, highlighting the substantial weight loss over the lack of appetite, psychomotor restlessness, long walks in the search for drugs in times of craving, and especially as a result of lesions in the upper aerodigestive tract arising from the inhalation of hot gases resulting from the combustion of the drug. Studies show still important metabolic changes, such as altered levels of alkaline phosphatase, increased serum levels of aluminum, glutamic-oxaloacetic transaminase and glutamic pyruvic transaminase.

## Recommendation

It is important that professionals who care for crack users in different levels of care, ownership of knowledge is related to nutritional and metabolic disorders in order to reduce the comorbidities in this group, through focus on the holistic approach.

## Recommendation for future research

This perspective, it is also understood the need to develop new studies that contribute to understanding the psychobiology of addiction for crack.

## Referência

SILVA JUNIOR, F. J. G. Alterações metabólicas e nutricionais entre usuários de crack. I Congresso Internacional de Atenção a Saúde: APS baseado em evidências, 1, 2013, Teresina. **Anais...** Teresina: Núcleo de Estudos, Pesquisa e Extensão em Educação Permanente para o SUS (NUEPES), 2013.

# Comparative performance analysis of machine learning classifiers and dimensionality reduction algorithms in detection of childhood pneumonia

Leandro Luís Galdino de Oliveira e Rafael Sousa

leandroluis.inf@gmail.com

Universidade Federal de Goiás/FAPEG/CNPq - PPSUS

## Objective

This work extends a computer-aided diagnosis system called PneumoCAD for detecting pneumonia in infants using radiographic images. The objective of a computer-aided diagnosis system is given a second opinion to assist with difficult diagnoses.

## Methods

In this case we work with childhood pneumonia, which errors are common in the interpretation of chest radiographs and are the leading cause of death in children worldwide. To improve the classification of system was made a comparison of five contemporary machine learning classifiers, namely: Naïve Bayes, K-Nearest Neighbor (KNN), Support Vector Machines (SVM), Multi-Layer Perceptron (MLP) and Decision Tree, combined with three dimensionality reduction algorithms: the feature selection wrapper Sequential Forward Selection (SFS), and two feature extraction algorithms: Principal Component Analysis (PCA) and Kernel Principal Component Analysis (KPCA). Each combination was evaluated from their correct rate (Accuracy) and ROC curve (Receiver operating characteristic). The images dataset used in our CAD system consists of 156 8-bit grayscale images obtained with a digital camera, which captured the chest X-rays images at a resolution of 1,024 x 768 pixels. Out of these images, 78 show pneumonia while the remaining 78 do not. These images were analyzed by two trained radiologists according to WHO guidelines. The radiologist's diagnosis was only considered as valid when they agree among themselves. All tests were made with Matlab along with their basic Toolboxes and Weka, and performed a 10-fold cross-validation with each combination. Classifiers parameters were optimized with an exhaustive search. The features tested are based on texture: coefficient of variation, contrast, correlation, energy, average energy, entropy, average deviation, difference variance, difference entropy, inverse difference moment, residual mean, sum average, sum entropy, sum variance, suavity, variance, standard deviation. All these features have been extracted in nine subspaces of Haar wavelet.

## Result and Conclusion

In summary, the Naïve Bayes and KNN classifiers produced most accurate results, 96% and 95% of accuracy and 0,959 and 0,958 of AUC (Area Under ROC Curve) respectively, and have shown to be more stable with this type of images so far. Moreover, it outperforms the best result from previous work, and even outperforms the diagnosis accuracy of radiologists.

## Reference

OLIVEIRA, L. L. G. et al. Computer-aided diagnosis in chest radiography for detection of childhood pneumonia. **International Journal of Medical Informatics**, Philadelphia, v. 77, n. 8, p. 555–564, 2008.

# Cost-minimization analysis (CMA) of valganciclovir hydrochloride compared with ganciclovir for prophylaxis of CMV infection in kidney transplants

Lucivaldo de Carvalho Alves, Aline Mendonça de Andrade, Waldélia Maria Santos Monteiro, Regina Cláudia Furtado Maia, Maria Dolores Montoya Diaz, Sílvia Regina Secoli

lucivaldoalve@msn.com

Proadi-SUS/Foundation for Economic Research Institute/Oswaldo Cruz German Hospital

## Introduction

Patients undergoing Solid Organ Transplantation (SOT) higher risk of developing opportunistic infections Cytomegalovirus (CMV), which required adequate prophylaxis to prevent such risks.

## Objetivo

Realizar Análise Custo-Minimização (ACM) do Cloridrato de Valganciclovir comparado com Ganciclovir na profilaxia da infecção por CMV em transplantados renais.

## Objective

Perform Cost-Minimization (ACM) of valganciclovir hydrochloride compared with ganciclovir prophylaxis of CMV infection in renal transplant recipients.

## Method

Data about the similar efficacy of antivirals was obtained through systematic review. Were listed the following categories of direct costs: antiviral medicine and disposables. We simulated three regimens of prophylaxis, namely ganciclovir 1g intravenous (IV) three times daily during hospital stay and ganciclovir 1g 3x/day until VO for one hundred days (Scheme A), IV ganciclovir 1g 3x/day hospitalized during the period followed by valganciclovir 900mg orally once/day until one hundred days (Scheme B) and valganciclovir 900mg orally during hospitalization and after discharge to complete one hundred days of use (Schedule C). Calculations were made for the years 2010 and 2011 based on the estimated number of transplant patients of a hospital's Health System – Brazil. The values of the drugs were obtained in the Bank Rates in Health (BPS) and the list of DATASUS compliance Chamber Market Regulatory Agency (CMED) Anvisa.

## Result

In 2010, the average cost per patient of Schedule A was R\$18,097.79, the second was R\$22,754.63 and the third was R\$21,096.00. In 2011, the average cost per patient in the first scheme was R\$16,393.27, the second was R\$22,603.35 and the third was R\$22,346.00.

## Conclusion

The results demonstrated a lower cost of CMV prophylaxis with ganciclovir 1g IV, and the second smallest with valganciclovir 900mg PO. The administration of IV ganciclovir versus valganciclovir the VO should be analyzed with other studies, also considering the inherent risks and adverse reactions of these antivirals.

# Cost-effectiveness analysis of 18FDG-PET/CT to detect metachronous liver metastases in resected colorectal cancer

Rosângela Caetano, Cláudia Regina Garcia Bastos, Laís Fraga de Lima Mendes da Silva; Luciene Schluckebier, Rondineli Mendes da Silva, Aline Navega Biz, Osvaldo Ulises Garay.

caetano.r@gmail.com

Instituto de Medicina Social, Universidade do Estado do Rio de Janeiro

## Objective

In our study we have done a cost-effectiveness analysis of 18FDG-PET/CT in addition of conventional work-up to identify unnecessary hepatic surgeries in resected colorectal cancer.

## Method

A decision analytic model was design based on three strategies: 1) conventional work-up with computed tomography (CT) of thorax, abdomen and pelvis; 2) PET/CT for all; and 3) PET/CT in negative CT results. The target population was primary colorectal cancer resected patients, both gender, who in routine follow-up presented high level of CEA and suspected hepatic lesion. The effectiveness was measured in unnecessary surgeries avoidable, i.e., considering PET/CT capable to detect irresectable liver lesions or extra-sites metastasis. Clinical parameters and tests accuracy were taken from the literature. The perspective was the Brazilian public health system as funder. Direct costs of diagnostic tests, surgical and non-surgical procedures were taken from the SIGTAP/DATASUS database. Since PET/CT was not yet incorporated at SUS, our PET/CT cost was based on the previous micro-costing study. One-way and probabilistic sensitivity analyses were performed to explore the uncertainties regarding the results.

## Result and Conclusion

The results show that the addition of PET-CT in the selection of patients for liver resection is accurate and eliminates unnecessary surgical procedures arising from undiagnosed extra-hepatic disease, compared to the traditional approach based on CT of thorax, pelvis and abdomen, but with very high costs. The incremental cost-effectiveness ratio (ICER) for PET/CT in negative CT strategy was R\$101.282,70/avoidable surgery and R\$118.096,13/avoidable surgery in PET/CT for all. Estimates of ICER were more sensitive to change by the influence of PET/CT cost, hepatic CT specificity and palliative treatment cost. Although effective, the higher incremental cost per avoidable surgery with PET/CT could not allow the incorporation in large scale into SUS.

## Recommendation for future research

Others economic evaluations should be running to explore the impact of PET/CT in terms of survival gain or QALY gain. Even as measuring the economic impact of the technology in the Brazilian health care budget.

# Cost-Effectiveness Analysis of 18FDG-PET/CT in Staging Primary Non-Small Cell Lung Cancer Patients

Rosângela Caetano, Cláudia Regina Garcia Bastos, Laís Fraga de Lima Mendes da Silva; Luciene Schluckebier, Rondineli Mendes da Silva, Aline Navega Biz

caetano.r@gmail.com

Instituto de Medicina Social, Universidade do Estado do Rio de Janeiro

## Objective

A cost-effectiveness analysis was done adding PET/CT to conventional work-up in primary non-small cell lung cancer in the SUS perspective.

## Method

A decision analytic model was designed based on four diagnostic strategies: 1) thorax computed tomography (CT) for all; 2) PET/CT for all; 3) PET-CT in patients with negative CT results; 4) PET-CT and CT for all and the decisions depends on both results. The model follows the Brazilian National Cancer Institute protocol for lung cancer. The effectiveness was measured in number of unnecessary surgeries due to inoperable disease, i.e. occult metastasis present. Clinical parameters and test accuracy were taken from the literature. The perspective was the Brazilian public health system as funder. Direct costs of diagnostic tests, surgical and non-surgical procedures were taken from the SIGTAP/DATASUS database. Since PET/CT was not yet incorporated at SUS, our PET/CT cost was based on the previous micro-costing study. One-way and probabilistic sensitivity analyses were performed to explore the uncertainties regarding the results.

## Result and Conclusion

The model shows the conventional staging work-up producing 2,832 unnecessary surgeries based on 10,000 population cohort. Despite all interventions reduce the number of unnecessary surgeries, the better was strategy (4) with 1,814 preventable surgeries followed by strategy (3) with 1,704. The incremental cost-effectiveness ratio (ICER) was more favorable to PET/CT in negative CT with R\$14,252.70 per avoidable surgery. Even varying the model parameters the number of avoidable surgery estimated was superior in all strategies compared to conventional staging. For PET/CT in negative CT the probability to be cost-effective is 90% with R\$20,000.00 willingness-to-pay. In situations of scarcity of resources, the recommendation should be linked by adding PET-CT exam in a subgroup of non-small cell lung cancer patients who CT is negative.

## **Recommendation for future research**

Others economic evaluations should be running to explore the impact of PET/CT in terms of survival gain or QALY gain. Even as measuring the economic impact of the technology in the Brazilian health care budget.

# Cost analysis of PET-CT with 18F-FDG radiotracer at the perspective of Brazilian Public Health System (SUS) as service provider: study in a public health unit in Rio de Janeiro

Rosângela Caetano, Cláudia Regina Garcia Bastos, Laís Fraga de Lima Mendes da Silva; Luciene Schluckebier, Rondineli Mendes da Silva, Aline Navega Biz, Osvaldo Ulises Garay.

caetano.r@gmail.com

Instituto de Medicina Social, Universidade do Estado do Rio de Janeiro

## Objective

The main purposes of this study were to evaluate the routine and to estimate the costs of the PET-CT procedure with radiotracer 18F-FDG from the perspective of a Brazilian public provider of health services.

## Method

The micro-costing technique was used, and all inputs consumed in the activities involved with the PET-CT procedure have been identified, measured and valued. Data for cost estimates were collected from the observation of 85 exams at the Brazilian National Cancer Institute (INCA), from March to June 2012, corresponding to 27 days of observation. The reference case considered adult cancer patients, daily production of five exams using one FDG dose per patient. The annual production was based on 240 work days varying between one to ten exams/day. INCA employees, because of their research activities, receive differentiated wages (from Science and Technology career – S&T), than the usual employees of federal public hospitals where new PET-CTs might be installed (from Ministry of Health career – MoH).

So, to avoid biases, two cost estimates were carried out considering different wage modalities (MoH and S&T careers), using values available for November 2012. Also, to evaluate the robustness of results, sensitivity analysis examined elements that might impact on the costs, as 18F-FDG dosage, 18F-FDG cost, minimal and maximum wage values, PET-CT equipment life-time, variations on fixed and variable inputs and the discount rate used.

## Result and Conclusion

The average costs of the procedure for the reference case were R\$3,150.30 (US\$1,612.23) for Science and Technology career's wages, and R\$2,927.19 (US\$1,498.05) for Ministry of Health's wages. The item that contributes the most for the total cost of the procedure was the number of procedures daily produced, regardless of the wage modality. The results of the sensitivity analysis showed that, for S&T career, the largest factors of impact on average costs was daily volume of procedures, Human resources and PET-CT equipment life-time.

For MoH career wages, tests annual production by PET sector, PET-CT equipment life-time and Human Resources were the relevant items. Nowadays, the limitations in providing 18F-FDG and the shortage of Human Resources

dedicated exclusively to the PET-CT are important restrictions to the studied health unit reaches its full performance, enabling lower average costs of the procedure. This study estimated a baseline value to be used in cost-effectiveness studies, and explored the elements that can impact the cost of the procedure for the public health institutions.

### **Recommendation for future research**

The generalizability (external validity) of the results of studies conducted in the perspective of a particular health care provider may be limited, as they tend to reflect the characteristics of the local institutional arrangements. It's suggested that new studies are conducted in other loci of public services that investigate potential differences in cost and its elements.

# Strategic analysis of the Modality of Day Hospital in the hospital unit of the National Institute of Traumatology and Orthopedics in Brazil

Bianca Cal Moreira Farizote

[bfarizote@into.saude.gov.br](mailto:bfarizote@into.saude.gov.br)

Escola Nacional de Saúde Pública/Fundação Oswaldo Cruz

## Objective

The hospital assistance lives deeply a moment of crisis in the attendance the carrying patients of muscle skeletal illnesses, happened of diverse and complex causes. The study it intends to disclose the modality of day hospital as an innovation of the hospital organization that can contribute for the attention of health in orthopedic and traumatology. For this, it considers an established strategical analysis in the planning methodology démarche stratégique applied to the process of institutionalization of the day hospital in the hospital unit of the National Institute of Traumatology and Orthopedic in Brazil. The results disclose the day hospital as believable alternative of contribution to the crisis of offers of services of health in the net of the traumatology and orthopedic; destined to the treatment of patients who need orthopedic surgeries of average complexity for short period of internment. That it can be capable to develop itself still more; thanks to modernization of surgical techniques that they make possible to deal with other pathologies with faster recovery the patients, to prevent the delay of the treatment and the aggravation of cases. Moreover, can be a fast local solution for resolution of the cases of average complexity, occupying a space in the secondary assistance of health with support to the redefinition of the assistencial paper of the hospital as tertiary entity of the net of services of health, responsible for carrying through more complex procedures and treating more serious patients, with determinative positive consequences in the social ones of health and quality of life of the population.

# Physical activity and cardiovascular risk factors in children: meta-analysis of randomized clinical trials

Cláudia Ciceri Cesa, Graciele Sbruzzi, Rodrigo Antonini Ribeiro, Sandra Mari Barbiero, Rosemary de Oliveira Petkowicz, Bruna Eibel, Natássia Bigolin Machado, Renata das Virgens Marques, Gabriela Tortato, Tiago Jerônimo dos Santos, Carina Leiria, Beatriz D'Agord Schaan, Lúcia Campos Pellanda

lupellanda@gmail.com

Instituto de Cardiologia do Rio Grande do Sul/Fundação Universitária de Cardiologia

## Objective

Through a systematic review and meta-analysis of randomized clinical trials (RCTs), the objective of this review is to assess the effects of physical activity interventions in preventing or treating obesity and other cardiovascular risk factors in childhood.

## Method

A search of online databases (PubMed, EMBASE and Cochrane CENTRAL) and published studies was conducted from inception until July 2012, with no language restrictions. RCTs enrolling children 6-12 years old conducted physical activity interventions longer than 6 months, assessing their effect on body mass index (BMI), systolic (SBP) and diastolic blood pressure (DBP), total cholesterol (TC) and triglycerides (TG). Data analysis was performed using a random-effects model.

## Result and Conclusion

Of 20,480 articles retrieved, 11 RCTs (10,748 subjects) were included. Physical activity interventions were not associated with reductions of BMI when compared to no intervention or less intensive interventions [-0.03kg/m<sup>2</sup> (95%CI -0.16, 0.13) I<sup>2</sup> 0%]. However, there was an association between the interventions and reduction of SBP [-1.25 mmHg (95%CI -2.47, -0.02) I<sup>2</sup> 0%], DBP [-1.34mmHg (95%CI -2.57, -0.11) I<sup>2</sup> 43%] and TG [-0.09mmol/L (95%CI -0.14, -0.04) I<sup>2</sup> 0%], and increase of TC [0.14mmol/L (95%CI 0.01, 0.27) I<sup>2</sup> 0%].

## Recommendation

As physical activity intervention programs lasting longer than six months are associated with reductions in blood pressure levels and triglycerides, they should be considered to be included in prevention programs for cardiovascular diseases in schoolchildren.

## Recommendation for future research

New approaches, including trials with greater exercise intensity, standardized interventions, and varied comprehensive strategies are needed to extend these results to other cardiovascular risk factors, such as obesity and hypercholesterolemia.

# Evaluation of the effectiveness of tuberculosis control activities in Campina Grande/PB/Brazil

Tânia Maria Ribeiro Monteiro de Figueiredo (coordenadora); Maria Aparecida Alves Cardoso; Neir Antunes Paes; Sheyla Nadjane Batista de Lacerda; Jessé Miranda de Figueiredo; Ardigleusa Alves Coelho; Mayrla Lima Pinto; Talina Carla da Silva; Valdênia Veríssimo de Lima; Fábila Vanessa Chalegre; Sonisa Maria G. Maul; Margarete Cristina O. de Carvalho; Neuman Gerônimo Leite; Elília Maria Pombo de Farias Santiago.

taniaribeiro@ccbs.uepb.edu.br

Universidade Estadual da Paraíba/UEPB

## Objective

To evaluate the effectiveness of tuberculosis control actions, comparing the model of attention in the Family Health Program, Basic Health Units and Tuberculosis Reference Clinic in Campina Grande/PB/ Brazil.

## Method

Descriptive, cross-sectional study, inquiry, health care evaluation with quantitative approach. The population was made up of 428 patients of tuberculosis notified in Sinan/PB in the period from January/2006 to December/2009. Among them, 81 were selected for interview. The data were collected from February to November/2010, using an instrument based on the component Primary Care Assessment Tool (PCAT), adapted to the tuberculosis attention by Villa and Ruffino-Netto (2008). To analyze the collected information, it was done statistical procedures (absolute and relative frequency, average calculation and standard deviation) and the calculation of epidemiological indicators of morbidity (incidence and prevalence coefficients), using Excel 2007 and SPSS Statistics, version 18.0.

## Result

40.1% of the respondents were met in the Tuberculosis Reference Clinic (AmbRef); 56.8% in the Family Health Basic Units (UBSF) and 3.1% in the Basic Health Units (UBS). To outlining the socio demographic profile, it was found that there was a predominance of males, economically active age group and low education. In the evaluation of the structure with regard to the implementation of the directly observed treatment, 56.5% attendances in UBSF performed this way, 50% in the UBS and 9,1% in AmbRef . When they were asked about the provision of medicines, 81.8% of respondents from the AmbRef, 58,7% from the UBSFs and 100% from the UBSs stated that during the treatment there was not lack of medicines. In the process assessment, for health education, it was found that only the UBSFs, sometimes, did campaigns in the community to inform about the disease. In relation to the pot delivery for sputum examination, the three services had unsatisfactory result. And to the establishment of the professional-patient relationship, the three services showed favorable results. In relation to the evaluation of the result, the coefficient of incidence was 28/100,000 inhabitants; the cure rate showed downward trend with 76.44% variation in 2006 to 66.39% in 2008, the percentage of abandonment was above the recommended, especially in 2007, in which it was registered the highest rate: 14.29%; in relation to the death, it was recorded just one case (0.7%) in 2009.

## Conclusion

It was possible to identify that the decentralization of tb control activities for primary care as recommended by the Ministry of Health, it still happens slowly in the studied city. Structure and result indicators were considered as unsatisfactory for the UBSFs, while the category process was evaluated as favorable for all services. There is the need to strengthen the tb control actions focusing on directly observed treatment strategy and in the planning of public policies directed to the patient's social reality, in the attempt to achieve the proposed targets (85% of healing).

## Recommendation

Directly observed treatment for all tb patients; Managers must make actions that can minimize the vulnerability of the tuberculosis patients.

## Recommendation for future research

Investigation of factors that interfere in the adherence to the directly observed treatment.

## Project data

Evaluation of the effectiveness of tuberculosis control actions, comparing the model of attention in the family health program, basic health units and tuberculosis reference clinic in Campina Grande/PB/Brazil; Public notice MCTCNPqCT-Saúde MS/SCTIE/Decit nº 672009-Rebrats; Coordinated by Figueiredo, T. M. R. M.

# Appraisal of the care for depression from the stand point of primary care in the municipality of Rio de Janeiro

Sandra Fortes, Karen Athié, Cláudia de Souza Lopes, Mônica Rodrigues Campos, Eloá Machado Borges, Marília Verdussen, Ellen Ingrid Aragão, Linda Gask e Peter Bower.

lipapsuerj@gmail.com

Universidade do Estado do Rio de Janeiro

## Objective

To study the care given to depression patients (detection and effectiveness of access and psychotherapeutic interventions) in the municipality of Rio de Janeiro, comparing two models of care in primary care.

## Method

Prospective study with a longitudinal cut-off point, quantitative with patients attended by general practitioners, evaluating the presence of depression, therapeutic strategies used and the types of interaction with specialized care, comparing Strategic Family Health Units (SFHs) and traditional Basic Health Units (BHUs), study of medical registers in order to evaluate these same indicators.

## Result

We can insert results into two areas:

1) Comparing models: it was found that the treatment for depression in the traditional BHUs was hindered by the organizations' very structure. The way procedures are held in these Units does not construct nor fortifies (doctor/patient) bonds. Patients are received at entrance without the opening of any registration form, only being included in a listing of the day's appointments, not in alphanumerical order, and which cannot be retrieved, and only those patients actually absorbed by appointments into the program have medical dossiers done. There are no ties either nor longitudinally in treatment. If a patient with multiple complaints (frequent in depression cases) comes to the Unit every week and is not admitted into a program, the team will not have any information about his/her numerous visits. This weak and uncompromised link reflects on the feeble binding of patient/Unit. While 50% of the patients treated by teams in SFHs were re-evaluated in the cohort follow-up, only 20% of those treated in the BHUs could be re-evaluated.

2) Detected types of care: when studying the existing types of care in the units visited (traditional BHUs and SFHs), we found: in BHUs, the prescription of psychotropic drugs was eminently given by psychiatrists, whenever they actually examined the patients. This type of care was not assumed by general practitioners. There were few records of consultations by psychologists, even though there were these professionals in the Units. In SFHs, with matrix patterns, we observed their proper use, often being prescribed after joint consultations. After the initial appointments, there were some problems/difficulties in maintaining the treatment by the mental health teams as part of their work routines. Here, patients were referred to mental health groups, both inside and outside SFHs, even though this type of care had

been greatly reduced. Lastly, there was a follow-up of 19 patients who, during the study, “migrated” from BHUs to SFHs. In these cases, after they had been registered into the SFHs, there was an increase in the number of consultations, with adequately registered appointments in medical dossiers, which had never been done beforehand.

## **Recommendation**

In the traditional BHUs there are no bonds, neither longitudinally in care, nor in the registration system of appointments. General practitioners merely send refer patients to specialists and there is no significant register of psychotherapeutic interventions. On the other hand, even though primary care in SFHs is only beginning, and difficulties having been found, such as maintenance of medical prescriptions and low adhesion to specific psychotherapeutic interventions one can already verify that mental health has been incorporated into the work routines of these teams. In this scenario, it becomes clear that matrix patters can help in detecting and structuring of an original proposal for a project in caring, keeping in mind the need for improvement in this type of practice.

# Assessment of the treatment of mood disorders: evidence and practice

Maurício G. Pereira

mauriciogpereira@gmail.com

Universidade de Brasília

## Objective

To assess the effectiveness of the treatment of bipolar disorder; risk factors for depression; and estimate the prevalence of depression, other chronic diseases and medicine consumption in Federal District.

## Method

We performed two systematic reviews of the literature and one population-based cross-sectional study in the Federal District, Brazil. The systematic reviews followed the Cochrane Collaboration methods and were registered at International Prospective Register of Systematic Reviews (PROSPERO), registry numbers: CRD42012001971 (bipolar disorder) e CRD42012003074 (depression). The cross-sectional study had a probabilistic sample in two stages, reaching a sample previously calculated of 1,820 interviewed in the residence.

## Result and Conclusion

The systematic review about the treatment of bipolar disorder found that olanzapine plus fluoxetine has a beneficial effect in those patients to response, remission, relapse, among other outcomes when compared with olanzapine and placebo. There was more adverse reaction in the intervention group. The review about risk factors for depression pointed that early puberty can be a risk factor for depression, but no association was found for late puberty in women. The cross-sectional study found that the adults living in Federal District had a prevalence of self-referred diseases: 11.2% of depression; 10.0% of diabetes; 22.8% of hypertension; 7.7% of cardiac diseases; 8.9% of respiratory diseases and 9.5% of other chronic diseases. Medicine consumption in the last seven days was reported by 35.5% of the study population. We identified several factors associated with the results, which we are analyzing in multivariate models.

## Recommendation for future research

New clinical trials with additional comparisons and higher patients compliance are needed to improve the quality of evidence about olanzapine plus fluoxetine for bipolar disorder. Further cohort studies about the effect of late or early puberty in the incidence of depression either to confirm or to discard the existence of association. Longitudinal studies are important to follow-up the population surveyed and investigate the incidence of chronic diseases.

## Reference

SILVA, M. T. et al. Olanzapine plus fluoxetine for bipolar disorder: a systematic review and meta-analysis. **Journal of Affective Disorders**, Philadelphia, v. 146, n. 3, p. 310-8, 2013.

# Evaluation of rapid tests for detection of hepatitis B virus surface antigen (HBsAg)

Livia Melo Villar, Helena Medina Cruz, Letícia de Paula Scalioni, Juliana Custódio Miguel, Elisângela Ferreira da Silva, Jaqueline Correia de Oliveira, Gabriela Cardoso Caldas, Vanessa Saete de Paula, Flávio Augusto Pádua Milagres, Priscila Pollo Flores, Ana Rita Motta-Castro, Marcelo Santos Cruz, Francisco Inácio Bastos, Lia Laura Lewis-Ximenez, Elisabeth Lampe.

lvillar@ioc.fiocruz.br

Fundação Oswaldo Cruz (Fiocruz)

## Objective

To evaluate the performance of rapid tests from different manufacturers to detect HBsAg marker in different populations and clinical specimens.

## Method

For this study, three groups were included: (G1) group with high endemicity for hepatitis B virus (HBV) infection (prevalence above 8%); (G2) group with low endemicity for HBV (prevalence less than 2%) and (G3) individuals with some risk behavior for HBV acquisition (beauty professionals and non-injecting drugs users). Two rapid tests were evaluated: (T1) Vikia HBsAg<sup>®</sup> (Biomérieux, France) and (T2) Imuno-rpápido HBsAg<sup>®</sup> (Wama, Brazil) and three clinical specimens: (CE1) serum samples (n=1181), (CE2) whole blood (n=1270) and (CE3) saliva (n=457) obtained with commercial collector Salivette<sup>®</sup> (Sarsted, Germany). The gold standard used to compare the results with rapid tests was the commercial enzyme immunoassay (ELISA) for HBsAg detection (ETI-MAK-4, Diasorin, Italy).

## Result and Conclusion

Rapid tests for HBsAg detection showed good performance in serum samples, particularly among individuals with high prevalence of HBV infection (agreement of 95.5% for T1 and 92% for T2). Using serum samples, the lowest rapid test performance was observed in group with low endemicity for HBV (agreement of 59.7% for T1 and 17.9% for T2). The specificity of rapid tests was above 95% in serum samples from all groups evaluated. Whole blood samples were tested only in T1, where the highest concordance was observed between individuals with some risk behavior (79.8%) and the lowest agreement was observed in low endemicity population (0.2%). The performance of rapid tests in saliva samples was measured only in the group with high endemicity for HBV, due to the low number of true positives between groups 2 and 3. It was observed low performance of both rapid tests in saliva samples (agreement 7.1% to T1 and 42.8% to T2), these tests were not developed for saliva samples, and this may explain the low performance of the sample. These results showed that rapid tests for HBsAg detection can be applied with good efficiency in serum samples in groups with high endemicity or with some risk behavior for HBV infection.

## Recommendation for future research

The use of rapid tests for HBsAg detection can be recommended for screening of hepatitis B cases using serum samples, in areas with high prevalence of HBV infection or in groups with risk behavior, such as drug users. We recommend further studies to evaluate these tests in other situations, such as, during the course of HBV infection, among individuals co-infected with HIV or with hematological alterations.

# Bone tissue bioengineering with the use of biomaterials

Fabiana Paim Rosa (coordenadora) (UFBA); Alexandre Malta Rossi (CBPF); Aryon de Almeida Barbosa Júnior (Fiocruz-BA); José Antônio Menezes Filho (UFBA); Ana Clara Alves de Carvalho (UFBA); Ana Emília Holanda Rolim (UFBA); Eliana dos Santos Câmara Pereira (UFBA); Isabela Cerqueira Barreto (UFBA); Luciana de Andrade Freitas Oliveira (UFBA); Manoel Bruno Guimarães de Souza (UFBA); Marcel Jhonnata Ferreira Carvalho (UFBA); Marion Alves do Nascimento (UFBA); Poliana Cerqueira da Silva Bahia (UFBA)

fabianapaim@hotmail.com

Federal University of Bahia/Health Sciences Institute/Foundation for Research Support of the State of Bahia/FAPESB – PPSUS

## Introduction

There is a set of procedures, in the context of the SUS and in certain situations/conditions needing care and treatment, which are aimed at meeting the major health problems and grievances of the population. The clinical practice of these procedures is grounded in the need to develop activities, services, and products (such as biomaterials and regenerative therapies). Therefore, this project has as its characteristics, to be multidisciplinary and multicenter, with the objective to investigate a new regenerative therapy, the potential osteogenic new biomaterials in tissue engineering bone with the development of new technologies applied to health. Bone lesions caused by trauma, tumors, degenerative diseases cause, in individuals, sequelae, mutilations and morbidity with functional and aesthetic impairments. They also reduce the quality of life of individuals, discourage their inclusion in social activities, and burden the health system.

For the repair of critical bone lesions, alternative and/or complementary therapies are necessary for bone regeneration. In this sense, research with biomaterials, such as hydroxyapatites (HA) and collagen are promising, because they feature physico-chemical and biological properties similar to autograft with desirable osteogenic properties and biocompatibility. In addition, researchers have tried to understand the action of strontium in bone repair and its systemic action. Strontium acts to reduce resorption, and promotes bone formation. The action of strontium on bone metabolism, in association with biomaterials, necessitates further investigation. Furthermore, the use of new therapies, such as cinesioterapia with the application of vibratory waves, is strategic for bone repair. It is known that the vibratory waves are effective at preventing bone and muscle loss, however there is no study on the regeneration potential of critical defects using vibratory waves.

## Objective

The aim of this study was to evaluate the osteogenic potential in critical defects submitted to a combination therapy of systemic application of vibratory waves through a vibrating platform, the strontium ranelate, and local implementation of different biomaterials (HA microspheres/alginate, gelatin granules, hydrolyzed collagen powder). The sample consisted of 165 male rats, divided into 11 groups, assessed the biological points of 15, 45 and 120 days. Critical defects were made in rat calvaria and their repair was analyzed histomorphologically.

## Result and conclusion

The results demonstrated that the application of vibratory waves is a dose-dependent therapy and enhances bone repair. The administration of strontium ranelate associated with deploying HAAlg produced less regeneration of the bone defect when compared with therapies alone. Gelatin, collagen hydrolyzate, and HAAlg are osteoconductive and bioactive scaffolds for bone repair and promote regeneration of bone defects. Therefore, it was concluded that all planned strategies to promote bone regeneration were promising and should proceed to the evaluation stage of clinical trials for subsequent production and commercialization of biomaterials along with the application of regenerative therapies to meet supply and demand in the market using products with national technology more accessible and available to SUS. This study is in the process of being revised for possible publication in scientific journals, as well as for the completion of two doctoral theses to be defended in the second half of this year.

# Construction and implantation of the arthroplasty register system performed at National Institute of Traumatology and Orthopedy

Tito Henrique de Noronha Rocha, Cláudia de Oliveira Passos, Cristiane Rocha de Oliveira, Juliana Batista de Souza, Tatiana Gargano L. Rosewarne e Verônica Clemente

nats@into.saude.gov.br

Instituto Nacional de Traumatologia e Ortopedia INTO

## Clinical protocol aim

Despite the improvements observed in the orthopedic prostheses and arthroplasties surgical results, complications may occur. As a source of data, arthroplasties registers present a great potential for clinical and economic assessments of these health technologies. For the National Institute of Traumatology and Orthopaedics can provide to the Ministry of Health information about monitoring and assessments of orthopedic prostheses and arthroplasties results, this study has the purpose: construct and implant the of arthroplasties registry system performed at INTO with prospective data collect about surgical techniques performed, orthopedic prostheses and clinical outcome at short and long time frame.

## Clinical protocol method

Descriptive study about the construction stages and Institutional arthroplasties register data analysis. Literature search in English and Portuguese books, manuals, legislation, specialized journals, MEDLINE, CAPES, using DeCs BVS descriptors of health sciences. Specialists query: meetings among specialists for consensus of information to be entered into the registry.

# Performance of rapid tests for detection of Hepatitis C virus antibodies

Lívia Melo Villar, Letícia de Paula Scalioni, Helena Medina Cruz, Vanessa Salete de Paula, Vanessa Alves Marques, Bruna Lemos Crespo Marques, Juliana Custódio Miguel, Elisângela Ferreira da Silva, Jaqueline Correia de Oliveira, Moyra Machado Portilho, Cristiane Alves Vilella-Nogueira, Ana Rita Motta-Castro, Flávio A. Pádua Milagres, Marcelo Santos Cruz, Francisco Inácio Bastos, Lia Laura Lewis-Ximenez, Elisabeth Lampe

lvillar@ioc.fiocruz.br

Fundação Oswaldo Cruz (Fiocruz)

## Objective

To evaluate the performance of rapid tests for the diagnosis of anti-HCV in serum, whole blood, and oral fluid samples from population with different endemicity profiles and risk behaviors.

## Method

Biological samples were obtained from three groups: I) 194 individuals who were referred to viral hepatitis ambulatory clinics in Rio de Janeiro (IOC/Fiocruz and UFRJ) that donated paired serum, whole blood and oral fluid samples which were evaluated in Wama Imuno-Rapido HCV and Bioeasy HCV Rapid Test, and 174 oral fluid samples that were evaluated in Oraquick HCV rapid test; II) individuals living in remote areas (Tocantinópolis, Tocantins and Pantanal of Mato Grosso do Sul), where 430 paired sera, whole blood and oral fluid samples were evaluated in Wama and Bioeasy rapid tests, and 459 oral fluid sample were evaluated in Orasure; III) crack users individuals from two geographic regions of Brazil (Southeast and Northeast) and beauty professionals who were living in the Rio de Janeiro State that donated 200 paired serum, whole blood and oral fluid samples which were evaluated in Wama and Bioeasy rapid tests, and 43 oral fluid samples tested in Orasure rapid test. Serum anti-HCV was evaluated using two enzyme linked immunosorbent assays (ELISA) (Radim and Diasorin), and those reactive samples were submitted to PCR for HCV RNA detection. Reproducibility, repeatability and cross reaction to other infectious agents (dengue, HIV, malaria, and syphilis) were also evaluated.

## Result and Conclusion

Sensitivities and specificities of rapid tests varied from 76.03% to 93.84% and 93.75% to 100% when all EIA anti-HCV reactive were included. When only anti-HCV/HCV RNA reactive samples were included, the sensitivity and specificity of assays in the group I were respectively 99.09% and 100% using Bioeasy with sera and whole blood; 98.18% and 93.75% using Wama and serum samples; 95.35% and 100% using Orasure and oral fluid; 90.91% and 93.75% using Wama and oral fluid; and 86.36% and 100% using Bioeasy and oral fluid. In group II, Orasure rapid test using oral fluid showed the best performance with only four anti-HCV false-negative result compared to ELISA, but all of these samples had no HCV RNA in serum. In group III, Bioeasy rapid test using whole blood and serum showed the best performance. Repeatability and reproducibility tests showed 100% concordance. In cross reaction evaluation, five false negative results were found, among Wama test: one sample was reactive for dengue and the other for HIV; using Bioeasy test:

one sample was reactive for dengue, one HIV reactive and the other Plasmodium vivax reactive. We also observed three false positive results for Wama assay when P. vivax reactive samples was used.

### **Recommendation**

Rapid tests for anti-HCV detection may be employed with good sensitivity for detecting active infection in populations with different endemicity profiles.

### **Recommendation for future research**

We recommend further studies to evaluate these tests in other situations, such as during the course of HCV infection, among individuals co-infected with HIV/HCV or patients with hematological changes, as well as to evaluate the cost benefit of rapid tests for hepatitis C diagnosis.

# Performance of the Family Health Program (PSF) compared with the Basic Health Units in control of systemic hypertension control and associated factors in the municipalities in the state of Paraíba/Brazil: a cohort study

Neir Antunes Paes, Tânia Maria R. M. de Figueiredo, Christiana Souto Silva, Jozemar Pereira dos Santos

antunes@de.ufpb.br

Departamento de Estatística – Universidade Federal da Paraíba

## Objective

To evaluate the effectiveness of the Family Health Strategy (ESF) in the control of hypertension and to identify associated conditions to the risk factors in João Pessoa and Campina Grande, Paraíba/Brazil from 2006 to 2011.

## Method

It was a retrospective double-cohort (accompanied and unaccompanied) study with quantitative and qualitative approaches about health services provided to hypertensive patients registered in the *HiperDia* Program of the Health Ministry. It was evaluated the health units professionals. For both, it was extracted a representative sample of population base and, questionnaires were prepared and validated to measure the degree of satisfaction. In addition, the users had their medical records reviewed. Additional interviews were conducted with a qualitative approach. The evaluation strategy had as theoretical-methodology framework the basic categories of health services quality: structure-process-outcome. Decision-making analyses were employed through statistical descriptive and multivariate techniques and speech analysis.

## Result and Conclusion

For João Pessoa and Campina Grande, respectively: 32,6% and 58,2% patients were accompanied by the ESF and, 32,4% and 44,3% had controlled blood pressure (BP) in 2009. In both municipalities, there was a predominance of the female genre, elderly, black and brown people, they couldn't read or write and the most hypertensive patients lived with fellow. There has been a satisfactory level of adhesion/ bonding (89,1%), although most of them did not have the controlled pressure. It was found an important percentage of data and information ignored by agents at the completion of *HiperDia*. From 2009 to 2011, the percentage of users accompanied with controlled BP ranged from 36,4% to 31,5% in João Pessoa and 45,0% to 66,7% in Campina Grande. Among those who followed the drug treatment, there were no significant differences in their profiles compared with those who did not follow the treatment.

## Recommendation

The results suggest that urgent interventions are required of managers and professionals responsible for health teams to monitor the follow-up and the BP control of the users. It was noticed teams with different degrees of commitment, both in attention as in the monitoring of the patient. There was a disagreement between what captured the SIAB

system and the *HiperDia*. It is suggested that various aspects need to be reassessed like: Organization, registration and maintenance of technical documentation memories relating to the patients, particularly the charts; flow of information and documentation.

### **Recommendation for future research**

Additional research is needed to explore the differences between registered users accompanied and unaccompanied.

### **Reference**

SILVA, C. S. et al. Controle pressórico e adesão/vínculo em hipertensos usuários da atenção primária à saúde. **Revista da Escola de Enfermagem da USP**, São Paulo (no prelo).

# Therapeutic guideline for the proximal femur fracture

Tito Henrique de Noronha Rocha, Cláudia de Oliveira Passos, Cristiane Rocha de Oliveira, Juliana Batista de Souza, Tatiana Gargano Lemos Rosewarne e Verônica Clemente

nats@into.saude.gov.br

Instituto Nacional de Traumatologia e Ortopedia INTO

## Clinical protocol aim

Clinical protocols and therapeutic guidelines perform an important part in improving the quality in health care. They promote: updating and dissemination of knowledge; safe and effective prescription; improving the quality of information provided to patients; and improvement of management processes of assistance programs. They are the result of a technical scientific consensus with community participation in their development. Clinical protocols and therapeutic guidelines consider the need to establish criteria for diagnosis, prognosis, treatment and prevention of diseases. In this context, the study aims to establish therapeutic guidelines for the proximal femur fracture in patients over 65 years old.

## Clinical protocol method

The Clinical protocols and therapeutic guidelines should be developed in three steps. Step I – bibliographic search: database, books, manuals and specific journals about the subject will be used to search the official vocabularies and their synonyms like MeSH (PubMed), DeCS (BVS) e Emtree (Embase). Step II – querying specialists, through meetings with center for specialized care of orthopedic trauma. Step III – Clinical protocols and therapeutic guidelines development

# Efficacy, safety and cost to use heliox in patients with acute exacerbation of chronic obstructive pulmonary disease in invasive mechanical ventilation: a rapid HTA

Andréa Diogo Sala; Ana Paula Cavalcante de Oliveira

fisiouti@haoc.com.br

Foundation for Economic Research Institute, Brazilian Ministry of Health, Oswaldo Cruz German Hospital: technical cooperation

## Background

The Chronic Obstructive Pulmonary Disease (COPD) causes chronic airflow obstruction and an acute deterioration in respiratory symptoms. It is frequently associated with a significant increase in mortality, hospitalization and use of health care. Mortality rate reaches 40% a year in patients who need invasive mechanical ventilation (IMV).

In 2011, the number of hospital admissions totaled 116.707 and cost the Brazilian Ministry of Health R\$87,1 million. From 2005 to 2010, the mortality rate has increased by 12% (from 33.616 to 37.592). Helium is an inert gas, whose main property is very low density, which can have important potential benefits to fluid dynamics in airways: transition from turbulent to laminar flow and reduced resistance even under persistent turbulent flow conditions. The helium/oxygen mixture administered to patients with COPD increases the release of oxygen and reduces both the work of breathing and airway resistance.

## Objective

To analyze the available scientific evidence of the efficacy, safety and cost of heliox in patients with acute exacerbation of COPD in IMV compared with nitrogen-oxygen.

## Method

Two reviews of scientific literature were performed in the following databases: PubMed, LILACS, EMBASE, Cochrane Library, CRD and Clinical Trials. The first review intended to identify meta-analyses, systematic reviews and randomized clinical trials (RCTs). The second concentrated on economic studies. The desired outcomes were mortality, length of stay in ICU and IMV, intrinsic PEEP (PEEPi), work of breathing (WOB), peak inspiratory pressure (PIP), plateau pressure (Ppl) and cost-effectiveness/cost-benefits. The classification of the level of evidence and strength of recommendation of these publications was performed using the GRADE System (Grades of Recommendation, Assessment, Development and Evaluation).

## Result and conclusion

The first review identified 372 publications. Only three of them were selected for the purposes hereof. A common outcome in all three studies was the PEEPi, which was significantly reduced by the use of heliox, with the reduction being directly proportional to the value of PEEPi. Total WOB (WOBt) was evaluated and showed statistically significant decrease.

One of the studies described a direct correlation between the reduction in PEEPi and WOB (WOBPEEPi), and reductions in PIP and Ppl. No adverse events or sentinels were reported. None of those studies evaluated mortality, length of IMV weaning, ICU stay and IMV duration. As for the second review, 172 publications were identified, but none of them approached economic aspects.

Thus, a questionnaire was applied to identify property costs (concerning acquisitions, operation and cost maintenance) to provide heliox. While the acquisition and maintenance costs to use either oxygen or heliox are relatively similar, the operational costs in using heliox is 40 times higher. Thus, although the use of heliox may result in decreased PEEPi and WOB, there is no evidence of relevant clinical outcomes to recommend its routine use in a clinical context and moreover, it has a high operational cost.

## Recommendation

Weak recommendation in favor of technology.

## Recommendation for future research

We suggest conducting RCTs for primary outcomes. This may increase the strength of recommendation in favor of heliox, which will help in making decisions. There are not enough studies to determine the best helium/oxygen mixture ratio to treat COPD exacerbated in IMV.

# Study on methods for the allocation of financial resources in the healthcare

Adriana Falangola Benjamin Bezerra; Marina Araújo Rosas; Paulo Duarte Neto; Islândia Maria Carvalho de Sousa; Antônio Carlos Gomes do Espírito Santo; Rogério Fabiano Gonçalves; Keila Silene de Brito e Silva

afalangola@uol.com.br

Universidade Federal de Pernambuco – Programa de Pós Graduação Integrado em Saúde Coletiva (PPGISC) – Grupo de Pesquisa em Economia Política da Saúde (GPEPS)

## Objective

The aim of the present study was to test methods described by Machado et al. (2004), Nunes (2004) and the GPEPS (Research Group on Economic Health Policies, 2010) for the allocation of financial resources in healthcare and associate the findings with the value *per capita* of expenditures in the Brazilian public healthcare system.

## Method

A quantitative study was conducted involving municipalities of the state of Pernambuco (northeastern Brazil) with all the necessary information in databases to compose the nineteen variables selected. Data collection for the determination of allocation factors and the distribution of municipalities among quartiles was performed using public domain databases and information from the Pernambuco Secretary of State. The data were standardized; descriptive statistics were performed and the degree of intrinsic associations among the variables was determined. Principal component analysis (PCA) was employed in the analysis of allocation factors tested using the methods described by Machado et al. (2004) and Nunes (2004) and an artificial neural network (ANN) was employed for the analysis of factors tested using the GPEPS (2010). ANN was also used to verify the results obtained using the methods described by Machado et al. (2004) and Nunes (2004). Comparisons were made between economic indicators of the Public Health Budget Information System (Siops) of each municipality and the results of the allocation factors determined using ANN.

## Result

The descriptive statistics revealed high mean values in the municipalities regarding mortality rate before five years of life, deaths due to circulatory diseases, percentage of live births with inadequate prenatal care and individuals with an income per capital less than R\$75.50. In contrast, improvements in mean values were found regarding literacy rate, percentage of homes with trash collection and deaths due to infectious and parasitic diseases. The allocation factors demonstrated differentiated scaling, with only 24.59% of the municipalities contained within the same quartile. The coastal region of the state had the largest number of municipalities in the quartile with the fewest health needs. In contrast, the southern *agreste* (transition region between coast and semi-arid interior) and the semi-arid Araripe region had a considerable number of municipalities with greater health needs. Mean expenditures *per capita* on health in the municipalities of Pernambuco was R\$270.28 in 2010 and 59.01% of the municipalities had values below the mean. The results of the five analyses performed in the present study reveal a need for greater expenditures on health in the state of Pernambuco as a whole.

## Recommendation for future research

For the establishment of allocation factors that consider criteria of equitability, it is necessary to consider the challenge of choosing variables that best represent the health needs of a population. The statistical model employed for such should also be considered carefully. In the present study, the first two allocation factors tested were determined using PCA. This type of analysis requires a larger number of calculations and inference tests to reach the end product. The last three allocations factors were determined using an ANN, which has considerable applicability and is indicated for studies with the aim of classifying a given situation. However, the complexity of the functioning of this method should be stressed.

## Reference

MACHADO, E. N. M.; FORTES, F. B. C. T. P.; SOMARRIBA, M. Efeitos da introdução do PAB sobre a distribuição de recursos e prestação de serviços: o caso de Minas Gerais. **Ciência & Saúde Coletiva**, Rio de Janeiro, v. 9, n. 1, p. 99-111, 2004.

NUNES, A. **A alocação equitativa inter-regional de recursos públicos federais do SUS**: a receita própria do município como variável moderadora. Brasília: Ministério da Saúde, 2004.

RESEARCH GROUP ON ECONOMIC HEALTH POLICIES. **Equitable allocation of financial resources for health in Pernambuco**: a methodological proposal. Notice PPSUS 09/2008, Partial Report, 2010.

ROSAS, M. A.; BEZERRA, A. F. B.; DUARTE-NETO, P. J. Uso das redes neurais artificiais na aplicação de recursos da saúde. **Revista de Saúde Pública**, São Paulo, v. 47, n. 1, 2013.

# Unfractionated heparin versus low molecular weight heparin for avoiding heparin-induced thrombocytopenia in postoperative patients

Daniela R. G. Junqueira, Edson Perini, Raphael R. M. Penholati, Maria das Graças Carvalho

danijunqueira@gmail.com

Centro de Estudos do Medicamento (Cemed), Universidade Federal de Minas Gerais (UFMG)

## Objective

The objective of this systematic review was to compare the incidence of HIT and HIT complicated by thrombosis in patients exposed to UFH versus LMWH in randomized controlled trials (RCTs) of postoperative heparin therapy.

## Method

The studies were searched in The Cochrane Peripheral Vascular Diseases Group Specialized Register (March 2012), CENTRAL (2012, Issue 2) and LILACS database (March 2012). Additional trials were sought from reference lists of relevant publications. We studied RCTs in which participants were patients submitted to any surgical intervention and allocated to receive UFH or LMWH, in a blinded or unblinded fashion. Eligible studies were required to have as an outcome clinically diagnosed HIT, defined as a relative reduction in the platelet count of 50% or greater from the postoperative peak (even if the platelet count at its lowest remained  $> 150 \times 10^9/L$ ) occurring within five to 14 days after the surgery, with or without a thrombotic event occurring in this timeframe. Circulating antibodies associated with the syndrome were required to have been investigated through laboratory assays. Study selection, data extraction and risk of bias assessment were performed in accordance with the standard methods of The Cochrane Collaboration. Meta-analysis was performed to estimate the risk of the outcomes according to the type of heparin used.

## Result and conclusion

Two studies involving 923 participants met the inclusion criteria and were included in the review. Pooled analysis showed a statistically significant reduction in the risk of HIT with LMWH compared with UFH (risk ratio (RR) 0.24, 95% confidence interval (CI) 0.07 to 0.82;  $P = 0.02$ ). This result suggests that patients treated with LMWH would have a relative risk reduction (RRR) of 76% in the probability of developing HIT compared with patients treated with UFH. It was demonstrated a statistically significant reduction in HIT complicated by VTE with LMWH compared with UFH (RR 0.20, 95% CI 0.04 to 0.90;  $P = 0.04$ ). This result indicates that patients using LMWH would have a RRR of 80% for developing HIT complicated by VTE compared with patients using UFH. Meta-analysis combining the subgroups of patients undergoing major surgical procedures (the scores of 586 patients undergoing major surgeries) demonstrated a significant reduction in the risk of HIT with LMWH compared with UFH (RR 0.22, 95% CI 0.06 to 0.75;  $P = 0.02$ ).

## Recommendation

Our results estimated a higher absolute risk (incidence) of HIT induced by UFH compared with LMWH, which is consistent with the scientific literature and the current clinical use of LMWH over UFH as front-line therapy. According to WHO standard categories for adverse drug reaction frequency, and considering our results, HIT induced by both types of heparins may be considered as a common adverse drug reaction (incidence > 1% and < 10%) and this may impact clinical recommendations regarding platelet count monitoring for HIT. Of note, a significantly lower risk for venous thromboembolism was seen in patients who developed HIT when exposed to LMWH compared with UFH. Implications for research: High quality evidence from randomized controlled trials is sparse about HIT. Only two randomized controlled trials were good enough to be included in this review. The research community and pharmaceutical industry should be aware of the need to include appropriate monitoring and testing for HIT in trials of anticoagulant therapy with heparin.

## Reference

JUNQUEIRA, D. R. G. et al. **Unfractionated heparin versus low molecular weight heparin for avoiding heparin-induced thrombocytopenia in postoperative patients**. Cochrane Database of Systematic Reviews, issue 9, art. n. CD007557. 2012. DOI: 10.1002/14651858.CD007557.

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

Marson A. G.; Coutinho A. M. N.; Trindade E.; Souza D.S.F.; Soares Jr J.; Sallum R.A.A.; Cecconello I.; Meneghetti J.C.

allangarms@gmail.com, arturcoutinho@gmail.com, evelinda.trindade@incor.usp.br, meneghetti@incor.usp.br.

Nuclear Medicine & Molecular Imaging and Health Technology Assessment/NATS-HC/FMUSP & Rebrats/MS, Heart Institute (InCor-HC/FMUSP), Gastroenterology Surgical Division – Central Institute (IC-HC/FMUSP); Clinics Hospital of the University of São Paulo Medical School, São Paulo – Brazil.

## Objective

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. Last cohort results are currently being presented.

## Method

154 patients (mean age of  $59 \pm 10$  years, 80% male) with biopsy proven esophageal cancer were included. All patients were prospectively evaluated between September 2006 and June 2012 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 94,9% of the cases. Only eight patients didn't have positive PET findings at the primary site, four of which were limited to the submucosa and four were in situ adenocarcinomas. There were no statistically significant differences in the degree of metabolism measured by SUV between adenocarcinomas and spinocellular carcinomas. But SUVs max in primary tumor was  $16,3 \pm 9,4$  and in regional tumors was  $8,0 \pm 6,6$ . PET showed no difference in initial staging in 47% of the patients. However, 23% of the patients were upstaged and 30% downstaged, translating into management decision changes for 30% of the patients.

## Conclusion

FDG-PET showed high sensitivity for the esophageal cancer detection and proved to be effective for preoperative staging of the disease, changing management decision for 30% of the patients.

## Recommendation

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.

## Reference

Results reported at Asociacion Latinoamericana de Sociedades de Biologia y Medicina Nuclear in 2013.

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

Vera Lúcia Edais Pepe, Rosângela Caetano, Lenice G. da Costa Reis, Clarisse P. D. D. Fortes, Cláudia R.G. Bastos, César A.O. Favoreto, Fátima Martins, Gizele Rocha, Ione A.G. Oliveira, Rafael Cota Rondineli M. Silva, Tatiana A. Figueiredo

verapepe@ensp.fiocruz.br

Escola Nacional de Saúde Pública Sérgio Arouca/Fiocruz e Instituto de Medicina Social/UERJ

## Objective

The aim of this study was to identify and synthesize the evidence regarding risk factors (RF) for death and severe maternal morbidity and birth care-related adverse events (AE), as well as methods for identifying these events in obstetric services.

## Method

Two systematic reviews (SR) were performed, guided by the questions:

1. What are the RFs for maternal death, maternal near miss and parturition care-related AE in maternity hospitals?
2. What are the methods used for identification of these events in maternity hospitals?

The electronic databases used were: MEDLINE, EMBASE, WEB OF SCIENCE; SCOPUS and LILACS. Reference lists of review articles served as an additional source of research. In the initial selection phase, two independent investigators reviewed studies based on title and abstract and excluded those that did not meet inclusion criteria. In a second step, the full text of articles was analyzed as to the eligibility criteria. Discrepancies between reviewers were resolved by consensus. The quality of the articles of the first SR was assessed using the STROBE and CONSORT tools, according to their nature.

## Result and conclusion

The study resulted in the identification of 29 articles (three including data from Brazil) addressing RFs for maternal death related to childbirth, such as type of delivery, duration of labor, analgesia/anesthesia, type of *birth assistant* and service location. Thirteen of the studied articles included type of delivery as a RF for maternal death and only two did not demonstrate a *statistically significant association* with cesarean delivery. Six studies included the birth assistant professional as an element of analysis and all indicated that this factor was associated with risk of maternal death. The duration of labor was an important RF for maternal death. We identified 100 articles addressing childbirth RFs for maternal morbidity and other AE. The obstetric AE studied in these papers comprised a broad spectrum of conditions that ranged from perineal and vaginal lacerations to ICU admission, with a great variety of definitions. The number of RFs for these events ranged from three to 17, with some studies examining factors for various events.

In 20 studies, we identified composite indices of morbidity, so called because the authors included several outcomes. Postpartum hemorrhage and perineal lacerations were the AEs most frequently examined, by about half and one third of the studies, respectively. We identified 22 RFs related to childbirth care, with a statistically significant association with AE. Type of delivery, duration of the 2nd and 3rd stages of labor, medical induction and acceleration of labor, episiotomy and analgesia were the most studied and were associated with unfavorable outcomes.

In the second SR, which addressed methods for childbirth-related AEs identification to, 42 studies were identified. The majority (57.1%) used two or more sources of data; 66,7% used administrative data (ICU and delivery room records, , admission and discharge documents, etc.). Structured forms for data extraction, diagnostic codes and/or procedures were frequently used. Some studies used the techniques of expert consensus for validation of the instrument used, or for confirmation of diagnosis of AE and near miss.

### **Recommendation**

It seems necessary to discuss the definitions of maternal near miss and obstetric AE among researchers and health professionals. The RF identified need to be recognized as such and it is important to broaden discussions about the results of obstetric services in the country.

### **Recommendation for future research**

The author suggests the development of specific studies on the RF identified to verify their influence in unfavorable outcomes. Based on the revised methods, a tool was developed and tested for identification of childbirth-related AE, and we recommend broadening its application to recognize the Brazilian reality in this area.

# Public involvement in the process of Health Technology Assessment: worldwide experience and proposals for its expansion in Brazil

Aline Silveira Silva

[aline.siva@saude.gov.br](mailto:aline.siva@saude.gov.br)

Escola Nacional de Saúde Pública Sérgio Arouca

## Introduction

Health Technology Assessment (HTA) is a multidisciplinary field of policy analysis that examines the clinical, social, ethical, and economic implications of the development, diffusion, and use of technology in healthcare, taking into consideration aspects such as efficiency, effectiveness, safety, cost and cost-effectiveness, among others. Although HTA should primarily consider the social, ethical and legal impacts associated with technology, other basic attributes (efficacy, effectiveness, safety and cost) end up taking precedence over the previous ones. But with the increasing emphasis on the engagement of patients as full partners in taking care of their own health, there is a need to establish effective means for their involvement in the decision-making process.

## Objective

The aim of this study was to explore the challenges in both the national and international contexts for involving the perspective of society (patients, caregivers, and health professionals) in the process of assessment and incorporation of health technologies in the Brazilian Public Health System (SUS). An integrative method was adopted, consisting of literature review and analysis of documents and official records from the Ministry of Health. The results showed international experiences developing rapidly, especially in the UK and Canada.

In Brazil, legal instruments for involving citizens in health and technology incorporation policies exist, but their practical implementation is still incipient. The main challenges identified both in the national and international scopes are those relating to cultural aspects. Based on the results, it was possible to identify proposals for improving the mechanisms of societal involvement in the processes of assessment and incorporation of technologies in the SUS.

## Reference

SILVA, Aline Silveira. **O envolvimento do público no processo de Avaliação de Tecnologias em Saúde: experiências mundiais e proposições para sua ampliação no Brasil**. 2013. 172 f. Dissertação (Mestrado em Saúde Pública) – Escola Nacional de Saúde Pública Sérgio Arouca, Rio de Janeiro, 2013.

# The role of Health Technology Assessment (HTA) in withdraw medical device obsolete in Public Health System of Brazil (SUS)

Eduardo Coura Assis

eduardo.assis@saude.gov.br

Escola Nacional de Saúde Pública Sérgio Arouca

This paper discusses how the Health Technology Assessment (HTA) has been used in decisions involving the withdraw of technologies of public health, in particular medical devices. This study covers the macro and meso levels of public countries with expertise in this area and identifies actions disinvestment in both HTA agencies, as well as in hospitals that adopt the ATS at the stage of obsolescence. Unlike drugs and other health technologies, medical devices are considered good disinvestment cases when it is withdrawn to associate operational obsolescence caused by its natural wear, fatigue or stress-friendliness, coupled also to issues of infrastructure and human resources that will handle them.

It can be seen through literature this dissertation explored the ATS but can contribute in making decisions during the stage of obsolescence of medical devices, but to succeed in this new front, new forms of behavior should be committed, such as those already embedded in other ATS performances, such as the involvement of various professionals who interact with technology, the application of new analysis methodologies, to improve managers' incentives, among others. It was found through a survey applied to the centers of health technology assessment in Brazil that the disinvestment process is exercised by a few centers, and even then, so still very early, which poses a challenge to managers in the formation of critical mass expressive face of budgetary imbalances and the potential risk that certain technologies can offer.

The main contribution of this paper is to propose some criteria for identification and prioritization of potential candidates for divestment technologies based on the experiences made by some agencies and national governments and ATS start a discussion on the possibilities of improving the management of health technologies in Brazil. Should be further explored through future studies, knowledge of new forms of reimbursement, valuation criteria and a possible incentive policy to services who wish to study the technologies that are already in use in SUS.

## Reference

ASSIS, Eduardo Coura. **O Papel da Avaliação de Tecnologias em Saúde (ATS) na retirada de dispositivos médicos obsoletos no Sistema Único de Saúde (SUS)**. 2013. 123 f. Dissertação (Mestrado em Saúde Pública) – Escola Nacional de Saúde Pública Sérgio Arouca, Rio de Janeiro, 2013.

# The septal occluders for closure of ostium secundum atrial septal defect: a legal approach to the import, registration for commercialization in Brazil and its inclusion in the Public Health System of Brazil (SUS)

Eliete Maia Gonçalves Simabuku

eliete.simabuku@saude.gov.br

Foundation for Economic Research Institute/Oswaldo Cruz German Hospital

## Introduction

This work is in the context of the use of septal occluders for closure of ostium secundum atrial septal defect as an alternative to surgery.

## Objective

To make a legal approach to the importation, registration for commercialization in Brazil and inclusion of septal occluders in the Brazilian Public Health System.

## Method

The methodology used was legal research, literature and documents, using as research sources the electronic addresses of Brazilian Ministry of Health (<[www.saude.gov.br](http://www.saude.gov.br)>), Anvisa (<[www.anvisa.gov.br](http://www.anvisa.gov.br)>) and The Presidency (<[www.presidencia.gov.br](http://www.presidencia.gov.br)>), aiming to identify laws and regulations pertaining to theme.

## Result

Identified that prices of septal occluders offered in Brazil appear to be higher than the costs abroad, which can be impacted by the administrative record and available for incorporation by SUS.

## Conclusion

Unlike what happens with drugs, there is no standardization of prices such as those established by the Board of Market Regulation of Medicines (CMED). Despite the difficulty inherent to the various technologies that can be used in the manufacture of health products, which hinders its standardization in the case of septal occluders, given its specific application and the relatively small difference between products with registration at Anvisa, a standardization of prices, would facilitate the analysis and incorporation available to SUS.

# Pay-for-Performance in Primary Health Care: initial results of the Brazilian Program for Improving Access and Quality on avoidable hospitalizations in Brazilian municipalities

Jorge Otávio Maia Barreto

jorgeomaia@hotmail.com

Foundation for Economic Research Institute/Oswaldo Cruz German Hospital

Pay-for-Performance (P4P) has been widely used for health outcomes' improvement around the world. However, a few experiments and their results were properly studied, especially in low-and-middle income countries. In 2011, Brazil launched a Payment-for-Performance scheme that must be the biggest one addressed to primary health care in the world, the Brazilian Program for Improving Access and Quality (PMAQ, in Portuguese). The objective of this study was to evaluate PMAQ's initial results in Brazilian municipalities, from the hospitalizations for Primary Care Sensitive Conditions (PCSC).

Reviewing the published literature, the P4P effectiveness in producing results or access and quality patterns in health services and systems was discussed. From the documentary analysis of PMAQ's official normative framework, it was characterized as a P4P model, identifying its goals and targets, evaluation units, performance measures, monitoring forms and results interpretation and financial incentives involved. From January to July 2012 the association between the PMAQ and the ICSAP paid by Brazilian Public Health System (SUS) was investigated using descriptive and probability statistics analysis through multiple linear regression model of ICSAP rate, the dependent variable, on explanatory variables, including control and exposure variables. The model was applied on sample strata (n=5,396), categorized according to quartiles of household income average per capita.

There are no conclusive and uniform evidence about the P4P effects to improve health outcomes, but these are conditioned by conceptual and implementation models. The PMAQ is a P4P scheme extremely complex and includes multiple addressing levels, objectives, targets and evaluation forms. Financial incentives arising from the program can be considered high in comparison with usual fundings, creating the need for permanent monitoring in order to prevent unwanted or unexpected effects.

The PMAQ effects on the hospitalizations for PCSC reduction were more evidenced in the municipalities with lower average of household income strata per capita, where expanding the proportion of PHC teams participating in the PMAQ was associated with the reduction of 21.37 ICSAP/10 thousand inhabitants in the first income quartile; and 12.88 ICSAP /10 thousand inhabitants in the second quartile. The regression in the higher income strata (third and fourth) showed no PMAQ significant results on the hospitalizations for PCSC, making the assumption that the program has provided greater effects in higher socioeconomic shortages scenarios, which implies in an equity component of the program.

From January to July 2012, the hospitalizations for PCSC represented an expense superior to 1 billion reais for the Brazilian government, and the PMAQ could be amplified and monitored in order to reduce these avoidable costs for the SUS and to improve primary health care access and quality in Brazil, favoring the entire Brazilian society. However, it is necessary to expand the studies on the PMAQ, as well as its permanent monitoring in order to better understand its impacts.

# The efficacy and safety of the use of rituximab in the treatment of Chronic Lymphocytic Leukemia: a mini-HTA

Kathiaja Miranda Souza e Christine de Nazaré Silva Koury

kathiaja.souza@saude.gov.br

## **Strength of recommendations**

Weak recommendation in favor of technology

## **Technology assessed**

Rituximab associated with conventional chemotherapy

## **Indication**

Chronic Lymphocytic Leukemia

## **Characterization of the technology**

Monoclonal antibody (humanized) to CD20 (an antigen of B cells). This agent binds to CD20 and induces apoptosis and promotes cell death mediated by complement.

## **Question**

The use of rituximab to standard chemotherapy is associated with more effective and safety compared to treatment with chemotherapy alone in patients with Chronic Lymphocytic Leukemia?

Search strategy and analysis of scientific evidence: For the development of PTC, we used the Methodological Guidelines for preparation of PTC the Ministry of Health of Brazil. Was onducted extensive search in Medline (via PubMed), Embase, Lilacs and CRD that compared regimens containing rituximab associated with conventional chemotherapy with Fludarabine Cyclophosphamide (FC). The search strategy was general and sensitive and included terms for chronic lymphocytic leukemia and rituximab.

## **Summary of the results of the selected studies**

Three studies were selected and the overall treatment regimen consisting of the use of rituximab, fludarabine and cyclophosphamide can effectively improve the rate of complete remission and overall survival, as well as prolong progression-free survival. For safety outcomes, treatment with RFC showed more adverse events compared to CF.

## **Recommendation**

The selected studies had low methodological quality, and results must be evaluated with caution. Moreover, being a disease that mainly affects people older than 65 years, is necessary to assess the possible impacts caused by the difference in age and disease stage.

# Children and adolescents' anemia prevalence in amazon communities

Daniela Sartori Paoli, Maria Arlete Meil Schimith Escrivão, Mario Maia Bracco

mariomb@einstein.br

Centro Assistencial Cruz de Malta; Universidade Federal de São Paulo/UNIFESP

## Objective

To evaluate prevalence of anemia and nutritional status in children and adolescents in five amazon communities.

## Method

Cross-sectional study of a convenience sample of 246 children and adolescents, 136 girls (55.3%) and 110 boys (44.7%), from 9 to 224 months, in four river basin communities located in Marajó Island (Afuá-PA) and one *quilombola* community in Macapá City, Amapá State. Nutritional assessment was performed by Body Mass Index (Z BMI) and Height to Age (Z H/A) index Z scores. Hemoglobin (Hb) levels were determined by hemoglobinometer Agabe®. The cutoff points adopted for anemia were: six to 59 months Hb < 11.0 g/dL (n=69); 60 to 119 months < 11,5g/dL (n=95); females > 120 months, and males between 120 and 168 months, Hb < 12mg/dL; males > 168 months, Hb < 13mg/dL (n=82). Data analyses were performed by the qui-square test for anemia prevalence comparisons, and multivariate linear regression to verify association of anemia and anthropometric, demographic and geographic variables (p < 0.05).

## Result

The prevalence of anemia was 53,6%, 66,3% and 65,8%, and mean hemoglobin values and standard deviations were 10,9(1,1), 11,2(1,8) and 11,2(1,3)g/dL, in the three age groups, respectively (p=0,19). Regarding nutritional status (Z-BMI), 80.1% eutrophic, 17.5% overweight or obese, 2.4% underweight, and 33.7% low body height (Z-H/A). Significant association was found between anemia and nutritional status, indicating higher Z-BMI as a protection factor against anemia (OR:0,72; IC:0,57-0,91; p=0,004). Anemia prevalence between river basin and *quilombola* communities were 59.5% and 91.7%, respectively (p=0,002), with higher risk factor for anemia in the latter (OR:7,50; IC:1,72-32,69; p=0,001). There were no differences in anemia prevalence related to sex, age and Z-H/A.

## Conclusion

This study raises evidences of high vulnerability of iron deficiency anemia among children and adolescents who live in amazonic river basin and *quilombola* communities by high prevalence found. The nutritional status protecting gradient effect for anemia found must be analyzed with caution by wide confidence interval as well as higher risk factor of *quilombola* community, possibly by sample selection bias.

## **Recommendation**

The use of portable point-of-care device for anemia diagnosis allows greater agility to healthcare teams to gather reliable data about anemia prevalence that could guide public health authorities to implement monitoring, control and intervention actions. This health technology has the potential effect to improve access to the health system with remarkable impact over anemia diagnosis and monitoring on Brazilian population.

## **Recommendation for future research**

To develop iron deficiency anemia prevalence and monitoring studies in all Brazilian regions with representative samples, mainly in vulnerable populations who live in regions with hard access to the Brazilian Public Health System (SUS).

# Agalsidase-beta therapy for fabry disease: health technology assessment – rapid review

Leonardo Vicente Glazar

leonardoglazar@saude.es.gov.br

Foundation for Economic Research Institute, Oswaldo Cruz German Hospital

## Abstract

Strength of recommendations: A. \*

## Technology

Agalsidase beta (Fabrazyme®).

## Indication

Treatment of patients with Fabry disease.

## Characterization of technology

Agalsidase beta is a high cost drug that contains an enzyme produced by genetic engineering which is administered every 15 days by intravenous infusion to supply the enzyme deficiency in patients affected by Fabry disease. This deficiency results in the accumulation of substances (Gb3), which is the primary cause of the disease.

## Question

Is the enzyme replacement therapy with agalsidase beta, compared to placebo, effective to stabilize renal impairment; decrease the progression to end-stage renal disease; reduce rates of stroke, transient ischemic attack and myocardial infarction; reduce angina attacks; reduce episodes of pain and pain intensity; improve the quality of life and decrease the mortality rate in patients with Fabry disease?

## Search and analysis of scientific evidence

The search in the databases Cochrane Library, Medline (via PubMed), LILACS, SciELO, Trip and CRD returned 119 references. Among them, only three randomized controlled trials met the inclusion criteria. We used a systematic review that included all three studies. The chosen review was assessed for quality and rated as good, but the primary studies show poor methodological quality.

## Summary of the results of the selected studies

The only benefit associated with the agalsidase beta treatment, compared to placebo, was the reduction of the accumulation in the skin, kidneys and heart of substances (Gb3), which are the primary cause of the disease. No clinical benefit was identified in relation to renal, cerebrovascular and heart impairment, quality of life and mortality reduction, which are the most important benefits for the patients.

## Recommendation

Strong recommendation against technology.

\* Systematic review of randomized controlled trials reflecting good intensity recommendation based on the Level of Evidence table of the Oxford Centre for Evidence Based Medicine.

# Rapid economic evaluation review for rare diseases treatments: the case of pegvisomant for acromegaly

Christine Koury; Marcus Tolentino da Silva

christinekoury@gmail.com

Fundação de Ensino e Pesquisas Econômicas, FIPE-SP e Ministério da Saúde do Brasil

## Introduction

Under the standard methods of health technology assessment (HTA) incorporating economic evaluation, orphan drugs do not usually prove to be cost-effective. Adding their high cost, it means that funding and patient access may be limited in the Brazilian Public Health System (SUS). Acromegaly is one example, with an annual incidence of 3-4 cases/million and prevalence rate of 40-90 cases/million. There is a new drug, pegvisomant, which presents relative efficacy at a high cost.

## Objective

Identifying the best pharmacoeconomic evidence of pegvisomant for acromegaly and to review the knowledge transfer in order to support a rapid economic review of rare diseases under the perspective of the SUS.

## Method

In the case of the rare disease acromegaly, a search was conducted on February 10<sup>th</sup>, 2013 using 'cost' OR cost AND effectiveness AND ('pegvisomant' OR Pegvisomant) AND ('acromegaly' OR acromegaly) in Medline (PubMed), EMBASE, Virtual Health Library (BVS), Center for Reviews and Dissemination (CRD), The Cochrane Library.

## Result

Only the study "Clinical effectiveness and cost-effectiveness of pegvisomant for the treatment of acromegaly: a systematic review and economic evaluation" was identified and selected. The study was conducted in the United Kingdom, where health costs are different from the Brazilian structure.

The study's evidence indicates that pegvisomant is not cost-effective for treating patients with resistant acromegaly. In Brazil, the cost of each dose in the public health system is about 25% more expensive than in the UK, and so is the cost of labor.

## Conclusion

The need of economic assessment transferability as a tool to support the management of political decisions, especially regarding high cost technologies and rare diseases, are not set as a priority in the research fostering agenda of the SUS.

## Reference

KOURY, C. D. N.; SILVA, M. T. Rapid economic evaluation review for rare diseases treatments – the case of pegvisomant for acromegaly. **Value in Health**, Philadelphia, v. 16, n. 3, 2013.

# Systematic review and economic evaluation of immunosuppressive drugs in prevention of kidney transplant rejection

Francisco Assis Acurcio (Coordenador), Maria das Graças Braga Ceccato, Eli L. Gurgel Andrade, Mariângela Leal Cherchiglia, Augusto Afonso Guerra Júnior, Luciana Tarbes Mattana Saturnino, Carla Grazielle Duraes, Micheline Rosa Silveira, Anderson Lourenço da Silva, Vânia Eloisa Araújo, Luiz Flávio Couto Giordano, Daniel Emílio da Silva Almeida, Juliana de Oliveira Costa, Livia Lovato Pires de Lemos, Celline Cardoso Almeida, Carlos Augusto Lins Reis

mgbceccato@gmail.com

Universidade Federal de Minas Gerais

## Objective

To perform a systematic review of efficacy/effectiveness and safety and an economic and epidemiological evaluation of maintenance immunosuppressive therapy in renal transplantation.

## Method

The study included the following components: systematic review of efficacy, effectiveness and safety of immunosuppressive drugs used in maintenance therapy: i) azathioprine (AZA), cyclosporine (CsA), mycophenolate mofetil (MMF), tacrolimus (TAC), sirolimus (SIR) and everolimus (EVR), in renal transplant patients aged 18 years and older; ii) historical cohort of renal transplant patients using immunosuppressive drugs provided by the Brazilian Health System (SUS) through the High-Cost Drug Program, between 2000 and 2004, from a database developed applying probabilistic matching technique based on SUS databases and elaboration of pharmacoepidemiological/pharmacoeconomic indicators regarding the use of these drugs; iii) cost-effectiveness analysis, where a Markov model was elaborated using a hypothetical cohort of 20 years. Costs were expressed in US dollar (US\$) and effectiveness was expressed in life-year gained (LYG), from SUS's perspective. Univariate and probabilistic sensitivity analyses were performed.

## Result and conclusion

TAC showed more efficacy than CsA in the prevention of acute rejection at 12 months, but there was no difference in terms of allograft and patient survival between the groups. The use of TAC+MMF resulted in low incidence of acute rejection and improved renal function, when compared with CsA+MMF. At 12 months all studies found a high patient survival rate, with a slight difference when comparing schemes. The historical cohort consisted of 8,307 patients, with the majority being male and aged 38 years and older. Immunosuppressive maintenance consisted of CsA+MMF (19.3%), CsA (17.9%), CsA+AZA (14.5%) and TAC+MMF (10.0%). Patient survival rate was 89.9% at four-year follow-up and it was higher between women. Along the 4 years of follow-up, patients using schemes containing TAC showed higher median spending than those using a scheme with CsA. In terms of cost-effectiveness analysis TAC+AZA+P provided higher LYG (10.18), while CsA+AZA+P was the less costly scheme (US\$56,905.10) and with less ICER (US\$5,738.14/LYG). All schemes were dominated by CsA+AZA+P, except TAC+AZA. However, the ICER between these two schemes (US\$95,977.10/LYG) was over than three times the GDP per capita in Brazil. The univariate sensitivity analysis did not demonstrate any qualitative changes and, according to probabilistic analysis, the CsA+AZA+P scheme showed likelihood more than 90% of being the most cost-effective scheme.

## Recommendation

Renal immunosuppressive therapy must transit from a scheme that is adequate for all to an individualized therapy approach. Continuous adjustments and monitoring of immunosuppressive therapy must be based on rejections episodes and on the incidence of infections, tumors and metabolic effects. Considering the different scenarios of analysis proposed, CsA+AZA+P proved to be the most cost-effective scheme and showed an effectiveness that was expected and higher than others schemes.

## Recommendation for future research

It is necessary to elaborate more accurate and standardized indicators in order to evaluate the immunosuppressive efficacy in renal transplantation. More studies of schemes involving SIR and EVR are recommended. Conduction of meta-analyses to obtain more conclusive results regarding effectiveness and safety is suggested.

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# Adalimumab, etanercept, infliximab and ustekinumab for adults with moderate to severe psoriasis: health technology assessment of multiple technologies (HTA-MT)

Ana Paula Cavalcante de Oliveira; Evelinda Trindade

anapaula\_olive@hotmail.com

Clinics Hospital of the São Paulo University Medical School/São Paulo Health Secretariat

## Objective

To review the scientific evidence of efficacy, effectiveness, safety and to estimate the budget impact of biologics drugs for the treatment of adults with moderate to severe psoriasis, aiming to assist the Ministry of Health Ministry and the Brazilian Public Health System (SUS) managers in the decision making process.

## Method

A search was performed on the Centre for Reviews and Dissemination, Lilacs, Medline, The Cochrane Library, Tripdatabase, SciELO and Sisrebrats databases using a PICO: population – adults with moderate to severe psoriasis; intervention – biologics adalimumab, etanercept, infliximab and ustekinumab; comparison – alternative therapies available on the SUS or if unavailable using placebo; and outcomes – Psoriasis Area and Severity Index (PASI), and Adverse Events (AEs) including neoplasm and severe infection. To evaluate the quality of evidence we used the Cochrane Collaboration (Jadad and colleagues) specific models for systematic reviews and randomized controlled trials.

## Result and conclusion

We identified 30 meta-analyses, seven were excluded due to different focus. Fifteen randomized clinical trials with a good quality score,  $\geq 3$  in the Jadad scale, evaluating the use of biologics compared with placebo, were common until the most recent meta-analyses. Those studies showed no significant trends of more AEs from 0 to 18% to several infections and 0 to 48% more malignancies. The results from international scientific literature, in general, favor the adoption of biological treatments and anti-TNFs as rescue in patients with moderate to severe psoriasis refractory to others systemic treatments, with significant effect from 11 to 21 times more patients achieving an improvement of at least 75% in PASI score comparative to placebo. Based on the first year of treatment of 647 patients in the Sao Paulo State during 2011, an annual cost for each drug treatment was estimated. Such preliminary data already suggested a possible significant budget impact.

The cost-effectiveness for each responder patient showed variability and estimates' confidence intervals overlap, denoting no significant difference between the alternatives, except for the treatment with etanercept that is, on average, 60%, 80% or double more expensive than infliximab, adalimumab and ustekinumab, respectively. Therefore, it remains to be established which specific group most can benefit from which biological treatment and by which treatment interval or intermittence.

## Recommendation

The biological drugs use is recommended to be restricted to specialized services capable to perform a longitudinal assessment and to report to the SUS managers the safety and effectiveness routine monitoring results.

## Recommendation for future research

Long term studies and direct comparisons between biologics and other systemic therapies used to treat moderate to severe psoriasis are needed. Also are necessary longitudinal studies to clarify the prevalence, the transition probabilities among the different states in the diagnostic and therapeutic itineraries required, the effectiveness of biologics drugs in Brazilian patients, as well as the best strategy and structure for this healthcare program.

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# Systematic review and effects of educational intervention in lifestyle habits in schoolchildren to reduce the overweight and obesity based on the Social Cognitive Theory

Maria do Carmo Fontes de Oliveira; Humberto Fontes de Oliveira; Polyana Roberto

mcfonoli@ufv.br

Universidade Federal de Viçosa

In a scenario that reminds us of the need to have parameters for public policy of obesity in childhood, it was conducted a systematic survey of the available evidence on interventions in the area of food, nutrition and physical activity based on Social Cognitive Theory (SCT) to promote the habit healthy life to reduce overweight in schoolchildren. Another objective was to analyze the effects of educational intervention on diet, nutrition and physical activity for students from public and private schools from Viçosa-MG city based on the SCT to promote life health habits to reduce the overweight and obesity.

Relevant published studies on the prevention of obesity were located by searching electronic computerized database (MEDLINE, PubMed, Cochrane Library, Web of Science, PsycINFO and SPORT Discuss in periodicals CAPES). To carry out the intervention developed longitudinal study with convenience sample of 117 students from one public and one private, both of Viçosa-MG. The anthropometric measurements were performed according Jelliffe (1968) and the Ministry of Health (2008). Educational interventions were developed through various activities which were planned based on Social Cognitive Theory (SCT) / Self-efficacy (Bandura, 2008). Before and after the educational interventions, was applied to the students a questionnaire evaluation of the self-efficacy of students with regard to fruit consumption in school.

Of the 127 studies initially selected eight studies met the inclusion criteria for the review. The studies showed that there was significant reduction of overweight and BMI in five of the eight studies, there was a reduction in the time that children spent watching television in three of them, and among these only one identified the decline of the practice of eating in front of the television.

Occurred increase in self-efficacy in relation to the improvement of nutritional status and change in eating habits, seeking a healthier diet and physical activity, self-efficacy has a positive association with BMI in one of these eight studies. Regarding educational intervention performed in the present study it was found that from the students participating (n=117) most of them (n=60, 51.3%) was at eight years old, was male and attended private school. The prevalence of overweight among schoolchildren was high (22%) before the intervention and reduced to 21% after that. The prevalence of overweight in private schools was significantly higher (p=0.001); The effects of the educational intervention of promoting the fruits consumption was evaluated by self-efficacy of the students with respect to the consumption of fruit at school snack.

Analyzing the values found for the mean total score before (15,23) and after intervention (18,02), there was a significant increase (p<0.01) of self-efficacy of students in relation to their ability power to bring fruit from home to school lunch and also the ability to be able to eat fruit in the period of stay in school. It was concluded that the

effects of educational intervention on diet, nutrition and physical activity of students, based on Social Cognitive Theory, provided some improvement in the nutritional status of the same as in the self-efficacy of children with respect to the ability to bring fruit from home and eat them during the period of staying in school. It is suggested expanding the intervention to the age group of preschool aiming to expand the benefits of promoting healthy eating and the pursuit of efforts to incorporate the intervention activities developed in the sphere of public policy for the prevention of childhood obesity.

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# Systematic review of positron emission tomography (PET-Scan) accuracy in recurrent differentiated thyroid cancer

Rosângela Caetano; Aline Navega Biz; Cesar Augusto Orazem Favoreto; Cláudia Regina Garcia Bastos; Laís Fraga de Lima Mendes da Silva; Luciene Schluckebier; Clarisse Pereira Dias Drumond Fortes; Ione Ayala Gualandi de Oliveira; Lenice Gnocchi Reis; Rondineli Mendes da Silva; Vera Lucia Eddais Pepe; José Ueleres Braga

caetano.r@gmail.com

Instituto de Medicina Social/Universidade do Estado do Rio de Janeiro

## Objective

A systematic review and meta-analysis was done to evaluate the diagnostic accuracy of 18F-FDG-PET and PET-CT in detecting recurrence of differentiated thyroid cancer (DTC). The focus was subgroup analysis stratified by I131 whole body scan (WBS) and histological type.

## Method

Studies were identified by a search of in several electronic databases (MEDLINE, EMBASE, LILACS and Cochrane) between 1985 and March 2012. References from articles and reviews were revised to identify additional material. Inclusion criteria was studies with more than ten individuals; published in English, Spanish, French or Portuguese language; in patients had undergone a total or subtotal thyroidectomy for DTC followed by I131 ablation of residual thyroid tissue or radioiodine therapy, suspected of having recurrences or metastases, and who underwent a whole-body FDG-PET or FDG-PET/CT scan; and the reported primary data were sufficient to allow the calculation of both sensitivity and specificity for tumor detection. Two independent reviewers have analyzed the articles and a third resolved disagreements reviews. Methodological quality was assessed by QUADAS scale. Statistical analyses were evaluated using MIDAS package of STATA software to assess accuracy pooled measures, publication bias and heterogeneity. A random-effects model was used to calculate pooled sensitivity and specificity. The summary receiver-operator characteristic (SROC) curve was used to plot the studies. The accuracy was estimated independent of PET equipment and stratified into PET or PET-CT. In terms of histological types of tumor, we analyzed the accuracy of FDG-PET for detecting of papillary thyroid cancer, follicular thyroid cancer, and Hurthle-cell carcinoma.

## Result and Conclusion

Thirty-four studies (1,676 individuals) were included after 2,230 citations revised. PET equipment was in the half of studies. It was considered three analysis level: patient (28 studies); lesion (6); and exam (4). The PET exam was accurate to detect recurrence lesions and the area under the summary ROC curve was 79%. In a subgroup analysis of negative I131 WBS, the area under the ROC curve was 90% superior. The better performance was identified in negative I131 WBS and PET-CT system (Sensitivity 93%, Specificity of 81% and SROC AUC>90%). It was possible to pooled measures in papillary thyroid carcinoma with 86% sensitivity and 78% specificity, using both PET systems. In metastasis level, the pooled results considering negative WBS and both PET systems with the SROC AUC 96%.

## **Recommendation**

Our findings indicate that FDG-PET is especially effective in detecting patients with elevated thyroglobulin levels and normal radioiodine WBS; FDG-PET/CT is a more sensitive method in the follow-up of thyroid cancer recurrence or metastases particularly in those with negative WBS.

## **Recommendation for future research**

Economic evaluations should be done in order to combine information about accuracy and costs and compare different diagnose strategies of recurrence differentiated thyroid cancer.



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