



LACOG

LATIN AMERICAN
COOPERATIVE
ONCOLOGY GROUP

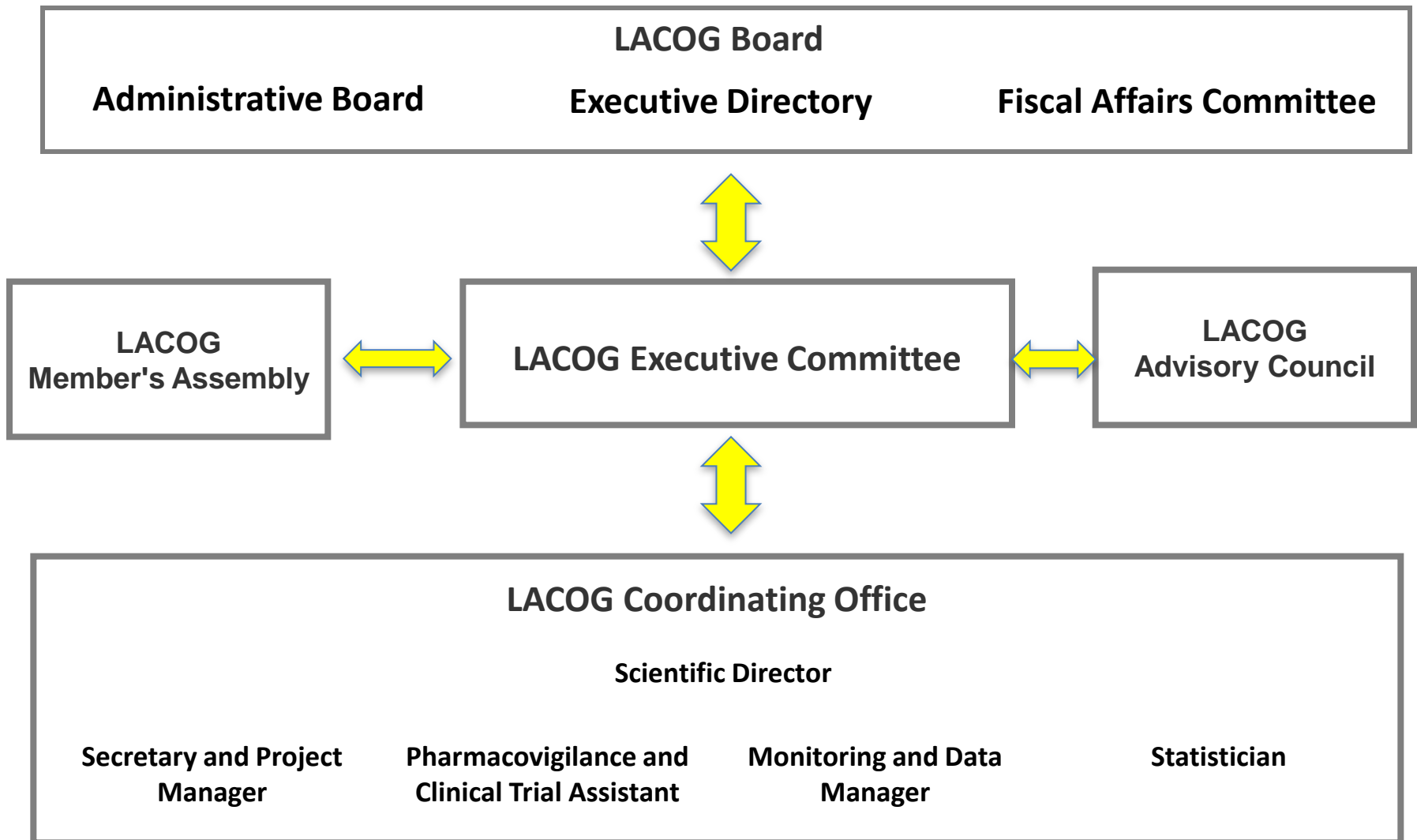
History and Structure



History and Objectives

- Was **founded in 2008** by medical oncologists from several Latin American (LA) countries:
 - ▣ Mexico: Dr. Alejandro Silva
 - ▣ Brazil: Dr. Carlos Henrique Barrios , Dr. Carlos Sampaio Filho
 - ▣ Argentina: Dr. Eduardo Richardet, Dr. Gonzalo Recondo
 - ▣ Ecuador: Dr. Hernan Lupera
 - ▣ Chile: Dr. Jorge Gutierrez
 - ▣ Uruguay: Dr. Mario Varangot
 - ▣ Panama: Dr. Roberto I. Lopez
- Is a **non-profit organization** and legal entity for academic cancer research in LA
- To build a **network** of LA **investigators** in oncology

LACOG Structure



LACOG Executive Committee 2012-15

- Define the group scientific strategy and decision making to collaborations events, etc.
- Advises the General Assembly on new activities to be ratified by the General Assembly.
- The ExCo meets at least twice a year.

Gilberto Lopes	A medical oncologist at Centro Paulista de Oncologia	São Paulo, Brazil
Carlos Barrios	LACOG Executive Director, Professor of Medicine Hospital Sao Lucas PUCRS University	Porto Alegre, Brazil
Gustavo Werutsky	LACOG Scientific Director, Former EORTC Fellow (2008-11), Assistant Professor Hospital Sao Lucas PUCRS	Porto Alegre, Brazil
Fernando Maluf	Head of Medical Oncology Department Hospital São José	São Paulo, Brazil
Carlos Gil Moreira	Coordinator of Clinical Research and Technology Incorporation of INCA (National Cancer Institute of Brazil)	Rio de Janeiro, Brazil
Guillermo Lerzo	Head of Medical Department Hospital Oncologico Marie Curie.	Buenos Aires, Argentina
Henry Gomez	Director of GECOPERU - Peru Cooperative Oncology Group, and Director of INEN (National Cancer Institute Peru).	Lima, Peru
Luis Fein	President GAICO Argentinian Cooperative Oncology Group, Director of Oncology Institute Rosario.	Rosario, Argentina



LACOG Executive Committee 2012-15 Advisory Council

The LACOG Advisory Council integrates the Executive Committee and contributes to the Group strategy and decision making.

▣ Max Mano

Assistant Professor of Medicine,
USP University, Director of Breast
Cancer, ICESP Hospital, São
Paulo, Brazil

▣ Paul Goss

Professor of Medicine, Harvard
Medical School, Co-Director
Breast Cancer Disease Program,
Director, Avon Breast Cancer
Center of Excellence, Boston, US

▣ Diane Finkelstein

Director of Biostatistics,
Massachusetts General Hospital
Biostatistics Center, Boston

▣ Denis Lacombe

Medical Director Headquarter
EORTC, Brussels, Belgium



Structure and Facilities

LACOG Coordinating Office

Study Design



Regulatory process

Statistics



Monitoring/Audits

CRF and
database



Communication

Porto Alegre, Brazil

LACOG Members

LACOG Membership Status

101 members
70 sites
15 countries



INSTITUTO NACIONAL
DE CANCEROLOGÍA



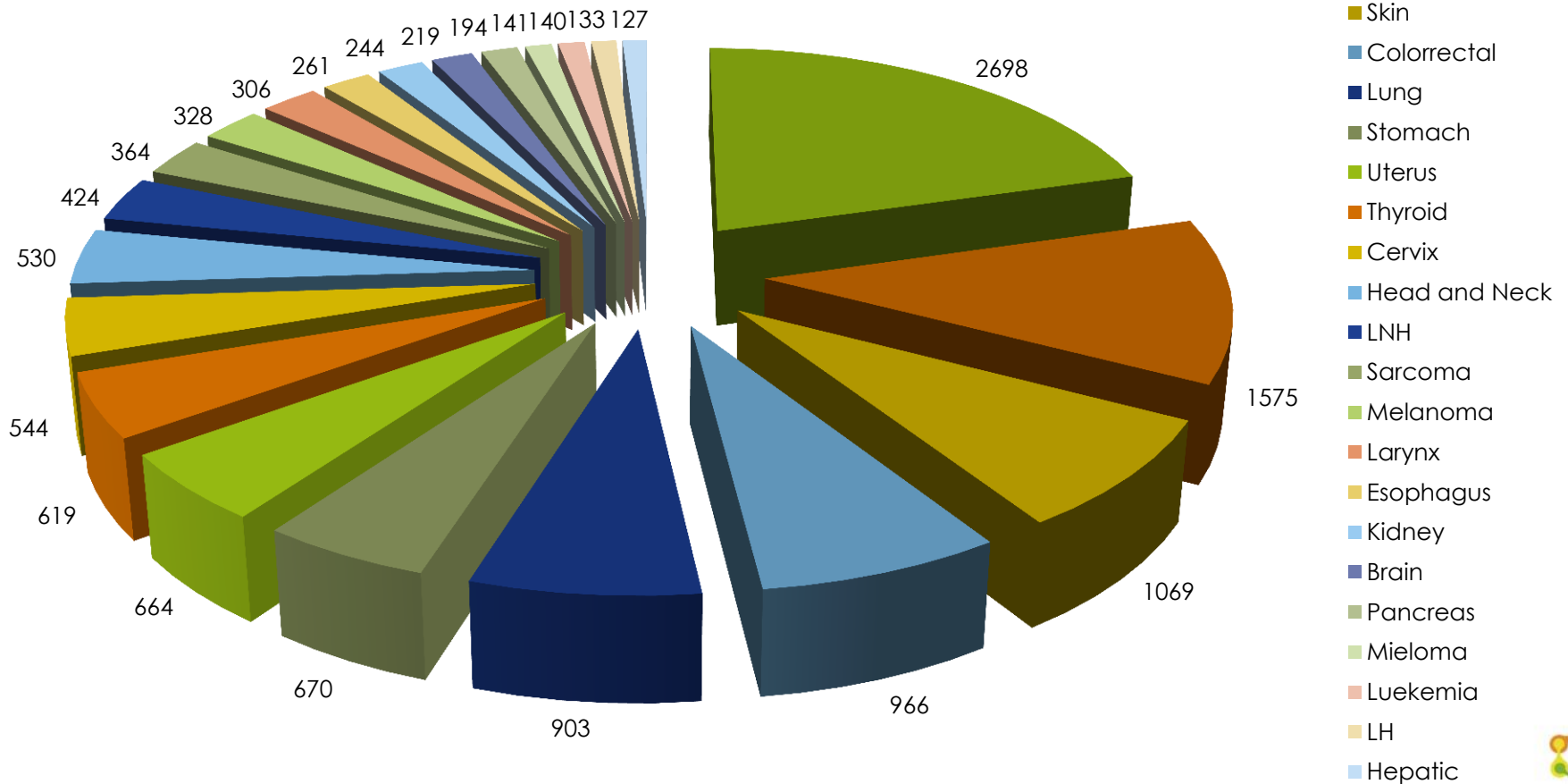
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*N=members

Potential of accrual

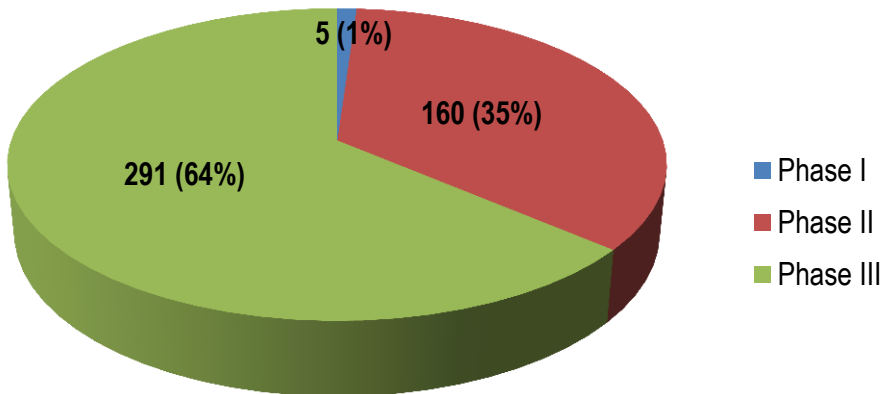
LACOG Members Institutions

Number of new cases *per month* = **13119**

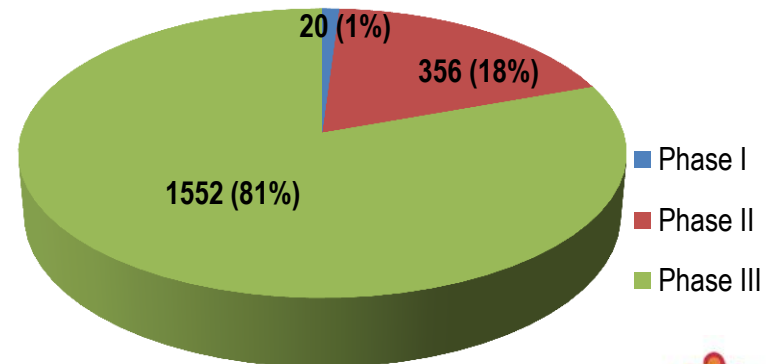


Experience in Clinical Trials

Clinical trials currently open for accrual or follow up
(N=456)



Patients enrolled in clinical trials in the last 12 months. (N=1928)



Quality Control

Investigator Site Audit – LACOG Survey

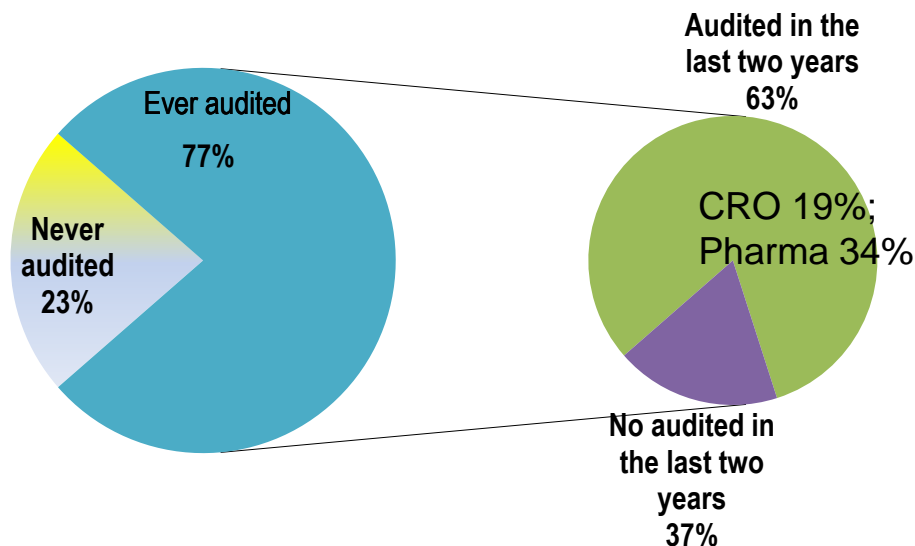
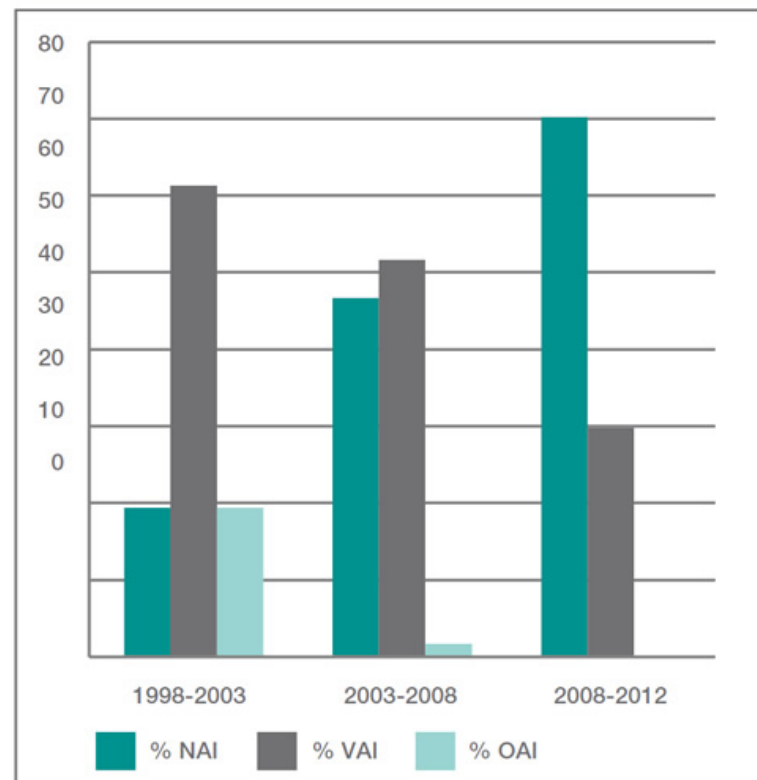


Figure 3. Results of FDA inspections 1998-Mar 2012 in LATAM.²



NAI – No Action Indicated / VAI – Voluntary Action Indicated / OIA – Official Action Indicated

All audited LACOG sites are active.

FDA The number of regulatory inspections from the FDA—as well as from country regulators—has been on the rise in Latin America. There’s been a commensurate increase in the overall quality standards and expectations for studies in the region.

Studies



Study Types

Study Type	LACOG Activities	Legal Sponsor
Investigator Initiated Research	Full management	LACOG
Intergroup Studies	Full/Partial management	Leading Group/LACOG
Pharma Sponsored	Partial management/ LACOG Investigator in the Steering Committee	Pharma

Ongoing Studies

Study Number	Sponsor	LACOG activities	Study Design	Population/Setting	Status
LACOG 0801	LACOG (financial support GSK)	<ul style="list-style-type: none"> Regulatory Monitoring Pharmacovigilance Drug distribution Outsourced: CRF and statistical analysis* 	Phase II, randomized, capecitabine/lapatinib, vinorelbine/lapatinib, gemcitabine/lapatinib	Metastatic breast cancer HER2 + (Argentina, Brazil, Peru)	Finished accrual (N=142) Dec 2012 Main publication under development
LACOG 0213	Celgene	<ul style="list-style-type: none"> Site selection Regulatory assistance Recruitment support LACOG Investigator in the Steering Committee CRO PPD 	Phase III, Double-Blind Randomized, Rituximab + Lenalidomide versus Rituximab + Placebo**	Follicular Lymphoma (Brazil)	Approved by CONEP and ANVISA Sites initiation ongoing
LACOG 0313	LACOG - GBG/BIG (financial support Pfizer)	<ul style="list-style-type: none"> Full management (site selection, regulatory, contracts, monitoring and coordination in Brazil) 	Phase III, Double-Blind Randomized, Palbociclib x Placebo**	Breast cancer, HER2 +, HR + (Brazil)	Regulatory process
LACOG 0114	Inscer (financial Cnpq)	<ul style="list-style-type: none"> Full management 	Phase II, [18F]FDG Inscer/PUCRS	Lung Cancer, stage I-III before surgery (Brazil)	Recruiting
LACOG 0214	Inscer (FINEP)	<ul style="list-style-type: none"> Full management 	Validation of Technetium x Indium to Neuroendocrine tumor staging	NETs staging (Brazil)	Regulatory process

*Since 2013 LACOG has a statistician and uses CRF system (OpenClinica)

**Registration trial

Ongoing studies

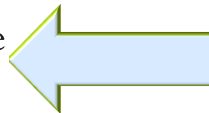
Study Number	Sponsor	LACOG Activities	Study Design	Population/Setting	Status
Epidemiologic/Translational					
LACOG 0413	LACOG (EORTC)	<ul style="list-style-type: none"> • Site selection • Regulatory Brazil + Latin America • Assistance trial coordination 	Prospective	Male Breast Cancer (Brazil, Peru, Mexico, Colombia, Panama)	Regulatory process (Brazil) Recruiting (Peru, Chile and Mexico)
LACOG 0113	LACOG (Novartis)		Retrospective	HR+, HER2- metastatic breast cancer (Brazil)	Protocol development and site selection
LACOG 0111	Massachusetts General Hospital	Full management (site selection, regulatory, contracts, monitoring and coordination in Brazil)	Retrospective, translational, gene signature	Metastatic breast cancer, HR+ (Brazil, and Peru)	Recruiting
LACOG 0211	INCA	<ul style="list-style-type: none"> • Site selection • Regulatory Latin America • Assistance trial coordination 	Epidemiologic, translational, EML4-ALK fusion	Non-small cell lung cancer (Chile, Colombia, Peru, Panama, Mexico, Cuba, Venezuela)	Recruiting (Chile, Mexico and Peru) Regulatory process (Colombia, Cuba and Panama)

Partnerships



Partnerships

Educational



Research Development



*



LACOG is a BIG member since 2013

Partnerships

LACOG – NCCN Prostate Cancer Guidelines 2014



NCCN Clinical Practice Guidelines in Oncology (NCCN Guideline®)

Prostate Cancer

Version 1.2014

NCCN.org

- LACOG Panel of Reviewers will adjust the guideline for Latin America
- Portuguese and Spanish translation
- Release April 2014

Partnerships



EORTC – LACOG Task Force on Cervical Cancer

- EORTC Gynecological and Radiotherapy Groups + LACOG investigators
 - Objectives
 - to qualify LACOG radiotherapy sites by QART
 - to develop phase II-III studies in locally advanced cervical cancer
 - to improve cure rates

**Strategic collaboration with a high recruitment potential
and trial management expertise**



Funding

Funding

IIR ou
Intergroup
studies

Donation

Public/Gov
ernment
Grants

Study Budget Parts:

- 1.Regulatory (cep, conep, anvisa)
- 2.Patient fee + insurance
3. Coordinating Office (development, managing, monitoring, etc.)



Legal Entity - OSCIP



LACOG is recognized by the Ministry of Justice and Health to participate in the PRONON project.

This allows LACOG to receive deductible donations for specific projects and events.

Publications

Publications 2013



Contents lists available at ScienceDirect

Preventive Medicine

journal homepage: www.elsevier.com/locate/ypmed



Inequalities in Pap smear screening for cervical cancer in Brazil

Jeovany Martínez-Mesa ^{a,*}, Gustavo Werutsky ^{a,b}, Raquel Barth Campani ^b,
Fernando César Wehrmeister ^c, Carlos Henrique Barrios ^{a,b}

^a Latin American Cooperative Oncology Group (LACOG), Porto Alegre, Brazil

^b School of Medicine, Hospital São Lucas, Pontifícia Universidade Católica do Rio Grande do Sul (PUCRS), Porto Alegre, Brazil

^c Postgraduate Program in Epidemiology, Universidade Federal de Pelotas (UFPEL), Pelotas, Brazil

ARTICLE INFO

Available online 1 July 2013

Keywords:

Papanicolaou smear
Cancer screening
Health inequities
Epidemiology
Uterine cervical neoplasm
Tumor virus infection

ABSTRACT

Objective. To examine the risk factors associated with never being screened for cervical cancer (CC) in Brazil.

Methods. Using the National Household Sample Survey 2008 (PNAD), we analyzed data from 102,108 Brazilian women ages 25–64 years. The patients were analyzed as having been or never having been screened with a Pap smear (Yes/No). Age-adjusted prevalence of never-screening was analyzed using a Chi-squared test. Crude and adjusted models using Poisson regression were performed.

Results. The prevalence of never-screened women for CC was 12.9%, 11.5% and 22.2% in Brazil in general, urban and rural areas, respectively. The Brazilian region with the highest prevalence of never-screening was the North (17.4%, 14.7% and 27.3% in general, urban and rural areas, respectively). The factors associated with a higher risk for never being screened were the following: poverty, younger age, lower educational level, non-white skin color, a greater number of children, no supplemental health insurance and not having visited a doctor in the past 12 months.

Conclusion. Socioeconomic and demographic conditions lead to inequalities in access to Pap smear screening in Brazil. Public health policy addressing these risk groups is necessary.

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Publications 2013

The Lancet Oncology Commission



Planning cancer control in Latin America and the Caribbean



Paul E Goss, Brittany L Lee, Tanja Badovinac-Crnjevic, Kathrin Strasser-Weippl, Yanin Chavarrí-Guerra, Jessica St Louis, Cynthia Villarreal-Garza, Karla Unger-Saldaña, Mayra Ferreyra, Márcio Debiasi, Pedro E R Liedke, Diego Touya, Gustavo Werutsky, Michaela Higgins, Lei Fan, Claudia Vasconcelos, Eduardo Cazap, Carlos Vallejos, Alejandro Mohar, Felicia Knaul, Hector Arreola, Rekha Batura, Silvana Luciani, Richard Sullivan, Dianne Finkelstein, Sergio Simon, Carlos Barrios, Rebecca Kightlinger, Andres Gelrud, Vladimir Bychkovsky, Gilberto Lopes, Stephen Stefani, Marcelo Blaya, Fabiano Hahn Souza, Franklin Santana Santos, Alberto Kaemmerer, Evandro de Azambuja, Andres Felipe Cardona Zorilla, Raul Murillo, Jose Jeronimo, Vivien Tsu, Andre Carvalho, Carlos Ferreira Gil, Cinthya Sternberg, Alfonso Dueñas-Gonzalez, Dennis Sgroi, Mauricio Cuello, Rodrigo Fresco, Rui Manuel Reis, Guiseppa Masera, Raúl Gabús, Raul Ribeiro, Renata Knust, Gustavo Ismael, Eduardo Rosenblatt, Berta Roth, Luisa Villa, Argelia Lara Solares, Marta Ximena Leon, Isabel Torres-Vigil, Alfredo Covarrubias-Gomez, Andrés Hernández, Mariela Bertolino, Gilberto Schwartzmann, Sergio Santillana, Francisco Esteve, Luis Fein, Max Mano, Henry Gomez, Marc Hurlbert, Alessandra Durstine, Gustavo Azenha

Non-communicable diseases, including cancer, are overtaking infectious disease as the leading health-care threat in middle-income and low-income countries. Latin American and Caribbean countries are struggling to respond to increasing morbidity and death from advanced disease. Health ministries and health-care systems in these countries face many challenges caring for patients with advanced cancer: inadequate funding; inequitable distribution of resources and services; inadequate numbers, training, and distribution of health-care personnel and equipment; lack of adequate care for many populations based on socioeconomic, geographic, ethnic, and other factors; and current systems geared toward the needs of wealthy, urban minorities at a cost to the entire population. This burgeoning cancer problem threatens to cause widespread suffering and economic peril to the countries of Latin America. Prompt and deliberate actions must be taken to avoid this scenario. Increasing efforts towards prevention of cancer and avoidance of advanced, stage IV disease will reduce suffering and mortality and will make overall cancer care more affordable. We hope the findings of our Commission and our recommendations will inspire Latin American stakeholders to redouble their efforts to address this increasing cancer burden and to prevent it from worsening and threatening their societies.

Lancet Oncol 2013; 14: 391–436

See [Comments](#) pages 383–90

Avon International Breast Cancer Research Program, Massachusetts General Hospital, Boston, MA, USA (Prof P E Goss MD, B L Lee MD, T Badovinac-Crnjevic MD, J St Louis BA, M Higgins MD, L Fan MD, D Finkelstein PhD); Harvard Medical School, and Beth Israel Deaconess Medical Center, Boston, MA, USA (B L Lee MD); Center for Oncology and Hematopathology, Dana-Farber Cancer Institute, Boston, MA, USA



Publications 2012

Review

Breast cancer in Brazil: present status and future goals

Brittany L Lee, Pedro E R Liedke, Carlos H Barrios, Sergio D Simon, Dianne M Finkelstein, Paul E Goss

Breast cancer is the most common cancer in women worldwide and 70% of breast cancer deaths occur in women from low-income and middle-income countries. Latin America has about 115 000 new cases of disease every year, with about 50 000 arising in Brazil. We examined the present status of breast cancer in Brazil as an example of the health effects of geographical, ethnic, and socioeconomic diversities on delivery of care. Our goal was to identify deficiencies that could be responsible for disparities in survival from breast cancer. We searched the English and Portuguese published work and reviewed national databases and Brazilian publications. Although the availability of publications specific to Brazil is low in general, we identified several factors that could account for disparities: delays in diagnosis due to low cancer awareness and implementation of mammography screening, unknown quality of surgery, and restricted access to radiotherapy and modern systemic therapies.

Lancet Oncol 2012; 13: e95-102
International Breast Cancer
Research Program,
Massachusetts General
Hospital Cancer Center, and
Harvard Medical School,
Boston, MA, USA (B L Lee MD,
P E R Liedke MD,
Prof D M Finkelstein PhD,
Prof P E Goss MD); Pontificia
Universidade do Rio Grande do
Sul (PUCRS) School of



Abstracts in Conferences



ASCO 2013:

A phase II randomized study of Lapatinib in combination with Capecitabine, Vinorelbine or Gemcitabine as first or second line-therapy in patients with HER2 positive metastatic breast cancer progressing after taxane (LACOG 0801). *Henry Leonidas Gomez, Silvia P. Neciosup, Celia Tosello, et al. (suppl; abstr 851426)*

Inequities in Pap smear screening for cervical cancer between Brazilian urban and rural populations. *Jeovany Martínez-Mesa, Gustavo Werutsky, Carlos Alberto Sampaio-Filho, et al. J Clin Oncol 31, 2013 (suppl; abstr e12510)*

ASCO 2012:

A randomized, open-label, phase II study of lapatinib / capecitabine, lapatinib / vinorelbine, or lapatinib / gemcitabine in patients with ErbB2-amplified metastatic breast cancer progressing after taxane treatment: Results of an interim analysis (GLICO-0801 / EGF111792). *Henry Leonidas Gomez, Silvia P. Neciosup, Celia Tosello, et al. J Clin Oncol 30, 2012 (suppl; abstr e11087)*

ASCO 2010

A randomized open-label, phase II study of lapatinib/capecitabine, lapatinib/vinorelbine, or lapatinib/gemcitabine in patients (pts) with ErbB2-amplified metastatic breast cancer (MBC) progressing after taxane treatment-GLICO-0801. *H. L. Gomez, S. P. Neciosup, Y. Neron do Nascimento, et al. J Clin Oncol 28:15s, 2010 (suppl; abstr TPS120)*



Abstracts in Conferences



Poster:

Breast cancer in the Pan-American region: inequities in incidence and mortality rates according to the human development index.

Poster:

A phase II randomized study of Lapatinib in combination with Capecitabine, Vinorelbine or Gemcitabine as first or second line-therapy in patients with HER2 positive metastatic breast cancer progressing after taxane (LACOG 0801).

Events Organized by LACOG 2013

LACOG Conference & The Lancet

LACOG Conference and The Lancet Commission Press Conference



26 April 2013 Last updated at 01:05 GMT



Latin America 'threatened by rising cancer cases'

Cancer is threatening to overwhelm Latin American countries, experts writing in Lancet Oncology warn.

There are far fewer cases of cancer in the region than in the US or Europe - but the proportion who die is far higher, they say.

Late diagnosis and poor access to treatment are the main reasons for the disparity, they add.

They said as life expectancy increased, cancer would become more common, and many countries would not cope.



Many Latin American communities do not have easy access to healthcare

Related Stories



Best of ASCO Brazil

OFFICIALLY LICENSED
Best of ASCO
Annual Meeting '13

September 13-14, 2013
Tivoli Ecoresort Praia do Forte
Bahia - Brazil

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LACOG Stat Course



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LACOG
STAT COURSE
2013
07 - 09 November, Brazil

SIMULTANEOUS TRANSLATION ENGLISH-PORTUGUESE-ENGLISH

OBJECTIVES

Understand the concepts and statistical methods required in clinical research.

TARGET AUDIENCE

Statisticians, epidemiologists, medical doctors, nurses, pharmacists, and all who have been working with clinical trials in Latin America. The LACOG Stat Course 2013 has 20 hours and is accredited by Universidade Federal de Santa Catarina (UFSC) to provide post-graduation hours of credit.

DATE & LOCATION

07 - 09 November 2013

Hospital São Lucas PUCRS
Anfiteatro Ir. José Otão (Av. Ipiranga, 6690 - 2nd floor)
Porto Alegre, Brazil

AGENDA

DAY 1 Principles of statistics

- Epidemiology in oncology research
- Cancer clinical trials in Brazil and Latin America: an overview
- General introduction to clinical trials statistics and hypothesis tests
- Analysis of time to event endpoints in oncology

DAY 2 Clinical Trials Design and Analysis

- Endpoints and design of Phase III trials
- Sample size for phase III trials
- Common problems in analysis and reporting of studies (Bias, ITT, multiple tests...)
- Data monitoring and early stopping rules in phase III studies
- Design and analysis of phase I trials
- Design and analysis of phase II trials, role of randomization
- Predictive and prognostic factors in clinical trials
- Paper discussion (Clinical trials design/analysis/endpoints)

DAY 3 Biomarkers and Clinical Trials

- Diagnostic tests
- Development and validation of gene signatures: experience in oncology
- Adaptive clinical trial designs
- Integration of biomarkers in phase II/III clinical trial designs
- Use of intermediate and surrogate endpoints in trials
- Non-inferiority trial: design, concepts and issues
- Introduction to Meta-Analysis
- Paper discussion (genes and biomarkers studies designs)

REGISTRATION

WEB SITE

https://www.sympa.com.br/lacog-stat-course-2013_13727

CONTACT

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ORGANIZER

This is a LACOG Activity



Under the auspices of the EORTC



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SUPPORT

Support for this educational activity is provided by:



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Events Organized by LACOG 2014

LACOG Events 2014

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BEST OF ASCO®

2014 ANNUAL MEETING

29 e 30 de Agosto de 2014
Pestana Bahia Hotel
Salvador - Bahia

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STAT COURSE 2014

13-15 NOVEMBER 2014
SÃO PAULO, BRAZIL



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