EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

Paulo Pereira

Work experience

16/10/2017 – CURRENT – Lisbon, Portugal

HEAD OF R&D DEPARTMENT ("GABINETE DE INVESTIGACAO, INOVACAO E DESENVOLVIMENTO") – Portuguese Institute of Blood and Transplantation

a) Promote the development of study and research in transfusion and transplantation medicine;
b) Organize and maintain a documentation, information, and technical-scientific dissemination system of national reference in the areas of transfusion medicine and transplantation, namely through participation in creation networks, dissemination of knowledge, and periodical publications;
c) Propose, organize, and ensure the execution of research, development, and innovation activities in which the institution participates at national, European, and international level.

01/06/2019 – CURRENT – Lisbon, Portugal

POSTDOC RESEARCHER ("INVESTIGADOR AUXILIAR") – Portuguese Institute of Blood and Transplantation

It is up to carry out, on a regular basis, research and development activities and all other scientific and technical activities within the scope of the missions of the respective institutions, as well as:
a) Participate in the design, development, and execution of research and development projects and in related scientific and technical activities;
b) Guide the work carried out within the scope of the projects under its charge;
c) Collaborate in the development of training activities within the scope of research and development methodology;
d) Monitoring the research work carried out by grant holders, research interns, and research assistants and participating in their training;
e) Guide and participate in the institution's training programs.

01/11/2019 – CURRENT – Wayne (PA), United States

TECHNICAL EXPERT – Clinical Laboratory and Standards Institue (CLSI)

Technical Advisor and Reviewer of the CLSI EP12-A3 guide "Evaluation of Qualitative, Binary Output Examination Performance"

Writing Team Member, Technical Advisor, and Reviewer of the CLSI EP21-A3 "Evaluation of Total Analytical Error for Quantitative Medical (DDC on Establishment and Verification of Qualitative Test Performance) Laboratory Measurement Procedures", CLSI EP46-A1 "Determining Total Analytical Error Goals for Quantitative Medical Laboratory Measurement Procedures" (DDC on Total Analytical Error), and CLSI EP24-A3 "Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves" (DDC on ROC Curves).

Advisor on the Expert Panel "ExP on Preexamination Processes"

01/06/2020 – CURRENT – Lisbon, Portugal

QUALITATIVE ANALYSIS WORKING GROUP MEMBER – EURACHEM

Writing Team Member, Technical Advisor, and Reviewer of the Assessment of performance and uncertainty in qualitative chemical analysis (AQA:2021)

01/10/2016 – CURRENT – Madison (WI), United States

CONTRIBUTING EDITOR – Westgard QC

Author of original scientific publications within the scope of laboratory quality control.

01/09/2008 – CURRENT – Lisbon, Portugal

PROFESSOR – School of Health Technologies, Lisbon Polytechnic Institute

Professor of Laboratory Quality Control, Master of Science in Clinical and Laboratory Technologies.

01/04/2012 – 16/10/2017 – Lisbon, Portugal

COORDINATOR OF QUALITY ASSURANCE DEPARTMENT – Portuguese Institute of Blood and Transplantation

Implementation, maintenance, and improvement of the combined quality management system based on ISO 9001 fulfilling technical specifications and other regulations for human blood, cells, tissues, and organs.

01/01/2010 – 31/12/2012 – Lisbon, Portugal

PROFESSOR – NOVA Medical School, Universidade NOVA de Lisboa

Invited professor of the Master in Sciences (M.Sc.) course"Organization and Quality in Laboratory Medicine" (Mestrado em "Organização e Qualidade no Laboratório de Análises Clínicas"). This is a joint MSc from Universidade NOVA de Lisboa and Universidade Atlantica.

01/01/2002 – 31/03/2012 – Lisbon, Portugal

QUALITY MANAGER – Regional Blood Center of Lisbon, Portuguese Institute of Blood

Quality management according to ISO 9001, Portuguese law, and European Directives.

01/06/2006 – 31/05/2019 – Lisbon, Portugal

RESEARCH ASSISTANT ("ASSISTENTE DE INVESTIGACAO") – Regional Blood Center of Lisbon, Portuguese Institute of Blood

The research assistant is responsible for executing, developing, and participating in research and development projects, under the guidance of a researcher or higher education professor.

01/09/2003 – 31/05/2006 – Lisbon, Portugal

RESEARCH INTERN ("ESTAGIARIO DE INVESTIGACAO") – Regional Blood Center of Lisbon, Portuguese Institute of Blood

The researcher intern is responsible for carrying out, under the guidance of a higher education researcher or professor, tasks corresponding to an introduction phase to scientific research and development activities integrated into scientific projects.

01/01/1995 – 31/08/2003 – Lisbon, Portugal

MEDICAL TECHNICIAN/VIROLOGY LABORATORY QUALITY MANAGER – Regional Blood Center of Lisbon, Portuguese Institute of Blood

Screening testing and implementation of good laboratory practices in the virology laboratory of the Regional Blood Center of Lisbon. The practices complied with the ISO/IEC 17025 standard and applicable CLSI guidelines.

Education and training

01/01/2015 – 31/12/2016 – Palma de Cima, Lisbon, Portugal

DOCTOR OF PHILOSOPHY (PH.D.), BIOTECHNOLOGY, SPECIALIZATION MICROBIOLOGY – Catholic University of Portugal

https://www.ucp.pt/?set_language=en

01/01/2000 – 31/12/2005 – Palma de Cima, Lisbon, Portugal

MASTER OF SCIENCE (M.SC.), HEALTH ENGINEERING – Faculty of Engineering, Catholic University of Portugal

01/01/1997 – 31/12/1999 – Campo Grande 376, Lisbon, Portugal

DESE/LICENCIATURA, METHODOLOGIES OF EDUCATION IN SCIENCES – School of Education Almeida Garrett, Lusófona University

https://www.ulusofona.pt/

01/01/1991 – 31/12/1994 – Av. Dom João II Lote 4.69 01, Lisbon, Portugal

BACHELOR OF SCIENCE (B.SC.), CLINICAL ANALYSIS AND PUBLIC HEALTH – School of Health Technologies, Lisbon Polytechnic Institute

SKILLS

- Biostatistics
- *In vitro* diagnostic medical devices
- Project management
- Process manager, including process and suppliers validation
- Quality assurance and quality control
- Performance assessment (method validation, internal quality control, external quality assessment, limits of detection, including cutoff and reference intervals)
- Metrology
- Measurement uncertainty
- Software validation

LANGUAGE SKILLS

Mother tongue(s): PORTUGUESE

UNDERSTANDING		SPEAKING		WRITING
Listening	Reading	Spoken production	Spoken interaction	
ENGLISH C1	C2	C1	C1	C2

Levels: A1 and A2: Basic user; B1 and B2: Independent user; C1 and C2: Proficient user

Additional information

Publications

Quality Control of Qualitative Tests for Medical Laboratories (BOOK AUTHOR)

ISBN 978-9892098579

https://www.medlabquality.com/product-page/quality-control-of-qualitative-tests-for-medical-laboratories – 2019

Why publish a book called "Quality Control of qualitative tests for medical laboratories"? • Address the need for a book dedicated to quality control of qualitative tests • The is a book written primarily for the laboratorian and aims to substantiate the selection of the best statistical tools considering the intended use of the qualitative tests' results (fitness for purpose) •

The purpose of the book is to answer most of the qualitative tests QC questions in a three-pronged vision: the statistical, the clinical, and the regulatory vision.

The book seeks to answer questions important to laboratory practice such as:—What is required, and what is not, in the ISO standards?—Which are the most significant sources of uncertainty?—What is the similarity and difference between "Uncertainty Approach," and "Error Approach"?—Which models do we use to compute both methodologies?—And which models to determine conditional accuracy, delta values, and seronegative window period?—Which are the best models to compute the agreement of binary results?—How do we identify "the best" cutoff point?—How do we control the performance of the qualitative results in our daily routine? • More than 20 examples based on real-world data are presented • The book includes several cases of immunoassays and NAT for screening in virology, ABO blood test, HLA typing, and karyotype tests • The statistical quality control tools applied to the examples are generic; they can be used in most of the qualitative tests •

Approx. 200 pages.

https://39678c7e-fb21-4ee3-bc02-33bba0e15d89.filesusr.com/ugd/97202f_6a4ae0ee944145ef9a6901dd995ea4db.pdf? index=true

Quality Management and Quality Control - New Trends and Developments (BOOK EDITOR)

ISBN 978-1-78923-877-8

https://www.intechopen.com/books/quality-management-and-quality-control-new-trends-and-developments – 2019

Quality management (QM) practices are the basis for the successful implementation and maintenance of any QM system.

Quality control (QC) is identified as a QM component. Therefore, QM effectiveness is dependent on the QC strategy. QC practice is more or less complex depending on the type of production. The book is focused on new trends and developments in QM and QC in several types of industries from a worldwide perspective. Its content has been organized into two sections and seven chapters written by well-recognized researchers worldwide. Several approaches are debated based on sample traceability, analytical method validation, required parameters, class of exponential regression-type estimators of the population means, determination of impurities, viewpoints, and case studies.

Uncertainty of Measurement in Medical Laboratories (BOOK CHAPTER AUTHOR)

ISBN 978-953-51-2477-1 (in New Trends and Developments in Metrology book)

https://www.intechopen.com/books/new-trends-and-developments-in-metrology/uncertainty-of-measurement-in-medicallaboratories

– 2016

The "Guide to the Expression of Uncertainty in Measurement" (GUM) is not systematically used in medical laboratories, for what the laboratorian should understand the Uncertainty Approach and its importance to recognize the level of realism of results. This chapter presents, discusses, and recommends the models fulfilling GUM principles. An example is given to a single test for an easier understanding of the determination of measurement uncertainty. All the practice uses freeware.

Results with larger measurement uncertainty intervals have a significant probability of being unrealistic, arising a high risk of the uncorrected clinical decision. A flow chart for the selection of models for the determination of measurement uncertainty in a medical laboratory is recommended.

Evaluation of Rapid Diagnostic Test Performance (BOOK CHAPTER AUTHOR)

ISBN 978-953-51-2580-8 (in Proof and Concepts in Rapid Diagnostic Tests and Technologies book)

https://www.intechopen.com/books/proof-and-concepts-in-rapid-diagnostic-tests-and-technologies/evaluation-of-rapiddiagnostic-test-performance – 2016

Rapid diagnostic tests are used for the determination of binary qualitative results not only uniquely in nonhospital-based but also in hospital-based tests. Principally, in developing countries, rapid diagnostic tests are the primary option since tests to be used in medical laboratories are discarded due to the higher cost. The test's performance is evaluated to assure that the chance of results being false is clinically acceptable. Therefore, the diagnostic accuracy of results (diagnostic sensitivity and specificity) is assessed to guarantee the safety of post clinical decision. The statistical approach requires that representative samplings of the populations of infected and healthy individuals are tested. The area under the receiver-operating characteristic (ROC) curve is a complementary measurement using the same samplings. It represents the diagnostic accuracy in a single outcome. When samplings with known

diagnostics are unavailable, samplings with known outcomes from a comparative test are used to determine the agreement of results. However, this approach is secondary, due to diagnostic accuracy being unmeasurable. The seronegative period is another critical measurement that allows determining an individual biological bias during a period where the results of an infected individual are false-negatives due to seroconversion. The claimed requirements should be defined for diagnostic accuracy and agreement outcomes. A spreadsheet is used to estimate the results considering the absolute value and the 95% confidence interval.

An Analytical Hierarchy Process to Decision Making in Human Blood, Cells, and Tissue Banks (BOOK CHAPTER AUTHOR)

ISBN 978-953-51-2560-0 (in Applications and Theory of Analytic Hierarchy Process book)

https://www.intechopen.com/books/applications-and-theory-of-analytic-hierarchy-process-decision-making-for-strategicdecisions/an-analytical-hierarchy-process-to-decision-making-in-human-blood-cells-and-tissue-banks – 2016

The decisions are critical in transfusion and transplantation principally because they could affect directly and indirectly the post - transfusion and post - transplantation safety. However, the blood, cells, and tissues banks should not be uniquely centered in the satisfaction of receptor (patient) requirements. All the decisions affecting the sustainability of the organization should also be considered. Despite not to be systematically used in these banks, the analytical hierarchy process could be useful for the improvement in the reliability of the decisions. This chapter reviews the basics of the analytical hierarchy process applied to the production of blood, cells, and tissues, and presents a case study that could be interpreted as applicable to other situations in these organizations.

Assessment of Performance and Uncertainty in Qualitative Chemical Analysis. (ARTICLE AUTHOR)

Chemistry International. 45(1):46-50. https://doi.org/10.1515/ci-2023-0127 – 2023

An online workshop organized in January 2022 was brought together by like-minded people who recognize the importance of the long-awaited Guide. While the Guide is published in an open-access format, proactive dissemination and communication are fundamental to achieving the desired impact, which encompasses continued implementation and application to a wide field such as analytical chemistry, forensics, and laboratory medicine.

Spotlights on the latest opinions on identification, prevention, and management of newer CoV-2 variants: A roundup appraisal on innovative ideas and designer vaccines for Omicron. (ARTICLE AUTHOR)

Transfusion and Apheresis Science. 61(3):103499. https://doi.org/10.1016/j.transci.2022.103499 – 2023

Although mass vaccination combined with some other preventative strategies and lockdown was associated with some early signs that COVID-19 infection might be fading away, the over 35 sites mutated a new South African variant, "Omicron", which emerged almost globally. Certain predisposed hosts may develop severe inflammatory thrombotic or mild long-Covid conditions due to this variant, which depletes T-cells, neutralizes antibodies circulating in the body, and coincidentally induces hypercoagulability.

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Methods to the statistical control of the production of blood components: basic SPC principles and introduction to control charts for variables. (ARTICLE AUTHOR)

Transfusion and Apheresis Science. 56(6):914–919.

https://doi.org/10.1016/j.transci.2018.04.009 – 2018

Statistical process control (SPC) is closely related to good quality control practices in the manufacturing process. One of the primary goals is to detect unnatural patterns, allowing the production service to control the conformity of the blood components produced. Despite being recommended by national and international standards, its exercise is not uniform, and sometimes the methodology used is misinterpreted as SPC. When the input data has a Gaussian distribution, control charts for variables are proposed. However, when the data distribution is not normal, control charts for attributes are suggested. This article presents and discusses four statistical procedures for the control of attributes using p-, np-, u-, and c-charts. An empirical demonstration shows these models are reliable for in routine use in the Blood Establishment quality control, as also suggests the use when the control charts for variables are inapplicable.

Statistical control of the production of blood components by control charts of the attribute to improve quality characteristics and to comply with current specifications. (ARTICLE AUTHOR)

Transfusion and Apheresis Science. 27(2):285-290.

https://doi.org/10.1016/j.transci.2018.04.009 – 2018

Statistical process control (SPC) is closely related to good quality control practices in the manufacturing process. One of the primary goals is to detect unnatural patterns, allowing the production service to control the conformity of the blood components produced. Despite being recommended by national and international standards, its exercise is not uniform, and sometimes the methodology used is misinterpreted as SPC. When the input data has a Gaussian distribution, control charts for variables are proposed. However, when the data distribution is not normal, control charts for attributes are suggested. This article presents and discusses four statistical procedures for the control of attributes using p-, np-, u-, and c-charts. An empirical demonstration shows these models are reliable for in routine use in the Blood Establishment quality control, as also suggests the use when the control charts for variables are inapplicable.

Sampling methods to the statistical control of the production of blood components. (ARTICLE AUTHOR)

Transfusion and Apheresis Science. 56(6):914-919.

https://doi.org/10.1016/j.transci.2017.11.022 – 2017

The control of blood components specifications is a requirement generalized in Europe by the European Commission Directives and in the US by the AABB standards. The use of a statistical process control methodology is recommended in the related literature, including the EDQM guideline. The control reliability is dependent of the sampling. However, a correct sampling methodology seems not to be systematically applied. Commonly, the sampling is intended to comply uniquely with the 1% specification to the produced blood components. Nevertheless, on a purely statistical viewpoint, this model could be argued not to be related to a consistent sampling technique. This could be a severe limitation to detect abnormal patterns and to assure that the production has a non-significant probability of producing nonconforming components. This article discusses what is happening in blood establishments. Three statistical methodologies are proposed: simple random sampling, sampling based on the proportion of a finite population, and sampling based on the inspection level. The empirical results demonstrate that these models are practicable in blood establishments contributing to the robustness of sampling and

related statistical process control decisions for the purpose they are suggested for.

Measurement uncertainty as a tool for evaluating the “grey-zone” to reduce the false negatives in immunochemical screening of blood donors for infectious diseases. (ARTICLE

AUTHOR)

Accreditation and Quality Assurance, 21(1):25-32.

https://doi.org/10.1007/s00769-015-1180-x – 2015

The risk of misclassifying infected individuals as healthy constitutes a crucial challenge when screening blood donors by means of immunoassays. This risk is especially challenging when the numerical results are close to the clinical decision level, i.e. in the ‘grey zone’. The concept of using measurement uncertainty for evaluating the ‘grey zone’ has previously not been systematically applied in this context. This article explains methods, models and empirical (top-down) approaches for the calculation of measurement uncertainty using results from a blood bank according to the internationally accepted GUM principles, focusing on uncertainty sources in the analytical phase. Of the different approaches available, the intralaboratory empirical approaches are emphasised since modelling (bottom-up) approaches are impracticable due to the lack of reliable model equations for immunoassays. Different methods are applied to estimate the measurement uncertainty for the Abbott Prism® HCV immunoassay. The expanded uncertainty obtained at the clinical decision level from the intralaboratory empirical approach was 36 %. The estimated uncertainty was used to set acceptance and rejection zones following the procedure set in the Eurachem guideline, emphasising the need to minimise the occurrence of false negatives.

Evaluation of the measurement uncertainty in screening immunoassays in blood establishments: Computation of diagnostic accuracy models. (ARTICLE AUTHOR)

Transfusion and Apheresis Science, 52(1):35-41.

https://doi.org/10.1016/j.transci.2014.12.017 – 2015

The European Union regulation for blood establishments does not require the evaluation of measurement uncertainty in virology screening tests, which is required by ISO 15189 guideline following GUM principles. GUM modular approaches have been discussed by medical laboratory researchers but no consensus has been achieved regarding practical application.

Meanwhile, the application of empirical approaches fulfilling GUM principles has gained support. Blood establishments' screening tests accredited by ISO 15189 need to select an appropriate model even GUM models are intended uniquely for quantitative examination procedures. Alternative (to GUM) models focused on probability have been proposed in medical laboratories' diagnostic tests. This article reviews, discusses and proposes models for diagnostic accuracy in blood establishments' screening tests. The output of these models is an alternative to VIM's measurement uncertainty concept.

Example applications are provided for an anti-HCV test where calculations were performed using a commercial spreadsheet.

The results show that these models satisfy ISO 15189 principles and that the estimation of clinical sensitivity, clinical specificity, binary results agreement and area under the ROC curve are alternatives to the measurement uncertainty concept.

Projects

Memberships

01/11/2019 – CURRENT

Clinical Laboratory Standards Institute (CLSI)

Annapolis Junction (MD), USA

CLSI and our volunteer members actively identify and develop new guidance on standards that raise laboratory testing quality, safety, and efficiency. We are setting the bar for how that guidance is delivered. CLSI and our volunteer members actively identify and develop new guidance on standards that raise laboratory testing quality, safety, and efficiency. We are setting the bar for how that guidance is delivered.

01/01/2019 – CURRENT

The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Academy

Milan, Italy

The EFLM Academy is a package of professional benefits for Specialists in Laboratory Medicine.

The aims of EFLM Academy are:

To provide a web domain comprising an information and communication platform;

To support education, training and continuous professional development of laboratory medicine practitioners;

To raise the profile of EFLM.

01/01/2019 – CURRENT

Sociedade Portuguesa de Medicina Laboratorial (SPML)

Porto, Portugal

The Portuguese Society of Laboratory Medicine is a scientific institution, born from the need for representation of Portuguese professionals in international institutions, with a view to promoting a high level of training and the indispensable requirement for quality professional performance. Indeed, this was the understanding of the Order of Pharmacists and the Order of Doctors, institutions that sponsored the birth of this Society. The Portuguese Society of Clinical Chemistry is the National Society member of IFCC (International Federation of Clinical Chemistry and Laboratory Medicine), EFCC (European Federation of Clinical Chemistry and Laboratory Medicine) and EC4 (European Communities Confederation of Clinical Chemistry and Laboratory Medicine).

01/01/2019 – CURRENT

RELACRE - Association of Accredited Laboratories of Portugal

Lisbon, Portugal

RELACRE's mission is to support and promote the Portuguese community of accredited conformity assessment entities, contributing to its recognition in society and to the development and credibility of its activity. RELACRE is the National Society member of the EFND (European Federation for Non-Destructive Testing), EURACHEM, EUROLAB, ICNDT (International Committee for Non-Destructive Testing), IMEKO (International Measurement Confederation), and UILI (International Union of Independent Laboratories).

Other Relevant Information