

# Quality of Life

QUARTERLY

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## PRESIDENT'S MESSAGE

*Jose M. Valderas, MD, MPH, PhD, University of Exeter*



Dear Colleagues,  
I hope your new year is off to a good start. For ISOQOL, the first few months have

once again been very busy. Because of our many volunteers, ISOQOL is continually able to offer its members new opportunities for professional growth and continued education. Here are just a few volunteer-driven accomplishments ISOQOL began the year with:

### HOT TOPICS WEBINAR SERIES

February saw the conclusion to ISOQOL's highly successful webinar series: Debating 'Hot Topics' in HRQOL Research. Most ISOQOL webinars average around 30 registrants. Each of the three webinars had a record number of registrants, with the last one having a total of 80 registrants!

Thanks to all the presenters for preparing and the delivering the

Webinars and special thanks to Rick Sawatzky and Tom Willgoss for organizing this Webinar Series.

If you have any suggestions for future webinars, please fill out the Webinar Planning Form and send it to [info@isoqol.org](mailto:info@isoqol.org).

### ANNUAL CONFERENCE PLANNING

This year is the 25<sup>th</sup> Anniversary for the Annual Conference, and the program planning is already shaping up to be what we hope is one of the best Annual Conference programs ISOQOL has ever seen. We received an outstanding number of high-quality workshop and symposium proposals last month which are currently undergoing peer review.

Special thanks to Co-Chairs Joanne Greenhalgh and Diana Rofail, as well as to all the 38 Symposium review volunteers, 35 Workshop review volunteers, and the 140 General Abstract review volunteers.

*Continued on page 2.*

VOLUME 24 ISSUE 1

*Newsletter for  
ISOQOL Members*

MARCH 2018





**The ISOQOL Newsletter is published four times a year by the International Society for Quality of Life Research.**

*Newsletter Editor*

**Ana Popielnicki, BA, USA**

Send articles with subject line addressed "Newsletter Submission" to:  
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*President's Message, Continued from page 1.*

#### **NEW EDUCATION COURSE**

The Industry Education Course Task Force is working to finalize plans for a brand new education course, tentatively titled: Introduction to Patient-Centered Outcomes Research (PCOR) for the Pharma/Biotech Industry. The pilot for this course takes place immediately following the Measuring What Matters Symposium, and registration for both events is now open.

Special Thanks to Co-Chairs Betsy Tschosik and Josephine Norquist, as well as committee members Ana Maria Rodriguez, William Lenderking, Amy DeLozier, Louise Newton, Helen, Kitchen, Diana Rofail and Somali Burgess.

Without the behind-the-scenes work of countless volunteers, ISOQOL would be unable to serve its many members around the world and ful-

fill its vision. Thank you to our volunteers for their great service.

As for me, I have been representing ISOQOL at the PaRIS taskforce set up by the Organization for Economic Cooperation and Development (OECD) for developing patient reported indicators of health system performance and a World Health Organisation Workshop on Universal Health Coverage and Primary Care in Geneva. These are both great opportunities for ISOQOL to have impact on international health care policy.

Sincerely,

Jose M. Valderas, MD, MPH, PhD,  
ISOQOL President



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CONVERSATION!**

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## FROM THE EDITOR'S DESK

By: Ana Popielnicki, BA



Dear ISOQOL family:

I am pleased to present to you our first issue of 2018. This year marks the 25<sup>th</sup>

Anniversary of the Annual Conference, and our co-chairs Joanne Greenhalgh and Diana Rofail are preparing a fantastic program for us – please read all about this and all other educational initiatives awaiting us this year in our President's Message. Speaking of our President, you do not want to miss our informative interview with Dr. Valderas – check out a few little-known facts about Chema in this issue!

Please also find details on the upcoming “*Measuring What Matters*” symposium, to be conducted in July in Washington, DC., as well as a comprehensive description of the “*Introduction to Patient-Centered Outcomes Research (PCOR) for the Pharmaceutical Industry: Using PCOR to Inform Decision Making for Regulators, Payers, Prescribers and Patients (IPCOR-Pharma Course)*” – brought to us by the IPCOR-Pharma Task Force.

For those of you who have been hesitant about getting involved in the Mentor-Mentee initiative, please find Dr. Carolyn Schwartz's piece on her experiences in her article “Unexpected Benefits”. There is a treasure of additional information in this issue; on the Annual Conference,

new publications, and you'll get a chance to meet the formidable force behind the scenes for all our Society activities: Our Executive Office Staff!! Without whom I guarantee you nothing would get done and you wouldn't even be reading this – thanks ladies!

As usual, please send any questions, comments, or submissions for our next issue to [info@isoqol.org](mailto:info@isoqol.org) with “Newsletter” as your subject line. Happy reading!

Ana Popielnicki  
Editor



Ana Popielnicki  
Editor



## WELCOME TO OUR NEWEST ISOQOL MEMBERS

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Mia Bergenmar

Denise P. Bury

Ellis Chow

Sarah Dobrozsi, MD, MS

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Nan Rothrock, PhD

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Hayley L. Simpson-Finch

Daniel Van Leeuwen, Opa RN MPH

Pitu Wulandari, DDS

Vladimir Zah, DPhil





## MEASURING WHAT MATTERS SYMPOSIUM

How should we be measuring functioning as a marker of clinical benefit in clinical trials?

23-24 July 2018 • Washington, D.C., USA



## MEASURING WHAT MATTERS – HOW SHOULD WE BE MENTIONING FUNCTIONING AS A MARKER OF CLINICAL BENEFIT IN CLINICAL TRIALS?

By Ana Popielnicki, Editor

In keeping with our educational initiatives around meaningful measurement, we are pleased to announce our second symposium on Measuring What Matters, to be held in Washington, DC on July 23-24, 2018. Many thanks to the co-chairs for this event, Tom Willgoss, Jennifer Petersen, and Andrew Mulberg, who have put together a wonderful program and a stellar cast of presenters! Special thanks go to the symposium sponsors, the **American Cancer Society** and **Vector Psychometric Group**, for their generous support.

Function is a multidimensional concept that is emerging as an important aspect of clinical benefit assessment across therapy areas, as well as a concept that matters greatly for patients (and families), regulators, HTA groups, clinicians and payers when making medical decisions.

The aims of the symposium are to discuss definitions and concepts of functioning, to identify fit-for-purpose approaches to measurement (including novel technologies) and to identify evidence needs for different stakeholders, including regulators, payers, clinicians and patients. By organizing a range of stakeholders together, we hope to inspire collaboration across fields, and further strategies to generate meaningful data on patients' functioning in clinical trials.

The Program Goals are:

1. To develop a greater understanding of measurement concepts related to functioning, and how these may vary by therapeutic focus.
2. To identify fit-for-purpose approaches to measuring functioning in clinical trial and real-world settings.

3. To understand evidence needs from different stakeholders including regulators, payers, clinicians and patients.

The 2-day symposium will be distributed into a series of sessions and workshops, ranging from conceptualization of functioning, measurement in clinical trials, key stakeholders, and data collection using cutting-edge technology. Both days also feature an Interactive Coffee Break with companies from the mobile device industry.

Don't miss this wonderful educational opportunity!

For more information about the program, logistics, and speakers (plus to register!), please visit the Measuring What Matters webpage at <http://www.isoqol.org/measuring-what-matters-symposium> or email [info@isoqol.org](mailto:info@isoqol.org).







## NEW BENEFITS INCLUDED IN ANNUAL CONFERENCE REGISTRATION RATES

Starting in 2018, ISOQOL's Annual Conference Registration rates will include membership fees and three buffet lunches.

### REGISTRATION BENEFITS OVERVIEW

- Access to all scientific content from Thursday through Saturday - including all plenary sessions, oral and poster sessions, and symposia
- Access to the exhibit area and the Welcome Reception
- Two coffee breaks daily, Thursday, Friday and Saturday
- **NEW!** Buffet lunch daily on Thursday, Friday and Saturday
- **NEW!** ISOQOL member registration includes 2019 membership fees with continued access to full member benefits
- **NEW!** Nonmember registration includes prorated 2018 membership fees and 2019 membership fees with access to full member benefits

### REGISTRATION RATES

Current members will pay the same amount in 2018 as they did in 2017 for their registration and membership. Non-members will pay less in 2018 than 2017.

	ADVANCED (through 10 September)	ONSITE (after 10 September)
ISOQOL Member	\$880	\$955
Student Member	\$397	\$472
Retired Member	\$397	\$472
Special Member*	\$382	\$457
Regular Patient Research Partner	\$490	\$565
Affiliate Patient Research Partner	\$397	\$472
Non-Member	\$955	\$1,030
Student Non-Member	\$428	\$503
Retired Non-Member	\$428	\$503
Special Non-Member*	\$405	\$480
Regular Patient Research Partner Non-Member	\$565	\$640
Affiliate Patient Research Partner Non-Member	\$428	\$503

*\*The Special Member and Nonmember Registration Rate is for current ISOQOL Members with an annual income of less than \$15,000 USD and/or members from developing countries. For a list of developing countries, visit [www.isi-web.org/index.php/resources/developing-countries](http://www.isi-web.org/index.php/resources/developing-countries).*

## AN INTERVIEW WITH OUR PRESIDENT, DR. JOSÉ M. (CHEMA) VALDERAS

By: Ana Popielnicki, Editor

I have known Dr. Valderas since I joined ISOQOL almost a decade ago. Correction: I have known *OF* Dr. Valderas ☺ He's always been there, like one of those scientists whose name one sees in the byline of numerous publications, and I've always been a little in awe of him – that is, un-til this past Annual Conference in Philadelphia, when I had the privi-lege of interacting with him at the SIG Counsel Meeting. It was then that I realized he's the most approach-able, warm, and friendly person, which is confirmed by his kindness in answering all my silly questions!

Chema has been involved in our Society for many years now. He has served as member of the Board of Directors, Associate Editor of our Quality of Life Research journal, member of the Scientific Committee for two Annual Conferences, and co-organizer of two ISOQOL-endorsed PROMs meetings in the UK. Dr. Valderas has presented his research (and chaired) in countless poster and oral sessions, as well as symposia



and workshops. He has contributed to ISOQOL's educational initiatives as part of the Education Committee, conducting workshops and webinars. Chema also led the Task Force for the development of the IPRO course, participating in its delivery as part of the team.

Although he's currently residing in the UK, Dr. Valderas will always be a Spaniard through and through. Proof that he keeps his mother land close at heart is his love for gazpacho, a flavorful cold soup from Spain which is his favorite food. He also enjoys watching the Spanish national basketball team – a sport he actually plays whenever his numerous duties allow.

Chema has little free time, but when he does find some extra hours in the day, he loves to spend quality time with his family and share activities with them. If there is any time left, he has always enjoyed reading plays, with playwright Tom Stoppard being one of his favorites. And in case you were wondering, a very important fact about Dr. Valderas: His favorite color is navy blue. I know you were dying to know ☺

I hope you enjoyed getting to learn a bit more about Chema – I know I did!

### ISOQOL PUBLICATIONS: NEW ADDITION

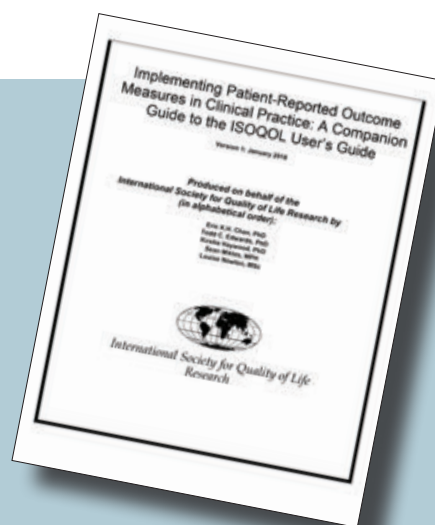
Implementing Patient-Reported Outcome Measures in Clinical Practice: A Companion Guide to the ISOQOL User's Guide

#### ***Special thanks to:***

Eric K.H. Chan, PhD  
Todd C. Edwards, PhD  
Kirstie Haywood, PhD  
Sean Mikles, MPH  
Louise Newton, MSc

Download your free copy at

<http://www.isoqol.org/research-publications-landing-page/isoqol-publications>



# INTRODUCTION TO PATIENT-CENTERED OUTCOMES RESEARCH (PCOR) FOR THE PHARMACEUTICAL INDUSTRY: USING PCOR TO INFORM DECISION MAKING FOR REGULATORS, PAYERS, PRESCRIBERS AND PATIENTS (IPCOR-PHARMA COURSE)

By: IPCOR-Pharma Task Force

## WHAT IS THE IPCOR-PHARMA COURSE?

Patient-centered outcomes research (PCOR) is crucial to successful product development in the pharmaceutical/biotechnology industry. Understanding the product development process, the product lifecycle, interactions with key industry stakeholders both internal and external, such as regulators and payers, and the scientific communication process is necessary for a PCOR scientist seeking to pursue a career in the industry or working closely with the industry. This one-day, intensive and interactive educational course offers a curriculum that will provide a basic level introduction to the application of PCOR research in the pharmaceutical/biotechnology industry. It will provide attendees with the opportunity to make informed decisions and hit the ground running in their career. Case studies will engage participants and give them a chance to test their new knowledge.

## HOW IS IT BEING DEVELOPED?

Development of the IPCOR-Pharma Course is one of the strategic initiatives of the ISOQOL Board. A Task Force of ISOQOL members with pharmaceutical/biotechnology industry expertise was formed to develop the core curriculum. The Task Force consists of Diana Rofail, Board Liaison; Josephine Norquist, Co-Chair; Betsy Tschosik, Co-Chair; William Lenderking; Somali Misra Burgess; Ana Maria Rodriguez; Louise Newton; Amy DeLozier; and Helen Kitchen. The Task Force is

leading course development with input from select expert advisors.

## WHO SHOULD ATTEND?

Although not an exhaustive list, this training will primarily be of interest to those:

- Interested in pursuing a PCOR career in the pharmaceutical industry
- Who have recently started working in the pharmaceutical industry
- Who are working in other areas of the pharmaceutical industry and want to gain a better understanding of PCOR-related activities
- Who are pursuing a career in an organization that works closely with the pharmaceutical industry (e.g., regulatory authorities, payer / health technology appraisal organizations, consulting companies), or
- In academia who are mentoring students in choosing a career path.

Attendees should have a working knowledge of PCOR, including basic principles of PRO measure development, validation and evaluation of measurement properties. Intro to Patient-Reported Outcomes (IPRO Course) is recommended for those who are seeking foundational background in these areas.

## WHAT ARE THE OBJECTIVES OF THE COURSE?

- Understand the different stages of drug development and the pharma/biotech product life-

cycle and PCOR needs associated with different stages.

- Describe the roles, responsibilities and scientific deliverables of a PCOR scientist in the pharma/biotech industry.
- Develop awareness of different functions in the pharma/biotech industry that are key internal stakeholders in the drug development process and partners for PCOR scientists.
- Define key industry terms, business deliverables and related PCOR responsibilities.
- Understand types of regulatory interactions that may involve PCOR and the preparation process for regulatory interactions, with a focus on FDA and EMA.
- Understand market access considerations for PCOR.
- Understand PCOR scientific communications and the importance of outreach to various audiences including patients and physicians.

## WHAT IS THE CURRENT STATUS OF THE COURSE?

The course is currently in development with plans to pilot the course on Wednesday, 25 July 2018 in Arlington, Virginia. The pilot will be offered at a discounted price, and attendees will be asked to participate in a 45 minute focus group directly following the course to provide feedback to improve the course content. Registration is limited to 25 attendees. For more information, go to: <http://www.isoqol.org/education-events/education-courses/pcor-course>





**REGISTER TODAY**

## **MEASURING WHAT MATTERS SYMPOSIUM**

How should we be measuring functioning as a marker of clinical benefit in clinical trials?

**23-24 July 2018 • Washington, D.C., USA**



<http://www.isoqol.org/measuring-what-matters-symposium/registration>

### **ABOUT THE SYMPOSIUM**

Function is a multidimensional concept that is emerging as an important aspect of clinical benefit assessment across therapy areas, as well as a concept that matters greatly for patients (and families), regulators, HTA groups, clinicians and payers when making medical decisions.

The aims of the symposium are to discuss definitions and concepts of functioning, to identify fit-for-purpose approaches to measurement (including novel technologies) and to identify evidence needs for different stakeholders, including regulators, payers, clinicians and patients. By organizing a range of stakeholders together, we hope to inspire collaboration across fields, and further strategies to generate meaningful data on patients' functioning in clinical trials.

### **SESSIONS AND WORKSHOPS**

#### **What I talk about when I talk about functioning**

Speakers share their definitions of functioning, what it means to them/patients, and why it is important to measure in clinical trials.

#### **Workshop: Conceptualizing Functioning**

The workshop will challenge attendees to think about how they conceptualize functioning and what it means to them in their work.

#### **Incorporating measurement of functioning in clinical trials: common pitfalls and lessons learned**

From the perspective of effectiveness of treatments, along with defining functioning to meet the needs of stakeholders what are the needs around measure development and implementation to support possible approvals? Feedback on development of measures, translation/cross cultural considerations, collection in clinical trials, opportunities for real-world data, and the possible pitfalls with various mechanisms of data capture will also be discussed.

#### **Generating meaningful evidence for key stakeholders**

In some disease areas, assessment of clinical benefit includes function. Speakers discuss the evidence needs for the evaluation, as well as how function outcomes may be used to evaluate the benefit new therapies.

#### **Measuring functioning in the 21st century: state of the science**

Speakers demonstrate the use of technology, collection of PROs and sensors to assess function and care. Meeting attendees will have the opportunity to engage in discussion with the presenters as part of a panel.

#### **Workshop: Looking to the future**

A small group workshop to close the symposium with an overall summary and opportunity to write a white paper to share with the FDA and scientific community.

For more information or to register, visit the Measuring What Matters webpage

<http://www.isoqol.org/measuring-what-matters-symposium>

or email [info@isoqol.org](mailto:info@isoqol.org)



## UNEXPECTED BENEFITS

By Carolyn E. Schwartz, Sc.D.

**"The mentor-mentee program at ISOQOL has been very beneficial event for me!"**

*~ Lene Kongsgaard Nielsen*

Since its inception, I have participated in the Mentor-Mentee Program at the ISOQOL Annual Conference. It seemed like a nice way to give back to an organization that has provided such rich stimulation and support of innovation over the years. Often I would be "matched" with not one but several young (usually) women, perhaps because there were not enough Mentors to go around. We would begin with "How would you like to use our time together..." and the conversations would flow for the brief hour of the Mentor-Mentee Reception. The content varied, sometimes focusing on something tangible like navigating their imminent job search or how to measure response shift in their thesis study. Most often, my Mentees sought advice as to how to maintain work-life balance and whether they would be able to have it all (career *and* family), a question their male colleagues might be unlikely to bifurcate.

This year I became aware of two unexpected benefits of participating in the Mentor-Mentee Program. As the years go by, more and more of my long-time ISOQOL colleagues are not coming to the annual conference anymore. Although ISOQOL's conference attendance has remained stable or increased over the years, the attendance by the founding leaders of the organization has decreased. Perhaps they are sick or are retiring; perhaps they have family commitments or competing demands. Or perhaps their not coming is a political statement in response to the current USA administration's policies, despite ISOQOL's clear [statement of support for international attendees](#)

and dedication to the open flow of scientific information. Although I had been noticing this trend for years, this year felt a bit like a "tipping point". So many people I had looked forward to seeing and hearing updates from were not there, and I missed them.

Their very absence made me aware, however, of a first hidden benefit of being a Mentor. I still sensed that invisible net that binds each and every one of us who makes the annual pilgrimage to ISOQOL, even though my usual circle of ISOQOL friends was missing prominent members. I would see my former Mentees at receptions or breaks, at paper sessions or even the women's bathroom, and we would remember each other. A personal connection had been formed those few or many years ago that lasted for as many years as the Mentee (and I) participated in the ISOQOL conferences.

A second unexpected benefit grew from a Mentee I met last year. Lene Kongsgaard Nielsen is a hematologist studying multiple myeloma, the cancer that afflicted my maternal grandfather and my mother. She is completing her PhD at the Odense University Hospital in Denmark, and is studying the quality of life of people with multiple myeloma. During the Mentor-Mentee reception last year in Copenhagen, we discussed how to measure response shift in her study, and that she should use the new Brief Appraisal Inventory (BAI) that my dear colleague Bruce Rapkin and I had developed quite recently. How was I to know what would come from this?

Immediately after returning from Copenhagen last year, I received a flurry of emails from Lene. She was intent on translating the BAI into Danish for inclusion in her thesis, a longitudinal study of 800 multiple myeloma patients in ten Danish centers. Due to hiccups in the process, we are still honing the translation at ISOQOL one year later. Over lunch on a beautiful sunny day in Philadelphia at ISOQOL 2017 (see photo), Bruce, Lene and I discussed the issues raised in cognitive interviews aimed at ensuring the cultural equivalence of the measure for use in Denmark. We honed the instructions, the examples, and the items. We gained a better understanding of our cultures, and of the uncommon opportunity presented to us in this collaboration. Who could have known that signing up for the Mentor-Mentee reception for yet another year would yield such insights and such fruits?

It is a remarkable program for growing our net of colleagues. This net can sustain us, even when those we hold dear no longer come to the annual meeting. And it can help to nurture continued innovation and



insights in our work, if we are open to enabling collaborations with those we meet through this program. Perhaps after reading this brief testament, you will decide to sign up as a

Mentor or Mentee at ISOQOL 2018. If so, this tribute will have served well.

**Note:** The opinions stated in this editorial are the author's and do not re-

flect the opinions of ISOQOL. Further, any mention of patient-reported outcomes tools does not reflect ISOQOL's promotion of this tool over any other.

## ANNUAL CONFERENCE TRAVEL SCHOLARSHIPS

Applications are now open for the ISOQOL Annual Conference travel scholarships. Travel scholarships provide our members access to the educational content of the annual conference, the opportunity to meet with their peers and to establish research contacts.

For eligibility requirements and full scholarship descriptions, click on the links below.

**Developing Country & Student/New Investigator Scholarship**

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Must be a current ISOQOL member to apply. Renew your membership dues today

### DEADLINES

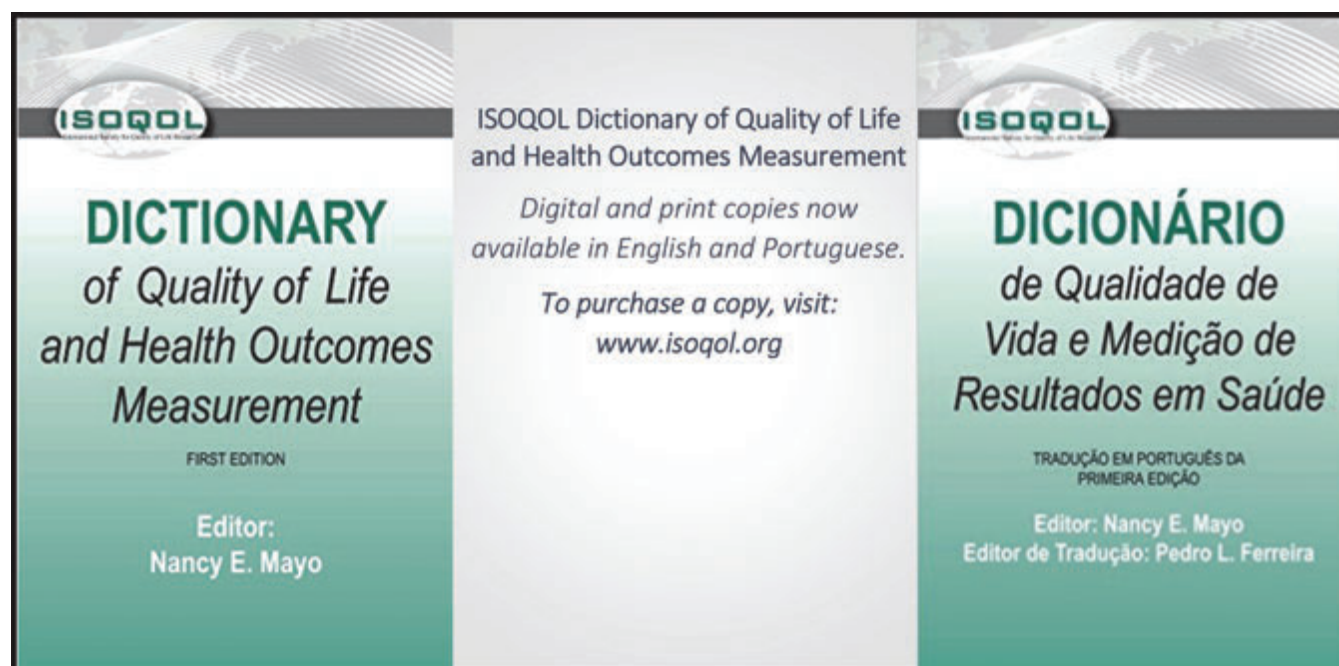
Friday, 25 May at 11:59 pm CDT

Applications Due

Mid-June

Recipients Notified

Contact [info@isoqol.org](mailto:info@isoqol.org) with any questions regarding the Scholarship Program.



ISOQOL announces the inaugural publication of articles in the  
***Journal of Patient-Reported Outcomes***

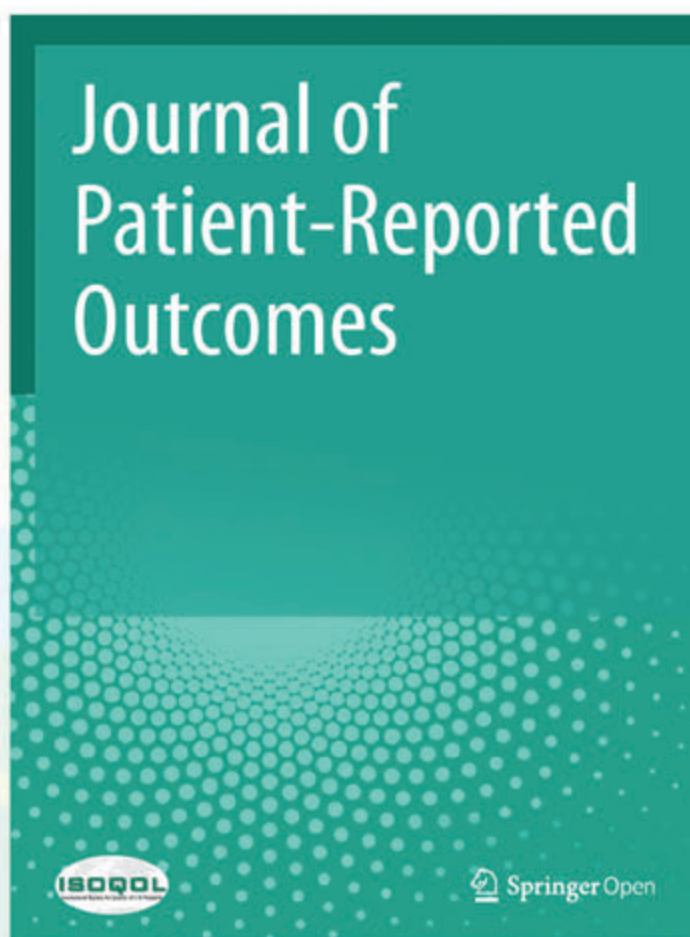
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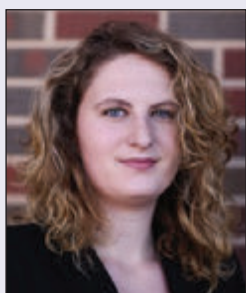
## MEET THE ISOQOL STAFF



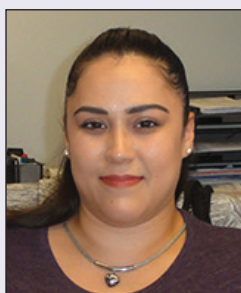
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