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## Quarterly Newsletter

Summer 2015

Welcome to the *Mycoses Study Group Quarterly Newsletter, Summer 2015*. This newsletter is intended to keep our investigators and supporters informed of the developments within the **MSGERC** and to encourage support and involvement in our ongoing activities.

### I. Meetings

#### **MSGERC 2015 Annual Meeting Reception at ICAAC**

The MSGERC will hold its Annual Meeting on Thursday, September 17th 2015 from 5-7 PM at the Marriott Marquis, Marina Ballroom G. Please join us for a brief reception followed by MSGERC clinical research update presentations and discussions.

**Registration will be held via the MSGERC website and by Email.**

#### **MSGERC CME Symposium at ICAAC**

The MSGERC will offer a Live CME symposium entitled, "*Current Controversies in Invasive Fungal Disease Management: Predicting the Future in Medical Mycology*" (Funded, CME). This event will be held on, September 18, 2015 at 7- 10:30 PM at the Marriott Marquis, Marina Ballroom D.

#### **Additional Meetings at ICAAC:**

- MSGERC Education Committee Meeting at ICAAC- Saturday, September 19<sup>th</sup> at 6:45 AM at the Marriott Marquis, Marina Kitchen- "The Porch."
- MSGERC Steering Committee Meeting at ICAAC- Saturday, September 19<sup>th</sup> at 6pm. Osetra Fishhouse Restaurant, Atlantic Room.
- MSGERC Biannual Meeting Planning Committee- TBA.

### II. Clinical Trials Update

#### **MSG-03: Invasive Aspergillosis Combination Study**

PI: Kieren Marr

Corporate Sponsor: Pfizer

This trial was completed on February 22, 2011 with a total of 459 patients enrolled and 454 patients dosed. A poster was presented at ECCMID in London in April 2012.

The manuscript was published earlier this year in *Annals of Internal Medicine* (Marr KA, Schlamm HT, Herbrecht R, Rottinghaus ST, Bow EJ, Cornely OA, Heinz WJ, Jagannatha S, Koh LP, Kontoyiannis DP, Lee DG, Nucci M, Pappas PG, Slavin MA, Queiroz-Telles F, Selleslag D, Walsh TJ, Wingard JR, Maertens J. Combination Antifungal Therapy for Invasive Aspergillosis: A Randomized Trial. *Ann Intern Med*. 2015; 162:81-89)

### **MSG-05: A re-analysis of the voriconazole versus amphotericin B followed by other licensed antifungal therapy for invasive aspergillosis trial (Herbrecht et al. NEJM 2002; 347: 408-15)**

PI: Raoul Herbrecht

Corporate sponsor: Pfizer

The purpose of this project was to reanalyze the existing database from the pivotal study comparing voriconazole to amphotericin B followed by OLAT for primary treatment of invasive aspergillosis. The analysis was presented at ICAAC 2012).

The manuscript from this project was published in *Clinical Infectious Diseases* in 2014 (Herbrecht R, Patterson TF, Slavin MA, Marchetti O, Maertens J, Johnson EM, Schlamm HT, Donnelly JP, Pappas PG. Application of the 2008 Definitions for Invasive Fungal Diseases to the trial comparing voriconazole versus amphotericin B for therapy of invasive aspergillosis: a collaborative study of the Mycoses Study Group (MSG 05) and the EORTC Infectious Diseases Group. *Clin Infect Dis* 2015; 60:713-20)

### **MSG-06: The Phaeohyphomycosis Registry**

PIs: Sanjay Revanker, John Baddley, Sharon Chen

Corporate sponsors: Merck, Gilead, Astellas

Enrollment began on October 31, 2012. To date, 97 cases have been enrolled. The registry will include cases diagnosed between January 1, 2011 and December 31, 2015. Sixteen sites are enrolling cases. Sites are located in South America (1), Australia (2), and North America (13). This project will prospectively identify up to 150 patients from these sites and collect all relevant clinical, diagnostic, mycological and treatment/outcome information relating to this uncommon mycosis. Enrollment will end on December 31, 2015. These data will ultimately be merged with relevant data from the ongoing *Fungiscope* project led by Oliver Cornely in FRG. An important component of this study is that CDC has agreed to serve as specimen repository for the project, providing access to these clinical specimens by all MSG investigators.

### **MSG-07: Cryptococcosis Combined Analyses**

PIs: John Baddley, Sharon Chen, Emilio DeBess, Eleni Galanis, Julie Harris, Nicola Marsden-Haug, John Perfect, Peter Phillips, Peter Pappas

Corporate Sponsor: Merck

This retrospective study will evaluate archived cases of *C neoformans* and *C gattii* from UAB, Duke, Australia, BC Canada, Washington, and Oregon. Over 800 well defined cases have been identified. UAB has obtained signed data use agreements with participating sites and has received data from each site.. Data merger is in progress. Analysis is planned to begin by late summer and to be completed by fall 2015. Manuscript preparation will begin late 2015 with a final manuscript planned for late 2016.

#### **MSG-08: Epidemic Mold Infections in U.S.**

PI: Carol Kauffman, Tom Chiller, Peter Pappas  
Corporate Sponsor: CDC, Gilead, Merck

MSG received funding from Merck, Gilead, and the CDC to support this project based on capturing the detailed, long term clinical and therapeutic features of this outbreak. Data points include diagnostic, clinical, radiologic, treatment and outcomes data, and these data have assisted with defining disease management. MSG's role has included site selection, electronic case report form development, data management and analysis, 7 sites rolled out with enrollment starting in September 2013. Current enrollment includes 459 cases entered in the REDCap electronic database out of the 473 cases identified. Data entry is nearing completion, data analysis and preparation of a manuscript will begin this fall.

#### **MSG-09: Prospective study of cryptococcosis among non-HIV infected patients**

PI: Kieren Marr, MD  
Sponsor: NIAID

This observational, prospective study started enrollment of patients with cryptococcosis who are HIV negative on March 14, 2014. This study captures all relevant epidemiology, clinical and therapeutic data. In addition, immunologic and genetic studies are being performed on each study participant to explore host response to infection and genetic predispositions to disease expression. There are 23 active U.S. sites and current enrollment is 90 subjects.

#### **MSG-10: A Prospective, Multicenter, Open-Label, Randomized, Comparative Study to Estimate the Safety, Tolerability, Pharmacokinetics, and Efficacy of Oral SCY-078 vs. Standard of Care Following Initial Intravenous Echinocandin Therapy in the Treatment of Invasive Candidiasis (Including Candidemia) in Hospitalized Nonneutropenic Adults**

PI: Peter Pappas, MD  
Sponsor: Scynexis

This phase 2 study is an ongoing open-label RCT. The primary focus of the trial is safety and PK; efficacy is a secondary endpoint given the small sample size (150 patients) and the trial design as a step-down strategy for candidemia. There are currently 15 active sites, 6 additional sites starting soon. 3 patients have been entered into the study, 2 have been randomized and received study medication.

### **MSG-11: Cryptococcal Infections in Non-HIV Infected Hosts: A Prospective International Study**

PI: Peter Pappas, MD

Financial Sponsor: Gilead

This study is an international observational study which is similar in design to MSG-09, which was originally proposed as an international study. As an international study, MSG 11 will include sites in Australia, France, Brazil, Canada, Vietnam, Taiwan and possibly other sites in Europe. The goal is to enroll 150 non-HIV infected patients with cryptococcosis over a 24 month period. Gilead has approved the study for funding and enrollment will begin after final contract negotiations are completed.

### **MSG-12: Retrospective review of candidemia outcomes in a large US cohort utilizing the Premier database**

PI: Brian Fisher, MD, Theo Zaoutis, MD, Luis Ostrosky-Zeichner, MD

Sponsor: CHOP

This study was initiated by Drs. Fisher and Zaoutis at CHOP following their purchase of aspects of the Premier database. The purpose of this study is to analyze treatment and outcomes among a large cohort (approximately 2000 patients) across the US with *Candida* BSI. The first analysis is being presented at ICAAC 2015 as an abstract in clinical mycology.

### **Potential MSG study: A Multi-Center, Case Control Study of a Lateral Flow Assay for the Diagnosis of Histoplasmosis (2R42-AI096945-03)**

PI: Peter Pappas, MD, William Powderly, MD

Sponsor: IMMY

The MSGERC and MSG Research Central Unit have joined efforts with IMMY to develop and manage this multi-center, pre-510k case-control study to test their investigational histoplasmosis assay. The plan includes asking up to 12 U.S. sites to participate. Enrollment goal will be 400 separate cases (100 histoplasmosis cases). The 400 cases will be bundled as 1 proven histoplasmosis case, 2 underlying disease matched controls, and 1 control with an invasive fungal infection other than histoplasmosis. Sites will be contacted in the next 3-4 months. This study will be sent to the Steering Committee for final review. Sites with a special interest in histoplasmosis should contact Dr. Pappas to discuss potential involvement in this trial

### **EORTC/MSG Update Treatment Definitions Project**

The EORTC and MSG have partnered again to update the definitions of invasive fungal infections. There are 10 working groups with member-investigators from both the EORTC and MSG are working to update the definitions which were last updated in 2008. Several of the groups have started the process of updating these definitions, and work will continue through 2015. A presentation of the revised guidelines is planned for TIMM in Lisbon, Portugal on October 11, 2015.

### III. Other Activities

#### MSGERC

On 12/15/14 the IRS designated the MSGERC as a non-profit organization (NPO) with a 501c3 status. The MSG's official name is now the **MSG Education and Research Consortium (MSGERC)**. The new MSGERC website, msgerc.org was launched early 2014. A [press release](#) was launched in July, 2014 through the website. The website provides information about MSGERC history, scholarly contributions (historically and currently), research activities, and links to MSGERC continuing medical education (CME) activities. The MSGERC website also links to Dr. Fungus (in the process of being re-engineered) and FungusCME.org.

In keeping with reorganizing the MSGERC and formalizing a non-profit business structure for the organization, the Steering Committee voted in favor of transitions that will occur in early 2016. The MSGERC will formalize its membership structure and request that members formally register membership. Heretofore, the membership directory of the MSG had evolved to a listing of over 200 members, yet a clear definition of which membership commitment has been lacking since NIH contract funding was discontinued for the group in 2005. Additional organizational structuring will also be evolving. Members from academic medical centers and government agencies will be asked to pay membership dues in the amount of \$100 per year to help sustain the central costs of operating the organization as an NPO. Reduced rates will be applied for pharmacists and infectious disease fellows.

**First Bi-Annual Meeting.** In September 2016, our group will hold its first MSGERC Biannual Meeting at a site to be determined. We are considering Tucson, AZ, Monterrey, CA and Big Sky, MT as potential venues for the meeting. Specific details about this meeting will be forthcoming. Since ICAAC will be discontinuing its September meeting after this year, we will schedule this meeting every other year in September beginning in 2016 (2016, 2018, etc.). This will be a two-day meeting with pre-clinical and clinical scientific content and will provide important opportunities for MSGERC members to work closely together in a relatively remote venue to address current gaps and future research for the epidemiology, diagnosis, prevention and treatment of fungal infections.

If you are interested in participating in current and future in MSGERC activities, and wish to have significant input into the direction of the group over the next several years, this meeting will be important to you, so please plan to attend. We will provide more information about this important activity very soon once a venue and specific dates have been selected.

#### Educational Initiatives for 2015

The MSGERC Education Committee worked diligently this year to vision and plan grant submissions as part of a more strategic educational plan, allowing us to expand our educational outreach and impact. We continue to work with Terranova Medica LLC to develop and manage our CME activity grants. This year, we have expanded our relationships with continuing education providers, adding a collaboration with the esteemed Postgraduate Institute of Medicine (PIM) as a pharmacy provider while maintaining our long-term relationship with UNMC CCE for physician accreditation. With

PIM, we also have gained access to PowerPak®, a powerful online distribution platform to reach pharmacists. This is in keeping with our recent inclusion of pharmacy experts in the MSGERC.

#### MSGERC 2015 Live Educational Activities:

- *May 2015 (Melbourne, Australia)* ISHAM entitled “Panel Discussion: Predicting the Future of Medical Mycology” (Non-funded, no CME, G.R Thompson, chair).
- *September 2015 (San Diego, CA)* ICAAC-ICC affiliated live CME symposium entitled, “*Current Controversies in Invasive Fungal Disease Management: Predicting the Future in Medical Mycology*” (Funded, CME, G.R Thompson, chair)
- *October 2015 (San Diego, CA)* ID Week-affiliated live CME symposium entitled, *Optimizing Outcomes in Invasive Fungal Disease: The Interdisciplinary Approach* (Funded, CME, Luis Ostrosky-Zeichner, chair)
- *December 2015 (Orlando, FL)* ASH Symposium and Enduring Activity entitled, “*Invasive Mycoses in Hematologic Malignancies: Disarming the Fungal Saboteur*”. (Funded, CME, Alison Freifeld, chair)

#### Additional Enduring CME Activities:

- ASH enduring activity (to be launched March 2016)
- A combined, web-based enduring materials initiative from both ICAAC/ICC and ID Week CME symposiums (to be launched January 2016)
- ICAAC 2014 Enduring (Launched December 2014)
- Antifungal Toolkit (Update 1 launched April 2015; planned Update 2 launch September 2015)

#### Additional Activities in planning for **2016**:

- Lunch & Learns- onsite webinars
- Case of the Month
- Planning for ECCMID (2016) and TIMM (2017)
- ID Week 2016
- Exploring other venues/audiences: Hospitalists, CHEST, Bone Marrow Transplant Meetings

## **IV. MSG Administration**

### **Administrative Structure**

**MSGERC:**

Peter G. Pappas, MD, Director  
Carolynn Thomas Jones, DNP, MSPH, RN, Consultant Executive Director  
Address: 4317 Corinth Drive Birmingham, AL 35213 USA  
Website: [msgerc.org](http://msgerc.org)

**MSG Central Research Unit, University of Alabama at Birmingham:**

Peter G. Pappas, MD, PI  
Beth Deerman, RN, MSN, Administrator  
Vicki Noles, Administrative Assistant  
Joy Fleisher, Financial Associate  
Dorothy Shaw and Deborah Lowman, Regulatory Specialists

**MSG Steering Committee (SC):**

Peter G. Pappas, Chair (US)		
David Andes (US)	Helen Boucher (US)	Peter Donnelly (NETH)
Raoul Herbrecht (FR)	Carol Kauffman (US)	Dimitrios Kontoyiannis (US)
Bart-Jan Kullberg (NETH)	Kieren Marr (US)	Marcio Nucci (BRA)
Luis Ostrosky-Zeichner (US)	Tom Patterson (US)	John Perfect (US)
Tania Sorrell (AU)	Thomas Walsh (US)	

Non-Voting Advisors: John Bennett, Jack Edwards, Emilio Bouza, Eric Bow, Thierry Calandra, Jack Sobel, and John Wingard

**MSG Education Committee (EC):**

George R. Thompson (Chair) (US)	John Baddley (Co-chair) (US)	
Barbara Alexander (US)	David Andes (US)	John Bennett (US)
Helen Boucher (US)	Oliver Cornely (FRG)	Graeme Forrest (US)
Alison Freifeld (US)	Susan Hadley (US)	Dimitrios Kontoyiannis (US)
Bart-Jan Kullberg (NETH)	Olivier Lortholary (FR)	Marcio Nucci (BRA)
L.Ostrosky-Zeichner (US)	Peter Pappas (US)	Tom Patterson (US)
Monica Slavin (AUS)	Luis Thompson (CHI)	Lisa Tushla (US)