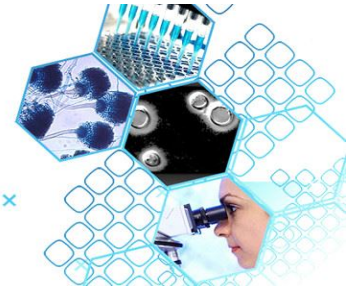
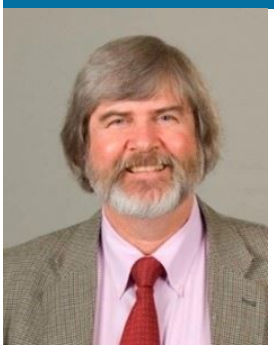
WHAT'S NEW WITH THE MSG...

MSG ERC
Mycoses Study Group
Education & Research Consortium



PRESIDENT'S MESSAGE



The MSGERC continues to expand its reaches for education and in 2019 has provided some support for a histoplasmosis conference in South America and an AIDS conference on Fungal Infections in South Africa. Along with the biannual meeting in Big Sky, MT in October 2018, the MSG-ERC has made substantial commitments to its educational mission. It is clear that there is much need for global education in clinical mycoses and the MSGERC has attempted to be part of the help. At present, we also have a close relationship with ISHAM that should help both groups to identify and strategically provide important but limited resources for regional groups to help grow medical mycology meetings and societies. I am proud of MSGERC's direction in support of global medical mycology. It is so important to the enlarging, worldwide risk populations for these deadly infections to have proper insights into diagnosis and management by the local medical community.

Thanks for your membership and commitment to our mission.

- John Perfect, MD

MEMBERSHIP INFORMATION

We thank you for your membership to the MSGERC. Many of our colleagues have been long-standing MSG members, but may or may not have become formal members of MSGERC. The MSGERC includes clinical, biotechnology and government members. Junior faculty membership is strongly encouraged. Membership dues are $175 for a two-year membership. Current ID fellows may join at $75/year. Go to MSGERC.org to join. You may use a credit card or send a check. Always update your member profile in the website. If you have difficulties, email Barbara Hamschin at headquarters@msgerc.org.

Official member benefits include:

1. *Recognition as a MSGERC member and the historic value of the group.*
2. *Identification as a key opinion leader in your mycology specialization.*
3. *Opportunities to serve as a subcontractor on MSGERC CME or research consultations.*
4. *Recognition as a preferred investigator for mycology clinical research studies.*
5. *Eligibility to vote on important MSGERC matters that are brought forth to membership.*
6. *Eligibility to run for MSGERC Board of Directors and hold a leadership position helping to shape the future strategy, goals and mission of our organization.*
7. *Eligibility to serve as a leader on one of MSGERC's standing committees.*
8. *Website access to* www.DrFungus.org
9. *Online, searchable Membership Directory and self-management of full profile.*
10. *Reduced meeting registration rates for the Biennial Meetings.*
11. *Unparalleled access to a global community network of experts and renowned leaders in the mycology field.*
12. *Opportunities to participate in MSG Studies.*
13. *Opportunities to initiate, create and receive validated Position Papers.*
14. *Newsletter updates and ability to join advocacy groups*

MSG ERC doctor fungus
Your online reference to all things mycological

HOW TO SUBMIT A "CASE OF THE MONTH"

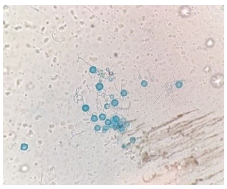
Drfungus.org uses a case presentation structure modified from the Gorgas Course. When submitting a case, please go to this link and complete the form. Submit to jones.5342@osu.edu. Include your .JPEG images as separate files.

We have instituted an **MSG Fellows Case Competition** through September 30, 2019 to allow an opportunity for Fellows to submit cases for potential MSGERC benefits. If your case is accepted, a one-year membership to MSGERC and a $250 stipend will be rewarded. Fellows are restricted to two awards annually. We will allow cases to be accepted that have been presented as a poster or podium presentation; however, we cannot accept cases that have been previously published in a journal. You must follow the Case of the Month Template. Dr. Jose Vazquez, MD will curate cases as they are submitted.

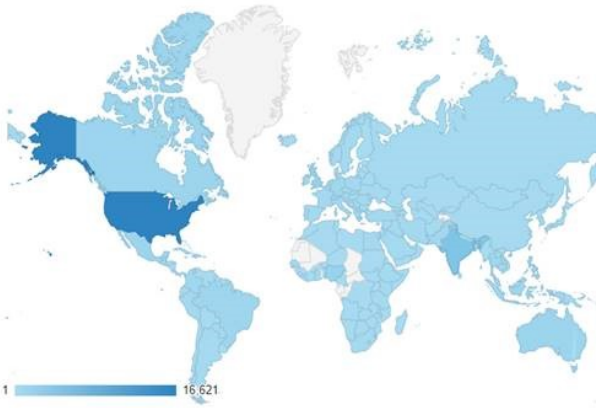
CASE OF THE MONTH TEMPLATE FORM:

https://drfungus.org/case-of-the-month-template.docx

Congratulations to:
Dr. Amy Spallone, MD and Laila Woc-Colburn, MD from Baylor College of Medicine for their Case of the Month entitled "Fever of Unknown Etiology and Pancytopenia in a Solid Organ Transplant Recipient".



DrFungus.org Users as of July 24, 2019



MSGERC ADVISORY ACTIVITIES

MSGERC is involved with multiple levels of clinical study project consultation such as:

- Input into protocol design and methods
- Development of the full study protocol
- Statistical methods, sample size calculation, analyses and reports
- Case Report Form design
- Database development
- Data Review Committees (DRC)
- Grant writing
- Publications
- Input on site selection
- Regulatory advising (NIH, FDA)
- Continuing medical education

Sponsors interested in contracting with MSGERC for consultation services would enter into a Master Services Agreement with the MSGERC, signed by the MSGERC President. Statements of work (per project) and budget are negotiated. The MSGERC enters into Consulting Agreements with MSGERC physician and statistician members for SOW-designated activities. MSGERC makes payments to the Consultants.

HOW CAN A STUDY BECOME AN MSG STUDY?

By: Peter Pappas, MD

We are often asked "What constitutes a study obtaining the label as an MSG study?" In a recent Scientific Committee meeting, it was agreed that in order for the study to be designated as an MSG study several of the following criteria must exist:

- Input into study design and statistical review
- MSG presence as study sites
- Receipt of regular study activity updates
- MSGERC DRC Activities (if applicable)
- Access to data
- Input into manuscript development and publication

We are also asked how being an MSG study impacts the study sponsor. Generally, sponsors would enter into advising agreements with MSGERC for services, but management of the trial and monitoring resides with the sponsor. Having the MSG designation can ensure a scholarly peer-review approach to study design and analyses. Otherwise there is no major impact in this collaborative and scholarly designation.

CLINICAL STUDIES UPDATED JULY 2019

MSG-03: Invasive Aspergillosis Combination Study

PI: *Kieren Marr*

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. Marr K*et al*., *Ann Intern Med.*2015;162(2):81-89. doi:10.7326/M13-2508

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*

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). Herbrecht R*et al*., *Clin Infect Dis*. 2015 Mar 1;60(5):713-20. doi: 10.1093/cid/ciu911

MSG-06: The Phaeohyphomycosis Registry

PIs: *Sanjay Revanker, John Baddley, Sharon Chen*

Sponsors: *Merck, Gilead, Astellas*

Enrollment began on October 31, 2012 and closed on 12/31/2015. A total of 99 cases were evaluated between January 1, 2009 and December 31, 2015. Eighteen sites participated and enrolled cases in South America, Australia and North America. This project captured all relevant clinical, diagnostic, mycological and treatment/outcome information relating to this uncommon mycosis. The specimen repository was maintained at the CDC with Confirmation and AF susceptibility performed at Wayne State. The analysis was published in October 2017 in Open Forum Infectious Diseases. https://academic.oup.com/ofid/article/4222456/A-Mycoses-Study-Group-international-prospective?searchresult=1

MSG-07:Cryptococcosis Combined Analyses (International Retrospective Cryptococcosis Case Review)

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

Sponsor: *Merck, CDC*

This retrospective study evaluated archived cases of *C neoformans* and *C gattii* from UAB, Duke, Australia, Canada (BC), Washington, and Oregon. Over 800 well-defined cases have been identified yielding approximately 70% C neoformans and 30% C gattii. UAB has obtained signed data use agreements with participating sites and has received data from each site. Data has been analyzed and manuscript is in progress, with a second manuscript under consideration.

MSG-08:Epidemic Mold Infections (Meningitis) in U.S.

PIs: *Carol Kauffman, Anu Malani, Tom Chiller, Peter Pappas*

Sponsors: *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. MSG's role included site selection, electronic case report form development, data management and analysis. Nine sites provided case data gathered over 12 months of follow up. Enrollment began in September 2013 and all data collection was complete by February

2016. Current enrollment includes 454 cases entered in the REDCap electronic database including. Final analysis is underway, and a manuscript is planned for Fall 2019.

MSG-09: Prospective study of cryptococcosis among non-HIV infected patients (CINCH)

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. This study was accepted by couple of weeks ago by *Clin Infect Dis.*

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 Non-neutropenic Adults

PI: *Peter Pappas, MD*

Sponsor: *Scynexis*

This phase 2 open-label RCT is completed. 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 is a step-down strategy for candidemia. Study findings were presented at ECCMID in 2017 and a manuscript is in development. This manuscript has been submitted to *Journal of Antimicrobial Chemotherapy*, provisionally accepted pending revision.

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

PI: *Peter Pappas, MD*

Sponsor: *Gilead*

This international observational study is actively enrolling in Australia, Canada (BC), Europe, Taiwan, and India. Peru and France are expected to be enrolling by early summer 2019. Study design is similar to MSG-09, which was performed as a domestic US study. Thus far 55 non-HIV infected patients with cryptococcosis have been enrolled of the 100 intended over a 36-month period. This study will close for data analysis to begin in Dec 2019.

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 was to analyze treatment and outcomes among a large cohort (approximately 2000 patients) across the US with *Candida* BSI. The first analysis was presented at ICAAC 2015 as an abstract in clinical mycology. Manuscript was published in 2016 in J Antimicrob Chemo.

MSG-13: A Multi-Center, Case Control Study of a Lateral Flow Assay for the Diagnosis of Histoplasmosis (2R42-AI096945-03)
PI: P*eter Pappas, MD, Andrej Spec, MD*
Sponsor: *IMMY/NIH Small Business Grant*
The MSGERC and MSG Coordinating Center have joined efforts with IMMY to develop and manage this multi-center, pre-510k case-control study to test investigational assays for diagnosing histoplasmosis (Lateral Flow Assay and Enzyme Immunoassay). This study closed in April 2018 with 164 evaluable subjects including cases and controls. Specimens were processed at the IMMY laboratory in Oklahoma. Clinical data was captured using the REDCap electronic database. Data analysis is underway.

MSG-14: Prophylaxis Surveys
PIs: *John Baddley, MD, Tom Patterson, MD, Oliver Cornely, MD, Julian Lindsay, MD; Orla Morrissey, MD; Eric Bow, MD; and Ricardo LaHoz, MD*
Sponsor: *Mayne Pharma*
A survey of physicians to determine current treatment patterns and challenges to treatment across patient populations including Lung Transplant, Lymphoma and BMT/HSCT. To date over surveys have been completed: Lung 52 of 124 recipients; Lymphoma 23 of 423 recipients; HSCT 100 of 148 recipients. The survey is hosted on REDCap and data analysis completed. An abstract on the Lung TX data was submitted to TIMM 2019.

MSG-15: Suba-Itraconazole vs Itraconazole for Endemic Mycoses
PIs: Andre Spec, Peter Pappas, GR Thompson)
Sponsor: Mayne Pharma
Actively enrolling. 6 Sites activated with an N of 34 (of 80). Activation pending for several more sites in the next few months. Managed by MSG Central Unit- UAB who holds the IND.

MSG 16- Natural History of Antifungal Failure in Invasive Candidiasis in the United States
PI: Luis Ostrosky-Zeichner
Sponsor: Scynexis, UT Houston
Currently in site registration, CRFs and database in final development.

POTENTIAL MSGERC STUDIES IN THE PIPELINE

Phase II/III Adaptive design randomized clinical trial comparing IV T2307 administered twice daily compared to standard of care therapy in patients with candidemia due to Candida auris and other AFR Candida species.

Advisory Team: Peter Pappas, Todd McCarty, Tom Patterson, Thomas Walsh, Luis Ostrosky-Zeichner, Bart-Jan Kullberg.

Sponsor: Toyoma/Fujifilm, NIH (potentially)

An R34 was submitted in May 2019 for a potential U-01 protocol development grant. Targeting sites in US, India, South Africa, Colombia and Panama, if funded. N=90

MSGERC OUTREACH

The **Histoplasmosis in the Americas II Regional Meeting** took place in Manaus, Brazil, March 22-24, 2019. MSGERC participated as a donating sponsor to this meeting. The objective "80 by 20" addresses a goal that 80% of countries in the Americas have the capacity to diagnose and treat Histoplasmosis by 2020.

On behalf of the Histoplasmosis Advocacy Group, Dr. Beatriz Gomez reports "We had a very successful meeting, with around 100 attendees from 22 countries in the Americas and 4 European participants as well. We tripled the assistance and participation from our previous meeting in Paramaribo in December 2015 and appreciate the assistance by the MSGERC."

MSGERC also contributed to the**3rd AIDS-related Mycoses Meeting: AIDS Mycoses 2019** in Capetown South Africa July 10-12, 2019.

Finally, MSGERC, under the leadership of Tom Patterson, MD has developed MSGERC lectures for the iFOCCUS program (OTB Live Science) in Dubai, UAE.

PUBLICATION NEWS

What is a breakthrough invasive fungal infection?

By Dr. Oliver Cornely

What is a breakthrough invasive fungal infection? That is a question that came up when MSG was asked to assist in clinical trial development on new antifungals. It turned out no such definitions had been consented yet. The European Confederation of Medical Mycology (ECMM) joined forces with MSGERC and shaped such definitions. During the process it rapidly became evident that defining breakthrough IFI demanded defining other clinical situations, too. Namely, persistent, refractory, and relapsed IFI. The result is a comprehensive set of definitions that can be employed in interventional and non-interventional clinical trials across a variety of patient populations including hematology, hematopoietic stem cell and solid organ transplant, and intensive care. This has been published in Mycoses June 29, 2019. https://www.ncbi.nlm.nih.gov/pubmed/31254420

Mucormycoses Guidelines

By Dr. Oliver Cornely

MSGERC joined the **One World - One Guideline initiative** of the ECMM for a mucormycosis guideline. For over a year, 74 expert authors from 33 countries in all UN regions actively participated in developing the most comprehensive guideline on mucormycosis to date. The work amounted to a 150-page manuscript. It comes with multiple clinical and microscopic images intended as reference for laboratory and clinical management of mucormycosis patients. Diagnostic and treatment paths are tailored to various settings from all management possibilities available to more limited options. The guideline covers adult and pediatric medicine. Following a 4-week public consultation phase, 51 medical societies endorsed the document. The guideline has just been accepted for publication in The Lancet Infectious Diseases and will be available open access upon publication.

EORTC/MSGERC Definitions 2019

By Peter Pappas and Peter Donnelly

After several rounds and edits, the EORTC MSG Definitions have been finalized and accepted for publication by Clinical Infectious Diseases, pending peer review comment resolution. This represents outstanding work of several teams of people representing both groups. Updates will be provided as new information becomes available.

MSGERC 2018 Biennial Meeting: Clinical Mycology Today – Meeting Summary Manuscript

By Peter Pappas

The 2018 Biennial Meeting was structured with disease-specific segments, featuring guest lecturers and panel discussions facilitated by expert moderators. The panel discussions resulted in key "state of the science" topics that set the groundwork for future clinical research. A publication containing summarized talks and discussion results is in its final stages and we are targeting submission by August or September after circulating to the Board of Directors and Facilitators.

ECMM UPDATE

ECMM has published pocket cards on Aspergillosis, Candidiasis, Mucormycoses and Cryptococcosis which are now available on the ECMM website in 12 languages. These are accessible on the ECMM website at: https://www.ecmm.info/equal-scores/

EDUCATION NEWS

Originally launched in 2014 and updated through 2019, The New Antifungal Toolkit is an Internet CME curriculum that provides current information about newer FDA-approved agents/formulations for the management of invasive fungal infections (IFIs) and evaluates their role in strategies to optimize antifungal therapy. In the 2019 updates, we provide a review of SUBA-itraconazole, updates on endemic mycoses, as well as updates to the pharmacopeia section. Go to http://funguscme.org

ADDITIONAL ACTIVE OFFERINGS/ACTIVITIES LOCATED ON FUNGUSCME.ORG:

- Invasive Mold Face-Off: Meeting the Challenge Across Disease Spectrum
- Fungal Frontiers: Expert Decision Making in Medical Mycology
- Mycology Minutes™from the 8thTrends in Medical Mycology (TIMM) Meeting and Top 2017 Papers
- Mycology Minutes™from the ID Week 2017 Meeting
- Invasive Mycoses: Emerging Paradigms and Practical Applications
- Invasive Mycoses in Hematologic Malignancies: Disarming the Fungal Saboteur

Future plans:
We continue to explore new educational venues, including plans to providing continuing education in Latin America and China.

TERRANOVA MEDICA
BREAKING NEW GROUND IN MEDICAL EDUCATION

Chest Imaging in Haematology Survey- ECMM

Chest imaging in haematology is essential for an early diagnosis of pulmonary infection. Hospital standards on imaging vary locally and underlie continuous changes. Recently, chest CT in asymptomatic patients has been evaluated in individual hospitals, and apparently several other centres adopted the practice in the past.

Under the umbrella of ECMM and ISHAM, the Division of Infectious Diseases at University Hospital of Cologne developed a survey to evaluate the current status of chest imaging in hematology patients throughout the world. We would love to have your input and kindly ask you to participate in the 5 minute survey you can find here:https://www.clinicalsurveys.net/uc/ECMM-ISHAM/survey-imaging/

If you have any questions regarding the survey, please contact:
Jannik Stemler, MD
jannik.stemler@uk-koeln.de

BIENNIAL MEETING ARCHIVES

The MSGERC YouTube channel hosts recordings from lectures and facilitated discussions from the 2016 and 2018 Biennial Meetings. These may be excellent continuing education for fellows and practitioners.

UPCOMING MEETINGS

21st ICHS Symposium on

Infections in the Immunocompromised Host

7 – 9 JUNE, 2020 MELBOURNE CONVENTION CENTRE AUSTRALIA

IDSA
Infectious Diseases Society of America

ID WEEK
October 2-6, 2019
Washington, D.C., USA

ID WEEK
October 20-25, 2020
Philadelphia, PA, USA

CONTACT US

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(Membership Evolving in SP/SU 19)

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