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European confederation of medical mycology expert consult— An ECMM excellence center initiative

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This study is carried out as part of our routine duties.

Summary

Objectives: Difficult-to-treat invasive fungal infections require infectious diseases expert consultation to improve treatment outcome and increase survival rates.

Methods: The European Confederation of Medical Mycology (ECMM) intends to provide expert help free of charge by a newly founded ECMM Expert Consultation Service for medical centres around the globe seeking advice when there is no fungal infection consultant available. The expert consult will provide recommendations and broad expertise on difficult-to-treat invasive fungal infections (eg azole-resistant *Aspergillus* species, *Candida auris*, mucormycosis) to improve diagnostic and therapeutic management and outcome.

Results: The initiative plans global outreach through video conferencing between ECMM Excellence Centers and treating physicians. FungiScope[®] registries will be used to structure case information and to evaluate the impact of the collegial advice system at regular intervals. Advice will follow recent guidelines, and EQUAL Scores will be used to measure guideline adherence.

Conclusions: Infectious diseases expert consultation should be an integral component of care for patients with difficult-to-treat invasive fungal infections. The ECMM Expert Consult will attend to this matter on a global scale.

KEYWORDS

aspergillosis, azole-resistance, *Candida auris*, Candidemia, candidosis, cryptococcosis, fusariosis, mucormycosis

1 | INTRODUCTION

Difficult-to-treat invasive fungal infections are increasing. One reason is the rise of emerging and multi-drug resistant fungal pathogens on a global scale, and another is the increasing number of patients at risk.^{1–5} Infectious diseases (ID) consultation leads to improved treatment outcome and increased survival rates.^{6,7} However, in the majority of settings there is no ID consultant and no fungal infection expert available. Members of the ECMM Academy are often asked for advice.⁸ The ECMM Excellence Center initiative aims at increasing visibility of experts, so that advice can more easily be obtained.⁹ Since its inception ten aspirational excellence centers were audited and accredited worldwide. Audit procedures

are currently ongoing for one more candidate seeking excellence center status.

2 | METHODS

The ECMM intends to provide expert help free of charge for virtually every medical centre in the world seeking advice for management of invasive fungal infections. Together with regional organisations, the ECMM promotes the ECMM Expert Consult by its ECMM Excellence Centers (Figure 1) in order to provide expert recommendations and broad expertise on difficult-to-treat invasive fungal infections (eg azole-resistant *Aspergillus* species, *Candida auris*, mucormycosis) to

improve diagnostic and therapeutic management and outcome. The initiative intends global outreach.

3 | RESULTS

The overall objective is to achieve best possible diagnosis and treatment guidance to improve patient outcomes. Coauthors have dedicated themselves to ECMM Expert Consult. For that purpose, regular videoconferences will be offered between ECMM Excellence Centers and treating physicians seeking advice on diagnostic and therapeutic management of specific patient cases. Patient initiated requests will not be suitable for the ECMM Expert Consult but will be referred to local or regional mycologists as appropriate. Isolates can be sent to reference laboratories for species identification, antifungal susceptibility testing and molecular analysis of potential underlying resistance mechanisms. In cases of suspected treatment failure, plasma samples can be sent for therapeutic drug measurement. The foundation of the ECMM Expert Consult will be announced on the www.ecmm.info homepage. Initial contact by physicians should be sought via email to expertconsult@ecmm.info. Therefore, we provide a single page compilation sheet (Table 1). Advice requests will be distributed among ECMM Excellence Centers according to individual centre expertise and geographical proximity (Figure 1 and Table 2). The ECMM Expert Consult will use FungiScope® Registries for data and advice documentation.^{10,11} The clinical site searching for advice will be asked to retrospectively document the case into the registries according to applicable regulations (Table 3).

Advice will follow recent guidelines, for example the global guideline for the diagnosis and management of mucormycosis,¹² and EQUAL Scores will be utilised to measure guideline adherence for aspergillosis, candidiasis, cryptococcosis and mucormycosis.¹³⁻¹⁶

3.1 | Case documentation and data collection

The appendix lists data categories and items to be collected in the FungiScope® registries. Response to antifungal therapy is evaluated after 2, 4, 6 and 12 weeks, and at day of final observation. In addition, treatment response and outcome of the underlying disease are captured. Information on outcome includes mortality and cause of death. If available, autopsy results are recorded.

The anonymised electronic case report form will be accessible through www.clinicalsurveys.net. ClinicalSurveys.net employs a customised version of Questback's internationally acclaimed EFS Survey® and EFS Leadership® technology to provide the user with an easy-to-use online documentation system. Personnel who will be entering data will receive training on the system via telephone or web conference, after which each person will be issued a unique user identification (ID) and password.

3.2 | Ethical and regulatory considerations

The FungiScope® Registries are in accordance with all applicable laws and regulations including the International Conference on Harmonization (ICH) Guideline for Good Clinical Practice (GCP) the ethical principles that have their origins in the Declaration of Helsinki (current official version: Fortaleza, 2013), and applicable privacy laws (Regulation (EU) 2016/679).

All Good Epidemiological Practice (GEP) requirements are met by the registry. Users can only view and modify their own contributions. All data transmissions are encrypted via TLS 1.2 with an AES 256 GCM bit key and ECDHE RSA key exchange; certificate is provided by COMODO RSA Domain Validation Server. Data are only documented anonymously; no directly identifying data other than the investigator names and email addresses are stored on Questback

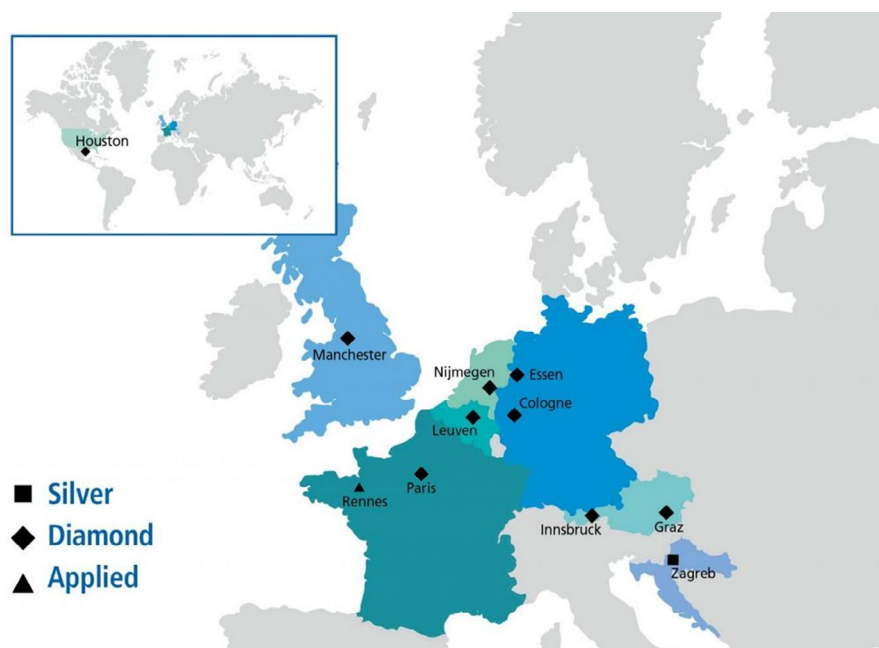


FIGURE 1 Participating ECMM Excellence Centers

TABLE 1 Compilation Sheet—ECMM Expert Consult—expertconsult@ecmm.info

Hospital					
Country					
Contact ID physician:					
Email / phone:					
Patient ID:		Age:		Weight:	
Questions to the experts:					
Underlying diseases / risk factors:					
Days in hospital:			Indwelling catheters:		
Surgery:			Allergies:		
Mechanical ventilation:			ECMO:		
Medical history incl. concomitant medication (e.g. immunosuppressants):					
Imaging:					
Mycological results (incl. biomarkers – β -D-glucan, galactomannan, lateral flow device, etc):					
Antifungal therapy & Therapeutic drug monitoring (prior and current):					
Current laboratory findings				Date:	
Leukocytes:	x1E9/L	PCT:	μ g/L	CRP:	mg/L
Platelets:	x1E9/L			GPT:	U/L
				GOT:	U/L
Platelets:	x1E9/L			gGT:	U/L
				Bilirubin:	μ mol/L
Creatinine:	μ mol/L	eGFR:	L/min	Hemodialysis:	
Diagnosis and treatment concept proposed					
Consultant:				Date:	

servers. Administration of the eCRF is limited to selected and named administrators at the University Hospital Cologne. Any data manipulation by users and administrators is logged in an audit trail allowing complete data reconstruction. The platform has been extensively used in hundreds of surveys and studies and has received approval by the responsible data protection officers at the University Hospital Cologne.

4 | DISCUSSION AND OUTLOOK

The ECMM Expert Consult serves as organisational platform for international cooperation and advice on difficult-to-treat invasive fungal infections. FungiScope[®] registries will be used to structure case information and to evaluate the impact of the collegial advice system at annual intervals.

TABLE 2 ECMM excellence center expertise

	Cologne ¹	Essen	Graz	Houston ²	Innsbruck	Leuven	Manchester ³	Nijmegen ⁴	Paris ⁵	Zagreb
Clinical advice										
Chronic pulmonary aspergillosis	x		x		x	x	x	x		
Cryptococcosis	x						x		x	
Dermatophytosis							x			
Fusariosis	x		x	x	x	x	x	x	x	x
Invasive aspergillosis	x	x	x	x	x	x	x	x	x	x
Invasive Candidiasis incl. <i>Candida auris</i>	x	x	x	x	x	x	x	x	x	x
Mucormycosis	x	x	x	x	x	x	x		x	x
Pneumocystosis	x	x	x	x	x	x	x		x	x
Rare yeasts and moulds	x	x		x	x	x	x	x	x	x
Diagnostic advice										
Panfungal diagnostics (microscopy, culture and non-culture based methods)	x	x		x	x	x	x	x		x
Fungal biomarkers (galactomannan, β -D-glucan)	x	x	x	x	x	x	x			x
Antifungal susceptibility testing (EUCAST and CLSI)	x	x			x	x	x	x		x
Pharmacotherapeutic advice										
Dosing and drug-drug interactions	x		x	x		x	x	x	x	
Therapeutic drug monitoring	x		x	x		x	x	x	x	

Abbreviations: CLSI, Clinical and Laboratory Standards Institute; EUCAST, European Committee on Antimicrobial Susceptibility Testing.

¹Fungal infections in immunodeficiencies, fungus-reactive T cells from peripheral blood, respiratory radiology.

²Fungal immunology.

³Molecular resistance screening for *A. fumigatus*, mycology of the indoor environment, respiratory radiology.

⁴Fungal infections in immunodeficiencies, hygiene and infection control, molecular typing of fungal outbreaks, serology endemic mycoses.

⁵Fungal infections in burn patients.

TABLE 3 Information captured in FungiScope® Registries

Category	Subcategory
Demographics	Age group at diagnosis, sex, year of infection, weight, ethnicity
Host and risk factors	Malignancy, SOT, HIV/AIDS, surgery, trauma, burn, chronic diseases, autoimmune disease, alcoholism, iv drug use, ICU stay, neutropenia, obesity, premature birth, central venous catheters, foreign bodies, low albumin levels, immunosuppression
Clinical presentation	Signs and symptoms, site(s) of infection
Diagnostics	Mycological procedures for diagnosis of invasive fungal infections, species, local susceptibility testing
Treatment	Prophylaxis, empiric and targeted therapy (antifungal drug, day of first dose, dose, duration, route of administration, reason for stopping, drug related adverse events, ambulatory parenteral antifungal treatment) surgical procedures, catheter management, clearance of fungal infection, therapeutic drug monitoring
Treatment response and outcome	Response to antifungal treatment, outcome of invasive fungal infection and underlying disease, overall mortality and investigator assessed attributable mortality, autopsy results, prolongation of hospital stay
Quality	Guideline Implementation and Adherence (ECIL, ESCMID/ECMM, IDSA, etc), EQUAL Scores, Infectious Diseases/Microbiology consulting services

Results derived from the ECMM Expert Consult platform will be shared as poster or oral presentations at national and international infectious diseases, mycology and health systems research conferences. Internationally visible publications will be submitted to peer-reviewed journals.

Currently, clinicians, microbiologists and researchers from eight countries and ten ECMM EC centres are involved (Figure 1).

In conclusion, the ECMM Expert Consult promotes international collaboration, aims to advance clinical care and will enhance knowledge about difficult-to-treat invasive fungal infections. Ultimately, ECMM Expert Consult intends to improve patient outcomes.

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CONFLICTS OF INTEREST

PK has received non-financial scientific grants from Miltenyi Biotec GmbH, Bergisch Gladbach, Germany, and the Cologne Excellence Cluster on Cellular Stress Responses in Aging-Associated Diseases, University of Cologne, Cologne, Germany, and received lecture honoraria from Akademie für Infektionsmedizin e.V., Astellas Pharma, Gilead Sciences and MSD Sharp & Dohme GmbH outside the submitted work. BD reports personal fees from Gilead, outside the submitted work. DD and family hold Founder shares in F2G Ltd, a University of Manchester spin-out antifungal discovery company. He acts or has recently acted as a consultant to Scynexis, Pulmatrix, Zambon, iCo Therapeutics, Roivant, Biosergen and Fujifilm. In the last 3 years, he has been paid for talks on behalf of Dynamiker, Hikma, Gilead, Merck, Mylan and Pfizer. He is a long-standing member of the Infectious Disease Society of America Aspergillosis Guidelines group, the European Society for Clinical Microbiology and Infectious Diseases Aspergillosis Guidelines group and the British Society for Medical Mycology Standards of Care committee. JPG reports grants and personal fees from Pfizer and personal fees from Gilead outside the submitted work. MH reports grants from Gilead, outside the submitted work. DPK reports research support from Astellas Pharma and honoraria for lectures from Merck & Co, Gilead, and United Medical. He has served as a consultant for Astellas Pharma, Cidara, Amplyx, Astellas, Pulmocide and Mayne, and he is a member of the Data Review Committee of Cidara. RK reports grants from Pfizer, personal fees from Pfizer, personal fees from Gilead, personal fees from MSD and grants from MSD outside the submitted work. KL has received non-financial support from Pfizer, personal fees and non-financial support from MSD, personal fees from SMB Laboratoires, personal fees from Gilead and personal fees from FUJIFILM Wako, outside the submitted work. CLF has received speaker fees from Basilea, Gilead Sciences, MSD, Pfizer, and grant and material support from Gilead Sciences, Pfizer and Egger. JM reports grants, personal fees and non-financial support from Gilead, personal fees and non-financial support from MSD, personal fees and non-financial support from F2G, personal fees and non-financial support from Cidara, personal fees and non-financial support from Gilead Sciences, personal fees and non-financial support from Pfizer Inc,

grants, personal fees and non-financial support from IMMY and grants from OLM, outside the submitted work. JFM has received grants from Pulmozyme and F2G; has been a consultant to Scynexis; and has received speaker's fees from United Medical, TEVA and Gilead outside the submitted work. IM received speakers' fees from Astellas Pharma and Biomedica and non-financial support (travel to congress) from Pfizer outside the submitted work. JMM reports grants from Gilead Sciences, personal fees from Gilead Sciences, Merck, ViiV Healthcare, Aelix, outside the submitted work. SP reports personal fees (lecture) and non-financial (travel to congress) support from Pfizer, personal fees (lecture) and non-financial (travel) support from Astellas Pharma, non-financial (travel to congress) support from MSD, non-financial (travel to congress) support from Biomedica outside the submitted work. JP is a stockholder of AbbVie Inc and Novo Nordisk and has received speaker honorarium and consulting fees from Gilead, outside of the submitted work. PMR has nothing to disclose. RR-R has received speaker honoraria from Astellas, Basilea, Gilead Sciences and Pfizer, and a research grant from Gilead Sciences outside the submitted work. MR has received speaker fees from Basilea, Gilead Sciences, MSD, Pfizer, and grant and material support from Gilead Sciences and OLM Diagnostics, Pfizer, Pulmocide Ltd, Pulmatrix Inc. and is funded by the National Institute of Health Research Manchester Biomedical Research Centre. ES has nothing to disclose. DS has nothing to disclose. IS has received research grants, travel support and speaker's fees from Pfizer, MSD, Gilead and Cidara, outside the submitted work. JS received lecture honoraria from Gilead Sciences and Pfizer outside the submitted work. PEV has received research grants from F2G, Gilead Sciences, Merck/MSD and Pfizer; is a consultant to F2G and Scynexis; and received lecture honoraria from F2G, Gilead Sciences, Merck/MSD and Pfizer outside the submitted work. OAC has received research grants from Actelion, Amplyx, Astellas, Basilea, Cidara, Da Volterra, F2G, Gilead, Janssen Pharmaceuticals, Medicines Company, MedPace, Melinta Therapeutics, Merck/MSD, Pfizer, Scynexis, is a consultant to Actelion, Allegra Therapeutics, Amplyx, Astellas, Basilea, Biosys UK Limited, Cidara, Da Volterra, Entasis, F2G, Gilead, Matinas, MedPace, Menarini Ricerche, Roche Diagnostics, Merck/MSD, Nabriva Therapeutics, Octapharma, Paratek Pharmaceuticals, Pfizer, PSI, Rempex, Scynexis, Seres Therapeutics, Tetrphase, Vical, and received lecture honoraria from Astellas, Basilea, Gilead, Grupo Biotoscana, Merck/MSD and Pfizer outside the submitted work.

AUTHOR CONTRIBUTIONS

PK founded the ECMM Expert Consult, is an ECMM Expert Consult Investigator, designed the study, created the manuscript, created tables and figures, revised and approved the final manuscript. BD, DD and JPG are an ECMM Expert Consult Investigator, revised and approved the final manuscript. MH founded the ECMM Expert Consult, is an ECMM Expert Consult Investigator, designed the study, revised and approved the final manuscript. DPK, RK, KL, CLF, JM, IM, JFM, JMM, SP, JP, PMR, RR-R, MR, ES, DS, IS, JS and PV are an ECMM Expert Consult Investigator, revised and approved the final manuscript. OAC founded the ECMM Expert Consult, is an ECMM Expert Consult Investigator, designed the study, revised and approved the final manuscript.

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