

## NEW CENTRE ENROLMENT FORM

#### Introduction

Aortic graft and endograft infection (AGI) complicates approximately 1-4% of deployments. Management of AGI is challenging and inconsistent, with highly variable and often poor outcomes. At present, high-quality published evidence to determine the optimum approaches to diagnosis and treatment is severely lacking.

The Management of Aortic Graft Infection Collaboration (MAGIC) was formed to address this deficiency and welcomes all vascular centres operating a multidisciplinary model of clinical care involving specialists from vascular surgery, infectious diseases/ microbiology and radiology to join the MAGIC service evaluation database. The database is supported by the Vascular Society of Great Britain & Ireland hosted by Guy's & St Thomas' Biomedical Research Centre.

#### Aims

The MAGIC database aims to collect high quality prospective clinical data in order to:

- 1. Characterize the clinical presentation of AGI more precisely.
- 2. Survey the range of approaches used in diagnosis and medical/ surgical management of AGI.
- 3. Evaluate criteria for diagnosing AGI and major clinical outcomes (e.g. fistula formation, limb amputation and survival).
- 4. In the future, it is hoped the data collected will define questions for research studies, help in development of a national AGI case registry and propose best practice recommendations and audit standards.

## Essential requirements for collaborating centres

In order to participate, collaborating centres must:

- 1. Operate a multidisciplinary model of managing AGI cases involving specialists from infectious diseases/microbiology, vascular surgery and radiology (see below).
- 2. Satisfy your organization's Information Governance process before entering patient data and adhere to the patient data security requirements.
- 3. Commit to recording consecutive suspected/ confirmed AGI cases and outcome data for each case at approximate intervals of 90 days.

## Information Governance and data security

The National Research Ethics Service has determined that the MAGIC database is a "service evaluation" and as such, ethical review is **NOT** required. However, we recommend that you still should obtain approval from your local information governance/ patient data security manager (as per your institutions local policies and procedures). Patient data is pseudo-anonymised and no patient-identifiable information is entered into the online MAGIC database, which also complies with NHS security requirements. A comprehensive Information Governance Checklist can



be downloaded from the MAGIC *Welcome* page if more details are required. Further data security questions should be directed to <u>bolaji.coker@kcl.ac.uk</u>

## Access

The MAGIC database *Welcome* page/ Log-on is available at <u>www.gsttbrc.com/MAGIC</u> A database username/ password will be provided upon emailing a completed enrolment form to: <u>gst-tr.magicadministrator@nhs.net</u>

## Instructions for users

A detailed user instruction manual can found under the *Documents* tab in the database. Note that all database activity is logged for audit purposes. Diagnostic criteria determining eligible AGI cases ("suspected and "confirmed") are available on-line at <u>http://dx.doi.org/10.1016/j.ejvs.2016.09.007</u>

## Submission of manuscripts for publication

- 1. Each center will be able to access their data at any time via the on-line database and can submit manuscripts for publication based upon data entered from their own centre at any time (with acknowledgement to the MAGIC).
- 2. For publications involving data from multiple participating centres, the aim will be to recognize all collaborators fairly, in accordance with their contribution. However, the MAGIC Steering Group will make the final decision regarding authorship i.e. the number of authors included from each participating centre and the order on the finalized manuscript.

## Duration

The initial enrollment will take place over two years and it is expected that follow-up will be required for two years from last enrollment.

## \*\*\*IMPORTANT\*\*\*

Submitting this form constitutes your application to join the MAGIC database AND means you agree to the following:

- **1.** Abide by the information governance/ patient data security requirements.
- 2. The conditions for publication using data entered into the MAGIC database.
- 3. The MAGIC database administrators/ Steering Group retain the right to withhold access from any participant, or centre, if information governance/ patient data security stipulations are not adhered to.



# **Proposed New Center Details**

1. Center name:	
2. Lead consultant for Microbiology/Infectious diseases	
Name:	
Email:	
3. Lead consultant for Vascular Surgery	
Name:	
Email:	
4. Further login/access required	
Name:	
Email:	
Name:	
Email:	
<ul> <li>5. Vascular surgery – microbiology/Infectious diseases model (tick all that apple formal in-person MDM</li> <li>virtual MDM</li> <li>joint vascular surgery-infection/microbiology clinic</li> <li>joint ward round</li> <li>other (specify)</li> </ul>	y)
6. Approximate number of aortic grafts & endografts inserted Jan 2015-Jan 201	5

Thank you for your interest in joining the MAGIC database. Email completed forms to <u>gst-tr.magicadministrator@nhs.net</u> or with any further questions about joining.

Dr Nicholas Price & Mr Oliver Lyons, on behalf of the MAGIC Steering Group