



SIMBA (Surgical site Infection in Major lower limb Amputation)

Audit Guide

Thank you for volunteering to participate in this international collaborative audit. This document summarises a step-by-step guide to the audit to be followed by each hospital site. If any aspects are not clear or you need any further advice, please contact the SIMBA project team at SIMBA.amputationstudy@gmail.com.

1. Establish Local Audit Team

Identify the collaborators who are interested in contributing to the audit, including a main contact for your hospital site who will be responsible for the SIMBA team registration. Further collaborators may be added during the duration of the audit. A supervising consultant/attending will need to be identified to ensure appropriate local support for the audit. The team may include a lead consultant /attending, and up to six further members of clinical staff. Ensuring each collaborator is registered for an ORCID iD at this stage will be helpful in anticipation of any future publications, although this is not essential.

2. Complete SIMBA team registration.

Register your audit team at: <https://redcap.link/simba> or by using the QR code here.
Only one registration form needs to be completed per hospital site.



3. Complete the SIMBA baseline unit survey on registration.

On registration you will be asked to fill in a baseline unit survey to provide us with information regarding current clinical practice at a centre level. Only one baseline unit survey needs to be completed per hospital site. This should be done by, or with the support of, the supervising consultant/attending.

4. Register audit locally for approval

In the UK, you can register SIMBA with your local audit department. SIMBA is not classified as research, therefore formal ethical approval is not required. We would recommend sending the letter of invitation which can be accessed via the QR code above. The audit protocol should also include all the relevant details for the local audit registration. However,

please get in touch if you require support with this e.g. additional documentation. Non-UK centres will need to follow their own guidelines (see SIMBA protocol for further details).

5. Login to REDCap

Once you have registered your audit team and we have received confirmation that your audit has been approved locally, you will be sent REDCap log-in details ready for data collection. If there are any problems with this stage please get in touch.

6. Begin data collection.

A REDCap guide will be provided and made available explaining the elements of REDCap data collection to make the process as straightforward as possible. If you are still unclear on any specific data collection points, please let us know. A paper data collection form will be provided should this be required, however this will need to be destroyed once the data is entered onto REDCap.

No patient identifiable data will be transferred to REDCap, patients will be identified by a 3-digit pseudo-anonymised number. Each local centre will hold a secure database with a minimum of 3 patient identifiers, and the 3-digit pseudo-anonymised number used to link peri-and post-operative data. A template excel document will be sent to centres on enrolment to be overseen by the local lead who will be responsible for ensuring data is only stored in a secure site, for example a secure NHS computer, and is disposed of following upload of all follow-up data.

Sites will be asked to submit mid-point outcomes in February 2024 to support interim data review prior to the close of the study. The deadline for completion of all data collection is 31/05/2024 to allow analysis and conclusion of audit.

Please consider advertising your engagement with the SIMBA audit when your site opens. Don't forget to tag in VERN on Twitter/X (@vascresearchnet; #SIMBA).

7. Complete data collection

Once you have completed your data collection, please inform the SIMBA project team via emailing SIMBA.amputationstudy@gmail.com. It is the responsibility of the supervising consultant to confirm all individuals in the team appropriately contributed to the audit. With this confirmation we will then be able to provide all contributors with a certificate confirming their role in a national audit, and we will be in touch with results and next steps following statistical analysis.

8. Keep in touch

Please keep in touch with the SIMBA team with your contact details, so we can inform you of the results of SIMBA and for you to review any draft collaborative publications. We also may collect 1 year outcome data (pending further funding; see protocol).