SOUTH AFRICAN ORTHOPAEDIC REGISTRY

STANDARD OPERATING PROCEDURE

Version 3 – November 2024

1. INTRODUCTION

The objective of the South African Orthopaedic Registry (SAOR) is to accurately and comprehensively collect data pertaining to patients with orthopedic admissions in South Africa (SA). The information will allow the South African Orthopaedic fraternity to (under the auspices of the South African Orthopaedic Association) audit its patient outcomes accurately in order to ensure that the best possible care is provide to all patients.

The SAOR will serve the main purpose of clinical auditing and peer-review

The specific objectives being to:

- provide a platform for peer-review
- provide a platform for auditing of patient outcomes
- allow for uniform collection of data within SA
- provide a platform for retrospective research
- allow rapid identification of participants for new treatments / therapies (if/when applicable)
- encourage collaboration between Orthopaedic surgeons and institutions within SA

The steering committee of the SAOR are affiliated to Stellenbosch University and the University of Cape Town. The SAOR will be hosted by Stellenbosch University, with the Health Research Ethics Committee (HREC) being the primary overseeing committee of the registry for research purposes. Reciprocal approval will be sought from the University of Cape Town. All other contributing institutions and individual Orthopaedic surgeons will be considered as data sources.

SAOA Postnet Suite #033 Private Bag 30004 Danhof Bloemfontein 9301
Telephone +27 51 430 3280 I Fax +27 86 564 7437 I Email info@saoa.org.za I www.saoa.org.za

2. PROCEDURE

a. Participating sites / data sources

All active members of the South African Orthopaedic Association (SAOA) will act as contributing sites. These include all academic institutions (as listed below) as well as all private orthopaedic surgeons within South Africa. (A list of names is available upon request).

Contributing academic institutions include:

- Division of Orthopaedic Surgery, Stellenbosch University
- Department of Orthopaedic Surgery, University of Cape Town
- Department of Orthopaedics, University of the Free State
- Department of Orthopaedics Surgery, Sefako Makgatho University
- Department of Orthopaedics, University of Pretoria
- Division of Orthopaedic Surgery, University of Witwatersrand
- Department of Orthopaedic Surgery, University of KwaZulu-Natal
- Department of Orthopaedics, Walter Sisulu University
- Independent (private) Orthopaedic surgeons

b. Participant identification

Any patient undergoing an Orthopaedic procedure (elective or emergency) at any of the participating sites, will be included in the registry.

c. Inclusion in the SAOR

It is important to note, that all patient data will be routinely captured onto the registry for *clinical purposes*. Each contributing site will have access to their own patient data, as per routine, standard of practice record-keeping procedures. Patients' data may be used for i)

SAOA Postnet Suite #033 Private Bag 30004 Danhof Bloemfontein 9301
Telephone +27 51 430 3280 I Fax +27 86 564 7437 I Email info@saoa.org.za I www.saoa.org.za

site auditing and ii) peer review procedures, as part of routine, standard of practice record-keeping procedures. In cases where investigators would like to retrospectively access routinely collected data for research purposes, they will need to provide a written motivation, together with a motivation for a waiver of informed consent, and only anonymized data will be released. The procedures for accessing data for peer review, auditing or research purposes are outlined in elsewhere in this document.

d. Allocation of unique participant number

All patients will be assigned a unique registry ID as soon as their information is captured on the online registry. This unique number will be used to de-identify patient details.

Although patient identifying details will still be collected as part of routine clinical work, data used for clinical auditing, peer review or any potential retrospective research purposes will only be identified using the unique participant number. No patient identifying details (such as name, family name or file/hospital number), will be made available for these purposes under any circumstances.

e. Patient care

Patient contact at all contributing sites will continue as per routine practice. All patient contact will be through the respective orthopaedic clinics and clinical information, to be captured onto the registry system, will be collected by the attending orthopaedic physician during these contacts.

f. Data capture

Each individual site will continue to capture data as per their normal, standard of practice protocols. These protocols might vary between sites, with some sites utilizing hard copy forms whilst others might capture information directly (via tablets/laptops in the clinics) onto the

SAOA Postnet Suite #033 Private Bag 30004 Danhof Bloemfontein 9301
Telephone +27 51 430 3280 I Fax +27 86 564 7437 I Email info@saoa.org.za I www.saoa.org.za

registry. Some sites already routinely use the secure, electronic registry platform (Amplitude) for clinical purposes. It is important to note that routine protocols, as part of medico-legal requirements, will be followed. Hard copy forms will be stored securely and on-site, as required by each individual institution/practice.

g. Capture of data to registry

Each individual site will be responsible for the capturing of patient data onto the registry. Sites that already routinely use the registry platform will continue their normal practice. Sites that have institutional requirements (for medico-legal purposes) of other data storage methods, will continue as per their standard protocols but will each have a dedicated individual responsible for the capturing of data onto the registry. The eventual objective is that all Orthopaedic practices in South Africa use the same platform to store data.

h. Registry platform

A dedicated, secure, electronic Amplitude database platform is utilized for the SAOR. Each individual user at each individual site has their own personal username and password for accessing the platform. All data processing is subject to the Data Protecting Act (1998) (refer to the Data Protection and Patient Confidentiality attachment). Backups are made on a daily basis and all website traffic is encrypted.

SAOA Postnet Suite #033 Private Bag 30004 Danhof Bloemfontein 9301
Telephone +27 51 430 3280 I Fax +27 86 564 7437 I Email info@saoa.org.za I www.saoa.org.za

3. REGISTRY MANAGEMENT

i. Registry managing team

Prof Jacques du Toit will be the overseeing manager, on behalf of the SAOR-steering committee, of the registry. All decisions pertaining to the SAOR will be made by the SAOR-steering committee consisting of: Dr Odette Koch (private), Prof Jacques du Toit (SUN), Dr Brian Bernstein (private), Dr Marilize Burger (SUN), Dr Maritz Laubscher (UCT), Dr Marc Nortje (UCT), Dr Koos Jordaan (SUN), Dr Thomas Hilton (UCT) and Mrs Lyndsay Gassert (SAOA).

The SAOR-steering committee will be responsible for the maintenance of the database. An Amplitude login will be made available to the other users at each contributing site, to allow data entry into the database. This login will only allow data entry as well as access to each site's own captured data and will not give access to any other aspect of the registry information (including other independent sites or collective information).

j. Registry Access

Access to the Amplitude electronic database will be password protected. The password will be changed periodically to ensure confidentiality.

Any contributing site has the right to request access to database information for i) audit, peer-review and ii) retrospective research purposes. Each site has access to their own site's captured information and can download that information directly from their own Amplitude accounts. Should a site want to access their own data for research purposes, the normal ethical and institutional protocols at each independent site will be followed

Any requests to use data for audit or research purposes, when data from more than the contributing site is involved, will be handled as outlined below:

SAOA Postnet Suite #033 Private Bag 30004 Danhof Bloemfontein 9301
Telephone +27 51 430 3280 I Fax +27 86 564 7437 I Email info@saoa.org.za I www.saoa.org.za

1. A research protocol application must be submitted to the individual's local Research Ethics Committee (REC)
2. Once approved by the local REC, the protocol together with the proof of ethical approval and official SAOR application form must be submitted to the SAOR-steering committee, via the official SAOR email address (registry@saoa.org.za).
3. The SAOR Chairperson (or a delegate from the SAOR steering committee in cases where a conflict of interest exists) will review the application to ensure that i) all documentation are in order and ethics approvals are current, ii) there is no possibility for institutional (SAOA) harm, and iii) data will be destroyed once it has fulfilled the purpose outlined in the research protocol. The SAOR steering committee will be informed of data requests, and can be consulted during the review of data requests at any point. Once approved by the SAOR-steering committee, one of the members of the steering committee will release the requested data to the investigators.
4. The researchers will not be given access to the registry itself.
5. Only anonymized data will be released – researchers will not be provided with any patient identifying details
6. All records associated with data application requests will be securely stored by the SAOR secretary for recording -keeping and reporting purposes.
7. Researchers will be expected to report any outputs related to SAOR data to the SAOR, for record-keeping and reporting purposes, via the official SAOR email address (registry@saoa.org.za).

k. Storage of registry-related documentation

Any registry-related documentation will be stored on secure, password protected computer of the SAOR secretary. These forms will mostly be managed and stored electronically. Any hard copies of documentation will be stored at each independent contributing site, as outlined earlier.

SAOA Postnet Suite #033 Private Bag 30004 Danhof Bloemfontein 9301
Telephone +27 51 430 3280 I Fax +27 86 564 7437 I Email info@saoa.org.za I www.saoa.org.za

An annual progress report will be submitted to SUN HREC, listing the following relevant information:

- Number of patients added to the database
- Number of research studies applying for access to registry information (to be linked with relevant REC numbers)

Number of outputs related to registry research (including conference and publication outputs)

4. DISSEMINATION OF INFORMATION GENERATED FROM THE DATABASE

The overarching goal in the establishment of this registry is to provide better care in the field of orthopedic surgery through uniform data collection, service audits, peer-review and retrospective research.

As such, any findings that originate from this database will be disseminated to the local and international orthopedic community through:

- Podium presentations at national and international conferences.
- Publications in local and international peer reviewed journals.

SAOA Postnet Suite #033 Private Bag 30004 Danhof Bloemfontein 9301
Telephone +27 51 430 3280 I Fax +27 86 564 7437 I Email info@saoa.org.za I www.saoa.org.za