

What is the British Orthopaedic Foot & Ankle Surgery Society (BOFAS) Registry? This is a database of information about foot and ankle orthopaedic surgery collected across the UK. This will help us to find out which operations work best by observing the outcomes of surgery as measured from questionnaires and monitoring of any complications.

What data is collected?

- a) Personal details are needed in order to link you to your surgery and the outcome, and in case you need any further foot / ankle surgery in the future so that your surgeon knows what previous surgery you have had. The personal information stored includes name, gender, date of birth, postal address, email address and NHS number.
- b) In addition, we store information about your general health, diagnosis, surgical procedure and your answers to the questionnaires (which is classed as sensitive personal information under the Data Protection Act).
- c) Details of surgical implants used: This includes the type and manufacturer of any devices used, such as plates, screws or joint replacements. This allows BOFAS to look at the performance of implants and detect any problems over time. Manufacturers of surgical implants are also required, by the Medicines & Healthcare Products Regulatory Agency (MHRA), to monitor their devices and submit reports. We envisage that the BOFAS registry will assist in this surveillance process by providing anonymised data to manufacturers, in return for payments needed to help run the Registry. This provides added protection for patients since, should data reveal an issue with an implant or device subsequently reported to the MHRA, as holders of patients' identifiable data BOFAS would be able to assist in alerting the individual patients affected. This is in line with Principles 4 and 7 of the Caldicott guidelines

This data is entered into the registry by a member of the team involved in your care.

Do I have to participate? No, your consent is entirely voluntary and if you prefer not to participate, your medical care will be delivered in the normal way. Your personal details in particular cannot be kept without your consent.

What would I be asked to do? You are asked to complete questionnaires before and after surgery. This is why your email address is important as we will send links to these questionnaires when they are due.

If I do participate, what are my rights? You are entitled to:

- a) **Withdraw consent at any time.**
- b) **Request access to your data**
- c) **Request correction**
- d) **Request erasure**
- e) **Request restriction of processing**
- f) **Request the transfer of your personal data**

Further information on all these rights can be found on the Information Commissioner's Office (ICO) website:
www.ico.org.uk

If you wish to exercise any of the rights set out above, you can contact us either:

Through the BOFAS website: <http://www.bofas.org.uk/> or

By emailing customer.support@amplitude-clinical.com

Conditions regarding requests;

a) Time limit to respond

We try to respond to all legitimate requests within one month. Occasionally it may take us longer than a month if your request is particularly complex or you have made a number of requests. In this case, we will notify you and keep you updated.

b) Fee

You will not have to pay a fee to access your personal data (or to exercise any of the other rights). However, we may charge a reasonable fee if your request is clearly unfounded, repetitive or excessive. Alternatively, we may refuse to comply with your request in these circumstances.

Who is the data controller? The data controller organisation (see www.ico.org.uk) for your personal data in the registry will be the British Orthopaedic Foot & Ankle Society (and not the NHS).

We have appointed a data protection officer (DPO) who is responsible for overseeing questions in relation to this consent form. If you have any questions about this consent form, including any requests to exercise *your legal rights*, please contact the DPO using the details set out below:

Name: Joanne Millard

Email Address: administrator@bofas.org.uk

Postal Address: BOFAS, PO Box 209, Bristol BS20 1DL

Telephone Number: **+44 7847 281130**

Data Retention

Details of retention periods for different aspects of your personal data are available in our retention policy which you can request from us by contacting us using the contact details above. **Is my data stored securely?** Your personal details are treated as confidential and will be stored safely. We have put in place appropriate security measures to prevent your personal data from being accidentally lost, used or accessed in an unauthorised way, altered or disclosed. Your personal details will not be available to anyone outside BOFAS and its secure IT provider, with the following exceptions:

(1) BOFAS may approve a specific research project related to your diagnosis or surgery. The majority of this research uses only anonymised information that means it is impossible to identify individuals. From time to time researchers

may wish to gather further information. In these cases we would seek your approval prior to disclosing your contact details. You would be free to decline and again this would not affect your care.

(2) We may in future consider linking to other healthcare information resources (including Hospital Episode Statistics and other orthopaedic registries). Linking this data allows us to collect information on other aspects of your health, e.g. if you ever have further surgery or develop health problems. We do this to improve our ability to monitor patient safety and patient outcomes, and so that people and organisations involved in improving surgery can better understand and develop improved or more cost-effective medical treatments. In order to obtain any linked data about you, we would provide your operation and personal details to the body responsible for these other datasets so that they can match with records they hold – this may be NHS Digital (e.g. for HES) or the relevant Data Controller (for other orthopaedic registries).

(3) Your surgeon and his / her clinical team can also access and analyse your data to check they are individually giving good care. In addition, your registry data can be accessed in the future by other medical professionals who are involved in your medical care.

Transfer of identifiable data outside of the European Economic Area is not permitted. *Anonymised* data, your identifying details removed, may be released to approved organisations. **How will my data be processed?** We process the data which participating patients provide to improve our understanding of orthopaedic problems and of their treatment, thus helping us provide future patients with the best care. BOFAS are responsible for all acts of processing. We retrieve and analyse your data so that we can compare large numbers of patients, usually removing anything that can identify you as an individual. Such analysis may have to be performed by a specialised third party, in which case they will be bound by the same high security standards and legal contract, whether identifying details had to be included or not.

You will not be identifiable within the results of any analyses which are shared, and any transfer of data will be encrypted. All studies using data from the Registry are recorded on the BOFAS website.

Children: Monitoring the outcome of surgical procedures in children is as important as it is for adults. It is the child's parents or guardian who is asked to consent for data to be collected.

Where can I find out more information? The BOFAS website (<http://www.bofas.org.uk/>) contains more information including details of any studies and any information obtained through analysis of the Registry data. If you want to see what data is stored on you, please write as detailed below;

Contact Details:

Visit our website <http://www.bofas.org.uk/>

Send an email to: customer.support@amplitude-clinical.com

If you would like to contact the Information Commissioner's Office (ICO), the UK supervisory authority for data protection issues, the details are as follows:

- Address: Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF
- Tel: 01625 545 745
- Email: international.team@ico.org.uk
- Website: www.ICO.org.uk

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BOFAS Registry Consent Form

Helping to improve patient care through knowledge

Please tick the box to confirm that you have been given, read and fully understand the patient information leaflet'

Please tick the box to confirm that you consent to us sending you a questionnaire before and after surgery, so that we are able to monitor any complications and overall outcomes from this kind of surgery.

Surname: _____

First Name: _____

Date of Birth: ____/____/____

Email address & mobile phone number: (in order for us to contact you regarding the questionnaires):

_____ | _____

I HAVE READ THE INFORMATION SHEET AND I CONSENT TO:

- Personal details being recorded in the BOFAS Registry and controlled by BOFAS
- My data being processed for the purposes set out in the patient information leaflet

I UNDERSTAND THAT:

I can ask for my details to be removed at any time and can request access to my personal data, as well as the right to request correction, object to processing, request restriction of processing and request the transfer of my personal data. To make a request regarding your data, please contact us through the BOFAS website: <http://www.bofas.org.uk/> or by emailing customer.support@amplitude-clinical.com

Patient / Parent agreement to data collection for Registry and Research:

Signature: _____ Date: ____/____/____

To be completed by the person accepting patient consent

Name: _____ Position: _____

Signature: _____ Date: ____/____/____

This form should be retained securely by the hospital.