

Position Statement

Implant retrieval and analysis services

Joint replacement is one of the most successful surgical interventions, but a proportion of implants fail prematurely, leading to adverse patient outcomes.

Decisions about the safety of implants with an unexpectedly high revision rate are informed by the National Joint Registry (NJR) Implant Performance Committee.

Whilst the value of registries in monitoring implant performance is uncontested, systematic analysis of failed implants has also proven to be invaluable in the detection of early failure.

It is essential to standardise implant analysis and the BOA recommends that:

- a. the following should be routinely considered for analysis:
 - implants in Beyond Compliance programme follow-up.
 - implants with a current manufacturer's Field Safety Notice
 - implant combinations with outlier status on the National Joint Registry (NJR) or equivalent.
 - hip or knee implants failing before 10 years.
 - low volume implants including those with bespoke indications, and custom-made devices.
 - some implants with non-mechanical failure, particularly infection, to provide information on normal wear.
- b. NHS England contracts appropriate providers and determines individual procurement models for implant analysis and banking. Evaluation of the market for each service will be required to identify existing specialist providers and determine their utility and value.
- c. services undertaking analysis should be subject to external peer review to ensure compliance with extant international standards.
- d. a statement reporting the methodology and internal quality assurance of accuracy should be available for each laboratory involved in implant analysis.
- e. analysis should meet minimum generic requirements
<https://www.iso.org/standard/79950.html>.
- f. an appropriate independent body should collate and review the findings of reports from analysis of retrieved implants.
- g. collated reports of implant analysis should be shared with Medicines and Healthcare products Regulatory Agency (MHRA), NJR (for arthroplasties included in the NJR), and Beyond Compliance.
- h. statutory bodies should have access to all data held by retrieval and analysis services.
- i. the funding model for a retrieval service and intellectual property must not be a barrier to the dissemination of retrieval results.
- j. some implants should be stored for a period of up to 10 years to allow targeted analysis if poor performance is identified.