

Information Standards Notice – New

Acting under delegated authority from the Secretary of State for Health and Social Care, the Data Alliance Partnership Board (DAPB) has approved a new information standard for publication under section 250 of the Health and Social Act 2012.

You must comply with this new standard by the full conformance date specified below.

| Standard details | |
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| DAPB unique identifier | DAPB3103 Amd 100/2021 |
| Name | Surgical Devices and Implants Core Data Set, version 1.0 |
| Approval date | 31 January 2022 |
| Publication date | 3 February 2022 |
| Standard definition | |
| Description | <p>This is a new information standard commissioned by the Department of Health and Social Care to support the Secretary of State’s strategic requirements to ensure patient safety in the use of surgical devices and implants and the equivalent requirements raised by the Independent Medicines and Medical Devices Safety Review: First Do No Harm (Cumberlege Report).</p> <p>The standard specifies a patient level, core data set to enable the capture of nationally consistent data linking patients to specific implants or devices, inserted by specific clinicians at a specific location.</p> <p>Data will be captured for any surgery involving the implanting, revision, replacement or removal of a Class III or Class IIb implantable medical device, defined as</p> <ul style="list-style-type: none"> • Any device, including those that are partially or wholly absorbed, which is intended: <ul style="list-style-type: none"> ○ to be totally introduced into the human body, or ○ to replace an epithelial surface or the surface of the eye, by clinical intervention and which is intended to remain in place after the procedure. • Any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days shall also be deemed to be an implantable device. <p>Source: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices</p> <p>Note that this information standard has evolved from the work undertaken by NHS Digital in respect of an existing data collection (DCB3103-01, the Pelvic Floor Registry) but concentrates on mandating this core data set across all surgical devices and implants activity. At the same time NHS Digital will continue to progress the existing Pelvic Floor data collection</p> |

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| | under the authority of a separate Data Provision Notice. |
| Scope (Health and Social Care Act 2012) | Health Services, NHS Services |
| Applies to | Health and care organisations that undertake surgery involving surgical devices and implants and alternative procedures within England, including: <ul style="list-style-type: none"> • providers of NHS funded care including NHS Providers and Independent Sector Healthcare Providers (ISHPs) • private healthcare providers in England. |
| Impacts upon | Implementation of this information standard impacts all health IT systems suppliers providing systems to the above providers; suppliers should work with their customers to determine necessary changes. |
| Legal authority | This information standard is published under section 250 of the Health and Social Care Act 2012. The data collection is the subject of Directions under section 254 of the Health and Social Care Act 2012, from the Department of Health and Social Care to NHS Digital: https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notice/secretary-of-state-directions/surgical-devices-and-implants-directions NHS Digital have issued a section 259 notification, under the Act, to notify providers of the requirement to supply data, published on the NHS Digital website: https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notice/data-provision-notice-dpns/surgical-devices-and-implants |
| Link to further documentation | The Requirements Specification, Implementation Guidance and Technical Output Specification are available on the NHS Digital website: www.digital.nhs.uk/isce/publication/dapb3103 Further guidance is published by NHS Digital: https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notice/data-provision-notice-dpns/surgical-devices-and-implants |
| Contacts | |
| Sponsor | William Vineall, Director of Acute Care and Quality Policy, Department of Health and Social Care |
| SRO | James Austin, Executive Director Data, Insights and Statistics, NHS Digital |
| Business Lead | Emma Summers, Programme Head, NHS Digital |

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| Help Desk | enquiries@nhsdigital.nhs.uk (quote 'surgical devices and implants core data set' in subject line) |
| Dates | |
| Implementation and conformance dates | <p>From 1 June 2022 providers in scope of this information standard must be able to collect the information as defined in the Technical Output Specification for local use.</p> <p>From 1 July 2022 providers in scope of this information standard that are NHS funded must begin submitting SDICDS submissions in accordance with this standard.</p> <p>Data should be reported to NHS Digital within 10 working days of an in-scope procedure occurring.</p> |
| Post Implementation Review date | 30 June 2023 |

The controlled version of this Information Standards Notice is published on the NHS Digital website: www.digital.nhs.uk/isce/publication/isns