Information Standards Board
for Health and Social Care

Title	Neonatal Data Set ISB 1595 Specification		
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Sponsor	Philip Walker	**Status**	Final
Developer	Neena Modi	**Version**	1.0
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Neonatal Data Set ISB1595 Specification

Amendment History:

Version	Date	Amendment History
0.1	23/08/2013	Draft
0.2	23/08/2013	Amendments by ISMS
0.3	26/08/2013	Addition of ISMS amendments
0.4	18/09/2013	Assessment amendments
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Approvals:

Name	Organisation	Version	Date
Neena Modi	Neonatal Data Analysis Unit	0.1	22/08/2013
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Neena Modi	Neonatal Data Analysis Unit	1.0	17/01/2014

Glossary of Terms:

Term	Acronym	Definition
Antimicrobial Resistance and Healthcare Associated Infection	ARHAI	The Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) was established in April 2007 to provide practical and scientific advice to the Government on strategies to minimise the incidence of healthcare associated infections and to maintain the effectiveness of antimicrobial agents in the treatment and prevention of microbial infections in man and animals.
Bliss		A UK charity aiming to improve care and support for premature and sick babies and their families.
British Association of Perinatal Medicine	BAPM	A professional body affiliated to the Royal College of Paediatrics & Child Health that supports the care of mothers and newborn babies and aims to improve perinatal care in the UK.
Healthcare Quality Improvement Partnership	HQIP	Promotes quality in healthcare, and aims to increase the impact of clinical audit in England and Wales.

Term	Acronym	Definition
Health Research Advisory – Confidentiality Advisory Group	HRA-CAG	The purpose of the Health Research Advisory is to protect and promote the interests of patients and the public in health research.
Healthcare Resource Groups	HRGs	The Health & Social Care Information Centre (HSCIC) publication that brings together all the key tools required to group healthcare resource data for payment analysis.
Medicines for Neonates	MfN	A National Institute for Health Research programme grant that has been instrumental in establishing the National Neonatal Research Database.
National Neonatal Audit Programme	NNAP	Commissioned by HQIP on behalf of the DH, to improve neonatal specialized care by auditing care against national standards.
Neonatal Data Set	NDS	The specification of selected data items collected during neonatal specialized care in England.
National Neonatal Research Database	NNRD	A database (repository of information) formed from Neonatal Data Set items.
Necrotising Enterocolitis	NEC	A serious acute inflammatory condition of the intestine that affects babies, especially premature and low birth weight babies, in the weeks after birth; mortality from this condition is high and survivors are at very high risk of long-term complications.
Neonatal Critical Care Minimum Data Set	NCCMDS	NCCMDS ensures standardised collection of data required to support operation of the Neonatal Critical Care Healthcare Resource Groups.
Neonatal Data Analysis Unit	NDAU	The Neonatal Data Analysis Unit is an academic unit based at Imperial College London. It aims to support UK Neonatal Units, Networks, and NHS Trusts to improve the quality of care for newborns and their outcomes through health services support and research.
NHS Data Dictionary	NHS DD	The NHS Data Model and Dictionary provides a reference point for assured information standards to support health care activities within the NHS in England. It has been developed for everyone who is actively involved in the collection of data and the management of information in the NHS.
Snomed CT		A standard clinical terminology is essential for the interoperability of electronic health records across care settings.
UK Neonatal Collaborative	UKNC	The NHS Trusts that contribute data to the National Neonatal Research Database are known as UK Neonatal Collaborative.

Contents

1 Overview

1.1 Summary

Standard	
Standard Number	ISB 1595
Title	Neonatal Data Set
Type	Inherited
Description	The Neonatal Data Set (NDS) comprises data items relating to neonatal patient demographics, clinical interventions, outcomes, and diagnoses. The aim is to extract NDS data items from once only collected electronic clinical records, create a database of these items, and make this available as a national resource to serve a variety of needs, so avoid duplicate data collection for different purposes, minimise the burden placed upon clinical teams, and promote data quality and completeness. The NDS contains the neonatal data items that are mandatory for NHS trusts to submit to fulfil Healthcare Quality Improvement Partnership's (HQIP) requirements. Mandatory data items are also included from the Neonatal Critical Care Minimum Data Set, although at present Trusts submit this dataset independently. NDS also contains currently non-mandatory data items. All NHS trusts in England and Wales, providing neonatal services, are currently submitting the NDS. Examples of current applications of the NDS include NHS Quality Improvement Programmes (e.g. East of England Care Bundle to reduce Necrotising Enterocolitis) and national reports for the: • Healthcare Quality Improvement Partnership (e.g. National Neonatal Audit Programme) • Department of Health (e.g. NHS Atlas of Variation in Healthcare) • NHS England (e.g. London ODN Reporting) Additionally the data set is in use by clinical research teams throughout the country (e.g. International Neo Study (iNeo); Downs In Neonates Study (DIN); UK Neonatal Collaborative NEC Study).
Applies to	All NHS Trusts providing neonatal care services. There are 179 neonatal units in England and Wales.
Release	
Release Number	Amd 32/2012
Title	Initial release
Stage	Full Stage Submission
Implementation Date	01 June 2014

1.2 Controlled Documents

Ref #	Reference	Title
1	NDS	Neonatal Data Set ISB1595 release 1 version 2.1

1.3 Supporting Documents

Document Reference	Title	Version	Date
Data Set	Neonatal Data Set ISB 1595 release 1 version 2.1	2.1	13/09/2013

1.4 Related Standards

Ref #	Reference	Title
	ISB0075	Neonatal Critical Care Minimum Data set
4	ISB1513	Maternity Services Secondary Uses Data Set
	ISB1069	Children and Young People’s Health Services Secondary Uses Data set

2 Background

Extracted from 179 neonatal units across England & Wales, the Neonatal Data Set (NDS) is being brought forth as an inherited standard or ‘NDS release 1’ to ensure consistency in extraction of neonatal data. In the course of the review by the Health & Social Care Information Centre (HSCIC) the dataset has been standardised and brought inline with the NHS Data Dictionary (NHS DD) which includes amendments to fit with other national collections. This new product was brought forth to public consultation over the course of a month between 08 June and 10 July 2013. Results of the consultation have also been incorporated into the NHS DD modelling of the NDS including an interim mapping to the UK edition of Snomed CT. In a follow-up publication the remodelled NDS will be released alongside a Snomed CT adaptation as ‘NDS release 2.’

The Neonatal Data Set (NDS)[1] is an on-going extraction from electronic patient records maintained by neonatal units across England and Wales through their local patient management systems. These systems are updated routinely by clinical staff on neonatal units. All the records are stored by the NHS trusts on a designated NHS approved server.

From this data repository a set of data items is extracted and known as the Neonatal Data Set. The Imperial College London academic unit Neonatal Data Analysis Unit (NDAU), based at the Chelsea & Westminster NHS Foundation Trust, receives this extract to form the National Neonatal Research Database (NNRD). Caldicott guardian agreements are held by the NDAU with every neonatal unit across England & Wales allowing the transfer of data an NDAU server[2]. This process is detailed in diagram 1 below.

In the main submission document an appendix section lists data products created using the NNRD. These outputs have only been made possible because of the extraction of the Neonatal Data Set.

However, since the original conception of the NDS, other national datasets have emerged, including Maternity Services Secondary Uses Data set[3]. The NDS was brought to the Health & Social Care Information Centre (HSCIC) for a review to standardise the NDS to other national collections, to the format of the NHS Data Dictionary, to incorporate Snomed CT and thereby facilitate any future neonatal data collection suppliers with an opportunity to extract the Neonatal Data Set.

Detailed in the data discovery report the review by HSCIC has resulted in the addition of 18 new data items or only 4% of the entire dataset. Consequently the NDS is being proposed as a national standard on the grounds that any changes made in the course of the review will be implemented at a later release of the dataset when the Snomed CT coding modelling will be made available for the dataset.

More specifically the inherited NDS, the remodelled items and the new items are being put forth as NDS release 1. While included in release 1 the new items have been marked as pilot because they cannot be extracted as of yet, they are not part of

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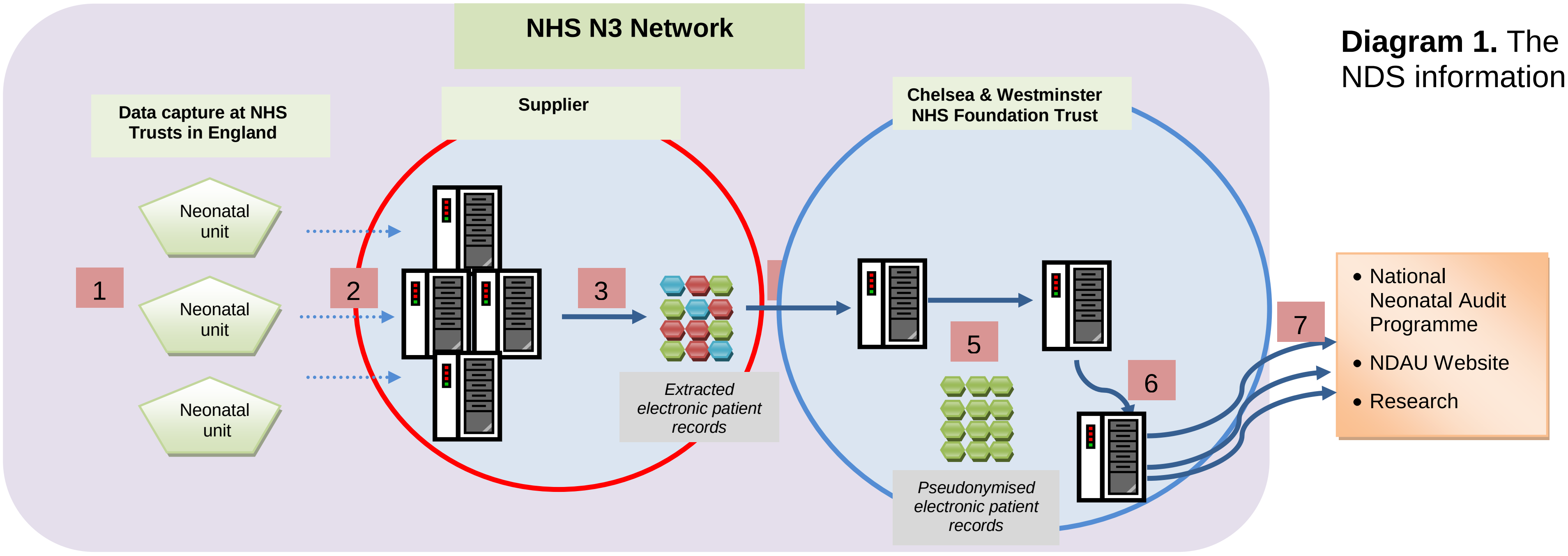
[1] NDAU, Neonatal Data Set ISB1595 release 1 v2.0, Y. Statnikov, Editor. 2013.

[2] NDAU, UK Neonatal Collaborative Caldicott Guardian Agreement 2012.

[3] ISB1513 Maternity Services Secondary Uses Data Set. 2012(2.2).

the existing data collection. During the development of Snomed CT coding for release 2 the pilot items will be extracted following the introduction into the suppliers data collection platform, more details in the implementation and maintenance document.

Diagram 1. The flow of NDS information



1 Neonatal units record clinical information on patients, including Neonatal Data Set, using their local patient management system.

   a. Supplier(s) provide the technical support to Neonatal unit staff by phone, email and web helpdesk while the NDAU publish annual data entry guidelines, staff and parent information leaflets and provide support over the phone, email and web.

   b. Data items from maternity services are added here. Method of data collection varies by individual NHS Trust, some gather directly from electronic records in or from patient notes in maternity.

2 Data is stored on a supplier's hosting server on N3.

3 Supplier(s) extract only Neonatal Data Set items using MS SQL, including patient identifiers, where allowed ,of NHS Number of Baby, NHS Number of Mother, Baby's Date of Birth, Mother's Post Code, and Date of events in the course of baby's stay.

   a. NHS Trusts authorise the NDAU to receive their data through Caldicott Guardian agreements.

   b. Individual NHS Trusts are able to download all of their data, not just the Neonatal Data Set, and forward that information to relevant commissioning areas.

4 Data are securely transmitted four times a year on N3 to Chelsea & Westminster NHS Foundation Trust where the receiving NDAU server is based.

   a. On receipt of data the Chelsea & Westminster NHS Foundation Trust becomes **the legal data controller** but only accessible to nominated indviduals, Y Statnikov and N Modi.

5 Staff employed **both by** Imperial College London and Chelsea & Westminster NHS Foundation Trust process the data using MS SQL and SAS and merge it into the NNRD.

   a. The data processing includes pseudonomisation of all patient and hospital identifiers, where applicable, thus the NNRD does not hold patient identifiers.

6 Data are aggregated by hospital, region, and national level. Analysis takes place at Chelsea & Westminster NHS Foundation Trust by staff employed both by Imperial College London and Chelsea & Westminster NHS Foundation Trust.

7 The Caldicott Guardian agreements allow for analysis that supports NHS services including NNAP and other non-research service evaluations. Analyses must be commissioned.

   a. All other projects, in research, while approved by the HRA-CAG, must also request specific permission from each individual NHS Trust in order to access their data in the NNRD.

   b. Data, aggregated by hospital, region or national level, are disseminated as reports with formats including PDF, MS Word, and MS Excel documents.

2.1 Introduction

Neonatal services are an innovative medical discipline keen on improving neonatal outcomes. Measurement of outcomes is facilitated by the Neonatal Data Set (NDS) and because of clinical innovations the NDS must be kept current to accurately depict present neonatal outcomes. NDAU has a responsibility to monitor clinical practise and alert neonatal units and IT suppliers of new data requirements.

The NDS extracts are held within the National Neonatal Research Database (NNRD) at the Chelsea & Westminster NHS Foundation Trust. NDAU have appropriate regulatory permissions to hold data in the NNRD from neonatal units sharing data with the NDAU. The supplier extracts data on behalf of the neonatal units and submits it to the NDAU. These relationships, including that of the HSCIC and the NDAU, are summarised in diagram 2 below. In the diagram all entities outside of the NDAU are able to influence the development of the NDS and the remaining sections of this document detail how this is achieved.

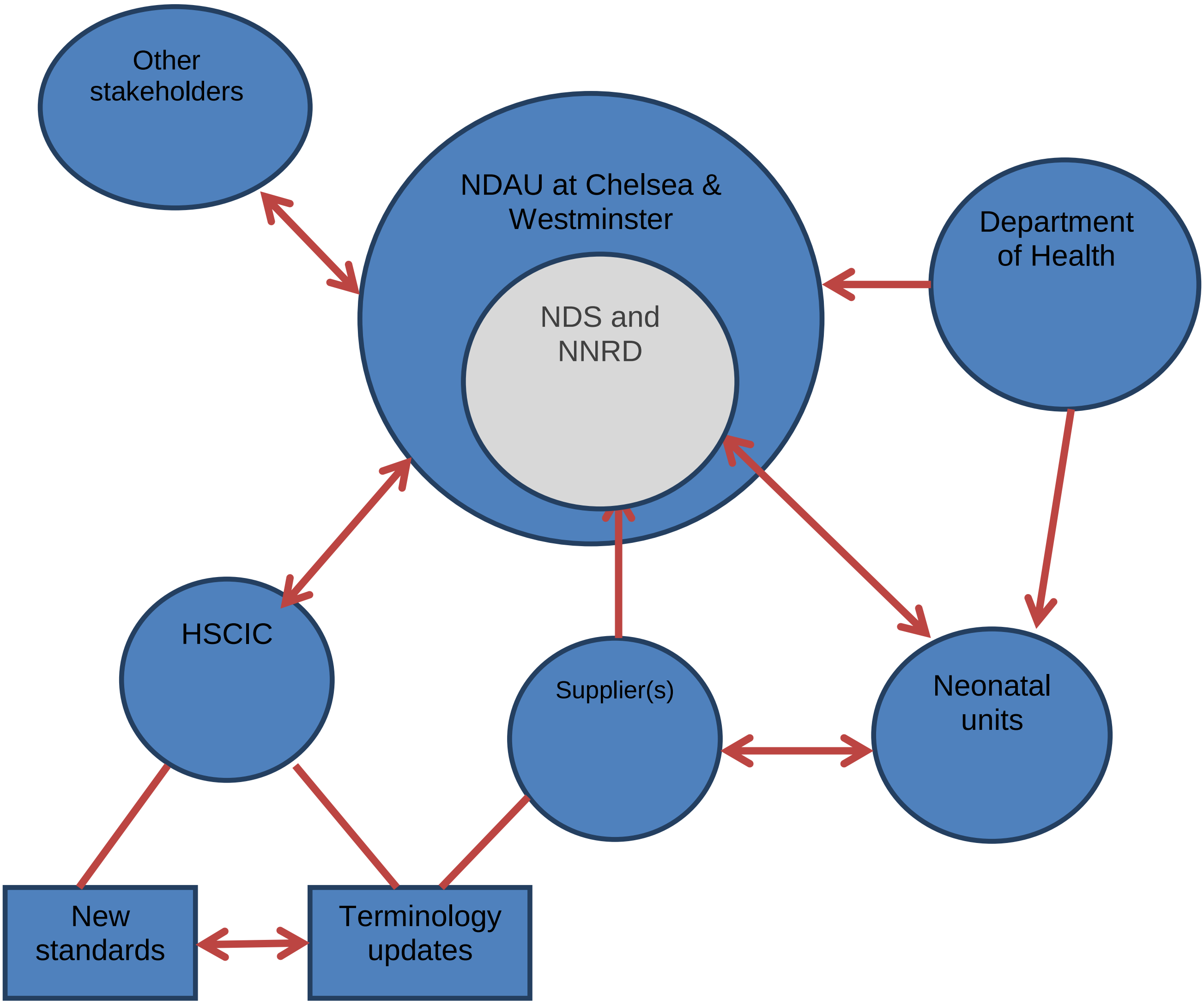


Diagram 2 Summary of organisational relationships involved in implementing and maintaining the NDS

3 Health and Care Organisations

3.1 Requirements

#	**Requirement** [4]
1	The organisation(s) providing neonatal care **MUST** review the Neonatal Data Set to understand the data extraction requirements.
2	The organisation(s) providing neonatal care **SHOULD** review the Neonatal Data Set to understand the data validation rules that apply to the extraction of the data set.
3	The organisation(s) providing neonatal care **MAY** consult with the company providing the existing national system for collection of the Neonatal Data Set .
4	The organisation(s) providing neonatal care **MUST** address data submission that breaches validation rules specified in the Neonatal Data Set .
5	The organisation(s) providing neonatal care **SHOULD** review their data completeness and quality reports at least once a week.
6	The organisations(s) providing neonatal care **MUST** sign a Caldicott Guardian agreement with the Neonatal Data Analysis Unit to submit their Neonatal Data Set to the National Neonatal Research Database.
When the Caldicott Guardian agreement is signed:	
7	The organisation(s) providing neonatal care **SHOULD** read the Neonatal Data Set document annually to review updates or alterations.[5]

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[4] The key words MUST, SHOULD and MAY are defined in the information standards development methodology. They follow RFC-2119.

[5] The NDAU will be responsible for maintaining the Neonatal Data Set and providing user documentation stating the items extracted for the dataset through the NDAU website (www.imperial.ac.uk/ndau). The supplier(s) remain responsible for technical guidance on data capture and will use own platform to disseminate this information..

3.2 Conformance Criteria

Organisation Type	**Criteria**
All NHS Trusts with a Neonatal Service	**MUST** address data quality checklists available on the supplier's live data entry platform, BadgerNet, on a regular basis.
	SHOULD address data entry validation issues (i.e. temporary NHS numbers) if highlighted by BadgerNet or NDAU on an adhoc basis.
	MUST review quarterly reports produced highlight data quality and completeness.
	Annual summary of data quality **SHOULD** be included in National Neonatal Audit Programme Reports.
All NHS Trusts with a Neonatal Service	Every three years the neonatal units are asked to share their data through Caldicott agreements they **MUST** contribute at least pseudonymised patient records.
All NHS Trusts with a Neonatal Service	**MUST** review publications produced by the NDAU including data entry guidelines and data quality reports produced annually.
Neonatal Data Analysis Unit	NDAU **MUST** support the neonatal units in evaluating their data extractions by producing quarterly data completeness reports for the NNAP.
Neonatal Data Analysis Unit	NDAU **MUST** maintain the Neonatal Data Set and brings forth new releases of the dataset.

4 IT Systems Suppliers

4.1 Requirements

#	**Requirement** [6]
1	The IT Supplier(s) **MUST** review the Neonatal Data Set to understand the data extraction requirements.
2	The IT Supplier(s) providing neonatal data collection systems **SHOULD** review the Neonatal Data Set to understand the data validation rules that apply to the extraction of the data set.
3	The IT Supplier(s) **SHOULD** alert organisation(s) when data submission breaches data validation rules specified in the Neonatal DataSet through their live data entry system.
4	The IT Supplier(s) **SHOULD** provide live or on demand data completeness and quality reports for the Neonatal Data Set to the organisations providing neonatal care through their live data entry system.
5	The IT Supplier(s) **MUST NOT** submit data files to the Neonatal Data Analysis Unit unless the organisation providing neonatal care signs a Caldicott Guardian agreement with the Neonatal Data Analysis Unit.
When the Caldicott Guardian agreement is signed:	
6	The IT Supplier(s) **MUST** contact the Neonatal Data Analysis Unit by email to initiate security clearance with Chelsea & Westminster Hospital NHS Foundation.
7	The IT Supplier(s) **SHOULD** transfer Neonatal Data Set returns to the National Neonatal Research Database every three months using SQL database replication or back up.
8	The IT Supplier(s) **MUST** read the latest guidance from the Neonatal Data Analysis Unit on format of data submission.
9	The IT Supplier(s) **SHOULD NOT** submit data collected by organisations providing neonatal care that are not specified in the Neonatal Data Set.
10	The IT Supplier(s) **MUST** implement changes, if any, to the Neonatal Data Set and the mandatory data set therein after the annual Information Standards Board, or relevant organisation, renewal process is complete.

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[6] The key words MUST, SHOULD and MAY are defined in the information standards development methodology. They follow RFC-2119.

4.2 Conformance Criteria

Criteria
NDS extract(s) **MUST** only contain data from hospitals with data sharing agreements as determined by supplier(s) validation on performing SQL extraction every three months.
NDS extract(s) **SHOULD** only contains data specified in the NDS release documentation as determined by supplier(s) validation on performing SQL extraction every three months.
NDS extract may have missing information, this **SHOULD** be cross referenced by the supplier against the supplier’s own data repository to ensure errors did not occur during SQL extraction every three months.
Supplier(s) **MUST** honour the contract with the NDAU to undertake SQL extracts of the NDS and transfer them over the N3 to the NDAU every three months.
Suplier(s) **SHOULD** provide technical expertise when revisions to the NDS are required including supporting the release 2 of the NDS.